

Harnessing Intellectual Property Rights for Development Objectives

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

Harnessing Intellectual Property Rights for Development Objectives

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

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

Find your free download on www.wolfpublishers.com/harnessingipr

Wolf LegalPublishers

POB 31051

6503 CB Nijmegen

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.

All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, without prior written permission of the publisher. Whilst the authors, editors and publisher have tried to ensure the accuracy of this publication, the publisher, authors and editors cannot accept responsibility for any errors, omissions, misstatements, or mistakes and accept no responsibility for the use of the information presented in this work.

Table of Contents

OVERALL INTRODUCTION	v
Willem van Genugten and Anna Meijknecht	
Acronyms	xi
PART I	1
TRADE VS. DEVELOPMENT: THE INTERNATIONAL INTELLECTUAL PROPERTY RIGHTS REGIME AND THE UN MILLENNIUM DEVELOPMENT GOALS	
<i>An Introduction to the Problems with International IPR Obligations in the Light of Development Priorities in Sub-Saharan Africa</i>	
Authors: Bernard Maister and Caspar van Woensel	
PART II	111
AGRICULTURAL SEEDS THAT REDUCE HUNGER AND POVERTY – POLICIES, PERCEPTIONS AND PRACTICES IN INTELLECTUAL PROPERTY RIGHTS	
Authors: Bram De Jonge, Godber Tumushabe, Julian Barungi, Niels Louwaars	
PART III	269
AFFORDABLE HIV DRUG RESISTANCE TEST FOR AFRICA (ART-A) INTELLECTUAL PROPERTY	
Authors: Grant Napier, Sibongile Gumbi and Tobias Rinke de Wit	
PART IV	393
SYNTHESIS, CONCLUDING REMARKS AND RECOMMENDATIONS	
Willem van Genugten and Anna Meijknecht	
ANNEX I Official list of MDG indicators	427
ANNEX II Focusbrief Ontwikkelingssamenwerking	430
ANNEX III ip protection, management and application model	454
ANNEX IV African IP organizations	472
ANNEX V National IP instruments: Uganda and South –Africa	478
List of Contributors	489

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 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-Profes'.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: on 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-Profes.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).

OVERALL INTRODUCTION

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 led 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 innovative 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

ACRONYMS

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

ACRONYMS

ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
IVD	<i>In Vitro</i> 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
NaCRRRI	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

ACRONYMS

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

ACRONYMS

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 III

AFFORDABLE HIV DRUG RESISTANCE TEST FOR AFRICA (ART-A) INTELLECTUAL PROPERTY

By:

**Grant Napier
Sibongile Gumbi
Tobias Rinke de Wit**

CONTENTS**CHAPTER 1 RESEARCH QUESTIONS AND METHODOLOGY**

1.1	Introduction	275
1.2	Aim of the Research	275
1.3	Objectives of the Research	276
1.4	Research Questions	276
1.5	Data Collection	276
1.6	Selection of Study Countries	277
1.7	Key Deliverables	277

CHAPTER 2 ART-A, MDG6, AND IPRS

2.1	Introduction	278
2.2	MDG 6: Reversing the spread of HIV and AIDS, Malaria and TB	278
2.2.1	Access to Healthcare	279
2.2.2	Public-Private Partnerships	279
2.2.3	Regulatory Issues	281
2.2.4	Access to Healthcare in Africa	282
2.3	IP and Access to Health Technologies	283
2.3.1	TRIPS Agreement and Public Health	285
	Box III-1: <i>The TRIPS Agreement: Implications for the IP Laws in Uganda</i>	286
	Box III-2: <i>The TRIPS Agreement: Implications for the IP Laws in South Africa</i>	287
	Box III-3: <i>Uganda and HIV – IP matters relating to access to medicine</i>	290
	Box III 4: <i>Threats and Access to Medicines</i>	291
2.3.2	Bilateral Agreements ('TRIPS - plus') and Access to Medicines	292
2.4	Concluding Remarks	293
2.4.1	Health Technology Research in Africa	293
2.4.2	Uganda	294
2.4.3	South Africa	295

CHAPTER 3 BACKGROUND TO ART-A

3.1	Introduction	296
3.2	Relevance of HIV Epidemiology and Treatment	296
3.3	HIV Drug Resistance (HIVDR)	297
3.4	The Affordable Drug Resistance Test for Africa (ART-A) Program	298
3.5	Technologies in Development by ART-A and Their Competitive Advantages	301
3.6	Technology Users and Beneficiaries	304
3.7	Intellectual Property Challenges faced by the Consortium	306
3.8	Freedom to Operate and Gene Patents	307

CHAPTER 4 CONSORTIUM IP ARRANGEMENTS

4.1	Introduction	309
4.2	Summary of Consortium Agreements	310
4.3	Initial Draft Terms of Consortium Agreement – Non- Binding Proposal	313
4.4	Confidential Disclosure Agreement	313
4.5	Consortium Agreement between all Parties	315

4.5.1	NACCAP Grant Terms and Conditions	315
4.6	Collaboration Agreements	315
	<i>Box III-5: Roche and Stanford University Dispute over Ownership of Patents for PCR-based Measurement of HIV Viral Load</i>	316
4.7	Other agreements	317
4.7.1.	Employment Agreements	317
4.7.2	Material Transfer Agreements	318
4.7.3	Memorandum of Understanding	319
4.8	Identified Ambiguities or Conflicts in Consortium Agreements	319
4.8.1	Intellectual Property Terminology Used	320
4.8.2	Background Intellectual Property	321
4.8.3	Confidentiality, Publication, Knowledge Dissemination and Disclosure	322
4.8.4	Ownership of Foreground IP	323
4.8.5	Costs Intellectual Property Protection	324
4.8.6	Access Rights	325
4.8.7	Commercial Use Licensing Options and Transfer of Ownership	325
4.9.	Intellectual Property Policies of Institutional Consortium Members	326
4.10	Ownership of Research Findings and Confidentiality	330
4.11	Revenues from Patents, Licenses and Companies	330
4.12	The Role of TTOs	331
4.13	Key Lessons in Consortium IP Arrangements	332

CHAPTER 5 ENSURING ACCESS TO ART-A TECHNOLOGY

5.1	Introduction	334
5.2	Non-IP Considerations	334
5.2.1	Technical and Lab Facility Considerations	334
5.2.2	Regulatory Considerations	335
5.3	ART-A IP	336
5.4	Identifying IP Protection Options Suitable for ART-A	336
5.4.1	Patents	337
5.4.2	Trade Secrets	339
5.4.3	Trademarks	340
5.4.4	Open Access	341
5.4.4.1	Public Domain Publication	341
5.4.4.2	Open Source for ART-A Software	341
5.4.4	Protected Common	342
5.5	Freedom to Operate (FTO)	343
5.5.1	FTO and ART-A Technologies with Respect to Patents	344
5.5.2	FTO and Gene Patents in Africa	351
5.6	Policies Promoting or Restricting ART-A FTO	352
5.7	How to Handle Publication vs. Patenting in the Consortium	353
5.8	Some Examples of Strategic Options for Ensuring Access to ART-A technology	354
5.8.1	Open Access – Public Domain with Open Source Software	355
5.8.2	Product Bundling Under License from Component Manufacturers	356
5.8.3	Commercial Licensing of ART-A Trademark	357

5.8.4	Commercial Licensing of Patented Technology	357
5.9	IP management Tools	358
5.9.1	Research Materials	362
5.9.2	Research Actors	362
5.9.3	IP Instruments	362
5.9.4	Institutional Actors	363
5.9.5	IP Options	363
5.9.6	Costs of IP Protection and Management	363
5.10	Key Observations from Analysis of ART-A IP Environment	363
	<i>Box III-6: Patent and Licensing Issues with Respect to one of the Reagents Components of ART-A HIV Drug Resistance Test</i>	366
CHAPTER 6 CONCLUSION		
6.1	Differing Levels of Development and IP Legislation Implementation	369
6.2	Access to Knowledge and Encouraging Open Source	370
6.3	Obstacles to Access for ART-A Technologies	371
6.4	Barriers to African Manufacture of Diagnostic Products	371
6.5	Other Key Challenges	372
6.5.1	Uganda's Challenges	372
6.5.2	South Africa's Challenges	373
6.6	The Opportunities for ART-A	373
6.7	Opportunities for Improving African R&D Output	374
6.8	Broader Suggestions and Recommendations	376
REFERENCES		378

CHAPTER 1 RESEARCH QUESTIONS AND METHODOLOGY

1.1 Introduction

Understanding both the enabling and limiting factors of intellectual property rights in improving access to knowledge for those who can most benefit from it, is of key importance if the Millennium Development Goals (MDGs) are to be obtained. The key objective of Millennium Development Goal 6 (MDG 6) is combating the HIV epidemic, malaria and other diseases.¹

In this study, we examine a unique European and African research consortium called the Affordable Resistance Test for Africa (ART-A) that was established to develop technologies for affordable HIV drug resistance testing in Africa.²

This consortium is a public-private partnership (PPP) and presents a great opportunity to study international, regional and institutional intellectual property laws and policies and how they affect access to knowledge and health innovations in Africa. Here we investigate the intellectual property landscape of this consortium in an attempt to identify how data and research output can be shared and protected by the consortium, and how consortium IP can be managed.

Medical diagnostics which rely on testing of genetic information have unique IP challenges as evidenced by ongoing debates around gene patenting.³ In this context we explore suitable IP protection models that could be used by public-private partnerships that are developing medical diagnostic technologies to facilitate broader access to diagnostic testing in Africa. This also provides the opportunity to highlight barriers or opportunities created by IP regulation, legislation, enforcement and implementation to inform policy-makers and funding organizations into the future.

In this study of ART-A we review institutional, national and regional IP policies, strategies and legislation that have relevance to and that could influence the ability of the ART-A research consortium to make its technology accessible to end users in Africa.

1.2 Aim of the Research

The aim of the study is to develop IP management recommendations that are appropriate for and that support the aims and objectives of the ART-A consortium's research program. It describes the IP environment and develops recommendations that seek to find the right balance between the private sector's need for IP protection and the public interest of making knowledge freely available for the benefit of all, especially developing countries. The end goal 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 epidemic.

¹ Millennium Development Goals [online]. <<http://www.undp.org/mdg/basics.shtml>>.

² Affordable resistance test for Africa [online]. <<http://www.arta-africa.org/>>.

³ Carbone, J., Gold, E. R., Sampat, B., Chandrasekharan, S., Knowles, L., Angrist, M. and Cook-Deegan, R. (2010), pp. 784-791.

1.3 Objectives of the Research

In order to achieve the above aim, the objectives of the project are to:

- Examine the role of European and African institutional collaborations in the generation of knowledge and IP within the consortium.
- Review the different forms of IP generated by the consortium and consider the legal and good practice mechanisms to ensure that the objectives of the consortium are achieved.
- Identify IP models or solutions designed to ensure that ART-A technology in particular, and innovative research in general, can be applied in practice to address the MDG 6.

It is intended that this research will inform the ART-A program, the WHO's Global Strategy for Prevention and Assessment of HIV drug resistance⁴ and other similar public-private partnerships of important intellectual property related issues. This includes informing practices that should be implemented and also agreements that may affect or may need to be put in place, to ensure the knowledge developed by such research consortia can reach clinical practice. The ultimate goal is to assist doctors, laboratories and thereby patients, particularly those who depend on public health services for their healthcare.

1.4 Research Questions

The leading research questions that the project attempts to address are:

1. What is the role of IP in the ART-A project in its fulfilment of MDG 6?
2. How can data and research output be shared and protected in a manner that promotes development?
3. How should existing and newly developed IP of the ART-A public-private partnership be managed?
4. How can the process concerning the transfer and sharing of IP between consortium members be formalised?
5. What are suitable IP protection and management models for this international public and private partnership to facilitate affordable access of the technologies developed by the consortium?

1.5 Data Collection

The main source of information is the internet, which was used to access published papers, textbooks, book publications, legal documents, reports and general information. All material collected and used in the project is referenced in the report.

In addition, meetings were conducted with key people responsible for research work in the ART-A collaboration and intellectual property management, policy and strategy development at a regional and national level.

⁴ Bennett, D. E., Bertagnolio, S., Sutherland, D. and Gilks, C. F. (2008), pp. 1-13.

1.6 Selection of Study Countries

The two African countries where ART-A research is being conducted to develop methods and protocols for HIV drug resistance testing are South Africa and Uganda. It is likely that only these two countries will be involved in any IP development related to ART-A and therefore these were the countries in Africa that were selected for this study. South African institutions are involved in both the development and evaluation of methods in centralised laboratories and those in Uganda are involved specifically in evaluation of the methods in remoter laboratories and clinical settings. These two countries also represent quite different levels of industrial development and have significant differences in their absorptive capacity for technology, as well as their capacity to innovate. Uganda is classified by the United Nations as a least developed country (LDC),⁵ with different opportunities and challenges with respect to IP, as opposed to South Africa which is regarded as a developing or middle developing country.

In the longer term, the technologies developed will be deployed in laboratories in at least six African countries that have been supported by a larger capacity building and research program called PharmAccess African Studies to Evaluate Resistance (PASER).⁶ These additional countries include Kenya, Zambia, Zimbabwe, and Nigeria.

1.7 Key Deliverables

The planned deliverables and outcomes of the project are:

- i. **Improved contracting efficiencies.** In collaboration with sub-project 1 (see Part I), assess the influence of international treaties and conventions on European-African research collaborators of the ART-A consortium. In addition, to review consortium agreements for coherence, proper integration and practical application. The purpose of this exercise is to identify the key components of these agreements in relation to the protection and management of IP to serve other African projects where IP is a critical component.
- ii. **Better IP transparency and Freedom to Operate (FTO).** Using ART-A as an example, to make recommendations for handling issues relating to infringement and licensing options.
- iii. **Exit strategies.** To provide exit strategy options for the consortium and address issues relating to IP ownership, maintenance and options for facilitating access to IP in Africa at the conclusion of the project.
- iv. **Information dissemination.** Produce an end-users chapter that is customized for policy-makers, entrepreneurs and (academic) institutions. This chapter is the basis for two information dissemination workshops in Europe and Africa, to be organized in after completion of the final report.
- v. **Develop practical IP management tools.** Where patented IP is generated by consortium members and needs to be managed to facilitate technology utilization, different options are considered and presented. Each option has its strengths and weaknesses and furthermore, non-IP related issues are also considered, like licenses, as well as regulatory, technical and capacity limitations.

⁵ UN-OHRLLS [online]. <<http://www.unohrlls.org/>>.

⁶ PharmAccess Foundation [online] <<http://www.pharmaccess.org/Default.asp?Page=126>>.