Harnessing Intellectual Property Rights for Development Objectives

The Double Role of IPRs
in the
Context of Facilitating MDGs Nos. 1 and 6

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Willem van Genugten, Anna Meijknecht (Project-coordinators), Bernard Maister, Caspar van Woensel, Bram De Jonge, Godber Tumushabe, Julian Barungi, Niels Louwaars, Grant Napier, Sibongile Gumbi, Tobias Rinke de Wit

ISBN: 978-90-5850-726-7

Project funded by the Netherlands Ministry of Foreign Affairs and

NWO-WOTRO, Science for Global Development

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Wolf LegalPublishers

POB 31051

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The Netherlands

www.wolfpublishers.com

2011

Cover image: Mr Mohamed Budarhaman. Vegetable seed merchant from Darfur in Konjo - Konjo market Juba, South Sudan selling commercially imported and locally produced vegetable seed (january 2009). Photo: Niels Louwaars.

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Overall Introduction

1. History of the Project

In 2007, the then Minister of Development Cooperation of the Netherlands, Bert Koenders, launched the so-called Schokland Agreement, named after the area of Schokland, a former island in the middle of the Netherlands and in 1995 recognized by UNESCO as a World Heritage Site. The Minister did do so in order to stimulate companies, NGOs, individuals – in short, everybody with a possible interest in development issues – to do their utmost to help realize the UN Millennium Development Goals (MDGs). In reaction to the initiative, a number of people with a background in universities, ministries and platforms with links to international education and research decided to join efforts, leading to the establishment of the '*Platform MDG-Profs*'.[1] As a first step, the Platform developed a plan to make better use of Dutch research institutions and higher education for the benefit of realizing the MDGs. The second step was to develop a large research project on the topic of 'intellectual property rights and development'. The Platform felt that the capacity to open up, generate, share, and use knowledge is an important prerequisite for worldwide development, while intellectual property rights (IPRs) play a central, but also double, role in the management and sharing of knowledge in innovation systems: one the one hand, they are meant to protect knowledge, to stimulate investments in innovation and to support R&D following inventions. On the other hand, they might as well reduce use of technological innovations forthcoming through IPR protected knowledge, because commercialization of knowledge impedes innovation by and for societies that, for instance, cannot provide a (legal) framework to effectively manage IPRs or that cannot promise financial returns. Thus, it was felt by the Platform that poorly developed IPR management hinders equal research partnerships between the South and the North, and often results in a reticent or one-dimensional Northern investment policy and unnecessary delays in the realization of some of the MDGs. This double side of IPRs – also to be labelled in terms like protecting legitimate economic interests *versus* (or alongside) the need to contribute to worldwide development from the perspective of sharing *global public goods*, to which also knowledge is often said to belong – inspired the initiators to set up the present project.

In 2008, the Platform was offered funding by the Ministry of Foreign Affairs and NWO-WOTRO, the division for scientific research on development issues of the Netherlands Organisation of Scientific Research (NWO).

2. Contributors to the Project and Acknowledgements

The project has been carried out by a large team of people, in various roles and with a variety of backgrounds relevant to the project. Nine people have acted as researchers, their names being mentioned on the cover of the present book and repeated here in alphabetical order: Julian Barungi (Uganda); Sibongile Gumbi (South Africa); Bram De Jonge (the Netherlands);

[1] See for its history and mandate: <http://www.vsnu.nl/Focus-areas/International-policy/Development-cooperation/Platform-MDG-Profs.htm>. The Platform is now called: Knowledge Forum for Development. The Platform is chaired by Prof. Martin Kropff, Rector Magnificus of Wageningen University, and is financially supported by NWO-WOTRO.

Niels Louwaars (the Netherlands); Bernard Maister (South Africa); Grant Napier (South Africa); Tobias Rinke de Wit (the Netherlands), Godber Tumushabe (Uganda); and Caspar van Woensel (the Netherlands). More information on each of them can be found in the List of Contributors.

The project could not have been carried out without the knowledge and the diversity of practical experiences of a group of experts in the field of intellectual property rights, together being the 'Steering Committee': Victoria Henson-Apollonio, former manager Central Advisory Service on Intellectual Property, Rome; Ruth Okediji, Nigeria, Professor of International Intellectual Property Law, University of Minnesota; Peter Munyi, IP Lawyer, Nairobi; William New, Director and Editor-in-Chief, *Intellectual PropertyWatch*, Geneva; Geertrui van Overwalle, Professor of Intellectual Property Law, Universities of Leuven and Tilburg; Michael S. Pepper, Professor in Health Sciences, Pretoria (had to step aside halfway); Orlando de Ponti, President of the International Seed Federation; and Rosemary Ann Wolson, Professor, Intellectual Property & Technology Transfer, Council for Scientific & Industrial Research, Pretoria. The Steering Committee members played a major role at all stages of the project. All of them attended two plenary meetings to discuss the set-up and the interim findings, while they delivered numerous contributions to the fine-tuning of the end-results. William New also co-edited the final report.

As will become clear below (Par. 3.3. especially), the project consisted of three sub-projects. While the Law School of Tilburg University served as the 'home base' for the project as a whole, as well as for the first sub-project, Wageningen University hosted the second sub-project, while the University of Amsterdam in cooperation with the Foundation PharmAccess hosted the third sub-project. Apart from the people already mentioned, the projects have profited greatly from the input by Julian Kinderlerer, University of Cape Town (sub-projects 1 and 2), while Wendy Stevens, Wits University, South Africa (sub-project 3) and Nico Schrijver as well as Dirk Visser, both Leiden University, the Netherlands, acted as co-readers of specific parts of the report of sub-project 1.

As said, the project had Tilburg University as its home base, but Bram De Jonge and Niels Louwaars, both Wageningen University, and Tobias Rinke de Wit, University of Amsterdam, Center for Poverty-related Communicable Diseases (currently: the Amsterdam Institute for Global Health and Development) and the Foundation PharmAccess International, played an important role as co-coordinators and 'sparring partners'.

3. The Project Itself

3.1 Introduction

The project focuses on one cumbersome aspect of globalization: the relationship between the international system for the protection of intellectual property and the achievement of the development objectives as formulated the MDGs, in particular MDG 1 ("Eradicate extreme hunger and poverty", target 1c: "Reduce by half the proportion of people who suffer from hunger"); and MDG 6 ("Combat HIV/AIDS, Malaria and other diseases", target 6b: "Achieve, by 2010, universal access to treatment for HIV/AIDS for all those who need it."). While intellectual property rights play a central role in the management and sharing of knowledge in innovation systems, the assumption of the project is that understanding both the enabling and limiting factors of such rights in improving access to knowledge and technology for those who can most benefit from it, is of key importance for the realization of the MDGs.

The project aims at understanding the role of intellectual property rights in relation to development. Its purpose is to strengthen the awareness, capacity, and knowledge of scientists, research organizations, and governments in the "South" and the "North" with regard to international and national strategies and attitudes in the field of IP and development. In this way, this projects aims to contribute to the development of sustainable scientific cooperation relationships between "North" and "South" and to the realization of MDGs Nos. 1 and 6. Due to the need to limit the research, this project will focus on two Sub-Saharan African countries (Uganda and South Africa) and the Netherlands. The project thus is situated on the interface between serving the direct (economic) interests of research centres and institutions in the "North" as well as the "South" and the need to contribute to the *global public good*.

3.2 Research Questions

The central question of the project is the following: What is the role of intellectual property rights (IPRs) in the management and sharing of knowledge for development, in particular, the achievement of the MDGs 1 and 6?

This central question builds upon 'a web' of four sub-questions. In order to obtain a balanced view of the role of IPRs in the context of the enhancement of the MDGs, it is not only relevant to find out what possible obstacles are created by IPRs in the context of the realization of development objectives (sub-question 1), but also to get a clear picture of best practices or positive experiences with using IPRs to deal with access to knowledge and technology (sub-question 2). Whereas the first two sub-questions define the (negative and positive) role of IPRs in the realization of MDGs, the other two sub-questions concern the way forward. How can the possibly negative relationship between IPRs and the achievement of the MDGs be repaired (sub-question 3)? And in what way can the results of the present project be used by the variety of relevant actors: practical recommendations (sub-question 4)?

These research questions are addressed by three interlinked sub-projects (placed in Parts I, II and III of this report), each covering different disciplines and applying a different method to establishing the relationship between IPRs and the achievement of the MDGs. In Part IV, the conclusions and recommendations of the three sub-projects, are brought together and analyzed in order to obtain a nuanced answer on the central research question (also see Par. 3.4 on Methodology).

3.3 Structure of the Report; Description of the Sub-Projects

Part I of this report contains the findings of sub-project 1: *Trade vs. Development: the International Intellectual Property Rights' Regime and the UN Millennium Development Goals***.** This project provides the background to and a discussion of the current policy and legal debate taking place in governments, universities and international organizations on the impact of the international intellectual property rights' system on the realization of development objectives. It outlines the development and history of IPR law in general and frames the obstacles to development created by IPR law and the application of the international IPR regime to developing countries. Most attention is given to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), as the dominant international IPR agreement in the modern era, and on patents as the most significant of the IPR instruments in this context. Other issues specifically covered include the need to have the domestic capacity to build an IPR system, the 'power differential' between developed and developing countries and the question how this differential impacts negotiations on and enforcement of existing IPR law. This is followed by discussion of the 'post-TRIPS world', e.g., the renewed importance of bilateral trade agreements.

Part II of the report consists of the findings of sub-project 2: *Agricultural Seeds That Reduce Hunger and Poverty – Policies, Perceptions and Practices in Intellectual Property Rights*. This project examines the relationship between IPRs, agriculture, and MDG 1c (see above). The study analyzes the roles that different IPR policies and practices play in agricultural research and development trajectories in both a developed context (in particular the Netherlands) and a developing context (in particular Uganda). Ultimately, the aim of the sub-project is: 1) to map the main obstacles and opportunities that IPRs create for the development and transfer of knowledge and technologies for the benefit of resource-poor farmers in developing countries; and 2) to contribute to the realization of IPR strategies and recommendations that improve the development and accessibility of agricultural inputs that are relevant for resource-poor farmers and that increase food security in developing countries. The research focuses on the full chain of actors involved, from ministries in the North and the South and research centres in both worlds, to the local end-users and producers of relevant IPR knowledge.

Part III of this report consists of the outcome of sub-project 3: *Affordable HIV Drug Resistance Test for Africa (ART-A) Intellectual Property***.** This study focuses on the relationship between IPRs, the medical diagnostics sector, and MDG 6b (see above). The study examines a European and African research consortium called the Affordable Resistance Test for Africa (ART-A: http://www.arta-africa.org/) that was established to develop technologies for affordable HIV drug resistance testing in Africa. The end goal of the study is to ensure that products and services developed by the ART-A research consortium can be successfully produced and effectively used in combatting the HIV and AIDS epidemics. For that purpose, the study describes the IPR environment of the ART-A research consortium and explores suitable IP protection models that could be used by public-private partnerships developing medical diagnostic technologies to facilitate broader access to diagnostic testing in Africa.

Part IV contains the synthesis, concluding remarks and recommendations of this research project. The synthesis and concluding remarks are based on a comparison and analysis of the conclusions formulated at the level of the sub-projects (Parts I, II, and III of the report). The last part of Part IV contains practical recommendations based on the outcomes and recommendations of the individual sub-reports and on the synthesis and concluding remarks. These recommendations are directed towards policy makers at the global, regional and national level, funding organizations, and universities and (other) research institutes.

3.4 Methodology; Complementarity of the Sub-Projects

Each of the sub-projects covers different disciplines, has a different focus and applies a different method to establish the relationship between IPRs and the achievement of the MDGs. They have been chosen this way in order to be complementary to one another. However, they also have commonalities: the binding element between the three sub-projects consists of a framework of questions, i.e., the above-mentioned core question together with the 'web' of four sub-questions. In the end, all three projects do search, each in its own way and applying its own method, for answers to the same set of questions. The outcomes of the individual sub-projects can be found at the end of each sub-report, while in Part IV the outcomes of the three sub-projects are linked.

When perceived together, the three sub-projects reflect a rather unique combination of researchers, disciplines and entrances to the debate on 'IPRs and development': a combination of North-South research partnerships, with multi-, inter- and trans-disciplinary cooperation between technological expertise in the field of agriculture/food and medicines and expertise in the field of international as well as national regulations and legislation on IPR law. This combination adds several dimensions to the outcomes of the three sub-project reports and offers a number of opportunities for comparison and analysis.

For instance, as already visible from the above descriptions, the three sub-projects approach the questions from a different angle: while sub-project 1 discusses the general theoretical and legal background that bears on the role of the current international IP regime in achieving the MDGs 1 and 6, the two case-studies shed light on the implications of IPRs for knowledge development and transfer in the field agriculture (MDG 1) and medical devices (MDG 6). Further to that, the first sub-project approaches the field of international IPRs with an overall 'helicopter' view, while the second sub-project provides a macro perspective by analyzing the chain of knowledge transfer from Dutch universities and research institutes to smallholder farmers in Uganda, and *vice-versa*. Next to that, the third sub-project provides a micro perspective on the relevant research questions by zooming in on the search for suitable IP protection models in the context of the ART-A consortium which aims to develop technologies for affordable HIV drug resistance testing in Africa.

Taking the findings together, it will become clear that due to the set-up of the project and the way the sub-projects have been carried out, conclusions can and will be drawn on a variety of levels. To conclude this introductory Part, we would like to mention three such levels and accompanying perspectives:

– The geographical perspective: a) the local level: farmers in Uganda, b) the national level: governments in the Netherlands, Uganda, and South Africa; c) the regional level: the Organisation Africaine de la Propriété Intellectuelle (OAPI), the African Regional Intellectual Property Organisation (ARIPO) and the EU (to some extent); d) the global level: the WTO, the International Union for the Protection of New Varieties of Plants (UPOV), and the World Intellectual Property Organization (WIPO).
– The actors' perspective: a) local farmers and breeders in Uganda, researchers and staff of medical laboratories in Uganda and South Africa; other private sector people in the South and the North, applying the findings analogously; b) research institutes and universities in the Netherlands, Uganda and South Africa; c) governments in the Netherlands, Uganda, and South-Africa.
– The perspective of the complementary approaches, chosen by and for each of the sub-projects: a) an overall approach, providing insights in historical developments and present international debates on the relation between IPRs and MDGs (sub-project 1), b) a chain-analysis conducted on IPRs in the agricultural context (sub-project 2) and c) a micro-analysis of a concrete model in the medical context (sub-project 3).

In conclusion: it has been an intense project, to be conducted in two years overall, with 1.5 years for the actual research only. However, the cooperation of totally different disciplines indicates that it would and actually will be very useful to establish more such coalitions, addressing North-South topics 'that really matter'. The confrontation between disciplines and the inclusion of the actors' perspective on a variety of levels has lead to insights that would not have been reached should the problem under scrutiny in this report have been defined in a mono-disciplinary and purely scientific way only. It has become clear again that research which finds its inspiration in practical issues can lead to innovate scientific insights. We hope the readers of this report feel as inspired as we do.

Willem van Genugten
Anna Meijknecht
Tilburg, 15 July 2011

Acronyms

AATF	African Agricultural Technology Foundation
ABL	Advanced Biological Laboratories
AIDS	Acquired Immunodeficiency Syndrome
AGRA	Alliance for a Green Revolution in Africa
AGT	Agro-Genetic Technologies Limited
AMC	Amsterdam Medical Centre
ANDi	African Network for Drugs and Diagnostics Innovation
ARIPO	African Regional Intellectual Property Organisation
ART-A	Affordable Resistance Test for Africa
ARV	Antiretroviral
ASARECA	Association for Strengthening Agricultural Research in Eastern and Central Africa
ASR	Analyte Specific Reagent
AUC	African Union Commission
AUTM	Association of University Technology Managers
AVRDC	World Vegetable Centre
AWT	Advisory Council for Science and Technology Policy (Netherlands)
BEE	Black Economic Empowerment
CAADP	Comprehensive Africa Agriculture Development Programme
CBD	Convention on Biological Diversity
CDA	Confidential Disclosure Agreement
CDC	Center for Disease Control and Prevention
CDIP	Committee on Development and Intellectual Property
CFC	Common Fund for Commodities
CGIAR	Consultative Group on International Agricultural Research
CIAT	International Centre for Tropical Agriculture
CIMBAA	Collaboration on Insect Management for Brassicas in Asia and Africa
CIMMYT	International Maize and Wheat Improvement Centre
CIP	International Potato Centre
CIPIH	Commission on Intellectual Property Rights, Innovation and Public Health
CIPRO	Companies and Intellectual Property Registration Office
CMH	Commission on Macroeconomics and Health (WHO)
CPA	Africa's Science and Technology Consolidated Plan of Action
CPA	Copyright and Patent Agreement
CPCD	Center for Poverty Related Communicable Diseases
CRP- Santé	Centre de Recherche Publique de la Santé
DDPSC	Donald Danforth Plant Science Centre
DFID	United Kingdom Department for International Development
DGIS	Netherlands Ministry of Development Cooperation
DMCA	Digital Millennium Copyright Act
DNA	Deoxyribonucleic Acid

DuRPh	Durable Resistance against Phytophthora
EC	European Commission
ECOWAS	Economic Community Of West African States
EL&I	Netherlands Ministry for Economy Agriculture and Innovation
EPAs	Economic Partnership Agreements
EPO	European Patent Office
EU	European Union
EZ	(former) Netherlands Ministry of Economic Affairs (now part of EL&I)
FAO	Food and Agriculture Organisation
FDA	Food and Drugs Administration (US)
FDC	Fixed-Dose Combination
FDI	Foreign Direct Investment
FTAs	Free Trade Agreements
FTO	Freedom to Operate
GATB	Global Alliance for TB Drugs
GATT	General Agreement on Tariffs and Trade
GAVI	Global Alliance Vaccine Initiative
GBS	Global Bio-Collecting Society
GFATM	Global Fund to Fight AIDS, Tuberculosis and Malaria
GI	Geographical Indications
GM	Genetic Modification
GMO	Genetically Modified Organism
GMP	Good Manufacturing Practice
GNU	GNU's Not Unix
GPL	General Public License
GSK	GlaxoSmithKline Plc
HIV	Human Immunodeficiency Virus
HIVDR	Human Immunodeficiency Virus Drug Resistance
HIV VL	Human Immunodeficiency Virus Viral Load
IAVI	International Aids Vaccine Initiative
ICCPR	International Covenant on Civil and Political Rights
ICTSD	International Centre for Trade and Sustainable Development
IFAD	International Fund for Agricultural Development
IFC	International Finance Corporation (World Bank Group)
IGWG	Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (WHO)
IITA	International Institute for Tropical Agriculture
IITC	Inter-Institutional Trade Committee
IMPACT	International Medical Product Anti-Counterfeit Taskforce
IP	Intellectual Property
IPC	International Patent Classification
IPFA	International Project Finance Association
IPGRI	International Plant Genetic Resources Institute
IPRs	Intellectual Property Rights
IPSF	Intellectual Property Support Fund

ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
IVD	*In Vitro* Diagnostic
IUO	Investigational Use Only
IUPGR	International Undertaking on Plant Genetic Resources
JCRC	Joint Clinical Research Centre
JITAP	Joint Integrated Technical Assistance Programme
KNAW	Royal Netherlands Academy of Arts and Science
LDC	Least Developed Country
LDT	Laboratory Developed Test
LNV	(former) Netherlands Ministry of Agriculture, Nature and Food quality (now part of EL&I)
MCC	Medicines Control Council
MDG	Millennium Development Goal
MOU	Memorandum of Understanding
MPEP	Manual of Patent Examining Procedure
MSF	Médecins sans Frontières
MTA	Material Transfer Agreements
MTTI	Ministry of Trade, Tourism and Industry
MVI	Malaria Vaccine Initiative
NACCAP	Netherlands-African Partnership for Capacity Development and Clinical Interventions against Poverty-Related Diseases
NaCRRI	National Crops Resources Research Institute
NANEC	National Network of Cassava workers
NARO	National Agricultural Research Organisation
NGI	Netherlands Genomics Initiative
NGO	Non-Governmental Organisation
NEPAD	New Partnership for Africa's Development
NIH	National Institutes of Health (US)
NIPMO	National Intellectual Property Management Office
NRM	Natural Resource Management
NWO	Netherlands Organisation for Scientific Research
OAPI	Organisation Africaine de la Propriété Intellectuelle
OAU	Organisation of African Unity
OECD	Organisation for Economic Cooperation and Development
OC&W	Netherlands Ministry for Education, Culture and Science
OIN	Open Invention Network
OSDD	Open Source Drug Discovery
PASER	PharmAccess African Studies to Evaluate Resistance
PBR	Plant Breeders' Rights
PCDA	Provisional Committee on Proposals Related to a WIPO Development Agenda
PCR	Polymerase Chain Reaction
PCT	Patent Cooperation Treaty
PEPFAR	US President's Emergency Plan for AIDS Relief
R&D	Research and Development
PIC	Prior Informed Consent

PIIPA	Public Interest Intellectual Property Advisors
PIPRA	Public Intellectual Property Resource for Agriculture
PPPs	Public-Private Partnerships
PRAPACE	Regional Potato and Sweet Potato Improvement Network in Eastern and Central Africa
PTAs	Preferential Trade Agreements
PVP	Plant Variety Protection
R&D	Research and Development
RUO	Research Use Only
SAHPRA	South African Health Products Regulatory Authority
SANAS	South African National Accreditation Service
SAP	Structural Adjustment Programme
SME	Small and Medium-sized Enterprise
SNP	Single Nucleotide Polymorphisms
STD	Sexually Transmitted Disease
STI	Sexually Transmitted Infection
STW	Technology Foundation (Netherlands)
TB	Tuberculosis
TDR	WHO Special Programme for Research and Training in Tropical Diseases
TK	Traditional Knowledge
TKDL	Traditional Knowledge Digital Library
TRALAC	Trade Law Centre for Southern Africa
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
TTI-GG	Technological Top Institute – Green Genetics (Netherlands)
TT(O)	Technology Transfer (Office)
UBOS	Uganda Bureau of Statistics
ULRC	Uganda Law Reform Commission
UMCU	University Medical Centre Utrecht
UN	United Nations
UNAIDS	Joint United Nations Programme on HIV/AIDS
UNBS	Uganda National Bureau of Standards
UNCST	Uganda National Council for Science and Technology
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNESCO	United Nations Educational, Scientific and Cultural Organisation
UNIDO	United Nations Industrial Development Organisation
UNSSPA	Uganda National Seed Potato Producers' Association
UPOV	International Union for the Protection of New Varieties of Plants
URSB	Uganda Registration Services Bureau
US	United States of America
USAID	United States Agency for International Development
USDA	United States Department of Agriculture
USPTO	United States Patent and Trademark Office
VCA	Visitors Confidentiality Agreement
VSNU	Association of Universities in the Netherlands

WCO	World Customs Organization
WHC	Wits Health Consortium (Pty) Ltd.
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WITS	University of the Witwatersrand
WOTRO	Science for Global Development Programme (of NWO)
WRR	Dutch the Scientific Council for Government Policies
WTO	World Trade Organisation
WUR	Wageningen University and Research Centre

PART II

AGRICULTURAL SEEDS THAT REDUCE HUNGER AND POVERTY – POLICIES, PERCEPTIONS AND PRACTICES IN INTELLECTUAL PROPERTY RIGHTS

By

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CHAPTER 4 IP POLICIES AND PRACTICES AT AFRICAN RESEARCH ORGANIZATIONS

CHAPTER 5 IP POLICIES IN THE NETHERLANDS: WHAT ROOM FOR PRO-POOR INNOVATION?

EXECUTIVE SUMMARY

Goals and Objectives

1. The Millennium Declaration contains a set of ambitious goals and targets that countries committed to, including under Goal 1 dealing with the eradication of extreme poverty and hunger, setting themselves a target to halve, between 1990 and 2015, the proportion of people who suffer from hunger (MDG 1c). Agriculture and particularly smallholder agriculture is central to meeting MDG 1c, and the use of good seed of adapted varieties is a major prerequisite for improving agriculture. Access by farmers to new varieties and access by breeders to the technologies and materials to develop them is central in this research, which aims to investigate the roles of Intellectual Property Rights (IPRs) in the management and sharing of knowledge for development.

2. We have studied the Intellectual Property Rights systems relevant to plant breeding (patents and Plant Breeder's Rights). We have taken the innovation chain approach, analysing the policies underlying the rights, perceptions and practices in applying the rights by stakeholders at funding organizations of fundamental and strategic research, research institutions and researchers in the Netherlands down to research for development funders and researchers in Africa (notably Uganda) down to smallholder farmers. The aim was to map the main obstacles and opportunities that IPRs create for the development and transfer of knowledge and technologies for the benefit of resource-poor farmers in developing countries, and secondly to contribute to the realization of IP strategies and recommendations that improve the development and accessibility of agricultural inputs that are relevant for resource-poor farmers and which increase food security in developing countries.

3. The innovation chain can be read in terms of a "push", where technology is translated to products for farmers, but also as a "pull" starting from the end user. It addresses what are the needs of smallholders and how is their access to the different seed systems (see below) translated into breeding objectives and research programs.

4. The research involved interviews with a large number of stakeholders along this innovation chain, and the analysis of relevant policy documents, contracts, and literature. Uganda is selected as it represents a typical African least developed country which is highly dependent on agriculture. The Netherlands has a leading position in agricultural research and development, and has a thriving seed sector.

IPRs may create obstacles at various points along the innovation chain:

5. Since resource-poor farmers almost exclusively source new varieties from informal sectors, any IPR system that effectively disallows the informal sharing of seeds such as patents and some forms of Breeder's Rights will obstruct access to new protected varieties. Even though awareness of IPRs is generally low with public research directors in Africa, a broadly shared perception is that such rights, when applied to publicly bred varieties, could solve budgetary constraints of public research (including breeding), and

supplement low wages of breeders in the public service. Few realize the potential to tilt the focus of these institutions towards more commercially viable crops and farmers and away from poverty reduction goals. A low capacity to manage intellectual property in public research and breeding organizations either shies away potential foreign research partners from collaboration, or puts the African partner in a disadvantaged position in negotiations towards access of technologies. Such institutes furthermore operate in a policy environment where the framing of national IP policies is strongly influenced by international pressures, which makes it impossible for developing countries to balance the rights of inventors with those of their society. Ugandan institutions exercising IP-related mandates are quite disjointed or only coordinate with each other in an ad hoc manner, not contributing to tangible benefits to the country and its resource-poor farmers.

6. Dutch IP law and national innovation policies lack a specific development clause despite several international agreements that emphasize the responsibility of the industrialized countries to promote technology transfer to least-developed nations. There is no general IP policy at the ministries that finance agricultural research, and opinions diverge on the need for such a policy, while awareness among policymakers is low with respect to possibilities for IP to impede access to technologies in developing countries. International development policy and knowledge and innovation policy are organizationally divided and generally perceived as two worlds apart.

7. Some Dutch funding agencies and programs, however, have "valorisation" strategies, which is the basis for public-private partnerships in research. These strategies lack specific references to international development. Valorisation of research is commonly narrowly understood by such programs as the need to turn knowledge into (economic) value for the Dutch society - through IPR protection - and by universities, the acquisition of royalties of new research contracts. The involvement of the private sector in public research affects the conditions under which university IP can be accessed, and commonly leads to more exclusive arrangements.

8. Dutch public research organizations hardly include humanitarian licensing strategies in their research and IP contracts with (private) research partners, which could increase availability of technologies for development purposes. The perception is widespread that such humanitarian licenses can negatively affect the organization's own interest in the negotiations.

9. It is difficult and costly to secure freedom to operate for humanitarian projects given the IP landscape in agricultural biotechnology: Material Transfer Agreements (MTAs) often do not allow for product development; strategic patenting and restrictive licensing conditions are common; many IP laws only include a weak research exemption;n biosafety procedures for GM crops are very expensive and regulatory dossiers are held confidential. All these issues create restrictions for the sharing of technology in both industrialized and developing nations. A lack of research capacity in the developing country or the capacity to effectively deal with IP may be additional impediments to the use of potentially useful technologies for development.

Policies and practices that are likely to ensure a positive role of IP in facilitating the development, transfer and access to agricultural innovations for smallholder farmers:

10. This includes a recent recognition in several African countries of the informal seed system leading to a more careful balancing of rights and obligations in seed and Breeder's Rights regulation. International research agencies and some donors investing in agricultural research provide safeguards for access to new varieties by smallholders. Moreover, Plant Breeder's Rights may - when carefully framed and implemented - support the uptake of new varieties in the product portfolio of a seed enterprise, where otherwise the variety might be left 'on the shelf'.

11. In the Netherlands, there are some developments worth mentioning: An "Incentive Fund for Open Access Publications" has been established by the Netherlands Organization for Scientific Research (NWO); and there are some recent voices calling on the Dutch government to create more synergy between the organizationally divided worlds of international development policy and research and innovation policy. Finally, the Plant Sciences Group of Wageningen UR concluded an important humanitarian use license with a CGIAR partner and one in the US, which is a sign of a policy shift towards making technology more readily available for contributing to MDG1c.

12. Several solutions have been proposed in order to counteract the blocking effect of patents on the availability of genetic material for further breeding; and several humanitarian and open licensing tools have become available to secure and facilitate the accessibility or transfer of IP protected knowledge, materials and technologies for development purposes.

We recommend that:

13. If Uganda and other African countries are to support poverty reduction through research for development, they should formulate IPR laws that take into account the need for farmer-to-farmer technology transfer.

14. Public research organizations in Africa need to frame their institutional policies in such a way that both commercial and (near-) subsistence agriculture of the country can be supported. They need to increase their capacity in IP management in order to avoid concluding contracts that are not to the benefit of the country or the poorer constituency of farmers.

15. African countries should actively pursue the integrated seed system development pathway that recognizes the importance of farmers' seed systems next to the formal system.

16. Uganda should increase its policy coherence relevant to seeds and IPRs by making sure that the various institutions involved and their mandates are properly coordinated.

17. The Dutch government should create much more synergy between its research and innovation policy and its international development policy in the formulation of a general IP policy with respect to public research. This should involve an evaluation of the current research funding system and the development of criteria and incentive mechanisms for valorisation that go beyond mere economic outputs for the Dutch society and reach across borders. More expertise needs to be developed with respect to humanitarian licensing strategies at public research organizations and funding agencies.

18. The current patent system may need to be evaluated at the global level with respect to the need for a breeder's exemption in patent law, mechanisms to curtail strategic patenting, expanding possibilities for compulsory licenses, reducing the costs and inefficiency of the patent system, and the expansion of the "private and non-commercial use" exemption in Plant Breeder's Rights to all resource-poor farmers.

19. Obligations in international agreements to facilitate technology transfer for development purposes need to be actively pursued, and generic competition secured after termination of IP protection.

Extending the outcomes to stakeholders and further research:

20. The outcomes of the study will be communicated with the relevant stakeholders in Europe and Africa, starting with the various actors interviewed.

21. The outcomes will be included in curriculum on IPRs in the Life Sciences at Wageningen University, and invitations have been accepted to discuss them with the Uganda Seed Trade Association and the African Union Secretariat in Addis Ababa. They will also be discussed in the Network of IP-Professionals of the Central Advisory Service on IP of the CGIAR (the National Partners' Initiative) during its annual meeting – scheduled in South Africa in July 2011.

22. The project results will be included in international mid-career training programs of the Centre for Development Innovation in Chennai (2011) and Wageningen (2012). There is also an interest from a SIDA-funded training program on Genetic Resources and Intellectual Property Policy that will be held in Alnarp – Sweden, and (probably) in Nairobi, Kenya in 2011.

23. The results also warrant further research. They will be included in the work plan of a project sponsored by Netherlands Organisation for Scientific Research (NWO) on "Intellectual Property Regimes for Pro-poor innovation in agriculture" under its "Responsible Innovation" program, and other research proposals on the development of criteria and incentive mechanisms for valorisation of agricultural research across borders.

CHAPTER 6 IP PRACTICES IN THE NETHERLANDS: IPRS AND TECHNOLOGY TRANSFER TO DEVELOPING COUNTRIES

Bram De Jonge & Niels Louwaars

Abstract
This chapter analyzes the effects IPRs have on the accessibility and transfer of research materials within the Dutch agricultural research sector, and with respect to four research projects that aim specifically at transferring agricultural technologies to developing countries. Ultimately, the positive and negative roles of IPRs are assessed, also in relation to non-IP factors. We found that most research materials (also when protected by IPRs) are still freely exchanged without serious delays. Public research can, however, be seriously thwarted due to the restrictive licensing conditions of some companies and the weak research exemption in the Dutch Patent Act. The importance of having freedom to operate is also illustrated by the current patents vs. Plant Breeder's Rights debate, with opponents of the current patent system warning that patents pertaining to plant varieties hamper further breeding and, thus, food security. The case studies illustrate that humanitarian projects, which aim to develop improved seeds for resource-poor farmers (something that goes beyond the standard permissions in material transfer agreements), can face serious transaction costs and legal uncertainties due to third-party IP. Furthermore, the idea that humanitarian licenses can negatively affect one's own interests appears to be widespread in the Dutch agricultural research system. Yet, the case studies also show that IPRs are not the only, and not necessarily the most important, stumbling block to technology transfer in research for development, especially when GM technologies are concerned.

6.1 Introduction

In this and the previous Chapter, we discuss the IP policies, practices, and perceptions of the main actors in the Dutch agricultural research system in the context of our central research question: What is the role of IPRs in the management and sharing of knowledge for development (the achievement of MDG 1c). Our objective is to investigate how IPRs affect the development and transfer of knowledge and technologies for the benefit of resource-poor farmers in developing countries. Whereas the previous chapter zoomed in on the policy level, this chapter focuses on the *practices* of IP protection, licensing, and the transfer of research materials. First, we will analyze the effects IPRs have on the accessibility and transfer of research materials within the agricultural research sector. This will be done by collecting the experiences from several high-level research and IP managers from both the public and private sector. Then, we study the use and management of IPRs in four case studies that aim specifically at transferring agricultural technologies to developing countries. Finally, we will assess the positive and negative roles of IPRs for pro-poor innovation. Hereby, we will not only discuss the problems and opportunities that IPRs can create, but also reflect on the relative importance of IPRs vis-à-vis non-IP issues.[327]

6.2 Experiences with accessing and transferring research materials and IPRs

To analyze the effects IPRs have on the accessibility and transfer of research materials, we have interviewed research and IP managers from both public organizations and companies active in the Dutch agricultural research sector. In this section, we will first report on the experiences and perspectives of public researchers and their IP managers,[328] followed by representatives from industry. Hereby, we discuss particularly the use and in-licensing of third party IP. In the next section, the focus will be on out-licensing and the transfer of agricultural technologies to developing countries.

6.2.1 Experiences of Public Researchers

The public researchers interviewed, all heads of their research groups with longstanding experience, indicated that the number of patent applications in their name do not reach double digits. Researchers involved in fundamental research on model organisms indicated that IPRs do not play a major role in their work, while those working in more applied research fields and in public-private partnerships typically have more to do with IPRs. Yet, all interviewees indicate that most research materials are still freely exchanged, either with or without a Material Transfer Agreement (MTA) attached. Such research and development license may demand that the provider of the material is appropriately referred to in publications and product information that relate to that material. In case of (potential) commercial value of the material, the MTA commonly addresses issues of ownership and commercialization, often setting conditions on further use and the transfer of the material to third parties (see Box II-14). Even though such agreements are normally dealt with by the universities' legal offices, no serious delays in the transfer of research materials were reported by the interviewees as a result of the screening those agreements go through.

Box II-14: ***MTA Conditions of EP Patent 0176112, US Patent 4.940.838.***

The first, and one of the most successful, university patents in plant biotechnology in the Netherlands was a patent on the process of incorporating foreign DNA into the genome of dicotyledonous plants by use of the soil bacterium Agrobacterium tumefaciens. This invention, whose patent was filed in 1983 by three researchers from Leiden University,[329] is globally used for the genetic modification of plants. The patent was first licensed exclusively and later sold to Mogen, a Dutch biotechnology company that was acquired by Zeneca (now Syngenta) in 1997. Yet, the inventors maintained the right to freely exchange the patented technology and material to colleagues for research purposes under the following MTA conditions:

[327] Input for these analyses in this and the previous chapter is derived from literature studies and semi-structured interviews with those responsible for IP and agricultural research at ministries (no. of people interviewed: **7**); funding agencies (**5**); national research programs (**2**); researchers (**12**) and IP officers (**7**) at public research organizations; the private sector (**7**); and science interest/advisory organizations (**4**).

[328] For reasons of simplicity we will refer to IP managers for all persons working in the field of IP management, technology transfer, and knowledge valorization.

[329] Schilperoort, Hoekema and Hooykaas 1983.

I state that the supplied materials or derivatives thereof will exclusively and restrictedly be used in my laboratory for fundamental research and under suitable containment conditions.
I state that the supplied materials will not be used in production or commercial applications (including contract research) or for patent purposes.
I state that the supplied materials will not be given out to other laboratories, institutions or companies either within or outside my institution.
I state that the source of the supplied materials will be acknowledged or properly referred to in publications.

Some national and international biotechnology companies, however, apply such restrictive conditions in their MTAs that several interviewees indicated not to use that material in their research programs. In these MTAs, the user has to agree that all derivative inventions and materials that result from doing research on or with the provided technology are not only available for use by the provider, but the provider also maintains the right to claim IP protection over them. So, by using the knowledge, technology or material provided under such MTAs, any kind of additional invention in any area would fall under ownership of the providing party. Such conditions - together with a weak research exemption, can seriously impede public sector research with commercially developed technologies.[330]

This is particularly the case with respect to genetic modification (GM) technologies. In 2009, a group of 26 researchers from several US universities lodged an anonymous public complaint stating that "No truly independent research can be legally conducted on many critical questions involving [commercial biotech crops]", because of "company-imposed restrictions".[331] Since almost all GM crops are developed by commercial entities, which carefully control the rights over their proprietary technologies, they are the ones "to decide who studies the crops and how."[332] Consequently, public researchers must ask permission to the technology holder for each project, usually by describing in detail what the research will be about. In response to the above public complaint, several biotech companies have started to negotiate umbrella licenses with universities in order to develop general agreements on research terms and permissions with respect to their crops. Although a first blanket agreement with Monsanto was positively received, it only allows researchers to conduct agronomic research ("studies on how crops interact with local environments and which varieties perform best"), and no breeding, reverse engineering, or studies on the genetic composition of a crop, amongst others.[333]

Despite the fact that some companies are very strict on the use of their IP, none of the researchers reported to have been subject to explicit controls or claims with respect to the use of third party IP or compliance with MTA conditions. In this context, some researchers reported to check their 'freedom to operate' before starting a new research project, mainly because funding agencies or private partners demand this, but also to keep open future possibilities for patenting and knowledge exploitation. Others, however, indicated seldom or never checking for such rights as they consider this unnecessary for their type of research (fundamental) or because they lack time and expertise to delve into patent databases. Those

330 Another effect of these restrictive conditions can be the public subsidizing of private research.

331 Waltz 2009, p. 880.

332 *Idem*.

333 Waltz 2010, p. 996.

that have some experience with patent searches also reported that due to the large number of patents and the complexity involved (e.g., patents with apparently very broad claims), one cannot do much research without running into third party IP.

The research exemption was also repeatedly mentioned as a reason not to worry about third party IP. Yet, this may not always be supported by the legal extent of that exemption in Dutch law.[334] Consequently, a technology transfer expert indicated that this is very risky, especially because commercial parties tend to direct their infringement claims to "the deepest pockets" – the large enterprises. Since several universities are quite rich (in terms of real estate) they might become the target of rent-seekers when they are too relaxed with the research exemption. The main reason not to sue universities is – according to this spokesman, that such actions could create negative publicity.

6.2.2 Experiences of IP Managers at Public Research Organizations

One of the challenges of IP managers at public research organizations is to make researchers more aware of the importance of taking care of their and others' intellectual assets. Another challenge is to negotiate the conditions for use and transfer of such assets in research collaborations with private partners. Even though few universities make public notice of the position they take in such negotiations (see chapter 5), it transpired from the interviews that freedom to operate, i.e. freedom to use all knowledge and materials resulting from research for or with private partners for further research and education, is generally considered a *sine qua non*. Everything else is up for negotiation. Key issues that have to be discussed in most research contracts concern the designation of background and foreground IP, the division of rights and duties with respect to this IP, and the rules for transferring IP rights between partners or to third parties.[335]

Such negotiations are seldom easy and clear-cut. Take for example the issue of ownership of IP. Leiden University normally aims to retain the IPRs that result from research partnerships and to issue licenses to the research partners involved.[336] In this way, the university can remain in control of the IPRs and, thus, their freedom to operate. Ownership rights are legally stronger than rights assigned by contract because in the latter only the contract parties are bound, whereas IPRs affect all potential users, e.g., the university might lose control over its technology in case a company that owns the IPRs involved goes bankrupt. Another reason for this strategy is that the university can license a technology to several companies operating in different markets in order to stimulate the wider application of their research results. Many companies, however, do not favor such agreement because they want to be in control of the IPRs themselves, often for strategic reasons but also to be sure that the IPRs are properly managed, e.g. that patent maintenance fees are paid in time, and infringements controlled.

Who gets the IP rights depends heavily on the relative contributions, in cash and in kind, of the different research partners and on their negotiation capabilities. Yet, the costs of IP protection also play an important role in the negotiations about the ownership and licenses of

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334 See Chapter 5, section 5.2.

335 See *e.g.* TTI GG 2008. Available at <http://www.groenegenetica.nl/pro1/general/start.asp? i=0&j=0&k=0& p=0&itemid=72> (accessed on March 16, 2011).

336 Leiden University 2008. Available at <http://media.leidenuniv.nl/legacy/instruction% 20on%20working%2 0for%20or%20with%20third%20parties.pdf> (accessed on March 16, 2011).

IPRs between public and private research partners. Several IP managers indicated that they, in spite of the above reasons to keep IPRs in one's own hands, have to limit the number of patents that are (co-)owned by the university because of the costs involved. As a consequence, most patents must as a rule of thumb be transferred or withdrawn within 30 months of their filing date because then the costs rise substantially (see Box II-15).

Box II-15: ***Costs of Patenting***

Asking how much a patent costs is like asking how much a house or a car costs. It strongly depends on what is patented (the complexity of the invention) and where. The Dutch Patent Office estimates the price of an application for a European patent between 25,000 and 50,000 euro.[337] *These are application costs over the first three years and include the hiring of a patent attorney to draft the patent, the filing fees, and an international novelty search. When a European patent is granted, the applicant has to decide in which of the European countries the patent will be registered. That decision greatly affects the costs as currently the patent must still be translated into all the languages of the countries in which it is being pursued. Additionally, maintenance fees must be paid separately in each country. When following the Patent Cooperation Treaty (PCT) procedure, the applicant has maximally 30 months to decide in which countries in the world the patent rights will be established.*[338] *From that moment, total costs can go over 100,000 euro when the patent is registered in both Europe and the US. This is especially the case for biotechnology patents, which, due to their complexity, can cost twice as much as a patent in electrical engineering.*[339] *Next to these filing and maintenance costs, one should take into account potential enforcement costs in case of patent infringement, which may run into the millions.*

Not all industry representatives are happy about universities building a patent portfolio. To some, public research organizations should focus on scientific excellence and leave matters of IP protection to the private sector. Both opponents and proponents, however, emphasized that the road from a patented technology to a marketable product is very long and involves many risks and major investments, which means that the commercial value of a university patent is easily overestimated.[340] Another issue mentioned by most industry representatives is that they have no problem with universities doing research on and with technologies that are patented by their company as long as the university does not behave as a competitor in the market. Yet, this situation might be different in the US, where public researchers have been complaining about the company-imposed restrictions to do research on commercial GM crops.[341]

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337 See <http://en.octrooicentrum.nl/patents-application/in-europe.html> (accessed on March 16, 2011).

338 WIPO 2010. Available at <http://www.wipo.int/pct/guide/en/gdvol1/pdf/gdvol1.pdf> (accessed on March 16, 2011).

339 EPO 2010. Available at <http://www.wipo.int/pct/guide/en/gdvol1/pdf/gdvol1.pdf> (accessed on March 16, 2011).

340 See *e.g.* Heimovaara 2010. Available at <http://www.dafne-entrepreneurship.nl/Pages/TT.aspx> (accessed on March 16, 2011).

341 Waltz 2009.

But according to the university's IP mangers, IPRs have simply become "part of the game"[342] due to the present-day environment in which their organizations have to operate. As we have seen in the previous chapter, the Dutch government strongly supports public-private partnerships, and contract research has become an important source of income for public research organizations. Hereby, IPRs do play an important role as most funding agencies demand a strong IP position as a precondition for research funding, and several IP managers reported that their IP portfolio is indispensable for attracting research contracts and partnerships, especially where multinational companies are concerned.

The conditions for accessing IPRs filed by public research organizations depend heavily on the context in which the technologies were developed. Interviewees at Wageningen UR indicated that IPRs resulting from 100% publicly funded research will only be available under non-exclusive licenses so that their availability is secured for all interested parties. Yet, many IPRs result from public-private partnerships, which means that the technology's availability depends on the conditions for access as agreed by the different research partners. This commonly leads to more exclusive outcomes, since a company contributing to the research project gets, usually, at least a right of first refusal to obtain a (non-)exclusive license for the technology in question, or an advantage of some years that information and materials will be withheld from others. However, *transparency* on these issues is still lacking for researchers, private partners and the general public alike, due to the absence of a clear IP and licensing policy with respect to research partnerships at most universities.[343]

6.2.3 Experiences of Private Sector Representatives

From the private sector we received diverging messages, which strongly relate to the current debate, both in the Netherlands as internationally, on 'patents versus Plant Breeder's Rights'. The plant breeding companies that oppose patenting in favor of Plant Breeder's Rights emphasize that patents pertaining to plant varieties seriously hamper the accessibility of these varieties for further breeding. Plant Breeder's Rights, on the other hand, allow breeders to use protected varieties for the development and exploitation of new varieties through the so-called breeders' exemption. Because the breeding of new plant varieties has and will always depend on crossbreeding with existing varieties or exotic materials with specific genetic traits, the continued accessibility of these building blocks is considered absolutely essential for further innovation in the sector. For that matter, the significant increase in plant-related patents over the last decades is considered to "have serious consequences for most plant breeding companies and the subsequent links in the food chain, right up to the consumer."[344]

In 2009, the ministries of Agriculture, Nature and Food Quality and of Economic Affairs[345] commissioned a study on the future of plant breeding in light of developments in

342 De Jonge 2008.

343 See Chapter 5.

344 Plantum NL 2009, p. 7. Available at <http://www.plantum.nl/plantum/documenten/Standpunt%20Octrooi%20en%20Kwekersrecht%20volledig%20ENG.pdf> (accessed on March 16, 2011). Plantum does not oppose patents per se: It supports patents on innovative processes and techniques, for which use a license is required. Yet, varieties that have been developed using a patented process should, again, be freely available for further breeding.

345 Since the inauguration of the new government in October 2010, the ministry for Economic affairs,

patent law and plant breeders rights (see Box II-8). This study confirms that patent positions in combination with technological developments and globalization trends have led to considerable consolidation in the sector, with only few companies controlling a major part of the world market for most major crops.[346] And it concludes that "access to genetic variation is so crucial for further innovation in breeding that a form of breeder's exemption within patent rights is required."[347] Furthermore, it recommends that if a diversified seed sector with full competition among larger and smaller companies is to be aimed at, strategic patenting (see Box II-16) has to be curtailed (by the industry itself) and patent quality is to be vigorously increased (by the patent offices).

Box II-16: *Strategic Patenting*

Strategic patenting is the deployment of the patent system to primarily serve strategic objectives rather than commercializing the very invention that is protected. In the extreme case it is applying for patents with the only objective to block competitors in the market or in a research area. This can for example be done by building 'patent thickets', i.e., "a dense web of overlapping Intellectual Property Rights that a company must hack its way through in order to actually commercialize new technology."[348] The overlapping patents make it very difficult or even impossible for others to assess the precise boundaries of claims and, thus, to determine how far protection is reaching. An even more offensive strategy is to patent inventions that are similar, but not identical, to the invention that one aims to commercialize in order to prevent others from commercializing competing products.[349]

The Dutch breeders association Plantum NL formulates the unwanted consequences of plant-related patents as follows:

> "First and foremost, we can expect a price increase for plant propagating material, since any costs which are associated with obtaining licenses and applying for or defending patents will be passed on to the growers. Not all plant breeding companies will be able to obtain licenses for important traits, as a result of which the growers will be faced with a more limited choice between the different suppliers of a particular crop. Finally, the expectation is that there will be even more consolidation as some plant breeding companies will no longer be able to maintain a competitive position in the market. This lack of players keeping up the competitive pressure will slow down the level of innovation in general across the sector."[350]

Ultimately, these consequences are considered to negatively affect global food security as "world food supply benefits when there is sufficient competition between the plant breeding companies and when open innovation is preserved."[351]

It must be acknowledged that the companies opposing the current patent system are

Agriculture and Innovation (EL&I).

346 Louwaars *et al.* 2009, pp. 24-28.

347 *Idem*, p. 53.

348 Shapiro 2001.

349 Blind, Cremers & Mueller 2009.

350 Plantum NL 2009, p. 7.

351 *Idem*, p. 8.

using that system themselves in order to currently secure their position in the market. Similarly, they demand strong IP protection of, and negotiate for their rights on, valuable assets that result from collaborative research projects with the public sector. The reason for this is that these companies, in their competition with others, cannot choose to apply a different set of rules unilaterally. They have to stick to the current rules of the game in order to protect their position, but they explicitly state that they favor a radical change of the present IP system.[352]

Opponents of the Plantum NL standpoint indicate that it is already becoming more difficult to file plant biotech patents. Recent court cases in the US and Europe show that the granting of patents is being tightened[353] and the European Patent Office is taking steps to improve patent quality through its 'raising the bar' initiative.[354] With regard to strategic patenting it is argued that problems result from patenting and licensing practices and not the patent law itself. So instead of changing the system, these problems should be solved by the different actors within the sector itself. Finally, it is remarked that opposition to the patent system is merely a result of inexperience and lack of knowledge of the system by smaller companies.

The proponents of the patent system emphasize that patents – as the strongest form of intellectual property protection, are indispensable for innovation.[355] Research and development in biotechnology involve huge investments, which can only be recovered when inventions can be properly protected. For that purpose, and because many biotechnologies are easy to copy, it is argued that patents and Plant Breeder's Rights should be considered supplementary protection tools that protect different aspects of plant research and innovation.[356] Furthermore, the Plantum NL standpoint to include a full breeders' exemption in patent law would require an amendment of the EU Biotechnology Directive 98/44.[357] Opening up this directive may lead to long-lasting debates featuring all kinds of social sentiments (e.g., about GMOs, the patenting of living organisms, stem cell research) that, as argued, have nothing to do with the protection of intellectual property *per se*. Such debates will create uncertainty, affecting many industries beyond the plant breeding sector and stifling investments and, thus, innovation across the board.

As an alternative, CropLife International – a federation representing the major agro-biotechnology companies,[358] proposes a "balanced breeders' exemption", which entails that:

352 See *e.g.* Tax 2010.

353 See Chapter 1, box 1.1.

354 See <http://www.epo.org/about-us/office/annual-report/2007/focus.html> (accessed on March 16, 2011).

355 NIABA 2010. Available at <http://www.niaba.nl/website/wp-content/uploads/2010/02/BRF-Verburg-22-juni-DEF.pdf> (accessed on March 16, 2011).

356 CropLife International 2009. Available at <http://vorige.nrc.nl/multimedia/archive/00242/Patentrecht_09-06-2_242607a.pdf> (accessed on March 16, 2011).

357 Plantum NL 2010. Available at <http://www.plantum.nl/plantum/persberichten/10-04-20.pdf> (accessed on March 16, 2011).

358 See <http://www.croplife.org/> (accessed on March 16, 2011).

> "…breeders may freely, without a license, use germplasm containing PTT [patented trait technology] for developing and commercializing a new variety *that does not contain the PTT* under the conditions that 1) the PTT-containing material is discarded as soon as practically possible and in compliance with all applicable laws and regulations and 2) continued breeding occurs only with PTT-free germplasm."[359]

In this way, CropLife aims to prevent restrictions on the use of the "germplasm base" necessary for further breeding while at the same time protecting all rights of a patentee to his or her invention.

It is clear that the current debate on patents vs. Plant Breeder's Rights entails strongly opposing viewpoints on the importance of patents for innovation in the plant sciences industry. Yet, all agree that patents affect the *accessibility* of technologies and genetic material for further breeding and commercialization, both in developed and developing countries. The pro-patent camp, obviously, does not consider this a problem. One of the arguments to support their case is that breeders in countries without a breeders' exemption in their patent law, like the US, are amongst the most successful in the world.[360] Advocates from the pro-PBR camp, on their turn, emphasize the anti-innovative effects of the current patent system. A lawyer from seed producer Limagrain, for example, testified that he had to stop researchers in his company in many cases from exploring new things because of IP rights granted to seed material.[361] These conflicting arguments make it difficult to come to one overarching conclusion, and they warrant further research on the subject. Yet, the observation that the current system is especially challenging for smaller companies[362] demands that the issue is taken seriously into account when discussing the impact of IPRs on developing countries. In section 6.4 we will look more specifically at the relevance of this debate for developing countries.

6.2.4 Conclusion

The public researchers indicated that most research knowledge, technologies and materials are still freely exchanged without serious delays. Yet, some companies were reported to include such restrictive Material Transfer Agreement conditions that the researchers preferred not to work with those materials. Together with the weak research exemption in the Dutch Patent Act, this can thwart public research on commercially developed technologies, as in the case of GM crops. The IP managers reported that the freedom to use all knowledge, technologies and materials, resulting from contract research or research partnerships, for further research and education, is generally considered a *sine qua non* in negotiations with third parties. Yet, the one who gets the IP rights depends heavily on the relative contributions, in cash and in kind, of the different public and private research partners and on their negotiation capabilities. The outcome of this strongly affects the conditions for access, and only the IPRs resulting from 100% public funds were guaranteed to be available under non-exclusive licenses. Yet, transparency on these issues is still lacking due to the

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359 CropLife International 2009, p. 3. Emphasis in original.

360 *Idem*, p. 1.

361 Intellectual Property Watch 2010. Available at <http://www.ip-watch.org/weblog/2010/07/21/international-experts-see-backswing-in-pendulum-of-biological-patenting/> (accessed on March 16, 2011).

362 Louwaars *et al.* 2009, pp. 51-52.

absence of a clear IP policy with respect to research partnerships at most universities. The industry representatives are particularly concerned about the current patent vs. Plant Breeder's Rights debate, and they have strongly diverging views on the pros and cons of including some breeder's exemption in patent laws. Whereas especially the largest multinational companies emphasize the importance of strong IP protection for stimulating innovation in the plant sciences industry, many of the smaller companies, also multinationals, warn that patents pertaining to plant varieties hamper further breeding and, thus, food security.

6.3 Technology Transfer to Developing Countries: Four Case Studies

Whereas the previous section discussed the use and in-licensing of third-party IP, this section focuses on the out-licensing of IP for development purposes. For that purpose, we looked for research projects (primarily) based in the Netherlands that aim at promoting technology transfer to developing countries. In total, we came across four cases in which IP issues play an important role.[363] These cases concern four different crops (shallot, cassava, potato and vegetable Brassica, respectively), but all involve the application of genetic engineering technologies. In three of the four cases, specific IP mechanisms and strategies are applied to facilitate the transfer of protected technologies to developing countries. For each case, we will analyze the various issues that surround the use and management of IPRs, and indicate the relative importance of these IP issues for the success or failure of the project vis-à-vis non-IP factors.

6.3.1 Shallot Case

The first case study took place in the context the Biotechnology, Plant Breeding and Seed Technology for Horticulture (BIOBREES) program, which started in 1994 as a collaboration between the Dutch and Indonesian ministries of agriculture.[364] Hereby, the Dutch ministry provided the research funds (0.9 million Dutch Guilders per year) matched by the Indonesian ministry with in-kind contributions. The program included horticultural research whereby "priorities were set with the interest of both sides in mind, and the outcome would be jointly owned."[365] Despite this objective, the program started without a specific strategy on the use and management of the IPRs involved. One of the projects aimed at developing shallots[366] that are resistant to the beet armyworm[367] through both conventional and transgenic breeding, executed at Wageningen UR and Bogor Agricultural University.

Shallots are an important vegetable crop in Asia, grown at 90,000 hectares in Java alone, especially by smallholder farmers. The beet armyworm is a major hazard to the production of shallot with yield losses up to 70%.[368] Insecticides are widely used, causing

363 For example, a project concerning the transfer of hybrid tomato seeds to small-holder farmers in Latin-America was not selected as IPRs did not feature as a major issue.

364 *I.e.* the Dutch Ministry for Agriculture, Nature and Food Quality (LNV), and the Indonesian Agency for Agricultural Research and Development (AARD).

365 Burg 2003, p. 3.

366 *Allium cepa* L.

367 *Spodoptera exigua* Hübner.

368 Zheng 2000.

serious threats to the environment and the health of farmers and consumers, and increasing production costs. Furthermore, they are far from adequate because the beet armyworm larvae protect themselves by webbing and because of reported insecticide resistance.[369] Since genetic resistance was found neither in the crop nor in its wild relatives, efforts were started to develop a transgenic shallot by using genes from the bacterium *Bacillus thuringiensis* (Bt). Early 2000, a transformation protocol was developed, Bt genes were successfully transferred and the resulting Bt-shallots were found resistant to the beet armyworm.[370] These were then crossed with several local varieties, ready to be tested in the field.

One of the used constructs carried the *Ho4* Bt gene, which had been supplied by Syngenta under a research license.[371] This implied that although the technology could be freely used for research purposes, further negotiation would have to follow once the technology was to be used in Bt-shallot varieties in the field. Also, Seminis Vegetable Seeds, today part of Monsanto, holds the IP rights over a method for transforming Allium species that was used. Yet, when Wageningen UR contacted Seminis/Monsanto to inform about the conditions for use, no reply was received. This is not uncommon when a company has no commercial interest. Spending time to negotiate use in small vegetable crops, and a potential market composed of small-holder farmers in developing countries, may be considered a bad investment. Yet, for the public research organizations such non-reply creates uncertainty as the IP holder can block the use of its technology at any moment. Furthermore, uncertainty about the freedom to operate can affect the willingness of other parties to join the project.

This became apparent when Wageningen UR started to look for a private partner that would be interested to take the technology further. As the next stage of the research project was to test the modified shallots in the farmers' habitat, the Bt-shallots had to go through the biosafety regulations, since Indonesia had established a national biosafety policy in the late 1990s, and ratified the Cartagena Protocol in 2004.[372] Because none of the public partners had the money and expertise to enter into the regulatory process that comes with the field testing of genetically modified organisms, Wageningen UR contacted several vegetable breeding companies whether they would be interested to join the project and take the Bt-shallots to the market.

In a letter to the vegetable breeding companies, it was stated that IP ownership over the material developed would initially stay with Wageningen UR, but could be transferred or licensed to the interested company at a later stage. Wageningen UR also performed an IP search on all the varieties, genes, regulatory sequences and methods used in the research project in order to assess third-party IP. From this, it appeared that about 15 patents and 2 PBRs were involved. Some of these patents were soon to be expired, or would only be infringed upon export to the US. Other gave rise to some uncertainties (e.g., with respect to the status of the patent or the reach of its claims), and for a few a license was to be negotiated (amongst which the Syngenta and Monsanto IP mentioned above). All these matters were left to the company that would eventually market the Bt-shallots.

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369 Zheng *et al.* 2005.

370 *Idem*.

371 *Idem*.

372 Ministry of Environment of the Republic of Indonesia and UNEP-GEF 2004. Available at <http://www.unep.org/biosafety/files/IDNBFrep.pdf> (accessed on March 16, 2011).

Yet, no company was interested to take the Bt-shallots through the deregulation trajectory with an estimated cost of about six to ten million Euros.[373] This was not considered economically feasible given the low profit margins for this crop and the third-party IP involved. Furthermore, the Dutch vegetable breeding companies were hesitant to get involved with a GM crop because of the public controversy surrounding that technology. So, even though the Bt-shallots had been developed and showed good resistance to the beet armyworm in the laboratory,[374] the technology has never been implemented. This to the frustration of the researchers involved. Wageningen UR maintained the Bt-varieties for some time in confined greenhouses, but this was stopped due to the costs involved and without a prospect for future use. Now, only the seed are kept in storage.

6.3.2 Cassava Case

The next three cases involve various IP strategies that aim to facilitate technology transfer to developing countries. One IP mechanism that can be used to secure the availability of technologies for use in pro-poor research is a *humanitarian use license* (see Box II-11). Several examples have been applied by the Plant Sciences Group at Wageningen UR in research contracts and IPR licenses. The first example in 1997 arose when researchers at Wageningen UR were involved in the Cassava Biotechnology Network, funded by the Dutch Directorate-General of International Cooperation (DGIS).

In the 1990s, research subsidies by DGIS were subject to the condition that the department would co-own any IP resulting from the research carried out and, thus, that it could co-decide on its use (see Chapter 5). At some point, a method for producing and transforming cassava protoplasts was developed, which was also of interest to private company Avebe, which specialized in the production of potato starch for food and non-food industries.[375] After negotiations with Wageningen UR, the technology was put at the company's disposal and they filed a patent in 1996.[376] Yet, DGIS demanded that the technology would stay available for humanitarian use. This led to a license agreement between the three parties in which the company grants DGIS "the right to apply the technology within the framework of development cooperation as well as the right to make the technology available to foreign institutions for aid to developing countries."[377] Yet, if the transfer of this technology could reasonably lead to competition for Avebe in the area of modification of starch, DGIS would have to consult the company beforehand.[378] In practice, this means that the technology could be used royalty-free for food security goals and local or national use, but not for the global starch trade. From the people involved we learned that such humanitarian license with 'field of use restriction' was a novelty at all three organizations, which meant that it took some time before a suitable agreement text was drafted.

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373 This estimate corresponds with the outcomes of a scientific study that calculated the compliance costs for regulatory approval of a new biotech crop in both the US and EU between 3.7 – 10.3 million € (COGEM 2008). Kalaitzandonakes *et al.* 2007 calculated 'slightly' lower costs (4.2 – 9.4 million € for ten countries).

374 A reason why the project was advertised as a big success, see *e.g.* Burg 2003.

375 See <http://www.avebe.com/AboutAVEBE.aspx> (accessed on March 16, 2011).

376 AVEBE *et al.* 1996.

377 License agreement [not public], Article 2 (translated).

378 *Idem*, Article 3.

After the agreement was signed and with the extra money received from Avebe, the Wageningen researchers developed transgenic cassava varieties that have been planted in field trials in Indonesia and the Virgin Islands. For some years, this was also tried in South Africa but that country did not authorize the field trials. Due to both agronomic reasons and the high costs of getting regulatory approval to cultivate the GM crop, the cassava varieties never reached the market.

According to the research manager and TT officer involved, Wageningen UR aims to include such licenses in IPR agreements with third parties more often but it appears difficult to materialize. The main reason is that most research takes place in public-private partnerships, where the humanitarian license issue has to be brought to the table by either party and accepted by all. If one research partner is not interested in the inclusion of such license, it may lead to a lower license fee, something that cash strapped public research organizations in practice do not prefer. Interviewees from both the public and private sectors indicate that many companies have reservations with respect to the application of humanitarian licenses because of the uncertainties that come with it. Doubts are especially created by the risk that protected technologies, which were provided royalty free for humanitarian purposes to a specific party or region, end up in a competitive product in the market. To others, this worry is unfounded as you can carefully spell these issues out in the humanitarian license. Still, the question is how such licenses, and compliance with their terms, can properly be controlled.

6.3.3 Potato Case

The effort required to balance the different interests can well be described by looking at the potato research at Wageningen UR. Potato is among the most important arable crops grown in the Netherlands.[379] Yet, because of fungus threats, especially late blight (*Phytophthora infestans*), the potato is also the most sprayed crop in the Netherlands, responsible for about 80% of fungicide use[380], amounting to an estimated annual cost of €133 million.[381] For these reasons, the ministry for Agriculture, Nature and Food Quality (LNV) finances several research projects with the aim to develop a late blight resistant potato. These projects often take place in close collaboration with private potato breeders.

In 2006, the ministry provided Wageningen UR with € 9.9 million for a 10-year project on Durable Resistance against Phytophthora (DuRPh), which aims to develop potato varieties with a durable and high level resistance against late blight using cisgenesis (see Box II-17). The project results are expected to reduce production costs and health and environmental burdens, and to help to maintain the competitive abilities and employment in the Dutch seed potato production sector.[382] Yet, as late blight is also a threat to the food security of millions of people in the developing world who rely on potato as a staple crop, the ministry prompted the researchers at Wageningen UR to also look at possible applications in these countries. In 2009, this resulted in Wageningen UR signing a Letter of Intent with the International Potato

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379 Annually, about 75 000 hectares of ware potatoes (mainly used for the production of chips and crisps), 50 000 hectares of starch potatoes and 40 000 hectares of seed potatoes are grown, of which the majority is exported. With a yield of 45 tons per hectare, this amounts to a produce of about €800 million worth (Projectgroep DuRPh 2008, p. 9-10).

380 LNV 2006.

381 Projectgroep DuRPh 2008, p. 12.

382 See <http://www.durph.wur.nl/UK/> (accessed on March 16, 2011).

Centre (CIP) and Cornell University to join forces in order to develop cisgenic late blight resistant potatoes for the benefit of the resource poor.[383]

Box II-17: *Cisgenesis*

Cisgenesis is a genetic modification (GM) technology that only makes use of genetic material from the same species and its crossable wild relatives. This distinguishes it from transgenic GM technologies that work with transgenes – i.e., synthetic genes or genes from non-crossable species. Conventional potato breeding is very time consuming because crossing creates an enormous diversity which makes it very difficult to align preferred genes in one clone. This is even more difficult when genes from distant (wild) sources are to be used and many unwanted genes have to be removed by means of repeated backcrossing. With cisgenesis, only the relevant resistance genes are inserted into existing varieties.

As the technology does not involve 'foreign genes' and basically creates varieties that could also have been obtained through crossing, repeated backcrossing and selection, the researchers hope that cisgenesis will not cause public controversy the way transgenic GMOs have . Furthermore, they argue for a cheaper and faster approval trajectory for cisgenic varieties.[384] This is considered important since current biosafety regulations are very time-consuming and expensive for public institutions and small or medium-sized enterprises serving niche markets and crops.

In the letter of intent, the three parties invite public research organizations in developing countries to join the project. Currently, the first meetings are taking place with National Agricultural Research Organizations (NAROs) in East Africa that may want to join the initiative. The research partners also call on donor organizations to provide funding and on potato breeding companies to support the initiative "by making know-how and material available."[385] To facilitate this last point, it is emphasized that, "While the focus is the impact on food security for the resource poor, parties aim to ensure at the same time that breeding and seed sales companies will not be adversely affected by this initiative".[386] This reflects the aforementioned issue that companies are hesitant to making technologies available for humanitarian purposes as this may backfire on their commercial interests. It also shows that public research organizations take much care not to harm companies' interests in their broader research activities, including those in the area of international development cooperation.

The main reason for this is that Wageningen UR works closely together with the private sector on various potato research projects. Together with the Ministry of Agriculture, Wageningen UR and several private companies agreed to join all the know-how, research materials (genes) and IPRs developed in the various research programs on potato and late blight in order to stimulate their broad and efficient use and increase the impact of their results. The owners of the resources in question have formed a consortium and signed a

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383 Wageningen UR, International Potato Center and Cornell University 2009. Available at <http://www.durph.wur.nl/NR/rdonlyres/FB82D838-39ED-4AB9-8319-691886CA0821/92525/LetterofIntent.pdf> (accessed on March 16, 2011).

384 See *e.g.* the White Paper on cisgenesis, available at <http://www.cisgenesis.com/content/view/4/28/lang,english/> (accessed on March 16, 2011).

385 Wageningen UR, International Potato Center and Cornell University 2009, p. 1.

386 *Idem*, p. 1.

Consortium Exploitation Agreement, in which the way the resources are managed and exchanged is established. These resources are normally exchanged under non-exclusive licenses for which (market-level) royalties are to be paid, but discounts apply depending on the size of contributions made to the consortium. With respect to the DuRPh project, a first concept of a humanitarian use license has been drafted that would apply to all contracts between the consortium members in order to secure the availability of the relevant knowledge, research materials, and IPRs. The consortium may also grant sublicenses to outside organizations for humanitarian use. The concept note will be worked out in detail once the development of marketable products will come into sight.

In the concept note, 'humanitarian use' is defined as "research and development activities (not-for-profit and non-commercial activity) conducted with public and/or charitable support for the public good and to the benefit of sections of the general public in developing countries in need of particular assistance. It is including but not limited to such aims as poverty alleviation and the movement of subsistence farming systems toward a market economy."[387] The relevant developing countries are selected from the World Bank classification lists of low-income and lower-middle-income economies[388] according to their specific needs and targeting the alleviation of hunger and poverty. 'Subsistence users' are more specifically defined as:

"users or consumers of products made from or embodying the relevant IP:
- for direct personal or family consumption
- for barter (exchange) for personal or family food, shelter, fuel or clothing
- in trade or business resulting in monetary income less than €10 000 per year per business entity"[389]

Further provisions hold that a humanitarian use license will be restricted to a country or region, and that such license will explicitly exclude the right to export the harvested potatoes or any type of product derived from it.[390] A final issue is that the late blight resistance genes will not be crossed with/placed in potato varieties that fall under IP protection (patents or PBRs) of third parties, in order to prevent royalties from having to be paid and the humanitarian license having to be negotiated with the owner of the protected variety.

As the movement of subsistence farming systems toward a market economy is also recognized as an important aspect for which materials provided under the humanitarian use license can be used, some of the people involved consider it a risk that the line between farmers that produce for local and national markets and those that also enter the global export market may be difficult to distinguish and control. Yet, does this mean that the humanitarian licensing strategy should indeed be feared and only be accepted in return for a lower licensing fee? Probably not: Albeit it may happen that some farmers or companies will misuse the licensing terms and sell their harvest or derivative products on the international market, competitors will be liable for damages as they do not fall under the above definition of 'subsistence users'. From a moral point of view, such risks do not outweigh the potential benefits of providing the material for humanitarian use, which may well be considered a

387 Draft Humanitarian Use License [not public] 2009.

388 See <http://data.worldbank.org/about/country-classifications> (accessed on March 16, 2011).

389 Draft Humanitarian Use License [not public] 2009.

390 *Idem*.

moral imperative for publicly funded research organizations. Furthermore, as the Dutch seed potato sector is the world's market leader, it will also benefit itself from the development of new markets in these countries.

In case the DuRPh project leads to late blight resistant potato varieties that are successfully marketed and, at the same time, sustainably grown by subsistence farmers in developing countries, the project can be considered a *best practice* of how to connect international development objectives with national knowledge and innovation agendas (see Chapter 5).

6.3.4 Brassica Case

In 2002, the public-private Collaboration on Insect Management for Brassicas in Asia and Africa (CIMBAA) was started, on initiative of the Natural Resources Institute (NRI) of the University of Greenwich. NRI invited Nunhems to join the initiative, which is a Dutch subsidiary of Bayer CropScience and one of the world's leading suppliers of vegetable seeds.[391] Next to NRI, the CIMBAA consortium included three other public partners (the World Vegetable Centre AVRDC, Cornell University and the University of Melbourne), plus a number of research partners, including WUR, that addressed specific research aspects of the project.[392] Nunhems financed about 50% of the project, while the other half was mainly funded by donor organizations such as the UK Department for International Development (DFID), the US Agency for International Development (USAID), and the Australian Centre for International Agricultural Research (ACIAR).

The project aimed to develop transgenic cabbage and cauliflower varieties[393] that are resistant to the diamond back moth.[394] This is a major pest in over 80 countries, causing production losses of 30% to 80% in the developing world at a cost of over $1 billion US dollars a year.[395] Losses even take place in insecticide protected crops that are sprayed weekly or even more often, adding significantly to production costs and creating substantial environmental and health hazards.[396] The project focused initially on India, which is the world's largest producer of cauliflower (on 45,000ha) and the second largest producer of cabbage (on 270,000ha), mostly grown by smallholder farmers.[397] Eventually, the project could be expanded to include other Asian and African countries.

The fact that the project concerned a GM technology complicated the start-up phase, mainly because several public funders and research organizations were hesitant to get involved for fear of the damage this could inflict on their public image. In order to ease social anxiety, the consortium took much effort to first investigate socio-economic aspects and to develop a safe and durable technology. It was decided to develop a dual Bt gene construct by using genes from two different Bt proteins (Cry1Ba and Cry1Ca) in order to substantially delay

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391 See <http://www.nunhems.com/www/nunhemsinternet.nsf/id/CW_EN_About_Us-_Overview?open> (accessed on March 16, 2011).

392 See <http://www.cimbaa.org> (Not accessible anymore).

393 *Brassica oleracea.*

394 *Plutella xylostella*; the project also aims at resistance to other lepidopterous pests such as cabbage cluster caterpillar (*Crocidolomia pavonana*) and cabbage webworm (*Hellula undalis*).

395 Talekar and Shelton 1993.

396 Sandur 2004.

397 Mohan & Gujar 2003.

the possible evolution of resistance within the targeted insect populations (see Box II-18). Once developed and tested, this technology would then be disseminated "for further breeding and commercialization under strict stewardship guidelines, to interested seed producers in countries in which the material is registered, without restrictive license or other fees."[398]

Box II-18: *Technology Development for Resource-poor Farmers*

The choice to develop a dual Bt gene construct had much to do with the aim to make the technology fit for use by resource-poor farmers in developing countries.[399] Normally, farmers are obliged to sow 'refuge areas' with non-resistant crops so as to delay the build-up of insect resistance against the Bt toxin. Yet, this can be problematic for resource-poor farmers who need to cultivate their entire holding to make a living, and their compliance with such regulations is difficult to control and enforce. The stacking of two Bt genes would delay the build-up of insect resistance even if no refuge areas are in place. The consortium had also chosen to closely link the two genes on one chromosome in order to secure their joint pairing in any further crosses, as the material would be available for further breeding – outside the control of the technology developers. A final decision was to develop male sterile hybrids instead of open pollinated varieties in order to eliminate the risk for unintended cross-pollination with cultivated and wild Brassicas.

By the end of 2006, a first series of contained field trials in India was started, resulting in two elite events – one for cabbage and one for cauliflower – demonstrating successful pest resistance in 2008. In spite of these successes, the consortium has recently decided to terminate further development of this material. Before discussing the main reasons for this, we will first describe some arrangements with respect to the ownership and management of IPRs within the consortium.

One important feature is that all IPRs related to the applied technologies and traits – about 20 patents in total – were covered by the patent and license portfolio of Nunhems' mother company, Bayer CropScience. This was considered "practically essential for the project to succeed"[400] as it guaranteed the freedom to operate for both the development and commercialization of the technology. Otherwise, the transaction costs for negotiating such freedom with third parties would likely be too high and time consuming for the project. In this context, it must be mentioned that transaction costs are relatively high for horticultural crops because of the smaller markets (e.g., as compared to field crops) in which R&D investments have to be recovered.[401] Yet, as the return on investment for any humanitarian project will be rather weak, IP-related transaction costs are likely to weigh heavily on the available resources, forming a serious impediment to the execution of such projects.

Another remarkable feature - as announced in various publications and presentations of the CIMBAA project[402] - is that the ownership of the material, including all IPRs and regulatory dossiers, would be transferred to AVRDC – a not-for-profit international research organization

398 Russell *et al.* 2008, p. 272.

399 Vroom 2009.

400 *Idem*, p. 109.

401 Graff *et al.* 2004.

402 See <http://www.cimbaa.org> (Not accessible anymore).

– once the Bt Brassicas had been developed and tested. This public partner would then license the material back to Nunhems and, from the day that Nunhems would enter the market, to any other competent breeder interested to breed the trait into their own varieties. Neither AVRDC nor any of the subsequent licensees would have to pay royalties for the material.[403] This would allow the price of the seed to be kept at a reasonable cost, making it affordable for resource-poor farmers. Furthermore, the non-exclusive license strategy allows for a differentiation in the market, in which each breeding company can choose to cross the Bt material with varieties that suit their own (niche) markets. This can stimulate a wide dissemination of the technology and increase its availability.

So, despite the fact that the Bt Brassicas would fall under various patents, it was decided to make the varieties freely available for further breeding (as is common with plant breeder rights). On the one hand, this decision resulted from the fact that public donors had invested 50% of the project. On the other, we learned from the interviews that the initiative was largely driven by a few individuals within Nunhems, who strongly emphasized 'their' corporate social responsibility. Yet, the company also had something to win. Firstly, Nunhems had the right to be the 'first to market', which in the breeding industry is a considerable advantage. Secondly, because Nunhems already had a market position in India, the company would have had a competitive advantage with its elite germplasm and advanced production system, producing high quality hybrids for the market's top segment. And thirdly, the new Bt technology was considered "instrumental in allowing for the continued cultivation of Brassica in India",[404] and, thus, for maintaining and possibly enlarging the market for the company's products.

Despite the well thought out organization of the research program and the first successful field trials, the program stopped late 2010. The main cause for this discontinuation relates to *liability*. According to the Cartagena Protocol on Biosafety, a technology developer can be held liable for financial claims in case of damage caused by GM technology. Bayer CropScience has been facing major lawsuits in the US as an unapproved GM rice variety developed by that company was found in the food chain in August 2006 after it had been tested by a US university.[405] This has not only scared Nunhems' mother company but also CIMBAA's public research partners, which "would not take 'ownership' and with that 'liability'".[406] Other reasons mentioned are the stewardship requirements being "too onerous to allow for germplasm sharing", and, again, the GM regulatory hurdles that "make time-lines and costs very uncertain."[407] Momentarily, discussions are continuing about some of the plant and genetic material to pass into public hands, for example the Indian Council for Agricultural Research and/or the CGIAR.[408]

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403 Yet, there was a plan to collect some revenues from the sublicensing in order to fund stewardship activities such as the training of farmers and resistance monitoring (Russell *et al.* 2008).

404 Vroom 2009, p. 105.

405 Reuters 2010.

406 Kaliaperumal *et al.* 2011.

407 *Idem*.

408 *Idem*.

6.3.5 Conclusion

The four case studies give a good picture of the major issues that can come to the fore when developing a technology that falls under IP protection (in-house or third-party IP) for use by resource-poor farmers in developing countries. Central issues relate to one's freedom to operate, the use of humanitarian licenses, and the costs and risks concerning GM technologies. These topics, and the conclusions that can be drawn from the above cases studies, will be discussed in detail in the next section.

6.4 How do IPRs Affect Pro-poor Innovation: Problems, Opportunities, and Non-IP issues?

So what can we now say about the effects IPRs have on pro-poor innovation, i.e., the development and transfer of knowledge and technologies for the benefit of resource-poor farmers in developing countries? In this section, we discuss the major findings from our research in the Netherlands, and assess the *problems* and *opportunities* that IPRs can create, but also reflect on the relative importance of IPRs vis-à-vis *non-IP issues*.

6.4.1 Problems

1. *Freedom to operate and other costs.*

When assessing the impact of IPRs on accessing and transferring research materials as experienced by the Dutch interviewees, we have to distinguish between different types of research. The public researchers indicated that for research purposes most research knowledge, technologies and materials are still freely exchanged, even when patented technologies are concerned. However, the Material Transfer Agreements (MTAs) that are currently applied do not allow for product development or any commercial application of the material. This can create problems for pro-poor innovation projects, as these often involve applied research trajectories that, for example, aim at the development of improved seeds for resource-poor farmers. This goes beyond the standard permissions in MTAs and does not fall under the research exemption of the Dutch Patent Act. It implies that for such projects, additional access and use conditions have to be negotiated with the technology owners, which will increase transaction costs.

Such costs do not merely relate to the payment of license fees and royalties but to all the costs involved in assessing and accessing third party IP, i.e., all the time and expertise needed to investigate one's freedom to operate and to negotiate the necessary licenses. The shallot and Brassica cases especially exemplified the importance of having access to a strong IP portfolio to secure freedom to operate both for the development, implementation and commercialization of a technology. Yet, most humanitarian projects will not be able to establish such position and, as the return on investment for any humanitarian project will be small, IP transaction costs can form a serious impediment to such projects. The shallot case showed that patent owners may simply not reply to questions concerning the conditions for using their technology, which creates legal uncertainty for the technology users.

The broader discussion on freedom to operate in the agricultural research sector appeared to be dominated by the patent vs. Plant Breeder's Rights debate. But what is the relevance of this debate for developing countries? According to the pro-PBRs camp, the current problems with the patent system are likely to impact heavily on developing countries, especially in the long term. Hereby, the increasing consolidation in the plant breeding sector is regarded to be most problematic for several reasons. First, genetic diversity might decline – with all consequences for global food security – when only one or two companies control the global seed market for a specific crop. Second, prices may rise due to the lack of competition. Third, a very small number of breeders will lead to ever more standardization in breeding and seed production, leaving aside the specific needs of developing country markets and climate zones.

More generally, the most referred-to obstacles that patents may create for developing countries and pro-poor innovation have to do with the costs involved. First, there is the high cost of drafting, filing and maintaining a patent (see Box II-15). Second, assessing, accessing and transferring patented technologies involve major transaction costs, as explained above. And third, the costs of litigation if one is accused of patent infringement, or if one has to oppose or defend a patent at the patent office or in court, are likely to be far higher. The fact that Dutch universities and even multinational companies report to have difficulties with bearing these costs leaves many questions for the position of research organizations in developing countries or pro-poor research initiatives.

The pro-PBRs camp emphasizes that PBRs are "very much cheaper" than patents.[409] First, the application and maintenance costs are lower. More importantly, the transaction costs are much lower because no royalties have to be paid when using protected varieties in breeding programs, and, consequently, no freedom to operate studies and negotiations have to take place. And third, the breeders' exemption also implies that PBRs are hardly ever challenged in court, saving all costs involved. Obviously, the pro-patent camp opposes these arguments by stating, in essence, that the weakening of patent protection through a breeder's exemption will threaten innovation in the sector by undermining the possibilities to recoup the necessary investments. Developing countries should keep a close eye on this debate in order to carefully balance the pros and cons of the different IP systems when implementing their own IP policies.

2. *Little use of humanitarian licensing strategies*

Where transaction costs come to the fore when using third party IP, one can decide under what conditions in-house IP can be accessed by others. Hence, public research organizations can make sure that their intellectual assets are available for humanitarian use in developing countries, even when patented and/or licensed to third parties. This is, for example, done by several public research institutions in the US (see Box II-18). In the Netherlands, however, we only came across one research group applying humanitarian use licenses in some of its research and IP contracts, and none of the examined universities have incorporated a reference to humanitarian licensing in their official IP policies.

409 Plantum NL 2009, p. 6.

Box II-19: ***Universities for Humanitarian Use***

In 2007, twelve universities in the US presented the white paper In the Public Interest: Nine points to consider in licensing university technology.[410] *In this paper they pledge to "Consider including provisions that address unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improved therapeutics, diagnostics, and agricultural technologies for the developing world."*[411] *The paper discusses various IP management tools to realise this objective, and it has an appendix listing several examples of contract clauses and licensing terms. One of the US universities that has put this into practice is the University of California, Berkeley. They developed a Socially Responsible Licensing Program, which involves various licensing mechanisms that aim to maximize the impact of their research by ensuring widespread availability of research materials, technologies and end-products for and in the developing world.*[412]

There are different reasons for this lack of humanitarian licensing in the Netherlands. One of them is that valorisation of research, narrowly understood as the need to turn knowledge into (economic) value for the Dutch society, is currently the primary driver for IP policymaking at all layers of the public research system. As discussed in the previous chapter, international development considerations do not feature in this discourse. Furthermore, there is little knowledge of humanitarian licensing strategies at the level of government and funding agencies, and they have no policies in this area. IP holders and managers at public research organizations therefore have no incentives to include humanitarian use clauses in their contracts with third parties.

Another important factor is that public research organizations are strongly focused on the private sector in order to generate alternative income streams by means of research contracts and partnerships. This is also strongly stimulated by the Dutch government.[416] This has consequences for the application of humanitarian use clauses, as it depends on the willingness and acceptance of all parties involved whether these are included in research contracts or IP licenses. The importance of the private sector for universities is also illustrated by the humanitarian licenses discussed above (i.e., the cassava and potato case). The text of these clauses are carefully phrased in order to make sure that the private partners' interests are not adversely affected, by explicitly excluding the right to export (derivatives from) the material provided for humanitarian use.

It was indeed reported that many companies do not favor the use of such licenses because of the risk that a protected technology, which is provided royalty free for

410 California Institute of Technology *et al.* 2007. Available at <http://www.fptt-pftt.gc.ca/eng/news/2007/docs/mar07_white_paper.pdf> (accessed on March 16, 2011).

411 *Idem*, point 9, p. 8.

412 Mohiuddin and Imtiazuddin 2007. Available at <http://www.acumenfund.org/ uploads/assets/ documents/ Acumen%20Fund%20-%20Socially%20Responsible%20Licensing%20-%20July%202008_kYAIb8kF.pdf> (accessed on March 16, 2011).

416 See Chapter 5.

humanitarian use, ends up in a competitive product on the market. Consequently, public research organizations are reluctant to make humanitarian licensing a standard policy because they fear that this would lead to less contracts and partnerships with companies or lower licensing fees. Specialists in the area of humanitarian licensing emphasize, however, that "Licensing IP for applications to benefit the poor can be achieved without compromising core commercial markets of the IP owners."[417] By using the right legal tools for a specific technology and project partnership, humanitarian licenses can mitigate risks and lower transaction costs.[418] There are several international organizations and initiatives to which Dutch universities can turn to in order to learn more about, and even to get advice on how best to reconcile their financial interests with their social responsibility to ensure that the research findings are available for those who need them most (see Box II-19).

The fear that companies are scared away by the inclusion of humanitarian licenses may well be unfounded. Public research organizations should not underestimate their negotiation position vis-à-vis the private sector, even if they would make humanitarian licensing a standard policy. They possess a wealth of knowledge and expertise that is of interest to companies, and most public-private partnerships are still financed for the majority with public money. Yet, relations of trust and proper IP management are important preconditions for companies to be confident about the inclusion of humanitarian licenses in their contracts with whatever research partner. So, in order to stimulate the use of such licenses, the public sector would benefit from developing clear and transparent policies, both at the level of ministries and funding agencies and at the level of individual research organizations, together with building more legal expertise and capacity on humanitarian licensing strategies, IP stewardship, and negotiation skills.

Box II-20: *International Knowledge Resources on Humanitarian Licensing*

The Public Intellectual Property Resource for Agriculture (PIPRA) initiative initially aimed to serve as a clearinghouse by bringing together patent information from major public research organizations, and helping these institutions with applying humanitarian use licenses, in order to reduce transaction costs and stimulate technology transfer to the developing world.[419] Now, PIPRA provides a range of IP and commercialisation strategy services that, supported by a pro-bono attorney network, help public research organizations to get their innovations to those who need them most. They have also published an elaborate IP handbook of best practices[420] on which website a long list of all sorts of sample agreements can be found.[421]

The initial PIPRA objective is now taken up by a new and promising initiative that is called Global Access in Action.[422] This initiative aims to assist owners of intellectual assets to "strike the right balance between preserving commercial markets and creating access to technology for the poor." The initiative will work through four major implementing partners: the World Intellectual Property Organization (WIPO), Global Access to Technology for Development (GATD), PIPRA, and the

417 See <http://globalaccessinaction.org/> (accessed on March 16, 2011).

418 *Idem*.

419 See <http://www.pipra.org/about/> (accessed on March 16, 2011); Atkinson *et al.* 2003. <http://www.sciencemag.org/content/301/5630/174.summary?ijkey=bJhyNVg9ELVzc&keytype=ref&siteid=sci>

420 Krattiger *et al.* 2007. Available at <www.ipHandbook.org> (accessed on March 16, 2011).

421 See <http://www.iphandbook.org/handbook/resources/Agreements/> (accessed on March 16, 2011).

422 See <http://globalaccessinaction.org/> (accessed on March 16, 2011).

Licensing Executive Society (LESI). Together, they aim to provide "legal tools to cut licensing and partnership transaction costs, connecting partners to demand driven innovation opportunities, and integrating commercial strategy into technology transfer for development."[423] *For this purpose, a patent information clearinghouse and IP licensing and partnership agreement toolkit are being developed, amongst others.*
Another resource for information on humanitarian licensing, and some examples of its implementation in agriculture (e.g., Golden Rice Consortium; Generation Challenge Program), can be found on the website of the Central Advisory Service on Intellectual Property (CAS-IP) of the CGIAR.[424]

6.4.2 Non-IP issues

1. *Broader challenges*

Several interviewees warn that the (negative) impact of patents or other IPRs on the development and transfer of knowledge, technologies and materials for the benefit of resource-poor farmers in developing countries, should not be overestimated. One of the central arguments is that most protected technologies go beyond the absorptive capacity of developing countries, and that there is much non-patented technology and knowledge available that is more relevant for developing countries at this moment. The respondents indicate that basic investments in local breeding programs and the implementation of some agronomic improvements at the farmer fields would already have major impacts on yields and product quality, especially in Africa. Overall, the lack of good infrastructure, educational system, and governance structures, next to deficient financial resources for research and development, are generally considered more important impediments to improved agricultural output than issues of IP. Looking purely at agricultural research and development, the lack of technological capacity in many developing countries, both in terms of facilities and the number of trained breeders and researchers, is considered the number one problem. This problem also limits the uptake of relevant non-patented technologies in developing countries.

Obviously, these broader challenges need to be addressed if a strong agricultural sector is to be realized in developing countries. IP protection is, however, an important factor in that development process, influencing both national and international technology and capital flows and power balances, and is therefore not to be ignored.

2. *Genetic modification*

The most influential non-IP issue affecting technology transfer to developing countries relates to the use of genetic modification (GM) technologies. Actually, this is the decisive factor

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423 *Idem.*

424 See <http://www.cas-ip.org/ip-agriculture/equitable-access-licences/> (accessed on March 16, 2011).

431 COGEM 2008; Kalaitzandonakes, Alston and Bradford 2007.

behind the failure of three of the four case studies discussed above, and it plays a major role in the future success of the potato case. There are several key problems to be discerned.

First, there is the *cost issue*. Apart from the fact that most GM projects involve substantial research costs, it is especially the costs of getting a GM crop through the biosafety procedures that count. One interviewee estimated these regulatory costs between six to ten million euros per crop.[431] As was exemplified by the shallot case, such costs are well out of reach for most if not all universities and even for many companies, particularly when applied to so-called 'orphan crops' and for resource-poor farmers in developing countries. But also for cash crops such as soybean, the costly and time-consuming regulatory process can create a new form of exclusivity that goes beyond patent protection. This is exemplified by the current debate on the first GM crop coming off patent in 2014 (see Box II-20).[432]

Box II-21 : *Biosafety Dossiers Can Block Generic Competition in Agro Biotechnology*

In the coming years, many GM technologies and traits will come off patent, and Monsanto's herbicide-tolerant Roundup Ready trait in soybean is the first in 2014. This is the first time that generic versions can be developed in agricultural biotechnology and, in contrast to the pharmaceutical industry, no specific legislation or sector protocol is yet in place to pave the way from patent monopoly to generic competition. This lack of transparency is worrying since a GM crop needs to go through extensive biosafety tests before it is allowed to be marketed in a particular country. The biosafety dossier that results from this regulatory process is confidential and the owner needs to maintain it over time. The technology developer can, therefore, decide to terminate the regulatory dossier by the time its patent on the technology expires. This would imply that no one can develop a generic version without going through the same costly and time-consuming regulatory process. In the case of Roundup Ready soybean, Monsanto has pledged to maintain export approval status through 2021.[433] Eventually, however, the sector or governments will have to develop a mechanism to maintain the biosafety dossiers long term, for example by making them publicly available.

A second problem is the *social controversy* that surrounds the technology and its products. The Brassica and shallot cases showed that public funders and research partners can be very reserved when it comes to supporting a project in which GM technologies are used. Furthermore, governments can easily decide to delay or deny the regulatory approvals for such projects. To counter both the cost and social controversy issue, researchers involved in the potato case take much effort to explain that cisgenesis should not be considered a GM technology as it only works with natural genes, i.e., genes from the same species or its crossable wild relatives.[435]

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[432] Parloff 2010.

[433] Abbott 2011. Available at <http://greenbio.checkbiotech.org/news/gm_crop_patents_near_end_us_farmers_ask_what_next> (accessed on March 16, 2011).

[435] See *e.g.* the White Paper on cisgenesis, available at <http://www.cisgenesis.com/content/ view/4/28/lang,english/> (accessed on March 16, 2011).

A third major issue relates to *liability*. According to the Cartagena Protocol on Biosafety, a technology developer (often the patent holder) can be held liable for financial claims in case of damage caused by the GM technology. Together with the social controversy surrounding the technology, companies and research organizations are generally very concerned about whom to share their technologies with and under what conditions, as they fear brand damage and liability claims in case of misuse or bad product performance. This has particularly been exemplified by the CIMBAA case, where liability risks discouraged both the private and public partners to continue the research project.

Furthermore, many governments have set up strict regulations on the growing of GM crops in order to allow for the coexistence with conventional and organic crops.[436] A GM variety is therefore released on the market with tight stewardship conditions attached. These circumstances can have different effects on IP management and technology transfer to developing countries. On the one hand, it is repeatedly indicated that the risks involved make patent holders hesitant to grant humanitarian use licenses, as this may weaken their control over the technology.[437] Also, breeders may focus even less on resource-poor farmers as these will be unable to adopt the necessary stewardship measures, resulting in liability issues. On the other hand, in relation to the potato case there are some voices that would like to investigate how IPRs, as a control tool, can contribute to the sustainable management of the late blight resistance genes in the field.[438]

6.4.3 Opportunities

1. *Patent databases*

With respect to accessing outside knowledge and technologies, several non-IP problems were mentioned. Central is the difficulty of getting to know 'who is doing what' and finding out what technologies are already available. The expensive subscription fees for many scientific journals are certainly problematic in this context. Patented technologies are, however, relatively easy to trace as they are registered in various patent databases, many of which can be freely accessed. Furthermore, the patent system demands the publication of each invention so that a person 'skilled in the art' can reproduce it. Patent databases contain thus a valuable source of information and, since currently many biotechnologies are not patented in developing countries, such databases could provide the researchers in these countries a manual for copying the patented inventions.

Yet, different opinions exist whether the information included in these databases is indeed sufficient for repeating the patented inventions, with some arguing that essential information is often deliberately omitted. Even though there is no doubt that some inventions can be copied by means of the disclosed information, the importance of *know-how* was also strongly emphasized, especially in biotechnology. Know-how generally refers to all information, materials, and technologies needed that are not publicly available. This includes all the facilities (labs, greenhouses, genebanks, etc.) that an inventor has access to and which can be indispensable to repeat the patented invention. Still, it must be emphasized that it can

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436 See *e.g.* <http://ec.europa.eu/agriculture/gmo/coexistence/index_en.htm> (accessed on March 16, 2011).

437 Heselmans *et al.* 2008. Available at <http://www.society-genomics.nl/uploads/media/IP-Policies-Conference-11april2008-Report.pdf>(accessed on March 16, 2011).

438 Haverkort 2009. Available at <http://www.durph.wur.nl/NR/rdonlyres/A03C74F6-7B5E-42A0-85B0-3919AD0BB3BE/82122/PotatoWorldaboutDuRPh.pdf> (accessed on March 16, 2011).

be more difficult to get access to an unpatented invention because of the simple fact that it was not disclosed to the world.

2. *Need for an effective protection system*
Several interviewees argued that developing countries would benefit from establishing a proper PBRs system as this would make it possible to have more control over the development, quality and dissemination of new seed materials. With respect to the patent system, the incentive that such system can create for innovators and investors was repeatedly mentioned as an important opportunity for developing countries. Other opportunities that IPRs can present to developing counties, according to the Dutch interviewees, relate to their effect on foreign partnerships and investments. Important in this respect is the observation that many research organizations and companies from the developed world only want to collaborate with partners in developing countries when they can be sure that their technologies are properly protected and managed. Along that same line, most industry representatives indicated that they will only invest in developing country markets if they can protect their products from being copied, either by legal (i.e., IPRs) or technical means (i.e., hybrid seeds[439]). Another argument why developing countries should establish an efficient IPR system according to some interviewees is that "you have to play by the rules if you want to be part of the game," meaning that if a developing country wants to enter an export market it has to comply with the international IP regulations and IPRs.

6.5 Conclusions

In this chapter, we have analysed the effects IPRs have on the accessibility of research materials and the transfer of agricultural technologies to developing countries, by discussing the experiences of actors in the public and private sector and four case studies. This was followed by an evaluation of the positive and negative roles of IPRs vis-à-vis non-IP factors.

The public researchers interviewed indicate that most research materials (also when protected by IPRs) are still freely exchanged without serious delays. However, some companies were reported to set very restrictive conditions, claiming that all future inventions made on or with the material provided will fall under their IP. Together with the weak research exemption in patent laws in many countries, this can thwart public research on commercially developed technologies as in the case of GM crops. Universities make sure to protect their own freedom to operate with respect to the IP that results from research for or with private partners. To do so, some try to retain the IPRs that result from research partnerships and only issue licenses to the partners involved. Others indicated, however, that such strategy is too costly in the long run due to the high costs of maintaining a patent. Ultimately, the outcome of 'who gets what rights' in research partnerships depends heavily on the relative contributions of the different research partners and on their negotiation capabilities. All these issues affect the conditions under which university IPRs can be

[439] To profit maximally from technical protection measures, the company involved will try to keep the production process secret –*e.g.* when producing hybrid seeds the parent varieties will be kept secret. Another technological protection measure is genetic use restriction technology (GURT), or 'terminator technology', which causes second generation seeds to be sterile. Currently, there is a de facto moratorium on this technology at the United Nations Convention on Biological Diversity (CBD). See *e.g.* <http://www.cbd .int/agro/gurts.shtml> (accessed on March 16, 2011).

accessed, with only 100% publicly funded research is available under non-exclusive licenses and the involvement of private research partners commonly leading to more exclusive arrangements.

Turning to the private sector, the debate on the accessibility of research technologies and materials concentrates strongly on the balance between patents and the 'open source character' of Plant Breeder'sRrights. Proponents and opponents of the current patent system have tabled different proposals, ranging from sector agreements about a restrictive breeder's exemption to the introduction of a full breeder's exemption in international patent law. Other issues under discussion concern the need to increase patent quality or to curtail strategic use of the patent system. Especially the multinational seed companies that are also producing agrochemicals or pharmaceuticals emphasize the importance of strong patent protection for stimulating innovation. Most medium sized and smaller companies however, claim that patents pertaining to plant varieties hamper practical breeding. This is likely to support further consolidation in the seed sector that might lead to higher seed prices and less genetic diversity, with consequences for global food security and particularly the needs of developing countries and poorer farmers.

The four case studies on shallot, cassava, potato and brassica illustrate that IPRs are not the only, nor necessarily the most important, stumbling block to technology transfer in research for development, especially when GM technologies are concerned. Biosafety regulations and the legal and financial risks (e.g., liability) that can come with them can create significant barriers. Furthermore, the public controversy surrounding GMOs can strongly affect the extent to which funders, research partners and, ultimately, farmers and consumers are willing to support the project. It is difficult to separate these issues and assign shares in terms of their importance in technology transfer, also because biotechnology is especially the field in which IP issues play an important role.

The case studies demonstrate the crucial importance of having freedom to operate for the development, implementation and commercialization of a technology. The problems described in the shallot case illustrate the legal uncertainties that can be encountered because of third-party IP. The potato and brassica cases show two strategies (being part of a consortium or having access to a strong IP portfolio) to strengthen or secure one's freedom to operate. Yet, it is very likely that many humanitarian projects will not be able to establish such position and, as the return on investment for any humanitarian project will be small, IP transaction costs can form a serious impediment to such projects.

The idea that humanitarian licenses can negatively affect one's own interests appears to be dominant in the Dutch agricultural research sector. It was reported that many companies have reservations with respect to the application of such licenses because of the risk that a protected technology, which is provided royalty free for humanitarian use, ends up in a competitive product on the market. Consequently, public research organizations are reluctant to make humanitarian licensing a standard policy because they fear that this will lead to less contracts and partnerships with companies or lower licensing fees. Carefully formulated licenses and good IP stewardship can, however, mitigate commercial risks for companies, so the public sector would better start building more expertise in this area, without underestimating their negotiating position or neglecting their public responsibility.

The information provided by patent databases and the importance of an effective protection system for stimulating foreign partnerships and investments, were mentioned as the main opportunities that IPRs can present developing counties.