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Impacts of Strengthened Intellectual Property Rights Regimes on the Plant Breeding Industry in Developing Countries

A Synthesis of Five Case Studies

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Report, commissioned by the World Bank

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Executive summary

The Study

In the past few decades the subject of intellectual property rights (IPRs) has occupied center stage in debates about globalization, economic development and poverty elimination. This study concerns the strengthening of IPRs in the plant breeding industry and its effect on agriculture in developing countries. This strengthening is reflected in the growth in the number of countries that grant such rights, an expansion of the types of inventions that can be protected, and a broadening of the scope of protection offered by extant IPR systems. Central to the spread of IPR systems is the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS 1993) of the World Trade Organization (WTO) requiring all WTO members to introduce a minimum level of protection for intellectual property in their national laws; and subsequent bilateral or multilateral trade agreements that call for further strengthening of IPR regimes in developing countries.

The principal objective of this study is to describe and evaluate initial experiences with strengthened IPRs in developing country agriculture, focusing on five case studies. Such an assessment is a prerequisite for the formulation of policy guidelines and 'good practice' lessons for implementing IPRs in ways that enhance their impacts on productivity and equity. The preliminary nature of developing countries' experience with IPRs in agriculture precludes most possibilities for quantitative evaluation of impacts, and in many cases possible effects of IPRs are confounded with other developments (such as domestic policy changes and the liberalization of international trade). The study thus concentrates on qualitative evaluation of initial experiences and analyzes the efficiency with which IPRs are implemented at the institutional level (including interactions with other regulatory mechanisms), the effectiveness of the new IPR regimes in providing added incentives for the breeding and seed sectors (both public and private), and the equity of outcomes for producers (with particular attention to smallholders).

The wide variation in plant breeding capacities and seed industries among developing countries demands a case study approach for this research. The range of types of IPRs in force or contemplated, as well as the great variation in local institutions and farming systems, adds to the justification for a careful examination of a relatively few cases in terms of countries and crops. The choice of examples is constrained, however, by the fact that many countries have yet to establish an IPR regime for plant varieties. China, Colombia, India, Kenya and Uganda were chosen to represent a wide range of situations. The study focused on three types of crop: export crops, crops (for market or subsistence) with good commercial seed potential, and crops that attract little commercial seed interest.

The study concentrated on patents, plant breeder's rights systems and trademarks. The protection of plant varieties with patents is fairly uncommon; the principal examples are found in the US, where certain vegetatively propagated species have been eligible for patent protection since 1930 and more recently utility patents have been accepted for varieties of any type of crop. The most common system of IPRs for plant varieties is known as plant variety

protection (PVP), related to several conventions of the Union for the Protection of New Varieties of Plants (UPOV). Patent protection is more common in biotechnology, where many of the genes, tools and processes are protected by patents, although there are considerable differences among countries regarding eligibility and coverage. The plant breeding industry also relies on other mechanisms to protect its varieties and limit their use. Perhaps the most common is hybridization, which encourages farmers to buy fresh seed each season and prohibits competitors from multiplying a variety. Other mechanisms include the use of seed laws, contract law, brands and trademarks.

The study assumes that the primary justification for the establishment of IPRs is to increase welfare in society. By offering a type of monopoly for the commercial exploitation of an innovation, IPRs are intended to provide an incentive for creative endeavor by inventors and authors. The monopoly may however disadvantage particular stakeholders. The establishment of an IPR, which is based on national law, thus requires careful consideration of the different seed systems in the country and of the balance of economic interests of different stakeholders in society. Such analysis at the national level also needs to be balanced against potential benefits from international harmonization at the legal and/or implementation levels. The analysis of IPRs also must take account of existing systems that regulate seed production, and marketing, set biosafety standards; and enable the operation of contract law.

The case study countries

Although three of the four case study countries with PVP laws are members of UPOV under the 1978 convention, there are significant differences between them in the details of their legislation and in the actual performance of PVP. Aside from TRIPS, a major pressure for the initiation of PVP came from the foreign horticultural industry in Colombia and Kenya. In China this was part of a wider policy to promote the development of the domestic seed industry and to establish a framework for interaction with foreign agricultural technology. The establishment of PVP in India had its major impetus from a well-developed private seed industry leading to an extensive public debate about the nature of PVP; the result is legislation whose eligibility for inclusion in a UPOV convention has yet to be tested. In Uganda, which has yet to establish PVP, the debate is currently restricted to a small committee of professionals dealing with breeding and genetic resources.

Plant varieties are not eligible for patent protection in the case study countries. Trademarks are commonly used in all case study countries to protect seed company names and marks, but not for official variety names. None of the case study countries have particular exemptions in their patent laws in line with those usually available in PVP for other breeders or farmers. The establishment of PVP in the case study countries was often marked by controversy regarding the level and extent of protection for extant varieties.

The experience of the case study countries indicates that the ease of implementing PVP seems to be overestimated. In all cases, the effectiveness of PVP is still being tested and refined, and the cases illustrate that establishing a PVP law and putting it into practice are two separate challenges.

There is not yet sufficient experience on levels of participation to draw conclusions about the local resources required to manage PVP. In Colombia and Kenya, most applications for protection concern horticultural crops, for which the testing is largely managed externally. In China, on the other hand, there is a considerable demand for PVP, largely to protect publicly-developed varieties. In large countries with extensive seed markets, investment in PVP will be easy to justify; for smaller markets and niche varieties the justification will be more difficult. It is worth noting that protection, testing and maintenance fees are currently uniform in each of the case study countries, without regard to type of crop or seed market.

Early experience indicates that sanctions for violations are often not well defined and that the courts are not well prepared to enforce the rights. In all cases, private and public plant breeders are learning that the major responsibility for identifying violations and pursuing cases rests with them, implying additional investments of staff and resources.

There is very little experience in the case study countries with the implementation of patents for plant breeding or biotechnology, with the exception of China. There is little or no case law in the case study countries relevant to the enforcement of such patents.

IPRs and the evolution of the private seed sector

The emergence of the private seed sector in the case study countries owes relatively little to national IP regimes. By far the most dynamic private seed sector in the sample (India) has grown and diversified without benefit of any IPRs but in the context of quite liberal seed laws and in many cases through the use of hybrids as a means of appropriation. While not necessary for initial private seed sector development, PVP may contribute to further growth and diversification. The nature and extent of this contribution will depend on the characteristics of the national seed system. Seed companies tend to take advantage of PVP and patents when it helps protect them against competitors gaining access to their materials. In Colombia and Kenya, protection is commonly not sought for hybrids. On the other hand, where hybrids are used in a competitive seed sector, such as India and China, they attract the majority of interest for PVP.

IPR systems can also limit farmers' seed saving and hence provide additional incentives for private seed provision; although there are no instances of this as yet in the case study countries, both Kenya and Colombia are considering modifications in their laws that could limit seed saving. Authorities admit that it would be difficult (as well as politically sensitive) to enforce such requirements with smallholders. In the flower industry, breeding firms' control of export markets is a very effective deterrent to on-farm multiplication of planting materials.

The question whether IPRs will create a shake-out in the industry at the cost of the smaller companies can not yet be answered in the case study countries. Such increasing concentration in the industry could be a result of the costs associated with protection, particularly for smaller companies. The situation in India, with many small seed companies in operation, deserves particular attention. In addition, restricted access to technology might become a bottleneck for smaller companies.

IPRs and the public research sector

The establishment of PVP regimes comes at a time when national agricultural research institutes (NARIs) are being asked to take much more responsibility for revenue generation. Research administrators see the possibility of earning income by licensing public varieties and other inventions but the degree to which such royalties can fulfill that promise depends on farmer demand for public varieties, and on the ability of the institutions to manage and enforce their rights. In the case study countries there is little evidence so far of actual revenue generation from public breeding through IPRs, with the exception of institutions in China. The expectations of NARI management are however quite high. Potential limitations, such as competition with the emerging private sector for human resources and lack of freedom to operate with third-party IPR are rarely taken into account in NARIs IP strategies.

A major problem with revenue generation from PVP is that the potential opportunities are patchy. There is a danger that this heterogeneity may be translated into inequitable and questionable public research resource allocations, further reducing research on orphan crops and a smallholder farmer focus in favor of breeding objectives and methodologies directed at large-scale commercial production. Mechanisms to share income with the individual researchers and research groups are under development in some institutions. NARI's capacity to market their own IP and to negotiate access to third party IP is currently very limited.

International Agricultural Research Centers (IARCs) have policies on IP that permit IP protection of inventions and materials if this will ensure that the subject materials and technologies will be available to its target groups. Several IARCs have some staff with legal background assigned to IP, plus access to a central advisory service. Resources are however limited and the increasing pressure to show impact at the local level will stretch current capabilities.

The IP issue is central in the balancing of relationships between private seed companies and public research. As IARCs focus on poverty alleviation and smallholder farmers, and NARIs place increased emphasis on earning royalties from their germplasm with commercial potential, IARCs have to rethink their relationships with NARIs. When IARCs can earn royalties on their materials from domestic seed producers, they find themselves in the same position as NARIs with regard to possibilities that opportunities for revenue generation may affect priorities.

The growth of the private seed industry would seem to provide a more effective link between public plant breeding and farmers' fields. However, many public varieties do not attract the interest of commercial seed enterprises, and this encourages many NARIs to organize their own seed production and marketing. In addition, many NARIs still find themselves with obligations to public seed production efforts. The establishment of IPR systems does little to resolve these challenges for public plant breeding.

IPRs and seed users

Farmers' seed systems are the main source of seed and new varieties for most crops in the case study countries. IPRs may reduce the effectiveness of these systems by limiting the saving, exchanging and selling of farmer-produced seed of protected varieties. There are no

instances to date of such restrictions in case study countries, but proposals for the strengthening of some national PVP regulations introduce these issues.

In some countries the choice of varieties is currently expanding through the opening of the seed sector, backed by economic policies and changes in seed regulations, and these trends may be further supported by IPRs. When the commercial seed market expansion is very rapid, IPRs can help control rogue traders (e.g. in India and China). However, restrictions on small seed enterprises and semi-commercial operations may jeopardize the provision of seed of some local varieties supplied commercially. In addition, the breeding of niche varieties and their delivery by small seed companies may be threatened.

IPRs help flower growers secure access to a wide range of varieties in the case study countries, but only when the establishment of IPRs contributes to a trustworthy business environment. These IPRs are not necessarily operational in the production countries, and their main point of application is in the main wholesale markets. Non-specific IPRs like trademark protection are an additional tool for the flower breeders.

It is likely that NARIs' focus on revenue generation, supported by the introduction of IPRs, may divert their attention from the needs of marginal farmers. This may also affect the conduct of participatory methods in breeding and variety selection.

Lessons

General

Many of the principal IPR strategies have only been in place a few years (or are still in the final stages of approval). Because the incentives provided by any IPR regime usually interact with various other factors (such as the liberalization of domestic agricultural markets, increased globalization, and a reduction of public expenditure for agricultural research and seed production) it is difficult to identify unambiguous conclusions regarding the possible contributions and concerns that IPR regimes might present for plant breeding in developing countries. However, the difficulty in identifying clear causality at this early stage does not mean that IPRs are unimportant. On the contrary, IPR regimes may lead to significant changes in plant breeding and seed production, and the subject warrants careful future study and monitoring. Despite the preliminary nature of the report's conclusions, the analysis points to a number of significant lessons that need to be presented and disseminated to different stakeholder groups.

There are several priorities for monitoring. These include assessing the extent to which IPR regimes (and other policy changes) in particular countries influence the priorities and products of public plant breeding, affect the structure and concentration of the domestic seed industry, and determine the options available to smallholders. On a global level, it is particularly important to monitor how IPRs are treated in multilateral and bilateral negotiations, and how IPRs influence the role of MNCs in technology transfer in developing countries.

Political realities, limitations in administrative resources, and varied economic incentives in most developing countries indicate that it is unrealistic to expect rapid establishment and effective enforcement of the type of IPR regimes that are found in some industrialized countries. In any case, IPR regimes should be part of developing countries' development pathways and consistent with their own priorities and capacities instead of being externally imposed. Donors and others hoping to support these processes must be prepared for a long-term and individualized development of national agricultural institutions.

IPR regimes must be developed at the national level, and much donor effort should support individual processes of multi-stakeholder debate, design, and implementation. Support for specifically-tailored IPR regimes is possible because of the range of options that are available for providing appropriate incentives. On the other hand, respecting individual country priorities and circumstances in the design of IPR regimes does not imply that opportunities for harmonization and cooperation should be forgone. Mechanisms such as UPOV and PCT facilitate the implementation of IPRs and reduce transaction costs, but the object of harmonization is to provide economic benefits rather than to promote coalitions whose standards are dictated by their strictest partners.

There should be particular attention in these discussions to issues related to international public goods, in particular, the conduct of international agricultural research with regard to IPRs in plant breeding and its relation with national research systems. A further issue that requires attention at the international level is access to some of the basic tools and processes of biotechnology. These may be protected in the North but the possible legal implications for the new varieties and agricultural products derived from such technology are often uncertain for the Southern scientists who use them.

The design of IPR instruments

Policymakers need to realize that IPRs are important not because countries may be required to accede to the conditions of an international agreement but rather because they offer possible mechanisms for stimulating research, enabling access to technology, and promoting enterprise growth, all for the good of society. As such, they are merely one tool in a range of policies that may be applied in specific contexts to further agricultural development (e.g. for supporting public agricultural research, regulating seed production and marketing, providing an enabling environment for agribusiness development, and empowering smallholders).

In most countries, the design and implementation of an IPR regime for plant breeding should be seen as a long-term process, subject to monitoring and adjustment. The establishment of PVP systems or patent offices is not necessarily sufficient to initiate widespread changes within the seed industry. It often takes considerable time for the infrastructure to be established, for plant breeders to become conversant with the system and for the courts to be able to handle complaints.

Not only do IPRs in plant breeding have to be seen in the context of a wider range of agricultural policies, but IPR regimes themselves must be carefully tailored to specific situations. It is important that countries recognize that they have choices in designing legislation consistent

with the TRIPS Agreement and that there are still opportunities for debating and interpreting the Agreement itself. The UPOV Conventions offer some important advantages for fulfilling the requirements for a *sui generis* system but they do not exhaust the possibilities. Similarly, there are several options with respect to tailoring national patent regimes for agricultural biotechnology. The key elements in IPR systems that can be adapted to the specific conditions of individual national seed sectors include the specific terms of the farmers' privilege and the breeder's exemption, the relationship between different IPRs (patents, PVP, trademarks, trade secrets), the exhaustion of these different types of IPRs, and possible differential treatment of particular crops.

Policy makers need to consider the resources required for the establishment or strengthening of IPR systems. Institutional capacity to deal with the processing of applications and the granting of rights is quite variable among countries. Cooperation and harmonization at the implementation level can lower some of these costs. Fee rates that make an office self-supporting should be welcome, but care must be taken to avoid unfairly taxing or discouraging applicants, and especially smaller players.

The introduction of transgenic varieties to developing countries presents special challenges, but does not necessarily imply the adoption of overly rigid IPR regimes. Limited experience to date has shown that in the absence of IPRs for GM plant varieties and biotechnological inventions, multinational companies have sometimes resorted to biosafety regulations in an attempt to protect their technology. Biosafety organizations are however not appropriate for such purposes, and policymakers need to create a clear division of responsibilities among various agencies for regulating the use of GM varieties. In many cases, the enforcement of existing seed laws can offer an appreciable improvement in limiting unauthorized sale of GM seed. Further research is needed on the extent of IP protection necessary for stimulating the development of GM varieties (where desired).

The implementation of IPR regimes

Policymakers must consider the institutional arrangements for PVP. A PVP authority may be included as part of an existing seed regulatory agency or established as a separate organization; the expense of setting up a separate entity must be balanced against possible concentration of power or conflict of interest. In addition, there must be confidence that the PVP authority is independent from the interests of (public) plant breeding organizations.

The challenges of adequate enforcement for IPRs in plant breeding should not be underestimated. There is very little legal capacity in most countries to support IPR regimes for plant breeding. Implementation of IPR regimes must include attention to strengthening the court system's knowledge of IPRs in plant breeding, and the ambitions and scope of any IPR system must be consistent with the capacities of the legal system, including contract enforcement.

For the establishment of PVP, there are a number of important parameters that require careful consideration. These include: the designation of which species are to be covered; fee structures (and possible subsidies or differentiation by crop); the nature of the breeder's exemption for use of protected varieties; and the implications for farmers' abilities to save, exchange and sell

seed in accordance with local custom. For patents the choices are similar: which processes and products are patentable and the scope of protection. For trademarks, the key question is whether a variety name can be protected.

Because the establishment of IPR regimes is a gradual process, careful monitoring is required. Policymakers need to assess whether particular IPR regimes are actually providing incentives for seed system development consistent with national agricultural goals. This includes analyzing if farmers have equitable access to an increasing diversity of crop varieties and if the structure of the commercial seed market provides confidence for participants while at the same time encouraging new entrants.

IPRs in international negotiations

IPRs for plant breeding are not a magic bullet that automatically stimulates or redirects agricultural growth, but they can be an important part of a comprehensive agricultural development strategy by helping support competitiveness and diversity in plant breeding and seed supply. Given the value of well designed IPRs for agricultural development, policy makers should not treat IPRs as a negotiable bargaining chip in trade negotiations or other international discussions.

IPRs need to be considered in international agreements that tackle related issues, in particular biodiversity and trade. National policies towards international agreements on biodiversity, negotiated by representatives with environment (CBD) or agriculture (IT/PGRFA) background need to be in line with the choices made in the field of IPR, which are primarily derived from economic and trade policies. Countries must be clear about how IPRs relate to national sovereignty over plant genetic resources and rights of indigenous communities (CBD), and Farmers' Rights (IT/PGRFA) in order to avoid conflicts of interpretation. This requires a capacity in IPR issues with a much wider group of stakeholders than commonly envisaged. Art 9 of the IT/PGRFA encourages open and informed national debates on issues related to genetic resources, including IPRs.

For many countries, the possibility of being required to establish particularly restrictive IPRs for plant breeding is more likely to be a product of bilateral trade agreements than to derive from TRIPS obligations. National policymakers need to be prepared to enter such negotiations with a full understanding of the implications of such 'TRIPS-plus' agreements for their national plant breeding and seed systems. This requires close cooperation between national policy makers with trade, agriculture and environment backgrounds to analyze the room for maneuver in interpreting and modifying any such requirements imposed by potential trading partners.

In the only case study country with legislation that includes Farmers' Rights (India), there is not enough experience to assess the degree to which this offers useful incentives for the development or promotion of farmer varieties. Further monitoring is required.

Agricultural policies

This study emphasizes that IPR regimes in plant breeding should provide incentives for diversifying and strengthening plant breeding and seed production. This implies that policy-makers cannot consider IPR regimes in isolation from wider issues of national agricultural policy.

The role of NARIs is a subject of considerable debate in light of generally declining national budgets and the growth of the private sector. Many NARIs are uncertain of whether to complement or compete with the private sector and hence are confused about how to take advantage of IPRs. Policymakers need to set clear guidelines in this area. NARIs need to distinguish between using IPRs in order to facilitate the use and delivery of their varieties, and seeing IPRs as a contributor to institute budgets through royalty income. Most NARIs seem to have little knowledge about the costs of obtaining and enforcing IPRs, and there is little realistic assessment within the NARI's of their capacity to compete with the private sector in producing commercially viable products (or in rewarding and maintaining staff for this task).

Most NARIs are too poorly organized to acquire access to complementary technology on equitable terms or to assess their 'freedom to operate' with protected techniques and tools. NARIs are no match for the legal and negotiation skills and resources of major technology firms. NARIs need assistance to formulate IP policies and strengthen their legal and negotiation capacities.

The strategies that NARIs adopt for using IPRs will depend on answers to fundamental questions about the role of public sector agricultural research. For instance, different approaches to relations with the private sector must be taken into account. In addition, the way that NARIs manage IPRs has a significant bearing on the extent to which germplasm resources are shared more widely. Policymakers 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, without appreciating the importance of facilitated access.

Policymakers also need to ensure the development of the private domestic breeding sector. With few exceptions, domestic firms do not have the resources to invest in high technology and must depend on MNCs and advanced research institutions that protect their inventions. There are a few examples of incipient consortia of local seed companies formed to negotiate access to biotechnology, and national policy should support such efforts.

There are still serious challenges with respect to delivering useful varieties, particularly of non-hybrids and so-called 'orphan crops', to smallholders. The combination of limited and isolated markets with widespread seed saving means that even fairly strong IPR regimes are unlikely to elicit commercial interest in the near future. Policymakers must find ways of combining (largely) public plant breeding, appropriate formal seed delivery (most likely private or cooperative), and support to local seed diffusion mechanisms, to serve the farmers dependent on these crops.

There are no indications in the case study countries to date that PVP unduly contributes to a concentration in the seed sector. Early experiences in biotechnology patents in the case study countries are insufficient to establish any evidence for concentration, despite the fact that most transgenics currently have one commercial source. However, it is important to support a critical assessment of developments in the coming years. This is an area in which industrialized countries could provide some useful guidance given their longer experience in monitoring and regulating anti-competitive practices.

Finally, it is worth reiterating that the purpose of IPR regimes in agriculture is to provide appropriate incentives for science and commerce to better serve the nation's farmers. National policies need to ensure that farmers are conversant with, and participate in, debates regarding possible IPR regimes; that they are well-informed consumers who understand their rights in agricultural input markets; and that their interests and priorities are reflected in the work of public agricultural research.

Abbreviations

AATF	African Agricultural Technology Foundation
AICCIP	All India Coordinated Crop Improvement Programme
AFLP	Amplified fragment length polymorphism
ARIPO	African Regional Intellectual property Organization
ARPOV	Argentinean Association for the Protection of Plant Varieties
BRI	Biotechnology Research Institute (China)
Bt	Bacillus thuringiensis
CAAS	Chinese Academy of Agricultural Sciences
CAS	Chinese Academy of Sciences
CBD	Convention on Biological Diversity
CGIAR	Consultative Group on International Agricultural Research
CIAT	International Center for Tropical Agriculture (Cali, Colombia)
CICR	Central Institute for Cotton Research (India)
CORPOICA	Colombian Corporation for Agricultural Research
CRI	Cotton Research Institute (China)
CSIR	Council for Scientific and Industrial Research (India)
DNA	Desoxyribonucleic acid
DUS	Distinctness, uniformity, stability
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FEDEARROZ	National Federation of Rice producers (Colombia)
FEDEPAPA	Colombian Federation of Potato Producers
FLAR	Latin American Fund for Irrigated Rice
FTO	Freedom to operate
GAAS	Guangdong Academy of Agricultural Sciences
GDP	Gross Domestic Product
GI	Geographic indication
GMO	Genetically modified organism
GUS	Beta-glucuronidase (selection marker)
HAAS	Hunan Academy of Agricultural Sciences
HHRRC	Hunan Hybrid Rice Research Center
IARC	International Agricultural Research Center
ICA	Colombian Institute for Agriculture and Livestock
ICAR	Indian Centre for Agricultural Research
ICRISAT	International Crops Research Institute for the Semi-Arid Tropics (Hyderabad, India)
IGC	Inter-Governmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore
IIHR	Indian Institute for Horticultural Research
IP	Intellectual property
IPR	Intellectual property rights
IT PGRFA	International Treaty for Plant Genetic Resources for Food and Agriculture

IVF	Institute for Vegetables and Flowers (Beijing, China)
KARI	Kenyan Agricultural Research Institute
KEPHIS	Kenyan Plant Health Inspectorate
KIPI	Kenyan Intellectual property Institute
KSC	Kenya Seed Company
MNC	Multinational corporation
MOST	Ministry of Science and Technology (China)
MTA	Material transfer agreement
MV	Modern variety
NARI	National agricultural research institute (generic)
NARO	National Agricultural Research Organization (Uganda)
NARS	National Agricultural Research System
NBPGR	National Bureau for Plant Genetic Resources (India)
NBRI	National Botanical Research Institute (India)
NGO	Non-governmental organization
NPT	National Performance Trials (Kenya)
NPT2	Neomycin Phosphotransferase II (selection marker)
OAPI	African Intellectual property Organization
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 breeder's rights
PVP	Plant variety protection
PVPA	Plant Variety Protection Act (USA)
RAI	Royalty Administration International (Co. Ltd)
RAPD	Random amplified polymorphic DNA
RFLP	Restriction fragment length polymorphism
PBR	Plant breeder's rights
PCR	Polymerase chain reaction
RMB	Yuan Remnimbi (currency in China)
RR	Roundup Ready
RRI	Rice Research Institute (China)
SIPO	State Intellectual Property Office (China)
SNP	Single nucleotide polymorphism
SSR	Simple sequence repeats
TRIPS	(agreement on) Trade Related Aspects of Intellectual Property Rights
UPOV	International Union for the Protection of New Varieties of Plants
URUPOV	Uruguayan Association for Plant Breeders Protection
USA	United States of America
VCU	Value for cultivation and use
V-GURT	Genetic use restriction technology operating at variety level
WTO	World Trade Organization

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1. Introduction

1.1 Background

In the past few decades the subject of intellectual property rights (IPRs) has moved from a relatively obscure corner of legal practice to occupy center stage in debates about globalization, economic development and the goal of poverty elimination. The growing prominence of IPRs is related to technological advances that are responsible for an increasing rate of scientific creativity in all fields and an expansion in the capacities and incentives for protecting such innovation. At the same time, the movement toward globalized trading regimes has brought pressure for the harmonization of IPR systems. These advances in technology and trade have affected the position of IPRs for a wide range of endeavors and have particularly important implications for developing countries. This study is concerned with one example, the strengthening of IPRs in the plant breeding industry and its effect on agriculture in developing countries.

The past few years have witnessed a significant worldwide strengthening of IPRs in plant breeding. This strengthening is the product of a growth in the number of countries that grant such rights, an expansion of the types of inventions that can be protected, and a broadening of the scope of protection offered by extant IPR systems. Although a system of IPRs has been internationally sanctioned for more than a century, since the Paris Convention of 1883, IPRs have not been an issue in the plant breeding and seed sector in most developing countries until recently. 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 a minimum level of protection for intellectual property in their national laws. Article 27.3(b) of the TRIPS Agreement requires WTO members to provide for the protection of plant varieties through patents, an effective *sui generis* system, or a combination thereof. Subsequent to the TRIPS Agreement in 1993, the USA and the EU have negotiated bilateral or multilateral trade agreements that reduce some of the flexibility of TRIPS, e.g. an agreement between the USA and Chile prescribes that the latter introduce patentability of plant varieties in addition to the TRIPS-compliant breeder's rights system operational in that country. In addition, issues of data exclusivity that are common in the pharmaceutical sector are beginning to appear in the agricultural field, potentially strengthening the rights of IPR holders in the breeding and seed sectors.

The nature and scope of IPRs for genetic resources (including plant varieties) are also part of discussions in the frameworks of the Convention on Biological Diversity and the International Treaty on Plant Genetic Resources for Food and Agriculture, which entered into force in 1993 and 2004, respectively. There are debates about the contradictions between IPRs and Farmers' Rights (Art. 9 of the IT/PGRFA), the concept of farmers' privilege in the UPOV system in relation to Farmers' Rights, and the issue of linking protection and the sharing of benefits derived from the use of genetic resources.

The importance of IPRs for plant breeding and the seed industry has been further enhanced by the development of plant biotechnology, which not only engendered patents for the genes,

tools and processes that are an increasingly common part of modern plant breeding, but also spurred the introduction of utility patents for plant varieties.

Most developing country members of the WTO have either enacted IPR laws or are about to do so, as prescribed by the TRIPS Agreement and/or the so-called 'TRIPS-plus' requirements of bilateral or multilateral trade agreements. The new laws include provisions governing ownership and use of crop varieties. While IPR regimes for agricultural inventions have been widely used in industrialized countries, most developing countries are in the early stages of implementation and/or enforcement of IPRs related to crop varieties. The application of IPRs for plant breeding in developing countries raises a number of important issues, including smallholder 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.

The role of IPRs in agriculture is an exceptionally controversial subject. The debates involve complex arguments from a range of interest groups. The outcomes of particular IPR regimes will vary according to local economic, institutional, and agricultural circumstances and may 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 in order to contribute to the public good. It is therefore the responsibility of policymakers to define the particular societal goals that IPRs in agriculture are meant to address and to develop appropriate legislation. It is important that policymakers have access to as much experience as possible for guiding the design and implementation of IP instruments appropriate to their goals.
The present study was initiated in the belief that an empirical analysis of the conduct and performance of IPR regimes in plant breeding in developing countries would be particularly useful. It is hoped that the information provided in this study, although only the product of initial country experiences, will help serve that purpose.

1.2 Objectives

The principal objective of this study is to describe and evaluate initial experiences with strengthened IPRs in developing country agriculture. Such an assessment is necessary in order to provide policy guidelines and 'good practice' lessons for implementing IPRs in ways that enhance their impacts on productivity and equity.

The preliminary nature of developing countries' experience with IPRs in agriculture precludes most possibilities for quantitative evaluation of impacts, and in many cases possible effects of IPRs are confounded with other developments (such as domestic policy changes and the liberalization of international trade). The study thus concentrates on qualitative evaluation of initial experiences and analyzes the efficiency with which IPRs are implemented at the institutional level (including interactions with other regulatory mechanisms), the effectiveness of

the new IPR regimes in providing added incentives for the breeding and seed sectors (both public and private), and the equity of outcomes for producers (with particular attention to smallholders).

The study thus involves a wide range of issues, including:

a. implementation of IPR regimes

- how changes in regulations and regulatory agencies have been implemented or are proposed
- support for IPR institutions and their technical and financial sustainability
- the capacity of these institutions to provide competent and transparent regulation
- the enforcement capacity of IPR regimes

b. changes in public and private plant breeding

- the access of public and private breeders to germplasm
- the access of public and private plant breeders to breeding technologies
- the investments in breeding by crop, technology, type of client
- types and numbers of seed enterprises
- seed production and sales

c. changes for farmers

- the type and number of varieties available to farmers
- the affordability of the seed
- the choices and flexibility available in the seed markets
- farmers' interactions with formal plant breeding and seed providers

1.3 Methodology

1.3.1 The case study approach

The wide variation in plant breeding capacities and seed industries among developing countries demands a case study approach for this research. The range of types of IPRs in force or contemplated, as well as the great variation in local institutions and farming systems, adds to the justification for a careful examination of a relatively few cases in terms of countries and crops. The choice of examples is constrained, however, by the fact that many countries have yet to establish an IPR regime for plant varieties. The chances of assessing even potential impacts are greatly enhanced in countries that have at least a minimum of experience with IPRs, implying a careful selection of sample countries for the study. In addition, the establishment of IPRs for plant varieties affects various institutions and organizations in developing countries and has important implications for the way that agricultural technology is developed, delivered and utilized. It is therefore necessary to collect data from many different stakeholders.

The study was carried out with the realization that there are many analyses and manifestos regarding the roles of IPRs in general and for agriculture in particular. The wide divisions of opinion suggest that there are no easy answers to the questions at hand and that quantitative

comparison, necessarily involving a limited number of inputs and outputs, would not yield convincing answers. In addition the study recognized that quantitative evidence would be hard to find, and in many cases confounded with the effects of other developments. Therefore, a wide range of evidence had to be sought in the small number of developing countries that have started implementing various IPR regimes in agriculture. In addition, given the necessity of pursuing crop-specific information amidst the diversity of issues within the study countries, certain crops were selected for particular attention.

The diversity of issues also required input by specialists with a range of backgrounds. The team consisted of seed systems specialists with knowledge of breeding, plant biotechnology and enterprise development; agricultural economists and social scientists with experience in seed and biotechnology issues; and specialists in environmental law, IPRs in biotechnology and the management of biotechnology projects. The team included a case study researcher for each of the five countries and a central team of four researchers based in Europe.

1.3.2 Choice of case study countries

Five case study countries were chosen to represent major segments of developing country agriculture, geographical spread, and level of experience with IPRs:

- **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 and is a market that attracts investors and inventors from all over the world. China also has a significant area planted to genetically modified crops (GMOs).
- **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 GMOs.
- **India** has a very well developed agricultural research capacity in breeding and biotechnology, and its large market attracts considerable interest from abroad. 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 political debate.
- **Kenya** is the sub-Saharan African country with the longest experience with IPRs in the breeding and seed sector after South Africa. It has a very diverse agriculture ranging from subsistence to export sectors and a relatively open policy towards biotechnology.
- **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.

1.3.3 Choice of crops within case study countries

Although the study looked at the effects of agricultural IPR regimes in general, it was decided that special attention should be given to a few focus crops in each country. These crops were chosen to provide as much opportunity for inter-country comparison as possible and to

represent a wide range of commodities that would illustrate important issues in terms of market orientation, public and private research and seed sector commitment, and biotechnology investment. The focus crops for the study include food staples important for subsistence and local market (rice, maize, and beans), cash crops (cotton and vegetables) and specialty export crops (flowers). These crops were given priority attention in discussions with research, the seed industry, and farmers, but relevant issues in other crops were also pursued.

	China	Colombia	India	Kenya	Uganda
Rice	■	■	■		
Maize	(■)	■	(■)	■	■
Beans		(■)		■	■
Cotton	■	(■)	■		(■)
Vegetables	■		■		
Flowers		■		■	■

■ *= primary focus (■) = secondary focus*

1.3.4 Process

A five-day organizational meeting for all nine team members was held in Wageningen in October 2003. The meeting established a common framework for the analysis of the study questions and, based on the framework, developed a set of comprehensive guidelines for semi-structured interviews. The initial meeting also included the participation of two World Bank staff, an IPR specialist from a multinational seed company, a member of an NGO working on biodiversity and seed access, and an economist studying agricultural patents in the US.

In the implementation phase of the study, a large number of people from the public, private and civil sectors were interviewed by different members of the team. Most interviews in the case study countries were conducted by the scientists in the respective countries. All countries were visited one or more times by the Europe-based members of the team to participate in interviews and analyze initial data. In addition, managers and IP specialists of multinational seed companies were interviewed during an IP seminar of the International Seed Federation in Berlin, May 2004.

The analysis of the secondary and interview data collected during the study focused on identifying major themes and outcomes, identifying commonalities (where they existed) and attempting to explain the context of differences in response and outcome. The initial analysis and conclusions were discussed at the individual country level with the relevant researchers, and this draft report is the subject of collective writing, editing and debate engaging the entire team.

The analysis of the secondary and interview data collected during the study focused on identifying major themes and outcomes, identifying commonalities (where they existed) and attempting to explain the context of differences in response and outcome. The initial analysis and conclusions were discussed at the individual country level with the relevant researchers.

A draft of this report has been discussed in Washington with World Bank staff and specialists in agricultural IPRs. This report has been the subject of collective writing, editing and debate engaging the entire team

1.3.5 Data collection

The study team collected data related to IPR-institutions, plant breeding and seed production organizations and farm-level outcomes.

Methodology

The country case studies are based on a combination of secondary data analysis and extensive interviews.

Available documentation on the seed and agricultural input sector and the policy framework concerning breeding, biotechnology and IPRs was compiled. Secondary data and previous studies were also used to provide information about farmer seed management practices, thus limiting the need for farmer surveys. Interviews were undertaken with relevant staff of IP institutions; public research and seed production managers; and management of private seed companies and biotechnology firms (see Annex I). A small number of interviews were conducted by telephone. Given the complexity of the issues, the interviews were based on detailed guidelines rather than on written questionnaires (see Annex II). A concerted attempt was made to develop uniform and comparable data sets, but the importance of pursuing specificity and detail combined with the variable experiences and interests of the interviewees meant that it was common to concentrate on particular aspects of the guidelines during an interview. Interviews were conducted by the scientists in the case study countries; the European team joined them in a number of visits: Louwaars in China, (northern) India, Kenya, Uganda; Tripp in Colombia, (southern) India, Kenya, Uganda; and Eaton in China.

IPR institutions

The country case studies describe the background of particular IPR regimes and the nature and scope of protection that is provided. Attention is paid to costs, technical and human capacities, transparency and performance. An IPR regime is worth little until it can be efficiently implemented and enforced, and institutional capacities must be assessed in their governance environment. We sought the experiences and perceptions of the relevant staff of IPR institutions and compared these to evidence from other stakeholders on their understanding of, and confidence in, the IPR regime.

Plant breeding and seed supply sector

The case studies evaluate the experience to date with IPR regimes in public and private organizations involved in seed provision, plant breeding and biotechnology. The study attempts to relate changes in the IPR regime to changes in investments and output for plant breeding and biotechnology programs. The study relates the introduction of new IPR regimes to changes in research policies, trends in variety release, and the relative focus on hybrids or open-pollinated varieties (OPVs). For seed enterprises, the study examines how specific aspects of IPR regimes (such as scope of protection and enforcement options) play a role in determining investment and protection decisions. In addition, the relation between public and private organizations,

including international research organizations, is examined. In the absence of relevant data that would have allowed a before-after statistical analysis, the study assesses the relative contribution of IPRs in light of concurrent changes such as market developments and modifications in other legal frameworks.

Impacts at the farm level

The ultimate concern of the assessment of the experience with IPRs is to understand the impact on the different types of crop producers, with specific emphasis on small-scale farmers and the challenge of poverty alleviation. However, where the recent legal developments often may not have visible and quantifiable impact on the breeding and seed provision sectors, analysis of effects at the farm level is necessarily speculative. Large-scale farmer surveys have thus not been undertaken, but interviews were conducted with representatives of farmer organizations and NGOs. Attention was also given to any substantial examples of on-farm variety development and local seed programs.

Challenges of the methodology

This methodology can provide valuable information, but it has some significant limitations as well. Any study of laws, regulations or policies must bear in mind that the written and implemented forms may differ significantly; it is necessary to describe both sides of the picture. In addition, policies may not be well articulated or uniformly shared, and some aspects of a legal framework may be more effectively implemented than others, leading to variation in understanding and experiences. The necessary reliance on interviews means that much of the interpretation is based on stakeholder perceptions, and these may be varied or mistaken (or at times even deliberately misleading). These biases are inevitable and it was the task of the researchers to identify and counteract them wherever possible, by understanding the context of the interview and by 'triangulating' sources of information. In addition, some observations and information were provided with the understanding that they were confidential; these requests were respected but they further limit the scope of the analysis. Even though attempts have been made to ensure as uniform a data collection strategy as possible, cultural differences among countries and interviewees, and differences between researchers, inevitably create some heterogeneity in data collection. As with many other studies, the quantitative data are as good as their sources; we have attempted to approach the most reliable sources, but can make no guarantees for the precision of national statistics.

Some of the data reflect a level of uncertainty among stakeholders and even contradictions in interpretations and perceptions; such results are seen as an important indicator of the nature of the impact of some IPR regimes. Finally, attributing impacts is particularly tricky in this field, since the introduction of IPRs has commonly gone hand in hand with changes in other policies that are directed to reducing public expenditures, commercialization or privatization of public organizations, promotion of the private sector or changes in development policies.
The research and the analysis try to understand the performance and outcomes of new IPRs in this broader policy and institutional context.

1.4 Structure of this report

This report starts with an overview of the basic issues in the application of IPRs to the plant breeding industry (Section 2). The case study countries are introduced, including a description of the breeding and seed sectors and the conventional regulatory frameworks in each country (Section 3) and an analysis of the current status of IP regimes with regard to enactment, management and enforcement (Section 4). The next sections analyze the impact of the recent developments in the field of IPRs on the private (Section 5) and public (Section 6) sectors. (The impacts of IPRs on biotechnology research, conventional plant breeding, seed production, and marketing are closely interrelated for both private and public activities, justifying this division by sector rather than by activity.) Section 7 discusses the impact on seed users, and we draw our conclusions in Section 8.

2. IPRs and the plant breeding industry

2.1 Introduction

2.1.1 Rationale for intellectual property rights

IPRs are legal instruments that allow an inventor or author to exclude others from commercializing an innovation for a specified period of time. IPRs provide a temporary monopoly, subject to specific conditions, that governs the commercial exploitation of an invention, at the end of which the subject matter is released into the public domain. The most common examples of IPRs are utility patents, copyrights, and trademarks, but there are other important special cases, such as the legal protection of industrial designs and plant varieties. This study focuses on the IPR mechanisms designed to provide plant variety protection (PVP) and on the applications of the patent system to plant breeding and biotechnology.

The primary justification for the establishment of IPRs is economic. By offering a type of monopoly for the commercial exploitation of an innovation, IPRs tend to provide an incentive for creative endeavor by inventors and authors. An IPR system can also offer additional, more widespread, economic benefits such as reducing transaction costs and clarifying ownership. Nelson & Mazzoleni (1997) review the patent system and posit four theories to justify its establishment. In addition to providing individual motivation for useful inventions, the patent system also offers a systematic means of disclosing information related to inventions, fosters the development of useful products based on inventions, and provides an orderly means for stimulating derivative inventions.

There is also a moral dimension to IPRs; the Universal Declaration of Human Rights (Art. 27) includes 'the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author'. It is important to acknowledge that IPRs include important qualifications; for instance, they are granted for a limited period of time and they are subject to exceptions such as compulsory licensing and competition law regimes (Maurer & Scotchmer, 2004) in the public interest. As the Commission on Intellectual Property Rights (2002) pointed out, 'an IP right is best viewed as one of the means by which nations and societies can help to promote the fulfillment of human economic and social rights'.

IPRs may thus be seen as a means to increase a society's welfare. Legal rights provide incentives for inventors and authors to invest in their work and to produce useful products or insights for the benefit of society. The patent system reflects this expectation of utility through 'industrial application' or 'use' requirements for new inventions; society does not intend to grant patent rights on something that it won't benefit from. For instance, these utilitarian goals are expressed in the progress clause of the US Constitution. Congress has the power to promote the progress of science and useful arts by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.' This also illustrates that in order to increase welfare, society may need to put limitations on the rights that are granted. In this sense, IPRs can be considered a contract between the inventor or author and society (Hardon, 2004) in which rights are granted under particular conditions (e.g. the obligation to

publish the invention for the benefit of the further advancement of science) and society can control misuse of the monopoly in the market (e.g. through compulsory licenses).

The establishment of an IPR regime requires careful consideration of the balance of economic interests. If an IPR regime is too weak it will not provide sufficient incentives for invention or for the orderly development of an industry. On the other hand, poorly conceived IPR systems may assign excessive privileges, restrict access to knowledge, or limit enterprise growth and diversification, and society at large may not benefit from the granting of the rights. Such considerations of benefits and costs are evident in much recent debate about the patent system. Davis (2004) suggests that the current patent system is characterized by increasing social costs and decreasing social benefits and Andersen (2004) specifies a number of the costs associated with the patent system, including the growing legal costs, the diversion of investment into protectable rather than productive areas, and the inefficient monopolies resulting from broad patents and threats of patent infringement. Patents are pursued not only for the direct commercialization of a product but also as strategies to block or hinder competitors' endeavors or to acquire bargaining chips that may help gain access to another inventor's patents (Thumm, 2001; Reitzig, 2004). While such business strategies may not preclude social benefit from a protection system, the balance can easily become skewed. Many observers are concerned about the effects of the widespread promulgation of strong protection schemes that have been developed in countries such as the US with the rationale that they will stimulate strong commercial sectors elsewhere.

The economic outcomes affected by an IPR regime represent the interests of a wide variety of stakeholders. In many cases there is no simple way of balancing these interests, and compromises are required. The arena in which such compromises are sought is political, and 'the design of an IPR system at any one time is based on a particular constellation of political power' (Andersen, 2004). As a result, IPR systems evolve over time and the analysis of IPR regimes must therefore be situated within an understanding of changing national and international political systems and priorities.

2.1.2 National and international aspects of IPRs

IPRs are territorial, i.e. they are based on national law and operate within the borders of the country that grants the rights. National legislators thus have to consider the rights of their citizens and the potential economic benefits in order to increase national welfare. Since countries and their industries differ widely, the optimum contribution to increased welfare may be achieved at different levels of protection. National policies on food security and public health have resulted in conflicts that have led to the establishment of exemptions in several countries (at certain points in time) for what are considered essential fields such as agriculture, food, pharmaceuticals, and chemicals. The national interest has also been used to justify provisions in national laws restricting or discouraging application for rights by foreign nationals. Historically, informed governments have been able to structure IPR regimes to promote domestic industry. The US did not recognize foreign copyrights until late in the nineteenth century and Swiss and Dutch companies benefited when their respective governments delayed

the implementation of patents until the early 20th century. The recent development of East Asian economies such as Taiwan took place with relatively little attention to IPRs (Wade, 1990).

Despite the wide range of historical trajectories for national IPR regimes, there have been long-standing attempts to achieve greater standardization and harmonization. International harmonization of protection systems has been a key issue since 1883 when the Paris Convention initiated a streamlining of the patent system in member countries. A number of mechanisms to promote standardization have been put in place. The Paris Convention forms the basis for international efforts to achieve mutual recognition of national IP practice in a group of member countries. From the Paris Convention, the Patent Cooperation Treaty (PCT) was developed, a worldwide system for simplified multiple filing of patent applications, with 124 member states in December 2004. The PCT forms an important tool for facilitating the application process for the filing of utility patents in member countries and facilitates the joint technical examination of applications. Similarly, regional patent organizations in Africa (ARIPO, mainly in southern/ eastern Africa and OAPI, in West and Central Africa) take much of the burden of processing patent applications from the offices of the member countries. Standardization at the implementation level through PCT, the European Patent Office (EPO) or ARIPO leaves the national integrity of IPRs intact, because the final responsibility for granting or rejecting the application remains with the national patent offices. OAPI is the only multinational system in which one application can be filed and result in a patent that is automatically effective in all member states. The most important development for harmonized IPR systems was provided in 1993 by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This agreement mandates the application of a range of minimum requirements for the protection of intellectual property by all member states of the World Trade Organization.

Powerful arguments for harmonization include the belief that right holders are more willing to transfer their technologies to other countries if their rights are respected in the same way as in their own country, and the fact that transaction costs can be reduced when procedures are harmonized. Lesser (1997b) strongly supports this view, while Correa & Musungu (2002) argue that IPRs should remain a tool of national policy, and that further substantive harmonization of patent law is not in the best interest of developing countries. Smith *et al.* (2004) cite changes in the distribution of costs and benefits among countries and support the relaxation of some international IPR rules. Scotchmer (2004) claims that harmonization will generally strengthen protection. The Commission on IPRs (2002) states that developing countries should identify a strategy for dealing with the risk that WIPO harmonization will lead to standards that do not take their interests into account. (The controversy is particularly intense with respect to the application of the TRIPS Agreement to developing countries. Does the application of the agreement increase the welfare of these countries? Is there enough flexibility in the agreement's minimum requirements to allow for meaningful adaptation to the needs of developing countries? With respect to the role of the patent system in food security in Africa, Taylor & Crayford (2003) propose mechanisms to improve access to patented technologies and to increase flexibility in the implementation of international agreements on IPRs. Follow-up discussions in the WTO in Doha tabled such questions with special reference to patenting of pharmaceutical products, triggered by limited availability of affordable HIV drugs in developing countries (McCalman, 2002).

Brazil and Argentina filed a formal request to the World Intellectual Property Organization (WIPO)[1] to increase the role of the development agenda in its work.

The structuring of national law and international agreements must also recognize that the establishment of IPRs involves a complex chain of institutional development that implies decades of adaptation and elaboration (Chang, 2002). For instance, the exclusive rights provided by IPRs are commonly implemented through contracts (usually called licenses in this context) that transfer (all or part of) the rights to other parties for use in prescribed ways and markets. In these cases the effectiveness of IPRs can then also depend on the traditions and implementation of contract legislation in a particular country. This is only one example of the dependence of effective IPR regimes on institutional capacities for devising, managing and enforcing appropriate legislation. The 2002 report of the Commission on Intellectual Property Rights places particular emphasis on the development of these institutional capacities, as well as emphasizing the underutilization of the flexibility that is included in TRIPS implementation at the national level.

2.1.3 Different property rights systems: applications to plant breeding

The emergence and development of effective IPR regimes are conditioned not only by specific political, economic and institutional parameters but also by the type of innovations that are the target of protection. This has resulted in a family of intellectual property rights systems for different types of products. Copyright for literary, scientific and artistic works (including software and its components) provides long-term protection of such works without formal scrutiny (they are automatically protected once published) and usually includes a simple registration system that assists in resolving possible claims. Industrial property rights relate to patents for inventions, industrial designs, trademarks, geographical indications and trade secrets, all with different regimes for registration, scope and duration of protection. Since these standard industrial property rights were not considered sufficiently adapted to particular sectors, so called '*sui generis*' systems have been developed for the protection of plant varieties (plant breeder's rights), integrated computer circuits, and databases. In addition, technological advance not only develops further types of innovation that are candidates for protection, but technological change can alter the possibilities for protecting (and copying) innovations, as illustrated by the controversies over the growth of the internet and its relations to copyright law (Lessig, 2004), and the introduction of 'business methods' patents where software applications can be protected by utility patent rights. IPR systems are not static. Society and inventors have to review regularly whether certain IP systems are still optimal when facing such new developments and challenges that result from interpretation of IP laws by the courts.

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 of the technology (and potential 'copiers') are millions of individual farms 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

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1 WIPO is the UN organization that administers many of the international treaties and conventions that deal with IPRs, such as the Paris Convention, the PCT, the Madrid Protocol on Trademarks, the Bern Convention dealing with copyrights, among others.

rural poor, making the imposition of any controls a sensitive political issue. 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 is there the possibility to protect individual varieties and genes, but the majority of the tools and processes of genetic transformation are patented. (The term of protection of several early but still important biotechnology patents expires shortly.) In addition, many of the techniques of biotechnology that are becoming an increasingly important part of conventional plant breeding are also protected, raising implications for the ownership of any variety resulting from such research. This is also related to concerns that patents can actually inhibit follow-on research, leading to a so-called 'anti-commons' in biotechnological research (Heller & Eisenberg, 1998). 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, providing new possibilities for utilizing or reproducing protected varieties and leading to pressures for even more stringent protection.

There is no doubt that plant breeding research and seed provision are vital industries that need to be fostered and stimulated. IPR regimes for plant breeding must play a central role in agricultural development, but the challenge is to strike the right balance between incentives for innovation and access to productive resources.

Despite the complexities of the plant breeding industry, the following is a list of possible functions that could be expected from an IPR regime in plant breeding, recognizing that controversy exists regarding the extent to which each of these functions is desirable:

In the interest of the rights holder:

i. to prevent farmers from saving seed of the protected variety, sharing the seed with neighbors, or engaging in large-scale informal sale of the seed ('brown bagging');
ii. to prevent competing commercial seed producers from multiplying and marketing the protected variety without a license;
iii. to prevent competing seed producers from using protected product names or logos;
iv. to prevent competing plant breeders from using a protected variety in the development of a new variety.

In the interest of the public:

i. to put material in the public domain when rights have expired;
ii. to stimulate improvements and innovations that increase the choices available to farmers.

Specific IPR systems are relevant to the breeding and seed industries. In this report we concentrate on plant breeder's rights and utility patents. The scope of protection may include methodologies used in plant breeding, the physical products that this industry provides (seeds and vegetative planting materials), and at times the disposition of the harvested agricultural product. In addition, the trademark system is important to the seed industry for the establishment of brands with commercial value, and trade secrets are particularly important for the seed

industry where breeders wish to avoid disclosure of the parents of hybrid varieties. There are also a number of mechanisms used by the plant breeding industry, independent of any IPR regime, that provide some level of protection, and this study examines their utilization.

2.2 The Plant Breeding Industry

2.2.1 Seed systems

IPRs in plant breeding may have effects on different components of the industry, or what may be called the seed chain. This chain consists basically of three components: research and plant breeding; seed multiplication; and marketing and distribution. These components have developed over time as specialized operations that are executed in various organizational patterns.

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 in order 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 have an important position in plant breeding, although the products are multiplied and marketed by private firms or co-operatives. 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 the field of plant breeding, and the associated opportunities for patenting, private industry has been very active in these areas since the early 1980s. This has been accompanied by a significant consolidation of the conventional seed companies into a much smaller number of 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 a profit center in its own right. In some cases such companies may detach themselves from the seed market, leaving operations in seed production and marketing to specialized companies that license the technology.

In most developing countries, the breeding industry has very different origins. Scientific plant breeding has largely been the responsibility of the public sector, often stimulated by the results of international research programs of the CGIAR centers. Plant breeding has been seen primarily as a contributor to rural development and national food security and thus a public responsibility. Similarly, seed production and distribution have been seen as vehicles for technology transfer rather than a commercial operation. More recently, some countries have stimulated commercial seed supply through privatization of public seed 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 remains a public responsibility while a variety of public, parastatal and private enterprises cater for seed production and marketing.

In addition to the formal seed system, there is a significant farmers' seed system that uses traditional methods of selection within and among varieties, on-farm seed multiplication, and informal diffusion of seed from farmer to farmer (Almekinders & Louwaars, 1999). These farmers' seed systems still provide the vast majority of all crop seeds used by farmers in most countries. Despite the fact that these farmers' seed systems are built on traditional methods and processes, they often involve modern varieties, some of which may have IPRs associated with them.

2.2.2 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. 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. The certification system introduces a strict generation control for seed production through which commercial seed can only be produced from breeder's seed ('pre-basic seed') through a prescribed number of generations. The breeder is in most cases designated as the maintainer of the variety and the sole source of this seed. Both variety release and seed certification systems can be compulsory or voluntary. The conditions established by seed laws and policy greatly influence opportunities for private enterprise, and seed policy change and regulatory reform are the subjects of continuing discussion in many developing countries (Louwaars, 2002; Tripp,1997).

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

International agreements on biodiversity provide the basis for additional national regulations that affect plant breeding, especially through their positions on access to genetic resources, Farmers' Rights and benefit sharing. The major agreements are the Convention on Biological Diversity (1993), covering all biodiversity and based on bilateral contracts; and the International Treaty on Plant Genetic Resources for Food and Agriculture, entering into force in 2004 and providing for a multilateral regime of access and benefit sharing, for a number of crops. Both CBD and IT PGRFA have attempted to avoid conflict with national IPR systems. There are however pressures from these bodies to directly connect to IPR systems, e.g. by including a declaration of origin in IPR applications. In addition, MTAs that are currently in operation based on these agreements may limit the opportunities to protect materials. Very few countries currently have enacted and implemented national laws in support of these international treaties, therefore, the present study did not focus specifically on the implications of these treaties.

Similarly the interplay between traditional knowledge, genetic resources and traditional cultural expressions (folklore), on the one hand, and IPRs, on the other, is the subject of international

forums, especially the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (the 'IGC') (see http://www.wipo.int/tk/en/igc/index.html). There are currently no substantial national regulatory frameworks that address this interaction, and it is not a subject of this report. However, the outcomes of these debates, such as the currently debated declaration (or certificate) of origin in IPR procedures, may have significant effects on the implementation of IPRs for the breeding industry.

2.3 The protection of plants and varieties

2.3.1 Historical perspective

Higher organisms have been exempted from consideration by patent law until very recently, and plant varieties have traditionally been subject to rather limited and very specific types of IPRs. There were ethical, political, legal, biological and technical reasons for this treatment. Ethical arguments include the notion that life is sacrosanct and that life forms should not be subject to commercial control. In addition, there have been political arguments regarding the concern that food security should not be the subject of commercial monopolies.

Legal and technical arguments arise from problems with the application of the patent system to plants and varieties. First, the industrial use criterion had to be expanded to include agriculture as well (as specifically included in the latest versions of the Paris Convention). Secondly, the novelty criterion of the patent system was difficult to maintain where the natural diversity of a plant variety is insufficiently known to the examiner. Third, the inherent genetic diversity within a plant variety and the inevitable changes between generations create problems with the description of the 'invention'. Fourth, there have been arguments about whether standard breeding methods constitute an inventive step. Fifth, the written description requirement that the invention needs to be disclosed in such a way to allow someone 'skilled in the art' to reproduce it is impossible in plant breeding; even if someone has access to the same parents and the same selection strategies it is impossible to breed the same variety. This problem has been solved for the patenting of micro organisms by the Budapest Treaty that allows a deposit of the protected organism as a mechanism for overcoming the enablement requirement. Other problems in the application of the patent system include the possibility that the patented subject matter may replicate itself (even without human intervention), and customs that have allowed the free movement of plant varieties within and among communities throughout the world.

Nevertheless, there have been arguments for establishing some mechanism to reward the creativity inherent in new crop varieties almost from the beginning of modern plant breeding. The emerging plant breeding and seed industry in the USA and Europe created pressure to develop specially designed protection systems (Van Wijk & Eaton, 2003). The first so called '*sui generis'* system was the Plant Patent Act of 1930 in the US which applied only to vegetatively propagated fruit and ornamental species, which does not preclude the use of the protected varieties as parental material for sexual propagation (Henson-Apollonio, 2003). This avoided the genetic diversity problem of sexually-propagated species and avoided some food

security issues by excluding edible tubers. In the years that followed, more generic protection systems for plant varieties developed in Europe, beginning with methods such as protected seals for seed from the original breeder (Germany) and monetary rewards (prizes) to breeders issued by farmers' organizations (Netherlands). The legal systems for the protection of plant varieties that were enacted in Europe from the 1940s onward were harmonized through the Convention for the Protection of New Varieties of Plants (Paris, 1961), which also established UPOV (Union for the Protection of New Varieties of Plants) to support and expand the new system. The UPOV system provides protocols for assessing and describing the unique characteristics of a new variety, ensuring that it is distinct, uniform and stable (DUS).

The UPOV system was revised 3 times, in 1972, 1978 and 1991, gradually strengthening the rights of the breeder. The rights defined under UPOV are known as plant variety protection (PVP). Currently, 55 countries have ratified a UPOV Convention; 28 follow the 1991 Convention, 25 the 1978 Convention, and 2 still operate under older versions. An expansion of the UPOV system took place in the early 1990s following the TRIPS agreement. PVP provides a protection system that is rooted in the agricultural sector and has some key differences with the patent system. Nevertheless, UPOV provides important harmonization functions. UPOV member countries may have quite different laws, based on different Conventions and interpretations, but almost all members use the same technical guidelines for DUS testing. This greatly facilitates the sharing of information among countries and reduces the transaction costs. Some countries, such as Switzerland, fully rely on foreign DUS reports, and thus don't need to develop specialized expertise and facilities.

The emergence of biotechnology has provided a second source of pressure for modifying the patent system to include the protection of living organisms. In the US, court decisions caused a gradual expansion of patentability (Landes & Posner, 2003). In the field of biotechnology this started with the Diamond vs. Chakrabarty case of 1980 which confirmed the patentability of a (genetically altered) micro-organism (Eisenberg, 1996). In 1985 sexually-propagated plant varieties were ruled patentable (Hibberd case), opening the door to a flood of applications for utility patents on plant varieties in the US. This was followed by the first patents on an animal (an oyster, in 1987) and on a mammal (Harvard's 'onco-mouse', in 1988). More recently, DNA sequences where a utility has been described have been considered patentable matter, first in the USA and subsequently in the majority of industrialized countries.

Since IPRs are national in scope, developments in the USA have few immediate implications for other states operating a patent system, but they are indicative of the type of pressure facing the plant breeding industry. There is currently a large diversity in patent legislation on plants and varieties; only a few countries allow patent protection for plant varieties, some exclude DNA patents, and some have special provisions in the patent system to limit the scope of protection when patents are provided affecting living organisms. The European Directive on the protection of biotechnological inventions includes a breeder's exemption and a farmers' privilege when the protection (e.g. on a gene) extends to a plant variety. However, bilateral agreements between the U.S. or EU and countries in the South often require that the partner country impose a level of patent protection that is comparable to that of the industrialized trading partner (Correa , 2004; Henson-Apollonio, 2004).

There are serious concerns that patent practices in the USA and Europe have contributed significantly to the oligopolization of the global seed industry, leaving four major international seed companies controlling the majority of the market and relegating other seed companies in industrialized countries to play only marginal roles.

2.3.2 Comparison of plant utility patents and PVP

The UPOV-based national laws for the protection of plant varieties (PVP) differ significantly from the patent system with regard to the conditions for protection (distinctness, homogeneity, stability, novelty and nomenclature: DUS-NN). DUS standards are adapted to the mode of reproduction of the variety and relate to the average of the existing varieties. For example, cross-fertilizing crops have a wide tolerance applied for uniformity, while requirements are very strict for vegetatively propagated crops. An applicant variety is considered new under PVP when it has not been offered for sale (anywhere in the world). There is furthermore no requirement for utility, such as a positive result of testing for the Value for Cultivation and Use (VCU). Furthermore, the two systems differ with respect to two major exemptions to the protection: the breeder's exemption allowing breeders to freely use any protected variety for further breeding; and a farmers' privilege, providing farmers the right to reproduce seed of a protected variety without the consent of the breeder. Table 1 summarizes the main differences.

The two exemptions are particularly crucial for understanding the differences in PVP between the various UPOV Conventions, on the one hand, and the differences between PVP and plant utility patents, on the other. Also the breeder's rights laws of countries that are not members of UPOV, such as India, Indonesia and African countries that base their laws on the model Law of the African Union, address these basic exemptions as well. These two exemptions address the two 'lines of protection' that IPRs offer the industry: protection against competing breeders (breeder's exemption) and protection against the customers (farmers' privilege).

Breeder's or research exemption

The Breeder's Exemption is one of the cornerstones of plant breeder's rights systems. It has not changed in the subsequent UPOV Conventions. Even in the 1991 Convention everyone is allowed to freely use any protected variety for further breeding, under the condition that the results of certain breeding methods that produce so-called 'essentially derived varieties' (EDVs) may fall within the rights of the breeder of the original variety. This is meant to reduce 'cosmetic breeding' and reward conventional breeders even when their variety is slightly altered through mutation breeding, repeated backcrossing or genetic transformation.

The Breeder's Exemption is also a matter of discussion within the breeding industry itself. Some larger companies would like to introduce the concept of 'genetic distance' in the EDV-definition but other companies fear that this could lead to opportunities for strategic protection behavior, monopolizing certain gene pools and effectively restricting the breeder's exemption. A discussion on the exemption itself among seed company representatives arose in a recent seminar organized by the International Seed Federation (ISF, 2004). A call by one participant for restricting the breeder's exemption in a future UPOV Convention was countered by a strong defense by another company of the need to balance access to parental materials and the level of protection through PVP, which was later published on the company's website.

There are major differences between the breeder's exemption under PVP and the so-called research exemption in utility patent systems. There is much debate on the research exemption in the patent systems of several countries. Academic institutions have long been exempted from patent claims for their research and education purposes based on the assumption that such research had no commercial intent (Eaton & Tongeren, 2004). In several countries such research exemptions are specifically included in the law; in others such as the USA it is an interpretation of clauses on private and non-commercial use provisions. The situation is under discussion as the result of a number of court rulings. *Maley v. Duke* in the USA seems to result in a restriction of opportunities to use patented products or processes for research, and indicates that scientists need a research license to use them. The research exemption would only apply to research *on* the invention, and not researching *with* the invention (Eisenberg, 1996). Research licenses are commonly granted without the payment of royalties, but specify the rights of the patent holder in case the research leads to something useful. Such interpretation would mean that a PVP-protected variety that is available for further breeding cannot be used when it contains a patented gene. In the European Union, this conflict between patents and PVP is solved by providing a specific breeder's exemption and a farmers' privilege in the patent system when the scope of the patent would extend to a plant variety (Kiewiet, 2001).

In order to avoid these controversies there was an explicit ban in UPOV 1978 on 'double protection'. Many countries still maintain that position, but more and more countries offer possibilities to obtain both patent and PVP protection on certain materials. This is one of the key demands by the current trade negotiations between the USA and a number of Latin American countries.

Farmers' privilege or Farmers' Rights

The right of farmers to save seed from their harvests to plant the following season is one of the most contentious aspects of IPRs in plant breeding. Early UPOV Conventions assumed that farmers were permitted to save and reuse seed of protected varieties. (UPOV refers to this as 'farmers' privilege', although many believe it is more correctly described as a farmer's right; this report maintains the term privilege, to distinguish it from broader concepts of Farmers' Rights, e.g. in the IT PGRFA.) In some countries the farmer's privilege was interpreted rather broadly. Perhaps the most notable case was the US, where farmers were allowed not only to save but also to sell seed of protected varieties to their neighbors as long as the sales accounted for less than half of total farm income. This led to extensive informal seed sale ('brown bagging') and significantly reduced revenues for seed companies. The issue was not resolved until an amendment to the US Plant Variety Protection Act (PVPA) and a Supreme Court decision in 1995 that effectively prohibits farmers from selling seed of protected varieties. The farmers' privilege issue was addressed by UPOV in the 1991 Convention, which allowed member states to specify crops for which the reuse of farm-saved seed in the same farm would be permitted. For other crops, any transfer of seed (through sale, barter or gift) between farmers is prohibited, and on-farm seed saving may be subject to restrictions or the payment of royalties. Utility patents on plant varieties in the USA are even more rigid with respect to the farmer's privilege; a patented variety cannot be saved for subsequent use as seed on-farm or in trade or exchange with other farmers.

These interpretations of the farmers' privilege lead to major discussions in many developing countries, many of which have chosen to use the provisions of the 1978 Convention when introducing breeder's rights. Making the transfer of seed from farmer to farmer illegal is widely considered incompatible with traditions of seed handling and sharing among farmers. In addition, such a restriction is considered incompatible with ongoing discussions in the framework of the International Undertaking (and the International Treaty on Plant Genetic Resources for Food and Agriculture) about the concept of Farmers' Rights which was to include provisions on the right to save, use, exchange and sell farm-saved seed/planting material. However, Article 9.3 of the IT PGRFA made this provision 'subject to national law and as appropriate'. Some countries, notably India, explicitly include Farmers' Rights in their national law.

Box 1. Saving of seed on-farm

One of the distinctions between plant breeder's rights systems and utility patents is the right of farmers to save (and in some cases exchange and sell on a non-commercial basis) seed of protected varieties. Discussions about IPRs in the breeding industry consider this a key issue in adapting IPR systems to the needs of the agricultural sector. Even within a single country, the requirements and conditions of different agricultural systems are not uniform, and it is possible to consider legal options that address this variability.

The Netherlands identified the need to restrict farm-saving of seed and planting materials for some highly commercial crops, notably the production of vegetatively propagated flowers like carnation, rose, and chrysanthemum. New varieties of these species can be propagated by farmers very quickly to cover large parts of commercial farms, leading to inadequate royalties for breeders and inadequate incentives for innovation in a sector that is very important for Dutch agriculture. Dutch law that is compliant with UPOV 1978 includes special provisions to make farm-level propagation of protected varieties of such species without the consent of the breeder illegal. This arrangement leaves the farmers' privilege untouched in areas where they are considered useful and necessary (e.g. cereals).

Developing countries could use this example in designing the appropriate levels of protection for different types of commodities which are included in various types of market systems and have different implications for the development of domestic plant breeding capacities.

2.4 The protection of plant biotechnology

2.4.1 Relevance of biotechnology in the plant breeding industry in developing countries

Plant biotechnology emerged in the 1980s following the first transformation experiments involving bacteria. Together with the developments in information technology, this has resulted in a scientific revolution. The understanding of the function of various types of DNA, combined with the ability to 'cut and paste' them in the genome of any living organism, has transformed the science of plant breeding. Initially, the technology was used in a rather crude form which led to herbicide resistant varieties, or using known functions of bacterial DNA, such as Bt. In the case study countries that allow GMOs in the field, only Bt crops were found in commercial production. All experiences in this report on the effects of patents in the plant breeding industry are thus derived from one type of transgenic in one major crop (cotton).

However, a wide range of transgenics are 'in the pipeline' in laboratories in industrialized countries, but also in the South. Atanassov (*et al.*, 2004) identify 209 transformation events[2] in developing countries, with over 50% of that total in China, South Africa, Indonesia, Argentina and India. The pipeline includes events in many different crops and includes functions far beyond the narrow scope of herbicide tolerance and insect resistance. Additional characteristics include virus resistance, agronomic properties, fungal resistance and product quality.

2.4.2 Patents in biotechnology

The vast majority of the innovations in plant biotechnology are subject to patents, although the scope of coverage varies considerably by country and technology. Patents are used to protect biotechnology laboratory tools and reagents, genes and gene sequences, and processes for transformation, regeneration and diagnosis. A genetically modified organism commonly includes an inserted construct that contains a functional gene, a selection marker, a promoter and other sequences that may all be patented (by different inventors). It is inserted using a transformation method that is patented (possibly including improvements on an original method that may itself be patented) and using equipment and other materials for which a research exemption may be required. A freedom to operate analysis on the commercialization of a product (variety) derived from such research may be required from a wide variety of patent holders (as long as the patents are valid in the country where the variety or its products will be used).Having a patent on a 'new' gene is thus no guarantee of freedom to operate when other technologies or processes must be used to make the gene functional in a plant.

The patent regime for biotechnology affects not only the development of transgenic varieties but also has important implications for the use of biotechnology in conventional plant breeding. Various diagnostic tools and equipment used for such increasingly important activities as marker- assisted selection may be protected. Even though a new crop variety may not contain

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2 A transformation event is defined as the stable transformation (incorporation of foreign DNA into a living plant cell) undertaken by a single institute, thereby providing a unique crop and trait combination.

any novel or protected genetic material, if its development relied on the use of protected tools or processes it may be subject to license or restriction by a range of patent holders.

Box 2. Biotechnology processes and products

1. Biotechnology processes

Transformation methods: particle gun; Agrobacterium mediated transformation; other bacteria mediated transformation. (Almost all transformations currently in use in developing countries are derived from the first two.)
Marker systems: RAPDS, RFLP, AFLP, SSRs, SNPs are methods to analyze the structure of DNA and the presence of particular characteristics in a given individual. Patented molecular marker systems may be used under a research license.
Regeneration methods: these include medium, temperature, light etc. regimes to create callus and plant (organs) out of cell suspensions. Many of these are published; methods to achieve higher efficiency or to regenerate specific species are often kept secret, since the use of such methods cannot be detected in the product.

Protected biotechnological processes are commonly provided under a research license. Such license may include provisions that regulate ownership and revenue sharing in case a commercial product is developed from the research. The holder of the rights on the process does not have IP-rights on the product, but a certain level of co-ownership, based on a contract.

2. Genes and sequences

Genes can be patented in many countries when their structure and their function can be described by the inventor. Gene patents can be the basis of very wide claims, covering many species and many uses.
Genes: functional genes include those for various types of Bt, herbicide tolerance, etc.
Selection markers: these include GUS and NPT2 and are used to check whether a cell is based on a successful transformation event.
Molecular markers: these are often small sequences (DNA, RNA, protein) that can be used to identify valuable characteristics, or to analyze the structure of a particular genome.
Promoters: 32S (close to expiry of the patent)
Start/end sequences
GMO variety: in the USA GM varieties and groups of varieties can be patented.

3. Tools relevant to plant biotechnology e.g.

Biotechnology equipment: sequencers, microsatellite analyzers, PCR-machines and their components. Similar to process patents, the inventor of a certain tool cannot claim IP on a variety, but can have rights, based on a contract with the scientist using the equipment.
Reagents: In most cases the inventor will obtain revenue through adding a mark-up on the price of reagents that are necessary to use the equipment.

4. A transformation event
A successful transformation commonly involves a gene construct (gene, promoter, selection marker and some additional bits of DNA) that has been inserted in a plant through a particular process. The number of repetitions and the place(s) of the construct in the genome determine the effectiveness of the event. Selection from large numbers of transformants will lead to a new modified organism that can be the basis of new varieties through conventional breeding, which may result in a range of new varieties.

However, many patented technologies are not protected in most developing countries. Binenbaum *et al.* (2003) indicate that since most commodities in developing countries may be traded in regional markets but rarely reach the North and hence there may be considerable opportunities for the use of protected technology without fear of immediate sanction.

The discussion about the possible monopoly effects of biotechnology patenting has triggered an initiative that is similar to that for open-source software, which is attempting to counteract the proprietary approach of large software companies. The idea in the agricultural biotechnology sector is that new (preferably enabling) technologies such as transformation systems and selection markers are developed in the public domain. These are then patented and licensed to everybody under the condition that any improvements or products developed from them are licensed out under the same conditions (see www.cambia.org). It is not clear yet whether this process will yield enough open-source technologies to enable biotechnologists to develop biotechnology-based plant varieties without major strings attached.

Another trend is the widening use of humanitarian licenses. A number of universities in the USA have taken the initiative to reduce the number of exclusive licenses on their patented inventions in order to retain control over opportunities to grant licenses on a preferential basis to users that work for the benefit of the poor. The Generation Challenge Program of the CGIAR (www.genesforcrops.org) has developed a format in its consortium agreement that will result in an automatic humanitarian license to all users for the benefit of the poor of IP developed in the course of the program's activities (Barry, in press).

Table 1. Comparison of four IP systems for plant varieties.

Criteria	UPOV '78	UPOV '91	Plant Patent (USA)	Utility Patent (USA)
Protection	Varieties of species/genera as listed	Varieties of all genera and species	Asexually reproduced plants	Sexually reproduced plants
Exclusion	Non-listed species	-	Uncultivated and tuber-propagated plants	First generation hybrids, uncultivated plants
Requirements	Novelty (in trade)	Novelty (in trade)	Novelty	Novelty (in invention)
	Distinctness	Distinctness	Distinctness	Utility
	Uniformity	Uniformity	Stability	Non-obviousness
	Stability	Stability		Industrial application
Disclosure	Description	Description	Description, including photographs and drawings	Enabling disclosure
				Best mode disclosure
				Deposit of novel material
Claims	Plant variety (listed species)	Plant variety (all species)	Plant variety (vegetatively reproduced, except edible tubers)	Any invention: plant (characteristic in any variety), Plant variety, genes, vectors, enabling technologies, equipment for producing plants, etc.
Rights	Prevent others from producing/ commercializing propagating materials	Prevent others from producing/ commercializing planting materials + under certain conditions: harvested materials	Prevent others from asexually reproducing, selling, or using claimed plant variety	Prevent others from making, using, selling, the claimed invention; prevent others from selling a component of the invention
Exemptions	For further breeding	For further breeding, restricted in case of EDV	Research exemption	Research exemption
	For private and non-commercial use	Farmers' privilege: permitted, taking into account the legitimate interests of breeder		Sexual reproduction of the claimed variety
				Products derived from the variety
		Private and non-commercial use		
		Experimental purposes		
Duration	15 – 20 years (depending on crop)	20 – 25 years (depending on crop)	20 years from filing or 17 years from granting (prior to 8 June 1995)	20 years from filing or 17 years from granting (prior to 8 June 1995)
Double protection	No	Yes	No	Yes

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

2.5 Empirical research on the impact of protection of plant varieties and plants

An IPR system is created to provide incentives for innovations based on the disclosure of their methods in exchange for temporary exclusive production and marketing rights. A considerable body of research has attempted to establish the nature and extent of the incentives created by IPRs. A full review of this literature is beyond the scope of the current study (see Lesser, 1997a, Srinivasan, 2001; Eaton, 2002), but it is generally acknowledged that the situation is quite complex and that IPRs can fulfill a variety of roles in strategies to protect IP and to defend market share (Granstrand, 1999). In the area of plant breeding, attention has concentrated on the effects of the introduction of PVP in a number of countries, including the U.S., the U.K., Canada, Australia and Spain. Taken together these studies provide little conclusive evidence of the effects of PVP in industrialized countries, and the results are thus open to various interpretations.

Studies in the U.S. have examined the trends in varietal release together with questionnaire-based surveys of breeders. Taken as a whole, these studies (Butler,1996; Butler & Marion, 1985; Perrin, Kunnings & Ihnen, 1983; Frey, 1996; Kalton, Richardson & Frey, 1989; Venner, 1997) indicate that private sector breeding in a number of non-hybrid crops has 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. For example, in the case of soybeans, considerable increases in breeding activity may be more attributable to growing demand for the crop. In the case of wheat, Alston & Venner (2002) demonstrate that private sector investments have remained relatively static, while those of the public sector have actually increased over 1970-1993.

Studies in other countries have also found inconclusive effects of PVP. Penna (1994) found a statistically significant increase in the development of new varieties of some horticultural varieties in the UK but not for others. In Canada, a survey of breeders reported some increased breeding activity in horticultural crops, but less in grains or oilseeds, following the introduction of PVP (Canada Food Inspection Agency, 2001). For Spain, Diez (2002) found a strong correlation between the number of PVP certificates granted per crop species and the availability of protection. It is difficult to draw firm conclusions on the effect of PVP in such studies because of the alternative explanations for the correlations seen. For example, in the case of Canada, impacts of PVP are difficult to separate from the effects of the U.S.-Canada Free Trade Agreement.

One study has examined the effect of PVP in a developing country. Jaffe & Van Wijk (1995) surveyed plant breeding companies in Argentina about their investments over the period 1986-1992. They concluded that PVP may have prevented domestic companies from reducing or eliminating some breeding programs, and may have helped in reactivating soybean research. Furthermore, MNCs operating in Argentina indicated that their investment decisions were influenced primarily by other factors.

The evidence is often interpreted as an indication of the methodological difficulties of determining the impact of PVP. Even where there is longer-term data allowing a comparison of

before-and-after, there is no counterfactual situation. Attribution of observed changes to PVP is still complicated by the longer-term nature of plant breeding as well as various other concurrent or subsequent developments. Some have interpreted this evidence (Alston and Venner, 2002) as an indication of PVP being a relatively weak form of protection, but this does not necessarily imply that further increasing the scope of IPR protection will yield greater impact.

There are no attempts to document the effect of patenting on plant breeding but studies of the introduction of GM crops have yielded other interesting information concerning the appropriability of benefits by the breeder. GM crops are usually protected through patents (on the plant and/or one or more genetic constructs) which are implemented using methods such as user agreements, supplier contracts and sales tied to agrochemical products. A growing number of studies (e.g. Falck-Zepeda, Traxler & Nelson 2000; Pray *et al.*, 2001 for Bt cotton in China) on the welfare impacts of GM crops estimate the proportion of benefits accruing to three separate groups: the breeding company, the farmers and the consumer (representing the rest of the supply chain). Seed suppliers, such as Monsanto or Syngenta, are generally able to obtain much higher margins from farmers for GM seeds, although the largest share of benefits is typically enjoyed by adopting farmers. But whether making patent protection available for such plants in developing countries has been an important factor in the decision to develop such varieties has not been well studied. It is important to remember that private sector development of GM crops was driven by the U.S. market situation where patent protection was introduced in 1980 but where PVP protection is relatively weak compared to PVP in e.g. Europe. This complicates any eventual inference of the relative incentive effects of patents versus PVP.

Another growing body of literature examines the relationship between IPR regimes and some measure of innovation, using a cross-section of national data and controlling for other factors such as market size. One recent example is a study by Kanwar & Evenson (2003) who found a significant correlation between an index of IPR strength and economy-wide expenditures on research and development (R&D). A few studies have looked at the specific situation in the plant breeding sector. Pardey, Koo & Nottenburg (2003) found a positive relationship between IPR strength and the number of PBR applications for a sample of 42 countries over the period 1997-2001. Using a cross-section of 13 countries over various time periods in the 1990s, Srinivasan, Shankar & Holloway (2002) found a positive correlation between IPR strength and the number of PVP certificates granted. They also find a similar relationship for the number of PVP certificates granted to foreigners, although the share of certificates granted to foreigners is negatively correlated with IPR strength and market size. Pray, Courtmanche & Govindasamy (2002) examined the issue of GM crops, revealing a positive relationship between field trials of GM crops and both the availability of PVP protection and the frequency of biotechnology patents for a cross-section of 58 countries over 1987-2000. A purely economic correlation is calculated by Lesser (2002) between the strength of IPRs in developing countries and the level of foreign direct investment.

While useful for quantifying the extent of correlation between IPRs and innovation, such studies need to be interpreted carefully and do not provide very strong evidence that increasing the scope of IPRs in any given country will lead to a corresponding increase in breeding activities. The econometric methods and data used do not permit an evaluation of alternative explanations for the correlation between IPRs and innovation. For example, in the studies above, IPR

indices could be capturing more generally the development of the legal system and the enforceability of contracts. Furthermore, the samples in these studies are often dominated by industrialized (OECD) countries, meaning that the relevance for developing countries of the observed correlation is not necessarily apparent. At the same time, cross-section econometric analysis over countries can be useful for identifying certain correlations and helping to define the need for more research on causal relationships using case studies.

There has been less empirical research conducted on the effects of patenting in agricultural biotechnology and little is known of the consequences. The risk that patenting of key technologies would stifle more applied research because of the cost and inconvenience of negotiating licenses was raised by Heller and Eisenberg (1998) in the context of biomedical research, with the coining of the term, 'anti-commons.' Mazzoleni and Nelson (1998) also indicated similar effects from broad patents in the biotechnology sector in general, referring to the U.S. context, while Falcon & Fowler (2002) warn of the consequences in the case of agricultural technology and genetic resources, in particular the patenting of gene sequences and their functions. Oldham (2004) illustrates such concerns with reference to a recent patent application concerning the regulation of flowering in rice, with additional claims potentially covering maize, banana and wheat. Little systematic research has been undertaken in this area with efforts concentrating on trends in the use of the U.S. patent system by the agricultural biotechnology sector (e.g. Buccola & Xia, 2004). Concerns of an 'anti-commons' have clearly been the motivation of researchers involved in establishing new clearing-house or 'open-source' initiatives, such as CAMBIA (mentioned in previous section) as well as efforts to establish widely applicable humanitarian license clauses in research consortia directed at the poor, such as the Generation Challenge Program. But the OECD (2004) points out that, aside from individual examples, 'there is no widespread breakdown in the licensing of biotechnology patents'. Nonetheless, the OECD recognizes that most changes to the patent system have been implemented without hard evidence or economic analysis, and thus continued vigilance is necessary to ensure that access to inventions does not become excessively restricted.

2.6 Additional strategies to protect the interest of the breeder and seed producer

2.6.1 Non-IPR protection mechanisms

The plant breeding industry does not rely solely on formal IPR systems to protect its varieties and limit their use. The alternatives include biological processes, conventional seed law, contract law, biosafety regulations, brands and trademarks, and secrecy.

2.6.2 Biological protection

The oldest, and still one of the most important, mechanisms for protecting a plant variety is hybridization. Hybrids are the products of the cross between two (or more) inbred lines. The discovery of the phenomenon of hybrid vigor opened new possibilities for producing high yielding varieties and offered two distinct advantages for variety protection. The seed of hybrid

origin will lose some yield potential and other valuable characteristics (such as uniformity) in subsequent generations, which drastically reduces farmers' incentives for seed saving. In addition, competing seed companies require access to the inbreds if they are to successfully duplicate the hybrid variety (although IPRs may be needed to fully protect the parent lines from use by competitors). The first commercial use of hybrid technology was in maize in the 1930s. Hybrids have since been developed in most cross-fertilizing crops such as sunflower, canola, cotton, cabbage, and high-value horticultural crops for which labor-intensive hand pollination is economic. More recently, hybrid technologies have been developed and commercialized for rice (China) and pearl millet (India). Hybrids overcome much of the uncertainty in the conventional seed market, where factors such as the weather determine the degree of on-farm seed saving and hence the demand for fresh seed. The use of hybrids provides a steady demand for seed. Hybrid seed is more expensive to produce but if the varieties thus developed are superior in homogeneity and yield potential, substantially higher seed prices can be charged.

A more recent example of biological protection mechanisms is the introduction of V-GURTs (Genetic Use Restriction Technologies, operating at the variety level) (Louwaars *et al.*, 2002). Such technologies lead to sterile seed when reproduced without special treatments and would ensure that commercial seed could not be saved by farmers for subsequent planting and make it difficult for another breeder to use the protected germplasm. There are several such mechanisms that are the subject of research based on genetic transformation. None of these is yet commercially viable, but the possibility of a 'terminator technology' has led to widespread debate in the popular press.

2.6.3 Seed laws

In the absence of IPRs, seed laws can be very useful for the breeding industry. For instance, when seed certification is compulsory for all seed, the breeder can control the market to a large extent by limiting access to breeders' seed. Any unauthorized multiplication will not be acceptable to the certification agency. This means, for instance, that a public research organization can establish an exclusive contract with a seed company for the production of its varieties, even in the absence of IPRs. Similarly, a private breeder may set a high seed price for breeder's seed or can develop a contract with more specific conditions concerning royalties and market segmentation, supported by seed certification regulations. Variety release regulations may also be used to offer some type of protection, for instance in limiting the extent to which a company can market an essentially derived version of a released variety (including the unauthorized use of a transgene) or prohibiting the sale of a released variety under another name.

2.6.4 Contracts

Various types of contracts can be very effective in providing legally enforceable agreements that restrict the use of a breeder's variety and offer substitutes or complements to IPRs. Such contracts are only useful if the provider of the genetic materials has exclusive access (secrecy), rights (IPRs), or can offer other benefits for the other contracting party. Some contracts are

aimed primarily at preventing seed saving and multiplication while others are aimed at protecting the germplasm from being used in competitors' breeding programs.

One type of contract that is becoming increasingly prevalent, at least in the US seed market, is the grower contract. This is a simple agreement (similar to that found on software) that restricts the farmer from using or disposing of any part of the harvest as seed.

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 seed saving or multiplication. One important example is the cut flower industry, where the output can only be sold in a limited number of wholesale markets in Europe. If a flower variety is protected in the country where the major market is located, growers in other countries may have to sign contracts limiting multiplication or unauthorized sale, or risk being denied further access to the major market. The contract can be effective even if the flower-growing country has no IPR system. A similar phenomenon is beginning to appear in several Latin American countries growing Monsanto's 'Roundup-Ready' soybeans and Bt cotton. In the latter case, control over ginneries provides a convenient point of enforcement; for soybeans there are indications that some grower associations appear ready to accept the collection of a royalty at the point of sale (e.g. the grain depot) in order to ensure unimpeded access to the technology.

Material transfer agreements (MTAs) are another form of contract that may be used in the plant breeding industry. These may be established between genebanks or other public institutions and private breeders, or may be used to govern transactions among private or public breeders. The MTAs can establish exclusive access, stipulate the type of benefit sharing in the case of commercialization, and generally prohibit legal protection by the recipient of the materials 'in the form received'.

A biotechnology company that owns genes or transgenic varieties (with IPRs established in one country), may establish contracts for their access in another country, even if the latter does not recognize the particular IPR. Thus there are examples of major biotechnology companies entering into contracts with national agricultural research organizations for the use of particular transgenes. The contract may specify how the genes are to be used, the rights to any technologies that are produced, and the obligations of the company (e.g. for providing training or other assistance).

Another strategy for companies is to negotiate a contract with a particular level of government. An example is the agreement in China between Monsanto /DPL and the Provincial Government of Hebei that excludes others from selling Bt cotton in the territory of the province. This contract does not rely on intellectual property rights. Similar arrangements in China have protected national breeding/seed parastatals or companies from competition.

Finally, MNCs may find that the commercialization of transgenic varieties in developing countries, including seed marketing, policing violations and enforcing rights, may not be as profitable as licensing rights to a transgene to local seed companies. In developing countries

with well developed private seed enterprises, such as India and China, this type of contract may be increasingly common.

2.6.5 Biosafety

Biosafety regulations are not meant to serve as IPRs, but primarily to protect the environment and to promote the safe use of biotechnologies. However, details of the biosafety system can create property-like rights. First, 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 itself may be valuable property.[3] The biosafety system generates data from extensive testing to demonstrate environmental and food safety. Such testing is very expensive, especially when feed and food trials are necessary and may require specialized testing facilities. Some countries require safety data for each 'event', i.e. the introduction of a particular construct (gene, promoter, etc.) at a particular place or places in the genome. When such a modified plant is used in conventional plant breeding to produce new varieties, the construct and its place are generally not altered and biosafety clearance for the new variety (on the basis of data from the original event) can be quickly accomplished. In other countries, the biosafety data must be presented for every new variety. Since such data are commonly confidential, access to the biosafety data has great commercial value and creates the basis for contracts that create rights over the genes. For example, in India genes cannot be patented, but Monsanto can control its Bt gene technology through keeping its biosafety data confidential. Breeders who want to release a new cotton variety that includes the gene construct have to enter into a contractual agreement with Monsanto in order to satisfy the biosafety regulations in the country and such contracts are likely to include a license fee based on the amount of seed sold.

2.6.6 Brands and trademarks

Brands and trademarks are part of intellectual property law but their utility in the seed industry is often overlooked. Seed companies often register their brands or trademarks as a way of distinguishing their products from those of their competitors. In the absence of other IP instruments, the development of a strong brand image and reputation can protect a company from some types of competition. It is much less common for crop varieties to be trademarked, and there is usually a prohibition against the use of the same name as a trademark and under PVP registration. The most important use of trademarks in the study was the practice of the flower breeding industry to pursue trademark registration for its most popular varieties (using different names than those for PVP). The trademark can be used and protected long after the expiration of PVP on the variety.

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[3] A similar situation can be found in the pharmaceutical sector, where test data are needed by the producers of generic drugs to register their products when the patent on the original product is due to run out. Extension of the confidentiality of the test data can provide additional protection to the inventor beyond the legal term of protection (W.J. Louwaars, pers. com.).

2.6.7 Secrecy

In some instances secrecy is an effective way to protect markets, and the choice between patenting and secrecy may depend on the type of technology and the size of the firm. In industries where a long lead time is required for imitation, being first to market may be more valuable than patent rights (Cohen *et al.*, 2000). In plant breeding, the primary example of a trade secret is the protection of the inbred lines used to produce a company's hybrids. 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. In some cases, companies can go to considerable lengths to protect their inbreds; a three-way cross maize hybrid may be the product of a single cross (produced from two inbreds in one country) and an inbred, with the final cross made in a second country. In the case study countries, trade secrets are not protected by a separate body of law but come under standard trade laws. With advances in biotechnology, secrecy becomes more difficult to maintain and less valuable. The reverse engineering of new varieties becomes easier and the copying into new genetic backgrounds is facilitated by the application of marker-assisted selection methods. The lead time thus becomes shorter for breeding companies, secrecy as a means of protection is more problematic, and IPRs assume greater value.

2.7 Summary

IPRs provide a legal mechanism meant to stimulate technological advance for the benefit of society and the growth of enterprise. They will play an increasingly prominent part in the plant breeding industry of developing countries by providing economic incentives for more productive research and commercial seed provision. At the same time, it is important to recognize that IPRs can only be justified by their contribution to the welfare of a society. IPR regimes in plant breeding must therefore be seen as part of a wider strategy for developing an efficient and equitable agricultural sector. IPRs are only one element of policies to stimulate the growth of institutions that serve broader development goals. The impact of IPRs in agriculture in a particular setting will depend on the performance of many other institutions, the status of the public and private seed sectors, the technology available, and the type of farming and rural communities. There are no simple rules that can be applied, and policymakers will have to learn from their own, and others' experience. It is particularly important to assess experience to date in countries that have taken early steps towards establishing IPRs for plant breeding.

In the present study, we have tried to address a few basic questions regarding the current experience with IPRs in plant breeding:

- Which IPR systems are relevant for the breeding industry; which choices have countries made based on the international agreements and organizations to which they belong?
- What is the relative importance of IPRs in the context of the various economic, technological and institutional factors that determine the development of the national plant breeding and seed sectors? To what extent do IPRs support or counter these developments?
- To what extent can the incentives offered by an IPR system be achieved through alternative legal or institutional mechanisms?

- What are the factors related to the implementation and enforcement of an IPR regime for plant breeding; what are the institutional options and the costs involved?
- To what extent, and in what ways, do IPRs affect the conduct and performance of public sector plant breeding?
- To what extent and in what ways, do IPRs affect the development of the private plant breeding and seed industries?
- To what extent and in what ways, do IPRs regimes affect the access by different classes of farmers to new varieties and seed?

3. Plant breeding and seed production in the case study countries

3.1 Agriculture

China

The growth of agricultural production in China since the 1950s has been one of the main accomplishments of the country's development and national food security policies. China has used 10% of the world's cultivated land to feed more than 20% of the world's population. Except during the famine years of the late 1950s and early 1960s, the country has enjoyed rates of production growth that have outpaced the rise in population, resulting in a significant improvement in food availability. Since the middle of the 1980s, China has been a net food exporter and since the mid-1990s China became a net cereal grain exporter. The rural household responsibility system, accompanied by price increases, has stimulated China's agricultural economy. From 1978-1984, grain production increased by 4.7% per year; the output of fruit rose by 7.2%.

However, the one-off efficiency gains from the shift to the household responsibility system were essentially reaped by the mid 1980s, and the growth rate of agriculture has since declined. The declining trend is most pronounced for grain. While dropping below the rate of growth generated in both the pre-reform and early reform periods, production of rice, other grains, and cash crops continued to expand after 1985. In the meantime, rapid economic growth, urbanization and food market development have boosted the demand for meats, fruits and other non-staple foods, changes that have stimulated sharp shifts in the structure of agriculture (Huang & Bouis, 1996; Huang & Rozelle, 1998). For example, the share of livestock output in total agricultural production value more than doubled, from 14% to 30%, between 1970 and 2000. One of the most significant signs of structural changes in the agricultural sector is that the share of cropping in total agricultural output fell from 82 to 56%. Within crops, grain area has gradually declined, while cash crop area has expanded.

Colombia

Although commercial agriculture (e.g. coffee, tobacco) has been an important part of the Colombian economy since the nineteenth century, agriculture has tended to grow more slowly than the rest of the economy since the 1960s, in part due to the increasing importance of manufacturing and service sectors. Nevertheless, in the late 1980s agriculture contributed 21% of GDP and 68% of export revenues. The country's diverse topography contributes to a wide range of commercial agriculture. Banana plantations are an important aspect of the lowland economy, while coffee dominates the highlands, with about 20% of all cultivated land in the country under coffee. More recently, the high central valleys have become an important center for the production of cut flowers. Cattle ranching is also important throughout much of the country. Commercial agriculture is characterized by the presence of strong commodity-based producer organizations (e.g. coffee, oil palm, rice) that provide support for agricultural

research and lobby for agricultural policies favorable to their membership. Although public support for agriculture has been important, there is a growing dominance of private investment in agricultural research and services. Colombia's agriculture is strongly dualistic, with 10% of the farms accounting for 80% of the farmland. After an initiation of land reform in the 1930s, there has been relatively little progress. Smallholders in the highlands grow a range of food crops, including small grains, maize, beans and potatoes; those in coastal areas rely on maize and root crops. More than 80% of the rural population is under the poverty line and rural unemployment has been increasing, in part due to the fact that 800,000 ha have been taken out of production in the past decade. The National Development Plan includes several initiatives for revitalizing agriculture in the country, such as plans to increase investments in cotton and maize production.

India

Indian agriculture is predominantly smallholder agriculture. The distribution of land holdings is highly skewed and small farmers (less than 2 ha) constitute 80.3% of total farm holdings and occupy 36% of agricultural land. The fragmentation of land holdings have reduced the average size of holding from 2.7 ha in 1961 to 1.4 ha in 1996. Agriculture supports 72% of the population and contributes about one-quarter to the national gross domestic products and about 12% to the total exports in 2002.

Agricultural land area remained constant around 140 million ha during the last three decades. The gross cropped area is 190 million ha, giving a cropping intensity of 136%. The area under food grains is 122 million ha with a record production of 212 million tons in 2001/02. The average productivity of rice and wheat – two major food grain crops – is 2.1 t/ha and 2.7 t/ha, respectively. Much of the growth in food grain production occurred during the 1970s and 1980s with widespread adoption of the new seed-fertilizer technology in the irrigated areas. Concurrently, the area under irrigation also expanded because of public investment in irrigation, which further accelerated the adoption of the new technology. Presently, about 40% of agricultural area is irrigated and fertilizer consumption (NPK nutrient) is 91 kg/ha. These growth trends were also echoed in rain fed agriculture with the availability of hybrid technology and emergence of the public and private seed industry. However, the growth momentum could not be sustained during the 1990s because of a leveling-off in crop yields, particularly in the rice-wheat system of northwest India, and slackening of public investment in irrigation and other infrastructure for agriculture.

Since the 1980s, livestock, fisheries and horticulture sectors have also witnessed tremendous growth. Non-price factors like irrigation, infrastructure development and R&D were the main sources of growth, and the total factor productivity grew 1.5-2.0% annually since the green revolution period, illustrating a crucial role of R&D (Evenson *et al.*, 1999). With the increasing commercialization of agriculture, there is greater participation in international trade and investment by the corporate sector is rising. There is now increasing pressure for rationalization of agricultural subsidies, particularly for electricity, irrigation and fertilizers, and support to food grain prices. Fiscal, administrative and legislative reforms are also undertaken to encourage participation of the private sector in agricultural marketing and trade. On the inputs side, the seed sector has received significant support from the government. These developments are

expected to transform Indian agriculture into a science-based sector. This coupled with domestic product market and policy reforms will make Indian agriculture competitive internationally.

Kenya

The Kenyan economy is agriculturally based with 85% of the population living in the rural areas. The bulk of the farming population are small-scale farmers growing staple food crops to meet household food requirements with little surplus for sale. A strong agricultural sector is considered not only to be a major contributor to self-sufficiency in food, but a requirement for the successful growth of both the secondary and tertiary production sectors of the economy.

Agriculture plays a major role in providing food, energy and incomes to a significant proportion of the population, it also provides raw materials for the country's manufacturing and distributing industries. Over the last 30 years the contribution of agriculture to GDP has averaged 30%, declining from 37% in early 70's to 25% in 2000. Smallholders account for 75% of the total agricultural production. Agricultural products constitute about 70% of the total export and the sector employs about 75% of the total labor force. Formal employment in the agricultural sector constitutes about 17% of the total waged employment.

Maize is Kenya's main staple food although production has fallen short of demand due to frequent droughts and low productivity. The area under maize has stabilized at around 1.5 million hectares with limited potential for further expansion given competition on land use. On average, maize yields are 2 tons per hectare. The production of pulses has been declining due to weather conditions, use of low quality seed and the high cost of inputs. The horticulture industry is currently the third most important foreign exchange earner after tea and tourism. Smallholder production constitutes 80% of all growers and produces 60% of horticultural exports. This sector is expanding rapidly.

Over the last decade the agricultural sector (with the exception of horticulture) experienced low and declining productivity in terms of export earnings, employment creation, food security and household farm incomes. From a real growth rate of 4.4% in 1996, it declined to a zero average growth in recent years. The country's traditional exports, coffee and tea, face declining real world prices coupled with low value addition that has led to low returns. Some of the reasons for the decline in agricultural productivity include: poor governance in key agricultural institutions; institutional failure due to lack of capacity by the private sector to take over functions previously performed by the state; poor access to farm credit, high cost of farm inputs, insecurity in certain parts of the country and taxation of farmers through local authority cess; high prevalence of HIV/AIDS; low level of public funding and inefficient infrastructure which has led to high cost of production. The new Kenya Rural Development Strategy proposes to address these problems through a series of policy measures.

Uganda

Uganda's economy has registered impressive performance since 1990 with real GDP growth since 1995 averaging 6.7% and inflation decreasing from 33% in 1990 to a mere 3.5% between 2000 and 2004. Uganda is a predominantly agricultural economy. The agricultural sector

contributes over 40% to the gross domestic product, provides employment to over 80% of the workforce in rural areas, and is the main source of export earnings (85%). Of the population of 25 million, 85% live in rural areas. Because nearly half of the population lives below the poverty line and face food insecurity the government has put special focus on agriculture in its socio-economic policies.

Food crop production contributes about two-thirds of agricultural GDP, while cash crops contribute about 7%, the rest coming from livestock and fisheries. Approximately 44% of the sector's GDP is made up of commodities produced for home consumption, but the proportion of agricultural production destined for the market is rising. In terms of value, cassava, sweet potatoes, and cooking bananas are the most important, followed by coffee, maize and beans.

Production gains in agriculture have been driven by the positive policy changes, but technology driven reforms have been limited. The majority of smallholder farmers hardly use improved seeds, fertilizers, or agro-chemicals. Production intensification is seen as the driver of agricultural transformation, if the gains made are to be sustained. In the Poverty Eradication Action Plan, the government has formulated and operationalized the Plan for Modernization of Agriculture (PMA) aiming at transforming subsistence farmers into market-oriented commercial farmers. The National Agricultural Research System is a key player in the implementation of the PMA.

Table 2. Selected Development Indicators for Case Study Countries.

	China	Colombia	India	Kenya	Uganda
Population (Million)	1,280	44	1,049	31	25
% rural	62	24	72	65	85
% arable land area	15	2.4	54	8	26
Under 5 Mortality	38	23	90	122	141
GNI/capita (2002 $)	960	1,820	470	360	240
GDP growth 1990-2002	9.7	2.3	5.8	1.9	6.9

Source: World Bank (2004).

Table 3. Selected agricultural productivity indicators for Case Study Countries.

	China	Colombia	India	Kenya	Uganda
Agriculture as % of GDP (2002)	15	14	23	16	40
Av. annual growth (%) in Agr. GDP (1990-2002)	3.9	-1.5	2.7	1.2	3.9
Crop production % over 1990-2002	56	6.4	24	23	39
Cereal yield increase 1980-2001 (%)	60	39	81	11	10
Agr. Productivity (value added per worker), in $ (1995)	338	3619	401	213	346

Source: World Bank (2004).

3.2 Public Sector Research

China

China's strong public agricultural research system has played an important contributing role in growth in agricultural productivity. This has become even more apparent in the last ten years, as growth has been based increasingly on technological change, replacing earlier input growth (Huang, Hu & Rozelle 2004). China's public agricultural research system includes more than 1,600 research institutes, employing more than 136,000 staff (including retirees). Approximately 10% of this research is carried out at the national level while 90% takes place in provincial and prefectural institutes. The total budget for agricultural research was $1,025m in 2002. About 73% is for crop-based research, of which 40% is devoted to crop breeding. China has invested heavily in agricultural biotechnology research, estimated at $112m in 1999 and a staff of more than 2000 (Huang & Hu, 2000).

China's large agricultural research system needs to be assessed relative to the task at hand in such a large country. After decades of increases between the 1960s and 1980s, financing for public agricultural research stagnated or even declined between 1985 and 1995 (Huang & Hu, 2000). In 1996, the public agricultural research budget was equivalent to 0.4% of agricultural GDP which is less than half of the FAO's rule of thumb of 1% (Huang *et al.*, 2003).

The public agricultural research system in China has also undergone a number of changes (Huang *et al.*, 2002). These include 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 drift away from goals of food security, poverty reduction and environmental sustainability. Thus despite impressive achievements, the system 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 (Colombian Institute for Agriculture and Livestock), but the government introduced an initiative to privatize research in the early 1990s with the creation of an independent research corporation, CORPOICA (Beintema *et al.*, 2000). ICA remained as a regulatory entity, and 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 its 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 semi-public institutes supported in part by grower associations (e.g. for coffee, sugar cane and palm oil). CORPOICA inherited a decentralized structure, based on quite autonomous research stations throughout the country; the corporation has only recently instituted a centralized matrix management based on commodities and disciplines. CORPOICA's budget for 2004 is $13.8m and it employs 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 institutes of the Indian Council of Agricultural Research (ICAR) 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 $625m i.e. 0.42 % of AgGDP (Pal & Byerlee, 2003), with about 55% contributed by central government and 45% from the states. It is estimated that approximately $25m is spent on biotechnology research.

Kenya

The major responsibility for agricultural research is with the Kenya Agricultural Research Institute (KARI), although some public agricultural research is also conducted by Kenyan universities. KARI has its headquarters in Nairobi and a number of experiment stations throughout the country. 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 2004/5 is nearly $40m, which is a sharp increase from the previous year ($25.5m), mostly due 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 of the country. KARI has invested in biotechnology and has been involved for several years in the development of transgenic sweet potatoes (with assistance from Monsanto). It has just inaugurated a biotechnology facility where it will continue collaborative work with CIMMYT on transgenic insect-resistant maize and other projects.

Uganda

Uganda's public agricultural research is managed by the National Agricultural Research Organization (NARO) which is also responsible for livestock, fisheries and forestry research. Its budget for 2004-05 is $11.1m, 70% of which is provided by donors. NARO is currently in the process of reorganization related to the PMA. The National Agricultural Research Act of 2003 outlines the development of an integrated agricultural research system that includes central research functions, zonal research centers and the strong participation of farmers in setting priorities through local farmer forums. NARO is expected to contribute to the PMA by making its research demand driven and market responsive. Future funding for 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 control over generated funds. The new policy envisions research funding rising from its current 0.6% of agricultural GDP to 2%. NARO is responsible for plant breeding for most of the important food crops in Uganda and its cotton varieties are the only ones currently used by the cotton industry.

International public research

The study also included consideration of IP management in the international agricultural research centers (IARCs) of the CGIAR. This study looked in particular centers that have a physical presence in the case study countries: ICRISAT (with headquarters near Hyderabad, India), CIAT (with headquarters in Cali, Colombia and an outreach program in Uganda) and CIMMYT (with an office in Nairobi, Kenya).

3.3 The Seed Sector in the case study countries

China

For many years, 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 were allowed to retain some of the profits from seed sales. The new law has 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 monopolized by the public county-level seed companies. This has now changed and many of the public seed companies at both county and prefecture level have gone bankrupt or changed status to co-operative companies, selling primarily non-hybrid or unprotected hybrid seed. In 2002, there may have been as many as 20,000 seed companies in the country, including individuals selling only small amounts at a 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 activities of breeding to include production and marketing. From the other end of the supply chain, some seed companies have begun investing in breeding activities. Although foreign companies began marketing 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. While there are currently more than 50 GMOs applying for approval, only 5 foreign applications have been commercialized and these are all varieties of Bt cotton. However, the sown area of these 5 varieties took more than half of the total Bt cotton area, but this market share is declining. While the public research institutes have invested heavily in the development of GM crops, regulatory approval appears to have been slowed down by concern over possible effects on exports to Japan and EU markets. Nonetheless, the area sown to Bt cotton is considerable. Bt cotton has been commercialized in China by a joint venture of Monsanto/Delta & Pineland with two provincial level seed companies in Hebei and Anhui (Ji Dai and An Dai), and also by the Chinese Academy of Agricultural Sciences who developed their own Bt constructs in 1997.

The role of the government has been less pronounced in regulating the vegetable seed sector. Private companies, including joint ventures with foreign companies, have been selling vegetable seed in China since at least the early 1990s. Information about the extent of production and

seed sources is also less reliable given the small scale of production and the lack of government attention. Nonetheless, vegetable production accounted for 15 m ha and, according to one estimate, vegetable seed sales may be roughly one-quarter of all commercial seed sales (Koo *et al.*, 2003), although CCAP estimates it at not more than 10%.

Colombia

In the 1970s and 80s, the Colombian government had a heavy involvement in the seed sector, with a state seed company of the Agrarian Bank (CRESEMILLAS) and subsidized credit that supported 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 the replacement of the state seed company by private firms, and these 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 rice growers' association that has moved from simply marketing inputs to breeding rice varieties and selling its own seed. There are several small local companies that breed and sell their own maize hybrids, but the market is dominated by hybrids from 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, such as wheat, barley, beans, and potatoes. For instance, the potato producers' federation (FEDEPAPA) administers the production of certified potato seed (of public varieties). Although beans are a very important crop in the diet of certain groups in Colombia, the majority of bean production is based on traditional varieties and there are no commercial bean seed producers. The majority of the cotton and maize varieties available for sale in Colombia are the products of foreign private breeding.

India

One of the contributors to India's Green Revolution was the development of state and national seed corporations that provided seed of the new rice and wheat varieties, and of other public crop varieties as well. With the exception of some vegetable seed production and import, the presence of the private seed sector was not significant in India until the mid-1980s and was limited to a few seed companies. 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, and the economy-wide reforms of 1991 further liberalized the seed sector, particularly for the participation of MNCs. Since that time, the private seed industry in India has expanded rapidly. Most of this expansion has been 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. 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 still survive, although their performance and financial stability varies

widely between states. They are mostly relied upon for the production of non-hybrid seed of major crops such as wheat, rice and pulses. Even for some of these self-fertilizing crops that normally provide few commercial incentives, the private seed sector has made significant inroads; for instance, private companies in Andhra Pradesh now provide more than half the state's rice seed (virtually all public varieties). Andhra Pradesh is one of the leading states for seed production and its Seedsmen Association lists 440 members, 249 of whom have processing plants. These 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 Kenya Seed Company (KSC), and no other commercial seed operations were allowed. KSC had exclusive rights to all KARI varieties and also established its own breeding program, principally for maize (and also wheat, pasture grass and sorghum). The policy shifted in the early 1990s, allowing the entry of MNCs (including from South Africa and Zimbabwe) selling hybrid maize (and to a lesser extent sorghum and sunflower). In addition, the policy change encouraged the development of a domestic seed industry. There are currently three seed companies (besides KSC) with their own breeding programs and several other small companies that produce and market seed of public varieties. KARI and KSC signed an agreement providing royalties to KARI for the use of varieties currently under KSC production, although some of the details of that agreement are still in doubt, including the degree to which KSC has exclusive access. KARI now assigns rights to its new varieties through a tendering process, in which KSC is expected to compete with other firms.

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 has recently been 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 (and relies on IARC germplasm); most multiply and sell NARO varieties. Several multinational and regional companies produce seeds in Uganda for export and some also market seed in Uganda (mostly hybrid maize). Kenya Seed Company has a subsidiary in Uganda that sells hybrid maize, pasture grass and vegetable seed. Most cotton seed is simply obtained from ginneries and distributed free to farmers as part of a production inputs package, but a company from Zimbabwe has recently proposed to take responsibility for the introduction of new varieties and cotton seed production.

A note on floriculture

This project included an examination of the flower production sectors in Colombia, Kenya and Uganda. Because virtually all of the plant breeding is done in foreign countries (with the exception of some small, recent ventures in Colombia), the focus of this report is on the flower producers themselves. Thus the main treatment of flower production is found in Section 7.6.

The floriculture sector is important in Colombia, Kenya and of growing importance in Uganda. In Colombia, flower exports in 2002 accounted for over $672m in earnings and the industry is credited with providing direct employment for 88,000 people (and indirect employment for a further 75,000). Flower exports are diversified, with the largest proportion (28.7%) accounted for by roses. In Kenya, cut flower exports provide $220m annually, with 70% of that in roses. Uganda is a more recent entry in the field, under government policy to promote non-traditional agricultural exports. Its exports of roses and flower cuttings earned $26.5m in 2003 (70% from roses).

The planting materials are provided under contract by representatives of the breeders. The price of rose plants consists of the cost of the plant itself plus a royalty, with these two components of approximately equal value. Contracts stipulate that further multiplication is either not allowed or restricted in numbers and subject to royalty payment. The contracts are based on breeder's rights (PVP or plant patents) in the producing country and/or the country that imports the flowers (commonly The Netherlands or the USA). Since the PVP rights extend to the harvested materials under UPOV 1991, breeders can claim royalties anywhere in the chain.

3.4 Seed Regulation

Seed regulations in case study countries determine the types of varieties and seed that may be sold. Similar to IPR regimes, such seed regulations can provide important incentives (or dis-incentives) for the seed industry, and it is important to understand their scope. In addition, it is frequently necessary to make conventional seed regulation compatible with new IPR regimes.

China

China's first seed law was decreed in 1989 ('Regulation for Seed Management of the People's Republic of China'), followed in 2000 by the 'Seed Law of the People's Republic of China'. The old seed management regulation ruled that new varieties of the major crops must pass 2-3 years of trials and be approved at the state or the provincial level before being extended and used. Currently this applies to rice, wheat, maize, cotton, soybean and one or two other crops determined by the agricultural administration department at various levels of government. The criteria for approval of new varieties are established by MOA or at provincial level and usually include a yield gain of more than 5%, or a significantly higher product quality compared to existing (check) varieties. The new seed law has not stipulated any approval mechanisms for less important crops.

There are rules for seed production and management including licensing systems for seed producers and traders. Based on 'The Regulation of Crops Seed Production and Operation Licenses Approval' decreed by the Ministry of Agriculture (MOA), there are four types of licensed seed companies of 1 million, 5 million, 1,000 million, and 3,000 million RMB Yuan certificated capital respectively. The first type of company is permitted to produce and market conventional crops seeds. The second can also deal with hybrids. The third type of seed company can be involved in foreign seed trade in addition to production and marketing of any kind of seeds 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 licenses.

Colombia

All 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 agro-ecological zones in the country (varieties are released for specific zones). These trials were until recently 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 certifies hybrid seed (e.g. from MNCs) without physical deposit of the inbreds; the company supplies sufficient information about the lines and ICA visits the seed production plots for confirmation. ICA is also responsible for monitoring seed sale and detecting violations of regulations.

India

All public crop varieties must be officially released and notified, which includes performance tests at either the state or national level and notification by the Central Seed Committee. (Although varieties may be released at the state level, notification is a national level function.) The national level performance testing is managed through the extensive All-India Coordinated Crop Improvement Programs (AICCIP). Descriptors of notified varieties are recorded, but there is currently no DUS testing done as part of the release process. Private varieties do not require release or notification, but may be entered in the AICCIP trials. The fees for the private companies are quite high, although there is a proposal to lower these. In practice only a minority of private hybrids are officially notified (although companies acknowledge the data from the tests is useful and the fact that a variety is notified is an aid to its promotion 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 current

seed regulations are being reconsidered, partly in light of the PVP legislation, and a revised Seed Act is expected by the end of 2004. This new act will make some form of variety registration compulsory, and liberalizes seed certification, involving possibilities for self-certification by companies. ICAR is currently working on the modalities of DUS-testing.

Kenya

Variety approval and release in Kenya was recently reorganized and placed under the auspices of the Kenya Plant Health Inspectorate Service (KEPHIS). All varieties of field crops (public and private) must be entered in National Performance Trials (NPTs) that are divided into agro-ecological zones. The NPTs may take up to three years, although if the breeder presents supporting field data the period may be less. DUS testing is also required for all varieties, and this takes two years. After an initial year of evaluation seed companies may receive permission for seed multiplication and test marketing of a variety. Seed of most field crops must be certified, and KEPHIS also has responsibility for seed certification, which it manages from several regional stations. Deposit of inbreds is not required for certifying hybrids or for obtaining DUS, if the company provides descriptors of the inbreds and pays for KEPHIS to visit company fields. 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 in the case of small-scale formal seed production (e.g. by donor project-sponsored seed producer groups) of crops such as beans and sorghum, although KEPHIS indicates that in the future such seed of some crops (but not maize) can be sold as standard seed, which only requires seed quality testing. KEPHIS insists that small scale farmers cannot sell their saved seed of maize since it is not certified. They can however re-use it themselves or share it with others (without selling). Kenya, Tanzania and Uganda have recently concluded a harmonization of seed regulations for Eastern Africa. The new accord includes an agreement that varieties released in one of the countries will have a 'fast track' in variety testing procedures in the others and adopts common certification requirements, including a short list of crops with mandatory certification. However, Kenya will insist that the other countries adopt the OECD certification scheme before allowing seed to be imported. This insistence has kept one MNC from selling its maize hybrids (produced in Malawi) in Kenya.

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 7 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 under-funded and the industry is anxious to see a system in which companies can be accredited for certification. Uganda is part of the recent Eastern Africa harmonization in seed policies and regulations.

Table 4. Variety Release, Case Study Countries.

Country	Rice	Maize	Beans	Cotton
*China **	1996-1999: 237 public and 3 private 2000-2002: 189 public and 28 private (54% of releases hybrid)	1996-1999: 170 public and 4 private 2000-2002: 105 public and 34 private (All releases hybrid)		1996-1999: 107 public and 10 private 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 + approx equal number of unnotified private hybrids		1995: 5 2000: 6 2001: 7 2002: 9 (mostly public) + many unnotified private hybrids
Kenya		1960-1999: 17 hybrids+5 OPVs (all public) 2000-2003: 43 private hybrids + 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)	

* *For China, a 'private variety' is one marketed by, but not necessarily bred by, a private firm.*

Source: Compiled by authors, based on data from CCAP, ICA, ICAR, KEPHIS, and NARO.

Table 5. Cost of Variety Release in Case Study Countries.

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

Source: Compiled by authors from relevant national authorities.

3.5 Seed Use

China

The source of seed for farmers in China varies by region and by crop, including the focus crops of this study (rice, cotton and vegetables). Marketed rice seed is divided roughly equally between OPVs (214,000 Mt in 2002) and hybrid seed (250,000 Mt). Over 90% of the area sown with hybrids uses seed purchased each year, while for OPVs this is estimated at 30%. Hybrid rice seed has gained considerable market share since 1980, despite the higher costs for farmers, and thus accounts for almost one-half of the sown area in rice. On the other hand, approximately 35-40% of the rice area is sown with farm saved, or informally acquired seed. Cotton seed is more heavily dominated by OPVs with hybrid seeds accounting for only about 15% of the estimated annual sale of 78,000 Mt. Purchased cotton seed from formal sources is estimated to be 35% of the total seed requirement, highlighting the importance of saved and exchanged seed. In 2003, approximately 56% of the cotton area was planted with Bt cotton (James, 2003) and sales of Bt cotton seed are 58% of total sales. Since its release, Bt cotton has been absorbed into farmer 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% for most major vegetables, 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. There are hardly any private bean varieties marketed and most of the production is in local varieties. The vast majority of seed is farm saved or informally acquired, even for those farmers who specialize in commercial bean production. In rice, on the other hand, 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 sale by farmers. A little more than 40% of rice seed sales are by FEDEARROZ and the rest is divided

among 6 other companies. Maize is much more of a small-farm crop and the proportion of purchased seed is much lower than in rice. However, the commercial maize sector, which grows maize mostly for feed, is heavily dependent on purchased hybrid seed. Currently three MNCs account for about 80% 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.

India

Seed use in India varies by crop and by region. Nearly 90% of rice seed is still home saved or locally acquired, but there are important regional differences, with very little commercial seed sold in some states, while in others, like 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 a considerable portion of maize is produced for home food and feed use and hybrids account for less than 10% of seed use. In other states, where maize is more of a cash crop, hybrids account for more than three-quarters of seed use. The vast majority of maize seed sale is proprietary hybrids, although state seed corporations and some small companies sell public hybrids and OPVs. Most vegetable growers use purchased seed from the private sector. Hybrids are important in tomato and cabbage, which are mostly imported, but some public hybrids and OPVs are in the market. For cotton, there are distinct regional patterns of seed use. Northern India relies 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 highland areas, where Kenya's commercial maize production is centered. Nationwide, annual purchase of commercial maize seed accounts for about 45% of maize area; the vast majority of this is hybrids, with some OPVs (public and private) being sold in more marginal production areas. Maize seed sale is still dominated by KSC, which accounts for roughly 90% of the market; the remainder of sales is divided among six other companies. There is little seed sale for other crops. A few companies sell a small amount of seed of KARI bean varieties and some of the MNCs market sunflower hybrids. Virtually all vegetable seed is imported. Most seed of crops for dryland areas (sorghum, millet, pigeon pea, etc.) is only produced through special donor or government 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 Mt, but jumped to nearly

5,000 Mt in 2003. Beans are in second place, with roughly 800 Mt sold annually. Smaller amounts of seed of sorghum, groundnuts and several other food crops are also sold. (About 7,000 Mt of cotton seed is procured from the ginneries each year.)

Table 6. Rice Seed in Case Study Countries.

Country	Area planted (000 ha)	Annual seed sale (000 mt)	Proportion of seed purchased from formal sources
China	30,000	464 (54% hybrid)	30% (OPV) 90% (hybrid)
Colombia	470	41 (all OPV)	50-60%
India	45,000	255 (98% OPV)	11%

Table 7. Maize Seed in Case Study Countries.

Country	Area planted (000 ha)	Annual seed sale (000 mt)	Proportion of seed purchased from formal sources
China	23,000	1,068 (90% hybrid)	96%
Colombia	550	2.5-3.0 (75% hybrid)	15%
India	6,100	28	25%
Kenya	1,600	15-20 (95% hybrid)	45%
Uganda	540	1.6 (2000/02) 5 (2003) (30% hybrid)	20-35%

Source: Area planted based on official statistics; other data based on expert opinion.

Table 8. Cotton Seed in Case Study Countries.

Country	Area planted (000 ha)	Annual seed sale (000 mt)	Proportion of seed purchased from formal sources
China	3,200	78 (15% hybrid)	35%
Colombia	44	0.76	35-65%
India	8,500	27 (35% hybrid)	65%
Uganda	160	(provided to farmers as part of production package)	n.a.

Source: Area planted based on official statistics; other data based on expert opinion.

Table 9. Examples of Annual Vegetable Seed Sales in India and China.

Crop	India			China	
	Hybrid (mt)	OPV (mt)	Seed Sale (m$)	All seed (mt)	Seed Sale (m$)
Tomato	28	300	11.1	464	44.8
Chilli	15	403	9.2	2,287	30.0
Cabbage	40	100	1.2	7,081	102.6
Cucumber	3	1,000	14.3	2,336	56.4

Source: India data from Anand 2003; China data from Koo et al., 2003.

Table 10. Seed Prices. Case Study Countries.

			China	Colombia	India	Kenya	Uganda
Rice	Seed price	OPV	0.16-0.80	0.22-0.70	0.33		
	($/kg)	Hybrid	0.60-2.50		2.60		
	Seed/grain	OPV	1.2-3.0	1.1-3.5	3.0		
	Ratio	Hybrid	7-17		22.6		
Maize	Seed price	OPV		1.55-2.63	0.33	1.00-1.56	0.70
	($/kg)	Hybrid	0.48-1.00	3.14-5.23	0.54-1.32	1.50-2.23	1.44-1.72
	Seed/grain	OPV		8-12	3.1	6.7-10	
	Price Ratio	Hybrid	4-12	16-20	5-13	10-15	
Cotton	Seed price	OPV	0.48-4.80	4.54	1.08-5.40		
	($/kg)	Hybrid	6.2		16.70		

Source: Local estimates; seed/grain price ratios based on estimates of farmgate grain price.

3.6 Summary

The context of evolving national seed systems

Until fairly recently, seed supply in all the case study countries was in the hands of the public sector and recent private sector involvement has been a function of policy change. Any assessment of the specific impact of PVP regimes and other IPRs on seed industry performance and investment must be seen in the context of these wider changes in the commercial and policy environment. The country with the longest experience of private seed industry participation is Colombia. However, the development of the private seed sector in Colombia depended to a considerable extent on government support to agriculture, and this was drastically curtailed in the early 1990s, before PVP was introduced. Thus the introduction of PVP met a small and contracting private seed industry. India has nearly two decades of experience with a private seed sector that is increasingly broad and diverse, but its PVP legislation is just being put in

place, so any assessment of the effects will necessarily be ex-ante. Kenya has PVP legislation in place, but government policy has only cautiously opened to private seed sector participation in the past few years, and the number of players is still limited. Uganda is also a recent convert to private seed industry participation and has yet to enact PVP. China's former state seed provision system is now being converted to one in which many public institutes are able to manage their own revenue generation and purely private seed enterprise is also encouraged. PVP is only one factor to be considered in this sharp reversal of dependence on state-managed seed production.

Incentives for formal seed provision

With or without PVP, national seed sectors tend to develop along certain pathways. The degree to which PVP can alter or accelerate such processes may be limited. In all the case study countries, hybrids are the major point of entry for the private seed industry (and in the African cases, the major product of the previously dominant public seed sector). Where OPV seed attracts private attention, as in rice, the clients are market-oriented farmers (relatively large-scale in Colombia, small-scale in India) who value the qualities of commercial seed. Strong consumer demand for a range of vegetables, whose seed is difficult to save even if it is not a hybrid, is another important stimulus for the seed industry (as in China and India). In all cases, a certain minimum size of market is necessary to elicit commercial response. The opportunity to take advantage of transgenic crops depends on having a biosafety regime in place. In summary, these biological, economic and regulatory parameters have at least as strong an effect on the development of plant breeding and seed markets as do PVP regimes.

The status of public agricultural research

Much of the plant breeding and some seed production still depend on the public sector in all the case study countries. In the smaller case study countries public research is either being reconsidered (as in Colombia) or is highly dependent on donor contributions (Africa). In China and India much larger public research systems are in place with significant government commitment, but even these systems are undergoing transition, as they are forced to redefine their roles vis-à-vis growing domestic private sectors. The national research programs also receive support from international agricultural research, but it too is facing sharp questions about its mandate at a time of changes in public research priorities, the strength of private agricultural research, and the emergence of domestic seed enterprises as competing clients. It is public agricultural research that faces the greatest challenges in adjusting to the new IPR regimes.

The role of conventional seed regulation

Plant breeding and seed production are already subject to a set of regulations on variety release and seed quality control. These regulations have played an important part in determining the current course of seed system development in the case study countries. In each case, the regulations have provided incentives (or disincentives) for certain types of breeding and have encouraged (or discouraged) certain commercial endeavors. The seed regulatory regimes control the type of seed that is available and in some instances act to control the unauthorized use of germplasm or sale of seed. Recently established IPR systems in the seed sector are meant to act in concert with conventional seed regulation and in some cases they are the

impetus for further changes in national seed regulations. It is important to understand the interactions between the two regimes.

IPRs in the context of wider policy and economic changes

Plant breeding and seed delivery in the case study countries are dependent on a range of factors, including commercial sector development, seed demand, public research strategies and seed regulation. IPRs are an additional factor in the equation. At this relatively early stage in the development of national seed systems and the recent establishment of PVP and patent regimes the majority of respondents claim that these IPRs will be a key factor determining seed sector performance. Although its current role may be in the background, its future influence may be very substantial, and it is important that its role should be played in harmony with the rest of national seed policies and agricultural development aspirations.

4. IP legislation and management in the case study countries

4.1 PVP Legislation

The five case study countries provide a wide range of experience with IP legislation for the protection of plant varieties. China, Colombia and Kenya are members of the 1978 UPOV Convention and have had a PVP system in operation for several years. India has just enacted PVP legislation and is still in the process of establishing implementation capabilities. Uganda has no PVP legislation in place but a draft bill is before Parliament. The rest of this section introduces the principal features of PVP legislation and administration in these countries.

China

Despite a longer history of other IPRs, PVP was introduced relatively recently in China. The first 'Regulations of the Peoples Republic of China on the Protection of New Varieties of Plants' was decreed on March 20, 1997 and is effective as of October 1, 1997. However, the first application was submitted only in 1999 when a ruling on 'Implementation methods of the regulations of the People's Republic of China on the protection of new varieties of plants' was decreed by the MoA. In that year, China became a member of the 1978 UPOV Convention. There are currently 41 species eligible for protection. This list concentrates on food crops and is based on priorities from national and provincial specialists. Cotton is not yet eligible for protection although the Ministry of Agriculture claims to have recommended its inclusion. Responsibility for granting PVP titles is divided between the Ministry of Agriculture, which handles most food crops, and the Ministry of Forestry, which is responsible for any woody species, including not only forestry species, but also woody ornamentals. The Ministry of Agriculture established an Office of Variety Protection for Agricultural Plants in 1999, which currently has 15 substations throughout the country for DUS testing. China's PVP legislation includes a broad farmers' privilege for saving and reuse of own seed, which is perceived as important in a country with many smallholder farmers. There is also no protection for essentially-derived varieties, consistent with the 1978 UPOV Act. According to staff interviewed at the Ministry of Agriculture, China is not yet considering amendments to make its PVP legislation conform to the 1991 Act. But it is acknowledged that breeders would like the stronger protection and both they and foreign governments are lobbying for such a change. Discussions with various individuals from private breeding companies and other Ministries indicated that the Government is likely to consider a move to the 1991 Act in the next few years.

Colombia

Although all countries of the Andean Community (Bolivia, Colombia, Ecuador, Peru, and Venezuela) have agreed to a common regime of PVP, the actual implementation and enforcement of PVP varies by country. Colombia joined UPOV in 1996. Much of the original pressure for UPOV membership came from the floriculture industry, and the majority of PVP certificates issued in Colombia are for flowers. Colombian officials stress that although the country is

member of UPOV 1978, most of its rules conform to those of UPOV 1991; the length of protection for field crops has been extended from 15 to 20 years and no crops are exempted from protection. In addition, a recent ruling (Resolution 2046 of July 2003) prohibits farmers with holdings greater than 5 ha from saving seed of protected varieties. Those with smaller farms may save such seed but they are required to report to a local ICA official and give details of how the home-saved seed will be processed and used. Administration of PBR in Colombia is managed by the Office of Plant Breeders Rights and Seed Production, which is part of ICA. ICA already had an office responsible for the regulation of seed production and this was assigned the responsibilities for PVP when the legislation was enacted.

Kenya

The legal framework for PVP in Kenya was established in the Seeds and Plant Varieties Act of 1977 which was revised in 1991. Further details were defined in a supplementary issue of the Act in 1994. An office for administering PVP began functioning in 1998 and Kenya acceded to the UPOV convention in 1999. As in the case of Colombia, much of the pressure for joining UPOV came from the horticultural industry, and the vast majority of the early applications for PVP in Kenya were from foreign breeders. A decision in 2001 provided an amnesty for extant public varieties, allowing them to be eligible for a full term of protection. This occasioned a great increase in PVP applications for public varieties, but the provision is controversial and has not yet been gazetted. Such varieties have thus not been issued with protection certificates. More recently, there is a move to make Kenya compliant with UPOV 1991; issues of particular importance are a more restrictive definition of essentially derived varieties (especially related to flower mutants and the possibility of the addition of a transgene to a protected variety) and greater control over farmer saving of seed of protected varieties (particularly the widespread practices of saving and local sale of wheat seed). The administration of PVP was initially assigned to KARI but in 1998 it was transferred to the recently established Kenya Plant Health Inspectorate Service (KEPHIS) which also administers plant quarantine, crop variety release, seed quality control and certification, and pesticide residue testing.

India

The Protection of Plant Varieties and Farmers' Rights Act was passed in 2001, after long debate. The original impetus for the Act came from India's commercial seed sector, and the government produced a first draft bill in 1993. However there was opposition to this draft from both the industry and NGOs opposed to the implementation of TRIPS, and two further drafts were produced and debated between 1996 and 1999. A Joint Committee of Parliament traveled through the country collecting the views of the industry, NGOs, farmer groups and others and redrafted the bill in 2000 for introduction to Parliament (Ramanna, 2003). In addition to the official parliamentary enquiry, the issue was widely debated in India's press. The resulting act has a number of unusual features. The Act is exceptionally liberal in its definition of farm-level seed saving, allowing farmers to save, use, exchange or sell (non-branded) seed of protected varieties in the same manner that they were entitled to previously. It thus appears that selling seed among neighbors is permitted, as long as the transaction is conducted informally and the seed is not sold with any commercial denomination or packaging. The Act also provides for the protection of extant varieties; any variety that has been officially released and notified is eligible

for protection for the specified period starting from the original notification date. In addition, the Act includes extensive definitions of Farmers' Rights, including the possibility of farmers or farming communities registering their own varieties; the expectation that farmers can claim compensation if a variety does not perform in the manner described by the breeder; and a method of benefit sharing through a National Gene Fund. Some provisions seem to go beyond the UPOV 1978 clauses, but UPOV is awaiting the implementation rules in order to judge whether the Indian system is in conformity with the 1978 Convention. India has received dispensation to access the Union under the old Convention. An authority is currently being established under the Ministry of Agriculture to administer the Act. Rules and protocols for DUS testing of 40 species have been established and the testing will be done by designated ICAR institutes and state agricultural universities. The implementation of the 2001 Act is expected to start in 2005.

Uganda

Like most countries in sub-Saharan Africa, Uganda is still in the process of establishing PVP legislation in order to comply with TRIPS requirements. A draft Plant Variety Protection Act was drawn up in 2002 and was still being debated in Parliament in 2004. There have been a number of public meetings regarding the act, but unlike India, the impending legislation has not been a subject of widespread debate, and both the private sector and NGOs complain that they have not been adequately consulted. The draft act includes both provisions for PBR and, drawing on model legislation from the African Union, for community and farmer rights. The act's conception of PBR is largely consistent with that of UPOV 1978, although it grants protection for field crops for a period of 20 years. Its definition of Farmers' Rights goes beyond UPOV 1978 by allowing farmers to not only save seed of protected varieties but also exchange and sell (on a non-commercial basis) such seed. In addition, farmers and farm communities may act as custodians of local plant varieties, require prior informed consent for the use of such varieties in plant breeding, and claim royalties as developers or conservators of varieties. Discussions are still underway regarding the nature of the authority that would administer the Uganda PVP legislation.

Table 11. PVP Legislation in Case Study Countries.

	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 will apply 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 is being debated in Parliament in 2004. It defines PBR as well as farmer and community rights
Scope of coverage	41 crops currently eligible. Certificates have been 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, etc.	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 woody species (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 is permitted. (Local/informal seed sale regulated by seed law)	Farmers with more than 5 ha not allowed to save seed of protected varieties. No farmers' privilege for horticultural or tree crops. No seed saving of transgenic varieties permitted	Seed saving, exchange and sale by farmers is 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'

Table 11. (continued)

	China	Colombia	India	Kenya	Uganda
Breeders' exemption	Protected varieties may be used for breeding (No protection for EDVs)	Protected varieties may be used for breeding	Protected varieties may be used for breeding. An essentially derived variety can seek protection, but requires agreement from 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 already available in China up to four years earlier, when a species/ genera first becomes eligible for protection (application must be made within one year for woody species and within two years for agricultural crops and is conditional on DUS test)	'Amnesty' for 1 year when PVP was introduced for officially released varieties. Protection period was based on remaining period, counting from year of release. Widely used for flowers (over 200), 4 cotton, 2 rice and 1 soya. ICA chose not to protect	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 or selection methodology'	Plant varieties cannot be patented, but GMOs may be patented because not found in nature	No patents of plant varieties	No patents of plant varieties	No patents of plant varieties

Source: Compiled by authors from interviews and relevant national authorities.

4.2 Other IP Legislation

China

In China, patents are administered by the State Intellectual Property Office (SIPO), which was the first government agency established for IP protection. SIPO is an independent organization in China and administratively at the same level as the Ministry of Agriculture. With respect to patenting of biological material, China studied the different approaches pursued in the U.S., the E.U. and Japan when formulating its own policy in this area. Living organisms, such as plants and plant varieties, are not eligible for patenting but genes are eligible, as they are considered to be only part of a living organism. As of 2003, there were more than 100 applications for patenting of genes related to agriculture. Biological processes, such as genetic transformations, are also patentable. Breeding and selection methodologies are also patentable, which effectively allows patent protection to extend to hybrid varieties. A number of such patents have been granted but the scope of allowable claims and impact of these patents is not well known. For example, in discussions with IP specialists of large MNCs active in China, none seemed aware of the possibility of patenting hybrid breeding and selection methodologies. China now has 20 years experience with its patent system. One hundred thousand applications were filed in 2003 divided among the three types of protection administered by SIPO: invention patents (which are similar to utility patents), utility models (which are similar to petty patents) and industrial designs. About 50% of all applications for invention patents are filed by foreigners, of whom about 60% use the PCT, whose use is increasing quickly. SIPO currently has about 1,400 examiners, of which 1,200 work on invention patents and the other 200 on utility models and industrial designs. Examiners with sufficient biological expertise for biotechnological applications are not reported as a constraint at least in comparison to other technological areas, such as business methods. Applications do not normally require more than 30 months to process.

Trademarks have been available in China since 1979 and are administered by the Trademark Office of the State Administration for Industry and Commerce. The Trademark law was amended in 1994 and again in 2001, when geographical indications were included to comply with TRIPS. The 2001 revisions have only become operationalized in 2003. The Trademark Office is an administrative management institute under the State Administration for Industry and Commerce, one of the Ministries under the State Council. It operates independently of SIPO, although they both participate in a high-level IP coordination group under the auspices of the State Council. Examinations for trademarks are normally processed within a few weeks. Trademarks are used by seed companies in China but their effectiveness is difficult to gauge. It is easy to find examples of logos on commercial seed packages that are extremely similar to competitors' trademarks.

The approval of varieties is completely independent from the trademark processes. Approved varieties are marketed by all legal seed producers under their official name, which cannot be trademarked (lack of novelty). If a variety name is first granted a trademark, then it may not be used in the variety registration and should be rejected. Officials of the Trademark Office have contact with the Ministry of Agriculture on an annual basis to check for double-use of variety names.

Geographical indications (GI) must be applied for by a group such as a co-operative or association, with the capacity to certify the origin of the products under the GI. GIs are being used for specialty, local agricultural products with a wider reputation. There were more than 100 registered as of March 2004, including for example a type of 'fragrant pear' from Xinjiang Province. Agricultural products covered under GIs include other fruits and teas. The Trademark Office plans to carry out awareness-raising activities on GIs at various levels of the offices of the Administration for Industry and Commerce in an effort to promote development of farmers and 'brand agriculture'.

Colombia

In Colombia trademarks and patents are administered by two sections of the Industrial Property Division of the Superintendence of Industry and Commerce under the supervision of Ministry of Commerce. The New Creation Office (i.e. patent office) employs 15 examiners, one of whom works on biotechnology. In 2003 this Division received 1,209 applications, 83% of which came through the PCT; 291 patents were granted in 2003. In the same year, the office also received 176 applications for utility models (petty patents) and 239 applications for industrial design. Genes and plant varieties cannot be patented (following an Andean Community agreement) but micro-organisms 'not found in nature' and GMOs are eligible for patents.

In Colombia, similar to the other case study countries, official variety names cannot be trademarked. However, for crops that do not require the use of the official variety name in trade, such as flowers, the varieties are effectively protected through this form of IPR. Even old varieties can thus be controlled by the breeder after the expiry of breeder's rights. The Distinctive Signs Office (i.e. trademark office) is also responsible for brands and geographical indications. Copyright is the responsibility of the National Copyright Directorate of the Ministry of the Interior. There is communication between the Industrial Property Division and the PVP office regarding variety denominations and the PVP Office. The various offices responsible for IP interact from time to time (e.g. when international trade negotiations are in progress) and although there is considerable sympathy for the formation of a single IP authority there are no government resources to bring about such a change at present.

India

India's patent system does not have experience with technologies related to agriculture. The current law excludes the protection of plants and excludes methods of agriculture. The patent office does not have any specific expertise in plant biotechnology, but it does have experience with other areas of molecular science. Several modifications in the patent law were implemented in 1999 to bring the system more in line with TRIPS. Exclusive marketing rights were introduced for pharmaceuticals that protected the inventor in the market for 5 years, but these have been superseded by a third amendment of the patent act which took effect 1.1.2005 through the issuance of an ordinance by the President. This latest amendment allows product patents in all fields of innovations, including the protection of micro-organisms and genes. It is unclear to what extent agricultural exceptions will limit the scope of gene protection for plant varieties, but the industry expects that case law will soon open the way for agricultural biotechnology patents.

The trademark system in India is well established. Official variety names cannot be protected. Trade secrets fall under unfair competition in the trade laws.

Kenya

The Kenyan patent law is administered by the Kenya Industrial Property Institute (KIPI) under the auspices of the Ministry of Trade and Industry. It has 20 examiners out of which seven have knowledge of biotechnology. KIPI has received 401 national applications of which 100 were granted and an additional 243 through PCT of which 69 were granted. There are also 2033 ARIPO patent applications designating Kenya (1103 granted in Kenya); 56 national utility model (19 registered); 556 national industrial design applications (216 registered) and 86 through ARIPO (64 registered). KIPI has an advanced documentation system. The Kenyan law allows protection of both process and product patents in biotechnology but excludes patents on plant varieties. Of the national patents granted by KIPI only two are plant-related. There may however be biotechnology patents valid in Kenya through PCT.

Trademarks and patents are administered by KIPI under two acts, the Trade Marks Act Cap 506 and Industrial Property Act 2001. Trademarks can be protected in Kenya, but not official variety names. KIPI is also responsible for geographical indications and trade secrets, however these two are being defined in acts of parliament. Copyright is the responsibility of the Attorney General Chambers. The communication between KIPI (patents), KEPHIS (PVP) and Attorney General Chambers (Copyright) concentrates mainly on awareness creation and planning for international negotiations. PVP cannot be administered outside the Ministry of Agriculture, so coordination will remain an issue.

Uganda

Almost all patents come in through the regional patent office in Harare (ARIPO). The national patent office has very few staff and does not have data available on plant-related patents that are valid in Uganda. The office has a very limited capacity to examine applications and concentrates on examining ARIPO and PCT reports with regard to specificities of the national patent law.

Table 12. Participation in International Treaties and Organizations.

Treaty or Organization	China	Colombia	India	Kenya	Uganda
UPOV	1978 convention, since 1999	1978 convention, since 1996	No	1978 convention, since 1999	Observer
IT/PGRFA	No	Acceded 2004	Ratified 2002	Acceded 2003	Acceded 2003
CBD	Ratified 1993	Ratified 1994	Ratified 1994	Ratified 1994	Ratified 1993
Cartagena Protocol	Signed 2000, not ratified	Ratified 2003	Ratified 2003	Ratified 2003	Ratified 2003
WTO	Yes, 2001	Yes, 1995	Yes, 1995	Yes, 1995	Yes, 1995
WIPO	Yes	Yes	Yes	Yes	Yes
PCT	Yes, 1994	Yes, 2001	Yes, 1998	Yes, 1994	Yes, 1995

Source: Compiled from interviews and information on websites of international treaties and organizations.

4.3 The Management of PVP in Case Study Countries

4.3.1 Applications for PVP

The experiences of the three case study country PVP offices are quite different.

In China, there are 70 scientists assigned to DUS testing at the 15 designated stations and another 16 examiners to test 41 species of crops. All PVP applications to date have used DUS testing carried out in one of the stations; there is as yet no experience in the use of foreign DUS reports. Applicants must complete a form that includes UPOV descriptors and other information. Many applicants find this difficult to complete and the majority (80%) of applications for PVP are prepared by an agent. The agents are licensed and they charge a fee of $350-500 for foreign applications and approx $250 for local applications.

China received 1,150 applications for PVP between 1999 and 2003. Of these, 411 have already been granted. Many applications made in 1999 have not yet been acted upon; for those applications granted, the average time from application to approval 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% of the applications, respectively. More than three-quarters of the maize applications in the MoA office for PVP are for hybrids and more than three-quarters of the rice applications involve either hybrids or inbred lines. Wheat, soybean and rape seed 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 prefecture level. Applications at the Ministry of Forestry PVP office are mainly for roses.

The PVP and Seed Production office in Colombia has a director and 6 technicians attached to it. None of these work full-time on PVP, and most contribute to DUS testing when necessary. ICA developed its own capacity for DUS testing for tropical crops from the initiation of the office, and received advice and training from UPOV. However, the vast majority of PVP applications are for ornamentals for which testing is done externally. Most foreign applications for PVP are handled by local law firms with the requisite expertise. If DUS data already exist for a variety the confirmation process usually takes about one year. If the data do not exist, the applicant pays for testing in an appropriate country. The office has good relations with testing authorities in France, Germany and the Netherlands.

Table 13. PVP Applications and Certificates Issued by MoA in China.

Crop	1999	2000	2001	2002	2003	Total applications	Total certificates issued (2003)	
Maize	95	58	126	120	121	520	248	(178 hybrid, 70 OPV)
Rice (non-hybrid)	2	5	12	21	43	83	15	
Rice (hybrid	4	4	17	31	53	109	25	
Rice (inbred lines)	9	15	31	29	89	173	42	
Wheat	-	3	10	30	41	84	21	
Soybean	-	13	4	6	7	30	19	
Rape seed (OPV)	-	3	5	12	18	38	11	(6 hybrid, 5 OPV)
Pepper	-	6	1	3	-	10	1	
Cabbage	4	1	5	-	5	15	7	
Groundnut	-	1	5	1	3	10	5	
Potato	1	-	3	-	3	7	1	
Pear	-	1	6	10	1	18	8	
Other	-	3	2	24	24	53	8	
Total	115	113	227	287	408	1150	411	

Source: Compiled by authors based on information obtained from Chinese Ministry of Agriculture. Data do not include applications made to Ministry of Forestry for woody species.

Table 14. Source of Applications for PVP in China.

Source	Number applications (and %)	Number certificates issued (and %)
Public research institution		
National	36 (3%)	13 (3%)
Provincial	319 (28%)	137 (33%)
Prefectural	329 (29%)	110 (27%)
University	85 (7%)	36 (9%)
Seed company	323 (28%)	107 (26%)
Individual	45 (4%)	8 (2%)
Foreign	13 (1%)	-
Total	1150	100

Source: Compiled by authors based on information obtained from Chinese Ministry of Agriculture. Data do not include applications made to Ministry of Forestry for woody species'.

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 account for 62% of all applications. The major examples of PVP for agricultural crops are rice (which has had 12 applications to date, with 6 granted) and cotton (25 applications and 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.

Table 15. PVP Applications in Colombia.

Crop	Applications made	Certificates granted
Roses	448 (62%)	279 (62%)
Other ornamentals	214 (30%)	139 (31%)
Rice	12 (2%)	6 (1%)
Cotton	25 (3%)	8 (2%)
Soybean	8	2
Potato	5	3
Tobacco	4	3
Sugar cane	5	5
Other	6	6
(All agricultural crops)	*64*	*33*
Total	727	451

Source: Compiled by authors based on information provided by ICA.

In Kenya, PVP is one of a range of services and regulatory duties performed by KEPHIS, which is a state corporation. KEPHIS employs 4 examiners and 10 technicians (in 3 locations) to administer PVP applications. KEPHIS carries out DUS tests on most of the agricultural crops that apply for PVP; more than 100 public varieties of 26 agricultural crops were submitted for testing, the majority in 2001 when the amnesty was announced. Applications for ornamental and horticultural crops come mostly from foreign entities and the DUS testing is usually done abroad, although KEPHIS is renovating glasshouses and other facilities in hopes of assuming more responsibility for the testing these crops. A significant proportion of the applications for agricultural crops come from the Kenyan public sector and researchers are expected to provide their own descriptors as part of the application process. KEPHIS then confirms these descriptors in two years of testing in at least two sites. (Note that DUS testing is also part of the variety release process in Kenya.) There are a number of instances where breeders and KEPHIS dispute the nature or quality of the data provided, and this undoubtedly slows the registration process in some cases. The majority of foreign applications are handled by local agents, either law firms or members of local flower growers. KEPHIS proposes to make the use of local agents for foreign applications mandatory.

Between 1997 and 2003 Kenya received over 600 applications for PVP. More than half of these are for ornamentals, with roses accounting for 41% of the total. Among field crops, maize has the highest number of applications, accounting for 9% of the total; all of these applications are for hybrids. In the first four years nearly three-quarters of the applications for Kenyan PVP were from foreign entities, but in the three most recent years about two-thirds of the applications are from Kenyan public research and domestic firms. The rise in domestic applications is partly due to the amnesty granted to previously released public varieties that were allowed to apply for a full term of protection. The fact that this amnesty is being

contested, and has yet to be gazetted, is one of the explanations for the relatively low number of PVP grants issued. One of the concerns was the ownership of the released varieties between KARI and the Kenya Seed Company. By mid-2004 only 108 certificates had been granted.

Table 16. PVP Applications in Kenya.

Crop	Source of application				Total Applications	Granted to date
	Foreign	*Kenya Public*	*Kenya Private*	*Joint Public & Private*		
Maize	-	25	14	15	54	-
Wheat	-	4	1	25	30	-
Barley	-	-	7	-	7	6
Sorghum	-	2	-	5	7	-
Other cereals	-	4	-	3	7	-
Rape seed	14				14	-
Sunflower	-	5	5	-	10	-
Soybean	-	7	-	-	7	-
Other oilseeds	-	3	-	-	3	-
Beans	-	6	1	6	13	-
Peas	7	-	-	-	7	-
Other pulses	-	11	3	-	14	-
Potato	-	4	-	-	4	-
Cassava	-	2	-	-	2	-
Cotton	-	1	1	-	2	-
Pasture grasses	-	9	1	-	10	-
Tea	-	12	21	-	33	-
Pyrethrum	-	23	-	-	23	23
Coffee	-	4	-	-	4	-
Macademia nut	-	4	7	-	11	-
Sugar cane	-	6	-	-	6	2
Rose	248	-	-	-	248	61
Alstromeria	28 (?)	-	-	-	28	9
Other ornamentals	33	-	-	-	33	6
French bean	13	-	-	-	13	1
Other vegetables	2	-	5	-	7	-
Fruit	5	-	-	-	5	-
Total	350	132	66	54	602	108

Source: Compiled by authors based on information provided by KEPHIS.

4.3.2 Retroactive protection

A decision that can have an important effect on the early performance of a PVP office regards the protection of extant varieties. In most cases in industrialized countries, extant varieties were not eligible for protection when PVP was initiated. But there are several instances in the case study countries where extant varieties are eligible.

In its 1999 legislation, China offered a 'window' when it established PVP that allowed protection for varieties that had been released up to four years previous to the initiation of the legislation. Its effects do not seem to have been very significant.

Colombia had a transition regime or 'amnesty' of one year for extant varieties when PVP was initiated, granting protection for varieties that were already in an official public registry, offering protection for a period based on the remaining time between the date of registration and the 15 or 20 years of protection offered under the law. ICA did not opt for PVP because it considered their varieties to be of public access, and would have had a conflict of interest. However, the amnesty seems to have been very significant, since 229 applications were filed under this transitional regime. The main beneficiaries of this were ornamentals, but 4 applications were filed for cotton, 2 for rice varieties of a local company, and 1 for soybean of another local company.

The decision in Kenya to grant an amnesty to released public varieties was responsible for a flood of applications from KARI for the protection of its crop varieties. If the amnesty is upheld, and KARI is willing to pay the testing and maintenance fees, it could exercise control over these varieties for another full protection period of 15 years. Although KARI has signed a separate agreement with KSC providing royalties for the use of its varieties currently in KSC production, the validation of the amnesty would mean that KARI could collect royalties from any other seed producer for a wide range of its crop varieties. The fact that KEPHIS is purchasing testing reports on very old flower varieties in the Netherlands seems to imply that such an amnesty is also available for varieties whose protection has expired in Europe, thus providing for a very significant extension of the protection in a major flower-producing country.

The new PVP Act in India will allow the protection of varieties that have already been released and notified, but the protection period will begin from the original notification date. Only a small proportion of commercial hybrids is notified and will be able to take advantage of this. The major impact will be for public varieties, some of whose seed is currently marketed by private companies or used as breeding lines. Many private companies are not aware of the possible implications of such protection of extant varieties and it is not clear what, if any, rights the public sector institutes will try to enforce in this respect.

4.3.3 Deposit of breeding lines

An additional concern regarding participation in a PVP scheme is the requirement for deposit of germplasm, particularly inbred lines. The issue has not arisen in Colombia, as no hybrids of agricultural crops have applied for PVP. In Kenya, KEPHIS currently does not have the facilities

to store inbreds and certifies domestic hybrid production by visiting seed production plots and checking inbred descriptors against a list provided by the seed producer. In India, current law requires that NBPGR manages all import of crop germplasm (for research or seed production purposes) and allows them to take samples for deposit. This has been an impediment for some firms wishing to import inbreds that cannot yet be protected in India, or germplasm under development e.g. in shuttle breeding programs, as the owners may worry about the security of such deposits. The new PVP law would require deposit of the inbreds of protected hybrids, and opinion in the seed industry is divided. Some companies feel that this will cause no problems, while others are wary about the prospect and are anxious to see how the system will be implemented.

4.3.4 Costs and budgets

The costs of applying for and maintaining PVP in the case study countries are presented in Table 14, along with relevant data from the EU and US for comparison. It should be noted that the costs of application in the case study countries are substantial; in addition there are significant transaction costs (justifying the use of agents in China and Colombia). In China maintenance fees rise steadily over the period of protection, in Colombia they rise only through the first 4 years, and in Kenya there is a flat annual fee for maintenance. It is important to remember that these are only the costs of obtaining PVP and that other expenses related to variety testing and release (VCU) must also be met.

Table 17. Costs of PVP Application.

Item	China	Colombia	Kenya	EU	US *
Application	$217	$233	$200	$1,060	$432
Testing	$556	$1,396 ($155 if done abroad)	$600	$1,300 – $2,825 (depending on type of crop)	$3,220
Granting of rights	-	$39	$240	-	-
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): $350-470 (2): $470-705 (3): $590-940 (4-20): $705-1,175 (depending on type of crop)	None

* *The U.S. does not charge annual maintenance fees. In addition, in the U.S. 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.*

Source: Compiled by authors from interviews and relevant national authorities.

China has quite high maintenance fees for PVP, compared to those in the other case study countries, although some subsidies are offered for public sector applications. While this may be justifiable given the large market for which exclusive rights are obtained, it is a frequent complaint from the private sector, but also from public sector breeders. The prefecture level public research institutes find it particularly difficult to apply for PVP due to a lack of funds (Huang et al, 2003). During this study, research managers at the Guangdong Academy of Agricultural Sciences pointed out, for example, that costs of a PVP (or patent) application can approach RMB 10,000 while a researcher's annual budget may be about RMB 20,000. A similar complaint was made by the Rice Research Institute of the Hunan Academy of Agricultural Sciences, who suggested that the application and testing fees for conventional rice varieties should be lower than for hybrid varieties, given the different market segments targeted.

In the private sector, especially the breeders of ornamentals complain since they need to protect a large number of varieties of a particular crop to start a significant production. The local market for flowers does not seem to sustain such investments and several foreign breeders avoid sending their elite materials to China as a result.

All income from the PVP office goes to the Treasury in Beijing. The fees charged are not sufficient to cover the costs of testing, especially because of the large number of testing sites and the resulting high investment budget for constructing facilities. In Colombia, the income from the PVP office goes directly to ICA (and hence to the Treasury), but rough calculations indicate that the PVP office is self-supporting. (Note that the current portfolio of applications in Colombia implies a relatively small amount of DUS testing to be done in-country.) In Kenya it was not possible to get a breakdown of the expenses and income related specifically to PVP within the operations of KEPHIS but there is no requirement that PVP be self-financing.

Box 3. Protection fees

Establishing the appropriate fees for protection is an important challenge for regulatory agencies. High fees create a barrier to widespread participation, especially for public institutes or smaller firms. On the other hand, low fees may cause financial problems for the registration and testing authorities, leading to reduced efficiency and/or rent seeking.

There are basically two types of consideration in calculating appropriate fees: i) the extent to which the agency establishes different fees for different types of crop variety and/or applicants, and ii) the extent to which government subsidizes the protection agency as a stimulus to national plant breeding activity.

With respect to fee rates, one option assumes that the cost of the authority's activities will be shared equally among all applicants and crops. This will probably involve a certain amount of cross-subsidizing between crops (e.g. few applications and high costs in testing sorghum 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 may lead to acceptable fees for crops with large numbers of applications each year (e.g. major cereals). But it can also lead to prohibitive fees if special facilities need to be maintained, and charged accordingly, for crops with few applications per year (e.g. minor vegetables).

A third option is based on the value of the protection for the applicant. Fees for applicant varieties with a potential large market can be higher than for varieties with a smaller market. Fee levels for highly commercial crops like maize may not be useful for minor crops like pigeon peas. This argument also underscores why it is difficult to make comparisons between countries. Fee levels that are acceptable in a large country like China may not stimulate applications in a smaller country like Uganda.

Countries could also establish different fee levels for different types of applicants. For example, patent application and maintenance fees for independent inventors, small businesses or non-profit organizations in the U.S. are now only 50% of the regular fees.

Countries may also subsidize certain operations of the testing authority, and they may choose to reduce costs through international cooperation. In the European Union, for example, national authorities share the responsibilities of testing particular species; Kenya and Colombia purchase test reports for flower varieties from abroad. A limitation to this option may be that some UPOV member countries share their test reports only with other UPOV-member countries.

The need to cover the costs of variety protection has to be balanced by the need to establish effective incentives for stimulating widespread invention and achieving equitable results for all sectors of the farming community.

4.3.5 Enforcement

To be effective, a PVP system must include adequate mechanisms for enforcement. The PVP systems in Colombia, Kenya and China have only been in place for a short time, so there is a limited amount of evidence available on enforcement capabilities.

PVP offices themselves are not actively engaged in enforcement. In Colombia, it is expected that the breeder or seed producer will pursue any cases of infringement. In a recent example 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 legally acquired and used the PVP office testimony to obtain an out-of-court settlement. Another case is being pursued where one company is marketing *Brachiaria* seed using the name of a popular (protected) variety. The seed company licensed to sell the variety is trying to mount a legal case. In general, the companies that sell rice seed are more concerned about the practice of large-scale informal seed sale and hope that Resolution 2046, which limits seed saving of protected varieties to small farms, will provide some relief. But the companies recognize that they will have to detect the violators and bring cases. It does not help that the Colombian PVP law currently has no description of penalties for violations.

In Kenya there have as yet been no major cases involving violations of PVP law. Probably the major example is a dispute between a small seed company and KEPHIS regarding the company's rights to market seed of an old KARI maize hybrid.
In India, there is a provision in the 2002 Act for the establishment of an Appellate Board to handle IP issues, so that knowledge can be drawn from different departments and experience can be concentrated in this body.

Chinese institutes market their own products (which is not necessarily an efficient practice) 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. Several respondents however complain that the level of knowledge of the courts is often insufficient to effectively enforce the rights. One company manager explained that he pursues rather minor infringements mainly 'to educate the courts'.

4.4 Management and enforcement of patents in case study countries

Experience with enforcing patents in the breeding industry has been very limited in the case study countries. Only in China and Colombia are there a few varieties that contain patented biotechnological inventions actually in the field, and enforcement is even more difficult than with PVP, especially when it comes to pursuing illegal reproduction by farmers. One MNC is confident that the recently concluded case in favor of the patent holder against a farmer in Canada will facilitate enforcement in other countries as well, but large numbers of cases against farmers in developing countries are not considered likely in the coming years.

However, unlike PVP, patents in agriculture can draw upon experiences of enforcement of the patent system in industrial applications. Law firms that have experience with patent infringement cases are available in all case study countries, even though the number is very limited in Uganda. The presence of vast international experience, concerns for respecting property rights and the threat of future claims can affect behavior. An example is provided in India, where the National Botanical Research Institute (NBRI) decided not to release its own Bt gene because it is not sure whether it will have enough freedom to operate regarding other components of the construct when the new patent law becomes operational.

4.5 Summary

Establishment of legislation

PVP has been (or is being) instituted in the case study countries in distinct ways. Although three of the four countries with PVP laws are members of the UPOV under the 1978 convention, there are significant differences between them in the details of their legislation and in the actual performance of PVP. Much of the explanation for these differences is in the distinct characters of the national seed sectors. In addition, the historical development of support for PVP varies among countries. The major pressure for the initiation of PVP came from the foreign horticultural industry in Colombia and Kenya. In China, the initiation of PVP was part of a wider policy to promote the development of the domestic seed industry and to establish a framework for interaction with foreign agricultural technology. The establishment of PVP in India had its major impetus from a well-developed private seed industry; the industry is large enough, and there is a similarly well developed civil society representing a range of rural interests, so that the public debate about the nature of PVP was open and extensive. In Uganda, on the other hand, neither the seed industry nor rural civil society organizations are well established. The debate about the nature of PVP has been restricted to a small committee of professionals dealing with both breeding and genetic resources. Many developing countries that currently face the establishment of TRIPS-compliant PVP will find themselves in situations similar to that of Uganda.
Once PVP legislation is in place, further developments are possible. The moves in Colombia and Kenya towards restrictions on seed saving of protected varieties are a case in point. It remains to be seen how such modifications are interpreted and applied. Right holders may say that they would not pursue seed saving by smallholder farmers, but farmers in any country require assurances that seed saving restrictions are not be applied in an arbitrary or politically motivated manner.

Plant varieties are not covered by patent law in the case study countries, although China offers patents for some special types of varieties (particularly hybrids) through provisions for the patenting of breeding methods. Trademarks are commonly used in all case study countries to protect seed company names and marks, but not for official variety names. None of the case study countries have particular exemptions in their patent laws that bring the patent system in line with the PVP system when the scope of the patent includes a plant variety or a group of plant varieties. It is still unclear how the Farmers' Rights clauses in the Indian law will relate to the patent system when the latter will allow the patenting of products, such as genes.

The protection of extant varieties

One of the factors affecting the initial size of demand for PVP will be the decision on protection for extant varieties. In many countries such a decision will be largely relevant to public varieties, although private varieties may be affected in some instances (such as certain popular, notified hybrids in India). If the public institutes are able to meet the fees for initial DUS testing, this could result in a significant initial backlog of requests with little clear commercial purpose. It should be possible to separate situations in which DUS testing is pursued as part of a plan for seeking royalties and licenses from those instances where the public sector is simply trying to ensure that private individuals do not usurp the products of their research. It is not clear if the potentially high investment in maintenance fees for public varieties that remain off the shelf is a good investment. In addition, such redefinitions of the status of public germplasm that is already in use may upset relationships between the public and private sector, as the disputes over the amnesty in Kenya illustrate.

Implementation of PVP

The ease of implementing PVP seems to be overestimated in several countries. It is incorrect to believe that once PVP legislation is in place the rules and consequences will be clear for all stakeholders, or that countries with similar legislation will have similar outcomes. In all cases, the conduct of PVP is still being tested and refined. Establishing a PVP law and putting it into practice are two separate challenges, and differences in the management of similar PVP regimes help explain differences in outcomes and impact. Countries require considerable time to experiment with the implementation of PVP and to understand the consequences.

The transparency of PVP management

An institution must be identified to manage PVP and for testing varieties. The duties may be assigned to an existing agency, perhaps the one responsible for seed regulation, or a new institution may be created. There are advantages of integrating PVP with an existing seed regulatory agency, but also possible conflicts of interest. The agency must be seen to have sufficient independence; for instance, there are some concerns in India about the fact that ICAR will be assigned duties for DUS testing for its own varieties. Some parts of the private sector also have concerns about deposits of inbreds. In addition, the agency must be transparent in its interpretation of the rules.

Administrative and technical resources required to manage PVP

There is not yet sufficient experience to draw conclusions from the levels of participation in the PVP system about the local resources required to manage PVP. In Colombia, a relatively small number of private OPVs of commercial crops (rice, cotton, and soybean) have sought protection and many of these are in production. In addition, a large number of horticultural crops have been granted PVP, but the DUS testing has been managed externally. In Kenya, very few private varieties of agricultural crops have yet applied for protection, but there has been a deluge of applications for a range of public varieties (in response to an amnesty for extant varieties). This has required an extensive amount of DUS testing, but what proportion of these public varieties will attract maintenance fees remains to be seen. Kenya is also considering developing its own

testing capacity for things such as ornamental crops, although it is not clear if this is an efficient use of resources. In China as well, there is a large, and continuing, demand for PVP, largely for public varieties.

Fees for PVP

Another factor affecting the demand for PVP is the level of fees. The high number of applications in Kenya and China in the early years of PVP is not necessarily an indication of the levels of demand that will eventually emerge. Whether private companies or government institutes will be willing to pay application fees and yearly maintenance will depend on their experience in the market. In large countries with extensive seed markets, investment in PVP will be easy to justify; for smaller markets and niche varieties the justification will be more difficult. The fees are uniform, without regard to type of crop or seed market (so that the costs of protecting a rice OPV, a rice hybrid, and a common bean variety are all the same, despite significant differences in their potential earning power in the seed market.) There is not much difference in the costs of PVP between the 3 countries in the sample, despite significant differences in potential market size. (For the 3 countries it costs between $1,200 and $2,400 to register and protect a variety for five years.) In addition, the countries take quite different approaches to the adjustment in fees during the period of protection; in some cases fees are lower in the earlier years (presumably to encourage testing the market). As experience with PVP systems develops, it will be important to see how the fee schedules affect the willingness to seek protection for different crop types (e.g. high-value horticultural exports versus local grain crops).

Financial sustainability of PVP authorities

Discussions about the level of fees charged for PVP are related to the question of whether a PVP authority can be expected to be self-supporting. If it cannot, then justifications for public investment are required. On the other hand, if it is self-supporting, care must be taken to ensure that revenues are not being generated by the enforcement of a protection system that encourages high-value applicants and locks out lower-value candidates. Questions of financial independence (and of the appropriate level of fees) also depend on the relative participation of public plant varieties (and the extent to which revenue is earned simply by moving money from one government agency to another). It was not possible to assess the degree of financial sustainability of the 3 case study PVP authorities in their early years of experience. The rapidly expanding Chinese PVP system is certainly not self-financing at this early stage in its career, while the Colombian system (which does its own testing on a very limited number of crops and earns substantial revenues from the protection of foreign-origin IP) would appear to be viable.

Enforcement capacity

The PVP agency itself is rarely the body responsible for enforcement, and if PVP is to function efficiently concomitant enforcement capabilities and resources must be developed. The few cases described in Colombia indicate that sanctions for violations are not defined and that the courts are not well prepared. Experience from China shows that it takes some time for the courts to develop requisite expertise in this area. In all cases, private and public plant breeders

must recognize that the major responsibility for identifying violations and pursuing cases rests with them, implying additional investments of staff and resources.

Implementation of patents and trademarks

Patents in the breeding industry do not require specific implementation needs apart from a capacity in the patent office to examine molecular biotechnology tools, methods and products. Countries can benefit from regional (e.g. ARIPO) or global (PCT) harmonization of application and substantive examination of applications. There is no or very little case law in the countries studied about the width of the claims, the scope of protection, etc. Enforcement of patents in the breeding industry can draw on the infrastructure in the case study countries for enforcing patents in other industries even though experiences differ among the countries.

5. Impact on seed companies

5.1 Seed Company Approaches to IPR

There has been significant private seed sector activity in many developing countries even before the establishment of national IP regimes for plant varieties. In these cases companies have tried to protect their products through other means (particularly through reliance on hybrids and being 'first-to-market') and have rarely devoted many resources to the consideration of IP issues. The MNCs that see a market for their (patent-protected) GMOs form an exception to the above. They have protected their inventions in the main markets outside the OECD-countries where possible. With the advent of PVP laws, companies must now reconsider their strategies and investments in IP.

In India, seed companies are anxious to apply for PVP for their hybrids. Many private seed companies compete, 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. (The industry politely describes this as 'cross-purchasing'.) 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. Another company spoke of its surprise at finding its sunflower hybrid entered by a competitor in an AICCIP trial. The hope is that the new PVP law will allow companies more control over their inbreds.

Many Indian companies decry the lack of contact with the public system and 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.

The private sector is now preparing for the implications of the new PVP law and of the seed and patent laws which are due in 2005. Until recently, private companies in India could sell their own varieties without having them released and notified, a requirement for public varieties. Non-notified varieties could not be certified, but many companies prefer to sell their seed, particularly hybrids, as truthfully labeled seed in combination with a well established brand name. Private companies are well aware of the new PVP law, and most hope to register their varieties despite what they generally consider 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 plant variety protection law. Most seed companies are adopting a 'wait and see' attitude. The companies understand that DUS testing will be required for PVP, and some believe that DNA fingerprinting may be used (which is not likely to happen in the short term), but opinions vary regarding the degree to which other tests will be required (as the new Seed Law has yet to be finalized). Some observers are concerned about costs and efficiency of managing large scale DUS testing that will be required. Although many companies welcome the possibility of protecting their hybrids (especially for controlling the theft of inbreds), some

express reservations about the requirement for depositing protected inbreds with NBPGR. In some of the larger firms, new posts have been developed for monitoring and advising on IP issues. The largest firms are developing considerable legal capacity. Some smaller companies have tried to deal with particular violations of their IP (such as the imitation of brand names or theft of inbreds) by hiring lawyers and occasionally pursuing court cases, but this has not resulted in any strengthening of company IP skills. Companies that are part of larger commercial holdings can draw upon the legal capacities of the parent company.

The situation is different for foreign seed companies operating in India that use biotechnology in their breeding programs. They expect that the new patent law will provide effective protection after an initial 'maturation' period, and many have filed applications, using a 'mail box' procedure; such applications will be considered when the new patent law becomes effective in January 2005. 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 eventually fall under an Indian patent.

In China, private sector participation in the seed sector is developing rapidly, as a result of the new seed sector regulation which eliminated the monopoly of the public seed companies. Many smaller, start-up companies, have appeared and several larger ones are seeking partnerships with foreign companies. Companies are concentrating attention on hybrid varieties for all major crops, but not exclusively. Attitudes towards IPRs differ depending on the size and nature of the companies. The larger companies, such as China National Seed Group, already make use of trademarks and are applying for PVP titles. These tend to be well-resourced companies that have their origins as public corporations that are in the process of some sort of privatization. Such companies are devoting professional staff to IPR management, primarily PVP and trademarks. However, it is not clear how some of these companies that are engaging in breeding, possibly with the use of transformation techniques or marker-assisted selection, are dealing with FTO issues. Also a wide range of vegetable seed companies have been using trademark protection for quite some time.

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 which does not have a long history of IPRs. The CEO of one major domestic seed company, active in maize and also in cotton, 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. 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 adopting a wait-and-see attitude concerning 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 in investing in major breeding programs (with partners). The situation with vegetables 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 protection has almost expired.

In the other case study countries the domestic seed companies are relatively small and do not have the resources to establish legal expertise. In Colombia, there are agents that help companies apply for PVP. In Kenya, the new private seed 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.

5.2 Seed Company Priorities

Although one of the objectives of PVP is to provide incentives for a wider range of breeding strategies and objectives, the evidence from the private seed sector in the case study countries provides few examples to date. However, the length of time that companies in these countries have had to gain experience with PVP legislation is admittedly limited, so the evidence must be interpreted with caution.

The majority of private seed company activity continues to focus on hybrids, and asked about whether investments might be directed to OP varieties or crops because of IPRs, all responded that they would concentrate on hybrids where these are feasible. Colombian rice breeding by the private sector seems to be an exception, but this was already ongoing long before PVP was established. Companies now seek protection for their rice varieties, but there is not sufficient evidence to demonstrate increased private rice breeding activity due to the IP regime. Most of the farmers who purchase rice seed manage commercial operations (average holding about 32 ha) and many purchase seed rather than saving it, so the rice seed industry has a reasonable market. Nevertheless, the considerable amount of informal seed sale, and the fact that there are no criminal penalties described for PVP violations, means that incentives for the seed companies are still limited. The advent of PVP in Colombia has not seen the emergence of private plant breeding for crops such as OPV maize or beans.

In Kenya, the major hopes of the private seed industry rest with hybrid maize despite the introduction of PVP. However, two companies are producing and marketing their own OPVs, and KSC also markets public OPVs. It is interesting to note that the private companies have so far not applied for PVP for these varieties. Private companies are not investing in breeding for other non-hybrid seed crops, although the brewery funds some of the public barley breeding. The flower sector claims that PVP is vital for the development of this sector. It is worth noting that part of the rationale for Kenya's proposed move towards UPOV 1991 comes from KSC complaints about the widespread sale of farm-saved seed among wheat farmers; KSC is currently the only firm supplying wheat seed.

In China, the PVP system has existed only four years but there is not yet much indication of private sector interest in breeding OPVs. One of the largest, diversified seed companies, China National Seed Group, indicated that PVP has not affected its hybrid/OPV mixture of products and breeding strategies. Breeding with OPVs seems to be minimal and concentrates, as does marketing of imported OPVs, on small market niches where there is demand from very professional, commercially-oriented growers who would not be interested in purchasing 'counterfeit' seed. Again both domestic and foreign companies do not yet have sufficient trust in enforcement possibilities to consider OPVs seriously. According to some, PVP can help improve the

protection of their hybrids through the protection of the inbreds, but those who can choose to continue to use (modified) three-way crosses that provide a reasonable protection from 'stealing' inbreds by competitors. Foreign companies may market some OPVs but are not yet bringing in elite material. Optimists claim that time is necessary for Chinese business culture, as well as the legal system, to adjust.

Monsanto and Delta & Pineland's experience with Bt cotton may indicate that confidence in the patent system is not much greater. Aside from complaints by their Chinese partners of the difficulties in enforcing the patent, Monsanto has clearly withheld from introducing its Bollgard II technology in China awaiting new strategies that can effectively deal with the business environment.

The Indian private seed industry is large and diverse and there is no single attitude that characterizes the attitude towards breeding strategies. However, there is relatively little evidence at this early stage that the new PVP law will elicit much additional breeding activity outside of hybrids. There are a few private companies that already have their own OPVs (e.g. rice, cotton, and certain vegetables); they expect the new legislation will help protect them from competitors, but at this point they have no plans to expand their breeding in this direction. A few companies say that if the PVP legislation is effective they may expand into non-hybrid 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 non-hybrids as a way into the hybrid market. For instance, several companies began conventional rice breeding programs as a way to gain a foothold on what they hope could be a lucrative hybrid rice market. One company in the sample hopes to begin mustard and wheat breeding, but again in the expectation that hybrid technology will eventually become feasible. One large company has temporarily abandoned its work on a transgenic mustard hybrid, but continues to market an OPV based on its brand recognition for seed quality. The strategy of offering a wide range of products to farmers in order to generate brand loyalty explains the fact that at least one large company expresses interest in crops like soybean, not as an important generator of revenue, but as an additional service to its clients of hybrid cotton and sorghum.

The existence of PVP legislation is reported to make foreign companies more willing to provide their more advanced breeding lines and varieties to a country, but this depends on the level 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, companies seem to be playing a wait-and-see game, watching the experiences of mostly domestic competitors in pushing through enforcement cases.

5.3 Protecting Bt Cotton

The most relevant example of the challenge of protecting a transgenic variety is the case of Bt cotton, already grown in China, Colombia and India (and a future possibility for Kenya and Uganda).

China has the longest history with Bt cotton, both through a joint venture between Monsanto, Delta and Pineland and the Hebei provincial seed company, and separate constructs and varieties developed by the public research organizations of CAAS, including BRI. Bt varieties of cotton have been quite successful in north China, in particular the provinces of Hebei, Shandong, and Henan. It was estimated that almost one-third of all of China's cotton area was planted with Bt varieties in 1999, and 58% in 2003 (Pray *et al.*, 2002; James, 2003). Difficulties in making precise estimates illustrate the special challenges of protecting Bt cotton in China. Monsanto and Delta and Pineland first introduced their 33B variety in 1999 in Hebei and two years later introduced their 99B variety. Biosafety approval, although nationally coordinated, is granted on a province-by-province basis and marketing of Monsanto's varieties has extended gradually to other provinces during the last six years, but not without reported delays (Pray *et al.*, 2002). Monsanto has some patent protection in China, including on their transformation methods and the 35S promoter gene. But they do not have protection on the Cry1Ac gene construct. Given that cotton is not yet eligible for PVP, this leaves trademarks and biosafety as possible modes of protection.

It is commonly acknowledged by many involved in the sector that there is widespread illicit production and marketing of Monsanto and Delta and Pinelands' Bt varieties (see Pray *et al.*, 2004). During a random visit to seed shops in Henan Province, packages marked as 99B seed, either illicit or counterfeit, were readily available. There are also no legal restrictions on farm-saving of seed and Monsanto's construct has reportedly been crossed into other varieties by farmers (and breeders). A similar situation faces the public-sector developers of Bt cotton in China even though BRI does have patent protection for its two Bt constructs. BRI acknowledges the problems that their joint venture company, Biocentury, has had in enforcing the patents. The Cotton Research Institute (CRI), based in Anyang City, Henan, also has Bt varieties containing constructs licensed from BRI. CRI management explained that biosafety regulations currently provided the most effective means to limiting illicit sales of their varieties, particularly given the ineligibility of cotton for PVP, But a visit to another seed shop in Anyang also revealed illicit or counterfeit CRI varieties (particularly CRI221) easily available. Thus neither BRI nor Monsanto and Delta Pine Land's Chinese joint venture (Ji Dai) is able to effectively control unauthorized sales of their varieties. Many, though not all, claim that the situation is improving, although the situation would be improved if PVP were available for cotton. Monsanto has yet to introduce its Bollgard II technology in China. This may be due to IP considerations, or the changing rules concerning foreign participation in the biotechnology and seed sectors.

India's first Bt cotton was released through a joint venture between Monsanto and India's largest seed company, Mahyco, which it partly owns. Mahyco cotton hybrids that were already marketed in southern India were transformed and submitted for biosafety approval. They were made available to farmers in 2002. The release of the varieties and their subsequent performance are the subjects of considerable controversy, as there are many anti-GM movements in India. Mahyco claims to be satisfied with the sale of the transgenic hybrids (which are priced at close to four times the cost of conventional cotton hybrid seed), but it faces a number of uncertainties related to IP strategies. It is not possible to patent genes in India, and the PVP system in not yet in force. It would appear that at present the only effective way of controlling the unauthorized sale of Bt varieties is through the biosafety regulations. The year before the Mahyco hybrids entered the market, a small seed company in Gujarat marketed an 'insect-

resistant' cotton variety that turned out to contain the same Bt gene. Although the company protested its innocence, claiming it must have been introduced through natural cross-fertilization, the most widely accepted explanation is that company breeders crossed commercial Bt cotton (from the US) with their own lines and produced a cotton variety that quickly became very popular with Gujarat farmers. The company was prohibited from continuing by the enforcement of biosafety legislation (i.e. their variety had not achieved clearance). Mahyco's own Bt varieties are only approved for certain states, but there is already a thriving underground market for the seed in north India. There are many rumors of other 'Bt' cotton varieties for sale, and although the majority are surely spurious, everyone admits that it is fairly straightforward to use commercial Bt varieties to develop new varieties. Despite the losses in control and royalty income by Monsanto/Mahyco, the widespread illegal introductions in Gujarat and other areas may have opened up future markets for the company, thus falling under 'optimum levels of piracy' strategies (G. Tansey, pers. comm.)

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 other Indian seed companies. A number of companies have entered into agreements for access to Monsanto's Bt cotton lines to use in their own breeding programs. As the company does not 'own' the gene, the contract is based on access to the biosafety data that will be necessary for approving any transgenic variety. At the same time, a consortium of seven seed companies entered into agreement with the National Botanical Research Institute for access to another Bt construct. That arrangement is currently on hold because of uncertainties about NBRI's freedom to operate, and some have turned to Monsanto for quicker access to Bt technology. In addition, another company has entered into agreement with Biocentury for access to the Chinese Bt gene for cotton.

Cotton is a less important crop in Colombia than previously, but it is now the subject of considerable government effort at expansion. Monsanto introduced a Bt cotton variety there in 2004. Both Monsanto and the Colombian government are anxious that the experiment works well, and considerable care has been taken to ensure that there is no unauthorized production. The production and sale 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. ICA and the seed company will monitor cotton fields to enforce access to the technology and to ensure that growers comply with the requirements for planting a non-Bt refuge. The Bt variety has been officially released, but does not yet have PVP. The Bt gene is not patented in Colombia, but it is felt that the strict enforcement planned for the introduction of Bt cotton will be sufficient to prevent any unauthorized activity. In addition, the recent Resolution 2046 makes it illegal for any farmer to save seed of any transgenic crop. Whether this type of intensive investment in regulatory enforcement would be feasible for the more widespread use of transgenic crops is uncertain.

The introduction of Bt cotton in Uganda is awaiting the establishment of a biosafety regulatory system and although Kenya is further along in defining biosafety regimes it is only beginning to consider the possibility of Bt cotton.

5.4 Managing IPRs and collecting royalties

Having rights is only the start of operating IPR from a company point of view. When a company itself cannot reach the entire market for its variety it commonly contracts with other seed producers. In addition, contracts may be signed with the end-users, particularly in the cases of flowers in several case study countries, and of genetically modified varieties and hybrids in industrialized countries. These are either signed contracts or so-called 'seed wrap' or 'bag tag' licenses that automatically enter into force when the bag is opened.

Companies may need to put considerable effort in enforcing such contracts. They need to know whether their licensees and customers live up to their obligations, i.e. whether they indeed produce and market only the amounts that they pay royalties for. It is even more difficult to control seed flows outside the contracts. In addition, the rights holders often have to establish the thin line between permitted farmer exchange and commercial sales of illegal farmer-produced seed.

Information and presence are the key elements in following up IPRs. Information is relatively easy to get in countries with a strict seed law, i.e. where all seed in the market is certified by an authority that can make its data available to the rights holder. Such authorities know exactly which amounts of seed are produced of each variety, and they have a role in policing non-certified seed in the market, providing valuable information for rights holders. In the absence of such regulated systems (such as for horticultural crops in most of the world) or where such systems are far from operational, the breeder has to follow-up on his rights himself. Licensees may have a role in pursuing cases of illegal seed in their own markets. Alternatively, the market intelligence staff of the seed companies actively follow up on the rights. In some cases breeder's/seed associations can play a role, or specialized agencies can offer assistance.

In the case study countries, seed associations are not primarily involved in pursuing royalties for their members. This may be contrasted with some Latin American countries such as Argentina and Uruguay where seed associations (ARPOV and URUPOV, respectively) are very active in taking illicit seed traders to court on behalf of their membership, which includes the majority of seed companies in these countries. Specialized agencies are active, especially in the flower business, in some of the case study countries. For example, the international company Royalty Administration International is active in many flower producing and importing countries, including Colombia and Kenya.

5.5 Alternatives for protection

Conventional IPRs on plant varieties are not the only way that seed companies can protect their products from being used by other companies or restricting farmers from saving seed. It is worth reviewing case study country experience with other alternatives that may be employed on their own, or in combination with IP instruments.

5.5.1 Biological protection

An exceptional investment in plant breeding research has attempted to extend the range of crops for which hybrid seed production is feasible; the incentives are both agronomic (the higher potential yields) and commercial. In many countries, including those in this study, the seed industry has been able to take advantage of this biological protection long before the advent of IPR regimes in agriculture. It is thus interesting to examine the behavior of firms regarding the protection of hybrids under new PVP laws. On the one hand, given that hybrids bring their own built-in protection, it may be argued that companies would not bother with the additional expense of seeking PVP for hybrids. 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, but the maize hybrids of the small domestic companies have yet to apply for PVP.

The possibility of industry applications of V-GURTs has a significant impact in the IPR discussions in some case study countries. Even though the technology is not commercialized anywhere, several respondents in the group of farmer representatives consider 'terminator technology' and IPRs as equivalents. Even though both may increase chances of concentration in the seed industry, education seems to be required in this field. 'Terminator' is prohibited in India through a special clause in the Act on Plant Breeders Rights and Farmers Rights.

5.5.2 Seed laws

Conventional seed law also can provide some aspects of protection against competitors. If varieties must be officially released and registered, and if seed can only be sold if certified, this may limit illegitimate use of company germplasm. For instance, certification rules would require a company to demonstrate access to a legitimate source of breeder seed or inbreds.

This method is being used by NARO in Uganda. License contracts with seed producers are not based on IPR, but on a gentlemen's agreement about the NARO-ownership of the varieties and backed by the seed law. Seed producers cannot produce commercial seed when they cannot prove access to NARO-supplied breeder's seed. Although this may not stop them from commercializing such varieties abroad, such behavior may exclude them from future releases.

In China, companies are also able to protect against some illegal sales of seed through the seed regulation which requires seed companies to be certified. Thus, smaller, 'fly-by-night' propagators or vendors can be shut down, or bags of seed removed from shops, by bringing these to the attention of the local (county or city) office of the Administration of Industry and Commerce. PVP seems to be more useful as a form of protection against established seed companies, especially operating at a county-level, some of whom reproduce established and registered varieties of other companies.

Kenya seems to use its seed law to protect local seed producers from competition by international companies. A recent interpretation of the seed law excludes imports from countries like Uganda and Malawi, countries used for seed production by emerging regional and multinational companies.

5.5.3 Contracts

Contracts are very commonly used in the seed sector. MTAs have been introduced as a standard practice between genebanks and breeders and are commonly part of technology transfer agreements between (public or private) breeders in case study countries and biotechnology firms or institutes. The study encountered several applications of contracts as a means to obtain and enforce rights.

Some foreign companies in case study countries appear to concentrate on contracts to manage their IPR on biotechnologies instead of commercializing them directly in the seed market. This is the case in India for Bt cotton technology. However, contracts may be difficult to monitor. In China, for example, there are contracts between Biocentury Transgene Technology and some breeders of Bt cotton varieties, but the technology fee obtained by Biocentury is significantly less than that expected from the estimated area of cotton containing its Bt gene. A recent change in the management of Biocentury has resulted in the company's direct involvement in seed production and seems to have provided an increase in revenues.

Since the coming into force of the Cartagena Protocol, liability issues are becoming more prominent in contracts involving genetically modified varieties. This development is expected to reduce the transfer of such technologies (Sullivan, in press).

In Kenya, KARI entered into a contract with a major biotechnology company for access to Bt technology. The contract stipulates how the genes can be used, who has rights on inventions made on the basis of the technology, etc. It also prescribes that KARI will have to use new versions of the technology (by the same supplier) as soon as they come onto the market. This means that KARI will have to use any new Bt gene that is likely to be patent protected in the future, and may also limit its opportunities to use other sources of Bt technology, such as those that go out of patent. The institute is now bound to these conditions, even though it knows that the patents on the genes and technologies are not valid in most of Africa, including Kenya. The reasons for entering into the contract were twofold: get additional support for the use of the technology (training), and the development of a good relation for future scientific collaboration. The long term value of the rights are important for the company, even though it does not see Africa as a profit center for years to come. On the other hand, it is questionable how the potential long-term 'losses' for KARI balance the short term value of training and access to the technology.

Uganda has entered into a contractual arrangement (MTA) with a German enterprise to supply coffee germplasm on an exclusive basis, stipulating among other things benefit sharing when the material is commercialized.

Contracts are particularly important in the floriculture sector, and are discussed in Section 7.6.

5.5.4 Biosafety

Biosafety regulations are not meant to create property, but primarily to protect the environment and to promote the safe use of biotechnologies. Nevertheless, we have seen in the case of Bt cotton in India that access to biosafety data is the principal protection mechanism currently available to the owners of the technology.

5.5.5 Trade secrets

Hybrid technology is a good example of a trade secret. But the protection offered by hybrids is only as good as the physical security provided to the inbreds. In Uganda, where a local seed company produces maize hybrids on contract for Monsanto, the lack of PVP for the hybrids means that the operation must be very closely supervised at the seeding phase (all inbred parent seeds provided by the company have to be planted) and by destroying the males immediately after pollination, which adds to the cost of the seed.

There is evidence that in some cases in the Indian biotechnology industry, companies currently prefer to maintain there innovations as trade secrets rather than seek (foreign) patents.

5.5.6 Business practices

Business practices can 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 developing farmer loyalty and protecting themselves from imitators. There are certainly limits to what can be accomplished through brand loyalty, but the investment doubtless has payoffs. Although not all farmers can easily recognize or depend on brand names, seed companies' efforts to build up a loyal following with seed dealers, on whom many farmers depend for advice, probably makes at least as important a contribution to defending market share. 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 only been able to catch the perpetrator twice, and the only case that made it to court resulted in just a small fine. In those cases where Indian companies market their own OPVs, management often responds confidently to questions about illicit competition by referring to farmer loyalty. Nevertheless, these same companies are usually resigned to a certain degree of leakage.

Practices of brand development are also common in China, but the case of Bt cotton shows that there are clear limitations.

MNCs are particularly experienced in the use of other business practices to help protect their varieties. The most important of these is 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. MNCs have generally low expectations of enforcing contracts in the study countries, and in any case once material has leaked out it is too late. Thus MNC activity tends to build up at a gradual pace and pays attention to many factors beyond IPR regimes. Many foreign seed companies have been active in some form or other in China for over 20 years, often in only a modest form.

5.6 Summary

IP and the evolution of the private seed sector

The emergence of the private seed sector in the case study countries owes relatively little to national IP regimes. By far the most dynamic private seed sector in the sample (India) has grown and diversified without benefit of any PVP regime but in the context of quite liberal seed laws and in many cases through the use of hybrids as a way of appropriation (e.g. Pray & Ramaswami, 1990) . Colombia's private seed sector is more than two decades old, but private seed enterprises in the other three countries are the outcome of fairly recent policy changes that move away from public monopolies on seed production. Thus PVP is not a necessary condition for initial private seed sector development, but it may contribute to its growth and diversification. The nature and extent of this contribution will depend on the characteristics of the national seed system. The only major example of private domestic plant breeding in Colombia is for rice, and the establishment of PVP almost certainly encouraged the further development of the industry, which is based on OPVs. Foreign companies also market protected OPVs of soybean and cotton, but it is difficult to point to examples of the diversification of the private seed industry in Colombia due to PVP. It is even more difficult to identify any effects of PVP on the nascent private seed industry in Kenya, where the few products of private domestic breeding have yet to seek protection and the hybrid maize offered by MNCs may not have PVP. In Uganda, exclusive rights over public varieties given to local private companies have contributed to the emergence of local seed enterprises, and it is worth noting that this was done without any formal IP-legislation. Although the (foreign) horticultural industry pressed for the establishment of PVP in Colombia and Kenya, and the national regimes certainly provide added confidence and contribute to the perception of a better business environment for expansion, neighboring countries with similar ecologies but less developed PVP (e.g. Ecuador and Uganda) can still participate strongly in the industry (see Section 7.6). The course of private seed sector evolution in China will depend on a wide range of factors, and the role of IP is uncertain.

IPRs' role in protection from competitors

Seed companies tend to take advantage of PVP and patents when it helps protect them against competitors gaining access to their materials. Thus OPV rice varieties are regularly protected in Colombia (as are cotton and soybean). Hybrid maize is not protected in Colombia because the hybrids are relatively secure. Similarly, OPV barley has sought protection in Kenya, but private hybrid maize varieties have yet to apply for PVP. In addition, those OPV crops that seek protection are ones that are grown in commercial systems, where variety and seed quality are important and where seed cost is a relatively small proportion of costs of production.
Where hybrids are used in diversified seed industries, such as India and China, hybrids attract the majority of interest for PVP.

PVP and protection against seed saving

PVP systems can also limit farmers' seed saving and hence provide additional incentives for private seed provision, but there are no instances of this as yet in the case study countries except for the flower industry where on-farm production of planting materials is fairly adequately

regulated by the breeders. The two cases where there is movement in this direction in field crops are Colombia and Kenya, and in each case specific complaints contribute to the argument for change. In Colombia there is a considerable amount of seed saving and informal commercial sale of farm-produced rice seed and the industry would like to control this; a new resolution limits seed saving to farms below a certain size. In Kenya, there are complaints that wheat farmers save and trade the majority of their seed, rather than buying commercial stocks, and Kenya proposes making its regulations compliant with UPOV 1991. In these two cases, the specific instances are related to relatively large-scale commercial agriculture where the extra costs to farmers of obligatory seed purchase will probably be acceptable, but the changes in law and regulation open the door to much wider control of seed use without any obvious mechanism for discretion. In both cases authorities admit that it would be difficult to enforce such requirements with smallholders (as well as being politically sensitive), and at this admittedly early stage the evidence points to these limitations on seed saving as merely strengthening already existing seed production rather than providing incentives for diversification. Any control on seed saving is explicitly ruled out in the Indian law, and this is one of the reasons why the majority in the private seed industry does not predict any PVP-derived expansion in investment in OPV seeds.

Implications of IPRs for structure of industry

The question whether IPRs will create a shake-out in the industry at the cost of the smaller companies can not yet be answered in the case study countries. Such increasing concentration in the industry could be due to the costs associated with protection (which is one of the reasons why smaller companies in Kenya don't yet pay attention to PVP). The situation in India, with many small seed companies in operation, deserves particular attention. In addition, restricted access to technology might become a bottleneck for smaller companies. One way to deal with this is the formation of company consortia for access to (public) technology. There is at least one example in India, and the idea has also been discussed in Latin America. Alternatively, technology providers may change their business approach to license their technology to a wide number of local companies instead of marketing the seeds themselves.

While it is assumed that the powerful multinational companies will be able to protect their interests both with and without IPRs, medium-sized local companies have much to gain from a secured market provided by license contracts or their own PVP-protected varieties. The introduction of PVP could be helpful in stimulating these companies' contribution to a diversified seed supply (Srinivasan, 2004).

Relations with NARIs

Most local seed companies start with the multiplication and marketing of public varieties. In most of the case study countries, a second step towards developing in-house breeding capacity is also visible. This evolution may lead towards accessing public breeding lines rather than public varieties, as is observed in India. The response of the public system is discussed in the following chapter.

6. Impact on public plant breeding and seed production

6.1 IP policies

IP policies in NARIs may address three types of goal: revenue collection, recognition of achievement, and technology transfer. These goals may not always be compatible, and the development of adequate policies for the NARIs is a difficult task.

NARIs in China tend not to have written policies on IP management, in particular with respect to patents and PVP. There are however policies in operation in the sense of guidelines and rules understood by employees and management. The situation varies and is certainly different for institutes working on transformation techniques, in contrast to crop research institutes. At BRI, where patents are one of the principal means of assessing achievement, individual researchers generally decide whether an invention has sufficient market potential to be patented, but they do receive some general support. CAS has an office to assist researchers in conducting patent searches and also in engaging the services of a patent agent for filling out applications at a relatively inexpensive fee of approximately $250 (RMB 2,000). The costs of application must generally be borne out of their research budgets although they may apply to a CAS fund for a subsidy. Assigning the responsibility to the individual researcher is justified, according to BRI, in order to allow the researcher to gain from a patent, both professionally and financially. The provincial and national crop research institutes are less oriented towards patents, but increasingly towards PVP. The Hunan Hybrid Rice Research Center (HHRRC) and the Rice Research Institute (RRI) of the Hunan Academy of Agricultural Sciences both apply for PVP for their new rice varieties that show market potential. In both cases, the director takes the decisions about whether to apply for PVP on a case-by-case basis. The Rice Research Institute of the Guangdong Academy of Agricultural Sciences (GAAS) seems to have somewhat less experience although they have been granted PVP for at least three varieties. But research management indicated that capacity to manage and enforce their rights is still being developed. They also do not see as much use for PVP, given that their government financing is partly based on adoption figures. At the broader level of GAAS, some of whose other institutes have been regularly granted patents for more than 10 years now, there is a written IP policy. Decisions concerning application for patents and PVP are taken by researchers and management in the institutes concerned. But ownership of the resulting rights rests with the Academy. In general, the approach seems to be different in each organization. As far as the crop research institutes are concerned, this may be an indication of a period of adjustment after the introduction of PVP. Over all, PVP varieties and hybrids fetch a slightly higher seed price than unprotected varieties.

In India, ICAR does not yet have a written IP policy, and its constituent institutes look to the center for guidance and direction on these issues. ICAR has guidelines on its website for seeking patents and instructions are being issued for DUS testing of extant varieties and registration of germplasm. IP is managed there at the highest level, but with very limited resources. There is only a small unit assigned to IP at ICAR headquarters. Similarly, most Indian agricultural universities do not have an IP policy; in some cases a knowledgeable staff

member may perform the role of IP advisor for the university, but without title or terms of reference.

In the other case study countries CORPOICA, KARI and NARO are still developing their own policies in this area. Attention to IP issues in KARI is divided between its lawyer and the head of its biotechnology center. NARO recognizes that it needs staff with some IP expertise but is not considering employing its own lawyer. Some institutions in Eastern Africa do have a written (often draft) IP policy developed under the guidance of the Eastern Africa Regional Network on Biotechnology (BIOEARN). These policies tend to concentrate on maximizing revenue.

NARI IP policies will have to strike a delicate balance among several factors, including the division of attention between commercial and public service activities, an equitable division of royalties within the institute, and the choice and enforcement of IP instruments.

In most cases NARIs will stand a better chance of earning royalties if they offer exclusive access to their varieties or breeding lines, but that may clash with the expectations of public service. Even if it can be demonstrated that an exclusive license provides the most effective delivery route for a particular variety the NARI may still be accused of ignoring its public mandate. Partly for this reason, KARI administration favors non-exclusive arrangements for its varieties, and lost the chance to license one of its maize hybrids to a company because of the exclusivity issue. In Uganda, NARO has licensed three maize hybrids on an exclusive basis but has yet to define its policy on the 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. One aspect of the IP-related policies is that the public sector sees one of its duties as counter-acting concentration and monopoly in the seed sector by creating a strong position for the public sector in the commercial seed industry.

6.2 Revenue generation strategies

The establishment of PVP allows NARIs to protect their germplasm and thus earn revenue from seed companies through royalties on finished varieties and fees for access to breeding lines. This potential for raising revenue is a welcome possibility for research administrators who have to contend with inadequate public budgets, but there is considerable uncertainty regarding both the level of revenues that can be expected and the effects that this revenue might have on research programs. The possibility of NARIs raising some of their own revenue is of course not solely dependent on the emergence of IP regimes.

India

The sale of source seed of public varieties to seed producers is an example of revenue generation that takes place in the absence of IPRs. In India, when private companies sell seed of public varieties they are expected to buy the source seed from the public institution. For instance, Andhra Pradesh Agricultural University sells more than 70 Mt of breeder seed of its rice varieties every year. The system does not work for all crops, however. Private companies rarely purchase fresh stocks of breeder seed of public vegetable varieties, preferring to

maintain their own supply. The companies complain about the relatively high price of breeder seed of vegetable varieties and point out that sometimes their requests for breeder seed are not met. In addition, because vegetable seed is not certified there is no requirement for using original breeder seed.

Many private seed companies complain that their access to public breeding lines has decreased in recent years. On the other hand, public institutions often express resentment of the fact that the private sector earns large profits from the products of public research and complain that private companies are unwilling to share some of their own lines or knowledge with public research. The degree of interaction varies by crop. There are a few examples where seed companies feel they have acceptable access to public lines (through field days and other contacts). In some cases (such as maize) this openness is a function of the influence of CGIAR policies on open access combined with willingness of the crop program itself to share materials. In the case of maize, the program's coordination unit has a policy to develop lines and to share these with all partners, including the private sector. For many crops, however, private companies frequently say that it is much easier to get access to CGIAR germplasm than to local public lines. There are also a few recent examples in which public institutes or universities have entered into non-exclusive agreements with seed companies for access to breeding lines, following guidelines set down by ICAR for such contracts. The Indian Institute of Horticultural Research (IIHR) made a one-time sale of the parental lines of a tomato hybrid to several private companies; some sell the hybrid under the original name while others modified the name.

Indian universities tend to be driven by strong public service mandates and many have no experience of interaction with the private sector, while a few others establish occasional links. The University of Agricultural Sciences in Karnataka sold access to three virus-resistant tomato OPVs to ten seed companies. The assumption was that the companies would market these varieties directly, although in many cases the companies' objective was to use the germplasm in their own breeding programs. A private company that has recently begun work on hybrid rice has agreements with two agricultural universities for non-exclusive access to inbreds and a large seed company occasionally buys germplasm for its vegetable breeding program from universities.

China

Revenue generation strategies among crop research institutes in China vary by crop and province. Many provincial crop research institutes in China have been selling rights to hybrid varieties of rice and maize well before the introduction of PVP. Both the Rice Research Institute of the Guangdong Academy of Agricultural Sciences and the Hunan Hybrid Rice Research Center of the Hunan Academy of Agricultural Sciences (HHRRC) have licensed exclusive rights to private companies for production and marketing. Before the new seed sector legislation introduced in 2000, purchasers tended to be the public seed companies at national, provincial and county levels. The Cotton Research Institute (CRI) of the Chinese Academy of Sciences (CAS) has on the other hand traditionally generated revenue through the sale of marketing rights to its seed, primarily OPVs. The Institute for Vegetables and Flowers (IVF) has also concentrated on generating revenue from sales of seed, also relying on companies for the marketing stage.

A number of officials indicated that this process of selling new varieties has been enhanced by the introduction of PVP. If an institute has acquired PVP for a variety, then it is in a position to request a higher price. In many cases, auctions have been organized to obtain the highest price. Agreements may be based on lump sum arrangements, such as the HAAS Rice Research Institute which auctioned non-exclusive production rights to its new protected variety 'Nongxiang103' for more than $45,000 (RMB 380,000) in 2003. The Rice Research Institute of the Guangdong Academy of Agricultural Sciences sold exclusive rights to a protected variety in 2002 for about $240,000 (2 mRMB). Such lump sum payments seem to be preferred by large companies, according to Doneed Seeds Company, one of the countries' largest diversified seed companies. But royalty arrangements based on seed sales are also common, particularly where the rights negotiated involve marketing but not production.

Uganda

In Uganda, NARO has recently licensed three maize hybrids to three different companies. The companies 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 the institute 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 offer one of these hybrids for sale. NARO also hoped to contract with the local brewing company for exclusive access to a sorghum OPV, but this agreement fell through and the brewery simply pays NARO for source seed which it uses to produce commercial seed for its outgrowers.

Colombia

In Colombia there are several important examples of the private funding of commodity research. The cotton growers association has provided some funding to CORPOICA for cotton breeding (the association originally asked to share in any royalties earned, but then agreed that royalties would go to a fund for cotton research). There are several commodity research institutes in Colombia (separate from CORPOICA) where growers associations fund plant breeding (e.g. for coffee). Given the fact 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) in which the private seed sector has little interest even if they can be protected. The few recent examples of contracts with the private sector have not turned out well; CORPOICA offered exclusive licenses on two maize hybrids to two seed companies in return for a 3% royalty, but the seed companies and CORPOICA blame each other for poor quality seed and CORPOICA has reverted to trying to produce and market these varieties itself. They also had a similar experience with a cotton variety.

Kenya

Kenya also 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 that have been the exclusive province of the Kenya Seed Company (KSC). The prior arrangement with KSC and the relatively recent

liberalization of the seed sector that allowed competition with KSC also explain the relative lack of progress in licensing KARI varieties. In addition, there are very few KARI crop varieties besides maize hybrids that are of interest to the private sector. KARI has a non-exclusive agreement with Kenya Breweries, who pay a royalty of 2.5% on the value of the seed of KARI barley varieties that the company produces for its outgrowers. The brewery's support for barley breeding has also led to several new barley varieties seeking PVP with the brewery and KARI as joint owners. In early 2004 KARI tendered 16 old and new maize hybrids, with the expectation that various seed companies would bid for production rights. The outcome was disappointing, however, and only three of the hybrids were contracted, in each case to very small seed companies. In one case, the KARI Seed Unit will take charge of seed production and the company will market the seed. KARI is now considering whether it should try to produce and market some of the new maize hybrids itself.

Future prospects

The potential for revenue generation through royalties on public varieties and sale of breeding lines varies by crop and by country. In India and China, the large and technically proficient public breeding programs will certainly have things to offer for their diverse and well-developed commercial agricultural sectors. In both countries there are many cases where private companies, particularly smaller ones, produce seed of public varieties (mostly OPVs) and it is likely that this will continue. Although most seed companies in India would prefer exclusive licenses for public varieties, there are smaller companies that are satisfied with sharing a market. But many of the seed companies either have, or aspire to develop, their own breeding programs and naturally tend to promote their own varieties.

In China, several larger seed production companies, such as China National and Doneed, are beginning to establish their own breeding programs, partly to ensure future sources of improved varieties, given the uncertainty of competing for access to varieties at public institutes. However, even though there will be many opportunities for NARIs in China and India to generate revenue from protected germplasm, the NARI's are not likely to rely on this income for the operation of their different breeding programs.

In the other case study countries the situation is even less clear. Where NARIs are relatively small and under-funded, there are relatively few opportunities for them to offer products that the private sector is willing to pay for. The dilemma is that in order for NARIs to generate a significant amount of revenue from private contracts they need sufficient public investment in the first place in order to establish their capacities. In addition, national seed markets need to be large and diverse. In Kenya, KARI's disappointing experience in its recent tender of maize hybrids is an indication of the problem. In Uganda, while NARO was completing the first contracts with seed companies for production of its maize hybrids, the institute's only maize breeder resigned in hopes of joining the private sector.

An additional possibility for revenue generation by NARIs 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 there are a few cases where they have simply purchased non-exclusive

access to public breeding lines. Once the PBR legislation is in place it can be expected that these interactions may be strengthened and formalized. Additional understandings would have to be developed to cover royalties or compensation when the MNC uses the germplasm outside of India, and similar considerations are warranted for the larger domestic seed companies with international marketing and research aspirations.

In Kenya, KARI has an agreement with Monsanto that provides Kenyan maize and cotton breeding lines for possible genetic transformation in return for a share (as yet unspecified) of royalties on any transgenic varieties. Interactions with MNCs may also be mediated through IARC programs.

Incentives for individual scientists

A particularly important administrative issue for NARIs is the degree to which royalties earned are shared with individual scientists. The emergence of private seed companies carry the risk that innovative and active breeders are absorbed by the private sector, leaving few capable staff in the public research institutes (Morris & Ekasingh, 2002). In general, staff promotion in NARIs is 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 for promotion. As NARIs begin to earn royalties from protected varieties, there is the possibility that the breeders may also share directly in the financial benefit. The NARIs in our sample are approaching this issue in various ways. Chinese NARIs have the broadest experience in earning royalties through commercial seed sale, and breeders generally are given a 'bonus' related to the level of royalties received. This was a common practice even before the introduction of PVP. The provincial academies of agricultural sciences and their institutes have developed their own approaches. Interviews revealed a range of revenue-sharing schemes although a general feature was to ensure that not only breeders, but other staff also benefited. It was not possible to gauge to what extent this is affecting incentives and motivation at an individual level.

In India, ICAR does have a formula for sharing consultancy income with its scientists, but not for sharing revenues from IP. CSIR however is working on a formula that would grant equal shares to the inventor(s), the institute and a special fund at the Council.
In Kenya, KARI has yet to establish a policy, but is under pressure from the Kenya Plant Breeders Association for the acceptance of a formula for division of royalties (based on type of crop) with the breeder; the association is even lobbying to have this formula included in the revised Seed Law (for both public and private sector breeders). The director of KARI admits that deciding how to divide royalties within the institute, between and among programs, is a significant management challenge. Despite Colombia's experience with PVP, CORPOICA has yet to establish a policy for the disposition of royalties, and NARIs in India and Uganda are only beginning to consider the issue.

6.3 NARI Seed Production

An alternative to contracting with private seed companies is the possibility of NARIs producing and marketing seed themselves. Despite several decades of generally unhappy experience worldwide with public seed production schemes, the problems of attracting private company interest combined with pressures for demonstrating revenue generation capacity have encouraged several NARIs to consider their own seed production strategies.

The situation in China is particularly complex, as there is a clear incentive and expectation for many research institutes to generate a significant proportion of their own budgets, but this clearly varies by province and by crop. The Institute for Vegetables and Flowers (IVF) has always undertaken its own seed production and then sold to retailers, in order to maintain control over parent lines. This situation, partly manageable because of the intensive nature of vegetable seed production in terms of land use, has changed little with the introduction of PVP. In the case of cotton and rice, incentives for generating income have led to some research institutes establishing their own subsidiary companies for production and marketing. For example, the Cotton Research Institute (CRI) markets essentially all of its varieties through joint ventures with seed companies. In other cases, contracts granting exclusive access to new varieties are negotiated with companies that have a special relationship with the institute. The case of HHRRC in China is perhaps most illustrative. The director of the Center established the Longping High-Tech Corporation which then established an exclusive rights agreement with HHRRC. NARI diversification into seed production and marketing, whether by the institutes themselves or a wholly-owned subsidiary company, has also been made possible by the changes in the seed sector regulation, allowing private companies or others to produce and market seed. The choice to diversify may reflect an expectation that revenues can be maximized by maintaining direct control over production, as opposed to licensing.

In India, on the other hand, there is much less possibility that research institutes or universities would attempt to produce and market seed on any appreciable scale. There are well established public seed corporations and other government programs (such as parastatal agencies for commodity development) that have the mandate for this type of activity. Although the role of public seed production institutions is being challenged and reformulated with the rise of the private seed sector in India, there is every likelihood that many of these public seed production activities will continue in the foreseeable future. The up-scaling of facilities to provide source seed under the National Seed Project illustrates this.

The smaller NARIs are in a difficult position when they fail to attract commercial interest in their varieties but face mounting pressure for generating revenue and demonstrating that public varieties are reaching farmers. KARI has a Seed Unit which was established to ensure that source seed of KARI varieties was readily available to seed producers. An important rationale for the creation of the Seed Unit was the fact that seed of many ‘orphan crops’ was not available to farmers because the few commercial seed enterprises took little interest in multiplying the (limited) output of orphan crop breeding programs. It was thought that a more transparent and efficient source seed facility would contribute to generating commercial interest and fostering smaller seed enterprises. The Seed Unit has been an important player in donor projects that support local groups in seed production. It is not clear if any of these producer

groups can survive commercially, and the Seed Unit continues to see government and donor programs as the major conduit for seed of orphan crops. In some cases the Seed Unit coordinates the production and sale of commercial seed (e.g. potatoes) at KARI stations. The unit is helping a small commercial firm produce seed of a KARI maize hybrid (the packaging includes the company's and the Seed Unit's logos) and with the failure to attract more interest in its latest offering of hybrids there is the temptation to expand into more commercial seed production and marketing. This would be done under KARI's newly established commercial arm.

A similar situation obtains in Colombia; CORPOICA has recently established a Seed Production Unit whose principal aim is to provide source seed of crops with little commercial seed demand. An inheritance from CORPOICA's origins as a public entity is the expectation that it should support various government programs that produce such seed, although the corporation is not always reimbursed for the source seed that is requested. The Seed Production Unit also has a mandate for producing and marketing commercial seed in certain cases. When CORPOICA was disappointed in the performance of private companies contracted to produce seed of maize and cotton varieties it began exploring the possibility of producing the seed itself.

In Uganda, the public seed enterprise has lost an important share of the market to newly established private companies. It competes with these companies for the licenses for new NARO varieties. There is no indication that NARO itself would like to venture into commercial seed production.

6.4 Patents

An additional mechanism for revenue generation open to NARIs is the patenting of inventions NARIs in China have the most experience among the case study countries. The Biotechnology Research Institute (BRI) of CAAS owns approximately 10 patents and has another 40 applications pending, of which 2 have been submitted for overseas protection under the PCT. BRI has patented two Bt genes and commercialized these in cotton varieties through a joint venture with Biocentury Transgene Technology. Biocentury has licensed these genes to the Cotton Research Institute (CRI). BRI receives one-third of the net revenues of Biocentury with half of this amount going to the research group that developed the Bt cotton genes and 10% to the individual scientist. Revenue generation has however been much less than expected due to difficulties in enforcing the patent. Most of CRI's Bt cotton varieties are OPVs, IP enforcement of which is very difficult with the local seed producers. Nonetheless BRI currently generates about 15% of its income from patents, primarily other than Bt, and is expecting to increase this significantly in coming years. BRI staff are assessed on both publications and patents obtained, and advisory and financial support is available from CAAS for submitting patent applications.

NARIs in India have limited experience in patenting and policies and modalities are being established. However, there is a growing experience in patenting plant-based products and processes for pharmaceutical uses (locally and abroad). The National Botanical Research Institute (NBRI) used this experience for the international patent applications for its Bt genes that have however not yet been commercialized. One commercially successful case involves a

method for detecting the Bt gene in a plant. A scientist at the Central Institute of Cotton Research (CICR) developed the technology and 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 to pursuing patents, or sharing costs and royalties. The process involved a great deal of time from CICR and ICAR staff, as well as the use of consultants. The present guidelines for contract research and consultancy are inadequate to address the entire IP-related issue.

A contrasting case from an agricultural university involves a scientist obtaining a patent on a method for gene insertion. Although the Department of Biotechnology (under the Ministry of Science and Technology) is supposed to help with such applications, it was slow to respond and the university scientist hired a patent lawyer using his own funds. The patent was eventually granted (in the university's name) but it is unclear if the university will even pay maintenance fees and little likelihood that it will offer any help in pursuing commercial partners. State Agricultural Universities look upon ICAR for policy guidance.

There is of course another side to NARI's pursuit of patents for their inventions, involving the rights to use patented genes or tools in NARI research. In all the case study countries researchers are using technologies that are patented (at least in industrialized countries), for activities such as genetic transformation or even marker assisted selection. Varieties or other products have yet to emerge from this work, but only a minority of bench researchers are aware of the implications of their use of protected technology, and NARIs in the case study countries rarely commission an FTO or other reviews to address possible consequences. In India, the National Botanical Research Institute (NBRI) which initially entered into negotiations with a consortium of local seed companies for access to NBRI's Bt construct for cotton is now reconsidering its position.

The study found two very distinct attitudes in laboratories towards third-party IP: ignorance and over-apprehension. As an example of the latter attitude, some institutes in ICAR, like IAR,I now insist on prior permission for the use of IP in research. On the other hand, researchers that do know about the possible consequences of patents may not realize that many patents are not valid in their countries and that they can freely use the technologies in their territory. But lack of awareness or lack of interest are also widespread.

6.5 Plant Breeding Priorities and Strategies

6.5.1 Research investments

The effects of pursuing compensation for the use of public varieties and breeding lines may have important effects on the nature of public plant breeding. Certain crops are much more likely to attract commercial interest than others, and one of the concerns is that the possibility of earning royalties may shift resources to the more commercially attractive crops, even though such a shift might not be in line with the NARI's mandate for poverty reduction. Similarly, research priorities within a particular crop may shift from solving production constraints in

smallholder agriculture to increasing output in commercial agriculture. The study examined evidence for shifts in NARI priorities regarding crop portfolios, breeding objectives and breeding methods. There are some noteworthy trends, although not all can be attributed to the advent of an IP regime.

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 sees its principal role as contributing to the development of commercial agriculture in Uganda and is prepared to allocate its resources accordingly. Although this means that priority will be given to crops such as hybrid maize (whose seed can earn royalties), the policy also assigns priority to any crop for which market demand is evident, even if there is little immediate opportunity for commercial seed sale. Thus NARO would invest significantly in cowpea research if there was evidence of growing commercialization of cowpea production. The hope is that demand from a particular industry or from 'the market' would be translated into specific funding for NARO research. But if cowpea remained a crop that featured mostly in subsistence production, it seems likely that NARO would assign it a lower priority. The possibility of earning royalties on certain seed products contributes to this shift toward research for commercial agriculture. The emergence of PVP in Uganda thus merely enforces a trend rather than being the instigator of change in research policy.

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

Colombia finds itself in a position somewhat similar to that of Kenya. CORPOICA is expected to earn an increasing proportion of its own revenue and hopes that royalties from its varieties make an important contribution. The greater diversity of Colombia's commercial agriculture offers several possibilities (maize, rice, cotton), but the choices are relatively few and the implications for research investment on other crops are unclear.

It is difficult to predict the effect of the PVP legislation in India on the relative distribution of research investment across crops. There is no indication at the present time that research administrators have any plans to adjust their portfolios because of potential royalties. Institute administrators believe that royalties, like other income of the institutes, will be remitted to ICAR headquarters (and to the Treasury), thus providing limited incentives for shifting priorities in favor of royalty-earning crops. Administrators of the agricultural universities that were interviewed also emphasized their mandate towards serving the needs of their state's farmers. For instance, the director of research at Andhra Pradesh Agricultural University expects that rice breeding will remain a high priority and that once PVP is in place the university will continue selling breeder seed of its varieties (perhaps at a slightly higher price) to any interested seed company, rather than attempt to negotiate licenses or royalties. ICAR leadership identifies a

role for the public sector in complementing as well as competing with the private seed sector as IPRs threaten to concentrate the market.

Given the many academies and institutes involved in agricultural research in China, it is also difficult to identify changes in public research investments and priorities that are a direct result of IPRs. Most institutes have crop mandates but the issue is the extent to which priorities within these crops may be affected. Many of the crop research institutes already became more oriented towards revenue generation through selling varieties or seed long before the introduction of PVP. Most of the rice and cotton research institutes interviewed indicated that developing varieties for all farmers, including poor farmers, remains a priority. In Hunan, the Rice Research Institute concentrates primarily on conventional (OPV) varieties, and emphasizes poor farmers as a target group even though its cheap seeds are also available to richer producers. Although it earns almost half its income from seed-related revenue generation, it is perhaps not likely to compete in more commercially-oriented hybrids given that another institute, the Hybrid Rice Research Institute, has that mandate.

Some institutes in China have a mandate to focus on adoption targets, including in a few cases a corresponding incentive in the amount of government funding. For example, the Rice Research Institute of the Guangdong Academy of Agricultural Sciences receives extra financing according to the area sown with their varieties, although the institute is also concentrating more on hybrid varieties due to income generation possibilities. There may be a fair amount of overlap in the variety characteristics sought by different types of rice farmers in those provinces. Management of the Cotton Research Institute (CRI) of CAAS pointed out that one of their mandates is to develop cotton varieties for poorer farmers, who show a preference for OPVs, including for those in other agro-ecological zones such as Xinjiang in the north-west. The vegetable seed market, which has been commercially-oriented for much longer, is quite different. The national-level Institute of Vegetables and Flowers of CAAS has concentrated on hybrid varieties and revenue generation. This would appear to have changed little since the introduction of PVP.

The Biotechnology Research Institute (BRI) of CAAS is influenced more by patents than by PVP. It has traditionally focused on the 5 major crops (rice, wheat, maize, soybean and cotton) and expects less success were it to apply for research funds on other crops. The situation with BRI's Bt cotton, commercialized by Biocentury and CRI, illustrates the potential shifts that might be expected to take place. CRI's Bt cotton varieties have been quite popular and widely disseminated, including among poor farmers. This is partly attributable to the difficulties in enforcing the patents and royalty collection. Thus BRI has not realized nearly as much revenue as was forecast. If this situation influences the institute and its partners to undertake research that can be better protected, then this will probably entail a shift in breeding priorities more oriented towards better resourced farmers. At this point, there is no indication yet as to how BRI is dealing with this issue. Thus in China, there are examples of measures that can mitigate against unwanted shifts in priorities due to IPRs, but this is only one aspect of a stronger and longer-term trend towards increased commercialization of the NARIs.

Even if a NARI's crop portfolio remains unchanged, it is possible that breeding priorities may shift within crops. Interviews with case study NARIs revealed some recent shifts in breeding priorities, although it is difficult to attribute many of these directly to the advent of PVP. The most consistently mentioned factor is market demand. In Colombia, public rice breeding now places much more emphasis on grain quality than on yield per se. A recently released CORPOICA potato variety failed to gain acceptance and researchers acknowledge this is because of a lack of involvement of end-users in the research. NARO bean breeders point to the importance of consumer qualities such as cooking time in determining the uptake of new varieties. These experiences all indicate a growing realization of the necessity for public research to take more cognizance of consumer and market demand, but as yet there are few examples of changes in breeding priorities that can be directly related to demand as interpreted through commercial seed enterprises.

But if NARIs become more dependent on income from private seed companies, it is fair to ask whether breeding priorities may be affected. NARO has released a number of bean varieties and several are produced, on a modest scale, by private seed companies. However, no seed company is yet willing to invest in seed production of climbing bean varieties. It remains to be seen if this will result in a diminished investment in climbing bean varieties within NARO.

6.5.2 Hybrids versus OPVs

There are other examples where the establishment of a PVP regime may directly influence breeding strategies. This is particularly true for the use of hybrid technology There is an expectation that IPRs offer incentives for the commercial exploitation of OPVs, diversifying away from exclusive reliance on hybrids and their built-in 'biological' protection. But since the commercial seed industry places value on hybrids despite legal protection, NARIs that respond to demand from seed producers will continue to focus on hybrids. As we have seen, both Kenya and Uganda place high expectations on hybrid maize as a source of revenue and although both NARIs continue to develop maize OPVs they show no inclination to increase their OPV maize research budget.

In China, where more than 50% of commercially marketed rice is hybrid, even some of those NARIs that previously concentrated on rice OPVs are tending to shift towards hybrids because they are seen as a much better source of revenue. The situation for hybrid cotton is somewhat different and the effects of IPRs are probably limited relative to other factors. Only a small minority of China's cotton is hybrid, partly because there are not many suitable hybrids for the North where most of the cotton is grown. A survey by CCAP indicated that yield differences between conventional and hybrid varieties in the north of China are insufficient to cover the higher price of hybrid cotton seed. Another reason is that cotton hybrid breeding is still not popular, partly because the parents are controlled by a few institutes such as CRI. On the other hand, the possibility of patent protection does appear to be a factor that motivated decisions to invest in OPV Bt cotton at BRI, Biocentury and later at CRI. With respect to vegetables, the Institute of Vegetables and Flowers has always concentrated on hybrids, and interviews did not indicate any new shift towards OPVs as a result of PVP. Indeed, staff interviewed indicated that the PVP system was too weak to ensure enforcement of the rights.

In India, although public research pioneered the development of hybrid cotton, the majority of CICR's efforts are in OPVs. This means that public cotton OPVs still occupy the majority of the market in northern India, where suitable cotton hybrids have yet to be developed, but that public sector participation is much lower in southern India, where the majority of cotton is commercial hybrids. In the latter case the rationale is that the public sector is expected to give particular attention to poorer farmers in more marginal conditions. The public sector also took the lead in developing India's first rice hybrids, but the private sector is now heavily involved and the majority of the (still small) hybrid rice area is grown with commercial varieties. There is still considerable public investment in hybrid rice breeding in India, although the university in Andhra Pradesh currently shows little interest in developing hybrid rice for the state's farmers. Similarly, the agricultural university in Karnataka serves the state's tomato growers with OPV breeding, leaving hybrid development to the private sector.

6.5.3 Participatory breeding

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. Participation of the end-user should on the one hand provide better focused information for the conventional breeding programs, and on the other hand empower farmers in the development of their own improved materials with specific adaptation to their own environments and needs. Where the former approach may feed into commercial seed production, the latter commonly feeds into the farmers' seed system that produces and disseminates seeds as part of crop production.

NARIs interviewed did not have policies on sharing ownership over varieties that would be developed through participatory approaches. Whether NARIs would continue to invest in approaches that would only feed into local seed systems when revenue collection becomes a guiding principle in research management is uncertain. NARIs may consider continuing these programs as an important part of their public task in supporting less-endowed farmers and reserve core funding from the government or redirect some revenues; or they may consider such programs only if they attract donor funding.

6.6 Enforcement

Another administrative challenge for NARIs wishing to take advantage of PVP is the investment required for the enforcement of agreements. If NARIs sell or license a protected variety to a seed company, then enforcement is not their problem (although enforcement possibilities do affect the value of a protected variety).

In China, rice institutes that are oriented towards revenue generation either sell or license the variety to a company, in which they may even have an ownership share. This is generally the case with the high-value rice varieties, particularly hybrids, developed by the institutes of the Hunan Academy of Agricultural Sciences. Other institutes such as the Rice Research Institute, Guangdong Academy of Agricultural Sciences have recently acquired their first PVP titles and

do not yet have much experience with trying to enforce the right, or even commercializing the varieties in question. The IVF has much more experience with their hybrid vegetable crops but acknowledge that the difficulties of enforcing PVPs is a major factor in their decision to continue exclusively with hybrids. BRI and BioCentury claim to have generated little revenue from their Bt cotton because of problems with enforcement of patent protection. Staff from the Cotton Research Institute are deployed to check local shops for illegal seed of their varieties in the seed sale season. This is only partly effective as illegal copies of one of their Bt varieties were readily available at a local shop in Anyang, where the institute is located. Without PVP protection, they must rely on trademarks and, in the case of Bt cotton, patent protection and biosafety regulations. CRI expects however that PVP would ease enforcement difficulties. The other case study countries have little experience, but acknowledge that extra administrative 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. Some research administrators, particularly in India (where there is a large and complex commercial seed market) admit that it may be difficult to pursue these issues thoroughly and a few say they would prefer more easily managed commercial agreements, such as the one-time sale of varieties or lines rather than the annual collection of royalties.

6.7 Impact on International Agricultural Research Centers

6.7.1 IARC IP Policies

All of the IARCs with a crop breeding mandate have written IP policies, although some are only in draft form. The actual implementation of these policies is still evolving. Several centers now have their own in-house lawyer while others have assigned staff for responsibilities in IP management. The CGIAR system has also established the Central Advisory Service on IP to assist the centers and to facilitate the sharing of experiences in IP management practice.

Most IARCs have seen their principal role as supporting NARI breeding programs. In many cases IARCs do not release their own varieties; NARIs either test and release IARC varieties or use IARC germplasm in the development of their own varieties. Germplasm, both improved varieties and genebank materials, is moved within and outside the system under material transfer agreements (MTAs). The MTAs that accompany genebank materials is standard for all of the centers under their agreement with the FAO and stipulates that no IPRs can be taken out over the material in the form received. MTAs used with improved materials can vary, although all versions of these MTAs would only allow that rights could be taken out if such protection could be shown to stimulate wider distribution and use of the materials.

6.7.2 Interactions with Seed Companies

Most IARCs also provide their breeding lines 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.

Box 4. CIMMYT's Collaboration with BASF for Striga-Resistant Maize

The parasitic weed Striga is one of the most serious yield-limiting factors for many African maize farmers. Hand weeding or conventional herbicide use are inadequate to control the weed, which does most of its damage before emergence by attaching itself to the maize roots. Research by the Weizmann Institute and CIMMYT indicated that an herbicide seed coating could effectively control Striga by killing the weed as it germinated in the soil. The innovation would require herbicide resistant maize varieties, and collaboration was initiated with BASF, the owner of a mutant gene that conferred resistance to an imidazolinone herbicide that BASF produced. The technology was already licensed for commercial use in the US (for conventional post-emergence weed control in maize), and because it does not involve a transgene the technology does not require biosafety clearance or regulation. BASF facilitated access to maize germplasm (through Pioneer) and CIMMYT began to develop a series of IR (imidazolinone resistant) maize OPVs and hybrids suitable to conditions of Western Kenya, where Striga is a particular problem. BASF granted access to the IR gene initially for research purposes only. CIMMYT has used its germplasm to develop three IR maize hybrids that 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 hopes to complete final regulatory and commercial arrangements. AATF has already drafted agreements with three seed companies in Kenya to produce the IR varieties. It is expected that royalty payments would be managed by AATF. However, further negotiation with BASF is still required to obtain permission for commercial use of the gene in Kenya and to define conditions for wider application of the technology (e.g. in neighboring countries). Although the IR varieties could be the subject of PVP in Kenya, it is not clear how the IR gene itself would be protected, if this were seen to be desirable.

In the case of maize, CIMMYT provides germplasm to seed companies that use this for developing and releasing their own commercial varieties. For instance, this germplasm has made a valuable contribution to the rise of several small seed companies in Kenya. In Colombia, CIMMYT has provided several maize hybrids to CORPOICA, which is expected to license them to local seed companies (and collect royalties). In southern Africa CIMMYT licenses its own 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 non-exclusive 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. However, its recent work on Striga-resistant hybrids in Kenya involves attention to PVP (See Box 4). The domestic breeding capacity in China means that Chinese companies generally prefer materials from domestic institutes, or

increasingly of foreign companies, to those of CIMMYT, but most Chinese wheat varieties have CIMMYT materials in their pedigrees (according to data collected by CCAP).

In India, ICRISAT's support of the domestic commercial pearl millet and sorghum seed sector has been so valuable that companies are willing to subscribe to consortia that provide access to breeding lines and inbreds (see Box 5); the subscriptions currently cover the cost of ICRISAT's hybrid pearl millet and sorghum breeding for 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.

Box 5. ICRISAT and Seed Company Consortia

The growth of the hybrid pearl millet and sorghum seed business is one of the great success stories of India's seed market liberalization. A number of domestic seed companies began producing and selling pearl millet and sorghum hybrids and then expanded into other seed products. Hybrid pearl millet and sorghum seed remain profitable enterprises and a significant proportion of the germplasm is still sourced from the public sector, mostly from ICRISAT. Until recently, ICRISAT has provided germplasm to any legitimate private company or NARI. In 1999, ICRISAT approached 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 paid a modest annual fee for access to breeding lines and NARIs continued to get free access to all material. Non-participating companies can have access to some ICRISAT germplasm as well. In 2003 the relationships were re-examined and a third consortium (based on ICRISAT's recent success with developing hybrid pigeon pea) was established. The three consortia have both full and provisional members (the former pay an annual $10,000 subscription and gain access to a wider range of breeding lines; the latter pay $5,000 and are limited to two years in that status). The pearl millet and sorghum consortia each have 11 full members and 6 provisional members and the pigeon pea consortium has 4 full and 2 provisional members. 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 PBR 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.

There is little commercial production of bean seed in developing countries (because of the high rate of seed saving and the relative expense of commercial seed) so CIAT's bean breeding program has little experience with private seed companies. Most of the materials go through NARS and particularly through participatory breeding and seed production programs. However, there is a very high dependence on purchased seed for snap bean production and CIAT has approached a foreign seed firm about possible collaborative research in Colombia, where CIAT

offers disease-resistant germplasm and the company brings its own breeding capacities and commercial experience.

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 to a company in Mexico for a limited time (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 ten 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.

6.7.3 IARC Priorities

The past decade has seen a wide range of pressures from donors and other stakeholders on IARCs regarding their roles and comparative advantage. There is a strong desire to make sure that their products reach the smallholder farmer and thus an emerging attitude that product development and distribution plans need to be a part of the research planning process. The establishment of national PVP regimes and the strengthening of the private seed sector in developing countries are two important factors in the environment of IARC priority setting, but there is no uniform response. CIAT relinquished most of its interest in breeding for commercial rice systems in Latin America in favor of concentration on subsistence growers and marginal environments. ICRISAT, on the other hand, invests the majority of its pearl millet and sorghum breeding resources for India in support of the commercial seed sector, and the research is almost completely funded by the industry. In Africa, CIMMYT provides maize germplasm to both NARIs and private companies but has yet to examine the implications or to see if the two sectors complement each other or compete.

There is a strong fear in several centers that the regional nurseries in which the best varieties (released or under development) are shared among members of a consortium of NARS for testing under different environments, may collapse due to unwillingness of members to provide their materials when their protection in all these countries cannot be guaranteed. This is a response to the increased commercial attitude of several NARS that is supported by the rise of IPRs.

6.7.4 IARCs and Biotechnology

Most of the commodity-focused IARCs have extensive biotechnology research programs. Many of the tools and genes used by the IARCs are patented in the North (and some are specifically licensed for research purposes) and there is little experience on how to proceed with products based on licensed technology. CIAT believes that a transgenic virus-resistant rice variety it has developed is nearly ready for deployment and commissioned an FTO search, which identified the principal IP holders with whom CIAT needs to negotiate. CIAT admits, however, that it is poorly prepared for such negotiations. Similarly, CIMMYT commissioned an FTO for its Bt maize

varieties for Africa, but the next steps are yet unclear. Even CIMMYT's negotiations for the non-transgenic Striga-resistant maize have proven to be complex (see Box 4). ICRISAT has developed a number of transformed crop lines but has yet to do an FTO on any of them.

The IARCs also have little experience in patenting their germplasm-related inventions. CIAT has filed a patent jointly with EMBRAPA for a technique for Brachiaria transformation, and one on a tissue culture technique (on guanabana, with potential impact on other fruits), 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.

Box 6. Latin American Fund for Irrigated Rice (FLAR)

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. The Colombian government (and others) expressed concern that commercial rice production would suffer and subsequent discussions led to the creation of FLAR, which currently has a membership of eight countries (plus CIAT). Each country has a single representative, which may be a NARI, a rice producers association, or a group of seed companies. FLAR's budget is largely provided through members' contributions. FLAR manages an extensive regional program of rice breeding, directed by its members. FLAR does not produce finished varieties but rather provides members access to breeding lines at 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 the registration and protection of 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. If a member produces and markets a variety based on FLAR germplasm in another member country there is a formula for determining the proportion of royalties that go to the second country representative. Companies outside the FLAR network may approach FLAR members for access to germplasm, but any such exchange must be approved by the FLAR board. The first FLAR varieties were released at the national level in 2003 (in Venezuela and Bolivia). The direction of FLAR research is determined by its members, through the FLAR board. Recent interest in pursuing an agreement with a US company for joint development of hybrid rice was recently halted by the board, largely because the representative from Brazil (FLAR's major contributor) is developing its own hybrid rice research program.

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 programs aim at making all protected technologies and materials available in order to provide technology and products to the resource-poor on a non-exclusive basis. However, terms such as 'resource-poor' are not yet well defined and require attention.

A newsworthy application of IP policy is found in the recent intervention by CIAT in a US patent application for yellow ('Enola') beans, which might interfere with CIAT's bean program in Latin America where yellow beans are fairly common. In a wider context, this challenge serves as a proof 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.

6.8 Impact on Public Seed Enterprises

The establishment of IPRs is only one of the factors that have affected public seed production activities in the past decade, leading to a general decline of the public sector in seed provision in developing countries.

In India, the state seed corporations concentrate almost exclusively on the production of public OPVs, although some of seed of hybrid maize is still produced by the public sector. The Maharashtra State Seed Corporation now has its own breeding programs to complement the ICAR varieties. As long as state universities and ICAR institutes continue to sell breeder seed of their varieties, most state seed corporations may not see much change due to PVP, although they are increasingly challenged by private sector activity, e.g. more than half of the seed of public rice varieties in Andhra Pradesh is supplied by private companies. In other states as well (e.g. Haryana) the private sector is getting involved in the paddy seed sector.

In China, it is difficult to define what should be understood by public sector seed production since most of the seed production units that were operated by the national, provincial or lower levels have been commercialized to such an extent that their decisions are almost exclusively based on business considerations. Several have entered into joint ventures with foreign companies.

The fate of the Kenya Seed Company, which has operated as a successful commercial enterprise with majority shares held by the Kenya government for many years, has yet to be decided. Although it continues to dominate the market, management problems and irregularities during the years of the former government have left doubts about its role, and even about the degree of public ownership. It 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 it would expect certain concessions. But emerging policy also seems to expect that KSC will have to compete on the basis of seed and varietal quality; the rights on the established hybrids could provide KSC with some valuable assets to maintain its strong position in the market.

The former Uganda Seed Project has now been converted into Uganda Seeds Ltd. and has been a candidate for divestiture for several years. It produces seed of public varieties only and its future without significant government backing is uncertain, especially as local private seed sector capacity continues to grow. Uganda Seeds can obtain licenses on public varieties like any other seed company in Uganda.

Although there is no longer any public seed company in Colombia, there is considerable seed production that takes place with some public support. The government expects CORPOICA to supply source seed of many public OPVs for crops such as beans and wheat to publicly-supported programs for seed multiplication and distribution. A more difficult case is that of FEDEARROZ, which is a producer association but also operates as a private seed company (with its own breeding program and protected varieties). It receives some tax revenues in its position as a producer cooperative and there are questions whether as a recipient of public funds it should be allowed to maintain its monopoly access to FLAR rice germplasm for Colombia.

6.9 Summary

IPRs and revenue generation in NARIs

The establishment of PVP regimes comes at a time when public agricultural research in developing countries is being asked to take much more responsibility for revenue generation. Among the case study countries, India is an exception, where revenue generation is encouraged but not compulsory (and ICAR revenue flows back to the treasury). These demands for revenue generation are not entirely explained by the emergence of PVP, but administrators certainly see the possibility of earning income by licensing their varieties and other inventions as an important response to the challenge of achieving greater financial self-sufficiency. The public sector appears to be a major supporter in the push towards PVP in most countries. The degree to which such royalties can fulfill that promise depends on farmer demand for public varieties, the efficiency of the domestic seed delivery system, and the ability of public breeders to compete with their private sector counterparts.

In Colombia there is little evidence so far of potential revenue generation from public breeding. In Kenya, the fact that most of the maize hybrids grown by farmers are products of public breeding would indicate the possibility of substantial revenues, but the domestic and foreign private plant breeding sector is expanding rapidly. In Uganda, public plant breeding has not yet resulted in a widespread use of public varieties by farmers, and because it concentrated on OPVs until recently it has not contributed to the nascent seed industry. The private sector is still insignificant in terms of breeding. In India, although the vast majority of hybrid seed is now the product of private plant breeding, huge areas of wheat and rice are planted to public varieties, and even though only a fraction of that area is planted to purchased seed, the royalties could be significant. But it would appear that there are no plans at present to shift away from the practice of selling breeder seed to any legitimate seed producer. In China, the system is in a state of flux, as public breeding institutions for major crops are making the transition to take partial responsibility for revenue generation. As there are substantial quantities of public varieties of many important field crops grown with purchased seed (especially hybrid rice and maize), the revenue generating possibilities are substantial. But public funding and broader mandates are also important.

In summary, the expectations of NARI management for the amounts of revenue that can be generated are quite high. For comparison, the income of universities in the USA from

intellectual property rights is approximately 2-3% of their annual turnover (J. Barton, pers. comm.). Income from PVP on plant varieties is likely to be more predictable than patent-based revenues (Fischer & Byerlee, 2001).

Can NARI plant breeding keep pace with the private sector with regard to human resources?

The degree to which a PVP system can help generate income for NARIs depends to a large extent on whether NARIs can keep control of plant breeding skills and resources for commercially important crops. The experience of India in the past two decades is instructive; as policy changes encouraged the emergence of private plant breeding, the expertise for commercial (largely hybrid) seed crops began to shift from the public to the private sector, even for supposedly 'marginal' crops like sorghum and pearl millet. As the private seed sector developed in India, NARI staff were hired away, and the private sector now offers an attractive alternative for recent graduates. Even where public sector research leads the way, as in hybrid rice, the commercial potential soon attracts resources (and results) to the private side.

The current situation in China is more difficult to characterize. Large companies are investing in breeding activities, particularly for hybrid maize and rice, and breeders from public institutes are getting involved. By helping to generate revenues, PVP is providing the institutes with resources that can be shared with breeders as an incentive for them to stay. The large investments in the application of biotechnology by CAAS may also be providing a scientific and prestige-related counterbalance to the lure of the private sector, where many companies do not yet have such resources. Thus there are uncertainties about the extent to which the private sector will be able to offer alternative employment to the best plant breeders.

In the smaller countries in the sample, the ability of the NARI to retain plant breeding personnel and resources in the face of an expanding private seed sector is much more in doubt. In Uganda NARO is struggling to maintain its maize breeding program. In Kenya KARI's traditional partner, KSC, is now a rival, with a separate breeding program, and other domestic companies are assembling their own breeding resources. The emergence of PVP thus comes at a time when there are many uncertainties about the role of NARIs vis-à-vis the private sector in terms of mandate crops and the division of labor between upstream and downstream research.

NARI administration of IPRs

The advent of PVP and the increased use of patented technology in agricultural research place an additional burden on NARI administrations to establish IP policies and procedures. Most NARIs in the study are moving very slowly in this direction, hampered by a lack of experience and resources. In most cases IP policies are still being drafted. Skills required for activities such as the pursuit and enforcement of PVP, organizing patent applications, and understanding freedom to operate, are in short supply and in any case would not be fully employed in most NARIs under current circumstances, but they are all required at certain key junctures in NARI technology development. In this regard, there is a difference between the national and provincial level institutes of the academies of agricultural science in China. The former generally have much more resources to assist scientists with IPR matters, in particular patent applications.

Another administrative challenge is the management of royalties received by the NARI. Decisions must be made about sharing such income more widely within the institute (to support less commercial research but at the risk of diluting the incentives offered by the royalty system). There is also understandable pressure that some part of the royalty earnings from a protected variety or a patented technology go to the scientists responsible for the innovation. In any public research system this can create potential inequalities, but in some developing country NARIs these could be quite problematic. In Kenya, for instance, a small share of the royalties (in line with proposals from the plant breeders association) from a widely-used maize hybrid could dwarf the breeder's normal salary and significantly jeopardize the institute's incentives for research in other crops. There are also more mundane administrative challenges. For instance, if NARIs hope to earn income from the sale of source seed, they need an efficient and transparent service in place. Such a system exists in some Indian NARIs, but is less well established in some of the other case study countries.

Implications of PVP for NARI priorities

A major problem with revenue generation from PVP is that the potential opportunities are patchy. There is a danger that this heterogeneity may be translated into inequitable and questionable public research resource allocations. Why, for instance, should hybrid rice research earn much more than wheat research just because of differences in seed systems? Although it makes sense to assign research resources to crops and problems for which there is high farmer demand, commercial seed systems often provide imperfect signals of that demand. There are already indications that these signals from the seed system and associated PVP are making their marks on NARI priority setting. This can be seen with the case of hybrid rice in Hunan and Guangdong provinces, as well as with the longer running approach to vegetable breeding in China. NARO in Uganda is encouraged to concentrate on research where commercial contracts or PVP will provide revenue, and KARI's calculations for income are based on hybrid maize.

NARIs need to manage their IP to maximize the benefits of public investments to society and to ensure equity in the distribution of these benefits in line with national policies (Fischer & Byerlee, 2001, 2002).

IARC IP policies and resources

IARCs have policies on IP that stipulate that the Centers can protect inventions and materials under the condition that this protection will ensure that the subject material will be available to stakeholders; in such situations provisions will be negotiated in the licenses with the intent that such material will be given out royalty-free for use for the poor. Centers are committed to having their products reach the smallholder farmer at little or no cost. Several centers have some staff assigned to IP with legal background, plus access to CAS-IP, in order to improve IP Management practice and to also focus on product development and distribution issues. Resources are however limited and the increasing pressure to show impact at the local level will stretch current capabilities.

The IP issue is central in the balancing of relationships between seed companies and NARIs. As IARCs develop wider relations with domestic commercial seed sectors, and NARIs place increased emphasis on earning royalties from their germplasm, IARCs have to balance between giving materials directly to seed companies or going through NARIs that the can earn royalties. In many countries, companies seem to prefer direct relation with the IARCs. When IARCs can earn royalties on their materials, they find themselves in the same position as NARS with regard to possibilities that opportunities for revenue generation may affect priorities. Contrasting examples are provided with CIAT's rice and ICRISAT's sorghum.

The dilemma of public seed production

The growth of the private seed industry (and the demise of many parastatal seed companies) would seem to provide a more effective link between public plant breeding and farmers' fields, with the added incentive of royalty earnings. However, many public varieties do not attract the interest of commercial seed enterprises, and this encourages NARIs to organize their own seed production and marketing. Such temptations are clearly evident in some of the smaller NARIs in the study. In addition, many NARIs still find themselves with obligations to public seed production efforts. The problem is that in most countries the conventional private seed sector does not have the incentives to produce and market the full range of public sector varieties for which there may be farmer demand, such as beans, but the public sector has shown itself incapable of organizing an efficient alternative. In China, the old system of seed production and distribution by public companies is shifting quickly to dominance by private companies. Few public breeding institutes are expanding into seed production, with the exception of the IVF which has long produced and marketed its own seed.

7. Impact on seed users

7.1 Diversity of Seed Firms

One of the principal arguments in favor of PVP legislation is that it will provide incentives for a wider array of seeds from which farmers can choose. The impact of PVP legislation on the seed industry in the case study countries was discussed in a previous section and although it is still too early to say anything definitive about how changes in domestic seed industries will affect farmers, some preliminary observations are possible.

When India's new PVP law is functional, and if the new seed law requires that all varieties be registered, there could be at least two major effects at the farm level. On the positive side, it will be easier to control the illegitimate seed producers whose products cause confusion and uncertainty. If companies can control the illegal use of their germplasm (e.g. theft of inbreds) by others, some of the fly-by-night operations that sell seed of uncertain origin will be curtailed. Although the net effect will be to reduce the number of players, it may bring positive benefits. For example, cotton farmers, particularly in southern India, currently confront an exceptionally complex market. It is generally acknowledged that in some cases a popular hybrid is being marketed under several names (because of illegal access to inbreds or commercial seed); in other instances, small companies go in and out of business, marketing hybrids of uncertain provenance. Eliminating the smaller, illegitimate players in the cotton seed business could bring added transparency to the market. On the other hand, 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. However, there may be few current examples of private seed companies investing breeding resources in small, specialized markets that can access proprietary materials through licenses from colleagues.

Perhaps a more relevant concern is the potential impact on public plant breeding for marginal environments. When such breeding can be linked to delivery by small private seed companies it is possible to imagine that the additional regulatory costs would discourage this type of activity. Evidence from Andhra Pradesh shows that even small private firms are fairly conservative in promoting new public rice varieties until there is evidence of sufficient demand. The initial activity in promoting the new rice varieties (and in meeting the needs of niche environments) depends in large part on the activities of certain larger farmers who test new public varieties and serve as seed sources for their neighbors (Pal *et al.*, 2000). Whether such a system will continue depends on public plant breeding policies.

Although some commercial seed activities emerged in China in the early 1990s, the truly private seed companies started selling seed only after the implementation of the new seed law in 2000. There has been a recent proliferation of seed companies, and many of these are selling Bt cotton seed. Some of this is legitimate and properly regulated, but much is legitimate seed sold in unapproved areas, pirated seed, or simply spurious imitations. This exceptional competition has driven the price of all Bt cotton seed down, but farmers pay the price of risking the use of fraudulent or poor quality seed and the legitimate seed producers do not get adequate compensation. Recent analyses have argued that better enforcement of IPRs in Bt

cotton would drive some of the smaller, illegitimate players out of the market and improve overall productivity (Pray *et al.*, 2004).

In both Kenya and Uganda farmers would certainly benefit from a wider range of seed sources, but the opening of these markets has been related to changes in national policies rather than PVP per se. In recent years farmers have increasingly complained about the quality of KSC seed; some of the complaints are related to grain sold in imitation seed bags by fraudsters but some may be the product of lax quality control by the company itself. In any case, farmers have been eager to try hybrid maize seed from other companies, even when it is significantly more expensive. The increased competition has been responsible for other innovations, such as the availability of smaller pack sizes, but has yet to elicit a wider range of crop seed into the market.

In Colombia, PVP was instituted at a time when government support to agriculture had declined and the seed industry was contracting. Farmers have a modest range of choice of companies for rice and maize seed, but there is little indication that the industry is diversifying further.

7.2 Farmer Priorities

There are also concerns about the extent to which PVP may shift plant breeding priorities, particularly for the public sector. We have seen several examples of how such priorities may be changing, although it is difficult to attribute such changes to PVP alone. In Uganda, NARO administrators and scientists consistently talk about using public plant breeding to serve the development of commercial agriculture. They express considerable faith in finding the commercial potential of most crops, and have less time for examples concerned solely with subsistence agriculture. This may likely to affect the distribution of funds between crops e.g. at the cost of attention to locally consumed crops like beans and cassava, and put more emphasis on the selection of high-yield potential maize at the cost of yield stability under low-input conditions. The private seed companies that have beans and other locally important crops in their portfolio confirm that this is mainly to cater for the demand of aid agencies and that they don't see a future for these products when that demand disappears. In India, ICRISAT's clients for hybrid pearl millet and sorghum breeding are now the members of the company consortia, and those companies naturally target commercial opportunities. For instance, they see particular importance in breeding for dual purpose sorghum that can be used for both food and fodder. The requirements of those farmers that depend on sorghum as a subsistence crop will be less in evidence.

7.3 Local Seed Production and Plant Breeding

The majority of farmers in the case study countries rely on farm-saved or other non formal sources of seed for many crops. Farmer-to-farmer seed exchange has been a key mechanism to transfer the green revolution technologies to farmers that could not be reached by the formal seed systems. This 'lateral spread' system is the basis of the inclusion of modern varieties in the farmers' seed systems.

A more recent mechanism to reach smallholder farmers in ecologically diverse countries are the different farmer participatory approaches to plant breeding and variety selection (Sperling *et al.*, 2001). Farmers become partners in breeding and in testing a wide range of (nearly) finished varieties on farm with the intention to either develop small-scale seed enterprises or to feed new varieties into the local seed systems.

Varieties selected in such participatory initiatives often bypass the regulatory system. Such initiatives could be affected by IPRs in two ways. First, NARIs that seek revenues from their research are likely to give very little priority to such participatory approaches because they will not likely lead to commercial varieties. Those varieties that are the products of participatory plant breeding may not meet uniformity standards, or participating farmers may reject the idea of ownership (Salazar *et al.*, 2004). Second, given the ecological and sociological diversity in which participatory plant breeding programs operate, there is a requirement for access to a wide range of genetic materials for breeding and testing. When more materials are protected by PVP or patents, there are fewer opportunities for participatory approaches.

7.4 Seed Saving

One of the major concerns about the establishment of PVP legislation is that it may restrict farmers' ability to save seed. The new Indian legislation specifically guards against this possibility and many seed companies feel that the law provides too much flexibility, not only for seed saving but also for extensive sale of saved seed under the rubric of 'seed exchange'. This is formally limited to genuine farmers, but may be misused by local operators for profit. In any case, Indian farmers who are used to saving commercial seed or obtaining seed of new varieties from their neighbors will notice no difference when the new law is in place. Similarly, the proposed PVP law in Uganda permits seed saving of protected varieties.

In Kenya and Colombia, both of whom have several years of experience with PVP, changes are being proposed that will affect farmers' ability to save seed. In some respects these changes are in response to the practices of commercial farmers that reduce seed sales. In Colombia, the seed industry complains that it suffers from widespread informal seed sale, where certain farmers produce and sell seed to their neighbors. Resolution 2046, which prohibits seed saving on properties of greater than 5 ha (and requires permission from ICA for seed saving on smaller farms) is meant to address this problem. If this is enforced it would raise the cost of production for certain rice farmers who are used to buying informal seed or saving their own seed, but in the context of the current seed market it may not have any other notable effects, as very few OPVs of other crops currently grown are protected (soybean may be the major exception). It could theoretically make a significant difference, for instance, in the case of protected potato varieties, whose yearly replacement with certified seed would add greatly to the costs of production. There are also uncertainties about the interpretation of the farm size limitation. If a farmer with 6 ha of land grew 3 ha of beans, the obligation to buy certified seed (of a hypothetical protected variety) would imply a significant investment. The actual effects of the resolution will be determined by its interpretation and management.

In Kenya, there are plans to revise the legislation so that it is compliant with UPOV 1991, which allows breeders to restrict seed saving of protected varieties. Probably the principal case of contention is wheat farmers, who use a large proportion of saved or locally-purchased seed. Many of these are fairly large farmers who at one time were more frequent customers of the Kenya Seed Company. The farmers contend that they would still be willing to buy KSC seed if it were of good quality and appropriate varieties. KSC, on the other hand, claims that the farmers are simply trying to save money, and that they are often abetted by the KARI station at Njoro that provides some seed (of its own released or experimental varieties) to local farmers, who then multiply and save it. No matter who is right, if a restriction on seed saving were introduced in Kenya, it might be possible to enforce with wheat farmers, who are relatively large, few in number and operate in a delimited environment. However, Kenyan wheat farmers' current range of choice for seed is much more restricted than the options available to Colombian rice farmers. In addition, a very large number of (mostly public) food crop varieties are in line for PVP in Kenya. Although there is no threat that a wholesale application of a restriction on seed saving would be enforced for subsistence farmers (it would be administratively impossible and politically unwise), there are legitimate questions about how farmers could be protected from the arbitrary application of such a law.

7.5 The views of farmer groups

The emergence of IPR regimes has caused a certain amount of concern among farmers and farmer groups, although relatively few farmers are conversant with the issues. Among the most prominent concerns are the dangers of excessive commercial control of the seed market, possible restrictions on seed saving, and the possible fate of local varieties. Several spokesmen of farmers' organizations who were interviewed indicated that they do not see many advantages of IPRs for their members. They claim that IPRs will lead to monopolies that will increase seed price and that will reduce the focus on the needs of farmers who will not benefit from foreign-bred materials. They fear that such monopolistic tendencies will not easily be curtailed in developing countries by anti-trust measures. Representatives from India and East Africa indicated that they do not expect such negative effects to take place immediately, but are concerned about the growing concentration of the seed market in certain areas. They fear that large commercial interests will gradually exclude alternatives (including the public sector). Local commercial seed companies will either be marginalized or purchased by the larger firms.

In general, these farmers did not distinguish between PVP and patents. The introduction of PVP (even the weak form in India) is seen by some farmer organizations as a first step in a process that will lead to strong patents. The capacity of the governments to balance the interests of the industry and smallholder farmers in this process is considered very limited given considerable international pressures. The TRIPS-plus negotiations in several countries are presented as an illustration of this pressure.

In India, the new law allows farmer groups (or NGOs representing farmers) to pursue the protection of farmers' varieties. There is little activity yet in this area, but one NGO expressed interest in documenting farmers' varieties, even if direct benefit-sharing turns out to be difficult. Another NGO pointed out that a considerable amount of capacity-building is required before

there is the possibility of protecting farmers' varieties. In addition, some NGOs already have experience in public interest litigation in support of issues related to Farmers' Rights and the new legislation will almost certainly provide further opportunities.

7.6 Flower producers

The flower producers of Colombia, Kenya and Uganda can be considered 'seed users' as well, and most of their production depends on the use of protected germplasm. Like seed users for agricultural crops, they are for the most part unacquainted with local PVP regulations. Most flower producers in Colombia and Kenya are only vaguely aware of the PVP offices in their own countries. They are well acquainted with the royalties that they pay on planting material, but these payments are negotiated with the flower breeding companies in Europe or elsewhere.

There is no standard format for paying royalties to the IP owners, and the nature of the contract depends in part on the length of the relationship and the trust between the two parties. Royalties may be charged on the planting material or on the marketed product, depending on species. In the former case, initial contracts may stipulate that the royalties for the lifetime of the planting material (e.g. usually four years for roses) be paid in advance, but once business relations are established the royalty payments may be spread out over the production period. In certain cases, a producer may negotiate for exclusive rights to produce a particular variety. There is surprisingly little difference in the level of royalties between rose varieties, which appear to account for about 3-6% of the cost of production for flower growers. For roses, the royalty cost is roughly equivalent to the cost of the planting material itself. The major cost of production is labor.

The monitoring of growers' conformity to royalty agreements is managed by occasional visits to their farms by breeding company representatives. The growers put much value on a good relation with the agent of the breeder since only through him can they access varieties that fetch a good price in the market. Some of breeder representatives are appointed agents resident in the country and others come from abroad. In Colombia, a Dutch company, Royalty Administration International (RAI), has an office that looks after the interests of a number of flower breeding firms. Those who monitor the flower growers are aware of the quantity of breeding stock contracted by the grower and check for evidence of excess production.
A second method of monitoring production is by reviewing export statistics. In Uganda, for instance, all flower exports go through one handling agent.

At present the major means of controlling illegal flower production is through close monitoring of the wholesale markets. Most flowers destined for Europe pass through a single market in the Netherlands and statistics from this market are closely monitored. Flower-producing firms depend on a limited number of wholesale outlets and this means that it is fairly easy to spot a company's extra-contractual production. The control over product markets is the principal instrument for enforcing royalty agreements. For instance, there was a landmark seizure of 20,000 roses in Miami exported from Colombia and Ecuador for Valentine's Day 2004.

The varieties are also grown by legitimate producers in Colombia, although it appears that the varieties are not protected by PVP in Colombia. The roses were the property of a US breeding company and the seizure was made on the basis of violations of trademark rather than PVP. RAI, Colombian security officials and US Customs collaborated in the operation.

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 Dutch flower industry is however lobbying for strong IPRs in the main production countries to create additional ways to tackle infringements. This is particularly important where additional wholesale markets develop, such as direct exports from Kenya to the Middle East and other parts of Africa (or as the domestic market for flowers expands). Some producers in Colombia believe their industry is better positioned than that of neighboring Ecuador (which does not have a functioning PVP system and suffers more illegal flower production). With respect to attracting new contracts, a local PVP regime also gives a breeding company the option of bringing (or threatening) a local court case.

The discussion has focused on large commercial flower growers, but it is worth asking what the possibilities are for small-scale production (and how PVP might apply). Unfortunately, most commercial flower production requires considerable infrastructure (greenhouses, irrigation) and hence it is not feasible on a small scale. Even where outgrower production is possible (for those species that can be grown in open fields), current regulations in the North regarding environmental and social conditions make monitoring smallholder production very unattractive. There was a case several years ago in Kenya where large firms organized the production of an Alstroemeria variety through outgrowers. The breeding company did not charge royalties on the variety initially, but when expanded sales encouraged it to begin charging royalties, the economics of outgrower production collapsed. Although the exercise of PVP was the initial cause for the failure of the outgrower scheme, the other economic and regulatory factors that have since appeared now make smallholder flower production uneconomic.

The situation with flower production may be quite similar to a number of other high-value commodities, such as export vegetables, tropical fruits, and possibly estate crops, where the rights can be controlled through export markets rather than by enforcing protection of the planting materials themselves.

7.7 Summary

Limitations on seed saving

Farmers' seed systems are the main source of seed for most crops in the case study countries. IPRs may restrict this practice. This could affect access to new varieties by farmers who cannot afford frequent purchase of seed from formal sources. In this respect the potential of plant patents is of most concern, but the changes in some national PVP regulations already introduce these issues, especially if legislation designed for the commercial farming sector is extended to subsistence crops.

Expanding choice

Farmers need choice; in some countries this choice is currently expanding through the opening of the seed sector through economic policies and changes in seed regulations. When the commercial seed market expansion is very rapid and uncontrolled, IPRs can help control rogue traders (e.g. in India, China). However, restrictions on small seed enterprises and semi-commercial operations may jeopardize seed supply of some local varieties supplied commercially, as in India. In addition, the breeding of niche varieties and their delivery by small seed companies may be threatened.

IPRs seem to secure access to a wide range of varieties by flower growers in the case study countries, but only when the implementation of the IPRs contributes to a trustworthy business environment. These IPRs are not necessarily operational in the production countries, as long as they can be exercised in the main wholesale markets. Where the introduction of PVP is strongly pursued and the lobby for strengthening the system comes primarily from this sector, non-specific IPRs like trademark protection appears a very strong tool for the flower breeders.

Addressing marginal farmers

It is likely that NARS' focus on revenue generation, supported by the introduction of IPRs, and may divert their attention from the needs of marginal farmers. Choices of crops, variety characteristics, and breeding strategies are less likely to take account of the needs of more marginal farming populations. This is particularly relevant to participatory methods in breeding and variety selection, although the impact of such approaches is quite variable at the moment. On the other hand, there are some indications in India that a strong and diverse seed industry may want to diversify into more marginal markets.

8. Lessons

This study has attempted to survey and analyze the design, management and impacts of various IPR instruments applied to plant breeding in five developing countries. Because many of the principal IPR strategies have only been in place a few years (or are still in the final stages of approval), and because the incentives provided by any IPR regime usually interact with various other factors, it is difficult to identify unambiguous conclusions regarding the possible contributions and concerns that IPR regimes might present for plant breeding in developing countries. We have attempted to make the precision of the conclusions provided in the 'Summary' sections of Chapters 4-7 consistent with the level of evidence that is currently available.

Despite the preliminary nature of the report's conclusions, we believe that the analysis points to a number of significant lessons that need to be presented and disseminated. This final chapter outlines the most important of these. Some of these lessons merely indicate the importance of vigilance and monitoring, while others imply the need for immediate action. The following presentation directs the lessons in a somewhat arbitrary fashion (given overlaps in interests and mandates) among: those with a general interest in the subject, particularly donors; national policymakers concerned with the design of IPR instruments; policymakers and officials engaged in the implementation of IPRs; national representatives and others engaged in trade negotiations; and those concerned with broader issues of national agricultural development policy.

General

It is too early to attempt a statistical or even a quantitative analysis of the impact of strengthened intellectual property rights on plant breeding and seed production in developing countries. In most developing countries the introduction of IPRs for plant breeding is a recent event which coincides with a series of other processes that have been set in motion, including the liberalization of domestic agricultural markets, increased globalization, and a reduction of public expenditure for agricultural research and seed production. All of these trends have a marked effect on the seed and plant breeding sectors. Although these concomitant trends may be compatible with a move towards strengthened IPRs in plant breeding, it is very difficult to attribute particular outcomes to changes in IPR regimes alone. But the difficulty in identifying clear causality at this early stage does not mean that IPRs are unimportant. On the contrary, IPR regimes may lead to significant changes in plant breeding and seed production, and the subject warrants careful future study and monitoring.

There are several priorities for careful monitoring. These include assessing the extent to which IPR regimes (and other policy changes) in particular countries influence the priorities and products of public plant breeding, affect the structure and concentration of the domestic seed industry, and determine the options available to smallholders. On a global level, it is particularly important to monitor how IPRs are treated in multilateral and bilateral negotiations, and how IPRs determine the role of MNCs in technology provision in developing countries in order to ensure that the significant concentration witnessed in the industry can be counterbalanced by measures that allow more widespread access to the tools and processes of biotechnology.

Although it is possible to conclude that this study only examines the very partial implementation of relatively weak IPR regimes, it is important to bear in mind that the case study countries capture a good deal of the wide range of experiences among developing countries with large populations of resource-poor farmers who have established IPRs for plant breeding. Political realities, limitations in administrative resources, and varied economic incentives in most developing countries indicate that it is unrealistic to expect rapid establishment and effective enforcement of the type of IPR regimes that are found in some industrialized countries. In any case, IPR regimes should be part of developing countries' development pathways and consistent with their own priorities and capacities instead of being externally imposed. Donors and others hoping to support these processes must be prepared for a long-term and individualized development of national agricultural institutions.

Support for specifically-tailored IPR regimes is possible because of the range of options that are available for providing the types of incentives that many believe (incorrectly) to be associated only with uniform and rigid IPR regimes. The following sections on design and implementation provide further details on the flexibility that is available for pursuing a more responsive approach to IPRs.

It is important to clarify that respecting individual country priorities and circumstances in the design of IPR regimes does not imply that opportunities for harmonization and cooperation should be forgone. Mechanisms such as UPOV and PCT facilitate the implementation of IPRs and reduce transaction costs. But the object of harmonization is to provide economic benefits (such as the development of regional markets) rather than to promote coalitions whose standards are dictated by their strictest partners.

Donor support for the development of appropriate national IPR regimes should not be limited to providing information and resources for the technical options related to design and implementation. Such support should be accompanied (or indeed, preceded) by encouragement for open and informed national debates among all stakeholders regarding options for IPRs as well as wider issues related to agricultural development. Such stakeholder involvement is also encouraged by Art 9. of the International Treaty on Plant Genetic Resources for Food and Agriculture.

Although IPR regimes must be developed at the national level, and much donor effort should support individual processes of debate, design, and implementation, there are also issues related to international public goods that require attention. In particular, the conduct of international agricultural research will be affected by decisions regarding IPRs in plant breeding. International agricultural research should support the development of local farmer capacities, strengthen national public research, and encourage the growth of domestic private seed sectors. This is a delicate balance, with much scope for contradiction and compromise, and more study is required to identify appropriate IPR instruments for supporting these multiple goals.

A further issue that requires attention at the international level is access to some of the basic tools and processes of biotechnology. In many cases, plant breeders in developing countries are using tools and processes that are protected in the North through patents, and they are

uncertain of the possible legal implications for the new varieties that they might develop aided by such technology, as well as the status of the agricultural products grown from these varieties. In addition, there is lack of clarity about access to certain technologies (and supporting information) that have, or will soon, go out of patent protection and are presumed to enter the public domain. Concerted attention at the international level is required.

The design of IPR instruments

Policymakers need to understand that IPRs are important not because countries may be required to accede to the conditions of an international agreement but rather because they offer possible mechanisms for stimulating research, enabling access to technology, and promoting enterprise growth, all for the good of society. As such, they are merely one tool in a range of policies that may be applied in specific contexts to further agricultural development. Carefully designed IPRs for plant breeding can make an important contribution, but they are unlikely to be effective unless combined with other policies (e.g. for supporting public agricultural research, providing an enabling environment for agribusiness development, and empowering smallholders). Policymakers should understand that IPRs for plant breeding are not a magic bullet that automatically stimulates or redirects agricultural growth, but they can be an important part of a comprehensive agricultural development strategy. Under the right conditions, IPRs can help support, but do not themselves create competitiveness and diversity in plant breeding and seed supply.
Given the value of well designed IPRs for agricultural development, policy makers should not treat IPRs as a negotiable bargaining chip in trade negotiations or other international discussions.

In most countries, the implementation of an IPR regime for plant breeding should be seen as a long-term process, subject to monitoring and adjustment. The nature of patent rights in the field of biotechnology is a subject of debate in most industrialized countries, and developing countries should approach the revision of their own patent systems armed with adequate information. Similarly, the establishment of a PVP office is not necessarily sufficient to initiate widespread changes within the seed industry. It often takes considerable time for the testing infrastructure to be established and for plant breeders to become conversant with the system. In some cases companies may be hesitant to invest in protection that they either feel is unnecessary or unenforceable. In other cases, even fairly weak IPR regimes are welcomed by the seed industry, especially when they help protect companies against infringement by competitors.

Not only do IPRs in plant breeding have to be seen in the context of a wider range of agricultural policies, but IPR regimes themselves must be carefully tailored to specific situations. It is important that countries recognize that they have choices in designing legislation consistent with the TRIPS Agreement and that there are still opportunities for debating and interpreting the Agreement itself. There is a range of instruments that may be established to fulfill the requirements for a *sui generis* system of IPRs for plant varieties. The UPOV Conventions offer some important advantages, but do not exhaust the possibilities. Even within the UPOV Conventions there is room for national policymakers to define specific aspects of coverage, such as what species, if any, are subject to limitations on seed saving. Similarly, there are several options

with respect to tailoring national patent regimes for agricultural biotechnology. For instance, when EU patent law was broadened to effectively include plant varieties within the scope of biotechnology patents, and EU Directive introduced a farmers' privilege with reference to the PVP laws that a standard interpretation of patent law would not have included. This illustrates the flexibility available within IPR systems. The key elements in IPR systems that can tailor them to the specific conditions of individual national seed sectors include the specific terms of the farmers' privilege and the breeder's exemption, the relationship between different IPRs (patents, PVP, trademarks, trade secrets), the exhaustion of these different types of IPRs, and possible differential treatment of particular crops.

Policy makers need to consider the resources required for the establishment or strengthening of IPR systems. Institutional capacity to deal with the processing of applications and the granting of rights is quite variable among countries. Many countries will find it difficult to identify staff with sufficient legal and/or scientific skills to establish PVP offices and testing facilities, and the opportunity cost of this personnel may be considerable (e.g. the release of experienced plant breeders for variety testing). Cooperation and harmonization can lower some of these costs (e.g. the utilization of external DUS tests or reliance on regional or international organizations such as PCT). Because IPR regimes should further national agricultural development goals rather than merely signal compliance with treaty obligations, the choices related to the degree of cost recovery for IPR offices are not straightforward. On the one hand, fee rates that make an office self-supporting should be welcome, but on the other hand care must be taken to avoid unfairly taxing or discouraging applicants, and especially smaller players.

PVP and patents are not the only (or even necessarily the most effective) instruments available to policymakers to help provide incentives for plant breeding and seed production. Particularly in countries where neither public nor private plant breeding has yet to have a substantial impact on the majority of farmers, the establishment and enforcement of effective seed laws and support for contract law and responsible business practices are likely to offer more immediate incentives. Trademark protection may be an underrated IPR in the debate, but is highly valued by the private seed sector. In addition, it is important to remember that most regulatory systems, including IPRs and conventional seed laws, present dangers of gate-keeping and rent-seeking, and policy makers must be vigilant in establishing transparent administrations.

The introduction of transgenic varieties to developing countries presents special challenges, but does not necessarily imply the adoption of extraordinarily strong IPR regimes. Limited experience to date has shown that in the absence of IPRs for GM plant varieties and biotechnological inventions, MNCs have resorted to biosafety regulations in an attempt to protect their technology (e.g. India). Biosafety organizations are however not appropriate for such purposes, and policymakers can offer an appreciable contribution by limiting an expansion of the role of biosafety regulations and by creating a clear division of responsibilities among various agencies for regulating the use of GM varieties. In many cases, the enforcement of extant seed laws can offer an appreciable improvement in limiting unauthorized sale of GM seed. In some cases, controls over output markets for GM crops may provide a significant level of protection. None of this implies that PVP or relevant patent law should not also be pursued for GM varieties but indicates that GM varieties, on their own, are not a sufficient rationale for establishing overly rigid IPRs; other types of regulation may be effective (or indeed a prerequisite), particularly in

the early stages of development of GM seed markets. Nonetheless, further research should concentrate on the extent of IP protection necessary for stimulating the development of GM varieties where desired.

The implementation of IPR regimes

Policymakers must consider the institutional arrangements for PVP. A PVP authority may be included as part of an existing seed regulatory agency or may be established as a separate organization; the expense of setting up a separate entity must be balanced against possible concentration of power or conflict of interest. In addition, there must be confidence that the PVP authority is independent from the interests of public plant breeding organizations.

The challenges of adequate enforcement for IPRs in plant breeding should not be underestimated. There is very little legal capacity in most countries to support IPR regimes for plant breeding. Although the application procedure for PVP may be quite straightforward, for instance, neither IPR-holders nor courts appear to be prepared for addressing cases of infringement. The experience of the case study countries is that the enforcement of PVP is often difficult, undermining confidence in the system. Implementation of IPR regimes must include attention to strengthening the court system's knowledge of IPRs in plant breeding, and the ambitions and scope of any IPR system must be consistent with the capacities of the legal system, including contract enforcement. Developing such legal capacities is not only a technical issue but also a process of institutional development that requires political commitment.

There is a danger that the implementation of IPR regimes for plant breeding will proceed using standard models rather than taking account of the specific circumstances of individual countries. For the establishment of PVP, there are a number of important parameters that require careful consideration. These include: the designation of which species are to be covered; fee structures (and possible subsidies or differentiation by crop); the nature of the breeder's exemption for use of protected varieties; and the implications for farmers' abilities to save, exchange and sell seed in accordance with local custom. For patents the choices are similar: which processes and products are patentable (e.g. sequence information or only functional genes) and the scope of protection, including the restrictions on the free use by breeders and by farmers. For trademarks, the key question is whether a variety name can be protected.

Despite the necessity of defining the parameters of IPR instruments as carefully as possible to fit national goals and circumstances, there are limits to the levels of specificity and targeting that are feasible. Because of these limitations, policymakers must be vigilant to analyze the implications of arguments made for further strengthening IPRs. For instance, although a legitimate case may be made for providing legal boundaries on the degree to which large farmers can multiply and sell seed of protected commercial varieties of a particular crop, a general limitation on seed saving may have very adverse affects on many smaller farmers growing other crops. Similarly, although rigorous restrictions may need to be applied in the case of plant breeding involving transgenes, strict general interpretations of breeder's or researcher's exemptions may be inimical to national plant breeding.

Because the establishment of IPR regimes is a gradual process (and the regimes should respond to changing conditions in national plant breeding capacities, seed markets, and farmer priorities), careful monitoring is required. Policymakers need to assess whether particular IPR regimes are actually providing incentives for seed system development consistent with national agricultural goals. This includes analyzing if farmers have equitable access to an increasing diversity of crop varieties and if the structure of the commercial seed market provides confidence for participants while at the same time encouraging new entrants.

In the only case study country with legislation that includes Farmers' Rights (India), there is not enough experience to assess the degree to which this offers useful incentives for the development or promotion of farmer varieties. Further monitoring is required.

IPRs in international negotiations

IPRs need to be considered in international agreements that tackle related issues, in particular biodiversity and trade. National policies towards international agreements on biodiversity, negotiated by representatives with environment (CBD) or agriculture (IT/PGRFA) background need to be in line with the choices made in the field of IPR, which are primarily derived from economic and trade policies. It must be clear how IPRs relate to national sovereignty over plant genetic resources and rights of indigenous communities (CBD), and Farmers' Rights (IT/PGRFA) in order to avoid conflicts of interpretation. This requires a capacity in IPR issues with a much wider group of policy makers than commonly envisaged.

For many countries, the possibility of being required to establish particularly restrictive IPRs for plant breeding is more likely to be a product of bilateral trade agreements (most often with the US but also with Europe) than to derive from TRIPS obligations. National policymakers need to be prepared to enter such negotiations with a full understanding of the implications of such 'TRIPS-plus' agreements for their national plant breeding and seed systems. They also need to research their room for maneuver in interpreting and modifying any such requirements imposed by potential trading partners.

Implications for agricultural policies

This study has emphasized that IPR regimes in plant breeding should provide incentives for diversifying and strengthening plant breeding and seed production. This implies that policymakers cannot consider IPR regimes in isolation from wider issues of national agricultural policy. Three relevant concerns here are the future of public agricultural research, the development of a robust domestic seed sector, and the empowerment of farmers.

Research policies

The role of NARIs is a subject of considerable debate in light of generally declining national budgets and the growth of the private sector. Many NARIs are uncertain of whether to complement or compete with the private sector and hence are confused about how to take advantage of IPRs. Policymakers need to set clear guidelines in this area. NARIs need to distinguish between using IPRs in order to control the use and delivery of their varieties, on

the one hand, and seeing IPRs as a contributor to institute budgets through royalty collection, on the other. In the former instance, there may be cases where the assignment of some type of IPR is necessary to provide a seed company with sufficient incentives to deliver a public variety to farmers. In the latter instance, many NARIs look upon IPRs as a way to counterbalance reduced public funding for research and show a keen interest in the opportunity to earn revenue on existing and new varieties. In some cases this interest is translated into a shift in priorities towards research that is most likely to earn royalties. However, most NARIs seem to have little knowledge about the costs of obtaining and enforcing IPRs, and there is little realistic assessment within the NARI's of their capacity to compete with the private sector in producing commercially viable products (or in rewarding and maintaining staff for this task).

There are also a number of unresolved issues for NARIs in terms of basic research goals and their relation to IPRs. NARIs have many valuable assets to contribute to plant breeding, including their own varieties, breeding lines, and basic research. But they are not equipped to establish or assign their rights in order that public research makes the strongest possible contribution to agricultural growth. Neither are most NARIs organized to acquire access to complementary technology on equitable terms or to assess their 'freedom to operate' with protected techniques and tools.

The use of IPRs depends on negotiations between right holders and users of technologies. There is no sign of equality in negotiations anywhere in the world for access to technologies for R&D or for use of protected products. Individual parties, especially NARIs are no match for the legal and negotiation skills and resources of major technology firms. NARIs need assistance to formulate IP policies and strengthen their legal and negotiation capacities. National and international platforms for institutional IP-managers may provide opportunities to exchange experiences and promote institutional learning.

The strategies that NARIs adopt for utilizing IPRs will depend on answers to fundamental questions about the role of public sector agricultural research. These questions are beyond the scope of this study, but experience in the case study countries highlights that the issues deserve more attention from policymakers. For instance, they must recognize that the maintenance and development of public scientific capacity requires attention to an appropriate mix of incentives (professional, public service, and monetary) and that the way NARIs choose to interpret IPR regimes determines how these incentives are presented. Different approaches to shaping relations with the private sector as a technology provider or distributor may be taken into account in this debate, from license contracts to joint ventures or full privatization of (parts of) the public research system. IPRs play an important role in these relationships. In addition, the way that NARIs manage IPRs has a significant bearing on the extent to which germplasm resources are shared more widely. Policymakers 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, without appreciating the importance of equitable access.

Breeding and seed sector policies

Policymakers also need to ensure the development of the domestic breeding sector. With respect to biotechnology, local companies are generally at a disadvantage to MNCs. With few exceptions, domestic firms do not have the resources to invest in high technology and must depend on MNCs and advanced research institutions that protect their inventions. There are a few examples of incipient consortia of local seed companies formed to negotiate access to biotechnology, and national policy should support such efforts.

IPR regimes will only be effective when there is an enabling environment for the growth of commercial agriculture. Policies need to be in place that support the type of information provision, contract enforcement, business practices and credit availability that stimulate agribusiness development and that encourage private seed production and plant breeding. Although many national seed and plant breeding sectors have experienced significant recent development, and judicious use of appropriate IPR instruments can facilitate further growth, there are still serious challenges with respect to delivering useful varieties, particularly of non-hybrids and so-called 'orphan crops' to smallholders. The combination of limited and isolated markets with widespread seed saving means that even fairly strong IPR regimes are unlikely to elicit commercial interest in the near future. On the other hand, there is sufficient evidence that public seed provision schemes are generally ineffective. Therefore policymakers must find ways of combining (largely) public plant breeding, appropriate formal seed delivery (most likely private or cooperative), and support to local seed diffusion mechanisms, to serve the farmers dependent on these crops.

There are no indications in the case study countries that PVP unduly contributes to a concentration in the seed sector that leads to monopolistic behavior. Early experiences in biotechnology patents in the case study countries are insufficient to establish any evidence for concentration. The vast number of transgenics in the pipeline in both the (inter-)national private and public sectors calls for a critical assessment of the developments in the coming years. Monitoring could be done on the number of seed suppliers for any crop; the number of competing proprietary key technologies (e.g. insect resistance) in crops; the development of the levels of 'technology fees' relative to seed costs, etc. This is an area in which industrialized countries could provide some useful guidance given their longer experience in monitoring and regulating anti-competitive practices, including in agricultural input markets, in particular.

Rural development policies and empowerment of farmers

Finally, it is worth reiterating that the purpose of IPR regimes in agriculture is to provide appropriate incentives for science and commerce to better serve the nation's farmers. National policies need to ensure that farmers are conversant with, and participate in, debates regarding possible IPR regimes; that they are well-informed consumers who understand their rights in agricultural input markets; and that their interests and priorities are reflected in the work of public agricultural research. From a good governance perspective, this is now (under the IT-PGRFA) an issue of Farmers' Rights.

References

Almekinders, C.J.M. & N.P. Louwaars, 1999.
Farmers' seed production: New approaches and practices. London, Intermediate Technology Publications. 291 pp.

Alston, J.M. & R.J. Venner, 2002.
The Effects of the U.S. Plant Variety Protection Act on Wheat Genetic Improvement. Research Policy, 31(4): 527-42.

Andersen, B., 2004.
If 'Intellectual Property Rights' is the answer, what is the question? Revisiting the patent controversies. Econ. Innov. New Techn. 13(5): 417-442.

Atanassov, A. *et al.*, 2003.
To reach the poor – results from the ISNAR-IFPRI next harvest study on genetically modified crops, public research, and policy implications. EPTD Discussion Paper #116, Washington, IFPRI. 43 p.

Barry, G., in press.
Humanitarian Licenses for Genomics and Plant Breeding for Development. Mexico, Generation Challenge Program.

Beintema, N.M., L. Romano & P.G. Pardey, 2000.
Agricultural R&D in Colombia: Policy, Investments, and Institutional Profile. Washington, DC: IFPRI and FONTAGRO.

Binenbaum, E., C. Nottenburg, P.G. Pardey, B.D. Right & 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.

Buccola, S. & Y. Xia, 2004.
The Rate of Progress in Agricultural Biotechnology. Review of Agricultural Economics, 26(1): 3-18.

Butler, L.J., 1996.
Plant Breeders' Rights in the U.S.: Update of a 1983 Study. In: J. van Wijk & W. Jaffe (Eds): Proceedings of a Seminar on the Impact of Plant Breeders' Rights in Developing Countries Held at Santa Fe Bogota, Colombia, March 7-8. Amsterdam: University of Amsterdam, pp. 17-33.

Butler, L.J. & B.W. Marion, 1985.
Impacts of Patent Protection in the Us Seed Industry and Public Plant Breeding. Madison, WI: University of Wisconsin. North Central Regional Research Bulletin No. 304.

Canadian Food Inspection Agency, 2001.
10-Year Review of Canada's Plant Breeders' Rights Act, Ottawa, Canada.

Chang, H.-J., 2002.
Kicking Away the Ladder. London: Anthem Press.

Cohen, W.M., R.R. Nelson & J.P. Walsh, 2000.
Protecting their intellectual assets: appropriability conditions and why US manufacturing firms patent (or not). Cambridge MA, National Bureau of Economic Affairs, Working Paper 7552. www.nber.org/papers/w7552.

Commission on Intellectual Property Rights, 2002.
Integrating Intellectual Property Rights and Development Policy. London, DFID, 195 p.

Correa, C.M. & S.F. Musungu, 2002.
The WIPO patent agenda: the risks for developing countries. South Centre, T.R.A.D.E. Working Paper 12, 30 p.

Davis, L., 2004.
Intellectual property rights, strategy and policy. Econ. Innov. New Technol. 13(5): 399 - 415.

Diez, M.C.F., 2002.
The Impact of Plant Varieties Rights on Research: The Case of Spain. Food Policy, 27: 171-83.

Eaton, D.J.F., 2002.
Trips and Plant Varietal Protection: Economic Analysis and Policy Choices. The Hague: Agricultural Economics Research Institute (LEI). Report Number 7.02.01. 36 pages.

Eaton, D.J.F. & F.W. van Tongeren, 2004.
Patents Versus Plant Varietal Protection. Paper presented at the 8th Annual Conference of the International Consortium on Agricultural Biotechnology Research (ICABR), Ravello, Italy, July 8-11, 2004. 22 p. Available at http://www.economia.uniroma2.it/conferenze/icabr2004/papers/default.asp

Eaton, D.J.F. & A.-J. van Wijk, 2004.
The Importance of Plant Variety Protection for the Development of Plant Breeding in the South. Wageningen, Centre for Genetic Resources the Netherlands. 20 p.

Eisenberg, R., 1996.
Patenting research tools in the law. Chapter 2 in National Research Council. Intellectual Property Rights and Research Tools in Molecular Biology*;* Summary of a Workshop Held at the National Academy of Sciences, February 15-16, 1996*.* http://books.nap.edu/html/property/2.html

Evenson, R.E., C. Pray & M.W. Rosegrant, 1999.
Agricultural research and productivity growth in India. Research Report 109. Washington, DC: International Food Policy Research Institute.

Falck-Zepeda, J.B., G. Traxler & R.G. Nelson, 2000.
Surplus Distribution from the Introduction of a Biotechnology Innovation.' American Journal of Agricultural Economics 82: 360-369.

Falcon, W.P. & C. Fowler, 2002.
Carving up the Commons–Emergence of a New International Regime for Germplasm Development and Transfer. Food Policy 27(3): 197-222.

Fischer, K. & D. Byerlee, 2001.
Managing Intellectual Property and Commercialisation in Public Research Organisations. SASKI Good Practice Note, Washington, The World Bank, 17 p.

Fischer, K. & D. Byerlee, 2002.
Managing Intellectual Property and Income Generation in Public Research Organisations. In: Derek Byerlee & Ruben Echeverría (Eds). Agricultural Research Policy in an Era of Privatization. Oxon & New York, CAB International. pp. 227-244.

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. Ames, Iowa: Iowa Agriculture and Home Economics Experiment Station, Iowa State University. Special Report 98.

Granstrand, O., 1999.
The Economics and Management of Intellectual Property: Towards Intellectual Capitalism. Cheltenham, UK: Edward Elgar.

Hardon, J.J., 2004.
Plant patents beyond Control; biotechnology, farmer seed systems and Intellectual Property Right. Wageningen, Foundation Agromisa: AgroSpecial 2, 80 p.

Helfer, L.R., 2002.
Intellectual property Rights in plant varieties: an overview with options for national governments. FAO Legal Papers #31, Rome, FAO, 59 p.

Heller, M.A. & R.S. Eisenberg, 1998.
Can Patents Deter Innovation? The Anticommons in Biomedical Research. Science, 280: 5364, pp. 698-701.

Henson-Apollonio, V., 2003.
Exceptions to Plant Protection, WIPO-UPOV Symposium, 2003.

Henson-Apollonio, V., 2004.
Intellectual Property Rights and Patent Regimes in Biotechnology and their impact on Agricultural Development in the Developing World. In: Paul Christou & Harry Klee (Eds) Handbook of Plant Biotechnology, vol 2. Hoboken (NJ) Wiley.

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

Hu, Ruifa, Victoria L. Cabanilla & Mahabub Hossain, 2002.
Contributing to each other: China's rice improvement programme and the Genetic Materials introduction in and out. Los Banos, IRRI working paper.

Huang, Jikum, & Ruifa Hu, 2000.
Agricultural R&D Investment System and Pattern: current situation and international comparison. Management World #3: 170-179.

Huang, Jikun, Ruifa Hu & Scott Rozelle, 2003.
Agricultural Research Investment in China: challenges and prospects. China's Finance and Economy Press, Beijing.

ISF, 2004.
In press. Protection of Intellectual Property and Access to Plant genetic Resources. Proceedings of an international seminar, Berlin, 27-28 May, 2004.

Jaffe, W. & J. van Wijk, 1995.
The Impact of Plant Breeders' Rights in Developing Countries. Amsterdam: Inter-Am Institute for Co-operation on Agriculture, University of Amsterdam.

James, C., 2003.
Global Review of Commercialized Transgenic Crops. ISAAA Newsletter.

Kalton, R.R., P.A. Richardson & N.M. Frey, 1989.
Inputs in Private Sector Plant Breeding and Biotechnology Research Programs in the United States. Diversity, 5(4): 22-25.
Kanwar, S. & R. Evenson, 2003.
Does Intellectual Property Protection Spur Technological Change? Oxford Economic Papers, 55: 235-64.
Kiewiet, 2001.
Modern Plant breeding and Intellectual Property Rights. Colloquium in Einbeck, Germany, January 26th, 2001.
Koo, B., P.G. Pardey, K. Qian & Y. Zhang, 2003.
The Economics of Generating and Maintaining Plant Variety Rights in China. Washington, International Food Policy Research Institute (IFPRI). EPTD Discussion Paper No. 100. 40 p.
Krattiger, A., 2004.
Editor's Introduction: PVP and Agricultural Productivity. IP-Strategy Today No. 9.
Landes, W.M. & R.A. Posner, 2003.
The Economic Structure of Intellectual Property Law. Cambridge, MA, Belknap Press. 448 p.
Lesser, W.H. & R.T. Masson, 1983.
An Economic Analysis of the Plant Variety Protection Act. Washington DC: American Seed Trade Association.
Lesser, W., 1994.
Valuation of Plant Variety Protection Certificates. Review of Agricultural Economics, 16: 231-238.
Lesser, W., 1997a.
Assessing the Implications of Intellectual Property Rights on Plant and Animal Agriculture. American Journal of Agricultural Economics, 79: 1584-1591.
Lesser, W.H., 1997b.
The Role of Intellectual property Rights in Biotechnology transfer under the Convention on Biological Diversity. ISAAA Briefs No.3, ISAAA, Ithaca NY
Lesser, W., 2002.
The effects of Intellectual Property Rights on Foreign Direct Investments and Imports into Developing Countries in the Post TRIPS Era. IP Strategy Today no.5-2002
Lessig, L., 2004.
Free Culture. New York: The Penguin Press.
Louwaars, N.P., B. Visser, D. Eaton, J. Beekwilder & 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 NY, Food Products Press (The Haworth Press Inc.) pp. 89 - 102.
Louwaars, N.P. (ed), 2002.
Seed Policy, Legislation and Law: widening a narrow focus. Binghamton NY, Food Products Press (The Haworth Press Inc.) 260 p.
Maurer, S.M. & S. Scotchmer, 2004.
Profit Neutrality in Licensing: The Boundary Between Antitrust Law and Patent Law. Competition Policy Center. Paper CPC04-43. Berkely, University of California, 42 p. http://repositories.cdlib.org/iber/cpc/CPC04-43

Mazzoleni, R. & R.R. Nelson, 1998.
The Benefits and Costs of Strong Patent Protection: A Contribution to the Current Debate. Research Policy, 27:3, pp. 273-84.
McCalman, P., 2002.
The Doha Agenda and Intellectual Property Rights. ADB, Manilla. 35 p.
Morris, M. & B. Ekasingh, 2002.
Plant breeding Research in developing Countries: What roles for the public and private sectors? In. Derek Byerlee & Ruben Echeverría (Eds). Agricultural Research Policy in an Era of Privatization. Oxon & New York, CAB International. pp. 199-225.
Nelson, R.D. & R. Mazzoleni, 1997.
Economic Theories about the costs and benefits of patents. In: Commission on Life Sciences, 1997. Intellectual Property Rights and Research Tools in Molecular Biology: Summary of a Workshop Held at the National Academy of Sciences, February 15-16, 1996, p. 17-27.
Oldham, P., 2004.
Global Status and Trends in Intellectual Property Claims: Genomics, Proteomics and Biotechnology. Submission to the Executive Secretary of the Convention on Biological Diversity by Dr. Paul Oldham from the ESRC Centre for Economic and Social Aspects of Genomics (CESAGen), United Kingdom.60 pages. Available at http://www.cesagen.lancs.ac.uk/docs/genomics-final.doc
Pal, S., R. Tripp & 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.
Pal, S. & D. Byerlee, 2003.
The funding and organisation of agricultural research in India: evolution and emerging policy issues. Policy Paper 16. New Delhi: National Centre for Agricultural Economics and Policy Research.
Pardey, P.G., B. Koo & C. Nottenburg, 2003.
Creating, Protecting, and Using Crop Biotechnologies Worldwide in an Era of Intellectual Property Paper presented at the WIPO-UPOV Symposium on Intellectual Property Rights in Plant Biotechnology, Geneva, October 24, 2003, Document WIPO-UPOV/SYM/03/4. 39 p.
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, University of London.
Perrin, R.K., K.A. Hunnings & L.A. Ihnen, 1983.
Some Effects of the Us Plant Variety Protection Act of 1970. Raleigh, N.C.: North Carolina State University Dept. of Economics and Business. Economics Research report No. 46.
Pray, C., D. Ma, J. Huang & F. Qiao, 2001.
Impact of Bt Cotton in China. World Development, 29(5), pp. 813-825.
Pray, C.E., A. Courtmanche & R. Govindasamy, 2002.
The Importance of Intellectual Property Rights in the International Spread of Private Sector Agricultural Biotechnology. Paper presented at the 6th Annual Conference of the International Consortium on Agricultural Biotechnology Research (ICABR), Ravello, July 11-14, 2004. 43 p.

Pray, C., J. Huang, R. Hu & S. Rozelle, 2002.
Five Years of Bt Cotton in China - the Benefits Continue. The Plant Journal, 31(4) pp. 423-430.
Pray, C., D. Ma, J. Huang & F. Qiao, 2001.
Impact of Bt Cotton in China. World Development, 29(5), pp. 813-825.
Pray, C.E., C. Fan, J. Huang, R. Hu & C. Zhang, 2004.
Biotech and Seed Industry Policies in China: Who Could Benefit from Policy Reform? Unpublished paper.
Pray, C.E. & B. Ramaswami, 1990.
A Framework for Seed Policy Analysis in Developing Countries. International Food Policy Research Institute, Washington DC, 1990.
Reitzig, M. 2004.
The Private values of 'Thickets' and 'Fences': towards an updated picture of the use of patents across industries. Econ. Innov. New Techn. 13(5): 457 - 476.
Scotchmer, S., 2004.
The Political Economy of Intellectual Property Treaties. J. of Law, Econ.& Organization 20 (2): 415-437
Salazar, R., N. Louwaars & B. Visser, in press.
Issues regarding the protection of new farmers' varieties. Rome, IPGRI.
Smith, R.D., H. Thorsteinsdottír, A.S. Daar, E.R. Gold & P.A. Singer, 2004.
Genomics knowledge and equity: a global public goods perspective of the patent system. Bulletin of the World Health Organisation 82: 385 - 389.
Sperling, L., J.A. Ashby, M.E. Smith, E. Weltzien & S. McGuire, 2001.
A framework for analyzing participatory plant breeding approaches and results. Euphytica 122: 439-450.
Srinivasan, C.S., 2001.
International Experience of Plant Variety Protection: Lessons for India. PhD Dissertation. University of Reading, U.K.
Srinivasan, C.S., 2004.
Plant Variety Protection, Innovation and Transferability: Some Empirical Evidence. Review of agricultural economics, Vol 28(4): 445
Srinivasan, C.S., B. Shankar & G. Holloway, 2002.
An Empirical Analysis of the Effects of Plant Variety Protection Legislation on Innovation and Transferability. Paper presented at the meeting of the European Association of Agricultural Economists, Zaragoza, Spain, August 2002. 17 p.
Sullivan, S., in press.
The evolving International regime of Liability and Redress relating to the use of genetically Modified Organisms, Mexico, Generation Challenge Program.
Taylor, M.R. & J. Crayford, 2003.
American Patent Policy, Biotechnology and African Agriculture: a case for policy change. Washington DC, Resources for the Future, 114 p.
Thumm, N., 2001.
Management of Intellectual Property Rights in European Biotechnology Firms. Technological Forecasting and Social Change, 67(2-3): 259-272.

Traynor, P.L. & J. Komen, 2002.
Regulating Genetically-Modified Seeds in Emerging Economies. In: N.P. Louwaars (Ed). pp. 213-229

Tripp, R. (Ed).
New Seed and Old Laws; regulatory reform and the diversification of national seed systems. London, Intermediate Technology Publications

Wade, R., 1990.
Governing the Market. Princeton, NJ: Princeton University Press.

Wijk, A.J. van, D.J.F. Eaton & N.P. Louwaars, 2003.
Framework for the Introduction of Plant Breeders' Rights in Developing Countries. Wageningen, Centre for Genetic Resources the Netherlands. 50 p.

World Bank, 2004.
World Development Indicators. Washington DC, World Bank.

Annex I.
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- King, International Food Policy Research Institute, Washington DC, USA
- B.-W. Koo, International Food Policy Research Institute, Washington DC, USA
- S. Kumar, Michigan State University, East Lansing MI, USA
- M. Maredia, Michigan State University, East Lansing MI, USA
- A. Michiels, International Food Policy Research Institute, Washington DC, USA
- E. Pehu, World Bank, Washington DC, USA
- Pray, Rutgers University New Brunswick NJ, USA
- R. Rajalathi, WorldBank, Washington DC
- G. Tansey, Hebden Bridge, UK

China

IP Organizations + other Government offices, China

- HE Yuefeng, State Intellectual Property Office (SIPO) = patent office
- LI Yianmei, State Intellectual Property Office (SIPO) = patent office
- LUI Bo, PVP Office, MoA
- SUN Junli, PVP Office, MoA
- SUN Xue Mei, MoA GMO Biosafety Office

– LIU Hai Peng, MoA GMO Biosafety Office
– REN Gang, Trademark Office
– HUA Jie, Trademark Office
– HU Li, Trademark Office
– SUN Yongjian, Ministry of Science and Technology (MOST)
– CHEN Linghao, Ministry of Science and Technology (MOST)
– WANG Jie, State Environmental Protection Agency (SEPA)
– CAI Li, State Environmental Protection Agency (SEPA)
– XUE Dayuan, State Environmental Protection Agency (SEPA)

Public Sector Research Organizations, China

– LI Ruiyun, Institute for Vegetables and Flowers, CAAS
– WANG Qinfang, Biotechnology Research Institute, CAAS
– WANG Kunbo, Cotton Research Institute, CAAS; Anyang, Henan Province
– GUO Xianmuo, Cotton Research Institute, CAAS; Anyang, Henan Province
– XING Chaozhu, Cotton Research Institute, CAAS; Anyang, Henan Province
– ZHAO Xinhua, Cotton Research Institute, CAAS; Anyang, Henan Province
– LIU Jinhai, Cotton Research Institute, CAAS; Anyang, Henan Province
– YUAN Longping, Hunan Hybrid Rice Research Center (HHRRC)
– WAN Yizhen, Hunan Hybrid Rice Research Center (HHRRC)
– ZHANG Yuzhuo, Hunan Rice Research Institute
– ZHAO Zhenghong, Hunan Rice Research Institute
– LI Xiaofang, Guangdong Rice Research Institute
– WANG Feng, Guangdong Rice Research Institute
– HUANG Qing, Guangdong Rice Research Institute
– HUANG Nongrong, Guangdong Rice Research Institute
– BAI Song, Guangdong Rice Research Institute
– LIANG Jingcai, Guangdong Academy of Agricultural Science (rice)
– CHEN Qinling, Guangdong Academy of Agricultural Science (rice)
– LUO Shaojia, Zhejiang Academy of Agricultural Science (rice)
– LU Hongxing, Zhejiang Academy of Agricultural Science (rice)
– CHENG Shihua, China National Rice Research Institute
– HU Huiying, China National Rice Research Institute
– FU Qiang, China National Rice Research Institute
– NI Jianping, China National Rice Research Institute
– YAO Haigen, Jiaxing Agricultural scientific institution (Zheijiang) (rice)

Private Companies, China

– ZHOU Weihua, China National Seed Group Company (rice, maize, cotton, vegetables)
– ZHANG Mengyu, China National Seed Group Company (rice, maize, cotton, vegetables)
– CUI Yingji, China National Seed Group Company (rice, maize, cotton, vegetables)
– HAN Yaomin, China National Seed Group Company (rice, maize, cotton, vegetables)
– HAN Gengchen, Beijing Origin Seed Technology Inc (maize)
– ZHAO Yuping, Beijing Origin Seed Technology Inc (maize)

– WANG Weizhong, Doneed Seed Company (D'long) (rice, maize, cotton, vegetables)
– WANG Li, Doneed Seed Company (D'long) (rice, maize, cotton, vegetables)
– Monsanto, China office
– YANG Yuanzhu, Yahua Seed Academy (rice)
– FAN Xiaobing, LongPing High-Tech Seed Corporation (rice)
– TANG Buocheng, Biocentury Transgene (China) Co. Ltd (Bt cotton)
– LIU Fenghua, Biocentury Transgene (China) Co. Ltd (Bt cotton)
– ZHENG Aizhong, Biocentury Transgene (China) Co. Ltd (Bt cotton)
– WANG Zhongyu, Gold Sun Agricultural China Co. Ltd (Maize, Rice)
– LIU Shukun, Gold Sun Agricultural China Co. Ltd (Maize, Rice)
– LI Degnhai, Shandong Denghai Seeds Co., Ltd (maize)
– LIU Jingguo, Shandong Denghai Seeds Co., Ltd (maize)
– WANG Tianxiang, China Trademark & Patent Law Office Co. Ltd (Patent Agent)

Others, China

– P. Gooren, Royal Netherlands Embassy, Agricultural Counsellor and attaché
– R. Konijn, Royal Netherlands Embassy, Agricultural Counsellor and attaché
– Seed shops, Anyang, Henan Province

Colombia

IP institutions & other Government offices, Colombia

– Ana Luisa Diaz, National Coordinator, Plant Breeders Rights and Seed Production
– Giancarlo Marcenaro, Deputy Superintendent for Industrial Property
– Alix Céspedes de Vergel, Patent Office Director
– María del Socorro Pimiento, Trademark Office Director
– Luis Angel Madrid, Head of the Colombian Delegation for the Free Trade Area of the Americas (FTAA) on IP issues
– Juan Lucas Restrepo, Former Viceminister of Agriculture
– Ricardo Torres, General Coordinator of Research Project on 'Policy Design on Access and utilization of genetic resources'
– Santiango Perry, Head of Corporación para el Desarrollo Participativo y Sostenible de los Pequeños Agricultores Colombianos, CDPSPA

Public sector research organizations, Colombia

Corporación Colombiana de Investigación Agropecuria, CORPOICA

– Luis Arango, Executive Director
– Tito Díaz, Deputy Director for Strategic Research
– Andrés Leignelet, General Coordinator, Management and Technology Innovation Program
– Jorge Suárez, Seed Coordinator
– Víctor Núñez, Director Biotechnology Unit
– Alba Marina Cotes, Researcher, Integrated Pest Management Unit

Centro Internacional de Agricultura Tropical, CIAT

– Aart van Schoonhoven, Director, Science Park (AgroNatura)
– Zaida Lentini, Plant Biologist/Geneticist, Biotechnology Unit & Rice Project
– Cesar Marinez, Rice breeder
– Stephen Beebe, Head, Bean Project
– Edith Hess, Head Information and Communications Unit
– Joe Tohme, Head Agrobiodiversity and Biotechnology Unit
– German Arias, Head Legal Office
– Rafael Posada, Head Impact Project
– Daniel Debouck, Head of Genetic Resources Unit

Private Sector, Colombia

– Luis Sanin, Executive Director Fondo Latinoamerica de Arroz de Riego, FLAR
– Andres Toro, Colibri Flowers S.A.
– Eduardo Villota, Director General, Semillano Ltda & Head of Asociación Colombiana de Semillas, ACOSEMILLAS & Head of Latin American Federation of Seed Associations (FELAS)
– Luis Enrique Acevedo, Royalty Administration International, Latin America
– Sabina Cajio, Auditor Royalty Administration International, RAI
– Rafael Aramendis, Regulation Manager for Andean Region, Central America and the Caribbean
– Jose I. Bolaños, Andean Research & Development Coordinator & Andean Biotechnology Research Coordinator
– Gustavo Mejia & others, Unique Latin Roses LTDA (Esmeralda Farms Holding)
– Pablo Robledo, Attorney PBR
– Rafael Aramendis, Monsanto
– Jose I. Bolanos, Dupont

Farmers' association, Colombia

– Augusto del Valle, Head of Federación Nacional de Papa FEDEPAPA

India

IP institutions & other Government offices, India

– H.C. Bakshi, Joint Controller of Patents and Designs, Patent Office, New Delhi
– Ms Premlata, Assistant Registrar, Trademark Office, New Delhi
– Dr K.K. Tripathi, Advisor (IPR), Department of Biotechnology, Ministry of Science and Technology, Government of India, New Delhi
– Prem Narain, Joint Secretary (Seeds), Ministry of Agriculture, Government of India, New Delhi
– S.V. Singh, Director (Seeds), Ministry of Agriculture, Government of India, New Delhi
– Babu Rao S., Managing Director, Andhra Pradesh Seeds and Development Corporation, Hyderabad, Andhra Pradesh

Public research organizations, India

Indian Council of Agricultural Research

- Dr Mangala Rai, Director General, Indian Council of Agricultural Research, New Delhi
- Dr G. Kalloo, Deputy Director General (Crops and Horticulture), Indian Council of Agricultural Research, New Delhi
- Dr S. Nagarajan, Director, Indian Agricultural Research Institute, New Delhi
- Dr J.P. Mishra, Assistant Director General (Intellectual Property Rights), Indian Council of Agricultural Research, New Delhi
- Dr G.S. Dhillon, Director, National Bureau of Plant Genetic Resources, New Delhi
- Dr K.R.M. Swamy, Director-in-charge and Head, Division of Vegetable Crops, and other Heads of the Division and senior scientists, Indian Institute of Horticultural Research, Bangalore, Karnataka
- Dr P. Singh, Director, and senior scientists, Central Institute of Cotton Research, Nagpur, Maharashtra
- Dr M. Ilyas Ahmed, Scientist-in-charge of hybrid rice program, and Scientist-in-charge, biotech programs, Directorate of Rice Research, Hyderabad, Andhra Pradesh

State Agricultural Universities

- Dr Kulkarni, Nodal scientist for IPR, and Dr P. H. Ramanjini Gowda, scientist with seeking patent for his innovation, University of Agricultural Sciences, Bangalore, Karnataka
- Dr A. Padmaraju, Director Research, Andhra Pradesh Agricultural University, Hyderabad, Andhra Pradesh

Other public research organizations

- Dr Rakesh Tuli, Scientist Bt transgenic program, National Botanical Research Institute (Council of Scientific and Industrial Research), Lucknow, Uttar Pradesh

International Centre for Research in the Semi-Arid Tropics, ICRISAT

- Dr Dyno Keatinge, Deputy Director General,
- B. Hanumanth Rao, IPR Officer, scientists of crop improvement programs
- C.L.L. Gowda, S. Nigam, C.T. Hash, K.N. Rai, Scientists of crop improvement programs
- J.H. Crouch, F. Waliyar, Scientists of biotechnology program

Private seed sector, India

Seed companies

- Uday Singh, President, Seed Association of India, and Managing Director, Namdhari Seeds, Dr N. Anand, Director Research, Namdhari Seeds, Bangalore, Karnataka
- Raju Barwale, President, Association of Seed Industry, and Managing Director, Maharashtra Hybrid Seed Company Ltd (Mahyco), Mumbai, Maharashtra
- R.V. Kaundinya, Managing Director, and A.R. Sadananda, Director Research, Emergent Genetics India, Hyderabad, Andhra Pradesh
- Dr M.J. Vasudeva Rao, Senior Vice President, Advanta India, Bangalore, Karnataka

- Dr M. Vinod Kumar, Manager (Regulatory issues), Proagro Seeds/Bayer Crop Science, Gurgaon, Haryana
- Raman Modi, General Manager, and rice breeders, Hybrid Rice International (Proagro group), Hyderabad, Andhra Pradesh
- L.P. Aurangabadkar, Director Research, Ankur Seeds, Aurangabad, Maharashtra
- R.S. Arora, Managing Director, Century Seeds, New Delhi
- Dr Y. Yogeswara Rao, President, Andhra Pradesh Seedmen Association and Managing Director, Vikky's Seeds, Hyderabad, Andhra Pradesh
- M. Prabhakar Rao, Managing Director, Nuziveedu Seeds, Hyderabad, Andhra Pradesh
- P.S. Dravid, President, JK Seeds, Hyderabad, Andhra Pradesh
- Dr N.K. Singh, Head Product Development and Dr A. Gopinath, Manager, Syngenta India, Pune, Maharashtra
- Vinod G. Broker, Managing Directors, Pocha Seeds, Suyash Seeds, and Prakash Navalakha, Navalakha Seeds (small seed companies in Pune)
- Dr A.S. Kataria, Director, Seed Association of India, New Delhi

Private agricultural biotech companies

- R.D. Kappor, National Regulatory Manager, and P.P. Reddy and H.H. Basappa, plant breeders, Monsanto India, Bangalore, Karnataka
- Dr Koen Wentink, Chief Logistics, and Dr K.R. Rajyashri, Director Research, Avesthagen, Bangalore, Karnataka
- Dr K.K. Narayanan, Managing Director, Metahelix, Bangalore, Karnataka

NGOs/FO, India

- Dr Anil Gupta, Professor, Indian Institute of Management, Ahmedabad, Gujarat, and Executive vice chairperson, National Innovation Foundation and Sristi
- Dr M.D. Gupta, Senior researcher, Suri Sehgal Foundation, ICRISAT, Patancheru, Hyderabad
- Dr A. Nambi, IP expert, MS Swaminathan Foundation, Chennai, Tamil Nadu
- Mr Akkineni Bhavani Prasad – Farmers' Association of Andhra Pradesh, Hyderabad

Kenya

IP-institutions and other government offices, Kenya

- Spencer Mathioka, Actg Director, KIPI
- Reuben Lang'at, Patent Examiner, KIPI
- Stanley Atsali, Patent Examiner, KIPI
- Eunice Njuguna, Lawyer, Kenya Industrial Property Institute
- C.J. Kidera, Managing Director, KEPHIS
- M.O. Gunga, Examiner of PVP, KEPHIS
- J.J. Gichuki, Deputy Director PBR, Ministry of Agriculture
- Prof. Kingoriah, Executive Secretary, National Council for Science and Technology
- Solomon Kuria, Trade officer, Ministry of Trade Kenya Government

Public research institutes, Kenya

Kenyan Agricultural Research Institute

- Romano Kiome, Director
- Betty Kiplagat, Legal Officer
- J.A. Ochieng, Assistant Director Crops (Maize breeder)
- Jane Ininda, Maize breeder
- Dr Kahiu Ngugi, Senior Bean Breeder
- J.B. Kamau, Cassava breeder
- Kiarie Njoroge, Maize Research Coordinator
- Dr Kabiro, Centre director, KARI-Tigoni
- G. Ombakho, Mazie breeder, KARI-Kitale
- L.F. Ragwa, Assistant Director Seed Unit
- Ben Odhiambo, Biotechnology Coordinator

Universities

- Levi Akundabweni, Chairman, Dept of crop science, University of Nairobi
- Prof Ogada, Moi University Holding, Moi University

International organizations

- Stephen Mugo, IRMA Coordinator, CIMMYT
- Dr Majiwa, Programme Manager, African Agricultural Trust Fund
- Richard Boadi, Legal counsel, African Agricultural Trust Fund
- Nancy Muchiri, Public Relations Officer, African Agricultural Trust Fund

Private sector, Kenya

- Obongo Nyachae, Executive Secretary, Seed Traders Association Kenya (STAK)
- Saleem Esmail, Chief Executive Officer/Maize breeder, Western Seed
- Graig Nelson, Marketing Manager, Pannar Seed Co.
- Valentine Miheso, Seed Sales Manager, Monsanto Kenya
- Johnson Thaiya, Seed Operations Manager, Monsanto Kenya
- Mosses Onim, Proprietor, Lagrotech Seed Company
- S. Omamo, Production manager, Lagrotech Seed Company
- Peter Rukwaro, Production manager, Valentine Flowers
- Samwel Gathara Kiarie, Representative, Pioneer Seed Company in Kenya
- Charles Nga,nga, General Manager, Faida Seed
- Francis Ndambuki, Research Manager Maize, Kenya Seed Co.
- Peter Veal, Regional Representative, Syngenta Company
- Wilfred Munyao, Farm/propagation Manager, Sian Roses
- Sunders, Production Manager, Magana flowers
- J. Kamau, Production Manager, Magana flowers
- John Njenga, Lead Auditor & Activity CEO, Kenya Flower Council
- Francis L. Oyatsi, Deputy Managing Director, Kenya Seed Company

– Rose Kauri, Company Secretary, Kenya Seed Company
– Hosea Sitienei, Sales Manager, Kenya Seed Company
– James Boit, R&D Manager, National Cereals and Produce Board
– Bruce Mc Arthur, Country Manager, Seed Co

NGOs/FOs Kenya

– Caleb Wangia, Winrock International: Seed Production & distribution
– Mercy Karanja, Chief Executive, Kenya National Federation of Agricultural Producers
– Leonard Nduati Kariuki - KENFAP Nairobi, Kenya
– Philip Kiriro - East African Farmers Union - Nairobi, Kenya

Uganda

IP-institutions and other Government offices

– Ltd. Bayiga, Fiona: Senior State Attorney/ Assistant Registrar, Ministry of Justice
– Mugoya, Charles: Uganda National Council for Science & Technology
– Bazaale, Joseph: Head, National Seed Certification Services, Ministry of Agriculture [MAAIF]
– Kyazze Lubega, Jean: Law Reform Commission, Ministry of Justice

Public research organizations

National Agricultural Research Organization NARO

– Otim Nape, George: Ag. Director General, NARO
– Aluma, John W.: Deputy Director General, Research, NARO
– Bigirwa, George: Head of Maize Research Program, NAARI/NARO
– Imanywoha, Justus: Maize Breeder, NAARI/NARO
– Kyetere, Denis: Maize Breeder & Director of Research, CORI/NARO
– Ogen, Michael: Bean Breeder, NAARI/NARO
– Opio, Fina: Director of Research, NAARI/NARO
– Sserunjogi, Lustus: Cotton Breeder & Director of Research, SAARI/NARO
– Wasswa, Mulumba: In-charge National Genetic Resources, NARO

University

– Rubaihayo, Patrick: Professor, Makerere University

International organizations

– Abebe, Demessie: Association for Strengthening Agricultural Research in Eastern & Central Africa [ASARECA]
– Kirkby, Roger: Head, CIAT Uganda

Private sector

- Gareeba Gaso, Emmanuel: General Manager, Uganda Seeds Ltd
- HiteshPanchmatia: MD, Bon Holdings Ltd - Cotton
- Kaijuka, Chris: Managing Director, FICA Seeds Ltd
- Kashaija, Steven: Cottco Uganda Ltd - Cotton
- Lutaaya, Yassin: Local Seed Merchant, Rakai District, Uganda
- Mugisa, Boniface: Seed Manager, Monsanto International, Uganda
- Ndemo, Job: Country Manager, Kenya Seed Company, Uganda
- Mulumba, Stanley: Uga Rose Ltd - Flower Firm
- Okot, Josephine: Chair, Uganda Seed Trade Association & GM Victoria Seeds Ltd
- Paku & Ravi: Dunavant Cotton, Uganda
- Pandya, Kashap: Xpressions Ltd - Flower Firm
- Rodneys, Nicolai: General Manager, NASECO Seeds Ltd
- Rutten, John: FIDUGA Flower Firm & Chair, Uganda Flower Exporters Association [UFEA]
- Peter Benders, Mairye Estates - Magic Flowers
- Yan Krul: Mairye Estates - Magic Flowers

NGOs/FOs

- Chemisto, Wilson: Kapchorwa Commercial Farmers Association, Uganda
- Kagweri, Florence: Bakusekamajja Women Farmers Group, Iganga District, Uganda
- Kambale, Daniel: Kasese Farmers Group, Uganda
- Mayiga, Rosemary,: Community Enterprise & Development Organization [CEDO]
- Gonza, Peter, Community Enterprise & Development Organization [CEDO]
- Mpeirwe, Arthur: Program Manager, IPR & Biotechnology Policy, ACODE

Annex II.
Interview questions

1. Guidelines for interviews: IP-institutions

Preparation before visiting office

1) If relevant - review the IP-offices webpage
2) To which international conventions, treaties, IP organization the country is a member of (including WTO, WIPO (which versions of which agreements, protocols, etc.), UPOV, CBD, IT/PGRFA (check with lead team if necessary)
3) National legislation on trademarks, trade secrets, geographical indications
4) Review state of laws, regulations, judicial review, case law
5) Reviewed state of laws, regulations, judicial review, case law, etc. as much as can be found
6) Note the names of high profile IP law firms, names of developed country law firms that have regional branches in the country, professional associations, etc.

1. General

1.1 What is the organization of IP Offices in the country - Patent protection, Plant Variety Protection? Trademark, Copyright, others (e.g. database and geographical indications)?
1.2 What is the cross-office relationship between/among the various IP Offices?
1.3 What is the procedure for the appointment of Directors for these offices?
1.4 When was (were) the institution(s) established? (Perhaps ask for a brief history of each office.)
1.5 In case of a regional system: what is the relationship between the national and regional office?
1.6 How are IPRs enforced in your country?
1.7 Do you have any special protection for infringement or 'stealing' of Trade Secrets?
1.8 Do you consider the courts to be effective in terms of helping owner enforce their IPRs?
1.9 Is the judicial system in your country active in interpretation of IP laws? If so, would you describe a case that has gone through your courts system and what affect that case has had on the way IPRs are awarded by your office.

2. Patent office

– *legal issues*

2.1 Does the country have a patent law, what revisions to the law have been made?
2.2 What interpretation of the law is given towards protection with regards to patents for plant varieties, plants, genes, biological processes such as transformation -compositions, processes?
2.3 Who is in charge of the interpretation? How are decisions appealed?

2.4 Is there a system that includes the possibility of seeking petty patents/innovation patents, or one that only allows for utility patents? What is your experience?
2.5 Are there special provisions in the patent law for biological inventions - such as exemptions for non-commercial use (would this include seed saving and exchange?) or a research exemption allowing further breeding?
2.6 How is the regional harmonization of patent regulation and practice /or: How would envision that a regional, harmonized system would work in your region? - and what are the effects on biological patents?
2.7 Does the country have special provisions ref TRIPS 27(3) b: plant variety protection or do plant varieties fall under the patent system? How did the legislation come about? How do you regard this outcome?
2.8 (If the country have laws on trademarks, trade secrets, geographical indications), how are these implemented in the agricultural field (specifically seed related) and how are these enforced (general impression of officer)?

– *Institutional/general implementation issues*

2.9 How many applications do you get in the national office:
- patents – national or PCT filings
- try to estimate proportion related plant biological inventions? (This could be difficult to determine. It might be better to ask for an example of a biotech patent that has been issued and then go from there to try to get a feel for how many biotech inventions involving plants.)
- Breeder's rights? – probably ask at the PVP-office again

2.10 How many examiners do you have in your office?
- For patents with knowledge of biotech, natural products, microbiological
- For breeder's rights (if handled by patent office)

2.11 How long does it normally take for an application to go through examination?
2.12 Does your office publish patent applications? If so, what is the process?
2.13 Is it possible to obtain copies of the examination records of a particular patent?
2.14 What is the appeal process? –How often does a rejection get overturned upon appeal?
2.15 What is the opposition practice?
2.16 What is the procedure for reexamination? –for invalidation of issued patents?
2.17 What are the requirements to be an examiner? how do you maintain/upgrade their knowledge and skills?
2.18 Does the same person carry out both search and examination?
2.19 What searching resources do your staff have?: computers, access to databases
2.20 How do you do your search for plant/biotech patents? (contract out, CD-Roms, On-line, scientific community in the country)
2.21 How are patent agents/attorneys certified?
2.22 How is the office funded - % Government / % fees / . . . .
2.23 What is your fee schedule? Is there a one-time charge at application or is there also a maintenance fee. What are the amounts?
2.24 Do you consider the amount of the fee prohibitive for certain applicants? - Do you have different fee amounts based on the size/status of the applicant?

2.25 What sort of political pressures do you perceive influencing/pressuring in your agency/office, Could you give examples?
2.26 Do you carry out educational or awareness-raising activities?

3. Plant Variety Protection

3.1 Does the country have special provisions ref TRIPS 27(3) b: plant variety protection or do plant varieties fall under the patent system? How did the legislation come about? How do you regard this outcome?
3.2 Does it conform to UPOV – which Convention? – is the country a member of UPOV (under which convention?) - expl.: a country may comply with a UPOV convention without being a member!!
3.3 What aspects may be different from UPOV? – if different: any plans for change??
3.4 For which crops is protection currently available? Is there a list of crops (under UPOV '78) or all crop plants protectable? In the latter case – for which crops has the law been implemented so far?
3.5 Who is responsible for the testing of applications? (breeder, office, any institution as certified by the office)
3.6 What training do the examiners have?
3.7 What is their link with the national research institutes / breeding stations?
3.8 In case they have a dual task – how do you avid conflicts of interest?
3.9 In case they have an official task only: do they have enough work? (there may be only 1 or 2 applications per year)
3.10 Do you get applications for protection from public research institutes or only from private breeders/seed importers
3.11 Number of applications for PVP (total, by crop specifically for target crops); trends (over years) in terms of numbers and source of applications,
3.12 Number of applications vs. number of certificates granted – trends.
3.13 Is there any regional cooperation in DUS-testing?
3.14 Do you accept (or promote) the use of foreign DUS-reports?
3.15 Does the DUS-testing follow the UPOV-guidelines?
3.16 What resources are available: access to databases, trial fields?
3.17 How do you do you establish novelty, and how do you identify the most similar varieties of common knowledge for each application?
3.18 How are examiners certified? (if you use outside examiners in line with the Australian system)
3.19 How is the office funded - % Government / % fees / . . . .
3.20 Is there a one-time charge at application or is there also a maintenance fee. What are the amounts?
3.21 Is there evidence that this fee is prohibitive for certain applicants?
3.22 Are there provisions for compulsory licensing?
3.23 Do you receive influences/pressures in your agency, What kind, by whom?
3.24 Do you carry out educational activities?
3.25 Do you consider the courts capable enough in terms of enforcing IPRs?

4. Scenario

Discuss what actions your office, a company, or the legal system would be expected to take if:

- A farmer sold seed of a company's protected (conventional) variety to a neighbour
- A farmer sold seed of a company's (GM) variety to a neighbour
- There is evidence that a competitor is using one of a company's inbred lines in a new hybrid
- There is evidence that a competitor is producing and selling one of a company's varieties

2. Guidelines for interviews: Private Companies in the seed sector

N.B. It is important to note when there is an explicit or implicit reluctance to share potentially sensitive information for particular questions. – Do mark such matters in your report!!!

1. Nature of Company

(may need to BRIEFLY clarify these issues at time of interview if not known beforehand)

1.1 What is the ownership structure? (eg. private limited, joint venture, etc.)
1.2 Is the company national or international?
1.3 How long has the company been in business?
1.4 How was it established?

2. Company Varieties

2.1 How many varieties (for target crops) does your company market?
2.2 Obtain a list of current and past varieties of target crops with release dates, relative market share, distinguishing characteristics
2.3 What specific traits and markets do you concentrate on?
2.4 What are the major trends in type of variety or market that your company targets? Explain any changes, including the relative importance of IPR legislation.
2.5 Discuss trends in seed price and reasons for these trends, including any influence/cost of IPRs.

3. Marketing of Non-company Varieties

(i.e. varieties not developed by another company or a public institute)

3.1 Does the company produce seed of any public-sourced varieties? (Identify them)
3.2 How does it acquire the rights for these varieties? (Exclusive license?)
3.3 What payments are made to the public institute (for source seed, royalties, licenses, etc.)? Estimate proportion of seed price.
3.4 Are there plans to continue marketing public varieties? If there are any changes, what are the reasons; what role do IPRs play?
3.5 Does the company produce seed of other companies' varieties? (Identify them)
3.6 How does it acquire rights for these varieties? (Exclusive license?)
3.7 What payments are made to the other company (for source seed, royalties, licenses, etc.)? Estimate proportion of seed price.
3.8 Are there plans to continue marketing other companies' varieties? If there are any changes, what are the reasons; what role do IPRs play?

4. Company Breeding Programme

4.1 Does the company have a research/plant breeding programme for the target crop(s)?
4.2 How many breeders work on the target crop? (If possible, budget proportion devoted to plant breeding research; try to separate proportion for biotechnology)

4.3 Germplasm sources. What proportion of germplasm from public sources? Specify these sources. Arrangements for acquiring access to this germplasm.
4.4 Any changes recently or envisioned in access to public germplasm. Reasons for any changes, including relative role of IPRs.
4.5 How have IPRs affected your relationship with national and international public sector research organizations (access to material, capacity building, information, collaborative research agreements, marketing)? Describe specific experiences.
4.6 Germplasm sources. What proportion of germplasm used in breeding programme from other companies? Specify these sources. Arrangements for acquiring access to this germplasm.
4.7 Any changes recently or envisioned in access to other companies' germplasm. Reasons for any changes, including relative role of IPRs.
4.8 Effect of IPRs (patents, PVP, trade secrets, trademarks) on dealings with national or international companies (access to material, technologies, marketing, licensing agreements, exchange, etc.)
4.9 How have IPRs affected the company research programme in terms of investment, types of crops or traits, research focus or methods (biotech, hybrids, etc.)?
4.10 Do IPR regimes encourage the company to invest more in non-hybrid varieties?

5. Use of Biotechnology

5.1 Outline the company's current and projected use of biotechnology, including any GM varieties.
5.2 For the following technologies, check if the company uses each of them. If so, (a) do you know if the technology is protected in your country? (b) under what terms was it acquired? (c) will this affect the commercialization of products?
- AFLPs, microsatellites, microarrays
- Gene gun, agrobactor mediated, selectable markers
- Genes, gene constructs, vectors, promoters

5.3 Are there instances in which your institute has tried to acquire protected technology (including databases) and was unable to do so? What were the reasons? Did your IP policy play a role?

6. Protection of Company Products

6.1 How does the company protect its research products (particularly for the target crop)?
6.2 Discuss the use of PVP, patents, trademarks, trade secrets (e.g., inbred lines).
6.3 What other business management techniques are used to protect company products (physical security measures, personnel practices, types of contracts, types of business partner)?
6.4 Are there differences between protection practices for domestic business and foreign business?
6.5 Discuss trends in the use of these various protection methods and practices. To what extent does recent national IPR legislation have an effect on these trends?

6.6 What aspects of IPRs influence the company's use of these instruments (costs, timeliness, granting procedures, associated variety registration/certification requirements, culture, reliability, enforcement potential, international/regional collaboration or harmonization)?
6.7 Are IPRs affecting your market shares or those of your competitors?
6.8 How does the company enforce its IPRs? Are there specific cases of (suspected) infringement (if so, describe)? What are the costs to the company of monitoring and enforcement?
6.9 If you could make use of geographical indications, are there specific varieties you would like to protect?

Scenarios

Discuss what actions the company or the legal system would be expected to take if:

- A farmer sold seed of the company's protected (conventional) variety to a neighbour.
- A farmer sold seed of the company's protected (GM) variety to a neighbour.
- There is evidence that a competitor is using one of the company's inbred lines.
- There is evidence that a competitor is producing one of the company's varieties.
- A competitor adopts a similar product name, brandname or logo.

7. Company IPR resources

7.1 Does the company have an IPR policy? (If so, describe or obtain a copy.)
7.2 If the company has no IPR policy, why not?
7.3 Any recent evolution in company policy.
7.4 Advantages and disadvantages to the way IP issues are handled in the company.
7.5 How many personnel handle IPR matters for the company (full-time, part-time)? Does the company outsource professional services (e.g., attorneys) for IPR issues?
7.6 Try to estimate what IPR management costs the company (as proportion of final seed cost).
7.7 How does the company manage DUS testing? (depending on national application procedure; DUS = distinctness, uniformity, stability)

8. Access to Technology

8.1 How have IPR regimes affected the company's relationship with national and international public sector research organizations, including CGIAR centers (access to material, capacity building, marketing, collaborative research agreements)? Describe specific experiences.
8.2 How have IPRs affected the company's participation in South-North linkages related to germplasm and technology?
8.3 What have been the effects of IPRs (patents, PVP, trade secrets, trademarks) on dealings with national or international companies (access to material, technologies, marketing, licensing agreements, exchange, etc.)?

3. Guidelines for interviews: Public Sector Plant Breeding Institutes

1. General IP policy and management

1.1 Does the institute have an IP policy? When was it established?
1.2 Provide details of the policy and if it is written, obtain a copy.
1.3 What is the policy used for? Does it apply to all crops?
1.4 Is there a mechanism for review/revision?
1.5 What personnel are assigned to IP in the institute? (Provide details on numbers, part/full time, training, special training).
1.6 Is there an expectation that the institute should generate some of its own revenues? If so, what place do IPRs play in this strategy?
1.7 Has there been any discussion about how the institute's IP policy relates to national rural development policy? (For instance, is it expected that research products should be available to the poor?)
1.8 How does the ability to protect the institute's technology, and the dependence on protected technology, affect the institute's research policy?
- Increased (or changed) revenue
- Concentration of research on protectable technologies/crops
- Leaving certain types of research to the private sector

2. The IP policy related to the institute's own innovations

2.1 Who has authority to sign MTAs, licenses in the institute?
2.2 Try to obtain an example of an MTA and/or license agreement
2.3 Who is in charge of filing for PVP?
2.4 Who is in charge of filing for patents? (Provide examples, where relevant.)
2.5 Are there examples of filing for trademarks? What are they and who has done the work?
2.6 If royalties are received, what proportion goes to: the institute, the specific crop programme, the scientist?
2.7 Is the employee asked to assign his/her rights to innovations to the institute?
2.8 Is the employee asked to assign his/her copyright on data, manuscripts, etc. to the institute?
2.9 What aspects of these assignments of rights are specified in the employee's contract?
2.10 Are there examples where employees have left the institute, taking things with them?
2.11 Are there private spin-offs that have been established from public innovations from the institute?

3. IPRs in practice in the institute

3.1 How many of the institute's varieties are currently protected? (Try to get specific lists, by crop)
3.2 Identify the varieties that currently receive royalties.
3.3 How many of the institute's varieties are currently seeking protection?
3.4 Estimate the amount or proportion of current budget of institute derived from royalties on crop varieties; what is the projection for 5 years? (Try to break down by crop.)

3.5 Are there factors that limit the feasibility or attractiveness of seeking protection for plant varieties (e.g., length of testing and approval process)?
3.6 How many of the institute's biotechnology innovations are protected? (Obtain a list, or major examples.)
3.7 How many of the institute's biotechnology innovations are seeking protection?
3.8 Identify the biotechnology innovations that currently receive royalties.
3.9 Estimate the amount or proportion of current budget of institute from royalties on biotechnology; what is the projection in 5 years? (Try to break down by crop.)
3.10 Are there factors that limit the feasibility or attractiveness of seeking protection for biotechnology innovations?

4. Institute's policy related to protected innovations from elsewhere

4.1 Does the institute's policy cover the use of others' protected innovations (protected varieties, biotech tools, genes)?
4.2 Does the policy cover IPRs on jointly developed products?
4.3 Are there patented varieties that cannot be used in crossing programmes? If so, who owns the patents?
4.4 For the following technologies, check if the institute uses each of them. If so, (a) do you know if the technology is protected in your country? (b) under what terms was it acquired? (c) will this affect the commercialization of products?
- AFLPs, microsatellites, microarrays
- Gene gun, agrobactor mediated, selectable markers
- Genes, gene constructs, vectors, promoters

4.5 Does the access to any of the above technologies rest on understandings about segmentation in commercial application (e.g., only for the poor; only for domestic use)?
4.6 Are there instances in which your institute has tried to acquire protected technology (including databases) and was unable to do so? What were the reasons? Did your IP policy play a role?

5. Relations between the public breeding institute and seed companies (public or private)

5.1 Inventory of institute varieties currently in commercial seed production. Inventory should include: variety name; seed producer(s); type of protection (if any); type and amount of compensation (including royalties and fees).
5.2 Describe major examples of relations with seed companies; terms of license (e.g. ever give exclusive license?). Is there a standard procedure/license for seed companies, or is it ad hoc?
5.3 What resources/strategies does the institute devote to enforcement of agreements with seed companies?
5.4 How are relations between the institute and seed companies likely to change in the next five years? Why?

5.5 Are there mechanisms that allow the institute to supply germplasm (source seed) of crop varieties (protected and unprotected) that are not in commercial seed production to farmer groups or to individual farmers for multiplication and informal seed sharing? Are there factors that make this difficult?

6. Research priorities (at the institute or programme director level)

6.1 Have there been changes in investment by crop in the institute over the past decade? (Get statistics where possible, e.g., number of breeders.) What are the major reasons (and do IPRs play a role)?

6.2 What is the current (and projected) strategy for 'orphan crops' that are unlikely to attract commercial seed production?

6.3 What is the policy for staff promotion, and to what extent is it related to factors such as varieties released, farmer uptake of varieties, royalties generated, number of publications, etc.? (Do ranking)

6.4 For focus crop(s), have there been changes in breeding priorities (e.g., drought versus insect tolerance) or type of farmer targeted in past decade? If so, why?

6.5 For focus crop(s) have there been changes in sources of germplasm used in breeding programme in past decade? If so, why?

6.6 For focus crop(s) have there been changes in breeding strategies (hybrid v. OPV, MAS, transformations) in past decade? If so, why?

6.7 For focus crop(s) have there been any efforts at participatory plant breeding or other close interaction with farmers? Will changes in IPR regime have any effect on these efforts?

7. Research priorities (at the scientist level)

(For programmes with many breeders, it may be useful to interview a small sample to understand the degree to which institute policies and priorities are understood.)

7.1 Describe the institute's IP policy.

7.2 Who in the institute has the authority to sign an MTA?

7.3 For focus crop(s), have there been changes in breeding priorities (e.g., drought versus insect tolerance) or type of farmer targeted in past decade? If so, why?

7.4 What is the policy for staff promotion, and to what extent is it related to factors such as varieties released, farmer uptake of varieties, royalties generated, number of publications, etc.? (Do ranking)

8. Access to technology

8.1 Access to germplasm (South-South): Has access changed in the past decade? If so, how and why? To what extent are IP issues contributing?

8.2 Does participation in regional/international collaboration improve access to protected technology for research purposes?