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Viola Prifti

The Breeder's Exception to Patent Rights

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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Chapter 1
Introduction

> The greatest service that can be rendered to any country is to add a useful plant to its culture (Thomas Jefferson)

These words of Thomas Jefferson beautifully embrace the significance of plant breeding for society. Plant breeding is the science and the art of ameliorating the genetics of plants, which has accompanied our society since its dawn. It started as a family or a village-based activity in order to satisfy dietary needs; nowadays, breeding new varieties of plants has developed into a well-established industry that provides food with enhanced nutritional properties as well as raw materials for sustainable industrial applications.[1] Indeed, statistical data point to a growth of international seed trade and estimate increasing values for domestic seed markets in recent years.[2] This growth of market for seeds has been paralleled by a global reduction of undernourished people.[3] While several factors involved in food security governance might have played a role in the fall of undernourishment levels, food availability remains key for providing an adequate food supply.[4] An adequate food supply can be ensured only through breeding new varieties of plants. Increasing plant variety production brings about social benefits to the extent that it offers a wider choice for fulfilling dietary requirements and lowers food prices. Plant breeding's contribution to a more environmentally friendly industry is equally

[1] For an understanding see the website of ISF (International Seed Federation), http://www.worldseed.org/isf/what_we_do.html, accessed 21 December 2014. Acquaah (2012), pp. 1–40 and Schlegel (2007), pp. 5–42.

[2] Please, note that the data do not include all type of commercialized varieties of seed. See in particular the data related to national imports and exports. ISF, http://www.worldseed.org/isf/seed_statistics.html, accessed 21 December 2014.

[3] For detailed figures see FAO, IFAD and WFP (2014), pp. 8–12.

[4] *Ibidem*, pp. 14–20.

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important for society.[5] Hence the need to create more plant varieties for the common good.

One factor that has led to a boost in plant variety production in the last decades is the employment of biotechnological methods in breeding processes.[6] These methods are often protected through intellectual property rights (IPRs), which may extend on plant varieties or parts thereof. In most countries, intellectual property rights in the form of patents or plant breeder's rights protect plant varieties as well.[7] IPRs recognize human ingenuity on the technical fruits of human mind and at the same time encourage innovation by granting to the right holder the faculty to exclude third parties from certain actions on the objection of protection. Neoclassical economic theory views exclusionary rights as necessary to spur innovation,[8] but excluding others from using protected plant varieties or parts thereof may impede plant variety creation. The reason lies in the cumulative nature of plant breeding activities. Breeding of new varieties of plants requires access to existing varieties that can be further improved during the breeding process. Preventing breeders from accessing plant varieties may, thus, come forth with the undesirable effect of hampering plant variety production. This effect may especially occur when plant varieties or parts thereof are protected through patent rights. This is because patent rights do not contain exemptions and block third parties from accessing the protected variety. Four European countries, France, Germany, the Netherlands, and Switzerland have sought to avoid such effect and stimulate plant variety production by exempting patent holders' rights in order to allow breeders to create plant varieties with patented elements.[9,10] Dutch plant breeders have proposed to further restrict patentees' rights by allowing commercialization of plant varieties containing patented biological material. Whether these exceptions to patent rights achieve their purpose and comply with requirements of international agreements on intellectual property is a relevant question for policymakers. This question is especially important for those World Trade Organization (WTO) countries that are required to implement the provisions of the Trade-Related Intellectual

[5] See Chap. 3 for more explanations.

[6] Campi (2014), pp. 4–6; Kesan (2007), p. xvii.

[7] For more explanations on IPRs applicable to plant varieties, please see Chap. 4.

[8] For an understanding see Merges (2011).

[9] For Germany see section 11.2.b of the Patent Act adopted in 2005; For France, article L. 613-5-3 of the Code de la Propriété Intellectuelle adopted in 2004, and for Switzerland, Article 9 (e) of the Federal Act on Patents for Inventions, adopted in 2008. The Netherlands adopted the same exception in 2013 which entered into force in 2014. See Article 53.2.b of the Dutch Patent Act. This exception has also been included in article 27.c) of the recent Agreement on a Unified Patent Court (AUPC), (2013/C 175/01). Note that 13 ratifications including Germany, France, and United Kingdom are required for the Agreement to enter into force. As per now, only six countries have ratified it: http://www.consilium.europa.eu/en/documents-publications/agreements-conventions/agreement/?aid=2013001, accessed 20 May 2015.

[10] Trojan (2012). Based on Trojan's report, this exception will be often termed as 'breeding exception' in the following pages.

Property Rights Agreement (TRIPS Agreement)[11] into their national legal systems. The TRIPS Agreement provides for minimum standards of intellectual protection and in particular, its art. 27.1 prescribes that patent rights should be available in all areas of biotechnology. At the same time, art. 30 of the said Agreement authorizes countries to adopt exceptions to patent rights provided that specific requirements are met. Exceptions, thus, should be *limited, not unreasonably conflict with a normal exploitation of the patent and not unreasonably prejudice the interests of the patent owner, taking account of the legitimate interests of third parties*. The vagueness of this provision does not allow drawing immediate conclusion on the type of exception that countries may adopt under the TRIPS Agreement. This is especially the case of those European countries that have adopted exceptions to patent rights for breeding purposes. In order to clarify this legal uncertainty, this book will assess the compliance of exceptions to patent rights with breeding purposes in light of legal and economic considerations. It should be noted since the beginning that neither law or economics, nor the economic analyses of law offer an exhaustive response to the multidimensional aspects involved in intellectual protection of plant varieties. Breeding of new varieties of plants for food security purposes forms part of a multidisciplinary framework of governance. Nevertheless, law and economics can represent a tool for interpreting and evaluating the effects of legal provisions in the field of plant breeding. To offer a comprehensive understanding of this issue, the book is structured as follows.

Chapter 2 will set the background by briefly describing the problem that gave rise to this study. It will further explain the practical and academic relevance of the matter at hand and indentify the relevant legal provisions that will be object of this study.

Chapter 3 will depict a picture of the plant breeding industry and its relevance for the society. It will first purport the beneficial role of plant varieties in various socio-economic sectors, and then explain the development of the breeding industry in terms of business structure and market concentration. This will provide the reader with a preliminary understanding of the breeding industry.

Chapter 4 will examine intellectual protection in plant breeding from a legal and economic perspective. The main property rights in plant breeding, patents and plant breeder's rights, will be explained. The examination of patent rights will be based on a study of legal precedents and legislations of the United States and European countries since most of the patents relevant in plant breeding are granted by the United States Patent and Trademark Office (USPTO) and the European Patent Office (EPO). The understanding of breeder's rights will build upon the text of the International Convention for the Protection of New Varieties of Plants (UPOV).[12] Afterward, the analysis will focus on the economic rationale of

[11] Agreement on Trade-Related Aspects of Intellectual Property Rights, April 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, The Legal Texts: The Results of The Uruguay Round of Multilateral Trade Negotiations 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) (hereinafter TRIPS Agreement).

[12] International Union for the Protection of New Varieties of Plants, Paris, 2 December 1961, as revised at Geneva on 10 November 1972, 23 October 1978, and 19 March 1991 (Geneva: UPOV. UPOV Doc. 221 (E), 1996).

intellectual protection in plant breeding. Both the legal and economic analysis will offer a critical assessment of intellectual property rights as applied to plant variety innovation. Finally, this chapter will provide information on the reasons that induced some countries to adopt a breeder's exception into their national patent laws. Only a good grasp of these issues will permit us to develop the analysis of the breeding exception in the subsequent chapters.

Chapter 5 will aim at conceptualizing the breeding exception within the broader category of exceptions to patent rights. To this purpose, the analysis will offer a comprehensive review of the legislation and most important case law on the research exception in the EU and other countries. The analysis will in particular identify the principles that have guided courts in defining which type of research activities are exempted from patent infringement and to what extent judges have opened the way to economic reasoning. Economic literature on patent exceptions will be thoroughly examined with the aim to provide relevant insight for the categorization of the breeding exception. In addition to the classical economic arguments on the incentive to innovate, the breeding exception will be purported as a legal remedy to the fragmentation of proprietary rights in the breeding phase. The findings of this chapter offer a preliminary understanding of the role of the breeding exception on innovativeness and will assist the analysis of the following chapter.

Chapter 6 represents the heart of this study. It will scrutinize the terms of art. 30 in order to assess whether the breeding exception may be deemed admissible in patent law. The first part of the chapter will focus on the breeding exception as already adopted in the aforementioned countries (limited exception), whereas the second part will examine the proposal of Dutch plant breeders for a broader breeding exception (comprehensive exception). The analysis will start from the findings of the WTO panel's decision in the Canada-Pharmaceutical Patents (or - EC-Canada) case,[13] the only decision on art. 30 of the TRIPS Agreement to date. Afterward the understanding of art. 30 will be enriched by a review of legal and economic studies on the incentive to innovate and social interests. These studies combined with an infield research with stakeholders in plant breeding will offer a method for an accurate assessment of a compliance test with art. 30. The infield research is based on semi-open interviews with stakeholders in plant breeding. The interviews were conducted in the period November 2012–February 2013 in the Netherlands, Germany, and Switzerland. The major part of the relevant information was obtained with the help of the Law and Governance group of the University of Wageningen in the Netherlands, where interviews were conducted with researchers, legal professionals, private firms, the Dutch gene bank, and policymakers working in the sector of plant breeding. In Germany, interviews were conducted with the German Plant Breeders' Association and the International Community of Breeders of Asexually Reproduced Ornamentals and Fruit Varieties (CIOPORA). Among

[13] WT/DS/114R.

private firms, information was also obtained from major multinationals in plant breeding such as Syngenta, Bayer, and KWS SAAT.[14]

Another novel element in this chapter is the elaboration of a 'reasonableness test' in accordance with the language of article 30 of the TRIPS Agreement. This test recognizes the importance of the proportionality principle already developed in the literature,[15] but it offers a more comprehensive approach by focusing on articles 7, 8 and 1.1 of TRIPS. This will provide a new and broader view of article 30. With regard to the comprehensive breeding exception, the compliance test will take account of other international agreements that might clarify the *reasonableness* of such an exception. This reading aims at enabling the realization of the purposes of the treaty to the highest extent possible.

Chapter 7 will present an overview of the major findings of this study. It will illustrate to what extent art. 30 of the TRIPS Agreement allows impairing patent rights and to what degree societal concerns may be relevant for interpreting art. 30. It will also indicate the role of national case law and legislation in shaping the rationale of exceptions and the interpretation of art. 30. Similarly, the importance of the economic reasoning and empirical studies in assessing the compliance of the breeding exception will be addressed. Finally, theoretical and policy implications as well as limitations of the current analysis and suggestions for further research will be discussed.

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[14] See Annex for a list of the interviewees.

[15] The doctrine has been mainly developed for copyright exceptions. See Kur (2011), pp. 208–261; Senftleben (2004), p. 407.

Chapter 2
Setting the Background

One effect of the TRIPS Agreement has been the establishment of patent rights in all WTO countries.[1] The reason is to be sought in art. 27.1 of the said Agreement which explicitly demands patent protection in all areas of technology. As a result, countries that did not provide for patent rights in some or all technological areas prior to the TRIPS Agreement, are now obliged to emanate patent laws for every technological sector. Art. 27.1 does, however, establish some exceptions. One of these exceptions, contained in paragraph 3 of the same provision, is specifically designed for plant breeding. Based on this exception, TRIPS signatories may protect plant varieties through patent rights, a *sui generis* system or a combination thereof. Under a *sui generis* protection, countries are free to exclude plant varieties from patentability; however, patent rights extend on plant varieties when they incorporate patented biological material.[2] This is because art. 27.3 (b) provides for the mandatory patentability of microorganisms. A consequence of such provision is, thus, the patentability of plant varieties despite their exclusion from patentable subject matter in some countries. It goes without saying that this situation creates legal uncertainty and impedes access to plant varieties for breeding purposes. Hence the need to adopt an exception for breeding purposes to patent rights in those countries where patent rights coexist with *sui generis* plant variety protection systems. A sui *generis* system implemented in most WTO countries is that of the breeder's rights provided for in the International Convention on the Protection of New Varieties of Plants (UPOV).[3] Two main differences distinguish this system of plant variety protection from patent rights. One concerns the subject matter; the other is related to the exception of rights. Under the breeder's rights regime, intellectual property protection is granted only to a unique combination of

[1] Please, note that least developed and developing countries have been granted a transitional period for implementing the TRIPS Agreement.

[2] Correa (2012).

[3] For a list of UPOV Members see UPOV (2014).

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genes expressed as a distinct, uniform and stable phenotype. The free access and use of material of the protected variety by other breeders is expressly allowed for the purpose of breeding their own varieties. This means that breeders are free to use their competitors' varieties to introduce beneficial traits into their own breeding lines without infringing the original breeder's rights. This practice is allowed under what is known as the 'breeder's exception'. This system of variety protection was weakened after the establishment of patents on biological material. Contrary to breeder's rights, patents provide for a stronger protection by covering not only plants, but parts of plants, single genes, and breeding methods. Even more significantly, protection is often extended to every plant containing the inventive element or resulting from a patented process. As a consequence, the use of plant material under patent law expressly requires the authorization of the patent holder. The transaction costs and difficulties related to patent licensing restrict breeder's freedom to use all available genetic material in their breeding programs.[4] Fearing a blockage of genetic flows among plant breeding activities, breeders associations in the aforementioned European countries lobbied for the introduction of a breeding exception to patent rights.[5] In the last years, the same issue was presented to the Dutch parliament, which adopted the same exception in 2013. The debate in the Netherlands distinguished between a 'limited' breeding exception (as already introduced in the patent laws of France, Germany, and Switzerland) and a 'comprehensive' breeding exception, that is an exception that allows the commercialization of plant varieties containing patented traits.[6] This last type of exception was proposed by Plantum, the Dutch association of plant breeders and is recently under discussion in the House of Representatives in the Netherlands.[7]

The introduction of exceptions to patent rights for breeding purposes poses challenges to policymaking by bringing to light the difficulties of reconciling opposing interests. These new exceptions incentivize plant breeding activities, while, at the same time, they pose new limits on biotechnological companies that rely on patent protection to create innovative products. This is mainly because the pharmaceutical, biofuel, chemical, and cosmetic industry protect their innovations with patent rights, whereas the plant breeding industry often uses breeder's rights but requires access to patented biological material. These different IP instruments lead to diverse interests and market power between patentees and plant breeders.

[4] Louwaars et al. (2009) Nr. 14.

[5] Please, note that lobbying activities were mainly undertaken by breeders of seed-propagated crops. Breeders of asexually reproduced plants, usually acting under CIOPORA, are against the introduction of a breeding exception to patent rights. Also note that the number of patents relevant for asexually propagated plants is very low.

[6] Trojan (2012).

[7] See the two letters of Ms Sharon A.M. Dijksma, Dutch Minister of Agriculture, dated 27 June 2013, Vergaderjaar 2012–2013, 33 365 (R1987) Nr. 6 and 28 June 2013, Vergaderjaar 2012–2013, 33 365 (R1987) Nr. 8.

Policy implications go hand in hand with the academic relevance of exceptions to patent rights. Economic theory suggests that exceptions to patent rights inevitably weaken patentee's rights and may undermine the structure of the patent system. Since the patent system is designed to promote innovations, the desirability of an exception to patent rights may appear controversial. A breeder's exception to patent rights further raises this debate given its aim to exclude research *with* patented subject matter. Indeed, breeders have an interest in using patented traits as tools in their breeding processes. For example, breeders may introduce a patented trait on pest resistance into a new variety. This type of activity does not involve work on the patented invention. It simply uses the patented trait as a tool for introducing a gene construct into the plant genome. Thereby it is ineligible for the commonly accepted experimental use exception *on* the patented material.[8] Many economists believe that an exception with patented subject matter significantly diminishes the incentive to invest in new technology.[9] These divergent interests and views on the breeding exception draw attention to the difficulties legislators face in giving a definite answer to the controversy accompanying the incorporation of a breeding exception into patent law.

The following chapters shed light on the above issues by clarifying all interests involved and by offering guidance on how to reconcile these interests with countries obligations under the TRIPS Agreement. In this respect, art. 30 of said agreement is most relevant since it explicitly authorizes countries to adopt exceptions to patent rights. The vague formulation of this article, however, does not provide clear rules for WTO Member countries that decide to adopt an exception to patent rights for plant breeding activities. Although a WTO panel offered some insights on the meaning of article 30 in the EC-Canada case, the panel's decision lacked a satisfactory clarification of the conditions set in article 30.[10] Thus, the question of TRIPS-compliance of national legislations that have adopted or intend to introduce a breeding exception to patent rights is still open.

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Chapter 3
The Industry of Plant Breeding

3.1 The Significance of Plant Breeding in Society

Plant breeding aims at creating useful plants for the benefit of humankind. At the heart of these activities, stands the knowledge of the art and science of ameliorating plant genetics.[1] The amelioration of the genetics of plants dates back to the Neolithic Age, when most of the major cereals, legumes and root crops where successfully domesticated.[2] These crops continue to be man's predominant source of food, although their production has undergone through continuous changes to enhance the quantity and quality of their yields. Initially, the improvement of plants was a communal activity. It relied on the knowledge that individuals and indigenous communities had acquired over time from one generation to another. Unaware of the scientific aspects inherent in plant amelioration, they based the selection and the creation of plants with desired properties on the characteristics of the phenotypes that could be observed with the naked eye.

While the principals of these ancient practices remain to this day an important foundation for plant breeding, breeding methods have substantially changed through time.[3] This is certainly due to the progress of science. Nowadays, plant breeding relies on the methods and techniques of applied genetics, usually combined with molecular biology, cytology, systematics, physiology, pathology,

[1] For an explanation see Acquaah (2012), 9-10 and Sleper and Poehlman (2006).

[2] For more see Borlaug (1983), p. 689.

[3] Traditional plant breeding, differently known also as informal plant breeding to denote the informal ways of breeding as opposed to the formalities required for modern plant varieties, remains an important reality for small farmers, indigenous communities and organic agriculture in the developed as well as developing countries. For the distinction between formal and informal breeding see Louwaars (2007).

V. Prifti, *The Breeder's Exception to Patent Rights*, International Law and Economics, DOI 10.1007/978-3-319-15771-9_3

entomology, chemistry, and statistics, as well as breeding techniques recently developed in plant biotechnology.[4]

The application of these scientific methods in plant breeding brings about considerable benefits for humankind. For instance, the possibility to obtain food with high nutritional qualities from modified plants is one of the greatest achievements of plant breeding in improving life quality and combating hunger. Besides food production, improved plants can be further employed in agriculture, industry and forestry to provide feed for livestock, fiber for clothing and furnishing, and fuel for cooking and heating. Employing modern plants in various industrial sectors does not only increase production and economic profits, but it supports sustainable development as well. This role of plant breeding will be further illustrated in the following paragraphs. Afterward, the evolution of the plant breeding industry will be briefly explained. This will provide the reader with a first understanding of plant breeding.

3.1.1 Plant Breeding and Food Production

Without exception, the main importance of plant breeding is directly perceived in food production. The urge for food supply arises from the constant growth of the world population which is expected to exceed nine billion by 2050. Providing food for the world population was also part of the objectives of the so-called 'green revolution'[5] Between the 1960s and the 1990s, the 'green revolution', supported by various agricultural centers operating under the auspices of the Consultative Group for International Agricultural Research (CGIAR), promoted the diffusion of modern varieties both in the developed and developing countries.[6] The results were remarkable. The major plant breeding breakthroughs were for maize and wheat. For example, wheat production more than tripled between the late 1960s and the mid-1980s in India. This represented sufficient grain to satisfy the dietary needs of 186 million people. In addition, new crop species with enhanced qualities were developed. This is the case of triticale—a crossing of wheat and rye—which has higher yield advantages over wheat.[7]

This enormous progress has lately been furthered by employing genetic modification (GM) techniques in plant breeding. These techniques propone to alleviate

[4] Better see ISAAA (2010). See also Powell et al. (2004), pp. 1–27.

[5] This term refers to a series of initiatives in agricultural development started by Norman Borlaug in Mexico in 1943 and continued until the late 1970s. The success of these initiatives which increased agricultural development around the world was markedly noticed in the 1960s.

[6] CGIAR was created by the Rockefeller and Ford foundations to support the Green Revolution. For a complete overview see Kloppenburg (2004), p. 157.

[7] For more see Borlaug (1983).

the problem of food insecurity and environmental degradation often caused by the intensive use of pesticides and fertilizers during the 'green revolution' by enhancing the nutritional content of food, reducing the use of pesticides, and improving crops resistance to draught, heat, frost and soil salinity.[8] The potential of this new technology in reducing poverty and hunger in the world is, however, controversial. Some studies have found a statistically significant relationship between increased crop yields and increased adoption of herbicide and pesticide tolerant crop seeds,[9] whereas others find no support for a direct link between the use of genetic engineering crops and yield increase.[10] Even if these last conclusions were not accurate, the role of GM crops in combating famine remains questionable if not accompanied by adequate social choices.[11] Indeed, the increase of food production does not guarantee access to foodstuff. This holds in the case of conventional breeding techniques as well.

For example, evidence shows that the number of hungry people during the 'green revolution' went from 536 million to 597.[12] FAO studies give further proof of the increased poverty. In 2010, the number of hungry people was 925 million. This represents an increase of 75 million compared to the period 2006–2008. There is no question that poverty and distribution issues are at the heart of the problem of access to food.[13] This, nevertheless, does not diminish the potential of plant breeding to fulfill the dietary needs of human beings. In this regard, the effects of GM crops on human health are surrounded by significant controversy. The most contended aspect is the risk of transferring allergens from one organism to another. This was the case of people allergic to nuts who reacted to GM soybeans into which a protein from a Brazil nut had been inserted.[14] Health fears combined with several institutional and social factors have led to a strong movement of opposition to the agricultural applications of GM crops.[15] This hostility is more perceivable in

[8] For further discussion see Nuffield Council on Bioethics (2004); Borlaug (2000), p. 487.

[9] Moreover, it has been found a positive impact of GM crops on the environment. For more see Brookes and Barfoot (2006), p. 139. For an overview of studies on the impact of GM crops in South Africa see Biosafety Clearing House (2013).

[10] For an overall argumentation see Heinemann (2013), pp. 203–210. This work points out that food security in countries that make use of GM techniques is either improving (US) or declining (see page 206).

[11] *Ibidem*. See also de Schutter (2009).

[12] According to FAO, the total food per capita globally increased by 11 % and the number of hungry also fell by 11 % in the 1970s–1990s. However, if this global analysis does not consider China, where there was no green revolution but far reaching land reform, then the results highlight that in spite of the Green Revolution, the number of hungry people went from 536 million to 597, an increase of 11 %, according to FAO. See Reichmann (2003).

[13] Sen (1982). See also FAO (2011).

[14] In this case, health problems were avoided by testing before commercializing and the company did not put the GM soybean in the market. See FAO (2001), pp. 14–18.

[15] Bonny (2003).

European countries where only a few GM organisms have been authorized for cultivation and use in aliments.[16]

3.1.2 Plant Breeding and Biodiversity

The Convention on Biological Diversity defines the term biodiversity as 'the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems.'[17] This definition presents a unified view of the three levels in which biodiversity has been traditionally identified by scientists: genetic diversity, species diversity, and ecosystem diversity.[18] Although a thorough description of these biodiversity levels and their relation with plant breeding would be interesting, it goes beyond the scope of this work. What matters most here, is to understand the importance of biodiversity as a whole, and if and how, plant breeding plays a role in biodiversity enrichment.

The value of biodiversity is strongly linked to the potential and the unknown importance of genetic variation. This uncertainty on the actual and future values of genetic diversity requires the maintenance of a broad base of biological variation. Two are the main reasons to be recalled: the possibility of dramatic events that could extinguish particular crops as a result of pest infestations or diseases, and the benefits associated with retaining a large number of genes. The former requires biodiversity because presence or absence of a single gene may be determinant to provide resistance to such threats. The latter, instead, relies on biodiversity to generate an incremental improvement or adaptation of different combination of genes, which is mainly dependent on the large numbers of genes.[19]

This understanding of biodiversity became a particular concern after the introduction of modern varieties, which present greater genetic uniformity. Two are the most worrying consequences of genetic uniformity: increase of vulnerability to pest and diseases, and the replacement of traditional landraces. The increased

[16] For a list of the authorized GMOs see the EU Registrar of genetically modified food and feed, available at http://ec.europa.eu/food/dyna/gm_register/index_en.cfm, accessed 4 October 2013. Note that only two crops, a type of maize (MON810) and a potato called Amflora (withdrawn in 2012 from the EU market) have been approved for cultivation in Europe. But several members have banned the cultivation of one or of both these crops. See better 'Questions and Answers to the EU's New Approach to the Cultivation of GMOs', available at http://europa.eu/rapid/press-release_MEMO-10-325_en.htm?locale=en, accessed 9 March 2014.

[17] See article 2 of the Convention on Biological Diversity 1760 UNTS 79; 31 ILM 818 (1992), hereinafter CBD.

[18] Better see Wilson (1999), p. 157.

[19] Simpson (2005). For a comprehensive review on the debate on biodiversity, please see Stanford Encyclopedia of Philosophy (2007).

vulnerability to pest and diseases does not mean that modern crops are more vulnerable than traditional ones, but that harmful effects of a potential pest attack significantly increase in case of genetic uniformity. This is mainly because uniform genes offer a greater base which can be successfully attacked. The Southern Corn Leaf Blight—which reduced by 15 % US corn yields in 1970—is a significant example in this respect.[20] Pest infections and diseases, however, have characterized agriculture production since its very beginnings. Creation and destruction of life forms are part of nature life cycles. In this regard, the merit of modern plant breeding has specifically been that of providing a stable release of varieties with greater resistance to pest and diseases.

Likewise, the gradual replacement of traditional landraces with new uniform varieties forms part of biodiversity concerns. FAO estimates that since the 1900s, some 75 % of plant genetic diversity has been lost as farmers worldwide have left their multiple local varieties and landraces for genetically uniform, high-yielding varieties. Today more than 90 % of crop varieties have disappeared from farmers' fields. Moreover, of the 4 % of the 250,000–300,000 known edible plant species, only 150–200 are used by humans.[21] There is no question that these figures offer proof of the disturbing effects of the genetic uniformity of modern varieties. What should be questioned in this respect are the methods used to measure biodiversity. Indeed, there are various measures for genetic diversity. According to the special reasons for studying biodiversity, biologists, ecologists, plant breeders, farmers, policymakers, and economists use different criteria to measure biodiversity. Obviously, this leads to different results. Even more significantly, it is not possible to identify a measure that fulfills all desired criteria.[22]

Thus, if we measure biodiversity by the number of landraces at country level, some studies show the decrease of genetic variation, while others give proof of diversity conservation. In 1935, for example, Germany witnessed a sharp decrease of the number of landraces of wheat varieties from 454 to 17 accepted cultivars and 54 accepted without reservation. On the contrary, a recent study showed an increase of diversity over time in wheat in Germany.[23]

Concerns on biodiversity conservation, however, have become less urgent after the introduction of *in situ* and *ex situ* preservation methods.[24] The *in situ* approach maintains biodiversity in its original habitats, i.e. farm fields, whereas the *ex situ* approach conserves biodiversity in areas different from their original habitats, such as zoos, botanical gardens, and germplasm banks. The access to these germplasm

[20] USDA (2005).

[21] Better see FAO (2004).

[22] See USDA (2005), citing Meng et al. (1998), p. 13.

[23] For further information see Le Buanec (2006).

[24] *Ibidem*. It is worth noting here that these considerations regard the loss of biodiversity after the replacement of traditional landraces with modern cultivars. Diversity reduction as a consequence of modern plant breeding represents fewer concerns. For more information see van de Wouw et al. (2010), p. 1241.

collections facilitates the work of plant breeders to keep ahead of pest and diseases through a continuous flow of genetic diversity. Facilitated access to genetic resources for breeding purposes has further been promoted by the Multilateral System for access and benefit-sharing provided by the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).[25] The Multilateral System involves all Contracting Parties, the international ex situ collections of the Consultative Group on International Agricultural Research, national agricultural research institutions[26] and, additionally, encourages the participation of the seed industry.[27] Given the role and the interest of the seed industry in a broad base of genetic resources, a meaningful and proactive participation of private firms shall be recommendable.[28] This would create a balanced participation of all stakeholders as well as contribute to their common goal of expanding the base of available genetic resources in view of better yields. Finally, it is worth noting that balancing high and quality yields with biodiversity conservation techniques should be the main concern of plant breeding policies in order to benefit from science.[29] The use of science, indeed, can be a double-edged sword when it is applied with no or little understanding of it. On the contrary, a well-informed comprehension of both negative and positive aspects of new technologies helps us shape future progress.

3.1.3 Plant Breeding and Sustainability

Since the Brundtland Commission of the United Nations introduced the concept of 'sustainable development', the term 'sustainability' has been used to indicate human activities on the environment.[30] Thus, sustainable development indicates that type of 'development that meets the needs of the present without compromising the ability of future generations to meet their own needs'. In the context of plant breeding, this means that the creation of new varieties should aim at the satisfaction of present needs while at the same time preserving genetic resources for future generations. This task is particularly challenging nowadays as climate changes are continuously depleting vital resources such as land and water.[31] The exhaustion of natural resources in concert with population growth imposes the necessity to

[25] See article 10.2 of the ITPGRFA. Note that this system covers only 64 forages and crops listed in Annex I of the treaty.

[26] See articles 11.5 and 15 of the ITPGRFA.

[27] Article 16.2 of the ITPGRFA.

[28] Chiarolla and Shand (2013). The study finds that private companies have large collections of genetic resources but they are not willing to share related information.

[29] Meng and Brennan (2009).

[30] UN (1987), transmitted to the General Assembly as an Annex to document A/42/427—Development and International Co-operation: Environment.

[31] The relationship between agricultural productivity and sustainability concepts has been object of several studies: OECD/FAO (2012); World Bank (2006); FAO (2002).

produce more food with fewer resources. The question is how and what can plant breeding contribute in this regard.

The approach taken by plant breeding to cope with these needs addresses in particular strategies of adaptation to climate changes.[32] This is especially important in areas where climate change increases the frequency of abiotic stresses such as heat or draught, the probability of biotic stresses like pest and diseases, and causes the loss of biodiversity. Having widely discussed biodiversity issues in the previous paragraph, emphasize will be put here on the role of plant breeding in tackling climate change issues.

The role of plant breeding in climate change through the production of improved varieties has been astonishing. For instance, Bangladesh breeders have developed a new type of rice (Sub1) tolerant to flood that can survive total submersion for more than 2 weeks. Another example is that of beans varieties developed to tolerate the heat of the hot Durango region in Mexico and the cold high altitudes of Colombia and Peru.[33] Recently, non-hybridized crops have given the same results. Scientists from the International Maize and Wheat Improvement Centre (CIMMYT) and the Kenya Agricultural Research Institute (KARI) developed maize seed varieties that yield well with minimum soil moisture. This type of maize is currently being adopted by smallholder farmers in Kenya's Eastern Province.[34]

In addition, the modern techniques of breeding require less land for cultivation due to the increased productivity of new varieties. This was confirmed in a study on grains and oilseeds.[35] Another stunning prospect is that of GM eucalyptus trees engineered to grow 20–30 % faster for use as paper, as pellets for power stations and as fuel for cars.[36] These examples make apparent how important plant breeding is for meeting sustainability criteria. By producing high-yielding and high-quality crops, plant breeding guarantees a continuous supply of varieties in the present, and at the same time responds to the needs of future generations by paying special attention to environmental and climate change issues.

3.1.4 Plant Breeding and Economic Growth

Plant breeding does not only contribute to our human survival, but contributes to the wealth of countries as well. North America was one of the first countries to

[32] Ceccarelli (2010), p. 637.

[33] FAO (2009).

[34] For more see Esipisu (2012).

[35] Better see Miller et al. (2010), p. 645.

[36] The Israeli biotech firm 'FuturaGene' spent 11 years on trials and will grow these trees commercially by 2015, after permission of the Brazilian government on 9 April 2015. Better see Vidal (2012) and http://www.futuragene.com/FuturaGene-eucalyptus-approved-for-commercial-use.pdf, accessed 10 April 2015.

recognize the fundamental role of the import of plant varieties in trade. During the nineteenth century, the consular and naval personnel largely supported the import of plant germplasm from every part of the globe. For example, the Perry naval expedition of 1853 opened the harbors of Japan to American trade.[37] The large base of germplasm acquired in foreign countries allowed American seed companies to create improved varieties, which were afterward exported in other countries. Extending trade with these other countries was particularly advantageous for the flourishing of the American seed industry.

The benefits of plant breeding for national economies, however, became better apparent after the Italian agronomist and plant breeder, Nazareno Strampelli, crossed different varieties of wheat to obtain new hybrids. This method proved to be more effective than the traditional selection of seeds within a single variety.[38] The production of hybrid wheat, thus, allowed Italy to go from an average yield of 1.0 t/ha at the beginning of the twentieth century to about 1.5 t/ha in the 1930s.[39] Thanks to Strampelli's work, Italy did not only become self-sufficient in wheat production, but could also export wheat varieties in foreign countries. Indeed, the wheat varieties exported in Mexico put the basis for the 'Green Revolution' started by Norman Borlaug.

Since this period, international seed trade has constantly increased. In 2012, United States followed by China and France was the leading country in the global seed market.[40] In 2010, seed imports and exports for flower seed, vegetable crop and field crop seed were dominated by countries such as US, the Netherlands, France and Germany.[41] Figure 3.1 plainly illustrates the growth of the global seed market.

The role of the seed industry in trade becomes apparent in the figure. Since the beginning of the Green Revolution in 1970, the improvements in plant breeding techniques and production have been accompanied by a steadily increasing trade. Being trade a key factor in the development of countries, the benefits deriving from it are directly perceived by the society.[42] For instance, trade might contribute to poverty alleviation.[43] Vietnam is an example in this respect. After increasing

[37] Kloppenburg (2004), p. 54.

[38] For further details on the origins of Strampelli's work see del Grano (2012).

[39] Mugnozza (2012).

[40] For more information see the document 'Value of the domestic Market for Seed in Selected Countries for the Year 2012', available at http://www.worldseed.org/isf/seed_statistics.html, accessed 30 January 2014.

[41] For further information see the documents provided by the International Seed Federation at http://www.worldseed.org/isf/seed_statistics.html, accessed 30 January 2014.

[42] The role of trade on the economic development of countries is recognized by economic theory. One of the cornerstones concepts in the trade theory is the notion of 'comparative advantage'. Comparative advantage suggests that countries benefit if they specialize on these products and services which they produce more efficiently than others, and trade the other products and services with the countries that produce them more efficiently. See Chipman (2008), p. 217. The role of trade, however, should be supported by adequate institutions.

[43] See De Schutter (2009).

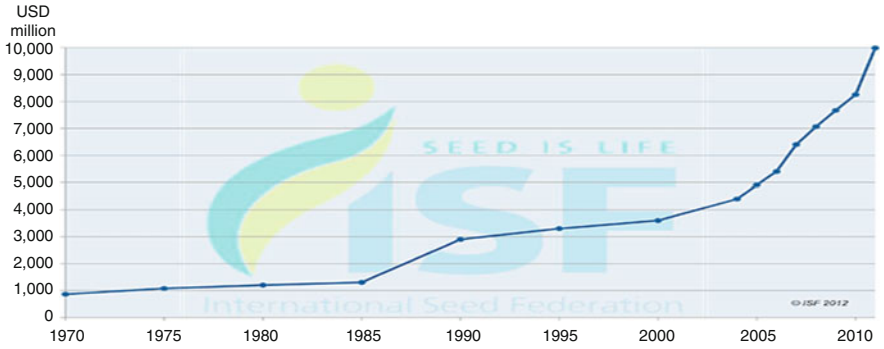

Fig. 3.1 The growth of the global seed market from 1970 to 2010

production and exportation of coffee of 15 % in 1990, the agricultural GDP grew 4.6 % per year. This was accompanied by a reduction of rural poverty from 66 % in 1993 to 45 % in 1998.[44]

Plant breeding represents a vital industry for the economies of industrialized countries as well. In the Netherlands, for example, between 8,000 and 10,000 employees were estimated to work in the plant breeding and propagation industry for the year 2009.[45] Moreover, increased yields enable countries to be self-sufficient in crop production. An illustrative case is the reversal of United Kingdom's historical dependence on North American wheat imports.[46] The benefits of plant breeding, therefore, are apparent in the economic development of countries besides food production and environmental sustainability.

3.2 The Evolution of Plant Breeding: From the Farmer to the Industry

Plant breeding started as a non-commercial activity carried out by farmers whose primary objective was to satisfy the needs of the family and eventually those of the village. At that time, the breeding of plants relied on farmers' knowledge and on a few unrefined farming tools. Farmers selected and crossed existing plants in order to obtain new varieties with desired characteristics. This idyllic vision of a single farmer cultivating its piece of land has been gradually overwhelmed by the flourishing of the industry of plant breeding. The success of modern plant breeding is mainly due to biotechnological discoveries which enabled the creation of new

[44] World Bank (2001).

[45] See LEI Wageningen University (2012), p. 7, hereinafter Wageningen report.

[46] British Society of Plant Breeders (2012), p. 6.

breeding tools.[47] These new techniques facilitated access to genetic resources of wild and unadapted varieties.

As a result of these discoveries, two main types of processes can be distinguished in plant breeding: conventional breeding and genetic engineering. Conventional breeding is performed by breeders who manipulate the sexual recombination process through selection and crossing of plants and their offspring in order to obtain a variety with desired characteristics. Whereas genetic engineering is carried out by biotechnologists in laboratories who modify plant genotype by inserting a genetic material from another organism (transgene). The 'transgene' may, for example, control for a specific trait and alter the original genotype of the plant and render it 'transgenic'.[48] Both conventional breeding techniques and new plant breeding techniques are necessary components of the so-called 'plant breeders' toolbox'.[49] Instead of replacing traditional breeding methods, the new plant breeding techniques further enriched them. In specific, the development of herbicide tolerance and insect resistance traits is deemed to serve as proof of the introduction of the new methods of plant breeding. The most recent breeding techniques are able to modify the genome of plants by inducing mutations through epigenetics[50] or inserting genes in a permanent or transient way.[51]

The first appearance of modern breeding techniques followed the discoveries of Darwin and Mendel in genetics. Mendel, in particular, provided a first explanation of genetic inheritance in the mid-nineteenth century. However, it was not until the early twentieth century that his work was recognized as the basis of modern plant breeding. Genetic discoveries allowed plant breeders to advance the understanding of plant genetics and enabled them to identify specific genes responsible for particular functions or attributes in a selected variety. This made possible a better adaption of plant varieties to human needs. The importance of this scientific evolution was first realized by public research institutions and universities which carried out basic research and delivered breeding products as public goods to farmers.[52] This put the basis for the initiation of commercial plant breeding.

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[47] Molecular marker studies allowed plant breeders to go beyond the phenotype by facilitating access to the genotype of plants, thus improving plant breeding. See better Tanskley and McCouch (1997), p. 1063.

[48] See Tansey (2002), p. 6 quoting Peter Lund. For more on different techniques in plant breeding see Lupi (2013).

[49] Lusser et al. (2011), p. 19.

[50] Epigenetics studies heritable changes in gene expression that are not due to changes in DNA sequence. For more see Bird (2007), p. 396.

[51] There is legal uncertainty whether the final plants developed by techniques which insert genes only temporarily should be qualified as genetically modified (OGM) products under the current technical definition of 'OGM' provided by article 2.2 of Directive 2001/18/EC. Although plants bred with some of these techniques do not occur naturally, they do not contain an inserted transgene in the final product. For further details see the above report.

[52] Commercial production of seed started in Europe in the mid nineteenth century, creating farmer cooperative companies. In the USA followed the establishment of the state agricultural

The potential profit deriving from the application of biotechnology in a business environment made crop research and breeding more appealing to the private sector. Additionally, the private sector had the knowledge and resources necessary for commercializing the products resulting from new technologies. However, business firms initially lacked scientific knowledge. It were highly motivated academic entrepreneurs that carried out the scientific knowledge into the commercial sector through the creation of new firms.[53] Subsequently, breeding products acquired a greater economic value and gradually started to be treated as private goods and protected through various forms of intellectual property. Since then, R&D investments in agriculture have witnessed 'an ebbing public sector and a rising private sector, aided and abetted by changes to IP'.[54]

3.2.1 Industrial Plant Variety Production

The breeding and commercialization of varieties goes through a long process that comprises four phases: formulation of breeding objectives, creation of variation, selection, and testing and finalizing varieties for the market.[55] The formulation of breeding objectives is, therefore, the phase that precedes variety production by setting the type of research and breeding to be conducted for the final variety. For genetically modified (GM) varieties, an additional middle phase can be distinguished between the first and the second one. This phase consists in conducting research and tests finalized at demonstrating that the variety containing genetically modified organisms is safe for environmental, food, and feed use. Environmental, food, and feed safety—or the so-called—biosafety assessment, is to be demonstrated in compliance with national and international rules.[56] These rules apply

experimental stations (SAEs) in 1887. For an account of the stations genesis see Kloppenburg (2004), p. 60.

[53] The economics of R&D in agriculture biotechnology has been similar to those of R&D in agrochemical or pharmaceuticals. For a general overview see Pisano (2006).

[54] Eaton (2013).

[55] The last three phases can be graphically represented by Fig. 4.3 depicted in Chap. 4. See Louwaars et al. (2009).

[56] See article 1 of the Cartagena Protocol on Biosafety added to the Convention on Biological Diversity on 29 January 2000 explicitly recalling Principle 15 of the Rio Declaration on Environment and Development, which allows countries to adopt a precautionary approach where 'there are threats of serious or irreversible damage' to environmental degradation. The EU has accepted this principle in Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms and Regulation (EC) No 1829/2003 on genetically modified food and feed. Whereas the United States has not ratified the Cartagena Protocol. Consequently, it does not make use of the precautionary principle but relies on regulatory safeguards enforced through the Environmental Protection Agency, the Food and Drug Administration and the Department of Agriculture. The precautionary principle has not been accepted by the WTO as well. For a better understanding see the WTO panel report, European Communities—Measures Affecting the

strict requirements which make this process very costly as well as lengthy. Producing a GM variety or applying a GM breeding technique is additionally expensive because the registration costs are particularly high for techniques classified as GMOs.[57]

Once a plant variety is finalized, it should comply with additional regulations in order to establish the value of the final variety. To this purpose, all crops, vegetables, and ornamentals are required to fulfill three requirements: distinctness, stability, and uniformity (DSU).[58] Varieties that do not comply with the DSU requirements cannot be registered in national catalogues and therefore, cannot be commercialized.[59] For field crops, there is an additional regulation: field trials have to be carried out in the whole country to ascertain the performance of the crop. These tests are deemed to be very useful in plant breeding since they stimulate the development and selection of the best varieties. The costs for this testing are particularly high for genetically modified seeds, which undergo a complex procedure of detection, identification, and quantification of specified traits.[60]

Breeding of new varieties is thus a complex, lengthy, and costly process. Although new and improved technological tools have recently enhanced the speed and accuracy of the breeding process,[61] the costs of breeding and marketing plant varieties have not significantly changed. It has been estimated that seed companies invest approximately 12–15 % of their annual turnover on research

Approval and Marketing of Biotech Products, WT/DS291,292,293/R, adopted on 21 November 2006, paras. 7.76–89.

[57] See Lusser et al. (2011). Please, note that it is not easy to advance research costs in case of transgenic research because the costs depend on the number of genetic traits targeted for breeding purposes. A higher number of genetic traits implies a longer and more expensive breeding process. See Trommetter (2008), p. 30. For OGM costs see also Schenkelaars et al. (2011).

[58] For an explanation of these criteria see the section dedicated to breeder's rights in the next chapter. Please, note that for the purpose of commercialization, these criteria should be fulfilled irrespective of the application for breeder's rights. An additional requirement for certification of seed is the value for cultivation and use, based on yield, quality, resistance to harmful organisms, and response to the environment. For clarifications see http://ec.europa.eu/food/plant/plant_propagation_material/plant_variety_catalogues_databases/index_en.htm, accessed 25 May 2015.

[59] Many developing countries, however, allow the commercialization of varieties not meeting the DSU requirements. These varieties are usually developed by farmers and sold in local markets. For farmers' seed systems in developing countries see Louwaars (2007b), p. 32.

[60] More information on the procedures of seed testing is available at the International Seed Testing Association, http://www.seedtest.org/en/home.html.

[61] For example, new technologies have reduced the term of development of new tomato varieties from (at least) 9 to 5 years. See the Wageningen report (n 45), p. 18. Marker-assisted selection (MAS) is one of the techniques that enable breeders to reduce breeding times and expedite the return on investment. It has been proposed that cross-breeding combined with this technique is less expensive than the adoption of GM technologies. Therefore, countries should consider the conditions under which access to MAS is more efficient than the application of GM techniques. For more see Trommetter (2008), pp. 28–29.

and development,[62] and breeding times for plant varieties may take from 7 to 15 years.[63] Research expenditures, nevertheless, do not guarantee success in the market place. Only a favorable outcome of seed testing determines whether the plant variety would enter the market. Above all, the success of further commercialization depends on the ability to respond to the market demand. Considering the length of breeding processes, this means that firms should anticipate costumers' preferences from 5 to 10 years in advance. Moreover, consumers' preferences on GM or non GM varieties further constrain breeder's choices. Depending on the structure and business model of seed companies, this type of decision may have an impact on its annual financial returns.

3.2.2 Concentration in the Seed Market

Since the creation of biotechnological firms, few companies have emerged in the breeding sector.[64] This may be due to the continuous mergers and acquisitions of seed companies resulting in a high concentration of few companies for the breeding sector. Three major waves of structural changes have been identified in the seed industry. The first wave started in the early 1930s after the establishment of new commercial seed firms. These seed firms continued to adapt public research mainly on hybridization with significant results in maize yields and other seed sectors. The second wave started in the 1970s after the introduction of various intellectual property rights, such as plant breeder's rights and patents which incentivized plant breeding research by increasing returns on investments. The majority of mergers and acquisitions in this period took place among R&D-oriented pharmaceutical, petrochemical, and agrochemical companies from the US and Europe. Finally, the third wave started in the 1980s, when US and European agrochemical multinationals invested substantially in genomics. The strategic mergers and acquisitions activities started thereafter as a response to the necessity of accessing know-how and seed germplasm for commercializing new biotech seeds.[65]

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[62] The Dutch plant breeding and propagation sector, in particular, invests approximately 15 % of the turnover. This is higher than 12.5 %—the EU average for R&D expenditure in the seed industry. For details see the Wageningen report (n 45).

[63] At least 7–12 years are required for annual plant varieties and 10–15 years for biannual plant varieties. See Meussen (1996), p. 172.

[64] Concentration in the global agricultural biotechnology industry is considered inevitable due to the high fixed costs and low variable costs associated with the new technology. See Wright and Pardey (2006), p. 12.

[65] For a detailed analysis see Schenkelaars et al. (2011). This study found out that in spite of the high levels of concentration in the US seed markets for cotton, maize and soybean, and the introduction of GM varieties, there have not been negative impacts on the level of innovation in these crops over the last 17 years. On the consolidation of the seed industry see also Howard (2009), p. 1266. Economic analysis has found a self-reinforcing relationship between consolidation in the seed industry and less sponsored research. For more explanations see Fernandez-Cornejo and Schimmelpfenning (2004), p. 14.

Table 3.1 Share of the global proprietary seed market by biotech companies

Company	2009 seed sales (US $ millions)	% of global proprietary seed market
Monsanto (US)	7,297	27
DuPont (US)	4,641	17
Syngenta (Switzerland)	2,564	9
Groupe Limagrain (France)	1,252	5
Land O' Lakes (US)	1,100	4
KWS AG (Germany)	997	4
Bayer C. S. (Germany)	700	3
Dow Agro Science (US)	635	2
Sakata (Japan)	491	2
DLF-Trifolium (Denmark)	385	1
Total	**20,062**	**73**

Source: ETC Group

In 2011, the ETC Group estimated that the top ten global seed companies accounted for 73 % of the global commercial seed market. Of the top 10, four are based in the US and control 50 % of the global proprietary seed market. Monsanto and DuPont account for 27 and 17 % of this market, respectively.[66] These figures are illustrated in Table 3.1.

The considerable growth of the global seed market can be attributed to a combination of four factors: introduction of biotechnology, intellectual property rights on seed germplasm, globalization, and mergers and acquisitions. Biotechnology contributed to the growth of the seed market in two different ways. One was the creation of seeds that are consumed in the production process; the other was the improvement of seed quality. As a matter of fact, technology defeated the biological barrier of seed reproducibility. Hybrid seeds, for instance, lower their productivity after the first harvest. This makes it easier for seed companies to sell new varieties every year. This technological change went hand in hand with the qualitative and quantitative benefits of using modern seed. Aware of these advantages, farmers started to purchase more seed.[67]

In a related vein, the role of intellectual property rights in increasing seed sales consists in limiting the capacity to save seed. In some countries, users of patented seeds cannot freely plant their progeny without the authorization of the right holder. This is why farmers need to acquire seed for every new sowing. Moreover, the end users of breeding products also pay for the intrinsic value embedded in intellectual

[66] ETC Group (2011), available at http://www.etcgroup.org/content/who-will-control-green-economy-0. For a comparison of these figures with previous data see ETC Group (2008).

[67] With regard to farmers' purchases see better Louwaars et al. (2009), p. 24.

protected seeds which have higher prices. All these practices obviously contribute to increasing the value of the seed market.

Additionally, the globalization process factor has contributed to the growth of the seed industry by opening up commercial markets for emerging economies. For example, multinational companies have been quick to enter the markets in India, China and Brazil, often through joint ventures with local seed companies and, where possible, through mergers and acquisitions.[68] Mergers and acquisitions have been another factor leading to the successful concentration of the seed industry.[69] Beside seed programs, seed companies are nowadays specialized in other related areas such as agrochemicals.[70] The economic rationale behind the acquisition of seed companies by firms selling other complementary products, such as fertilizers and pesticides, lies in the need to expand markets while reducing the related costs for these firms.[71] Vertical and horizontal integration between firms enables maximizing the appropriability of investments in research through a better control of distribution channels.

These mergers and acquisitions have the important consequence of changing the market structure.[72] Beginning with a large number of competing firms, the market may be dominated by one firm and a monopoly would be created, or by a small number of large firms resulting in an oligopoly. An oligopolistic market is currently the case of the seed market. As already noted above, the top three seed companies control 53 % of the global commercial seed market.[73] The concerns raised on this market power relate to the distortive effects on market competition. A healthy competitive market is positively linked by neoclassical economics to social welfare. In this view, a healthy competitive market is allocatively efficient.[74] This means that productive resources are organized in such a way that it is not possible to reorganize them so as to make at least one person better off without making someone else worse off. When the market is efficient in these terms, it is said that a competitive market maximizes social welfare. Therefore, a competitive market in the seed industry is desirable as long as it responds to the logic of welfare maximization.

But when is a market competitive? Economists believe than when four firms control 40 % of the market, the market is no longer competitive.[75] Table 3.1 shows

[68] Teh et al. (2009). This paper laments that access to the markets of developing countries is accompanied with undesirable effects, such as restricted choice of lines of high quality seed, lack of access to germplasm for breeding, and lack of control over price.

[69] For an overview of the empirical analysis of IPRs on market structure see Eaton (2013), pp. 28–29.

[70] Note that the world's largest seed and agrochemical companies are the same companies. See ETC Group (2011), available at http://www.etcgroup.org/sites/www.etcgroup.org/files/publication/pdf_file/ETC_wwctge_4web_Dec2011.pdf, p. 25.

[71] Claffey (1981), pp. 29 and 32. Recently, reverse mergers are seen as a response to the difficulties of raising capital. See, for example, PharmaLicensing (2011).

[72] For the impact of IPRs on business structure, see Lesser (1998), p. 56.

[73] For information on the concentration of the biotechnological industry based on patent applications see Winnink (2012).

[74] Samuelson and Nordhaus (1998), p. 147.

[75] See Howard (2009), p. 1270.

that the top four seed companies significantly pass this threshold by controlling 58 % of the market. The distortion of competition would, however, require a careful assessment of other elements such as the degree of complementarity and substitutability of the marketed goods, and the geographical market for every specific crop. These figures, nevertheless, should drive the attention to possible negative effects that industry concentration might have in the seed market.

3.2.3 Final Remarks

This chapter illustrated the significance of plant breeding for our society. To this purpose, its role in food production, in conserving biodiversity and promoting sustainability was explained. In addition, attention was dedicated to the link between the growth of breeding activities and the growth of national economies. This link was highlighted by providing figures on the growth of the global seed market. The growth of the seed market has gone hand in hand with the progress of biotechnological discoveries. Their application to plant breeding has revolutionized the process of variety creation by reducing its length and costs. The boost in variety production has witnessed an increasing role of the private sector and the need for regulating the commercialization of the new varieties. Nowadays, plant breeding is an expanding industry characterized by mergers and acquisitions among firms, and rising market concentration of the largest biotechnological companies. The impact of such concentration on market competition deserves further investigation. This is especially important in a globalized world, where seed varieties are continuously imported and exported by countries with various levels of economic development. This aspect of globalization should be kept in mind while analyzing the consequences of market concentration on societal welfare.

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Chapter 4
Intellectual Property in Plant Breeding

Intellectual property rights may be defined as rights granted by a state authority for certain products of intellectual effort and ingenuity. Intellectual effort and ingenuity applied in plant breeding has, however, not always been protected with property rights. Until the beginning of the twentieth century, the prevailing view was that IPRs were not suitable for plant protection: plants and other living organisms were considered as products of nature,[1] rather than as fruits of human ingenuity. Later on, this view was mitigated by the advances of biotechnology, and different laws and court rulings at national level.[2] The United States was the first country to provide for patents on plants with its 1930 Plant Patent Act. Afterward, in 1961, some European countries established the International Union on the Protection of New Varieties of Plants (UPOV), which provides for breeder's rights, a special form of intellectual property.[3] Several questions naturally arise: Why did countries change their view on plant protection? Are plants products of nature or fruits of human ingenuity? Is it beneficial for society to protect plants and their varieties? The historical, legal and economic aspects of the above issues have already been examined by several authors. This chapter contributes to previous literature by

[1] In this regard, it should be specified that it was the genetic constitution of agricultural products that was considered as a product of nature. Agriculture products *per se* or processes could be the object of intellectual protection in the countries adhering to the Paris Convention for the Protection of Industrial Propriety. Article 1(3) of this Convention provides that 'Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour'. See Paris Convention for the Protection of Industrial Property, 1883, 21 UST 1583, 828 UNTS 305, 20 March 1883, as last revised at Stockholm, 14 July 1967, and as amended on 28 September 1979.

[2] See Kevles (2002). For a thorough analysis of the US legislation on plant varieties see Kloppenburg (2004) See also Aoki (2003), p. 247. For Europe see Llewelyn (2012).

[3] The list of ratifications is available on the UPOV website: http://www.upov.int/upovlex/en/notifications.jsp, accessed 24 October 2014.

V. Prifti, *The Breeder's Exception to Patent Rights*, International Law and Economics, DOI 10.1007/978-3-319-15771-9_4

analyzing the legal and economic concerns on plant-related intellectual property protection in light of recent developments in plant breeding. To this purpose, the chapter is divided into two parts. The first part provides an overview of the main IPRs that have a direct influence in the plant breeding process, patents and breeder's rights.[4] A comparative view of these rights will allow us to better assess their role in plant breeding. The second part explains the rationale of IPRs, how it is applied in plant breeding and its relevance in the innovation process.

4.1 Legal Aspects of Intellectual Property in Plant Breeding

Intellectual property rights are enacted by national legislators and their form and scope may significantly vary across countries. However, countries that adhere to international IP agreements must comply with the minimum standards of protection provided for in these agreements. The Trade-Related Intellectual Property Rights Agreement (TRIPS) is the most comprehensive international agreement which sets minimum standards for the protection of intellectual property rights.[5] This means that Member countries may provide for stronger IP protection but cannot elude the rules of TRIPS and enact weaker protection for IPRs. With regard to plant breeding, article 27 of TRIPS recognizes different forms of intellectual protection. It leaves the patenting of plants, biological processes for the production of plants and plant varieties to the discretion of WTO Members, but it requires Members to provide patent protection for microorganisms and non-biological and microbiological processes for the production of plants. In addition, its paragraph 3.b obliges countries to protect plant varieties 'either by patents or by an effective sui generis system or by any combination thereof'.

This provision seems to recognize the diverse agricultural development and legislations of WTO members. Before the adoption of TRIPS, not all countries provided for property rights on plant varieties. Intellectual protection of plants was more idiosyncratic to developed countries. So, for example, the US and Australia protected innovations related to plant breeding through patents, while EU countries had chosen a combination of patents and breeders rights. Asian and African

[4] Please note that breeding products can also be protected by other proprietary rights such as trade secrets, trademarks, and geographical indications. Other exclusive rights can be found in private contracts such as material transfer agreement, bag labels and technology use agreements. Another restriction is represented by governmental regulations. For example, seeds undergo an approval process and should be listed in national catalogues before they could be marketed. For the EU Catalogue of Varieties of Agricultural Species, see http://ec.europa.eu/food/plant/plant_propagation_material/plant_variety_catalogues_databases/index_en.htm, accessed 12 March 2014. For an overview of IPRs in plant biotechnology see Boettiger et al. (2004), pp. 1088–1113.

[5] With the exception of least developed countries during the transitional periods, the text of TRIPS is binding for all other WTO members.

Kingdom	Plantae
Division	Magnoliophyta
Class	Magnoliopsida
Order	Rosales
Family	Rosaceae
Genus	Rosa
Species	*Rosa gallica*
Variety	*Rosa gallica* var. *violacea* hort., *gallica* var. *officinalis*, etc.

Fig. 4.1 Taxonomic classification of plants. For the classification of plants see the website of USDA Natural Resources Conservation Service. Available at https://plants.usda.gov/java/ClassificationServlet?source=display&classid=ROGA. Accessed 2 April 2015

countries, on the other hand, had no specific legislation. After TRIPS, most of these countries signed the 1991 UPOV Convention in order to comply with the requirements of article 27.3.b.[6] Others adopted a *sui generis* system designed to respond to their local socio-economic conditions by providing for rights for farmers.[7]

In order to further understand article 27 of TRIPS, it is important to distinguish between plants and plant varieties. From a botanical perspective, plants and their varieties are subdivisions of the Kingdom of Plantae.[8] The taxonomic classification aims at grouping plants with similar morphological characteristics.[9] Figure 4.1 aims to graphically represent this distinction with regard to the family of Rosaceae.

Similar plants are placed in the same Genus. Individual plants within Genera are called 'species', while plants with slight differences from their 'species' are known as varieties. Varieties may be the result of changes in plant species that occur in nature through cross-pollination, mutation and adaptation or may be created with the help of human assistance.[10] In the first case, varieties are highly heterogeneous and do not retain their distinctive characteristics when propagated. In the second case, human assistance prevalently aims at creating varieties that express the same distinguishing features through generations. The second type of plant variety is subject to breeder's rights provided by UPOV whereas the first type of plant variety

[6] Article 37.3 of the 1991 UPOV closed accession to the Act of 1978 after 31 December 1995 for developing countries and after 31 December 1993 for other countries. Note also that least developed countries have adopted the 1991 UPOV Convention as a result of FTAs with the United States or the European Union.

[7] The Indian legislation is an example in point. See The Protection of Plant Varieties and Farmers' Right Act, The Gazette of India, Extraordinary Part II, Section I, nr. DL-33004/2001. For other Asian countries see Kanniah and Antons (2012).

[8] Note that this is the accepted scientific classification according to the current understanding of the biological system. For an explanation see Stace (2000).

[9] This classification was first proposed by the father of modern taxonomy, Carl Linnaeus.

[10] In this case, the modified plants are called 'cultivars'. The term 'cultivar' derives from 'cultivated variety'.

may be protected under *sui generis* regimes.[11] In legal terms, a plant variety is 'a plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a breeder's right are fully met, can be defined by the expression of the characteristics resulting from a given genotype or combination of genotypes, distinguished from any other plant grouping by the expression of at least one of the said characteristics and considered as a unit with regard to its suitability for being propagated unchanged.'[12] When bred varieties comply with these requirements, states may grant property rights on human ingenuity applied in the breeding process of new varieties. Plants, on the other hand, can be protected when their genome is altered in order to obtain modified plants. Changes in the genome of a plant are usually carried out by biotechnologists who insert gene constructs[13] that confer new characteristics to the original plant. The modified (transgenic) plant cannot be qualified as a plant variety under breeder's rights since it does not propagate unchanged.

This distinction between plants and plant varieties should be kept in mind when explaining different intellectual property rights. TRIPS gives countries the option to protect plants with patents, but obliges them to protect plant varieties with patents, an effective *sui generis* regime or a combination thereof. The provision of 'an effective *sui generis* regime' is controversial since TRIPS does define neither its form nor content.[14] However, there seems to be general agreement that the breeder's rights provided for by UPOV meet the requirements of article 27.3.b of the TRIPS Agreement.[15] Moreover, many *sui generis* systems build upon the UPOV model. Thus, patents and breeder's rights appear to be the most recurrent form of protection in plant breeding. The following paragraphs will provide the reader with a general understanding of these systems of intellectual protection. The focus of the analysis will be on the US and European legislations since most of the patents relevant for plant breeding are issued in these countries.

[11] Note that countries can provide protection for both these types of variety. See chapter V (§§ 52–53) of The Plant Variety Protection Act B.E.2542 (1999) (Thailand), available at http://www.wipo.int/edocs/lexdocs/laws/en/th/th016en.pdf (accessed 3 Dec. 2014).

[12] This definition is found in article 1 of the UPOV Convention, article 5.2 of Council Regulation (EC) No 2100/94 on Community Plant Variety Rights, in the decisions of the European Patent Office and in section 41.9 of the US PVPA. This latter adds that 'A variety may be represented by seed, transplants, plants, tubers, tissue culture plantlets, and other matter'. Please, note that this definition of plant variety responds to commercial and legal considerations rather than to scientific rigor. For more see Janis and Smith (2013), pp. 1570–1577.

[13] A gene construct is a 'functional unit necessary for the transfer or the expression of a gene of interest'. For more see the Glossary of the project 'Communication Management of Biosafety Research' funded by the German Ministry of Education and Research, available at http://www.gmo-safety.eu/glossary/667.gene-construct.html, accessed 07 October 2013.

[14] For more see Dhar (1999). Dhar suggests that the *sui generis* regime is to take account of both plant breeders and farmers interests. Several developing countries have followed this interpretation. For a deeper analysis of this issue see Leskien and Flitner (1997).

[15] Dutfield (2011).

4.1.1 Patent Rights

As already explained in the introduction, TRIPS provides for the minimum requirements for patent protection at international level. Other regional agreements provide for similar requirements. In Europe, for example, the European Patent Convention (EPC)[16] and the European Directive of 6 July 1998 on the legal protection of biotechnological inventions[17] apply. These agreements and other national laws will be taken into consideration if relevant for the purpose of this thesis. Before starting with the analysis, it is necessary to clarify the concept of patent rights. Rights conferred with patents are negative rights. This indicates that the patent owner has only the legal faculty to prevent others from doing certain acts relating to the invention, but not the right to take actions on the patented invention. In practice, this means that the patentee of a transgenic plant has the right to prevent others from using the plant but he/she can commercialize the transgenic plant after complying with biosafety regulations.[18]

4.1.1.1 Object of Protection

Article 27 of TRIPS provides for patent rights for any inventions, whether products or processes, in all fields of technology. Thus, inventions are object of patent rights. But what is considered to be an 'invention'? TRIPS does not offer a definition. Hence guidance will be found in national laws. With some exceptions,[19] national laws do not explicitly define inventions, but rather what cannot be considered an invention.[20] In this regard, it is worth noting that most countries do not consider discoveries to be inventions. The US Patent Act (PA), however, allows for both discoveries and inventions to be object of protection, provided that they are new and useful.[21] Similarly, the US Plant Patent Act (PPA) grants patents for 'Whoever

[16] Convention on the Grant of European Patents of 5 October 1973 as revised by the Act revising Article 63 of the EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000. Please note that the EPC is not an instrument of the EU, although all EU member countries are part of the EPC. The EPC currently applies to 38 countries. Since 1 September 1999, the EPC has incorporated the provisions of the EU directive on biotechnological inventions 98/44/EC in Rules 23 (b)–(e) EPC. It is interesting to note in this regard that the EU directive applies to all EPO members although not all of them are EU members.

[17] OJL 213, 30.7.1998, p. 13–21. Hereinafter, EU directive.

[18] Compare with UNCTAD-ICTSD (2005).

[19] The patent laws of Mexico and Argentina, respectively, article 15 and article 4.a, similarly provide that invention is 'all human creation that permits the transformation of matter or energy that exists in nature, for the benefit of man and to satisfy his concrete needs'. See Correa (2007), p. 271, note 2.

[20] See, for example, article 52.2 of the EPC and article 15 of the Decision No. 486 on the Common Regime on Industrial Property of the Andean Community (WIPO lex).

[21] 35 US.C. 101.

invents or discovers and asexually reproduces any distinct and new variety of plant'.[22] From these provisions, it can be inferred that 'discovery' and 'invention' have two different meanings. Whereas 'discovery' indicates the fact that something new is found, 'invention' implies the use of thought (human ingenuity) in the creation of something new.[23] So, for example, when a breeder finds a new plant, he simply discovers it. Conventional wisdom would suggest that the breeder remains a discoverer even if she/he further breeds the plant and creates new varieties since the plant is a product of nature. UPOV, indeed, does not consider the breeder to be an inventor. US law, however, adopts another approach. The United States Patent and Trademark Office (USPTO) clarifies that 'if one person discovers a new and distinct plant and asexually reproduces the plant, such person would be a sole inventor'.[24] The term 'inventor' appears to be associated with the activity of discovery of a new plant. The simple discovery of a new plant is nevertheless not a sufficient condition to be object of patent protection. The PPA requires the discoverer to reproduce a new distinct variety of plant. It appears that the US concept of 'invention' refers to the efforts that the breeder puts in the breeding process.[25] Thus, the borderline between discovery and invention for plants in the US seems to lie in the human work on discovered new plants. With regard to the US concept of 'invention' applied to biological matter, section 161 of the PA applies. According to this section, the invention or the discovery should concern 'any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof'. Biological matter can be considered under the terms 'composition of matter'. In addition to the requirements for plant patentability, the discovery or invention of biological material forms object of patent protection only if it is useful.[26]

Further elucidations can be found in the 2012 Guidelines for Examination of the European Patent Office (EPO).[27] The Guidelines identify 'technicality' as the main criteria for distinguishing between 'discovery' and 'invention'. Accordingly, an invention is characterized by technical skills, technical features and application in a technical field. In these terms, a discovery may be patented if it applies to a technical solution of a technical problem.[28] So, for instance, a gene with a particular

[22] 35 US.C. 161.

[23] See Correa (2007), p. 272.

[24] See the section 'Inventorship' of General Information about 35 US.C. 161 Plant Patents, USPTO. Available at http://www.uspto.gov/web/offices/pac/plant/, accessed 12 March 2014.

[25] For an historical overview see Kevles, pp. 7–8.

[26] This requirement is not provided for plant varieties. Probably the reason lies in the widely acknowledged utility of plant breeding.

[27] The EPO is set up on the basis of the EPC in order to carry out the procedures laid down in the EPC.

[28] The 2013 Guidelines for Examination of the European Patent Office (hereinafter EPO Guidelines) have highlighted the difference between a discovery and an invention: 'If a new property of a known material or article is found out, that is mere discovery and unpatentable because discovery as such has no technical effect and is therefore not an invention. If, however, that property is put to

function existing in nature is a mere discovery. But the isolation of this gene from its natural environment requires the application of technical skills, and therefore, may be considered as an invention.[29] Article 3.2 of the EU directive clarifies that 'Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature'. An 'invention', thus, is characterized by 'technicality' created by human ingenuity. The object of intellectual protection in this case is represented by the knowledge applied in the technical skills. It should be further noted that the terms 'biological material' used in article 3.2 of the directive, broaden the scope of patentability with regard to all living matter existing in nature. In order to advance reader's knowledge on the subject, the following paragraphs will explain this concept of invention with regard to products and processes relevant for plant breeding.

4.1.1.1.1 Plants

Patents can protect both plant varieties and transgenic plants. Plant varieties can be explicitly protected through patents in Australia and in the US. By contrast, European laws do not allow for the patenting of plant varieties. Plant varieties, nonetheless, can be indirectly patented in Europe. According to the Board of Appeal of the EPO, 'a claim wherein specific plant varieties are not individually claimed is not excluded from patentability (...)'.[30] This means that a group of plants comprising more than one variety can constitute a valid patent claim, while a single plant variety does not. The rationale behind this choice lies in the differences of genetic constitution. As the Enlarged Board of Appeal (EBA) explained, 'a plant defined by single recombinant DNA sequences is not an individual plant grouping to which an entire constitution can be attributed', but an abstract and open definition embracing an indefinite number of individual entities defined by a part of its genotype or by a property bestowed on it by that part'.[31] On the contrary, a plant variety as defined in UPOV and national European laws is characterized by its whole genome. According to the EBA, a plant defined by single recombinant DNA sequences is 'neither limited nor even directed to a variety or varieties'. Here it is important to note that a patent may be issued on the gene sequence/s characterizing

practical use, then this constitutes an invention which may be patentable.' See Part G, Chapter 2, Section 3.1. Thus, the mere isolation of an organism and the identification of its use are sufficient criteria to qualify for patentability. Most of the national jurisdictions apply this criterion. See UNCTAD-ICTSD (2005). See also the US Manual of Patent Examining Procedure (MPEP), Chapter 2107.

[29] Note that isolation of biological material as found in nature is explicitly excluded in Brazilian, Andean, Argentinean, and Chilean laws. For more see Bently et al. (2010), p.83.

[30] See Transgenic Plant/Novartis II OJ EPO 2000, (Decision 12 G 1/98 of the Enlarged Board of Appeal) 141.

[31] *Ibidem*, para. 3.1.

the modified plants, not on the variety. So, for example, a plant grouping containing a special disease resistant gene can be patented because it is characterized by the disease resistant element. Transgenic plants, which are characterized by such a special gene construct and have a technical application to a group of plants broader than the variety, can be patented in Europe as well as in the United States.

The US seems to offer the strongest form of protection for plants. Two types of patent rights, the 1930 PPA and section 101 of the Patent Act—offer protection respectively for asexually produced plants; asexually and sexually reproduced plants, part of plants including seeds and tissue cultures. Additionally, the 1970 Plant Variety Protection Act (PVPA) offers protection for seed-propagated plant varieties.[32] Asexually propagated plants are those that are reproduced by cutting or grafting rather than by germinating seeds. Such plants are, for example, fruit trees and ornamental flowers.[33] Varieties created by this type of breeding are identical to their parent plant. Not all asexually propagated plants are, however, protected by the PPA. This Act explicitly excludes tuber propagated plants such as the Irish potato and the Jerusalem artichoke. The US Manual of Patent Examining Procedure[34] explains that such exclusion is justified on the basis that this group of plants is propagated by the same part of the plant that is sold as food.[35] In any case, tuber propagated plants can be protected under the PVPA. Additionally, this Act provides for breeder's rights for sexually reproduced varieties. Breeder's rights are granted for any kind of seed-propagated variety, but they offer a weaker form of protection since they contain some exceptions.[36] The so-called utility patents provided for by Section 101 of the PA provide for the most comprehensive form of protection. These patents may claim plants, seed, genes, methods for the production of plants, seeds, genes, etc. The US utility patents for plants are comparable to the standard patents usually granted in other countries.

4.1.1.1.1.1 Plants: Relevant Case Law for Patentability in Europe

The most important precedent in Europe is the 'Novartis Case', which has put the basis with regard to what can be patented.[37] Patent claims, in this case, concerned transgenic plants transformed by recombinant DNA techniques to introduce

[32] This Act reflects the provisions of the UPOV Convention.

[33] Note that some of these plants may also be capable of sexual reproduction. The apple tree is an example. Apples can be sexually reproduced by seed but in this case, the offspring does not have the desired qualities of the parent. This happens only if the apple is asexually reproduced by grafting and budding, layering etc. Therefore, the PPA covers plants capable of sexual reproduction if they have been asexually reproduced.

[34] See Chapter I600, Section 1601.

[35] It is not clear, however, if they are excluded based on their use as food or on the difficulty of enforcing patents on such plants. For more see Kevles (2002), pp. 8–9.

[36] See *infra* the section on exceptions.

[37] Transgenic Plant/Novartis II OJ EPO 2000 (Decision 12 G 1/98 of the Enlarged Board of Appeal) 111–141.

pathogen resistance and also methods for preparing such plants. The original patent application made by Ciba Geigy (afterward Novartis, now Syngenta) was initially rejected by the EPO Technical Board of Appeal. Later on, the Enlarged Board of Appeal reversed the decision of the Technical Board of Appeal and held that patent claims were valid because they did not confine to a single plant variety. As clarified in the above paragraph, the Board held that a plant defined by a single recombinant DNA sequence neither expressly nor implicitly defines a single plant variety. Such a plant is not an individual plant grouping to which an entire constitution can be attributed. Therefore, a claim wherein specific plant varieties are not individually claimed is not excluded from patentability. Based on the interpretation of article 53 (b) of the EPC, the Board further explained that plant cells can also constitute relevant object matter because they are neither a plant nor a plant variety, but microorganisms. In addition, the EPO decision explained that a process for the production of plant varieties does not represent patentable subject matter.

4.1.1.1.1.2 Plants: Relevant Case Law for Patentability in the United States

In the US, three important precedents have shaped the protection of plants: the *Diamonds v Chakrabarty*,[38] the *Ex Parte Hibberd,*[39] and the *J.E.M. Agricultural Supply v Pioneer Hi-Bred International*.[40] The *Diamonds v Chakrabarty* was the first case to allow the patentability of living organisms by expressly stating that 'a live human-made organism is patentable subject matter'. After this decision the relevant distinction for the patentability of biological matter is not between living and inanimate things but between products of nature, whether living or not, and human-made organisms. Subsequently, the *Ex Parte Hibberd*[41] established the right of plant breeders to patent sexually reproduced plants. This decision was upheld by the US Supreme Court in the *J.E.M. Agricultural Supply v Pioneer Hi-Bred International*. The Supreme Court explained that the lack of an explicit exclusion of plants in the provision of the PA that provides for utility patents provides no reason to view plant patentability as contrary to Congressional intent.

4.1.1.1.2 Plant Genes

A gene is a heredity unit located on a strand of DNA or RNA. Genes control the development of a trait or phenotype and can be self-replicated and transmitted to

[38] *Diamond v Chakrabarty*, 447 US. 303 (1980).

[39] *Ex Parte Hibberd*, 227 US.P.Q. 443 Bd. Pat. App. (1985).

[40] See *J.E.M. Agricultural Supply v Pioneer Hi-Bred International*, 122 US. 593 (2001).

[41] *Ex Parte Hibberd*, 227 US.P.Q. 443 Bd. Pat. App. (1985).

descendents.[42] Plant genes, thus, are responsible for all plant characteristics. It is common knowledge that the existence of a gene is a product of nature. But can a gene form object of patent protection? Courts—both in the US and Europe—have affirmatively answered to this question by relying on the technical aspects of the concept of invention.[43] So, for example, a DNA sequence or a partial DNA sequence qualifies for patent protection if it is isolated by means of a technical process and a specific function is identified.[44] The mere location of a gene or gene sequence cannot be patented because it does not provide any technical information that may be usefully applied.[45] Only the description of a specific use or function of the gene or gene sequence requires human ingenuity, and can therefore be deemed an invention in the USA and EU.

A specific function of a gene may be, for example, the production of a particular enzyme. But a single gene may have more than one function. Some of these functions may not be identified at the moment of the patent application. The issue raised in this regard concerns the patentability of other gene functions discovered after the first patent application. Do they fall within the scope of the first patent? Many authors agree that new gene functions cannot be exploited without the explicit consent of the first patent holder.[46] This issue seems to have been solved in the case Monsanto Technology LLC vs. Cetefera BV and Others.[47] The European Court of Justice explicitly stated that the EU directive prevents national laws from assuring to patentees rights beyond the purpose disclosed in the claims.[48] In line with this reasoning, gene protection is limited only to the functions actually disclosed in the patent application.

With regard to subject matter eligibility, the recent case of *Myriad Genetics* offered important elucidations in the US.[49] The US Supreme Court ruled in this case that 'a naturally occurring DNA segment is a product of nature and not patent

[42] Adapted from Treccani, L'Enciclopedia Italiana Online (Treccani, The Online Italian Encyclopedia), available at http://www.treccani.it/enciclopedia/tag/gene/, accessed 14 March 2014. Note that it is difficult to comprise all complexities that characterize gene expression in one definition. Various definitions of a gene can coexists in different disciplines. For more see Calvert and Joly (2009), pp. 113–114.

[43] Calvert and Joly emphasize the role of molecular biology in gene patentability. *Supra note*, 105–121.

[44] A gene sequence obtained in this way is deemed to be a chemical product, therefore, patentable. Other patentable chemical products in the USA are DNA sequences that code for a protein, purified or isolated proteins and transformation vectors containing a gene sequence.

[45] See Recital 23 of the directive 98/44EC: 'Whereas a mere DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention'.

[46] Joly and Bertrant (2003).

[47] *Monsanto Technology LLC v Cefetra BV and Others* (C-428/08). See the Curia Press and Information. Available at http://curia.europa.eu/jcms/upload/docs/application/pdf/2010-07/cp100073en.pdf, accessed 5 August 2013.

[48] See Article 9 of the EU directive.

[49] 569 U. S. ____ (2013). The decision is available at http://s3.documentcloud.org/documents/713216/scouts genedecision.pdf, accessed 6 August 2013.

eligible merely because it has been isolated'.[50] Additionally, the Court held that composite DNA (cDNA) is patent eligible because it does not naturally occur.[51] cDNA represents strands of nucleotides that code for aminoacids (exons). Scientists may synthetically create such strands and exclude nucleotides which do not code for aminoacids (introns). According to the Court, the inventive aspect of cDNA lies in the efforts of the scientists to create something new that does not exist in nature.

Expressed sequence tags (ESTs) have also been subject of broad controversy with regard to patentability. ESTs are small pieces of DNA sequence (usually 200–500 nucleotides long) that are generated by sequencing either one or both ends of an expressed gene and are used in locating and mapping genes.[52] Their function in plant breeding may be that of finding new plant genes, mapping the plant genome, and identifying coding regions in genomic sequences. The controversy underlying the patenting of ESTs is that they are sequences with an unknown function. The only recognized function is their use as a probe for screening libraries, identifying nucleotide sequences, and mapping their position within a genome. Although there is not yet explicit case law concerning the patentability of ESTs, it is generally accepted that ESTs are not patentable in Europe as long as their functions are not disclosed in order to fulfill the requirements for industrial application.[53] The US jurisprudence, on the other hand, has made explicit that expressed sequence tags (ESTs) do not constitute a valid patent claim because of lack of specific and substantial utility and failure to comply with the disclosure requirement.[54]

4.1.1.1.3 Microorganisms

Article 27.3.b of TRIPS provides for patents on microorganisms. Microorganisms are usually defined as 'living microscopic or submicroscopic organisms not observable by the naked eye.' They include bacteria, fungi, archaea, protists.[55] In contrast to this scientific definition, the EPO Guidelines opt for an open definition which encompasses 'bacteria and other generally unicellular organisms (. . .), including plasmids and viruses and unicellular fungi (including yeasts), algae, protozoa and,

[50] See pp. 10–18 of the decision.

[51] This view is put into question. See pp. 16–17 of the decision.

[52] For a better explanation see US National Center for Biotechnology Information, 'ESTs: Gene Discovery Made Easier', available at http://www.ncbi.nlm.nih.gov/About/primer/est.html, accessed 5 August 2013.

[53] See, for example, Zimmer (2013).

[54] Better see *Re Fisher*, 421 F.3d 1365 Federal Circuit (2005).

[55] The Dictionary of Biology Online, http://www.biology-online.org/dictionary/Microorganism, accessed 1 October 2013. See also 'Microorganism' (New World Encyclopedia), available at http://www.newworldencyclopedia.org/p/index.php?title=Microorganism&oldid=695572, accessed 9 October 2013.

moreover, human, animal and plant cells'.[56] Although scientists have bespoken the limits of taxonomy and the problems in delineating species boundaries,[57] EPO's definition appears to challenge the scientific understanding of microorganisms. In order for microorganisms to form a species, they shall share some characteristics in common. Being an 'unicellular' microorganism might not be sufficient. Moreover, the classification of viruses as microorganisms is controversial. The controversy emerges from the fact that some scientists have erroneously relied on the infectious characteristics of viruses.[58] A virus is more similar to cellular components rather than to microorganisms.[59] However, it is worth noting that a more accurate definition would not influence virus patentability. In Europe as well as in the United States, patents can be issued on all biological material regardless of their living nature. Rule 26 of the EPC Implementing Regulations defines 'biological material' as 'any material containing genetic information and capable of reproducing itself or being reproduced in a biological system'.[60] Whenever these microbes are isolated from their natural environment or produced by means of a technical process, they may constitute an invention.

4.1.1.1.4 Non-biological and Microbiological Processes

TRIPS requires its Members to provide patent protection for processes, but it allows them to exclude essentially biological processes for the production of plants. This rule does not apply to non-biological and microbiological processes for the production of plants. On this point, TRIPS provisions seem to build upon European legislation. Therefore, an explanation of these technical terms can be found in the EPC and in the EU directive.[61] Accordingly, 'essentially biological' refers to a process which consists entirely of natural phenomena such as crossing or selection, whereas the term 'microbiological' indicates a process that involves or performs upon or results in microbiological materials.

The definition of 'essentially biological' may open the way to different interpretations with respect to the natural criterion.[62] The EPO offered an understanding

[56] EPO Guidelines, Part G, Chapter II, Section 5.5.1. It is worth noting that the taxonomic classification of viruses is controversial.

[57] Environmental Information Centre (2013).

[58] The Nobel Prize winner, Lwoff, beautifully explains this issue. See Lwoff (1957), pp. 239, 249.

[59] *Ibidem*, 248.

[60] For the US definition see the US Manual of Patent Examining Procedure (MPEP), Chapter 2403. See also *Diamond v Chakrabarty*, 447 US. 303 (1980).

[61] See article 2 of the directive 98/44/EC and Rule 23b (5), (6) of the Implementing Regulations to the EPC.

[62] See Kock (2007), p. 286.

of this issue by focusing on the degree of human intervention in Lubrizol/Hybrid Plants.[63] The EBA judges clarified that the nature of human intervention in the process is decisive in qualifying a process as 'essentially biological'. The simple fact that human intervention is required to assist the process is not relevant. What matters is whether human assistance has influenced the final result. The judges further explained that classical breeding methods are indisputably essentially biological despite the degree of human control. This is justified by the fact that breeding steps such as crossing and selection already occur in nature and are influenced by 'complex, various, and non-predictable circumstances'.[64] Therefore, natural breeding processes involve uncertainties. The role of the breeder in essentially biological processes is that of assisting what already occurs in nature. On the contrary, breeder's role in non-essential biological processes is that of altering the natural breeding process by modifying the genome of the plant or by introducing new traits into its genome. On EBA's understanding, this type of modification confers technicality to the process. It is human ingenuity that significantly changes natural breeding steps and controls the results of the process. Regardless of the biological steps the process involves, the utilization of at least one technical step which has an impact on the process or on the product obtained from it, determines its patentability. Marker-assisted selection (MAS) is an example of a patented process regardless of its use in breeding processes that consist on crossing and selection.[65]

This reasoning was reiterated by the Enlarged Board of Appeal in 2010, which further ruled that methods for conventional breeding of plants cannot be considered as a technical process and therefore cannot be covered by patents.[66] Nevertheless, this ruling generated some legal uncertainty on the patentability of plants bred by methods of conventional breeding.[67] The uncertainty seems to stem from the current rules which do not indicate whether plants obtained by essentially biological processes are patentable.[68] This issue was solved by the Enlarged Board of Appeal in 2015, after nearly 10 years of review.[69]

[63] See *Hybrid Plants/Lubrizol* (T-320/87) of 10.11.1988.

[64] *Ibidem*, 9.

[65] Molecular marker technologies visualize the genetic make-up of a plant and are used in the selection process of plant breeding.

[66] EPO, Enlarged Board of Appeal, decision of 9 December 2010 in consolidated cases G 2/07—Broccoli/PLANT BIOSCIENCE and G 1/08—Tomatoes/STATE OF ISRAEL.

[67] In practice, the products of plant breeding remain patentable. For more see the report of Then and Tippe (2011).

[68] See the first sentence of article 53.2 of the EPC. Note that Dutch patent law exempts from patentability plants obtained by essentially biological processes (Art. 3.1.d of the Dutch Patent Act 2010) while the German Patent Act amended in 2013 its sec. 2a(1)1 in order to exclude from patentability plants *exclusively* obtained through essentially biological processes. For an explanation see the German Parliament resolution 17/14222.

[69] The texts of the decisions are available at http://www.epo.org/law-practice/case-law-appeals/eba/number.html, accessed 17 april 2015.

4.1.1.2 Exclusions from Patentability

In some cases, biological material can be excluded from patentability even if it were object of an invention. Art. 27 of TRIPS provides for two exclusions. A general exclusion for reasons of *ordre public* or morality is found in its paragraph 2, whereas a specific exclusion for plants is contemplated in paragraph 3.b. An understanding of these exclusions will be provided below.

4.1.1.2.1 Exclusions for *Ordre* Public or Morality

> Members may exclude from patentability inventions, *the prevention within their territory of the commercial exploitation of which is necessary* to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law. (*emphasis added*).

It is important to note that this paragraph does not, *sic et simpliciter*, allow for exclusions on grounds of *ordre* public or morality.[70] This can be deduced from the term 'necessary' as well as from the need to prohibit the commercialization of the invention. Based on WTO dispute settlement panel decisions, a measure is 'necessary' only when there is no alternative measure available,[71] whereas the need to prohibit the commercialization of the invention is decided by national laws. This provision seems to reflect article 53.a of the EPC. The US legislation does not take into consideration any constrains on patents based on *ordre public* or morality.

4.1.1.2.2 Exclusion of Plants

The third paragraph of article 27 allows for the exclusion of plants and essentially biological processes for the production of plants from patentable subject matter. Since essentially biological processes were discussed in the above paragraphs, the exclusion of plants will be here object of attention. Under TRIPS, states have the option to exclude plants form patentability, but they are obliged to provide for protection on plant varieties and for patents on microorganisms. This has two consequences. Firstly, even if states exclude a plant from patentability, protection

[70] The terms '*ordre* public' and 'morality' are vague concepts to be defined by national laws. A common understanding of these definitions can be carved out by the jurisprudence of EPO. In particular, *Plant Cells/Plant Genetic Systems* (T 356/93–OJ EPO 1995, 545) has specified that 'inventions the exploitation of which is likely to breach public peace or social order or to seriously prejudice the environment are to be excluded from patentability as being contrary to "*ordre* public"'. The concept of morality consists in a common belief that some behavior is right while other behavior is wrong, belief that stems out from accepted norms in a particular culture. For more on the issue see Correa (2007), pp. 289–291.

[71] WTO, '"Necessity Tests" In the WTO', 2 December 2003, WTO doc. S/WPDR/W/27.

for its varieties should be still available. Secondly, if a patented gene construct is inserted into a plant, the effects of patent protection will extend to the plant itself. This second consequence renders void the exclusion of plants from patentability. Therefore, countries that exclude patents on plants should consider excluding parts of plants as well.[72]

4.1.1.3 Requirements for Protection

Countries must grant patents on the above described plant-related innovations subject to three conditions laid down in TRIPS: novelty, inventive step, and industrial application. Since TRIPS does not offer a definition of these requirements, their interpretation and application may differ among Member countries.

4.1.1.3.1 Novelty

The compliance with 'novelty' demands countries to patent only those inventions that are original and new with respect to the state of the art. The definition of the state of the art entails the disclosure of the invention by any means to the public.[73] Prior to the coming into force of the America Invents Acts (AIA) on 16 March 2013, the US adopted a different understanding of novelty which allowed patenting plant-related material known in other countries, but not divulged in written form. This generated several controversies. The US patent on basmati rice granted to the RiceTec company is a well-known case for raising biopiracy concerns on the Indian rice variety.

4.1.1.3.2 Inventive Step/Non-obviousness

Once the novelty requirement is satisfied, the invention should have an inventive step or should not be obvious to a person skilled in the art. The first criterion is applied in Europe, whereas the second in the US. Despite similarities in assessing these criteria, they have different meanings. The 'inventive step' requirement denotes an intellectual process to develop the invention. 'Non-obviousness', on the other hand, may exclude intellectual effort when the subject matter is simply found.[74] Indeed, the evaluation of these criteria appears to be different under EPO

[72] For more see Correa (2007), pp. 5–6.

[73] See article 54.2 of the EPC and 35§ U.S.C. 102.

[74] See article 56 EPC. The US PA requires the invention not to be obvious (35 USC 103). For the difference between 'technical step' and 'non-obvious' and its legal implications, see Correa (2007), p. 278.

and USPTO practice. The EPO evaluates the inventive step requirement on the basis of the 'problem-solution' approach. This means that the solution claimed in the invention shall not be evident to the person skilled in the art.[75] For the USPTO, the decision on obviousness considers 'whether the improvement is more than the predictable use of prior art elements according to their established functions'.[76] Both Offices, however, determine the criteria with regard to common knowledge of those skilled in the art. If the claimed invention is evident to those skilled in the art, it means that the invention lacks ingenuity, and therefore, fails to introduce a novel step in the state of the art.

4.1.1.3.3 Industrial Applicability/Utility

According to article 57 of the European Patent Convention, 'industrial application' denotes that the object of invention can be made or used in any kind of industry, including agriculture. Besides agriculture, plants and plant-related innovations may find application in other industries such as the pharmaceutical, biofuel, chemical, and the cosmetic sector. Section 101 of the US Patent Act, on the other hand, requires patents to be useful. 'Utility' slightly differs from 'industrial application' since a useful invention might not always have an industrial application.[77] The key to interpreting 'utility' lies in enabling one skilled in the art to 'use the claimed discovery in a manner which provides benefit to the public'.[78] US Courts have clarified that the benefits should be specific and well-defined. Translated into practice, this means that the invention should disclose specific uses instead of broad and general claims. Additionally, the 'utility' shall be substantial in the sense that the benefit has to be significant and presently available to the public.[79] In other terms, the invention should have a 'real world' use and should not require further research to determine its utility.

4.1.1.3.4 Sufficiency of Disclosure

In addition to the above mentioned criteria, article 29 of the TRIPS Agreement establishes that a 'patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in

[75] See Visser (2013), p. 103.

[76] Manual of Patent Examining Procedure (MPEP), Chapter 2141.

[77] See also Correa (2007), p. 278.

[78] See the US Manual of Patent Examining Procedure (MPEP), Chapter 2107.01.

[79] *Ibidem*. See also the EPO Guidelines, Part G, Chapter III, Section 4.

the art'.[80] This provision ensures that the invention depends on human ingenuity instead of random coincidence.[81] Only those inventions that rely on systematic scientific research enable others skilled in the art to further reproduce for the benefit of the public. But the reproducibility of the invention presents a challenge for biotechnological inventions. It is very difficult to describe biological matter in such a way that another skilled in the art recreates the same organism with an identical genetic code. US law loosens the disclosure requirement for asexually propagated plants. Based on section 162 of the PPA, a clear description is not necessary for the grant of a plant patent. What is important for other breeders to reproduce the plant is the description of the plant 'as complete as is reasonably possible.' In other words, plant patent claims combined with knowledge in the prior art, replace the disclosure requirements provided for other biological material. Protection of plant material required under the PPA is also not subject to the deposit rules on biological matter. However, deposit of plant material is obligatory for utility patents.[82] This facilitates access and reproduction of protected plant material.

4.1.1.4 Scope of Protection

Article 28 of TRIPS specifies the minimum patent rights that countries should provide for products and processes.[83] Paragraph 1 of this article confers exclusive rights with regard to the acts of making, using, offering for sale, selling or importing for any of these purposes the patented product. From the wording of this provision, patent protection seems to be confined to the object of invention. However, the matter is different with regard to biological material. Patentee's rights cover products that contain or derive from patented material. A few elucidations can be found in articles 8.1 and 9 of the EU directive. According to article 8, if a patent is granted on biological material possessing specific characteristics, the protection extends to all biological material derived from the patented biological material provided that the derived material possesses the same characteristics. Article 9 further clarifies that patent protection embraces all material where patented genetic information is contained and performs its function.

These provisions have in common the characteristic of extending patent protection to biological material that maintains its inventive features and function. Thus, inventive features and function represent the limit for exercising patent rights.

[80] This provision seems to reflect section 112 of the US PA and article 83 of the EPC. See also the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (adopted 28 April 1977, entered into force 19 August 1980) 1861 UNTS 361. This Treaty provides an international framework for the mutual recognition of deposits of microorganisms' strains.

[81] An example of random coincidence discovery is that of a microbiological process involving mutations. See EPO Guidelines, Part H, Chapter III, Section 3.

[82] US MPEP, Chapter 2403.02.

[83] See 35§U.S.C.154 for US, and article 64 of the EPC for European countries.

Since biological matter might self-replicate indefinitely, concerns arise with regard to the principle of exhaustion of rights. According to this principle, the patent owner cannot control the use of the product after its first sale. A controversy on this point has been raised in *Bowman v Monsanto*.[84] The case concerns a US farmer who acquired commodity seed from a grain elevator containing Monsanto patented seeds. After planting and harvesting Monsanto seeds, Bowman replanted some of them for eight consecutive years. The main question that this case poses is whether the replanting of Monsanto seeds constitutes 'use' of a patented product, and thus infringes the patent, or the authorized sale of seeds justifies the application of the patent exhaustion doctrine and allows Bowman to legitimately replant patented seeds. The Court ruled that the patent exhaustion doctrine allows Bowman to plant patented seeds in one season, and subsequently consume the resulting crop or sell it as a commodity, but not to reproduce them through planting and harvesting without patentee's consent. This reasoning was based on the fact that the patent holder had 'received his reward' only for the sold seeds, not for subsequent replanting.[85] Conversely, Bowman argued that by replanting harvested seed, he was 'merely using them in the normal way farmers do'. In the Court's understanding, replanting harvested seed is equivalent to 'making a new product'. It could be argued that the genetic constitution of the replanted seeds is different from the patented Monsanto's Roundup Ready soybeans. Therefore, Bowman has not 'copied' Monsanto's soybean seeds. But it is also true that the harvested soybeans contain the genetic modified Roundup Ready seeds. Without doubt, the self-replicating nature of patented material poses serious difficulties to patent exhaustion. Unlike other commodities, the scope of patent protection on biological products appears to be overbroad. Besides the principle of patent rights' exhaustion, another important issue that the broad scope of protection for biological material raises is the indirect patentability of plants when they contain or consist of patented material. As a result, countries that exclude plants form patentable subject matter are forced to provide an indirect protection.

Contrary to patent rights on products, the rights on processes appear less stringent. Paragraph 2 of article 28 confers exclusive rights with respect to the utilization of the process as well as to the product directly obtained by that process. Although the rights on the obtained product are the same as those of the first paragraph, here it is made explicit that these rights concern 'at least' the product directly obtained by the patented process. Nevertheless, countries have chosen to broaden the scope of patent protection. Article 8.2 of the European directive, for example, extends the scope of protection to all biological material derived from the directly obtained product.

[84] *Bowman v Monsanto Co. et al.*, 569 U.S. __ (2013). Opinion of Justice Kagan available at http://www.supremecourt.gov/opinions/12pdf/11-796_c07d.pdf, accessed 9 October 2013.

[85] Note that the Court did not investigate whether the reward was sufficient to cover R&D costs in line with the economic rationale of patent rights.

Not all processes, however, aim at creating a product. It should be differentiated between working and production processes.[86] Working processes do not result in a product (plant-related material), whereas production processes aim at creating a product. Given that working processes do not lead to product creation, the scope of patent protection does not extend to the product. If plant breeding were classified as a working process, there would be no extension of patent protection on breeding products. But is plant breeding a working process? Although some of the plant breeding steps are working processes—i.e. selection of parents and selection of offspring with desired traits—other steps, such as crossing of selected parents to produce offspring and propagation of offspring clearly result in products and are, therefore, production processes. Furthermore, being the objective of plant breeding that of the creation of new plants, it seems reasonable to classify it as a production process.

Process protection poses a few problems with regard to the product 'directly' obtained from the process. Processes may result in several products, but are all of them 'directly' obtained? It has been suggested that the term 'directly' implies a direct relationship between the patented process and the product. In other words, patent claims should cover all material and important steps that lead to the creation of the product.[87]

4.1.1.5 Exceptions and Restrictions to Patent Rights[88]

TRIPS provides for exceptions to patent rights in its article 30. It does not list acts that may be excepted but gives countries the option to provide limited exceptions to the rights conferred by a patent subject to the following conditions: (1) the exceptions should not unreasonably conflict with a normal exploitation of the patent; (2) should not unreasonably prejudice the legitimate interests of the patent owner; (3) they should take account of the legitimate interests of third parties. This vague formulation does not permit to draw immediate conclusions with regard to the type of activities that may be exempted from patent law. Therefore, it is useful to look at national legislations to assess the practice of countries in this regard.

US law lacks specific rules on patent exceptions,[89] whereas EU countries have adopted exceptions that reflect the provisions of articles 10 and 11 of the EU directive. Article 10 allows reproducing patented biological material when the multiplication or propagation necessarily results from the application for which the biological material was marketed. But subsequent propagation or multiplication

[86] Feindt (2010), p. 9.

[87] For more see UNCTAD-ICTSD (2005), p. 421.

[88] Exceptions to patent rights will be thoroughly examined in the next chapter. Here the aim is to provide some basic knowledge in line with the aim of this chapter.

[89] An implicit statutory exception might though be carved out of section 35 USC§ 163 of the PPA. Plant patent rights exclude others from asexually reproducing the plant and parts thereof. The sexual reproduction is thus not covered by the PPA. This means that seeds of an apple, for example, can be freely used. However, as explained above, the offspring of sexual reproduction is heterogeneous and does not necessarily retain desirable qualities. Therefore, their commercialization brings no profit.

of the reproduced material is not permitted. This provision seems to confirm the basic exceptions which existed prior to the EU directive on biotechnological innovations. These basic exceptions concern the use of the patented products for private and research purposes. Thus, patent rights do not extend to private individuals reproducing the patented subject matter for their own use and to those parties that use the patented innovation in scientific research activities. Some countries additionally allow for the exception of research activities that aim at the development of a commercial product or process.[90] However, final commercialization is not exempted. Additionally, paragraph 1 of article 11 provides for a farmer's exception by permitting farmers to use the harvest deriving from patented material.[91] This exception is unique to the EU directive since no other patent law provides for patent exceptions in favor of farmers.

A recent exception to patent law is the so-called breeder's exception or breeding exception. The breeding exception allows for the free use of patented biological material limited to the breeding or discovery and development of new varieties. Four European countries, France, Germany, the Netherlands and, Switzerland have already adopted this type of exception into their patent laws. A provision on the breeding exception has also been incorporated in article 27.c of the recent Agreement on a Unified Patent Court (AUPC). This agreement has not yet entered into force,[92] thus, it remains to be seen whether EU countries will implement such provision into their national patent law.

Besides exceptions, the grant of compulsory licenses by national governments represents another restriction to patent rights. To regulate the compulsory licensing of patented products and processes, TRIPS offers a complex set of rules in its article 31. Compulsory licenses may reveal to be particularly relevant in plant breeding because of its dependence on patented products or processes. This peculiarity of plant breeding innovation has especially been taken into consideration by the EU directive, which provides for a compulsory license for non-exclusive use of patented inventions as well as protected varieties in its article 12. In both cases, the license is subject to the payment of an appropriate royalty. It should be, however, noted that the specific conditions required by article 12.3 of the EU directive are difficult to satisfy. Article 12.3 (a) obliges applicants to demonstrate that they have been denied authorization to use the protected material. As it will be explained further in this chapter, patent holders often do not reply to licensing requests. Thus, it is difficult to provide proof of an explicit denial. It may be argued that breeders

[90] Correa (2005).

[91] See also recitals 46–51 of the Directive 98/44/EC and article 14 of the Council Regulation No. 2100/94 of 27 July 1994 on Community Plant Variety Rights. Article 14 allows small farmers to freely use harvested material of some plant species listed in its paragraph 2.a. Other farmers should pay an equitable remuneration. For more information see paragraph 3 of article 14 of the Council Regulation.

[92] The Agreement will enter into force as soon as 13 ratifications are reached. As per now, only six countries have ratified the AUPC. For an overview of the signatory countries and ratifications see http://ec.europa.eu/growth/industry/intellectual-property/industrial-property/patent/ratification/index_en.htm, accessed 4 April 2015.

might adopt the same behavior with patent holders asking for a license on a plant variety. However, the need of patent holders to obtain a license from a plant breeder might appear as a remote possibility. It will be clarified in the next sections that plant breeder's rights confer protection on the variety as a whole and at the same time allow other innovators to use the variety.[93] This means that patent holders do not need to obtain a license for using the variety. If they have an interest in accessing patented genetic material of the protected variety, they can use advanced biotechnological methods such as MAS or reverse breeding. Therefore, a license on a plant variety might be unnecessary.[94] Article 12.3 (b) of the EU directive further requires the applicant to demonstrate that the 'plant variety or the invention constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety'. It is not easy to show the significance of the technical progress and the economic interest embodied in the plant variety or invention if a product has not yet been developed.[95] Only the potential to bring technical progress and economic benefits might be illustrated at this stage. Applicants should rely on the vagueness of terms like 'significant' and 'considerable' to advance their interests.

4.1.1.6 Period of Protection

Article 33 of the TRIPS Agreements sets a minimum term of 20 years from the filing of the patent application.

4.1.1.7 Critical Assessment

Patent rights on biological material raise a plethora of concerns with respect to economic, legal, and ethical aspects.[96] Since economic aspects will be explained in the second part of this chapter, this section focuses only on the legal and ethical issues of patenting relevant for plant breeding.

4.1.1.7.1 Legal Concerns

One of the main purposes of legal rules is that of reducing uncertainties. The current rules on patentability seem to fail on this point. TRIPS creates a first confusion

[93] Note that patent rights do not allow using patented material.

[94] A license on a plant variety becomes necessary when other breeders create essentially derived varieties from the original one. See the section on breeder's rights for more clarifications.

[95] See also Correa (2012), p. 15.

[96] It is important to note that the first objections against plant patenting focused on economic and evidential reasons. Objections on ethical, societal, ecological and safety grounds have only been raised in the last years. For more see Van Owervalle (1999), p. 143.

when it allows countries to exclude plants from patentability but it requires them to provide for patents on microorganisms. Several authors have argued that this results in a nullification of the option to exclude plants from patentability.[97] Hence it is not clear how countries can successfully implement this option on plant patentability. A similar concern can be raised for plant varieties in European laws. Although the EPC excludes patents on plant varieties, it is legally possible to obtain a *de facto* protection on plant varieties through patents on plant-related material. This can be attained in one of the following ways:

1. the technical feasibility of the patented invention is not confined to a specific variety;
2. a patented process claims a non-essentially biological process for the production of plants;
3. when a patented gene construct is introduced into the variety.

Another vagueness of EU law is related to the scope of patent rights on biological material. As explained above, the patentee can exercise his rights on biological material as long as the material performs its function. Since patentee's rights extend to any other material where the invention is incorporated, patent rights cover material which may not fall under patentable subject matter. While specific rules limit the extension of such rights to human body, there are no similar provisions for plant breeding. Given that plant breeding is our source of food supply, patent rights on plant biological material have a direct impact on our daily lives. A landmark case, *Monsanto v Cargill* can better clarify the issue at hand.[98] Cargill imported into the UK soybean meal from Argentina, which was made from Monsanto's genetically modified soybeans. In specific, patent claims concerned DNA sequences that allow soybeans to express an enzyme that confers resistance to the herbicide glyphosate (RoundUp Ready®). Given that the Monsanto patent was disallowed in Argentina, Monsanto claimed infringement of its patent after importation into the UK. Based on article 9 of the EU directive, the dispute was about whether the genetic information embedded in the plant still performs its function when grain and flour of the patented soybean is traded. In the UK, judges expressly rejected the argument that the soybean meal was a direct transformation of the patented DNA molecule and concluded that the DNA in the soymeal did not perform the function for which it had been patented. Monsanto tried to prove infringement of his patents also in Spain and in the Netherlands, where soybean meal was imported. Spanish judges arrived at the same conclusion of UK judges, whereas the District Court of The Hague submitted a number of questions to the European Court of Justice (ECJ) with regard to the applicability of article 9 of the EU directive in the present case. The ECJ clarified that article 9 is not applicable 'when the genetic information has ceased to perform the function it performed in

[97] Correa (2012); Leskien and Flitner (1997). This criticism is based on a narrow definition of 'microorganism'.

[98] For an analysis see Cohen and Morgan (2008), p. 289.

the initial material from which the material in question is derived'.[99] Although different courts excluded the extension of patent rights to processed meal, others might take opposite decisions. This is mainly because there are no rules that limit the scope of patent protection in plant breeding. Therefore, it would be desirable that states adopt specific limits for patents that affect our daily food.

Other uncertainties of patent law regard patent quality. A patent is deemed to be of quality when it protects innovations that are new, involve an inventive step, have an industrial utility, and that have valid, well-defined, and clear claims. When patents do not satisfy these criteria, they can be opposed and invalidated. Obviously, patent litigation involves considerable social costs. This provides an intimately link between legal uncertainties on patent quality and costs on the society. Therefore, a critical analysis of patentability requirements is extremely important in order to reward only true inventions that bring social benefits.[100] The way in which patentability criteria are being evaluated by patent offices has been object of growing worries in recent years.[101] The EPO itself admits the risk of misinterpreting patent requirements as a result of increasing patent filings, which slows down the examination procedures.[102] US courts on the other hand, have started to adopt a stricter interpretation of patentability requirements in some cases. An imminent example was the rejection of patents on expressed sequence tags because of insufficient proof of utility.[103] With regard to the inventive step, biotechnological advancements pose new challenges to patentability criteria. New discoveries make existing technologies obsolete. For example, gene sequencing hardly involves an inventive step nowadays. This has led some authors to require a redimensioning of patent requirements.[104] The US jurisprudence has already started to go in this direction by signaling in *RE Kubin* that significant advances in technology raise the level of what is to be considered obvious to one of ordinary skill in the art.[105] The 'novelty' requirement has also come under the scrutiny of US judges which have invalidated patent claims on unknown gene properties that already exist in plants or existing

[99] *Monsanto Technology LLC v Cefetera BV and* Others, Case C-428/08, 6 July 2010, para. 38.

[100] For a specific analysis of 'raising the bar' and avoiding the proliferation of economically undesirable patents see Barton (2003), p. 475.

[101] See, for example, Harhoff (2006) and Niels Louwaars et al. (2009). The concerns of civil society are also noticeable. For a critical view of patentability criteria see the patent cases in the website of 'No Patents on Seeds', available at http://www.no-patents-on-seeds.org/en/information/patent-cases accessed 14 October 2013.

[102] The current world backlog stands at over ten million unexamined patents. For more see European Patent Office (EPO) (2011), p. 16. See also EPO Economic and Scientific Advisory Board (2012). In addition, it has been argued that the financing model of the EPO, which is mainly funded from procedural fees and annual fees for pending patent applications and patents in force, creates incentives to grant patent applications in case of doubt. See Feindt (2010).

[103] *Re Fisher*, 421 F.3d 1365 (Federal Circuit 2005).

[104] See Feindt (2010), p. 13.

[105] *Re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009). Other cases referring to the patentability of human genes further support the US courts tendency to apply restrictive patent rules. See, for example, *Ariad v Eli Lilly*, 560 F.3d 1366 (Fed. Cir. 2009) and the recent case *Association for Molecular Pathology v Myriad Genetics* 569 U.S. 12-398 (2013).

methods for preparing food containing such properties. Here the invention would concern the simple discovery of useful plant characteristic. In this respect, the US judges have clearly stated that the mere description of unexpected beneficial results of a known process is an invalid claim because of lack of novelty.[106] This decision, however, has not prevented companies from patenting other similar claims. Monsanto, for example, has obtained a patent covering a virus-resistant melon plant, its parts, fruits, and seeds, modified by introducing a publicly available gene first found in melon plants in India.[107] The patent has already been opposed by both biotech firms and civil society organizations.

The formulation of patent claims further complicates the debate on patent quality. A study has pointed out that patent claims on breeding technologies are too vague. They describe the process of the technique without indicating a specific trait or plant to be obtained.[108] For example, it was found that a patent concerning the breeding technique of RNA-dependent DNA methylation (RdDM) claims no specific plant species. It simply claims that gene silencing can be directed towards harmful genes for the plant or unwanted traits like over-ripeness. Vagueness of claims often leads to broadness of patent's scope. For example, by non specifying the relevant plant species, the above patented method can be enforced on all plant species. Furthermore, patentees tend to extend the patent claims on a wide range of products and processes without knowing in advance if the innovation can be applied to each of these claims. The following example can illustrate this point:

> The methods and means described herein *are believed* to be suitable for all plant cells and plants, both dicotyledonous and monocotyledonous plant cells and plants including but not limited to cotton, Brassica vegetables, oilseed rape, wheat, maize or corn, barley, alfalfa, peanuts, sunflowers, rice, oats, sugarcane, soybean, turf grasses, barley, rye, sorghum, sugar cane, vegetables (including chicory, lettuce, tomato, zucchini, bell pepper, eggplant, cucumber, melon, onion, leek), tobacco, potato, sugar beet, papaya, pineapple, mango, Arabidopsis thaliana, but also plants used in horticulture, floriculture or forestry (poplar, fir, eucalyptus etc.) (a patent registered by Bayer BioScience NV, EP2449108 A1, *emphasis added*).

Words such as 'are believed to be suitable' do not indicate certainty on the application of the patented methods on the claimed plants, but only a mere hypothesis that has not yet been verified. In addition, the above example shows a broadly formulated claim. Broad claims grant market power as well as keep open the possibility to strengthen market power whenever the claimed uses are put into practice in the future.

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[106] See *Brassica Protection Products LLC and Johns Hopkins University, Plaintiffs-Appellants, v Sunrise Farms et al.* 301 F.3d 1343 (Fed. Cir. 2002).

[107] Monsanto introduced a virus-resistant gene taken from Indian melon plants to other type of melons using conventional breeding techniques. The patent is being opposed by Nunhems, the vegetable seed-producing subsidiary of Bayer CropScience and a number of NGOs acting under 'No Patents on Seeds' on the basis of lack of inventiveness, clear and complete disclosure and contrariety to morality and public order. See 'Opposition to Monsanto's Patent on Indian Melon', available at http://www.no-patents-on-seeds.org/en/information/news/opposition-monsanto-s-patent-indian-melon, accessed 3 August 2013.

[108] Lusser et al. (2011), see Annex 6.

It goes without saying that all these concerns do not offer legal certainty. In such a situation, patent law may impede plant breeding innovations instead of furthering them. Therefore, countries should emanate clearer rules on the patentability of biological material.

4.1.1.7.2 Moral and Ethical Concerns

Distinction should be made between 'ethics' and 'morality'. These terms are very often used interchangeably but they have different meanings. Whereas 'morality' is used to differentiate between 'good' and 'bad' based on the principles of a particular group or individual, ethics is 'a set of concepts and principles that guide us in determining what behavior helps or harms sentient creatures'.[109] Thus ethics does not dictate moral rules but it serves as a means to determine 'morality'. In terms of the issue at hand, both morals and ethics are important. The sources of morals are various. Morals based on religious beliefs dictate that life is sacred. Hence any attempt to provide for property rights on life forms may be deemed immoral. What is more, God is the only creator of any form of life, thereby there can be no invention of any biological material.[110] The morals based on law, on the other hand, accept patenting of biological matter when humans modify nature to realize social goals. The controversy over the patentability of life forms is, however, not confined to law and religion. A critical observation of natural phenomena finds that every kind of life form stems from an interaction of precise laws and energy cycles existing in nature. Human beings can control and direct natural phenomena, can find new scientific laws, but cannot create them from scratch. Hence humans can 'innovate' but not 'invent'. In this view, 'invention' is interpreted in function of nature supremacy. Some, indeed, accept that nature reigns over mankind and refrain from any action that might disrespect her. Others, however, believe in the dominant abilities of men and reward their creations for improving nature. When the reward goes to innovators who do not compensate the efforts of traditional farming, the reward is often seen as immoral. This phenomenon is known with the term 'biopiracy' and generates great societal worries. All these views are important given that societal wellbeing is determined by the welfare of its individuals. But the prevalence of one view over the other may lead to social discontent.[111] This is currently the case with respect to the patentability of biological material.

Turning to the ethical aspects of patents on biological matter, it is sustained here that universally accepted values on human life should guide what 'behavior helps or harms sentient creatures'. Universally accepted values are found in UN documents

[109] Paul and Elder (2013).

[110] For a comprehensive understanding of theological and ethical arguments see Evangelical Church in Germany (2013), pp. 69–87.

[111] In recent years, a number of organizations operating under the slogan of 'No patents on seeds' are attempting to voice societal concerns on the legal flaws of patents in plant breeding. For more see http://www.no-patents-on-seeds.org/en/about-us/home, accessed 3 August 2013.

such as the Universal Declaration of Human Rights (UDHR) and the International Covenant on Economic, Social and Cultural Rights (ICESCR). Article 25 of the UDHR and article 11 of the ICESCR are relevant in the context of plant breeding. Both these articles state that food is a component of an adequate standard of life. Article 11, in particular, recognizes the right to food and to be free from hunger. Food and patents are nowadays closely linked. When patents are issued on plants, their varieties or plant materials, the final price of the products reaching the market is higher. This might not necessarily affect the budget of consumers since markets offer multiple choices. Nevertheless, patented food affects the buying power of consumers in poor countries. In this case, patents would harm the interests of poor people.[112] In terms of ethics, the universal value of ensuring access to food and eliminating hunger indicate that patenting activity harms some communities. Therefore, it appears that patenting is not ethical with respect to the right to food. Patenting, however, brings substantial monetary benefits to firms and to the countries where they do business. A growing economy undoubtedly benefits people living in these countries. In rich countries, patents may support food supply since theoretically they bring about innovations. But this is not sufficient to conclude that patents are ethical. A critical approach would recall universally accepted principles. In this respect, article 1 of the UDHR appears as the most important. It recommends that all human beings 'should act towards one another in a spirit of brotherhood'. The concept of 'spirit of brotherhood' impels the rich to alleviate the suffering of the poor. Such a broad approach to societal problems is the premise for sustainable development. In this context, benefits surmount the monetary costs that some might endure. Therefore, it appears that eliminating patents is ethical whenever the right to food comes into play. It should be noted, however, that in absence of patents, biological inventions can be protected by other rights.

4.1.2 Breeder's Rights

Breeder's rights are an intellectual protection system specifically designed for the breeding of new varieties of plants. They confer to the holder the right to exclude others from a number of activities related to the protected variety. The first efforts to provide varietal protection date back to the early decades of the twentieth century. Following the Czechoslovak and French laws in 1921 and 1922—other countries like Austria, the Netherlands and Germany—introduced plant breeder's rights respectively in 1938, 1941 and 1953.[113] These national laws were afterward harmonized by the UPOV Convention in 1961.[114] After several amendments

[112] Even though patents are only a component of a multitude of factors that might limit access to food, their role should not be underestimated.

[113] See Rangnekar (2000).

[114] Note that the Convention came into force only in 1968.

in 1972, 1978, and 1991, the 1991 version is in force in most countries.[115] The US and the EU has also ratified the latest version. Therefore, the following paragraphs will explain the characteristics of plant variety protection based on the 1991 UPOV.

4.1.2.1 Object of Protection

Contrary to patents, breeder's rights do not protect an invention but the improvement of existing varieties. As a matter of fact, there is no real invention in the field of plant breeding.[116] Plant varieties are products of breeders as well as of nature. When breeders create a variety, there is no guarantee that other breeders will produce the same variety. The specific outcomes of each crossing are subject to random variation and thus neither predictable nor necessarily reproducible. However, breeders can intervene to 'modify' nature for their own purposes and create varieties with desirable traits. These modifications confer to the plant variety different characteristics from the original plant species. It is, thus, the betterment of the original characteristics of plant species that is deemed to be worthy of intellectual protection.

Innovation may consist in 'breeding' a new variety or in 'discovery and development' of a new variety. The simple discovery of a new variety cannot be qualified for UPOV protection since the discovered variety is a mere product of nature. If the breeder further improves the discovered variety in order to produce a stable and distinct variety, the outcome can be qualified for breeder's rights protection. For instance, a red flowering variety may develop from a plant species that is known to bloom pink. The red flowering variety is not subject to breeder's rights unless breeders develop a stable and uniform line of the distinct red flowering variety.

4.1.2.2 Requirements for Protection

Assuming that a plant variety falls within a protected genera or species, it is eligible for protection only if it is new, distinct, uniform, and stable.[117] These conditions are explained below.

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[115] See http://www.upov.int/export/sites/upov/members/en/pdf/pub423.pdf, accessed 05 August 2013. For European Union breeders, it is also possible to apply for a Community plant variety protection, which provides for similar rights to those provided in the UPOV Convention. See Council Regulation (EC) No 2100/94 of July 1994 on Community Plant Variety Rights. Although this regulation takes into account the UPOV Convention, it prohibits cumulative protection of the plant variety with breeder's rights and patents. See article 92 of the Community Plant Variety Rights.

[116] Correa (2000), p. 176 citing Vignoli (1986).

[117] Article 5 of 1991 UPOV. Please, note that the industry has recently proposed to include DNA fingerprints as an additional requirement for protection. DNA fingerprints are already used in private dispute settlements. For more on this issue see APREBES (2015).

4.1.2.2.1 Novelty

Given the particular nature of innovation in plant breeding, the characteristic of novelty does not refer to varieties not existing in nature, but to varieties not having been exploited in the market for a certain period before the filing date of the application for the grant of breeder's rights. In the country where the application is submitted, the term required is 1 year, whereas in other countries it provides for 4 years for plant varieties and 6 years for trees and vines.

4.1.2.2.2 Distinctness

This requisite is essential to determine the scope of breeder's rights in plants that are closely related, but not identical. Both UPOV Acts state that a 'variety shall be deemed to be distinct if it is clearly distinguishable from any other variety whose existence is a matter of common knowledge at the time of the filing of the application.' The concept of distinctness is further explained in the Guidelines for the Conduct of Tests for Distinctness, Uniformity and Stability.[118] To define distinctness, these tests use qualitative, pseudo-qualitative and quantitative plant characteristics such as draught tolerance and color. A red rose, for example, is distinct from a pink rose. A crop containing a draught-resistant trait is deemed distinct from the same crop missing such trait.

4.1.2.2.3 Uniformity/Homogeneity

Uniformity consists in the display of plant relevant characteristics by every plant of the variety, having regard to the particular features of its propagation. Although UPOV does not further define uniformity, the Guidelines clarify that the variation between varieties should be as limited as necessary to permit a precise description and assessment of distinctness and to guarantee stability.

4.1.2.2.4 Stability

The requisite of stability demands that plant characteristics are preserved through generations or, in the case of a special propagation cycle, at the end of such cycle. In this respect, the UPOV Guidelines affirm that uniform plants are usually stable.

[118] See in particular, UPOV, 'General Introduction to the Examination of Distinctness, Uniformity and Stability and the Development of Harmonized Descriptions of New Varieties of Plants' (19 April 2002) UPOV doc. TG/1/3.

4.1.2.2.5 Disclosure

Unlike patent rights, breeder's rights do not provide for disclosure requirements. The particular reproductive characteristics of genetic material make it extremely difficult for the breeder to disclose its work in such a way that a person skilled in the art can reproduce an identical variety merely by following the information contained in the specification. In addition to propagation features, the difficulty of precisely describing plant innovations resides in the impossibility of relying on verbal explanations to distinguish plant characteristics such as taste and smell.[119] Although scientific developments have made it possible to identify the genotype of plants, yet it is argued that hybrids provide inherent trade secret type protection against competitors since their parental lines are not disclosed and are difficult to identify by any process similar to reverse engineering in pharmaceuticals.[120] Hybrid protection is limited only to sexually propagated varieties, that is those varieties created by seed. Vegetatively reproduced varieties cannot be hybridized and breeders are not able to provide secret-type protection.

4.1.2.3 Scope of Breeder's Rights

The 1991 UPOV requires that breeder's rights extend to all genera and species that meet the protection requirements. It should be noted, however, that breeder's rights protect the physical variety as such and do not extend to the methods employed in variety creation. Breeder's rights are conferred under UPOV 1991 on the following acts: (1) production or reproduction, (2) conditioning for the purpose of propagation, (3) offering for sale, (4) selling or other marketing, (5) exporting, (6) importing, and (7) stocking for any of the above purposes.[121] Additionally, UPOV entitles the breeder to exclude acts relating not only to propagating material, but also to harvested material, including entire plants and parts of plants.[122] This means that any person that intends to use harvested material should require the

[119] Van Owervalle (1999), pp. 143, 155.

[120] Evenson et al. (1999); Goss (1996), pp. 1395, 1418.

[121] As specifically stated by article 5 of the 1991 UPOV Convention, the aforementioned acts require the authorization of the breeder, which may make it subject to conditions and limitations. Examples of conditions and limitations which a breeder might include are: remuneration, period of authorization, quantity and quality of the material to be reproduced, methods of production and reproduction, etc. See better UPOV, Explanatory Notes on Conditions and Limitations Concerning the Breeder's Authorization in Respect of Propagating Material under the UPOV Convention (21 October 2010) UPOV/EXN/CAL/1.

[122] Article 14(2), (3) of the UPOV Convention 1991. It should be noted that the full scope of the breeder's right is also provided for acts that would require the breeder's authorization during the period of provisional protection. Provisional protection is valid once the right is granted. If the right is not granted, provisional protection is not applicable. See art 13 of the UPOV Convention 1991 and UPOV, Explanatory Notes on Provisional Protection under the UPOV Convention (22 October 2009) UPOV/EXN/PRP/1.

authorization of the breeder. The contracting parties of the 1991 UPOV may also further extend breeder's rights to products made directly from harvested material. This extension of protection seems to be similar to the scope of protection under patent rights. Breeder's rights, however, offer a more flexible protection. Moreover, if the breeder has had reasonable opportunity to exercise his right in relation to harvested material,[123] the use of this material is considered to be legitimate.

The scope of breeder's rights may additionally include essentially derived varieties (EDVs). This type of variety is explicitly defined in the 1991 text, which explains that an essentially derived variety is essentially derived from another variety when it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining its essential characteristics. It must also be clearly distinguishable from the initial variety while confirming to the initial variety in the expression of the essential characteristics, except for the differences which result from the act of derivation.[124] Figure 4.2 has the purpose to clarify the above definition for readers not familiar with these technical terms.[125]

The protection of essential derived varieties was deemed necessary to reduce the so-called 'cosmetic breeding' that is, when the original variety is slightly altered through mutation breeding, repeated backcrossing or genetic transformation.[126] For instance, a breeder may slightly improve a variety by simply inserting a new genetic construct. A natural mutation of the characteristics of the variety may also occur—such as a small alteration of the color—for example. The possibility to make such mutations in a short time was blatantly increased by the wide utilization of genetic engineering technologies in the production of new varieties of plant. Considering that a biotechnologist can carry out 'cosmetic breeding' in few months, whereas a conventional breeder may employ more than 10 years to develop a new variety, the protection of EDVs is necessary to guarantee a satisfactory reward for the breeder's work.

The assessment criteria of EDVs are, however, not a defined issue. A common agreement on a definition of the minimum genetic distance required for second

[123] For an understanding of 'reasonable opportunity' see UPOV Explanatory Notes on Acts in Respect of Harvested Material Under the 1991 Act of the UPOV Convention, UPOV/EXN/HRV/1, 24 October 2013, available at http://www.upov.int/edocs/expndocs/en/upov_exn_hrv.pdf, last accessed 11 December 2014.

[124] See article 14 (5) (b), UPOV Convention, 1991. A decision on whether to grant protection to a variety does not take into account whether the variety is essentially derived or not: the variety will be protected if the conditions for protection as set out in Article 5 of the UPOV Convention are fulfilled (novelty, distinctness, uniformity, stability, variety denomination, compliance with formalities and payment of fees). The determination of an EDV is left to the courts to decide. For more on the assessment of EDV see ISF (2005).

[125] For more see UPOV, *Explanatory Notes on Essentially Derived Varieties* (22 October 2009) UPOV/EXN/EDV/1.

[126] Louwaars et al. (2005).

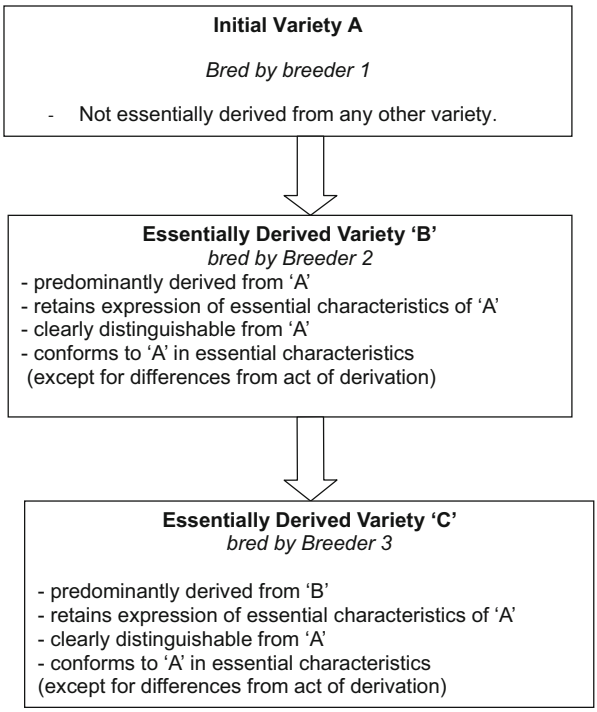

Fig. 4.2 Explanation of the concept of EDV

generation varieties to be qualified as a non-EDV has not been reached yet.[127] Given that the definition of the minimum genetic distance determines the scope of the rights of the original breeder, the definition of an EDV is of extreme relevance. Court cases have so far experienced great difficulties in trying to resolve this issue.[128]

4.1.2.4 Exceptions and Restrictions to Breeder's Rights

Article 15 of UPOV distinguishes between four types of exceptions: private use; research exception; breeding exception; farmers' privilege. The first allows private individuals to freely use the protected variety for non-commercial purposes. The research exception permits research and testing of protected varieties only for experimental purposes, whereas the breeding exception allows breeders to freely cross their varieties with protected ones. The resulting variety cannot be

[127] See *Essential Derivation Information and Guidance to Breeders* (International Seed Federation 2005), available at http://www.amseed.org/pdfs/EDVInfoToBreeders_0605.pdf, accessed 4 April 2012. See also Helfer (2002).

[128] For a detailed analysis of the problematic aspects of an EDV definition see Janis and Smith (2013), pp. 1592–1600.

commercialized if it contains elements of the protected variety. If this were the case, this new variety may fall under the concept of essentially derived varieties of UPOV 1991. In spite of the controversial aspect of EDV determination, the breeding exception fulfills an important role in plant breeding by enabling free access of protected varieties for the purpose of developing new varieties of plants. This assures a constant flow of genetic resources.

Another important exception is the farmers' privilege.[129] Under the 1991 UPOV, states have the option to 'permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holding'.[130] Although this wording does not authorize farmers to sell or exchange seeds with other farmers, these practices are commonly accepted by many countries as part of farmers' privilege.

Other limitations to breeder's rights are imposed by compulsory licenses. Although compulsory licenses are not explicitly named, they are found in article 17 of the 1991 UPOV. This article allows states to limit breeder's rights only 'for reasons of public interest' and upon an equitable remuneration.

4.1.2.5 Dual Protection

A dual protection of plant varieties with patents and breeder's rights is explicitly permitted under the 1991 Act.[131] The breeder may, thus, apply for a double protection in member countries. By contrast, in countries that comply with the 1978 Act, it is possible to apply only for one type of protection.

4.1.2.6 Period of Protection

The 1991 UPOV provides a minimum of 20 years for plant varieties, and 25 years for trees and vines.

4.1.3 Patents and Breeder's Rights: A Comparison

This section highlights conflicting aspects between patents and breeder's rights and briefly explains how the intersection between these rights affects plant

[129] Although this wording does not authorize farmers to sell or exchange seeds with other farmers, these practices are commonly accepted by states as part of farmers' privilege.

[130] Note that 1991 UPOV has restricted the so-called farmers' privilege provided for by the 1978 UPOV. Under the 1978 UPOV farmers were allowed to save, re-sow, and exchange seed for non-commercial purposes without the authorization of the breeder.

[131] Dual protection is also possible under article 27.3 (b) of TRIPS.

breeding.[132] Before developing the analysis, it is worth mentioning here that breeder's and patent rights are both relevant in plant breeding. They both aim at incentivizing innovation by excluding others from commercializing plant-related innovations for a limited period of time. The market power that derives from such exclusion, however, differs in proportion to the scope of these rights. In these terms, patent rights are stronger rights since they provide for less flexibilities than breeder's rights. Whereas patent law is based on the principle of dependence (protection is granted to any material derived from the protected biological invention) breeder's rights are granted on the principle of independence. The divergence between breeder's and patent rights becomes even more perceivable if we look at their object of protection. Under the breeder's rights regime, intellectual property protection is granted only on the plant variety, understood as a unique combination of genes that are expressed as a distinct, uniform and stable phenotype.[133] On the contrary, patent rights protect not only plants, but parts of plants, single genes, and breeding methods. Furthermore patent protection is extended to every plant containing the inventive element or resulting from a patented process. This means that plant-related material is accessible only after obtaining the authorization of the patent holder.

The authorization of the patent holder is also necessary for accessing a plant variety, when the latter is concomitantly protected with breeder's and patent rights. By applying both these rights on the same plant variety—it derives that the variety as a whole is protected with breeder's rights—whereas its specific traits are controlled by the patent holder. Since patent rights extend to all biological material where the patent traits are incoporated and perform their function, [134] this leads to a *de facto* protection of the whole variety. As a result, the variety containing the patented trait cannot be freely used by other breeders in crossing even if that trait is not expressed in the final variety. The same applies to varieties bred by means of a patented process.[135] The difficulty of accessing patented innovation can be better perceived in Fig. 4.3 illustrating the innovation chain in agriculture.

Companies specializing in fundamental (E type) and/or applied biotechnological research (D type) generate most of their income via licensing patent rights rather than from seed sales. Most of these companies operate at international level and often cover the total innovation chain, thus, consolidating their strategic research capacity. As we move on the right of the innovation chain, we find other companies (C) that use biotechnological tools in plant breeding. Although they protect their innovations with patent rights, their main source of income is based on selling

[132] Please, note that this situation may be common in Europe and in those countries that allow the coexistence of patents and breeder's rights.

[133] See arts. 5–9 of UPOV 1991.

[134] Article 9 of the EU directive.

[135] On the concerns of breeders' and patent rights intersection see also GHK Consulting in association with ADAS UK for DG SANCO (2011).

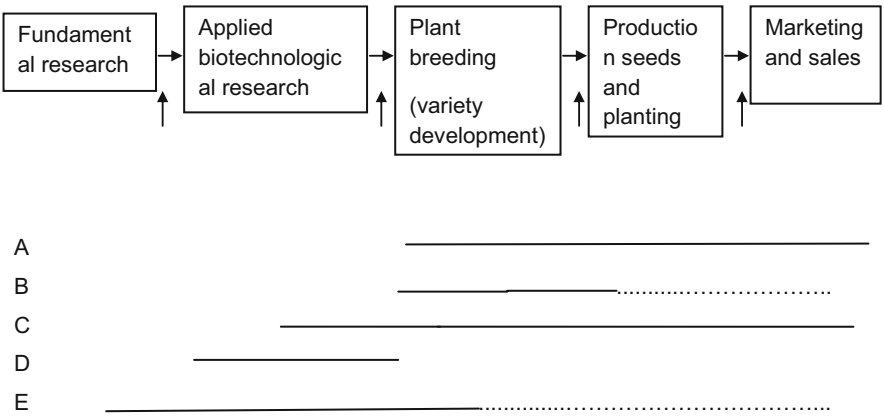

Fig. 4.3 The innovation chain in agriculture. The *vertical arrows* indicate where companies can generate their income. *Source*: Louwaars et al. (2009)

seeds. Traditional breeding companies, on the contrary, perceive their revenue by selling seeds and plant materials (A type). Among these last companies, we can identify those which protect their varieties with breeder's rights and generate profits by licensing these rights (B type).[136]

From this brief description, it emerges that the patent system is mainly based on laboratory research, whereas the breeders' rights system on the creation and selection of plant varieties with traditional breeding techniques. Laboratory research is usually larger and more expensive for the development of varieties containing genetic modified organisms. Thus, the technological process by which plant variety creation takes place, influences the cost of plant breeding, and consequently, the adoption of patents or breeders' rights. Patents and breeder's rights, on the other hand, affect the market power of companies. Since patents are frequently used in upstream research, the possibility to obtain patent licenses has a direct impact on downstream breeding.

4.1.4 The Introduction of the Breeding Exception to Patent Rights

The situation described in the above paragraph induced breeders' associations to claim restriction of their freedom to use all available genetic material in their breeding programs. The reason is to be found in the high transaction costs and difficulties for obtaining licenses on patented biological material. In this respect,

[136] This paragraph mainly builds upon section 2.1.3 of the report prepared by Louwaars et al. (2009) and is reproduced here with the consent of Niels Louwaars.

Transgenic varieties containing patented elements and protected by breeder's rights may be of particular concern since patent rights on a gene sequence extend to the plant variety and extinguish the breeding exception provided for by UPOV. Therefore, fearing a blockage of plant breeding activities, the associations of plant breeders in France, Germany, the Netherlands, and Switzerland exercised influence for the introduction of an exception to patent rights that allows for the use of patented material in breeding processes. Their request was accommodated and French, German, and Swiss patent law were amended respectively in 2004, 2005, and in 2008. The Dutch parliament adopted the same exception in December 2013. Besides the mentioned breeding exception, the debate in the Netherlands includes the introduction of a 'comprehensive breeding exception'. A comprehensive breeding exception to patent rights has been advocated by the Dutch Association of Plant Breeders (Plantum). This type of exception would permit breeders to insert patented biological material and further commercialize the plant varieties containing these patented elements. Plantum's proposal is concerned only with patented products (gene traits) and not with patented processes (breeding techniques). Such choice is based on breeder's interest to freely access biological material for plant breeding purposes and align the UPOV and patent system. Therefore, the comprehensive breeding exception would not cover the simple commercialization of varieties containing patented traits, but only those improved varieties that are a result of breeding activities.[137] The formulation of the comprehensive breeding exception might, thus, be as follows: 'The effects of a patent shall not extend to the use of biological material for breeding, discovery and development, and commercialization of a new variety type'. Such a broad patent exception for the breeding sector differs from the scope of breeder's rights provided for in the 1991 UPOV. This act recognizes exceptions to plant breeder's rights in its article 15, but circumscribes them to the concept of essentially derived varieties (EDVs). The aim of this provision is to avoid plagiarism in breeding. In simple terms, this means that breeders, who make trivial improvements to the original variety, should pay royalties to the first breeder. Practice has, however, showed that the determination of an EDV is extremely difficult. Litigations over EDVs involve extremely complicated scientific aspects and high costs.[138] The Dutch breeders, therefore, take the unsuccess of the EDV concept into account and propose a comprehensive breeding exception.

This type of exception has generated many worries among patent holders who claim that its introduction will severely cut investments in biotechnological research. They accept the introduction of a breeding exception that builds upon UPOV (so-called 'limited exception'), but firmly oppose a full breeding exception. As per now, the Dutch parliament has accepted only the limited breeding exception. Finding a common solution for the comprehensive breeding exception is not an easy task. This task requires the understanding of the role of the patent system on

[137] See Trojan (2012), pp. 8–10.

[138] These considerations are based on interviews with stakeholders in the plant breeding sector. For a list of the interviewees see Annex.

incentivizing innovations and their diffusion. General information on this role of the patent system will be provided in the second part of this chapter.

4.2 The Function of Intellectual Property in Plant Breeding

The necessity to protect plant creations dates back to the nineteenth century, when breeders resorted to artistic illustrations of their fruits to promote their work and avoid its misappropriation.[139] Protection offered by paintings of vegetables and fruits was based on the phenotype features such as color and shape of the variety. This did not impede other breeders from using these varieties and further modify them. The reproducibility of biological material, indeed, makes possible to exploit plant varieties by everyone. Hence protection of plant genotype became necessary. For this reason, paintings were soon substituted by seed certificates and afterward by patent rights. The adoption of specific patent rights for plants was the result of years of lobbying from US plant breeders, which claimed economic losses due to continuous 'thefts' of their varieties. 'Variety stealing' deprived them from significant economic returns. Imitators could place varieties on the market with cheaper prices since they had not incurred breeding costs for the original variety. Nowadays, breeders can even more easily access and use their competitors' varieties since they can rely on advanced techniques such as marker-assisted selection. This might discourage plant breeders from developing new varieties if they obtain no returns on their significant financial and time investment. Hence protection of breeding efforts appears necessary.

Intellectual property rights protect the knowledge applied in the process of plant breeding. The reason of this protection lies in the non-rivalry feature of knowledge.[140] When knowledge is disclosed, it opens the possibility for everyone to enjoy it. Its use by an individual does not affect others' possibility to make use of it. Other innovators might build upon the original innovation and create competing products with lower prices. In this case, the original inventor would not be able to recoup the resources invested and innovation would be discouraged *ex ante*. Financial support for the R&D costs of the original innovation can be guaranteed by government intervention or by intellectual property rights that confer monopoly power for a limited number of years. In the first case, the financial support of R&D costs have to be spread across all societal groups through general tax funding,[141]

[139] For more see Kevles (2011).

[140] The concept of non-rivalry can be described by the words of Thomas Jefferson: '. . .He who receives an idea from me, receives instruction himself without lessening mine; as he who lights his taper at mine, receives light without darkening me.' See the letter to Isaac McPherson dated August 13, 1813, available at http://www.let.rug.nl/usa/P/tj3/writings /brf/jefl220.htm, accessed 5 March 2011.

[141] Note that countries investing in R&D might create positive externalities for those that do not engage in R&D activities due to the non-rivalry of knowledge.

whereas in the second the costs would be internalized within the value chain of firms activities.[142] Both the public and the private sector are involved in plant variety production, but public participation is more relevant for crops not usually bred by the private sector and in fundamental research.[143] Thus, the private sector plays a determinant role in plant breeding. In this context, patent and breeder's rights appear as a necessary form of protection. This protection builds on a classical trade-off inherent in intellectual protection. The trade-off involves societal losses caused by the monopoly power of IPRs in return for the benefit of knowledge disclosure.[144] The following paragraphs will focus on this trade-off by countervailing the advantages and shortcomings of intellectual protection.

4.2.1 The Economic Function of Patent Protection

Economics justifies the adoption of patents based on three main theories: reward theory, prospect theory, and commercialization theory.[145] The reward theory considers patents as necessary instruments to incentivize innovations. The main reason resides in the non-rival aspect of knowledge as explained above. Some economists fear that if the inventor is not able to recoup its R&D costs, innovations might be discouraged or even worse, they will be protected with trade secrets.[146] Others, however, note that the natural headstart which the innovation gives to the inventor over competitors allows recovering the expenses of R&D.[147] Indeed, history shows that most of the groundbreaking innovations have occurred in absence of an IP system. Moser observes that patents started to be applied in those sectors which protecting innovations through secrecy became difficult as a result of technological developments.[148] This is the case of biotechnology. As stated elsewhere in this chapter, the self-replicating nature of the biological material makes it difficult for innovators to protect their inventions. To avoid imitation, innovators can use patents to recoup their R&D costs despite of the disclosure of the inventive idea. Patent disclosure is another benefit strongly linked to the reward theory. The new knowledge which stems from patent protection is deemed to be a public asset rather

[142] Eaton (2013).

[143] Public institutions show a tendency not to patent their innovations in plant breeding techniques. In the EU the ratio of patents of private companies to public institutions was 83 % versus 17 %, in the USA 68 % versus 32 %. For further explanations see Lusser et al. (2011), pp. 35–37.

[144] Nordhaus (1969).

[145] For more see Kitch (1977), p. 265.

[146] For an understanding of these theories see Abbott et al. (2007); Dutfield (2008); Landes and Posner (2003); Mazzoleni and Nelson (1998), p. 273; Pugatch (2006).

[147] See in particular, Machlup (1958), pp. 38, 59–60; Machlup and Penrose (1950), pp. 1–29.

[148] Moser (2013), pp. 3–22.

than a private property.[149] The benefits from disclosure are usually greater than the incentive effects and where the portability of using secrets is higher.[150] But it can be argued that this function of the patent system is not relevant since similar ideas are usually developed concomitantly and only few secrets can survive in the long run.[151] Moreover, the incentive role is based on the hope that competitors might undertake further innovations.[152] Related empirical work in this regard does not allow drawing clear conclusions on a direct relationship between the patent system and innovations. Some studies suggest that patents yield high welfare gains in nonsequential innovations (breakthrough innovations), but in some sequential cases the original inventor is better off without patents because of spillover from follow-on innovation. Furthermore, a positive link of patent protection with R&D is noticed in countries with higher levels of economic development but not in less-developed countries.[153] Further evidence suggests that patent rights are not very important as a prerequisite for R&D.[154] What is more, firms tend to use patents once an innovation occurs rather than prior to innovation decisions.[155] This means that firms do not consider patents to be a very efficacious means of protecting innovations. These results can be further supported by critically reviewing neoclassical theory since this theory ignores the performance of the system based on other factors, such as cooperation, for example.[156] Historical evidence, as well, does not offer a strong message on the effectiveness of intellectual monopoly for increasing innovation.[157]

However, a body of work has shown that patents do play a role in appropriating returns to innovations in the biotechnological sector.[158] This might be due to the fact that the biotechnological market is characterized by large gaps between innovation costs and imitation costs.[159] The role of the patent system in innovation is put into question in this case as well. In the long run, patents increase returns, but make follow-on innovations more costly.[160] This is because patents increase the expected rate of return to R&D investments for the first innovator, but on the other

[149] Intellectual property rights represent a policy tool intended to solve appropriability concerns related to knowledge-based goods, rather than a form of real property. See Reichman (1993), p. 75.

[150] Lander and Posner (246).

[151] Machlup (1958), p. 24.

[152] *Ibidem*, 55.

[153] For an overview of the empirical studies see Boldrin and Levine (2008); Hall and Harhoff (2012), pp. 541–565.

[154] Scherer (2009), pp. 167–216.

[155] Mansfield (1986), p. 173; Levin et al. (1987), pp. 783–820.

[156] Andersen and Konzelmann (2008), p. 12; Greenspoon and Cottle (2011).

[157] Bessen and Meurer (2008); Boldrin and Levine (2008); Moser (2013), pp. 3–22.

[158] Allred and Park (2007), p. 91; Hall and Harhoff (2012), pp. 12–15. Mansfield (1986); Levin et al. (1987); Harabi (1996).

[159] For more see Barnett (2011), pp. 178–211.

[160] Boldrin and Levine (2008).

hand, they increase R&D costs for competitors who would be forced to invent around or acquire access to other patented inventions which serve as inputs for successive inventions.

Other benefits of patent protection become relevant under the prospect and the commercialization theories. According to the prospect theory, patents increase efficiencies in investments since they avoid duplication of effort among competitors. This theory is also closely related to disclosure. The disclosure of patented knowledge allows other firms to build upon the protected invention instead of replicating R&D costs for the original invention. In this case, social benefits would also be higher because society pays only one firm to create innovation. Conversely, it can be argued that not all inventive ideas are patented. When more inventors develop the same idea concomitantly and one of them obtains patent protection, he is entitled to block any further activity of the other concomitant inventors.[161]

Other benefits of patent protection are proffered by the commercialization theory which sees patents as bargaining chips in negotiation.[162] Indeed, studies for the biotechnological sector show that patents secure competitive advantage by signaling to venture capital investors that a firm has valuable assets.[163] As argued by the economist Hadley, the primary function of the patent system is not to incentivize inventions and their disclosure but to guide '*the investment of capital in the use and development of preexisting developments*'.[164] In Hadley's view, this function of the patent system overrides the American theory on incentives and the English theory that considers patents as a reward for disclosing knowledge to the public.[165] But this function of the patent system might be distant from its purported role in promoting innovations. If this were the case, the scope of patent rights would urge reassessment.

4.2.2 The Economic Function of Breeder's Rights

With some differences, the economic theories on patent protection are valid for breeder's rights. The reward theory allows breeders to 'capture a larger portion of the additional benefits generated by the cultivation of a new variety'.[166] If the

[161] For an overview of empirical studies on disclosure see Hall and Harhoff (2012), pp. 16–18. They conclude that the social value of disclosure is small compared to the private value of patents.

[162] For more see Andersen and Konzelmann (2008), p. 211; Hall and Harhoff (2012), p. 4.

[163] Hall and Harhoff (2012), pp. 21–22. This function is more emphasized for small start-ups. Better see Sichelman and Graham (2010), pp. 111–180.

[164] Sichelman and Graham (2010) page 2, note 3 citing Hadley (1986), p. 134.

[165] Hadley, *supra note*, 134. Hadley's book is available online at http://archive.org/details/economics019432mbp, last accessed 18 October 2013.

[166] Eaton (2007).

breeder is not able to reap monetary returns, he would lack incentives to invest on the long and costly process of plant breeding. Although this view is centered on the incentive to innovate, it is not as strong as in patent protection. The limited scope of breeder's rights gives reason to believe that they recognize that access to the variety (innovation) spurs further innovation in plant breeding. The incentive role of plant breeder's rights is nevertheless not clear. The results of the few empirical assessments are divided between a positive relationship between BRs and innovation and a lack of such relationship.[167] The most cited studies are that of Butler and Marion which show that the US PVPA had a positive effect on R&D for certain crops.[168] Here it is worth noting that incentives in plant breeding vary according to different crops. For some crops, such as maize, efficient protection can be given by hybridization technology. Thus, even if BRs were not granted, breeders will be able to recoup their costs through seed selling. Moreover, given that plant breeding is closely related to national agricultural policies, there might be other factors that influence the decision to invest in crop development. In this respect, the study of Jaffe and van Wijk in Argentina suggested that the increase in R&D in plant breeding was due to economic policies rather than the introduction of intellectual protection.[169] These studies suggest that similarly to patents, the relevance of the reward theory is ambiguous. But unlike patents, breeder's rights do not allow for disclosure since breeders can maintain the parental lines of their varieties secret. BRs, however, provide for the breeder's exception which furthers subsequent innovation.[170]

With regard to prospect and commercialization theory, it should be noted that both find application in BRs. But commercialization theory is not as effective when compared to patent rights. In negotiations between a BRs holder and a patent holder, the balance would be in favor of the latter.

4.2.3 New Institutional Economics of Intellectual Protection in Plant Breeding

Besides the classical economic arguments on intellectual protection, law and economics scholars have identified another role of IPRs by focusing on the purpose of such rights. Building upon the general theory of property rights, this view considers patents to reduce negative externalities in a system with no intellectual

[167] For an overview of the literature see Eaton (2013), pp. 25–26.

[168] Butler and Marion (1985).

[169] See the study of Jaffe and van Wijk (1995), p. 8.

[170] For a discussion of the innovative role of the breeder's exception for cereal crops see Janis and Smith (2013), pp. 1557, 1601–1606.

protection.[171] Given the failure of empirical evidence to show a direct link between IPRs and innovation, this reasoning should gain further attention. A related feature of this view is that IPRs should be evaluated 'on the basis of transaction costs associated with developing, marketing and exchanging innovations'.[172] In terms of the issue at hand, the exchange of innovations is most relevant since it broadens the possibility to use innovations in plant breeding. A broad scope of protection would induce competitors to incur higher transaction costs for accessing negotiations, whereas a narrow scope would give them more freedom in research. As argued in the first part of this chapter, patents in biotechnology have a broad scope of protection. Therefore, they create a few problems with respect to accessing biological innovations. Patent thickets and licensing procedures might be a major source of difficulty for plant breeders. A patent thicket is usually defined as 'a dense web of overlapping intellectual property rights that a company must hack its way through in order to actually commercialize new technology'.[173] It has been argued that this situation can easily occur in life sciences since genes can code for more than one function and moreover, several genes may be necessary to code for a function. So, for example, in order to carry out research on a plant trait which function depends on the use of patented genes, it would be necessary to obtain a license for every single gene.[174] The immediate consequence of this situation is the uncertainty of determining the precise subject matter claimed by these overlapping rights.[175] As a matter of fact, the interpretation of patent claims may not always be straightforward for plant breeders, who often lack the necessary expertise in this field.

Identifying patented claims in such a situation, involves not only financial and time costs, but technical knowledge as well. These costs further increase when breeders need to collect all the necessary licenses for the commercialization of the protected innovation. Search and transaction costs, as described for licensing practices, are incurred before the deal can be concluded. This can be particularly cumbersome for breeders. Identifying prior relevant patents, for example, necessitates searching in the patent database. This requires hiring experienced lawyers able to recognize potential infringements. Legal offices are already part of large biotech firms, but hiring expensive patent attorneys is an unaffordable luxury for small breeding companies. Once the relevant patent is identified, breeders can start

[171] For a detailed analysis see Eaton (2007), pp. 4–6. This view could be better understood based on the reasoning of law and economics scholars that absent or poorly defined property rights do not allow for efficient bargaining. For more see Cooter and Ulen (2011).

[172] Eaton (2007), pp. 5–6.

[173] Shapiro (2009), pp. 291–322.

[174] See in specific for research in animal breeding, Joly and Bertrant (2003), p. 5. With regard to plant breeding, the Golden Rice project constitutes an emblematic example with more than 70 patents involved to develop the new rice variety. Kryder et al. (2000), p. 20. A recent study in the Netherlands has, nevertheless, showed that most of the research materials are freely shared among public researchers though some companies apply restrictive conditions in their material transfer agreements (MTAs). See de Jonge and Louwaars (2011).

[175] de Jonge and Louwaars (2011), p. 225.

negotiating the rights to use the desired protected matter. Here transaction costs become relevant.[176] The most crucial matter in the negotiation phase is the agreement on a licensing fee. This is mainly so because negotiators face asymmetric information problems.[177] Informational asymmetries, indeed, create an imbalance of powers between negotiators. The patent holder has the advantage of knowing better the economic value of the innovation, but he is relatively uninformed on the upcoming breeder's innovation. Fearing the imitation of its innovation, the patentee may refuse granting the license or may set an unreasonably high price.[178] The same may happen if the patentee knows that a breeder has a good competitive variety. Another practice followed by biotech firms is that of delaying licensing practices or simply not replying to requests from plant breeders.[179] In this way, business firms avoid providing the grounds for compulsory licensing.

Obtaining a compulsory license may be further aggravated by national legislations. The United States patent law is emblematic in this regard because it does not provide for compulsory licensing.[180] The right to compulsory licensing can be established only by courts following civil action of the patentee for infringement of his patent. The costs of a trial represent a serious hurdle for small breeding companies. This obviously discourages them to undertake research that may potentially infringe patent rights. The consequence of this situation would be that of restricting breeding innovations in downstream research. European Union countries, on the contrary, have a more flexible legislation, especially after the adoption of the EU directive which allows for compulsory licenses for varieties and other plant-related products.

When a license on at least one of the patents is denied, the breeding program may be blocked,[181] and efficient bargaining is impeded. Considering that the success of new varieties is not always certain and immediate, downstream companies are not always willing to negotiate. This may be especially true for small companies that

[176] This is especially so because agricultural markets are dynamic and values are in continuous evolution. See Wright and Pardey (2006).

[177] On licensing patented innovations in presence of asymmetric information see Gallini and Wright (1990), p. 147.

[178] When licensing is not refused, companies may alternatively require contracting out experimental use exceptions provided by some countries in patent law. This practice is currently being followed by Monsanto and Syngenta. See Gibson (2009). The effects of such activity on plant breeding are perceived when countries have broad exceptions that allow research with the patented subject matter.

[179] A project of Wageningen UR and Bogor Agricultural University in Indonesia developed a new shallot variety resistant to an insecticide, which never reached the market due to the inertia of biotech companies in negotiating licensing conditions. For details on this issue see de Jonge and Louwaars (2011), p. 229.

[180] US law provides for compulsory licensing for plant varieties which wide usage is in public interest. See section 7 §USC 2404.

[181] Even if the breeding program is not immediately blocked, there is the risk that the patent holder may block the use of the patented material in further stages of breeding to the detriment of downstream companies' economic and intellectual effort. Therefore, this situation creates high legal uncertainty.

usually lack negotiation power and the necessary financial resources. In this context, the lack of negotiation power can be especially detrimental when companies with newly developed interesting breeding traits swap their complementary patents. This situation can easily occur for agricultural crops, where large companies have interesting patents and are reluctant to share patented traits with competitors. When two large companies, for example, develop complementary traits, they may decide to exchange their patents but refuse to license their patents to other competitors. In this case, other plant breeders would have no negotiation power and would be left out of the deal. This is how patent rights in plant breeding increase transaction costs of accessing innovations. This seems to conflict with the purpose of patent rights to reduce transaction costs associated with commercializing innovations as suggested by new institutional economics.

4.2.4 Economic Concerns on IPRs

The main concern on intellectual protection regards societal welfare. In this respect, IPRs are considered to be a double edged sword. On the one hand, they foster innovation and growth by disclosing information. On the other hand, they impose on customers a price which is higher than the marginal cost of production, hence generating an economic inefficiency, a 'deadweight loss'. This produces the so-called 'Schumpeterian dilemma' between static and dynamic efficiency.[182] At the basis of this dilemma, stands the non-rivalrous characteristic of knowledge. Once new knowledge is disclosed, everyone will benefit from its positive externalities. The greater the number of beneficiaries, the higher the value that will accrue to society. As explained in the above paragraphs, economic theory suggests that this situation will create a static efficiency, but from a dynamic efficiency viewpoint, it will diminish the incentive to innovate because first innovators will not be able to recoup their initial investments. Hence the need to adopt IP rights to spur innovation. But IP rights come along with societal costs. Patents, in particular, create a monopoly[183] which is a static inefficiency, while fostering competition in innovation which is dynamically efficient. A monopolistic market is, however, not always a burden for the society. In some cases, it may respond to the principle of 'allocative efficiency', which justifies the protection granted to a particular class of inventors and the costs imposed in the short-term on the basis of the long-term benefit flowing to the society.[184] In fact, the limitation in time and scope offers an important instrument for balancing society's interest in having more innovations with the

[182] See Schumpeter (1976).

[183] It is worth emphasizing here that IPRs do not automatically confer monopoly power under EU competition law. EU law requires a case by case examination to determine the existence of monopoly power. The same is affirmed in the Antitrust Guidelines for the Licensing of Intellectual Property issued by the US Department of Justice and the Federal Trade Commission, see DOJ/FTC IP Guidelines, Section 2, p. 4.

[184] Coase (1990).

interest to access these innovations. The instrumentality of intellectual property rights to societal interests is further confirmed by their limitation in time. For example, breeder's rights confer different periods of protection for crops, on one hand, and trees and vines on the other. A longer period of protection is conferred for trees and vines because their breeding process requires more time and financial resources. This differentiated treatment takes into account breeders' interests to recoup their larger investment costs to the disadvantage of societal interests to freely use the newly created varieties for commercial purposes.

Thus, rather than the protection *per se*, the core matter of intellectual protection in plant breeding is that of the length, the breadth, and the height of protection. The length of a right defines the time of protection, whereas the latter two indicate the scope of protection by demarcating the boundaries between uses that fall under patent protection and those which infringe patent rights. The breadth, in particular, refers to the range of products covered by intellectual property rights, whereas the height of a right determines which kind of improvements can be done on the protected subject matter.[185] From an economic perspective, these three parameters imply a trade-off between dynamic and static efficiency.[186] For example, the trade-off for the time protection of plant varieties consists in balancing the positive effect of IPRs on incentivizing innovations (dynamic efficiency) with the negative effect of increasing innovations prices (static inefficiency). In terms of the issue at hand, the main question becomes: how to give incentives to breeders without creating static efficiency losses? The answer lies in an effective combination of length, breadth, and height of protection, which determines the value of the right and ensures the social optimum. Put it in simple terms, this requires a determination of a form of protection that incentivizes plant variety creation and at the same time allows the use of varieties. In this respect, the breadth of protection is of particular relevance. The optimal breadth of protection should be large enough to encourage innovation and at the same time spur sequential innovation.[187] This may vary in various industries and in specific circumstances. Therefore, there is no conclusive argument in this respect.

4.2.5 Final Remarks

The aim of this chapter was to offer an understanding of both legal and economic aspects of IPRs in plant breeding. The origin of patents and breeder's rights can be attributed to the necessity to avoid imitation of original inventions and to the technical developments which permitted scientists to improve nature and 'invent' what cannot naturally occur without human assistance. Given that nature is the basis of all technological innovations, the inventive concept in biotechnology is

[185] For more see Langinier and Moschini (2002).

[186] This is an original argument of Nordhaus. See Nordhaus (1969). See also Gilbert and Shapiro (1990), pp. 106–112.

[187] Green and Scotchmer (1995), pp. 20–33; Scotchmer (1991), pp. 29–41.

highly controversial. The controversy becomes more evident when the economic function of IPRs comes into question. Empirical evidence does not provide sufficient grounds for the justification of IPRs. In this regard, the large scope of patents in biotechnology raises concerns associated with accessing patented innovations. These concerns are particularly important for plant breeding given its role in food security. Therefore, it would be desirable that legislators pay attention to the growing scope of patents as well as to ethical issues for food security purposes.

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Chapter 5
Conceptualizing the Breeding Exception to Patent Rights: A Legal and Economic Appraisal

The main objective of this chapter is to conceptualize the breeding exception in the broader framework of patent exceptions in international law. To this purpose, the first part focuses on patent exceptions permissible under national laws. An overview of their legal and economic framework will set the necessary theoretical background. The reader should take notice since now that an extensive examination of patent exceptions is beyond the scope of this work.[1] Only those aspects that are relevant for qualifying the breeding exception will be considered. In line with this purpose, the research exception is deemed relevant and will constitute object of analysis.[2] The relevance of this exception stems from its functional similarity with the breeding exception. Both these exceptions have a similar innovative role since they aim at using protected subject matter for the creation of further innovations. To better comprehend this role, the first part will provide an overview of the main legislations and court cases in order to determine the rationale underlying the adoption of research exceptions.

Based on the considerations of the first part, the second part of the chapter offers an understanding of the legal categorization of the breeding exception and explains the reasons for adopting a breeding exception to patent rights. In particular, it will be explained why some legislations might need to amend their patent laws while others do not have this necessity. Furthermore, it will be illustrated how the adoption of a breeding exception to patent rights reflects economic theory. The

[1] Research exceptions are object of numerous studies. For an extensive review see Bently et al. (2010) hereinafter, WIPO study; Cook (2006); Dent et al. (2006) hereinafter, OECD report; Gilat (1995); Misati and Adachi (2010); Paradise and Janson (2006), pp. 148–154; University of Alberta, *The Research or Experimentation Use Exception: A Comparative Analysis*, prepared for Health Canada by the Centre for Intellectual Property Policy & the Health Law Institute, hereinafter, Canada report; Van Eecke et al. (2009).

[2] Other exceptions to patent rights, which are not relevant to the purpose of this study, are, for instance, the prior use exception and the preparation of medicinal products in individual cases in a pharmacy.

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final aim of this analysis is to purport a thorough justification of the breeding exception based on legal and economic theory.

5.1 Defining Exceptions to Patent Rights

What are exceptions to patent rights? This simple question has for a long time afflicted scholarly research without a definite answer. With respect to intellectual property rights in general, the main concern has been the differentiation of 'exceptions' as a separate conceptual category from 'limitations'. In this respect, Prof. Kur argues that there is no agreement or uniform practice on the international level.[3] She sustains that there is no structural difference between the two terms and each provision containing whether limitations or exceptions should be interpreted in accordance with its aim and purpose.[4] Indeed, studies have shown that countries make use of these terms in different ways.[5] Courts have further added to the uncertainty characterizing the issue at hand. In the field of biotechnology, for example, judges have assumed that 'exceptions to rights conferred' could be regarded as encompassing exclusions of rights as well as limitations on those rights.[6] This interpretation seems to elevate 'exceptions' to a higher and broader category able of defining both *ex ante* and *ex post* boundaries of intellectual property rights.

Recently, however, it has been proposed to overcome the failure to conceptualize these terms.[7] In this respect, dictionaries facilitate shedding light on the issue. To begin with 'limitation', the Oxford dictionary connotes its meaning to 'limit'. A 'limit' is itself defined as 'one of the fixed points between which the possible or permitted extent, amount, duration, range of action, or variation of anything is confined; a bound which may not be passed, or beyond which something ceases to be possible or allowable.'[8] Thus, a limitation sets the margins of the scope of patent rights.[9] This means that the patent holder is, *ab initio*, not entitled to exercise his rights in the area covered by limitations.

Exceptions, on the other hand, are defined as 'something that is exempted; a particular case which comes within the terms of a rule, but to which the rule is not applicable'.[10] This allows us to conclude that contrary to 'limitations', the subject

[3] Kur (2008).

[4] *Ibidem*, p. 8. This point is further supported if we look at the decisions of the European Patent Office. In the case G01/07, Medi-Physics/Treatment by Surgery (2011) 3 OJ EPO 134, the Board of Appeal held that exceptions to patentability 'are to be interpreted to give effect to their purposes'.

[5] See the studies mentioned in note 1.

[6] EU Case of *Monsanto Technology LLC v Cefetra BV*, Case C-428/08, 6 July 2010, para. 76.

[7] Christie (2011), pp. 121–135.

[8] *Ibidem*, p. 123.

[9] Here the terms 'limitation' and 'exclusion' are considered as synonyms.

[10] *Ibidem*, p. 124.

matter covered by exceptions falls within the scope of intellectual property rights. But in virtue of exceptions provided for in the law, acts that would otherwise fall within the exclusive rights of the right holder, become permissible. In other terms, exceptions remove liability for infringing IP rights.[11] This general understanding on exceptions to IPRs applies to exceptions to patent rights as well. Exceptions may be referred in national laws as 'defences', 'permitted acts', 'free uses', 'restrictions'.[12] Exceptions may also be subject to the payment of a fee. Eminent examples are compulsory licenses.

5.1.1 The Rationale of Exceptions to Patent Rights

The following paragraphs provide an explanation of the two main reasons that underpin the existence of patent exceptions. These reasons are economics and public policy concerns. The main economic argument focuses on the importance of preserving the incentive to invest, while public policy considerations highlight the need to promote social interests in specific industrial areas.

5.1.1.1 Economic Concerns

The question of the optimal design of patent law for promoting innovations has been thoroughly analyzed by Scotchmer.[13] She sustains that the main challenge that economics faces for promoting innovations is providing the right incentives. In this context the core question is: how to reward innovators for the contribution they provide and at the same time enable other innovators to create new innovations? This question stems from the cumulative nature of innovations. The metaphor 'standing on the shoulders of giants' often used in the literature describes cumulativeness of innovations, which are a result of several steps of invention, modification, and improvement. Cumulativeness, therefore, implies that the research and development process of a particular innovation requires the knowledge and practice of prior art of the respective technological field. In this respect, access to patented innovations becomes crucial in order to promote new innovations. The facility of accessing patented innovations is proportional to the strength of patent protection. Strong patent rights put high barriers to access, whereas weak patent rights set lower boundaries. Weak patent rights, thus, might facilitate cumulative innovations. But it is not clear whether strong patent rights lead to more innovation in a

[11] Note that this understanding corresponds to that of Ricketson developed for copyright law. See WIPO Study on Limitations and Exceptions of Copyright and Related Rights in the Digital Environment, prepared by Sam Ricketson, 2003 (WIPO Doc. SCCR/9/7).

[12] WIPO study; OECD report (n 1).

[13] Scotchmer (2004); Green and Scotchmer (1995), pp. 20–33; Scotchmer (1991), pp. 29–41.

cumulative context. This is mainly because strong patent protection has two main effects. Firstly, it increases return to R&D in the short run. According to the reward theory,[14] this generates high incentives to invest and consequently, to innovate more. Secondly, it increases the costs for R&D activities in the long run for other innovators who would be forced to invent around or obtain a license on the protected invention. This means that cumulative innovation comprises a trade-off between the incentive to innovate and access to knowledge as a public good. It is worth emphasizing that accessing knowledge is crucial for cumulative innovation, even though this may be to the detriment of the first innovator.

This situation generates the economic concern of preserving the incentives of patent holders to invest in R&D. Economists have largely analyzed the issue by focusing on the division of profit.[15] This analysis is important since the social value of early innovations includes the net social value of the applications it facilitates. Economic modeling suggests that if the first innovator does not collect that value of its innovation as profit, he might not invest. This may occur even when follow-on innovations are not direct competitors to the early innovation (for example, secondary market applications of the first innovation).[16] These considerations imply that if an exception were to be introduced to patent rights, it should take account of welfare gains. This view reflects the basic trade-off of patent law between benefits and costs.[17] Thus, if exceptions significantly weaken the incentives to invest, patentees will not be willing to invest in research and development and less innovation will accrue to society.[18] In this case, exceptions would bring about greater costs than benefits and they would not be desirable for society. But when are exceptions desirable?

A cost-benefit analysis suggests that exceptions would be adopted when their benefits overcome losses for the society. A classical example is the patent exception for private uses. For instance, a 10-year old boy who acquires a patented seed for the purpose of creating a plant for a school project is exempted from patent infringement since legal remedies would bring about substantial costs compared to the insignificant damages of the 'infringement'.[19] Another rationale based on the cost-benefit analysis is related to transaction costs of licenses. In this regard, Gilat suggests that if consensual licensing is likely to occur, an exception will not be required. Conversely, when transaction costs are so high as to impede bargaining,

[14] See Chap. 4, second part.

[15] See, for example, Koo and Wright (2010), p. 489.

[16] Scotchmer (2004), p. 132.

[17] Nordhaus (1969).

[18] Note that these considerations are based on neoclassical economic theory. In a real word scenario, the role of patents should be understood in a broader context that takes account of other factors influencing the innovation system. For a better comprehension see Freeman (1995), pp. 5–24.

[19] WIPO study (n 1), p. 56.

an exception would be desirable.[20] In his view, however, exceptions should be guided by public policy issues that best promote the purpose of the law.

Additionally, Moschini and Yerokhin argue that when R&D costs are low, relative to the potential returns, a broad exception may be desirable because it provides a large pool of innovators in follow-up inventions. On the contrary, when research is costly and risky, a broad exception may not render enough incentives to invest.[21] This view recognizes the basic trade-off between static and dynamic efficiency inherent in patent law. In these context, the 'desirability' of patent exceptions stands on the dilemma between a weak and a strong patent protection. Weak patents may provide insufficient incentives, but strong patents may inefficiently restrict the use of an innovation. Here it should be noted that it is impossible to define the 'right' scope of patent rights since there is 'no measured negative or positive correlation between investment in R&D and the breadth of experimental use exception'.[22] Thus, the form and the extent of the optimal IPR system is still an open question and the economic implications of patent exceptions cannot yet be defined.

These reasons, together with the heterogeneity of the subject matter would suggest a specialized treatment for different types of inventions.[23] Relatedly, economic studies on patent exceptions have focused on two main types of exceptions: exceptions that allow research to improve the patented subject matter and exceptions that use the patented subject matter as a tool in research. They will be examined below separately.

5.1.1.1.1 The Economics of Patent Exceptions for Research on Protected Inventions

This type of exception is seen as positive for innovation since it avoids the transaction costs of licensing for research purposes on the subject matter. In addition, it enhances innovation by increasing the difference between the return from the new innovation and that from the old innovation. As a consequence, prices for consumers lower. Research on protected inventions seems to be more desirable when research is conducted for academic or non-commercial purposes. In this case, the low willingness of researchers to pay licensing fees, issues related with avoiding patent enforcement in academia and the large spillovers of academic research seem to justify the adoption of the patent exception.[24] Considering the importance of academic research for the progress of science, it appears advisable to adopt a broader exception if patents on basic research are broad and vice versa.[25] Moreover,

[20] Gilat (1995), p. 19.

[21] Moschini and Yerokhin (2007), pp. 190–203.

[22] For more see the Canada Report (n 1), pp. 48–49.

[23] For more see Gallini and Scotchmer (2002).

[24] Nagaoka and Aoki (2006).

[25] Gilat (1995), pp. 77–81.

even if 'the commercial versus the non-commercial distinction is dropped and the focus is returned to the underlying goals of the patent system, the analysis of experimentation "on" the subject matter of an invention shows that it is essentially a species of enabling disclosure. Such disclosure enhancement promises to have beneficial effects on the pace of follow-on innovation for non-self-disclosing inventions and minimal effects on the invention for self-disclosing inventions.'[26] Therefore, this type of exception has not been object of large controversy so far.

5.1.1.1.2 The Economic Controversy on Research Tools

While there is general agreement between economists on patent exceptions adopted for conducting research on protected subject matter, they are more skeptical with respect to the second type of exception, which allows using patented inventions as a tool in the research process. The main controversial argument on the economic feasibility of an exception that makes use of inventions as research tools lies on the fact that 'one man's research tool is another man's business'.[27] There is common belief among economists that the use of research tools by second innovators might deprive the first innovator of substantial profit. This may be especially true for inventions with a significant market among researchers, but exempting even purely academic research from patent infringement could also deprive patent holders of a portion of their expected profits. Consequently, their incentive to innovate will be undermined.[28] Those against the introduction of an exception on research tools further argue that there exists no barrier to licensing.[29] They see no reason for the patent holder to refuse bargaining with other innovators, thereby, an exception to patent rights is deemed unnecessary.

Other commentators fear that, on the contrary, the first inventor might be granted too much power in the innovation process. This stems from the different characteristics of innovativeness embedded in research tools. While for most innovations, the contribution that the invention makes is the inventive idea, for research tools, is the tool itself.[30] Therefore, the patentee might have more interest in ensuring a financial return from exclusive control of the research tools rather than from widespread commercial use of an embodiment of the inventive idea. If patentees control research tools in view of maximizing their own profits, technological progress will slower at the expense of the society.[31] This might be particularly worrying when the research project is aimed at addressing important societal concerns, such as food or health issues. In this case, the societal harm resulting

[26] Strandburg (2003).
[27] Eisenberg (2007).
[28] Eisenberg (1989).
[29] Eisenberg (1987), pp. 177 and 225; Gilat (1995), p. 44.
[30] Strandburg (2003), p. 41.
[31] *Ibidem*.

from a slower technological progress may be very severe while the private incentives to delay so as to keep a larger share of the monetary and nonmonetary benefits of the research may be stronger.[32]

This hypothesis generates worries because it weakens the primary function of research tools: the facilitation of technological progress. Hence, the relevant question becomes: how to provide appropriate returns for incentivizing inventions while spurring technological progress? In this regard, Mueller proposes a limited exception for experimenting with research tools that compensates the patentee for use of the tool through a compulsory licensing requirement.[33] This proposal has been further elaborated by Strandburg, who subjects the exception to two conditions.[34] The first condition requires that there must be no close substitutes for the research tool, while the second prohibits close substitutes for the research projects that require the tool.[35] She suggests that only when the tool is of unique importance to a uniquely important problem, it will have an impact on the society. If researchers are relatively indifferent between problems requiring a patented tool and a whole host of interesting problems for which they do not need to use the tool, then the patentee will not exercise significant power over research progress.

These considerations allow inferring that economic theory on patent exceptions is centered around the incentive to innovate. Empirical studies, however, are not able to define the 'right' scope of patent exceptions given the lack of a direct correlation between R&D expenditures and the breadth of experimental use exception, and the heterogeneity of subject matter. Therefore, it is impossible to find a definitive answer in economic arguments. Nevertheless, economic reasoning provides useful guidelines for evaluating the effects and desirability of patent exceptions. This guidelines aim at increasing social welfare, which in turn is inspired by public policy issues.

5.1.1.1.3 Public Policy Issues

'Public policy' is usually understood as 'the governing policy within a community as embodied in its legislative and judicial enactments which serve as a basis for determining what acts are to be regarded as contrary to the public good'.[36] Therefore, in terms of patent law, public policy considerations should aim at guiding the legislator towards the public good, which itself is the main underlying concept of patent law. Indeed, the rationale of patent law is not to remunerate inventors, but to

[32] Strandburg (2003), p. 48 citing Lemley (1997), pp. 1059–1061.

[33] Mueller (2001).

[34] Strandburg (2003), p. 43.

[35] Strandburg recalling chapter V on case studies of the report of the National Research Council.

[36] Merriam Webster online dictionary, available at http://www.merriam-webster.com/dictionary/public%20policy, accessed 25 May 2013.

promote the disclosure of their innovations for the benefit of society. The disclosure of inventions avoids duplication of R&D investments and facilitates follow-on inventions. In turn, more knowledge accrues to society. This makes it apparent that patent law is conceived for the good of the society.

In these terms, some exceptions can be considered as necessary to the patent system.[37] For example, when inventions are not-self-disclosing, exceptions are considered necessary for the benefit of the public.[38] This necessity becomes even more imperative when patents are granted on basic research given its influence on subsequent innovations. It is often suggested in the literature that when patents on basic research are broad, then the research exception should also be broad.[39] The adoption of exceptions, in this case, recognizes the fact that the purposes of the patent system cannot be achieved due to the exclusive rights conferred upon the patentee. In any case, the exception should be granted in view of the public interest and the purpose of the exception.[40]

This view implies a balance of countervailing interests. Whenever a patent conflicts with an important social goal, the latter should be given priority. Important social goals may be represented but not limited to 'national security and emergencies, such as the exception in the Bangui Accord that permits exploitation by an administration or organization authorized by the Minister of the Member State concerned, for the purposes of "vital economic interest, public health, defense other country's needs", subject to remuneration'.[41] Thus, public policy issues guide the adoption of exceptions to patent rights whenever there is a need to disclose the invention for the benefit of the public. In this respect, a WTO panel has also stated that the absence of exceptions to patent rights 'would frustrate part of the purpose of the requirement that the nature of the invention be disclosed to the public'.[42] The relevance of public policy issues in judicial decision-making will be further explained when analyzing national practices on research exceptions.

5.1.2 Research Exceptions to Patent Rights: An Overview of National Practices

This section helps provide the reader with a general understanding of the research exception adopted by single countries. The following paragraphs will not thoroughly examine the issue of research exceptions, but will focus only on those aspects relevant for qualifying the breeding exception. The first part will outline the international legal framework and briefly describe national practices for

[37] WIPO study (n 1), p. 59.

[38] For a detailed explanation see Strandburg (2003), pp. 31–32.

[39] Gilat (1995), pp. 77–81.

[40] Gilat (1995), p. 19.

[41] WIPO study (n 1), p. 59.

[42] WT/DS/114R, para. 7.69.

research exceptions. Special attention will be dedicated to the research exceptions of France, Germany, Netherlands, and Switzerland in order to understand why they have incorporated a breeding exception into their patent laws.

5.1.2.1 International Legal Framework

The most important international agreement on intellectual property law is the Trade-Related Intellectual Property Rights Agreement (TRIPS). Part II, section V of this Agreement provides for specific provisions on patent law. An exception to patent rights is formulated by its article 30 as follows:

> Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Vagueness of language is the first element to be noticed in this formulation. The second is the fact that this makes it impossible to draw conclusions with regard to the type of permissible exceptions as distinguished by economists. But another important and recent agreement for European patent law, the Agreement on a Unitary Patent Court (UPC), offers some guidelines in this context.[43] Its article 27 is entitled 'limitations to the effects of a patent' and provides that *inter alia* the rights of the patentee should not extend to:

(a) acts done privately and for non-commercial purposes;
(b) acts done for experimental purposes relating to the subject matter of the patented invention;
(c) the use of biological material for the purpose of breeding, or discovering and developing other plant varieties;

This article recognizes three types of exception: research for non-commercial purposes, research relating to protected inventions commonly known as research on protected subject matter and additionally, allows for a breeding exception. This is the first international legal instrument to provide for a breeding exception. As already explained in the previous chapters, only Germany, France, the Netherlands, and Switzerland have adopted such an exception in patent law prior to the coming into force of the Agreement on a Unitary Patent Convention. In this context, it appears that international law acknowledges established national practices rather than influencing them. Indeed, there is no internationally accepted definition of 'research exception' and all countries have drafted it in a variety of ways. The following paragraphs will briefly illustrate this issue.

[43] Agreement on a Unified Patent Court, (2013/C 175/01), available at http://www.unified-patent-court.org/images/documents/upc-agreement.pdf, accessed 22 May 2015.

5.1.2.2 National Practices: Judicial and Statutory Research Exceptions

Countries have chosen to introduce exceptions to patent rights in two main ways. Some countries have developed research exceptions through judicial decisions, while others have provided for specific exceptions in their patent laws.[44] Common law countries, such as, Canada, New Zealand, UK, and US, have usually developed exceptions through judicial decisions, whereas civil law countries have opted for statutory exceptions. But there is no uniform practice even in this regard. Australia, for example, is a common law country but it was unclear whether a research exception existed until 2012, when the Patents Act of 1990 was amended in order to introduce an exception for research purposes in its section 119C.[45] Civil countries, on the other hand, have enriched the interpretation of their statutory provisions through judicial cases. These issues will be further explained below.

5.1.2.2.1 Judicial Exceptions

Here the focus will be on the US research exception in order to provide an example of exceptions developed through judicial decisions. The choice of the US exception is based on the fact that that the US courts offer a rich and interesting jurisprudence for the purpose of the analysis. The birth of the research exception in the US is attributed to Justice Story, who affirmed in the *Whittemore v Cutter* case that:

> it could have never been the intention of the legislature to punish a man, who constructed such a machine merely for *philosophical* experiments, or for the purpose of *ascertaining* the sufficiency of the machine to produce its described effects (emphasizes added).[46]

In the same year, he explained in *Sawin v Guild* that experimentation must not be with an intent to infringe patent rights and deprive the owner of the lawful rewards of his discovery.[47] These two cases seem to create the basis for differentiating between experiments for research and commercial purposes. Whereas the former have been deemed permissible by courts, the latter have been strictly prohibited. A landmark case—*Roche Products v Bolar Pharmaceutical*[48] or so-called Bolar case has mitigated this view. The case will be briefly examined below in order to understand the circumstances that influenced the decision.

The defendant, Bolar Pharmaceutical, was a generic drugs manufacturer who aimed at marketing a drug covered by a patent of Roche Pharmaceuticals, the

[44] For an overview of the research exceptions in different countries see Correa (2005).

[45] For more see Australian Government, IP Australia http://www.ipaustralia.gov.au/about-us/ip-legislation-changes/ip-laws-amendment-act-2012/factsheet-experimental-use/, accessed 17 October 2013.

[46] *Whittemore v Cutter* 29 F. Cas. Qt 1121. For further analysis see Bee (1957), p. 357; Bruzzone (1993), p. 52; Hagelin (2005).

[47] *Sawin v Guild*, 21 F. Cas. 554 (1813)(C.C. D. Mass. 1813).

[48] *Roche Products v Bolar Pharmaceutical*, 733 F.2d 858 (Fed. Cir. 1984).

plaintiff. The marketing of the generic drug required a marketing permission from the health authorities. Since the process for obtaining this permission was time-consuming, Bolar decided to conduct clinical tests and apply for marketing authorization prior to the expiry of Roche's patent. Roche filed suit. Bolar's defense was based on the experimental use exception. But the appeal court said that it was not applicable to the concrete case since the exception is narrow and limited only to experiments which are not in any way motivated by commercial interests. This decision negatively affected the interests of drug manufactures which exercised pressure upon Congress to change the result of the decision. Less than 6 months after, the Congress emanated Section 271-e-1 of the Drug Price Competition and Patent Term Restoration Act, informally known as the 'Hatch-Waxman Act'.[49] This solution was a compromise between the diverging interests of the generic and proprietary drugs manufactures.[50] Although it softened the categorical prohibition of experiments with commercial intent, it allowed a research exception *solely* for the purpose of obtaining regulatory approval. Patentees interests were safeguarded by enabling them extend patent rights beyond the statutory patent term of 17 years from the grant of the patent. In this way, they were compensated for their 'loss'.

This decision is significant on an international level because it paved the way for other countries to adopt exceptions to patent rights for regulatory purposes.[51] The compliance of such exception with the main international rules for IPRs has been clarified by a WTO panel.[52] However, the exception is very narrow and limited only to experimental trials for obtaining regulatory approval for generic medicines. This was further reaffirmed in *Embrex v Service Engineering, where* the court of appeal indicated that they were extremely narrow in scope and could not be used to escape liability for infringement simply by cloaking infringing activities in the 'guise of scientific inquiry'.[53]

A more recent case that supports this view is *Madey v Duke University*.[54]*Madey was* a researcher at Duke University, who owned patents covering a new laser device, and left Duke University without licensing or assigning any rights to his inventions. After he left, the university continued to use his inventions without permission. The court found Duke's research ineligible for the common law research exception because it 'unmistakably furthers the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects'. This decision was justified by the fact that academic institutions have legitimate business objectives since the research they conduct

[49] Public Law 98-417.

[50] See Dreyfuss (2004), p. 457.

[51] The EU has adopted a Bolar type exception in respect of patents. See article 10(6) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code relating to medicinal products for human use.

[52] For a detailed explanation of this issue see Chap. 6 of this study.

[53] *Embrex* Inc. *v Service Engineering* Corp., 216 F.3d 1343 (2000).

[54] *Madey v Duke University* 307 F. 3D 1351 (Fed. Cir. 2002).

increases the status of the institution and lures lucrative research grants. The court, however, reaffirmed that the research exception remains viable for experimental-use that is 'for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry'. Such a restrictive interpretation of the common law research exception in the US has induced most commentators to argue that *Madey v Duke* signals an end to the common law research exception to patent infringement.[55]

The restrictive approach of US judges is further confirmed with regard to the interpretation of the statutory exception. In *Integra Lifesciences v Merck,* the court argued that basic scientific research not aimed at obtaining regulatory approval is not exempted under Section 271-e-1 of the Hatchman-Waxman Act since the research is surely not 'reasonably related to the development and submission of information' to the Food and Drug Administration (FDA) authorities.[56]

All these decisions seem to center around two core concepts: 'philosophical' inquires and 'commercial' intent. The first are deemed permissible by US courts whereas the second are considered to prejudice the rights of patentees, thereby not eligible for an exception. An exception to courts' decisions is represented by the US statutory exception, which took the interests of pharmaceutical companies at large into consideration. With regard to the rationale of research exceptions, both courts and legislation appear to strictly reflect the predominant economic view on research done on patented subject matter and without commercial purposes. This narrow approach to research exceptions is perceived in *Madey v Duke*, which did not exempt academic activities given their potential commercial objectives. The prevalence of patentees' interests can additionally be noted in a lack of specific attention to public interest issues by US courts.

5.1.2.2.2 Statutory Research Exceptions

The research exception introduced in civil law countries is formulated in various ways. Although there are some differences in the language used, the practice followed by countries is to provide an exception for 'acts done for experimental purposes'. In many EU States, for example, the statutory exception is identical or substantially similar to Article 27.b of the Agreement on a Unified Patent Court (ex art. 31 of the Community Patent Convention). The Czech Republic, Denmark, France, Germany, Ireland, Luxembourg, Spain, Sweden, and the UK all almost identically reproduce this provision relating to the research exception, namely 'acts done for experimental purposes relating to the subject matter of the patented

[55] Conversely, Strandburg claims that this decision should not be generalized, but understood in the specific context. See Strandburg (2003).

[56] *Integra Lifesciences v Merck* 331 F.3d 860, Fed. Cir. 2003. For a broad interpretation of the US statutory research exception see Rubin (2006). Another common law country, the UK, has adopted a broad interpretation of research exceptions. See *Auchinloss v Agricultural* and *Veterinary Supplies Limited* in Van Eecke et al. (2009), p. 153.

invention'.[57] Other countries have chosen different formulations. Italy, for instance, exempts non-commercial or experimental acts aimed at obtaining regulatory approval for pharmaceutical products.[58] Belgium, on the other hand, has adopted a broad exception by expressly permitting scientific acts done both on and with the patented invention.[59] The particularity of this exception is its impact on protected research tools. The Swiss Patent Act also distinguishes between research on the patented invention and research with the patented invention.[60] But only research on the patented invention is exempted since access to patented research tools is explicitly assured through non-exclusive licensing.[61] Unlike most countries, Swiss law exempts research done for both non-commercial and commercial purposes, as long as the objective of the research is to generate new knowledge about the patented invention.[62] Similarly, the Dutch exception relates solely to research on the patented subject matter. Article 53.3 of the Dutch Patent Act of 1995 provides as follows: 'The exclusive right shall not extend to acts solely serving for research on the patented subject matter, including the product obtained directly as a result of using the patented process.' The Dutch law, thus, clarifies that the scope of the research exceptions extends to the products of research.

This brief overview of statutory exceptions makes it apparent that civil law countries have adopted a liberal approach with respect to exceptions for research purposes compared to US practice. Civil law courts have further contributed to this approach by embracing a broad interpretation of the scope of research exceptions. Two German decisions, Clinical Trials I[63] and Clinical Trials II[64] are a cornerstone in this regard and they are often brought as an example in many EU countries when interpreting research exceptions.[65] These decisions will be examined below.

5.1.2.2.2.1 Clinical Trials

The German decisions on Clinical Trials are most relevant for giving an interpretation of Section 11.2 of the German Patent Law. The court argued that the language of Section 11.2 supports a broad interpretation of the scope of patent

[57] See better Van Eecke et al. (2009), pp. 149–151.

[58] Article 68 of Code of Industrial Property, Decreto Legge N.30 of 10 February 2005.

[59] (aux actes accomplis à des fins scientifiques sur et/ou avec l'objet de l'invention brevetée.) <L 2005-04-28/33, art. 11, 006, in force since 23 May 2005. The Belgian exception is also exceptional in that it has replaced 'for experimental purposes' with 'for scientific purposes' which is arguably wider than experimental purposes alone. See Van Eecke et al. (2009), p. 231.

[60] Article 9 (b) of the Loi fédérale sur les brevets d'invention, 2008.

[61] Article 40 (b) of the same law.

[62] Further clarifications on Swiss law are available at https://www.aippi.org/download/commitees/202/GR202switzerland.pdf, accessed 25 May 2013.

[63] *Clinical trials I*, [1997] RPC 623.

[64] *Clinical Trials II* [1998] RPC 423.

[65] For France and the Netherlands see Van Eecke et al. (2009), pp. 159–161 and the Canada report (n 1), p. 32.

research exception. To support its argument, the court additionally clarified that 'an experiment in the sense relevant here is any (planned) procedure for obtaining any information, irrespective of the purpose which the information gained is intended to serve'.[66] The court explained that Section 11.2 exempts all experimental acts as long as they serve to gain information and to carry out scientific research into the subject matter of the invention, including its use. In Clinical Trials II, the court confirmed that the research exception covers acts for experimental purposes undertaken with the subject matter of the invention in order to discover the effects of a substance or possible new uses. It further explained that:

> Since the provision makes no limit, either qualitative or quantitative, on the experimental acts, it cannot matter whether the experiments are used only to check the statements made in the patent or else to obtain further research results, and whether they are employed for wider purposes, such as commercial interests.[67]

With respect to the relationship between commercial activity and the object of research, the court noted:

> ... the commercial orientation does not from the outset turn the experimental activity into an impermissible patent infringement. Something else will then have to determine when it is no longer a matter of further elucidation of the conditions, effects, applicability, and producibility of the object of the invention, but of clarification of commercial facts such as the needs of the market, acceptance of prices, and possibilities of distribution.[68]

Most importantly, the court observed that 'clinical experiments with a genetically engineered pharmaceutical will always be based on commercial considerations' because of their immediate or potential application. According to the German judges, if the existence of a commercial interest were to exclude the applicability of Section 11.2, then the effectiveness of the provision on patent exceptions would be severely undercut. In 2000, the German Constitutional Court concluded that patent owners had to 'accept such limitations on their rights in view of the development of the state of the art and the public interest'.[69] Unlike the US courts, German courts seem to dedicate more attention to public policy issues. In this respect, they put importance on technological development for the benefit of the society. German judges have explicitly claimed that:

> From the viewpoint of the further technical development in the general interest, which is the aim of patent law, it is therefore appropriate to exempt clinical trials and investigations with active substances on humans as experimental acts according to Section 11 Nr. 2 as long as these experiments are directly aimed at obtaining information.[70]

The court has further explained that it would be inconsistent with the purpose of promoting technical progress and stimulating the spirit of invention for industry in a

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[66] *Clinical trials I*, [1997] RPC 623, 631.

[67] *Ibidem*, 632.

[68] *Clinical trials I*, [1997] RPC 433–434.

[69] OECD report (n 1), p. 18.

[70] *Clinical trials I*, [1997] RPC 643.

profitable manner to exclude experimental acts which serve research and further technical development. In Clinical Trials II, the public interest in scientific and technological progress became evident when the court linked the ground for granting a patent with the public interest. On the court's opinion, 'the unlimited protection of the patent is not justified in a case where the further development of the technology is hindered'. The importance of public policy issues is implicit in the overall reasoning of the German courts. In Clinical Trials II, for example, when the court states that—trials must not be carried out for the sole purpose of demonstrating to a third party that the product works—the court seems to have in mind the beneficial outcome of the trials for the public as a whole. Without doubt, the reference to public interest requires a balance of different interests between patent holders and society. While allowing for a research exception, the court reminds that this exception creates no disadvantage for the patentee since the invention cannot be used without his final consent. This is how the German court acknowledges the rationale of patent law. It recognizes the importance of the economic interests of the patentee but countervails it with the general public interest.

5.1.3 Differentiating Research Exceptions to Patent Rights

Although there exists no uniformity across national jurisdictions with respect to the research exception, two characteristics seem to play a role in defining exceptions to patent rights: (1) research on or with an invention; (2) research for commercial or non-commercial purposes. The following paragraphs offer a brief explanation of their meaning.

5.1.3.1 Research on or with the Patented Invention

Experimentation and research on the patented subject matter covers scientific research about the invention. It usually aims at verifying, designing around or improving upon a patented invention; challenging the validity of a patent; confirming the value for the purpose of licensing; experimentation for the purpose of improving the invention or finding its use; research for inventing around the invention, etc.[71] Research with the patented invention, on the other hand, requires the use of patented subject matter in scientific work. The use of patented material as a research tool is not exempt from infringement since a research tool facilitates an experiment, and is not the subject of the experiment. The term 'research tool' may have many meanings. Researchers who use them in the laboratory may view them as tools, whereas firms who primarily manufacture and sell these resources may consider them end products.[72] The following example aims at clarifying the

[71] Gilat (1995), p. 20. Van Eecke et al. (2009).

[72] Mueller (2001).

distinction between these two types of research. When it is experimented on a patented gene sequence (that determines a plant trait, for example) to understand or further develop its technological function, the research is on the invention. When the same sequence is used in the breeding process to help creating a plant variety containing the patented trait, the research is with the patented invention since the inventions serves as a tool for breeding new varieties. Research tools may consist on a wide range of products, such as cell lines, monoclonal antibodies, reagents, growth factors, combinatorial chemistry libraries, etc. While most countries exempt research on a patented invention from claims of patent infringement, they do not exempt research with the patented invention. In this regard, Belgium patent law is an exception since it exempts both types of research.

5.1.3.2 Research for Non-commercial and Commercial Purposes

Non-commercial research usually indicates those experiments that have the sole purpose of conducting research without obtaining any profit. The discovery of an unknown gene function for the purpose of furthering knowledge, for example, has no commercial purpose. When research is aimed at obtaining a commercial advantage, the research has a commercial purpose.[73] Distinguishing between 'commercial' and 'non-commercial' purpose, however, is not an easy task. The differentiation between these terms started to blur after universities began to commercialize their innovations.[74] In the US, the definition of 'commercial' has been object of controversy in several cases. It seems that 'commercial' is intrinsic to modern innovation systems.[75] The products of research, indeed, are better valorized when they are commercialized. A case in point is Scripps Clinic and *Research Foundation v Genentech Inc*. After conducting research aimed at improving the prior art technique of obtaining purified Factor VIII:C patented by Scripps Clinic, Genentech entered into a licensing agreement with Cutter Laboratories in order to develop a commercial scale production method of recombinant Factor VIII:C and to conduct bioequivalency tests. Although no factor had been sold at the time of the trial, the court found Genentech to have infringed Scripps patent rights.[76] The importance of commercial intent in defining the scope of the research exception was again reconfirmed in *Embrex Inc. v Service Engineering*. Here the court held that a patent on a method for inoculating chicks against diseases *in ovo* was

[73] For more on the distinction between research-oriented and market-oriented experiments, see Gilat (1995), p. 4.

[74] The commercialization of university research in the US was boosted with the adoption of the 'Bayh-Dole Act'. (36 U.S.C. §200–212). To a limited extent, this trend has been followed by Europe. The Wageningen University in the Netherlands and the Centre National de la Recherche Scientifique (CNRS) in France seem to be the most active. On this point see Lusser et al. (2011).

[75] This seems to be related to the transformation in the organization of science and information. For a brief explanation see Dreyfuss (2004), p. 462.

[76] For more see Gilat (1995), pp. 9–10.

infringed by university researchers who were trying to find a way to work around the patent. According to the court, the common law defense was inapplicable because the ultimate intent of university scientists was commercialization.

A similar approach has been adopted by European judges. Court cases date back to the nineteenth century, when the English case of *Frearson v Loe* indicated that acts do not constitute use of an invention where there is no commercial purpose.

> . . .no doubt if a man makes things merely by way of bona fide experiment, and not with the intention of selling and making use of the thing so made for the purpose of which a patent has been granted, but with the view to improving upon the invention the subject of the patent, or with the view to seeing whether an improvement can be made or not, that is not an invasion of the exclusive rights granted by the patent.[77]

Based on this decision,[78] the New Zealand judges held that:

> Doubtless experimentation will usually have an ultimate commercial objective; where it ends and infringement begins must often be a matter of degree. If the person concerned keeps his activities to himself (. . .) even though commercial advantage may be his final goal, he does not infringe. But if he goes beyond that, and uses the invention (. . .) in a way that serves to advance him in the actual market place, then he infringes, for the marketplace is the sole preserve of the patentee.[79]

Both these decisions highlight the intent to commercialize the invention as an important element for drawing the line between commercial and non-commercial research. Similarly, the German Federal Supreme Court clarified that the research should not exceed the scope which research normally has and should not unreasonably interfere with the use of the invention by the patentee. More elucidations on the contraposition between 'commercial' and 'non-commercial' can be found in the doctrine. Hantman, for example, bases the distinction on monetary profit.[80] Accordingly, research is commercial when it makes or attempts to make profit. On the same line, Israelsen and Eisenberg argue that research is commercial if it essentially aims at providing the experimenter's own benefit.[81] In practice, when an experimenter is an ordinary consumer of the invention and derives profit from its exploitation, his activities do not fall within the research exception. This conclusion seems to be in line with current legislations and with the opinions of leading commentators.

[77] *Frearson v Loe* (1876) 9 ChD 48.

[78] For the influence of this decision on other common law countries see the Canada report, p. 14 and the OECD report p. 19.

[79] *Smith Kline & French Laboratories Ltd v Attorney-General* (NZ) [1991] 2 NZLR 560.

[80] Hantman (1985), p. 617.

[81] Israelsen (1988–1989), pp. 457 and 469; Eisenberg (1989), pp. 1017 and 1078.

5.1.4 Final Remarks

The first part of this chapter showed that there is significant variation in the scope of research exceptions across different countries. As a result of the existence of different national laws, and differing judicial interpretations of those laws, there is no uniform view of patent exceptions, although significant similarities can be seen with respect to the object and purpose of the exception. Most countries, thus, differentiate between research done on or with patented subject matter and research for non/commercial purposes. Research done on patented subject matter is usually exempted from infringement, whereas research with is considered to conflict with the patent. However, case law in developed nations is not sufficiently developed to explain the applicability of the research exception for research with a patented product.[82] Similarly, research for commercial purposes seems to be prohibited by most countries. But there is no harmonized definition of 'commercial'. Therefore, the status of research at both national and international level appears to be quite unclear. This uncertainty on the scope of research exceptions may present difficulties for companies who need to operate in different countries. In particular, it may hinder the ability to accurately predict licensing and consequently, proliferate litigation. Most importantly, the uncertainty on patent exceptions does not allow drawing conclusions with respect to the breeding activities that might be deemed permissible in patent law.

5.2 Conceptualizing the Breeding Exception

The above analysis allows us to set the background for conceptualizing the breeding exception in the broader framework of research exceptions. Therefore, in line with the aforementioned argumentation, the below paragraphs will explain what type of research activities the breeding exception aims at exempting and why there is a need to modify the current research exception. Afterward, the rationale of the breeding exception will be evaluated in light of economic theory.

5.2.1 The Concept of the Breeding Exception

The main question that this section aims at clarifying is whether the breeding exception exempts research done on/with patented subject matter and research for non/commercial purposes. With regard to the first distinction, it is important to note that the breeding exception to patent rights should not be confused with the breeder's exception to breeder's rights provided for by UPOV. The latter is based *on the use and betterment of existing plant varieties* for the purpose of creating new varieties. The breeding exception to patent rights has the same purpose of creating

[82] Misati and Adachi (2010), p. 4, note 19.

new varieties, but it aims at *using patented biological matter*. Under the current research exception, breeders (provided they have the necessary resources and innovation capacities) or researchers might use and improve patented material but this is not specifically relevant in the process of plant breeding. The main objective of those who breed new varieties is to access patented traits since they confer particular characteristics to the plant. These traits may be crossed out during the breeding process or might be present in the final variety. Therefore, the main interest of breeders is to use patented material as a tool. This means that the breeding exception aims at exempting research done with protected subject matter.

With respect to the distinction of non/commercial purposes, the breeding exception appears to have commercial purposes since it mainly serves to create products that will be commercialized in the marketplace. Indeed, using patented material solely for breeding varieties that will never be commercialized has no practical utility. The very purpose of plant breeding is that of making plant varieties available for the whole society. Commercial purpose, thus, is inherent in the breeding process. Therefore, in light of the aforementioned considerations on research exceptions, the breeding exception seems to be an exception with commercial purposes.

5.2.2 *The Need for a Breeding Exception to Patent Rights: A Legal Assessment*

As already explained in the first part of this chapter, most of the countries exempt only research done on patented subject matter from infringement. Since this type of exception aims only at determining the scope of a patented invention, its claims, how it works, seeking an improvement, inventing around the patented invention or doing pure research, it does not allow working with patented material for breeding purposes. Therefore, there is a need to broaden the scope of the research exception in order to encompass breeding activities. Moreover, there is a need to provide for exceptions that cover commercial purposes since the breeding exception may be considered as an exception with commercial purposes.

Germany, France, Switzerland, and the Netherlands, however, did not broaden the existing research exception, but introduced a specific exception for breeding purposes. The reason behind this choice lies in the worries that a broad research exception may create for biotechnological sectors other than plant breeding.[83] Some studies have shown that patent protection might be important for the pharmaceutical, biofuel, chemical and cosmetic industry.[84] Therefore, the introduction of a specific exception for the breeding industry appeared as more appropriate.

The need for a specific breeding exception has also been taken into account by the recent Agreement on a Unified Patent Court (AUPC), which in its article 27.

[83] Trojan (2012), p. 11.

[84] Harabi (1996), Levin et al. (1987), and Mansfield (1986).

(c) reproduces an identical provision to those of Germany, France, and Switzerland. It appears now that an adoption of a breeding exception becomes imperative for those countries that adhere to the AUPC.

5.2.3 *The Need for a Breeding Exception to Patent Rights: An Economic Assessment*

It should be noted from the beginning that this section does not explain the reasons for introducing the breeding exception. It was already discussed in the fourth chapter that the current introduction of the breeding exception is a result of plant breeder's lobbing based on public policy issues rather than economic considerations. Here it will be explained how the breeding exception reflects the economic theory on patent exceptions. The theoretical background provided in the following paragraphs might serve as a further support for countries that decide to adopt a breeding exception into their patent laws. Thus, the main question here is centered on the incentive to innovate: does the breeding exception provide incentives to innovate for patentees and at the same time allow breeders to create new varieties of plants? The answer should start with an understanding of the type of cumulativeness in plant breeding innovations. According to Scotchmer, three types of cumulativeness characterize innovations:

- an initial innovation leading to several second-generation innovations or a research tool leading to a single innovation.
- several first-generation innovations (research tools) act as input for a second-generation innovation.
- a quality-ladder innovation process in which each innovation builds on the previous generation of the same product and serves as a basis for further improvements.[85]

The first type of cumulativeness is not applicable in plant breeding since it involves breakthrough innovations. The last two, on the other hand, find a direct applicability in plant breeding.[86] The last one describes the traditional process of breeding plants, which relies upon existing varieties for creating new improved ones. The second type of cumulativeness describes the (modern) process of breeding plants by making use of patented products. One or several first-generation innovations (research tools) help breeders create a second-generation innovation (plant variety). This type of cumulativeness is of interest for the discussion on the breeding exception since the breeding exception to patent rights aims at exempting the use of patented tools from infringement.

[85] Scotchmer (2004), p. 132.

[86] See also Moschini and Yerokhin (2007).

Unlike conventional breeding, the interests of the parties involved in modern breeding are protected by different legal frameworks. The breeder who needs to use a patented tool protects the product of his work with breeder's rights, while the inventor of the tool uses patents. This means that the legal frameworks for analyzing their incentives to invent are different since their innovation process is not the same. The innovation process of research tools involves substantial costs compared to that of developing and breeding new varieties. In this regard, the argument of Moschini and Yerokhin explained in the first part of this chapter offers reasons for doubting the desirability of the breeding exception to patent rights. Since patentee's research is costly and risky, a broad exception may not render enough incentives to invest.[87] Indeed, the 'breeding and development' of plant varieties is commercially relevant and may undermine the original innovator's profit. His profit would be even further reduced if a full breeding exception were to be implemented to patent rights.

However, two other important reasons support the introduction of the breeding exception. The first is the fear that the patentee might be granted too much power and consequently, abuse of patent rights to control downstream innovation. The proposal of Strandburg to apply a patent exception only when the protected tool is of unique importance to a uniquely important problem finds full application here. The uniqueness of the breeding exception is rooted in the particular relevance of plant breeding for society. Except for plant breeding, there is no other scientific sector that can deal with the problem of creating plant varieties. Similarly, patented tools do not and cannot have close substitutes since they code for specific gene traits. In absence of an exception, the patentee might abuse of his 'monopoly power' and slower technological progress.

The direct impact of this consequence on the society is closely related to the second reason for introducing the breeding exception: public policy issues. The importance of promoting breeding activities for ensuring access to food can be better understood in absence of economic studies that offer a direct correlation between R&D expenditures and breadth of experimental use exception.[88] If it is not possible to know the gains or losses of strong patent protection for the society, then it would be better to avoid losses related to food supply. In this context, it seems reasonable to exempt patented tools for the public benefit of having more access to plant varieties.

5.2.4 The Breeding Exception as a Response to a Potential Anticommons

An 'anticommons' is often described as a mirror image of a 'commons' where too many individuals have privileges of use in a scarce resource. In an 'anticommons', by converse, too many individual have rights of exclusion in a scarce resource.

[87] *Ibidem*.

[88] More on economic studies for R&D and the incentive to innovate, see Chap. 4.

Whereas a 'commons' situation leads to an overuse of the scarce resource, the 'anticommons' give rise to an underuse of the scarce resource. The 'anticommons' effect of patents has been analyzed by Heller and Eisenberg for the biomedical sector.[89] Although the authors do not provide specific empirical evidence of the problem, they argue that a 'proliferation of rights in upstream biotechnological research may be stifling life-saving innovations further downstream in the course of *research* and product development'. Although there is lack of evidence of anticommons effects in plant breeding,[90] the potential materialization of these effects should not be underestimated.[91] To illustrate this possibility, the following paragraphs explain how the fragmentation of rights may prevent exploiting biological resources in plant breeding and consequently, impede the creation of useful varieties.

One of the major factors that may lead to an anticommons effect in plant breeding is the fragmentation of rights among various right holders. So, for example, when a plant breeder needs to breed a new variety containing several patented genetic sequences, he will have to obtain the necessary licenses from patent holders. Collecting licensing rights may be particularly costly. High fees and transaction costs of identifying and negotiating the relevant rights are at the basis of inefficient cooperation. This problem combined with the uncertainty on the success of breeding programs may discourage breeders from investing in breeding or discovery and development of new varieties. This may be particularly true for breeders with limited financial resources. As a result, plant breeders may underinvest in breeding and development. Hence efficiency problems will arise.

Scholars who have investigated efficiency problems associated with fragmented rights in research distinguish between two situations: simultaneous and sequential anticommons.[92] In the first situation, different right holders exercise independently exclusion rights at the same level of the value chain. In the sequential case, multiple owners exercise exclusion rights at different levels of the value chain. Both these situations can occur in plant breeding. A simultaneous anticommon may arise during the 'creation of variation' phase,[93] when two different varieties, each containing a patented element, are crossed.[94] This situation is further aggravated when the varieties contain more than one patented element. The protection of varieties with breeders' rights does not pose any difficulty in accessing plant material since breeders' rights already provide for a breeding exception. Accessing plant material becomes problematic when varieties have patented elements that can be used only after obtaining patent licenses. A sequential anticommons may occur

[89] Heller and Eisenberg (1998), p. 698.

[90] Zwahlen (2011). Previously, evidence of a modest anticommons effect in molecular biology has been provided by Murray and Stern (2007), pp. 648–687.

[91] Some studies suggest that this is a real concern in biotechnology. See Graff (2009), p. 34.

[92] Parisi et al. (2004), p. 175.

[93] See Chap. 3 for the stages of plant breeding.

[94] Patented tools are also used to introduce specific genetic sequences into the plant genome.

when breeders face problems in collecting rights in different stages of breeding, such as 'creation of variation' and 'selection', for example. In the selection phase, breeders often apply patented tools to select the desired plant characteristics. They need to obtain a license for using these tools in the selection phase. When the encumbrance of obtaining patented tools is combined with the difficulties of collecting other patent rights in the 'creation of variation' phase, breeders have to cope with a variety of patent holders who exercise exclusive rights in different stages of the value chain of plant breeding.

Economic modeling suggests that the mere existence of fragmented property rights, despite their extension, results in anticommons with a direct impact on deadweight loss.[95] This is mainly because individual owners fail to internalize all the costs or benefits of their actions. The refusal of granting a license, for example, diminishes the value of similar rights held by other patentees. Other individuals will consequently bear the costs of negotiations failure. Cooperation, on the other hand, would lead to an efficient outcome since the total returns to the group would be larger than those in case of defection.[96] This is the reason why fragmented property rights generate worries among economists.[97] This is especially so because the costs of collecting the relevant rights are usually reflected in the final price. This means that fragmented rights harm both breeders and consumers.[98] The harm can be directly perceived when breeding projects are abandoned as a result of licensing refusals and, consequently final varieties do not reach the market.[99]

These considerations lead us to the conclusion that the current fragmentation of patent rights among different right holders might discourage plant breeding activities instead of spurring them. Without doubt, intellectual property rights are necessary to overcome inefficiencies related to common use of genetic resources.[100] Property rights indeed solve the problem of overuse in common resources, but they can also cause underuse of scarce resources.[101] Further scientific inquiries would be necessary in order to have an accurate assessment of underuse of

[95] Parisi et al. (2004). The costs of excessive property fragmentation were first recognized by Posner (1998), p. 76.

[96] If the deal does not occur, inefficiency problems arise since every person would be worse off. If the deal occurs, the outcome is efficient because everyone takes a share of the surplus. In this last case, distributive and fairness issues may arise, but not efficiency ones. See Fennell (2004), p. 829.

[97] Heller (2009), pp. 291–322.

[98] See the argumentation of Shapiro on fragmented rights on copper and zinc, key inputs for producing brass. Shapiro (2009), pp. 291–322.

[99] Here it should be noted that abandoned projects are not usually publicized. Therefore, it is not always easy to create public awareness of this effect of fragmented rights. For concrete examples on this point see de Jonge and Louwaars (2011), pp. 234–240.

[100] It would be more appropriate to state that IPRs 'partly' overcome inefficiencies since biopiracy concerns persist even after the implementation of IPRs. Moreover, the efficiency of privatization should take into account State's property rights over genetic resources and their implementation, and communities' rights over genetic resources.

[101] For a comprehension of the link between the commons and anticommons tragedy see Buchanan and Yoon (2000), pp. 1–13; Fennell (2004), pp. 829–898.

genetic resources in the breeding sector. Nevertheless, today's worries should not be tomorrow's regrets.[102] Therefore, the question naturally arises: how can we prevent fragmentation in plant breeding in order to incentivize innovations? The common response to the high fragmentation of rights is the creation of collaborative mechanisms which aim at reducing transactional costs. These mechanisms have already been adopted in plant breeding in the form of patent pools and clearing houses. Patent pools overcome anticommons concerns by bringing together 'multiple patent holders which assign or license their individual rights to a central entity, which exploits the collective rights by licensing, manufacturing or both'.[103] Similarly, clearing house models overcome information problems on patented technologies by grouping licensors and licensees and additionally provide services such as negotiating licensing conditions, and collecting and distributing royalties.[104] Although patent pools and clearing houses have the advantage of significantly lowering transaction costs and collecting all fragmented rights necessary for the commercialization of final products, they have their drawbacks. The major shortcoming is that of creating the risk of anticompetitive practices. Especially since most of these collective arrangements are created *ex post* and may aggregate perfectly substitutable patents. This may cause a monopoly to the detriment of consumers.[105] To circumvent the detrimental effects of bad patent pools, a license may be necessary.[106] But this would further increase transaction costs. In addition, the success of patent pools and clearing houses mechanisms depends on the voluntary participation of companies.

The adoption of a breeding exception to patent rights would avoid these problems. The breeding exception overcomes problems of *ex ante* licensing and uncertainty on patent scope in the breeding phase by exempting a limited number of activities from patent protection. The limited number of exempted rights seems to reflect the doctrine of *numerus clausus* in civil law. The *numerus clausus* in civil

[102] Future concerns on fragmentation of rights that cause underuse can be better summarized by the following quotation: '(...) withholding productive resources may create dynamic (or future) externalities because the underuse of productive inputs today bears consequences into the future, as standard growth theory suggests.' See Parisi et al. (2004), p. 176.

[103] Merges (1999), p. 5. This paper is available at http://www.law.berkeley.edu/files/pools%281%29.pdf, accessed 22 May 2013. Examples of patent pools are the Public Intellectual Property Resource for Agriculture (PIPRA) in the United States and the European Collective Management of Public Intellectual Property for Agricultural Biotechnologies (EPIPAGRI) in Europe.

[104] For further explanations see Van Overwalle et al. (2007). See also Graff and Zilberman (2001), pp. 1–13; Graff et al. (2001), pp. 15–30. A clearing house model is that of the CAMBIA BIOS Initiative, which offers a free public database of US, Australian, and European life science patents see http://www.cambia.org/daisy/cambia/home.html. Building on a clearing house model, some Dutch companies have proposed the adoption of a 'licensing code of practice', to obtain clear licensing conditions (based on a free, responsible and non-discriminatory approach) on all patents owned by the participating companies.

[105] Shapiro (2009), pp. 291–322.

[106] Trommetter (2008), p. 18.

law constitutes an important regulatory principle aimed at minimizing informational problems caused by an uncontrolled fragmentation of property rights.[107] This principle has traditionally focused on exclusive rights over tangible assets, but it may be applied to intellectual property rights since regulatory and information issues are common among intangible assets as well.[108] In the area of intellectual property, the *numerus clausus* principle specifies a number of rights which are detracted from the free availability of individuals. In terms of the breeding exception, the *numerus clausus* confers definite rights to plant breeders by limiting the rights of the patentee.

As already explained elsewhere in this work, such rights are granted only during the breeding phase. This would be of no benefit if breeders encounter the same problems in the commercialization phase. The high transaction costs in *ex-post* licensing and patent quality issues may, indeed, be as cumbersome as in *ex-ante* licensing. Exempting patented material only for breeding purposes, does, however, solve some of the problems related to the anticommons effects of patents in the research stage. Firstly, it allows breeders to avoid *ex ante* licensing negotiations. This has three important consequences. It eliminates transaction costs of obtaining the required patented element and it lowers the financial hardships of breeding new varieties of plants. By making plant-related material freely available, breeders would be prone to undertake more breeding programs. Currently, negotiation costs and licensing fees constrain breeder's choices by directing their breeding programs towards 'safer' projects that give certain financial returns. In absence of such constraints, they would be free to explore various projects. Avoiding *ex ante* licensing may, in addition, have larger beneficial effects for the society. The costs of obtaining a license are usually charged on the end-consumers. By eliminating this cost, varieties will come into the market at lower prices. Secondly, it overcomes the problems related to patent quality as explained in Chap. 4 of this study. By making 'patented biological material' freely available for further breeding, breeders do not have to fear patent infringement and expensive litigation procedures with patent holders. This provision would furthermore increase the flow of genetic diversity among breeding programs. This is mainly because breeders would not only have access to existing varieties but to innovative plant-related material as well. The use of diverse germplasm provides them with a wide range of choices to improve the plant genome. Thirdly, the introduction of a breeding exception to patent rights creates legal certainty on access of patentable subject matter. Legal certainty would be better assured by including in the law a specific clause that declares void limitations or exceptions to the said provision.[109]

[107] Better see Merrill and Smith (2000), p. 1.

[108] Merril and Smith affirm that 'The *numerus clausus* is probably at its weakest in the area of intellectual property'. For a more detailed analysis on the applicability of the *numerous clausus* on intangible assets see Mezzanotte (2012), p. 1.

[109] See article 9.2 of the Swiss RS 232.14 Legge federale sui brevetti d'invenzione.

Moreover, the role of the breeding exception in the commercialization stage should not be underestimated. It has two main advantages. Firstly, commercial licensing may be avoided when the patent has already expired or is approaching its end. In the latter case, it may be beneficial for the breeder to market its varieties immediately after patent expiry. Secondly, a breeding exception softens the difficulty of obtaining a license. In this respect, two are the positive effects of a breeding exception in this phase: it increases the negotiation power of breeders and creates the basis for compulsory licensing. Having already developed a new valuable product, breeders can offer more certainty on potential markets and the market value of their final variety. This makes patent holders aware of the profits that can be obtained by licensing some of their rights. If the license were denied, breeders, however, would be able to comply with the cumbersome technical requirements of compulsory licensing.[110] Instead of demonstrating the value of a potential product, the breeding exception allows breeders to use the new developed variety to demonstrate that it constitutes significant technical progress of considerable economic interest compared with the invention claimed in the patent.

5.2.5 Final Remarks

The second part of this chapter proffered an understanding of the breeding exception in light of the legal and economic framework characterizing research exceptions. The breeding exception appears to exempt research done with patented material and is guided by commercial purposes. This is in contrast with major national laws on research exceptions. The recognition of the breeding exception by the recent Agreement on a Unified Patent Court, however, gives hope for a harmonization of the breeding exception in EU countries. But its admissibility should be examined under article 30 of TRIPS since EU is legally bounded to this international agreement.

Additionally, the introduction of the breeding exception appears to be controversial from an economic viewpoint since it might weaken the incentive to innovate of patent holders. However, the risks associated with abuse of 'monopoly power' granted by patent rights might pose a greater weight on society compared to the economic losses suffered from patentees. In this context, the public interest of ensuring large access to plant breeding innovations prevails. This interest is even more urgent in absence of empirical studies that show a direct correlation between R&D investments and innovation. Therefore, the introduction of the breeding exception seems to be better supported by public policy objectives.

[110] See article 12 of the EU directive on biotechnological inventions 98/44/EC. See also article 31 of TRIPS.

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Chapter 6
The Breeding Exception to Patent Rights: Analysis of Compliance with Article 30 of the TRIPS Agreement

This following sections aim at examining in detail article 30 of the TRIPS Agreement in order to assess whether the breeding exception might be deemed permissible. The importance of this analysis stems from the applicability of TRIPS in a large number of countries.[1] Whenever these countries decide to exempt particular activities from patent infringement, they should conform their laws with TRIPS provisions. In this respect, article 30 is designed to provide specific guidance since it explicitly provides for exceptions to patent rights. This article requires states to allow for exceptions to patent rights only when they are *limited*, *do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner*, *taking account of the legitimate interests of third parties*. Obviously, this formulation does not proffer a clear guidance. The language used in delineating the conditions under which an exception is permissible appears as a compromise to accommodate the diverging interests of WTO countries. Therefore, interpretation is required in order to concretize its meaning. The following paragraphs will first offer a brief explanation of interpretation issues in the WTO and afterward clarify the meaning of article 30. The analysis will focus on the compliance of both a limited and a comprehensive breeding exception. As explained elsewhere in this study, the limited exception, already adopted in the Dutch, French, German, and Swiss patent laws, allows breeders to commercialize varieties obtained by using patented elements in their breeding processes, whereas the comprehensive exception would permit breeders to freely commercialize varieties containing patented traits.

[1] Note that although TRIPS membership coincides with WTO membership, not all WTO countries are members of TRIPS since least developed countries have been granted a grace period.

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6.1 Principles of Interpretation

The interpretative task of TRIPS articles appertains to the WTO dispute settlement mechanism.[2] Article 3.2 of the DSU recites:

> The dispute settlement system of the WTO is a central element in providing security and predictability to the multilateral trading system. The Members recognize that it serves to preserve the rights and obligations of Members under the covered agreements, and to clarify the existing provisions of those agreements in accordance with customary rules of interpretation of public international law. Recommendations and rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements.

This article recognizes the role of the dispute settlement mechanism in clarifying TRIPS provisions.[3] Clarification of provisions necessitates interpretation of the text in order to arrive at a determinate meaning. A clear and precise meaning creates legal certainty and thus, provides for 'security and predictability to the multilateral trading system'. By virtue of this requirement, the dispute settlement body cannot create new rights and obligations other than those provided in TRIPS. This means that interpretation operates within the limits provided by the agreement itself. As indicated in the above provision, this process is guided by the customary rules of interpretation of public international law. The customary rules of interpretation comprise a set of codified and non codified principles.[4] Codified principles are found in articles 31 and 32 of the Vienna Convention on the Law of Treaties (VCLT). Article 31 sets general rules of interpretation. Its first paragraph recognizes the principle of good faith in treaty interpretation. This principle aims at ensuring a balanced interpretation of the treaty terms in order to avoid unfair advantages of one party over another.[5] The same paragraph requires the interpreter to give to the terms their ordinary meaning in their context and in the light of treaty's object and purpose. This necessitates both a textual and a teleological interpretation. Indeed, the purpose and the object of the treaty have an instrumental role in interpretation since their 'use never exclusively determines the meaning of a treaty'.[6] Therefore, their role has to be assessed together with the context.

The second paragraph clarifies that the context comprises the text, its preamble, and annexes; any agreement between parties in connection with the conclusion of the treaty; and any instrument made by at least one party in connection with the conclusion of the treaty and accepted by others as an instrument related to the treaty. This provision allows the interpreter to take account of every element that

[2] See Article 3.2 of the Understanding on rules and procedures governing the settlement of disputes (Dispute Settlement Understanding or DSU), Annex 2 of the WTO Agreement, 1869 UNTS 401; 33 ILM 1226 (1994).

[3] The legal basis for the application of the Understanding to TRIPS is found in article 1.1 of the Understanding.

[4] For more see Van Damme (2009), pp. 32–55.

[5] Panizzon (2006), p. 20.

[6] Van Damme (2009), p. 263.

might shed light on the context. Additionally, paragraph 3 of the same article expands the interpretative scope by referring to subsequent agreements between parties, subsequent practices related to treaty interpretation, and relevant rules of international law applicable between parties.[7] This means that the interpreter should consider any additional element relevant for the interpretation of the terms of the treaty. If the application of these instruments leaves the meaning 'ambiguous or obscure; or it leads to a result which is manifestly absurd or unreasonable', article 32 suggests to apply supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion.

Besides these codified principles of interpretation, other non codified principles play a role in treaty interpretation.[8] Among them, the principle of effectiveness developed under WTO judgments is the most important.[9] This principle requires the interpreter to ensure the integrity of the text of the treaty by opting for a reading that enables the realization of the purposes of the treaty to the highest extent possible. Effectiveness of interpretation helps to keep focus on a coherent interpretation. The above described interpretative principles guide WTO panels to give a determinate meaning to a term. In terms of article 30 of TRIPS, the interpretative function of the panels becomes relevant whenever a member state challenges another state's measure adopted under article 30.

6.2 The Interpretation of Article 30 in the EC-Canada Case[10]

Since TRIPS has entered into force, only one WTO panel has addressed the issue of interpretation of article 30 while examining the EC-Canada case. Following a complaint of the EC and its Member states in 1998, the panel analyzed the compliance of section 55.2 (1) and (2) of the Canadian Patent Act. Section 55.2 (1) concerns the regulatory review exception or the so-called Bolar exception, while section 55.2 (2) is referred to as the stockpiling exception. The Bolar exception, firstly established in US law, allows pharmaceutical firms to start the necessary studies, tests, and trials before the patent expires, in order to obtain regulatory approval.[11] The stockpiling exception was subject to the successful implementation

[7] Please compare with article 38 of the Statute of the International Court of Justice, 3 Bevans 1179; 59 Stat. 1031; T.S. 993; 39 AJIL Supp. 215 (1945). For more see Cattaneo (2000), pp. 627 and 673.

[8] Van Damme (2009), pp. 52–56.

[9] This principle was first defined in *US – Gasoline* (WT/DS2/AB/R) and recalled in *Korea-Dairy* (WT/DS98/AB/R), para. 80. For more on the principle of effectiveness in the WTO dispute settlement see Cameron and Gray (2001), pp. 248–298; WTO Analytical Index (2007), p. 1118.

[10] Please, note that the following paragraphs largely build upon author's previous publication, Prifti (2013), pp. 218–239.

[11] Section 271-e-1 of the Drug Price Competition and Patent Term Restoration Act, informally known as the "Hatch-Waxman Act" [Public Law 98-417] after a court case *Roche Products v Bolar Pharmaceutical*, 733 F.2d 858 (Fed. Cir. 1984).

of regulatory requirements. Afterward, competitor firms could start manufacturing and stockpiling of patented goods in the 6 months preceding patent expiry. The rationale of this exception was that of permitting competitors to place their products into the market immediately after patent expiry. The WTO panel rejected this second exception, but upheld the compliance of the Bolar exception.

In its reasoning, the panel refers to articles 31 and 32 of the Vienna Convention on the Law of Treaties. While applying these articles, the panel recalls the objectives and principles of TRIPS, its preamble and preparatory works, and the preparatory works of the Berne Convention. The interpretative outcome of the panel on article 30 can be deemed quite limited since it did not clearly specify the meaning and the content of each step, but provided a general argumentation instead. Several aspects of this approach have been questioned in respect to each step.[12] Here it is worth mentioning that the panel's reasoning has been mostly criticized for neglecting the specificities of national innovation systems.[13] An additional remark is addressed to the failure to take account of TRIPS principles and objectives.[14] These comments suggest that the panel's viewpoint might refrain countries from adopting flexible solutions for their differing and evolving socio-economic systems.[15] Despite these controversial aspects, the panel's report might offer some guidance for countries which need to assess the compliance of their exceptions with the TRIPS Agreement.[16] The panel, indeed, offered some useful indications on the meaning of the terms of article 30. In specific, it affirmed that the conditions of article 30 should be cumulatively satisfied.[17] In order to better understand the analysis of these conditions in the context of the breeding exception, the panel's interpretation will be proffered in the following paragraphs.

6.3 A Limited Breeding Exception Under Article 30

The aim of this section is to explain the wording of article 30 and in addition, analyze the compliance of the breeding exception in light of the panel's findings. It should be noted that the compliance analysis mainly builds upon the findings of the WTO panel in spite of the fact that it does not create a binding precedent for future

[12] Correa (2005), pp. 10–16.

[13] *Ibidem*, 14.

[14] *Ibidem*; Kur (2011), pp. 239–240; Rodrigues (2012).

[15] Prof. Kur argues that this might be particularly the case if the three conditions of article 30 must be cumulatively satisfied. See Kur (2011).

[16] For more on the interests of different parties on weakening the TRIPS Agreement see Cattaneo (2000). In interpretative terms, the interests of parties on weakening or strengthening the TRIPS provisions can be reflected in the scholarly debate between 'activists' and 'strict constructivists'. See Cattaneo (2000), p. 657, note 118.

[17] Para. 7.20 WT/DS114/R.

decisions.[18] This choice is based on the assumption that the panel's report reflects the political will of WTO dispute settlement body to adopt exceptions to patent rights. Therefore, an elaborated analysis of articles 31 and 32 of the VLCT will be purposely omitted. Nevertheless, relevant principles of interpretation, such as the objectives and principles of TRIPS will be taken into consideration whenever it is necessary for the purpose of the analysis.

6.3.1 First Condition: Limited Exception

In the panel's view, a 'limited exception' is an exception that makes only a small diminution of the rights of the patent holder under article 28 of TRIPS.[19] The panel explicitly indicated that the legal text should be read literally, focusing on the extent to which legal rights have been restricted. Considerations such as the degree of the economic impact or the number of the curtailed rights were explicitly excluded with respect to the 'limited exception' requirement (para. 7.31). Only the level of impairment caused to patent rights in legal terms was deemed relevant for determining the 'narrowness' of patent exceptions.[20] The term 'limited', however, may lend itself to a vague interpretation. Dictionaries may help us to further shed light on the term.[21] Although 'limited' may have several definitions, the one that indicates a restriction on 'size, amount or extent'[22] seems to be the most appropriate in this context. The online Merriam Webster dictionary further clarifies this term by offering an understanding of 'limited' as 'confined within limits'.[23] This last definition better helps us to comprehend scholars' interpretation of 'limited exceptions'. Prof. Correa, for example, argues that exceptions are limited when their boundaries are specifically set. In his view, boundaries can be defined by the purpose of the exception (research exception), the purpose of the use (private or commercial), the acts involved (importation, exportation) etc.[24]

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[18] WTO panels play a significant role in shaping interpretation of the DSU. For a comprehensive analysis of the interpretative function of the WTO see Van Damme (2009).

[19] Para 7.30 WT/DS114/R.

[20] Para. 7.32 WT/DS114/R. In another dispute on copyright exceptions, the panel established a maximum requirement of narrowness in a quantitative as well as qualitative sense. See WT/DS160/R (para. 6.109). This has been interpreted by an author as a leeway for determining whether these thresholds are decisive. See Senftleben (2006), p. 407. The considerations of the copyright panel can be relevant for the interpretation of article 30, given that both patent and copyright exceptions are inspired by article 9 (2) of the Berne Convention.

[21] Dictionaries have become an essential research tool in WTO TRIPS litigation. See Dinwoodie (2002), p. 993; Van Damme (2009), pp. 22–223.

[22] See the online Oxford dictionary, available at http://oxforddictionaries.com/definition/english/limited?q=limited, accessed 12 March 2014.

[23] See the online Merriam Webster dictionary, available at http://www.merriam-webster.com/dictionary/limited, accessed 12 March 2014.

[24] For more see Correa (2007), p. 307. On the practice of countries on patent exceptions see also UNCTAD-ICTSD (2005), p. 437.

In terms of the issue at hand, the rights of the patent holder should be first identified in order to assess the 'narrowness' of the breeding exception. The TRIPS Agreement lists patentees' rights in its article 28. The first part of paragraph one provides for rights on patented products.[25] It allows the patentee to exclude third parties from making, using, offering for sale, selling, or importing patented products without his consent. In this respect, the breeding exception curtails the right of the patentee to authorize the *use* of protected products. The second paragraph of the same article grants to patent holders the 'right to assign, or transfer by succession, the patent and to conclude licensing contracts'. The breeding exception does not limit these rights, but it might limit the revenues accruing from the exercise of such rights. Based on the panel's argumentation, the issue here is the extent of the curtailment, not the number of rights and their economic impact. Thus, the limited breeding exception does not impair the right of the patentee to commercialize or license its products for commercial goals. This means that it is confined only to 'breeding' purposes. Further commercialization of varieties bred with patented elements necessarily requires the consent of the patent holder.

The limits posed by the breeding exception can be further qualified by the acts involved: 'breeding' and 'discovering or developing' a new variety. The first activity refers to the process of changing the genetic of plants by crossing and selecting, or using new techniques to obtain improved varieties, while the second contemplates those situations when one simply 'finds' a deviant plant in a variety. For example, a deviant plant may differ in color but retain all the other characteristics of the variety. The change of color is due to genetic mutations normally occurring in nature. The breeding exception, thus, authorizes breeders to use the discovered mutant for further developing a new plant variety. Whoever makes use of patented genetic material in order to carry out the above described activities falls under the breeding exception.

The 'limited' nature of the breeding exception may, however, be arguable when it is employed by companies for breeding varieties that are subsequently commercialized in the market. The use of the patented material in this case is limited to breeding activities, but the original intent of these activities is the commercialization of the final products. The free use and exploitation of patented biological material permits breeders to better identify the economic value and potential markets for their new varieties. In this way, they can create actual or potential competitive products. In this regard, the panel recalled that the analysis of the first step should focus only on the legal effects of the patent exceptions. Therefore, the above economic considerations should be ignored. Even if we take the commercial intent into consideration, a limited breeding exception allows only for a 'breeding' use. Further commercialization of varieties would require an explicit authorization from the patent holder.

[25] Please note that paragraph one of Article 28 provides for rights on both products and processes, but only patented products are relevant for examining the breeding exception.

Therefore, based on an understanding of 'limited' as proffered by the panel, the dictionary, and scholars' proposals, the breeding exception should be deemed a limited exception since its boundaries are specifically set by breeding purposes and the acts involved.

6.3.2 *Second Condition: Not Unreasonably Conflict with a Normal Exploitation of the Patent*

The interpretation of this condition firstly requires an assessment of the term 'normal exploitation'. If the exception is found to be conflicting with the 'normal exploitation' of the patent, the further examination of 'unreasonableness' would be necessary.[26] The panel explained 'normal exploitation' but did not offer any indication on the meaning of the term 'unreasonably' since it found that the exceptions of Canadian patent law were not in conflict with the normal exploitation of the patent.

In the Panel's view, 'normal exploitation' combines an empirical approach about 'what is common within a relevant community' with a normative understanding of what is accepted by community's values. The panel did not further clarify these concepts, but we may find some guidance in the literature. Senftleben, for example, sustains that exploitation is common within a relevant community if most patent owners use this area to extract value from their patents. If this type of exploitation is also essential to the achievement of goals of patent policy, then the exploitation should be considered as normal.[27] In addition, the panel argued that 'the normal practice of exploitation by patent owners, as with owners of any other intellectual property right, is to exclude *all forms of competition* that could detract significantly from the economic returns anticipated from a patent's grant of exclusivity'.[28] As Prof. Correa notes, the normal exploitation of patent rights consists of 'the acts of making, using or commercializing the inventions without third parties' competition.' This means that the exclusion of competition is not a form of exploitation of the patent, 'but a legal power established by law that may be exercised or not.'[29] Prof. Correa further questions the exclusion of 'all forms of competition' since improved patented products may legitimately compete with the original ones. In terms of the issue at hand, this reasoning can be better understood by referring to the concept of essentially derived varieties (EDVs) explained in Chap. 4. UPOV 1991 requires a minimum genetic distance between EDVs and the original variety in order to grant protection to EDVs. The distinction between original varieties and

[26] Para. 7.59 WT/DS114/R.

[27] Senftleben (2006), pp. 407 and 428.

[28] Para. 7.55, emphasis added WT/DS114/R.

[29] Correa (2005), p. 12.

EDVs is therefore based on genetic differences. When the genetic differences[30] satisfy the requirements set by UPOV, the improved variety (EDV) legitimately competes with the original one. Patent rights, on the other hand, may exclude improved products from competition. This is because the scope of patent rights often covers all material where the patented element is incorporated or where it performs its function. With regard to plant breeding, patent rights extend to all those varieties that contain a patented genetic construct. Patented biological material may be used (and crossed out in the breeding process) for creating varieties with different traits from the patented material. In this case, the new variety does not enter into direct competition with the first innovator. The commercialization of these improved varieties would foster two main objectives of competition law: consumer welfare and the opportunity of breeders to legitimately compete in the market. Undoubtedly, new and improved varieties increase consumer welfare. The opportunity to compete in the plant breeding market is equally relevant since competition motivates breeders to invest in plant variety creation. This reasoning implies that excluding all forms of competition from 'normal exploitation' does not respond to the rationale of patent law to foster innovation and diffusion of knowledge.

In the panel's view, however, 'normal exploitation' should be in line with the *changing forms of competition* due to technological progress and evolution of marketing practices. It is unclear whether this reasoning refers to actual or potential exploitations of patented inventions. If the latter is considered as prevalent, patent exceptions risk losing their effectiveness. As one author reasonably argues, new technical findings open up new possibilities for exploiting the patented invention.[31] It is opinion of the author of this book that only the profit derived from the *actual* application of patents as ordinarily employed by patent holders, should qualify as 'normal'. An ordinary use of patents involves acts such as, making, using, selling, offering for sale, importing and licensing patented products.[32] The interpretation issue here is whether the breeding exception conflicts with the normal understanding of such exploitation. Building upon Senftleben's reasoning, it is argued that exploitation is common within a relevant community if most patent owners use this area to extract value from their patents. If this type of exploitation is also essential to the achievement of goals of patent policy, then the exploitation should be considered as normal. Thus, the following paragraphs first look at how inventors generate profits and then assess the public policy pursued by national laws.

With regard to the empirical element, the normal practice of deriving value from patent rights is that of selling patented products or rights, or licensing patent rights. The breeding exception does not detract the profits obtained by commercializing patented products, but it diminishes the profits that patentees might obtain by licensing their rights for breeding purposes. Here the matter is that of defining if

[30] Note that the definition of genetic distance is a controversial point. See better Chap. 4.

[31] Geiger (2007).

[32] See article 28 of TRIPS.

profit detraction is significant so as to impede investments on innovative products. Considering that patentees maintain the right to commercial licensing, they might increase the licensing fee and still capture a high profit if this is deemed necessary for recouping the incurred R&D costs. Hence there is no reason to see the breeding exception as a significant detractor of patentee's profit. With regard to the normative aspect, the goals of national patent policies come under scrutiny. Dutch, German, French, and Swiss laws grant a temporal right of 20 years to exclude competitors, but at the same time they establish maintenance fees for patents.[33] When fees are not paid, patent protection lapses. As a consequence, protected knowledge becomes publicly accessible before the expiry term. This reasoning seems to recognize the fact that patents are a cost on the society. Indeed, studies have shown that not all patents make it through their entire term. In Germany, for example, the average patent life is less than 8 years.[34] Moreover, if the patentee declares his willingness to grant licenses, maintenance fees are halved in Germany. Considering that licenses allow other parties to improve the original invention, this provision shows the intention of the German legislator to promote follow-on innovations.

All these considerations indicate that the public policy goal followed by the concerned countries is that of enabling follow-on innovations. An exception to patent rights for breeding purposes fully supports this objective.

In the EC-Canada case, the panel also clarified whether the market exclusivity following the expiry of a patent was 'normal'. Adopting a flexible approach, the panel stated that:

> Some of the basic rights granted to all patent owners, and routinely exercised by all patent owners, will typically produce a certain period of market exclusivity after the expiration of a patent. For example, the separate right to prevent 'making' the patented product during the term of the patent often prevents competitors from building an inventory needed to enter the market immediately upon expiration of a patent. There is nothing abnormal about that *more or less brief* period of market exclusivity after the patent has expired.[35]

The interpretation of 'more or less brief' further complicates drawing a clear line between 'normal' and 'abnormal'. The panel, however, neglected the definition of the relevant 'normal' period. It solved this problem by determining that the additional period of *de facto* market exclusivity is:

> an *unintended* consequence of the conjunction of the patent laws with product regulatory laws, where the combination of patent rights with the time demands of the regulatory process gives a greater than normal period of market exclusivity to the enforcement of certain patent rights.[36]

[33] For an overview of the fees in these countries see: http://www.patentvista.nl/kosten_taksen_overzicht_en.php, accessed 16 March 2014.

[34] Fewer than 5 % of German patents remain in force during their entire term. See Cooter and Ulen (2011), p. 123.

[35] Para. 7.56 WT/DS114/R, emphasis added.

[36] Para. 7.57 WT/DS114/R, emphasis added.

This greater period of protection was considered to be not normally employed by most patent owners. An accurate examination of the breeding exception further requires an investigation of the erosion of patentee's market exclusivity. Patent holders enjoy *de jure* market exclusivity during the 20 years of the patent term and a *de facto* exclusivity after patent expiry. We can define the period of *de facto* exclusivity by looking at the development time of plant varieties. Breeding is a lengthy process that may take from 7 to 15 years.[37] This means that in absence of a breeding exception, the *de facto* market exclusivity may range from 27 to 35 years. The exclusive protection is further extended in case of varieties containing or resulting from genetically modified organisms. Commercializing new genetically modified varieties may take several years since an assessment of compliance with biosafety regulations is required under national and international regulations.[38] This procedure can significantly delay the entry of plant varieties in the market. In this case, the *ex post* monopoly may exceed 20 years by doubling the normal patent life.

In terms of the issue at hand, it is worth drawing the attention of the reader to the fact that the first patentee faces the same hurdles. Long regulatory approvals reduce his market exclusivity. If competitors put varieties containing the patented element into the market, patent exclusivity could be even more significantly limited. The problem, however, might emerge only when competitors commercialize varieties containing patented elements that significantly deprive patent holders from recouping the initial R&D costs.[39] R&D investments may be recovered by selling the products and licensing. But depending on the market conditions (free entry, high competition), products sales and licensing fees might not be sufficient for compensating R&D costs. Economic theory considers the recoup of R&D costs as a basic element for the patents to work as an incentive for innovations.[40] In this view, optimal patent term should be long enough to compensate the innovator for the R&D expenditures. But the definition of the optimal length is still an open question.[41] The optimal patent term might vary for different technological sectors and for different type of patents (processes or products). Hence it is difficult to assess whether the introduction of the breeding exception will undermine the returns on R&D. Some innovations might require a patent term of 5 years, others 10, 15 or 20 years, while others might not necessitate patents to recoup the initial R&D investments (e.g. the lead-time gained by the innovator may be sufficient, as it is often the case).[42] If patents were not relevant for recovering R&D costs for some

[37] British Society of Plant Breeders (2000).

[38] The European Food Safety Authority (EFSA) is the competent authority within the EU, http://www.efsa.europa.eu/en/topics/topic/gmo.htm. For recent developments on this topic see Gillam (2012).

[39] Please, note that new varieties do not necessarily contain patented elements. Patented genes are often crossed out in the breeding process.

[40] For a better explanation see Chap. 4.

[41] For further argumentation see Langinier and Moschini (2002).

[42] See better the article from Nobel economist, Becker (2013).

innovations, the deadweight loss for the society would be significant. The society would not have access to new information and follow-on innovators would not be able to build upon the patented invention. In this case, the breeding exception would compensate some of the negative effects of these types of patents. The same logic applies in cases where the patent term is longer than the term required to recoup R&D investments. Problematic aspects will arise when a 20-years patent term will be necessary for recovering the initial investments. If this were the case, biotechnological companies would speak up against the breeding exception. To the author's knowledge, this has not yet happened. Ten years have passed since the first breeder's exception was adopted by the French parliament in 2004. If the exception had had significantly deprived patent holders from recouping the initial R&D costs, concerns would had already been voiced by biotechnological companies. Therefore, introducing an exception to patent rights might not necessarily undermine the incentive to invent.[43]

6.3.3 Third Condition: Not Unreasonably Prejudice the Legitimate Interests of the Patent Owner, Taking Account of the Legitimate Interests of the Third Parties

In order to determine whether the exception prejudices the interests of patent owners and third parties, it is first important to clarify the meaning of 'legitimate interests'. In order to take account of interests of both parties—those of right holders and third parties—the panel adopted a broad interpretation of 'legitimate interest'.[44] It dismissed the European Communities' understanding of 'legitimate interests' as strictly defined within the legal meaning of article 28.1 of TRIPS. The WTO judges stated that this term 'must be defined in the way that it is often used in legal discourse – as a normative claim calling for protection of interests that are 'justifiable' in the sense that they are supported by relevant public policies or other social norms'. For illustrative purposes, the panel brought the attention to the experimental use exception already established in most of national patent laws. In this respect, it argued that the absence of such an exception would frustrate part of the nature that the invention be disclosed to the public. Disclosing patented knowledge for further supporting the advance of science and technology is considered to be a 'legitimate interest' of both society and the scientists.[45] Third parties, indeed, are parties who do not have a legal claim with respect to the patented

[43] This argument rejects suggestions to introduce supplementary protection certificates in order to compensate the 'loss' from reduced patent length. For more on this suggestion see Kock (2009), pp. 167 and 172–173.

[44] Para. 7.68, WT/DS114/R.

[45] Para. 7.69, WT/DS114/R.

invention. Only a broad interpretation of 'legitimate interests' allows us to take their interests into consideration.

6.3.3.1 The Legitimate Interests of Patent Owners

Although the main concern of patentees is profit maximization, the recoup of R&D costs seems to be a legitimate interest. According to utilitarian theory and some empirical studies, recouping R&D costs is essential for firms in order to preserve the economic incentive to innovate.[46] If this were not possible, firms would face great financial losses. Consequently, inventions may be impeded from coming into the market. The breeding exception, thus, should permit patent holders to recover R&D expenses. The difficulty of proving a direct correlation between patents and R&D decisions, however, does not allow drawing definite conclusions. Empirical studies have shown that the effect of patents on R&D decisions vary across industries and countries.[47] Moreover, a study of 26 OECD countries showed that patent rights are fragile determinants of R&D decisions.[48] As the head IP of Syngenta—Michael Kock—notes, it is not clear whether patents directly provide an incentive to invest into yield or yield is caused by an increased use of technology, which causes a higher use of patents.

Nevertheless, the role of patents in biotechnological innovation is deemed to be important.[49] But modern economists believe that weakening patent rights is not necessarily counterproductive. Evidence suggests that patent rights are not very important as a prerequisite for R&D.[50] Moreover, in the long run, patents increase returns, but make follow-on innovations more costly.[51] This means that patents increase returns for the first innovator but create barriers for follow-on innovators who need to access patented inventions. In the first case patents might increase the incentives for R&D investments, whereas in the second they might decrease the willingness to invest in R&D.

In light of these considerations, the introduction of a breeding exception might appear as a measure to facilitate innovations in plant breeding. The breeding exception, indeed, allows breeders to invent around the patented element, use the patented element and its genetic background to create new varieties. Undoubtedly, this deprives patentees from obtaining a profit from *ex ante* licensing. But profit-making is not the objective pursued by patent law. Patents are a tool to incentivize

[46] For further discussion see Kanwar and Evenson (2003), pp. 235–264; Machlup and Penrose (1950), p. 1; Landes and Posner (2003); Pugatch (2006).

[47] Arora et al. (2003); Hall and Harhoff (2012), pp. 541–565.

[48] Wang (2010), pp. 103–116.

[49] See Chap. 4, Part 2 for further argumentation.

[50] Scherer (2009), pp. 167–216.

[51] Boldrin and Levine (2008).

innovations. As such, they should be used in line with the public policy of facilitating plant breeding innovations.

The above argumentation is further supported by the findings of an *ad hoc* qualitative field research undertaken between December 2012 and February 2013. The aim of this qualitative research was to understand whether the introduction of the breeding exception is detrimental to innovation. The investigation was organized in the form of semi-structured in-depth interviews with stakeholders in the plant breeding sector representing private companies and industry associations in Germany, the Netherlands, and Switzerland. In the Netherlands, interviews also included relevant professional figures in the breeding sector.[52] The central result of this investigation is that the breeding exception seems to play no role on the R&D decisions of biotechnological companies. Industry representatives have no data on the innovativeness effect of its introduction, but they don't see it as a deterrent for R&D. One of the interviewees affirmed that the innovativeness of biotech companies operating in France, Germany, and Switzerland was not affected by the breeding exception. Although biotechnological companies point out that the breeding exception reduces a portion of their profits, they accept its introduction in order to enlarge the genetic background and further plant breeding. Some companies (KWS, for example) believe that the breeding exception drives innovation, whereas others (Syngenta) claim that the rationale of this exception is that of avoiding the problem of accessing genetic material rather than fostering innovation. On the other hand, plant breeders of major food crops make wide use of this exception and consider it essential for plant breeding innovations.[53] Most importantly, business firms themselves have no objections to the introduction of the breeding exception. Both small and big companies consider the breeding exception as an important means to access genetic material. Although they are aware that the introduction of a breeding exception to patent rights reduces their profits, they do not see it as a hindrance for innovation activities. Thus, the breeding exception does not prejudice the rights of patent holders.

6.3.3.2 The Legitimate Interests of Third Parties

Third parties are those that have a direct or indirect interest in plant breeding. According to the panel, a legal relation with the patentee is not necessary. Therefore, follow-on innovators (plant breeders, public breeding institutions, research centers, universities) and the society at large (governments, consumers) should all

[52] See Annex for a list of the interviewees.

[53] It is worth noting that the International Community of Ornamental and Plant Fruits Breeders (CIOPORA) has a diverging opinion. This category of breeders is concerned only with vegetatively propagated ornamentals and fruits. Only a few multinationals operate in this sector and the number of patents is very low. Thus, the breeding exception in patent law does not affect the sector of vegetatively reproduced ornamentals and fruits. Nevertheless, these breeders call for stronger rights and for a weakening of the breeder's exception in the UPOV Convention.

be considered as interested third parties.[54] The relevance of their interests stems from the significance of plant breeding for the whole society. International agreements, such as the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and the Convention on Biological Diversity (CBD) offer further evidence of the importance of societal interests.[55] One of the aims of the ITPGRFA and the CBD, for example, is to provide access to plant genetic resources.[56] By allowing breeders to freely access and improve patented genetic material, the breeding exception is instrumental for realizing the goals of the above treaties.

In addition, the introduction of a breeding exception to patent rights could lower what is now a high entry barrier for new companies wishing to enter the plant breeding sector. This would stimulate innovation and competition in plant breeding and society as a whole would benefit. Studies, indeed, have shown that patent amendments that facilitate entry and encourage competition might be an effective mechanism to encourage innovation.[57]

6.3.4 The Non-discrimination Clause of Article 27.1

In addition to article 30, the panel argued in the EC-Canada case, that patent exceptions are TRIPS-compliant when they satisfy the non-discrimination clause of article 27.1. Thus, the breeding exception is TRIPS-compliant when it does not discriminate 'as to the place of invention, the field of technology and whether products are imported or locally produced'. Considering that the breeding exception is specifically conceived for the plant breeding industry, it seems plausible to raise a conflict with the non-discrimination clause. The use of 'biological material' for plant breeding, in particular, may discriminate against other industrial sectors. 'Biological material' involves the use of plant material as well as additional material such as bacteria, viruses etc.[58] These types of materials are used in other industries as well (for example, some bacteria used to produce antibiotics can be used in plant breeding). An explicit use of such material for the purpose of creating

[54] The recognition of the legitimate interests of third parties redimensions the view on patent law. The latter, indeed, is shifting from its original narrow definition of private law towards a more social approach. See Schneider (2009), pp. 129 and 131.

[55] Note that the WTO system does not explicitly take social and cultural rights into account. Exceptionally, related arguments were brought up in the case of access to patented knowledge for pharmaceuticals. However, the WTO does not impede member states to consider social and cultural aspects. For more see Herstemeyer (2012), pp. 71–105.

[56] See arts. 5.2 and 6 of the ITPGRFA and arts. 1, 15.2, 16 of the CBD.

[57] Moser (2013), pp. 3–22.

[58] Article 26.3 of the Implementing Regulations of the European Patent Convention and paragraph 2403 of the US Manual of Patenting Examining Procedure.

other plant innovations may create discrimination with regard to other sectors such as pharmaceuticals and biofuels.

The first question to ask in this regard is that of the meaning of 'non-discrimination'. Given the broadness of the term, the panel explicitly refrained from giving a definition,[59] but it distinguished between *de jure* and *de facto* discrimination. With regard to the *de jure* discrimination, it examined whether the patent exception was legally available to every product that was subject to marketing approval requirements.[60] In the case of *de facto* discrimination, it explained that it occurs when the actual effect of the norm is to impose differentially disadvantageous consequences on certain parties, and because those differential effects are found to be wrong or unjustifiable.[61] Additionally, the panel clarified that the word 'discrimination' is to be distinguished from 'differentiation' and that the WTO Members can adopt different rules for particular product areas, provided that the differences are adopted for *bona fide* purposes.[62] Third parties in the proceeding also suggested that not all differential treatment is 'discrimination'.[63] It appears, thus, that a key issue for understanding the meaning of 'discrimination' is defining the term 'differentiation'. The terms used by the panel 'differentially disadvantageous consequences' which are 'wrong or unjustifiable' are important in order to distinguish 'discrimination' from 'differentiation'. The above terms denote a value of judgment about the consequences of the exception. Thus, 'discrimination' arises whenever it produces unjustifiable negative effects. 'Differentiation', on the other hand, seems to have a neutral meaning because it simply refers to the act of recognizing or ascertaining differences. Dictionaries, for example, always relate one of the definitions of 'discrimination' with prejudice, but suggest no similar connection with regard to 'differentiation'.[64] This suggests that 'discrimination' arises when there is 'differentiation' without justification. In terms of the issue at hand, the question to be posed is whether there is a justification for a differential treatment of the plant breeding sector.

To this purpose, article 27.1 itself can help us to shed light on the issue. The second sentence of article 27.1 restricts the applicability of the non-discrimination clause to the provisions of paragraph 3. In the context of the breeding exception, the second sentence of paragraph 3.b is extremely relevant. Here, TRIPS allows for patents or a *sui generis*[65] system or a combination thereof for the protection of plant varieties. This paragraph seems to be designed for the plant breeding industry. Taking into account the characteristics of plant breeding, TRIPS recognizes the

[59] Para 7.98, WT/DS114/R.

[60] Para 7.98, WT/DS114/R.

[61] Para 7.101, WT/DS114/R.

[62] Para 7.92, WT/DS114/R. See also UNCTAD-ICTSD (2005), p. 370.

[63] Para 7.100, WT/DS114/R.

[64] See the online Oxford and Merriam Webster dictionary.

[65] '*Sui generis*' is a Latin phrase that means 'of its own kind', thus it denotes the particularity of a system.

peculiarities in the economic development of countries in this sector and provides for a special protection. Therefore, the justification for differentiating the plant breeding sector can be found in the body of TRIPS.

To further support the reasoning of the panel, the exception should be issued on good purposes. Thus, the question becomes whether the breeding exception is a *bona fide* exception that deals with problems that may exist in plant breeding.[66] The answer is affirmative. As already explained in the beginning of this chapter, the very purpose of the breeding exception is that of overcoming the difficulties of accessing patent material relevant for plant breeding purposes. The need to overcome this problem is particularly compelling given the crucial role of plant breeding in food supply.

However, questions may arise as to the extent to which *bona fide* may justify exceptions to patent rights. Some guidelines can be found in the Doha Declaration on the TRIPS Agreement and Public Health which advises a differential treatment for public health-related patents.[67] The rationale of this special treatment is linked to the importance of health for human life. This choice can be better understood if we keep in mind that law is an instrument at the service of our society and it could never take precedence over basic principles that protect human life. Therefore, superior principles that guide the adoption of the law should motivate the *bona fide* of patent exceptions. The same logic can be applied in plant breeding. Given the renowned importance of these activities in food security, it appears reasonable to differentiate in the treatment of patent rights in the plant breeding sector. In order to better comprehend the role of plant breeding in this regard, it appears necessary to clarify the concept of food security. 'Food security' was first coined during the 1996 World Food Summit. It was explicitly stated that 'food security exists when all people, at all times, have physical and economic access to sufficient, safe and nutritious food that meets their dietary needs and food preferences for an active and healthy life.' It is widely accepted that this concept of 'food security' involves four dimensions: food availability, food access, utilization, and stability.[68] Plant breeding plays a direct or indirect role in all of these dimensions. With regard to food availability and stability, it ensures the basis for sufficient quantities of food resources at all times. A sufficient quantity of food indirectly facilitates access and utilization of food. Undoubtedly, the full realization of these dimensions of food security requires an adequate socio-economic environment.[69] But the role of the breeding exception should not be underestimated. The breeding exception can represent an important legal instrument for implementing the policy concept of food security. The importance of the exception is inherent in its capacity of providing a constant and sufficient source of food supply. This role of the breeding exception is particularly relevant given the interdependence of countries on genetic

[66] Para 7.92, WT/DS114/R.

[67] See UNCTAD-ICTSD (2005), p. 374.

[68] For a better explanation see *Food Security*, FAO Policy Brief, June 2006, Issue 2.

[69] For more see the FAO (2005).

resources for food and agriculture (GRFA). Climate change is envisaged as a decisive factor in increasing countries' interdependence on GRFA. Local self-sufficiency might not be possible in view of climate changes impact on the suitability of currently adapted landraces and varieties.[70] Therefore, the breeding exception plays a crucial role in realizing the abovementioned dimensions of food security in the present and in the future. The role of the exception in the future is inevitably linked to the concept of 'intergenerational equity' explained in Chap. 3 of this study. A comprehensive approach to 'intergenerational equity' should take account of the breeding exception as a means for achieving food security.

Turning to the analysis of article 27.1, it should be further noted that the option to combine patent protection with a *sui generis* system opens up opportunities for countries to adapt the patent regime to their specific needs of food security.[71] As already illustrated in Chap. 4 of this study, some Asian countries have adopted plant variety protection regimes that differ from UPOV. The Indian legislation, for example, provides for specific rights for farmers. In this case, the combination of patent rights with the Indian *sui generis* regime might support the introduction of other amendments to patent law that allow farmers to save, use, exchange and sell farm saved seed. A similar provision is foreseen under article 11 of the EU directive on the legal protection of biotechnological inventions, which combines patent rights with the farmers' privilege envisaged in article 15.2 of the UPOV.

6.3.5 The Reasonableness Test

The last two conditions of article 30 require the interpreter to assess whether the breeding exception is reasonable if it were found in conflict with the normal exploitation of the patent or with the legitimate interests of the patent holder and the interests of third parties. The panel did not offer any indication on the meaning of this requirement since it found that the Bolar exception was not in conflict with the requirements of article 30.[72] The literature suggests that a conflictual exception is reasonable when it is proportionate to the objective that it intends to achieve.[73] The achievement of such an objective should produce social benefits capable of overcoming the harm to patentees and third parties' interests. For example, providing more innovative plant varieties creates social benefits that go beyond the economic loss of all economic actors. With these important considerations in

[70] Fujisaka et al. (2011). For the role of human action on GRFA interdependence see Hufler and Lefber, pp. 237–248.

[71] For a further discussion of the role of IP in food security, see Tansey (2012).

[72] Para. 7.59, WT/DS114R.

[73] For the need to interpret the three-step test in the light of the proportionality principle see Kur (2011), p. 246.

mind, this chapter elaborates a broader legal framework for analyzing 'reasonable exceptions'.

It first starts with a textual interpretation based on a literal reading of terms. The Oxford dictionary defines 'reasonable' as 'having sound judgment; fair and sensible'; 'not as much as is appropriate or fair; moderate'. In these terms, a reasonable exception is the one that is fair and appropriate, that does not excessively impair the rights of the patent holder. Applying these general terms to the breeding exception is, however, not an easy task. It requires a judgment of balance based on TRIPS goals and principles. The preamble of TRIPS gives indication of these goals and principles, which further serve as a source of interpretation.[74] The fifth paragraph of the preamble, for instance, recognizes 'the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives'. This paragraph has been incorporated in articles 7 and 8 of the TRIPS Agreement. Article 7, jointly with article 8 and the preamble are considered of particular importance for interpreting the rights enshrined in the body of TRIPS.[75] In addition, the panel in the EC-Canada case, affirmed that 'both the goals and limitations stated in articles 7 and 8.1 must obviously be borne in mind when doing so as well as those of other provisions of the TRIPS Agreement which indicate its object and purposes'.[76]

An understanding of 'reasonable exceptions', therefore, should take these articles into consideration. In addition, article 1.1 which allows WTO Members to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice is relevant. Article 1.1 provides some flexibility for complying with the obligations stemming from TRIPS. The qualification of a 'reasonable' or 'unreasonable' measure would, thus, require an investigation of 'the conceptual framework that underpins the granting of patents in a given jurisdiction and at a certain point in time'.[77] This necessitates a weighing of different interests involved in the light of the proportionality principle. The limit that a 'reasonable' exception should face in this respect is its scope.[78] Only exceptions that restrict patent rights as much as necessary as to achieve their objectives may be admissible. The following paragraphs will deepen these considerations in relation to the breeding exception. If the breeding exception satisfies the requirements of the above provisions, it will be deemed a 'reasonable' measure even if it conflicts with the normal exploitation of the patent.

[74] In accordance with article 31.2 of the VCLT. See also UNCTAD-ICTSD (2005), p. 2.

[75] For more see Correa (2007), p. 92; Stoll et al. (2009), p. 180. Moreover, articles 7 and 8 have been identified as relevant in interpreting the TRIPS Agreement by the Doha WTO Ministerial 2001.

[76] Para. 7.26, WT/DS114/R.

[77] Correa (2007), p. 309.

[78] Correa (2007), p. 309; Kur (2011), p. 246.

Article 7 (Objectives)

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Although the vague language of this article reflects developing countries' concerns about the impact of IPRs on their economic and social development, it may serve as a fertile ground for identifying its role in several areas. One role of article 7, for example, may be that of facilitating the development of future exceptions and limitations.[79] The applicability of this provision on patents can be deducted from its explicit reference to 'technology' and 'innovation' on patent protection.[80]

While defining the objectives of TRIPS,[81] article 7 highlights the promotion of technological innovation and the transfer and dissemination of technology as the guidelines for protecting intellectual property rights. 'Technological innovation' is a term broader than 'technical invention'. The latter refers only to technical knowledge, while the former covers the whole period of R&D up to implementation, leading to commercial maturity.[82] Article 7, thus, promotes innovation beyond simple inventions. If we look at the breeding exception, we see that its main purpose is that of enabling 'technological innovation' by facilitating access to patented knowledge. With a breeding exception, breeders develop new products which further commercialize into the market. Besides, the breeding exception furthers the 'transfer and dissemination of technology' defined in general terms as availability of technical knowledge. Indeed, the breeding exception makes freely available the use of patented technical knowledge in the breeding process. If the breeding exception were not adopted, breeders would be forced to enter into long and costly licensing negotiations which would delay (or prohibit in case of license denial) the transfer and dissemination of technology. This reasoning implies an inherent economic trade-off in patent law between the interest to incentivize and ensure access to innovations. The breeding exception weakens patent rights to counterbalance the negative effects of patents on the transfer and dissemination of technology and therefore, facilitate access to innovation. The exception, on the other hand, should not undermine the incentive to invest in new technology. Indeed, article 7 of the TRIPS Agreement explicitly requires that IP protection should lead to the 'mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and

[79] For more on this issue see Yu (2009), p. 12.

[80] Correa (2007), Stoll et al. (2009), and UNCTAD-ICTSD (2005).

[81] Pires de Carvalho sustains that this article does not indicate the objectives of TRIPS, but those of the protection and enforcement of some IPRs. He admits though the relevance of article 7 in interpreting the Agreement. See de Carvalho (2006), p. 172.

[82] Keßler in Stoll et al. (2009), p. 182 citing Machlup (1958) and Demaret (1978). The distinction between 'innovation' and 'invention' was first recognized in the theory of economic development by Schumpeter.

obligations'. These broad and general terms reflect a compromise between the diverging opinions of developed and developing countries.[83] The balance of rights and obligations, therefore, should be understood in a large social context, disregarding their legal meaning. In these terms, the balance would lay in reconciling the economic interests embedded in patent rights with the moral obligation of disclosing the patented invention for the larger benefit of the society. But the 'balance between rights and obligations' is understood by some as relevant for promoting individual interests as well.[84] In these terms, the quest for 'balance' may require to strengthen the position of follow-on innovators (breeders) who build on earlier patented inventions.

The term 'balance' has been traditionally associated to a 'desirable equilibrium between at least two forces that is characterized by cancellation of all forces by equal opposing forces'.[85] Within this definition, the term 'equilibrium' as used by economists promotes 'efficiency' matters. This means that policymakers focus on providing the right incentives to economic actors rather than on the distributive values of the patent system. This is mainly due to the complexities and the inaptness of the present institutional design to achieve a balance through distributive decisions. Legal scholars, on the other hand, offer a more comprehensive approach of 'balance' that takes account of weak parties' interests in view of development objectives.[86]

The introduction of the breeding exception supports both understandings of 'balance'. From an efficiency point of view, the exception provides incentives to newcomers to enter the plant breeding market and innovate. At the same time, it preserves the incentives to innovate of patent holders since it maintains their right to sell the protected subject matter and to grant commercial licenses, and thus, the recoup of their investment cost. In view of the development objectives perspective, the breeding exception brings about more innovation into the market by making biological material freely available. In addition, it supports the interests of 'weak' breeders who do not have the necessary financial resources to identify the relevant infringing patents and ask for a patent license. This undoubtedly increases the benefits for the society. A balance of rights and obligations, though, should be imposed on both parties since both patent holders and breeders can be producers and users of technological knowledge. The balance resides in the obligation of patent holders to inhibit the exercise of their rights with regard to the use of the invention for breeding activities, combined with their right to prevent the use of the invention for commercializing final breeding products.

[83] Correa (2007), p. 91.

[84] Keßler in Stoll et al. (2009), p. 184.

[85] Wechsler (2009), p. 2.

[86] *Ibidem*.

Article 8.1 (Principles)

> 1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

This provision does not clearly state rights and obligations, but adopts an open and all-comprehensive language. This allows a large margin of discretion for its interpretation. Commentators, indeed, argue that article 8.1 may have several interpretative functions.[87] Among these, its role in the interpretation of TRIPS is relevant for the purpose of this analysis. As already argued above, the panel stated that both the goals and the limitations of Article 8.1 must obviously be borne in mind when interpreting the words of the conditions in art. 30.[88] Thus, whenever a state challenges another's state breeding exception, and the panel finds that this measure conflicts with article 30, the reasonableness test should allow the panel to take the principles of article 8.1 into account. The next paragraphs seek to understand whether the breeding exception can be deemed reasonable in light of the principles enshrined in article 8.1.

The breeding of plants is an important activity in agriculture, as well as other industrial sectors, including textiles and forestry. Hence its vital importance in *socio-economic and technological development* stems from its broad and significant role in several industrial sectors.[89] This means that the breeding exception can be considered as a measure adopted by states to promote the public interest of facilitating and enriching the creation of genetic variety in a sector of vital importance such as plant breeding.

To define if a breeding exception reflects the principles of this article, the 'necessity' and the 'consistency' of the exception should be further examined. The meaning of these terms in the context of TRIPS has not been yet clarified by the WTO jurisprudence. However, some guidelines on 'necessity' can be found in WTO jurisprudence in the area of GATT and GATS, though they cannot be automatically applied to TRIPS provisions.[90]

Nevertheless, we can try to identify the rationale behind the 'necessity' applications and relate it to TRIPS since all WTO Agreements serve the same purposes of promoting trade. In the area of GATT and GATS exceptions, panels apply a necessity test which combines three main elements: the measure to be tested; the objective pursued; and, the necessary link between the measure and the objective. Defining this last element seems to be at the heart of every WTO decision, thus, we focus our attention on whether the breeding exception is a necessary measure to

[87] See Correa (2007), p. 108; Gervais (2008), p. 209; de Carvalho (2006); UNCTAD-ICTSD (2005), p. 127.

[88] Para. 7.26 WT/DS114/R.

[89] The definition of sectors of vital importance in socio-economic and technological development is, however, a matter of national policy.

[90] For more on this issue see WTO (2003).

achieve public policy objectives by states. In this respect, it is worth noting that article 8 does not require states to adopt measures to achieve public interests. It simply states that states may adopt measures necessary to *promote* public interest. This loosens the 'necessity' test requirement since states 'need not prove that such measures actually achieve their intended objectives, but that they are suitable to do that in the particular context where they apply'.[91] Following this line of interpretation, the breeding exception seems to satisfy the necessity requirement. It certainly constitutes a suitable measure for promoting innovation in plant breeding since business firms themselves accept its introduction to patent rights. The breeding exception is also less trade restrictive compared to other measures available to states. An alternative to the breeding exception would, for example, be that of excluding biological matter from patentability. This solution would restrict trade to a greater extent than the limited breeding exception.

It should be noted, however, that states can adopt measures inspired to the principles of article 8.1, provided that they are *consistent* with the TRIPS provisions. Here interpretative problems arise because the 'reasonableness test' is applied only if the breeding exception is found to be not consistent with article 30. In this regard, it is worth reminding the reader that article 27.3.b requires Member countries to patent micro-organisms, non-biological and microbiological processes, but does not oblige them to provide patent protection for plant varieties. Patent rights, however, may extend to plant varieties when varieties incorporate a protected micro-organism. The breeding exception limits the effects of such patent extension with regard to the breeding phase. If the function of article 8.1 is that of clarifying that 'Members must not take measures which systematically undermine the level of intellectual property protection guaranteed by TRIPS',[92] countries that provide for patent protection but subject the exploitation of patent rights to certain obligations in order to comply with other TRIPS provisions should be deemed compliant. In this regard, a conflict between article 27.3.b and article 30 is to be excluded since the provision of article 27.3.b is a specific exception while article 30 represents a general exception.[93] By virtue of the legal maxim, *lex specialis derogat legi generali*, the rules of article 27.3.b prevail. This interpretation does not aim at weakening the rules contained in article 30, but at ensuring effectiveness of interpretation of the text of the treaty. In the event that a panel or the Appellate Body considers the breeding exception as non compliant with article 30, a careful reading should take other provisions related to plant breeding into consideration. In this way, the interpretation can permit the realization of the purposes of the treaty to the highest extent possible.

[91] Correa (2007), p. 105.

[92] Stoll et al. (2009), p. 198.

[93] For an explanation of the general and specific exceptions provided by TRIPS, see Gervais (2008), pp. 380–381.

Article 1.1 (Nature and Scope of Obligations)

> Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

This article allows Members to freely determine the appropriate method of implementing the provisions of TRIPS within their own legal system and practice. The question here is whether the breeding exception would be an appropriate method for implementing article 30 of TRIPS. As already argued while introducing the 'reasonableness' test, national laws provide the grounds for analyzing the 'appropriateness' of the implemented method. Thus, if we consider national patent laws, we note that a similar exception for research purposes has been widely accepted by most countries.[94] This conclusion can be further supported if we take into account the practices of Germany, France, the Netherlands, and Switzerland regarding patent exceptions for research purposes. The last period of article 1.1 allows states to determine an appropriate method within their own legal systems and practices. Considering that the aforementioned countries have implemented patent exceptions in their national laws prior to the provision on the breeding exception, the introduction of the breeding exception seems to be in line with their legal system and practice.

But an appropriate method should be reasonable. Here, a reasonable exception is deemed one that is proportionate to its final aim. Thus, if the scope is too broad with regard to its intended objective, the exception cannot be considered as proportionate to its final aim. In terms of the issue at hand, the aim of the patent exception is that of supplying a constant flow of genetic variation in the breeding sector for creating new varieties of plants. The exception involves only these acts necessary for accessing patented material. After accessing this material, breeders use it in their breeding processes and create new plant varieties. At this stage, all breeding acts are limited to the use and enrichment of genetic variety. It is apparent that the scope of the breeding exception is strictly guided by the necessity to acquire the necessary material for further breeding. In these terms, the breeding exception can be considered as an 'appropriate' method of implementing article 30 of the TRIPS Agreement.

All the above considerations, allow us to deduce that the breeding exception as formulated in the patent laws of the aforementioned countries does not conflict with the normal exploitation of the patent. Even if the opposite were argued, there should be no unreasonable conflict in light of articles 7, 8, and 1.1 of the TRIPS Agreement.

[94] Correa (2005) and Bently et al. (2010).

6.3.6 The Reasonableness Test and the Link to International Trade

The reasonableness test purported above builds around the TRIPS preamble as an indicator of its goals and principles. The analysis showed the importance of paragraph five of the preamble in defining these goals and principles. Along with paragraph five, paragraph one plays a significant role in further clarifying the reasonableness test. One of the aims of this paragraph is the reduction of distortions and impediments to international trade, taking into account the need to promote effective and adequate protection of intellectual property rights.[95] The link between trade and IPRs was first proposed by developed countries during TRIPS negotiations, which purported that introducing international trade rules for intellectual property would contribute to more order and predictability in trade relations. Setting minimum standards for intellectual protection was seen as a means to alleviate trade tensions stemming from different national laws.[96] These tensions became more pressing after the rise of knowledge-based industries.[97] These industries invest considerable financial resources in innovation, research and development, to produce new knowledge embedded in final products. Therefore, most of the value of their products lies in the newly created knowledge. Before TRIPS, developed countries had specific IPRs to protect different knowledge-based industries but most of the developing and least developed countries lacked similar provisions. It is apparent that the lack of IP protection in some countries was not commercially appealing for business firms. It was already explained in Chap. 4 that knowledge could be easily imitated, reproduced at a lower cost than the first inventor, and cause substantial economic losses to the first inventor. Hence the need to require IP protection in developing and least developed countries. This view was initially rejected by these countries based on the North–South asymmetry in the capacity to innovate.[98] Indeed, the enormous discrepancy in innovation capabilities undoubtedly advantages the economies of developed countries. Afterward, under the pressure of US trade retaliations and the need to influence the outcome of TRIPS negotiations, developing and least developed countries changed their perspective.[99]

[95] '*Desiring* to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade.' Compare with the preamble of the 1947 General Agreement on Trade and Tariffs (GATT), which purpose is 'the *substantial reduction of tariffs and other trade barriers* and the elimination of preferences, on a reciprocal and mutual advantageous basis' (emphasis added).

[96] WTO (2011), p. 39.

[97] Note that there are additional factors that contribute to trade tensions. For more see Reichman (1995), pp. 345 and 346.

[98] Developed countries accounted for more than 90 % of global R&D expenditures in the 1990s. See Correa (2011), p. 154.

[99] For a better explanation, see *supra note*, pp. 154–156.

The aim of this brief excursus is to highlight the divergent positions of WTO countries in applying the principles of GATT to IP-related matters during TRIPS negotiations. This is especially relevant since negotiations are a means of treaty interpretation. What specifically emerges from TRIPS negotiations is the controversial relationship between IP and trade. It should be clarified that trade *per se* is not questioned here. What matters in terms of the issue at hand is the role of IP in promoting trade. The reluctance of developing and least developed countries to link IP with trade finds justification in the literature. An authoritative investigation of basic theoretical models and empirical evidence concludes that IP protection in the South leads to less foreign direct investment and innovation. The empirical evidence, in particular, shows an ambiguous relationship between strong patent protection and trade value. Patents seem to promote inward flows of imports and foreign direct investment only in large and middle income countries.[100] A recent quantitative analysis further supports the finding that the impact of IPR on trade varies according to the level of economic development of countries.[101] This study differentiates between factor-driven, efficiency-driven, and innovation-driven economies. For factor-driven countries, it found that a strong IPR can make it difficult to access technological goods and services in order to produce products with a higher added value. These countries compete mainly through cheap labor and natural resources and the amount of innovation in these countries is very small. Hence there is no advantage in adopting patent rights. For efficiency driven and innovation-driven countries, the above study argues that the impact of IP on trade is unclear. This is mainly because intellectual protection has both good and bad effects on trade that cancel each other. Innovation, however, is cited to be one of the good aspects of intellectual property rights. It could be argued that the positive spillovers will affect factor-driven countries. This might be true for some aspects, but it does not seem to hold with respect to trade flows. The reason is to be found in the low economic development and weak patent protection of these countries. Since the impact of IPRs on promoting trade seems to be quite unclear, there would be no reason to object the introduction of a breeding exception to patent rights.

In terms of the breeding exception, a relevant question would be whether it impedes trade between countries. As per now, there have been no complaints or evidence suggesting a negative impact of the breeding exception on trade flows and innovation.[102] In light of the findings of the abovementioned investigations, such complaints would be very unlikely.[103] The irrelevance of the breeding exception on R&D decisions of biotechnological firms suggests that there is no reason to

[100] Saggi (2008), pp. 329–355. See also Saggi (1999).

[101] Prasetyo et al. (2013). Moreover, this study found that IPR protection has either had a negative impact on trade or no impact at all for the year 2011.

[102] On the contrary, a recent empirical study has found that the tightening of IPRs after the adoption of the TRIPS Agreement in 60 developed and developing countries, has negatively effected trade in these countries. See Campi and Duenas (2014).

[103] This information is based on some of the interviews conducted for the purpose of this research. See Annex for a list of the interviewees.

interrupt investments in countries with a breeding exception. Conversely, it might be argued that the breeding exception facilitates trade since it incentivizes small breeders to undertake more breeding projects and consequently, produce more varieties that respond to different market needs. Most importantly, the lack of clear empirical evidence on the relationship between IPRs and trade suggests that it would be unwise to see the exception as a barrier to trade. Although the above mentioned studies should be collocated in a broader context that takes account of worldwide trade flows and of the long term impact on economic development, they represent an important signal for further investigating the role of IPRs on trade. Therefore, it would be recommendable that panels and the Appellate Body pay attention to the link between IP protection and trade. If this link were found to be weak, there would be no reasons for objecting patent exceptions.

6.4 A Comprehensive Breeding Exception Under Article 30 of the TRIPS Agreement

As already anticipated in Chap. 4 of this book, the Dutch Association of Plant Breeders (Plantum) has recently advocated the introduction of a comprehensive breeding exception to patent rights. For clarity, it is worth to hark back to the proposed formulation of such exception: 'The effects of a patent shall not extend to the use of biological material for breeding, discovery and development, and commercialization of a new variety type'. This exception would allow for the breeding and commercialization of plant varieties containing genetic constructs that confer specific traits to plants. The commercialization of new varieties represents the main difference with the so-called limited breeding exception. An obvious consequence of this exception would be a considerable economic loss of patentees' profits. Therefore, its proposal is surrounded by large controversy. This controversy could be further lingered and fueled by the actual intention of the Dutch legislator to adopt a comprehensive breeding exception.[104] Against this background, the following analysis appears necessary in order to provide some clarifications on the feasibility of such exception in light of article 30 of TRIPS.

6.4.1 First Condition: Limited Exception

A first reading suggests that the comprehensive breeding exception might curtail all patent rights since its introduction would make patent licensing less appealing for

[104] See the two letters of Ms Sharon A.M. Dijksma, Dutch Minister of Agriculture, dated 27 June 2013, Vergaderjaar 2012–2013, 33 365 (R1987) Nr. 6 and 28 June 2013, Vergaderjaar 2012–2013, 33 365 (R1987) Nr. 8.

third parties operating in the breeding sector. This reasoning reflects the conclusions of the WTO panel on the stockpiling exception. Similar to the stockpiling exception, the comprehensive breeding exception allows for the commercialization of final products containing patented elements. In this regard, the panel stated that the 'make' and 'use' of patented products curtailed all patentees' rights and that the market benefits after patent expiry are within the purpose of patent rights. It further clarified that 'In theory, the rights of the patent owner are generally viewed as a right to prevent competitive commercial activity by others, and manufacturing for commercial sale is a quintessential competitive commercial activity'.[105] The panel, however, did not indicate the relevant period during which market benefits should be enjoyed neither defined what level of right's curtailment would be disqualifying. This would have been relevant in understanding the scope of patent protection. Most importantly, the panel did not analyze in detail the patentee's rights as provided for in article 28 of TRIPS. As clarified in the first part of this chapter, article 28, paragraph 1.a) lists the rights conferred by a patent where the subject matter is a product. For the sake of clarity, these rights are here described *ex novo*. Thus, the patent prevents third parties not having the owner's consent from the acts of 'making, using, offering for sale, selling, or importing for these purposes that product.' In order to understand the degree of curtailment, it is useful to assess how the comprehensive exception affects these rights. With regard to 'making', it is important to explain that the exception would not curtail the right of the patentee to prevent others from making the product. The comprehensive exception aims at using the patented product in breeding lines in order to further improve it. The final goal of breeders is not that of reproducing the invention, but the creation of a new variety containing a protected genetic construct. The creation of a new variety is not equivalent to 'making' the protected product. Under the comprehensive exception, the patentee additionally maintains the right to exclude others from offering for sale, selling, or importing the invention. The right to exclude others from 'using' the product is the only right that the exception would curtail. Here it should be noted that the 'use' of the product would be exempted only for breeding purposes. Similarly, the right to 'assign, or transfer by succession, the patent and to conclude licensing contracts' as set in paragraph 2 of article 28, would not be affected. The patentee will be free to license the patent though the introduction of a comprehensive exception would undoubtedly make patent licensing less appealing for the breeding sector. It appears thus that only a few rights will be curtailed after the introduction of a comprehensive breeding exception. But this does not seem to be relevant in light of the panel's reasoning. According to the panel, only the degree of curtailment plays a role in defining the 'narrowness' of the exception. Since the panel excluded economic considerations from the analysis of this first condition, it appears reasonable to look at the meaning of 'limited'. This term was already explained in the first part of the chapter. It is worth recalling that 'limited' indicates a restriction on 'size, amount or extent' or it refers to 'confined within limits'.

[105] Para. 7.35, WT/DS114/R.

The description in the first part of this chapter clarified that the comprehensive breeding exception is confined to the breeding sector. This means that the exception does not deprive the patentee from exercising his rights, but limits his right to prevent others from using the patented invention in the breeding sector. Since the curtailment of patentee's rights encounter a specific limit, it would be logical to assume that the comprehensive breeding exception is limited. Furthermore, it is worth reminding that the comprehensive exception is confined to plant characteristics and not to breeding processes. This should be seen as an additional specific boundary for the introduction of a comprehensive breeding exception. This understanding corresponds to Prof. Correa's proposal for qualifying limited exceptions to patent rights, as already mentioned in the first part of the chapter.

But this interpretation blatantly differs from the panel's reasoning with regard to the 'stockpiling exception' though the panel's report lacked a detailed analysis. The interpretation adopted by the panel has raised further concerns because it does not allow to investigate whether the exception is '*limited enough* in view of its purpose and potential impact'.[106] To support this view, a flexible reading of 'limited' might be carved out of TRIPS objectives and principles.[107] In these terms, the comprehensive breeding exception would be limited if it responds to TRIPS objectives and principles. The breeding exception would, for example, promote TRIPS objectives and principles when it incentivizes innovation in plant breeding. In support of this, it is worth reminding that the stimulation of breeding activities is the very purpose of the comprehensive breeding proposal. But such a broad interpretation encompasses social interests that go beyond the legal curtailment of patent rights as understood by the WTO panel in the EC-Canada case.

Another reading of 'limited' purports a provision that contains well-defined rights, instead of a vague and open formulation.[108] In these terms, a provision that lists the rights to be exempted can be considered 'limited'. The comprehensive breeding exception may, for example, specify the degree of curtailment of patent rights related only to specific patented genetic constructs. But this interpretative issue is a difficult one. A feasible solution may be that of exempting a limited number of plant varieties from patent infringement. This exception may regard the 64 crops listed in Annex I of the International Treaty of Plant Genetic Resources for Food and Agriculture (ITPGRFA). Given the role of these crops in furthering 'the objectives of conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of benefits arising from their use',[109] the exception may also promote TRIPS objectives and principles in the

[106] Kur (2011), p. 228. This view is supported by the European Board of Appeal (EBA) judgment on restrictions to patentability. In G01/07, *Treatment by Surgery/Medi-Physics* of 15 February, 2010, the EBA affirmed that exceptions to patentability are to be interpreted in a way that gives effect to their purposes.

[107] Rodrigues (2012).

[108] Senftleben (2006).

[109] See article 11.1 of the ITPGRFA.

technological field of plant breeding. This means that the exception may be qualified as 'limited' in view of the boundaries set by a specific number of crops as well as by the purpose of the exception. Even if the panel in the EC-Canada case did not take the purpose of the exception into account, a broad interpretation of the TRIPS Agreement may be necessary for plant breeding. As clarified in the first part of this chapter, article 27 of TRIPS allows countries to differentiate patent rights in the technological field of plant breeding. However, it is not easy to predict future choices since WTO panel decisions do not create binding precedents. Depending on the interests at stake and socio-political implications of the case, future WTO panels might consider any of the above interpretations while examining the compliance of a comprehensive breeding exception.

In conclusion, the reader's attention should be drawn to the fact that the analysis of 'limited exception' should take account of the purpose of the comprehensive breeding exception to promote plant breeding. This might be a sufficient condition to justify the limited nature of the exception.

6.4.2 Second Condition: Not Unreasonably Conflict with a Normal Exploitation of the Patent

In order to assess whether the comprehensive breeding exception conflicts with the normal exploitation of the patent, the empirical and the normative element of 'normal exploitation' should be examined. As already mentioned in the first part of this chapter, the panel related the first element to the practice of extracting profit by working the patent. When patent exceptions do not *significantly* detract from patentee's economic profit, a conflict cannot be depicted. The problem with a comprehensive breeding exception is that it may *significantly* deprive the patent owner from economic returns. If this type of exception to patent rights were to be introduced, the interest to obtain patent licenses would be reduced and consequently, patentees would reap less financial return on their investments. Since the value of the 'patent portfolio' is often understood as determinant in indicating the value of a company, the introduction of a comprehensive breeding exception may affect company's market value. In addition, a competitive disadvantage might be expected for breeding and biotechnological companies with intensive R&D activities. In the biotechnological sector, patents secure competitive advantage by signaling to venture capital investors that a firm has valuable assets. Evidence shows, for example, that patent applications are considered important to attract investors in German and British biotech companies.[110] If a comprehensive breeding exception were introduced, this role of patents would fail and fewer investments would be dedicated to biotechnological innovation activities. Therefore, it seems that a comprehensive breeding exception conflicts with the empirical element of

[110] Hall and Harhoff (2012), pp. 541–565.

'normal exploitation' of the patent as understood by the panel This reading, however, does not take account of the role of patent rights in promoting innovations. It has been argued several times in this thesis that the recovery of R&D investments as opposed to profit-making is the main purpose of patent law.

With regard to the normative element, national patent policies should come under scrutiny. As shown above, countries value the innovative role of patents. In this respect, it is not clear whether the introduction of a comprehensive breeding exception would help countries to achieve their innovation policies. Biotechnological companies, on the one hand, claim that a comprehensive breeding exception would decrease investments on innovative breeding traits, and, therefore, no benefit will accrue to the society. Plant breeders, on the other side, argue exactly the opposite. With a comprehensive exception they would access a wide range of biological material, which would allow them to easily breed innovative plant varieties. The issue is a difficult one and necessitates specific studies that analyze the effect of a comprehensive breeding exception on innovativeness. Other factors that might influence innovativeness in a particular sector should also be considered. Given the different performance of crops, the results may differ between the field crops and the vegetable sector as well as within the same sector.

6.4.3 Third Condition: Not Unreasonably Prejudice the Legitimate Interests of the Patent Owner, Taking Account of the Legitimate Interests of the Third Parties

6.4.3.1 The Legitimate Interests of Patent Owners

As previously argued, the recoup of R&D costs represents patent owners' legitimate interest. If a comprehensive breeding exception were to be introduced, patent holders might not be able to recover the initial costs since the interest of breeders to obtain a license would decrease. Unlike breeders, biotech companies invest substantial resources in laboratory research.[111] Patents may be considered as a tool for recouping these investments. But patents are not the only tool for recouping initial R&D costs. Innovators might be able to capture high return rates as they have the lead-time advantage to be the first to market the product.[112] Indeed 'lead time advantage arises naturally in a model where imitation requires time or stochastic discovery.'[113] Moreover, innovators might obtain additional profits from selling the products and complementary products or services, even if they do not opt for patent protection. In this regard, empirical findings suggest that firms see lead time advantage as strong sources of appropriability. However, these findings seem to

[111] For an understanding see Louwaars et al. (2009), Nr. 14, p. 10.

[112] Bessen and Meurer (2008), p. 89.

[113] Bessen (2003), p. 8.

be not valid for the pharmaceutical and chemical industries.[114] In these industries, patents are considered an important instrument for recouping R&D costs. The biotech companies interviewed for the purpose of this study claim that they would stop investments, invest less, or protect their inventions with secrets[115] if a comprehensive exception were to be adopted. Consequently, the reader might conclude that weakening patent rights for the biotechnological sector will prejudice the interests of the patentee. But the matter is not as simple. It is worth recalling that the comprehensive exception would weaken patent protection only for the breeding sector. This means that patentees could still assert their patents in other sectors. For example, protected biological material found in a pharmaceutical product could be freely used by plant breeders, but innovators in other industrial sectors (biofuels, chemicals, cosmetics) would need a license to use the protected material. Concerns, however, arise when a new plant variety containing a patented material enters into competition with the first innovator. This may be the case of a plant variety bred for therapeutic purposes.[116] Therefore, a careful evaluation of these issues is necessary in order to reach a final conclusion. This would be particularly relevant to address the concerns of biotechnological firms which particularly emphasize the negative consequences of the comprehensive breeding exception.[117]

6.4.3.2 The Legitimate Interests of Third Parties

Given that the interests of third parties coincide with the interests of the society at large, they are intimately linked to the interests of patent holders. If biotech companies reduce patenting and increase secret protection of their inventions, it means that less innovation will be disclosed for the benefit of society. Consequently, less plant varieties and medicines may reach the market place. This would have negative repercussions on all stakeholders and halt breeding activities in the first place. But the issue is more complicated than it might appear. The core matter is to identify how useful patenting is for plant breeding activities. As already clarified in Chap. 4, neoclassical economics provides for a direct link between patent protection and innovation activities. But this theory has recently been put to the test by various studies. From a theoretical point of view, patenting effects on innovation are not clear since neoclassical theory ignores the performance of the

[114] Levin et al. (1987), pp. 783–820.

[115] Please, note that the reproductive nature of the biological material makes it very unlikely to protect inventions with trade secrets. If secrets were used in the biotechnological sector, they would give only a few years of lead time advantage.

[116] Please, note that if a comprehensive exception were limited to the 64 crops listed in Annex I of the ITPGRFA there would be no concerns in this regard since the exception would allow breeding of plant varieties for the sole purpose of food and agricultural use.

[117] See, for example, the letter of Monsanto to the concerned Dutch ministries: http://vorige.nrc.nl/multimedia/archive/00242/Patentrecht_09-07-0_242612a.pdf, accessed 24 October 2013.

system based on other factors, such as cooperation, for example.[118] Moreover, historical evidence and empirical studies do not offer a linear relationship between intellectual monopoly and increasing innovation. The literature on the positive effects or negative effects of IP protection on the rate of innovativeness is various,[119] but the role of patents in appropriating returns to innovations in the biotechnological sector appears to be quite consistent.[120]

This inconclusive empirical evidence on the effectiveness of the patent system on innovation does not allow drawing clear conclusions. The attention should be brought to the fact that economists rely on imperfect data and causality is not always uniquely determined. The real world consists of an interaction of several factors that might influence innovation in different ways. But the difficulty in identifying clear causality does not mean that economic studies are unimportant. On the contrary, they offer useful indications on structuring the unknown. These indications might be deemed particularly relevant in absence of an agreement among industry representatives. The proponents of a comprehensive breeding exception argue that its introduction will facilitate breeding activities and bring more innovation to the society, whereas the biotechnological sector anticipates fewer innovations accruing to society. The first sustain that plant breeding has proved to be a very profitable business in the last century despite the lack of patent protection. The second lament that the introduction of a comprehensive breeding exception might go beyond plant breeding and directly affect the chemical and biofuel sector. In terms of the issue at hand, the role of patents in plant breeding should be further evaluated by taking account of other incentives that the institutional system might offer for biotechnological innovations. In this respect, account should be taken of domestic research capabilities[121] and interpret empirical findings on innovativeness in the national context. Panels ought to consider these peculiarities of patent protection while determining the prejudice of the breeding exception on third parties interests. This is necessary in order to render a judgment freed from political constrains, but based on sound economic and legal principles.

[118] Andersen and Konzelmann (2008); Bessen and Meurer (2008); Boldrin and Levine (2008); Greenspoon and Cottle (2011); Moser (2013), pp. 3–22.

[119] For an overview of the economic literature and for the impact of IPRs in the US market see Dhar and Foltz (2007).

[120] Allred and Park (2007), pp. 91–109; Hall and Harhoff (2012), pp. 541–565; Harabi (1996). Mansfield, in particular, concluded that 60 % of inventions in the pharmaceutical industry would not have been developed without patent protection and 38 % would not have been developed in the chemical industry. See Mansfield (1986), p. 173.

[121] Evenson and Kislev (1975). In particular, Evenson and Kislev found that the absorption of foreign-generated technology depends on domestic research capacities. On the role of national systems in innovation see also Freeman (1995), pp. 5–24.

6.4.4 The Reasonableness Test

If the comprehensive breeding exception were found to be non-compliant with the last two conditions of article 30, the panel should further consider the reasonableness test. Here it is worth recalling that a patent exception might be deemed reasonable only when it is proportionate to the objective that it intends to achieve.[122] The objective merits to be pursued to the extent that it produces social benefits capable of overcoming the interests protected by patent law. The adoption of a full breeding exception may thus be considered reasonable when societal needs call for a better food supply. Situations that require countries to assure food supply are inevitably linked to the right to food. This right is contemplated in article 11 of the International Covenant on Economic, Social, and Cultural Rights (ICESCR), which is legally binding for the signatory countries. If conflicts between the right to food and patents on biological matter arise,[123] countries that are part of both TRIPS and ICESCR would face the dilemma of whether to respect their human right obligations under international law or TRIPS provisions. In this respect, the reasonableness test can provide significant leeway. If a panel or the Appellate Body (AB) finds that the realization of the right to food creates more benefits that patent rights, the comprehensive breeding exception should be deemed proportionate to its objective of respecting the right to food. In order to have a better grasp of the issue at hand, it appears necessary to clarify the content of the right to food. This, however, is not an easy task.[124] The basis for understanding the 'right to food' is provided for by General Comment 12 of the United Nations Committee on Economic, Social and Cultural Rights.[125] Paragraph 15 of the General Comment specifies States' obligations with regard to the right to food. These obligations consist in the duty to *respect*, to *protect* and to *fulfil*. The obligation to *respect* requires States not to take any measures that result in preventing access to food. The obligation to *protect* requires measures by the State to ensure that enterprises or individuals do not deprive individuals of their access to adequate food, whereas the obligation to *fulfil* means the State must take positive actions to strengthen people's access to and utilization of resources and means to ensure their livelihood, including food security. This last obligation implies both an obligation to *facilitate* and an obligation to *provide*. In light of the importance of the breeding exception in food production and quality, the adoption of an exception to patent rights for breeding purposes represents an adequate legal instrument to realize the obligation to

[122] Kur (2011), p. 246; Rodrigues (2012).

[123] Conflicts may arise when patents contribute to the concentration of the market and push local varieties out of the market. For a better explanation see Evangelic Church in Germany 'Biopatents and Food Security from a Christian Perspective', a study of the Evangelical Church in Germany's Advisory Commission on Sustainable Development, April 2013. For the possible influence of patents on food security and genetic diversity see De Schutter (2009).

[124] For the development of the right to food, see Wernaart (2010), pp. 43–81.

[125] E/C.12/1999/5, 12 May 1999.

facilitate. For obvious reasons,[126] the exception is also instrumental for respecting, protecting and providing, the right to food. It would certainly be too naive to overstate the role of the exception in the implementation of the right to food. This right is strictly connected to the concept of 'food security' explained in the first part of this chapter, which necessitates action undertaken from a plurality of legal orders and a multilevel coordination for food and natural resources.[127] This necessity is recognized in paragraph 36 of the General Comment 12, which invites States parties to:

> take steps to respect the enjoyment of the right to food in other countries, to protect that right, to facilitate access to food and to provide the necessary aid when required. States parties should, in international agreements whenever relevant, ensure that the right to adequate food is given due attention and consider the development of further international legal instruments to that end.

Clearly, the above paragraph acknowledges the importance of international cooperation in food security matters. A quick reading of TRIPS might reach the conclusion that this agreement does not pay due attention to the right to food. The multidimensional aspects of food security, however, demand a reading that takes account of the peculiarities of the institutional complexity surrounding the 'right to food'. Patent rights are a component of this institutional complexity when they are granted on genetic material that is and/or might be used in food. Although patents do not provide food for society, they play a role in food access. This might be a sufficient condition to include considerations on food security in TRIPS interpretation. In this context, a 'reasonableness' exception under article 30 might recall the terms 'whenever relevant' used in paragraph 36 of the General Comment 12. Thus, States might be able to include food security matters whenever they deem it relevant. This flexible reading provides countries with the possibility of adopting a breeding exception as an 'international legal instrument' to support the content of the General Comment. This would be in line with the international dimension[128] of food security and it is especially relevant when patents granted in developed countries do not allow developing countries to use protected genetic material. If this were the case, urgent action may be required to 'take steps to respect the enjoyment of the right to food in other countries, to protect that right, to facilitate access to food' as set in paragraph 36 of the General Comment. Besides international cooperation, this action appears necessary in view of the concept of intergenerational equity. This reasoning appears to justify the adoption of a comprehensive exception limited to 64 crops covered by the Multilateral System of the ITPGRFA. As stated in article 11.1 of the ITPGRFA, these crops are established according to criteria of food insecurity and interdependence. Therefore, the panel

[126] The reasons are related to the importance of plant breeding as depicted in Chap. 3.

[127] For more on this point see Hospes et al. (2010), pp. 19–38.

[128] Please, note that food security incorporates both an international dimension and an important local dimension. For this reason, it is named as a 'glocal' problem.

should carefully consider the content of right to food when applying the reasonableness test.

In order to further emphasize the importance of the reasonableness test developed in the first part of this chapter, it appears necessary to take account of articles 7, 8.1, and 1.1 of TRIPS. It seems futile to reproduce a detailed analysis. Attention should be drawn solely to those aspects that are decisive in justifying the exception. With regard to article 7, it is worth recalling that the comprehensive breeding exception would enable the 'promotion of technological innovation and to the transfer and dissemination of technology' to the advantage of the users of the technology since it would make freely available the use of inventions. The question to be asked here is whether there would be a mutual advantage for the producers of technology and whether it would conduce to 'social and economic welfare, and to a balance of rights and obligations'. The answer should take account of the importance of the exception in food security and of the preservation of the incentive to innovate in the biotechnological sector. The assessment of the incentive to innovate should be based on the fact that the comprehensive exception is designed for the breeding sector and may not reduce the return that might be obtained from the use of the invention in other sectors. The relevance of plant breeding in defining the boundaries of the exception serves as a further justification of the comprehensive exception in light of article 8. As already clarified in the first part of this chapter, the peculiarities of plant breeding assist national legislations in adopting an exception to patent rights that promotes a sector of vital importance in respect of other TRIPS provisions. As regards article 1.1, it is important to assess the relevance of 'public interest' reasons in defining the scope of patent exceptions in the countries concerned. Chapter 5 showed that national legislations differ in terms of public policy issues for adopting patent exceptions. In view of the findings of this chapter, it might be expected that a comprehensive exception would be more of an 'appropriate' method for implementing article 30 in European countries rather than in the US. However, the definition of public policy issues is a matter of national legislations. This means that countries may decide to adopt new rules in conformity with their current economic interests. With regard to the reasonableness of the comprehensive exception and the link with trade, the considerations developed in the first part of this chapter find here full application. From an economic perspective, the above considerations stand on the inherent trade-off in patent law between costs and benefits. The definition of an efficient balance between costs and benefits determines societal welfare. It is opinion of the author that societal welfare increases when countries adapt their laws in order to implement the right to food. Laws may be considered efficient only when they serve to the superior purpose of eliminating food insecurity.

Although the previous paragraphs argued in favor of the 'reasonableness' of the comprehensive exception, a panel or the AB might arrive at the conclusion that the economic incentive to innovate might be deemed more important than food security. This reasoning appears plausible in developed countries where markets offer multiple choices for consumers. In this case, the comprehensive breeding exception would blatantly contradict article 30. Nevertheless, countries might be offered the

possibility to exempt plant traits from patentability if they take adequate measures to preserve the incentive to innovate. Indeed, the absence of patent protection would require an alternative system to incentivize innovations. A compelling system of incentivizing innovations seems the liability regime proposed by Reichman for small-scale innovations. This regime can be applied to plant variety creation since plant breeding usually involves improvement of prior knowledge on existing varieties. Taking into account market failures of property rights in small-grain innovations, he suggests compensating the first innovator's efforts with a set of royalties levied on a fixed percentage of his gross revenues that vary within a specified range of options.[129] This system purports to take account of community's contribution in plant breeding and to involve fewer social costs than patents since it avoids legal incentives to invest when they are not needed. Third parties legitimate interest in this case would not require a retribution since the society at large would benefit by having immediate access to plant innovations.

The implementation of the liability regime necessitates an agency to deal with the financial and administrative aspects of rewards. This may represent the major shortcoming of this solution since the costs involved in a bureaucratic system may be considerable. But this does not seem to be the case in terms of the issue at hand. This compensatory mechanism would be created only for the specific reason of accessing relevant biological material for creating plant varieties in particular situations, such as actual or potential food crisis, or simply when societal needs demand a better food supply.

In these cases, the social benefits of accessing patented innovation would overcome the harm caused to the monetary interests of all parties. If a liability regime were not implemented, plant breeders would be forced to enter into negotiations in order to obtain commercial licensing. In this case, the costs involved in private bargain may overcome those of public intervention. This is mainly because negotiations may fail or involve higher transaction costs than governmental intervention. This risk is particularly high when plant breeders need to access genetic material which is owned by different patentees. Even if all the licenses were issued, the time dedicated to negotiation procedures would undoubtedly delay the coming of new varieties into the market.[130] In a liability regime, this would not occur since breeders would be free to access relevant patented material subject to the reward mechanism. Moreover, the liability regime would help breeders to focus their efforts in variety creation rather than in expensive and complicated licensing agreements.

Following this line of reasoning, a feasible regime of plant variety protection may be that of the Multilateral System of the ITPGRFA. Under this system, a set of rules facilitates access to plant genetic resources (PGR) that are in the public domain and under the direct control of the Contracting Parties.[131] Those who access

[129] Reichman (2000), pp. 1743 and 1784.

[130] This phenomenon might lead to a the so-called 'Tragedy of anti-commons'. For more details refer to second part in Chap. 5 of this thesis.

[131] See arts. 10–12 of the ITPGRFA.

plant genetic resources under the Multilateral System may agree to share further improvements on PGR or decide to keep them for themselves. In this case, they agree to pay a percentage of any commercial benefits they derive from their research into a common fund to support conservation and further development of agriculture in the developing world.[132]

From a legal perspective, the reasonableness test for the comprehensive breeding exception should further take account of issues related to doubts on plant patentability. It was already argued in Chap. 4 that patenting parts and components of a plant circumvents the exclusion of plants from patentability. Likewise, patents on native traits obtained through conventional or essentially biological breeding processes nullify the exclusion of these processes from patentability. In this respect, the European parliament as well as national parliaments and civil society organizations have solicited the EPO to exclude from patenting products deriving from conventional breeding.[133] The introduction of a comprehensive breeding exception would certainly overcome all of the problems related to patentability issues. However, it should be noted that if a comprehensive breeding exception were adopted, compulsory licensing provided for by article 31 of TRIPS will no longer apply to plant breeding with respect to patented plant traits. Its legal significance would be circumscribed to other biotechnological sectors such as pharmaceuticals and biofuels, and patented processes in plant breeding. As already explained above, this differential treatment finds its legal justification in article 27.3 b.

6.5 Final Remarks

This chapter analyzed the compliance of patent exceptions for breeding purposes with article 30 of TRIPS. The analysis largely focused on the compliance of exceptions limited to research or breeding and developing of new plant varieties by using patented biological material. Based on the general principles of interpretation and WTO panels reasoning, the so-called breeding exception was deemed consistent with the three-step test of article 30. This conclusion takes account of the underlying rationale of patent rights to spur innovations for society. Contrary to conventional wisdom, patent rights should be seen as promoters of societal interests rather than instruments for profitmaking.

[132] See art. 13 of the ITPGRFA.

[133] For more see the 'Open Letter Regarding the Vegetable Licensing Platform' elaborated by the Berne Declaration. Available at http://www.evb.ch/en/p25021548.html, accessed 9 March 2014. See also De Schutter (2014). In page 22 of the Report, the UN special rapporteur on the right to food recommends not to '. . .allow patents on plants and establish research exceptions in legislation protecting plant breeders' rights'. Please, note that Germany amended in 2013 its Patent Act in order to exclude plants bred from essentially biological processes from patentability. See section 2 (a) 1.1 of the German Patent Act and German Parliamentary resolution nr. 17/10308.

The compliance of a comprehensive breeding exception with article 30 of TRIPS, on the other hand, meets several obstacles since it erodes the basic principles of patent law. The objectives and principles of TRIPS, however, leave considerable room for states to promote public interest in plant breeding. The respect of the human right to food or special circumstances, such as food crisis, may induce states to resort to general principles instead of applying strict rules. A broad interpretation of TRIPS certainly reforms the current view of the 'supremacy' of patent rights, but it is necessary in order to balance various interests involved in plant breeding for the benefit of the society. It was sustained that even if patent protection were found to be relevant, a retributive system might successfully overcome potential negative effects of limitations to patent rights.

This interpretation is particularly relevant for accommodating the divergent interests of countries. Identifying a coherent relationship between national plant breeding interests and TRIPS objectives might result in different answers. Special solutions might be needed for Europe as opposed to, for example, the U.S. or developing countries. The air of vagueness surrounding article 30 gives good reasons for adopting flexible solutions in patent law.

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Chapter 7
Overview

The book shows the relevance of exceptions to patent rights with breeding purposes from both an academic and policy perspective. From an academic perspective, this study categorizes the breeding exception as a type of permissible exception within the broader category of exceptions to patent rights. In policy terms, the analysis clarifies the vagueness of language in art. 30 in order to reconcile the conflictual views surrounding the introduction of a breeding exception to patent rights. Attention is drawn to the fact that the debate on the breeding exception involves stakeholders with different interests. From one hand side, the pharmaceutical, biofuel, chemical, and cosmetics sector endorse strong patent rights in order to be more innovative in the biotechnological market. On the other hand side, plant breeders in the seed sector ask for a flexible patent system that allows the free flow of genetic material among breeding programs. In specific, they ask for a limited exception that allows for breeding and developing new varieties of plants *with* patented subject matter. The Dutch association of plant breeders, Plantum, demands to broaden this exception by permitting breeding, development, and commercialization of plant varieties containing patented traits (the so-called comprehensive exception).

Elaborating an exhaustive response to this issue is not an easy task as the analysis involves an understanding of complex matters in relation to the science of plant breeding, the legal and economic aspects of intellectual protection, and TRIPS interpretation. Moreover, there is a lack of a specific legal and economic literature on this subject. The general literature on patent exceptions is inconclusive with respect to the type of activities that can be exempted from patent infringement. Although national case law offers insight on the type of activities that might be exempted from patent rights, there is significant variation in the scope of research exceptions across countries. The WTO panel in the EC-Canada case provides some indications, but it does not comprehensively clarify the issue of permissible patent exceptions. Therefore, there is legal uncertainty on the type of activities that can be exempted from patent rights. In terms of the issue at hand, this means that it is not clear if breeding, developing, and commercializing a plant variety containing

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and/or building upon patented elements is admissible in patent law. This book seeks to offer a solution by analyzing different modalities of a breeding exception in light of panel's findings in the EC-Canada case. The analysis is, however, broadened in order to take account of other relevant TRIPS provisions and international legal instruments. This assures a effective interpretation of art. 30 in line with the principles of treaty interpretation. Furthermore, a thorough examination of the terminology of art. 30 is based on the results of interviews with stakeholders in plant breeding. These results, combined with an understanding of economic theory and empirical studies on patents as incentives for innovation enrich the understanding of art. 30. The following sections explain how legal and economic considerations assist the analysis of both a limited and comprehensive breeding exception. On this basis, recommendations for adopting different modalities of a breeding exception to patent rights will be put forward.

7.1 A Limited Breeding Exception

This section explains the compliance of the breeding exception with each of the conditions set in art. 30: 1) the exception must be 'limited'; (2) the exception must not 'unreasonably conflict with normal exploitation of the patent'; (3) the exception must not 'unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties'. Firstly, the breeding exception is found to be a limited exception. This conclusion is based on the understanding of *limited* as proffered by the panel, the dictionary, and scholars' analyses. The analysis relies on the extent of curtailment of patentee's rights from a legal viewpoint. Thus, it is found that the breeding exception impairs the right of patent holders to authorize the *use* of patented products as provided for by article 28 of TRIPS. The breeding exception, however, does not impair the right of the patentee to commercialize or license its products for commercial goals. The breeding exception is limited only to breeding purposes. Further commercialization of varieties bred with patented elements necessarily requires the consent of the patent holder. This means that the extent of curtailment of patentee's rights is narrow and confined to breeding purposes. It is also shown that this type of exception has definite boundaries and corresponds to scholars' view on patent exceptions.

Secondly, the breeding exception does *not* conflict with the normal exploitation of the patent. In the EC-Canada case, the panel understood 'normal exploitation' as a combination of an empirical understanding about 'what is common within a relevant community' with a normative view of what is accepted by community's values. The analysis in this book concretizes these abstract terms in the legislations of those countries that have already adopted a breeding exception, France, Germany, the Netherlands, and Switzerland. Based on legal literature, it is argued that the empirical element is related to the use of patents to extract value through selling patented products or rights, or licensing patent rights, whereas the normative element considers whether patent exploitation is essential to the achievement of goals of

patent policy. With regard to the empirical element, a careful examination finds that the breeding exception does not significantly diminish patent holder's profit. Considering that the breeding exception allows the patentee to maintain his rights for commercial licensing, the patentee might increase licensing fees if he deems that this is necessary to recoup his R&D investments. The normative aspect requires an investigation of national patent policies. In this respect it is found that the abovementioned countries establish maintenance fees for patents. Despite national characteristics, the establishment of patent fees is deemed to be an indicator of legislators' willingness to promote follow-on innovations. This conclusion is based on the fact that the existence of patent fees recognizes that patents impose costs on society. This reasoning finds additional support in German law, where fees are halved if the patentee declares his willingness to grant licenses. The goal of promoting subsequent innovations becomes apparent in the first part of Chap. 5 as well. This part shows that France, Germany, and Switzerland have adopted research exceptions to patent rights and national courts seem to pay attention to public policy issues. In specific, the German cases of Clinical Trial I and II emphasize the need for an exception to patent rights in the general public interest. It appears, thus, that the goals of national patent systems are not centered on the right to exclude of the patentee, but on the goal of making inventions accessible for the benefit of the society. The analysis further explaines the consistency of the breeding exception in view of the normative approach by taking into consideration the length of breeding processes and patent rights. It is argued that in absence of a breeding exception, long breeding periods might significantly increase the *de facto* market exclusivity of patent holders. Consequently, the breeding exception is deemed necessary to bring a balance into patent law.

Thirdly, this study finds that the breeding exception does *not* prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. Prior to assessing the compliance of the breeding exception with this last step of article 30, the meaning of 'legitimate interest' is clarified. In accordance with panel's reasoning, it is argued that a 'legitimate interest' does not stem from a legal claim, but from the interest of the society as a whole to benefit from patented innovations. In these terms, the legitimate interest of the patent holder is identified in recouping the R&D investments. The argumentation in Chap. 4 on the economic function of the patent system puts the basis for the understanding of the relationship between R&D expenditures and incentives to innovate. It is shown that empirical investigations do not favor a linear correlation between R&D expenditures and innovation. However, a significant body of work has proven the importance of patents for the biotechnological sector. But this does not allow drawing conclusions in terms of the issue at hand. Therefore, this study seeks to find an answer in economic theory and in a qualitative infield research. Based on economic theory, it is argued that the breeding exception does not prejudice the patentee's interest since it deprives him only from obtaining a profit from *ex ante* licensing. But the reduction of profit is not a cause for not recouping R&D investments. The patentee may recoup his initial investment costs through different instruments: sales, after-sales services, market advantage, commercial

licensing. Business firms, themselves, have no objections to the introduction of the breeding exception. Both small and big companies operating in the seed sector consider the exception as an important means to increase the flow of genetic material. They are aware that the introduction of a breeding exception to patent rights diminishes their profits, but they do not see it as a hindrance for innovation activities. Moreover, it is found support for promoting the interests of third parties. Third parties are identified in those that have a direct interest in plant breeding: plant breeders, public breeding institutions, research centers, governments, consumers. Thus, the society as a whole has an interest in the breeding exception. This interest is promoted by introducing an exception for breeding purposes to patent rights. It is also argued that the breeding exception avoids societal costs associated with deadweight losses and difficulties of accessing patented innovations. This function of the breeding exception is deemed to incentivize innovations in plant breeding since it significantly lowers the costs of accessing protected innovations. The interviews with plant breeders allow establishing the validity of this argument. This result should be understood together with the finding of the second part of Chap. 5. The analysis in Chap. 5 notes that there is a need for a breeding exception in order to further innovations in plant breeding. Several benefits of the breeding exception are here ascertained both in the *ex ante* licensing phase and in the commercialization phase. Moreover, the breeding exception is proffered as a solution to the fragmentation of rights in plant breeding and problems related with patent quality. These last concerns are widely assessed in Chap. 4 of this study, which puts the basis for a better understanding of the necessity to adopt a breeding exception to patent rights. All these arguments put together provide support for introducing a limited breeder's exception to patent rights.

Additionally, the analysis of a limited breeding exception takes account of the 'reasonableness' of the exception. If a panel were to find that this exception contradicts the last two conditions of art. 30, the compliance test should consider whether the exception is reasonable in accordance with the wording of art. 30. This book formulates an original 'reasonableness test' which rests upon arts. 7, 8.1 and 1.1 of TRIPS. It is specifically shown that the breeding exception promotes the objectives and principles of TRIPS as stated in art. 7 and 8.1. Based on a thorough analysis of the terminology of these articles, it is determined that the breeding exception 'contributes to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations' and represents a TRIPS-consistent measure which promotes the public interest in a sector of vital importance to the socio-economic and technological development of countries. This conclusion is also strengthened by a comprehensive description of the industry of plant breeding in Chap. 2. Moreover, the examination of article 1.1 allows observing that the breeding exception is in line with the legal systems and practices of France, Germany, the Netherlands, and Switzerland. The reasonableness of the breeding exception is further supported in view of its potential to promote trade flows in plant breeding.

The analysis elaborated in this book also dedicates attention to the non-discrimination clause of art. 27.1. This appears necessary since the panel has decided that patent exceptions should not discriminate 'as to the place of invention, the field of technology and whether products are imported or locally produced'. Based on the reasoning of the panel, the analysis concludes that the breeding exception is to be considered as a differentiation for *bona fide* purposes. Art. 27.3.b provides support for the argument that a different treatment for the plant breeding industry is found in the text of TRIPS. This different treatment is further justified by the central role of plant breeding in food security. Therefore, the analysis of compliance with the non-discrimination clause by a panel might be redundant. This conclusion strengthens the hypothesis that a limited breeding exception is TRIPS-compliant.

7.2 A Comprehensive Breeding Exception

Similarly to the limited exception, this section explains the compliance of a comprehensive breeding exception with the conditions set in art. 30: 1) the exception must be 'limited'; (2) the exception must not 'unreasonably conflict with normal exploitation of the patent'; (3) the exception must not 'unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties'. Firstly, based on a critical analysis of the panel's argumentation, this study finds that the comprehensive breeding exception is a limited exception. This finding is in line with legal scholars' viewpoint. Indeed, some scholars propose a flexible reading of 'limited' in order to allow an assessment of the purpose and the impact of the exception or an interpretation that allows the exceptions to realize TRIPS goals and principles. These proposals, however, touch issues that go beyond the extent of the legal curtailment of patent rights as defined by the panel. This book shows the 'limitedness' of the exception based on a detailed elaboration of the panel's argumentation. It is worth noting, however, that the panel's decision does not create a legal precedent and future panels might adopt a broader interpretation of 'limited exception'. This may be particularly justified by the relevance of plant breeding and its differential treatment with respect to other technological sectors as allowed by art. 27 of TRIPS. In line with this reasoning, this book suggests that a comprehensive exception may be deemed a limited exception if it exempts patent rights on 64 crops for food and agricultural use covered by the Multilateral System of the ITPGRFA. This recommendation would also promote TRIPS objectives and principles in plant breeding.

Secondly, this book finds reasons for a conflict between the breeding exception and the empirical element of the patent exploitation. The reasoning is mainly based on the fact that if this type of exception were to be adopted, patents might not be an efficacious means of attracting investments in the biotechnological sector since patentees would reap less financial returns on their investments. With regard to the normative element, the study is not able to reach a conclusion. Biotechnological companies, on the one hand, claim that a comprehensive breeding exception would

reduce investments on innovative breeding traits, and, therefore, no benefit will accrue to the society. Plant breeders, on the other side, argue exactly the opposite. With a comprehensive exception they would access a wide range of biological material, which would allow them to easily breed innovative plant varieties. The issue is a difficult one and necessitates empirical studies that investigate the relationship between patent protection and incentives for innovation in the biotechnological sectors affected by the breeding exception. Exploring this issue would contribute to a better assessment of the compliance of the comprehensive breeding exception with article 30. In order to generate sound results, there is a need for an investigation of other factors at local level that may influence innovation in biotechnology.

Thirdly, this book is not able to conclude whether a comprehensive breeding exception would prejudice the interests of patent holders to recoup their R&D expenditures. The main reason for an inconclusive answer lies in the unclear role of patents in innovation activities. It is not yet well understood whether patents or other socio-economic factors are determinant for promoting inventions. Therefore, the matter requires a careful evaluation of the interests involved. The second part of Chap. 4 provides the basis for the understanding of this finding and the qualitative research in Chap. 5 offers further support. The analysis developed in these chapters is also unable to assess whether a comprehensive breeding exception would prejudice legitimate interests of third parties. It is argued in Chap. 4 that the neoclassical view on a direct link between patent protection and innovation is put into question by several empirical studies. Indeed, factors such as cooperation, other informal systems or the necessity to survive in the market might play a role in driving investments. In absence of specific evidence on the impact of a comprehensive breeding exception on biotechnological innovations, it is not easy to determine whether the society will benefit from the introduction of this exception to patent rights.

With regard to the reasonableness test, the considerations elaborated for the limited exception should be applied. But it is further proposed that the comprehensive breeding exception may be considered reasonable when societal needs call for a better food supply. This is intimately linked to the right to food and situations of food insecurity. In this regard, the link between the breeding exception and the right to food is shown and it is argued that patents on genetic material are a component of the institutional complexity governing the realization of the right to food. Therefore, TRIPS provisions should be read in coherence with countries' obligations on the right to food. This view seems to justify the adoption of a comprehensive exception limited to the 64 crops governed by the Multilateral System of the ITPGRFA. Such an interpretation takes account of the inherent trade-off in patent law between the need to incentivize innovations for the benefit of the society and the related costs on societal welfare. The ultimate goal of the trade-off is guided by societal welfare. This study clarifies that societal welfare is enhanced when patent rights serve the purpose of realizing the right to food and eliminating food insecurity. It further suggests that even if the breeding exception were found to be non-compliant with art. 30, countries should be offered the possibility to exempt plant traits from patentability if they take adequate measures to preserve the incentive to innovate through liability mechanisms. In line with this reasoning,

the Multilateral System of the ITPGRFA appears as a feasible solution to deal with current problems of accessing PGRFA.

The non-discrimination clause was not taken into consideration since the analysis of the first hypothesis clarifies that plant breeding deserves a differential treatment.

7.3 Implications of a Breeding Exception to Patent Rights

A wide range of interests (biotechnological companies, plant breeders, consumers) are involved in the adoption of the breeding exception. This implies that the introduction of this exception affects different incentives and innovation processes. It is clear that the legislator should take this specifity into account in order to promote innovations for the benefit of society. But it is not easy to define when benefits accrue to society. Law and economics suggest that it is the basic trade-off between costs and benefits of the patent system that should drive lawmaking. Based on this argument and the analysis elaborated in the previous chapters, the following sections clarify the theoretical and policy implications of the study.

7.3.1 Theoretical Implications

The findings of this study contribute to the current understanding of the concept of exception to patent rights by conceptualizing the breeding exception as a new type of permissible exception. Most importantly, the analysis shows that exceptions with commercial intent might be deemed permissible. The conceptual framework developed in this study suggests that this finding is especially relevant for those exceptions that respond to the objectives and principles of TRIPS or public policy issues. This observation may be consistent with the practice of civil law countries, but contradicts that of common law countries. It further contradicts the arguments of some economic scholars.[1] Moreover, the admissibility of an exception *with* patented material is in contrast with the opinions of leading commentators,[2] but finds some support in a few studies on research tools.[3] The reason for this differing conclusion lies in the specific characteristics of plant breeding and in the methodological approach of this study, which built upon a legal and economic analysis. This allowed taking into account a wider range of interests involved in the adoption of the breeding exception. In this context, special attention was dedicated to the role of public policy issues in defining the reasonableness of patent exceptions. This

[1] See Hantman (1985), p. 617; Eisenberg (1989), pp. 1017 and 1078; Israelsen (1988–1989), pp. 457 and 469.

[2] Correa (2005). Eisenberg (1989); Eisenberg (1987), pp. 177 and 225; Gilat (1995), p. 44.

[3] Mueller (2001) and Strandburg (2013).

approach recognizes the basic trade-off of patent law between costs and benefits. Thus, the benefits of promoting societal concerns on the negative effects of patents in plant breeding were deemed to play an important role in defining law and economics considerations. In this view, law and economics should be an instrument for the benefit of the society, not a dictator of abstract rules detached from real world problems.

7.3.2 Policy Implications

The theoretical and empirical results of this study indicate that the adoption of a limited breeding exception to patent rights does not diminish the incentive to invent. On the contrary, it increases innovation in plant breeding and does not negatively affect the biotechnological sector. This finding should encourage countries to introduce this exception into their patent laws. Distinction should be made between common and civil law systems. In common law countries, an explicit exception should be introduced to patent rights, whereas civil law countries may choose to adopt a new exception to patent rights or broadly interpret their research exceptions with commercial intent. The choice will depend on the type of research exception currently in force. With respect to the comprehensive breeding exception, this study observes several concerns on the preservation of the incentive to invent by patent holders. This suggests that the Netherlands and other countries which might consider adopting a comprehensive exception should carefully evaluate the impact of this exception on the incentive to innovate in the concerned biotechnological sectors. Given the recent introduction of the breeding exception, the variety of the biotechnological sectors involved, and their different innovation systems, empirical investigations may be challenging at present. It would be more pragmatic to recommend that countries take account of their public policy priorities. The validity of this argument can be better understood given the absence of a direct correlation between patents and the incentive to invent. Special circumstances, such as food crisis, or the implementation of international agreements related to plant breeding (CBD, ITPGRFA, Nagoya Protocol), may induce states to resort to general principles instead of applying strict rules. In this respect, countries may opt for a retributive system which might successfully overcome potential negative effects of the lack of IP protection or limit the comprehensive exception to a number of plant varieties that are of particular relevance for public policy objectives. This interpretation is particularly relevant for accommodating the divergent interests of countries. Identifying a coherent relationship between national plant breeding interests and TRIPS objectives might result in different answers. Special solutions might be needed for Europe as opposed to, for example, the US or Asia.

7.4 Limitations of the Study and Recommendation for Future Research

This study offers an assessment of the compliance of the breeding exception based on law and economics considerations. The economic considerations based on theoretical arguments and empirical findings contribute to a better understanding of article 30, but they cannot provide an answer to the conflict with the normal exploitation of the patent and the prejudice of the legitimate interests of patent holders and third parties with regard to the comprehensive breeding exception. This might be a consequence of the lack of an empirical investigation on the relationship between patent protection and incentives for innovation in the biotechnological sectors affected by the breeding exception. While some data were retrieved for the purpose of this investigation, the limited number of empirical observations did not permit to conduct a study in order to fully understand the effect of patent protection on firms' rate and type of innovation. Exploring this issue would contribute to a better assessment of the compliance of the comprehensive breeding exception with article 30. In order to generate sound results, there is a need for an investigation of other factors at local level that may influence innovation in biotechnology.

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Annex: Interviewees (in Alphabetical Order)

1. Bert, Visser	Director, Center of Genetic Resources—NL Genebank
2. Dons, Hans	Wageningen Business School; Managing director of Bioseeds B.V.
3. Hallebach, Claudia	Head of R&D, Legal Affairs and IP, KWS SAAT AG
4. Herrlinger, Christoph	Vice-Secretary General, German Association of Plant Breeders
5. Huijten, Rob	Global Head of Law, Patents and Compliance, Bayer AG
6. Kock, Michael	Head IP, Syngenta International
7. Krieger, Edgar	Secretary General of CIOPORA (International Community of Breeders of Asexually Reproduced Ornamental and Fruit Varieties)
8. Louwaars, Niels	Managing Director of Plantum, the Dutch Association of Plant Breeders
9. Ponti, Orlando de	Former Director of International Seed Federation/Genetic Resources Policy Committee of CGIAR (Consultative Group on International Agricultural Research)
10. Satter, Jaap	Ministry of Economic Affairs (Directorate for Agriculture), The Netherlands
11. Vijn, Irma	Senior Policy Advisor at NIABA, the Netherlands Biotech Industry Association
12. Württenberger, Gert	WürttenbergerKunze, Munich, Germany and Chairman of the GRUR Expert Committee on the Protection of Plant Varieties

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