AgroSpecial 2

Plant patents beyond control

Biotechnology, farmer seed systems and Intellectual Property Rights

Jaap J. Hardon

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Author: Jaap J. Hardon

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Foreword

This book has its origin in a broadly shared unease about the application of Intellectual Property Rights on biological material as they affect access to, and the use of biotechnology in agriculture and especially small farmer seed systems and crops. These problems arise because of the unique properties of plant materials to be reproduced, hybridised and transformed, both as a result of natural processes and through human intervention. This can lead to a quagmire of legal and civic prpblems that will harm the development and application of biotechnology as a useful technology in agricultural research. This study is concerned only with the transformation through biotechnology, and more specifically with IPR protection, of transgenic new characteristics in crop varieties, generally referred to as Genetically Modified Organisms (GMOs) or, in crops, GM varieties. We do not argue against the need to provide adequate and legally protected rewards to promote useful inventions in this area. However we question the "one-system-fits-all" approach that appears to have been adopted by industrial countries. This approach disregards important biological and social factors that are inherent to agriculture and food production. By highlighting such problems, especially evident in the agriculture of many developing countries, the report aims to provide a basis for debate on more appropriate sui generis (unique) forms of IPR that are tailored to the special nature of biological (planting) materials. It consciously refrains from aiming to provide solutions. Solutions depend on first properly understanding the problem. In our view the polarised nature of the controversy currently raging over biotechnology is obscuring an understanding of this key issue. The research that forms the basis of this book was financed by OXFAM - the Netherlands (formerly NOVIB). We gratefully acknowledge the flexibility afforded to us in executing this project. Their support does not necessarily imply specific endorsement of the content of this book. The project was undertaken by the AGROMISA Foundation for Small Scale Agriculture, located in Wageningen, the Netherlands. The analysis is done from two different perspectives: (i) from the perspective of international and national law and (ii) from the perspective of agriculture, farmers and plant breeding. These two perspectives do not necessarily lead to a common viewpoint and they are presented in a dialectical fashion.
The legal perspective is provided by Mr. Jan Anne Vos, who is an expert on international agreements of the T.M.C. Asser Institute, an inter-university research institute on international law in the Hague. The author Jaap J. Hardon is a former director of the Centre for Genetic Resources (CGN) in the Netherlands, with a long-term career in developing country agriculture. First as a plant breeder. He was subsequently involved in research and policy issues and was member of the Netherlands' representation in the FAO International Commission on Genetic Resources for Food and Agriculture and in the Consultative Group on International Agriculture Research (CGIAR). In these capacities, and as a trained geneticist, he has followed the developments in biotechnology in aid of food security closely and with great interest over the years.

Initially it was envisaged that the project would start with analysis of the various international agreements and selected national legislation on IPR relevant to biological planting materials. Subsequently this analysis would be followed by a workshop with various stakeholders, including farmers, representatives from private industry and the research community, IPR issuing authorities and civil society. As the study progressed this proved to be a bridge too far. The private industries approached were reluctant to commit themselves to stating their position or even entering into dialogue. Equally, a number of Civil Society Organisations expressed difficulties with our assumption that, in time, biotechnology might be accepted as a useful technology. IPR issuing authorities, with some exceptions, just took a narrow legal view, based on what constitutes an invention regardless of the content matter and its effect on society. This, in a way, typifies the stalemate in the present international dialogue and a confrontation of these

divergent views in a workshop was considered unlikely to modify such positions at the present time.

As a result, we decided to lower our ambitions. The present book is submitted as an attempt to analyse the problems, as we see them, that accrue from applying conventional IPR protection to biological planting materials that are important to farmers and food security, and to progress of this research in the general interest. A potential and valid criticism of this book is that it refrains from providing possible solutions. What we think is needed at this stage is that the various stakeholders in this controversy recognise that there is indeed a problem that needs to be considered.

We want to give special thanks to Mr Ab van Eldijk of the Agricultural University of Wageningen who shared with us his knowledge and understanding of the subject and the many people took the time to share their views and opinions with us. We would like to give special mention to the international NGO SEARICE who conducted farmer meetings and consulted national authorities in the Philippines. Their efforts, and especially those of Neth Dano and Elpido Ven Peria (Ping), were extremely helpful in understanding the concerns of farmers with regard to national policies. An important contribution was rendered by Dr.Bala Ravi, legal advisor to the M.S. Swaminathan Foundation in Madras (India) and former Assistant Director General (Intellectual Property Rights) of the Indian Council of Agricultural Research, who has been closely associated with the innovative Indian legislation on the subject.

We want to acknowledge the very helpful assistance provided by Harry Oppenoorth of HIVOS, in facilitating the analysis provided by national legal experts on the IPR legislation in Uganda - Arthur Mpeira, ACODE, Nicaragua - El Centro Alexander von Humbold, and El Salvador - CESTA. Special thanks are due to representatives of the various international organisations including the FAO - Jose Esquinas Alcazar, Alvaro Toledo Chavarri and Victor Mosoti, WTO - Mrs Jayashree Watal, UPOV - Dr. R. Joerdens and Dr. Makoto Tabata and WIPO - Mr. Shakeel Bhatti and Dr. R.Kjelgaard who provided us with important insights into the content of the various international agreements relevant to IPR. They gave their views in a personal capacity, which proved to be much more helpful than re-stating official policies and for which we are much indebted. The same applies to representatives of the Netherlands Biotech Industry Association - Dr. H. Raven, Dr. M.B.M. Bruins and Mrs. E.M.van Dijk - and Mr. K.A. Fikkert of the Netherlands Council for Plant Breaders' Rights. Dr. Michael Halewood, legal expert at IPGRI (Rome), Niels Louwaars (PRI -Wageningen) and Dr.C. Noome struggled through an early draft and provided many useful comments based on their intimate knowledge and understanding of international developments in intellectual property protection in agriculture. We want to express our special gratitude to personal contacts and colleagues in private industry , who in a personal capacity were willing to share their professional concerns and views on IPR as applied to planting materials with us. Special thanks are due to Dr. Janice Jiggins, Dr. Nicholas Parrott and mr. Edwin Nuijten who helped in critically reviewing and editing this document. They coped with a stylistic dialectical presentation with great understanding of the subject matter. Finally we want to acknowledge the help of Eva Kok of Agromisa who ably took care of the final editing and lay-out.

The author hopes that this document will contribute to a more rational international debate on the use of biotechnology in the general interest and to a better understanding of how IPR features in these developments.

Jaap J. Hardon.

Summary

This document covers:

- An introduction to the practices of Farmer Seed Systems in Developing Countries and of traditional plant breeding.
- Analysis of the introduction of Intellectual Property Rights (IPRs) regimes relating to biotechnology into International Agreements (such as WTO/TRIPS, the FAO Treaty on PGRFA, the CBD, WIPO and UPOV), International and National law.
- Analysis of the conflicts that exist between the interpretation of IPRs over genetically modified plant resources and traditional farmers' and plant breeders' practices relating to the ownership and distribution of planting material.
- Assessment of the effects of IPRs in hindering biotechnological developments that would be of benefit to small farmers and contribute to improving food security.

Biotechnology offers new options for crop improvement, which may potentially benefit agriculture and food security. However, its development, and introduction into agriculture, is riven with conflicts. These revolve around food safety and environmental issues as well as ethical concerns. Entrenched and conflicting views about the benefits and drawbacks of biotechnology are stifling dialogue about its potential, regulation and the structures required for equitably sharing the associated benefits and risks.

Drawing on two disciplinary perspectives, a perspective from international and national law and a perspective from agriculture, farmers and plant breeding, this document highlights the problems and conflicts created by applying Intellectual Property Rights (IPRs) to biological materials. Historically this has occurred because the promise of biotechnology has attracted a new group of players (multinational chemical and pharmaceutical companies) into plant breeding, who have bought a different set of protocols with them. The traditional concept, shared by farmers and plant breeders, that genetic material is a common good to be shared for universal benefit, has been displaced by one that views biotechnologically engineered plant materials as a private resource.

These companies, and their governments, have successfully lobbied organisations such as the WTO/TRIPS to extend the concept of IPRs to genetically modified plant resources. Their main justification is that such protection is needed to recoup the high levels of investment required for R&D. Yet the extension of patent rights to genetic materials also implies unprecedented levels of market control over plant materials, with serious implications for the practices of traditional Farmer Seed Systems and traditional plant breeders and potentially lucrative profits for these companies' shareholders.

The report analyses the legal basis and interpretation of IPRs provided through various International Agreements, international law and, national legislation in a selection of developing countries. A number of scenarios are used to describe events that have taken, or may take, place when genetically modified and patent-protected materials (GM varieties) are introduced into farmers' fields. These findings are set against the perspectives of agriculture and, particularly of those of small farmers. It is concluded that the various international agreements are sufficiently flexible to allow interpretations at the national level that are not necessarily inconsistent with the functioning of Farmer Seed Systems. However, such interpretations are subject to intense pressures through bilateral trade agreements and through the negotiations in the context of the WTO.

This exercise shows how the application of IPRs to planting materials creates a number of problems:

- It does not make biological sense to provide exclusive ownership rights in self-reproducing and hybridising living materials;
- It conflicts with the evolutionary nature of crop improvement;
- It conflicts with the practices and cosmo-vision of farmers and the functioning of Farmer Seed Systems, which form the basis of agriculture and food production in most developing countries.
- It conflicts with ways in which plant breeding regimes and the exchange of genetic material have operated for more than a century. In so doing it shifts access to, and control over, such resources from the public to the private domain.

The report concludes that IPRs, which are intended to provide a balance between rights provided to an inventor and the interests of society itself, are skewed in favor of inventors and corporations. This imbalance has far reaching effects on the application of, and access to, biotechnology and is one of the main factors hindering the acceptance and social usefulness of biotechnology. While it is indisputable that useful inventions in plant biotechnology (as in other research) should be rewarded and legally protected, this could be better achieved through a more appropriate sui generis solution, that also reflects the interests of society and food production.

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1 Introduction

The present document is the outcome of the project "Consequences of Intellectual Property Rights on biological materials as enforced by WTO/TRIPS on Farmer Seed Systems in Developing Countries" carried out by the Agromisa Foundation in co-operation with the T.M.C. Asser Institute on International law. NOVIB – Oxfam Netherlands, funded the project.

This study adopted a dialectical approach, building on the two different perspectives. These are, on the one hand, the perspective of Agromisa on small scale subsistence agriculture, and on the other, a legal perspective on the evolving international and national legislative framework relating to the use and development of genetic resources in agriculture with an emphasis on biotechnology. A dialectical approach in presenting the results and views has been adopted since the problems raised in this area have no simple or singular solutions.

Intellectual Property has become a contentious issue in agricultural crops with the birth of modern plant biotechnology. An early ruling of the Supreme Court of the United States in the Diamond v. Chakrabaty case in 1980 approved a patent for a genetically modified micro-organism. This opened the floodgate to expand patent protection to other living materials and associated processes. It superseded a far more modest existing *sui generis* Plant Breeders' Rights (PBR) legal protection. Plant Breeders' Rights evolved since the nineteen thirties when crop improvement, formerly practised by farmers, became an applied form of genetics carried out by specialised institutions and commercial seed companies. This seed industry was initially firmly embedded in the agricultural sector, guided by the interests of farmers. The chemical and pharmaceutical industrial complex was well placed to play a major role in further development of biotechnology and saw enormous potential for this technology in agriculture through genetic engineering. This industry demanded patents for a variety of biological products and processes resulting from biotechnological interventions and succeeded in extending the range of patentable subject matter in this direction. It was argued that biotechnology is similar in principle to other technologies, and that Intellectual Property Rights (IPRs) should not discriminate against this new technology. These developments have had far reaching consequences for plant breeding and access to new technologies for farmers. They have contributed significantly to a further shift of control over variety development from farmers and public research to the private sector, in tandem with an already apparent world-wide trend of increased privatisation of agricultural research.

Intellectual Property Rights on GMO's (Genetically Modified Organisms) and on technologies enabling the identification of useful genes and their transfer were considered by private industry to be important, not only in capturing return on investment in research, but also in gaining access to agricultural markets. Pressure from industrial countries and an intense lobby of multinational corporations at negotiations of the World Trade Organisation (WTO) led to a special Agreement on Trade Related Intellectual Property Rights regimes (TRIPs). At the same time initiatives were taken to harmonise patent laws through the World Intellectual Property Organisation (WIPO) in a "one size fits all" approach. Recognition of IPR protection was also included in the texts of the Convention on Biological Diversity (CBD) and the FAO Treaty on Genetic Resources for Food and Agriculture (FAO Treaty).

The TRIPs Agreement affords developing countries considerable flexibility in tailoring IPR regimes to their requirements in support of technological development. Article 7 of the WTO/TRIPS Agreement states that the objectives of the Agreement are: –"*the protection and enforcement of Intellectual Property Rights (IPRs) contribute to the promotion of technological*

innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to balance of rights and obligations". In addition the agreement provides for exceptions in granting rights in the general interest (Art. 30), including compulsory licenses (Art.31) under certain conditions. A key Article (27.3 (b)) allows countries to exclude plants and animals and essential biological processes from patentability. It provides the option of alternative *sui generis* systems of IPR protection, including forms of PBR. In effect, this Article would seem to allow developing countries to tailor IPR regimes to their economic development and agricultural requirements in a manner akin to the historical, and evolutionary, development of IPR regimes in industrial countries.

However, as an agreement TRIPS merely provides minimum standards which countries must adhere to as a condition of membership of the WTO. In addition to pressures exerted through WIPO, a concerted effort is being made through bilateral trade agreements, notably by the USA, to strengthen the level of patent protection in developing countries (Taylor et al, 2003). Essentially this means that developing countries are being denied the same conditions that, from the 1930s to the 1990s, allowed industrial countries to tailor IPR regimes to their national interests. This contradicts the stated objectives of the TRIPS agreement.

The present book is concerned with the interests of small and often subsistence, farmers. Recognising the realities of a global economy that is ruled by powerful industrial interests, it seems likely that many developing countries may succumb to strong pressures to adopt IPR regimes that provide more or less exclusive ownership rights over GMOs and enabling technologies.

Policymakers in the many developing countries where Farmer Seed Systems are the main source of seeds need to fully understand the consequences of such exclusive patent regimes when they are applied to GM crop varieties. Equally, the farming community needs to recognise how such patent regimes will affect their access to protected GM varieties and how they might protect their interests. Representatives of developed countries at WIPO and the WTO should not just take account of their own industrial interests, but also take into consideration how strengthened IPR legislation affects agriculture, food security and the availability of technology to farmers who are operating outside the global economy. For the purpose of illustration and analysis, this study develops a number of scenarios that describe what might happen if IPR is adopted to cover GM varieties and if such varieties enter into Farmer Seed Systems. These scenarios are described in chapter 3. A primary concern is equity of rights and specifically the issues of enforcement and enforceability.

An analysis was made of the various International Agreements, Conventions and Treaties (hereafter called "agreements") pertaining to ownership issues as they effect farmers. These include the World Trade Organisation (WTO) and associated agreement on Trade Related Aspects of Intellectual Property Regimes (TRIPs), the World Intellectual Property Organisation (WIPO) agreements, the Union for the Protection of New Varieties of Plants (UPOV), the Food and Agriculture Organisation (FAO) Treaty on Genetic Resources for Food and Agriculture (TGRFA) and the Convention on Biological Diversity (CBD).
Discussions were held with representatives of the Secretariats of these International agreements. These representatives, with the exception of those of UPOV, stressed that their opinions were personal and should not be considered as official statements. However, we were impressed and gratified by the apparent willingness shown in sharing their views with us in an open and critical manner.

In addition, in co-operation with national legal experts, we analysed national legislation passed in response to these Agreements in a few selected countries, including India, the Philippines, Brazil, Nicaragua, Uganda and Costa Rica. .

In chapter 2 - Setting the Scene- we provide an overview of Farmer Seed Systems and issues related to concepts of ownership, access and use of plant materials, from the perspective of agriculture and small farmers. We also deal with the actual and potential contributions of plant breeding and biotechnology of relevance to farmers operating within Farmer Seed Systems. This is done in the present economic and legal context of research and agricultural development.

In chapter 3 a number of scenarios are described and developed to illustrate actual and potential biological and legal consequences of the introduction of varieties protected by Intellectual Property Rights (IPR) in Farmer Seed Systems.

Chapter 4 deals with IPR in the context of international law and the various international agreements and institutions relating to ownership, access and use of crop genetic resources and small Farmer Seed Systems.

Chapter 5 provides a discussion of issues raised by the scenarios in the context of the various international Agreements and national laws in the selected countries. This is placed in the context of the economic and political realities confronting the concepts and interests of Farmer Seed Systems and those of the Industrial and Institutional Seed Industry.

Chapter 6 provides concluding remarks and recommendations.

2 Setting the scene

2.1 Introduction

The term "Plant Genetic Resources" (PGR) here refers to the total genetic diversity in crops and related wild species. They are an essential component of agriculture worldwide. For thousands of years, since the dawn of agriculture, biological diversity and the PGR of crops were considered a "gift of nature", a common heritage to be shared by all. When plants were being domesticated and evolved into crops, farmers realised the mutual inter-dependence with genetic diversity as crops spread from their original centres of diversity and were introduced into new environments. The genetic diversity contained in these crops allowed adaptation to an ever-widening range of different environmental conditions and human requirements.

Crop improvement takes place through an evolutionary process, with each generation of farmers and breeders making use of the efforts of past generations in slow processes of change, providing food and other products for livelihood security. It was not claims of ownership over crop improvement that brought gains to farmers, but the sharing and unrestricted utilisation of results. Therefore, farmers worldwide and most others involved in agriculture have always considered genetic diversity as a common good. Good neighbourliness is an essential survival strategy of (poor) farming communities and has contributed to the incredibly rich diversity of crops. The exchange of good seed is considered to be a shared interest. It is a sobering thought that, in spite of enormous investments in plant breeding, agricultural research and lately biotechnology, modern science has not created any genuinely new crops. Humanity is still totally dependent on what was inherited from the past efforts of farmers.

From the Industrial Revolution onwards, and with an ever-growing momentum through the twentieth century, the common good principle associated with PGR has been eroded. In the process farmers have become increasingly pushed to the sideline. From autonomous developers and owners of their crops and harvested products farmers have increasingly become mere producers of agricultural commodities, integrated in industrial processes. An agricultural philosophy of shared benefits and mutual inter-dependence has increasingly been replaced by an industrial philosophy dependent on a seed supply industry, motivated by market control and corporate profits. Modern developments surrounding PGR are guided less and less by the common good, and increasingly by the aim of securing private control. Ever-increasing yields go side by side with ever-increasing dependency.

2.2 Seed Systems

The universal interest of farmers is access to good planting materials, including seeds, tubers, roots and other vegetative parts used for the reproduction of appropriate varieties at affordable cost and available when required in the planting season. The term 'seed' in this book is used to refer to all of these planting materials.

Essentially two systems of seed supply can be recognised, which contrast in some basic principles of variety development and ownership and which have consequences for access and use.

The primary interest of farmers and agriculture is access to good planting material

- A Farmer Seed System (FSS), existing since farmers started to domesticate crops and develop locally adapted varieties (referred to as landraces or farmer varieties), in continuing processes of both human and natural selection.

- An Institutional or Industrial Seed System (ISS), where the tasks of farmers in improving and developing varieties have been taken over by specialised institutions, both public and private, using modern science. Seeds of such varieties are largely sold to farmers through quasi-governmental or commercial companies.

The FSS is part of what is generally referred to as traditional agriculture, while ISS is a component of modern agriculture. These descriptions can be misleading however as both have a role to play in both traditional and modern agriculture settings.

Traditional agricultural practices are relevant and appropriate to subsistence agriculture, to environments outside main market-oriented agricultural production areas and for minor crops of lesser economic importance. However, these crops typically are of major importance to local food security.

Modern agriculture, on the other hand, is relevant for market-oriented agriculture in environments and crops that are large enough to justify investments in formal plant breeding. A basic requirement of modern agricultural practices is that farmers can afford to buy modern varieties and provide inputs (fertilisers, chemical plant protection, irrigation etc.) to realise the improved genetic yield potential over locally adapted landraces. It can be argued that the main advance achieved in formal plant breeding is better use of external inputs to utilise increased genetic yield potential.

In most countries both systems operate side by side. In advanced industrial countries the commercial sector dominates but allows farmers, to various degrees, to save part of the harvest of modern varieties for their own use in subsequent planting seasons. In most developing countries the FSS is the major source of seeds, and may utilise both landraces and, often, modern varieties. In developing countries modern varieties are primarily supplied by public institutions, such as the International Future Harvest Institutes, funded internationally through the Consultative Group on International Agricultural Research (CGIAR). However, stimulated by globalisation, privatisation and economic development, the private seed industry is gradually becoming important in major commercial crops, even in developing countries.

Of central importance to the present project is the fact that these seed systems have totally contrasting basic principles, notably where it concerns ownership of varieties and genetic materials.

2.3 Ownership

The concept of ownership of planting material resulting from human interventions is central to the growing controversy that is the subject of this study. Analysis of the problems involved requires an understanding of the dichotomy in basic principles and practices and the differences in rationale that exist between traditional and modern agriculture.

Traditional agriculture

Humanity began to change from hunting and gathering to growing plants and keeping animals for its livelihood some 10,000 years ago. In the process, crops evolved through domestication that markedly differ from their wild ancestors, better satisfying human requirements and adapted to agricultural practices in ever widening environmental conditions. There is convincing evidence that even the earliest farmers consciously selected their plant material, a practice that continuous today. As agriculture expanded from original centres of origin, crops were introduced to new environments, encountered different a-biotic (soils, climate, temperature) and

biotic (pests and diseases) stresses and adapted to these. This adaptation has led to large numbers of local landraces of the various crops, both within and between regions and communities of farmers. A key characteristic of landraces is that genetic diversity is maintained, through natural processes and human intervention, which allows on farm selection and adaptation processes to continue, thereby establishing natural protection against pests and diseases and buffers against vagaries in the environment, both in time and in place. More than maximising yield, traditional agriculture aims at providing harvest security and sustainability of production over time.

Since the dawn of agriculture farmers selected in their planting material

The central role played by genetic diversity within and between crops in traditional agriculture is evident today. This genetic diversity has been developed and is largely maintained through use. Farmers grow their crops and apply a variety of practices, such as selecting seed after harvest for the next planting season. Seeds are a tool and not an objective in their own right. There is, by now, a wealth of documented evidence describing such practices, which differ in selection intensity, the division of labour and the often important role played by women, the major characteristics favoured and so on (for a review see Almekinders and de Boef, 2000). Landraces are often named on the basis of identifiable characteristics shared among communities. However, a common name may cover genetically diverse materials, due to independent selection by different farmers or even different genetic origins. As a rule, it can be said that farming communities share common gene pools (the total genetic diversity within shared genetic materials) with considerable exchange between communities. Due to the proximity of fields planted to different landraces for a variety of reasons (adaptation, yield security, taste, cooking quality etc.), there is a continuous gene flow between landraces. This occurs through incidental hybridisation. The limited quantities of seed selected for future planting also leads to random divergence between farmers using named landraces (referred to as "genetic drift").
This is clearly a rather schematic overview of traditional agriculture and FSS and many exceptions can be cited. However the main purpose is to present some overall principles relevant to concepts of ownership.

The previous paragraphs suggest that claiming ownership over the genetic content of specific planting materials is extremely difficult. However, this does not seem to be the main reason why in most traditional agriculture genetic materials are considered a common good. Throughout the history of traditional agriculture farmers have benefited from free exchange, recognising their mutual interdependence in their constant search for better materials. This free exchange has become part of a common agricultural philosophy in the struggle of mainly subsistence farmers for survival. It is an essential component of traditional agriculture.

Throughout the history of agriculture farmers benefited from free exchange

Modern plant breeding has benefited enormously from this principle in its search for and collection of material in farmers' fields for use in crop improvement programmes. Plant collectors from many industrial countries over the years obtained large collections of landraces, either directly from farmers' fields or donated willingly by farmers without asking for meaningful compensation. These collections are presently stored in numerous gene banks in both the public and the private sector.

Modern agriculture

What can be regarded as the elements of modern agriculture were introduced in Western Europe and North America in the Nineteenth Century. Technological developments in this era included chemical fertilisers, mechanisation, increased possibilities of irrigation and chemical

control of pests and diseases. This coincided with a better understanding of genetics, which provided the basis for scientific plant breeding. These developments led to increasing possibilities to control the diversity of environmental and other conditions affecting plant growth (soil fertility, water requirement, pests and diseases), adapting the environment to the requirements of specific crops and even to individual varieties. This represented the beginning of a dramatic change in agriculture. While previously crops and cropping systems were adapted to local and diverse environments, environments started to be adapted to the requirements of individual crops and even specific varieties; a process which continues today.

In modern agriculture, adaptation of crops to local environments is replaced by adapting the environment to crops and specific varieties

In modern plant breeding the need to breed for adaptation and yield security has been reduced, because it is possible to control external stresses. Breeding can now concentrate on maximising genetic yield potential. The logical consequences of the trends in modern agriculture are monocultures of a limited number of uniform varieties maximising yield and produced by specialised institutional and/or commercial plant breeding and seed production systems. The self-sufficient, farmer-controlled and self-reproducing FSS has thus been gradually replaced by a more linear process. Farmers are supplied with new varieties through a primarily private supply chain of plant breeding, seed production and distribution activities.

It is relevant to note that in industrial countries the evolution from traditional to modern practices, and from the FSS into the ISS, proceeded gradually. In this process rules and regulations for commercial planting material were developed with a twofold objective:

1 To protect the interests of farmers and to create a level playing field for competing seed companies. This led to Seed Legislation setting minimum standards for performance of marketed varieties, to Seed Certification and to agreed seed quality standards (regarding vigour, purity etc.).
2 To stimulate investment in private plant breeding. Plant Breeders Rights legislation was adopted (PBR) to protect the interests of plant breeders and to provide exclusive rights on the sale of protected varieties to recover the cost of research. Since 1961 PBR legislation in industrial countries has been harmonised in an International Convention (UPOV see Chapter 4) with major revisions strengthening protection in 1978 and 1991.

The Paris Convention of 1882, which formalised patents internationally, specifically excluded living materials. In the nineteen thirties, when legal ownership protection of new varieties by commercial companies became an issues, a conscious decision was made not to adopt the more stringent industrial patent protection. Important limitations of protection included a "Farmers' Privilege", allowing farmers to keep part of their harvest for the next year's planting and in some countries allowing "over the fence" sale of seeds of protected varieties to neighbouring farmers. In addition there were no restrictions placed on the use of protected varieties by others for the breeding of new varieties. This was referred to as the "Breeders' Exemption". Hence modern varieties remained freely available as a genetic resource, in the age-old tradition of agriculture. However, as the commercial seed industry became incorporated in large multinational companies, especially since the nineteen eighties, the industry has gradually demanded more stringent protection of new varieties, resulting in the 1991 revision of UPOV, which limited farmers' privileges in producing their own seed.

2.4 Biotechnology

The development in molecular biology, generally referred to as biotechnology, has far reaching consequences for plant breeding by adding new tools for the improvement of crops. Scientifically it represents an ongoing advancement in the understanding of the biological complexities of genetic control in living organisms.

Biotechnology refers to a range of research methods including, according to Persley *et al*, (1999):

- Genomics: the molecular characterisation of species
- Bioinformatics: the assembly of data from genomic analysis into accessible forms
- Transformation: the introduction of one or more genes conferring potentially useful traits into micro-organisms, plants, livestock, fish and trees
- Molecular breeding: the identification and evaluation of desirable traits in breeding programmes in living organisms by the use of marker assisted selection
- Diagnostics: the use of molecular characterisation to provide more accurate and rapid identification of pathogens and other organisms
- Vaccine technology: the use of modern immunology to develop recombinant DNA vaccines for improving control against diseases.

The present study is only concerned with transformation, and more specifically with IPR protection of transgenic new characteristics in crop varieties, generally referred to as Genetically Modified Organisms (GMOs) or, in crops, GM varieties.

The development and use of GM varieties in agricultural crops is mired in conflicts. There is an ethical concern, that transformation crosses natural species barriers and thereby affects the existing natural order. There is a concern about the possible side effects of transferred gene-complexes on the safety of foods. There is concern about the ecological effects of the introduction of GM varieties into the environment. Biotechnology has so far not yielded results that really convince consumers of its benefits, nor has it demonstrated an ability to contribute significantly to food security. In consequence many people, as consumers and citizens, are resisting a technology which they view as containing uncertain risks.

Here we do not enter into the above debate, however valid or important. For the scenarios that are tested in this book, the assumption is that new varieties may be developed by means of biotechnology and that these could provide real benefits in terms of food security, and to farmers and consumers without negative effects to the environment. Furthermore it is assumed that, over time, appropriate research into risk-analysis and meaningful control over various GM applications is possible and would lead to satisfactory results. However, the battle over these issues is far from finished. The struggle originating from a technology driven by an industry primarily concerned with immediate corporate profits threatens not only advancement in biotechnology research but also the trust of society in science and the motives of the scientists concerned. The argument used by industry, seemingly supported by the US government, that "no evidence of risk is evidence of no risk" is clearly insufficient to satisfy a majority of the industry's opponents

The conflicts over the introduction of GM crops are therefore based largely on bio-safety considerations, the safety of GM food products and of GM crops on the environment. While this falls outside the scope of this study, some observations may be made. Different approaches to bio-safety laws and regulations are becoming apparent, notably between the European Union (EU) and the US. These find expression in programmes aimed at assisting developing countries

in bio-safety capacity building. A US programme announced in 2003, funded by the U.S. Agency for International Development (USAID), takes as its premise that GM crops are safe unless proven otherwise. A German financed assistance programme, on the other hand, is based on the assumption that GM crops must be proven safe for human health and the environment before they can be commercialised. It should be noted that the US has so far not ratified the UN Carthagena Protocol on Bio-safety. Hence, developing countries, lacking in expertise in biotechnology and its many implications, are under pressure to implement bio-safety programmes for this new technology based on fundamentally conflicting approaches by industrial countries.

This study centres on the problems raised by applying industrial patent regimes to self-replicating planting materials (crop varieties), and more specifically when such materials are introduced into agricultural systems whose planting materials are generated by common-good principles for plant genetic resources.

2.5 Intellectual Property Rights (IPR)

Why patents in planting materials?

In the famous 1980-ruling of the Supreme Court of the US in the Diamond v. Chakrabaty case (referred to earlier) a patent was approved for a genetically modified micro-organism.

The chemical/pharmaceutical complex, which dominates biotechnology, demanded and succeeded in extending patentable subject matter to cover a variety of biological products and processes resulting from biotechnological interventions. They argued that biotechnology is in principle similar to other technologies and that IPR should not discriminate against this new technology.

Patents are a right conferred by society to an inventor. Society has an interest in stimulating innovation and does so by providing exclusive rights to the economic exploitation of a patented invention. Another way of looking at patents is to see them as a contract between society and the inventor. A common situation in contractual arrangements is that the separate interests of contracting parties have to be satisfied before a contract is entered into.

Patents are not an inherent right, but conditional rights conferred by society on the inventor

The rationale for subsequently extending the patent system from micro-organisms to plants and animals was the development of genetic engineering and related techniques, which allowed the transfer of genes across natural species barriers in living organisms, including plants and animals. Like in the USA, many patent offices in developed countries decided that biotechnology did indeed introduce new techniques that met criteria for patentable inventions, unlike the common techniques used in conventional plant breeding. In addition it was felt that biotechnology involved higher costs of research and development justifying higher levels of IPR protection than PBR, that would assist in the recovery of these higher costs. This would seem to be a reasonable argument.

Problems with patents in plants

Some important aspects would appear to have been conveniently overlooked in the decision to extend patent protection to biological materials. The decision assumes that there is no difference between biological material and non-living matter as a subject for invention, nor does it take account of differences in the use of such inventions.

According to common interpretation, a patent is a right granted by a government to inventors to exclude others from imitating, manufacturing, using or selling a patented process or product for commercial use for a period of usually 17-20 years. In return for a patent the inventor discloses how the invention works so that the knowledge is available to the public. To obtain a patent, the subject matter has to be novel and inventive, i.e. not obvious to a person skilled in the art. Patent law contains a provision known as 'research exemption': which allows others the right to study the protected subject matter, but not to commercially benefit from it. The extent of this research exemption is however subject to interpretation. For instance, in the US this exemption does not exist on statute and is interpreted extremely narrowly i.e. for philosophical or private purposes only. Hence, unlike PBR, reproducing or multiplying the patented material in any form is not permitted.

However, the attempt to restrict the use of patented biological products or processes is fraught with problems as patented biological products have an inherent natural ability for reproduction and hybridisation with material that does not contain the patented subject. Natural cross-pollination between crops in neighbouring fields often goes undetected. Thus, the transfer of the patented subject is virtually impossible to avoid, especially under conditions found in Farmer Seed Systems.

Legal ownership of (biological) entities the spread of which through natural processes can not be contained creates a legal quagmire

Secondly, restrictions on the use of the patented subject matter do not take account of the evolutionary nature of plant breeding. It ignores relevant national and public interests, such as food security and the health of rural communities, notably in more marginal environments. Common PBR legislation recognises that a new variety is usually based on past achievements in variety improvement. In order to benefit society at large such improvements need to be bred into other varieties that are adapted to the diverse environments in which the crop is grown. The assumption of 'one variety fits all environments' does not make biological sense. Enforcing exclusive access to patented improvements restricts their use to single varieties, typically often only bred for high potential environments and profitable markets. Hence improvements leave out characteristics that may benefit less commercially developed farmers and regions.

Restriction in he use of patented subject matter in plant breeding conflicts with its evolutionary nature and limits use of biotechnology in the interest of food security

A further consideration, also linked to the complex and step-wise process of plant breeding and the nature of biological material, is that improvements through the techniques of biotechnology often not depend on a single patented technology, but require access to a number of them. If such patents are held by different IPR holders, as is often the case, obtaining licenses for their use involves complicated negotiations and the need for a strong bargaining position. This puts small companies and the government institutions that are mainly responsible for agricultural research for small farmers, at a disadvantage. This conflicts with the objectives of patents, stated in Article 7 (objectives) of the TRIPS agreement. This affirms that: *"the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovations and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations".*

Private industry sources argue that the need to gain access to patented technologies held by different patent holders is a common requirement for companies that want to produce new products for different markets. A standard example put forth is the production of radios involving numerous patented technologies. However, the difference here is, that it may exclude indi-

vidual industries from producing certain products, but does not exclude users from access to such products. A radio works wherever it is used. In biotechnology, restricted access and use of technologies exclude access for use in crops and varieties for the poor and negatively impacts on food security.

Patents have become important pawns in competition for control over agricultural and food markets

The proliferation of patent holders is proving to be a serious problem in biotechnological research and access to its results for the common good. Expectations that biotechnology would revolutionise crop improvement motivated a number of pharmaceutical/ chemical corporations that hold leading positions in biotechnological research, to establish a dominant position in plant breeding by buying-up seed companies on a global scale. They viewed food production as an interesting new market. The merging of agricultural chemicals, plant breeding and pharmaceutical industries into what is commonly referred to as the "Life Sciences Industry" was facilitated further by a trend over the past twenty years towards the privatisation of previously public research in plant breeding and agriculture. The need for universities and public research institutes to supplement their finances with external sources of funding reinforced this trend. Much research, even if carried out in the public domain, is now at least partially funded by private seed companies, and is often subject to various forms of IPRs and commercial agreements. The result is that restrictions are imposed on universities regarding the way in which they may distribute such materials. Patents have become important pawns in the competition for control over agricultural and food markets. It is reasonable to conclude that the opening of the possibility of obtaining exclusive patent rights in biotechnology has contributed to a seed industry that is now dominated by a few huge international, industrial conglomerates that only serve commercially profitable markets. In applying patent protection to planting materials, patent issuing authorities do not seem to have considered how such patents affect a broad range of producers and users. It compromises the social and economic systems of small farmers and farming communities and their contributions to national food security in many developing countries.

Objectives of the present study

The present study was carried out to highlight the problems that accrue from introducing patent protected plant materials (varieties of crops) into Farmer Seed Systems that are based on free exchange and mutual inter-dependence. It questions:

- How patent protection on planting materials and enabling technologies affects the transfer and dissemination of technology
- Whether this is to the mutual advantage of producers and users.
- Whether such patenting is conducive to social and economic welfare.
- How they effect access, use and conservation of agrobiodiversity

The US, and to a lesser extent the EU actively promote agricultural biotechnology and support a strong patent protection for gene traits, tools for transformation and genetically improved varieties (see Taylor and Cayford, 2003). In addition, through WTO/TRIPS and WIPO, pressures are exerted to obtain worldwide recognition of such patents, with little concern for the social outcomes or how society can obtain maximum benefit from such innovations. The main beneficiaries so far seem to be large corporations that have little economic incentive to develop and disseminate the technology to meet the needs of overall food security and the interests of small farmers in developing countries. How are the interests of millions of small farmers represented? How are the requirements for seed of small farmers, as major producers of food and seeds in developing countries, considered? What is the impact on the role of small farmers as creators and custodians of agrobiodiversity? What role do these considerations play in various

international agreements? To what extent do these international agreements allow nation-states to tailor their IPR legislation to take account of these farmers and their particular needs? These were the questions that motivated this project and the writing of this report. They are developed in a number of scenarios described in chapter 3.

These questions were (partially) answered by analysing various international agreements relevant to conservation and use of biological diversity in Chapter 4. These include the FAO Treaty on Plant Genetic Resources for Food and Agriculture (FAO Treaty), the Convention on Biological Diversity (CBD), the WTO/TRIPS agreement, the World Property Organisation (WIPO) agreement and the International Union for the Protection of Plant Varieties (UPOV). These analyses were followed-up by discussions with representatives of the secretariats of the various agreements. In addition, national IPR legislation enforced by WTO/TRIPS, passed by a number of selected developing countries - India, the Philippines, Brazil, Nicaragua, Costa Rica and Uganda -were reviewed with the assistance of national experts in those countries.

The scenarios, developed to illustrate what may happen when IPR protected materials enter farmers' fields, are described and analysed in chapter 5, from both the legal and the farmers' perspective. This illustrates the legal, social, technical and economic problems that will surface.

It should be stated emphatically that no argument is made about the need to stimulate useful inventions by providing appropriate rewards. Also no position is taken on the (potential) significance of biotechnology in crop improvement.

3 Scenarios on introduction of IPR protected varieties into farmer seed systems

3.1 Project Rationale

This chapter analyses the possible consequences of the recognition of Intellectual Property Rights (IPRs) on crop genetic material for Farmer Seed Systems.

Given the important role of Farmer Seed Systems in the agriculture of most developing countries, the consequences of the recognition of IPRs on genetic material in conventional international law needs to be analysed and fully understood.

In consultation with, and legal support from, the T.M.C. Asser Institute, a Dutch inter-university research institute on international law, Agromisa identified a number of questions regarding the normative situation of small farmers and local communities *vis-à-vis* IPRs on genetic materials. In order to present these questions in a realistic context, scenarios were developed to cover actual and potential situations that might arise if genetic material protected by IPRs enter into Farmer Seed Systems. These questions and scenarios are described in this chapter. The objective is to consider and illustrate how IPRs on genetic material might, or might not, be compatible with Farmer Seed Systems. A central problem underlying the various scenarios is that the reproduction and spread of genetic material protected by IPRs and its incorporation into other genetic materials, is affected by natural processes, which cannot be contained in the context of the agricultural practices and socio-economic conditions of Farmer Seed Systems. This basic feature of genetic material is highly relevant in the consideration of the normative situation of local/traditional farmers *vis-à-vis* IPRs on genetic material. It seems to constitute an inherent conflict between the concept of an IPR, which relates to a particular characteristic or gene and therefore isolates such a gene or characteristic from other genetic material, and the natural processes through which genetic material combines and reproduces.

3.2 General considerations

1 An IPR is issued on the basis of national legislation. To what extent does the granting of such an exclusive right take into account other relevant public interests, such as sustainable agriculture, food security, environment, or health?
2 If an IPR is granted on a gene or genetic characteristic in State A, but State B does not recognise that IPR, how should such a situation be considered from the perspective of (conventional) international law? In asking this question we need to pay particular attention to:
   - The TRIPS Agreement
   - The Convention on Biological Diversity
   - The International Treaty on Plant Genetic Resources for Food and Agriculture
   - The UPOV Convention
   - Relevant WIPO Conventions

These International Agreements all affect, in one way or another, the conservation, use and access of the genetic resources used in agriculture. However, they start from different objectives and were largely negotiated in different international fora and separately interpreted within their own context. The following scenarios are used to analyse the extent to which these Agreements take account of the fundamentals of Farmer Seed Systems and what the actual or potential consequences are or might be. Final responsibility for interpreting international law rests with national governments. These scenarios are meant to aid policy makers to arrive at an

interpretation that is compatible with the requirements of their agricultural sector. In addition, the scenarios may clarify what is at stake for farmers and how they need to protect their specific interests.

3.3 Scenarios

Scenario 1: Access to, and use of, modern varieties by small farmers

Farmers can obtain seed of an IPR protected variety in different ways. They may obtain such seeds under specific contractual arrangements. It is also possible that they obtain seed material (unknowingly) contaminated with an IPR protected variety or trait (for instance in food aid shipments - Box 3.1, or contaminated non-GM seed – Box 3.2.). When other farmers in this, or neighbouring communities, wish to try the variety, the farmers who acquired the seed will give it to them in accordance with the social practices of traditional farming. Through such farmer-to-farmer exchange the modern variety can spread rapidly, similar to the processes of diffusion following the release of "Green Revolution" varieties by the CGIAR Centres. Without such farmer-to-farmer exchange, the Green Revolution would not have had the rapid impact that it did in increasing national food production in many developing countries in the 1970s and 1980s. However, the holder of the IPR will consider this practice to form an infringement of the IPR. Boxes 3.1 and 3.2 provide reported examples of how this has already happened.

Box 3- 1

Accidental distribution of GMO seed
It is reported that farmers in some Angolan provinces are growing genetically modified (GM) seeds that entered the country through food aid shipments. Elizabeth Matos, coordinator of Angola's National Centre of Phyto-Genetic Resources, said that the farmers did so because of a lack of available seeds for this years planting season. Matos warned that GM plants could contaminate and alter local crop varieties and said that the Angolan Government should stop allowing GM products to enter the country.
XINHUA News Agency (2003)

Box 3-2

Distribution through Farmer Seed Systems
Monsanto Co. has stopped selling genetically modified (GM) soybean seeds in Argentina because it is unable to make a profit on their sale. The company says that widespread farmer-to-farmer seed exchange, which it refers to as "a huge black market" for seeds has made it impossible to recoup its investment.
http://www.agbios.com/main.php?action=ShowNewsItem&id=5178

If the IPR holder wishes to enforce his rights, this is likely to involve identifying the farmers growing the new variety in its original form and instigating legal procedures against them. This will raise a number of problems including:

- Identifying where the new variety is grown will require visiting numerous fields of small farmers in possibly remote areas.
- Small farmers may be growing the new variety in mixed stands with their traditional varieties.
- Non-existence of extension services in many areas, or their lack of co-operation, will complicate identification of farmers growing the new variety.
- National courts may be reluctant to deal with proceedings against large numbers of small subsistence farmers, in order to avoid social and political problems.
- The enforcement of the IPR may create a public relations problem for the holder of the IPR.

- Whether or not the farmer knew, or ought to have known, that his planting material contained a protected GM trait (i.e. the state of farmers' knowledge).

Commentary

IPRs on self-reproducing biological material seem difficult to enforce under conditions of Farmer Seed Systems. Adopting legislation that either cannot be enforced or is detrimental to a system that forms the basis of agriculture in most developing countries would seem undesirable. On the other hand, without IPR protection, potentially valuable new varieties might not become accessible to small subsistence farmers, adversely affecting food security.

Legal questions

Consideration of the above raises the following legal questions:

1 In the context of the TRIPS Agreement and national legislation, what workable options can be identified that enable small farmers to have access to new protected varieties in a manner that is compatible with Farmer Seed Systems, which are an important source of genetic diversity for modern plant breeding?
2 In the context of the TRIPS Agreement and national legislation, what workable options can be identified that enable IPR holders to protect their rights when a variety is used in Farmer Seed Systems?
3 If a farmer mixes a protected variety into a landrace and exchanges this mixture with a neighbour, does this constitute an infringement of the PBR? Is it relevant whether the protected variety constitutes 10%, 49%, 51% or 90% of the mixture? Does it make a difference whether the farmer knew, or did not know that the variety mixed into his landrace contained IPR protected material?
4 If a farmer transfers the seed of a landrace containing an IPR-protected characteristic to a neighbour who produces for non-commercial purposes, does this constitute an infringement of the IPR or PBR? Is it relevant whether the seed is exchanged through barter (1 to 1), barter of planting material (1 to 2 or more), or sold?

Scenario 2: Gene-flow in traditional agriculture

A modern GM variety (for instance of maize) is purchased in small amounts by a number of small farmers. This maize variety is grown in small plots adjacent to plots grown with local landraces. The modern variety hybridises through natural pollination with local landraces. Farmers harvesting those local landraces observe increased variability and select to maintain the quality of the local landraces, and possibly increase yield potential through the newly introduced genes from the modern variety. This is a normal procedure in Farmer Seed Systems. If the purchased variety also contains a gene covered by an IPR, this is likely to have become incorporated in the local landraces (see Box 3.3).

Box 3- 3

GM Corn Spreading in Mexico

A new study sponsored by a coalition of indigenous and farmers groups (2003) has found that "contamination" of Mexican maize crops by GM maize is more widespread than previously reported. Working with biologists from the National Autonomous University of Mexico, the coalition used commercially available GM test kits on some 2000 crop plants from 138 farming and indigenous communities. Transgenes were identified in native corn from 33 communities, in nine Mexican states. The transgenes all originated from GM maize varieties patented by international biotechnology companies. Silva Ribeiro of the environmental organisation ETC Group says that GM "contamination" is probably the result of farmers planting some of the five to six tons of maize that enter Mexico each year from the US. The imported maize, some of which is brought in as food aid, is intended for consumption, but as Ribeiro explained drought in some areas of the country has caused "farmers who don't have any of their own seed left to use the US corn", in spite of the government ban on GM cultivation.

http://soyatech.com/bluebook/news/viewarticle.ldm?a=20031016-7

This raises a number of problems including:

- It is difficult and costly to trace introgressed, IPR-protected, characters in genetically variable planting material grown by numerous small farmers.
- The occurrence of genes protected by IPRs within farmer varieties may vary, from occasional to frequent, depending on both natural and farmer selection.

Commentary

Once new varieties are grown in farmers' fields, it is impossible to contain their genetic identity because of processes of natural introgression. If a right is granted on characteristics, of which the spread cannot be controlled, this would seem to affect the rights of farmers over the use of contaminated local landraces.

Legal questions

This scenario raises a number of questions:

1 How is the question of the relation between IPRs and the process of natural introgression considered in the TRIPS Agreement?
2 Can the holder of an IPR on a gene be held liable for not containing this gene, especially if it has detrimental side effects on local landraces?

Scenario 3: Gene-bank Collections

A collector for a gene bank collects local landraces. These are entered into the gene bank and later released to a plant breeder who uses the material as one of the parents in a conventional breeding programme. After the usual 8-12 rounds of selection the plant breeder releases a final variety. It then appears that (through previous natural introgression) it incorporates a character or gene protected by an IPR, which was linked to another characteristic or gene that the plant breeder had selected for. The holder of the IPR might adopt the position that the final variety infringes their IPR on the characteristic or gene. The plant breeder might respond that the breeding material was obtained from a gene bank and that he or she did not have had any knowledge of the gene or the IPR. While there are no reported examples yet of such events, similar events could occur in other ways, including mistaken identity of seed samples distributed by gene banks (Box 3- 4).

Box 3-4

Accidental distribution of GMO seed

Researchers at the University of California (Davis), say that they have accidentally shipped genetically modified (GM) tomato seeds to researchers around the world over the past seven years. These seeds, originally donated by a seed company, were misidentified as belonging to a non-GM line and distributed to researchers in 14 countries and to demonstration gardens in the UK and Ethiopia, two countries where the product was not approved. Michelle Marvier, assistant-professor of biology at Santa Clara University stated "Its disturbing, but fits into a pattern. This kind of thing is going to happen over and over again, no matter how careful we try to be, and next time it might be something not so benign". Joe Mendelson, legal director at the Centre for Food Safety in Washington DC , agreed. "There is a setting for those mix-ups to happen". http://www.agbios.com/main.php?action=ShowNewsItem&id=5107

This raises a number of questions:

- A gene bank generally does not have the facilities to screen collected materials for individual characteristics, and therefore cannot guarantee their genetic properties.
- A requirement on the part of the plant breeder to screen breeding material for the possible inclusion of genes protected by IPRs, would seem to be burdensome and contravene the purpose of the gene bank system.

Commentary

Under the conditions of a Farmer Seed System, the holder of an IPR cannot control dispersal of a gene protected by the IPR through natural introgression. Furthermore, under the present state of knowledge, a plant breeder or the owner of the IPR, cannot selectively remove a gene protected by an IPR from a newly bred variety, except by a lengthy and costly process of repeated backcrossing.

Legal questions

The questions considered above raise a number of legal questions:

1 Is a gene bank responsible for the material it distributes? Would a gene bank be infringing an IPR if, without prior knowledge, it distributed material that contains a patented gene?
2 Can the owner of an IPR on a gene claim legal rights over a newly bred variety, if both the gene bank and the plant breeder acted in good faith and could not be expected to have prior knowledge of the occurrence of that gene in the breeding material?
3 Can the plant breeder of a newly bred variety claim compensation from the holder of the IPR for not containing the gene or for contaminating the breeding material?

The Genetic Resources Policy Committee of the CGIAR will address these issues in a meeting in August of 2004 to provide guidance to gene banks.

Scenario 4: Essential derivation

According to Article 14(5) of UPOV (1991), a breeder's right does not apply to a variety that is essentially derived from a protected variety. If a breeder changes a variety minimally through e.g. the selection of a mutant after repeated backcrossing, the new variety, assuming it satisfies the PBR requirements for Distinctiveness, Uniformity and Stability (D.U.S.) can get PBR protection. However, according to Article 14(5) of UPOV (1991), the breeder of the original variety can claim rights over such an "essentially derived" variety. This means that the breeder of the variety has to enter into an agreement with the holder of the rights of the initial variety in order to commercialise his, essentially derived, variety. On the other hand, essential derivation is a common and accepted feature in Farmer Seed Systems.

Legal question

1 If a breeder uses a local landrace that is more or less uniform, identifies a mutant and applies for a PBR, can the owner (a farmer or community) from whom the local landrace was obtained oppose the PBR on the basis of the concept of essential derivation?

Scenario 5: Inventions of general interest

Through research in the commercial sector a new genetic system is developed and protected by an IPR. For instance a gene is isolated that provides a new form of resistance against pests or diseases. With regard to food security, it seems to be in the interest of society as a whole that this new characteristic is incorporated into as many varieties as possible, including farmer-bred landraces in different environments. However, such wider societal interest seems incompatible with the exclusivity of the IPR. The same applies to IPR protected technologies needed for developing GM varieties in crops, or for environments, not covered by the patent holder. This applies specifically to numerous smaller crops of lesser economic importance. Fragmentation of IPRs in multiple private and public institutions is identified as an important barrier to the biotechnology being applied in the general interest. The general nature of this problem is illustrated in Box 3-5.

Box 3-5

Concern about access to patented technology

Public Sector Collaboration for Agricultural IP Management.

A group of scientists of major universities in the US led by the president of the University of California (R.C. Atkinson) note that through biotechnology and increased IP protection of agricultural inventions, agricultural research in major crops and enabling technologies is shifting from the public sector to the private sector. This leaves responsibility for research in smaller crops, including subsistence crops important to developing countries, mostly in the hands of the public sector. While many significant discoveries and technologies are still generated by public research, privatisation and reduced public spending in research frequently leads to licensing such discoveries on an exclusive basis to private industry. Fragmentation of IPR in the hands of multiple private and public institutions is identified as an important barrier to the application of biotechnology in the public interest and agriculture, notably in developing countries. The group, referred to as the Public-Sector Intellectual Resource for Agriculture (PIPRA) stops short of challenging the appropriateness of patenting biological materials, but intends to explore options for broadening access to IP protected inventions in agriculture and IP management by public institutions in the general interest.

Science, vol. 301, 11 July 2003

http://www.pipra.org

This raises the following question. National authorities grant IPRs to an inventor. Are there options for such national authorities to limit IPRs in order to ensure the rapid incorporation of the genetic system in other varieties, including farmer-bred varieties, while providing a reasonable and appropriate financial reward to the holder of the IPR?

Commentary

PBR includes the possibility of issuing licenses for the production of seed of PBR-protected varieties by third parties, if the holder of the PBR fails to provide an adequate supply of seed to cover demand. In the case quoted here, by seeking to limit the new characteristic to their own variety, adapted only to particular (often high potential) environments, the patent holder does not seem to be adequately satisfying demand.

Common patent systems also include a compulsory licensing clause. The key question is how easily this clause can be applied. Most companies strongly oppose application of this clause for the obvious reason that this reduces their exclusive use and control.

Legal questions

1 Are there options for limiting the rights afforded by IPRs in individual cases on the basis of inadequately meeting market or societal demands?
2 In this respect, how is the possibility of compulsory licensing evaluated?
3 What mechanisms are available to establish reasonable and appropriate payment for the use of IPR-protected inventions in the general interest of society?

In chapter 5 these scenarios are analysed in the legal context of national and international law and the legal consequences are discussed from both the perspective of small farmers and the economic realities facing developing countries.

4 The normative relation between IPRs relating to genetic material and farmer seed systems – a perspective from international law

The five scenarios described in chapter 3 refer to situations involving Farmer Seed Systems and raise questions regarding the normative relation between farmers participating in a Farmer Seed System and holders of an IPR (PBR or patent) relating to genetic material. This chapter discusses the concepts and rules of international law as a prelude to discussing the issues in more depth in the following chapter. Particular, reference is made to the TRIPS Agreement and the UPOV Convention (1991). In addition, we consider the relevance of the Convention on Biological Diversity and the International Treaty on Plant Genetic Resources for Food and Agriculture and relevant parts of the agreements reached as part of the World Intellectual Property Organisation.

4.1 The concept of international law

International law is commonly defined as governing relations between States, which are considered by international law to be sovereign and independent institutions. International law is commonly considered as having two main constituent sources; customary international law and conventional international law. The former is formed on the basis of the practice of States and the latter is considered to consist of binding texts denominated as treaties, conventions, and agreements or otherwise. This chapter concentrates on conventional international law.

In theory and practice international law is commonly constructed in a vertical manner. This means that the rules of international law, derived from the sources of international law, are constructed above States. Two forms of this vertical construction may be identified: an obligating form and an authorising form. In the obligating form the function of rules of international law is constructed as limiting the otherwise factual and normative freedom of States to act. In the authorising form, the function of international law is constructed as authorising States to act factually and normatively. In the absence of such rules, States are considered not to have a factual and normative power to act. It should be noted that the obligating form of international law is considered to constitute the predominant role within international law.

In general, the application of rules of international law is considered to be limited to States. That means that these rules do not apply directly to members of societies that are situated within States. This also applies if the rules of international law confer rights upon members of societies, for example intellectual property, or human, rights. In this way, the rules of international law only apply indirectly to members of societies situated within States, as a reflection of obligations imposed on States by rules of international law. It should be noted that, in both the theory of international law and in the practice of States, the rules of international law can apply directly upon members of societies situated inside States. However, this ‘direct effect’ is dependent on the constitutions of States and not on rules of international law. Thus the constitution of a State determines whether rules of international law apply directly to members of society situated inside the State.

As with international law, the function of the internal law of the State is also constructed in a vertical manner. The same two forms of a vertical construction can be identified: an obligating form and an authorising form. In the obligating form, the function of rules of the internal law of the State limits the factual and normative freedom of members of society to act. The obligat-

ing form is based on the assumption that, in the absence of internal rules, members of society have a factual and normative freedom to act. In the authorising form, members of society are allowed to act factually and normatively. The authorising form is based on the assumption that in the absence of such rules, members of society do not have a factual and normative power to act. In practice these two forms are commonly combined.

4.2 The concept of Intellectual Property Rights

The concept of intellectual property right (IPR) seems to combine both forms of the vertical construction of the function of the internal law of the State. On the one hand, it seems to assume that the intellectual activity of members of society (inventors) is stimulated in an environment in which the members of society have a factual and normative freedom to act. It is considered, however, that the freedom of other members of society to act may be detrimental to the interests of those performing this intellectual activity. By exercising their freedom to act, these other members of society might deprive inventors performing the intellectual activity from the fruits of that activity. In the obligating form, rules limiting the factual and normative freedom to act of the other members of society are relied on to protect the interests of those (the inventors) performing the intellectual activity. Hence, the concept of IPR seeks to protect the interests of inventors by conferring a right upon them to exclude acts of other members of society. The concept of IPR thereby adopts elements of the authorising and obligating forms of the internal law of the State.

The concept of IPR is thus based on the assumption that the intellectual activity of an inventor should be protected. This assumption is not disputed in this report. At the same time, however, the inventor should not be able to hinder the intellectual activity of other members of society. Accordingly, the exclusive right conferred on the inventor must be limited, so that other members of society can use the knowledge in further intellectual work. The same rights of protection will apply to this subsequent work.
Interpretation of the latter is of primary concern in the area of agriculture, food and health where the application of an IPR protected invention, for socially beneficial purposes, may depend on the application on crops and in environments that are not covered by the inventor for economic or other reasons.

IPR should not prevent use of protected technologies in crops and environments not covered by the patent holder.

In Section 2.5, reference was made to two ways of viewing the concept of a patent. In one view, a patent is regarded as a right conferred by society (or national legislation reflecting the interests of society) on an inventor. According to another view, a patent is the result of a contract between society and an inventor. The authorising form of a vertical construction of the function of the internal law of the State follows the first approach. A patent is regarded as dependent on, and conferred by, national legislation. The institution of the State is deemed to represent society at large. National legislation, which confers patents, is assumed to balance all the interests involved. If this first route is followed, this means that, although a patent may be regarded as an exclusive right, it is not an unlimited right. If it were, it would arrogate to the holder of the patent the right to determine the extent of the patent and disregard the role of the institution of the State and the factual and normative power and freedom of other members of society.

The concepts of sovereignty and independence commonly associated with the institution of the State imply that a State may adopt its own political, economic, social and cultural systems.[1] In the context of IPRs, this freedom is considered to extend to and include IPRs. Thus, State A and State B may adopt diverging policies regarding IPRs. For example State A may consider that genetic material constitutes an appropriate subject matter for protection by an IPR, while State B may consider that it does not and that it cannot be protected by an IPR. Within the structure of sovereign equality (both State A and B are considered sovereign and independent) neither state can criticise the other for their policy stances. The exception to this is if rules of international law have been established which limit the respective freedoms of States. These freedoms are limited only to the extent of such international laws. In any consideration of such disputes between States A and B could thus be referred to the relevant rules of international law.

It should also be noted that the concept of sovereignty is also deemed to include the resources of States (including economic or biological resources). According to Article 3 of the CBD, States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental or economic policies. This right also includes the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States, or of areas beyond the limits of national jurisdiction. Similarly, Article 10.1 of the FAO Treaty provides that, in their relationships with other States, the Contracting Parties recognise the sovereign rights of (other) States over their own plant genetic resources for food and agriculture. This includes the authority to determine access to those resources.[2]

International humanitarian law, which is not considered here, provides other examples where international law recognises exceptions to absolute state sovereignty providing potentially useful precedents.

A distinction is commonly made between the terms "intellectual property" and "industrial property". The term intellectual property is regarded as more comprehensive, comprising all rights relating to intellectual activity. The term industrial property is considered to cover all rights relating to intellectual activity with industrial application, but to exclude copyright. The concept of industrial property is further subdivided into specific rights, such as trademarks and patents. A patent is commonly defined as an exclusive right relating to an invention, which satisfies the requirements of novelty, inventive step and industrial application. A plant breeding right (PBR) is commonly defined as an exclusive right relating to a plant variety, which is new, distinct, uniform and stable. In this report, IPR is used to refer comprehensively to both patents and to PBRs. A PBR is essentially a *sui generis* form of IPR allowing the direct use, and not just the knowledge, of the patented product for further development. This is a very basic and important difference.

4.3 Interpretation

It is important to stress the role of interpretation in determining how the rules of conventional international law are applied to given situations. These rules are inferred from the texts of the applicable conventional international law. In this regard reference is often made to Article

[1] Resolution 2625 (XXV), *The principle of sovereign equality of States* (e): Each State has the right freely to choose and develop its political, social, economic and cultural systems.

[2] See also Resolution 3/91 of the Conference of the FAO, point 1: [Endorses] that nations have sovereign rights over their plant genetic resources.

31(1) of the Convention on the Law of Treaties. This prescribes as a 'general rule of interpretation' that a treaty will be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in its context and in the light of its object and purpose. This rule of interpretation is also adhered to in WTO jurisprudence.[3]

It should, however, be noted that the ordinary meaning of the terms of a treaty, in the context and in the light of the object and purpose of the treaty, does not necessarily lead to a definitive interpretation of the text of the treaty, which can exclude other possible interpretations. In other words, the text of a treaty may allow two (or more) diverging interpretations, both of which may appear consistent with the text of the treaty. This space for interpretation can be viewed from different perspectives. On the one hand, it may be seen positively, as a flexible attribute that allows for adaptation of the treaties to developments in international society. On the other hand, it may be seen as revealing the inherently political character of conventional international law.

4.4 Conventional international law

The scenarios described in the previous chapter refer to the TRIPS Agreement and to the UPOV Convention (1991). They relate to what is commonly referred to the *sui generis* option under TRIPS (Art.27(3)b) and *inter alia* to the Paris Convention (1882) for patents. In addition, the Convention on Biological Diversity (CBD) and the International Treaty on Plant Genetic Resources for Food and Agriculture (FAO Treaty) also have relevance for these scenarios in the light of conventional international law. This chapter describes these agreements in more detail in order to provide the basis for the more detailed examination of the implications of these scenarios that follows in chapter 5.

International Convention for the Protection of New Varieties of Plants (UPOV - 1991)

The UPOV Convention (1991) seeks to harmonise the national plant breeders' rights legislation of member states. These protect the normative position of plant breeders with respect to new varieties of plants by conferring an exclusive right, itself consisting of rights, on the plant breeder. Contracting Parties to the UPOV Convention (1991) have undertaken to guarantee to meet these obligations. This is specified in Article 2 of UPOV (1991), which states that the basic obligation of the Contracting Parties consists of granting and protecting PBRs.

PBR is a *sui generis* IPR adapted to the special nature of biological materials in the form of newly bred plant varieties. It takes account of the evolutionary and step-wise process common to the breeding of new plant varieties, allowing use of results achieved previously as the raw material for further improvement. There is no requirement for a unique invention. The main requirement is that a variety is "new" in the sense of not having been commercialised before and Distinct from "varieties of common knowledge". It should satisfy reasonable standards of Distinction and Uniformity to allow recognition, and Stability in further multiplication. These requirements are generally referred to as the DUS standards. The criteria for ownership are restricted, in that they are limited to commercialisation of the protected variety. Use of the protected variety in further breeding by other parties is not restricted. The following section provides a summary of the key Articles of the UPOV Convention.

[3] Report of the Appellate Body, *United States – Gasoline*, 16-17; Report of the Appellate Body, *Japan – Taxes on Alcoholic Beverages*, 10-12.

Summary of major Articles of the UPOV Agreement

Conditions of protection

Article 5(1) UPOV (1991) enumerates the conditions of protection and provides that a PBR will be granted if a variety is new, distinct, uniform and stable.

Criteria of protection

Articles 6-9 of UPOV (1991) define criteria that determine whether those conditions are satisfied. Under Article 6, a variety is deemed to be 'new' if, at the date of filing the application for a PBR, propagating or harvested material of the variety has not been sold, or otherwise disposed of, to others, by, or with the consent of, the breeder for the purposes of exploiting the variety. This is subject to certain time limits. Article 7 provides that a variety will be deemed to be 'distinct' if it is clearly distinguishable from any other variety whose existence is a matter of common knowledge at the time of the filing of the application. Under Article 8, a variety will be deemed to be 'uniform' if, subject to the variation that may be expected from the particular features of its propagation, it is sufficiently uniform in its relevant characteristics. Article 9 stipulates that a variety will be deemed to be 'stable' if its relevant characteristics remain unchanged after repeated propagation or, in the case of a particular cycle of propagation, at the end of each such cycle. Attention should be drawn to the circularity of these definitions. For example, the definition of the term 'distinct' in Article 7 refers to the requirement that a variety be 'distinguishable'. Similarly, the definition of 'uniform' in Article 8 refers to the requirement that a variety be sufficiently 'uniform'. In practice, this does not detract from the usefulness of these criteria. However, the interpretation and level of criteria applied remains subject to continuous debate as new techniques are developed in both crop improvement and in measuring genetic differences.

Exclusive rights

Article 14(1)(a) specifies a number of acts in respect of the propagating material of a protected variety that require authorisation of the holder of the PBR. These include: production or reproduction (multiplication); conditioning for the purpose of propagation; offering for sale; selling or other marketing; exporting; importing; and stocking for any of these purposes. Paragraphs 2-4 of Article 14 detail the rights of the PBR holder in respect of unauthorised use of propagating material and state that authorisation of the breeder is required unless the breeder has had reasonable opportunity to exercise his rights. These rights cover: acts in respect of the harvested material (para. 2); acts in respect of certain products made directly from the harvested material (para 3), and; possible additional acts that reasonably interfere with the rights of the PBR holder (para. 4). While PBR rights are essentially exhausted once protected varieties, obtained through channels authorised by the breeder, reach farmers' fields, paragraphs 2-4 are included in order to provide reasonable opportunities for the breeder to exercise his rights on unauthorised use of his varieties.

Essential derivation

Article 14(5) relates to essentially derived and certain other varieties. It protects the breeder against use of his variety in a manner that does not involve a meaningful breeding effort and that retains the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety. Hence, a variety is considered to be essentially derived if it results from selection of a natural or induced mutant, or of a soma-clonal variant, the selection of a variant individual plant of the initial variety, from repeated backcrossing or from transformation by genetic engineering.

Exceptions

Article 15 deals with exceptions to the PBR. Article 15(1) provides that a PBR does not extend to: acts done privately and for non-commercial purposes; acts done for experimental purposes, and acts done for the purpose of breeding other varieties, and in respect of such other varieties. In addition, Article 15(2) provides that each Contracting Party may, within reasonable limits and subject to the safeguarding of the legitimate interest of the holder of the PBR, restrict a PBR relating to any variety. This can be done in order to permit farmers to use, for the purposes of propagation, on their own holdings, the product of a harvest that they have obtained, by planting the protected variety, on their own holdings.

Exhaustion

Article 16 deals with exhaustion of the PBR. Article 16(1) stipulates that the PBR will not extend to acts concerning:

i) any material of the protected variety which has been sold, or otherwise marketed, by the holder of the PBR, or with his consent in the territory of the Contracting Party concerned, or;

ii) any material derived from that material, unless such acts involve further propagation of the protected variety, or involve export of material of the protected variety which enables the propagation of the protected variety.

Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)

The TRIPs Agreement became part of the WTO negotiations largely as a result of pressure from industrial countries. It was a response to the increased involvement of private industry, and notably since the 1980's large multinational agrochemical companies, in plant breeding and associated biotechnology activities, which had previously been largely carried out by public institutions. This industry saw strengthened IPR protection of their varieties on a worldwide basis as the most effective way to obtain return on their investments. Central to this Agreement in the context of the present analysis is Article 27. 3(b), which states " ... *Members will provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof*". The most relevant articles in this agreement are outlined below.

Review of relevant articles of the TRIPs Agreement

The TRIPS Agreement contains obligations upon States that concern trade-related aspects of IPRs. Part I contains general provisions and basic principles. Part II, Section 5, contains standards concerning the availability, scope and use of patents.

Exhaustion, objectives and principles

For the consideration of the scenarios, attention may be drawn to Articles 6-8, contained in Part I of the TRIPS agreement. Article 6 deals with the question of exhaustion of IPRs. According to Article 6, for the purposes of dispute settlement under the TRIPS Agreement, nothing in the Agreement will be used to address the issue of the exhaustion of IPRs. Article 7 describes the objectives of the TRIPS Agreement. It states that the protection and enforcement of IPRs should contribute to the promotion of technological innovation and to the transfer and dissemination of technology. It specifies that this should be to the mutual advantage of producers and users of technological knowledge, in a manner conducive to social and economic welfare, and which maintains a balance of rights and obligations. Article 8 formulates the principles of the TRIPS Agreement. Article 8(1) provides that Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development. However any such measures should be consistent with the provisions of the TRIPS Agreement. Article 8(2) stipulates that appropriate measures, so long as they are consistent with the provisions of the TRIPS Agreement, may be needed to prevent abuse of IPRs by rights holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

Availability of patents

Part II, Section 5, of the TRIPS Agreement deals with patents. Article 27(1) provides that patents will be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Article 27(2) stipulates that Members may exclude certain inventions from patentability, if their commercial exploitation within the territory is considered to endanger public order or morality, including the protection of human, animal or plant life or health and/or the avoidance of serious prejudice to the environment. However, such exclusions should not be made merely because such exploitation is prohibited under their law. Article 27(3)(b) provides that Members may also exclude from patentability plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. It further provides that Members will provide for the protection of plant varieties either by patents, by an effective *sui generis* system or by any combination thereof.

Exclusive rights

Article 28 determines the rights conferred by a patent. Article 28(1)(a) provides that, where the subject matter of a patent is a product, exclusive rights are conferred on the owner to prevent third parties, who do not have the owner's consent, from making, using, offering for sale, selling, or importing for these purposes that product. Article 28(1)(b) provides that, where the subject matter of a patent is a process, exclusive rights are conferred on the owner to prevent third parties, who do not have the owner's consent, from using that process and from using, offering, selling or importing for such purposes, the product obtained directly by that process. It should be noted, however, that pursuant to footnote 6 of Article 28, that while conferring exclusive rights on the holder of a patent, this does leave open the question of the exhaustion of those rights.

Exceptions
Article 30 of the TRIPS Agreement deals with exceptions to the rights conferred. Article 30 stipulates that Members may provide for limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner. Such exceptions must take the legitimate interests of third parties into account.

Convention on Biological Diversity (CBD)

The Convention on Biological Diversity (CBD) was a major outcome of the United Nations Conference on the Environment and Development (UNCED) at Rio de Janeiro in 1992. Its objective was to safeguard biological diversity worldwide, to promote sustainable use of such resources and to facilitate appropriate access and fair and equitable sharing of benefits accruing from the use of genetic resources. Emphasis is placed on national sovereignty over natural biological diversity and the responsibility of States to take the necessary actions to conserve such diversity. Obligations include the development of national strategies, plans and programmes for conservation and sustainable use of biodiversity, the identification and monitoring of biodiversity, research, training and public education. In the context of the present document, the obligation to respect IPRs, wherever they are recognised is important. This obligation must, however, conform to the objectives of the Convention (Article 16).

Review of relevant articles of the CBD

Definitions
The central concept in the Convention on Biological Diversity is the concept of biological diversity. According to Article 2 of the CBD, biological diversity means the variability amongst living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part. The concept includes diversity within species, between species and of ecosystems. Article 2 further defines genetic material as any material of plant, animal, microbial or other origin containing functional units of heredity. Genetic resources are defined in Article 2 as genetic material with an actual or potential value.

Objectives
Article 1 of the CBD defines the objectives of the CBD as the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising from the utilisation of genetic resources. This is specified as including appropriate access to genetic resources, appropriate transfer of relevant technologies (taking into account all rights over such resources and technologies), and by appropriate funding.

Sovereignty
Article 3 defines as a principle that States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies. They also have the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or to areas beyond the limits of their national jurisdiction.

In Situ Conservation and Sustainable Use
Article 8 addresses the objective of *in-situ* conservation. Article 8(j) provides that each Contracting Party will, as far as possible and as appropriate, and subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity. Contracting parties will with the approval and involvement of the holders of such knowledge, innovations and practices, promote their wider application and encourage the equitable sharing of the benefits arising from the utilisation of such knowledge, innovations and practices. Article 10 addresses the objective of sustainable use of components of biological diversity. Article 10(c) CBD provides that each Contracting Party will, as far as possible and as appropriate, protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation and sustainable use requirements.

Fair and Equitable Sharing of Benefits
Articles 15 and 16 address the objective of the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources. Article 15 CBD deals specifically with access to genetic resources. Article 16 CBD deals specifically with access to and transfer of technology.

Access to Genetic Resources
Article 15 deals with access to genetic resources. Article 15(1) provides that, given the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with national governments and is subject to national legislation. Article 15(4) provides that access, where granted, will be on mutually agreed terms. Article 15(5) provides that access to genetic resources will be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.

Access to and Transfer of Technology
Article 16 CBD deals with access to and transfer of technology. Article 16(1) provides that each Contracting Party undertakes to provide and/or facilitate access for and transfer to other Contracting Parties of technologies relevant to the conservation and sustainable use of biological diversity or make use of genetic resources that do not cause significant damage to the environment. The second sentence of Article 16(2) provides that in the case of technology subject to patents and other IPRs, such access and transfer will be provided on terms that recognise, and are consistent with, the adequate and effective protection of IPRs. Article 16(5) provides that the Contracting Parties, recognising that patents and other IPRs may have an influence on the implementation of the CBD, will co-operate in this regard in order to ensure that such rights are supportive of, and do not run counter to, its objectives. Such co-operation will be subject to national legislation and international law.

International Treaty on Plant Genetic Resources for Food and Agriculture (FAO)

The FAO Treaty on Plant Genetic Resources for Food and Agriculture (FAO Treaty) has its origin in the early 1980's. There was an increased awareness of perceived inequalities in access to and use of the remaining genetic diversity important to agriculture. It was argued that centres of origin of most crops are located in the tropics and sub-tropics, mainly in developing countries. Such resources are, with few restrictions, accessed by plant breeders in developed countries and the resulting products (improved varieties), are subsequently subject to PBR protection. It was recognised that there was a need for developing countries and farmers that supply sources of genetic diversity to share in the benefits of such plant breeding. After long and often acrimonious debate it was finally agreed that, in the interest of agriculture, genetic resources important to crops should be viewed as a "Common Heritage of Mankind" This concept entails open access. Also relevant in this context are the requirements for a Mutual Transfer Agreement (MTA) and the principle of Prior Informed Consent (PIC) that were introduced by the CBD to safeguard the interests of countries and farmers supplying genetic diversity for use in plant breeding. It was also realised and stated in a resolution in 1989 that in the *sui generis* PBR protection the principle of open and unrestricted access for further breeding of protected varieties remained upheld. These principles seemed to provide a reasonable balance between interests. However, the development of biotechnology protected by exclusive patent rights pertaining to GM varieties upset this balance. The FAO Treaty differs from the CBD in that it is primarily concerned with (potential) genetic diversity in agriculture, whereas the CBD is primarily concerned with natural biodiversity. Equally importantly, the emphasis of the CBD on the national sovereignty over genetic resources appears to be in conflict with the basic principle of agriculture that views the genetic resources for food and agriculture as a "Common Heritage of Mankind". This common heritage principle appeared in the text of the FAO International Undertaking on PGR preceding the FAO Treaty, but was excluded from the latter to avoid conflict with the CBD. These tensions illustrate once again the basic problem of reliance on international agreements negotiated in different fora with different objectives. The attempt to make the FAO Treaty compatible with the CBD led to an arduous process of negotiation in the FAO Commission on Plant Genetic Resources for Food and Agriculture, particularly in order to address the issue of benefit sharing. As a compromise it was proposed to establish a mul-

tilateral agreement to which countries may voluntary subscribe. This facilitates open access to genetic resources for specifically identified crop species in a Multilateral System of Access and Benefit Sharing.

Review of relevant articles of the FAO Treaty

Objectives
Article 1 defines the objectives. Article 1.1 provides that the objectives of the FAO Treaty are the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the CBD, for sustainable agriculture and food security.

Farmers' Rights
Part III, consisting of Article 9, deals with Farmers´ Rights. In Article 9.2 the Contracting Parties agree that the responsibility for realising Farmers´ Rights, as they relate to PGRFA, rests with national governments. Article 9.2 further provides that, in accordance with their needs and priorities, each Contracting Party should, as appropriate, and subject to its national legislation, take measures to protect and promote Farmers´ Rights. These measures can include:
i. protection of traditional knowledge relevant to genetic resources;
ii. the right to equitably participate in sharing benefits arising from the utilisation of genetic resources; and
iii. the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of genetic resources.
Article 9.3 specifies that the concept of Farmers´ Rights will not be interpreted as limiting any rights that farmers have to save, use, exchange and sell farm-saved seed or propagating material, subject to national law and as appropriate.

Multilateral System of Access and Benefit-Sharing
Part IV, consisting of Articles 10-13, establishes a Multilateral System of Access and Benefit Sharing. Article 10.1 provides that, in their relationships with other States, the Contracting Parties recognise the sovereign rights of States over their own genetic resources, including that the authority to determine access to those resources rests with national governments and is subject to national legislation. Article 10.2 stipulates that, in the exercise of their sovereign rights, the Contracting Parties agree to establish a multilateral system, which is efficient, effective and transparent. This is intended to facilitate access to genetic resources and to ensure that the benefits arising from the utilisation of genetic resources are shared in a fair and equitable way and in a complementary and mutually reinforcing basis.

Facilitated Access
Article 12 deals with facilitated access to PGRFA within the Multilateral System. Article 12.3(d) provides that recipients of PGRFA will not claim any IPRs or other rights that limit the facilitated access to the PGRFA or their genetic parts or components, in the form received from the Multilateral System. Article 12.3(f) provides that access to PGRFA protected by IPRs and other property rights will be consistent with relevant international agreements and relevant national laws.

Benefit Sharing
Article 13 deals with benefit sharing in the Multilateral System. Article 13.2(b)(i) provides that access to, and transfer of, technology, improved varieties and genetic material will be provided and/or facilitated, while respecting applicable property rights and access laws. Article 13.2(b)(iii) stipulates that such access to and transfer of technology will be provided on terms that recognise and are consistent with the adequate and effective protection of IPRs.

4.5 International institutions

Several international institutions are relevant in connection with the scenarios set out in chapter 3. These include the WTO, the FAO, the WIPO, the UPOV and the bodies of the CBD. These international institutions have varying relationships with the international conventions, treaties and agreements described in Section 4.4.

CBD

Article 23(1) of the CBD establishes a Conference of the Parties. According to Article 23(4) the Conference of the Parties will keep under review the implementation of the CBD and perform the functions set out therein. In addition, Article 24(1) establishes a secretariat and defines its functions. The CBD has thus established its own institutional bodies that are not formally related to an existing international institution.

UPOV

According to Article 23 of the UPOV Convention (1991), the Contracting Parties establish and are members of a Union. According to Article 24(1), the Union has a legal personality. Article 25 provides that its permanent organs are the Council and the Office of the Union. The tasks of the Council are enumerated in Article 26(5). As with to the CBD, the UPOV Convention has thereby established its own institutional bodies.

FAO Treaty

Article 19.1 of the FAO Treaty establishes a Governing Body. Article 19.3 provides that the functions of the Governing Body will be to promote the full implementation of the treaty and in particular the performance of the tasks enumerated therein. In addition, Article 20.1 provides for the appointment of a Secretary whose functions are defined in Article 20.2. Article 1.2 further determines that the objectives of the FAO Treaty, set out in Article 1.1 will be achieved by closely linking the FAO Treaty with the FAO. According to the last recital of the Preamble, the FAO Treaty is concluded as an international agreement within the framework of the FAO under Article XIV (1) of the Constitution of the FAO. The treaty is a result of the work of the Commission on Genetic Resources for Food and Agriculture (CGRFA), established under Article VI (1) of the Constitution of the FAO.[4] It is important to note, however, that this does not provide the FAO as an international institution, its organs (Conference; Council) or the Commission with competences with regard to the FAO Treaty. The FAO Treaty is therefore formally linked to the FAO, but simultaneously constructed as an autonomous structure.

WTO

The TRIPS Agreement is a Multilateral Trade Agreement that forms Annex 1C to the Agreement establishing the World Trade Organisation. In accordance with Article II(2) of this Agreement, it is an integral part of the Agreement establishing the World Trade Organisation. The main organs of the WTO are the Ministerial Council and the General Council, established respectively by Articles IV(1) and IV(2) of the Agreement establishing the World Trade Organisation. In addition, Article IV (5) establishes a Council for Trade-Related Aspects of Intellectual Property Rights (Council for TRIPS) with the task of overseeing the functioning of the TRIPS Agreement. Article VI (1) establishes the Secretariat of the WTO. The WTO differs from the other international institutions and bodies that we have considered previously in it has a formal and binding mechanism (the Dispute Settlement Body - DSB) for the settlement of trade disputes between members. This is set out in the Understanding on Rules and Procedures governing the Settlement of Disputes (DSU), which forms an integral part of the Agreement establishing the World Trade Organisation. Article 3(2) of the DSU provides that the dispute settlement system of the WTO is a central element in providing security and predictability in the multilateral trading system. Members recognise that it serves to preserve their rights and obligations under the 'covered agreements', which includes the TRIPS Agreement, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law. It provides further that the recommendations and rulings of

[4] Resolutions 9/83 and 3/95.

the DSB cannot add to or diminish the rights and obligations provided for, *inter alia*, in the TRIPS Agreement.

WIPO

The WIPO is not formally connected to any of the four international agreements considered in Section 4.4, but does play a central role with respect to IPRs. According to Article 3(1) of the Convention establishing the World Intellectual Property Organisation, its objectives include the promotion of intellectual property throughout the world through co-operation among States and, where appropriate, in collaboration with other international organisations. In addition, WIPO is responsible for performing the administrative tasks of the Paris Union, established by Article 1(1) of the Convention for the Protection of Industrial Property. Members of the WTO are required to comply with Articles 1-12 and 19 of this Convention, pursuant to Article 2(1) of the TRIPS Agreement. In addition WIPO has established an Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore, which is relevant to consideration of the scenarios.[5]

4.6 Interrelations

Relations between conventions, treaties and agreements

To understand how these treaties, conventions and agreements, relate to the scenarios discussed in chapter 3, it is first necessary to outline the normative relationships that exist between them. In the theory of international law and in the practice of States, an international agreement is regarded as an autonomous instrument that reflects the collective will of the States / contracting parties with respect to the subject matter regulated therein. This means that all applicable agreements should be applied simultaneously. In addition, it is assumed that such agreements (or provisions contained within them) are not in conflict with one another.[6]

If conflicts do exist between different international agreements (or provisions contained within them) there are two ways in which such conflicts can be dealt with under international law:

- the relation between the international agreements may be determined in the texts thereof;
- the relation between those international agreements may be determined by virtue of the rules (i) *lex posterior derogat priori* and (ii) *lex specialis derogat generali*.[7]

We fist consider the possibility that relationship between international agreements is determined in the texts thereof[8]. Article 1.2 of the FAO Treaty provides that the objectives defined in Article 1.1 of that treaty will be attained by closely linking the FAO Treaty to the CBD. At the same time, recitals 9-11 of the Preamble determine that the relation between the FAO Treaty and other treaties or conventions is not to be understood as representing a relation of hierarchy.[9]

[5] WO/GA/26/6; WO/GA/26/10.

[6] Report of the Panel, *Indonesia – Automobile Industry*, 14.28.

[7] [Pauwelyn, Role,]

[8] Convention on the Law of Treaties, Article 30 (2).

[9] Preamble, recitals 9-11 ITPGRFA: *Recognising* that this Treaty and other international agreements relevant to this Treaty should be mutually supportive with a view to sustainable agriculture and food security; *Affirming* that nothing in this Treaty shall be interpreted as implying in any way a change in the rights and obliga-

Article 22(1) CBD claims a qualified precedence over other international agreements. This means that the provisions of the CBD will not affect the rights and obligations of any Contracting Party deriving from any other existing international agreement, except where the exercise of those rights and obligations would cause serious damage or threat to biological diversity.[10] However, it must be noted that a full hierarchy between the CBD and other treaties, conventions and agreements would also require the recognition of the precedence of the CBD in relevant other international agreements. In addition, the precedence of the CBD over other agreements is dependent on establishing the occurrence or potential danger of serious damage or threat to biological diversity caused by the exercise of rights and obligations deriving from that other international agreement.

We can conclude therefore that the texts of these international agreements do not provide sufficient basis for establishing a hierarchical relation between these agreements. The rule of *lex posterior derogat priori* (the later treaty prevails over the earlier treaty)[11], only applies if both treaties deal with the same subject matter.[12] This does not appear to be the case with the international agreements under consideration in this report. Although the subject matter of these agreements may be related, their subject matter may be said to be different. Application of the *lex specialis derogat generali* (a special treaty prevails over a general treaty)[13], requires the establishment of a relation of generality-speciality between international agreements. It seems difficult to establish such a relationship between the international agreements that we are considering. For example, the CBD deals with biodiversity in both a general and specific sense.

The conclusion is that the rules of international law do not provide a sufficient basis to establish a hierarchy between these various international agreements. However, this issue arises only if one international agreement (or a provision of) is considered to conflict with (a provision of) another.[14] Such a conflict would then lead back to the question of the interpretation of conventional international law, referred to in Section 4.3. In view of the inherent flexibility of interpretation of conventional international law, it is commonly considered that the interpretation of conventional international law should be directed at avoiding conflicts between (the provisions of) different agreements.[15] This is sometimes referred to as 'harmonious' interpretation.

Relations between international institutions

If the question of the normative relation between IPRs relating to genetic material and Farmer Seed Systems falls within the competence of different international institutions, the question of the normative relation between those international institutions must also be addressed. This question can fall within the competence of the WTO (trade relations between Members), of the FAO (agriculture) and of the WIPO (protection of intellectual property). Accordingly, the question of the normative relation between these international institutions arises. With regard to this question, the constitutions of international institutions commonly provide for the possibility of

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tions of the Contracting Parties under other international agreements; *Understanding* that the above recital is not intended to create a hierarchy between this Treaty and other international agreements.

[10] Marceau, Conflicts, 1090-1091.

[11] Marceau, Conflicts, 1091-1092.

[12] Convention on the Law of Treaties, Article 30 (3).

[13] Marceau, Conflicts, 1092-1093.

[14] In this connection, reference may be made to the diverging positions adopted within the TRIPS Council over the question whether the TRIPS Agreement conflicts with the CBD; TRIPS Council, Relationship, 5-13.

[15] Marceau, Conflicts, 1086-1090.

concluding agreements of co-operation with other international institutions.[16] One such Co-operation Agreement was concluded between the WTO and the WIPO in 1996. However, this Agreement does not address questions such as the interpretation, and application, of conventional international law to specific situations.[17] In this context, it seems the WTO, the FAO and the WIPO all have a competence to address the question of the normative relation between IPRs relating to genetic material and Farmer Seed Systems, but that none of these organisations have an exclusive competence in this area.

[16] Constitution of the Food and Agriculture Organization of the United Nations, Articles XIII(1); Convention establishing the World Intellectual Property Organization, Article 13(1); Agreement establishing the World Trade Organization, Articles III(5) and V(1). See also CBD: Decision VI/6 and Decision VI/20.

[17] In the Agreement between the IMF and the WTO, which seems similar in this regard, the Appellate Body explicitly remarked that 'it does not provide any substantive rules concerning the resolution of possible conflicts between obligations of a Member under the WTO Agreement and obligations under the Articles of Agreement of the IMF or any agreement with the IMF; Report of the Appellate Body, *Argentina – Footwear*, 72.

5 International agreements, national law and farmer seed systems

This chapter analyses implications of international and national law (as described in chapter 4) on the workings of Farmer Seed Systems. It does so in a dialectical manner, on the basis of the scenarios described in chapter 3. These scenarios illustrate, in a general sense, the potential legal problems arising when biological material containing patent protected characteristics is released into the environment and a transfer of such characteristics through natural, or other means, takes place. In a more specific sense, the scenarios consider how patent protection can conflict with the established principles of Farmer Seed Systems and the culture of farming communities.

5.1 Applying international and national law to Farmer Seed Systems: Legal perspectives

We asked responsible staff within the relevant international institutions to comment on, and respond to, the scenarios set out in chapter 3. Their responses commonly emphasised the flexibility of applicable conventional international laws. For example, the Secretariat of UPOV stressed that UPOV 1991 seeks to harmonise the national legislation of the Contracting Parties with regard to the protection of new varieties of plants. Ultimately, however, the authority to interpret the provisions of UPOV 1991 lies in the hands of the Contracting Parties. Thus, the question of where the authority lies to interpret the provisions of UPOV 1991 was answered by reference to the national legislation of the Contracting Parties. Similarly, the Secretariat of the WTO made reference to the flexibility of the TRIPS Agreement, under which a Member may challenge the national legislation of another Member. A persisting dispute between Members might be resolved through the dispute settlement system of the WTO. The Secretariat of the WIPO also suggested that, in the absence of compulsory dispute settlement, the authority to interpret conventional international law relating to IPRs lies with governments as a matter of national sovereignty. The question is whether, since IPR has now have become subject to the TRIPS agreement, responsibility for settling disputes might now lie with the WTO.

These Secretariats thereby seem to confirm that the question of interpretation lies at the heart of conventional international law. This suggests that the general rule of interpretation prescribed in Article 31(1) of the Convention on the Law of Treaties, which refers to the ordinary meaning of the text, the context and the object and purpose of the treaty, does not provide determinate rules of conventional international law. This presents a basic challenge to the concept of international law as such. If the interpretation of rules of international law is ultimately dependent on the internal law of States, the rules of international law do not seem to limit the factual and normative freedom to act of States in any meaningful way. At the same time, this reading presupposes that the internal law of the State is not affected by similar problems of interpretation.

5.2 Applying international law and national law to Farmer Seed Systems: Farmers' perspectives

The rights of traditional subsistence farmers to continue to operate within their own agricultural and socio-economic context is a central concern of the present study. These rights seem to be largely overlooked in the various international agreements. Even the FAO Treaty on Plant Genetic Resources for Food and Agriculture does not give explicit expression to such rights. In the FAO Treaty (Article 9.2), Farmers' Rights are defined as follows:

International agreements seem to largely ignore the rights of farmers to operate within their own agricultural and socio-economic context

Contracting Parties agree that the responsibility for realising Farmers' Rights rests with national governments, and each Contracting Party should, as appropriate and subject to its national legislation, take measures to protect and promote Farmers' Rights, including: (a) protection of traditional knowledge relevant to Plant Genetic Resources; (b) the right to equitably participate in sharing of benefits arising from utilisation of plant Genetic Resources; and (c) the right to participate in making decisions, at the national level, on matters related to conservation and sustainable use of plant Genetic Resources.

A number of observations seem relevant here.

The Farmers' Rights concept was adopted in the FAO Treaty to provide a balance against IPR in industry and PBR in commercial plant breeding. It appeared to solve the problems that arose in the negotiations of this international agreement. However, what does it mean to farmers, who were conspicuously absent from these negotiations and only represented by national policy makers?

Traditional Farmer Seed Systems were confronted with:

- a concept assigning rights on sharing in benefits which would seem to imply monetary value assigned to their genetic resources and, as a consequence,
- the introduction of a concept of ownership of genetic resources that is vested in farmers or farming communities.

Interpretation of Farmers' Rights in terms of individual or community ownership over genetic resources contradicts with principles of free exchange and mutual inter-dependance that forms the basis of traditional agriculture

What was seemingly not fully understood is that both these concepts are in total contradiction to the basic principles of free and open access that have been practised throughout the history of agriculture. Free access has been fundamental to the practices of plant breeding and the functioning of Farmer Seed Systems. It is central to the socio-economic context in which traditional farmers operate. It may be argued that the concept of Farmers' Rights, embedded in this treaty, does at least give credit to farmers as important suppliers of genetic resources that have been harnessed, improved and conserved by their activities. It recognises, in principle, the right of farmers to share in the benefits that accrue from the use of their genetic materials. However, the agreements did not create mechanisms through which this principle could be implemented in a way that would provide real benefits to farmers. Rather, this responsibility was conveniently referred to national legislation. Nations retain sovereign rights over their plant genetic resources and in some (the Philippines, and member countries of the Andes Pact) farmers are involved in establishing arrangements for Prior Informed Consent (PIC) which seek to balance

restrictions on access by requirements to promote use. However, the question of whether such arrangements will provide real benefits to farmers remains unanswered.

Even before the adoption of the FAO Treaty and the CBD, a number of practical issues became apparent, in effect limiting the concept of Farmers' Rights in providing real benefits to farmers.

- First, there are practical difficulties in assigning monetary value (and ownership) to genetic resources. The market for genetic resources used by farmers has many potential suppliers but few, if any, buyers. The main sources of genetic diversity for commercial plant breeding are the numerous gene banks that, by now, contain a large and easily accessible reservoir of genetic diversity collected prior to the FAO Treaty and the CBD coming into force. The question of whether or not such collections are subject to these agreements is till unresolved and remains a matter of debate and interpretation. Even if they are, the records of many collections (such as those held by the CGIAR) lack sufficient geographical precision to identify the original owners. The records mostly just contain a description of general location and the physical characteristics of the collection site. Only recently has the knowledge of the farmers growing the collected material also been documented.

- Secondly, due to the process of evolution of genetic diversity in farmers' fields, as explained in Chapter 2, assigning individual or even communal ownership in a fair manner is difficult, if not impossible, to achieve.

- Thirdly, claiming ownership over planting material as a genetic resource is foreign to the cosmo-vision of farmers. Most plant breeders also share this vision. It is upheld in the *sui generis* Plant Breeders' Rights legislation as harmonised by the UPOV Convention in which even PBR protected varieties are viewed as a free resource for further breeding. This represents a basic value in the philosophy of agriculture, which is apparently poorly understood by policy makers and legal experts.

The concept of Farmers' Rights therefore appears not only to be an empty shell but can even be construed as an attempt to impose a system of ownership on farmers to justify appropriation of genetic resources by industrial interests that conflict with the universal interests of agriculture in general. Basically the conflict is about two views on agriculture; agriculture as an economic activity and agriculture as a biological activity, the products of which happen to have economic value.

Another problem that raises questions of interpretation is the relation between the FAO Treaty and the CBD on the issue of National Sovereignty over genetic resources. Nation States are assumed to have sovereignty over their territorial resources including genetic resources. The FAO Undertaking, preceding the FAO Treaty, after long and often acrimonious debates settled on a modest interpretation that views the genetic resources of crops as a "Heritage of Mankind". It was realised that agriculture, plant breeders and farmers benefit from access to gene pools of crops across national borders. The CBD, however interpreted National Sovereignty in the context of natural biological diversity in a stricter sense, with two objectives in mind. First, to place responsibility for the conservation of such resources squarely in the hands of national governments and, secondly, to counter the perceived unethical appropriation of genetic resources by foreign interests, sometimes referred to as "bio-piracy". This interpretation was adopted in the negotiations in the FAO Commission that led to the final text of the FAO Treaty in an attempt to make it more consistent with the CBD.

Agriculture, plant breeding and farmers benefit from open access to genetic resources across national borders

The CBD provides two instruments to facilitate national sovereignty and government control. The concept of Prior Informed Consent (PIC) aims to inform farmers about the purposes of collection and obtain their consent prior to collection of genetic resources. The second, Material Transfer Agreements (MTA's), regulates the conditions for transfer and use. These concepts facilitated the negotiation processes in the international policy arena and seemed to level the playing field. However, their practical implementation can create bureaucratic barriers, which restrict access to genetic resources for plant breeding. This has a negative impact on plant breeding and may ultimately be harmful to farmers in general. This is already becoming evident in the plant breeding activities of the publicly funded Future Harvest Institutes of the CGIAR, which are occasionally encountering problems in retrieving experimental materials from international testing programs for further improvement. To cope with these problems, a major purpose of the FAO Treaty was to include a Multilateral Agreement of open access for selected crops to which parties to the FAO Treaty can voluntarily subscribe.

Box 5-1

Need for policy change

The TRIPs Agreement explicitly recognises the need of developing countries for maximum flexibility in implementing their patent laws in ways that enable them to create a "sound and viable technological base". It contains several provisions that give countries the flexibility to grant exceptions to patent rights under certain circumstances. Article 30 provides a broad authority for countries to grant exceptions when the interests of the patent holder will not be adversely affected. Article 31 provides the authority for countries to provide for compulsory licenses, subject to some conditions, when the rights of the patent holder are affected. Furthermore, Article 27.3(b) permits countries to exclude plants and animals from patentability altogether, provided an alternative "sui generis" system of protection is provided. This is an important opportunity for countries that might judge it in their interests to adopt a system of plant variety protection that allows for the use of protected plants in the breeding of new varieties and for farmers to save their seed for planting the next year. These provisions reflect the reality documented by expert commissions and commentators that the patents and other intellectual-property needs of developing countries vary and can be sharply different from the needs of industrialised countries.

From: American Patent Policy, Biotechnology, and African Agriculture: The Case for Policy Change. RFF Report, Michael Taylor and Jerry Cayford, 2003.
http://www.rff.org/rff/news/features/american-patent-policy-biotechnology-and-african-agriculture.cfm

Except for the FAO Treaty, the overall conclusion is, that the agendas of various international agreements, while seemingly protecting national interests, do not adequately consider the requirements of agriculture or the interests of farmers. The main interest of farmers is the availability of, and access to, improved varieties of crops adapted to their environment, cultural practices and household requirements. These benefits are far more important to farmers than benefits that may, if at all, accrue from compensation for use of genetic resources for plant breeding. Questions of the ownership of genetic resources and of establishing their relative contribution to a new variety (developed through often complex breeding programmes involving numerous parental lines) are both based on vague concepts and are largely incompatible with Farmers Seed Systems.

Except for the FAO Treaty, international agreements do not seem to adequately consider the requirements of agriculture and the interests of farmers

The issue then, in our view, is not how to refine and make Farmers' Rights operational, but to formulate and adopt appropriate *sui generis* patent protection that benefits both the inventor and farmers and that satisfies the special nature of biological materials. The latter issue has strangely, but perhaps not surprisingly, been missed in the international debate. Recognition of

the special nature of biological materials would fundamentally conflict with the appropriateness of exclusive patent rights on GM varieties.

The WTO/TRIPS Agreement provides Nation States the space to include these considerations in formulating national legislation. TRIPS states in Article 1.1 (Nature and Scope of Obligations) that: *Members may, but will not be obliged to, implement in their law more extensive protection than required by this agreement and will be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.* The overall economic justification for moderating exclusivity of legal ownership is detailed in Box 5.1.

This wording seems to give support to Article 9.3 of the FAO Treaty, which specifies that the concept of Farmers' Rights will not be interpreted as limiting any rights that farmers have to save, use, exchange and sell farm-saved seed and propagating material, subject to national law and as appropriate. This Article would seem to be fully in accordance with the practices of Farmer Seed Systems, in which farmers produce their own seed on farm and practice open exchange without claiming ownership of the genetic constitution of the material. However, the added "subject to national law and as appropriate" has important consequences; if there is no national law, the FAO Treaty does not provide farmers with any rights.

Through bilateral trade agreements, pressures are already being exerted, notably by the US, to grant more extensive protection than is required under the TRIPS Agreement (Correa, 1999). Current disputes over IPR in medicines may indicate what can be expected to happen with regard to patenting in GM crops. For instance, it has been reported that, at the end of 1999, the US Trade Representative was involved in *"46 current actions against poor countries for using internationally accepted and WTO compliance measures such as compulsory licensing and parallel import to save lives"* (ACT-UP, 1999). The WHO has noted that some countries have, formally and informally, reported pressures to exclude TRIPS provisions intended to safeguard access to essential drugs from their national legislation (WHO, 1999). In a similar vein, *"the US and other Western industrialised countries are leading a concerted effort through WIPO to achieve international harmonisation of patent law beyond that provided in the TRIPS Agreement"* with regard to plant biotechnology (Taylor and Cayford, 2003).

Considering present political and economic realities, it would seem likely that many developing countries will continue to be pressured to include patent protection of GMOs in their legislation. This will probably especially apply to GMOs developed and patented under US and EU law by the same international corporations who are lobbying for protection for pharmaceuticals that exceeds the requirements of TRIPS and who are strongly opposing the application of compulsory licensing in the general interest.

The attitudes of industrial countries and WIPO contradict the stated objectives of patents to benefit society by promoting useful inventions whose performance is properly evaluated from the perspective of the social outcomes they achieve. If, as is generally claimed, biotechnology has the potential to make significant contributions to world food security and human welfare, the policies of industrial countries that promote strong world-wide patent protection and oppose compulsory licensing are denying or hindering developing countries from gaining access to such technologies. Such policies appear to be in conflict with the full support that industrial countries have pledged for, amongst others, the United Nations' Millenium Development Goals (see Taylor et al, 2003) the objective of which is the eradication of extreme poverty and hunger.

5.3 Analysis of the Scenarios

In this section we explore the relevant provisions of the four agreements that we see as relevant to the scenarios set out in chapter 3 and summarised in figure 1. In addition, we outline relevant provisions in the national legislation of the selected States. We remark at the outset that it does seem possible to exclude extreme interpretations, which involve disregarding the interests of other members of society. Beyond that, the relevant provisions do not provide definitive guidance regarding the question of how to structure the normative relations between the different interests involved.

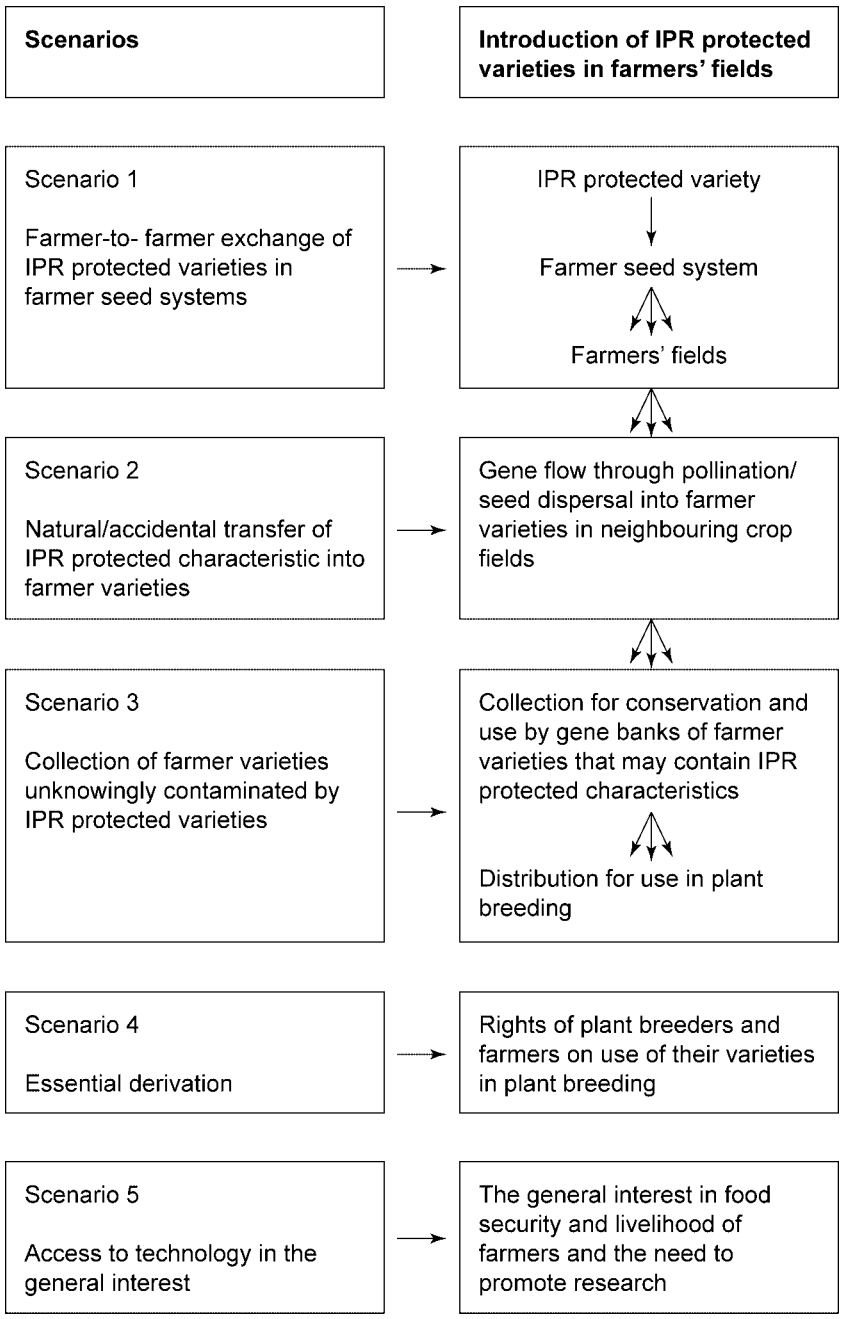

Figure 1: Overview of Scenarios

The set of scenarios was developed to illustrate this lack of clarity and, in particular, the problems encountered when the functioning of international agreements is confronted by totally different social and agricultural constructs. These scenarios are meant to analyse the consequences of legal ownership regimes on biological materials employed in agriculture, as embodied in WIPO, WTO/TRIPS and UPOV and the related needs for the conservation of such resources for the common good, as reflected in the CBD and the FAO Treaty. A primary concern on which these scenarios are based is the functioning of these various agreements as part of the body of international law, in the context of Farmer Seed Systems, which represent the major source of planting material for a majority of farmers and crops in developing countries. A major cause of problems is the inherent conflict between the exclusive ownership afforded by patents and the capacity of biological materials for self-reproduction and hybridisation. Effective containment of these natural phenomena is necessary for enforcing such rights, but containment is not only difficult, it also goes against the cultural and social structures of many societies depending on traditional agriculture and free exchange of planting material.

Scenario 1: Access to and use of modern varieties by small farmers

Scenario 1 concerns the access to modern varieties by farmers participating in Farmer Seed Systems, and the use of these modern varieties by those farmers. It is assumed that the modern varieties are the property of a commercial breeder. It is further assumed that the commercial breeder is the holder of an IPR (PBR or patent) over these modern varieties. The first question that is raised in scenario 1 is whether farmers participating in a Farmer Seed System can have access to those modern varieties. The second question is whether farmers participating in a Farmer Seed System, who have obtained a modern variety, can subsequently exchange genetic material of this modern variety, or, whether such exchange contravenes the IPR. This question is raised both with respect to a patent and to a PBR .

Legal perspective

The first question is whether farmers participating in Farmer Seed Systems can have access to modern varieties. Planting material protected by a PBR is considered to be the property of the holder of the PBR. The PBR holder is obliged to provide an adequate supply at a price that includes a license fee for use. The main restriction is that farmers cannot sell the PBR protected variety as seed for planting to other farmers. In case of a patent, ownership covers the patented characteristic. Here, the access of farmers is dependent on the consent of the holder of the IPR. The holder of a patent cannot be compelled to grant access to a modern variety protected by the IPR. Facilities such as compulsory licensing, which are considered in scenario 5, constitute exceptions to this principle. IPR's are most normally enforced (at least in the US) by means of a contract between the holder of the IPR and the farmer(s). Farmers participating in a Farmer Seed System could also obtain access to such modern varieties through this means, allowing the holder of the IPR to receive remuneration.

The question that then arises is whether farmers participating in a Farmer Seed System can be prevented from subsequently exchanging the genetic material within the Farmer Seed System. Most respondents addressed this question from the context of the UPOV Convention (1991). The provisions of Article 27(3)(b) of the TRIPS Agreement, relating to micro-organisms and microbiological processes, do not generally seem to be seen as requiring the patentability of genetic material or processes relating to genetic material.

Patent law

Examples where patent law applies to this issue can be found in the national legislation of the Philippines and of Brazil. Under Subsection 22.4, of the IPR Code of the Philippines, plant varieties, animal breeds and essential biological processes for the production of plants and animals are excluded from patent protection. Article 10(IX), of Lei 9.279 of Brazil, relating to industrial property, provides that the whole or parts of natural living beings and biological materials found in, or isolated from, nature, including the genome or germplasm of a natural living being and natural biological processes, are not to be considered as inventions. Article 18(III) provides that the whole, or parts of, living beings are not patentable, except transgenic micro-organisms which conform to the three requirements of patentability – novelty, inventive activity, and industrial application – and are not a mere discovery.

The TRIPS agreement provides a potentially different perspective on the question of exchange of genetic material within a Farmer Seed System. Here the key question is the extent of the exclusive rights conferred by Article 28 of the Agreement, and the related question of the exhaustion of these exclusive rights, which is excluded from the TRIPS Agreement under Article 6. Thus, from a legal perspective we cannot answer conclusively whether the exchange of the genetic material within a Farmer Seed System would infringe Article 28, of the TRIPS Agreement, as we do not know the extent of the rights conferred. It could be argued that such exchange infringes this right; but it could also be argued that if the genetic material enters the Farmer Seed System, the right has been exhausted.

The national laws that we have examined commonly consider that a patent is exhausted once it has been placed on the market. Reference may again be made to the national laws of the Philippines and Brazil. Section 71, of the IPR Code of the Philippines, determines that a patent will confer the following exclusive rights on its owner:

(a) where the subject matter of a patent is a product, to restrain, prohibit, and prevent any unauthorised person or entity from making, using, offering for sale, selling or importing that product;
(b) where the subject matter of a patent is a process, to restrain, prevent or prohibit any unauthorised person or entity from using the process, and from manufacturing, dealing in, using, selling or offering for sale, or importing any product obtained directly or indirectly from such process.

Section 72 deals with limitations of patent rights and outlines the circumstances in which the owner of a patent does not have the right to prevent third parties from performing, without his authorisation, the acts referred to in Section 71. Subsection 72.1 concerns the use of a patented product which has been put on the market in the Philippines by the owner of the product, or with his express consent, insofar as such use is performed after that product has been put on the said market. Subsection 72.2 concerns acts done privately and on a non-commercial scale, or for a non-commercial purpose, provided that it does not significantly prejudice the economic interests of the owner of the patent.

Similarly, Article 42 of the Lei 9.279 of Brazil, relating to industrial property, determines that a patent confers on its holder the right to impede third parties, who without consent, produce, use, prepare for sale, sell or import for these purposes. It states that it concerns (i) the product that is the object of the patent and (ii) the process or the product obtained directly from the patented process. Article 43 provides that the disposition of Article 42 does not apply to acts of third parties, not authorised by the holder of the patent, of a private character and without commercial purpose, if these do not cause prejudice to the economic interest of the holder of the patent. It does not restrict third parties who, in the case of patents relating to living material, use without economic purpose the patented product as the initial basis for variation or

propagation to obtain other products. The implication here is that this does not restrict the use of the patented product for non-commercial purposes, including multiplication and propagation of the living material in question.

According to the Indian respondent this question does not arise in the context of patents as the Patent Act 1970 specifically excludes genetic material from patentability.

If we consider that a patent is not exhausted when the genetic material is exchanged within a Farmer Seed System, this leads to consideration of whether the exchange of genetic material within a Farmer Seed System falls within the limited exceptions provided in Article 30 of the TRIPS Agreement. These must satisfy the requirement that they may not unreasonably conflict with a normal exploitation of the patent and that they may not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties. The question of whether exchange of the genetic material within a Farmer Seed System satisfies this requirement depends on definitions of what constitutes a normal exploitation of the patent, what conflicts unreasonably with it, as well as balancing the legitimate interests of the patent owner and third parties. The subjectivity of these criteria (normal; unreasonable; legitimate) permits interpretations that view the exchange of the genetic material within a Farmer Seed System as both falling within and outside this exception.

Plant breeders' rights

Most respondents in this study viewed the question of the exchange of genetic material within a Farmer Seed System from the context of the UPOV Convention (1991). This then raises the questions of the exceptions to the PBR, and of the exhaustion of a PBR, dealt with respectively in Articles 15 and 16 of the UPOV Convention.

Article 15(1) of the UPOV Convention provides that the PBR will not extend to:
(i) acts done privately and for non-commercial purposes;
(ii) acts done for experimental purposes; and
(iii) acts done for the purpose of breeding other varieties.
In addition, Article 15(2) of the UPOV Convention provides that each Contracting Party may, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder´s right in relation to any variety. This is in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest that they have obtained by planting a protected variety or essentially derived variety on their own holdings.

The Secretariat of UPOV indicated that exchange of genetic material protected by a PBR within a Farmer Seed System may be covered by the exception provided in Article 15(1)(i). In October 2004 UPOV plans to consider whether the exchange of genetic material within a subsistence oriented Farmer Seed System may be interpreted as an act done privately and for non-commercial purposes. The respondent commenting on the national legislation of El Salvador believed that this interpretation should be upheld and adopted.

The Indian respondent answered that the question can only be answered from the context of PBRs and farmers' rights. The exchange of genetic material protected by a PBR within a Farmer Seed System would be compatible with Section 39(1)(iv) of the Protection of Plant Varieties and Farmers´ Rights Act. This Article bestows the right to farmers to save, use, sow, resow, exchange, share or sell their farm produce, including seed of a variety protected under the Act, in the same manner as they were entitled to do before the Act came into force. However, it should be noted that this Act does not comply with either UPOV 1978 or 1991.

In the case of the Phillipines our respondent answered this question by reference to Section 43(d) of the Plant Variety Protection Act. This legislation limits the rights of holders of a Certificate of Plant Variety Protection, which do not extend to the traditional rights of small farmers to save, use, exchange, share or sell their farm produce of a variety protected under the Act. An exception to this is made when such a sale is for the purpose of reproduction under a commercial marketing agreement. Section 43(d) provides further that this provision also extends to the exchange and sale of seeds among, and between, said small farmers: *"Provided, that the small farmers exchange or sell seeds for reproduction and replanting on their own land"*. The respondent recognised that, although this exception seems to create a compatibility between PBR and exchange of genetic material within a Farmer Seed System, the terms used (small farmers; commercial marketing agreement) are vague and require further clarification. The National Plant Variety Protection Board, instituted pursuant to Title XI of the Plant Variety Protection Act, has been designated to determine the conditions under which the exception will apply, taking into consideration the nature of the plants cultivated, grown or sown. We also note that Article 43(d) of the Plant Variety Protection Act does not seem entirely consistent. For example, the sentences preceding and following the word "Provided" seem to confer a right on farming communities, even though the word "Provided" suggests a contrast between the two sentences. In addition we note that the allocation of the burden of proof is important in the interpretation of this provision. For example, who bears the burden of proof in respect of the exception to the rights conferred? Is it the holder of the PBR or the farming community?

Brazil's position is set out in Article 10 of the Lei 9.456, relating to Plant Variety Protection. This complies with UPOV 1978, but not to UPOV 1991. This provides that a PBR is not infringed if someone:

(i) saves and plants seeds for their own use, on their establishment or on the establishment of a third party which they hold;
(ii) uses a variety as a basis for variation in genetic improvement;
(iii) being a small rural producer, multiplies seeds, exclusively for other small rural producers, in the context of programmes for financing or support of small rural producers, conducted by public organs or NGOs authorised by the Public Power.

Section 3 of the Article sets out criteria that specify what constitutes a small rural producer.

Our respondent commenting on the position of national legislation of Nicaragua considered that the exchange of genetic material protected by a PBR within a Farmer Seed System would be incompatible with Articles 8 and 9(b) of *Ley 318 de Proteccion para las Obtenciones Vegetales.* They also considered that an IPR (patent or PBR) protecting genetic material extends to any genetic material in which it is incorporated.

By contrast the respondent commenting on the national legislation of Uganda considered that an IPR (patent or PBR) is exhausted in the case of exchange of genetic material within a Farmer Seed System. It was considered that if a protected variety of planting material has been put on the market, with the consent of the patent holder, that their right to control such use is exhausted. This means that the farmer has the right to share it with fellow farmers, to resell or to donate it.

Concluding remarks

Overall then, these responses create a very mixed picture (see Table 1). At one extreme,(in Nicaragua) the exchange of genetic material protected by an IPR within a Farmer Seed System is considered to be incompatible with the exclusive rights conferred by an IPR. The other respondents consider that the exchange of genetic material within a Farmer Seed System may be

compatible with the PBR and, between them, they identify at least three bases for this compatibility:

(1) The position that such exchange consists of acts done privately and for non-commercial purposes: this position was suggested by the Office of UPOV as a possible interpretation and was shared by the respondent commenting on the national legislation of El Salvador;
(2) The position that such exchange falls within provisions specifically applying to exchange (and other acts) between farmers that relate to farm produce and seed. The respondents commenting on the national legislation of India and the Philippines adopted this position.
(3) The position that such exchange falls outside the reach of the PBR because the PBR is exhausted once the genetic material is freely put on the market. The respondent commenting on the national legislation of Uganda adopted this position. The national legislation of Brazil provides an extensive catalogue of exceptions to both rights, which may accommodate the exchange of genetic material within a Farmer Seed System. These vary according to whether the scenario is considered on the basis of a patent relating to a transgenic micro-organism or on the basis of a PBR.

Table 1: Summary of the question whether farmers participating in a Farmer Seed System are allowed to subsequently exchanging the genetic material within the Farmer Seed System.

Respondent	context of Patent Law	context of PBR
TRIPS	regulations are inconclusive	
UPOV		exchange is allowed
Philippines	is not applicable	regulations are inconclusive
Brazil	is not applicable	exchange is not allowed
India	is not applicable	exchange is allowed
El Salvador		exchange is allowed
Nicaragua	exchange is not allowed	exchange is not allowed
Uganda	exchange is allowed	exchange is allowed
Canada		Exchange is not allowed

It should be noted that interpretations which permit the exchange of genetic material within a Farmer Seed System appear to be compatible with the concepts of a PBR, as set out in Articles 8(j) and 10(c) of the CBD and with Article 9.3 of the FAO Treaty. (See previous section). However, these articles, especially 8(j) of the CBD and 9(3) of the FAO Treaty are so vague and open to conflicting interpretations that, it may be difficult in practice to implement them in the spirit in which they were formulated.

Farmers' perspective

As stated in Chapter 4, modern varieties protected by PBR are available to farmers with few restrictions. These generally do not infringe the farmers' customary privilege of saving seeds from the harvest for next years planting. Whether or not exchange of seeds with other farmers in Farmer Seed Systems is allowed under PBR, when, as is usually the case, it is not done for commercial purposes remains open to question.

However, problems do arise when farmers use IPR-protected GMOs. In some countries (India, the Philippines, Uganda) varieties may be excluded from IPR protection. The question is whether such exclusion will be upheld under economic trade pressures. As suggested in section 5.1 the industries and countries that dominate biotechnology take seriously the need for adherence to patents in this field. Furthermore, in most cases, GM varieties are sold under individual

contracts, that generally state that the farmer will not use harvested seed for replanting on his own farm, nor exchange such seeds with other farmers for the same purpose. Even if farmers are willing to abide by these conditions, they may not be able to prevent other farmers acquiring some seeds and using them as planting material for further multiplication. A case in point is the reported on-farm multiplication and spread of Monsanto GM (herbicide tolerant) soybean through farmer exchange in Argentine and smuggled across the border into southern Brazil and Uruguay (see box 5.6 under Scenario 5).

Farmers in the Philippines who were consulted by SEARICE, stated that they would be very reluctant to use GM varieties under strict contractual conditions, as they realised that their circumstances make it extremely difficult to adhere to such conditions. They not only fear possible court action, but even are concerned for the safety of their families or property by illegal retaliatory actions of seed middleman taking the law in their own hands. Hence, unless the rights of the IPR or contract holder are exhausted when genetic materials enter Farmer Seed Systems, such legislation will restrict the access of small farmers to new technology by setting conditions that are impossible to comply with. It may even lead to illegal actions, that threaten the livelihood of farmers and the safety of their families.

Scenario 2: Gene-flow in traditional agriculture

Scenario 2 is concerned with gene flow from modified genetic material protected by an IPR to genetic material that forms part of a Farmer Seed System (introgression). It raises the question of whether the farmers participating in a Farmer Seed System may be regarded as infringing the IPR. A second question is whether the holder of the IPR can prevent the farmers participating in the Farmer Seed System from using the genetic material. It also raises the converse question of whether the holder of the IPR may be liable for damage caused to the genetic material forming part of the Farmer Seed System.

Legal perspective

For these questions, Plant Breeders Rights as defined in the UPOV agreement are our main reference. The respondent from UPOV observed that Article 15(1)(iii) of the UPOV Convention (1991) provides that a PBR does not extend to acts done for the purpose of breeding other varieties and acts in respect of such other varieties. As a consequence the farmers participating in the Farmer Seed System cannot be prevented from using the genetic material for further breeding in the way that the scenario describes. The respondent commenting on the national legislation in Uganda shared this view.

In contrast, the respondent commenting on the national legislation of Nicaragua considered that, pursuant to Article 9(b) of *Ley 318 de Proteccion para las Obtenciones Vegetales*, the protection of the IPR extends to the introgressed material. In the case of El Salvador, this question was answered in the context of the TRIPS Agreement, which led to a similar conclusion to that from Nicaragua.

Differing views were also expressed over the question of whether the holder of the IPR may be liable for damage caused to the genetic material that forms part of the Farmer Seed System. The respondent referring to the national legislation of India considered that, in the case of undesirable introgression from a transgenic variety to their landraces, a community may demand damages or protection under the Environmental Protection Act 1986. However, it was added that this situation would normally be pre-empted by provisions of that Act which require a prior assessment by the Environmental Regulatory Authority of the likely impact of releasing a transgenic variety on a landrace. Any dispute would be more likely to arise between the com-

munity and the Environmental Regulatory Authority rather than between the holder of the IPR and the community.

The respondent commenting on the national legislation of Uganda remarked that the holder of the IPR can only be held liable only if the requirements determining liability for damage as established in the case of Rylands v. Fletcher are satisfied. Alternatively it might be possible to establish a case under the law of negligence, but this may be difficult to prove. However, it was noted that there is growing pressure for a regime that imposes liability on holders of uncontained modified genetic material.

The respondent referring to the national legislation of the Philippines considered that, it may be possible in theory to sue for damages in the case of contamination by introgression. However, in practice it may be difficult to prove damage to genetic material, or that such damage was caused by introgression of modified genetic material.

Although our information relating to this scenario is less complete than for scenario 1, we can draw some observations (see Table 2).

Table 2: Summary of the answers of the repondents to the two questions posed in Scenario 2.

Respondents	Is use of introgressed IPR allowed?	Can the IPR-holder be held liable?
UPOV	yes	
Nicaragua	no	
El Salvador	no	
India		is possible, but it is difficult to prove
Uganda		see response India
Philippines		see response India

As the Office of UPOV suggested in discussion, scenario 2 may not pose any problem for a Farmer Seed System if it is resolved on the basis of the concept of PBR. This concept is based on the idea that a protected variety may form the basis of the development of other varieties. The practice of the farmers therefore seems entirely consistent with the concept of PBR. However, this may not be so straightforward. For instance, in Canada the Sale of Goods Act includes exchange within its definition of a sale. Canada has therefore interpreted farmer exchanges of material as sales and as a result these are not permissible under UPOV 1978.

If scenario 2 is considered on the basis of patents relating to genetic material, a number of considerations seem to apply.

- First, if a patent relating to genetic material would extend to genetic material with which the protected genetic material combined or into which it introgressed, it would override and disregard any right of property of another member of society relating to that genetic material. The proposition that a patent extends to other genetic material in this manner seems to be based on an assumption that is inconsistent with the interests of other members of society. This is perhaps even clearer if this question is answered on the assumption that a Farmer Seed System is not based on a concept of property. Although this may be the case, a Farmer Seed System does involve interdependent intellectual activity. If it were considered that introgressing genetic material protected by an IPR could extend to the genetic material forming part of a Farmer Seed System, this would be inconsistent with the basis of

the concept of IPR. This holds that the work of (a) member(s) of society (in this case the farmers participating in a Farmer Seed System) should not be susceptible to appropriation by other members of society, and that those members of society who have performed the work should be able to reap the benefits of thereof.

- The last question concerns the possibility of claiming damages from the holder of the IPR for contaminating the genetic material of a Farmer Seed System. In this context we note that it seems difficult in practice to satisfy the requirements of a law relating to damages: proof of damages, proof of causality, and proof of fault. Given these difficulties, we do not believe that this would be a fruitful way forward. Yet, in contrast to this The European Union Liability Directive, currently under negotiation, does propose that GM containment be recognised as offering grounds for liability claims.

Farmers' perspective

Once genetic material is introduced into the environment, natural hybridisation with surrounding compatible materials of the same crop will inevitably take place. The spread of seeds cannot be prevented, irrespective of their legal status. This is not just an issue in traditional agriculture, where the same crops are grown by different farmers in small fields in close proximity to one another. A telling example is reported from New Zealand (Wills, 2003). Non-GMO seed and feedstock imported from North America were found to be widely contaminated with IPR-protected GMOs resulting from outcrossing or accidental mixing. The reasons are obvious. Seeds can be carried long distances on farm machinery, during transport and by other means and pollen can travel by wind or insects over considerable distances and cause hybridisation. All this makes the complete containment of transgenes grown in the field impossible. Granting exclusive legal ownership over such materials therefore seems inappropriate, even if it otherwise satisfies conditions for IPR. A seminal court case on this issue (Monsanto Canada vs. Schmeiser) in Canada started in 1997 and led to a ruling of the Canadian Supreme Court in May 2004. (See box 5.2). This ruling provides companies with broad powers of exercising patent rights regardless of how patented subjects are spread or transferred into other materials.

Box 5-2

Canadian Supreme Court rules against farmer in biotech dispute.

Canada's highest court sided with Monsanto Co. in a seven-year dispute over technology in farming, giving the agri-business company titan broad rights under patent law to control its genetically engineered crops. The legal battle dates from 1997 when Monsanto found a canola variety that it had engineered to resist its powerful Roundup weedkiller on Percy Schmeiser's farm. The farmer contended that he was an innocent bystander and that the seeds of the Monsanto variety arrived in his fields through accidental means, such as loss during transport by blowing off a passing truck and/or through natural pollination from neighbouring fields. Furthermore he contended that he did not use the Roundup weedkiller, hence did not benefit from the genetically engineered resistance. The Supreme Court rejected these arguments and validated Monsanto's patent and gave the company the broadest authority to exercise it, apparently regardless of how such seeds or the patented characteristic had appeared in farmers' fields or in his planting material. It ruled that that the farmer had to turn over all remaining crops and seeds to Monsanto. Andrew Kimbell, director of the Center for Food Safety, A Washington D.C. based watchdog said that it would set "a disturbing precedent" if biotech companies own not just the gene transferred in a crop variety but everything that it gets into. Farmers, especially in developing countries, fear that natural or accidental contamination of their crops and their farmer varieties with IPR protected biotech varieties will give biotech companies like Monsanto licenses to seize their crops and varieties. Agbios/Associated Press; May 23, 2004

Monsanto and private industry in general will probably be pleased with this legal 'victory', but may well come to regret it. The ruling would seem to ignore biological realities and ignore the broader interests of farmers.

If IPR-protected ownership extends to accidental transfer, it immediately raises the legal issue of liability. As noted earlier, the European Union Liability Directive, currently under negotiation, proposes that GM containment be recognised as offering grounds for liability claims Companies are protesting. However, legal ownership would seem to imply liability. Once IPR-protected biological materials are freely circulating, they cannot be recalled, nor does science currently have the tools that can selectively remove the patented characteristic from their material, except by an extensive selection activity identifying non-introgressed individual plants as base material for further propagation. Hence the ruling of the Supreme Court of Canada does not provide clarity. It raises a spectre of numerous, and potentially very substantial, liability claims. The main beneficiary will be the legal profession. The biotechnology industry can look forward to increased legal costs while such court cases will further damage the acceptance of biotechnology in agriculture.

Box 5-3

Problems of enforcement of IP

Farmers across the Indian state of Gujarat have implemented small-scale on-farm breeding programs to incorporate the patent protected Bt gene, conferring insect resistance into other strains of cotton. Apart from some token raids, the government has done little to stop proliferation of these private breeding programs. “It is impossible to control something at this scale. When we go to the fields, we become targets for trying to take away a beneficial technology from farmers” said A.K.Dixit, director of Agriculture. AgBiotech Reporter. July 2003. 13

Because PBR is grounded in an agricultural philosophy, accidental or biological contamination offers no problems, since the rights concerning use by farmers who obtained their planting material through channels authorised by the breeder are exhausted once the protected materials are in the field. On the other hand, strict enforcement of exclusive patent rights on particular GM traits, that cannot be contained within varieties, can lead to a multitude of bizarre situations in Farmer Seed Systems. The question arises, for instance, whether the patent holder of a transgene could prevent farmers from using their own landraces if they have been naturally contaminated. According to the ruling of the Supreme Court of Canada, this would be the case, and would include the obligation to hand over contaminated seeds and harvested product to the patent holder. As stated in the legal analysis of this scenario, such a position would be inconsistent with the concept of IPR, namely that work of (a) member(s) of society, in this case farmers participating in a Farmer Seed System, should not be susceptible to appropriation by other members of society which prevents them from benefiting from the fruits (their landraces) of their work. If that is the case, and considering that it will be extremely difficult to differentiate between accidental and wilful contamination for further on-farm selection, the patent protection of a transgenic characteristics will be virtually meaningless under conditions of a Farmer Seed System (see boxes 5-1 and 5-3). This, presumably, played a role in the decision of the Supreme Court of Canada not to differentiate between accidental or wilful contamination. From a legal point of view this might make sense, but considering the laws of biology, which are not open to re-interpretation, it creates absurd situations.

However, according to a recent report (www.checkbiotech.org, 2004) Monsanto is considering the possibility of trying to collect royalties on crop shipments at the point of entry into the US. Janice Armstrong, a Monsanto official, said that they will ask to test shipments of soybean from Brazil and Argentina that are not accompanied by appropriate licences for use of patent-protected herbicide tolerance. If found positive for round-up ready soybean, Monsanto would request payment of royalties on the shipment. This might seem a reasonable course of action, and compatible with protection under PBR Article 14(2). However, if such a course of action were approved, it could lead to soybean material that has been accidentally contaminated

through natural pollination or seed dispersal also being liable for royalty payments. This would effectively extend the patent protection to include contaminated material of other varieties.

Box 5-4

Co-existence of GM and non-GM varieties

The British Agriculture and Environment Biotechnology Commission (AEBC) in a report titled "GM Crops: Coexistence and Liability" deals with the most important issues concerning co-existence and liability when GM crops are introduced into farmers' fields. The AEBC advises a number of legal measures that should be adopted prior to the approval of GM crops. These include, for instance, legislation concerning liability for harm to the environment and a package of measures of compensation to farmers whose fields are contaminated with GM materials. The report suggests a trial period for co-existence of GM crops with conventional crops and biological agriculture, noting problems in ensuring freedom of seeds from GM contamination during seed production, storage and accidental mixing at harvest, cross pollination, transport etc. The report further elaborates on what measures can be taken within the legal context, which are constrained by EU regulations including zonation (GM free zones). The only options available are agricultural measures such as isolation distances, control during storage, crop rotation and others, none of which will completely prevent contamination.

IGD, Consumer Watch 2003, August edition: GM Food and Farming: What are Consumers' latest views? *http:www.igd.com/ConsumerWatchaugustContents.pdf*

Farmers who wish to keep their crops free from contamination by transgenes, to avoid such consequences, or for any other reason, will face serious problems. Contamination is difficult to avoid. Claiming damages will be legally extremely difficult. As Box 5.4 shows, this is not just a problem for developing countries.

Suggested measures to avoid introgresssion by isolation through zonation, control during storage, crop rotation and others are extremely difficult to implement and, even if practical, will not exclude occasional, or even frequent, contamination. This is well recognised by insurance companies (see Box 5-5)

Box 5-5

Transgenic risk excluded from insurance

According to this newspaper article, the British action group FARM interviewed five major Insurance Companies (Norwich Union, Sun Alliance, the Royal Insurance Group and the mutual insurance companies of the National Farmers Union and NFU Mutual) about possibilities for farmers insuring against transfer of IPR material through such events as accidental seed mixing, seed spilling or natural pollination. These companies specifically excluded transgenic risks from their agricultural policies, both for causing, or being subject to, such transfers. The reason given was, that the uncertainties were too great, i.e. that such events are very difficult to avoid.

Algemeen Dagblad 09.10.2003

The reported illegal introduction of a GM variety of soybean across the border of Argentina into Brazil, suggests that this problem cannot even be solved individually by nation-states (see Box 5-6 on page 62).

Scenario 3: Collection of local landraces

Scenario 3 may be seen as an extension of scenario 2 in the context of the role of a gene bank. A gene bank may be seen as an intermediary between farmers, as contributors to a gene bank, and plant breeders who use genetic material provided by the gene bank for further breeding. When genetic material contributed to the gene bank is protected by an IPR, this raises the question of the normative relation between the holder of the IPR and the plant breeder, as well as of the responsibility of the gene bank.

Legal perspective

In the case of Nicaragua, it was considered that, under national legislation, both the gene bank and the breeder may be responsible to the holder of the IPR. This is because the IPR extends to situations in which the genetic material is entered into a gene bank and subsequently distributed for multiplication.

In Uganda, the national legislation differentiates responsibilities, according to the practice of the gene bank. The gene bank may be responsible if it identifies and selects the genes that it banks and determines the ownership of individual genes. In contrast, if the gene bank does not identify individual genes, it is not responsible for the genetic material that it distributes. If it is considered that both the gene bank and the breeder acted in good faith, the holder of the IPR cannot claim legal rights in respect of the genetic material. Conversely, it is considered that the breeder cannot claim compensation from the holder of the IPR for not containing the genetic material or for that genetic material contaminating the seed stock. It was noted that gene contamination is bound to occur with all new varieties. In such a natural process, it is very difficult for a breeder to contain genetic flow. If compensation were allowed, it would keep rotating from one breeder to another. In this situation, the notion of the exhaustion of rights should be reversed to protect breeders because they retain no control over genetic material once it has been sold on.

Although we had relatively few responses to this question, we are generally in agreement with this response. If a patent relating to genetic material cannot extend to any genetic material that the protected material combines with, or into which the genetic material introgresses, then *a fortiori* it cannot extend if this material is subsequently collected for a gene bank.

In practice legal answers and interpretations as to whether farmers, gene banks or plant breeders "knew or ought to have known" about the presence of IPR protected traits in their material will, in many instances pose an insurmountable obstacle. The ruling of the Supreme Court of Canada (see Box 5.2) appeared to provide legal clarity on this point, but its effects illustrate that one-size-fits-all patents applied to biological materials are totally unworkable.

Plant breeding perspective

Farmers do not normally require material from gene banks. Gene banks only conserve small samples of seeds, mainly as a resource for plant breeding. An exception to this sometimes arises when, because of natural calamities or wars, farmers have lost their original farmer varieties (landraces). Cambodia is an illustrative example. Many farmer varieties of rice were lost during Pol Pot's regime, and were subsequently re-introduced from the gene bank of the International Rice Research Institute (IRRI) in the Philippines. Hence, instead of a farmer's perspective, the perspective given here is from the position of plant breeding.

The collection, conservation and documentation of genetic diversity important for food and agriculture are urgent, in view of the serious threat of genetic erosion. Genetic erosion takes place through replacement of original landraces by uniform modern varieties, by destruction of habitats of wild relatives of crop species, by replacement of minor crops by those with higher market value etc. Genetic diversity forms the basis of plant breeding. No nation or gene-bank meets all the present or potential requirements for national or international plant breeding, even for individual crops. Therefore, from the 1980s onwards, close international co-operation has begun under the aegis of the FAO Global Plan for Genetic Resources and the FAO Treaty. In the past collection activities, which are focused in the original centres of diversity, (primarily located in the tropics and sub-tropics) were generally carried out with few restrictions, emphasising a common interest in conservation of a dwindling resource. However, the coming into force of the CBD stressing national sovereignty and control, has had a negative impact on this co-operation. There are exaggerated expectations about the immediate commercial value of genetic resources. This, in combination with the strict interpretation of national sovereignty in the CBD, results in bureaucracy, complicating collection and access to genetic diversity between countries. This is harmful to plant breeding and (*ex situ*) conservation at large. Hence, ironically, while the CBD was meant to promote the conservation and use of biological diversity, for genetic resources it appears to be having the opposite effect.

The FAO Treaty attempts to minimise this negative impact by facilitating a multilateral system of open exchange of genetic resources for food and agriculture between countries, which is free of bureaucratic obstacles. When the dust settles, it may be expected that national governments will realise the benefits of open exchange to their agriculture and food production and opt for expanding the FAO multilateral system.

However, the main concern of scenario 3 is the nature of the problem created by biotechnology. What is the position of gene banks when they collect landraces which inadvertently contain IPR-protected transgenic characteristics and distribute such materials to plant breeders? Many gene banks now require recipients to sign a Material Transfer Agreement in which the gene bank disclaims any knowledge of such introgressed IPR protected transgenic characteristics. Assuming that all goes well with biotechnology and many such transgenic characteristics are reaching farmers' fields, they will undoubtedly transfer to other local materials through natural hybridisation. Such materials may be collected by gene banks and enter their collections without them having knowledge of contamination by IPR-protected characteristics. When subsequently distributed to plant breeders, the presence of an IPR-protected characteristic might only be identified when the new variety is released. In such an event, what are the rights of the original IPR holder in relation to the rights of the breeder of the new variety? This may be a theoretical problem, partly because the time needed for collection, release and inclusion in a new variety may well be longer than the period for which the IPR is valid. Gene banks, however, require clear and unambiguous guidance about how to deal with such events and what the legal consequences might be. This should be included in legislation in order to avoid complex and costly legal procedures, which will add to the costs of plant breeding and ultimately will raise the price of new varieties to farmers. Already it has been reported that, in the absence of legal clarity, protecting legal rights in biotechnology substantially increases the cost of such research and thus of its products to farmers.

Scenario 4: The concept of ´essential derivation´

Scenario 4 concerns the question of whether landraces can be freely used and modified in order to obtain a new variety on which PBR can be claimed. The concept of essential derivation applies only when an initial variety is protected by a PBR. This is usually not considered possible

in the case of a landrace. But does this mean that a landrace can be used freely in order to derive a new variety on which PBR can be claimed regardless of the level of essential derivation?

Legal perpective

In response to this question the UPOV Secretariat remarked that the concept of essential derivation can only be relied on if the initial variety is protected. In the situation described in this scenario, the initial variety is a local landrace and does not seem to be protected. Therefore, the owner of the landrace cannot claim that the resulting variety is essentially derived from the landrace.

The respondent interpreting the Indian national legislation emphasised that, apart from new plant varieties, both extant and farmers´ varieties are eligible for protection under the Protection of Plant Varieties and Farmers´ Rights Act. This means that in the case described in question 4.1 the breeder would, pursuant to Sections 23(6) and 43 of the Protection of Plant Varieties and Farmers´ Rights Act, require authorisation from the farmer or community for any commercial exploitation if the variety is essentially derived from the initial variety.

The response referring to the national legislation of Nicaragua considered that the concept of essential derivation does not apply in this case, because the initial variety is not protected. Alternatively, however, it was considered that a community might rely on the Political Constitution, which provides that all genetic resources are part of the national patrimony and belong to the State.

In Uganda's national legislation, it was considered that the community does not hold IPRs on its landraces. This means that it is impossible for a community to oppose an application to register a derived variety. Nevertheless, the respondent commented that, from a community perspective, such a grant would be irregular and therefore open to challenge.

In Brazil, a new or essentially derived variety is susceptible of protection under Article 4 of Lei N° 9.456. Article 3(IX) defines an essentially derived variety as a variety essentially derived from another variety if, cumulatively:

(a) it was predominantly derived from the initial variety or other essentially derived variety, without losing the expression of the essential characteristics resulting from the genotype or combination of genotypes of the variety from which it was derived, except for the differences resulting from the derivation and;
(b) it is clearly distinct from the variety from which it was derived, by a minimum margin of descriptors, in accordance with criteria established by the competent authority.

Article 3(IV) defines a variety as distinguishable from other varieties in accordance with the minimum margin of descriptors, which is homogenous and stable. Article 3(V)-(VIII) sets out the criteria of newness, distinctiveness, homogeneity and stability. Article 3(III) defines the minimum margin as the minimum ensemble of descriptors, as determined by the competent organ, sufficient to differentiate a new variety or essentially derived variety from other surrounding varieties. These provisions may suggest that the landrace, as changed by the breeder, cannot be regarded as an essentially derived variety, because the landrace itself cannot be regarded as a variety under the meaning of Article 3(IV). This would mean that the landrace as changed by the breeder would itself need to satisfy the criteria of Article 3(V)-(VIII). However, this answer depends on whether landraces are included in the comparison prescribed by Article 3(III).

These various interpretations are summarised in Table 3.

Table 3: Can the concept of essential derivation be applied to landraces?

Respondent	Answer
UPOV	No, only possible with protected varieties
India	Yes
Brazil	Yes, if landrace meets DUS requirements
Nicaragua	No, following UPOV regulations Yes, following Political Constitution
Uganda	No, but IPR is challengable

Some additional observations should be made about this scenario. The concept of essential derivation is intended to extend the PBR of a breeder to a variety that is so close to the protected variety that it would be unfair if another member of society could appropriate it. This seems to be a fair concept, even though it may be difficult to define in legal terms. In the situation considered in scenario 4, even though the a new variety derived from a landrace by a plant breeder may not be opposed on the basis of the concept of essential derivation, it would still have to satisfy the normal DUS criteria. It should be noted that, according to UPOV 1991 the D here refers to distinctness from "varieties of common knowledge" and not just any existing material These criteria presuppose that the breeder has performed an intellectual activity with respect to the variety for which protection is sought. If the nature of the initial landrace is not taken into account and a decision on PBR protection is only based on DUS criteria, then indeed it could happen that it is protected, even though no meaningful intellectual activity has taken place. Pursuant to UPOV 1991, PBR protection may be applied for as long as the new variety is (I) commercially novel and (ii) is distinct from a variety of common knowledge. The key issues here are the definitions applied to "commercial novelty" (often very narrow) and "varieties of common knowledge".

Farmers perspective

The concept of essential derivation in PBR does not seem to be inconsistent with Farmer Seed Systems. In fact, essential derivation is central to such systems, allowing farmers to select genetic materials (landraces) that are freely exchanged. Such selection in an, essentially common, gene pool leads to a broad spectrum of landraces similar in overall appearance but differing in gene frequencies for particular genetic expressions according to individual human and natural selection. The Indian PBR legislation has gone furthest in recognising the rights of farmers, by allowing registration of such landraces to provide some form of ownership protection, if they are used in commercial plant breeding. This legislation recognises the difficulty of assigning ownership of such landraces to individual farmers or communities. When registered materials are used for commercial purposes, compensation will be paid into a general fund that is used for supporting farmer activities in conservation. This mechanism appears to provide some natural justice to farmers as a community. However, in our view, the implementation of such a system will require extensive testing and documentation. The cost of implementation may well exceed the financial benefits that may accrue from the use of such materials by commercial plant breeding.

There is a certain apparent inequity in UPOV-harmonised PBR legislation. Essential derivation in PBR only applies to other varieties that are already protected by PBR. Hence essential derivation does not apply to landraces used by farmers, unless, as is provided for in the Indian legislation, these are registered in some form. The question is who has to prove, and on what basis, that the new variety does not differ in essential characteristics from the original landrace. It will not be difficult to satisfy the level of uniformity and stability through selection that is required for PBR protection. Moreover, few farmers in Farmer Seed Systems will feel prejudiced

and instead may happily adopt the new variety if it provides improved performance under their circumstances, and the right to subsequently save and exchange seeds for their own non-commercial practices is upheld. If, as is often the case, the new variety is introduced in other regions, most farmers will be even less concerned.

This imbalance could be regarded in another way. All rules and legislation seem to be directed at imposing conditions of commercial plant breeding and modern agriculture on Farmer Seed Systems. An alternative approach in countries where Farmer Seed Systems are still the major source of seeds would be, to adapt legislation to the requirements of on-farm seed production, including situations where such varieties contain IPR-protected transgenic traits. If such transgenic characteristics provide an important contribution to farmers and national food security compulsory licensing, financed at the national governmental level, could provide both a solution and fair compensation to the originator(s) of such improvement(s).

Scenario 5: Compulsory licensing

Scenario 5 concerns the possibility of compulsory licensing of genetic material that has been developed by a breeder and that is considered beneficial for farmers participating in a Farmer Seed System. This raises the questions whether access to this genetic material can be enforced through compulsory licensing and whether compulsory licensing will guarantee fair compensation to the holder of the IPR.

Legal perspective

In general, the provisions regulating both patents and PBRs commonly provide for the possibility of compulsory licensing. In applicable conventional international law, both Article 31 of the TRIPS Agreement and Article 17 of UPOV (1991) also provide for the possibility of compulsory licensing.

National legislation relating to both patents and PBRs also commonly provides for the possibility of compulsory licensing. The IPR Code of the Philippines provides for two ways of limiting patents in the public interest. The first is the use of an invention made by Government. Section 74.1 permits a Government agency, or third person authorised by the Government, to exploit the invention even without agreement of the patent owner under specified circumstances. This is possible when: (a) the public interest, in particular national security, nutrition, health or the development of other sectors, as determined by the appropriate agency of the government, so requires; or (b) a judicial or administrative body has determined that the manner of exploitation, by the owner of the patent or his licensee, is anti-competitive.

The second way of limiting a patent in the public interest is through compulsory licensing. Title II, Chapter X, of the IPR Code, contains elaborate provisions in this respect. Section 93 provides that the Director of Legal Affairs of the Intellectual Property Office may grant a license to exploit a patented invention, even without the agreement of the patent owner, in favour of any person who has shown his capability to exploit the invention. This can be done under any of the following circumstances:

i. a national emergency or other circumstances of extreme urgency (subsection 93.1); requirements of the public interest, in particular, national security, nutrition, health or the development of other vital sectors of the national economy as determined by the appropriate agency of the Government (subsection 93.2);
ii. following a ruling by judicial or administrative body that the manner of exploitation by the owner of the patent or his licensee is anti-competitive (subsection 93.3);

iii. public non-commercial use of the patent by the patentee without satisfactory reason Subsection 93.4. or;
iv. failure to implement the patent on a commercial scale in the Philippines without a satisfactory reason, if the invention is capable of being implemented, provided, that the importation of the patented article will constitute working or using the patent (Subsection 93.5).

The subsequent sections, Sections 94-102 contain further terms and conditions with respect to compulsory licenses.

Similarly, with regard to patents, Title I, Chapter VIII, Section III, of Brazil's Lei 9.279 contains elaborate provisions relating to compulsory licensing. Article 68 provides that compulsory licensing is possible in the case of abusive exercise of rights or abuse of economic power. § 1, attached to Article 68, provides further that a compulsory license may be granted in the case (i) of non-exploitation of the patent because of non-production or incomplete production of the product, or (ii) if commercialisation does not satisfy the necessities of the market.

As an example of national legislation relating to PBRs, reference may be made to Lei N° 9.456, of Brazil, which incorporates two possibilities for restricting a PBR. The first possibility for restricting a PBR is compulsory licensing. Article 28 provides that a protected variety may be the object of a compulsory licence that ensures:

(i) the availability of the variety on the market, at reasonable prices, if the maintenance of regular supply is being unjustifiably impeded by the holder of the PBR;
(ii) the regular distribution of the variety and the maintenance of its quality, and;
(iii) reasonable remuneration to the holder of the PBR.

The second possibility for restricting a PBR is the concept of restricted public use. According to Article 36, a protected variety may be declared of restricted public use, in the exclusive public interest, to meet the necessities of agricultural policy, in cases of national emergency, abuse of economic power, or other circumstances of extreme urgency and in cases of non-commercial public use.

Uganda is currently drafting a Plant Variety Protection Bill, which, in Article 18.1, provides for the possibility of compulsory licensing. In the case of compulsory licensing, pursuant to Article 18.2 of the draft bill, the government may award appropriate and reasonable compensation to the holder of the IPR. Only in Nicaragua does the national legislation (Ley 318) appear not to make provisions for the possibilities of limiting IPRs in particular cases or, of compulsory licensing.

Thus in general the principle of compulsory licensing is recognised in applicable conventional international law and national legislation. Two points must be noted, however. The first is that the facility of compulsory licensing is difficult to reconcile with the idea of intellectual property, which presupposes that the grant of an exclusive right with respect to an intellectual activity which will, through the operation of the market also be beneficial, to society as a whole. Resort to the facility of compulsory licensing undermines this assumption. The second point is that the facility of compulsory licensing entails additional problems, including the problem of determining what constitutes appropriate remuneration for the holder of the patent.

Farmers' perspective

The legal options for compulsory licensing have been reviewed above. Private industry is largely opposed to compulsory licensing, for obvious reasons. It reduces their exclusive control and market position. The pharmaceutical industry successfully resisted compulsory licensing of medicines and was supported in this by patent-issuing authorities. When challenged through international action over HIV medicines, elaborate conditions were set that limited the extent

of compulsory licensing. It is curious that patent-issuing authorities tend to be primarily concerned with interpreting patent law in a manner that gives maximum protection to the patent holder, rather than viewing patents as a temporary right given by society to a patent holder. Equally, they appear to pay insufficient attention to the need to balance rights in the general interest. Even though patent rights are a contract between society and the inventor, patent-issuing authorities appear increasingly to neglect their primary responsibility to represent the interests of society. The interpretation of patent law *per se* has come to take precedence over questions of societal purpose or social consequences.

Compulsory licensing would seem to be an effective instrument for broadening access to knowledge and technology in the interests of society, while providing patent holders with reasonable means to recover their investments in research. A *de facto* and temporary form of compulsory licensing has been agreed upon between Monsanto and the farm sector of Brazil's Rio do Sul State on GM soybeans illegally introduced from Argentine (see Box 5-6).

Box 5-6

Brazil Soy Trade to Pay Monsanto Royalties
The farm sector in Brazil's Rio do Sul state in Brazil has agreed to pay royalties to Monsanto for use of the company's GM Roundup Ready soybean variety smuggled into Brazil from neighbouring countries. Under the agreement buyers of transgenic soy beans, such as the crushing industry, co-operatives and exporters, will collect the charge and pay it back to Monsanto. This agreement is valid for one season only and it is not certain whether it will be extended.
http://www.agbios.com/main.php?action=ShowNewsItem&id=5211

The collection of "royalties" negotiated centrally between the farm sector and the patent holder at the point of delivery of harvested products is essentially a variant on compulsory licensing, i.e. open access at a reasonable price. The reason why this agreement in Rio do Sul is valid for one season only is obvious. The payment fully satisfies the principle of patent legislation in allowing the originator to recover costs of investment on his invention. The question, however, is whether Monsanto will agree to this as a permanent arrangement. So far the biotechnology industry has strongly resisted the option of compulsory licensing, as it limits their control over such varieties. It would set a precedent that, if followed in other countries, would have far reaching consequences.

Box 5-7

Corporate fights for market control through patents
Bayer, Monsanto end IP war
On October 14 [2003] an agreement was reached between Bayer Crop Science AG and Monsanto to create reciprocal IPR licensing agreements. In doing so the companies ended many, but not all, law suits between them. Both companies were granted licenses for techniques related to the development of herbicide-resistant crops. In addition Bayer dropped its IPR claims against YieldGard, a Bt corn developed by Monsanto, and "marked down" Monsanto's existing license for technologies needed to create crops with more than one Bt toxin. The article reports that Monsanto "eased the terms" of Bayer's license for glyphosate - tolerant Bt cotton. The piece notes that this agreement gives the two multinationals access to a wider range of technologies than their competitors. The article notes that in April 2002 Monsanto 'struck a similar agreement with Dupont". In a related story (Yahoo News, Nov.30, 2003) Bayer AG, parent company of Bayer Crop Science AG won "the longest running battle in the history of plant biotechnology" when its exclusive license to a technology based on plant-parasite interactions was upheld. The [public financed] Max Plank Society holds the patent for the technology, and, in late November (2003), the US Patent Office found that a similar Monsanto technology interfered with the institute's patent. According to a Bayer spokesman, the technology will now become "the dominant patent in relation to the production of transgenic plants".
SRC: Nature Biotechnology - ATH: Peter Vermij;
Ref. fs-afbiotech@list.merid.org of 6.12.2003

While patenting was originally designed for the purpose of recovering costs of research, in biotechnology it now has become a major factor in achieving market control of products of innovation in a way which exceeds the original objectives of IPR protection. (See Box 5-7).

This problem is exacerbated by the fragmentation of IP-protected enabling technologies. A prominent example of the complexity resulting from such fragmentation is "Golden Rice" (high pro-vitamin A) in which at least 40 (some reports claim up to 70) patents and contractual obligations are involved. This presented significant constraints for development by researchers working in publicly financed institutions in Switzerland and Germany (Block 5-8)

Box 5-8

The dilemma of nutritionally enriched GM crops.

Biotechnology offers options to enrich major food crops with essential nutrients. A prime example is the high vitamin-A "Golden Rice". It was developed by Dr. Ingo Potrykus of the Swiss Federal Institute of technology and Dr. Peter Beyer of the University of Freiburg in Germany with major financial support from the Rockefeller Foundation, the Swiss Federal Office for Education and Science, and the European Community Biotech Programme.

The rights on the technology, developed by public institutions were licensed to the Syngenta Corporation for further development and seed production. The reason was that the institutes lacked the capacity to exploit this technology for use, as it required access to at least 40 separate IPR protected inventions held by different patent holders. Syngenta, after succeeding in solving the complex ownership rights, in fairness, released the technology free of charge to interested parties on specific conditions - free use by farmers in developing countries with a GDP of less than US$ 10.000 per capita and royalty payments by all other users. It was highly publicised in a campaign to promote acceptance of GM crops for the general good and, as some critics maintain, primarily to polish the reputation of the biotechnology industry.

Jaap Hardon

This illustrates that, as a result of IPR's, biotechnology research and development has become by necessity dominated by international corporations. Only very large corporations can assemble the sizeable sets of patents needed for product development and have the power to negotiate access to other required patents. Such corporations, as was earlier indicated, have little incentive to address problems of small farmers and food security. Public institutions are traditionally responsible for that sector, but in the field of biotechnology they require access to the technology: which today has to be negotiated and paid for through IPR's and mutual licensing agreements that are largely in the hands of large multinational corporations.

The question of access in the interest of society and farmers needs to be addressed in the context of WIPO. However, legitimate action on protecting traditional knowledge and genetic resources (Box 5-9) has been delayed, because countries in the International Government Committee and the General Council of WIPO cannot agree on how to tackle these issues.

Block 5-9

WIPO action on traditional knowledge and genetic resources

SRC; the Lancet - ATH: Clare Kapp

WIPO has agreed to intensify efforts to protect traditional knowledge and genetic resources but has stopped short of committing to a full international treaty. During its recent meeting (Sept. 22 - Oct.1, 2003) WIPO's General Assembly authorised "the possible development of an international instrument(s)". According to the article, the agreement came after a divisive debate among WIPO member states. Brazil, Venezuela and some African states advocated an international treaty in the next two years, while industrialised countries wanted a more gradual approach. A compromise decision was reached, and WIPO officials "hope" that there will be some form of international agreed action on traditional knowledge and genetic resources in the next three or four years.

http/:www.scidev.net/news/index.cfm?fuseaction=readnews&itemid=1049&language=1

The reluctance to commit themselves to initiatives aimed at protecting traditional knowledge and genetic resources is symptomatic of the whole IPR-issuing bureaucracy in industrial countries. They see themselves as merely interpreters of existing IPR legislation rather than as responsible for balancing ownership rights with the general interests of society. In this respect a noteworthy initiative has been taken by the Australian non-profit organisation GAMBIA (Box 5-10).

Block 5-10

Push to Free Up Biotech Tools for all

The Centre for the Application of Molecular Biology to International Agriculture (GAMBIA), an Australian non-profit organisation, is urging the global biotechnology community to support a new programme for "open access" to the scientific tools of modern biology and genetics. The new programme, called Biological Innovation for Open Society (BIOS) was announced in January 2004 to the World Economic Forum in Switzerland. The founding director of GAMBIA, Richard Jefferson stated that the tools of biotechnology, through exclusive IP protection, were withheld from potential innovators, stifling competition, fair play and creativity, as well as leading to "legitimate unease by the public about biotech". He argues that one can make its own application as proprietary as one wants, but the tools to do so must be a public good.
http:www.checkbiotech.org/root/index.cfm?fusaction+news&doc_id=6680&start=1&control=211&page&page_start=1&page_nr101&page=1

In the present economic and political climate a satisfactory solution is obviously a long way off. In the meantime, the existing ambiguous state of affairs, leads to the main beneficiaries of plant biotechnology being not farmers, but shareholders and the legal profession protecting those interests.

6 Implications and conclusions

6.1 Implications of IPR Protection

The problems encountered when GM varieties containing IPR-protected transgenic characters are introduced into Farmer Seed Systems are complex. The analysis of these problems has been placed in the wider context of agricultural practices in modern and traditional agriculture and in the context of various international agreements and national and international law pertaining to conservation, access and use of plant genetic resources.

An important conclusion is that international agreements are, through necessity, flexible and therefore may lack clarity and consistency, particularly when there are overlapping issues. This gives rise to problems that are, in part, caused by the nature of the various negotiation processes, typically carried out by different national representatives of different ministries and in pursuit of different objectives. The finalisation of such negotiations is generally the responsibility of policy makers, who seek compromise and often lack sufficient knowledge and understanding of biological processes, agriculture and the needs of farmers. In the flexible nature of international agreements, conflicting issues are often referred back to national legislation for interpretation and implementation in the expectation that this provision will cover possible inconsistencies and ambiguities.

The issues have been dealt with in this document in a critical fashion in order to highlight the problems. However this should not be interpreted as questioning the overall importance of such international agreements. The CBD and the FAO Treaty in particular have highlighted the importance of biological diversity and the shared international responsibility to safeguard these resources for future generations. They oblige national governments to take actions that otherwise might not have been taken.

This document applies the same approach to biotechnology. We do not question the potential importance of biotechnology in itself in increasing the options for improving crops and contributing to food security. Our analysis of factors that affect the use of and access to biotechnology accepts these assumptions. Our main concern is that applying common IPR protection to contributions made by biotechnology in a one-size-fits-all approach is inappropriate in two respects. First, it is inappropriate in an economic sense for countries at different stages of technological development. Secondly, as we illustrate and argue, in our view convincingly, that exclusive legal ownership of transgenes in crop varieties does not make biological sense, since their spread cannot be controlled once seed is sold to farmers.

Our main concern is with small (subsistence) farmers and the Farmer Seed Systems that hey rely on as their main source of planting material. The number of such farmers is still huge, but as economic development progresses it will decline. In tandem, Farmer Seed Systems will gradually be replaced by institutional and commercial plant breeding and seed production. Again, we do not question these developments. However, they will take much time. We argue that, in the mean time, access to technologies needs to be structured so that it does not discriminate against small farmers. In a more general vein, it should provide an equitable balance between the interests of farmers and corporate interests.

Implications for Farmer Seed Systems

Our attention centres on countries where Farmer Seed Systems are the main source of planting materials. The results of our analysis suggest that in such countries a standard application of IPR protection regardless of the content matter may not be appropriate. IPR rights are time-limited rights granted by society to an inventor and are required to consider the interests of society as well as those of inventors and corporations. At present IPR rights appear to primarily protect the interests of the latter group.

Crop improvement is an evolutionary process and enabling technologies need to be made available for application to numerous crops in a wide diversity of environments. It is only under such conditions that biotechnology's potential to benefit farmers and contribute to world food security will be realised. It will not be achieved through restrictive access and near-monopoly control of biotechnology by a relatively few corporations and individuals.

In our analysis, IPR protection applied to planting materials (varieties of crops) has been shown to conflict with fundamental aspects of Farmer Seed Systems and to be difficult to enforce. In developing countries, Farmer Seed Systems are the main source of seeds for farmers, and frequently the source of 80% or more of the total national seed requirement. It seems peculiar that under such circumstances it is Farmer Seed Systems that are having to accommodate to conditions set by the still minority interest of a commercial sector. This accommodation nevertheless has been written into international agreements and national legislation, compromising the rights of farmers to produce their own seed, and assigning proprietary rights to their materials (Farmers' Rights) as a mirror image of IPR legislation. We conclude that proprietary rights are incompatible with the cultural cosmo-vision and practices of small farmers. We suggest that the concept and application of Farmers' Rights should incorporate, as its main principle, the freedom of farmers and farming communities to continue to operate within the context of their own cultural and agricultural livelihood systems. This implies the right to maintain the integrity of Farmer Seed Systems.

Implications for national seed industry development

Through WTO/TRIPS developing countries are obliged to enact at least effective *sui generis* IPR legislation in the form of PBR. The argument, that such legislation would at least stimulate breeding by private industry and wider access to improved varieties and thus benefit developing countries, is questionable (Fugli et al, 2003). The seed industry is an essential component of national agriculture. The development of national seed production capacity is important for the long-term security of seed supply to its farmers. Over-dependence on foreign companies prior to establishing a national seed industry carries considerable risks. In the absence of meaningful competition, foreign companies will easily achieve a dominant position in the more commercially attractive crops, taking over small local companies in the process. This will make control of national seed supply of major crops dependent on foreign corporate decisions and leave only the less economically attractive markets and crops open to national companies, which will significantly reduce their economic prospects. Governments will have to decide whether this is in the long-term interest of their farming sector.

Pray and Fugli, (2002), in a survey of seven Asian countries, argue that PBR may indeed increase private incentives to invest in agricultural research, so long as countries allow the private sector to compete in agricultural input markets, establish a productive public research system, and maintain good legal institutions. Few developing countries fully satisfy these requirements. Hence, while in industrial countries IPR in agriculture evolved slowly, in tandem with developments in other sectors and in institutional capacity, many developing countries

are, through WTO/TRIPS and trade pressures required to adopt IPR systems that bear no or little relation to their situation and needs. This often occurs at considerable cost.

WTO/TRIPS, WIPO and the policies of industrial countries should reflect the fundamental social purpose of patent systems, to serve the interests of society in both invention and access to technology and consider the diversity between countries in how best this can be achieved. Hence one-sided trade pressures aimed at limiting the flexibility, permitted under the WTO/TRIPS agreement, should be opposed, to ensure that patent systems can be tailored to local and national needs. Patent systems in developing countries should consider more than just the requirements of commercial crop improvement and seed production. They should also take account of Farmer Seed Systems and the important and essential role that they play in the agriculture of most developing countries. The social and legal consequences of ignoring this role conflicts with the interests of society.

Implications for research and development

The biotechnology industry argues that without strong and harmonised patent protection it will not be able to justify the presently huge investments in this technology. This argument deserves scrutiny. Strong and exclusive patent protection is not an inherent right. Such a right needs to be carefully balanced by clear benefits to the society that issues such rights. If someone makes a significant contribution he or she should obviously be allowed to gain some financial benefit from it. However, such benefits should not lead to monopolies that impair overall progress in research. Neither should these rights conflict with the basic human needs of food security and livelihood, especially those of poor people. In agricultural research these are important considerations.

The limited use of developments in biotechnology to address poor people's crops has much to do with the structural concentration of plant breeding and associated biotechnology in the hands of a few large international corporations. This concentration, at least in part, has been brought about by the possibility of obtaining standard and exclusive patent protection. The concentration of such patents, notably for enabling technologies, complicates the role of public institutions in addressing problems associated with less profitable markets. While the research can be done, bringing the results to the field often requires access to a large number of patents. This demands complex and costly negotiations with uncertain outcomes. The inter-dependence between different patented technologies required to realise a final product (variety) is inherent to crop improvement but may restrict the development or application of crops that are of general benefit to society.

There is no doubt that private industry has become the major holder of patents in biotechnology. As reported by Atkinson et al (2003) private industry accounts for an estimated 76% of the patents, while universities and other public institutions are so far responsible for only 24%. However the latter figure includes many of the types of technologies that are necessary in order to conduct basic agricultural research and develop new GM plant varieties. Public institutions have made important contributions to technologies to transfer genes into plant cells, a technique to characterise specific DNA elements that drive unique patterns of gene expression, and have identified many genes that confer important plant traits. The problem is that ownership of these technologies is highly fragmented and IPRs developed by publicly financed institutions often are licensed on restrictive terms to private industry thereby limiting public use. This is especially harmful to many developing countries where plant breeding is mainly carried out by government institutes that lack the resources to negotiate access to such potentially useful technologies.

The current emphasis of biotechnology research on primarily labour-saving and product quality traits that are of interest to the food industry is clearly illustrated by a "Review of GMOs under Research and Development and in the Pipeline in Europe" of the EU Joint Research Centre (2003, box 6-1).

Box 6-1

Pipeline GM products
For the next 5 years
Herbicide tolerant maize, oilseed rape, soybeans, wheat, sugar beet, fodder beet, cotton and chicory
Insect-resistant maize, cotton and potatoes
Modified starch and fatty acid content in potatoes, soybean and oilseed rape
Modified colour/form in flowers
Modified fruit ripening in tomatoes
Both herbicide tolerant and insect-resistant traits in maize and cotton

For the next 5 to 10 years
Fungi-resistant wheat, oilseed rape, sunflower and fruit trees
Virus-resistant sugar beet, potato, tomato, melon and fruit trees
Herbicide-tolerant wheat, barley and rice
Modified fatty acid content in soybeans and oilseed rape
Modified protein content in oilseed rape, maize and potatoes
High erucic acid content in oilseed rape

Research on production constraints of particular importance to developing countries; tolerance to a-biotic stresses such as drought and salinity or generally increasing genetic yield potential, is rare and is mainly carried out by often poorly funded public, or not-for-profit, institutions. Even if such research leads to significant new options, the development of such research into meaningful products, such as new and improved GM varieties for a great diversity of environmental conditions, requires ready access to the technologies involved. As in "Golden Rice" (Atkinson et al 2003), such access should not be based on the voluntary willingness of patent holders to allow use of the technologies involved, but should be facilitated in a fair manner that gives adequate credit to the originators. Developments in agriculture and food security should not depend on charity.

These problems are not solely limited to developing countries. In industrial countries universities and agricultural research institutes are increasingly forced to financially exploit their research, including through patenting and licensing. This further constrains the application of biotechnology for humanitarian purposes or for the improvement of minor and/or subsistence crops for developing countries. Noting this problem, a number of universities in the US have launched a "Public Sector Collaboration for Agricultural IP Management" (PIPRA) initiative. This initiative is seeking better access to IPR protected technologies in the general interest (Atkinson et al, 2003). A group of 59 scientists, including several Nobel prize winners and economists, have written to the director-general of WIPO, drawing attention to the fact *that "excessive and unbalanced or poorly designed intellectual property protection may be counterproductive"* to the development of science and the interests of society (Nature 10.7.2003). They request WIPO to address the issues in a major conference. In effect they are asking for *sui generis* solutions combining adequate rewards for innovations with appropriate benefits to society.

- Problems are not caused just by fragmented IPR's of enabling technologies. The transfer and expression of new gene complexes into the genomes of plants have uncertain outcomes and possible side effects that may require extensive research. A recent example is provided by attempts by Kenya's KARI Biotechnology Centre to transfer virus resistance into sweet potato (Box 6.2).

Box 6.2

Imported GM technology fails in sweet potatoes

A gene construct developed by Monsanto coding for a coat protein responsible for virus resistance was donated to Kenya's KARI biotechnology centre for incorporation in sweet potatoes. This programme was much publicised as an example of private-public co-operation. The US special envoy, Dr Andrew Young, attended its launch in 2001 and stated that "with biotechnology, we are going to make a green revolution in Africa". However 3 years later, it appears in field tests that the gene construct had failed to produce virus resistance, either by inadequate expression or because it did not address the diversity of virus strains in Kenya. In fact the GM strains yielded considerably less than the non-GM controls. According to the article, the study offered new evidence against claims of the miracle potential of biotechnology for dealing with famine and poverty in Africa. KARI will continue its research, now based on local strains of the virus.
http:www.agbios.com/main.php?action=ShoeNewsItem&id=5211

This should not be interpreted as a critique of biotechnology *per se*. The example illustrates that nature is more robust than biotechnologists- or at least biotech companies - seem to give it credit for. There are no easy solutions. It points to the need for an extensive, lengthy and costly research effort to explore and exploit the exciting new options that biotechnology provides. Gene constructs are no silver bullets. Their expression in foreign genomes is always uncertain and requires research and access to technologies, both in the public and private sector in a manner that benefits the common good.

Implications for agriculture and food production

Strong IPR protection of both GM products and enabling GM technologies is both cause and effect of the dominant position of a limited number of large multinational corporations in biotechnology. This has far reaching consequences. *"Private firms invest in agricultural in order to earn profits for their shareholders. Their profits depend, among other things, on the size of the potential market for their inventions. To earn return on investments, such large corporations tend to concentrate on products with potential billion dollar markets. Firms are unlikely to invest very much money on research to improve crops for which the market is small and the potential payoff is low"* (Pray and Naseem 2003). The results achieved by biotechnology over twenty years and with substantial investments support this statement. What do we see in farmers' fields? In 2003 GM varieties covered around 58 million hectares, but were mainly restricted to 4 crops: soya (61%), corn (23%), cotton (11%) and canola (5%) (ISAAA 2003 - http://www.isaaa.org). The range of introduced new characteristics is also modest. They are so far restricted to herbicide tolerance (73%), Bt. insect resistance (18%), a combination of both (9%) (ISAAA 2003). When one looks at how these technologies have been developed and are used by private industry and what the benefits to agriculture have been to date, the results are less than spectacular.

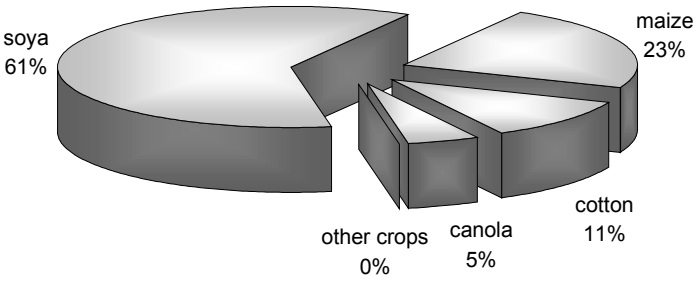

Figure 2: Distribution of total GM crop area over crops in percentages

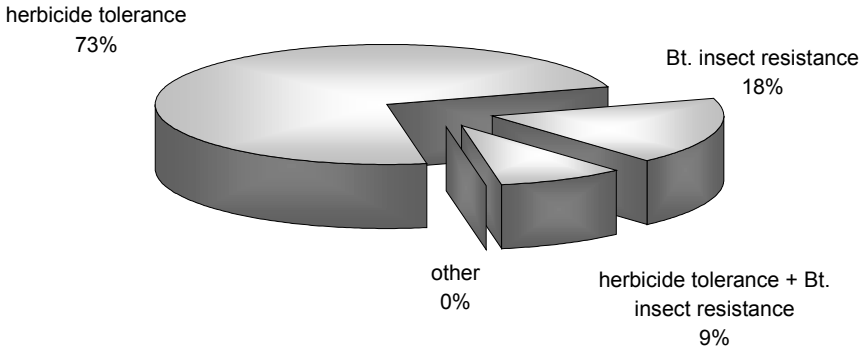

Figure 3: Distribution of total GM crop area over traits in percentages

The development of herbicide tolerance is a case in point. There is no doubt that control of weeds is a major problem in agriculture. This creates a huge potential for using IPRs to capture an enormous market for both the chemical weed control agent and its tolerant varieties. This example also highlights a number of problems.

The industry claims that genetic approaches to weed problems can lead to a reduction in the use of chemical herbicides, both in total amount of herbicides applied and in the frequency of spraying. In addition they can facilitate no-till practices, reducing the threat of soil erosion on fragile soils, which is especially important in high or intense rain-fall areas. These are real benefits. However, there are also potential risks. Many agronomists have warned that use of a single herbicide, for which varieties are made tolerant, may lead to shifts in the composition of weed complexes and over time may lead to the emergence of (relatively) more resistant weed species. The control of such weeds will either require increased application of the herbicide in question or additional spraying with other herbicides. The first signs of this in soya have been reported from Argentina (Branford 2004). According to a report by Benbrook Consultancy

Services (*http://biotech-info.net/technicalpaper6.htm*) similar resistance is emerging in a number of US states. These results are hotly challenged by industrial sources, which blame anti-biotechnology activists and claim an absence of research evidence to support such observations (http://www.monsanto.co.uk/). Yet, the biotech industry has failed to provide any research evidence to refute these claims.

This shows that agriculture depends on complex interactions and that new technologies need to be tested in their context before wide spread adoption occurs. Dependence on single-bullet technology pushed by profit oriented multinational companies may carry great risks. It should be pointed out, that these developments take place at a time that agricultural research in general has moved away from addressing single production constraints, realising that sustainable agricultural production requires more ecologically sensitive approaches that consider the total production environment.

In the context of agriculture and food security, this suggests the need for greater public research and proper risk analysis to balance the dominant role of private industry. It shows the dangers inherent in the global trend towards the privatisation of such research. In biotechnology such a balance requires, in part, appropriate forms of IPRs. IPRs should not lead to monopoly situations and the push for adoption of a technology for short-term profits should not take priority over the need to broadly test for long-term effects on the environment, agricultural production and food security.

6.2 Conclusions and Recommendations

Our major conclusion is that international agreements fail to give adequate recognition to Farmer Seed Systems as the major source of seeds in many developing countries. This failure, in our opinion, biases interpretation of international agreements. It also has a negative impact on national interests of agricultural, the development of national seed industries and on providing access to biotechnology and its benefits in the general interest of agriculture, food production, that include benefits extended to small and resource poor farmers.

We illustrate that trying to apply one-size-fits-all patent protection to biological (planting) materials in agriculture is inoperable, creates a legal quagmire and conflicts with the general interests of society. While meant to stimulate innovation and its application, in this context it actually blocks progress and meaningful use except in capital-intensive industrial agricultural production. The result so far is an overall failure of biotechnology to address the real problems faced by agriculture to secure adequate food for a growing world population and alleviate rural poverty. IPRs may not be the only cause for this. However, we contend that IPRs at least play an important role. Their application to biological materials need to be re-considered. In our view, it requires new and effective *sui generis* forms of intellectual property protection that are grounded in agricultural practices, rather then just designed to serve industrial interests.

Conclusion on the Concepts of International Law

1 Positions adopted with respect to IPRs (for example that the exchange of genetic material within a Farmer Seed System is incompatible with patents relating to genetic material or that, in the case of introgression, patents extend to the introgressed genetic material) are dependent on an interpretation of the applicable conventional international law. Such interpretations cannot be imposed coherently or unilaterally by one State on another State or by the holder of the patent on farmers participating in a Farmer Seed System.

2 The question of consistency between different international agreements is inter-related with the question of the interpretation of the applicable agreements. Only if it is assumed that an agreement has a fixed meaning does the question of the inconsistency between different agreements arise. Current applicable conventional international law contains provisions that may be regarded as requiring the recognition of IPRs relating to genetic material (although this is dependent on the possibility of distinguishing between the concept of 'micro-organism' and the concept of 'genetic material'). They also contain clauses which, albeit only tenuously, recognise, or bear relevance to Farmer Seed Systems. This leads to ambiguous and inconclusive interpretations.

3 Nevertheless, the construction of the international legal framework does seem to contain an element of bias in that IPRs are explicitly recognised as private rights, and are presented as full rights in themselves. In contrast, the recognition of the concept of farmers' rights is presented in an incomplete and conditional manner and its enforcement or defence is the responsibility of national governments.

4 Companies cannot rely directly on IPRs provided for in conventional international law. Conventional international law seeks to prescribe the conditions under which national legislation must recognise and defend IPRs. As such, the existence and exercise of IPRs is always dependent on national legislation.

5 Both the concepts of IPR and Farmer Seed Systems are based on the idea that the intellectual and physical work of a human being should not be subject to appropriation. The concept of IPR is based on the assumption that protection against such appropriation must be afforded in the form of an exclusive right. If it is considered that the protection of Farmer Seed Systems against intrusive effects of IPRs requires the creation of a protective right, such as a farmers' right or a right to the protection of traditional knowledge, this implies that, in the absence of such rights, the intellectual and physical work embodied in a Farmer Seed System may be subject to such appropriation. This conclusion seems inconsistent with the basis on which the concept of IPR is constructed.

6 Reconciling the equitable idea underlying the concept of IPR with the normative situation of Farmer Seed Systems requires a normative construction that relates IPRs on genetic material and Farmer Seed Systems to each other. This construction cannot permit exclusive and contradictory presumptions to co-exist.

Recommendations on the functioning of Farmer Seed Systems

1 IPRs on planting material, as defined by common patent law, should be re-considered in the light of the nature of biological materials whose spread, through natural means, cannot be contained.

2 IPRs on planting material should consider, and be compatible with, the practices and cultural and socio-economic conditions that form the basis of traditional agriculture and Farmer Seed Systems.

3 Farmers' Rights, as defined in the FAO Treaty on Genetic Resources for Food and Agriculture merely urge countries to provide ownership rights to local genetic resources that do not effectively provide benefits to farmers. In effect they provide rights that seem to conflict with the basic practices of Farmer Seed Systems. Such rights would seem to merely represent an attempt to justify appropriation of biological materials through IPRs. The basic right afforded to farmers should be the freedom to continue with the practices and cultural and socio-economic context of Farmer Seed Systems, while having access to all relevant technologies on appropriate and reasonable terms that do not depend upon charity.

4 There is a need for greater scrutiny of the developmental effects of IPRs, particularly the linkages with poverty and food security, and adoption of *sui generis* legislation that is compatible with Farmer Seed Systems and promotes the development of national seed industries with access to relevant technologies.

5 Proposals for reform of the TRIPs regime, currently under consideration, should preserve the rights of WTO members to tailor their IPR regimes according to their particular circumstances, which should pay particular regard to the special needs of poor farmers and to maintaining the integrity of Farmer Seed Systems. Countries should not be subject to bilateral trade pressures in this area.

6 Options for IPR legislation on crops that satisfy WTO/TRIPS requirements, should at least allow for effective compulsory licensing in order to facilitate broad access to biotechnology relevant for food and agriculture against a reasonable fee.

Appendix 1: Important Web Sites

FAO Plant Genetic Resources for Food and Agriculture (PGRFA)
http://web.icppgr.fao.org/home.htm
This site provides access to issues relevant to the FAO Commission.

GRAIN
http://www.grain.org
This site provides access to information on topics related to genetic resources, conservation, ownership national IPR legislation etc. The site is fully available in English, French and Spanish.

International Plant Genetic Resources Institute: IPGRI
http://www.cgiar.org/ipgri
As a CGIAR centre, IPGRI has a mandate to advance the conservation and use of genetic diversity for the common good. Its site provides access to information on IPGRI itself (e.g. mandate, vision, strategy, impact), issues on genetic resources (e.g. conservation, legal and policy matters), networks, events, training opportunities, country related programmes etc.

International Union for the Protection of New Varieties of Plants: UPOV
http://www.upov.org
This site contains all the relevant information relating to UPOV, including its role and functions, the full text of the convention (Acts of 1961, 1978, 1991), National Plant Variety Protection Laws, membership, ratification situation, addresses, meetings, press releases, documents and publications.

ETC, formerly Rural Advancement Foundation International: RAFI,
http://www.ETC.org
ETC is an international non-governmental organisation based in Canada. ETC's focus is on the conservation and sustainable improvement of agricultural biodiversity and socially responsible development of technologies useful to rural societies. RAFI organises campaigns and publishes thematic documentation.

World Intellectual Property Organisation: WIPO
http://www.wipo.org/eng/main.htm
The site is accessible in English, French and Spanish and provides official information on all internationally agreed treaties related to intellectual property rights. The search engine gives access to discussions on the relationship between patenting and plant and animal life forms.

World Trade Organisation: WTO
http://www.wto.org/wto/intellec/intellec.htm
This site provides information with regard to news, works of the TRIPS council, notifications, reviews of members' implementation of legislation, technical co-operation and disputes. The special page for Community/Forums is intended to involve NGOs in TRIPS issues. A page with Frequently Asked Questions gives an introduction into some elementary TRIPS aspects. The site is accessible in English, French and Spanish via the home page. One then finds the way to TRIPS via "trade topics".

Meridian Institute
http://www.merid.org
The Meridian institute facilitates debate on issues involving multiple points of view. Meridian's experience encompasses environment, natural resources, agriculture, sustainability, science and technology and security. They work at the local, national and international level. Their mailing service provides up-to-date information on Food Security and agricultural biotechnology news and it was an important source for many of the topical boxes contained in this book (*http://www.merid.org/fs-agbiotech*)

Appendix 2: Literature consulted

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