International Law and Economics

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Analysis of Compliance with Article 30 of the TRIPS Agreement

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Viola Prifti
Max Planck Institute for Innovation and Competition
Munich
Germany

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To my mother, Liliana.
For instilling in me the love for knowledge

Foreword

The use of biotechnological tools and other techniques to improve crops has given rise to a significant increase in the patenting of plant components and plants. At the same time, the exclusionary rights conferred by patents have generated concerns about their implications for a sustainable agriculture and food security. As a result of these trends, it becomes critical to examine the intersection between plant breeding and patent rights. This book makes an original and important contribution to this still relatively unexplored area of research.

A few countries grant patent rights on plants as well as plant varieties as such. While most jurisdictions exclude plant varieties from patentable subject matter, they allow for the patent protection of genetic constructs, including in some cases isolated genes, used to modify plants. The protection of different biological materials contained in plants may lead to the control over the plant varieties themselves, even if the law does not permit their patenting.

Plant breeding proceeds through the continuous improvement on existing plant varieties. Ensuring access to such varieties as a source for further research and breeding is crucial for farming systems. This has been recognized under plant variety protections regimes, which provide for a 'breeder's exception' allowing third parties to use protected varieties to develop new ones. However, patents rights can normally be exercised to restrict such use, thereby raising questions about the continuous improvement of crops, the impact of such rights on the plant breeding industry and the adequate supply of seeds to farmers at affordable prices. Such questions become particularly relevant in a context of high concentration of patent ownership in a small group of large biotechnology-based companies.

An outstanding issue is, hence, the extent to which the patent law can be framed so as to allow for a kind of 'breeder's exception' for further breeding when patented elements exist. This book addresses in detail this issue, particularly what could be the scope of an exception for that purpose admissible under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) of the World Trade Organization (WTO).

The TRIPS Agreement does allow for limitations to patent rights; yet, there is uncertainty on the type and degree of limitations that may be deemed compatible. Can a national patent law provide, without violating the TRIPS Agreement, that a third party may use a patented plant material to develop a new variety? Most scholars and analysts of said Agreement would probably agree that the reply would be affirmative, as an exception of this type would be equivalent to a research or experimentation exception that is generally deemed compatible with the TRIPS Agreement. In fact, as examined in this book, some European countries already contemplate in their patent laws an exception of this type.

But could also an exception to patent rights allow for the *commercialization* of a new variety developed by a third party if it contains a patented component? Would it still be compatible with the TRIPS Agreement? These questions raise complex issues of legal interpretation. They also raise questions about the economic impact of possible exceptions, namely the extent to which they may encourage or undermine the incentives for breeding activities.

This book investigates the possible limits and TRIPS-compatibility of both narrow and broad versions of a breeder's exception to patent rights. Significantly, it applies an interdisciplinary approach to explore a topic that has received little attention in the legal and economic literature. It introduces in a didactic manner concepts that are key to understand the problem addressed by intellectual property protection in this field, such as the distinction between 'plants' and 'plant varieties'. It also contains an interesting discussion on ethical and moral aspects of patentability as related to plant breeding and on the issue of 'patent quality' stemming from the lax application of the patentability standards.

A common theme that runs through the book and will help the reader understand the interests at stake is the need to reach a balance between the incentive to innovate that, under some circumstances, may be created by patent rights, and the benefits that society may obtain by allowing third parties to use protected materials for breeding new plant varieties. Although the analysis extensively relies on the WTO panel's opinion in the EC-Canada pharmaceuticals case, it goes beyond this opinion by elaborating on an interpretation of the reasonableness test established by that provision in relation to a possible conflict with the interests of the patent owner.

In addition to a thorough analysis, the author discusses some possible ways forward to look into this issue, in line with the objectives and principles of the TRIPS Agreement. Thus, the need to interpret patent-related provisions in concert with the broad regulatory objectives found in international regimes governing food and agriculture is emphasized. Another interesting suggestion is to consider a broad breeder's exception in relation to the 64 crops covered by the Multilateral System of the International Treaty for Plant Genetic Resources and Agriculture. These crops have been recognized as particularly relevant for the world's food security. The author also elaborates on the growing importance of human rights considerations in the field of patent law, especially for developing countries confronting situations of food insecurity, and rightly concludes that a breeding exception in patent law seems to be supported by sound public policy objectives.

In summary, this book provides useful insights to integrate the objectives of a sustainable agriculture and food security into patent law, by exploring some of the important flexibilities available under the TRIPS Agreement. It fills a significant gap in the literature and may be an important source of guidance for policy making in this field.

December 2014 Carlos M. Correa

Preface

This book stems from my personal interest in food-related policy issues. Through my leisure readings, I learnt that plant breeding governance is the answer to many food security challenges. It was my wish to combine my curiosity about plant breeding with my knowledge on legal and economic theory that led to the present text. The book explores the need to incorporate an exception for breeding purposes into the patent laws of those countries where patent and plant breeder's rights coexist. It examines the question of compatibility of such an exception with the TRIPS Agreement and indicates the relevance of the exception for food security. I hope that in this book, academics will find a useful legal and economic analysis of research exceptions to patent rights as well as of the relationship between patent exceptions for breeding purposes and food security issues. I also envisage that this book will help inform national legislators and generate meaningful debate on exceptions to patent rights for promoting plant breeding practices in line with the right to food.

Besides my commitment and enthusiasm in writing this book, many persons have contributed in a direct or indirect way in facilitating this work. First and foremost, I thank my family and friends for their understanding and support during the many challenges I encountered while writing this book. My sisters, Eta and Mirela, deserve particular acknowledgment for finding a humorous approach to what I thought of as "difficulties". I extend my wholehearted gratitude to Prof. Carlos Correa for being my intellectual guide and giving me the privilege to gain from his knowledge. I also feel indebted to Dr. Niels Louwaars, Dr. Bram de Jonge, and Prof. van der Meulen (University of Wageningen, NL), who provided the necessary support for conducting the first interviews with stakeholders in plant breeding. All the interviewees deserve my greatest appreciation since they helped clarify the business and scientific aspects in plant breeding. Special acknowledgments go to Dr. Jaap de Satter of the Ministry of Economic Affairs (Directorate for Agriculture) in the Netherlands for his kindness and continuous encouragement.

Much appreciation to Dr. Ingrid Schneider and Dr. Holger Hestermeyer for their moral support and Prof. Annette Kur for her comments, to Prof. Thomas Eger for strengthening my confidence in my work. Lastly, I thank the German Research Foundation for financially supporting my research stay at the Graduate School "The economics of the internationalization of law" in Hamburg and Prof. Stefan Voigt and Prof. Thomas Eger for supporting this publication.

Munich, Germany Viola Prifti

List of Abbreviations

AUPC	Agreement on a Unified Patent Court
BA	Board of Appeal
BIOS	Biological innovation for open society
BRs	Breeders' rights
CAMBIA	Independent non-profit institute creating new technologies, tools and paradigms to promote change and enable innovation
CAS-IP	Central Advisory Service on Intellectual Property
CBD	Convention on Biological Diversity
cDNA	Complementary DNA
CGIAR	Consultative Group on International Agricultural Research
CIMMYT	International Maize and Wheat Improvement Centre
CIOPORA	International Community of Breeders of Asexually Reproduced Ornamental and Fruit Varieties
CVPO	Community Plant Variety Office
DNA	Deoxyribonucleic acid
DSB	Dispute settlement body
DSU	Dispute settlement understanding
DSU	Distinctness, stability, uniformity
EBA	Enlarged Board of Appeal
EC	European Communities
ECJ	European Court of Justice
EDVs	Essentially derived varieties
EPC	European Patent Convention
EPIPAGRI	Towards European Collective Management of Public Intellectual Property for Agricultural Biotechnologies
EPO	European Patent Office
ESTs	Expressed sequence tags
ETC Group	Action Group on Erosion, Technology and Concentration
EU	European Union
FAO	Food and Agricultural Organization
FDA	Food and Drug Administration

FTA	Free Trade Agreements
GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
GDP	Gross domestic product
GM	Genetic modification
GMOs	Genetic modified organisms
GRFA	Genetic resources for food and agriculture
ICESCR	International Covenant on Economic, Social and Cultural Rights
ICTSD	International Centre for Trade and Sustainable Development
IP	Intellectual protection
IPRs	Intellectual property rights
ISAAA	International Service for the Acquisition of Agri-biotech Application
ISF	International Seed Federation
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
KARI	Kenya Agricultural Research Institute
MAS	Marker-assisted selection
MPEP	Manual of Patent Examining Procedure
OECD	Organization for Economic Cooperation and Development
PA	Patent Act
PIPRA	Public Intellectual Property Resource for Agriculture
PPA	Plant Patent Act
PVPA	Plant Variety Patent Act
R&D	Research and development
RdDM	RNA-dependent DNA methylation
RNA	Ribonucleic acid
TRIPS	Trade Related Intellectual Property Rights Agreement
UDHR	Universal Declaration of Human Rights
UK	United Kingdom
UN	United Nations
UNCTAD	United Nations Conference on Trade and Development
UPOV	International Union on the Protection of New Varieties of Plants
US	United States
USDA	United States Department of Agriculture
USPTO	United States Patent and Trademark Office
VCLT	Vienna Convention on the Law of Treaties
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

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