BACKGROUND STUDY PAPER NO. 58

July 2011

E

COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

TRENDS IN INTELLECTUAL PROPERTY RIGHTS RELATING TO GENETIC RESOURCES FOR FOOD AND AGRICULTURE

by

Michael Blakeney[1]

This document has been prepared at the request of the Secretariat of the FAO Commission on Genetic Resources for Food and Agriculture, to provide an overview of recent developments in intellectual property rights relating to genetic resources for food and agriculture.

The content of this document is entirely the responsibility of the authors, and does not necessarily represent the views of the FAO or its Members.

[1] Michael Blakeney is Professor of Law at the University of Western Australia, Perth, Australia.

TABLE OF CONTENTS

ABBREVIATIONS

ABS	Access to genetic resources and fair and equitable sharing of benefits (access and benefit sharing)
ACP	African, Caribbean and Pacific Group of States
AFD	Agence Française de Développement
AnGR	animal genetic resources
AnGRFA	animal genetic resources for food and agriculture
ARIPO	African Regional Intellectual Property Office
AU	African Union
CAS-IP	Central Advisory Service on Intellectual Property (of the CGIAR)
CBD	Convention on Biological Diversity
CGIAR	Consultative Group on Agricultural Research
CGRFA	Commission on Genetic Resources for Food and Agriculture
CIAT	International Center for Tropical Agriculture
CIRAD	Centre de coopération internationale en recherche agronomique pour le développementCGRFA Commission on Genetic Resources for Food and Agriculture (FAO)
CIMMYT	International Maize and Wheat Improvement Center
CIP	Centro Internacional de la Papa
CNSDOQ	Commission nationale des signes distinctifs d'origine et de qualité
COP	Conference of the Parties of the Convention on Biological Diversity
CSIR	Council for Scientific and Industrial Research (South Africa)
DNA	Deoxyribonucleic acid
EC	European Community
EDV	Essentially Derived Variety
EFTA	European Free Trade Organization
EPC	European Patent Convention
EPO	European Patent Office
EST	Expressed Sequence Tags
ETC	Group Action Group on Erosion, Technology and Concentration
EU	European Union
FAO	Food and Agriculture Organization (of the United Nations)
FTA	Free Trade Agreement
FTO	Freedom to Operate
GMO	Genetically Modified Organism
GR	Genetic Resources
GRRF	Genetic Resources Recognition Fund

GSPC	Global Strategy on Plant Conservation
HT	herbicide tolerant
IARCs	International Agricultural Research Centres
ICARDA	International Center for Agricultural Research in Dry Areas
ICC	International Chamber of Commerce
IGC	WIPO Intergovernmental Committee (on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore)
ICRISAT	International Crops Research Institute for the Semi-Arid Tropics
ICTSD	International Centre for Trade and Sustainable Development
INBio	Instituto Nacional de Biodiversidad (Costa Rica)
INSTAR	International Network for Sustainable Technology Applications and Registration
IP	Intellectual Property
IPBN	Indigenous Peoples' Biodiversity Network
IPEN	International Plant Exchange Network
IPM	integrated pest management
IRGSP	international rice genome sequencing project
IPRs	Intellectual Property Rights
IRRI	International Rice Research Institute
ISAAA	International Service for the Acquisition of Agribiotechnology Applications
ISF	International Seed Federation
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
IUCN	International Union for the Conservation of Nature
LDC	Least Developed Country
MAS	molecular marker-assisted selections
MoU	Memorandum of Understanding
MS	Multilateral System
MTA	material transfer agreement
NARS	national agricultural research systems
NBC	National Biosafety Committee (Costa Rica)
NEPA	National Environmental Policy Act
NGO	non-governmental organization
OAU	Organization of African Unity
OAPI	Organisation Africaine de la Propriété Intellectuelle
OECD	Organisation for Economic Co-operation and Development
OJ EC	Official Journal of the European Community
ORIGIN	Organization for an International Geographical Indications Network
PBR	Plant breeders rights
PCT	Patent Cooperation Treaty

PDO	Protected designation of origin
PGI	Protected geographical indication
PGRFA	Plant genetic resources for food and agriculture
PIC	Prior Informed Consent
PIPRA	Public Intellectual Property Resource for Agriculture
PLT	Patent Law Treaty
PVP	Plant Variety Protection
R&D	Research and development
RuR	Roundup Ready
SADC	Southern Africa Development Community
SARS	systemic acquired resistance syndrome
SIDS	Small Island Developing States
SKGI	Swiss-Kenyan Geographical Indications Project
SMEs	Small and Medium Enterprises
SMTA	Standard Material Transfer Agreement
SPLT	Substantive Patent Law Treaty
TFSRP	Transcription Factor Stress-related Proteins
TK	traditional knowledge
TRIPS	(WTO Agreement on) Trade-Related Aspects of Intellectual Property Rights
UK	United Kingdom
UN	United Nations
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNEP	United Nations Environmental Programme
UNFCCC	UN Framework Convention on Climate Change
UPOV	International Convention for the Protection of New Varieties of Plants
USA	United States of America
USPTO	United States Patent and Trademark Office
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

EXECUTIVE SUMMARY

The principal IPRs which may be applied to genetic resources (GRs), including microorganisms, plants and animals, are: patents, plant variety rights and trade secrets, although it should be noted that in the commercialisation of genetic resources, trademarks, and geographical indications, (GIs) may play an important role. Finally, in the conduct and representation of research conducted in relation to genetic resources, copyright and the protection of layout designs of integrated circuits, as well as patents and trade secrets may play a role. Developing countries and Least Developed Countries (LDCs) have been advocating the creation of IPRs in relation to traditional knowledge (TK), including the knowledge of traditional farmers and in relation to the protection of traditional cultural expressions (TCEs), including traditional recipes, magic and scared rites.

In recent years bilateral Free Trade Agreements (FTAs) contain IPR chapters which either raise the minimum requirements prescribed by TRIPS, or prescribe the form of compliance with TRIPS. For example, the USA's FTAs prescribe UPOV 1991 as the form of compliance with the obligation in Article 27.3(b) of TRIPS for Members to introduce plant variety rights protection.

The UPOV Convention

The key recent developments concern the definition of essentially derived varieties and the availability of patented genes and proprietary tools for the breeding of new varieties. In a 2010 review of the Australian Plant Breeders Rights legislation, it was argued that the test for "predominantly derived" was not sufficiently rigorous for the determination of essential derivation and breeding organisations argued that genetic descriptions of relatedness, possibly based on molecular markers, would be a more appropriate method of quantifying the extent to which the derived variety was "predominantly derived" from the original variety. The adoption of the approach to quantifying genetic relatedness developed by the International Seed Federation was urged and the suggestion was made that DNA profiling could be required as part of the plant breeders right application to assist the evaluation of whether the applicant variety was essentially derived.

On 6 May 2009, Plantum NL declared that:

1. Biological material protected by patent rights should be freely available for the development of new varieties.
2. The use and exploitation of these new varieties should be free, in line with the 'breeders' exemption' of the UPOV Convention.
3. The aforementioned free availability, use and exploitation should not be allowed to be obstructed in any way, either directly or indirectly, by patent rights.

Patenting of Plant Breeding Methods

The exclusion by the European patent legislation of "essentially biological processes for the production of plants or animals" defined in Article 2.2 of the Biotechnology Directive as consisting "entirely of natural phenomena such as crossing or selection", would have been thought to deny patent protection to plant breeding methods, but this was tested recently by the EPO Enlarged Board of Appeal (EBA) in two decisions. One concerned whether a process involving crossing and selection of broccoli could be patentable. Another referral concerned a similar type of invention relating to crossing and selection of tomatoes. The EBA ruled that breeding methods were not patentable, although conventionally-bred plants, their seed and products of harvests remain patentable.

Geographical Indications (GIs) and Certification/Collective Trademarks

In signalling the association between product quality and origin, GIs and certification/collective trademarks, provide both a trade benefit in generating market appeal for agricultural products and a non-trade benefit of promoting local agricultural traditions and methods. In relation to the first

benefit, the ability to charge premium prices is attributed to GI branding. As a means of tracing the origin of products, GIs have also been identified as a guarantee of food safety.

In an endeavour to generate empirical evidence about the value of GIs, the African members of the African Caribbean Pacific (ACP) group of countries have commissioned country/sub-regional and product case studies, regarding the benefits that ACP Group can obtain from enhanced multilateral GIs protection. This information will provide a basis for the African Group to engage in the Doha negotiations on the establishment of the multilateral register for wines and spirits and the proposed extension of additional protection to products other than wines and spirits under Article 23 of TRIPS. A project is currently being implemented by Organisation Africaine de la Propriété Intellectuelle (OAPI) to develop four pilot GIs: Oku honey and Penja pepper in Cameroon, Korhogo clothes in Ivory Coast and Ziama coffe in Guinea. In April 2009 argan oil from Morocco, valued for its nutritive, cosmetic, and medicinal properties, was registered as a Protected Geographical Indication (PGI) by Morocco's Commission nationale des signes distinctifs d'origine et de qualité (CNSDOQ), it was also registered as a PGI by the European Commission.

GIs constitute a significant part of the Doha development negotiating agenda. Clause 18 of the Doha Declaration, states that with a view to completing the work started in the Council for TRIPS members agree to negotiate the establishment of a multilateral system of notification and registration of geographical indications for wines and spirits, as well as the extension of GI protection beyond wines and spirits. The most recent developments in this regard concern a draft composite text on the Multilateral Register which was examined at an open-ended meeting of the TRIPS Council on 18-19 April, 2011. Ambassador Darlington Mwape, who chaired this meeting, reported that this text was "without prejudice to Members' positions on the overall outcome of the negotiations" and that "Members are working on the understanding that nothing is agreed until everything is agreed, and that Members may revert to any issue of the text at any time."

Animal genetic resources

Since the early 1990s the exclusion from patentability of animals has been considered in inquiries in a number of countries, including Australia and Canada. The question of whether patents are available to protect animal breeding methods has been raised in relation to a patent granted by the EPO on marker assisted selection of pigs based on the porcine leptin receptor (pLEPR) gene with a view to enhancing meat production. The recent EBA determination in relation to the non-patentability of the methods of breeding broccoli and tomatoes will probably apply also to the breeding of animals.

Micro-organisms

Article 27.3(b) of the TRIPS Agreement requires members not to exclude of micro-organisms from patentability. However, as there is no definition of micro-organism in the TRIPS Agreement. Countries may permit the patenting of all kinds of microscopic biological materials, including cells and genes.

Synthetic Biology

The emergence of synthetic biology, which is defined as the "synthesis of complex, biologically based (or inspired) systems which display functions that do not exist in nature"[2] and which can be applied at all levels of the hierarchy of biological structures, from individual molecules to whole cells, tissues and organisms, has raised the same sorts of questions about its patentability as applies to microorganisms and genetic material. It has been pointed out that even in its nascent state, the synthetic biology research space is filled with proprietary rights, which could result in synthetic biology being in a situation like information technology, rather than biotechnology. The same kinds of warnings issued by the NGO community in relation to the commodification of

[2] European Commission, Synthetic Biology: Applying Engineering to Biology, Report of a NEST High-Level Expert Group. Brussels, EC, 2005, at 2.

genetic material has been issued in relation to the patenting of synthetic biology, particularly the potential impacts upon market concentration in the biofuels market. The ethical implications of the patenting of synthetic materials is already under review.

Traditional knowledge (TK) and farmers rights

The traditional knowledge of indigenous peoples and farmers has played an important role in identifying biological resources worthy of commercial exploitation. One of the foundational tasks of the WIPO IGC has been the formulation of guidelines on the IP aspects of access and benefit-sharing in relation to GRs, identified through the utilisation of TK. On May 6, 2010, the Delegations of Australia, Canada, New Zealand, Norway and the United States of America submitted a working document on GR for the 17th session of the IGC held December 6 to 10, 2010. Further to comments which were received, a revised document identified five objectives with underlying principles. The objectives were: 1. ensure inventors using genetic resources and any associated traditional knowledge comply with any conditions for use, access and benefit sharing; 2. prevent patents being granted in error for inventions that are not novel or inventive in light of traditional knowledge associated with genetic resources; 3. Ensure patent offices have available the information needed to make proper decisions on patent grant; 4. relationship with relevant international agreements and processes; 5. maintain the role of the IP system in promoting innovation.

On December 8, 2010, the Delegation of Angola submitted the proposals of the African Group which suggested the commencement of negotiations on a mandatory disclosure requirement and an appropriate way to ensure prior informed consent and fair and equitable benefit sharing, in line with the Nagoya Protocol. The African proposal suggested that negotiations be based upon two current proposals for a mandatory disclosure requirement, and the incorporation of the "internationally recognized certificate of compliance" as stipulated in the Nagoya Protocol, together with any other submission that may be tabled by member countries. In relation to the option for guidelines and recommendations on defensive protection, the African Group proposed consideration of the use of available databases on GR and/or associated TK.

At the 3rd Intersessional Working Group of the IGC, which met from February 28 to March 4, 2011, a Working Group was appointed to review and rationalize the various Objectives and Principles which had been received by the IGC with a view to clarifying the key and divergent policy positions and issues, which the IGC would need to make informed decisions. This report was transmitted to the IGC for its consideration at its
18th session (May 9 to 13, 2011).

Farmer's Rights under the International Treaty

At its Third Session in Tunis, 2009, the Governing Body of the TPGRFA adopted a resolution on Farmers' Rights (Resolution 6/2009), in which it requested the Secretariat to convene regional workshops on Farmers' Rights, subject to the agreed priorities of the Programme of Work and Budget and to the availability of financial resources. The aim of the workshops was to discuss national experiences on the implementation of Farmers' Rights as set out in Article 9 of the International Treaty, involving, as appropriate, farmers' organizations and other stakeholders.

A Global Consultation Conference on Farmers' Rights was held in Addis Ababa from 23 to 25 November 2010 and hosted by the Institute of Biodiversity Conservation, Ethiopia. Participating delegations recommended that the Governing Body take measures to support the Contracting Parties technically and financially in building capacity to recognize TK and facilitate its use and in developing and implementing legal provisions on TK. These recommendations were communicated to the fourth session of the Governing Body (GB 4) of the ITPGR convened from 14-18 March 2011, in Bali, Indonesia. In the final resolution the Governing Body recalls that farmers' rights is one of the key components of the ITPGR and requested the Secretariat to invite the views on the protection of Farmers Rights from farmers and stakeholders.

International Developments in the Protection of TK

At a diplomatic conference on 9-10 August 2010 in Swakopmund, Namibia, organized by the African Regional Intellectual Property Organization (ARIPO) a Protocol on the Protection of Traditional Knowledge and Expressions of Folklore was promulgated. The Protocol is meant to "protect creations derived from the exploitation of traditional knowledge in ARIPO member states against misappropriation and illicit use through bio-piracy." In October 2010, the 17th session of the IGC, to be held from 6 to 10 December 2010, was identified as the occasion for the first text-based discussion of the establishment an international TK and EC regime. An "informal drafting group" was set up to provide a text on Traditional Cultural Expressions for the next meeting of the IGC, May 9-13, 2011. Further proposals for the protection of TK were made by a number of countries and were considered by an Intersessional working group which met from February 21 to 25, 2011.

A collaboration treaty on TK and expressions of culture was submitted to the 18th Melanesian Spearhead Group Leaders' Summit in Suva on 31st March, 2011 which agreed in principle. The Government of Fiji proposes to sign the Treaty in May 2011 and the Governments of PNG and Vanuatu are currently undertaking in-country consultations on the Treaty before their Governments sign the Treaty.

Climate change and patenting

Somvanshi in a 2008 study identified 30 patents relating to drought tolerant genes. A study in the same year by the ETC Group identified 55 patent "families" (a total of 532 patent documents) that were applied for and/or granted to a number of biotechnology companies on so-called "climate-ready" genes at patent offices around the world. Its 2010 update of this study "examined patents containing claims concerned with abiotic stress tolerance (ie traits related to environmental stress, such as drought, salinity, heat, cold, chilling, freezing, nutrient levels, high light intensity, ozone and anaerobic stresses". It noted "a dramatic upsurge in the number of patents published (both applications and issued patents) related to 'climate-ready' genetically engineered crops from June 30, 2008 to June 30, 2010, identifying 262 patent families and 1663 patent documents.

The 2008 ETC report was subjected to a close analysis by Nottenburg who pointed out that the number of patent families is the better indicator of the incidence of the patenting of stress-tolerant genes, than patent filings. She dismissed criticisms of over-broad patent claims as a matter of impression. The 2010 report of the ETC described a high level of market concentration in this area which it said gives cause for concern for those who espouse the positive role of competition.

Enforcement and Liability Issues

There have been no cases on the IP liability of governments, research institutes and farmers for the use of proprietary seed since the 2009 report. However, the liability of exporters and importers was considered by the European Court of Justice in litigation concerning the importation into the UK and the Netherlands of soy meal manufactured in Argentina from patented RuR soy. The Court ruled that as the soy contained only fragments of the patented DNA, which was no longer capable of performing its herbicide resistance function, the importation was unobjectionable.

I. INTRODUCTION

1.1 Evolution of IPRs as applied to GRs

Intellectual property rights (IPRs) may be defined as statutory monopolies conferred by the state for a prescribed term in relation to certain creations of the mind. There is no all-embracing definition of IPRs to be found in any national laws or international treaties. Typically, an instrument will contain a list of matters which are considered to be IPRs. Thus the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) states that for the purposes of the Agreement, the term "intellectual property" (IP) refers to all categories of IP "that are the subject of Sections 1 through 7 of Part II" of the Agreement. Those categories are: 1. Copyright and Related Rights; 2. Trademarks; 3. Geographical Indications; 4. Industrial Designs; 5. Patents (including plant varieties rights); 6. Layout-Designs (Topographies) of Integrated Circuits; and 7. Protection of Undisclosed Information (trade secrets).

"Intellectual property" is usually divided into two branches; (i) industrial property and (ii) copyright and the rights which neighbour upon copyright. The principal categories of industrial property are: patents, trademarks, geographical indications, industrial designs and trade secrets. Industrial property according to the 1883 Paris Convention for the Protection of Industrial Property is to be understood 'in the broadest sense' and to apply 'not only to industry and commerce proper' but also to 'agricultural and extractive industries and to all manufactured or natural products ' including 'wines, grain, tobacco, leaf, fruit, cattle, minerals, mineral waters, beer, flowers and flour'.

Copyright law is concerned with the protection and exploitation of the expression of ideas in a tangible form. The central right which the law confers is to prevent unauthorised persons from copying a work. To be protected as copyright, ideas have to be expressed in an original way; that is they must have their origin in the labour of the creator. Works are protected irrespective of their quality. Originally, the subject matter of copyright protection was printed literary artistic and literary works. As reprographic technology has improved, protection has been extended to technical drawings, maps, paintings and to three-dimensional works such as sculptures and architectural works and to photographs and cinematographic works. More recently, copyright protection has been extended to computer programmes, Internet web sites and to data bases.

The principal IPRs which may be applied to genetic resources (GRs), including microorganisms, plants and animals, are: patents, plant variety rights and trade secrets, although it should be noted that in the commercialisation of genetic resources, trademarks, and geographical indications, (GIs) may play an important role. Finally, in the conduct and representation of research conducted in relation to genetic resources, copyright and the protection of layout designs of integrated circuits, as well as patents and trade secrets may play a role.

It should be noted that IPRs have developed by gradual accretion, usually as the result of the lobbying activities of commercial interests, thus plant variety rights were recognised as a category of IPR for the first time in 1961, largely as the result of the lobbying activities of European fruit and flower breeders.[3] It is thus possible for new IPRs to be created in the future. By way of example, developing countries and LDCs have been advocating the creation of IPRs in relation to traditional knowledge (TK), including the knowledge of traditional farmers and in relation to the protection of traditional cultural expressions (TCEs), including traditional recipes, magic and scared rites.

[3] M.Blakeney, 'Stimulating Agricultural Innovation' in K.E Maskus and J.H.Reichman, eds., *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime*, Cambridge: Cambridge University Press, 2005, 367-390.

1.2 IPR Standards of the TRIPS Agreement

The reasons offered by economists as to why a state might confer IPR monopolies include the encouragement of invention and innovation and of technology transfer and investment. For most countries, however, IPR legislation has been introduced in the first instance for the purpose of implementing international treaty obligations or obligations under intergovernmental agreements. Until 1994, the international IPR regime was largely administered by the World Intellectual Property Organization (WIPO).[4] The perceived failure of WIPO to deal with the growth of counterfeiting and piracy and the difficulties which were being experienced in negotiating improvements to the WIPO-administered IPR regime caused a number of countries to persuade the parties to the General Agreement on Tariffs and Trade (GATT) to assume responsibility for IPRs.[5] This resulted in the promulgation in 1994 of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) as one of the results of the Uruguay Round of the GATT.

Article 1.1 of the TRIPS Agreement requires WTO Members to "give effect to the provisions of this Agreement" but it points out that "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." In other words the norms which are prescribed by TRIPS are taken to define a legislative minimum. This provision concludes by pointing out that "Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice."

In recent years bilateral Free Trade Agreements (FTAs) contain IPR chapters which either raise the minimum requirements prescribed by TRIPS, or they prescribe the form of compliance with TRIPS. For example, the USA's FTAs prescribe UPOV 1991 as the form of compliance with the obligation in Article 27.3(b) of TRIPS for Members to introduce plant variety rights protection.

The "Objectives" of the TRIPS Agreement are set out in Article 7. It states that;

> 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.

Article 8, sub-titled "Principles" provides that

> 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.

The meaning of these provisions has not yet been subject to any detailed analysis, since neither provision requires any action by WTO Members. However, being included in the body of the

[4] WIPO administered all of the international IPR conventions and treaties with the exception of the Universal Copyright Convention, administered by UNESCO and the Convention for the Protection of Plant Varieties administered by UPOV.

[5] See M. Blakeney, *Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPS Agreement*, Sweet & Maxwell, London, 1996; C. Correa, A. Yusuf eds, *Intellectual Property and International Trade: The TRIPS Agreement*, Kluwer Law International, London, Boston, 1998; P. Drahos, *Information Feudalism* Earthscan 2001; J. Watal, *Intellectual Property Rights in the WTO and Developing Countries*. New Delhi, Oxford University Press. 2001; S. Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights*, Cambridge University Press, 2003; C. May, and S. Sell, *A Critical International History of Intellectual Property Rights*, Lynne Rienner Publishers 2005; C.M. Correa, *Trade Related Aspects of Intellectual Property Rights. A Commentary on the TRIPS Agreement*. Oxford. Oxford University Press. 2007; D. Gervais, *The TRIPS Agreement: Drafting History and Analysis*, 3rd Ed, Sweet & Maxwell, London, 2008.

Agreement they have assisted WTO bodies concerned with the settlement of IPR disputes under the TRIPS Agreement to identify ”the object and purposes” of the Agreement.[6]

1.3 Status of review of the TRIPS Agreement and relevant developments in the Doha Round

When the TRIPS Agreement was finalised in April 1994 it was envisaged that further reviews of the instrument would be required to take account of technological change and to refine those provisions which were acknowledged to require further refinement. Article 71(1) obliged the Council for TRIPS to review the implementation of the Agreement in 2000 and thereafter every two years. In practice these reviews have been conducted at the periodic meetings of trade ministers, namely: Singapore 1997, Seattle 1999, Doha 2001, Cancun 2004, Hong Kong 2005 and Geneva 2009.

In the years following the commencement of TRIPS a number of developing countries urged that Articles 7 and 8 should be “operationalised” particularly as a means of securing the transfer and dissemination of technology as promised in Article 7.[7] Reflecting this pressure, Clause 19 of the Doha Ministerial Declaration 2001 ‘instructed’ the Council for TRIPS, to “be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and … take fully into account the development dimension’ in pursuing its review programme under Article 71 of TRIPS.[8] However, only very limited progress has been made in completing the Doha Work Programme, particularly in relation to IPRs. A threshold problem is identifying what is considered to be an implementation issue. It is agreed that there is a negotiating mandate to discuss the creation of a multilateral register for geographical indications for wines and spirits. However, some WTO Members have argued that this negotiation should include consideration of whether this register could also include agricultural products and handicrafts. Two other matters have been raised: “GI extension”: a proposal to extend to other products the higher level of geographical indications protection now given to wines and spirits; and “disclosure”: requiring that patent applicants disclose the origin of genetic material and traditional knowledge used in their inventions, or alternative proposals. Members differ over whether these are subjects for negotiation or not. This is a particular problem as a consensus is developing that the Doha Work Programme should be part of a “single undertaking” in which all Doha round subjects form part of a single package, with nothing agreed until everything is agreed.

One of the results of the lack of progress with the Doha Programme within the WTO is that IPR obligations are being varied by bilateral free trade agreements (FTAs), which contain IPR chapters which supplement the TRIPS Agreement.[9] Another result is that WIPO is again being entrusted with the formulation of IPR norms, for example in relation to TK and TCEs and other international organizations have begun to fashion IPR provisions within their fields of competence. The most significant of these for GRs is FAOs International Treaty on Plant Genetic Resources for Food and Agriculture.

---

[6] See Canada-Patent Protection for Pharmaceutical Products, Report of the Panel, WT/DS114/R (2000), para. 7.26. See the discussion of the role of Articles 7 and 8 of TRIPS in P.K. Yu, ‘The Objectives and Principles of the TRIPS Agreement’ (2009) 46 *Houston Law Rev* 979.

[7] WT/GC/W/147.

[8] WTO, Ministerial Declaration, Doha, 2001, WT/MIN(01)/DEC/1, 20 November 2001.

[9] See, eg P. Drahos,’BITS and BIPS -- Bilateralism in Intellectual Property’, (2001) 4 J. *of World Int. Prop.* 791; D. Vivas-Eugui, *Regional and Bilateral Agreements and a TRIPS-plus world: the Free Trade Area of the Americas (FTAA)*, TRIPS Issues Papers 1, QUNO/QIAP/ICTSD, Geneva, 2003; F. M. Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements*, Occasional Paper 14, QUNO, Geneva, April 2004; P. Roffe , *Bilateral Agreements and a TRIPS-plus World: the Chile-USA Free Trade Agreement*, TRIPS Papers, 4, QUNO, Geneva, April 2004; A. Endeshaw, "Free Trade Agreements as Surrogates for TRIPS-Plus", (2006) 28 *European Intellectual Property Review*, 374.

II. GRS AS A SUBJECT MATTER OF IPRS

2.1 Introduction

One of the problems with determining the legal protection of genetic resources through IPRs or any other kind of law is the fact that scientific constructs do not sometimes lend themselves to legal categorization. For example, the TRIPS Agreement in Article 27.3(b) provides that WTO Members may also exclude from patentability: "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes." The division between plants and animals on the one hand and micro-organisms on the other, is not as scientifically certain as the legal categories seem to suggest.[10] Additionally, a number of international organizations, with varying levels of scientific competence, are now concerning themselves with IPRs and genetic and biological resources. At its sixteenth session, held from May 3 to 7, 2010, WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore IGC) Member States identified the need for a glossary to clarify the meanings of key terms related to genetic resources to facilitate the negotiations of the Committee.[11] The Secretariat prepared a document drawing, as far as possible, from previous glossaries of the IGC and from existing United Nations and other international instruments, also taking into account definitions and glossaries which can be found in national and regional laws and draft laws, multilateral instruments, other organizations and processes and in dictionaries.[12]

For the purposes of this study, the definitions assembled in the IGC glossary will be utilised.

The term "genetic resources" is defined in the glossary by reference to Article 2 of the Convention on Biological Diversity (CBD) which defines the term as "genetic material of actual or potential value." Further, it defines the term "genetic material" as meaning "any material of plant, animal, microbial or other origin containing functional units of heredity". Article 1 of the Andean Decision 391 defines "genetic resources" broadly as "all biological material that contains genetic information of value or of real or potential value".

"Plant genetic resources" are defined in Article 2 of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture as "any material of plant origin, including reproductive and vegetative propagating material, containing functional units of heredity". Article 2 of the FAO International Code of Conduct for Plant Germplasm Collecting and Transfer defines plant genetic resources as "the reproductive or vegetative propagating materials of plants".

Article 2.1 (a) of the FAO International Undertaking on Plant Genetic Resources (1983) defines plant genetic resources as "the reproductive or vegetative propagating material of the following categories of plants: i) cultivated varieties (cultivars) in current use and newly developed varieties; ii) obsolete cultivars; iii) primitive cultivars (land races); iv) wild and weed species, near relatives of cultivated varieties; and v) special genetic stocks (including elite and current breeders' line and mutants)".

Other legal instruments on IPRs do not use the term genetic resources and refer to "biological material". For example, the EU Directive on the legal protection of biotechnological inventions defines it as "material containing genetic information and capable of reproducing itself or being reproduced in a biological system."

Discussed below are the recent developments in those areas of IP which impact upon genetic resources, primarily plant variety protection, patents and geographical indications.

---

[10] See M. Adcock, and M. Llewelyn, *Micro-organisms, Definitions and Options under TRIPS.* Quaker United Nations Office Programme, Occasional Paper 2, 2000.

[11] Draft Report of the Sixteenth Session of the Committee (WIPO/GRTKF/IC/16/8 Prov. 2), para. 227

[12] WIPO/GRTKF/IC/17/INF/13, October 4, 2010.

2.2 Plant Variety Protection (PVP)

The protection of plant varieties is a mandatory obligation for signatories of the TRIPS Agreement is mandated by article 27.3(b). Countries are given the option of protecting plant varieties by patents or sui generis protection or by a combination of both, but since the commencement of the TRIPS Agreement in 1995, most countries tend to adopt the 1991 Act of the UPOV Convention, by way of compliance. Thus as of April 4,, 2011, the UPOV Convention has 69 signatories, with 41 of those joining after 1 January, 1995.[13] Despite numerous commentaries and proposals for the adoption of alternative *sui generis* models,[14] only a few countries have adopted alternatives to UPOV. This is, in particular, the case of India, Malaysia and Thailand that have combined PVP with benefit sharing provisions inspired by the CBD.[15]

One of the reasons why countries have tended to adopt UPOV 1991, rather than to craft a *sui generis* alternative, is that the IPR chapters in the FTAs signed since the 1990's by the USA and the EU with their bilateral partners includes the obligation to join UPOV.

2.2.1 The UPOV Convention

Introduction

Generally, under plant variety rights legislation the plant breeder is conferred an exclusive right to do or to licence the following acts in relation to propagating material of the variety:

- produce or reproduce the material;
- condition the material for the purpose of propagation;
- offer the material for sale;
- sell the material;
- import the material;
- export the material;
- stock the material for the purposes described above.

The protection under this legislation is afforded to a "breeder" or persons claiming through the breeder who is defined in Article 1 (iv) of the 1991 UPOV Act as the person who bred, or discovered or developed a variety". "Breeding" is generally defined as including the discovery of a plant together with its use in selective propagation so as to achieve a result.

The general duration of plant variety rights under legislation based on the 1991 UPOV Act is 25 years in the case of trees and vines and 20 years for any other variety. During these periods the

---

[13] http://www.upov.int/export/sites/upov/en/about/members/pdf/pub423.pdf, accessed 14 March 2011.

[14] Eg Biswajit Dhar, *Sui Generis Systems for Plant Variety Protection. Options under TRIPS. A Discussion Paper*, Geneva, QUNO, 2002; , L.R. Helfer, *Intellectual Property Rights in Plant Varieties: An Overview with Options for National Governments.* FAO Legal Papers Online #31. Rome: FAO, 2002; Daniel Robinson, *Exploring Components and Elements of Sui Generis Systems for Plant Variety Protection and Traditional Knowledge in Asia*, Geneva, UNCTAD, IDRC and ICTSD, 2007; Daniel, Robinson, '*Sui Generis* plant variety protection systems: liability rules and non-UPOV systems of protection', Journal of Intellectual Property Law & Practice 2008 3 (10): pp. 659-665.

[15] A. Ramanna, 'India's Plant Variety and Farmers' Rights Legislation: Potential Impact on Stakeholder Access to Genetic Resources', *EPTD Discussion Paper No. 96.* IFPRI, Washington D.C. (2003); I.M.A.G Azmi,, 'The Protection of Plant Varieties in Malaysia', *The Journal of World Intellectual Property*, 2004, V.7. (6) 877-890; R. Kanniah, 'Plant Variety Protection in Indonesia, Malaysia, the Philippines and Thailand', *The Journal of World Intellectual Property*. V.8. (3) pp283-310, 2005; Rohan Dang and Chandni Goel, 'Sui Generis Plant Variety Protection: The Indian Perspective' *American Journal of Economics and Business Administration*, 2009, 1 (4): pp. 303-312; Prabhash Ranjan, 'Recent Developments in India's Plant Variety Protection, Seed Regulation and Linkages with UPOV's Proposed Membership', *Journal of World Intellectual Property*, 2009, 12(3) 219-243; GRAIN, 'Beyond UPOV: Examples of Developing Countries Preparing Non-UPOV Sui Generis Plant Variety Protection Schemes For Compliance With TRIPS' (2009), http://www.grain.org/briefings/?id=127; Adam Masarek, 'Treetop View of the Cathedral: Plant Variety Protection in South and Southeast Asian Least Developed Countries' *Emory International Law Review*, 2010, 24: pp. 433-467. Abeba Tadesse Gebreselassie, 'The Idea of Sustainable Development to Reconcile the Environmental and the Intellectual Property Protection of Plants' *Journal of Sustainable Development in Africa* 2010, 12(5): pp. 125-128; Pratibha Brahmi and Vijaya Chaudhary, 'Protection of plant varieties: systems across countries' Pratibha Brahmi and Vijaya Chaudhary, *Plant Genetic Resources,* Published online: 04 February 2011, DOI:10.1017/S1479262111000037;

breeder or other licensee or owner of the right is entitled to exclusivity in its exploitation and commercialisation.

Plant variety protection is established after a registration process. Some of the particulars of this process and its inter-relationship with phytosanitary legislation was recently considered by the European Court of Justice (ECJ).[16] This case concerned an application to the European Community Plant Variety Office (CVPO) for the apple variety (Malus Mill) Gala Schnitzer, which was sought by a New Zealand applicant. The CPVO requested the applicant to submit to it the material necessary for the technical examination[17] and also stated that the applicant was responsible for complying with all phytosanitary and customs requirements applicable to the delivery of the material. In 2001, the applicant stated that it was impossible for it to provide the phytosanitary certificate requested, because it had emerged that the material sent in March 1999 for the purposes of the technical examination was infected by latent viruses and requested that it be allowed to submit new, virus-free material in order to restart the technical examination. It was argued by interveners that the CPVO was required to refuse the application as soon as the failure to comply with phytosanitary and customs requirements had been established. The ECJ rejected this argument, considering that the CVPO had a discretion to allow the relevant health certificate to be made available at a subsequent date.

Distinctness

A plant variety is considered to be registrable, if it has a breeder, is distinct, uniform, stable and has not been or has only recently been exploited. A plant variety is considered distinct if it is clearly distinguishable from any other variety whose existence is a matter of common knowledge. This issue was considered by the European Court of Justice of the First Instance in a case concerning a PVP application for a variety of the species *Plectranthus ornatus*.[18] The applicant's competitors successfully opposed the grant of the right being sought, on the ground that it was not distinct from a wild variety originating in South Africa as it was regarded as a matter of common knowledge because it had been marketed for years in that country, where it was also found in private gardens.

This decision is also interesting because some of the comments made by the court are applicable to the questionable novelty of inventions derived from traditional knowledge. The Court in deciding the question of common knowledge took into account the academic literature which referred to the fact that *P. ,* originally native in Ethiopia and Tanzania was "cultivated and semi-naturalised" in South Africa.[19]

A variety is considered uniform if, subject to the variation which may be expected from the particular features of its propagation, it is uniform in its relevant characteristics on propagation. A plant variety is stable if its relevant characteristics remain unchanged after repeated propagation. A plant variety is taken not to have been exploited if it or propagating material has not been sold to another person by or with the consent of the breeder.

Essentially Derived Variety (EDV)

Plant variety protection following from the 1991 UPOV Act, discussed below, also extends to varieties which are "essentially derived" from protected varieties. Article 14(5) of UPOV provides that

> "(b)... a variety shall be deemed to be essentially derived from another variety ("the initial variety") when

[16] Case T-135/08, 13 September 2010.

[17] Ie 10 dormant shoots for grafting

[18] Schrader v OCVV (SUMCOL 01) [2008] EUECJ T-187/06 (19 November 2008).

[19] L.E. Codd in 1975, '*Plectranthus* (Labiateae) and allied genera in southern Africa', *Bothalia* 11(4):371-442; confirmed by Andrew Hankey in *Plantlife* No 21, September 1999; Dr H.F. Glen, 'Cultivated Plants of southern Africa names, common names, literature', 2002, p. 326.

(i) it is predominantly derived from the initial variety, or from a variety that is itself predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety,

(ii) it is clearly distinguishable from the initial variety and

(iii) except for the differences which result from the act of derivation, it conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety.

(c) Essentially derived varieties may be obtained for example by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering."

Although in practice there is a fair degree of confusion as to the criteria to be applied in ascertaining whether a variety is EDV, the purpose of this requirement is to prevent the breeder of a derived variety that has no stand-alone merit of its own from obtaining PVP for it and thereby preventing the owner of the original variety from obtaining a fair return on investment.

In a 2010 review of the Australian Plant Breeders Rights legislation, it was argued that the test for "predominantly derived" was not sufficiently rigorous for the determination of essential derivation and breeding organisations argued that genetic descriptions of relatedness, possibly based on molecular markers, would be a more appropriate method of quantifying the extent to which the derived variety was "predominantly derived" from the original variety.[20] The adoption of the approach to quantifying genetic relatedness developed by the International Seed Federation[21] was urged and the suggestion was made that DNA profiling could be required as part of the plant breeders right application to assist the evaluation of whether the applicant variety was essentially derived.[22] On the other hand it has been pointed out that DNA profiling has limitations in determining essential derivation because: (i) there is much less inherent genetic variability in some species (eg. cotton) than in others (eg. barley); (ii) absolute measures of genetic relatedness are not feasible as they rely on a sampling strategy; and (iii) scientific technologies evolve over time.[23]

Farmer's Privilege ("Seed-saving" Exception)

Usually excepted from plant variety rights is seed saved by a farmer from harvested material and treated for the purpose of sowing a crop on that farmer's own land. Thus Article 15 (2) of the UPOV Convention 1991 provides as an optional exception that "each Contracting Party may, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder's right in relation to any variety in order 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 holdings, the protected variety...." It should be noted that although this is colloquially defined as the "seed-saving" exception, Article 15(2) refers to "the product of the harvest". This exception in the 1991 version of the UPOV Convention is contrasted with the 1978 UPOV Act under which it is argued that "the scope of plant variety protection does not cover farm saved seeds and therefore technically there is no need for an institutionalized farmers' privilege."[24] UPOV 1991 may also be contrasted with Article 9.3 of the International Treaty for the Protection of Plant Genetic Resources for Food and Agriculture, which provides that "Nothing

[20] Australian Government Advisory Council on Intellectual Property (ACIP), *A review of enforcement of Plant Breeder's Rights. Final Report*, January 2010, Canberra, AGPS, p.67.

[21] See ISF guidelines for handling disputes on essential derivation, http://www.worldseed.org/enus/international_seed/edv.html.

[22] ACIP, n.21 supra at 7.4.

[23] Jay, Sanderson, 'Essential derivation, law and the limits of science', (2006) 24(1) Law in Context, pp.34-53.

[24] See H. Ghijsen, 'Plant Variety Protection in a Developing and Demanding World' , (1998) *Biotechnology and Development Monitor*, No. 36, p. 2-5.

in this Article shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate."

The use in Article 15(2) of the term "product of the harvest" instead of "seed" has raised questions about the proper scope of the exception.[25] Some countries have clarified the scope of the exception in their national legislation, thus Costa Rica[26] and the Dominican Republic[27] exclude "fruit, ornamental and forest species" from farmer's privilege "where planted for commercial ends". Mexico limits the exception to "grain for consumption or seed for sowing".[28]

The Breeder's Exemption

Article 15.1(i) and (ii) o the 1991 Act of the UPOV Convention provides exemptions from liability for "acts done privately and for non-commercial purposes [and] for experimental purposes". UPOV has stated that the concept of the "breeder's exemption" reflects its view that "the worldwide community of breeders needs access to all forms of breeding material to sustain greatest progress in plant breeding and, thereby, to maximize the use of genetic resources for the benefit of society".[29] The International Treaty on Plant Genetic Resources for Food and Agriculture in Article 13.2. (d)(ii)) recognizes the concept of the breeder's exemption, in that breeders are excepted from financial benefit-sharing whenever their products are "available without restriction to others for further research and breeding". Finally, UPOV 1991 in Article 17.1, provides that *"*no Contracting Party may restrict the free exercise of a breeder's right for reasons other than of public interest*."* This is in effect a compulsory licensing obligation.

On 6 May 2009, Plantum NL, the Dutch association for breeding, tissue culture, production and trade of seeds and young plants, announced its position on the relationship between patents and plant breeders' rights.[30] It stated that:

1. Biological material protected by patent rights should be freely available for the development of new varieties.
2. The use and exploitation of these new varieties should be free, in line with the 'breeders' exemption' of the UPOV Convention.
3. The aforementioned free availability, use and exploitation should not be allowed to be obstructed in any way, either directly or indirectly, by patent rights.

It notes that contemporary plant breeding involves the use of various high-tech procedures which serve to improve and/or speed up the selection process, such as EMS mutagenesis, gene mapping, embryo rescue, double haploidisation and selection based on DNA markers. Since patent laws in general do not have a provision which can be compared to the breeders' exception, varieties containing patented traits or which have been developed using a patented process are not freely available for further breeding. Planum NL notes the significant increase in the number of plant-related patent applications[31] and that although France and Germany have included an exemption for plant breeding in their national patent law, since 2004, a number of companies with strong patent portfolios have been advocating that this position should be changed to disallow further breeding of progeny containing a patented trait. It claims that this agitation "has resulted in some companies explicitly requesting that their competitors abandon plant breeding programmes which allegedly infringe their patent applications with the "immediate effect of dramatically hampering

[25] Eg see ACIP, n.19 supra.

[26] Law No. 8631 on the Protection of New Varieties of Plants, Article 23.

[27] Law on Protection of Breeder's Rights for Varieties of Plants, Article 18.

[28] Federal Law on Plant Varieties, Articles 2, 4, 5.

[29] UPOV, 'Access to Genetic Resources and Benefit-Sharing', *Reply of UPOV to the Notification of June 26, 2003, from the Executive Secretary of the Convention on Biological Diversity (CBD),* adopted by the Council of UPOV at its thirty-seventh ordinary session on October 23, 2003.

[30] Planum NL, 'Position on Patent- and plant breeders rights' http://www.plantum.nl/plantum/documenten/Standpunt%20Octrooi%20en%20Kwekersrecht%20samenvatting%20ENG.pdf

[31] 4500, most of which have been filed in the past 10 years.

innovation and posing a threat to those companies which are trying to develop competitive varieties." Plantum NL concludes that "these developments pose a threat to the tried and tested system of open innovation within the plant breeding sector."

2.2.2 Critiques of the PVP System

Over the last two decades commentators on the PVP system have begun to question to its relevance, raising the possibility that it might have become "the Neanderthal of intellectual property systems".[32] One reason for this critique is the impact of patents upon PVP, described above. At a more fundamental level it is observed that PVP in focussing upon a phenotypic paradigm, based upon "characteristics" and "features" has become outmoded as plant breeding moves towards a genotypic approach, utilising genetic modification and molecular breeding techniques.[33] Mark Janis and Stephen Smith argue that plants should be reconceptualised as datasets that breeders manipulate to express particular characteristics, which could be better regulated by unfair competition laws rather than by a sui generis PVP scheme.[34] A related observation is that the nature of plant breeding, with the use of gene-based technologies, has changed significantly since the commencement of UPOV. However, it is also pointed out that very often new technologies are used in conjunction with (rather than instead of) traditional plant breeding methods.[35]

It has been generally assumed that the increasing number of varieties released and planted is an indication of the greater availability of PVRs[36] However, it is considered to be uncertain as to whether the availability of protection caused the increase in varietal release, as well as whether this is an economic good.[37] An Australian study of PVP applications in Australia from 1987 to 2007 observed a notable decrease in the number of applications for the period 2003 to 2007.[38] This was tentatively attributed to changing environmental conditions such as drought and increased salinity which have had an effect on plant breeding investment either by reducing the level of plant breeding, or by focusing breeding programs on developing particular traits (for example, drought resistance and salinity tolerance) in new plant varieties. In Australia the highest number of PVP applications (61%) came from the nursery sector, which is perceived to be particularly vulnerable to changing climatic conditions.

2.3 Patents

2.3.1 Introduction

According to Article 27.1 of the TRIPS Agreement, patents "shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step [in the sense of not being obvious] and are capable of industrial application [ie useful]. The governing concept is that of "invention". In *Dimminaco AG v. Controller of Patents*

---

[32] Cary Fowler, *Unnatural Selection: Technology, Politics, and Plant Evolution*, Gordon and Breach, Switzerland and Langhorne Pa, 1994, p. 152.

[33] Eg see Mark Janis and Stephen Smith, 'Technological Change and the Design of Plant Variety Protection Regimes' (2007) 82 *Chicago Kent Law Review* 1557, at pp. 1566–70.

[34] Ibid at pp. 1607–14. See also Laurence Helfer, 'The Demise and Rebirth of Plant Variety Protection: A Comment on Technological Change and the Design of Plant Variety Protection Regimes' (2007) 82 *Chicago Kent Law Review* 1619 and the discussion in Jay Sanderson, 'Back to the Future: Possible Mechanisms for the Management of Plant Varieties in Australia' (2007) 30 University of New South Wales Law Journal 686 at pp.690–6.

[35] See J. Brown and P. Caligari, An Introduction to Plant Breeding, Oxford, Blackwell, 2008.

[36] Eg see: W. H. Lesser, 'Sector issues II: Seeds and plants' in W. E. Siebeck, R. E. Evenson, W. Lesser and C. A. Primo Braga, *Strengthening Protection of Intellectual Property in Developing Countries*, Washington, DC, The World Bank, 1990, pp. 59-68.

[37] Dwijen Rangnekar, *Access to genetic resources, gene-based inventions and agriculture – issues concerning the TRIPs Agreement*, Prepared for the UK Government Commission on Intellectual Property Rights, London, CIPR, 2002 at pp. 45-50.

[38] Jay Sanderson and Kathryn Adams, 'Are Plant Breeder's Rights Outdated? A Descriptive and Empirical Assessment of Plant Breeder's Rights in Australia, 1987–2007' (2008) *Melbourne University Law Review* 80.

and Designs the Calcutta High Court was concerned with a patent for a process for the preparation of a vaccine, which was capable of protecting poultry against Bursitis infection.[39] The Controller of Patents had rejected the claims on ground that it did not involve an invention. The Court ruled that an invention involved the process of manufacture by which it has become a material "which is different from the starting material" and that this meaning did not exclude from patentability the process of preparing a product that contains a living substance.

A patent is granted by a government, following an application process, to an inventor and to other persons deriving their rights from the inventor, for a fixed period of years, to exclude other persons from manufacturing, using or selling a patented product or from using a patented method or process. The protection secured by the registration of a patent is usually limited to a term of around 20 years[40] at the end of which period the patented invention is said to be within the public domain, i.e. available for anyone to exploit.

The novelty requirement means that before an invention can be patented, it should not form part of the prior art. The registration process usually involves a search by the patent office of the scientific literature, including other patent documents, to see whether the technology has been previously disclosed.

Most patent systems draw a distinction between a patentable invention and a non-patentable discovery. A discovery is considered unpatentable because it is the unearthing of causes, properties or phenomena already existing in nature. A key issue around the patenting of genetic resources is whether a DNA sequence can be characterised as an "invention". In the early history of patent law an invention was thought to involve some kind of technical innovation and a distinction was drawn between patentable inventions and non-patentable discoveries. The TRIPS Agreement provides no guidance as to what is a patentable invention. The US Supreme Court in *Diamond* v *Chakrabarty*[41] ruled that a bacterium genetically engineered to degrade crude oil was an invention. The European Parliament in its Biotechnology Directive has provided that biological material which is isolated from its natural environment or produced by means of a technical process is deemed to be an invention even if this material previously occurred in nature.

The patentability of genetic materials and gene fragments, such as expressed sequence tags (ESTs) and single nucleotide polymorphisms (SNPs), as well as enabling gene-based technologies led to what has been described as a "genomic gold rush" in the 1990s as vast numbers of gene-based patent applications were filed, particularly in the USA.[42] Significant misgivings were expressed by numerous commentators. Probably the most influential among these were HelIer and Eisenberg who suggested that genetic research tool patents could create a "tragedy of the anticommons" in which multiple patent owners would tie-up genetic materials in a thicket of IP patent rights.[43] This was perceived to be a particular problem for the genetic improvement of crops since this is an incremental process and each new patent would constrain the "freedom to operate" particularly of public agricultural research institutes.[44]

A recent US case which has raised the very question of the patentability of genetic material is *Association for Molecular Pathology v. USPTO*[45] in which a Judge of the United States District

---

[39] Discussed in S. Senan, M. G. Haridas and J. B. Prajapati, 'Patenting of microorganisms in India: a point to ponder' (2011) 100 (2) *Current Science*, 159-162.

[40] This is the minimum term prescribed by Art.33 of the TRIPS Agreement.

[41] 447 US 303 (1980).

[42] Eg see Y. Joly, 'Accès aux mèdicaments: le système international des brevets empêchera-t'il les pays du tiers monde de bénéficier des avantages de la pharmacogénomique' (2003) 16 Les cahiers de Propriété intellectuelle 135.

[43] MA Heller and RS Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research" (1998) 280 Science 698-701, at p.700.

[44] See the authorities referred to in Carlos M. Correa, 'Trends in Intellectual Property Rights Relating to Genetic Resources for Food and Agriculture', Background Study Paper 49, Commission on Genetic Resources for Food and Agriculture, October, 2009, p.2.

[45] *Association For Molecular Pathology et al v United States Patent and Trademark Office et al,* 09 Civ. 4515, March 29, 2010

Court for the Southern District of New York delivered a summary judgement which invalidated patents related to the BRCA 1 and 2 breast and ovarian cancer susceptibility genes, which had been held by Myriad Genetics. He held that the claims to DNA sequences in isolation were held to be insufficiently distinct from naturally occurring genes in the body and were thus products of nature rather than inventions. Significantly, the Judge concluded that "purification of a product of nature, without more, cannot transform it into patentable subject matter. Rather, the purified product must possess 'markedly different characteristics' in order to satisfy the requirements" [46] In his search for "markedly different characteristics" the judge focussed on the function of a gene. He observed that "DNA represents the physical embodiment of biological information, distinct in its essential characteristics from any other chemical found in nature and that DNA in an 'isolated' form alters neither this fundamental quality as it exists in the body not the information it encodes".[47] This decision strikes at the patentability of genetic material. Hitherto, the position taken was that because genes are chemically different in isolation, they could not be considered products of nature. The information-carrying function of genes was considered to be irrelevant to their patentability. This decision was appealed to the U.S. Court of Appeals for the Federal Circuit in Washington, D.C., which heard oral argument in April 2011 and it will probably proceed to the Supreme Court.

2.3.2 Patenting of Plant Varieties in the USA

In the USA it was argued that the enactment of the US Plant Variety Protection Act (PVPA) had removed seed-produced plants from the realm of patentable subject matter under the US Patents Act. In a number of decisions the Federal Circuit Appeals Court ruled that when two statutes are capable of co-existence, it was the duty of the courts to regard each as effective.[48]

2.3.3 Patenting of Plant Varieties in Europe

The situation in Europe is complicated by the fact that the European Patent Convention (EPC) takes account of UPOV and in Article 53(b) specifically excludes the patenting of "plant or animal varieties or essentially biological processes for the production of plants or animals', explaining that "this provision shall not apply to microbiological processes or the products thereof". Rule 23b(5) of the EPC explains that a process for the production of plants and animals is essentially biological if it consists entirely of natural phenomena such as crossing or selection". This language is replicated in the EU Biotechnology Directive which in Article 4.1 excludes from patentability: (a) plant and animal varieties; and (b) essentially biological processes for the production of plants or animals. Article 2.2 states that a process for the production of plants or animals is essentially biological "if it consists entirely of natural phenomena such as crossing or selection."

The Biotechnology Directive leaves the door open to the patenting of plant varieties because Article 4.2 provides that "Inventions which concern plants or animals shall be patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety."[49]

2.3.4 Patenting of Plant Breeding Methods

The exclusion by the European patent legislation of "essentially biological processes for the production of plants or animals" defined in Article 2.2 of the Biotechnology Directive as consisting "entirely of natural phenomena such as crossing or selection", would have been thought to deny patent protection to plant breeding methods, but this was tested recently by the EPO Enlarged Board of Appeal in two decisions. One concerned whether a process involving

[46] Ibid., p.121.

[47] Ibid., pp.3-4.

[48] Eg *Monsanto Co. v. McFarling* 302 F.3d 1291 (Fed. Cir. 2002).

[49] See *Novartis/Transgenic Plant* [2000] *O.J. EPO* 511.

crossing and selection of broccoli[50] could be patentable. Another referral concerned a similar type of invention relating to crossing and selection of tomatoes[51].

The broccoli patent application was filed by Plant Bioscience Ltd. (Norwich/UK) for a "method for selective increase of the anticarcinogenic glucosinolates in brassica species".[52] The tomato patent application was filed by the Israeli Ministry of Agriculture for a "method for breeding tomatoes having reduced water content and product of the method".[53] Both of the patent applications were opposed by interested parties. These oppositions were heard by the EPO's Technical Board of Appeal which referred a number of questions to be determined by the EBA. The critical questions to the EBA were:

1. Does a non-microbiological process for the production of plants which contains the steps of crossing and selecting plants escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, an additional feature of a technical nature?
2. If question 1 is answered in the negative, what are the relevant criteria for distinguishing non-microbiological plant production processes excluded from patent protection under Article 53(b) EPC from non-excluded ones? In particular, is it relevant where the essence of the claimed invention lies and/or whether the additional feature of a technical nature contributes something to the claimed invention beyond a trivial level?

The questions raised in respect of the tomatoes referral were:

1. Does a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants fall under the exclusion of Article 53(b) EPC only if these steps reflect and correspond to phenomena which could occur in nature without human intervention?
2. If question 1 is answered in the negative, does a non-microbiological process for the production of plants consisting of steps of crossing and selecting plants escape the exclusion of Article 53(b) EPC merely because it contains, as part of any of the steps of crossing and selection, an additional feature of a technical nature?
3. If question 2 is answered in the negative, what are the relevant criteria for distinguishing non-microbiological plant production processes excluded from patent protection under Article 53(b) EPC from non-excluded ones? In particular, is it relevant where the essence of the claimed invention lies and/or whether the additional feature of a technical nature contributes something to the claimed invention beyond a trivial level?

The EBA answered the questions as follows:

1. A non-microbiological process for the production of plants which contains or consists of the steps of sexually crossing the whole genomes of plants and of subsequently selecting plants is in principle excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC.
2. Such a process does not escape the exclusion of Article 53(b) EPC merely because it contains, as a further step or as part of any of the steps of crossing and selection, a step of a technical nature which serves to enable or assist the performance of the steps of sexually crossing the whole genomes of plants or of subsequently selecting plants.
3. If, however, such a process contains within the steps of sexually crossing and selecting an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen

[50] Case G2/07.

[51] Case G1/08.

[52] Patent specification EP 1069819, published 24.7.2002.

[53] Patent specification EP 1211926 published, 26.11.2003.

for sexual crossing, then the process is not excluded from patentability under Article 53(b) EPC.

4. In the context of examining whether such a process is excluded from patentability as being "essentially biological" within the meaning of Article 53(b) EPC, it is not relevant whether a step of a technical nature is a new or known measure, whether it is trivial or a fundamental alteration of a known process, whether it does or could occur in nature or whether the essence of the invention lies in it.

The EBA identified from the jurisprudence the following elements which had been enumerated as relevant to determining whether a process is not essentially biological:

1. The totality of human intervention and its impact on the result achieved is to be determined.
2. This has to be judged on the basis of the essence of the invention.
3. The impact must be decisive.
4. The contribution must go beyond a trivial level.
5. The totality and the sequence of the specified operations must neither occur in nature nor correspond to the classical breeders' processes.
6. The required fundamental alteration of the character of a known process for the production of plants may lie either in the features of the process, i.e. in its constituent parts, or in the special sequence of the process steps, if a multistep process is claimed.[54]

It had been argued in the proceedings that crossing and selection should be understood to mean only crossing and selection as they take place in nature. In particular, the term selection did not address the selection made by man in a breeding process but only the selection that takes place in nature and is not controllable by man, and that determines which plants survive in nature, The EBA ruled that applying the principles of treaty interpretation the meaning of a term of a treaty could not be established in a purely semantic manner but its interpretation must be made in good faith, in accordance with the ordinary meaning to be given to the terms of the treaty in their context.[55] Thus it observed that a definition which completely disregarded the fact that the context of the terms crossing and selection in the provisions of the EPC is given by the processes for the production of plants, the terms "crossing" and "selection" refer to acts performed by the breeder. These are characterised by the fact that the breeder intervenes in the processes in order to achieve a desired result. Hence, in that context, crossing and selection are not natural phenomena but are method steps which generally involve human intervention.

A study published in March 2011[56] pointed out that the EPO's Board of Appeal decided in May 2010 that conventionally-bred plants, their seed and products of harvests were patentable, even if the process for breeding them was not[57] and that following the Broccoli and Tomato decisions the EPO was notifying this to patent applicants. The study noted that of over 30% of 350 applications made for patents on plants to WIPO under the Patent Cooperation Treaty (PCT) covered the conventional breeding of plants, such as for marker-based selection, regeneration and reproductive processes, measuring constituent substances, hybrid breeding and mutagenesis, "as well as for material used in breeding such as seed, genes and parts of plants, whole plants, their harvests and products (sometimes processed) like food, feedstuff and biomass."[58]

---

[54] Eg Case G1/08, at p.35.

[55] Ibid, at pp. 38-39.

[56] Christoph Then & Ruth Tippe, *Seed monopolists increasingly gaining market control Applications and granting of patents in the sphere of animal and plant breeding in 2010*, March, 2011.http://www.no-patents-on-seeds.org/sites/default/files/news/patente_report_2011_final_en.pdf

[57] Case T1854/07, patent on sunflowers granted to Consejo Superior de Investigationes Cientificas in Spain (EP 1185161).

[58] Then and Tippe, at p.16.

2.3.5 The Technical Requirement for Patentable Inventions

The Broccoli and Tomato decisions of the EBA, raise the underlying question of what botanical innovations constitute a patentable invention for the purposes of patent law. The answer to this question will differ according to the national patent law which is in force. In the USA in *Diamond v Chakrabarty*[59] the Supreme Court held that some human intervention was required to render a biological innovation as patentable.[60] The European Patent Office focuses upon the necessity for a claimed invention to have a "technical" character. Rule 27 Implementing Regulations to the Convention on the Grant of European Patents defines patentable biotechnological inventions as those which concern:

(a) biological material which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature;

(b) plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety;

(c) a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety.

This requirement that inventions have a technical character was considered by the EBA in the Broccoli and Tomato cases to be an important matter in its consideration of whether plant breeding methods were patentable. In examining the historical documents which led up to the formulation of the EPC in 1960, the EBA observed that with the creation of new plant varieties, for which a special property right was going to be introduced under the subsequent UPOV Convention in 1960, the legislative architects of the EPC were concerned with excluding from patentability the kind of plant breeding processes which were the conventional methods for the breeding of plant varieties of that time. These conventional methods included in particular those based on the sexual crossing of plants deemed suitable for the purpose pursued and on the subsequent selection of the plants having the desired trait(s). These processes were characterised by the fact that the traits of the plants resulting from the crossing were determined by the underlying natural phenomenon of meiosis. This phenomenon determined the genetic make-up of the plants produced, and the breeding result was achieved by the breeder's selection of plants having the desired trait(s). That these were processes to be excluded also followed from the fact that processes changing the genome of plants by technical means such as irradiation were cited as examples of patentable technical processes.

The EBA also referred to the explanations given in the memorandum of the Secretariat of the Committee of Experts for agreeing to the replacement of the words "purely" biological by the word "essentially" was deliberate as reflecting the legislative intention that the mere fact of using a technical device in a breeding process should not be sufficient to give the process as such a patentable technical character. The EBA concluded that the provision of a technical step, be it explicit or implicit, in a process which is based on the sexual crossing of plants and on subsequent selection does not cause the claimed invention to escape the exclusion if that technical step only serves to perform the process steps of the breeding process.[61]

The decision of the EBA was that a process for the production of plants which is based on the sexual crossing of whole genomes and on the subsequent selection of plants, in which human intervention, including the provision of a technical means, serves to enable or assist the performance of the process steps, is excluded from patentability as being essentially biological within the meaning of Article 53(b) EPC. On the other hand, if a process of sexual crossing and selection includes within it an additional step of a technical nature, which step by itself introduces a trait into the genome or modifies a trait in the genome of the plant produced, so that the introduction or modification of that trait is not the result of the mixing of the genes of the plants chosen for sexual crossing, then that process leaves the realm of the plant breeding and

[59] 447 US 303 (1980).

[60] Ibid., at p.310.

[61] Ibid., pp.66-67.

consequently, is not excluded from patentability. This principle applies only where the additional step is performed within the steps of sexually crossing and selection, independently from the number of repetitions, otherwise the exclusion of sexual crossing and selection processes from patentability could be circumvented simply by adding steps which do not properly pertain to the crossing and selection process, being either upstream steps dealing with the preparation of the plant(s) to be crossed or downstream steps dealing with the further treatment of the plant resulting from the crossing and selection process. The EBA noted that for the previous or subsequent steps *per se* patent protection was available. This will be the case for genetic engineering techniques applied to plants which differ from conventional breeding techniques as they work primarily through the deliberate insertion and/or modification of one or more genes in a plant.

It is important to note that the EBA disallowed the patenting of methods of plant breeding. It has been pointed out that the products of plant breeding remain patentable.[62] An analysis of the examination reports for recent patent applications at the EPO indicate that claims in relation to the breeding of plants would have to be deleted, but that the plants themselves (sunflowers[63] and coreless tomatoes[64]) were patentable.

2.4 Confidential Information (Including Trade Secrets)

Under intellectual property law information which has been originated by a person and which is not in the public domain and in relation to which efforts have been made to keep it confidential may be protected by the law of confidence. For example, where plant breeding information has been kept confidential, the theft of that information in documentary form would be actionable. Similarly, it has been held that the theft of genetic material is actionable For example in *Franklin* v *Giddins*[65], the Queensland Supreme Court was concerned with the theft by a defendant of budwood cuttings from the plaintiffs' orchard which enabled the defendant after grafting to grow Franklin Early White nectarines, in competition with the plaintiffs. The Court held this to involve a theft of confidential information embodied in the genetic composition of the budwood.

In *Pioneer Hi-Bred Int'l v. Holden Found Seeds*[66] the US Eighth Circuit Court of Appeals found that the defendant had developed a seed from misappropriated seed which the plaintiff successfully claimed as its trade secrets. The Appeal Court noted the efforts of the defendant to obtain the plaintiff's genetic material, which included searching "friendly farms" for stray inbred plants.

2.5 Trade Marks

2.5.1 Introduction

A trademark is a distinctive sign indicating the origin of goods or services. A trademark serves as a form of "shorthand" upon which consumers can rely in making rational product selections. In jurisdictions where there is no consumer protection legislation or legislation regarding standards in relation to the goods, for example foodstuffs or pharmaceuticals, the trademark performs a valuable function, not merely in indicating quality, but also by indicating likely safety and fitness for purpose. For developing countries and LDCs, trademarks can be used first as a form of self-funded consumer protection since the trademark proprietor will be the person most vigilant in the policing of deceptive practices and in taking enforcement action against counterfeiters. They can also be used to facilitate the penetration of lucrative overseas markets.

---

[62] Christoph Then & Ruth Tippe, Seed monopolists increasingly gaining market control. Applications and granting of patents in the sphere of animal and plant breeding in 2010, March, 2011, http://www.no-patents-on-seeds.org/sites/default/files/news/patente_report_2011_final_en.pdf, accessed 13 March 2011.

[63] EP 1793661 application by the Biogemma company.

[64] EP 1026942, application by Seminis company.

[65] (1978) Qd R 72.

[66] 35 F.3d 1226 (8th Cir. 1994).

Trademarks are usually protected by registration. To be registered as a trademark a sign must be capable of representation in a visible form. Visible signs typically include names, invented or existing words, letters, numbers, pictures and symbols, or combinations of these signs. To be capable of registration a sign must be capable of distinguishing goods or services of one undertaking from those of other undertakings. The requirement of distinctiveness has been held to disqualify from protection trademarks which are registered designation of plant varieties. For example the attempt to register AR1 as "the name of a registered variety of ryegrass endophyte" was rejected as this was already a registered plant variety and the test applied by the courts was whether a mark is one which other traders are likely in the ordinary course of their business and without any improper motive, to desire to use upon or in connection with their goods.[67]

Also, the requirement of distinctiveness tends to disqualify geographic names from protection. This disqualification may be contained in national trademark laws or as a result of the decisions of judicial decisions. However, it may be possible to register names which have a geographical derivation, but not a geographical connotation in the place of registration. For example, since 2005 trademark applications for three Ethiopian coffee designations: *Harar/Harrar, Sidamo and Yirgacheffee* were filed in 36 countries, including: Australia, Brazil, Canada, China, India, Japan, the European Union, Saudi Arabia, South Africa and the USA despite the fact that these marks had geographical connotations.[68]

2.5.2 Collective and Certification Marks

An exception to the non-registrability of geographical signs are special types of registered trademarks: collective and certification marks. A collective mark is that registered by an association whose members may use it if they comply with the requirements fixed in the regulations concerning the use of the collective mark. Thus, the function of the collective mark is to inform the public about certain particular features of the product for which the collective mark is used. An enterprise entitled to use the collective mark may in addition also use its own trademark.

Certification marks are those registered by bodies to certify the quality or compliance with production standards by producers.

Three Kenyan examples of these types of marks are: “ECHUCHUKA” registered on 25 September 2006 as a collective mark for detergents, cleaning preparations, soaps, perfumery, essential oils, cosmetics and hair lotions/shampoos by the Turkana Bio Aloe Organization (Tubae)), located in Loima in Turkana District.[69] The applicant for registration was Echuchuka means aloe in the Turkana language. The rules filed with the trade mark application forbids the use of the mark by anyone outside TUBAE. Membership of TUBAE is available to any organised and registered Aloe group in the Turkana districts in the Rift Valley.

COFFEE KENYA was registered as a certification mark by the Coffee Board of Kenya on 25 November 2005 in class 30 for red cherry coffee, parchment coffee, clean coffee, roasted and ground coffee.[70] The Tea Board of Kenya (TBK) on 15 April 2009 obtained registration of a certification mark in classes 16 (printed matter), 25 (clothing and head gear) and 30 (tea) for a “Mark of Origin”.[71]

A similar approach is taken in the USA. For example, the certification mark VIDALIA is owned by the State of Georgia’s Department of Agriculture and is “intended to be used by persons authorized by certifier, and … in connection with which it is used are yellow Granex type onions and are grown by authorized growers within the Vidalia onion production area in Georgia as

[67] Heritage Seeds Pty Ltd [2007] Australian Trade Marks Office (ATMO) 4 (25 January 2007).

[68] G. Mengistie, “Intellectual Property as a Tool for Development: The Ethiopian Fine Coffee Designations Trade Marking and Licensing Experience”, *International Trade Law and Regulation*, 2010, 16 (1) 38-45.

[69] Trade Mark No 59849.

[70] Trade Mark No. 66945.

[71] Trade Mark No. 65335.

defined in the Georgia Vidalia Onion Act of 1986."[72] Similarly, FLORIDA CITRUS is owned by the State of Florida's Department of Citrus and certifies that the goods bearing the mark "either consist of citrus fruit grown in the State of Florida, under specified standards, or are processed or manufactured wholly from such citrus fruit."[73] Non-US agricultural producers have also registered certification marks in the USA. For example, the Thai Ministry of Commerce of Thailand, has registered THAI HOM MALI RICE "harvested in Thailand per the standards set by the Ministry of Commerce of Thailand in "Regulations of the Department of Foreign Trade Re: Usage of the Certification Mark of Thai Hom Mali Rice."[74] Similarly, the Tea Board of India has registered DARJEELING to certify "that the tea contains at least 100% tea originating in the Darjeeling region of India and that the blend meets other specifications established by the certifier."[75]

A certification mark may only be used in accordance with the defined standards. The main difference between collective marks and certification marks is that the former may be used only by particular enterprises, for example, members of the association which owns the collective mark, while the latter may be used by anybody who complies with the defined standards. An important requirement for the registration of a certification mark is that the entity which applies for registration is "competent to certify" the products concerned. Thus, the owner of a certification mark must be the representative for the products to which the certification mark applies.

The system of registered certification marks is a departure from the trademark principle that no one can obtain an exclusive right in geographic names, which other traders might legitimately wish to use. In Europe, the preference is for such marks to be registered as geographical indications.

2.6 Geographical Indications (GIs)

2.6.1 Introduction

A GI is a sign that indicates that a product originates in a specific geographic region where the characteristic qualities of the product are due to the geographical environment, including natural and human factors. Since it is a generic description which is applicable to all traders in a particular geographic location referring to goods which emanate from that location, a GI may be distinguished from a trademark, which is a sign which distinguishes the products of a specific trader from those of its competitors. The right to protect a geographical indication from wrongful appropriation is enjoyed by all traders from the particular geographical location, whereas a trademark is protected from wrongful appropriation at the suit of the registered proprietor of that mark. Generally, geographic indications are monitored and protected by producer associations from the relevant region. Geographical indications are obtained through registration. A specification is usually filed indicating the relevant geographical area and the product quality characteristics attributable to that area. The application for registration is usually filed by a body representing the producers of that area. This body will also usually be responsible for bringing actions against wrongful users of the GI.

2.6.2 Geographical Indications (GIs) and Agriculture

In signalling the association between product quality and origin, GIs provide both a trade benefit in generating market appeal for agricultural products and a non-trade benefit of promoting local agricultural traditions and methods. In relation to the first benefit, the ability to charge premium

[72] U.S. Reg. No. 1709019.

[73] U.S. Reg. No. 1559414.

[74] U.S. Reg. No. 2,816,123.

[75] U.S. Reg. No. 2,685,923.

prices is attributed to GI branding.[76] A 2005 study states that in the EU, the price difference between PDO (Protected designation of origin) and PGI (Protected geographical indication) products and similar products without such designations is on average 10-15%.[77] As the first recital of the preamble to the 2006 EC Regulation on the protection of geographical indications and designations of origin for agricultural products and foodstuffs[78] states: "The production, manufacture and distribution of agricultural products and foodstuffs play an important role in the Community economy."[79] Thus today in the EU the 640 GIs and designations of origin for foodstuffs, and over 4,200 registered designations for wines and spirits, together generate a turnover of more than €40 billion annually.[80] Similarly, the second recital of the preamble to the EC Regulation states that:

> "The diversification of agricultural production should be encouraged so as to achieve a better balance between supply and demand on the markets. The promotion of products having certain characteristics can be of considerable benefit to the rural economy, particularly in less favoured or remote areas, by improving the incomes of farmers and by retaining the rural population in these areas."

The role of GIs to sustainable rural development objectives was referred to by the European Commissioner responsible for Agriculture, Rural Development and Fisheries. He noted that:

> "…several studies have shown that they have an important role to play in the regeneration" of the countryside since they ensure that agri-foodstuffs are produced in such a way that conserves local plant varieties, rewards local people, supports rural diversity and social cohesion, and promotes new job opportunities in production, processing and other related services. The needs of today's population are met, while natural resources and traditional skills are safeguarded for generations to come.[81]

The agro-food industry is characterised by the production of standardised food in which producers must contend with the economic power of processors, distributors and retailers who are interposed between them and consumers. GIs permit the aggregation of market power by small farmers to enable collective action by producer collectives in relation to the promotion and marketing of their products and in dealings with intermediaries.

As a means of tracing the origin of products, GIs have also been identified as a guarantee of food safety. This has become particularly important where agricultural diseases such as BSE and Avian Flu are attributed to particular localities.[82]

It has been suggested that the traditional agricultural knowledge of traditional farmers and indigenous people could be protected through geographical indications.[83] Addor states that "GIs are based on collective traditions and a collective decision-making process; they reward traditions while allowing for continued evolution; they emphasise the relationship between human efforts,

---

[76] Eg milk produced for Comte cheese is estimated to command a 10% price premium and Toscano olive oil is sold at a premium of 20% EC, See B. A. Babcock and R. Clemens, 'Geographical Indications and Property Rights: Protecting Value-Added Agricultural Products' *MATRIC Briefing Paper 04-MBP 7*, May 2004, Iowa State University.

[77] See O'Connor and Company, *Geographical Indications and the Challenges for ACP Countries. A Discussion paper*, Brussels, CTA, April 2005, at, http://agritrade.cta.int/

[78] Council Regulation (EC) No 510/2006 of 20 March 2006.

[79] For a recent analysis of European GIs legislation, see L. Bently and B. Sherman, The Impact of European Geographical Indications on National Rights in Member States' (2006) 76 *TMR* 1.

[80] See O'Connor and Company, n. 82 *supra* at p.3.

[81] F. Fischler, 'Quality Food, CAP Reform and PDO/PGI', speech delivered at the Congress Fondazione Qualivita, Siena, 17 April, 2004.

[82] See M.A. Echols, *Geographical Indications for Food Products: International Legal and Regulatory Perspectives*, Alphen aan der Rijn, Kluwer Law International, 2008, 8.

[83] See R. Silva Repetto and M. Cavalcanti, "Module 3: Provisions of the TRIPS Agreement Relevant to Agriculture (Part I)." <www.fao.org/ur/manual/>.

culture, land, resources and environment".[84] As the overwhelming majority of the food insecure population of the world lives in rural economies, any benefit which a system of GIs can secure is going to be very significant.

In the area of biotechnological patenting, the role which a geographical indications law might play is illustrated by the recent dispute between the Indian Basmati rice marketing authorities and a US corporation which had developed a strain of rice from Basmati genetic material. The US corporation sought to market this rice, under the brands: Texmati, Kasmati and Jasmati[85]. Had a geographical indications regime been in place in the countries in which protection for these brands was sought, the resolution of this dispute would have been simpler. A similar controversy developed in Australia, where an agricultural research institute sought to obtain plant variety protection for strains of chick peas which had been developed from Indian stock and which were sought to be registered with Indian names.[86] Ultimately, this dispute was resolved without litigation, but could have been settled in the context of geographical indications.

Plant breeding by the large life-sciences companies has been criticized for encouraging monocultures. In fostering agricultural diversity, GI systems contribute to the preservation of natural resources. In this context the protection of traditional knowledge in the field of agricultural plant genetic resources offers the potential of "appropriate flanking policies".[87]

Thus it has been urged that GIs should not be exclusively evaluated from a commercial viewpoint as they "exist in a broader context as an integral form of rural development that can powerfully advance commercial and economic interests while fostering local values such as environmental stewardship, culture and tradition."[88] A catalogue of the benefits of GIs is contained in a 2008 Study for the Quakers United Nations Office by Sisule Musungu.[89] He pointed out that GIs, unlike patents, require very low levels of innovation which allows a larger number of players to benefit from protection. He mentioned that GI strategies converge with other market incentives such as organic certification, which is useful for small organisations. The collective approach to GIs can benefit small producers that could normally not be able to finance marketing and brand development activities.

Once small producers have achieved the quality standards needed to access new markets, precise use of geographical information in labelling can easily be implemented with or without GI registration. GIs can help prevent bio piracy of traditional knowledge as well as help protect or provide recognition to traditional production methods such as seed selection criteria and food conservation practices. This will permit the transformation of TK into marketable products.

In an endeavour to generate empirical evidence about the value of GIs, the African members of the African Caribbean Pacific (ACP) group of countries have commissioned country/sub-regional and product case studies, regarding the benefits that ACP Group can obtain from enhanced multilateral GIs protection.[90] This information will provide a basis for the African Group to engage in the Doha negotiations on the establishment of the multilateral register for wines and spirits and the proposed extension of additional protection to products other than wines and spirits

---

[84] F.Addor, 'Geographical Indications- Where Now After Cancun', paper presented at OriGIn, 2nd Meeting, Alicante, 27-28 November, 2003, 2.

[85] See S. Lall, 'India and Pakistan. Geographical Indications - The Basmati Issue'., paper delivered at International Trademark Association (INTA), Annual Meeting, Seattle - May 1999

[86] See M. Blakeney, 'Intellectual Property Rights in the Genetic Resources of International Agricultural Research Institutes- Some Recent Problems' [1998] 1 *Bioscience Law Rev.* 3

[87] See S. Biber-Klemm, T. Cottier, P. Cullet & D. Szymura-Berglas, 'The Current Law of Plant Genetic Resources and Traditional Knowledge', *Traditional Knowledge on Plant Genetic Resources for Food and Agriculture*,, Wallingford, Oxfordshire: CABI Publishing, 2005, 57-81.

[88] See D. Giovannucci et al, *Guide to Geographical Indications: Linking Products and Their Origins*, Geneva, International Trade Centre (2009) available at http://www.intracen.org/publications/

[89] Sisule F. Musungu, *The Protection of Geographical Indications and the Doha Round: Strategic and Policy Considerations for Africa*, QUNO IP Issue Paper No. 8, December 2008, 13.

[90] Project Ref: 9 ACP RPR 140 – 011-10.

under Article 23 of TRIPS. The countries studied in January – March 2011 were: West and Central Africa: Cameroon, Gabon, Ghana, Nigeria and Senegal; East and Southern Africa: Kenya, Mauritius, Rwanda and Tanzania.[91]

It should be noted that the above project is one of a number of similar evaluations of GIs in Africa. Principal among these are the evaluations of potential Kenyan GIs conducted in the context of the 2009 Swiss-Kenyan Project on GIs (SKGI). Kenya was also surveyed in a paper commissioned by the ACP-EU programme Trade.Com and published in April 2010.[92] An ACP-EU Regional Workshop on the protection of GIs held in Cape Town with the collaboration of ARIPO, 10 – 11 May 2010 in considering "GIs Experiences in African ACP Member States", received reports on Vanilla from Madagascar, Bark cloth from Uganda and Argane oil from Morocco. A similar workshop organised under the auspices of OAPI in Douala, Cameroon, 27 – 28 April 2010 received reports on the GIs potential of Penja white pepper, Cameroon (Poivre blanc du Penja), Onions from Dogon, Mali (Echalote du Pays Dogon), Attiéké from Grand-Lahou, Côte D'Ivoire, Korhogo cloth - Côte d'Ivoire and products of Argan trees in Morocco. Also as part of the ACP-EU programme a report was commissioned on potential GIs in Côte d'Ivoire.[93] This report considered the GIs possibilities for: cashew nuts, attieke of Grand-Lahou, Fakaha cloth (Toiles de Fakaha) and the Kent mango of Cote d'Ivoire, as well as the para rubber tree of Grand Boudoury, Katiola pottery, Tiebissou cloth, cocoa, the kponan yam of Bondoukou, savannah cotton and mountain rice. An "International expert consultation on Geographical Indications (GIs) for coffee and cocoa sectors in Cameroon" was organised by the Technical Centre for Agricultural and Rural Cooperation ACP-EU (CTA), the Organization for an International Geographical Indications Network (OriGIn) and the National Coffee and Cocoa Board of Cameroon (NCCB) in Yaoundé on September 28th – 30th 2010. Training on Legal Aspects of Trade Policy, Regional and GIs were also the subject of a Regional Workshop organized by Tradecom and ECOWAS on "Multilateral Trade Negotiations for the West African Region" held in Accra, Ghana on 8-12 November 2010.

A workshop held by the French Ministry for Agriculture and Fisheries, the agricultural research institute CIRAD, and INAO, the French national institute for designation of origin, and supported by OAPI in Montpellier from 24 to 27 March 2009 on the challenges related to Geographical Indications (GIs) for ACP countries, considered the GIs potential of shea butter from Burkina Faso, shallots from the Dogon area of Mali, rooibos tea from South Africa and argan oil from Morocco. Galmi onions (Niger), Fouta Djalon potato (Guinea) and Madagascar Vanilla. Key issues for GIs protection in the member states of OAPI were addressed by the Director General of OAPI.

Pursuant to Recommendation 37 of the Development Agenda, WIPO's Committee on Development and Intellectual Property has initiated a "Project on Intellectual Property and Socio-Economic Development" to conduct studies on the protection of intellectual property, to identify the possible links and impacts between IP and development.[94] Among the projects which have been initiated are Needs Evaluation and Technical Support for the Development of a Sectoral IP Development Strategy to enhance the competetiveness of the cotton and clove sectors in Uganda and Zanziabar and improve income of small producers Small Scale Clove Producers in Zanzibar. These projects are considering, inter alia, the utilisation of GIs to promote these various products.

The FAO has also been executing a number of capacity building projects concerned with GIs in Africa. In 2010 these included projects in Kenya and West Africa to improve the production and

---

[91] Industries studied were: Cameroon – Oku White Honey; Gabon – Okoumé Timber; Ghana – Cocoa; Kenya – Black Tea; Mauritius – Demerara Sugar ; Nigeria-Yams ; Rwanda – Coffee ; Senegal – yêtt de Joal ; Tanzania – Cloves.

[92] G. Bocedi, *Country paper on potential GI products for Kenya,* Paper commissioned by the ACP-EU programme Trade.Com in the frame of the ACP regional workshops on geographical Indications, April - May 2010.

[93] M. Bagal and M. Vittori, *Preliminary report on the potential for geographical indications in Cote d'Ivoire and the Relevant Legal Framework,* Paper commissioned by the ACP-EU programme Trade.Com in the frame of the ACP regional workshops on geographical Indications, April - May 2010.

[94] WIPO Doc., CDIP/5/7, February 22, 2010.

distribution of safe and high quality vegetables and a decision-making guide for African farmer organizations and exporters wishing to export organic and fair-trade certified products and for business support organizations. From 2005 to 2009 a project funded by the German government and executed in Burkina Faso, Cameroon, Ghana, Senegal and Sierra Leone aimed at increasing incomes and food security of small farmers in West and Central Africa through exports of organic and fair-trade tropical products assisted farmer groups and small exporters to help them take advantage of remunerative markets.

As a result of these various activities, a number of countries have or are promulgating GIs legislation. A project is currently being implemented by OAPI, funded by Agence Française de Développement (AFD) and supported by CIRAD, aims to develop four pilot GIs: Oku honey and Penja pepper in Cameroon, Korhogo clothes in Ivory Coast and Ziama coffe in Guinea. In April 2009 argan oil from Morocco, valued for its nutritive, cosmetic, and medicinal properties, was registered as a Protected Geographical Indication (PGI) by Morocco's Commission nationale des signes distinctifs d'origine et de qualité (CNSDOQ), it was also registered as a PGI by the European Commission.[95] Argan oil is the first product from Africa to receive such protection.

2.6.3 Definitions

The TRIPS Agreement in Article 22 defines geographical indications as:

> "... indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin."

Article 22.2 of the TRIPS Agreement requires that Members 'shall provide the legal means for interested parties to prevent 'the use by any means in the designation or presentation of a good that indicates that the good in question originates in a geographical area other than the true place of origin in a manner which misleads the public as to the geographical origin of goods'. The TRIPS Agreement does not specify the legal means to protect geographical indications. This is left for Members to decide.

Article 22.2 TRIPS also prohibits any use which 'constitutes an act of unfair competition under Article 10*bis* of the Paris Convention. The ambit of Art 10*bis* is extended to a geographical indication 'which, although literally true as to a territory, region or locality in which the goods originate, falsely represents to the public that the goods originate in another territory'.

The interrelationship between the protection of trademarks and of appellations of origin is accommodated by Art.22.3 of the TRIPS Agreement which permits a Member, *ex officio* if its legislation so permits or at the request of an interested party, 'refuse or invalidate the registration of a trademark which contains or consists of a geographical indication with respect to goods not originating the territory indicated, if the use of the indication in the trademark for such goods in that Member is of such a nature as to mislead the public as to the true place of origin'.

In addition to the general protection for geographical indications for wines and spirits within the general context for the protection of geographical indications contained in Art.22, additional protection is accorded geographical indications for wines and spirits by Art.23. This additional protection has two components: (i) protection for each geographical indication for wines in the case of homonymous indications; and (ii) the establishment of a multilateral system of notification and registration of geographical indications for wines eligible for protection in those Members participating in the system.

These provisions give geographical indications for wines and spirits stronger protection than that provided in Article 22 for other products. Some countries regard this additional protection as an unacceptable discrimination against all other products and they advocate an extension of that protection to all kinds of geographical indications.

---

[95] See http://www.wipo.int/ipadvantage/en/details.jsp?id=2656.

Article 24.1 obliges Members 'to enter into negotiations aimed at increasing the protection of individual geographic indications under Art.23'. Although Art.24 contains a number of paragraphs excepting certain matters from protection as geographical indications, Art.24.1 disallows Members from using these exceptions as an excuse for the refusal to conduct negotiations. Also in implementing this negotiation obligation, Art. 24.3 requires that a Member 'not diminish the protection of geographical indications' which existed in that Member prior to the date of the entry into force of the WTO Agreement. Nevertheless a group of countries considers the above interpretation to be a very legalistic approach. They believe that this provision permits negotiations to extend the additional protection for geographical indications for wines and spirits to all kinds of products.

In order to facilitate the protection of geographical indications for wines, Art.23.4 provides that "negotiations shall be undertaken in the Council for TRIPS concerning the establishment of a multilateral system of notification and registration of geographical indications for wines eligible for protection in those Members participating in the system". The effect of this provision will be to absorb the registration scheme established under the Lisbon Agreement and to remove the justification for the negotiations within WIPO for a new treaty on the protection of geographical indications which has been under preparation since 1974.

2.6.4 Review of the TRIPS Agreement

The Council of TRIPS was obliged under Art.24.2 to conduct a review of the operation of the geographical indications provisions within the first two years of entry into force of the WTO Agreement. The Council confined its initial review to the question of a multilateral register of geographical wine indications. This issue was taken up by WIPO's Standing Committee on Trademarks and Geographic Indications.

GIs constitute a significant part of the Doha development negotiating agenda. Clause 18 of the Doha Declaration, states that with a view to completing the work started in the Council for TRIPS members are to negotiate the establishment of a multilateral system a register for wines and spirits, as well as the extension of GI protection beyond wines and spirits. The principal protagonists in negotiations are the European Union (EU), which favours an expanded international regime, and the US, which argues that the current TRIPS and trade mark protections are sufficient.

In July 2008, a group of WTO members called for a "procedural decision" to negotiate three intellectual property issues in parallel: these two geographical indications issues and a proposal to require patent applicants to disclose the origin of genetic resources or traditional knowledge used in their inventions.[96] To date WTO Members remain divided over the proposal to negotiate the three subjects in parallel, with opponents arguing that the only mandate for the TRIPS Council is to negotiate the multilateral register. Under the Chairmanship of Ambassador Trevor C. Clarke (Barbados) during 2008-2009, the Special Session of the TRIPS Council considered the various proposals which had been made and the Chairman identified as "crucial" the two issues of participation and consequences/legal effects of registration.[97]

With respect to the issue of whether participation in the system should be voluntary or mandatory, some WTO Members interpreted the reference in the mandate concerning "a multilateral system" to mean that the system should apply to all Members. Other Members argued that the words "those Members participating in the system" mean that not all Members are expected to participate. Ambassador Darlington Mwape (Zambia), Chairman of the Special Session of the Council for TRIPS, announced, upon assuming this office that the specific negotiating mandate of

[96] Communication from Albania, Brazil, China, Colombia, Ecuador, the European Communities, Iceland, India, Indonesia, the Kyrgyz Republic, Liechtenstein, the Former Yugoslav Republic of Macedonia, Pakistan, Peru, Sri Lanka, Switzerland, Thailand, Turkey, the ACP Group and the African Group, TN/C/W/52 of 19 July 2008

[97] Multilateral System of Notification and Registration of Geographical Indications for Wines and Spirits, Report by the Chairman, Ambassador C. Trevor Clarke (Barbados), TN/IP/19, 25 November 2009, para.10.

the Special Session was limited to the negotiations of a Register of GIs for wines and spirits.[98] Ambassador Mwape circulated a work programme suggesting a list of the six ""Possible Elements for Developing Texts" for the future Register[99], which were:

1. Notification
2. Registration
3. Legal Effects / Consequences of Registration
4. Fees and Costs
5. Special and Differential Treatment
6. Participation

Applying this structure, a drafting group developed a single draft composite text on the Register.[100] This draft composite text was examined by the wider membership at an open-ended meeting on 18-19 April, 2011 and changes resulting from this meeting were included in the Draft Composite Text which was last circulated on 20 April 2011.[101] Ambassador Mwape reported that this text was "without prejudice to Members' positions on the overall outcome of the negotiations" and that "Members are working on the understanding that nothing is agreed until everything is agreed, and that Members may revert to any issue of the text at any time."[102] Ambassador Mwape reported that despite the fact that this text reflects the current state of negotiations, views differ on "whether and how the negotiating mandate should be accurately reflected in the Draft Composite Text" and that both sides appear to prefer that the text represents "the factual representation of the state-of-play in this negotiating group" at this time. [103]

2.6.5 GIs and the Protection of Traditional Knowledge (TK)

In the absence of an international regime to protect TK, existing categories of intellectual property, such as GIs have been called in aid. In its *Review of Existing Intellectual Property Protection of Traditional Knowledge*[104]the IGC Secretariat observed that

> Geographical Indications as defined by Article 22.1 of the TRIPS Agreement and appellations of origin, as defined by Article 2 of the Lisbon Agreement…rely not only on their geographical connotation but also, essentially on human and/or natural factors (which may have generated a given quality, reputation or other characteristic of the good). In practice, human and/or natural factors are the result of traditional, standard techniques which local communities have developed and incorporated into production. Goods designated and differentiated by geographical indications, be they wines, spirits, cheese, handicrafts, watches, silverware and others, are as much expressions of local cultural and community identification as other elements of traditional knowledge can be.[105]

Three examples provided by the IGC Secretariat of traditional knowledge protected by geographical indications are: "Cocuy the Pecaya" liquor from Venezuela, "Phu Quoc" fish sauce and "Shan Tuyet Moc Chau" tea, both from Vietnam.

---

[98] Multilateral System of Notification and Registration of Geographical Indications for Wines and Spirits, Report by the Chairman, Ambassador Darlington Mwape (Zambia), TN/IP/20, 22 March 2010, para 4.

[99] See WTO Doc TN/IP/21, 21 April 2011.

[100] That was circulated as JOB/IP/3 on 11 April 2011.

[101] JOB/IP/3/Rev.1

[102] WTO Doc TN/IP/21 at para. 15.

[103] Ibid., paras 15-17.

[104] WIPO/GRTKF/IC/3/7 May 6, 2002.

[105] Ibid., para 40.

2.7 Animal genetic resources

This section of the Report focuses on the patenting of animal genetic resources. However, it is also of relevance for other genetic resources for food and agriculture, such as aquatic genetic resources, invertebrate genetic resources microorganism genetic resources and breeding methods.

Article 27.3(b) of the TRIPS agreement permits the exclusion from patentability of "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes."[106] Under this provision, micro-organisms cannot be excluded from patenting, while animals and essentially biological processes for the production of plants or animals may be excluded. For example, Article 15 of Decision 486 of the Andean Community of Nations negatively defines an invention by proscribing the patenting of:

b) any living thing, either complete or partial, as found in nature, natural biological processes, and biological material, as existing in nature, or able to be separated, including the genome or germplasm of any living thing.

The patenting of animals and genetic materials derived from animals has been highly controversial, resulting in many challenges to patent applications principally on moral grounds. Article 27.2 of the TRIPS Agreement permits the exclusion from patentability inventions, the commercial exploitation of which "is necessary to protect *ordre public* or morality". In a some countries animals and their parts are eligible for patents, whereas in others the patenting of animals and animal materials is refused. In a third group of countries exceptions along the lines of Article 27.2 of the TRIPS Agreement are relied upon to refuse patents on animals in others the patenting of animals is subject to limitations. For example, Article 6.2(d) of the European Biotechnology Directive refuses patentability to "processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes. This reflects the reasoning of the Board of Appeal of the European Patent Office Boards in the Harvard "oncomouse" patent. This concerned an application for a method for inserting an oncogene which increased sensitivity to cancer enabling the inventors to clone laboratory test animals (generally mice). After consideration by the EPO Examining Division and Board of Appeal a granted patent was granted including claims to the technique and also to non-human animals produced by the technique.[107] Following oppositions, largely on morality grounds the Opposition Division of the EPO maintained the granted patent, with the claims restricted in scope to cover the invention carried out in rodents only (rather than any non-human animal as per the originally granted claims). The patent claims upheld by the Opposition Division covered methods of making transgenic rodents. Appeals from this decision led to the patent being confined further to mice. The Appeal Board weighed up of the suffering of the animals and possible risks to the environment on the one hand, and the invention´s usefulness to mankind on the other in allowing the patent.[108]

Since the early 1990s the refusal of patentability to animal genetic material has been considered in inquiries in a number of countries.[109] In Canada, it was accepted that the "momentum of the biotech industry, the long history of patentability of gene sequences and the impact and complexity of existing international trade agreements make this, at present, an impractical and

[106] Ibid., article 27 (3) b).

[107] EP Application No. 85304490.7, Publication No. 0 169 672B, 13 May 1992.

[108] Decision T. 19/90, para. 5.

[109] Australia, Senate Standing Committee on Industry Science and Technology, Report on the Consideration of the Patent Bill, Canberra, AGPS, 1990; Canada, House of Commons Standing Committee on Health, *Assisted Human Reproduction: Building Families*, Ottawa, 2001; Ontario Ministry of Health and Long-Term Care, *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare: Report to the Provinces and Territories* 2002; Australian Law Reform Commission, *Genes and Ingenuity: Gene patenting and human health* , ALRC Report 99, Canberra, AGPS, 2004.

unrealistic option."[110] The Australian Law Reform Commission pointed out that the exclusion of genetic materials from patentability may conflict with Article 27.1 of TRIPS which requires that patents shall be available for any inventions, and that patent rights shall be enjoyable without discrimination as to "the field of technology".[111] In practice, there has been a considerable growth in the patenting of animal cells and tissues.[112]

The question of whether patents are available to protect animal breeding methods has been raised in relation to a patent granted by the EPO on marker assisted selection of pigs based on the porcine leptin receptor (pLEPR) gene with a view to enhancing meat production.[113] The recent EBA decision in relation to the non- patentability of the methods of breeding broccoli and tomatoes will probably apply also to the breeding of animals.[114]

2.8 Microorganisms

Article 27.3(b) of the TRIPS Agreement provides for the patenting of microorganisms. This reflects the majority decision of the US Supreme Court in *Diamond v. Chakrabarty*[115] that an engineered microorganism is patentable under the US Patent law.[116] However, as there is no definition of microorganism in the TRIPS Agreement, it is open to countries to permit the patenting of all kinds of microscopic biological materials, including cells and genes.[117] For example the Indian Patents (Second Amendment) Act, 2002 provides for the patenting microorganisms including fungi, bacteria and viruses.[118]

The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of patent procedure has established a mechanism for the recognition, for the purposes of the granting of a patent, of the deposit of a microorganism with a foreign depositary authority.

2.9 Synthetic Biology

The emergence of synthetic biology, which is defined as the "synthesis of complex, biologically based (or inspired) systems which display functions that do not exist in nature"[119] and which can be applied at all levels of the hierarchy of biological structures, from individual molecules to whole cells, tissues and organisms, has raised the same sorts of questions about its patentability as applies to microorganisms and genetic material.[120] For example, the spectre of over-broad patents has been identified in this field. Rai and Boyle instance US patent 6,774,222, issued on August 10, 2004 to the US Department of Health and Human Services entitled "Molecular Computing

---

[110] See T.A. Caulfield, B.M. Knoppers, E.R. Gold, L.E. Sheremeta and P.J. Bridge, 'Genetic technologies, health care policy, and the patent bargain' (2003) 63 *Clin Genet.* 15–18 at 16.

[111] ALRC, Genes and Ingenuity: Gene patenting and human health , at para. 7.35.

[112] A six-fold growth between 2000 and 2003 compared with 1990-2000 was noted by P. Oldham, Global Status and Trends in Intellectual Property Claims: Microorganisms, Submission to the Executive Secretary of the Convention on Biological Diversity, 2004, Figure 3, available at www.twnside.org.sg/.../Intellectual_Property/.../microorganisms-Paul_Oldham.doc.

[113] EP 1651777.

[114] See S. Biber-Klemm and M. Temmerman, *Rights to Animal Genetic Resources for Food and Agriculture - Notes from an Interdisciplinary Workshop*, NCR Trade Regulation Working Paper No 2010/05| May 2010.

[115] 447 U.S. 303, 310 (1980).

[116] This decision was referred to in the recent Supreme Court decision in Bilski v. Kappos, 130 S. Ct. 3218 (2010) as authority for the proposition that "laws of nature" are not patentable.'

[117] See, e.g., M. Adcock and M. Llewelyn, Micro-organisms, Definitions and Options under TRIPS and Micro-organisms, Definitions and Options under TRIPS: Supplementary Thoughts, QUNO, Occasional Paper 2, Geneva, 2000.

[118] Discussed in R. B. Nair and P. C. Ramachandranna, 'Patenting of microorganisms: Systems and concerns' (2010) 16 *Journal of Commercial Biotechnology***,** 337–347.

[119] European Commission, Synthetic Biology: Applying Engineering to Biology, Report of a NEST High-Level Expert Group. Brussels, EC, 2005, at 2.

[120] J. Calvert, 'The commodification of emergence: systems biology, synthetic biology and intellectual property' (2008) 3 *Biosocieties* 383–398.

Elements, Gates and FlipFlops."[121] They note that this patent covers using the combination of nucleic-acid binding proteins and nucleic acids to set up data storage as well as logic gates that perform basic Boolean algebra and thus could be used not only for computation but also for complex ("digital") control of gene expression. In addition to the problem of broad foundational patents, they identify a plethora of narrower patents eg which claim the use of DNA to produce specific gene regulation mechanisms such as a multi-state oscillator,[122] Bistable genetic toggle switch[123] and adjustable threshold switch.[124]

It has been pointed out that "even in its nascent state, the synthetic biology research space is filled with proprietary rights, which may offer benefits, particularly to the extent that venture financing in biotechnology appears to be linked to patents, but that this propertization "could result in synthetic biology ends up looking more like information technology than like biotechnology".[125] The same kinds of warnings issued by the NGO community in relation to the commodification of genetic material has been issued in relation to the patenting of synthetic biology, particularly the potential impacts upon market concentration in the biofuels market.[126] The ethical implications of the patenting of synthetic materials is already under review[127]

2.10 Traditional knowledge and farmers rights

2.10.1 Introduction

The traditional knowledge of indigenous peoples and farmers has played an important role in identifying biological resources worthy of commercial exploitation. For example, the search for new pharmaceuticals from naturally occurring biological material has been guided by ethnobiological data.[128] Examples of traditional knowledge with agricultural application include: "mental inventories of local biological resources, animal breeds, and local plant, crop, and tree species" as well as plants which are indicators of soil salinity, seed treatment and storage methods and tools used for planting and harvesting.[129] A similarly significant contribution has been made by the knowledge of indigenous peoples and farmers in the development of new crop types and biodiversity conservation. The economic value of biological diversity conserved by traditional farmers for agriculture is difficult to quantify.[130] It has recently been suggested that "the value of farmers' varieties is not directly dependent on their current use in conventional breeding, since the gene flow from landraces to privately marketed cultivars of major crops is very modest" because "conventional breeding increasingly focuses on crosses among elite materials from the breeders

[121] A.K. Rai and J. Boyle J Synthetic biology: caught between property rights, the public domain, and the commons' (2007) 5 *PLoS Bio* e58, accessed at http://www.plosbiology.org/article/info:doi/10.1371/journal.pbio.0050058.

[122] US 6,737,269, May 18, 2004.

[123] US 6,841,376, January 11, 2005.

[124] US 6,828,140, December 7, 2004.

[125] S.Kumar and A. Rai, 'Synthetic Biology: The Intellectual Property Puzzle' (2007) 85 Texas Law Review 1745-1768.

[126]ETC Group *The new Biomassters. Extreme Genetic Engineering: An Introduction to Synthetic Biology*. Ottawa, ETC, 2007 accessed at http://www.etcgroup.org/upload/publication/pdf_file/biomassters_27feb2011.pdf.

[127] Eg see A. Balmer and P. Martin *Synthetic Biology: Social and Ethical Challenges. Independent Review Commissioned by the Biotechnology and Biological Sciences Research Council (BBSRC)*. London, BBSRC, 2008.

[128] See K. ten Kate and S. A. Laird , *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit,* London, Earthscan, 2000; G. McChesney, 'Biological Diversity, Chemical Diversity and the Search for New Pharmaceuticals' in M.Balick, E. Elisabetsky and S. Laird, eds., *Medicinal Resources of the Tropical Forest: biodiversity and its importance to human health*, Columbia, U. of Columbia Press, 1996, 12.

[129] S. A. Hansen and J.W. Van Fleet. 'Issues and Options for Traditional Knowledge Holders in Protecting Their Intellectual Property Economies' in A Krattiger, RT Mahoney, L Nelsen, et al. eds , *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*, Oxford, . MIHR, and PIPRA: Davis, U.S.A, 2007, 1523.

[130] Eg see S.Brush, *Providing Farmers' Rights Through In Situ Conservation of Crop Genetic Resources,* Berkeley, University of California, 1994.

own collections and advanced lines developed in public institutions."[131] On the other hand, those collections and advanced breeding lines are often derived from germplasm contributed by traditional groups. An increasingly significant economic value of biodiversity is the extent to which it provides a reservoir of species available for domestication, as well as genetic resources available for the enhancement of domestic species. The modern biotechnological revolution has enabled the engineering of desirable genetic traits from useful local species. It is estimated that about 6.5% of all genetic research undertaken in agriculture is focussed upon germplasm derived from wild species and land races.[132]

2.10.2 Traditional Knowledge and Prior Art

An alternative approach to the protection of traditional knowledge as a category of intellectual property, is its recognition as part of "prior art." As prior art it would call into question the novelty and inventive of inventions which are the subject of patent applications. The practical difficulty which patent examiners have in identifying relevant traditional knowledge as prior art, arises from the fact that they do not have access to traditional knowledge information in classified non-patent literature and because there are no effective search tools for the retrieval of such information. The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) has begun to address practical measures to establish linkages between IP Offices and traditional knowledge documentation initiatives.[133]

The draft Substantive Patent Law Treaty, which was submitted to the fifth session of the WIPO's Standing Committee on the Law of Patents (SCP), held in Geneva from May 14 to 19, 2001, contained two alternatives for a draft article on the definition of prior art. The draft provisions on the definition of prior art provide that any information made available to the public, anywhere in the world, in any form, including in written form, by oral communication, by display and through use, shall constitute prior art, if it has been made available to the public before the filing date, or, where applicable, the priority date.

2.10.3 Disclosure of the Source of GRs, Access and Benefit Sharing – Recent International Developments

One of the foundational tasks of the WIPO IGC has been the formulation of guidelines on the IP aspects of access and benefit-sharing in relation to GRs. A draft set of guidelines was submitted to the seventh session of the IGC in November 2004[134] which sought to provide assistance in the negotiation of contracts for access to genetic resources and related information, including traditional knowledge, and for benefit-sharing arrangements. This document has been through a number of drafts, the most recent of which was prepared for the third Intersessional Working Group which met from February 28 to March 4, 2011.[135] This document, together with documents which have been prepared on the subjects of traditional knowledge and traditional cultural expressions, are to be taken into account in "text-based negotiations" by the IGC, ultimately with a view to formulating an international treaty.

At the Seventeenth Session of the IGC which met in Geneva, December 6 to 10, 2010, the Secretariat identified the options which were then under consideration**.**[136] There were three

---

[131] C. Correa, *Options For The Implementation of Farmers' Rights at The National Level,* South Centre, Trade-Related Agenda, Development And Equity Working Papers, No. 8, December 2000, citing Wright, 'Intellectual Property and Farmers' Rights' in R. Evenson, D. Gollin and V. Santaniello, Eds., *Agricultural Values of Plant Genetic Resource*s, Wallingford, FAO/CEIS/CABI, 1998, 228.

[132] J. A. McNeely, 'Biodiversity and Agricultural Development: The Crucial Institutional Issues' in D.R.Lee and C.B.Barrett, eds, Tradeoffs or Synergies? Agricultural Intensification, Economic Development and the Environment, Wallingford, CABI, 2001,, 399 at 404.

[133] WIPO Doc., WIPO/GRTKF/IC/2/6, July 1, 2001, para. 6.

[134] WIPO/GRTKF/IC/7/9.

[135] WIPO/GRTKF/IWG/3/12, January 10, 2011.

[136] 'Genetic Resources: Revised List of Options and Factual Update' WIPO/GRTKF/IC/17/6, September 15, 2010.

categories of options: (i) those concerning the defensive protection of genetic resources; (ii) those in relation to disclosure requirements; and (c) those concerning the IP aspects of access and benefit-sharing.

In relation to defensive protection, one category of options was the compilation of an inventory of existing periodicals, databases and other information resources which document disclosed genetic resources, with a view to discussing a possible recommendation that certain periodicals, databases and information resources may be considered by International Search Authorities for integration into the minimum documentation list under the Patent Co-operation Treaty. The second option in this regard concerned the extension of the Online Portal of Registries and Databases, established by the Committee at its third session, to include existing databases and information systems for access to information on disclosed genetic resources. A third option was for the formulation of recommendations or guidelines for search and examination procedures for patent applications to ensure that they better take into account disclosed genetic resources.

Options on disclosure requirements, included: the development of a mandatory disclosure requirement. Alternatively, it was proposed that the IGC could consider whether there is a need to develop appropriate (model) provisions for national or regional patent or other laws which would facilitate consistency and synergy between access and benefit-sharing measures for genetic resources, on the one hand, and national and international intellectual property law and practice, on the other. Another disclosure option was the development of guidelines or recommendations concerning the interaction between patent disclosure and access and benefit-sharing frameworks for genetic resources.

On May 6 2010, the delegations of Australia, Canada, New Zealand, Norway and the United States of America submitted a working document[137] on GR for the seventeenth session of the IGC held December 6 to 10, 2010. Comments on this document[138] were made by the Delegations of Chile, Colombia and the Russian Federation and a number of accredited observers,[139] which resulted in a revised document identifying five objectives with underlying principles:[140] On December 8, 2010, the Delegation of Angola submitted the proposals of the African Group.[141] This suggested the commencement of negotiations on a mandatory disclosure requirement and an appropriate way to ensure prior informed consent and fair and equitable benefit sharing, in line with the Nagoya Protocol. The African proposal suggested that negotiations be based upon two current proposals on a mandatory disclosure requirement,[142] and the incorporation of the "internationally recognized certificate of compliance" as stipulated in the Nagoya Protocol, together with any other submission that may be tabled by member countries. In relation to the option for guidelines and recommendations on defensive protection, the African Group proposed consideration of the use of available databases on GR and/or associated TK.

The African Group proposed a number of amendments to the Submission made by Australia, Canada, New Zealand, Norway and the United States of America. The common position between all groups of countries is that the objectives of the mandatory disclosure requirement should be: that: (i) the use of GRs and associated TK should be on the basis of benefit sharing; (ii) patents should not be granted for inventions that are not novel or inventive in light of genetic resources and/or associated traditional knowledge; (iii) patent offices should have available the information

[137] WIPO/GRTKF/IC/16/7.

[138] WIPO/GRTKF/IC/17/INF/10.

[139] Association des Étudiants et Chercheurs sur la Gouvernance des États Insulaires (AECG), the Biotechnology Industry Organization (BIO) jointly with the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), and the Eurasian Patent Organization (EAPO).

[140] WIPO/GRTKF/IC/17/7.

[141] WIPO/GRTKF/IC/17/10.

[142] Ie the "Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications: Proposal by Switzerland" (WIPO/GRTKF/IC/11/10) and EU Proposal "Disclosure of Origin or Source of Genetic Resource and Associated Traditional Knowledge in Patent Applications" (WIPO/GRTKF/IC/8/11) with a view to amending the Patent Cooperation Treaty (PCT) and the Patent Law Treaty (PLT) to reflect a mandatory disclosure requirement of the origin of the genetic resources.

needed to make proper decisions on patent grant; (iv) the principles developed should consistent with other international and regional instruments and processes; and (v) Ip should maintain a role in promoting creativity and innovation.At the Third Intersessional Working Group of the IGC, which met from February 28 to March 4, 2011, a Working Group was appointed to review and rationalize the various Objectives and Principles which had been received by the IGC with a view to clarifying the key and divergent policy positions and issues, which the IGC would need to make informed decisions. This report[143] is to be transmitted to the IGC for its consideration at its 18th session (May 9 to 13, 2011).

2.10.4 Farmer's Rights under the International Treaty

The concept of Farmers' Rights was developed as "a counterbalance to intellectual property rights."[144] Farmers' rights were intended to promote a more equitable relation between the providers and users of germplasm by creating a basis for farmers to share in the benefits derived from the germplasm which they had developed and conserved over time.[145] At its Third Session in Tunis in 2009, the Governing Body of the ITPGRFA adopted a resolution on Farmers' Rights (Resolution 6/2009), in which it requested the Secretariat to convene regional workshops on Farmers' Rights, subject to the agreed priorities of the Programme of Work and Budget and to the availability of financial resources. The aim of the workshops was to discuss national experiences on the implementation of Farmers' Rights as set out in Article 9 of the International Treaty, involving, as appropriate, farmers' organizations and other stakeholders.

The fourth session of the Governing Body of the ITPGRFA held from 14 to 18 March 2011 in Bali, Indonesia adopted a resolution on Farmers' Rights that , *inter alia*:

- requests the Secretariat to convene regional workshops on Farmers' Rights, subject to availability of funding;
- encourages parties to submit views, experiences and best practices on the implementation of Farmers' Rights;
- invites parties to consider convening national and local consultations on Farmers' Rights with the participation of farmers and other stakeholders;
- requests the Secretariat to collect and submit these views, as well as reports from regional workshops to GB 5; and
- encourages parties to engage farmers' organizations and relevant stakeholders in matters related to the conservation and sustainable use of PGRFA, through awareness raising and capacity building.[146]

2.10.5 International Developments in the Protection of TK

As it has turned out the work of the IGC has been very slow. During the first 10 years of its existence the IGC has concentrated on the formulation of "objectives" and "principles" which should animate the protection of TCEs and TK.[147] Concern has been expressed about the apparently slow pace in formulating an international instrument dealing with TK. The African group of countries at WIPO were in the forefront of agitation there to accelerate the international negotiations, but a true reflection of their appreciation of the realistic likelihood of action was the promulgation by a diplomatic conference on 9-10 August 2010 in Swakopmund, Namibia, organized by the African Regional Intellectual Property Organization (ARIPO) of a Protocol on

---

[143] 'Draft Objectives and Principles Relating to Intellectual Property and Genetic Resources Prepared at IWG 3', WIPO/GRTKF/IWG/3/17, March 16, 2011.

[144] FAO, 'Revision of the International Undertaking. Issues for consideration in stage II: access to plant genetic resources and Farmers' Rights', CPGR-Ex1/94/5, Rome, 1994.

[145] See L. Glowka, *A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources*, Gland, IUCN, 1998, 20.

[146] http://www.iisd.ca/vol09/enb09550e.html.

[147] The most recent contribution in this regard is a document of June 7, 2010 on the 'Protection of Traditional Cultural Expressions/ Cultural expressions of Folklore. Revised Objectives and Principles' which has been prepared for the 17th meeting of the IGC in December 2010, WIPO/GRTKF/IC/17/4Prov.

the Protection of Traditional Knowledge and Expressions of Folklore. The Protocol is meant to "protect creations derived from the exploitation of traditional knowledge in ARIPO member states against misappropriation and illicit use through bio-piracy." The protocol is also intended to prevent the "grant of patents in respect of inventions based on pirated traditional knowledge … and to promote wider commercial use and recognition of that knowledge by the holders, while ensuring that collective custodianship and ownership are not undermined by the introduction of new regimes of private intellectual property rights."

A brief palpitation of enthusiasm on the international front was generated in October 2010, when the 17th session of the IGC, to be held 6-10 December 2010, was identified as the occasion for the first text-based discussion of the establishment an international TK and EC regime. The results of this session, were not so exciting.[148] An "informal drafting group" was set up to provide a text on Traditional Cultural Expressions for the next meeting of the IGC, May 9-13, 2011. Further proposals for the protection of TK were made by a number of countries, was considered by an Intersessional working group which met from February 21 to 25, 2011.

The slowness of the developments at WIPO reactivated Pacific considerations for a regional solution. The decision was also taken for the Pacific Island states to avail themselves of technical assistance which was being made available by the EU as part of the Partnership Agreement between the members of the African, Caribbean and Pacific (ACP) Group of States and the European Union (EU) signed on 23 June 2000 ("Cotonou Agreement") and concluded for a twenty-year period from March 2000 to February 2020. Two EU projects were initiated under this Agreement. The first, entitled: "Technical Assistance to the Pacific Regional Action Plan for Traditional Knowledge Development"[149] has as its specific objective the provision of technical assistance for the establishment of national systems of protection for TK in six of the member states of the Pacific Islands Forum, namely Cook Islands, Fiji, Kiribati, Palau, Papua New Guinea and Vanuatu. A second project provided technical assistance to study the "Feasibility of a Reciprocal Recognition and Enforcement Mechanism" for TK between Fiji, PNG, Solomon Islands, the so called Melanesian Spearhead Group (MSG) countries.[150]

The Terms of Reference for this latter project recognised that a regional approach would operate as a parallel, viable and faster alternative to the international developments. It was pointed out that any future collective arrangement would not preclude other countries from the wider Pacific region to participate in the system. These developments would instruct and inform global treaty making processes currently taking place in institutions such as WIPO and possibly lead to engagement with other like-minded regions given the slow impetus to conclude a global regime for TK at WIPO, WTO and CBD.

Both projects have been productive. National mapping of TK and EC has been conducted in the target states and draft IP laws and policies have been formulated for Fiji, PNG and the Solomon Islands and a collaboration treaty has been drafted for the MSG states. The Treaty was submitted to the 18th Melanesian Spearhead Group Leaders' Summit in Suva on 31st March, 2011 which "agreed in principle pending decisions by members on the signing of the Treaty."[151] The Government of Fiji proposes to sign the Treaty in May 2011 and the Governments of PNG and Vanuatu are currently undertaking in-country consultations on the Treaty before their Governments sign the Treaty. [152]

---

[148] See Decisions of the Seventeenth Session of the IGC, December 10, 2010 at http://www.wipo.int/meetings/en/details.jsp?meeting_id=20207.

[149] Project No: 9.ACP.RPR.007.

[150] See M. Blakeney, 'Protecting traditional knowledge and expressions of culture in the Pacific' (2011) 1(1) *Queen Mary Journal of Intellectual Property*, 80–89.

[151] 18th Melanesian Spearhead Group Leaders' Summit, *Communique*, 31st March, 2011, accessed at http://www.google.com.au/search?q=Treaty+Traditional+Knowledge+MSG+Secretariat&hl=en&biw=1596&bih=687&rlz=1W1ADRA_en&num=10&lr=&ft=i&cr=&safe=images&tbs=,qdr:y.

[152] In August 26-28, 2010 a Regional Workshops on the Protection of Geographical Indications (GIs) and Traditional Knowledge in the Pacific was held in Nadi. This was organized by the EC's TradeCom Facility and sponsored by the European Development Fund (EDF).

III. CLIMATE CHANGE AND PATENTING

3.1 Introduction

Since the late 1980s studies have predicted significant adverse impacts of climate change upon world food supplies both globally[153] and in relation to developing countries, in particular.[154] The key findings of the 2001 Third Assessment Report of the Intergovernmental Panel on Climate Change (IPCC)[155] with respect to food, fibre, forestry and fisheries were that: CO_2 effect may be relatively greater (compared to that for irrigated crops) for crops under moisture stress; crop yields would decline in both the tropics and mid- to high-latitudes with associated declines in plant health. The Report observed the possibility of increases in diseases and algal blooms in the aquaculture industry as seawater temperatures rise. A number of studies have highlighted the influence of climate change upon the development of weeds, insect pests and crop diseases[156] and the ways in which plants can be engineered to withstand salinity[157] and aridity[158].

---

[153] Eg see B. Smit, L. Ludlow and M. Brklacich 'Implications of a global climatic warming for agriculture: A review and appraisal', (1988) 17 (4) *Journal of Environmental Quality*, 519–27. C. Rosenzweig and M.L. Parry, 'Potential impact of climate change on world food supply' (1994) 367 *Nature* 133-138; R. Mendelsohn, W. Nordhaus, and D. Shaw, 'The impact of global warming on agriculture: A Ricardian analysis' (1994) 84(4) *American Economic Review* 753-771; C. Rosenzweig, and A. Iglesias (eds.). *Implications of Climate Change for International Agriculture: Crop Modeling Study*, EPA 230-B-94-003. U.S. Environmental Protection Agency, Washington, DC , 1994; M.L Parry, C. Rosenzweig, A. Iglesias, G. Fischer, and M.T.J. Livermore, 'Climate change and world food security: A new assessment' (1999) 9 *Global Environmental Change* S51-S67; G. Fischer, M. Shah and H. van Velthuizen,, *Climate change and agricultural vulnerability*, IIASA Special Report commissioned by the UN for the World Summit on Sustainable Development, Johannesburg 2002. International Institute for Applied Systems Analysis, Laxenburg, Austria, 2002; R Darwin, 'Effects of greenhouse gas emissions on world agriculture, food consumption, and economic welfare' (2004) 66 *Climatic Change* 191–238; R. Parry, M., Rosenzweig, C. and Livermore, M. 'Climate change, global food supply and risk of hunger' (2005) 360 (1463) *Philosophical Transactions of the Royal Society London B Biological Sciences*, 2125–38; S.M. Howden, J.F. Soussana, F.N. Tubiello, N. Chhetri, M. Dunlop and H.M. Meinke, 'Adapting agriculture to climate change' (2007) 104 *Proceedings of the National Academy of Sciences*,,19691-19696; J. Quiggin, *The impact of climate change on agriculture*, Australian Public Policy Program Working Paper: C08#3, August 19, 2008.

[154] S. Gadgil, A.K.S. Huda, N.S. Jodha, R.P. Singh, and S.M. Virmani 'The effects of climatic variations on agriculture in dry tropical regions of India' in *Assessments in Semi-Arid Regions*, M.L. Parry, T.R. Carter, and N.T. Konijn (eds.), Kluwer Academic Publishers, Dordrecht, 1988, pp. 495-521; T.E. Downing, 'Vulnerability to hunger and coping with climate change in Africa' (1991) 1 (5) *Global Environmental Change* 365-380; S. Kane, J. Reilly and J. Tobey, *Climate Change: Economic Implications for World Agriculture*, Resources and Technology Division, Economic Research Service, U.S. Department of Agriculture, Agricultural Economic Report No. 647, 1991; P. Muchena and A. Iglesias,'Vulnerability of maize yields to climate change in different farming sectors in Zimbabwe' (1995) 59 *American Society of Agronomy*, Special Publication, 229-239; A. Iglesias, L. Erda, and C. Rosenzweig. 'Climate Change in Asia: A Review of the Vulnerability and Adaptation of Crop Production' (1996) 92(1/2) *Water, Air, and Soil Pollution* 13-27; C. Benson and E. Clay. *The Impact of Drought on Sub-Saharan African Economies*. World Bank Technical Paper No. 401, The World Bank, Washington, D.C., 1998; A.F. Abou-Hadid, 'Assessment of impacts, adaptation and vulnerability to climate change in North Africa: food production and water resources. Assessments of Impacts and Adaptations to Climate Change', Washington, District of Columbia, 2006; J. Adejuwon, 'Food Security, Climate Variability and Climate Change in Sub Saharan West Africa. Assessments of Impacts and Adaptations to Climate Change', Washington, DC 2006; P.K Aggarwal, 'Impact of climate change on Indian agriculture' (2003) 30 *J. Plant Biol*, 189-198; A.C. Chipanshi, R. Chanda and O. Totolo, 'Vulnerability assessment of the maize and sorghum crops to climate change in Botswana' (2003) 61 *Climatic Change*, 339-360; T.A. Butt, B.A. McCarl, J. Angerer, P.T. Dyke and J.W. Stuth, 'The economic and food security implications of climate change in Mali' (2005) 68 *Climatic Change*, 355-378; L. Erda, X. Wei, J. Hui, X. Yinlong, L. Yue, B. Liping and X. Liyong, 'Climate change impacts on crop yield and quality with CO_2 fertilization in China' (2005) 360 *Philos. T. Roy. Soc. B*, 2149-2154. C. Vogel, 'Seven fat years and seven lean years?" Climate change and agriculture in Africa'. (2005) 36 IDS *Bull-I Dev. Stud*., 30-35; Xiao, G., W. Liu, Q. Xu, Z. Sun and J. Wang,: Effects of temperature increase and elevated CO_2 concentration, with supplemental irrigation, on the yield of rain-fed spring wheat in a semiarid region of China, (2005) 74 *Agr. Water Manage*., 243-255; X.C. Zhang, and W.Z. Liu, 'Simulating potential response of hydrology, soil erosion, and crop productivity to climate change in Changwu tableland region on the Loess Plateau of China' (2005) 131 *Agr. Forest Meteorol*., 127-142; C. Müller, W. Cramer, W. L. Hare and H. Lotze-Campen, 'Climate change risks for African agriculture' (2011) Proceedings of the National Academy of Sciences, accessed at http://www.pnas.org/content/early/2011/02/23/1015078108.full.pdf+html.

[155] Accessible at http://www.grida.no/publications/other/ipcc_tar/.

[156] B. Boag, J.W. Crawford, and R. Neilson, 'The effect of potential climatic changes on the geographical distribution of the plant-parasitic nematodes *Xiphinema* and *Longidorus* in Europe' (1991) 37 Nematologica,312-323, 1991;

These agricultural stresses arising from climate change present opportunities as well as problems. IPRs have been identified as a means for incentivising the development of CO2 and N2O abatement strategies through the management of animal feed to alter the rumen microbial population and its activity.[159] Similarly, computer software decision support tools, based on biophysical models of the agronomic system, have been identified as offering considerable scope to reduce N2O emissions from broad acre agriculture and emissions from wet rice cultivation by optimising management of agricultural inputs such as fertilisers.[160] At the genomic level climate change has led to the identification of and patenting of stress-tolerant genes.

3.2 Patenting of stress-tolerant genes

Somvanshi in a 2008 study identified 30 patents relating to drought tolerant genes.[161] These included: (i) patents related to Proline biosynthesis;[162] (ii) patented dehydration responsive element binding factors (DREB) and C-repeat sequences binding factors (CBF);[163] (iii) patents related to Protein Kinases;[164] (iv) various patents awarded for transcription factors involved in improving drought stress tolerance in plants[165], and (v) patents related to miscellaneous drought tolerance genes.[166] A 2008 study by the ETC Group identified 55 patent "families"[167] (a total of 532 patent documents) that were applied for and/or granted to a number of biotechnology companies on so-called "climate-ready" genes at patent offices around the world.[168] Its 2010 update of this study "examined patents containing claims concerned with abiotic stress tolerance (ie traits related to environmental stress, such as drought, salinity, heat, cold, chilling, freezing,

---

A.Iglesias and C. Rosenzweig, 'Climate and Pest Outbreaks' in D. Pimentel (ed.). *Encyclopedia of Pest Management*. Marcel Dekker, New York, 2002; M.C Todd, R. Washington, R.A. Cheke and D. Kniveton, 'Brown locust outbreaks and climate variability in southern Africa' (2002) 39 *J. Appl. Ecol.*,, 31-42; Ziska, L.H. and K. George, Rising carbon dioxide and invasive, noxious plants: potential threats and consequences', (2004) 16 *World Resource Review*, 427-447; J. Agrell, P. Anderson, W. Oleszek, A. Stochmal and C. Agrell, 'Combined effects of elevated CO_2 and herbivore damage on alfalfa and cotton' (2004) 30 *J. Chem. Ecol*., 2309-2324; F. J. Chen, G. Wu and F. Ge, 'Impacts of elevated CO_2 on the population abundance and reproductive activity of aphid Sitobion avenae Fabricius feeding on spring wheat' (2004) 128 *J. Environ. Nutr*., 723-730; S. Chakraborty and I.B. Pangga, 'Plant disease and climate change', in: M. Gillings and A. Holmes (eds.) *Plant Microbiology*, BIOS Scientific, London, 2004, pp.163-180; K.A Garrett, S.P Dendy, S.G. Pritchard and J.S. Amthor, *Crops and Environmental Change*, Binghamton: Food Products Press, 2005; R.N Strange and P.R. Scott, 'Plant disease: A threat to global food security' (2005) 43 *Annual Review of Phytopathology*, 83-116; E.E. Frank,. M.N. Rouse and S.E Travers, 'Climate change effects on plant disease: genomes to ecosystems' (2006) 44 *Annual Review of Phytopathology* .489-509; T. Kobayashi, K. Ishiguro, T. Nakajima, H.Y Kim, M. Okada, and K. Kobayashi, 'Effects of elevated atmospheric CO_2 concentration on the infection of rice blast and sheath blight' (2006) 96 *Phytopathology*,.425-431,

[157] Eg T. J. Flowers, 'Improving crop salt tolerance'. (2004) 55 (396) *J. Exp. Bot* 307-319.

[158] L. Cattivelli, F, Rizza, FW Badeck *et al.* 'Drought tolerance improvement in crop plants: An integrated view from breeding to genomics' (2008) 105 *Field Crops Res* 1-14. R Tuberosa and S.Salvi, 'Genomics-based approaches to improve drought tolerance of crops' (2006) 11 *Trends Plant Sci* 2006 405-412.

[159] R. Thomson and E. Webster, 'The Role of Intellectual Property Rights in Addressing Climate Change: the Case for Agriculture,' (2010) 2(1) *The WIPO Journal*, 133-141.

[160] Thomson and Webster, *ibid*., refer to an interactive computer based decision support tool called "Nutrient Manager" developed by International Rice Research Institute(IRRI) which calculates the optimal amounts of fertiliser to be applied.

[161] V. S. Somvanshi 'Patenting Drought Tolerance in Organisms' (2009) 3 *Recent Patents on DNA & Gene Sequences* , 16-25, accessed at http://www.benthamscience.com/dnag/samples/dnag3-1/0003DNAG.pdf, at Table 2.

[162] Eg US Patent 20087385106.

[163] Eg US20087368630, US20077259297 and US20077253000.

[164] Eg US20087345219.

[165] US20087332651, WO2007028165A2, EP1676921, US20060272059, US7332651.

[166] US20077262338.

[167] A patent family contains a set of related patent applications and/or issued patents that are published in more than one country or patent office (including national and regional patent jurisdictions). Issued patents and/or applications that belong to the same family have the same inventor and they refer to the same "invention.").

[168] ETC Group, 'Patenting the "Climate Genes"…and Capturing the Climate Agenda' *Communiqué*, no.99, May/June 2008, Available at http://www.etcgroup.org/upload/publication/687/03/etcgroupclimategenesfinal05_08.pdf

nutrient levels, high light intensity, ozone and anaerobic stresses".[169] It noted "a dramatic upsurge in the number of patents published (both applications and issued patents) related to 'climate-ready' genetically engineered crops from June 30, 2008 to June 30, 2010, identifying 262 patent families and 1663 patent documents.[170]

3.3 Debate on role of corporations in the patenting of stress tolerant genes

The 2008 ETC report was subjected to a close analysis by Dr Carol Nottenburg[171], the Principal of a US Patent firm and it is useful to examine the claims and counter-claims to identify the significant elements of the debate about the patenting of stress tolerant genes, as her comments are equally applicable to the 2010 ETC report. The ETC report stated that the so-called "Gene Giants", exemplified by BASF, Bayer, DuPont, Monsanto and Syngenta "are staking sweeping patent claims on genes related to environmental stresses" in patent offices around the world. Dr Nottenburg points out that the patenting of gene sequences is not permitted in a number of developing countries, including Andean countries and an examination of the patents which are identified in the 2008 report have been sought in Argentina, Brazil and China, leaving more than 200 countries "in which these patent applications will never be pertinent". A similar argument was advanced by Attaran and Gillespie-White, that patents did not stand in the way of access to HIV anti-retrovirals in most African countries,[172] but the political impact of the patents in a few of those countries, far outweighed their practical significance and brought about the first amendment of the TRIPS Agreement.[173]

Dr Nottenburg also pointed out that the number of patent families is the better indicator of the incidence of the patenting of stress-tolerant genes, than patent filings. This is certainly the case, as a number of filings are duplicated in different countries. The 2010 report identifies some 262 patent families which is a considerable advance on the 55 identified in the 2008 report. However, it should be noted that even a small number of patent families can have a considerable political impact. For example, if the number of biopiracy incidents was totalled, they would probably not exceed around 20 causes celebres.

The 2008 report is critical of over-broad patent claims, but Dr Nottenburg considers this to be a matter dictated by the "eye of the beholder" and in one case involved an error in the published patent document. She concludes that "visions of gene-grabbing and holding farmers hostage are unwarranted". A particular problem had been that patent applicants had been allowed to make bulk claims in relation to genetic material of which the use had not yet been identified. However, the 2010 report concedes that in 2001 the USPTO put a brake on "bulk claims" by issuing new guidelines requiring that claimed inventions must have "well-established" utility and that in 2007 the USPTO limited bulk claims by notifying its patent examiners that they the option of restricting claims to only a single nucleotide sequence in each patent application.[174]

The 2010 report of the ETC contrasts the ownership of 9% patent families by public sector institutions (9% of the total) with the private sector which holds 91% of the total. As is the case with biotechnological patenting generally, proprietary biotechnologies are concentrated in the

---

[169] ETC Group, 'Gene Giants Stockpile Patents on "Climate-ready" Crops in Bid to become "Biomassters" Patent Grab Threatens Biodiversity, Food Sovereignty' Issue no. 106, October 2010, Available at http://www.etcgroup.org/upload/publication/pdf_file/FINAL_climate-readyComm_106_2010.pdf

[170] Ibid., Appendix A.

[171] C. Notenburg, 'Patenting the "Climate Genes...and Capturing the Climate Agenda": A Communiqué by the ETC Group' Harvest Choice Commentary, August 7, 2009, accessed at http://www.harvestchoice.org/files/Nottenburg%202008%20HarvestChoice%20--Patenting%20the%20Climate%20Genes~2S.pdf

[172] A. Attaran and L. Gillespie-White, 'Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatments in Africa' (2001)286 *JAMA* 1886.

[173] See H. Hestermeyer in *Human Rights and the WTO. The Case of Patents and Access to Medicine* , Oxford University Press, Oxford, 2007.

[174] Referring to 1316 O.G.13, 27 March 2007.

same few corporations.[175] The 2010 report points out that "just three companies – DuPont, BASF, Monsanto – account for two-thirds (173 or 66%) of the total." This level of market concentration gives cause for concern for those who espouse the positive role of competition.

In addition to the possible adverse impacts this market concentration might have upon the vigour of competition, the market dominance of these private corporations also has an important influence upon the sort of biotechnological research which is undertaken. For example, to what extent will the dominance of private corporations in biomedical and agricultural research direct that research towards Northern concerns away from Southern Southern food priorities.[176] It has been estimated that only 1% of research and development budgets of multinational corporations is spent on crops of interest be useful in the developing world.[177] Almost entirely neglected by these corporations are the five most important crops of the poorest, arid countries - sorghum, millet, pigeon pea, chickpea and groundnut.[178]

IV. ENFORCEMENT AND LIABILITY ISSUES

This section briefly considers patent infringement that may possibly arise from the importation of patented genetic material. IP liability may arise from the development, cultivation and use of GM crops and may be attracted by governments, research institutes, farmers, exporters and importers. Others who might attract liability are: plant breeders, bulk handlers and food processors. The range of legal categories of possible liability will depend upon the nature of the legal system and will include liability under: (i) tort (in common law systems), delict in civil law systems; (ii) contract; (iii) consumer protection laws; (iv) intellectual property laws; and (v) biosafety laws. Legal liability of seed developers arising from the unwanted presence of GM crops in non-GM canola under tort law was comprehensively examined by the Saskatchewan Court of Queen's Bench in *Larry Hoffman and others v Monsanto Canada Inc and Bayer Cropscience Inc*.[179] However, there have been no cases on the IP liability of governments, research institutes and farmers for the use of proprietary seed since the 2009 report.

Patent infringement may possibly arise from the importation of patented genetic material, even where a patent might not exist in the exporter's country. This situation has been addressed by a number of European courts before which Monsanto brought actions against importers of its patented RuR soy. In 1996 Monsanto had obtained a European Patent claiming, inter alia, a method of making transgenic plants into which an enzyme EPSPS[180] had been inserted to render plants them resistant to glyphosphate. Monsanto had inserted a gene encoding this enzyme into soy. Some 90% of the soy meal exported from Argentina contained this enzyme, but Monsanto had not obtained a patent in that country. In June 2005 and March 2006 Monsanto had used the EU border control regulation to have the cargo of soy meal on two ships arriving in Rotterdam from Argentina detained and tested. The tests revealed the presence of a DNA molecule in the meal which contained EPSPS. Monsanto brought actions against importers in the Netherlands, the UK and Spain.

---

[175] Eg see W. Lesser, 'Intellectual property rights and concentration in agricultural biotechnology.'(1998) 1(2) *AgBioForum* 56.

[176] J. Alston, G.Pardey and J. Rosenboom 'Financing Agricultural Research: International Investment Patterns and Policy Perspectives' (1998) 26 *World Development* 1045.

[177] P.L. Pingali and G. Traxler, 'Changing focus of agricultural research: will the poor benefit from biotechnology and privatization trends?' (2002) *Food Policy* 27.

[178] Human Rights Council, *Report of the Special Rapporteur on the Right to Food, Jean Ziegler,* A/HRC/7/5, 10 January 2008, para. 44.

[179] 2005 SQKB 225.

[180] An enzyme called 5-enolppyruvylshikimate synthase, which confers glyphosphate resistance to a plant in which the enzyme is expressed.

In the Dutch litigation Monsanto sought an injunction prohibiting the infringement of the patent in all European countries[181] The importer denied infringement relying on Article 9 of the EU Biotechnology Directive which confers protection upon material "in which the genetic material is contained and performs its function". It argued that as a result of the processing of soy beans to produce the meal, the DNA was dead material and could not perform its function of expressing the EPSPS enzyme. The District Court of the Hague stated a number of questions to the ECJ to obtain an interpretation of the relevant provisions of the Biotechnology Directive. In the Spanish proceedings, this argument was effective in defeating Monsanto.[182] To meet this argument Monsanto argued that the application of Article 9 derogated from the patent protection to which it was entitled under Dutch patent law and under Article 27 of the TRIPS Agreement.

In the UK the trial judge in the High Court found that as the defendant had not infringed the plaintiff's patent as the defendant had not isolated the patented DNA, nor had it constructed recombinant DNA molecules, nor had it transformed plants and it had not produced and farmed glyphosphate resistant soy plants. It was merely, the importer of a derivative product of beans produced from such plants and he observed that the DNA in the soy meal was dead material in the sense that it did not perform the function (disease resistance) for which it had been patented.[183]

The ECJ, in its consideration of the Dutch Court's questions considered whether Article 9 of the Biotechnology Directive could be interpreted as meaning that the protection provided under that provision can be invoked even in a situation where a patented DNA sequence formed part of a material imported into the EU, but did not perform its function at the time of the alleged infringement, but would possibly again be able to perform its function after it has been isolated from the soy and inserted into the cell of an organism.[184] The Court ruled that the protection provided for in Article 9 of the Directive was not available "when the genetic information has ceased to perform the function it performed in the initial material from which the material in question is derived."[185]

The Hague District Court also asked whether Articles 27 and 30 of the TRIPS Agreement affect the interpretation given of Article 9 of the Biotechnology Directive. The Court noted that under European law the provisions of the TRIPS Agreement were not such as to create rights upon which individuals may rely directly before the courts.[186] However, the Court conceded that under EU jurisprudence it would as far as possible, to supply an interpretation in keeping with the TRIPS Agreement, even though no direct effect may be given to the provision of that agreement at issue.[187] In this regard it noted that Article 9 of the Directive governed the scope of the protection conferred by a patent on its holder, whilst Articles 27 and 30 of the TRIPS Agreement concern, respectively, patentability and the exceptions to the rights conferred by a patent. On the assumption that "exceptions to rights conferred" could be regarded as encompassing not only exclusions of rights but also limitations on those rights, the Court pointed out that an interpretation of Article 9 of the Directive limiting the protection it confers to situations in which the patented product performs its function does not appear to conflict unreasonably with a normal exploitation of the patent and does not "'unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties", within the meaning of Article 30 of the TRIPS Agreement.[188]

---

[181] *Monsanto Technology LLC v Cefetra BV and the State of Argentina* District Court of the Hague 249983/HA ZA 05/2885, 19 March 2008.

[182] See C. Baldock, 'Monsanto Puts Biotech Directive Under the Spotlight' [2206/2007] 4 *Bioscience Law Rev* 160 at 161.

[183] *Monsanto Technology LLC v Cargill International S.A* [2007] EWHC 2257 (Pat), per Pumphrey J.

[184] *Monsanto Technology LLC v. Cefetra BV and others*, Case C-428/08, 6 July 2010

[185] Ibid, at para. 38.

[186] Ibid at para 71 citing Joined Cases C-300/98 and C-392/98 *Dior and Others* [2000] ECR I-11307, paragraph 44.

[187] Ibid at para 72 citing Case C-431/05 *Merck Genéricos - Produtos Farmacêuticos* [2007] ECR I-7001, paragraph 35).

[188] Ibid, at paras 75-76.

V. CONCLUSIONS

The application of IPRs to GRs has become a pronounced feature of agricultural innovation in the past decade. The FAO' Panel of Eminent Experts on Ethics in Food and Agriculture has observed that "while most innovation for food and agriculture does not depend on IPRs, the acquisition and exercise of IPRs in this field raise a variety of ethical concerns".[189] These include the fact that "IPRs protection may just mean the lack of access to innovations for the poor" and the concerns raised by the "patenting of merely isolated genes, the basic building blocks of life", which "are not invented, but are part of nature."[190] More practically, the ability of individuals and corporations to obtain proprietary rights over agricultural innovations has important implications for food security[191], particularly as the expense and general transactional costs has tended to concentrate such IPRs in a few hands. In particular, IPRs on GRs may impede their use by third parties for further research and breeding during the term of protection, and thereby inhibit the development of new products and the capacity to address emerging problems, such as agricultural stresses caused by climate change.

An important issue which has been addressed by the EPO and its appeal bodies over the last year is the question of the patentability of breeding methods. Had this patenting been permitted it might have rendered the PVP system largely redundant. However, it is noted that the products of breeding remain patentable, with the consequential implications which that has for food security.

The IPRs landscape which confronts countries is of course dominated by the TRIPS Agreement. However, that Agreement contains a number of flexibilities. First, it allows the exclusion from patent protection of plants and animals (whether genetically modified or not). Secondly, the criteria under which patents are granted, ie novelty, and inventive step and industrial applicability may exclude materials identified through the application of TK, or GRs which exist in nature (even if isolated) as well as microorganisms. Article 30 of the TRIPS Agreement, provides that "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." Thus patent laws may allow third parties to undertake research and breeding during the patent term and farmers may be granted the right to save and re-use seeds where plant varieties, or certain components thereof, are subject to patent protection, in a way similar to the 'farmer's privilege' under PVP.

Over the last few years, there has been a significant amount of patenting in relation to genetic material which might be useful in permitting organisms to resist the stresses of climate change. This patenting mirrors the high market concentration levels which has already been observed in the seed industry and the control of patent thickets by a small number of companies. It should be noted in this regard, both in relation to patent rights and PVP, national laws may provide for compulsory licenses in situations of national emergency. There is also the possibility for the intervention of the competition authorities to remedy abuses in the exercise of patent rights.

Instances of the unauthorised appropriation of the GRs of countries, typically involving the application of the TK of indigenous peoples to identify those resources, continue to be reported. WIPO continues to make slow progress in identifying the objectives and principles which might animate international legislation to deal with this appropriation. Currently under discussion is the adoption of an international obligation to disclose the origin of genetic resources and associated TK claimed in patent applications. As with a number of other matters within the "Development Agenda", agreement is required as to the legal effect of such an obligation. Similar debates are being conducted within the context of the Doha Development Round, with a similar lack of progress. What would have been thought to have been a "low hanging fruit" was the

---

[189] Panel of Eminent Experts on Ethics in Food and Agriculture, *3rd Report* , 2005, available at http://www.fao.org/docrep/010/a0697e/a0697e00.htm.

[190] Ibid.

[191] See M. Blakeney, Intellectual Property Rights and Food Security, Wallingford, Oxford, Cab International, 2009.

establishment of a "multilateral system of notification and registration of geographical indications for wines" mandated by Article 23.4 of TRIPS, but to date a text has not been agreed on this subject. More useful, particularly for developing countries and LDCs is the possibility of the extension of special protection for GIs to agricultural products and handicrafts, but on the evidence of the difficulties in relation to the multilateral register, this would seem to be a fruit much higher up the tree.

The practical effects of the application of IPRs to GRs, is reflected in the actions which are brought for infringements of IPRs. To date, these actions have mainly been brought against farmers who have cultivated patented GM crops without the permission of the relevant rights holder, as well as actions against importers of products containing patented GM ingredients. Potential IPR liability lies against governments, research institutes (international and national) and seed breeders who supply or utilise proprietary technologies. The TRIPS Agreement establishes machinery to deal with the international trade in infringing goods and this machinery is currently being supplemented by the proposed Anti-counterfeiting Trade Agreement (ACTA), of which the final text was settled on 3 December 2010.