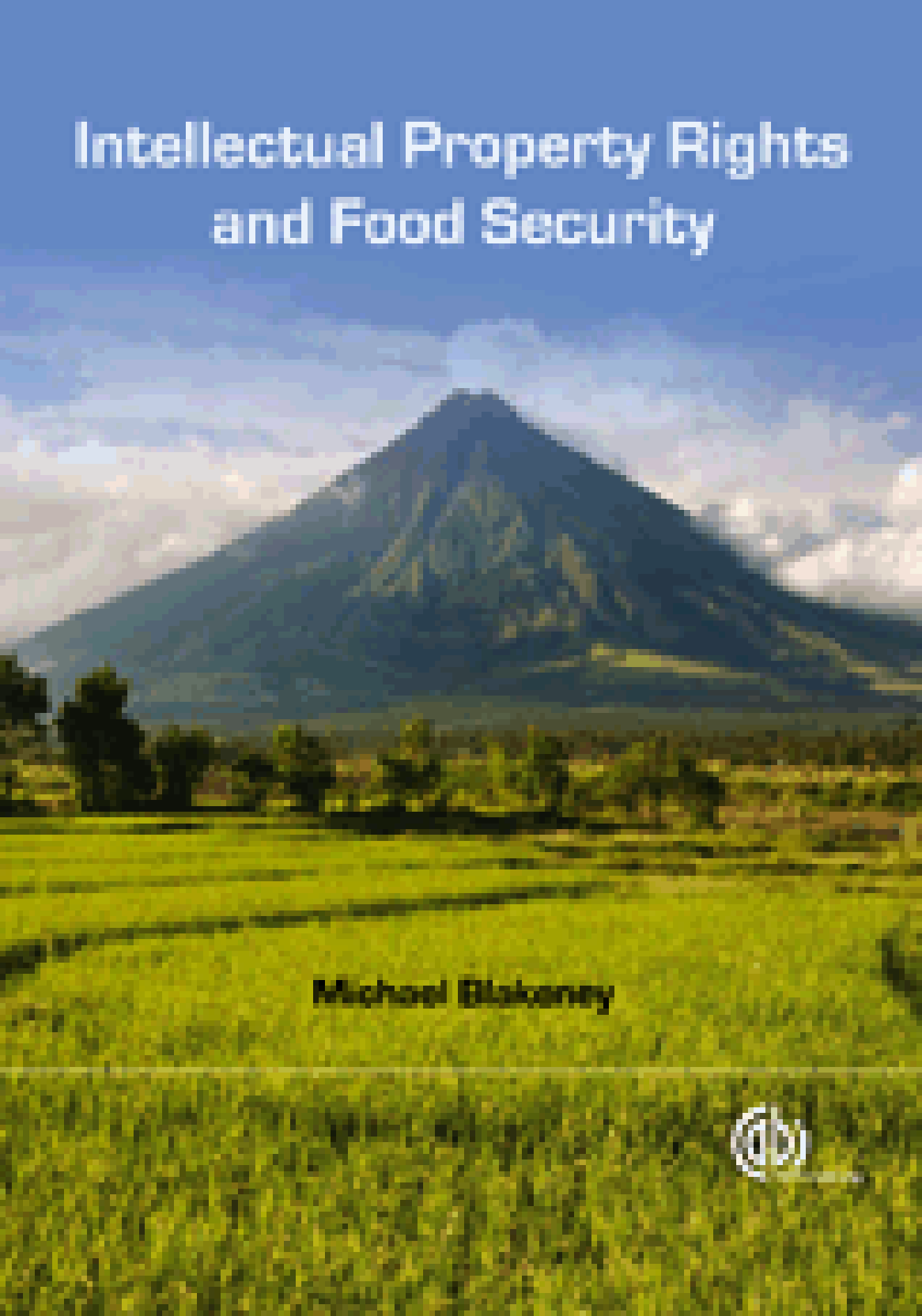
Intellectual Property Rights and Food Security



Michael Blakeney

INTELLECTUAL PROPERTY RIGHTS AND FOOD SECURITY

For Louise, a Loaf of Bread and Thou are Paradise enow

Intellectual Property Rights and Food Security

Michael Blakeney

Herchel Smith Professor of Intellectual Property Law
Queen Mary, University of London
Professor of Law, University of Western Australia

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CABI is a trading name of CAB International

CABI Head Office
Nosworthy Way
Wallingford
Oxfordshire OX10 8DE
UK

Tel: +44 (0)1491 832111
Fax: +44 (0)1491 833508
E-mail: cabi@cabi.org
Website: www.cabi.org

CABI North American Office
875 Massachusetts Avenue
7th Floor
Cambridge, MA 02139
USA

Tel: +1 617 395 4056
Fax: +1 617 354 6875
E-mail: cabi-nao@cabi.org

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Preface

At the time of the first World Food Summit in 1996 it was estimated that more than 800 million people did not have enough food to meet their basic nutritional needs. The steep rise in global food prices has exacerbated the situation, causing the 2008 G8 Hokkaido Toyako Summit to issue a Statement on Food Security which expressed concern that global food security was under a severe threat. The root cause of food insecurity is poverty. Trade liberalization is part of the long-term solution, as are improvements in agricultural productivity. This book examines the contribution which intellectual property rights can make in the struggle for food security in developing countries.

Chapter 1 locates intellectual property rights within the armoury of food security policies. Chapter 2 deals with definitional issues and examines the role of intellectual property rights in incentivizing agricultural research and development. Chapter 3 examines the international landscape of intellectual property and the approaches taken to the relationship between intellectual property rights, agricultural biotechnology, access to biological resources, food security and globalization which are taken by the WTO, FAO, CBD and WIPO among the various international and development agencies. Plant variety rights (PVRs) are a specially created form of intellectual property right originally minted to encourage agricultural innovation and Chapter 4 examines the effectiveness of PVRs in a food security context.

Agricultural innovation is in part dependent upon access of researchers to the genetic resources of the biodiverse countries of the South. Chapter 5 considers the attempts to construct an international regime to secure this access. The important role of traditional farmers in preserving landraces and cultivars from which improvements can be derived has generated for a call for the recognition of farmers' rights, and this is examined in Chapter 6 together with agitation for the protection of the traditional knowledge which often informs access to the useful genetic resources.

Chapter 7 examines the intellectual property implications of the use of genetically modified (GM) crops as a technological solution to food insecurity. The protection of GM crops is achieved through patent protection and Chapter 9 looks at the competition law implications of patent licensing, patent pools and patent thickets.

An old intellectual property device that underpinned the commercial development of European agricultural marketing is the geographical indication, and Chapter 8 examines the contribution it might make to achieving food security.

Returning to the theme of the role of intellectual property law in incentivizing innovation, Chapter 10 examines its role in promoting agricultural research.

The concluding chapter proposes a number of recommendations for action in deploying intellectual property law in the struggle for food security.

This book was made possible by the grant of study leave by Queen Mary, University of London, which was profitably spent at the University of Western Australia, where I have to acknowledge the support of Professor Bill Ford, Dean of the Faculty of Law, and the staff of the International Centre for Plant Breeding and Research at the University of Western Australia. My research was enriched by the support and counsel of Dr Victoria Henson-Apollonio of the CGIAR's Central Advisory Service on Intellectual Property, but of course any shortcomings remain mine.

Michael Blakeney

Acronyms and Abbreviations

ABS	access and benefit sharing
ACCC	Australian Competition and Consumer's Commission
ACMG	American College of Medical Genetics
ACRE	Advisory Committee on Release to the Environment (UK)
AGRA	Alliance for a Green Revolution in Africa
AHTEG	Ad Hoc Technical Expert Group
AIPPI	International Association for the Protection of Industrial Property
AMS	aggregate measure of support
AoA	Agreement on Agriculture
AOC	Appellations d'Origine Contrôlée
APHIS	Animal and Plant Health Inspection Service
APMU	Agricultural Pest Management Unit (The Gambia)
ARIPO	African Regional Intellectual Property Organization
ASEAN	Association of Southeast Asian Nations
ASSINSEL	International Association of Plant Breeders for the Protection of Plant Varieties
AU	African Union
BAB	Biosafety Authority Board (Botswana)
BIOS	Biological Innovation for Open Society
BIRPI	Bureaux Internationaux Réunis pour la Protection de la Propriété Intellectuelle
Bt	*Bacillus thuringiensis*
CAADP	Comprehensive Africa Agricultural Development Programme
CAC	Codex Alimentarius Commission
CAMBIA	Centre for the Application of Molecular Biology to International Agriculture
CAP	Common Agricultural Policy
CATIE	Tropical Agriculture and Higher Education Research Centre

CBD	Convention on Biological Diversity
CDIP	Committee on Development and Intellectual Property
CESCR	Committee on Economic, Social and Cultural Rights
CFA	Comprehensive Framework for Action
CGIAR	Consultative Group on International Agricultural Research
CGRFA	Commission on Genetic Resources for Food and Agriculture
CIAT	Centro Internacional de Agricultura Tropical
CIFOR	Center for International Forestry Research
CIMMYT	Centro Internacional de Mejoramiento de Maiz y Trigo (International Maize and Wheat Improvement Center)
CIP	Centro Internacional de la Papa (International Potato Center)
CIPIH	Commission on Intellectual Property Rights, Innovation and Public Health
CIPR	Commission on Intellectual Property Rights
CITP	*Charter of the Indigenous-Tribal Peoples of the Tropical Forests*
CLIMA	Centre for Legumes in Mediterranean Agriculture
CNBS	National Council for Biosafety (Brazil)
COGENT	Coconut Genetic Resources Network
CONABIA	National Advisory Committee on Agricultural Biotechnology (Argentina)
COP	Conference of the Parties
CPC	Community Patent Convention
CPG	Common Policy Guidelines
CTNBio	National Technical Biosafety Committee (Brazil)
DBT	Department of Biotechnology (India)
DEFRA	Department for Environment, Food and Rural Affairs (UK)
DNMA	Directorate of Agri-Food Marketing (Argentina)
DOSA	Department of State for Agriculture (The Gambia)
DSU	*Understanding on Rules and Procedures Governing the Settlement of Disputes*
DUS	distinct, uniform and stable
ECJ	European Court of Justice
EIS	Environmental Impact Statement
EPA	Environmental Protection Agency
EPC	European Patent Convention
EPO	European Patent Office
EST	expressed sequence tag
ETC Group	Action Group on Erosion, Technology and Concentration
FAO	Food and Agriculture Organization (of the United Nations)
FDA	Food and Drug Administration (USA)
FFDCA	Federal Food, Drug, and Cosmetic Act
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FOB	farmer-owned brands
FTA	free trade agreement
FTO	freedom to operate

GATS	General Agreement on Trade in Services
GATT	General Agreement on Tariffs and Trade
GEAC	Genetic Engineering Approval Committee (India)
GI	geographical indication
GM	genetically modified
GMOs	genetically modified organisms
GRDC	Grains Research and Development Corporation
GRPC	Genetic Resources Policy Committee
GRRF	Genetic Resources Recognition Fund
GRULAC	Group of Countries of Latin America and the Caribbean
GURTs	genetic use restriction technologies
GUS	beta-glucuronidase
HapMap	haplotype mapping
HLTF	High Level Task Force
IARCs	International Agricultural Research Centres
IBRD	International Bank for Reconstruction and Development
ICARDA	International Center for Agricultural Research in the Dry Areas
ICCPR	*International Covenant on Civil and Political Rights*
ICESCR	*International Covenant on Economic, Social and Cultural Rights* 1966
ICIS	International Crop Information System
ICLARM	International Center for Living Aquatic Resources Management
ICRAF	World Agroforestry Centre
ICRISAT	International Crops Research Institute for the Semi-Arid Tropics
ICT	Information and Communication Technology
IFAD	International Fund for Agricultural Development
IFPRI	International Food Policy Research Institute
IGC (WIPO)	Intergovernmental Committee (on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore)
IGWG	Intergovernmental Working Group
IIM	inter-sessional intergovernmental meetings
IITA	International Institute of Tropical Agriculture
ILRI	International Livestock Research Institute
IMF	International Monetary Fund
IMI	Initiative for Mainstreaming Innovation
INAO	Institut National des Appellations d'Origine
INASE	National Seed Institute (Argentina)
INBio	Instituto Nacional de Biodiversidad (Costa Rica)
INRA	Institut National de la Recherche Agronomique
IP	intellectual property
IPER	International Preliminary Examination Report
IPGRI	International Plant Genetic Resources Institute
IPR	intellectual property rights

IRRI	International Rice Research Institute
ISAAA	International Service for the Acquisition of Agribiotechnology Applications
ISF	International Seed Federation
ISNAR	International Service for National Agriculture Research
ITO	International Trade Organization
ITPGRFA	International Treaty on Plant Genetic Resources for Food and Agriculture
IUCN	International Union for the Conservation of Nature
IWMI	International Water Management Institute
KARI	Kenyan Agricultural Research Institute
LAAD	Latin American Agribusiness Development Corporation
LDC	least-developed country
LMO	living modified organism
MFN	most-favoured-nation
MIT	Massachusetts Institute of Technology
MLS	multilateral system
MTA	material transfer agreement
NARS	national agricultural research systems
NBC	National Biosafety Committee (Costa Rica and Benin)
NEPA	National Environmental Policy Act
NGO	non-governmental organization
NGO-C	Committee of Non-governmental Organizations
NIAB	National Institute of Agricultural Botany (UK)
OAPI	Organisation Africaine de la Propriété Intellectuelle
OAU	Organization of African Unity
PBR	plant breeders' rights
PBRA	Plant Breeders' Rights Act
PCDA	Provisional Committee on Proposals Related to a WIPO Development Agenda
PCR	polymerase chain reaction
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
PPA	Plant Protection Act
PVP	plant variety protection
PVPA	Plant Variety Protection Act
PVR	plant variety rights
PVRA	Plant Variety Rights Act
RAFI	Rural Advancement Foundation International

RBG	Royal Botanic Gardens
RCGM	Review Committee on Genetic Manipulation (India)
RuR	Roundup Ready
S&D	special and differential
SAARC	South Asian Association for Regional Cooperation
SAGyP	Secretariat of Agriculture, Livestock, Fisheries and Food (Argentina)
SARS	systemic acquired resistance syndrome
SBSTTA	Subsidiary Body on Scientific, Technical and Technological Advice
SCP	Standing Committee on the Law of Patents
SENASA	National Service of Health and Agrofood Quality (Argentina)
SMTA	Standard Material Transfer Agreement
SNP	single nucleotide polymorphism
SPLT	Substantive Patent Law Treaty
SPS	Agreement on the Application of Sanitary and Phytosanitary Measures
STV	Treuhandverwaltungsgesellschaft mbH
TBT	Agreement on Technical Barriers to Trade
TDI	Tropical Diseases Initiative
TK	traditional knowledge
TNC	Trade Negotiations Committee
TRIPS	(WTO Agreement on) Trade-Related Aspects of Intellectual Property Rights
TSCA	Toxic Substances Control Act
UDHR	*Universal Declaration of Human Rights* 1948
UNCTAD	United Nations Conference on Trade and Development
UNDP	United Nations Development Programme
UNEP	United Nations Environmental Programme
UNESCO	United Nations Educational and Scientific Organization
UNGA	United Nations General Assembly
UNIDO	United Nations Industrial Development Organization
UPOV	International Convention for the Protection of New Varieties of Plants
USAID	United States Agency for International Development
USPTO	United States Patent and Trademarks Office
WARDA	Africa Rice Center
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WSSD	World Summit on Sustainable Development
WTO	World Trade Organization

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1 Intellectual Property and Food Security – Policy Issues

1.1 Food Security Defined

Hunger is a profound affront to human dignity and human rights. It is a fundamental constraint to development, fuels conflict and crime, reduces productivity and shortens life span. At the World Food Summit, convened in Rome in 1996 by the Food and Agriculture Organization of the United Nations (FAO), it was reported that more than 800 million people, particularly in developing countries, do not have enough food to meet their basic nutritional needs. It was estimated that some 400,000 people were killed by malnutrition daily. The 185 countries participating at the Rome Summit vowed to achieve universal food security.

The Rome Declaration, which was issued by the 1996 Summit, pledged to cut the number of hungry people in half by 2015. This goal was also included in the Millennium Declaration of the United Nations (UN) in 2000. This objective required the number of undernourished to fall at a rate of 20 million per year. However, data in 2001 indicated that the rate of decline was less than 8 million per year.[1]

At the current rate of global population increase, it has been estimated that the global demand for cereals will increase by 20% between 1995 and 2020 and that net cereal imports by developing countries will have to double to meet the gap between production and demand.[2] Currently, the developing world is a net importer of 88 million tons of cereals a year at a cost of US$14.5 billion and the global demand for cereals will increase by 40% between 1995 and 2020.[3] Paradoxically, a 1999 study

[1] FAO (2001) Some issues relating to food security in the context of the WTO negotiations on agriculture. *FAO Geneva Round Table on Food Security in the Context of the WTO Negotiations on Agriculture,* 20 July, 2.

[2] P. Pinstrup-Andersen, R. Pandya-Lorch and M.W. Rosegrant (1999) *World Food Prospects: Critical Issues for the Early Twenty First Century*. International Food Policy Research Institute, Washington DC, chapter 1.

[3] I. Serageldin and G.J. Persley (2000) *Promethean Science. Agricultural Biotechnology, the Environment and the Poor*. CGIAR, Washington DC, 3.

of the International Food Policy Research Institute (IFPRI) has estimated that world food supply would continue to outpace population growth at least to 2020.[4]

Food security as defined by the 1996 World Food Summit is a situation in which all people at all times have physical and economic access to sufficient, safe and nutritious food to meet their dietary needs and food preferences for an active and healthy life. However, it should be noted that there is a large number of definitions of food security[5] and that these tend to be influenced by perceptions of the policy options by which food insecurity might be cured. Scoones[6] traces the definition from its 1974 World Food Conference connotation of access to the availability of food,[7] through the World Bank's 1986 definition of food security in the sense of access to sustain a healthy life.[8] Indicators of food security can be defined at different levels – for the world as a whole, for individual countries or for households.[9] At the national level, adequate food availability means that on average sufficient food supplies are available, from domestic production and/or imports, to meet the consumption needs of all in the country.

As can be seen from the 1996 World Food Summit definition, in the most recent discussions food security is discussed in a human rights context as concerning the individual. Its principal determinant therefore is the individual's entitlement to food – ability to produce and/or purchase food.

1.2 Causes of Food Insecurity

The opposite of food security is food insecurity. Food insecurity can be transitory (when it occurs in times of crisis), seasonal or chronic (when it occurs on a continuing basis). A person can be vulnerable to hunger even though he or she is not actually hungry at a given point in time. For example the FAO Report, *The State of Food Insecurity in the World 2000*, gives the example of Benin where close to half the population is vulnerable to hunger whereas only one-seventh of the population is undernourished, using the FAO estimate of undernourishment.

There is a complex of factors that have been identified as contributing to food insecurity in developing countries. Principal among these factors is poverty. Over 1.3 billion of the world's population have incomes of less than US$1.00 per day, while another 2 billion people are only marginally better off.[10] Although the number of people living on an income of less than US$1.00 per day declined from 29% in 1987 to 26% in 1998, the number of poor people has remained unchanged because of population growth.

[4] See Pinstrup-Andersen, n.2 supra.

[5] Some 200 definitions of food security were noted by S. Maxwell and M. Buchanan-Smith, Household food security: a conceptual review. In: S. Maxwell and T. Frankenburger (eds) (1992) *Household Food Security: Concepts, Indicators, Measurements: A Technical Review*. UNICEF and UNCTAD, New York and Rome.

[6] I. Scoones (2002) *Agricultural Biotechnology and Food Security: Exploring the Debate,* IDS Working Paper 145, January.

[7] Referring to UN, Report of the World Food Congress, New York, 5–16 November 1974.

[8] Referring to World Bank Policy Study (1986) *Poverty and Hunger: Issues and Options for Food Security in Developing Countries*. World Bank, Washington DC.

[9] FAO (2001), ibid.

[10] World Bank (2002) *World Development Report 2002*. Oxford University Press, Oxford.

The contribution of food imports to food security, while crucial, is limited by the foreign exchange earning capacity of developing countries. Thus, closing the food gap through commercial imports is not a realistic possibility for most countries that have poor prospects for substantial increases in foreign exchange earnings and/or already face heavy external debt burdens.

For some countries, food imports accounted for more than 50% of total export earnings, minus debt servicing. Food aid, which has in the past been used in some cases to meet uncovered market demands as well as to feed hungry people directly, has been on the decline and in any case is not a sustainable solution.

With 70% of the world's extremely poor and food insecure people living in rural areas, the role of agriculture, which is the predominant economic activity in rural areas, is crucial in the eradication of poverty and food insecurity. The rural poor depend on agriculture for both their incomes and food entitlements. More generally, in most countries with a high incidence of food insecurity, agriculture is the mainstay of the economy. It accounts for a large share of gross domestic product, employs a large proportion of the economically active population, represents a major source of foreign exchange and supplies the bulk of basic foods.

Another factor contributing to food insecurity is the lack of access to land for people in agrarian societies. The concentration of land ownership in societies like Brazil, where 1% of landowners own 46% of all farmland and where 4.5 million peasant families are landless, is mirrored in Central America where 60% of the population is landless or near landless.[11] In Africa the proportion is around 40%. The redistribution of land is an obvious solution to this particular problem and the FAO in its 2002 report on food insecurity has reported that in developing countries where land has been more equally redistributed there has been progress in reducing hunger.[12]

Land redistributions, such as in Zimbabwe under the Mugabe regime, have converted a situation of food self-sufficiency into food dependency. Part of the reason for this is corruption, which itself is another factor contributing to food insecurity. There have been a number of notorious instances where international aid from the World Food Programme has been diverted to non-food programmes, such as to the purchase of arms. This then leads to another cause of food insecurity – wars. For example, the FAO noted that at the time of the 1994 famine in Ethiopia, the Government applied 46% of the national budget to arms purchases.[13]

A more recently identified contributor to food insecurity is the impact of climate change. The FAO has observed that with global warming 'many of today's poorest developing countries are likely to be negatively affected in the next 50–100 years, with a reduction in the extent and potential productivity of cropland'.[14] A 1996 FAO study estimated that the largest reduction in cereal production will occur in developing

[11] UN Commission on Human Rights (2001) 57th sess., Economic, Social and Cultural Rights: the Right to Food, 7 February.

[12] FAO, The State of Food Insecurity in the World 2002, www.fao.org/docrep/005/y7352e/y352e00.htm.

[13] FAO, Recent Shocks to Food Security, www.fao.org/docrep/003/y1500e/y1500e04.htm, 2.

[14] FAO (2003) Committee on World Food Security, Impact of Climate Change on Food Security and Implications For Sustainable Food Production, Rome, 12 May. FAO Doc. CFS:2003/INF.

countries, averaging about 10%.[15] Placing this in perspective, a projected 2–3% reduction in African cereal production for 2020 was estimated to be enough to put 10 million people at risk. Particularly vulnerable to climate change are those low- to medium-income groups in flood-prone areas who may lose stored food or assets; farmers who may have their land damaged or submerged by a rise in sea level; and fishermen who may lose their catch to shifted water currents or through flooded spawning areas.

The High Level Conference on World Food Security, convened by the FAO in June 2008, noted that during the first 3 months of 2008 international nominal prices of all major food commodities reached their highest levels in nearly 50 years while prices in real terms were the highest in nearly 30 years.[16] The High Level Conference observed that the constriction of food supplies was caused by the shift of farmers into the production of biofuels and also the impact of global warming on food supplies. The Declaration issued by the High Level Conference requested an immediate response to requests for food assistance by affected countries and in the longer term to enhance investment in agriculture.[17]

1.3 Policies for Countering Chronic Food Insecurity

Technological solutions

The earliest policy approach to dealing with the question of food security addressed technological improvements in agriculture. The massive increase in food productivity in the 30 years between 1960 and 1990, which is described as the Green Revolution, was achieved by developing high-yielding crop varieties. The productivity of cereals was also enhanced by expanding the area of arable land and by massive increases in fertilizer and insecticide use. Publicly funded national and international agricultural research institutes played a significant role in the development of these new varieties. For example, the Consultative Group for International Agricultural Research (CGIAR)[18] network of international agricultural research institutes developed from the innovative developments of Norman Borlaug at CIMMYT with high-yielding dwarf wheat. The research at CIMMYT and at IRRI, which was responsible for

[15] FAO, Global climate change and agricultural production: direct and indirect effects of changing hydrological, pedological and plant physiological processes, CFS:2003/INF/11.

[16] FAO, Soaring Food Prices: Facts, Perspectives, Impacts and Actions Required. FAO doc., HLC/08/INF/, para.1.

[17] http://www.fao.org/fileadmin/user_upload/foodclimate/HLCdocs/declaration-E.pdf.

[18] Consultative Group for International Agricultural Research, today comprising: Africa Rice Center (WARDA); Bioversity International CIAT, Centro Internacional de Agricultura Tropical; CIFOR, Center for International Forestry Research; CIMMYT, Centro Internacional de Mejoramiento de Maiz y Trigo; CIP, Centro Internacional de la Papa; ICARDA, International Center for Agricultural Research in the Dry Areas; ICRISAT, International Crops Research Institute for the Semi-Arid Tropics; IFPRI, International Food Policy Research Institute; IITA, International Institute of Tropical Agriculture; ILRI, International Livestock Research Institute; IRRI, International Rice Research Institute; IWMI, International Water Management Institute; World Agroforestry Centre (ICRAF); WorldFish Center.

similar developments in high-yielding rice varieties, was largely funded from charitable donation. Four-fifths of agricultural research was then undertaken at publicly funded research institutes.

At the time of the Green Revolution, there was no consideration of any role that intellectual property (IP) might play in agricultural innovation. It was largely the development of the new biotechnology based upon genetic engineering that precipitated IP into the agricultural and into the food security arena. These technological developments were underpinned by changes to the international IP landscape effected by the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS Agreement in Art. 27.1 extended patent protection to inventions in all fields of technology. Judicial determinations in the USA[19] and legislation in Europe[20] treated the modification of genetic material as inventions rather than discoveries, thereby creating the possibility of the patenting of genetic material and of enabling technologies. This intrusion of IP into agriculture has been paralleled by a significant diminution of the role of publicly funded research institutes in agricultural research. This is in part a function of the expense of the new biotechnology both in terms of research investment and because of the legal expense associated with the protection and enforcement of agricultural innovations. A feature of the involvement of the private sector in agricultural research has been the privatization of the fruits of its research, whereas the public agricultural research sector has tended to eschew the process of seeking IP rights (IPR) in its research. The budgets of public research institutes are not even sufficient to permit them to defend their biological assets from third-party appropriation.

A second Green Revolution to meet the modern challenge of increasing food insecurity will have to deal with the new economic reality of the dominant role of the private sector, which seeks to commercialize its agricultural innovations. Exacerbating this problem is the fact that, as food insecurity is grounded in poverty, a way has to be found to secure for poor farmers the productivity benefits of the new biotechnology, while satisfying the shareholders of the life-sciences companies that are investing in this technology.

1.4 Sustainable Agriculture

By the 1980s, it became accepted that reliance upon the chemically nurtured, high-yielding crop varieties, which had precipitated the Green Revolution, was no longer economically or environmentally acceptable.[21] Thus it was argued that to meet the food security needs of the next 30 years and to create wealth in poor communities, there was a need to increase agricultural productivity on the presently available land, while conserving the natural resource base.[22] The CGIAR called for a second Green

[19] *Diamond v Chakrabarty*, 447 U.S. 303 (1980).

[20] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions OJl L 213 , 30/07/1998 P. 0013–0021.

[21] See G. Conway and J. Pretty (1991) *Unwelcome Harvest. Agriculture and Pollution*. Earthscan, London.

[22] See G. Conway (1997) *The Doubly Green Revolution: Food for All in the Twenty-First Century*. Penguin, Harmondsworth.

Revolution, which combined traditional agronomic wisdom with modern agricultural science.[23]

The agricultural practices of traditional farming communities were used as a basis to underpin sustainable agriculture.[24] An important implication for food security is the contribution that traditional farmers and traditional communities have made in conserving and identifying useful biological material, which are embodied in biotechnological innovations. The research and breeding activities of the international agricultural research institutes associated with the CGIAR commenced with the collection of useful germplasm from many of the countries that are now considered to be food insecure. The contribution of these source countries to new proprietary varieties or to patented genetic material has not yet been recognized by the international IP regime, but as is indicated below, there is significant agitation to confer IPR upon traditional knowledge (TK) and to acknowledge the role of source countries in the patenting of biotechnological inventions. There is also agitation to graft upon IP legislation the obligation for rights holders to share benefits and technology with source countries and communities.

From the civil society perspective, the intrusion of IP into agriculture is to be deplored. As is indicated in subsequent chapters, allegations are made about 'biopiracy' and questions are raised about market concentration and the ethics of patenting 'life'. To a large extent, the current debate about protecting TK and recognizing 'farmers' rights' and the rights of source countries is a response to these civil society criticisms. Some parallels with the impact of IP upon food security can be found in the contemporary debate on the impact of IPR upon access to essential medicines.

At the end of the 1990s, there was a perception that access to the medicines needed to deal with the HIV/AIDS pandemic in developing countries was hindered by the patent provisions of the TRIPS Agreement.[25] A particular problem with the TRIPS Agreement was that the effect of Art. 31 (f) was to permit the compulsory licensing of relevant patents to produce HIV/AIDS drugs only to countries that had a domestic pharmaceutical production capacity. Following an effective non-governmental organization (NGO) campaign and as a result of pressure brought by a number of developing countries, WTO Members promulgated a Declaration on the TRIPS Agreement and Public Health at the 4th Ministerial Conference in Doha on 14 November 2001.[26] The Doha Public Health Declaration affirmed that the TRIPS Agreement does not and should not prevent measures to protect public health and that the TRIPS Agreement should be interpreted and implemented in a manner supportive of WTO Members' rights to protect public health and, in particular, to

[23] See I. Serageldin and G.J. Persley (2000) *Promethean Science. Agricultural Biotechnology, the Environment and the Poor*. Consulting Group for International Agricultural Research, Washington DC, 6.

[24] See J. Pretty (1995) *Regenerating Agriculture. Policies and Practices for Sustainability and Self-Reliance*. Earthscan, London.

[25] See e.g. Richard P. Rozek (2000) The effects of compulsory licensing on innovation and access to health care. *Journal of World Intellectual Property* 3, 889, at 896; Richard P. Rozek and Renee L. Rainey (2001) Broad-based compulsory licensing of pharmaceutical technologies: unsound public policy. *Journal of World Intellectual Property* 4, 463, at 471.

[26] *The Doha Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/W/2,14 November 2001.

promote access to medicines for all.[27] By a decision of 6 December 2005, the General Council of the WTO inserted Art.31*bis* into TRIPS, permitting the extension of compulsory licences to overseas suppliers.

Although this amendment to the TRIPS Agreement resulted only after extensive negotiations, it does illustrate the possibility of changing the primary international IP instrument in response to the same sort of international emergency that characterizes the food security crisis. Indeed, at the same time as the 4th Ministerial Conference in Doha issued the Public Health Declaration discussed above, it issued a general declaration setting out what has been described as a development agenda for the WTO. Clause 19 directed the TRIPS Council 'to examine, *inter alia*, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore'. In undertaking this work, the TRIPS Council was directed to 'be guided by the objectives and principles set out in Arts 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension'. This direction suggests a refashioning of the TRIPS Agreement to include TK as a new category of IP or to insert development perspectives in the interpretation of its provisions.

To some extent this already exists within Arts 7 and 8. Article 7 expresses as an objective of the Agreement that the protection and enforcement of IPR 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'. Arguably, the patenting of biological material of source countries, for agricultural purposes, often informed by the knowledge of traditional communities, could through the sharing of the benefits deriving from this activity become conducive to the social and economic welfare of those providers and contribute to a balancing of rights and obligations between all parties.

Article 8 of the TRIPS Agreement provides that:

> 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 role of Art. 8 is unclear, given that measures for the protection of public health and nutrition have to be consistent with the other provisions of the Agreement, but it has singled out matters germane to food security for special treatment. The TRIPS Council is currently discussing how to 'operationalize' this provision.

1.5 Human Rights Discourse

The human right to food has been identified directly and indirectly in over 100 international instruments.[28] The first of these was the Universal Declaration on the Eradication of Hunger and Malnutrition of 1974, which stated 'that every man,

[27] See e.g. E. Noehrenberg (2003) TRIPS, the Doha Declaration and Public Health. *Journal of World Intellectual Property* 6, 379, at 381.

[28] See e.g. Katarina Tomasevski (ed.) (1987) *The Right to Food through Applicable International Law*. Martinus Nijhoff Publishers, Dordrecht.

woman and child has the inalienable right to be free from hunger and malnutrition in order to develop fully and maintain their physical and mental faculties'. The right to adequate food was also reaffirmed in the Declaration on the Rights of Disabled Persons of 1975, the provisions of the Convention on the Elimination of all Forms of Discrimination against Women of 1979 and the Declaration on the Right to Development of 1986. The Declaration of the Rights of the Child of 1959 and the Convention on the Rights of the Child of 1989 recognized the right of every child to a standard of living adequate for the child's physical, mental, spiritual, moral and social development. The ILO Convention No. 169 concerning Indigenous and Tribal Peoples in Independent Countries also affirmed the right to adequate food.

The *Universal Declaration of Human Rights* 1948 (UDHR), in Art. 25, recognizes that everyone has the 'right to a standard of living adequate for the health and well-being of himself and his family, including food'. Similarly, Art. 11 of the *International Covenant on Economic, Social and Cultural Rights* 1966 (ICESCR) in Art. 11 (2) details the measures state parties to the ICESCR should take once they have recognized the 'fundamental right of everyone to be free from hunger'. State parties should 'improve methods of production, conservation and distribution of food by making full use of technical and scientific knowledge' and 'ensure an equitable distribution of world food supplies in relation to need'. The *International Covenant on Civil and Political Rights* 1966 (ICCPR) in General Comment no. 6 on Art. 6 provides that 'states parties are required to take positive steps to reduce infant mortality and to increase life expectancy, especially in adopting measures to eliminate malnutrition and epidemics'. Similarly, the *Convention on the Rights of the Child* provides that 'States parties are required to take appropriate measures to combat disease and malnutrition including through the provision of nutritious food and drinking water'.

The rights to adequate food and freedom from hunger are not only associated with the inherent dignity of humankind, but underpin the fulfilment of the other human rights enshrined in the UDHR, ICESCR and ICCPR.[29]

The right to adequate food is realized when everyone, regardless of gender or age, alone or in a community with others, has 'physical and economic accessibility at all times to adequate foods or means for its procurement'.[30] The UN Commission on Human Rights points out that adequate food does not mean merely the 'minimum package of calories, proteins and other specific nutrients' but requires food being made available in 'quantity and quality sufficient to satisfy the dietary needs of individuals, free from adverse substances, and acceptable within a given culture'.[31] The availability of food also has to be on a sustainable basis such that food security for both present and future generations is not undermined.

Civil society organizations have entered the human rights discourse by calling for food sovereignty 'that challenges the current model of agricultural trade, which they see as cultivating an export-oriented, industrial agriculture that is displacing peasant and family agriculture. Via Campesina originally developed and introduced the concept in 1996, introducing it into the discussions at a parallel meeting held by

[29] See Committee on Economic, Social and Cultural Rights, General Comment 12: The Right to Adequate Food (Article 11), UN ESCOR, 20th Sess., Agenda item 7, UN Doc. E/C.12/1999/5 (1999) at para. 4.

[30] Ibid., at para. 6.

[31] Ibid.

NGOs and civil society organizations during the 1996 World Food Summit.'[32] The term was refined during the World Food Summit in 2002, where representatives of civil society and farmer organizations defined the concept of food sovereignty to mean ' the primacy of people's and community's rights to food and food production, over trade concerns. This entails the support and promotion of local markets and producers over production for export and food imports.' It seeks to guarantee food security first, by favouring local production for local markets. The central idea is that small-scale, peasant agriculture should be protected for its role in ensuring food security, employment and environmental objectives – as long as that protection does not threaten the livelihoods of other farmers in other countries. Under the logic of food sovereignty, subsidies should never be permitted to large-scale farming or the export sector.

Food sovereignty calls for equitable access to land, seeds, water, credit and other productive resources so that people can feed themselves. It implies challenging the increasing concentration of ownership of agricultural trade, processing and marketing by transnational agribusiness corporations through, for example, improving competition law at a transnational level and through the prohibition of the appropriation of knowledge through IPR regimes.[33] Jean Ziegler, the UN Human Rights Commission's Special Rapporteur on the right to food, suggests that food sovereignty offers an alternative vision that puts food security first and treats trade as a means to an end, rather than as an end in itself.[34]

An unresolved problem, which is addressed in this book, is the collision of the right to adequate food with other international obligations, particularly those within the WTO package of agreements, such as the Agreement on Agriculture (AoA), Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) and the Agreement on TRIPS.

1.6 Food Security, Trade and the AoA

Jean Ziegler observed in his 2004 report that in the European Union, the average European dairy cow has a bigger annual income than half the world's people, and it is estimated that 70% of subsidies go to 20% of Europe's largest farms.[35] He noted that, despite preaching the benefits of free trade in agriculture, the EU, the USA, Japan and other industrialized countries still heavily protect their agriculture in order to ensure the production of basic staple foods.[36]

[32] Via Campesina, 'Priority to people's food sovereignty', 1 November 2001 www.peoplesfood sovereignty.org/statements.

[33] Commission on Human Rights, The right to food. Report submitted by the Special Rapporteur on the right to food, Jean Ziegler, in accordance with Commission on Human Rights resolution 2003/25, E/CN.4/2004/10, 9 February 2004, para. 31.

[34] Ibid., para. 32.

[35] Commission on Human Rights, The right to food. Report submitted by the Special Rapporteur on the right to food, Jean Ziegler, in accordance with Commission on Human Rights resolution 2003/25, E/CN.4/2004/10, 9 February 2004, para. 38.

[36] Ibid.

Domestic subsidies encourage overproduction, which in turn increases supplies on world markets and depresses world prices. These low prices make it harder for producers in developing countries to compete in their home markets, as well as in international markets, thus reducing incentives for production and retarding the development of the agricultural sector. Export subsidies have a similar effect in depressing world prices. Developing countries would appear to have an interest in the reduction of both domestic support and export subsidies in the developed countries.

The WTO was established as part of the trade liberalization programme which was inaugurated at the time of the promulgation of the General Agreement on Tariffs and Trade (GATT). A key factor constraining agriculture in developing countries has been the high levels of subsidies and protection provided to agriculture in the developed world.

The objective of the AoA, one of the agreements annexed as a membership obligation for the WTO, is to establish 'a fair and market-oriented agricultural trading system' through 'reductions in agricultural support and protection'. The expectation is that this would result in 'correcting and preventing restrictions and distortions in world agricultural markets'. IP considerations have had a limited role to play in the negotiations on the AoA. The main subject discussed has been the role that geographical indications for agricultural products can play in improving market access for developing countries.

The focus of the WTO AoA is not food security. Its objective is to promote free trade in agriculture through the removal of subsidies and tariffs. The most direct form of trade distortion is the escalating use of export subsidies (subsidy 'wars') to dispose of surpluses on world agricultural markets.

Food security has been identified as a 'non-trade concern' to be taken into account in the reform of agricultural trade.[37] A number of submissions have emphasized that in developing countries, where the majority of the population depends on agriculture for their livelihood, physical access to food can be ensured only through a minimum level of self-sufficiency.[38] The findings by the FAO on the interrelationship between the promotion of economic growth, reduction of poverty, the enhancement of food security and the development of agricultural capacity were cited in these submissions.[39] Thus, for example, India submitted that the particular vulnerability of agriculture in developing countries justified the extension of special provisions to the developing country members for ensuring their food and livelihood security concerns, such as exempting product-specific support given to low-income and resource-poor farmers from AMS calculations.

[37] WTO Agreement on Agriculture, Art. 20.

[38] See e.g. Submission to the Special Session of the WTO Committee on Agriculture by Barbados, Burundi, Cyprus, Czech Republic, Dominica, Estonia, the European Communities, Fiji, Iceland, Israel, Japan, Korea, Latvia, Liechtenstein, Madagascar, Malta, Mauritania, Mauritius, Mongolia, Norway, Poland, Romania, Saint Lucia, Slovak Republic, Slovenia, Switzerland, and Trinidad and Tobago. WTO doc., G/AG/NG/W/36/Rev.1; Submission by India, WTO doc., G/AG/NG/W/102, 15 January 2001; Proposal by Nigeria, WTO doc. G/AG/NG/W/130, 14 February 2001.

[39] See e.g. FAO Symposium on Agriculture, Trade and Food Security: Issues and Options in the forthcoming WTO Negotiations from the Perspective of Developing Countries, Geneva, 23–24 September 1999.

The requirement in Art. 20 of the AoA that WTO Members in their reform of the Agreement shall have regard to non-trade concerns, special and differential treatment to developing country members and the principles of equity and fairness was reformulated in the Doha Ministerial Declaration to take account of the needs and interests of the developing countries, particularly the vulnerability of the least-developed countries (LDCs) and the importance of the objective of sustainable development. In the work programme decided in March 2002, non-trade concerns, including food security, and 'special and differential treatment' were to be an integral part of the negotiations.

A particularly difficult issue in the context of food security is the impact of the AoA on food aid. The AoA makes a distinction between domestic support measures, which have at best a minimal distorting effect upon trade 'Green Box' Measures (Annex 2 of the AoA) and trade-distorting support 'Amber Box' Measures (Art. 6 AoA). Public stockpiling for food security purposes and domestic food aid for people in need is exempted as Green Box Measures, provided that the public authority buys at market prices.[40]

Article 9 provides for the general reduction of export subsidy commitments. Excluded from this reduction is food aid, although Art. 10 provides that subsidized food aid should not be used as a means of circumventing commitments to reduce and eliminate subsidized agricultural production.[41]

Given the obviously deleterious impact that the AoA restrictions upon food aid might have, a *Decision on Measures Concerning the Possible Negative Effects of the Reform Programme on Least Developed Countries and Net Food-Importing Developing Countries* was adopted as part of the Uruguay Round of the GATT. This *Decision* of the Trade Ministers agreed on a set of measures, including financial support, to ensure that adequate food imports on reasonable terms could be maintained during any structural dislocations caused by the agricultural reform process. To date, the *Decision* has not been implemented, despite the fact that food aid has dropped to very low levels. Implementation has been hampered by several factors, which include the requirement of undisputed proof of the need for assistance and the variety of instruments called under the *Decision* to respond to such needs, without precise specification of the respective responsibilities of all concerned. As the FAO explained, 'more basically, however the *Decision* addresses a transitional problem whereas the food security problem in the countries concerned is long-term and complex and encompasses broader development issues that go beyond just trade'.[42]

Article 20 of the AoA envisages that further negotiations would be undertaken to continue trade liberalization and that food security would be included in these negotiations. The Doha Ministerial Declaration in para. 13 identified special and differential treatment for developing countries as 'an integral part of all elements of the negotiations and shall be embodied in the schedules of concessions and commitments … to enable developing countries to effectively take account of their development needs, including food security and rural development'. This

[40] AoA Annex 2, paras 3 and 4.

[41] See M.G. Nesta (2001) Food security and international trade law, an appraisal of the World Trade Organization approach. *Journal of World Trade* 35, 449–468, at 451.

[42] FAO, Issues at stake relating to agricultural development, trade and food security. FAO Special Programme for Food Security website (www.fao/orgs/spfs/lifdc).

commitment was reaffirmed in para. 4 of the Ministerial Declaration issued in Hong Kong on 18 December 2005. In para. 6 of that Declaration, it was proposed that a 'safe box' for bona fide food aid would be provided 'to ensure that there is no unintended impediment to dealing with emergency situations'. It was proposed that the disciplines on food aid would be completed by 30 April 2006 'as part of the modalities, including appropriate provision in favour of least-developed and net food-importing developing countries as provided for in paragraph 4 of the Marrakesh Decision'.

1.7 The Right to Food and the SPS and the Agreement on Technical Barriers to Trade

Some of the arguments in favour of the application of recombinant DNA technology in the areas of food and agricultural production concern its capacity to increase food security through higher-yielding and disease-resistant crops.[43] Opponents of these applications point to the environmental and public health implications of this technology.[44] Overlaying and incorporating all this is enormous consumer concern about genetically modified organisms (GMOs), especially where they occur in food or are used in food production. These consumer concerns range generally across issues concerned with health, environmental protection and ethics. The WTO has responded to these concerns through the Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) and the Technical Barriers to Trade (TBT) Agreement. These Agreements define rules for setting national standards and regulations relating to sanitary and phytosanitary measures as well as technical requirements for food safety and quality so that such regulations do not unduly restrict trade.

The SPS Agreement is essentially concerned that measures for the protection of human, animal or plant life or health are 'not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members … or a disguised restriction on international trade'.[45] The SPS Agreement permits an assessment of risks, relying upon scientific principles, where they have been established or within the context of the precautionary principle, where the science is evolving. This principle, which is embodied within Art. 5.7 of the Agreement, provides that in cases where relevant scientific evidence is insufficient, 'a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members'. This principle was explored by the WTO panel and Appellate Body in the US/EU Beef Hormone dispute, which concerned an evaluation of whether an EU ban on trade in

[43] See e.g. C.L. Ives, B.M. Bedford and K. Maredia (1998) The agricultural biotechnology for sustainable productivity project: a new model in collaborative development. In: C.L. Ives and B.M. Bedford (eds) *Agricultural Biotechnology in International Development* 1, 2; Nuffield Council on Bioethics, *Genetically Modified Crops: The Ethical & Social Issues*, esp. ch. 4, http://www.nuffield.org/bioethics/publication/modifiedcrops/index.html.

[44] See e.g. K. Barrett and G. Flora (2000) *Genetic Engineering and The Precautionary Principle: Information for Extension*. Science & Environmental Health Network, Minnesota, ch. 2.

[45] SPS Agreement, Art. 2.3.

beef from any source containing artificially administered growth hormones violated the SPS Agreement.[46]

The SPS Agreement probably has an indirect relationship to the right to food. The fifth recital to the SPS Agreement recognizes 'that developing country Members may encounter special difficulties in complying with sanitary or phytosanitary measures of importing Members, and as a consequence in access to markets, and also in the formulation and application of sanitary and phytosanitary measures in their own territories'. Thus where developing countries are dependent upon overseas agricultural markets to generate revenues to underpin domestic production or for the procurement of food supplies, the rigorous application of sanitary and phytosanitary measures to exports from developing countries can undermine food security. The Beef Hormones case indicated that there had to be a rational relationship between the protective measure and the risk assessment. The EC rules were considered not sufficiently specific as they dealt with the carcinogenic effects of the hormones in question in general. 'They do not focus on and do not address the particular kind of risk here at stake – the carcinogenic or genotoxic potential of the residues of those hormones found in meat derived from the cattle to which the hormones had been administered for growth promotion purposes.'[47]

Food safety scares, such as those associated with BSE and avian flu, can generate strong political agitation for sanitary and phytosanitary measures. This was recognized in the Beef Hormones case where the Appellate Body noted that 'responsible, representative governments commonly act from perspectives of prudence and precaution where risks are irreversible, e.g. life-terminating, damage to human health are concerned'.[48]

1.8 The Right to Food and the WTO Agreement on TBT

To a considerable extent, the TBT Agreement reflects the obligations found in the SPS Agreement. Thus the general obligations under the TBT Agreement are to ensure that technical barriers (which comprised technical regulations, standards and conformity assessment procedures) are subject to national treatment and MFN obligations[49] and that they do not create 'unnecessary obstacles to international trade'.[50] There are, however, some important differences, including the scope of the Agreement and the latitude it gives for members to justify measures apparently outside the obligations contained in the Agreement.

[46] *EC – Measures Concerning Meat & Meat Products (Hormones)*, Panel Reports: Case WT/DS26/R/USA, 18 August 1997 & Case WT/DS48/R/CAN, 18 August 1997; Appellate Body Report: WT/DS26/AB/R & WT/DS48/AB/R, 16 January 1998.

[47] Ibid., para. 200.

[48] Ibid., para.124.

[49] TBT Agreement, Art. 2.1 (technical regulations); Art. 4 & Annex 3, para. D (standards); Arts 5.1.1, 7, 8 & 9 (conformity assessment procedures).

[50] Ibid., Art. 2.2 (technical regulations); Art. 4 & Annex 3, para. E (standards); Arts 5.1.2, 7, 8 & 9 (conformity assessment procedures).

The TBT Agreement applies to technical regulations, standards and conformity assessment procedures. Each of these types of measures is defined in Annex 1.[51] A 'technical regulation' is defined in paragraph 1 as a:

> Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

A 'standard' is defined in paragraph 2 as a:

> Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

Finally, a 'conformity assessment procedure' is defined in paragraph 3 as:

> Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.

The particular application of the TBT Agreement to the field of biotechnology is in relation to labelling or marking requirements. Such requirements explicitly fall within the definitions of technical regulation and standard, the main difference between the two is that the former are mandatory requirements, whereas the latter are not. Whether mandatory or recommended, the issue of labelling, especially eco-labelling, has been a hotly contested one within the WTO. Traditionally, the issue of eco-labelling, in general, has been one of the bones of contention between the developed and developing countries.[52] As with the SPS Agreement, the imposition of labelling requirements can imperil access to the agricultural market for developing countries.

1.9 The Right to Food and the Agreement on TRIPS

One of the most significant recent developments in the field of food security is the application of recombinant biotechnology to agriculture and the concomitant intrusion of IPR into agriculture. The provision of the TRIPS Agreement which is most relevant to food security is Art. 27, which defines patentable subject matter and which obliges WTO Members to provide protection for plant varieties. Article 27.1 obliges the protection of inventions in all fields of technology, which includes agriculture. This provision also requires that 'patents shall be available and patent rights enjoyable without discrimination as to … the field of technology and whether products are imported or locally produced'.

[51] Ibid., Art. 1.2.

[52] See Surya Subedi (1999) Balancing international trade with environmental protection: international legal aspects of eco-labels. *Brooklyn Journal of International Law* 25, 373.

The patenting of genetic material and the conferral of plant variety rights has enabled the propertization of both plant material and research tools. Developing countries face two sets of difficulties in this area. On the one hand, most of them, particularly the LDCs, lack the scientific capability to innovate and patent new materials and are not even in a position to fully catalogue the natural resources of bio-materials that they currently possess. They also do not have appropriate legislation in this area. On the other hand, there is a growing concentration of transnational corporations in biotech industries, notably in the seed sector. This concentration or lack of competition (reinforced by global patentability) enables these industries to exact monopoly rents from farmers worldwide. In addition, aside from the issue of costs, many countries feel it is unsafe to rely entirely on external sources for an input as important as seeds. The market dominance of these private corporations also has an important influence upon the sort of agricultural research that is undertaken. For example, the observation is made that biotechnological research will be diverted away from Southern food priorities.[53]

The mandatory obligation imposed by TRIPS for WTO members to protect plant varieties has resulted in most countries adopting laws based on the 1991 iteration of the International Convention for the Protection of New Varieties of Plants (UPOV Convention). This latest version of the Convention may be contrasted with the earlier versions because it does not guarantee the right of farmers to save, exchange and replant seed. It is suggested that these restrictions on the rights of farmers risk exacerbating the crisis of hunger and malnutrition and would be a 'violation of international norms'.[54]

The TRIPS Agreement states as a basic principle that 'Members may, in formulating or amending their national laws and regulations, adopt measures necessary to protect vital health and nutrition … provided that such measures are consistent with the provisions of this Agreement'. A matter yet to be tested is the extent to which countries can rely upon this provision to exclude from protection proprietary rights that may have a bearing on food security. For example, the exclusion from patent protection of inventions that might have a bearing on food security would conflict with the obligation in Art. 27.1 of TRIPS to provide patent protection in all fields of technology.

Because of the internal difficulties within the TRIPS Agreement to resolve the tension between IPR and the right to food, principles of human rights law have had to be applied. The UDHR does not expressly refer to IPR, but Art. 27.2 states that 'Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author'. This is complemented by the proclamation in Art. 17.1 of a general right of property. This Art. states that '[e]veryone has the right to own property' and 17.2 states that '[n]o one shall be arbitrarily deprived of his property'. The implication of Art. 17.2 is that states do have a right to regulate the property rights of individuals, but that they must do so according to the rule of law.

[53] See J.P. Alston, G. Pardey and J. Rosenboom (1998) Financing agricultural research: international investment patterns and policy perspectives. *World Development* 26, 1045.

[54] S. Edwardson (2005) Reconciling TRIPS and the right to food. In: T. Cottier, J. Pauwelyn and E.B. Bonanomi, *Human Rights and International Trade*. Oxford University Press, Oxford, 383 at 386–87.

A question raised by these provisions is whether the right of property forms part of the norms of international law. States through practices and treaties routinely recognize the property rights of their citizens as well as those of other states and their nationals. Schermers argues that most property rights cannot be included in the category of fundamental human rights as the latter are 'human rights of such importance that their international protection includes the right, perhaps even the obligation, of international enforcement'.[55] It was for this kind of reason that the European Commission of Human Rights concluded that the grant under Dutch law of a compulsory licence in a patented drug was not an interference in the patent holder's rights under Art. 1 of Protocol 1 of the European Convention of Human Rights. The 'compulsory licence was lawful and pursued a legitimate aim of encouraging technological and economic development'.[56]

The tension between IPR and human rights was first significantly debated in the lead-up to the Doha Ministerial Conference of the WTO at the end of 2001. A report of the UN Sub-Commission on Human Rights noted that:

> [A]ctual or potential conflicts exist between the implementation of the TRIPS Agreement and the realisation of economic, social and cultural rights in relation to … impediments to the transfer of technology to developing countries, the consequences for the enjoyment of the right to food of plant variety rights and the patenting of genetically modified organisms, 'bio-piracy' and the reduction of communities' (especially indigenous communities') control over their own genetic and natural resources and cultural values …[57]

The UN Sub-Commission declared that 'the implementation of the TRIPS Agreement does not adequately reflect the fundamental nature and indivisibility of all human rights'.[58] To this end, the Sub-Commission requested 'all Governments and national, regional and international economic policy forums to take international human rights obligations and principles fully into account in international economic policy formulation'.[59]

1.10 Political Initiatives, e.g. World Food Summit

The First World Food Conference held in Rome in 1974 promulgated the *Universal Declaration on the Eradication of Hunger and Malnutrition*, which stated that 'it is a fundamental responsibility of governments to work together for higher food production and more equitable and efficient distribution of food between countries and within

[55] H.G. Schermers (1988) The international protection of the right of property. In: F. Matscher and H. Petzold (eds) *Protecting Human Rights: The European Dimension*. Carl Heymanns Verlag KG, Köln, 565, at 579.

[56] Application 12633/87 *Smith Kline and French Laboratories Ltd v The Netherlands*, (1990) 66 European Commission of Human Rights, *Decisions and Reports*, 70, 80.

[57] Intellectual property rights and human rights, Sub-Commission on Human Rights Res. 2000/7, UN ESCOR, Commission on Human Rights, Sub-Commission on the Promotion and Protection of Human Rights, 52nd Sess., 25th mtg., UN Doc. E/CN.4/Sub.2/Res/2000/7 (2000).

[58] Sub-Commission on Human Rights, Intellectual property rights and human rights Sub-Commission on the Promotion and Protection of Human Rights, 52nd Sess., 25th mtg., UN Doc. E/CN.4/Sub.2/Res/2000/7 (2000), para. 2.

[59] Ibid., para. 4.

countries'. Subsequent world food conferences reaffirmed states' commitments to eliminate hunger and malnutrition. The most significant of these meetings was the 1996 World Food Summit, which promulgated a *Plan of Action* that contained seven commitments related to food security.[60] A key commitment was the fourth which identified the commitment of governments to ensure that 'trade policies are conducive to food security'. Within this commitment the first objective of signatory governments is to provide financial and technical assistance and to encourage the transfer of technology to developing countries so that they are in a position to take advantage of new market opportunities. A second objective within this commitment is 'to meet essential food import needs in all countries, considering world price and supply fluctuations and taking especially into account food consumption levels of vulnerable groups in developing countries', which obliges exporting countries to reduce food subsidies and to avoid market disruptions.

The third objective committed signatories to support the reform process under the Uruguay Round, particularly in relation to Art. 20 of the AoA under which WTO Members committed themselves to supporting the reform process agreed in the Uruguay Round and to promoting the food security of developing countries by facilitating their access to markets.

As part of the *Plan of Action*, a process was initiated to define the content of the right to food and the relevant state obligations. The FAO and the UN High Commissioner for Human Rights have undertaken three expert consultations to clarify the content of the right to food. The first two of these in 1997 and 1998 formulated General Comment no. 12, which was adopted by the Committee on Economic, Social and Cultural Rights (CESCR). This General Comment provides an interpretation of the right to food which is utilized by the CESCR in its implementation of the ICESCR. A code of conduct is being formulated to provide a precise definition of states' obligations in relation to the guarantee of the right to food under the ICESCR.

The third consultation in 2001 addressed the connection between hunger and poverty, and recommended that States review existing impediments to full implementation of the right to adequate food, develop a legislative agenda to strengthen implementation and repeal incompatible laws.

A key development was the Doha Ministerial Conference of the WTO in November 2001, which prioritized a development agenda for the organization. The

[60] 1. We will ensure an enabling political, social and economic environment designed to create the best conditions for the eradication of poverty and for durable peace.
2. We will implement policies aimed at eradicating poverty and improving economic access by all to sufficient, nutritionally adequate and safe food.
3. We will pursue participatory and sustainable food, agriculture, fisheries, forestry and rural development policies and practices, which are essential to adequate food supplies at the household, national, regional and global levels.
4. We will strive to ensure that food, agricultural trade and overall trade policies are conducive to fostering food security for all through a fair market-orientated world trade system.
5. We will endeavour to prevent natural disasters and man-made emergencies and to meet transitory and emergency food requirements in ways that encourage development and a capacity to satisfy future needs.
6. We will promote use of public and private investments to foster human resources, sustainable food and rural development.
7. We will implement, monitor and follow-up this plan of action at all levels in cooperation with the international community.

Declaration issued by the Trade Ministers acknowledged the need for a differential treatment for developing countries to meet their needs in food security and rural development.

In June 2002, the World Food Summit: Five Years Later was held to review the progress which had been made since 1996. The participating states renewed their commitment to halve the number of hungry in the world no later than 2015 and called on all parties (governments, international organizations, civil society organizations and the private sector) to reinforce their efforts so as to act as an international alliance against hunger to achieve the World Food Summit targets no later than 2015. The commitment to halve the number of hungry people by 2015 was endorsed also by the Millennium Summit on Poverty.

An International Code of Conduct on the Human Right to Adequate Food was drafted in 1997 by the NGO community as a follow-up to the World Food Summit. It was intended to 'provide a guide for the conduct of the international community, states and all relevant actors in civil society to better focus their policies and action on those persons and groups vulnerable to hunger' and 'to provide guidance for legislation at both national and international levels'.[61] Article 4 of the Code defined the right to adequate food as meaning that 'every man, woman and child alone and in community with others must have physical and economic access at all times to adequate food or by using a resource base appropriate for its procurement in ways consistent with human dignity'. The realization of this right requires: 'a) the availability of food, free from adverse substances and culturally acceptable, in a quantity and quality which will satisfy the nutritional and dietary needs of individuals; and b) the accessibility of such food in ways that do not interfere with the enjoyment of other human rights and that is sustainable'.

Article 5 called upon States 'to take joint and separate action to advance the respect and observance of human rights including the right to adequate food'. The obligations of States at the national level were defined in Art. 6 to 'protect everyone under their jurisdiction from having their access to food being undermined by a third party'. This obligation was defined to include 'the State's responsibility to ensure that private entities or individuals, including transnational corporations over which they exercise jurisdiction, do not deprive individuals of their access to adequate food'. This obligation could be considered to be in tension with the right of individuals to exercise their IPR.

The Committee on World Food Security of the FAO, noting the broad subscription to the Draft Code within the NGO, addressed the question of the way in which the Code could best be pursued.[62] At the World Food Summit: Five Years Later, the decision was taken to establish within FAO an Intergovernmental Working Group (IGWG) to elaborate a set of voluntary guidelines to support the progressive realization of the right to adequate food.[63]

[61] International Code of Conduct on the Human Right to Adequate Food, Preamble.

[62] FAO (2002) Committee on World Food Security, 'Progress in the Implementation of the Right to Food', FAO Doc., CFS: 2002/ Inf.7, 6–8 June.

[63] FAO (2002) *Declaration of the World Food Summit: Five Years Later, International alliance against hunger*, Operative paragraph 10, Report of the World Food Summit: Five Years Later, part one, Appendix.

In response to the serious challenges to world food security caused by the dramatic escalation of food prices, at the beginning of 2008 the UN system developed a Comprehensive Framework for Action (CFA). At a meeting in Berne on 28 and 29 April 2008, the Secretary General of the UN established a High Level Task Force (HLTF) on the Global Food Security Crisis under his chairmanship, with FAO Director General as Vice Chairman, and bringing together the Heads of the UN specialized agencies, Funds and Programmes, Bretton Woods institutions and relevant parts of the UN Secretariat, in order to create a prioritized plan of action and coordinate its implementation. The CFA identified both immediate and longer term actions to address the food crisis. The longer term actions addressed underlying, structural issues to help build resilience and contribute to sustainable improvements in global food security and poverty reduction within the context of the Millennium Development Goals.

On 3–5 June 2008, the FAO convened a High-Level Conference on World Food Security to address the challenges of climate change and bioenergy. The Conference concluded with the adoption of a declaration calling on the international community to increase assistance for developing countries, in particular the least developed countries and those that are most negatively affected by high food prices.[64] Article 3 of the Declaration identified 'an urgent need to help developing countries and countries in transition expand agriculture and food production, and to increase investment in agriculture, agribusiness and rural development, from both public and private sources'. It urged the international community, including the private sector, to increase investment in science and technology for food and agriculture.

The 2008 G8 Hokkaido Toyako Summit, held in the month following the FAO High Level Conference, issued a *G8 Leaders Statement on Food Security*,[65] which expressed their concern that the steep rise in global food prices coupled with availability problems was threatening global food security and that this 'trend could push millions more back into poverty, rolling back progress made towards achieving the Millennium Development Goals'.[66] In addition to pledging US$10 billion for short-term food aid and other measures to increase agricultural output, the G8 Statement expressed strong support for FAO leadership of a coordinated programme to boost food security. The leaders undertook to 'work toward the urgent and successful conclusion of an ambitious, comprehensive and balanced Doha Round' and expressed their support for the removal of export restrictions and for the expedition of the WTO negotiations on this subject.

In analysing the policy options for dealing with food insecurity and the application of IP in pursuing these options, it is useful to list the long-term initiatives which were enumerated in the G8 Leaders Statement. They undertook to:

> (a) reverse the overall decline of aid and investment in the agricultural sector, and to achieve significant increases in support of developing country initiatives, including – in Africa – through full and effective implementation of the Comprehensive Africa Agricultural Development Programme (CAADP);

[64] http://www.fao.org/fileadmin/user_upload/foodclimate/HLCdocs/declaration-E.pdf.
[65] http://www.g8summit.go.jp/eng/doc/doc080709_04_en.html.
[66] Ibid., para.1.

(b) support CAADP's goal of 6.2% annual growth in agricultural productivity, and work toward the goal of doubling production of key food staples in African countries meeting CAADP criteria in 5–10 years in a sustainable manner, with particular emphases on fostering smallholder agriculture and inclusive rural growth;

(c) promote agricultural research and development, and the training of a new generation of developing country scientists and experts focusing on the dissemination of improved, locally adapted and sustainable farming technologies, in particular via the Consultative Group on International Agricultural Research (CGIAR), and through partnerships such as the Alliance for a Green Revolution in Africa (AGRA);

(d) support improvement of infrastructure, including irrigation, transportation, supply chain, storage and distribution systems and quality control;

(e) assist in the development of food security early warning systems;

(f) encourage the efforts of international financial institutions … to address the needs of food-importing countries facing balance of payments difficulties, including through the Poverty Reduction and Growth Facility and the review of the Exogenous Shocks Facility;

(g) accelerate research and development and increase access to new agricultural technologies to boost agricultural production; we will promote science-based risk analysis including on the contribution of seed varieties developed through biotechnology;

(h) support country-led development strategies in adapting to the impact of climate change, combating desertification, and promoting conservation and sustainable use of biological diversity, while intensifying our efforts to address climate change;

(i) ensure the compatibility of policies for the sustainable production and use of biofuels with food security and accelerate development and commercialization of sustainable second-generation biofuels from non-food plant materials and inedible biomass; in this regard, we will work together with other relevant stakeholders to develop science-based benchmarks and indicators for biofuel production and use;

(j) promote good governance in developing countries with particular emphasis on their food security and market policies; and

(k) mainstream food security objectives into the development policies of donors and recipient countries, reaffirming our common commitment to the principles of the Paris Declaration on Aid Effectiveness.

Of these objectives, (a), (b), (f) and (k) are concerned with funding initiatives. All of the other objectives have a potential IP implication, because they involve various forms of technological innovation.

1.11 A Legally Enforceable Right to Food?

As with all categories of rights, a critical question is the extent to which the right to food imposes legally enforceable obligations. Gonzalez-Pelaez[67] applies the analytical

[67] A. Gonzalez-Pelaez (2005) *Human Rights and World Trade. Hunger in International Society*. Routledge, London and New York, 69–77.

model developed by Kenneth Abbott *et al.*[68] that legislation can be classified along the dimensions of obligation, precision and delegation to the various international legal instruments that could underpin a right to food. According to this scheme, the Doha Declaration takes on the character of soft law in that it sets out the terms for negotiation, but does not require that these terms are met. Gonzalez-Pelaez discerns a stronger obligation embodied in the Declaration of the World Food Summit. This she sees in the large number of states (186) that participated in the Summit, the World Food Summit Plan of Action, supported by a number of governments in Latin America and Europe, and in General Comment no. 12 of the UN Committee on Economic, Social and Cultural Rights, which 'gave a specific legal framework to the right to food'. Set in the balance against this was the post-summit statement of the USA that 'the fundamental right to be freed from hunger is a goal or aspiration to be realized progressively that does not give rise to any international obligations … the United States does not recognize any change in the current state of conventional or customary law regarding rights related to food, even if it accepts the right of everyone to have access to safe and nutritious food'.[69]

A report by Mary Robinson, UN High Commissioner for Human Rights, which was presented to the World Food Summit: Five Years Later,[70] identified some 20 countries that had 'adopted constitutions that more or less explicitly refer to the right to food or a related norm'. For example, the South African Constitution provides in section 27 that 'Everyone has the right to have access to (…) sufficient food and water'. Norway was identified as leading the field in comprehensive action. Its Ministry of Agriculture presented to Parliament *White Paper No. 19 on Agricultural Food Production*, which adopted a rights-based approach to agricultural policy expressly referring to the right to food and to General Comment No. 12.

An example provided by the High Commissioner for Human Rights of the justiciability of the right to food was a decision of the Indian Supreme Court, which affirmed that where people are unable to feed themselves adequately, governments have an obligation to provide for them, ensuring, at the very least, that they are not exposed to malnourishment, starvation and other related problems.[71]

[68] K. Abbott, R. Keohane, A. Moravesik, A.-M. Slaughter and D. Snidal (2000) The concept of legalisation. *International Organization* 54, 420–456.

[69] World Food Summit: Interpretative Statements by the Government of the United States of America. www.fas.usda.gov./icd/summit/interpre.html.

[70] M. Robinson (2002) *The Right to Food: Achievements and Challenges*. Report presented to the World Food Summit, Five Years After, Rome, 8–10 June.

[71] People's Union for Civil Liberties v Union of India and Others, Writ Petition [Civil] No. 196 of 2001. Also cited in Commission on Human Rights, Background paper prepared by the Secretariat, *Selection of case law on economic, social and cultural rights* E/CN.4/2005/WG.23/CRP.1 15 November 2004.

2 Intellectual Property and Agriculture

In an examination of the impact of IP upon food security an immediate question is: how has IPR come to insinuate itself into agriculture? The early history of patenting was a history of the development of the mechanical arts. IP protection was thought to be appropriate for the stimulation of technology transfer and industrialization. However, from a philosophical perspective, the function of IPR in capturing and commodifying first mechanical and then chemical invention is equally relevant to agricultural innovation. IP law is merely a legal device that captures value and permits the encouragement of innovation. As John Locke observed in 1690:

> Though all the fruits [the earth] naturally produces, and beasts it feeds, belong to mankind in common, as they are produced by the spontaneous hand of Nature, and nobody has originally a private dominion exclusive of the rest of mankind in any of them … yet being given for the use of men, there must of necessity be a means to appropriate them someway or other before they can be of any use, or at all beneficial, to any particular men.[1]

This book considers the ways in which IPR may be deployed to alleviate food insecurity.

2.1 Definition and Sources of IP Law

IP may be defined as those creations of the mind in relation to which the state confers a statutory monopoly for a prescribed term to prevent their unauthorized exploitation. The reasons why a state might confer such monopolies are to encourage invention and innovation, and to encourage technology transfer and investment. As was noted in the preceding chapter, each of these reasons is of course relevant to proposed solutions for food insecurity. 'Intellectual property' is usually divided into

[1] J. Locke (1690) *Concerning the True, Original, Extent, and End of Civil Government*, ch.5, sec. 26.

two branches, namely 'industrial property' and 'copyright and the rights which neighbour upon copyright'.

The principal categories of industrial property are patents, trademarks, geographical indications (GIs), industrial designs and trade secrets. Patents are granted in relation to commercially applicable inventions. Trademarks, service marks and GIs consist of signs that are distinctive of enterprises in the eyes of potential consumers. Industrial designs are typically ornamentation and aesthetic features of goods that are produced in industrial quantities. Trade secrets are confidential matters, which usually concern the know-how involved in commercializing inventions. 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'. Consequently the relevance of industrial property to food security is self-evident.

Copyright law is concerned with the protection and exploitation of the expression of ideas in a tangible form. The central right that the law confers is to prevent unauthorized persons from copying a work. To be protected as copyright, ideas have to be expressed in an original way, i.e. 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 and paintings, 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 programs, Internet sites and to databases.

2.2 IP and Agriculture

A threshold consideration in the food security debate is whether agriculture is a proper subject for IP protection. This issue was usefully considered by the High Court of Australia in *The Grain Pool of WA v The Commonwealth*,[2] in which the plaintiff challenged the constitutional validity of the Plant Variety Rights Act 1987 (Cth) and its successor, the Plant Breeders' Rights Act 1994 (Cth). The Grain Pool had received a protected variety of barley, Franklin, for the limited purpose of growing trials and malting evaluation. Commercial negotiations with the representative of the Tasmanian proprietor of the variety had broken down, and it was alleged that the Grain Pool without permission had grown the barley in Western Australia. The Grain Pool's response questioned whether the plant variety rights (PVR) legislation fell within the definition of IP envisaged by the Australian Constitution.

The Australian Constitution of 1900 empowered Parliament to legislate on the subjects of 'Copyrights, patents of inventions and designs, and trademarks',[3] but under Australian constitutional theory these terms are treated as general categories of

[2] [2000] HCA 14.
[3] Section 51(xviii).

legislative subject. Thus in the High Court's decision in *Nintendo Co Ltd v Centronics Systems Pty Ltd*[4] upholding the validity of the Circuit Layouts Act 1989, the Court observed that '… it is of the essence of that grant of legislative power that it authorizes the making of laws which create, confer, and provide for the enforcement of, IPR in original compositions, inventions, designs, trademarks and other products of intellectual effort'.

Applying this reasoning, the High Court in the *Grain Pool* case said that 'it would be wrong to regard the legislative grant of monopoly rights in new plant varieties as being, in 1900, outside the "central type" of the subject of patents of inventions'.[5] The High Court noted the comments of Rich J. in the US Court of Appeals decision *Imazio Nursery, Inc v Dania Greenhouses*[6] who explained that:

> At least as early as 1892, legislation was proposed to grant patent rights for plant-related inventions. Plant patent legislation was supported by such prominent individuals as Thomas Edison who stated that '[n]othing that Congress could do to help farming would be of greater value and permanence than to give to the plant breeder the same status as the mechanical and chemical inventors now have through the law.' It was also supported by Luther Burbank, a leading plant breeder of the day … whose widow stated that her late husband 'said repeatedly that until Government made some such provision [for plant patent protection] the incentive to create work with plants was slight and independent research and breeding would be discouraged to the great detriment of horticulture.'[7]

In a separate concurring judgement Kirby J. observed that given the objects of the constitutional head of power included the facilitation and protection of intellectual inventiveness within Australia, it would be destructive of the achievement of those objects if the grant of power were to be attached to the particular subjects notions, which, up to 1900, had been protected by the law. He referred, without deciding the question, to the possibility that copyright law could extend to GMOs.[8]

Relevant to the question of food security policy is the fact that legislatures and courts have tended to respond positively to the creation of new categories of IPR to protection for the products of intellectual effort. For example, in the USA, the development of genetically engineered organisms[9] and inventions in the field of information technology[10] have been approved by the Supreme Court as ways in which IP law can sometimes encourage technological innovation to the economic and social benefit of the USA and beyond.

In the context of food security, it is worth bearing in mind the US Supreme Court's qualification in *Graham v John Deere Co*[11] that Congress may not 'enlarge the

4 (1994) 181 CLR 134 at 160.
5 [2000] HCA 14 at para.26.
6 69 F 3d 1560 (1995).
7 69 F 3d 1560 at 1562-1563 (1995).
8 Referring to J. Stanley and D.C. Ince (1997) Copyright law in biotechnology: a view from the formalist camp. *European Intellectual Property Review* 3, 142; R.S. Eisenberg (1996) Intellectual property issues in genomics. *Trends in Biotechnology* 14, 302; G. Karnell (1995) Protection of results of genetic research by copyright or design rights? *European Intellectual Property Review* 8, 355; A. Speck (1995) Genetic copyright. *European Intellectual Property Review* 4, 171; I. Kayton (1982) Copyright in living genetically engineered works. *George Washington Law Review* 50, 191.
9 *Diamond v Chakrabarty* 447 US 303 (1980).
10 *Diamond v Diehr* 450 US 175 (1981).
11 383 US 1 at 5–6 (1966).

patent monopoly without regard to the innovation, advancement or social benefit gained thereby'.

2.3 Categories of IP

Although this chapter commences with a definition of IP, the principal international IP agreements generally avoid a definition of 'intellectual property', rather they provide a catalogue of subjects considered to be embraced by the term. Thus the Convention Establishing the World Intellectual Property Organization (WIPO) concluded at Stockholm on 14 July 1967, in Art. 2(viii), defines IP as rights relating to:

[1] literary, artistic and scientific works;

[2] performances of performing artists, phonograms and broadcasts;

[3] inventions in all fields of human endeavour;

[4] scientific discoveries;

[5] industrial designs;

[6] trademarks, service marks and commercial names and designations;

[7] protection against unfair competition.

This catalogue of rights has become somewhat dated. Since the date of that Convention, IPR have been considered to attach to plant varieties, integrated circuits, trade secrets and confidential information, and expressions of folklore. A fuller catalogue of IPR is listed in Part II of the TRIPS Agreement as the subject matter of that agreement, namely copyright and related rights, trademarks, GIs, industrial designs, patents, layout designs (topographies) of integrated circuits and confidential information.

The principal categories of IP that are relevant to food security are: PVRs, patents, industrial designs, trademarks, GIs, confidential information, copyright and database rights.

PVRs

Scheme of protection

Plant varieties are protected in most countries by specialist (*sui generis*) legislation modelled on the UPOV. The protection under this legislation is afforded to a 'breeder' or persons claiming through the breeder who is defined in Art. 1 (iv) of the UPOV Convention 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 UPOV Convention defines 'plant variety' in terms of a plant grouping within a single biological taxon of the lowest known rank, the grouping of which can be:

- defined by the expression of characteristics (such as shape, height, colour and habit) resulting from a given genotype or combination of genotypes;
- distinguished from any other plant grouping by the expression of at least one of the said characteristics; and
- considered a unit with regard to its suitability from being propagated unchanged.

An important distinction exists between a 'plant', which for reasons of public policy cannot be the subject of a private proprietary right, such as under PVR law or the law of patents, and a plant variety. This distinction was considered in 1984 in the *Ciba/Geigy* determination by the Technical Board of Appeal of the European Patent Office (EPO).[12] This determination concerned a plant that had been treated with a chemical compound to confer on the plant a degree of protection from the toxic side-effects of certain herbicides. It stated that 'plant varieties … are all cultivated varieties, clones, lines, strains and hybrids'.[13] This approach was applied by the Technical Board of Appeal in the *Lubrizol (Hybrid Plants)* case[14] where the Board held that 'the term "plant varieties" means a multiplicity of plants, which are largely the same in their characteristics (i.e. homogeneity) and remain the same within specific tolerances after every propagation or every propagation cycle (i.e. "stability")'.[15] The European Biotechnology Directive permits the patentability of inventions concerning plants, where 'the technical feasibility is not confined to a particular plant … variety'.[16] Patent claims can therefore be made in respect of plant groupings, or as stated in Recital 31 to the Directive:

> whereas a plant grouping which is characterized by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is not excluded from patentability even if it comprises new varieties of plants.

Generally, under PVR legislation the plant breeder is conferred an exclusive right to do or to license 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 general duration of plant breeders' rights (PBR) under legislation based on the UPOV Convention is 25 years in the case of trees and vines and 20 years for any other variety.

Plant variety protection (PVP) is established after a registration process. A plant variety is considered able to be registered if it has a breeder, and if it is distinct,

[12] Case T 49/83 [1984] O.J. EPO 112.
[13] Ibid., at 114–115.
[14] Case T320/87 [1990] O.J EPO 71.
[15] Ibid. at 79.
[16] *Directive on the Legal Protection of Biotechnological Inventions*, Article 4(1) para.2, 98/44/EC [1998] O.J. L213/130.

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. It is uniform if, subject to the variation that 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. The test of no commercial exploitation is easier to satisfy than the test for novelty under patent law and the choice between the two forms of IPR is a matter to be considered by the agricultural research institute.

PVP following from the 1991 version of UPOV, discussed below, also extends to varieties that are 'essentially derived' from protected varieties, although in practice there is a fair degree of confusion as to the criteria to be applied in ascertaining whether a variety is essentially derived.

Legislation based on the UPOV Convention generally provides for the grantee of PVRs to take all reasonable steps to ensure reasonable public access to the plant variety. This requirement is taken to be satisfied if propagating material of reasonable quality is available to the public at reasonable prices, or as gifts to the public, in sufficient quantities to meet demand. An appropriate person may be licensed to sell or produce propagating material of plants of that variety on reasonable terms and conditions. Generally an exception to the grant of a compulsory licence applies in the case of a plant variety that has no direct use as a consumer product.

Farmer's privilege (agricultural exception)

Usually excepted from PVRs is seed saved by a farmer from harvested material and treated for the purpose of sowing a crop on that farmer's own land. For example, Art. 14 of the European Community Plant Variety Rights Regulation sets out the terms for the so-called agricultural exemption (farmer's privilege). This exemption gives farmers the right to use farm-saved seed without the consent of the owner (right holder) of the variety in question. However, the farmer, with the exception of small farmers, must pay the holder an equitable remuneration, which shall be sensibly lower than the amount charged for the licensed product.[17] If the parties cannot agree upon the level of the remuneration, such remuneration should be 50% of the amounts charged for the licensed production of propagating material.[18]

Article 14(2) of the European Regulation limits the agricultural exemption only to the agricultural plant species listed there. Those species are divided into four categories, namely fodder plants, cereals, potatoes, and oil and fibre plants. To assist the policing of this provision Art. 14(3) of the Regulation imposes on farmers an obligation to provide certain information such as: (i) the name of the farmer, the place of his domicile and the address of his holding; (ii) the fact whether the farmer has made use of the product of the harvest belonging to one or more varieties of the

[17] Council Regulation (EC) No 2100/94 on Community plant variety rights, OJ No L 173/14, 25.7.95 CPVR, Article 14(3).

[18] Council Regulation (EC) No 1768/95 of 24 July 1995 implementing rules on the agricultural exemption provided for in Article 14(3) of CPVR.

holder for planting in the field or fields of his holding; (iii) the amount of the product of the harvest belonging to the variety or varieties concerned, which has been used by the farmer in accordance with Art. 14(1). The information to be provided must refer to the current marketing year, and to one or more of the three preceding marketing years for which the farmer had not previously provided relevant information on request made by the holder in accordance with this provision. This obligation to provide information was explored by the European Court of Justice (ECJ) in *Schulin (Agriculture)*.[19]

Treuhandverwaltungsgesellschaft mbH (STV) was a German seed company engaged by a number of breeders and holders of PVP rights to enforce, in its own name, the rights to remuneration *inter alia*, which they derive from the cultivation of protected plant varieties. STV asked Mr Schulin to inform it whether and, if appropriate, to what extent he, as a farmer, had sowed a total of 525 plant varieties, of which 180 were varieties protected by Regulation No 2100/94, in the 1997/98 cropping season. STV argued that it could demand that information from Mr Schulin without being required specifically to establish that he had grown a particular variety. Mr Schulin objected to this open-ended inquiry and the ECJ was asked to rule on the nature of the obligation to provide the requested information. The Court held that only farmers who had purchased protected varieties could be subject to the obligation to provide information and that STV should be in a position to know the name and address of those farmers who had bought propagating material of a protected plant variety. Thus there was no obligation for a farmer to provide information where there was no indication that the farmer had used or would use, for propagating purposes in the field, on his own holding, the product of the harvest obtained by planting, on his own holding, propagating material of a protected variety.

Patents

Introduction

PVP laws were developed in response to industry calls for *sui generis* protection for agricultural and horticultural innovation. The inclusion of a seed-saving exception for farmers was a public policy safeguard, which was an early reflection of food security concerns. This safeguard does not exist in patent statutes and this absence was an inducement for seed companies to shift their attention to the patent system as a means of protecting their innovations. This attention shift coincided with the development of modern biotechnologies.

Patent protection was not originally considered to be a particularly effective system for the protection of plant varieties. Prior to the development of modern biotechnology, the breeding of a new variety could not be said to involve an inventive step and such innovations as were made, could be considered to be obvious rather than inventive. However, with the extension of patent protection to recombinant methods for producing transgenic plants and the resulting products, patents have begun to assume an increasing significance in PVP. The broader ambit of patent

[19] [2005] 1 CMLR 17, [2003] EUECJ C-305/00.

rights is a particular advantage of this form of IP protection, covering, as it does, plants, seeds and enabling technologies. PVRs are highly specific to the variety and their scope is limited by reference to the physical (propagating) material itself, combined with the description of the variety given in the documentary grant of the rights.

The modern biotechnological revolution has enabled the engineering of desirable genetic traits from useful local species. Genetic engineering has permitted the expeditious introduction of a wide range of desirable traits into plants. These include:

- pest control traits such as insect, virus and nematode resistance as well as herbicide tolerance; post-harvest traits such as delayed ripening of spoilage-prone fruits;
- agronomic traits such as nitrogen fixation and utilization, restricted branching, environmental stress tolerance;
- male and/or seed sterility for hybrid systems; and
- output traits such as plant colour and vitamin enrichment.

The production of transgenic plants has become possible through the development of a number of enabling and transformation technologies. These technologies, together with the introduction of beneficial plant traits, have become the subject of IP protection, as a consequence of the favourable decisions of courts in the USA and Europe.

A patent is a statutory privilege granted by a government 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. Patent rights are conferred by statute as a matter of right to the person who is entitled to apply for it and who fulfils the prescribed registration requirements. The protection secured by the registration of a patent is usually limited in time. For example, under the UK Patents Act 1977, s.25, the term of protection is 20 years. In some countries there may be opportunities for extensions of protection for particular categories of invention, such as for pharmaceutical processes. At the end of the period of protection, the patented invention is said to be within the public domain, i.e. available for anyone to exploit.

An invention is usually defined as an idea that permits the solution of a specific problem in a field of technology. The applicant for the protection of an invention is usually the inventor or his successor in title. For an invention to be protected by a patent under most systems of laws it must: (i) be new; (ii) involve an inventive step; (iii) be industrially applicable; and (iv) not be a category of excluded invention.

Invention

The decision by a state to confer a statutory monopoly upon inventions has had a turbulent history. In England, from the 14th century, protection had been extended by the English monarchs to foreign craftsmen to encourage the inflow of technological skills; however, by the reigns of Elizabeth I and James I, the sale of patent monopolies had become a valuable source of royal revenue, occasioning strong protests in

Parliament.[20] This culminated in 1624 with the passage through parliament of the Statute of Monopolies, which provides the basis for the modern patent laws of England. Section 6 of the statute excluded patents from the general prohibition of monopoly provided the patent was granted for a maximum term of 14 years, provided it was for the: 'sole working or making of any manner of new manufactures within the realm'. In this way, it was hoped to exclude from protection those matters that made no practical contribution to the common weal.

Most patent systems draw a distinction between an invention and a discovery. A discovery, which is taken to be the unearthing of causes, properties or phenomena already existing in nature, is not patentable. A patentable invention is the application of that knowledge to a practical end. Whitford J. said in *Genentech*:[21]

> It is trite law that you cannot patent a discovery, but if on the basis of that discovery you can tell people how it can be usefully employed, then a patentable invention may result. This in my view would be the case, even though once you have made the discovery, the way in which it can be usefully employed is obvious enough.

The distinction between inventions and discoveries was explored by the Australian High Court in *National Research Development Corporation v Commissioner of Patents* (the *NRDC* case).[22] This case concerned a patent that was sought in relation to a chemical method of killing weeds growing in fodder crops, leaving the useful plants unharmed. The court considered the process to be patentable because it proposed 'taking advantage of a hitherto unknown or unsuspected property of the material' to produce a useful result. In that case, the chemicals involved in the weed-killing process were not new compounds, rather the inventiveness lay in their combination for a new purpose.

From the perspective of food security, it would have been thought that the distinction between invention and discovery would have preserved in the public domain both traditional agricultural knowledge and the properties of plants and animals existing in nature. However, the distinction between invention and discovery has become rather blurred in its application as there are numerous examples of the patentability of discoveries existing in nature, where they are combined with technical applications. As IP laws take their existence from legislation and judicial determinations, it is possible for legislation and case determinations to decree that something considered a discovery is deemed to be an invention. For example, the European Parliament in its Biotechnology Directive provides 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 US Supreme Court took a similar position in *Diamond v Chakrabarty*[23] in ruling that a bacterium genetically engineered to degrade crude oil was an invention. Interestingly, this approach ties in with what John Locke had suggested almost 300 years earlier, when he wrote that 'whatsoever then he removes out of the state that nature hath

[20] See E.R. Foster (196) The procedure of the House of Commons against Patents and Monopolies, 1621–1624. In: W.A. Aiken and B.D. Henning, *Conflict in Stuart England: Essays in Honour of Wallace Notestein*. London, 59–85.

[21] [1987] RPC 553, 566.

[22] (1959) *Commonwealth Law Reports* 102, 252.

[23] 447 US 303 (1980).

provided, and left it in, he hath mixed his labour with, and joined to it something that is his own, and thereby makes it his property'.[24]

The courts have ruled that where genetic material had no previously recognized existence, and can be adequately identified without reference to the process by which it is obtained, then it may be patentable per se. In *Genentech Inc's Patent*,[25] the English Court of Appeal held that the discovery of the amino acid sequence for the substance tPA when incorporated into a process for the commercial manufacture of tPA using conventional techniques led to a valid claim. Likewise, in its decision in the *Howard Florey Institute of Experimental Physiology*,[26] the EPO's Opposition Division ruled that because the protein human H2-relaxin had no previously recognized existence, its chemical characterization and that of the DNA encoding it, together with the fact that the proprietor had found a use for the protein, meant that both the protein and the DNA were patentable.

Of course, it is equally open to a court or a legislature to rule or provide that genetic material is not patentable, even in its isolated or purified form, because it is a mere discovery. A number of developing countries exclude the patentability of genetic materials (Mexico), or of materials existing in nature (Argentina, Brazil and the Andean Group Decision 486).

Novelty

The novelty requirement means that before an invention can be patented, it should not have been anticipated by prior art. The registration process should include a search of the scientific literature, including other patent documents, to see whether the technology has been previously disclosed. Disclosure may also have occurred through scholarly publication, through a public address or lecture, being placed on the Internet or through use of a product or process embodying the invention. Given that the right to patent an invention can be lost through disclosure, the cataloguing and publication of traditional agricultural knowledge may place it in the public domain, but at the same time prevents the communities that might have developed that knowledge from patenting it. However, from a food security perspective, having that knowledge in the public domain makes it available for the public good.

Inventive step

The law requires that before an invention can be patented, it must make an inventive step, i.e. significantly advance the state of the art. In *Graham v John Deere Co*,[27] the US Supreme Court was concerned with the alleged infringement of a patent for a device designed to absorb shock from plough shanks in rocky soil to prevent damage to the plough. This involved a combination of old mechanical elements. The Court declined to uphold the validity of the patent since the differences between the invention and the pertinent prior art would have been obvious to a person reasonably

[24] Locke, n. 1 supra at sec. 27.
[25] [1989] RPC 147.
[26] [1995] 6 OJEPO 388 (V 08/94).
[27] 383 US 1 at 5–6 (1966).

skilled in that art. The Supreme Court usefully analysed the policy justifications for patent protection and the role which the requirement of inventive step/non-obviousness operated as a constraint upon excessive patenting.

As is the situation in Australia, discussed above in the context of the *Grain Pool* case,[28] the federal US patent power stems from a specific constitutional provision which authorizes the Congress 'To promote the Progress of … useful Arts, by securing for limited Times to … Inventors the exclusive Right to their … Discoveries'. This provision is regarded as both a grant of power and a limitation. The Supreme Court in *Graham v John Deere Co*[29] observed that 'Congress may not grant patents whose effects are to remove existent knowledge from the public domain, or to restrict free access to materials already available'. The Supreme Court referred to the views of Thomas Jefferson, who has been described as the 'first administrator of our patent system',[30] who was the author of the 1793 Patent Act, as well as being an inventor of ploughs and agricultural machinery. He observed that although the patent monopoly was an inducement to bring forth new knowledge, the grant of an exclusive right to an invention was the creation of society at odds with the inherent free nature of disclosed ideas. Consequently, only inventions and discoveries that furthered human knowledge, and were new and useful, justified the special inducement of a limited private monopoly.[31] The test developed by the Supreme Court to select between inventions worthy of protection and those not was formulated in 1851 in *Hotchkiss v Greenwood*[32] that '[U]nless more ingenuity and skill … were required … than were possessed by an ordinary mechanic acquainted with the business, there was an absence of that degree of skill and ingenuity which constitute essential elements of every invention'.[33]

The dichotomy posited in *Hotchkiss* was between inventions that are obvious and unpatentable and inventions that are non-obvious. In practice these dichotomies are somewhat difficult to apply, particularly in the area of agricultural research. The threshold question of obviousness was considered by the US Patent Office in a 1992 determination concerning a patent application in relation to disease resistance bred into soybeans. The claimed, novel soybean plant differed from the prior art soybeans in pod colour, pubescence colour and *Phythopora* root rot resistance. The Patent Office reasoned that it was well known in the art that resistance to root rot and other phenotypes could be bred into a soybean line by crossing it with one that possessed the desired phenotype. In assessing whether an invention effects an advancement of the pre-existing art, the test the courts apply is whether the claimed invention was obvious to one who is skilled in the relevant technology.

Industrial application

The law requires that for patentability an invention must be capable of an industrial application, i.e. that products can be produced or that industrially useful results can be

[28] *The Grain Pool of WA v The Commonwealth* [2000] HCA 14.
[29] 383 US 1 at 6 (1966).
[30] P.J. Federico (1936) Operation of the Patent Act of 1790, 18 J. Pat. Off. Soc. 237, 238.
[31] Quoted in 383 US 1 at 7 (1966).
[32] 11 How. 248 (1851).
[33] Ibid. at 267.

achieved through the application of a process. Agricultural patents are considered to satisfy this requirement. Thus in the *NRDC* case, the Australian High Court ruled that the weed killing process had an industrial application in the agricultural or horticultural industries. In ascertaining whether an invention is industrially applicable, most laws require that the patent application must describe the invention in sufficient detail to enable others in the field to make the invention and the patent specification must teach those of skill in the art how to make the invention and must describe the best mode of carrying out the invention. Describing the best way to make a biological organism in words may be difficult and may not allow others in the field to make exactly the same organism. This was illustrated in a 1993 US case, *In re Goodman*,[34] which claimed a method of manufacturing mammalian peptides in plant cells. Using *Agrobacterium*-mediated T-DNA transfer, the applicants introduced a gamma-interferon gene into tobacco plants, filing for their patent in 1985. The Appeal Court concluded that at that date, the production of proteins in monocotyledonous plants would require overcoming extensive problems, which had not been addressed in the patent specification.

Exclusions of immoral inventions from patentability

As was indicated above, European patent law excludes from patentability plant and animal varieties and essentially biological processes for the production of plants and animals. These exclusions arise from the idiosyncrasies of the evolution of European law and its articulation with European PVR law. A more general exclusion from patentability, which can be found in patent laws, is the exclusion from patentability of inventions the publication or exploitation of which could broadly be considered 'contrary to *ordre public* or morality'. As will be considered in a later chapter, the patenting of genetic material insofar as it imperils food security might be considered an immoral invention.

There is a substantial literature on the ethical implications of permitting the propertization of the 'building blocks of life'. A number of religions consider human intervention in relation to living material to violate the divine creation. Art. 27.2 of TRIPS permits Members to exclude from patentability 'inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality'. This includes the necessity 'to protect human, animal or plant life or health or to avoid serious prejudice to the environment'.

The first occasion in which the morality exception in the context of the TRIPS Agreement was raised concerned the review of Art. 27.3(b) of the TRIPS Agreement. A Joint Communication of the African Group to the TRIPS Council on taking forward this review stated that patents on life forms were unethical and 'contrary to the moral and cultural norms of many societies in Members of the WTO'.[35] The Joint Communication invoked the exception in Art. 27.2 for protecting *ordre public* and morality, as a justification to outlaw patents on life forms.

The morality exception will come into play when a patent office is called upon to determine the patentability of an invention. It is questionable whether unelected

[34] 11 F. 3d 1046 (1993).
[35] IP/C/W/404, 20 June, 2003.

patent office examiners are the proper bodies to adjudicate the application of moral and ethical issues to the patent system.[36] In any event, the patent offices have generally abstained from exercising moral judgements in this area, which has rendered the morality exception something of a dead letter.

A number of challenges to patents on morality grounds, which have been considered by the EPO and its Boards of Appeal, raise food security implications. *Lubrizol Genetics Inc.*[37] concerned an application for a patent for a transgenic plant. Environmental groups objected on the ground that the grant of the patent would result in a loss of biodiversity as well as leading to restrictions in the free flow of plant germplasm. Religious groups objected that patenting living matter was against fundamental moral principles deeply embedded in European religion and culture. The EPO applied its *Guidelines on Examination of Patents*, which provided that, in determining whether an invention was contrary to *ordre public* or morality, 'a fair test' is 'to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of a patent right would be inconceivable'. Applying this test the EPO rejected these grounds of opposition. Rather than depleting biodiversity, the EPO pointed out that biotechnology increased diversity by introducing new plant varieties. The religious objection was dismissed on the basis that many European countries, as well as the USA which has Christian traditions, have granted patents over living matter so it was arguable whether European religious sensibilities would be offended by the grant of the patent.

In *Greenpeace v Plant Genetic Systems NV*,[38] in an opposition to an application for a patent directed to transgenic plants engineered to be resistant to the herbicide Basta, Greenpeace argued that it was immoral and therefore in breach of Art. 53(a) of the European Patent Convention (EPC), to 'own' plants that were the common heritage of humankind. The Technical Board of Appeal of the EPO sustained the Examination Division's view that it was not the proper forum for discussing the advantages and disadvantages of genetic engineering. The Board stated that plant biotechnology per se could not be regarded as being more contrary to morality than traditional selective breeding, since both involved the introduction of novel genetic material in order to change plant properties. In the case before the Board, the form of herbicide resistance could also have been obtained by traditional selection techniques. This determination left open the question of the morality of transgenics.

In evaluating the environmental objections, the Technical Board of Appeal held that the concept of *ordre public* raised the question whether the exploitation of the invention conformed to the conventionally accepted standards of conduct inherent in European society and civilization. The Board rejected as 'not decisive' survey and opinion evidence from Sweden and Switzerland concerning public attitudes to genetically modified (GM) plants. It noted that these countries did not represent Europe and that the results of the surveys could be 'easily influenced and controlled' depending on the question asked, and the size and representativeness of the poll sample. The Board also held that revocation under Art. 53(a) of the EPC on the basis

[36] See R. Ford (1997) The morality of biotech patents: differing legal obligations in Europe? *European Intellectual Property Review* 6, 315; M. Llewelyn (2000) The legal protection of biological material in the new millennium: the dawn of a new era or 21st century blues. *Bio-Science Law Review* 4, 123.

[37] T0320/87 (1990).

[38] OJ EPO 8/1995 545.

of serious prejudice to the environment required that the threat to the environment be sufficiently substantiated, as it would be 'unjustified to deny a patent … on the basis of possible, not yet conclusively documented hazards'. In any event, the Board considered that it was the task of other regulatory bodies to evaluate whether the risks justified the banning or limiting the use of an invention.

In *Novartis/Transgenic Plants*,[39] the Extended Board of Appeal of the EPO considered the debate over genetic engineering too controversial for it to sustain Greenpeace's opposition to the patent. The EPO conceded that 'the positions adopted in society on genetic engineering are controversial … there is no consensus among Contracting States condemning genetic engineering in the development of plants'. The Board noted that the European Biotechnology Directive was an indication that the European Parliament considered there to be some benefit in genetic engineering.

In October 1998, the Netherlands, among other countries, requested that the ECJ should annul the Biotechnology Directive on grounds that included the arguments that it lacked legal certainty and that it was in breach of the fundamental right to respect for human dignity. The ECJ declined this annulment request.[40] Article 6 of the Directive contained the *ordre public*/morality exception, which the Netherlands and others argued infringed the principle of legal certainty, as it gave insufficient guidance and was too general and equivocal. The ECJ responded that

- The provisions of the Patent Law which allow patents to be refused where there is a threat to *ordre public* or morality are well-known and appear in the relevant international legal instruments.
- The EU legislature gives guidelines for applying the concepts at issue which do not otherwise exist in the general law on patents.
- A directive cannot be considered contrary to the principle of legal certainty if it relies for its implementation on concepts known to the laws of the member states, specifying, as here, their scope and limit and taking account of the specific nature of the subject matter.

Exclusions of 'essentially biological processes' from patentability

Article 53(b) of the EPC provides that patents should not be granted in respect of 'essentially biological processes for the production of plants and animals' and points out that this provision 'does 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 Art. 2(2) of the EU Biotechnology Directive. This exclusion ties in with the balance of the language of Art. 53(b), which excludes plant and animal varieties from patentability.

The scope of this exclusion from patentability for the production of plants was recently considered by the Enlarged Board of Appeal of the EPO in a case that concerned a method for the production of *Brassica* with 'elevated levels of

[39] Decision G0001 of 20 December 1999.

[40] *R. v Legal Protection of Biotechnological Inventions: The Netherlands (Italy and Norway, intervening) v European Parliament and EU Council (E.C. Commission, intervening)* Case C-377/98.

methylsulfinylpropyl glucosinolates', which have an anticarcinogenic property, by backcrossing and selecting plants with elevated levels of this substance.[41] Molecular markers were used to select the appropriate plants.

The Board had to consider the level of human intervention that was permitted before a plant was produced by a method which was not 'essentially' biological.[42] The Board of Appeal, whose decision was being considered by the Enlarged Board of Appeal, reviewed the legislative history of the exclusion noting that selection or hybridization of existing varieties were examples of essentially biological processes, even if, as a secondary feature, technical devices were involved, such as 'use of a particular type of instrument in grafting, or a special type of greenhouse in growing a plant'.[43] The Board of Appeal suggested that to be patentable the 'process … as a whole, does not exist in nature and is more than a traditional breeding process'.[44]

The exclusion was crafted to permit the patentability of processes involving the genetic engineering of plants and to reserve natural processes employed in plant breeding to the realm of PVR protection.

Research exception

An important contributor to effective agricultural research is the access that researchers may have to protected materials and technologies. A research exception, permitting the use of protected materials for non-commercial research and product development purposes, exists under most patent laws. However, recent case law suggests that this exception has begun to narrow.

An experimental use exception was first laid down in US patent law in the early 19th century, holding that where it was held that a patented product may be used as an experiment, whether for gratification of scientific tastes, curiosity or to ascertain the verity and exactness of the specification or for amusement, without an intent to use for profit, this would not amount to patent infringement.[45] This exception was held to be 'truly narrow' in *Roche Products, Inc v Bolar Pharmaceuticals Co., Inc*[46] and the slightest commercial purpose or intention for carrying out an experiment has been held to be patent infringement.[47] The scope of this exception was more recently explored in *Madey v Duke University*.[48] Madey was employed by Duke University as a laboratory director and owned two patents over an electron laser, which he had secured prior to his appointment at the University. After his services were terminated, Madey's patented equipment continued to be used by Duke University and he sued for patent infringement. The University raised the experimental use exception defence. The Federal Circuit refused to allow the exception to exempt university research activities from infringing a patent, as it held that these research activities

41 G 2/07 considering T 0083/05, 27 May 2007.
42 See S. Bostyn (2006/2007) Do you want biological or essentially biological vegetables? *Bioscience Law Review* 4, 146.
43 T0083/05 para. 40.
44 Ibid, para. 51.
45 *Whittemore v Cutter*, 29 Fed. Cas. 1120 (1813).
46 733 F.2d 858 [Fed. Cir. 1984].
47 See e.g. *Pfizer Inc. v International Rectifier Corp.*, 217 USPQ 157 (C.D. Cal. 1982); *Embrex, Inc. v Service Engineering Corp.*, 216 F.3d 1343 (Fed. Cir. 2000).
48 307 F.3d 1351 (Fed. Cir. 2002).

'unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects'.

The narrowing of the experimental use defence in the USA is particularly problematic in the plant biotechnology research sector, where access to patented germplasm is crucial for innovation in crops that will be made available to the agricultural sector.

The extent to which experimental use of patented inventions is permitted in Europe is governed by national patent laws. Article 64 (1) of the EPC provides that the rights conferred by a European patent in all designated countries to which the European patent extends shall be the same as those conferred by a national patent granted in that state. Article 64 (3) of the EPC provides that any infringement of a European patent shall be dealt with by national law.

The experimental use exception in Europe, however, finds its roots in Art. 31(b) of the Community Patent Convention of 1975, which was transposed into Art. 27(b) of the Community Patent Convention. Article 27(b) provides that a 'Community Patent shall not extend to acts done for experimental purposes relating to the subject matter of the patented invention'. Unlike the USA, all the member states of the EU, except Austria, have introduced a general non-industry-specific experimental use exception in their patent statutes.

Most of the European case law concerned with the experimental use exception has developed in the pharmaceuticals area. The principal question in these cases is whether during the period of protection of a pharmaceutical patent clinical tests may be conducted. Where a substance is protected as a pharmaceutical for a certain indication, two different kinds of test can occur during the duration of a patent: first, tests with the aim of finding new indications of pharmaceutical substances that have been patented only for one indication; and secondly, tests for market approval of a patented substance for an already patented indication during the protection of a pharmaceutical patent. If the latter kind of test is permitted, a competitor of a patentee can prepare for market approval well ahead of the expiration of the respective patent. Thus, upon the expiry of a patent, a generic equivalent of the formerly patented pharmaceutical can be marketed immediately without risk of patent infringement.

For example, the German Patent Act of 1981 uses the identical language of the Community Patent Convention (CPC) in providing the experimental use exception in Art. 11.1. In 'Clinical Trials II',[49] the Court held that experimental use exception encompassed any trials including those to obtain data for clinical approval, even if such clinical trials were conducted for the same indication as that of the protected product. The BGH excluded from this general permission clinical trials that would not be justified for the purpose of the experiments or that were conducted for the purpose of interfering with the marketing efforts of the patentee.

The UK section 60(5)(b) of the Patents Act 1977 incorporates the experimental use defence using the same words as that of the CPC. Under this provision: (i) the acts must be done for experimental purposes; and (ii) those purposes must relate to the subject matter of the invention. The exception was considered by the court in

[49] (1998) RPC 424.

Monsanto v Stauffer.[50] Stauffer had developed a market variant, 'Touchdown', of Monsanto's successful patented weed-killer 'Roundup', for which they had obtained provisional clearance from relevant authorities. In order to obtain final clearances, Stauffer had run tests at its own research farm and also organized a series of tests outside their research farm where interested parties could observe the results. Monsanto moved for an interlocutory injunction on the grounds of patent infringement. Both the Patent Court and Court of Appeal ruled that the outside tests could not qualify for an experimental use exception.

The Court in *Smith Kline & French Laboratories Ltd v Evans Medical Ltd*[51] observed that 'what is or is not an experiment must depend upon the facts of each case but can include experiments designed with a commercial end in view'. This approach may form a basis for exempting experimentation with a view to agricultural innovation.

The registration procedure

To obtain a patent an application is filed with the Patents Office. The application will contain, among other things, a description of the invention, with any drawings referred to in the description and the claims made for the invention. The description must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. The disclosure of the invention has to present the invention in the context of the state of the art. Since to be patentable the invention must offer a novel solution to a technical problem, the description has to relate the invention to the background art. The function of the claim is to define the scope of the protection sought. A patent application is examined by the Patents Office to ensure that the application meets the formal registration requirements. The application may then proceed to examination as to substance. For example, the registration authority may institute a search of the patent documents of other nations, and of significant technical journals and other publications, to ensure that an applicant's invention has not been previously disclosed. Some countries permit the registration of patents for inventions that have only been partially disclosed in prior art. Some countries confine relevant prior art to national disclosure, or to prior use and prior oral disclosure.

The application may be published or laid open for public inspection before a patent is granted. An opportunity may be given for third parties to oppose the grant of protection. After the examination of the application as to form and to substance and after the consideration of any opposition, the registration authority will decide on whether to grant a patent. The fact of the granting of the patent will be published in an official gazette.

A matter currently under discussion in various international fora, which is of some importance for food security, is whether a patent document concerning a biotechnological invention should disclose the source country for the biological material upon which the invention is based and/or the nature of any benefit sharing arrangements with the source country.

[50] [1985] RPC 515 CA.
[51] [1989] F.S.R 513.

Infringement

The operation of the law in relation to patent infringement is illustrated by the US decision in *Monsanto Co. v Scruggs*.[52] In the early 1980s, Monsanto scientists Robert Fraley, Robert Horsch and Stephen Rogers discovered it was possible to insert a foreign gene into a plant, get the plant to regenerate and to express the foreign gene. The synthetic gene required a promoter, a protein sequence of interest and a stop signal, all of which came from different sources, which was the basis of Monsanto's US patent 5,352,605 ('605 patent). Monsanto used the art taught in the '605 patent to develop GM soybeans and cotton which were resistant to glyphosate herbicide. After developing the biotechnology, Monsanto licensed it to seed companies, imposing two provisos: (i) it forbade seed companies from selling seed that contained Monsanto's biotechnology to growers unless the grower first signed a technology licensing agreement, reserving the patented technology to Monsanto; and (ii) seed so sold could only be used by growers to grow a single commercial crop, i.e. growers could not save seed produced from a harvested crop for replanting during the following growing season.

Mitchell Scruggs, who had not signed a technology licensing agreement, purchased a small quantity of Roundup Ready (RuR) 5601 Asgrow soybeans from a seed company in Memphis. The seed was sufficient to plant approximately 10 acres of soybeans. After the fall harvest, Mr Scruggs retained the soybean seed from those 10 acres; he cleaned it and saved it for planting during the 1997 crop season. Through saving seed from all subsequent crop seasons up to the year 2000, by 2000, Scruggs had enough saved RuR soybean seed to plant more than 8000 acres. Similarly Scruggs purchased a small quantity of cotton seed containing the Bollgard and RuR traits. He retained the cotton seed from the fields he planted with the cotton seed and sent it to a facility for cleaning and delinting. By 2000, Scruggs had saved enough cottonseed to plant in excess of 2000 acres.

Monsanto claimed that its patent had been infringed by Scruggs.

The Court explained that patent infringement cases involve a two-step analysis: (i) claim interpretation, which requires the court to construe the patent's claims and to establish their meaning and scope. In doing so, the court is to consider the specifications of the patent, its prosecution history and the prior art. (ii) Infringement analysis where the court is to compare the alleged infringer's product (in this case, the soybean and cotton in the defendant's fields) with the claims of the patent. A patent is infringed if a single claim is infringed.[53] In this case Monsanto relied both on the admission of Scruggs to purchasing its patented soybean and cotton seed and on the results of a series of three scientific tests, to demonstrate that Scruggs' 2000 soybean and cotton crops contained patented RuR and Bollgard biotechnology.

The Court rejected Scruggs' defence that neither Monsanto's biotechnology nor the plants in their fields were covered by the '605 patent. Similarly the Court rejected Scruggs' argument that by the first sale by a patentee of an article embodying the invention, the patent rights were exhausted. The Court noted that Monsanto never made an unrestricted sale of its seed technology, as it licensed its technology to seed companies with a proviso: subsequent sales of seed containing its transgenic trait must

[52] 342 F. Supp 2d 584 (2004).
[53] Ibid. at 591.

be limited to growers who obtained a licence from Monsanto and for only a single growing season.

The defendant in *Monsanto v Scruggs* was obviously compromised by the fact that he had directly purchased Monsanto's proprietary technology. Of greater significance in assessing the impact of patenting on food security is illustrated in Canadian litigation between Monsanto Canada, Inc. and a farmer, Percy Schmeiser, who had never purchased the patented technology. In 1993, Monsanto US was issued Canadian Letters Patent No. 1,313,830 (the '830 patent) for an invention termed 'Glyphosate-Resistant Plants'. The '830 patent granted Monsanto US the exclusive right, privilege and liberty of making, constructing, using and selling the invention for the full term of the patent. Monsanto Canada was a licensee under the '830 patent. The invention was used by Monsanto in Canola and marketed under the trade name 'Roundup Ready (RuR) Canola'. Schmeiser grew canola commercially in Saskatchewan. He had never purchased RuR Canola nor did he obtain a licence to plant it. Yet, in 1998, tests revealed that 95–98% of his 1000 acres of canola crop was made up of RuR plants. The origin of the plants is unclear. They may have been derived from RuR seed that blew onto or near Schmeiser's land, and was then collected from plants that survived after Schmeiser sprayed Roundup herbicide around the power poles and in the ditches along the roadway bordering four of his fields.

Monsanto brought an action for patent infringement claiming that by planting glyphosate-resistant seeds Schmeiser was said to use, reproduce and create genes, cells, plants and seeds containing the genes and cells claimed in the plaintiffs' patent.

At the trial of the case, Schmeiser argued that by the unconfined release of the gene into the environment Monsanto had not controlled its spread, and did not intend to do so, and they had thus lost or waived their right to exercise an exclusive patent over the gene.[54] Schmeiser further asserted that the patent was invalid and void because:

> (a) the alleged invention is a life form intended for human consumption and is not the proper subject matter for a patent; it is self-propagating and can spread without human intervention;
>
> (b) the patent was obtained for an illicit purpose of creating a noxious plant that would spread by natural means to the lands of innocent parties so as to entrap them with nuisance patent infringement claims;
>
> (c) if infringement is found the plaintiffs would in effect obtain a patent for a plant, which it is urged is not possible in Canada in light of the Plant Breeders' Rights Act (PBRA) which provides for protection of new varieties of plants and which preserves the right of a farmer to save and reuse seed.

The trial judge rejected each of these arguments, in finding that Schmeiser had infringed Monsanto's patent. He held that the fact that replication of the gene may occur in the natural course of events, without human intervention after insertion of the gene in the original plant cells, and plants, produced for seed, did not in itself preclude registration as an invention, under the Canadian Patent Act, the creation of

[54] *Monsanto Canada, Inc and Monsanto Company v Percy Schmeiser and Schmeiser Enterprises* 2001, FCT 256, para. 12.

the gene and the process for inserting the gene. He considered that there was no evidence that the patent was obtained for an illicit purpose. Finally, there was nothing in the PBRA that precluded an inventor from seeking registration under the Patent Act.[55]

The trial judge observed that Schmeiser had grown canola from seed which he knew was RuR. He ruled that the growth of the seed, reproducing the patented gene and cell, and sale of the harvested crop constituted taking the essence of Monsanto's invention, using it without permission, and in so doing infringed the patent.

The case was appealed to the Federal Court of Appeal, where it was heard by a court of nine judges.[56] The Chief Justice McLachlin C.J. and Justices Major, Binnie, Deschamps and Fish ruled that the patent was valid. In determining whether Schmeiser had infringed s. 42 of the Patent Act by 'using' the patented cell and gene, the word 'use' in that section was interpreted taking into account its plain meaning, the purpose of s. 42, its context, and the case law. They held that the plain meaning of the word 'use' or 'exploiter' denoted utilization with a view to production or advantage. The question in determining whether a defendant has 'used' a patented invention is whether the defendant's activity deprived the inventor in whole or in part, directly or indirectly, of full enjoyment of the monopoly conferred by law. A contextual examination shows that there was a commercial benefit to be derived from the invention. In this case, Schmeiser's saving and planting seed, then harvesting and selling plants that contained the patented cells and genes, appeared to the Court, on a common sense view, to constitute 'utilization' of the patented material for production and advantage, within the meaning of s. 42. By cultivating a plant containing the patented gene and composed of the patented cells without licence, Schmeiser deprived Monsanto of the full enjoyment of the monopoly.

The Court noted that Canadian case law had established that an infringement occurred where a defendant's commercial or business activity involves a thing of which a patented part is a component. Infringement therefore did not require use of the gene or cell in isolation. Infringement also did not require that Schmeiser had used Roundup herbicide as an aid to cultivation. Schmeiser did not provide sufficient evidence to rebut the presumption of use. He actively cultivated RuR Canola as part of his business operations, thus in light of all of the relevant considerations, Schmeiser had used the patented genes and cells, and infringement was established.

The joint judgement of Judges Iacobucci, Bastarache, Arbour and LeBel considered the infringement issue to be whether the appellants used the invention so as to interfere with the exclusive rights of the patentee, keeping in mind that the scope of the claims does not extend patent protection to plants. They held that the test for determining 'use' under s.42 of the Patent Act is not whether the alleged user has deprived the patentee of the commercial benefits flowing from his invention, but whether the alleged user has deprived the patentee of his monopoly over the use of the invention as construed in the claims. These judges ruled that the lower courts erred not only in construing the claims to extend to plants and seed, but also in

[55] Ibid., para. 82 applying *Pioneer Hi-Bred International Inc. v J.E.M. Ag Supply Inc.* 53 USPQ (2d) 1440 (2000).

[56] *Monsanto Canada, Inc. v Schmeiser* [2004] 1 S.C.R. 902, 2004 SCC 34.

construing 'use' to include the use of subject matter disclaimed by the patentee, namely the plant. Schmeiser was entitled to rely on the reasonable expectation that plants, as unpatentable subject matter, fell outside the scope of patent protection. Accordingly, the cultivation of plants containing the patented gene and cell did not constitute an infringement. To conclude otherwise would, in effect, confer patent protection on the plant. Since there is no claim for a 'glyphosate-resistant' plant and all its offspring, saving, planting or selling seed from glyphosate-resistant plants does not constitute an infringing use. As was done here, the respondents can still license the sale of seeds that they produce from their patented invention and can impose contractual obligations, such as prohibition on saving seeds, on the licensee.

Counsel for Schmeiser raised the moral question of whether it was right to manipulate genes in order to obtain better weed control or higher yields. The Federal Court of Appeal ruled that his was a question for Parliament to consider and that the court's job was to 'interpret the Patents Act as it stands'.[57] The majority explained that, 'Under the present Act, an invention in the domain of agriculture is as deserving of protection as an invention in the domain of mechanical science. Where Parliament has not seen fit to distinguish between inventions concerning plants or other inventions, neither should the courts.'[58]

As the minority judge pointed out, the TRIPS Agreement in Art. 27.2(b) permits the exclusion of plants from patentability, but that plant varieties might be patented. The *Novartis* determination, among others, suggests that the addition or modification of genetic material to confer disease resistance is not the creation of a new variety. If the view of the majority in Schmeiser, that the patenting of a cell confers exclusive patent rights in relation to a plant in which that cell is included, then the Art. 27.2(b) exception becomes meaningless.

An area of infringement of importance for food security concerns 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 importers of its patented soya. This litigation concerned Monsanto's RuR patent as it applied to soya. In 1996, Monsanto had obtained a European Patent claiming, *inter alia*, a method of making transgenic plants into which an enzyme EPSPS[59] had been inserted to render plants resistant to glyphosphate. Monsanto had inserted a gene encoding this enzyme into soya. Some 90% of the soymeal 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 soymeal 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.

In the Dutch litigation – *Monsanto Technology LLC v Cefetra BV and the State of Argentina*[60] – Monsanto sought an injunction prohibiting the infringement of the patent in all European countries. Cefetra denied infringement relying on Art. 9 of the

[57] Ibid., para. 93.
[58] Ibid., para. 94.
[59] An enzyme called 5-enolpyruvylshikimate synthase, which confers glyphosphate resistance to a plant in which the enzyme is expressed.
[60] District Court of the Hague 249983/HA ZA 05/2885, 19 March 2008.

Biotechnology Directive, which confers protection upon material 'in which the genetic material is contained and performs its function'. Cefetra argued that as a result of the processing of soybeans to produce the meal, the DNA was dead material and could not perform its function of expressing the EPSPS enzyme. In the Spanish proceedings, this argument was effective in defeating Monsanto.[61] To meet this argument Monsanto argued that the application of Art. 9 derogated from the patent protection to which it was entitled under Dutch patent law and under Art. 27 of the TRIPS Agreement.

In an argument that is germane to our consideration of food security, the State of Argentina intervened to allege that Monsanto was abusing its patent rights and contravening standards of reasonableness and fairness by promoting the planting of RuR soya in Argentina without any indication that it would oppose exports of soymeal.

The District Court stated a number of questions to the ECJ to obtain an interpretation of the relevant provisions of the Biotechnology Directive. It rejected the arguments of the State of Argentina, taking the position that Argentina was entitled to enforce its patent rights wherever possible.[62]

In the UK, Pumprey J. considered Monsanto's infringement claim in *Monsanto Technology LLC v Cargill International S.A*,[63] which concerned 5000 tonnes of soymeal imported to the UK from Argentina. As in the Netherlands, the 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 soya plants. It was merely the importer of a derivative product of beans produced from such plants. An appeal is currently pending against this decision.[64]

PATENTING OF PLANT VARIETIES A subject of some significance in the area of food security is the possibility that plant varieties might be patented. As we have seen, the PVP legislation provides an exception for farmers who save seed for future plantings and also there is an exception for researchers to develop further varieties. These exceptions are absent from patent legislation. Therefore where varieties can be patented both seed saving and future research might be compromised.

In Europe, as was mentioned above, Art. 53(b) of the EPC excludes plant varieties from patent protection. It will be recalled also that Art. 4(1) para. 2 of the European Biotechnology Directive permits the patentability of inventions concerning plants, where 'the technical feasibility is not confined to a particular plant … variety'. This qualification was addressed by the Technical Board of Appeal of the EPO in *Novartis/Transgenic Plant*.[65] The patent application in that case concerned a patent containing claims to transgenic plants comprising in their genomes specific foreign genes, the expression of which resulted in the production of antipathologically active substances, and to methods of preparing such plants. The EPO had denied

[61] See C. Baldock (2006/2007) Monsanto puts biotech directive under the spotlight. *Bioscience Law Review* 4, 160, at 161.
[62] See ibid. at 162.
[63] [2007] EWHC 2257 (Pat).
[64] Baldock, n.61 at 163.
[65] [2000] O.J. EPO 511.

registration, supported by the Technical Board of Appeal, on the ground that Art. 53(b) denied the patentability of an invention that could embrace plant varieties. In its decision of 20 December 1999, the Enlarged Board of Appeal indicated that it would favour the application because, in substance, it did not involve an application for a plant variety. This determination contains some useful guidance on the legal definition of plant varieties. The Enlarged Board of Appeal noted that the definitions of plant variety in the UPOV Convention and the EC Regulation on Community Plant Variety Rights refer to 'the entire constitution of a plant or a set of genetic information', whereas a plant defined by a single recombinant DNA sequence 'is not an individual plant grouping to which an entire constitution can be attributed'. It observed that the claimed transgenic plants in the application before it were defined by certain characteristics, which allowed the plants to inhibit the growth of plant pathogens. No claim was made for anything resembling a plant variety. The tribunal noted that in the case of PVRs an applicant had to develop a plant group, fulfilling in particular the requirements of homogeneity and stability, whereas in the case of a typical genetic engineering invention, a tool was provided whereby a desired property could be bestowed on plants by inserting a gene into the genome of a specific plant. It observed that the development of specific varieties was not necessarily the objective of inventors involved in genetic engineering.

The USA has never excluded biological material, including plant varieties, from the scope of patentable subject matter. Plant varieties can be protected in the USA under a system of plant patents, or under a system of utility patents or under the Plant Variety Protection Act (PVPA). The Plant Patent Act[66] makes available patent protection to new varieties of asexually reproduced plants. Under this scheme a plant variety must be novel and distinct and the invention, discovery or reproduction of the plant variety must not be obvious. One of the disadvantages of the scheme is that only one claim, covering the plant variety, is permitted in each application. In practice, this scheme has been in decline since the *Hibberd* decision of the Patent Office Board of Appeals and Interferences opened up the normal patent system to applications that covered plant varieties.[67]

In the USA, the Federal Circuit resolved any potential conflict between patent protection and protection under the PVPA in its decision in *Pioneer Hi-Bred International Inc. v J.E.M. Ag Supply Inc*.[68] Pioneer held patents over the manufacture, use, sale and offer for sale of the company's inbred and hybrid corn seed products as well as certificates of protection under the PVPA for the same seed-produced varieties of corn. The defendants argued that the enactment of the PVPA had removed seed-produced plants from the realm of patentable subject matter in the Patents Act. The Federal Circuit rejected this argument noting that the Supreme Court held that 'when two statutes are capable of co-existence, it is the duty of the courts … to regard each as effective'.

This decision was followed by the US Federal Circuit Court in *Monsanto Co. v McFarling*.[69] Monsanto had developed GM plants that were resistant to glyphosate herbicides such as its Roundup brand herbicide. The herbicide could be sprayed,

66 35 U.S.C. §§ 161–164 (1994).
67 227 USPQ 443 (1985).
68 200 F.3d 1374 (Fed. Cir. 2000), *cert. granted*, 148 L. Ed. 2d 954 (2001).
69 302 F.3d 1291 (Fed. Cir. 2002).

killing any weeds but not harming the resistant crops, which resulted in substantial savings in labour costs for weed control. Monsanto patented the glyphosate-tolerant plants, the GM seeds for such plants, the specific modified genes and the method of producing the GM plants.[70] Monsanto required that sellers of the patented seeds obtained from purchasers a 'Technology Agreement', in which they agreed that the seeds were to be used 'for planting a commercial crop only in a single season' and that the purchaser would not 'save any crop produced from this seed for replanting, or supply saved seeds to anyone for replanting'. Mr McFarling, a farmer in Mississippi, purchased RuR soybean seed in 1997 and again in 1998; he signed the Technology Agreement. He saved 1500 bushels of the patented soybeans from his harvest during one season, and instead of selling these soybeans as crop he planted them as seed in the next season. He repeated this activity in the following growing season. This saved seed retained the genetic modifications of the RuR seed. Mr McFarling did not dispute that he violated the terms of the Technology Agreement but claimed that the contractual prohibition against using the patented seed to produce new seed for planting, when he produced only enough new seed for his own use the following season, violated the seed-saving provision of the PVPA,[71] which permits farmers to save seeds of plants registered under the PVPA. The Court applied *Pioneer Hi-Bred International Inc. v J.E.M. Ag Supply Inc* declining to limit the patent law by reference to the PVPA. Consequently Mr McFarling was found to have infringed Monsanto's patent.

Given the interrelationship between patents and PVP there is the possibility that a plant breeder in developing a new variety might infringe a patent. To deal with this situation, the EU Directive on Protection of Biotechnological Inventions in Art. 12 provides for compulsory cross-licensing in situations where a breeder cannot acquire or exploit a PVR without infringing a prior patent. In such instances, the breeder may apply for a compulsory licence for non-exclusive use of the patent, which will be granted 'subject to payment of an appropriate royalty'. Reciprocally, a compulsory licence also applies in situations where a patent holder cannot exploit an invention without infringing a PVR.

COMPETITION ASPECTS In *Monsanto Co. v Trantham*,[72] the defendant raised an antitrust defence to Monsanto's patent infringement claim arising from the defendant's use of Monsanto's patented RuR and Bollgard technology. The defendant had purchased the seed subject to the licensing arrangement, that permitted a grower use of the technology only in one growing season and subject to the prohibition against saving seed for later planting, produced from plants grown using the purchased seed.

The defendant claimed that Monsanto had monopolized its position in the US markets for cottonseed and soybeans. However, the Court was critical of the failure of the defendant to define the relevant market, which is an indispensable element of any monopolization or attempt case. The only proof put forward was that the plaintiff owned three seed producers of soybeans and no seed producers of cottonseed. As such, it had roughly a 20–30% share of the US soybean seed production market and

[70] U.S. Patents Nos. 5,633,435 and 5,352,-605.
[71] Section 2543 PVPA
[72] 156 F. Supp. 2d 855 (2001).

no share of the cottonseed production market. Generally, 20–30% and 0% market shares have been insufficient to meet the standards of monopoly power in a relevant market. Therefore, the defendant could not meet the first prong of the test for monopolization.

As to the second prong of the monopolization test, there was no proof that the plaintiff had wilfully acquired or maintained monopoly power other than through the development of a superior product that has been successfully patented.

The Court also declined to find that the licensing agreements between Monsanto and seed producers, which required farmers purchasing seed grown with its technology to sign the licensing agreements prohibiting the farmer from saving seed, were unreasonable restraints of trade in violation of the Sherman Act.

Industrial designs

An industrial design is the ornamental or aesthetic aspect of a useful article. The UK Copyright, Designs and Patents Act, 1988 defines 'design' as 'the design of any aspect of the shape or configuration (whether internal or external) of the whole or part of an article, other than surface decoration'. Industrial designs are protected through registration. As with patents, most countries require novelty. The standard of novelty varies between universal or national novelty. A difficult issue in designs protection is the extent to which a design must differ from an earlier design to be considered novel. Minor variations are usually inadequate. A desirable test is 'whether the design claimed is subjectively new in the sense that it is not an imitation of designs already known to the creator'. The critical feature of industrial applicability is that the design is repeatable in commercial quantities. Thus items of artistic craftsmanship are outside the scope of design protection and more properly protectable under copyright laws.

Industrial designs are protected against unauthorized copying or imitation for 15 years, dated from the end of the calendar year in which the design was first recorded in a design document, or an article was first made to the design, whichever occurred first.

It is true to say that industrial designs do not have much of an impact upon food security. Some agricultural equipment has been the subject of design protection, but in areas of traditional production the equipment used has been in existence for well beyond the life-span of industrial designs and the significant features of that equipment are their functional elements, rather than their ornamentation.

Trademarks

Introduction

Trademark law developed from the common law action of passing off, which was an action to prevent the unfair competitive practice of filching another's commercial reputation. A trademark was considered to be the quintessential symbol of a commercial reputation. A particularly important function of trademarks is their use

in advertising and product promotion. The way in which trademarks facilitate this process is by their ability to distinguish and identify goods and services. This is important in markets where there is a proliferation of homogenous goods, as it allows purchasers to identify the goods of a particular trader. Thus in the market for agricultural products, which have tended to be homogenous, there has been some success in the marketing of 'Chiquita' bananas and 'Jaffa' oranges.[73]

A trademark is a concise way in which to refer to a product. Given the expense of advertising, use of a trademark will reduce the amount of information that needs to be communicated. The development of an advertised brand acts as a powerful incentive for the advertiser to secure repeat purchases to cover the advertising spend, by offering goods of a consistently high standard. Because consumers can use trademarks to identify goods that will meet their needs, an incentive is created for manufacturers and distributors to meet the reasonable expectations of consumers with regard to product quality. Accordingly, the use of trademarks tends to encourage trademark owners to maintain consistent standards of quality for goods and services offered under their marks.

Thus 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, e.g. foodstuffs or pharmaceuticals, the trademark performs a valuable function, not merely in indicating quality, but also by indicating likely safety and fitness for purpose.

The 'goodwill' inherent in a trademark can be a valuable intangible property asset belonging to the trademark owner. The law recognizes this value and allows the trademark owner to prevent unauthorized uses of the trademark which might tend to diminish the value of the mark. The trademark owner has the ability through infringement proceedings to protect its investment in creating the goodwill. The value of this goodwill can be used as security in raising new capital, or in attracting further licensing.

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. This will ultimately generate tax revenues, which can be used to underpin food purchases.

Registered trademarks

Trademarks may be 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. Excepted from registration in most countries are marks that are not distinctive or are deceptively similar to existing marks, and marks that violate public order or morality.

[73] UNCTAD (1980) Trade Marks and Developing Countries 14 *Journal of World Trade Law* 80, 85.

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 that 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.[74]

Most trademark laws allow separate registrations for a mark in respect of each of the 45 categories of goods and services laid down in the International Classification of Goods and Services, which was established in accordance with the Nice Agreement of 1957 and its subsequent revisions. Registration may be permitted with the disclaimer of some elements of a mark. For example, in a word mark there may be disclaimer of those words that would be common to the relevant trade.

The application process usually requires an examination by the granting office to ensure compliance with the formal registration requirements, as well as with the substantive requirement of distinctiveness. There also has to be a check as to whether a mark is in conflict with prior rights. After the publication of an application, most countries provide for an opposition process whereby an interested third party may protest the registration of a mark, usually on the grounds of prior rights or deceptive similarity with another mark. Upon acceptance of a mark, registration is conferred for a term of between 10 and 20 years, with a possibility for renewal. A mark will expire if a renewal is not sought. Expungement of a mark may also be sought where its use becomes deceptive or where the mark becomes generic of goods or services. For example the marks 'Vaseline' and 'gramophone' are two examples of marks that became generic descriptions of the type of goods to which they were appended.

A controversial requirement of some trademark laws is the requirement that registration of a trademark be contingent upon its use or a bona fide intention to use upon or in close association with the classes of goods or services in respect of which it is registered. A similar requirement provides for the removal of the registration after a prescribed period of non-use. Protection without registration may be extended to 'well-known marks', i.e. those with a significant reputation in a country. Such marks invariably have a substantial international reputation through advertising and use.

Registration of a mark confers protection against emulation by traders using identical or substantially similar marks. Most systems of registration permit assignment or licensure. A system of registered user may be provided to record trademark licences. In the event of infringement of a registered mark, a trademark proprietor may seek relief in the form of injunction, compensation orders and seizure of infringing goods.

As the use of a trademark is a warranty of the quality of the goods or services supplied under that mark, the name, acronym or logo of a research institute is often a warranty of the quality of the services supplied by that institute. Its designation is worthy of protection, particularly because unauthorized traders may falsely represent an affiliation with the institute. Similarly, the products that are produced by an agricultural research institute may also be worthy of protection, e.g. the IRRI prefix

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

for rice types developed at that institute. Similarly, the research institute may wish to protect its Internet domain name as a trademark.

Collective and certification marks

A special type of registered trademark is a collective mark, which may be 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. In the USA, collective marks are used by agricultural cooperatives of produce sellers. The collective mark owner is an organization that does not sell its own goods or render services, but promotes the goods and services of its members.

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, e.g. 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 that 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.

In the USA, collective and certification marks are typically used by agricultural producers in much the same way as GIs are used in Europe. US state governments typically encourage the registration of certification marks to encourage agricultural producers. 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 defined in the Georgia Vidalia Onion Act of 1986'. [75] 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'.[76] Non-US agricultural producers have also registered certification marks in the USA. For example the 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'.[77] Similarly, the Tea Board of India has registered DARJEELING to certify 'that the tea contains at least 100% tea originating in the

[75] U.S. Reg. No. 1709019.
[76] U.S. Reg. No. 1559414.
[77] U.S. Reg. No. 2,816,123.

Darjeeling region of India and that the blend meets other specifications established by the certifier'.[78]

The leading US case involving the enforcement of a GI as a certification mark is *Community of Roquefort v William Faehndrich, Inc*.[79] This case held that the designation 'Roquefort' was not a generic designation of blue cheese and that the owner of the certification mark was entitled to prevent the use of the mark on all cheeses not made in the French city of that name.

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 GIs.

GIs

Introduction

Marks indicating the geographical origins of goods were the earliest types of trademark. Until the Industrial Revolution, which commenced in the 18th century, the principal products that entered international trade were agricultural products and simple manufactured goods, such as pottery and woven fabrics. In the competition to earn revenues from the trade developing at that time it became apparent that the products of particular regions were more saleable than comparable products from other regions, because of their superior quality. This superior quality resulted either from natural geographic advantages, such as climate and geology (e.g. Seville oranges, Kentish hops, Bresse poultry), or from recipes and food processing techniques, local to a region (e.g. Roquefort cheese, Parma ham, Burgundy wine, Frankfurter sausages).

In each case, the commercial attractiveness of these products was attributable to the TK of the local communities. To protect the commercial reputation of these communities, local legislators passed laws to prevent the adulteration of local produce by the addition of inferior introduced goods or ingredients. These laws punished the adulteration of goods and established systems of marking approved local goods with marks certifying their quality (e.g. wool marks for cloth, hallmarks for goods made from precious metals). Where the reputation of local goods was attributable to the skills and technology of local artisans, associations, or guilds, of masterworkers grew up. The taxing authorities saw an advantage in preserving the skills and revenue earning capacities of these guilds and conferred upon them a monopoly of manufacture. To regulate this monopoly, the guilds developed service marks or heraldic-type designs, which were placed upon goods produced by guild members.

The legislation that sought to protect the commercial reputation of traders in discrete geographical localities evolved principally in Europe into systems for the protection of GIs. As will be seen below, these systems permit products emanating from the region to carry the geographic indication. Producer representatives from those regions police the use of GIs.

[78] U.S. Reg. No. 2,685,923.
[79] 303 F. 2d 494 (CA 2 1962).

The Industrial Revolution saw the emergence of the modern trademark. The development of large-scale industrial production led to the desire of individual producers to identify themselves as the place of origin of goods, as a warrant for the quality of those goods. The registered trademarks system was thus developed to permit individual traders to enforce their marks as private proprietary rights. This contrasted with the system for the protection of GIs, which conferred public rights upon producers in defined localities.

The evolution of the private trademark system did not result in the disappearance of geographic marks. Particularly in Europe, substantial processed foods markets and markets for alcoholic beverages are dependent upon the continued recognition of geographical marks. These marks are protected typically within a *sui generis* system for the protection of GIs.

Modern GI protection

GIs may be indications of source, in referring to the fact that a product originates in a specific geographical region. However, more usually a GI is a sign that indicates that a product originates in a specific geographic region only when 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 that emanate from that location, a GI may be distinguished from a trademark, which is a sign that distinguishes the products of a specific trader from those of its competitors. Thus it is not likely to be descriptive and it cannot be generic.

The right to protect a GI 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, GIs are monitored and protected by producer associations from the relevant region.

Unlike trademarks, GIs are not freely transferable from one owner to another, as a user must have the appropriate association with the geographical region and must comply with the production practices of that region.

GIs 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.

GIs are becoming increasingly relevant for food security. Some 43 developing countries and LDCs depend on exports of a single agricultural commodity for more than 20% of their total revenues from merchandise exports.[80] For example, Benin depends on cotton for over 80% of its merchandise export earnings. Ethiopia relies on coffee for over 70% of agricultural exports. The use of GIs, sometimes together with

[80] For a brief overview of price trends and other developments for these commodities, see FAO *Food Outlook* April 2005, No. 1.

'fair trade' trade-marking, could assist their ability to market their produce in international trade and in this way support the sustainability of this agriculture. This is particularly the case in those countries that have sought to remain free of GMOs.

Confidential information (including trade secrets)

Under IP law, information that has been originated by a person and that 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*,[81] 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*,[82] the US Eighth Circuit Court of Appeals was concerned with a dispute between competing breeders of corn seed, Pioneer and the defendant, Holden. Pioneer claimed that Holden had developed a seed from misappropriated seed, which it claimed were its trade secrets. Holden disputed the genetic similarity between its seed and Pioneer's H3H/H43SZ7. In an attempt to evaluate the parties' competing claims, the court oversaw three series of tests: electrophoresis, reverse phase high-performance liquid chromatography and growouts. Each test was supervised by the court, performed by independent experts and monitored by the parties. Although the court found that each of the three tests had its own set of limitations and inadequacies, they served to demonstrate the unlikelihood of Holden's explanation of the parentage of the seeds and the greater likelihood of Pioneer's theory of parentage. At first instance, the district court awarded Pioneer US$46 million for misappropriation of its trade secrets.

The case is not a particularly good authority for the proposition that genetic information can qualify as trade secrets as Holden did not dispute this point, therefore the court assumed 'without deciding that genetic messages can qualify for trade secret status'. The appeal focused upon the District Court's application of trade secrets doctrine. Under Iowa law, a plaintiff must generally show: (i) existence of a trade secret; (ii) acquisition of the secret as a result of a confidential relationship; and (iii) unauthorized use of a secret. Holden argued that it should not be liable for misappropriating Pioneer's seed because Pioneer failed: (i) to keep the genetic messages secret; (ii) to prove that Holden actually possessed the protected genetic messages; and (iii) to prove that Holden obtained the material by improper means.

Holden argued that H3H/H43SZ7 were not trade secrets because Pioneer failed to maintain their secrecy. The District Court found that the genetic messages of H3H and H43SZ7 were trade secrets as the 'formula' did not exist outside Pioneer's and its

[81] (1978) Qd R 72.
[82] 35 F.3d 1226 (8th Cir. 1994).

contractors' fields, and that Pioneer took reasonable precautions to protect the secrecy of the genetic message. Pioneer took several measures to preserve the secrecy of its inbreds. Growers operated under contracts, which prohibited disclosure of the seed. Fields have no labels indicating what seed is being grown, and all seed bags were coded to avoid identification. Pioneer removed male inbred lines and commingled them with other corn, thereby frustrating those seeking to obtain the inbred seed. The Appeal Court considered there to be sufficient evidence to support the District Court's finding that Pioneer took reasonable precautions to protect the secrecy of the genetic message of H3H/H43SZ7.

Holden contended that since none of the scientific tests could conclusively prove parentage, the District Court erred in finding possession. Holden pointed out particular shortcomings with each of the tests. The Appeal Court held that there was sufficient evidence to warrant a finding that Holden had derived its seed from H3H/H43SZ7.

The Appeal Court noted that a confidential relationship was not a prerequisite to a trade secret action, since a plaintiff may prevail in the absence of such a relationship by showing that the secret was obtained by improper means. The Appeal Court noted that Pioneer presented no direct evidence regarding how Holden obtained H3H/H43SZ7. However, direct evidence of industrial espionage was rarely available and not required.

The Appeal Court noted that the record displayed a long history of Holden attempts to obtain Pioneer's genetic material. These efforts included searching 'friendly farms' for stray inbred plants. Although the court concluded that Pioneer has not specifically shown that these efforts were the exact source of Holden's seed, the testimony supported such an inference. Holden's inadequate explanation of its faulty record-keeping and the untimely disposal of all its impugned seed also gave rise to an inference of misappropriation.

A matter of some relevance to the issue of food security is the relationship between trade secrets protection and the protections provided to farmers to save seed under PVR laws. In *Pioneer Hi-Bred Int'l v Holden Found Seeds*, Holden argued that the Federal PVPA[83] pre-empted state trade secret law as applied to sexually reproducing plants. However, the Appeal Court was not persuaded by the argument and it noted that the Supreme Court has expressly held that trade secret and patent protection can 'peacefully coexist'.[84]

Copyright

Copyright law is concerned with the protection and exploitation of the expression of ideas in a tangible form. The central right that the law confers is to prevent unauthorized persons from copying a work. To be protected as copyright, ideas have to be expressed in an original way, i.e. they must have their origin in the labour of the creator. Works are protected irrespective of their quality. Works are also protected, typically from the date of publication and without any requirement of registration.

[83] 7 U.S.C. Secs. 2321–2582.
[84] *Kewanee Oil*, 416 U.S. at 485–487.

The relevance of copyright law to food security issues is primarily in the suggestion that copyright might be asserted over the written representation of a gene or amino acid sequence in addition, or as an alternative, to applying for a patent or other IP protection.

Subject matter of protection

Originally, the subject matter of copyright protection was printed literary artistic and literary works. A 'literary work' for the purposes of copyright law includes a table or compilation expressed in words, figures or symbols; and a computer program or compilation of computer programs. Consequently, copyright protection may cover scientific databases, as well as laboratory notebooks, academic writings and computer displays of information.

It has been suggested that the written representation of a sequence of modified DNA or protein may be protected as an original literary work under copyright law.[85] On the other hand, Professor Gunnar Karnell states that:

> It is an internationally recognised, distinguishing feature of copyright that no-one should be allowed to appropriate for himself, by means of copyright law, either the only way to express or describe a certain type of real matter (here: a DNA sequence, recombinant or other) or such matter as can only be described in such a way.[86]

The matter of copyright doctrine, which is at issue here, is whether copyright protection is being sought for the idea rather than for the expression of that idea. It is well-established that the former is not susceptible of copyright protection. One way of resolving this issue is to ask whether sufficient skill, labour and effort is involved in creating the representation of a genetic sequence.[87]

However, even if copyright did subsist in the written representation of a gene or amino acid sequence, it would be unlikely that this would hinder the use of that sequence in research. As is indicated below, it would probably fall within the fair dealing exception to copyright infringement.

Rights comprised in copyright

The owner of a copyrighted work may exclude others from using it without authorization. The acts that require the authorization of the copyright owner are usually: copying or reproducing the work; performing the work in public; making a sound recording of the work; making a motion picture of the work; broadcasting a work through the electromagnetic spectrum or through cable diffusion; and translating or adapting the work.

[85] S. Coke (2002) Copyright and gene technology. *Journal of Law and Medicine* 10, 97, 102, see also the discussion in I. Kayton (1982) Copyright in living genetically engineered works. *George Washington Law Review* 50, 191; N. Derzko (1993) Protecting genetic sequences under the Canadian Copyright Act. *Intellectual Property Journal* 8, 31, 39.

[86] G. Karnell (1995) Protection of results of genetic research by copyright or design rights? *European Intellectual Property Review* 17, 355, 357.

[87] Australian Law Reform Commission (2004) *Genes and Ingenuity: Gene Patenting and Human Health* ALRC 99, para. 28.21.

In addition to these rights certain 'moral rights' are recognized by national legislation. These include the right to claim authorship of a work and the right to object to any distortion, mutilation or other modification of, or other derogatory action in relation to, a work which would be prejudicial to an author's honour or reputation. These moral rights usually remain with an author, even after the transfer of the various economic rights mentioned above.

The duration of copyright protection is typically in the range of 50–70 years from the date of publication.

Neighbouring rights

Three kinds of rights neighbour upon copyright protection. These are the rights of performing artists in their performances, the rights of producers of phonograms and the rights of broadcasting organizations in their radio and television programmes.

Infringement

Copyright is infringed if a person does or authorizes the doing of any act falling within the copyright in a work without the copyright owner's permission. Such conduct must relate to the whole or a substantial part of the work.

Fair dealing for research or study

Most copyright laws except from copyright infringement certain acts of 'fair dealing' in a copyright work for the purpose of research or study. Matters typically taken into account in determining whether the reproduction of the whole or a part of a work constitutes a fair dealing for the purpose of research or study include:

- the purpose and character of the dealing;
- the nature of the work or adaptation;
- the possibility of obtaining the work or adaptation within a reasonable time at an ordinary commercial price;
- the effect of the dealing upon the potential market for, or the value of, the work or adaptation; and
- where only a part of the work is copied, the amount and substantiality of that part compared to the whole work or adaptation.

Database rights

The European Database Directive, which was implemented in the UK in the Copyright and Rights in Databases Regulations 1997, provides for the protection of material contained in databases against unauthorized extraction or reutilization. A 'database' is defined as 'a collection of independent works, data or other materials arranged in a systematic or methodical way and individually accessible by electronic or other means'. Relevant databases in the context of food security will be breeding records and genetic databases comprising compilations of the sequences of genomes,

including whole genomes, single genes and gene fragments, such as single nucleotide polymorphisms (SNPs) and expressed sequence tags (ESTs).[88]

TK

As will be discussed in Chapter 3, most of the categories of IP listed above are components of the international IP landscape. These categories were formulated by the courts and legislatures of the countries of the industrial North and, as a consequence, reflect the commercial and industrial aspirations of those countries. Confronted with this fait accompli, the agricultural countries of the South have begun to identify IP possibilities that are more suited to their circumstances. Two possibilities currently being discussed are the protection of traditional cultural expressions and the protection of TK. The former is not relevant to our examination of IP and food security. On the other hand, TK has been taken to embrace subjects such as knowledge of plant genetic resources for food and agriculture (PGRFA), knowledge of the properties of fauna and flora and the innovations and practices of indigenous and local communities relevant for the conservation and sustainable use of biological diversity.

There is no universally accepted definition of TK, but the term is generally taken to refer to the content or substance of knowledge resulting from intellectual activity in a traditional context, and includes the knowhow, skills, innovations, practices and learning that form part of TK systems, and knowledge embodying traditional lifestyles of indigenous and local communities, or contained in codified knowledge systems passed between generations.[89] It is not limited to any specific technical field, and may include agricultural, environmental and medicinal knowledge, and knowledge associated with genetic resources.

Aspects of TK are protected to a limited extent by existing categories of IP law;[90] however, a comprehensive *sui generis* TK right does not yet exist.

[88] See E. Baba (2003) From conflict to confluence: protection of databases containing genetic information. *Syracuse Journal of International Law and Commerce* 30, 121.

[89] For a recent example, see WIPO/GRTKF/IC/13/5(b) Rev, 11 October 2008.

[90] See M. Blakeney (2000) Protection of traditional knowledge under intellectual property law. *European Intellectual Property Review* 22, 251.

3 International Intellectual Property Landscape

The first international IP conventions were promulgated at the end of the 19th century as a means of formulating agreed legislative norms among the newly industrialized countries of the North. At that time, the rules agreed by the great metropolitan powers automatically applied to their colonies. In the postcolonial period after the Second World War, IP became a concern of the UN and in 1967 the WIPO was created as a specialized agency to facilitate the establishment of a global, harmonized IP regime. Through the establishment, at the same time, of the UN Conference on Trade and Development (UNCTAD), the global IP and associated technology transfer regimes were scrutinized from the perspective of developing countries. The polarization of developed and developing countries within WIPO prevented the evolution of the international IP regime to embrace new categories of IP and to deal with the growth in counterfeiting and piracy. One consequence of this inertia was the initiative of the USA to shift the forum for the development of the international IP regime to the GATT/WTO through the promulgation of the Agreement on TRIPS, as a membership obligation of WTO Members.[1] Very quickly the Council for TRIPS, within which possible amendments to TRIPS are debated, became as log-jammed as WIPO had become, with the polarization between developed and developing countries.

Relevant to the question of food security were the discussions within the TRIPS Council about the nature of WTO Members' obligations to introduce PVP and the application of patenting to agricultural innovations. Apparently emulating the forum shifting example of the USA, developing countries have carried these debates into the FAO.[2] Other soft law forums such as the World Health Organization (WHO), the UN

[1] See P. Drahos, with J. Braithwaite (2002) *Information Feudalism*. Earthscan, London; S. Sell (2003) *Private Power, Public Law: The Globalization of Intellectual Property Rights*. Cambridge University Press, Cambridge.

[2] See S. Sell, Corporations, seeds, and intellectual property rights governance. Paper presented at the annual meeting of the International Studies Association 48th Annual Convention, Chicago, www.allacademic.com/meta/p179777_index.html, 24.

Environmental Programme (UNEP) and the Convention on Biological Diversity (CBD) have been identified as 'significant incubators of alternative approaches, or "counter-regime norms", to TRIPS'.[3] Within WIPO, developing countries have pressed for the recognition of the contribution of source countries to biotechnological patenting by means of disclosure of origin and benefit sharing systems. They sought to link these issues to the 1999 WIPO Patent Law Treaty (PLT) negotiations and the WIPO responded through the establishment of the Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore. In 2004 a group of developing countries proposed a development agenda for WIPO and in 2005 they expressly linked the development agenda to the Substantive Patent Law Treaty (SPLT) under elaboration at WIPO. In February 2006, WIPO held the first meetings of the Provisional Committee on Proposals Related to a WIPO Development Agenda (PCDA).

Outlined below are these inter-related developments that have influenced the contours of the international IP landscape and its impact upon the food security agenda.

3.1 Introduction

The impact of IP laws upon food security is being debated in the first instance in the international IP arena. However, it should be noted that IPR exist primarily by virtue of national laws. So-called global or international IPR are actually bundles of nationally enforceable rights. On the other hand, it is true to say that in most countries those national rights exist not only as a consequence of domestic legislation or jurisprudence, but because of international, multilateral, bilateral and regional obligations. In a number of regional associations, such as the EU, there is the possibility of regional legislation either with direct national effect or which prescribe national IP norms.

International IP treaties and conventions play an important role in harmonizing national substantive legal norms, as well as procedural rules. The first of these international agreements were the 1883 Paris Convention on the Protection of Industrial Property, which prescribed general rules on the protection of patents, trademarks and industrial designs, and the Berne Convention for the Protection of Literary and Artistic Works 1886. The gradual development of the international IP regime evolved through the promulgation of special treaties under these two treaties, such as the Madrid Trademark Agreement 1891 and the Patent Cooperation Treaty (PCT) 1970. A significant recent development was the promulgation in 1994 of the Agreement on TRIPS, which prescribes domestically enforceable norms for the protection of IPR as a condition of membership of the WTO.

In the Paris Convention, agriculture was envisaged as an area of enterprise in respect of which property rights could be secured, thus Art. 1(3) of the Convention had declared that:

[3] Ibid., 20.

> Industrial property shall be included within the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers and flour.

Given the state of technology in 1883, the inclusion of these agricultural subjects within the Paris Convention was probably in the context of the protection of trademarks and indications of source. The importance of the latter was reflected in the Second Conference of Revision of the Paris Convention, held at Madrid in 1890–91, which proposed a special agreement for the repression of false indications of origin.

TRIPS sets multilaterally agreed minimum standards of protection for all forms of IP as well as for the judicial and administrative enforcement of rights. The starting point is the obligations of the main international agreements of WIPO such as the Paris Convention, which are incorporated by reference. The norms established by these conventions are supplemented by provisions dealing with each category of IPR.

One major significance of TRIPS is that as a membership requirement for the WTO, it has a greater number of signatories than the previous conventions. For example, when the Uruguay Round of trade negotiations was launched in 1986, more than 50 countries (including some developed countries) did not confer patent protection on pharmaceuticals.

As is indicated below, the first significant application of IP to agriculture occurred with the evolution of the initiative of associations of horticulturalists and plant breeders of the UPOV Convention for the protection for plant varieties. The traditional practice of farmers in replanting, exchange and sale of seed from the previous harvests impacted upon the capacity of breeders in recouping investments through repeat sales of improved varieties. Consequently, the UPOV convention was amended to permit limitations to the extent of seed saving. These limitations have had an impact on food security in circumscribing the availability of saved seed to farming communities.

Although the patent laws and UPOV recognize and reward the contribution made to agricultural innovation by plant breeders and agricultural biotechnologists, they ignored the contribution of traditional farmers to the conservation and development of plant genetic resources from which some of these new varieties derived. The FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), which is discussed in the next chapter, seeks to establish principles for facilitating access to plant genetic resources and establishing fair and equitable mechanisms of benefit sharing.

A recent suggestion for the protection of the contribution of traditional farmers, both to the conservation of genetic resources and to the preservation of traditional varieties, is through the application of GI protection.

3.2 Patent Treaties

The Paris Convention for the Protection of Industrial Property prescribes minimum standards for the protection of patents. It offers, to parties that are filing patent applications in a member country, a grace period within which patent applications

can be filed in other member countries. Thus, the Paris Convention allows an applicant to file in one country that is a party to the convention and to claim the same filing or 'priority' date in another member country, if the application is filed in that other country within the applicable grace period. Priority dates are of critical importance enabling an inventor to state that s/he is the first to file a patent application for a particular invention.

The Paris Convention provides for subordinate treaties for the protection of industrial property. This includes the worldwide system for simplified multiple filing of patent applications – the PCT. The PCT allows applicants to prepare one patent application that can be submitted to any national patent office that is a contracting party to the treaty. This treaty also covers rules for cooperation in searching and examination of patent applications. A PCT application must contain 'a request, a description of the invention, one or more claims, one or more drawings (where required) and an abstract'.

This treaty provides for a standard application format and regulations dealing with how a filing date is obtained, the publication of the application (disclosure) and search procedures. A certified patent searching authority performs an international search and the results are published as an international search report. The examination authorities, such as the EPO, have become recognized as the world's leading authorities for performing prior searches for patent application examinations. The international search seeks to ensure that there is no prior art that is the same or that suggests the innovation claimed in the application. Most national offices will use this International Preliminary Examination Report (IPER) as the basis for their decision to issue a national patent on the claims in an application, when the application has been filed through the PCT.

An inventor (or assignee) can file a PCT application if the applicant is a national or a resident of one of the PCT Contracting States. An application can be filed in a national office of one of the contracting states (an international receiving office). At the time of the filing, the applicant lists (or designates) the national (or in some cases the regional) offices in which it is anticipated a national application will be filed.

The PLT, which was signed on 11 June 2000, covers the regional phase or the national phase of a PCT application. Standards are set for the assignment of a filing date, priority dates for applications and other procedural details such as the recording of a change in name or address, change in applicant or owner, or licence or security interest.

Under the Strasbourg Agreement Concerning the International Patent Classification 1971, an international system of classifying technologies for use by patent offices has been developed. This is extremely useful in both searching and the retrieval of information in patent documents. The primary purpose of the IPC is to be 'an effective search tool for the retrieval of relevant patent documents by industrial property Offices and other users in order to establish the novelty and evaluate the inventive step (including the assessment of technical advance and useful results or utility) of patent applications'. It also serves as an instrument for the orderly arrangement of patent documents in order to facilitate access to the information contained therein; a basis for selective dissemination of information to all users of patent information; a basis for investigating the state of the art in given fields of

technology; and a basis for the preparation of industrial property statistics which in turn permit the assessment of technological development in various areas.[4]

In order to reduce the expense and complexity of the multiplication of the disclosure of an invention involving a microorganism through the deposit of the microorganism in each country in which protection is sought, the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure 1977 provides for a centralized filing of deposits.

An SPLT is currently under discussion, to attempt to harmonize the substantive principles of patent law that currently divide nations. A key area of substantive patent law, which will be relevant to food security, is the US approach to patenting that permits the patenting of 'anything beneath the sun'. This is in opposition to the rest of the world where a protectable invention has to contribute to the solution of a technical problem. Also under discussion in the SPLT negotiations is whether source countries will be acknowledged in applications for patents of genetic material.

3.3 Trademark Treaties

The Paris Convention of 1883 contained a number of general provisions dealing with trademarks. The proposal to streamline international trademarks protection by effecting a single application, which would apply to other designated countries, was mooted in the Rome Revision Conference of 1886 and consummated at the Madrid Revision Conference of 1890–91. At the Madrid Conference in 1890, the draft arrangement was signed and adopted in 1891 by nine countries. The application could be filed with the industrial property office of the country of origin. Upon registration by the International Bureau, the trademark would secure the same protection in each of the signatory countries as if registration had been sought in those countries. The principal reasons attributed to the reluctance of countries to subscribe to Madrid included the automatic extension of trademark protection to all signatory countries. This was a particular problem for common law countries, where registration was dependent upon use or a bona fide intention to use a mark. Also, applicants in those countries which had time-consuming examination and opposition procedures were placed at a disadvantage by the requirement that an international registration could not be sought, until registration had been obtained in the country of origin.

A Protocol to the Madrid Agreement, which was concluded in 1989, eliminated a number of perceived weaknesses. Principal among these was the collapse of an international registration, which was successfully attacked in the country of origin. Under the Protocol, a successful home country attack would divide the registration into a bundle of national registrations.

The Nice Agreement Concerning the International Classification of Goods and Services for the Purposes of the Registration of Marks 1957 provides a uniform system of 34 classes for classifying goods for which trademarks could be registered and 11 classes of services. Class 42 provides for the registration of marks in relation to

[4] WIPO (1999) *IP Handbook*. WIPO, Geneva, para. 5.424.

'Scientific and technological services and research and design relating thereto' and Class 44 in relation to 'Medical services'.

The harmonization of procedural aspects of trademarks law was sought by the Trademark Law Treaty 1994. This Treaty was updated in 2006 by the Singapore Treaty on the Law of Trademarks.

3.4 Industrial Designs Treaties

Paralleling the PCT and the Madrid trademarks systems, a centralized system for the filing of industrial designs was established by the Hague Agreement Concerning the International Deposit of Designs 1925. Protection is obtained for one or more industrial designs in the states that are members of the Hague Union, through a single deposit filed with the International Bureau of WIPO. This relieves applicants of the need to make separate national deposits in each of the Hague Union states and avoids the complication of variations between state practices.

In 1968, the Locarno Agreement Establishing an International Classification for Industrial Designs was promulgated. A permanent committee of experts was established to make amendments and additions to the international classification as required by changes in technology and trade or as dictated by experience.

3.5 Copyright Treaties

The first copyright treaty was the Berne Convention for the Protection of Literary and Artistic Works 1886. The basic principle of 'national treatment' provides that works originating in one of the contracting states must be given the same protection in each of the other contracting states as the latter grants to the works of its own nationals. Such protection must be automatic and not conditional upon compliance with any formality. Also international copyright protection is said to be 'independent' (i.e. independent of the existence of protection in the country of origin of the work).

Minimum standards of protection relate to the works that are protected and to the duration of protection. The Berne Convention provides that protection must be extended to 'every production in the literary, scientific and artistic domain, whatever may be the mode or form of its expression'.

Subject to certain permitted reservations, limitations or exceptions, the rights that are required to be recognized include: the right to translate, the right to make adaptations and arrangements of the work, the right to communicate to the public the performance of such works, the right to broadcast, the right to make a reproduction in any manner or form, the right to use the work as a basis for an audiovisual work, and the right to reproduce, distribute, perform in public or communicate to the public that audiovisual work.

The Convention also provides for 'moral rights', i.e. the right to claim authorship of the work and the right to object to any mutilation or deformation or other modification of, or other derogatory action in relation to, the work, which would be prejudicial to the author's honour or reputation.

The general rule in relation to the duration of protection is that protection must be granted until the expiration of the 50th year after the author's death. Exceptions are made in respect of anonymous or pseudonymous works, where the term of protection expires 50 years after the work has been lawfully made available to the public, except if the pseudonym leaves no doubt as to the author's identity or if the author discloses his identity during that period: in the latter case, the general rule applies. In the case of audiovisual (cinematographic) works, the minimum term of protection is 50 years after the making of the work available to the public or from the creation of the work, where it is not released. In the case of works of applied art and photographic works, the minimum term prescribed is 25 years from the creation of such a work.

As with the Paris Convention, the Berne Convention provided for special agreements to take account of new matters that would arise in the future. The WIPO Copyright Treaty of 1996 was designed to take account of new forms of information and communications technology and the development and widespread use of the Internet. A particular issue was the introduction of a legal regime to deal with security technologies, designed to protect digital works.

3.6 TK Proposals

Despite an extensive international debate concerning the protection of TK,[5] there is not yet a comprehensive *sui generis* treaty concerned with its protection. A number of international instruments refer to TK in specific contexts, such as: knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity;[6] TK relevant to PGRFA;[7] TK including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora;[8] and TK relevant to animal breeding and production.[9]

The position that WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore has reached at its 2008 Thirteenth Session is the preparation of a gap analysis on the protection of TK, with a view to considering the possibility of international protection.[10]

3.7 International Organizations

A complicating feature of the emergence of IPR as an issue in food security is the fact that a number of international agencies claim an interest in or a jurisdiction over international IP matters. The earliest intergovernmental organization to concern

5 See S. von Lewinski (ed.) (2008) *Indigenous Heritage and Intellectual Property: Genetic Resources, Traditional Knowledge and Folklore*, 2nd edn. Wolters Kluwer, Alphen aan den Rijn.
6 Art. 8(j), Convention on Biological Diversity.
7 Art. 9.2(a), International Treaty on Plant Genetic Resources for Food and Agriculture.
8 Art. 31, United Nations Declaration on the Rights of Indigenous Peoples.
9 Para. 12, Interlaken Declaration on Animal Genetic Resources.
10 WIPO/GRTKF/IC/13/5(b) Rev, 11 October 2008.

itself with IP was the United International Bureau for the Protection of Intellectual Property, more commonly known by its French acronym, BIRPI (Bureaux Internationaux Réunis pour la Protection de la Propriété Intellectuelle). The precursors of BIRPI were the secretariats, established by the Swiss Government in 1893 to administer the Paris Convention for the Protection of Industrial Property and in 1886 to administer the Berne Convention for the Protection of Literary and Artistic Works. BIRPI was itself the precursor to the WIPO, which in 1974 became the only specialized agency of the UN to be concerned exclusively with IP matters.

The WTO is the most recent of a number of UN specialized agencies, which include IP within their portfolio of activities and concerns. Among these are the UN Conference on Trade and Development (UNCTAD) and the FAO. The role of each of these organizations in the IP and food security debate is considered below.

WTO

The WTO came into existence on 1 January 1995. The establishment of the WTO was the result of the Uruguay Round of trade negotiations conducted under the auspices of the General Agreement on Tariffs and Trade (GATT) between 1986 and 1994. The WTO institutionalized the GATT, which from 1947 to 1994 had been the principal multilateral treaty governing trade. In 1944, an international meeting at Bretton Woods sought to establish an institutional framework that would lend stability to the international economic order. The International Monetary Fund (IMF) and the International Bank for Reconstruction and Development (IBRD), or World Bank, were successfully established, but the proposed International Trade Organization (ITO) failed to secure the support of the US Congress. In parallel with the negotiations on the ITO Charter, countries also negotiated an agreement on the reduction of tariffs. These negotiations were successfully concluded in Geneva and resulted in the General Agreement on Tariffs and Trade of 1947. Anticipating that the ITO would eventually supersede their interim arrangements, 51 states concluded the GATT, embodying the commercial terms of the draft ITO Charter, by way of the Protocol of Provisional Application. The treaty remained in effect under this arrangement until the conclusion of the Uruguay Round in 1994.

Although the GATT was not intended to establish an organization, it developed institutional functions, including a secretariat and a dispute settlement system. Following a number of 'rounds' of negotiations, the GATT developed a network of side-agreements or 'codes', regulating various categories of trade, such as agriculture and textiles. In the Uruguay Round, which commenced in 1986, the establishment of a new international organization for trade, however, was initially not on the agenda of the Round. It was only in 1990 that the first proposals for the establishment of a new international trade organization were tabled by Canada and the European Community, followed in 1991 by a joint proposal by Canada, the European Community and Mexico.[11] Initially many developing countries were quite critical with respect to the idea of establishing a new international organization for trade,

[11] See P. Demaret (1995) The metamorphoses of the GATT: from the Havana Charter to the World Trade Organization. *Columbia Journal of Transatlantic Law* 34, 123.

partly because they considered that UNCTAD could and should fulfil this function. Also the USA initially objected to the establishment of a new international trade organization, but by 1993 the political barriers had been overcome, and the WTO was created under the terms of the Marrakesh Agreement Establishing the WTO.

The WTO was established by Art. I of the WTO Agreement and Art. II affirmed that it would provide the common institutional framework for the conduct of trade relations among its Members in matters related to the multilateral and plurilateral trade agreements annexed to the WTO Agreement. Article II provided that the functions of the WTO would include the administration of relevant agreements, as well as providing a forum for negotiations among members concerning their multilateral trade relations. Additionally, the WTO was to administer the disputes settlement mechanism and the Trade Policy Review Mechanism. Hearkening back to the first discussions concerning the ITO in 1943, paragraph 5 of Art. II enjoined the WTO 'with a view to achieving greater coherence in global economic policy-making' to cooperate as appropriate with the IMF and the World Bank.

The US proposal for a biennial Ministerial Conference, with the functions of the WTO conducted by a General Council between those Conferences, was adopted in Art. IV. The General Council was responsible for convening a Dispute Settlement Body and the Trade Policy Review Body. A Council for Trade in Goods, A Council for Trade in Services and a Council for TRIPS are to operate under the direction of the General Council.

As a general principle, the GATT practice of decision-making by consensus was adopted in Art. IX. Interpretations of the Multilateral Trade Agreement and the exceptional waiver of Members' obligations required a two-thirds majority of votes. Amendments of the WTO, not obtaining the consensus of the Ministerial Conference, required a two-thirds majority of Members. The obligations of least-developed nations under the WTO Agreement was modified by Art. XI 'to the extent consistent with their institutional development, financial and trade needs or their administrative and institutional capabilities'.

The preamble to the WTO Agreement recognized the importance of equating the increase in living standards, full employment, the expansion of demand, production and trade in goods and services with the optimal use of the world's resources in accordance with the objective of sustainable development. The preamble also recognized the need to 'secure for developing countries, particularly the least-developed, a growth in the share of international trade commensurate with the needs of their economic development'. The preamble affirmed the contribution to these objectives by the entry of members into 'reciprocal and mutually advantageous arrangements directed to the substantial reduction of tariffs' and other trade barriers.

The purpose of the WTO was to provide a 'common institutional framework for the conduct of trade relations among its Members in matters related to the agreements and associated legal instruments included in the Annexes to [the WTO Agreement]'. The WTO was endowed with international legal personality, and signatories agreed 'to provide to the WTO such legal capacity and privileges and immunities as may be necessary for the exercise of its functions'. The WTO Agreement established a single institutional framework encompassing the GATT, as modified by the Uruguay Round, all agreements and arrangements concluded under its auspices, and the complete results of the Uruguay Round.

The substantive part of the WTO Agreement is Annex 1. This Annex consists of three parts. Annex 1A contains 13 multilateral agreements on trade in goods, including the GATT 1994. Annex 1B contains the General Agreement on Trade in Services (GATS) and Annex 1C the TRIPS Agreement. Annexes 2 and 3 hold respectively, the Understanding on Rules and Procedures Governing the Settlement of Disputes and the Trade Policy Review Mechanism.

The policy objectives of the WTO are set out in the Preamble to the WTO Agreement. This recognizes that the relations of the Parties:

> … in the field of trade and economic endeavour should be conducted with a view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services, while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing so in a manner consistent with their respective needs and concerns at different levels of economic development.

A number of these objectives are obviously relevant to the question of food security.

The TRIPS Agreement

The TRIPS Agreement originated from the concern of a number of industrialized countries about counterfeiting and piracy. In 1979, the USA and the European Community had reached agreement on a draft 'Agreement on Measures to Discourage the Importation of Counterfeit Goods'.[12] This US initiative was carried forward into the ministerial meeting of 1982 for the preparations for the forthcoming GATT Round.[13] The response of developing countries led by Brazil and India was that IP issues were the exclusive territory of WIPO and that, in any event, the GATT was concerned with trade in tangible goods and therefore, that the GATT had no jurisdiction over trademark counterfeiting. Responding to this concern a Ministerial Declaration requested the Director General of GATT to hold consultations with his counterpart at WIPO in order to clarify the appropriateness of joint action in relation to counterfeiting.[14] Between 1982 and 1986 a Preparatory Committee of the GATT identified the issues that would be the concern of the forthcoming GATT Round.[15] The USA proposed that the Round consider all IPR, affirming that the GATT was the appropriate forum to seek the enforcement of IPR. Subsequent negotiations led by the Swiss and Columbian Ambassadors sought a compromise between the opposing views on the jurisdiction of GATT in these matters and produced a proposal that served as the basis for the Ministerial Declaration of 20 September 1986, which launched the Uruguay Round.

[12] GATT Doc. No. L/4817 (31 July 1979).

[13] See J.A. Bradley (1987) Intellectual property rights, investment and trade in services in the Uruguay Round; laying the foundations. *Stanford Journal of International Law* 23, 57.

[14] *Ministerial Declaration* GATT, *BISD* 30th Supp. 9 (1983).

[15] For a comprehensive account of the negotiating history of the Round, see Terence P. Stewart (ed.) (1993) *The GATT Uruguay Round. A Negotiating History (1986–1992)*, vols I–III. Kluwer, Boston; Daniel Gervais (2003) *The TRIPS Agreement, Drafting History and Analysis*, 2nd edn. Sweet and Maxwell, London.

The Negotiating Plan settled by a Decision of 28 January 1987 under the heading 'Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods' identified that the initial phase of the negotiating process would be taken up with gathering relevant factual material and with the tabling of the texts of interested participants. In response to this invitation, the Office of the United States Trade Representative in Geneva on 19 October 1987 submitted a substantive proposal for the interdiction of the trade in infringing products through the implementation of Customs controls and through the promulgation and implementation of legislative norms for the protection of IPR.[16] Further suggestions were tabled by Switzerland, Japan and the European Community. The EC proposal was the most far reaching in that it suggested that a TRIPS Agreement should adhere to the basic GATT principles of national treatment, non-discrimination, reciprocity and transparency, as well as applying to the new categories of IPR, such as semi-conductor layouts, and plant varieties as well as to the traditional categories, including utility models and appellations of origin.[17]

The subsequent negotiations of the Round were dominated and frustrated by a series of deadlocks over agricultural policies. In December 1991 Arthur Dunkel, the Director General of the GATT, attempted to precipitate a conclusion of the Round by tabling a Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, which included a new TRIPS text which attempted to settle outstanding difficulties by proposing compromise formulae.[18] Negotiations were resumed in Geneva in late 1992 following the resolution of differences between the EC and the USA on agricultural policies and in the result the final draft of the TRIPS Agreement, which was adopted when the Uruguay Round was brought to a close at the Ministerial meeting at Marrakesh, 12–15 April 1994, was very close in form and content to the Dunkel Draft.[19]

The TRIPS Agreement came into effect on 1 January 1995. The negotiating parties appreciated that the exigencies of negotiation had produced a document which would require subsequent amendment and improvement and that the speed of implementation would depend upon the level of economic development of a country. Thus, built in to the TRIPS Agreement itself was a reform agenda applying to a number of the specific substantive provisions, including GIs (Art. 23.4) and the patentability of biological inventions (Art. 27.3.b). Additionally, Art. 71 required the Council for TRIPS to review the implementation of the Agreement after the expiration of 5 years from the commencement of the Agreement and at 2-year intervals after that.

Concern for developing countries in the TRIPS Agreement was purportedly reflected in the statement of 'Objectives' in Art. 7 which declared that:

[16] *Suggestion by the United States for Achieving the Negotiating Objective*, GATT Doc. No. MTN.GNG/NG11/W/14 (20 October 1987).

[17] *Guidelines Proposed by the European Community for the Negotiations on Trade Related Aspects of Intellectual Property Rights* GATT Doc. No. MTN.GNG/NG11/W/17 (20 November 1987).

[18] The Dunkel text is reproduced in (1992) *World Intellectual Property Reports* 6, 42–55.

[19] Agreement on Trade-Related Aspects of Intellectual Property Rights, reproduced in (1994) *International Legal Materials* 33, 1197–1225.

> 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.

Also, developing country members of the WTO were granted 4 years additional grace to implement the TRIPS Agreement,[20] and LDCs 10 years grace and the possibility of extensions.[21] However, in advance of the Seattle Ministerial of 1999, which was scheduled to be held at the end of the period of grace, a number of developing countries contrasted the pressure imposed on them to implement the TRIPS Agreement with the failure of developed countries to provide incentives for the transfer of technology to developing countries, as required by Art. 66.2 and to provide technical assistance to developing countries, as required by Art. 67.[22]

A number of developing countries (e.g. Cuba, Dominican Republic, Egypt, Honduras) indicated that the transitional implementation period of 5 years, granted under Art. 65.2, was insufficient to undertake the complex and costly administrative tasks required under the TRIPS Agreement, such as the modernization of their administrative infrastructure (IP offices and institutions, the judicial and customs system), as well as the promulgation of new IP laws. They sought an extension of the implementation period for the developing countries.[23]

Opposed to the desire of developing countries to delay the implementation of the TRIPS Agreement were pressures from developed countries to initiate the review of the implementation of the Agreement under Art. 71.1. The EU reminded negotiators that the TRIPS Agreement establishes minimum IP standards 'from which to seek further improvements in the protection of IPR. There should therefore be no question, in future negotiations, of lowering of standards or granting of further transitional periods'.[24] Similarly Japan declared that 'We should not discuss the TRIPS Agreement with a view to reducing the current level of protection of IPR. To the contrary, the TRIPS Agreement should be improved properly in line with new technological development and social needs'.[25] This divergence of views between developed and developing countries has characterized the debates on the TRIPS Agreement to the present.

Doha Development Agenda

The Seattle Ministerial, which was held in November 1999, had to be abandoned and the concern of developing countries to seek modification of TRIPS rules was renewed during the negotiations for the Doha Ministerial, which was scheduled for November 2001. India, noting the difficulties faced by developing countries to obtain

[20] TRIPS Agreement, Article 65(2).
[21] TRIPS Agreement, Article 66(1).
[22] See e.g. communications to the Council on TRIPS by Egypt (WT/GC/W/109), India (WT/GC/W/147) and the African Group (WT/GC/W/302).
[23] See e.g. WT/GC/W/209.
[24] WT/GC/W/193.
[25] WT/GC/W/242.

access to foreign technology, suggested that 'the TRIPS Agreement may be reviewed to consider ways and means to operationalize the objective and principles in respect of transfer and dissemination of technology to developing countries, particularly the least developed amongst them'.[26] A typical catalogue of the sorts of things which were urged to be included in a general review of the TRIPS Agreement are those contained in Venezuela's communication, 6 August 1999, to the Council for TRIPS,[27] namely:

> 1. Include the principles of the United Nations Convention on Biodiversity in the TRIPS Agreement … to prohibit the granting of patents to those inventions made with foreign genetic material that are inconsistent with Art. 15 of the CBD relating to the recognition of sovereignty and access to genetic resources.
>
> 2. Establish on a mandatory basis within the TRIPS Agreement a system for the protection of intellectual property, with an ethical and economic content, applicable to the traditional knowledge of local and indigenous communities, together with recognition of the need to define the rights of collective holders.
>
> 3. Extend the list of exceptions to patentability in Art. 27.3(b) of the TRIPS Agreement to include the list of essential drugs of the World Health Organization, in order to develop the principles established in Art. 8 of the Agreement.
>
> 4. Extend the incentives mentioned in Art. 66.2 of the TRIPS Agreement in favour of developing country Members. Review the objectives and principles set out in Arts 7 and 8 of the TRIPS Agreement with the aim of making them effective and operational.
>
> 5. Establish mechanisms of support for developing and least-developed countries through electronic commerce which involve strengthening development strategies and modifying the productive structures, as well as facilitating open technology transfer on a reasonable commercial basis.

The Doha Ministerial was held in the immediate aftermath of 9/11 and this may well have influenced the preparedness of developed countries, particularly the USA, to embrace development issues. In the Ministerial Declaration which was issued at Doha, clause 19 adopted a number of items in the Venezuelan list above. It instructed the Council for TRIPS,

> … in pursuing its work programme including under the review of Art. 27.3(b), the review of the implementation of the TRIPS Agreement under Art. 71.1 and the work foreseen pursuant to paragraph 12 of this Declaration, to examine, *inter alia*, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to Art. 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Arts 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension.

In clause 18, the Council for TRIPS was instructed to address the extension of the multilateral system (MLS) of notification and registration of GIs for wines and spirits, referred to in Art. 23 to products other than wines and spirits, which was a developing country request.

[26] WT/GC/W/147.
[27] WT/GC/W/282.

In the Doha Ministerial Declaration, the trade ministers reaffirmed special and differential (S&D) treatment for developing countries and agreed that all S&D treatment provisions '… be reviewed with a view to strengthening them and making them more precise, effective and operational'.

The pro-development spirit of Doha began to dissipate soon after the Ministerial and the development agenda appeared to have been abandoned by the industrialized group of countries, by the time of the Cancún Ministerial in September 2003. This Ministerial collapsed principally because of the lack of political will of developed countries to engage with the multilateral free trade process. The EU was reluctant to agree to reform its agricultural sector and there was a reluctance to listen to developing countries on Singapore issues. The USA in an election year was unwilling to make concessions that could anger lobbyists and by this time it had shifted its focus to bilateral free trade agreements, where it considered that concessions were more easily extracted from developing countries than at the WTO. Also the industrialized countries sought to focus on multilateral investment issues, which had been the focus of the first WTO Ministerial in Singapore, November 1996.

Negotiations were resumed in 2004 and on 31 July 2004, WTO members approved a Framework Agreement that included proposals to resolve the critical differences in agriculture.[28] Little progress was made, which highlighted the importance of the 2005 Ministerial in Hong Kong. The Ministerial Declaration adopted on 18 December 2008[29] in clause 1 reaffirmed the Declarations and Decisions adopted at Doha. Clause 2 stated the acceptance by the Trade Ministers of 'the central importance of the development dimension in every aspect of the Doha Work Programme' and their recommitment 'to making it a meaningful reality, in terms both of the results of the negotiations on market access and rule-making and of the specific development-related issues set out below'. In clause 35 the Trade Ministers reaffirmed 'that provisions for special and differential (S&D) treatment are an integral part of the WTO Agreements'. Deadlines were established at Hong Kong for concluding negotiations by the end of 2006.

Talks in Geneva in July 2006 and in Potsdam in June 2007 failed to overcome the impasse between the USA, the EU, India and Brazil over reducing agricultural subsidies and opening up agricultural and industrial markets. This impasse continued in the negotiations that were held 21–29 July 2008. Negotiations are not expected to resume until 2009.

'Joint Modalities' Proposal

In addition to the lack of progress on agriculture, almost no progress was made in the TRIPS Council on the three topics listed in clauses 18 and 19 of the Doha Declaration: (i) extending to all products the additional protection accorded to GIs of wines and spirits; (ii) making it mandatory for patent applicants to disclose the origin of any genetic resources and/or associated TK involved in their inventions; and (iii)

[28] See Ian F. Fergusson (2006) *The Doha Development Agenda: The WTO Framework Agreement*, CRS Report RL32645. Congressional Research Service, Library of Congress, July.

[29] WTO Doc. WT/MIN(05)/DEC.

the establishment of a register for GIs of wines and spirits. The Director-General of the WTO had repeatedly warned that a failure to resolve differences on IP issues was potentially a major roadblock to the successful conclusion of the Doha Round.[30] The three issues were discussed separately. In an effort to break this deadlock, a coalition of developed and developing countries led by Brazil, the EU, India, and Switzerland, developed a set of 'draft modalities'[31] to resolve these issues in the July 2008 mini-ministerial conference.

The draft modalities proposal was rejected on 6 June by Australia, Canada, Chile, Mexico, New Zealand, South Korea, Taiwan and the USA. Those countries stated that they objected to bundling the three issues together, arguing that 'the extent and interest of Members in the content and potential outcomes for each issue varies considerably'. And that including IP issues in the horizontal negotiations on modalities in the industrial and agricultural sectors would 'substantially set back efforts to arrive at a viable way forward for the Doha negotiations'.[32]

This failure of the Doha Development Agenda in the TRIPS Council will mean a shift of negotiation on these subjects to WIPO.

Agreement on Agriculture

The focus of the WTO AoA is not food security. The objective of the AoA is to establish 'a fair and market-oriented agricultural trading system' through 'reductions in agricultural support and protection'. The expectation is that this would result in 'correcting and preventing restrictions and distortions in world agricultural markets'. The Agreement was primarily directed at the distortion of world agricultural markets through use of export subsidies to dispose of agricultural surpluses. The problems for developing countries were precisely the opposite: inadequate production and insufficient support to increase agricultural productivity. Thus the need of developing countries has been for increased, rather than reduced support. It is suggested that such increased support would have negligible effects on the distortion of world agricultural markets.[33] This issue has been addressed in the negotiations on the AoA after the failure of the Seattle Ministerial.

IP considerations have had a limited role to play in the negotiations on the AoA. The main subject discussed is the role that GIs for agricultural products can play in improving market access for developing countries.

Food security has been identified as a 'non-trade concern' to be taken into account in the reform of agricultural trade.[34] A number of submissions have emphasized that in developing countries, where the majority of the population depends on agriculture for their livelihood, physical access to food can be ensured

[30] See Ian F. Fergusson (2006) *The Doha Development Agenda: The WTO Framework Agreement*. CRS Report RL32645, Congressional Research Service, Library of Congress, July.

[31] WTO Doc., TN/AG/W/4/Rev.2, 19 May 2008.

[32] Kaitlin Mara, Modalities drafted for WTO geographical indications, biodiversity amendment, *IP Watch*, Geneva, 15 July 2008. http://www.ip-watch.org/weblog/index.php?p=1151

[33] *FAO papers on selected issues relating to the WTO negotiations on agriculture*. FAO, Rome, 2002, 6.

[34] WTO Agreement on Agriculture, Art. 20.

only through a minimum level of self-sufficiency.[35] The findings by the FAO on the interrelationship between the promotion of economic growth, reduction of poverty, the enhancement of food security and the development of agricultural capacity were cited in these submissions.[36] Thus, for example, India submitted that the particular vulnerability of agriculture in developing countries justified the extension of special provisions to the developing country members for ensuring their food and livelihood security concerns, such as exempting product-specific support given to low income and resource-poor farmers from aggregate measure of support (AMS) calculations.

The requirement in Art. 20 of the AoA that WTO Members in their reform of the Agreement shall have regard to non-trade concerns, S&D treatment to developing country members and the principles of equity and fairness was reformulated in the Doha Ministerial Declaration to take account of the needs and interests of the developing countries, particularly the vulnerability of the LDCs and the importance of the objective of sustainable development. In the work programme decided in March 2002, non-trade concerns, including food security, and S&D treatment were to be an integral part of the negotiations. However, the failure of the Cancun Ministerial prevented settlement of a common position on a draft text.

3.8 WIPO

Introduction

As mentioned above, the precursor to WIPO was the intergovernmetal organization, known as BIRPI, which the Swiss Government had formed in 1893 to administer the Paris and Berne Conventions. By a convention agreed at Stockholm on 14 July 1967, it was provided that BIRPI would become an intergovernmental organization, prefatory to it becoming part of the UN. By an agreement signed with the UN on 17 December 1974, WIPO became a specialized agency of the UN.

WIPO's activities are of four kinds: registration, the promotion of intergovernmental cooperation in the administration of IPR, specialized programme activities and latterly, dispute resolution facilities. The registration activities of WIPO are pursuant to the various international conventions and treaties, which designate the organization as the registering or coordinating authority. For example, under the PCT, WIPO is designated as the coordinating authority. Under the Madrid Agreement Concerning the International Registration of Marks, WIPO is the registry for trademark registrations having effect in signatory countries.

The development assistance programmes of WIPO are typically of three types: first, it provides educational assistance to developing countries, both to induce

[35] See e.g. Submission to the Special Session of the WTO Committee on Agriculture by Barbados, Burundi, Cyprus, Czech Republic, Dominica, Estonia, the European Communities, Fiji, Iceland, Israel, Japan, Korea, Latvia, Liechtenstein, Madagascar, Malta, Mauritania, Mauritius, Mongolia, Norway, Poland, Romania, Saint Lucia, Slovak Republic, Slovenia, Switzerland, and Trinidad and Tobago. WTO doc., G/AG/NG/W/36/Rev.1; Submission by India, WTO doc., G/AG/NG/W/102, 15 January 2001; Proposal by Nigeria, WTO doc. G/AG/NG/W/130, 14 February 2001.

[36] See e.g. FAO Symposium on Agriculture, Trade and Food Security: Issues and Options in the forthcoming WTO Negotiations from the Perspective of Developing Countries, Geneva, 23–24 September 1999.

familiarity with the concept of industrial property and, more specifically, for the training of relevant government officials. Secondly, WIPO provides assistance to developing countries in the promulgation of appropriate legislation. Such assistance is usually provided through expert advisers who are recruited to advise relevant countries, as well as through the Organization's own corpus of model laws. Thirdly, WIPO provides assistance for developing countries in establishing appropriate administrative infrastructures.

In response to the charge that it may have neglected the enforcement of IPR, WIPO through a resolution of its Governing Bodies of September 1993, established the WIPO Arbitration Center, which commenced operations in October 1994. The Center administers a number of procedures for the non-judicial resolution of international commercial disputes. Disputes may be submitted to the Center only with the consent of both parties.

Development Agenda

In September 2004 Argentina, Brazil and Bolivia informally circulated a proposal to establish a 'development agenda' at WIPO.[37] The proposal argued that it was time for the institution to integrate the UN-wide development agenda, including the commitments set out in the Millennium Development Goals, in its mandate. The proposal included a proposition for the establishment of a new subsidiary body in WIPO, which would look at measures within the IP system that could be undertaken to ensure an effective transfer of technology to developing countries. The proposal also suggested that the negotiations for the SPLT should reflect the interests of developing countries and that the SPLT and other treaties in WIPO should include the contents of Arts 7 and 8 of the TRIPS Agreement.

The joint proposal was presented to the 2004 WIPO General Assembly,[38] which referred it to hold a series of inter-sessional intergovernmental meetings (IIMs). Three sessions of the IIM on a Development Agenda for WIPO were organized in 2005. The 2005 session of the WIPO General Assembly agreed to establish a PCDA. The PCDA forwarded a set of 45 proposals which were adopted by the WIPO General Assembly in 2007, which further recommended the establishment of the Committee on Development and Intellectual Property (CDIP). The 45 recommendations were divided into six clusters, of which the following are relevant to the issue of food security: Cluster A: Technical Assistance and Capacity Building; Cluster B: Norm-setting, Flexibilities, Public Policy and Public Domain; Cluster C: Technology Transfer, Information and Communication Technology (ICT) and Access to Knowledge; Cluster D: Assessments, Evaluation and Impact Studies; Cluster E: Institutional Matters Including Mandate and Governance.

In its first meeting in March 2008, the CDIP held discussions on the meanings of various terms within the six clusters.[39] A number of developing countries have stressed the importance for a holistic approach to IP and development by bringing

[37] http://www.iprsonline.org/resources/docs/BrazilArgentina_WIPO.pdf.
[38] WIPO Doc WO/GA/31/11.
[39] See South Centre, Implementing the WIPO Development Agenda: Next Steps Forward (February 2008) *Policy Brief* 13, 2.

together the 45 agreed proposals. In particular, WIPO was enjoined to cooperate with all UN agencies concerned with development.

WIPO has considered each of the subjects within the joint modalities proposal over the years within its various committees. The collapse of the proposal within the TRIPS Council will add to the focus of WIPO's deliberations.

3.9 UNCTAD

UNCTAD was founded in 1964 as an organ of the General Assembly of the UN.[40] The motive force for the creation of UNCTAD was the perception of a bloc of developing countries, the 'Group of 77', that the pattern of world trade disproportionately favoured the industrialized nations.[41] While world trade had more than doubled in the decade after 1950, exports from developing countries had increased only by one half. During this period the share of developing countries in world trade had declined to nearly one third from about one half. The failure of US ratification of a proposal to establish an International Trade Organization deprived developing countries of an effective voice on this issue. In July 1962, a Conference on the Problems of Economic Development was held by 36 non-aligned countries. The conference adopted a declaration calling for the holding of an economic conference to deal with 'all vital questions relating to international trade, primary commodity trade and economic relations between developing and developed countries'.[42] A series of regional meetings of the developing countries of Latin America, Africa and Asia followed this conference, making a similar request. The establishment of UNCTAD in 1964 was the result of this pressure.

At its inaugural conference, the principal functions of UNCTAD were identified as the promotion of international trade between countries at different stages of economic development and the formulation of principles and policies on international trade and the related question of economic development.[43] To these ends, UNCTAD's activities have included: (i) negotiating international commodity agreements on behalf of developing countries; (ii) the provision of technical advice and assistance to regional and sub-regional groupings of developing countries in their cooperation programmes; (iii) the negotiation of tariff relief through the GATT; and (iv) negotiating codes on the elimination of restrictive business practices and on the transfer of technology.

UNCTAD comprises all the member states of the UN, together with its specialized agencies and the International Atomic Energy Agency. It meets every 3 or 4 years, however; its Trade and Development Board meets annually.

To ensure the primary influence of the developing countries, voting was by groups of countries. Until the collapse of the socialist bloc, four groups were

[40] Resolution 1995 (XIX) of the General Assembly of 30 December 1964. See R. Cordovez (1967) The Making of UNCTAD, 1 *Journal of World Trade Law* 243.

[41] See B. Gosovic (1972) *UNCTAD: Conflict and Compromise*. Sijthoff, Leiden, 310.

[42] UN doc. A/5162, para. 59 quoted in S. Dell (1985) The origins of UNCTAD'. In: M.Z. Cutajar (ed.) *UNCTAD and the North–South Dialogue*. Pergamon, New York, 30.

[43] See K. Hagras (1966) *United Nations Conference on Trade and Development*. Praeger, New York, chap. 1.

represented: Group A – the developing countries of the Afro-Asian region and Yugoslavia; Group B – western industrialized countries, including Japan, Australia and New Zealand; Group C – Latin American countries; Group D – Socialist countries, including Mongolia. With Groups A and C, representing the developing countries voting together, and invariably being supported by Group D, the Group B, western industrialized countries, were in an almost permanent voting minority. Probably more significant was the institutional solidarity that resulted from Group discussion and voting. Groups A and C would meet together as the Group of 77 developing countries. This habit of Group consultation was carried to other organizations such as WIPO, where issues would be discussed in group-based sub-committees.

IP in developing countries and the related issue of the role of IP in the transfer of technology to those countries was an early concern of UNCTAD. A resolution of the General Assembly of the UN of 19 December 1961 had demanded 'a study on the effects of patents on developing countries'.[44] The resolution had also requested a study of relevant legislation in both industrialized and developing countries and had sought 'recommendations on the advisability of an international conference'. A subsequent report by the UN Secretary General indicated the necessity of directing a major effort towards the rectification of problems experienced by developing countries in gaining access to appropriate technologies.[45] At its inaugural conference in Geneva in 1965, UNCTAD considered a resolution of the Economic and Social Council of the UN (ECOSOC) calling on it to 'explore possibilities for adaptation of legislation concerning the transfer of industrial technology'.[46] To this end the UNCTAD Secretariat commissioned a number of empirical and analytical studies of world technology markets.[47] These included studies on the role of the patent system in the transfer of technology, the role of trademarks in developing countries and on the channels and mechanisms for the transfer of technology to developing countries.

In 1970, an Intergovernmental Working Group was established as an organ of UNCTAD to commence work on a draft code of conduct for the transfer of technology. A series of diplomatic rounds between 1979 and 1988 resulted in the publication of a Draft Transfer of Technology Code comprising a preamble and nine chapters covering definitions and scope of application (chapter 1), objectives and principles (chapter 2), national regulation of transfer of technology transactions (chapter 3), restrictive business practices (chapter 4), responsibilities and obligations of parties to transfer of technology transactions (chapter 5), special treatment for developing countries (chapter 6), international collaboration (chapter 7), international institutional machinery (chapter 8) and applicable law and settlement of disputes (chapter 9).[48] Some of this Code has been embraced by Art. 40 of the TRIPS Agreement.

[44] General Assembly Resolution 1713 (XVI), reproduced in UNCTAD doc, TD/B/AC.11/12 (1974).

[45] UN Secretary General (1964) *The Role of Patents in the Transfer of Technology to Developing Countries*. UNO, New York.

[46] ECOSOC Re. 1013 (XXXVII), 27 July 1964.

[47] For a comprehensive list of these studies, see UNCTAD, Bibliography of Documents on Transfer and Development of Technology, UNCTAD doc. TD/B/C.6?INF.2/Rev.5 (23 October 1986).

[48] For a detailed examination of the Draft TOT Code, see M. Blakeney (1989) *Legal Aspects of the Transfer of Technology to Developing Countries*. ESC, Oxford, chap. 6.

3.10 The FAO

The FAO was founded in 1945 with a mandate to raise levels of nutrition and standards of living, to improve agricultural productivity, and to better the condition of rural populations. To this end the FAO provides a neutral forum for international policy dialogue, develops international norms, standards and conventions, and provides technical assistance.

In 1983 the FAO Conference had established the Commission on Plant Genetic Resources as a permanent intergovernmental forum to deal with questions concerning plant genetic resources. The 1995 FAO Conference adopted Resolution 3/95, which broadened the Commission's mandate to embrace all components of biodiversity of relevance to food and agriculture. This broader mandate was reflected in the renaming of the Commission as the Commission on Genetic Resources for Food and Agriculture. The FAO considered that this would 'facilitate an integrated approach to agrodiversity'.[49] The statutes for the broadened Commission provide for cooperation between the FAO and other governmental and non-governmental bodies, in particular the Conference of the Parties to the Biodiversity Convention (COP). The Commission was specifically required to cooperate with the COP in the area of genetic resources of relevance to food and agriculture. In the discharge of its mandate, the Commission has coordinated the development of the *Global System for the Conservation and Utilization of Plant Genetic Resources for Food and Agriculture*. The objectives of the Global System are 'to ensure the safe conservation and promote the availability and sustainable utilization of plant genetic resources by providing a flexible framework for sharing the burdens and benefits'.[50] The Global System comprises three elements: (i) voluntary codes of conduct for plant germplasm collecting and transfer and on biotechnology, as well as the 1994 FAO/CGIAR Agreement on Genebanks; (ii) a 'Global Mechanism' comprising a World Information and Early Warning System, networks of *ex situ* and *in situ* and on farm collections and crop-specific networks; and (iii) three global instruments – an inventory of the 'State of the World's Plant Genetic Resources', a 'Global Plan of Action on Plant Genetic Resources' and the 'International Fund for the Implementation of Farmers' Rights'.

In 1983, the Conference of the FAO adopted the International Undertaking on Plant Genetic Resources (the Undertaking) as a non-legally binding instrument. The Undertaking provides for the exploration and collection of genetic resources (Art. 3), for conservation *in situ* and *ex situ* (Art. 4), for the availability of plant genetic resources (Art. 5), for international cooperation in conservation, exchange and plant breeding (Art. 6), for international coordination of genebank collections and information systems (Art. 7) and for funding (Art. 8).

On 3 November 2001, the 31st FAO Conference adopted the ITPGRFA, which replaced the International Undertaking. The International Treaty entered into force on 29 June 2004.

[49] FAO, *Progress Report on the FAO Global System for the Conservation and Utilization of Plant Genetic Resources for Food and Agriculture*, UNEP/CBD/COP/3/15, http://web.icppgr.fao.org/CPGR/COP/cop3gs.html.

[50] Ibid. para.6.

In November 2005, the FAO Council approved a cooperation agreement between the FAO and WIPO.[51] Included in the fields of cooperation were cooperation on such matters where IPR may intersect aspects of:

- farmers' rights and TK;
- agricultural biotechnology;
- genetic resources for food and agriculture;
- promotion of innovation and the effective capture of benefits from public investment in research;
- access to, and transfer of, technology in the food and agriculture sector;
- plant protection and production;
- use of distinctive signs in the food and agriculture sector;
- ethical issues in food and agriculture;
- information and analysis on patterns and trends of IP use in the food and agriculture sector;
- creation, development and dissemination of agricultural information and data, particularly on the Internet and on CD-ROM.[52]

Joint projects between the two agencies were envisaged under this agreement.

Criticisms of this agreement have been reported, apparently by those concerned that the FAO might 'be contaminated with the non-development friendly approach of WIPO'.[53] Tansey noted that the Agreement as originally developed by an FAO committee in April 2005 included a preamble, which premised 'that access to food may be more important than the protection of intellectual property *per se*'.[54] However, by November 2005, when the final text was approved at FAO, the preamble was deleted. Tansey advised that the FAO, 'rather than accepting uncritically WIPO's pro-industry line and function … should do the opposite and make the case for changes in the intellectual property regime as and when necessary in the interest of small farmers and other local communities'.[55] Of course, now that WIPO has adopted a development agenda and has appointed a new Director General, the organization might well overcome the various concerns which have been expressed.

3.11 The International Fund for Agricultural Development

The International Fund for Agricultural Development (IFAD), a specialized agency of the UN, was established as an international financial institution in 1977 as one of the major outcomes of the 1974 World Food Conference. The Conference was organized in response to the food crises of the early 1970s that primarily affected the Sahelian countries of Africa. The Conference resolved that 'an International Fund for Agricultural Development should be established immediately to finance agricultural development projects primarily for food production in the developing countries'. The Conference addressed the insight that the most significant cause of food insecurity

[51] C 2005/LIM/6 Rome.
[52] Ibid., Art. III, (g).
[53] *Intellectual Property Watch*, 1 October 2006, http://www.ip-watch.org/weblog/index.php?p=411.
[54] Geoff Tansey (2007) Fear over growing WIPO–FAO links, Grain. *Seedling*, July.
[55] Ibid.

arose from structural problems relating to poverty and to the fact that the majority of the developing world's poor populations were concentrated in rural areas. IFAD has developed an innovation strategy to promote new and better ways to enable the rural poor to overcome poverty.[56]

The Initiative for Mainstreaming Innovation (IMI) began in 2004 as a first IFAD effort to focus on innovation. The IMI Operational Framework for the Main Phase stated that IFAD is called to play a key role in developing 'new, more coordinated and effective approaches to rural poverty'. IFAD's Strategic Framework 2007–2010 views innovation as central to 'improved development effectiveness and to enabling the rural poor to develop better strategies to face emerging challenges'.

IFAD co-finances research and development with the CGIAR, the International Land Coalition and the Global Forum on Agricultural Research, and with private foundations, particularly in farming and seed technology development, value chain development, water and soil use and conservation technologies.[57]

[56] http://www.ifad.org/pub/policy/innovation/e.pdf.
[57] Ibid., 17.

4 Plant Variety Protection and Food Security

4.1 Historical Background

The first legislative proposal for the protection of agricultural innovations was the Papal States Edict of 3 September 1833 concerning the declarations of ownership of new inventions and discoveries in the fields of the technological arts and agriculture.[1] This general measure was never implemented. The inclusion of agriculture in this instrument could not be attributed to the incentivization of innovations in plant breeding, as it anticipated, by three decades, the 1865 publication of the experiments of Mendel on the principles of heredity and, by almost 70 years, the rediscovery of his work by Correns, von Teschermak and de Vries in 1900.[2]

With the dissemination of Mendelian theories in the early 1900s, the establishment of plant breeding on genetic principles became feasible. Prior to this time farmers had, of course, selected and harvested seeds from plants that had desirable traits, such as disease resistance, and suitability to their local conditions, without being aware of the genetic mechanisms that produced these results. The significance of the publication of Mendel's theories is that it made possible the establishment of a plant breeding industry. A significant food security aspect of this industry is that agricultural innovation shifted away from farmers to corporations. The primary corporate objective of seed companies, to secure repeat purchases of seed, was in direct contradiction to the practice of farmers to save seed for future plantings. The subsequent history of the seed breeding industry has been characterized by the development of legal and technological means to preserve innovations and to secure repeat purchases of seed.

[1] B. Laclavière, *La protection des droits des obtenteurs sur les nouvelles espèces ou varieties des plantes et la Convention de Paris du 2 décembre 1961 pour la protection des obtentions végétales* (April 1962) No.168, *Bulletin D'Information des Ingenieurs des Services Agricoles*, cited in A. Heitz (1991) The history of the UPOV Convention and the rationale for plant breeders' rights. Paper delivered at UPOV Seminar on the Nature of and Rationale for the Protection of Plant Varieties under the UPOV Convention, Buenos Aires, 26–27 November.

[2] See R.W. Allard (1960), *Principles of Plant Breeding*. John Wiley & Sons, New York, 7 et seq.

The development of high-yielding hybrid varieties was a technological guarantee of future seed sales, as hybrid vigour tended not to be transmitted between generations. Trade secrets law could also be used to prevent access to breeding information.[3] A parallel development was the growth of large-scale, mechanized agriculture in which seed saving and cleaning by farmers was apparently less convenient than the purchase of farm-ready seed from dealers.[4]

The first national proposal that foreshadowed the protection of agricultural innovations under patent law was the introduction, in the USA Congress of 1906, of a 'Bill to amend the laws of patents in the interest of the originators of horticultural products'.[5] This bill was unsuccessful, as were similar bills introduced in 1907, 1908 and 1910. It was not until the Townsend–Parnell Act of 1930, the 'Plant Patent Act', that agricultural innovations were recognized by Congress. This statute endures as sections 161–164 of the current USA patent law.[6]

Although part of the US Patents Code, the Plant Patents Act created a *sui generis* system of protection for agricultural innovations that anticipated a number of the features of the UPOV.[7] For example, section 161 of the Plant Patent Act confined protection to asexually reproduced plants, because of the view that sexually reproduced varieties lacked stability.[8] The section also excluded tuber-propagated plants principally because of a concern that this would lead to monopolies in basic foodstuffs, such as potatoes.[9]

Applicants for plant patents were accordingly required to asexually reproduce the plant in relation to which protection was sought, in order to demonstrate the stability of the characteristics that were claimed.

Section 161 also required that eligible new varieties should be 'distinct'. The statute did not define this requirement, although the Senate Committee Report accompanying the Act stated that 'in order for a new variety to be distinct it must have characteristics clearly distinguishable from those of existing varieties' and that it was not necessary for the new variety to constitute 'a variety of a new species'.[10]

Legislation similar to the US Plant Patents Act was adopted in Cuba in 1937, South Africa in 1952 and the Republic of Korea in 1973, in an endeavour by those countries to align their patent systems with that of the USA.[11] The US Act was further

[3] See J. R. Kloppenburg (2004) *First the Seed: the Political Economy of Plant Biotechnology, 1492–2000*, 2nd edn. University of Wisconsin Press, Madison, WI.

[4] See C. Fowler (1994) *Unnatural Selection: Technology, Politics and Plant Evolution*. Yverdon, Gordon and Breach Science Publishers, London.

[5] A Bill to Amend the Laws of the United States Relating to Patents in the Interest of the Originators of Horticultural Products, H.R. 18851, 59th Cong. (1906), quoted in *Arguments Before the House Comm. on Patents on H.R. 18851, To Amend the Laws of the United States Relating to Patents in the Interest of the Originators of Horticultural Products*, 59th Cong. 3–18 (1906).

[6] 35 U.S.C. §§ 161–164 (2000).

[7] International Convention for the Protection of New Varieties of Plants (UPOV), 2 December 1961, as revised in 1972 and International Convention for the Protection of New Varieties of Plants 23 October1978] [hereinafter UPOV 1978]. A further, important revision occurred in 1991. See below n. 13 et seq.

[8] 35 U.S.C. § 161 (2000). See S.B. Williams (1983) Intellectual property aspects of plant variety genetic engineering: view of an American lawyer. In: *UPOV, Genetic Engineering and Plant Breeding* 23.

[9] S. REP. NO. 71-315 (1930).

[10] Ibid., cited in J. Rossman (1935) The preparation and prosecution of plant patent applications. *Journal of the Patent Office Society* 17, 632.

[11] See Heitz, above n. 1, at 23.

emulated in the draft Seeds and Seedlings Law, which was submitted to the German Parliament in 1930, the year in which the US Act was adopted.[12] The German legislation provided protection to plant breeders for new varieties that were distinguishable from existing varieties in characteristics that were inheritable or transferable by vegetative propagation. The UPOV Convention's later concern with 'essentially derived varieties'[13] was anticipated by the German Law's denial of protection to a variety obtained by a mere selection without important or substantial improvement of an existing protected variety.[14] The Law also authorized the registration of protected varieties as trademarks. However, this draft Law was never adopted by the German Parliament.

4.2 The Road to UPOV

In Europe, the first formal suggestion for a *sui generis* type of protection for plant varieties occurred in the Congrès pomologique de France of 1911. A French Decree of 5 December 1922 introduced a Register for Newly-bred Plants,[15] and a similar system of seed certification was established by the Netherlands in 1932. The first national statute that clearly anticipated the UPOV Convention was the Czech Law of 1921 on the Originality of Types, Seeds and Seedlings and the Testing of Horticultural Types.[16] It provided that registration of plant seed types entitled the registrant to place its material in commerce under a registered indication. The horticulturalist or producer who produced the original material obtained the exclusive right to make use of a registered trademark covering the type.

A more obvious precursor to the UPOV Convention was the German Law of 27 June 1953, on the Protection of Varieties and the Seeds of Cultivated Plants. Art. 1 of this statute stated that the purpose of protection was to promote the creation of useful (*wetvoll*) new varieties of cultivated plants. An exception was provided for non-food plants and varieties intended for export. A precondition for protection was that a variety should be 'individualized' and stable. This anticipated the UPOV requirements of distinctiveness and stability. The registered owner of a protected variety had the exclusive right to produce and sell seed of the variety. The Law also permitted the use of a protected variety for the creation of new varieties.

Also anticipating UPOV was the requirement that anyone who marketed seed of the protected variety was obliged to use the registered designation for the variety. As with UPOV, where under the German Law the variety designation was a registered trademark, the trademark proprietor could not object to the use of the designation where such use was compulsory.

Attempts had been made with varying degrees of success in a number of European jurisdictions to obtain patents covering plant varieties. In Germany, there were a number of decisions of the Beschwedesenat in 1934 and 1936 that approved the acceptance of applications for patents on tobacco and lupin seed, and in relation

[12] *GRUR* 244 [1930].
[13] UPOV 1978, above n. 7, art. 5.
[14] Law on the Protection of Varieties and the Seeds of Cultivated Plants, 1953.
[15] *PI* 28–29 (1923).
[16] *PI* 70–71 (1922).

to the 'seed of a small-seeded garden pea'. However, these applications were withdrawn because of concerns about compromising agricultural policy that had been expressed by the Reichsnärstand.[17] In France, a patent had been secured on a rose variety in 1949, by a celebrated rose breeder, Roger Meilland.[18] He then pursued successful patent applications in Belgium and Italy, but failed in an application in Switzerland. There were no applications in any of these countries outside the field of ornamental plants.

As with other categories of intellectual property, a key role in the inclusion of agricultural innovations within the international regulatory regime was played by industry associations. Mention has been made of the Congrès pomologique de France, held in 1911, which had called for special protection of plant varieties. The International Union of the Horticultural Profession also considered the matter at its Congresses in Luxemburg (1911), London (1912) and Ghent (1913). The International Institute of Agriculture in its 1927 Congress had stated that the protection of a denomination was insufficient and that a way had to be found to require 'any grower who engaged in reproduction of those breeds for the purposes of sale to pay a royalty to the producer'.[19]

The International Federation of Breeders of Staple Crops had, in its 1931 conference, expressed the hope that the legal status of new varieties should be assimilated to that of industrial inventions. Discussions concerning the creation of a new organization to agitate for the promulgation of an international legal regime for the protection of plant varieties occurred at the meetings of the International Breeders' Congress at Leeuwarden in 1936 and the 1937 Conference of the International Organization of Agricultural Industries, also held in the Netherlands. The direct result of these discussions was the foundation in Amsterdam, on 17 November 1938, of the International Association of Plant Breeders for the Protection of Plant Varieties (ASSINSEL). The first ASSINSEL Congress, held in Paris on 8–9 July 1939, adopted a three-point resolution:

> (a) To accept internationally the filing of trademarks and appellations as a means of protection (pending introduction of a patent);
>
> (b) To adopt the principle of a licence, to be drawn up by ASSINSEL for the purposes of multiplication and sale; and
>
> (c) To accept internationally the definition of the word 'original' [as] seed produced, offered or sold by the breeder of the variety or under his control by his licensees or successors in title.

The Second World War interrupted these developments. At its Semmering Congress in June 1956, a resolution of ASSINSEL called for an international conference to promulgate an international system for the protection of plant varieties. The French Government had been approached by ASSINSEL, because it had indicated a favourable attitude.[20] Invitations were issued to 12 Western European

[17] See Heitz, above n. 1, at 27.
[18] See B. Laclavière (1971), The French law on the protection of new plant varieties. *Industrial Property* 10, 44.
[19] Quoted in UPOV (1987) The history of plant variety protection. In: *The First Twenty-five Years of the International Convention for the Protection of New Varieties of Plants*. UPOV, Geneva, 80.
[20] Ibid. at 82.

countries[21] to attend a diplomatic conference in Paris, from 7 to 11 May 1957. The notes of invitation to the conference referred to the conclusions that had been reached at the 1954 conference on the Development of Seed Production and Trade, held in Stockholm, that there should be an international agreement favourable to the protection of new plant varieties.

4.3 Plant Variety Protection under the Paris Convention

Meanwhile, the German delegation to the London Congress of the International Association for the Protection of Industrial Property (AIPPI) in 1932, which was led by Franz and Freda Wuesthoff, had proposed that patent rights should be established for plants manifesting entirely new characteristics, and that a lesser right, in the nature of a new denomination, should be provided for lesser creations. Other delegations opposed this initiative, particularly the British, which fought the extension of patenting to plants because of the damage that might be done to the patent system if protection became over-broad.[22]

The matter was taken up again in 1939, when it was decided to address the issue in the 1940 Congress of the IAPPI. However, with the interruption of war, the subject was not taken up again in any serious way by AIPPI, until its 1952 Congress in Vienna, when a variety of proposals were advanced. The Wuesthoffs renewed their proposal for a hybrid system of protection that would depend on the level of inventiveness. The delegations from Luxemburg, the Netherlands, Switzerland and the UK proposed a specific protection system. The Congress unanimously adopted the following text:

> The Congress expresses the view that, in order to achieve effective protection for new plant varieties, the legislation of the countries of the [Paris] Union must:
>
> 1. Provide, in so far as it is not yet granted, for patent or equivalent protection for plants that possess important new properties, with a view to their exploitation, provided that their propagation is assured;
>
> 2. Place on an equal footing an invention's suitability for use in agriculture, forestry, market gardening and other comparable fields, and an invention's suitability for use in industry as provided in the patent laws of many countries.[23]

Another text was submitted to the subsequent AIPPI Congress at Brussels, which met in 1954. It declared that

> The Congress expresses the wish that, in the legislation of each country of the Union:
>
> 1. Inventions relating to the plant kingdom be assimilated, with respect to their legal protection, to industrial inventions, in accordance with Art. 1(3) of the text of the Paris Convention for the Protection of Industrial Property;
>
> 2. For plants that possess definable new characteristics, in so far as their faithful

[21] That is, Austria, Belgium, Denmark, Finland, Federal Republic of Germany, Italy, the Netherlands, Norway, Spain, Sweden, Switzerland and the UK.
[22] See UPOV, above n. 19, at 78.
[23] Ibid.

> reproducibility is assured, there be provision for protection, where it is not yet granted, by the patent law, amended where appropriate, or by any other legislative or regulatory measure.

The various delegations adopted separate negotiating positions, and the final resolution of the Congress expressed the wish that 'in the legislation of each of the countries of the Union, inventions relating to the plant kingdom be assimilated, with respect to legal protection, to industrial inventions and that plant varieties be also protected'.[24] In practice, however, AIPPI was unable to interest the contemporaneous Paris Revision conferences to adopt plant variety protection (PVP) as a subject for discussion.

4.4 The Paris Conferences on Special Protection of 1957 and 1961

On 22 February 1957, the French Government issued invitations to 12 Western European countries[25] to attend a diplomatic conference in Paris, to be held from 7 to 11 May 1957, to consider establishing an international regime for the protection of plant varieties. Participation was limited by the French to those states who were known to share its own concerns on this subject. Thus, the USA was not invited because it had 'confined itself to plant patents for vegetatively reproduced varieties, with at best only a minor part to play as foods'.[26]

The conclusions of the 1957 Conference were set out in its Final Act, adopted on 11 May 1957. This instrument recognized the legitimacy of breeders' rights and established, as the preconditions for protection, that a variety had to be distinct from pre-existing varieties and sufficiently homogenous and stable in its essential characteristics. It defined the rights of the breeder and acknowledged the principle of the independence of protection in each country. It proposed that these principles be enshrined in an international Convention and that a Drafting Committee and a Committee of Experts be established.

Following three meetings of the Drafting Committee and two meetings of Committees of Experts, the second session of the Conference was held in Paris from 21 November to 2 December, 1961. A UPOV Convention was presented for the Consideration of the Conference. An important question debated there was whether the UPOV Convention would be compatible with the Paris Convention. The debate on that subject produced the inclusion of Art. 2(1), which stated that 'each Member of the [UPOV] Union may recognize the right of the breeder … by the grant of a special title of protection or a patent. Nevertheless, a Member State of the Union, whose national law admits of protection under both these forms may only provide one of them for one and the same genus or species.'

Article 4(1) applied the draft UPOV Convention to 'all botanical genera and species', but it was envisaged that the Convention would have a gradual introduction. A list of 13 genera was annexed to the Convention: wheat, barley, oats or rice, maize, potato, peas, beans, lucerne, red clover, ryegrass, lettuce, apples, roses or carnations.

[24] Ibid. at 80.
[25] That is, Austria, Belgium, Denmark, Finland, Federal Republic of Germany, Italy, the Netherlands, Norway, Spain, Sweden, Switzerland and the UK.
[26] See UPOV, above n. 19, at 82.

Art. 4(3) required each member State on entry into force of the Convention to apply it to at least five genera from this list and, within 8 years, to all the listed genera.

The UPOV Convention was signed on 2 December 1961 by the representatives of Belgium, France, the Federal Republic of Germany, Italy and the Netherlands. On 26 November 1962, the signatures of Denmark and the UK were added, followed by Switzerland on 30 November 1962. The Convention entered into force on 10 August 1968, following its ratification by the Netherlands, the Federal Republic of Germany and the UK. Denmark deposited its instrument of ratification on 6 September 1968 and France on 3 September 1971. Sweden deposited an instrument of accession on 17 November 1971.

4.5 Additional Act of 1972

Article 27 of the 1961 UPOV Convention provided for its periodic review, with the first revision scheduled for 1972. A Diplomatic Conference for this purpose was held on 7–10 November 1972. The primary objective of this Conference was to arrange the financial contribution rates of member states. The Additional Act for this purpose was signed by Belgium, Denmark, France, Federal Republic of Germany, Italy, the Netherlands, Sweden, Switzerland and the UK. The Additional Act entered into force on 11 February 1977, after which it also obtained the accession of South Africa (7 October 1977), Israel (12 November 1979) and Spain (18 April 1980). Thus, within the first 19 years of its life, the UPOV Convention had attracted the accession of only twelve states.

One reason for the reluctance of States to adopt the Convention was the stringency of its provisions, in particular the obligation of states to select either patent or UPOV-style protection for plant varieties. Work on a revision had begun as early as 1973, and in October 1974, the UPOV Council set up a Commission of Experts for the Interpretation and Revision of the Convention. Six sessions of this Commission were held between February 1975 and September 1977, and in December 1977, the Council called for a Diplomatic Conference to be held on 9–23 October 1978.

4.6 Revision of 1978

In an endeavour to broaden the membership of the Convention, invitations were widely circulated, to permit non-member states to participate as observers. In the end, some 27 non-member states attended, including the USA and a number of developing countries. One result was an amendment of Art. 2 of the Convention to permit the accession of countries like the USA, which had laws allowing the double protection of varieties under patent and *sui generis* laws.[27]

The list of genera, annexed to the 1961 Convention, was removed. This list had contained mainly species from temperate climates. Under the new Art. 4, member states agreed to apply the Convention to at least five genera or species, rising to 24

[27] See N. Byrne, Commentary on the Substantive Law of the 1991 UPOV Convention for the Protection of Plant Varieties. London, CCLS, 1991, 13 at 20.

genera or species within 8 years. Additionally a grace period was introduced to permit the marketing of varieties twelve months prior to an application for PVP being made. The revised Convention attracted the ratification of the USA on 12 November 1980.[28]

4.7 The Revision of 1991

A further broadening of the UPOV Convention occurred with the 1991 Revision.[29] The 1991 Act requires states to protect at least 15 plant genera or species upon becoming members of the Act, and to extend protection to all plant varieties within 10 years.[30] In response to demands from breeders in industrialized countries, the 1991 Act required signatory states to make dual protection mandatory. The 1978 text merely permitted states to grant dual protection if they so desired. Through the definition of a 'breeder' in Art. 1(c) as including a 'person who bred, or discovered and developed, a variety', the 1991 Act makes explicit the requirement that even discovered varieties should be protected.[31]

The 1991 Act recognizes the right of breeders to use protected varieties to create new varieties. However, this exception is itself restricted to such new varieties as are not 'essentially derived' from protected varieties.[32] The drafters added this restriction to prevent second generation breeders from making merely cosmetic changes to existing varieties in order to claim protection for a new variety. The concept of essential derivation has proved highly controversial in practice, however. Breeders have been unable to agree on a definition of the minimum genetic distance required for second generation varieties to be treated as not essentially derived from an earlier variety and thus outside of the first breeder's control.[33]

From the perspective of farmers, probably the most contentious aspect of the 1991 Act is the limitation of the farmers' privilege to save seed for propagating the product of the harvest they obtained by planting a protected variety 'on their own holdings', 'within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder'.[34] Unlike the 1978 Act, the 1991 version of the farmers' privilege does not authorize farmers to sell or exchange seeds with other farmers for propagating purposes. This has been criticized as inconsistent with the practices of farmers in many developing nations, where seeds are exchanged for purposes of crop and variety rotation.[35] According to ASSINSEL, the 'reasonable limits' referred to in Art. 15(2) requires states to restrict the acreage, quantity of seed and species subject to the farmers' privilege, while the requirement to safeguard breeders' 'legitimate

[28] See http://www.upov.org/eng/convntns/1978/act1978.htm. The USA became a party to the 1978 UPOV in 1981 by Executive Agreement. See H.R. Rep. No. 103–699, at 9 (1994).

[29] Act of 1991, International Convention for the Protection of New Varieties of Plants (official English transl.) (1991), at http://www.upov.org/ eng/convntns/1991/act1991.htm. [UPOV II].

[30] Ibid., art 3(2).

[31] Ibid., art. 1(c).

[32] Ibid., arts 14(5), 15.

[33] See L. Helfer (2001) *Legal Study on Intellectual Property Rights in Plant Genetic Resources*. FAO, Rome, ¶ 1.1.1.4.

[34] UPOV II, above n. 29, art. 15(2).

[35] D. Leskien and M. Flitner (1997) Intellectual property rights and plant genetic resources: options for a sui generis system. In: *Issues in Genetic Resources*, No. 6, at 60 (June).

interests' requires farmers to pay some form of remuneration to the breeder for their privileged acts.[36]

It has been suggested that for both social equity and food security reasons there are justifications for providing a 'farmers privilege' for smallholder and resource poor farmers, especially in developing countries, whereby poorer farmers who do not represent an immediate or lucrative market would enjoy the 'farmer privilege' to save seed, while their richer counterparts would be required to pay royalties on saved proprietary seed.[37]

A number of developing countries have resisted adopting the 1991 Act as the standard for PVP laws. The foreign ministers of the Organization for African Unity issued a statement at a January 1999 meeting calling for a moratorium on IPR protection for plant varieties until an Africa-wide system had been developed that granted greater recognition to the cultivation practices of indigenous communities.[38] This option is not open to those 90 or more countries that have entered into free trade agreements with the USA, since it insists that signatories adopt the 1991 version of UPOV.[39]

4.8 The TRIPS Agreement 1994

Probably the most notorious requirement of the TRIPS Agreement is that in Art. 27.3(b), which requires that Members 'shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof'. Article 8 of the Agreement, in enunciating the principles which are to animate it, provides that 'consistent with the provisions of the Agreement', signatories may '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'.[40] It would not be too difficult to construct an argument that the obligation to protect plant varieties might be inconsistent with a given nation's need for food security. However, the opening words of Art. 8 suggest that, in case of a conflict between these provisions, the obligations within the Agreement, such as Art. 27.3(b), are paramount.

[36] ASSINSEL, Development of New Plant Varieties and Protection of Intellectual Property, Statement approved by the CSTA Board of Directors as a CSTA Position Document, No.A.99.47 (21 July 1999), available at cdnseed.org/press/A.99.47IP.htm.

[37] C. Spillane (1999) Recent developments in biotechnology as they relate to plant genetic resources for food and agriculture, Background Study Paper No. 9, Commission on Genetic Resources for Food and Agriculture, April, 41–42.

[38] See Helfer, n.33 supra at ¶ 2.2.3.

[39] See P. Drahos (2001) BITS and BIPS: bilateralism in intellectual property. *Journal of World Intellectual Property* 4, 791–808.

[40] TRIPS Agreement, art. 8.

4.9 Technical Issues Concerning the *Sui Generis* Protection of Plant Varieties Under Art. 27.3(b)

The principal technical issues concerning the implementation of effective *sui generis* protection of plant varieties under Art. 27.3(b) of the TRIPS Agreement[41] are: (i) what are 'plant varieties'? and (ii) what *sui generis* options are open to Member states?

As noted above, a crucial issue in the establishment of a *sui generis* regime would be the definition of the protected subject matter. Article 27.3(b) of the TRIPS Agreement requires the protection of 'plant varieties', but it does not provide a definition of this term. Therefore, national laws have ample room to determine what is to be deemed a plant 'variety' for the purposes of protection.

There have been lengthy discussions about the concept of 'plant variety', particularly within the framework of UPOV. The scientific notion does not necessarily coincide with the legal concept. The law may require certain characteristics for a *protected* variety that may not be essential for a scientific definition. When breeders seek protection under the traditional PBR system, plant varieties must meet the criteria that require them to be distinct, uniform and stable (DUS).[42] It has been suggested that 'uniformity' and 'stability' could be replaced by a criterion of 'identifiability', which would allow the inclusion of plant populations that are more heterogenous, and thus take into account the interests of local communities.[43] The scope of protection could be limited to cover only the reproductive parts of plants, or it could be extended to include also harvested plant materials.

The TRIPS Agreement does not prescribe any particular form of protection for plant variety innovations. It could have prescribed the UPOV Convention as the legislative norm, as it did with the Berne Convention for copyright and the Paris Convention for industrial property.[44] Thus Members have the option of enacting UPOV-like protection, of including plant varieties within their patent laws, of combining both forms of protection, or of combining UPOV-like protection with biodiversity conservation legislation.[45] The TRIPS Agreement does not prohibit the development of additional protection systems. Nor does it prohibit the protection of additional subject matter to safeguard local knowledge systems or informal innovations, as well as to prevent their illegal appropriation.

As is discussed below, the possibility of *sui generis* options for the protection of plant varieties has been used as an opportunity to introduce into the TRIPS Agreement, principles of prior informed consent (PIC) and benefit sharing, which were first enunciated in the context of the CBD. It has also been suggested that it is possible to include within the sui generic protection of plant varieties some of the Doha principles: the development dimension and the protection of TK.

41 See above n. 40 and accompanying text.
42 See, e.g., UPOV II, above n. 29 art. 6(1).
43 A. Seiler (1998) Sui generis systems: obligations and options for developing countries. *Biotechnology and Development Monitor* 34, 2.
44 See TRIPS Agreement arts 2(1), 9(1).
45 See e.g. Various systems for sui generis rights systems. *Biotechnology and Development Monitor* 36, 3 (1998), available at http://www.biotechmonitor.nl/new/index.php?link=publications.

Among the suggestions relevant to food security is the inclusion within protected varieties, those developed by local communities and national/public research institutes.[46]

4.10 Review of Art. 27.3(b)

The concluding words of Art. 27.3(b) envisaged its review by the Council for TRIPS by the end of 1999. At the 23 March 2001 meeting of the Council for TRIPS, the Chairman set out a list of key issues, which had arisen in the review of Art. 27.3(b).[47] Most of these issues are relevant to the subject of food security. These key issues were identified as:

- the link between Art. 27.3(b) and development;
- technical issues relating to patent and PVP under article 27.3(b);
- technical issues relating to the *sui generis* protection of plant varieties;
- ethical issues relating to the patentability of life-forms;
- the relationship to the conservation and sustainable use of genetic material; and
- the relationship with the concepts of TK and farmers' rights.

The link between Art. 27.3(b) and development

A number of developing countries had noted the tension between the development and technology transfer objectives of the TRIPS Agreement and the way in which the Agreement made it possible for rights owners to impose unreasonable terms for technologies. It will be recalled that Art. 7 identified the objectives of the TRIPS Agreement as including the facilitation of the transfer and dissemination of technology. India, noting the difficulties faced by developing countries to obtain access to foreign technology, urged that 'the TRIPS Agreement may be reviewed to consider ways and means to operationalize the objective and principles in respect of transfer and dissemination of technology to developing countries, particularly the least developed amongst them'.[48]

This argument was reflected in part in clause 19 of the Doha Ministerial Declaration of November 2001, which instructed the Council for TRIPS, 'in pursuing its work programme including under the review of Art. 27.3(b) … [to] be guided by the objectives and principles set out in Arts 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension'. The Doha Ministerial had set the deadline of December 2002 within which the review, referred to in Clause 19 of the Doha Declaration, was to be finalized and reported to the Trade Negotiations Committee (TNC) 'for appropriate action'. However, after Doha, the discussions in the TRIPS Council were dominated by the consideration of the public health and patenting issue and the question of PVP under Art. 27.3(b) was

[46] F. Mangeni (2001) *Technical Issues on Protecting Plant Varieties by Effective Sui Generis Systems*. South Centre, Geneva.
[47] WTO Doc., IP/C/M/26.
[48] WT/GC/W/171.

somewhat neglected. However, in anticipation of the Cancun Ministerial, Morocco, on behalf of the African Group of countries, made a Joint Communication to the Council for TRIPS, on 20 June 2003, in an endeavour to finalize the longstanding issues relating to the review of Art. 27.3(b): (i) indicating the solutions that the African Group considered needed to be found; (ii) setting out possible areas of agreement on issues that had arisen; and (iii) providing suggestions on how to resolve issues on which members had not been able to reach a common understanding.[49]

The Joint Communication maintained that the requirement to protect plant varieties should be consistent with and supportive of the public policy goals of Member States relating to food security, nutrition, the elimination of rural poverty and the integrity of local communities. Also asserted was the importance of the preservation of the system of seed saving and exchange as well as selling among farmers in which the legitimate rights of commercial plant breeders should be protected but balanced against the needs of farmers and local communities, particularly in developing Members.

The Joint Communication urged that in implementing the TRIPS Agreement, the CBD and the ITPGRFA in a mutually supportive and consistent manner, Members should retain the right to require, within their domestic laws, the disclosure of sources of any biological material that constitutes some input in the inventions claimed, and proof of benefit sharing.

Areas that were identified as those where delegations had not reached a common understanding concerned the possibility under Art. 27.3(b) for members to grant patents on microorganisms and on non-biological and microbiological processes for the production of plants or animals.

The Cancun Ministerial Meeting terminated before any TRIPS issues could be raised, but the Ministerial Declaration which was issued by the Hong Kong Ministerial meeting on 18 December 2005 reaffirmed in clause 1 the Declarations and Decisions adopted at Doha and renewed the 'resolve to complete the Doha Work Programme fully and to conclude the negotiations launched at Doha successfully in 2006'. Clause 2 of the Hong Kong Declaration emphasized 'the central importance of the development dimension in every aspect of the Doha Work Programme' and the signatories recommitted themselves 'to making it a meaningful reality' both in relation to the negotiations on market access and to a number of specific development-related issues discussed below.

The development implications of Art. 27.3(b) in relation to food security have been raised in two contexts: (i) the privatization of rights in genetic material and plant varieties, as well as in enabling technologies; and (ii) the securing of intellectual property rights in biological resources obtained from developing countries ('biopiracy').

As is discussed in subsequent chapters, the privatization of biological material could compromise agricultural innovations by developing countries, first, by depriving them of advantageous traits, such as disease resistance, early ripening and postharvest storage capacity. The unauthorized acquisition and privatization of the biological materials of developing countries deprives the latter of exploitable resources.

[49] WTO Doc., IP/C/W/404, 20 June 2003.

A communication to the WTO from Kenya, on behalf of the African Group, to assist in the preparations for the 1999 Ministerial Conference, proposed that:

> … after the sentence on plant variety protection in Art. 27.3(b), a footnote should be inserted stating that any *sui generis* law for plant variety protection can provide for:
>
> (i) the protection of the innovations of indigenous and local farming communities in developing countries, consistent with the Convention on Biological Diversity and the International Undertaking on Plant Genetic Resources;
>
> (ii) the continuation of the traditional farming practices, including the right to save, exchange and save seeds, and sell their harvest;
>
> (iii) preventing anti-competitive rights or practices which will threaten food sovereignty of people in developing countries, as is permitted by Art. 31 of the TRIPS Agreement.[50]

Relationship of Art. 27.3(b) to the CBD

In the TRIPS Council meeting of 5–7 March 2002, the WTO Secretariat was requested to prepare a report on the agenda items related to review of the provisions of Art. 27.3(b), the relationship between the TRIPS Agreement and the CBD and the protection of TK and folklore. In a summary of the issues that had been raised in the TRIPS Council on the relationship between the TRIPS Agreement and the CBD, the WTO Secretariat reported[51] that opposing arguments had been raised as to whether there was conflict between the two instruments.

Conflict was perceived by those Members, who argued that the possibility that the TRIPS Agreement provides for the privatization of genetic material by patents or PVRs is inconsistent with the sovereign rights of countries over their genetic resources as provided for in the CBD[52] and does not ensure that the provisions of the CBD, including those relating to PIC and benefit sharing, are respected.[53] The proponents of this view have suggested that Art. 27.3(b) should be amended to oblige all Members to make life forms and parts thereof non-patentable, or if this was not possible, at least those inventions based on traditional or indigenous knowledge and essentially derived products and processes should be excluded from patentability.[54] In addition there has been a suggestion that patents inconsistent with Art. 15 of the CBD not be granted and that such an obligation be incorporated into the TRIPS Agreement.[55]

The alternative argument, which was raised by a number of Members in the TRIPS Council, was that the TRIPS Agreement and the CBD have different objects and purposes and deal with different subject matter[56] and that the granting of patent rights over inventions that use genetic material does not prevent compliance with the

[50] WTO Doc., WT/GC/W/302. 6 August 1999.
[51] WTO Doc., IP/C/W/368, 8 August 2002.
[52] Ibid., para 7.
[53] Kenya, IP/C/M/28, para. 144.
[54] India, IP/C/M/25, para. 70.
[55] India, IP/C/W/196.
[56] EC, IP/C/M/30, IP/C/W/254; Japan, IP/C/M/26, IP/C/M/25,, IP/C/W/236; Norway, IP/C/M/32,, IP/C/W/293; United States, IP/C/W/209, IP/C/W/162.

provisions of the CBD regarding the sovereign right of countries over their genetic resources, PIC and benefit sharing.[57]

A third view taken in the TRIPS Council is that, while there may be no inherent conflict between the two agreements, there is considerable interaction between them[58] and a need for international action to ensure that the two agreements are implemented in a mutually supportive manner.[59] China has submitted that consideration should be given as to how the TRIPS Agreement could be implemented in a way supportive of the CBD.[60]

4.11 PVP in Developing Countries

From a food security perspective it should be noted that the UPOV Convention was originally designed to serve the interests of principally European seed breeders and in this respect reflects the industrial interests of European agriculture. Although the TRIPS Agreement does not oblige countries to follow the UPOV model in implementing their PVP obligation in Art. 27.3(b) of the TRIPS Agreement, developing countries have tended to adopt legislation on the 1991 UPOV model. As is mentioned above, this model circumscribes the seed-saving possibilities for farmers.

The value of PVRs for encouraging agricultural innovation in developing countries has not been authoritatively established. A UPOV study in 2005 looked at the impact of PVP laws in Argentina, China, Kenya, Poland and the Republic of Korea.[61] It concluded that the impact of PVP varies country-by-country and crop-by-crop. In Argentina, the introduction of new, protected varieties from non-resident breeders was observed in important agricultural crops (e.g. soybean, lucerne) and in horticultural crops (e.g. rose, strawberry). The demand for new, protected varieties was shown by their increased proportion of the certified seed area by 80–90%, particularly in soybean and wheat. An increase of horizontal cooperation in the seed industry, involving foreign seed companies and agreements for technology transfer between national research institutes and breeding entities with other national companies resulted in more rapid movement of germplasm.

As China's PVP systems have only been in operation for 5 years and for a limited number of genera and species, it was not yet possible to evaluate their full impact. Nevertheless, a rapid uptake by farmers of new, protected varieties seen, for example, in maize and wheat in Henan Province was noted, with an increase in the number of breeders in that province, as well as the introduction of new, protected varieties for major staple crops (e.g. rice, maize, wheat), horticultural crops (e.g. rose, Chinese cabbage, pear), including traditional flowers (e.g. peony, magnolia, camellia) and for forest trees (e.g. poplar).

In Kenya, an increase in the number of varieties developed and released in the 6-year period after the introduction of PVP (1997–2003), compared to the previous

[57] EC, IP/C/W/254, IP/C/M/30, para. 143.
[58] EC, IP/C/W/254.
[59] Australia, IP/C/W/310; Czech Republic, IP/C/M/33, para. 126; EC, IP/C/M/35, para. 233; Japan, IP/C/M/32, para. 142; Norway, IP/C/M/32, para. 125, IP/C/W/293.
[60] China, IP/C/M/35, para. 248.
[61] UPOV (2005) *Report on the impact of plant variety protection*. UPOV, Geneva.

6-year period (1990–1996), across a number of agricultural crops and for maize in particular was noted. Also the study noted the diversification of the horticultural sector (e.g. the emergence of the flower industry) and the increased introduction of foreign germplasm in the form of new, protected varieties (especially of horticultural crops).

In the Republic of Korea a particular impact was the extension of protection to a range of agricultural and horticultural crops, including traditional crops (e.g. ginseng) and varieties of ornamental crops such as rose. The report also noted the stimulation of rice breeding.

4.12 IP Protection of Plants and Seeds in Developing Countries

This discussion on how PVP affects food security and nutrition in developing countries leads one to consider in more general terms the applicability of such an IPR to these countries. Unfortunately, we have very few empirical studies to go on. One of the few was a joint project of the Inter-American Institute for Cooperation in Agriculture and the University of Amsterdam carried out in 1994, which examined 'the (expected) impact of PBR on developing countries with respect to: private investment in plant breeding, breeding policies of public institutes, transfer of foreign germplasm, and diffusion of seed among farmers'.[62]

Five countries were used as case studies of which three (Argentina, Chile and Uruguay) had PVP systems already in place, and two (Colombia and Mexico) were about to introduce them. These countries are similar in the sense that there are basically two seed markets. The hybrid seed market is controlled by transnational corporations, whereas the seed market for self-pollinating varieties is dominated by domestic firms.

However, Argentina differs from the others in that it is the only country in which PVP right owners have successfully enforced their rights to the extent that their control over seed supply for wheat and soya is comparable to that of their counterparts in the USA. This leads the authors of the study report to conclude that, in all probability, PVP in that country has 'prevented the local wheat companies from reducing or even terminating their breeding activities and triggered the reactivation of some soya bean breeding programmes'.

In a 2002 study for the UK Commission on Intellectual Property Rights (CIPR), Rajnekar observed that the release of new varieties as an indicator of the impact of PVPs was equivocal evidence as a number of inquiries remain before a conclusive statement on the impact of PBRs on varietal release rates can be accepted as an economic good. First, there is only partial evidence on rates of varietal release in the pre- and post-PVR period. Secondly, the availability of varieties is not necessarily an economic good in itself, as it might be that the increase in varieties may be part of wider appropriation strategies involving planned obsolescence as a means of

[62] W. Jaffé and J. van Wijk (1995) *The Impact of Plant Breeders' Rights in Developing Countries: Debate and Experience in Argentina, Chile, Colombia, Mexico and Uruguay*. Directorate General International Cooperation, Ministry of Foreign Affairs, The Hague.

maintaining market shares, which result in faster rates of varietal turnover and higher varietal release rates.

The Final Report of the CIPR noted that the evidence relating to the impact of PVP on research was sparse and mainly from developed countries and indicated that there was little or no evidence that total R&D activity had increased as a result of the introduction of PVP, suggesting that the main impact of PVP was as a marketing tool.[63]

A 1995 study conducted in middle-income developing countries in Latin America found little evidence of an increased range of plant material available to farmers or increased innovation as a result of PVP protection.[64] A UNEP study of 1996 stated that there was 'mixed and inconclusive evidence' about the direct benefits of introducing IPRs in plant varieties in developing countries.[65]

Rajnekar concludes that existing evidence of the focus of private sector plant breeding is not entirely promising because 'the range of crops focussed on and the type of agro-ecological niches being targeted do not cater to the wider needs of the majority farming populations in developing countries'.[66]

Many resource-poor farmers cultivate minor food crops that enable them to meet the nutritional needs of rural communities much better than if major crops such as wheat, rice and maize alone are cultivated. In the hills and valleys of Nepal, for example, villages may grow more than 150 crop species and cultivated varieties.[67] However, PVP generally does not encourage breeding related to minor crops with small markets. This is because the returns on breeders' research investment will be quite small. Rather, they encourage breeding targeted at major crops with significant commercial potential. Moreover, protected varieties of plants may not even be food crops. In Kenya, for example, until very recently, about half the protected new varieties were foreign-bred roses cultivated for export.

No country has yet introduced food security concerns as a factor in implementing PVR protection. However, Kenya, one of the first developing countries to have PVP legislation when it passed the Seeds and Plant Varieties Act, 1975 makes a requirement that 'the agro-ecological value [of the variety] must surpass, in one or more characteristics, that of existing varieties according to results obtained in official tests'. It should be noted however, that there was little demand from domestic breeders for this legislation; it being precipitated more by foreign horticultural firms.

[63] CIPR (2002) Integrating intellectual property rights and development policy. Report of the Commission on Intellectual Property Rights, London, CIPR, 67.

[64] J. Van Wijk and W. Jaffe (1995) *Impact of Plant Breeders Rights in Developing Countries*. Inter-American Institute for Cooperation on Agriculture, San Jose, and University of Amsterdam.

[65] UNEP (1996) *The Impact of Intellectual Property Rights System on the Conservation and Sustainable Use of Biological Diversity and on the Equitable Sharing of Benefits from its Use*.

[66] Rajnekar, n.63 supra.

[67] See A. Kothari, and R.V. Anuradha (1997) Biodiversity, intellectual property rights, and GATT Agreement: how to address the conflicts? *Economic and Political Weekly* 32, 2814–2820.

5 Genetic Resources for Food and Agriculture

It is estimated that about 6.5% of all genetic research undertaken in agriculture is focused upon germplasm derived from wild species and landraces.[1] Human intervention has been responsible for the domestication over the millennia of wild plants through a process of selection and breeding of beneficial traits. Traditionally, this germplasm was regarded as common heritage,[2] but with the expansion of IP law to agriculture, political pressure has developed for the establishment of legal means for the commons to be enclosed.[3] Consequently, a major impact upon food security is the way in which IP rights limit access to genetic resources.

Valuable genetic traits embodied in landraces and traditional varieties are identified to be valuable national resources, either *in situ* on the farm or *ex situ* in the germplasm collections of international agricultural research institutes, such as those of the CGIAR.

The CBD represents an attempt to place PGRFA within national sovereignty and accessible only through a regime that obliges the sharing of benefits and technologies. Similarly, discussion has occurred within WIPO and the WTO to make patenting of biological resources contingent upon the identification and remuneration of source countries.

The privatization of national PGFRA through IP protection is of critical importance for food security as all countries are interdependent in their reliance upon germplasm from other countries. Thus by way of example it is estimated that Bangladeshi rice contains four varieties from its own landraces and 229 borrowed landraces, and USA rice comprises 219 native landraces and 106 borrowed

[1] See J.A. McNeely and S.J. Scherr (2002) Wild biodiversity under threat. In: *Ecoagriculture: Strategies to Feed the World and Save Wild Biodiversity.* Island Press, New York, chap. 2.

[2] A. Crosby (1986) *Ecological Imperialism: The Biological Expansion of Europe, 900–1900.* Cambridge University Press, Cambridge.

[3] See A.J. Stenson and T.S. Gray (1999) *The Politics of Genetic Resource Control.* St Martin's Press, New York.

landraces.[4] A similar interdependence applies to all major food crops.[5] The interdependence of countries on PGRFA is reflected both at the level of international exchanges of plant genetic materials in support of research, breeding and production, and, as indicated above, at the level of individual cultivars, which incorporate PGRFA from numerous countries. Consequently, legal regimes concerned with the protection of these resources have to recognize the difficulty of identifying the countries of origin for crops that have been widely exchanged and that may have developed their distinctive properties in any number of different areas.

These facts concerning interdependence and food security were taken into consideration by the international community in the negotiation of the ITPGRFA.[6] The Treaty creates, *inter alia*, an MLS of access and benefit sharing (ABS) under which 'facilitated access' is provided to the PGRFA of crops and forages listed in Annex 1 to the Treaty. These crops and forages are selected 'according to criteria of food security and interdependence' (Art. 11.1). Access to PGRFA of such crops and forages is to be provided free or at a minimal cost. In this way, the MLS constitutes a common pool of genetic material available for all for the purposes of research and breeding. The Treaty attempts to create an international genetic resources commons, by seeking to circumscribe the propertization of certain important categories of crops and forages.[7]

In 1990, the FAO initiated the preparation of a comprehensive programme for the sustainable management of animal genetic resources at the global level. In 1993, the FAO launched the Global Strategy for the Management of Farm Animal Genetic Resources to guide national, regional and global efforts to strengthen the contribution of domesticated animals and their products to food security and rural development, and to prevent the erosion of animal genetic resources. In September 2007, 109 countries participated in the first International Technical Conference on Animal Genetic Resources for Food and Agriculture held in Interlaken, Switzerland. The Conference adopted the Global Plan of Action for Animal Genetic Resources and the Interlaken Declaration on Animal Genetic Resources to ensure that the world's livestock biodiversity is utilized to promote global food security.

5.1 CGIAR

Introduction

The First Green Revolution can be traced back to the work of Norman Borlaug, a US plant breeder, who won the Nobel Prize in 1970 for his work in developing high-yielding wheat varieties for Mexico. Borlaug was the founding father of the

[4] See C. Fowler and T. Hodgkin (2004) Plant genetic resources for food and agriculture: assessing global availability. *Annual Review of Environmental Resources* 29, 10.1–10.37.

[5] See the studies referred to in System-wide Genetic Resources Programme (SGRP) (2006) *Annotated Bibliography Addressing the International Pedigrees and Flows of Plant Genetic Resources for Food and Agriculture.* IPGRI, Rome.

[6] See UNEP/CBD/GTE-ABS/1/3/Add.2, 13 December 2006.

[7] See M. Halewood and K. Nnadozie (2008) Giving priority to the commons: the International Treaty on Plant Genetic Resources for Food and Agriculture. In: G. Tansey and T. Rajotte (eds) *The Future Control of Food. A Guide to International Negotiations and Rules on Intellectual Property, Biodiversity and Food Security.* Earthscan, London, 115.

CIMMYT, which became the first of the international agricultural research centres, and became associated with the CGIAR.[8] Each of these centres undertakes research into crops, livestock and materials of interest to developing countries. In addition to conducting research, the CGIAR supports a collection of germplasm, which currently comprises over 600,000 accessions of more than 3000 crop, forage and pasture species held at the research centres. In addition to the so-called 'designated germplasm', which is held under the trust relationship with the FAO, the various CGIAR Centres have developed 'elite germplasm' and biological tools, such as isogenic lines, mutants and mapping populations, from the materials which have been deposited with them.

The international agricultural research centres of the CGIAR were at the forefront of the public agricultural research effort, which until the 1990s represented some 80% of funding for agricultural research. Subsequently, the research expenditures of national research institutes have exceeded that of the CGIAR,[9] but more significantly, the investment in agricultural research by private seed companies has increased to about one third of global expenditure.[10] The application of IPR in agricultural research is the principal explanation for what in effect has become the privatization of agricultural research. As is discussed below, the creation of IPR in plant varieties developed through classical breeding and the propertization of genetic resources and associated enabling technologies through innovations in patent law have been the vehicles through which private agro-industrial enterprises have assumed a dominant position in agricultural research.

This development has a number of significant implications for food security. Principal among these are: (i) the research priorities of the private agricultural research sector are not necessarily congruent with the interests of developing countries, particularly in relation to the food crops which are the focus of private research; (ii) enabling technologies and useful genetic materials have increasingly become concentrated in the private sector; (iii) the commercial objective of private agricultural innovators, to secure control over seed germination to oblige farmers to pay for each planting, is inconsistent with the traditional seed-saving practices of farmers; and (iv) the commercial objective of private seed companies has been to encourage monocultures based on their proprietary products, which has resulted in a loss of important genetic diversity and in adverse environmental impacts.

'Biopiracy'

The propertization of agricultural research has invested the biological resources of the CGIAR Centres with considerable value as source materials for the development of PGRFA. An indication of this value is illustrated by a number of instances of

[8] These centres are: the CIAT, CIFOR, CIP, ICARDA, International Center for Living Aquatic Resources Management (ICLARM), ICRAF, ICRISAT, ILRI, IITA, International Plant Genetic Resources Institute (IPGRI), IRRI and WARDA.

[9] P. Pardey and R. Beintema, Slow Magic; Agricultural R&D a Century After Mendel, IFPRI, 26 October 2001.

[10] Ibid., 8.

'biopiracy' in which the genetic resources of CGIAR Centres have been used as the basis of IPR applications by private parties.[11]

For example, germplasm ownership concerns were raised in 1998 as a consequence of PBR applications made in Australia by a number of agricultural research institutes in relation to a peavine and a lentil, which had been bred from genetic stock obtained from the CGIAR gene bank: the ICARDA, located in Aleppo, Syria. The 14 February 1998 issue of *New Scientist* contained an editorial and leading article on the alleged biopiracy of two Australian agricultural agencies. The two agencies, Agriculture Western Australia and the Grains Research and Development Corporation (GRDC), had apparently applied for PBR under the Australian PBRA, 1994, in relation to two species of chickpea which had been bred from material which had been provided by the ICRISAT. The Australian PBR Office did not have an opportunity to make a determination on the registrability of these varieties because the furore caused by these applications led to their withdrawal, prior to determination.

The *New Scientist* editorialized that 'it was hard to imagine what two Australian government agricultural agencies thought that they were up to when they applied for property rights on chickpeas grown by subsistence farmers in India and Iran'.[12] A feature article in the *New Scientist* carried an accusation from a spokesperson from the South Asian Network on Food, Ecology and Culture, which described the PBR applications as 'blatant biopiracy' by 'privatising seeds that belong to our farmers and selling them back to us'.[13]

Reacting to the biopiracy controversy, CGIAR called for a moratorium on the granting of IPR over plant germplasm held in its centres. CGIAR Chairman, Dr Ismail Serageldin, explained the call for a moratorium as 'the strongest signal the CGIAR can send governments to ensure that these issues be resolved and the materials in the CGIAR remain in the public domain'.[14] In Australia, serious concerns were expressed about the implications that such a moratorium would have, particularly for its cultivation of cereals. Consequently, to prevent a recurrence of this incident, the operating regulations of the Australian PBR Office were amended to oblige applicants for PBRs in relation to varieties derived from germplasm obtained from CGIAR Centres, to document that such applications were made with the permission of the relevant Centre.

An illustration of the impact of patenting upon the research activities of the CGIAR Centres is provided by an incident arising from the development by the IRRI of blight-resistant rice. In the late 1970s, a strain of rice from Mali, *Oryza longistaminata*, was identified by a researcher, working in Cuttack, North India, as being resistant to bacterial blight, a disease that particularly afflicts rice. In 1978, this resistant sample was taken to the IRRI in Los Banos, Philippines for further investigation. Over a 15-year period, IRRI researchers developed through conventional breeding, a high-yielding, blight-resistant strain of rice. The IRRI researchers

[11] For an Analysis of Claims of Unauthorised Access and Misappropriation of Genetic Resources and Associated Traditional Knowledge, see UNEP/CBD/WG-ABS/4/INF/6, 22 December 2005.

[12] Editorial. Lest We Starve. *New Scientist*, No. 2121, 3, 14 February 1998.

[13] Edwards and Anderson, Seeds of Wrath. Ibid., 14.

[14] CGIAR Press Release. CGIAR Urges Halt to Granting of Intellectual Property Rights for Designated Plant Germplasm, 11 February 1998, http://www.cgiar.org:80/ germrel.htm.

identified that this resistance was contributed by a single locus called Xa21. A post-doctoral research fellow, Dr Ronald, from the University of California at Davis, who was working at IRRI, was permitted with co-workers at Stanford University to map, sequence and clone the Xa21 gene. The molecular mapping process was facilitated by the construction of a BAC library utilizing a biological tool provided by IRRI.

On 7 June 1995, the Regents of the University of California filed a patent application for 'Nucleic acids, from *Oryza sativa*, which encode leucine-rich repeat polypeptides and enhance *Xanthomonas* resistance in plants'. The inventors named in the application were Dr Ronald and her co-workers. The patent was granted by the US Patents and Trademark Office (USPTO) on 12 January 1999 (US patent 5,859,339). This patent generated some controversy in CGIAR circles because it was perceived to compromise IRRI's research efforts and those of its clients in the rice-producing regions of Asia. Bacterial blight is not a particular problem for US rice producers and a primary effect of the patent was to prevent the export of bacterial blight-resistant rice, utilizing the patent to the USA. UC Davis initially sought royalties from IRRI for the use by it or its clients of Xa21. A licence was negotiated with UC Davis to allow non-commercial researchers access to the gene, provided they did not develop commercial products based on that gene. This would have the effect of preventing rice producing countries, which used the gene, from exporting into the US market. This patent also raised the question of equitable compensation, at least for the traditional farmers of Mali who had conserved *O. longistaminata*. The UC Davis dealt with the issue of compensation by establishing a Genetic Resources Recognition Fund (GRRF) as a mechanism to share benefits arising from the commercial utilization of its patent. It was also acknowledged that in the absence of this sort of mechanism, it would have been 'more difficult for the university in the future to obtain research access to developing countries' national genetic materials'.[15]

A particularly egregious example of the propertization of germplasm relied upon by developing country farmers was the grant by the US Patent and Trademarks Office of a patent (no. 5,894,079) on 13 April 1999 to Larry Proctor for an invention described in the patent grant as relating to 'a new field bean variety that produces distinctly colored yellow seed which remain relatively unchanged by season'. Mr Proctor was the president of a Colorado (USA)-based seed company, POD-NERS. Upon the grant of the patent, this company was reported to have written to all the importers of Mexican beans in the USA, requiring the payment of a royalty of 6 cents per pound.[16] According to Miguel Tachna Felix, of the Agricultural Association of Rio Fuerte, this would have meant an immediate drop in export sales, over 90%. POD-NERS was reported to have brought infringement actions against two companies that were selling Mexican yellow beans in the USA. In January 2000, the Mexican Government announced that it would challenge the US patent. On 20 December 2000, CIAT filed a formal request for re-examination of the US patent

[15] P. Ronald quoted in WIPO/UNEP (2001) *The Role of Intellectual Property Rights in the Sharing of Benefits Arising from the Use of Biological Resources and Associated Traditional Knowledge. Selected Case Studies.* WIPO, Geneva, 13.

[16] Mexican Bean Biopiracy, Biotechnology Notice Board, posted by: PANUPS panupdates@panna.org , 24 January 2000.

concerning the yellow bean, which was alleged to be the Mexican Enola bean.[17] CIAT's official request for re-examination of the patent stated that the claims for inventiveness contained in the patent failed to meet the statutory requirements of novelty and non-obviousness, and ignored the prior art widely available in the literature. The challenge was particularly critical of the patent's claim of exclusive monopoly on any *Phaseolus vulgaris* (dry bean) having a seed colour of a particular shade of yellow. Although there was no evidence that the patent owner obtained his yellow beans from CIAT's germplasm collection, the patent challenge noted that CIAT maintained some 260 bean samples with yellow seeds, and six of the accessions were 'substantially identical' to claims made in the patent.[18] CIAT's patent challenge also asserted that the yellow bean was 'misappropriated' from Mexico, and that this was in breach of Mexico's sovereign rights over its genetic resources, as recognized by the CBD.

The USPTO revoked Proctor's patent on 29 April 2008. During that time, in 2004, scientists published evidence that the Enola bean was identical to at least six bean varieties in the gene bank of CIAT.[19]

In November 1999, five traditional Peruvian varieties of yacon held in the genebank at the CIP in Peru were distributed to the Peruvian Ministry of Agriculture, which passed them to researchers in Japan. Yacon (*Smallantus sonchifolius*), an ancient Andean crop, is eaten raw as a fruit in the Andes. It has a high fructose content with a high percentage of insulin and leaves reported to have antidiabetic properties.[20] CIP's Potato Germplasm Curator, Dr Zozimo Huaman, alleged that this distribution of yacon by CIP was in breach of its trust obligations, particularly because the biosafety requirements of the Centre were apparently not followed.[21] Japanese researchers, in a seminar at CIP in September 2000, indicated that the area cultivated with yacon in Japan had been greatly increased in recent years and that it was utilized as a vegetable, pickles and juices. They also reported that the National Shikoku Agriculture Experiment Station had released the first commercial variety named 'Sarada-Otome' on 25 August 2000. Dr Huaman expressed concern that, apparently because of PBR, the Japanese researchers were not prepared to send germplasm of 'Sarada-Otome' to be tested in Peruvian farmers' fields. He questioned the equity of denying to a source country, new derivatives of deposited germplasm. Upon learning of Dr Huaman's allegation, CIP requested its Genetic Resources Policy Committee (GRPC) to determine if any violation of the FAO agreement had occurred. The GRPC, chaired by Dr M.S. Swaminathan, was established by CIP as an independent advisory committee made up of internationally known scientists as well as representatives of the NGO community, private sector, and developing and developed country governments. The committee concluded that CIP had no right to interfere in Peru's sovereign decision to

[17] RAFI, Enola Bean Patent Challenged. News Release, 5 January 2001, www.rafi.org.
[18] Ibid.
[19] http://www.scidev.net/en/news/-biopiracy-thwarted-as-us-revokes-bean-patent.html.
[20] National Research Council (1989) *Lost Crops of the Incas: Little Known Plants of the Andes with Promise for Worldwide Cultivation*. National Academy Press, Washington DC.
[21] See e.g. Z. Huaman, Unethical distribution to Japan of Yacon held in trust by CIP. Circulated on the biodiv-conv listserver run by BIONET (http://www.bionet-us.org), 7 April 2001.

send the germplasm to Japan and commended CIP for its proper management of its germplasm held 'in-trust'.[22]

On 21 March 2000, a patent[23] was granted to a US corporation in relation to a 'bean-nut popping bean' apparently derived from crosses involving at least 33 Andean nuna bean varieties from Peru, Bolivia, Ecuador and Colombia. In February 2001, a meeting of a tribunal of indigenous elders from six Andean communities demanded that the CIAT, the CGIAR Centre based in Cali, Colombia, uphold its obligation under the FAO 'trust agreement' to keep farmer-bred bean varieties in the public domain. The patent was described as 'particularly offensive to Andean farmers and indigenous people' because it extended to crosses involving at least 33 Andean nuna varieties traditionally bred and developed over centuries in Peru, Bolivia and Ecuador, all of which were freely provided by Andean farming communities, 'who allowed their bean varieties to be put into the public realm in order to ensure the continued maintenance of the world's seed biodiversity'. Nine of these varieties were held in CIAT's international bean collection as designated in-trust accessions, all being farmers' varieties collected in Peru.

A final illustration of biopiracy influencing the international IP environment is the so-called Basmati affair.[24] This commenced when RiceTec, an American company based in Alvin, Texas, was granted a patent by the USPTO in September 1997 for 'Basmati rice lines and grains'.[25] The 'novel rice lines' were described in the patent as 'lines whose plants are semi-dwarf in stature, substantially photoperiod insensitive and high yielding' and which 'produce rice grains having characteristics similar or superior to those of good quality basmati rice'. In March 1998, an NGO, the Research Foundation for Science, Technology and Ecology, petitioned the India Supreme Court to direct the government to challenge the patent, or to commence an action with the Dispute Settlement Body of the WTO. The Indian Government commenced an action in the USPTO in April 2000, challenging three of the patent claims (15–17). In response, RiceTec withdrew four claims, one of which was not being challenged, and in August 2001 the USPTO claims 15–17, as well as several others that were not being challenged.

Responding to concerns about the impact of IPR upon the operation of the CGIAR, it commissioned a report on the use of proprietary technologies by CGIAR Centres by the International Service for National Agriculture Research (ISNAR), which operates as its legal advisory body.[26] The report noted the burgeoning use of proprietary technologies by the centres and recommended that they undertake audits of their IP management policies. ISNAR established a Central Advisory Service to provide legal counsel for the centres on IP matters.

The principal impact of these biopiracy episodes, relevant to the question of food security, has been the reluctance of countries to contribute germplasm to CGIAR Centres. This will have an adverse effect upon the plant breeding programmes of the

[22] See K. Zandstra, Potato Center Upholds Letter and Spirit of FAO Agreement (http://www.bionet-us.org), 9 April 2001.

[23] US Patent No. 6,040,503; Patent Cooperation Treaty patent no.WO99/11115.

[24] Discussed in M. Lightbourne (2005) Of rice and men: an attempt to assess the Basmati affair. *Journal of World Intellectual Property* 6, 875.

[25] Patent 5,663,484 (USPTO).

[26] J. Cohen, C. Falconi, J. Komen and M. Blakeney (1998) *The Use of Proprietary Biotechnology Research Inputs at Selected CGIAR Centres*. CGIAR, The Hague.

Centres and the consequent provision of improved seed to poor farmers. Another effect has been the response of the donor community, which funds the CGIAR Centres, to induce them to emulate the private sector and to exploit their biological resources in support of their research mandate. Some CGIAR Centres perceive that Centre-generated IP might be used as a bargaining chip, to be traded for biological tools patented by the private sector. For example the *Policy on Intellectual Property* of the CIMMYT envisages that IP protection may be sought 'to facilitate the negotiation and conclusion of agreements for access to proprietary technologies of use to CIMMYT's research and in furtherance of its mission'.[27] It is questionable whether the trade in CGIAR products will counterbalance the reduction in funding.

A final agricultural example of 'biopiracy' from outside the CGIAR system which has food security implications, is the patenting by AgrEvo of a gene isolated from *Streptomyces viridochromogenes*,[28] a microorganism isolated from Cameroonian soil, which is responsible for the tolerance of their herbicide, glufosinate, sold under the tradename Basta, which is one of their best-selling products.[29] Despite the successful commercialization of this chemical, no benefits have been shared with Cameroon.[30]

These various episodes concerning the 'biopiracy' of agricultural resources, together with the many examples of similar activities concerning medical resources,[31] have generated considerable impetus for legal measures to regulate this activity. 'Biopiracy' has been described as 'the manipulation of IPR by those intending to have exclusive control over genetic resources and traditional knowledge without giving adequate recognition or remuneration to the original possessors of these resources'.[32] As will be seen below, the focus of the legislation that seeks to deal with this activity is to guarantee the equitable sharing of benefits on the basis of informed consent.

5.2 The CBD

Introduction

The Rio Earth Summit, which was convened in June 1992, promulgated the CBD, The Rio Declaration on Environment and Development and Agenda 21. The CBD represented an attempt to establish an international programme for the conservation

[27] CIMMYT, *Policy on Intellectual Property*, Article III.4.v, www.cimmyt.org/resources/obtaining/seed/ip_policy/htm/ip-policy.htm.

[28] US patent No. 5,276,268.

[29] P.R. Mooney (1988) The parts of life: agricultural biodiversity, indigenous knowledge, and the role of the third system. *Development Dialogue,* Special Issue. Dag Mammrskjolk Foundation, Uppsala.

[30] M.T. Mahop (2006) Community rights and biodiversity regulations: lessons from Cameroon and South Africa. PhD thesis, Queen Mary, University of London, 132.

[31] See M. Blakeney (1997) Protection of traditional medical knowledge of indigenous peoples. *European Intellectual Property Review* 19, 298; P.R. Mooney (2000) Why we call it biopiracy. In: H. Svarstad, and S.S. Dhilion (eds) (2000) *Responding to Bioprospecting. From Biodiversity in the South to Medicines in the North.* Spartacus Forlag AS, Oslo, 37; P. Shuler, Biopiracy and commercialisation of ethnobotanical knowledge. In: J.M. Finger and P. Schuler (eds) (2004) *Poor People's Knowledge: Promoting Intellectual Property in Developing Countries.* Oxford University Press, Oxford, 159; P. Cullet (2005), *Intellectual Property and Sustainable Development.* LexisNexis, New Delhi, 298ff.

[32] M. A. Bengwayan (2003) *Intellectual and Cultural Property Rights of Indigenous and Tribal Peoples in Asia.* Minority Rights Group International, London, 22.

and utilization of the world's biological resources[33] and for the 'fair and equitable sharing' of the benefits arising from the utilization of genetic resources.[34] 'The single most divisive issue in the negotiations was the relationship between intellectual property rights and access to genetic resources.'[35] The developing countries of the South, generally speaking the most with substantial source of genetic resources, sought to use the CBD as a means of bargaining access to those resources for royalties, technology and research data. Thus the CBD contains articles on access to genetic resources (Art. 15); access to and the transfer of technology (Art. 16); informed consent and the distribution of benefits of biotechnological innovations (Art. 19). The industrialized group of countries, obviously the principal source of biotechnological innovation, insisted that the CBD did not conflict with IPR. Thus for example, Art. 16 (2) contains the statement that 'In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights'.

Reflecting the uncomfortable political deal which was struck in bringing the CBD to conclusion, the language of the Convention is unfortunately vague. The positive affirmation of principles in a number of areas is qualified by vague transcendental values. Thus the respect for IP affirmed by Art. 16 (2) is counterbalanced by the phrase in the same provision that 'access to and the transfer of technology … shall be provided and/or facilitated under fair and most favourable terms …'. Similarly, Art. 15(4) provides that 'access [to genetic resources] where granted shall be upon mutually agreed terms'. Art. 19(2) provides that 'access … to the results and benefits arising from biotechnologies … shall be on mutually agreed terms'. Since mutuality is a precondition for an agreement of any sort, these provisions may be mere rhetoric. On the other hand, they may be a guarantee against unilateral expropriation.

Scope of the CBD Access Regime

Article 1 of the CBD envisages 'appropriate access to genetic resources' and 'the fair and equitable sharing of benefits arising out of the utilization of genetic resources'. 'Genetic resources' are defined in Art. 2 as meaning 'genetic material of actual or potential value'. The term 'genetic material' is then defined in Art. 2 to mean 'any material of plant, animal, microbiological or other origin containing functional units of heredity'. On a strict analysis of this definition, it is suggested that biochemical extracts which do not contain DNA or RNA would be outside the scope of the CBD.[36] Thus the Convention would apply to seeds and cuttings and DNA extracted from a plant, such as a chromosome, gene, plasmid or any part of these such as the promoter part of a gene.[37]

[33] See F. McConnell (1996) *The Biodiversity Convention. A Negotiating History.* Kluwer, London.

[34] CBD, Art. 1.

[35] P. Chandler (1993) The Biodiversity Convention: selected issues of interest to the international lawyer. *Colorado Journal of International Environmental Law and Policy* 4, 141 at 161.

[36] See L. Glowka, F. Burhenne-Guilmin and H. Synge (1994) *A Guide to the Convention on Biological Diversity.* International Union for the Conservation of Nature (IUCN), Gland, 3.

[37] See L. Glowka (1998) *A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources.* IUCN, Gland, 4.

Article 9 deals with 'the conservation of components of biological diversity outside their natural habitats', e.g. in germplasm and seed banks, botanical gardens, museums, laboratories and agricultural research institutions. This article calls for national legislation to provide for the acquisition, conservation, storage and management of these *ex situ* collections. The ABS provisions of the CBD do not apply to the genetic resources of a country that were collected prior to the entry of the CBD into force in that country.[38] Thus a country with a pre-existing collection of genetic material has the sovereign right to control access to that collection, but has no legal right to insist upon a share of any benefits derived from the use of that collection. Also, the CBD applies to those genetic resources that originate in the country of a contracting party.

The rationale for the access regime of the CBD is that countries with genetic diversity, typically developing countries, would be able to generate funding for development and conservation.

Sovereign rights over genetic resources (Art. 15(1))

Article 15(1) of the CBD affirms 'the sovereign rights of States over their natural resources' and provides that 'the authority to determine access to genetic resources rests with the national governments and is subject to national legislation'. This provision, dealing as it does with access to genetic resources, does not refer to the question of the ownership of genetic resources. This leaves unanswered the ownership issues raised by the creation of the CGIAR germplasm collections.

Mutually agreed terms, PIC and benefit sharing

Article 15(4) of the CBD envisages that where access is granted it will be subject to mutually agreed terms. Currently the conventional form of access agreement is the Material Transfer Agreement (MTA). A number of the provisions of the CBD refer to the equitable sharing of benefits arising from the utilization of the genetic resources of a signatory. Article 15(7) requires each Contracting Party to 'take legislative, administrative or policy measures, as appropriate' and in accordance with a number of specified provisions of the Convention, 'with the aim of sharing in a fair and equitable way, the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources'. Article 8(j) envisages the 'equitable sharing' of benefits with indigenous and local communities, arising out of the use of the TK, innovations and practices of those communities. Article 21 provides for the establishment of a 'mechanism' for the provision of financial resources to developing country parties to the CBD.

Complementary to the equitable sharing of benefits, the CBD provides for the access of developing country signatories to technologies which may result from the

[38] CBD, Art. 15(3) and see A.A. Yusuf, International law and sustainable development: the Convention on Biological Diversity. In: A.A. Yusuf (ed.) (1995) *African Yearbook of International Law*, vol. 2. Kluwer, The Hague, 109.

utilization of the genetic resources which they may provide. Article 16(1) recites the importance of access to biotechnologies to attain the objectives of the CBD and Art. 16(2) provides for the access to technologies by developing countries on 'fair and equitable terms, including on concessional and preferential terms'. Article 19(1) requires parties to take appropriate measures to 'provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research'. Article 19(2) requires parties to 'take all practicable measures to promote and advance priority access on a fair and equitable basis … especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contacting Parties' on mutually agreed terms.

Development of an international access regime

At the second COP, held in Jakarta, 6–17 November 1995, a Report including 'Possible elements of guidelines on mutually agreed terms' was tabled.[39] The possible elements suggested to Parties for inclusion in ABS arrangements included, *inter alia*, 'agreeing on respective *intellectual property rights* over the genetic resources and technologies developed using them'. The fourth COP decided in Decision IV/8 to establish a Panel of Experts with the mandate 'to draw upon all relevant sources … in the development of a common understanding of basic concepts and to explore all options for access and benefit sharing on mutually agreed terms including guiding principles, guidelines, and codes of best practice for access and benefit-sharing arrangements'.

The Panel of Experts on ABS, at its first meeting held in San José, Costa Rica, 4–8 October 1999, concluded that one of the 'key lessons with respect to promoting mutually agreed terms in access and benefit-sharing arrangements' is that 'Contractual agreements, for the moment, are the main mechanism for gaining access to genetic resources and delivering benefits'.[40] Considering that transaction costs have a significant impact on actual use of genetic resources, the Panel identified 'standardized Material Transfer Agreements' as one of the mechanisms to reduce transaction costs.

The fifth COP in Decision V/26 had decided, *inter alia*, to establish an Ad Hoc Open-Ended Working Group on ABS with

> … the mandate to develop guidelines and other approaches for submission to the Conference of the Parties and to assist Parties and stakeholders in addressing the following elements as relevant to access to genetic resources and benefit-sharing, *inter alia*: terms for prior informed consent and mutually agreed terms; roles, responsibilities and participation of stakeholders; relevant aspects relating to *in situ* and *ex situ* conservation and sustainable use; mechanisms for benefit-sharing, for example through technology transfer and joint research and development; and means to ensure the respect, preservation and maintenance of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and

[39] UNEP/CBD/COP/2/13, Section H, paras 90–92.
[40] See UNEP/CBD/COP/5/8, paras 50 and 53.

> sustainable use of biological diversity, taking into account, *inter alia*, work by the World Intellectual Property Organization on IPR issues.

At COP V, the Ad Hoc Open-ended Working Group on ABS was established and at its first meeting in Bonn, in October 2001, the Ad Hoc Working Group on ABS developed the draft *Bonn Guidelines on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising Out of Their Utilization*. The Seventh COP in Decision VII/19 adopted the Bonn Guidelines on a non-binding basis.

The World Summit on Sustainable Development (WSSD) in 2002 called for an international regime to be negotiated within the framework of the CBD and the Bonn Guidelines to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources.[41] The status of the international regime on ABS was reported to the eighth meeting of the COP in Curitiba, 20–31 March 2006. Much of the text of the proposed regime remains unresolved and within square brackets.[42] Agreement has still to be reached as to whether the international regime will be legally binding and/or non-binding. The parties have agreed that 'access procedures shall be clear, simple and transparent and provide legal certainty to different kinds of users and providers of genetic resources with a view to the effective implementation of Art. 15, [paragraph 2], of the Convention on Biological Diversity'. However, the scope of application of the regime has not been agreed, nor the minimum conditions for the fair and equitable sharing of the benefits arising out of the use of genetic resources, derivatives or products.

Sanctions for non-compliance with the access regime are also to be agreed. Currently listed within square brackets as acts or cases of misappropriation are:

> (a) Use of genetic resources, their derivatives and products and/or associated traditional knowledge without compliance with the provisions of the international regime;
>
> (b) Any acquisition, appropriation or utilization of genetic resources, their derivatives and products and/or associated traditional knowledge by unfair or illicit means;
>
> (c) Deriving commercial benefits from the acquisition, appropriation or utilization of genetic resource, derivatives and products and/or associated traditional knowledge when the person, using genetic resource, derivatives and products, knows, or is negligent in failing to know, that these were acquired or appropriated by unfair means;
>
> (d) Other commercial activities contrary to honest practices that gain in equitable benefit from the genetic resource, derivatives and product and/or associated traditional knowledge;
>
> (e) Use of genetic resources, their derivatives and products and/or associated traditional knowledge for purposes other than for which it was accessed; and
>
> (f) Obtaining unauthorized information that can be used for the reconstitution of genetic resources, derivatives or products or traditional knowledge.

[41] Para 44(o), Plan of Implementation adopted by the World Summit on Sustainable Development, Johannesburg, September 2002, www.un.org/esa/sustdev/documents/WSSD_POI_PD/English/WSSD_PlanImpl.pdf

[42] See UNEP/CBD/COP/8/1/Add.2.

Patentability of genetic resources and the CBD

As was noted in Chapter 3, a key food security concern is the tension between the TRIPS Agreement and the CBD. For example, the principle in Art. 27 of TRIPS that patents be available in all fields of technology, for example in relation to biotechnology, might be inconsistent with the CBD because in limiting access to genetic material there is a perceived conflict with the sovereign rights of countries over their genetic resources[43] and PIC as a condition of such access.[44] On the other hand it is stated a patent on an isolated, identified and modified gene provides the patentee only with the ability to prevent others from producing, marketing and using the modified gene. The source from which the gene was taken would be unaffected by the patent.[45]

Concern has also been expressed that the grant of overly broad patents could impede access to and use of genetic resources in a way that gives rise to questions of compatibility with the CBD.[46] A related concern has been expressed about patent rights over genetic resources that restrict research by third parties.[47] It has therefore been suggested that the TRIPS Agreement should be amended so as to require, or to enable, WTO Members to require that patent applicants disclose, as a condition to patentability: (i) the source of any genetic material used in a claimed invention; (ii) any related TK used in the invention; (iii) evidence of PIC from the competent authority in the country of origin of the genetic material; and (iv) evidence of fair and equitable benefit sharing.[37] It has been suggested that such provisions could be incorporated into the TRIPS Agreement by amending Art. 27.3(b)[48] or Art. 29.[49]

In response to this, the view has been expressed that such a provision is neither necessary nor desirable for implementing the PIC and benefit-sharing provisions of the CBD. IP rights do not aim to regulate the access and use of genetic resources or the terms and conditions for bio-prospecting. In accordance with the CBD, countries could incorporate in their national legislation requirements for the conclusion of contracts between the authorities competent for granting access to genetic resources and those wishing to make use of such resources and TK. Such contracts would detail the terms and conditions under which access and use is granted.[50] It has also been suggested that the benefit-sharing provisions of the CBD could be implemented through governmental fund-granting activities.[51]

In response, it has been said that reliance on a system of voluntary contracts has a number of significant drawbacks from the perspective of developing countries. It does not address the situation where bio-prospecting and use of genetic resources and TK might take place without the authorization of the competent authority in the country of origin and therefore without the conclusion of any contract.[52] While such actions

[43] WTO Docs., Kenya, IP/C/M/28, para. 141; Peru, IP/C/M/29, para. 175.
[44] EC, IP/C/W/254, IP/C/M/30, para. 143.
[45] United States, IP/C/W/162.
[46] Brazil, IP/C/W/228, IP/C/M/29, para. 146; India, IP/C/M/28, para. 126.
[47] Kenya, IP/C/M/28, para. 141; Mauritius on behalf of the African Group, IP/C/W/206.
[48] Brazil, IP/C/W/228, IP/C/M/32, para. 128, IP/C/M/33, para. 121.
[49] India, IP/C/W/195, IP/C/M/24, para. 81.
[50] United States, IP/C/W/257.
[51] Japan, IP/C/W/236.
[52] Peru, IP/C/M/35, para. 236, IP/C/M/32, para. 133.

might be illegal under the law of the country of origin, there might be little that could be done under that law once the genetic material and TK is being used outside that jurisdiction.[53] There is also the problem of inequality of bargaining power between parties.[54]

At COP VIII in Curitiba, 20–31 March 2006, the text of the proposed access regime in relation to IP applications whose subject matter '[concerns or makes use of] [is directly based on] genetic resources [and/or derivatives and products] and/or associated traditional knowledge' proposes that such applications 'should disclose the country of origin or source of such genetic resources, [derivatives and products] or associated traditional knowledge, [as well as evidence that provisions regarding prior informed consent and benefit sharing have been complied with, in accordance with the national legislation of the country providing the resources]'. It is also agreed that 'the international regime may establish an international certificate of origin/source/legal provenance of genetic resources' to be issued by 'the [provider country] [country of origin]'. It is yet to be agreed whether this certificate will certify compliance with national consent and benefit sharing arrangements and whether the recipients of genetic material can make applications for patents related to such genetic materials, without the consent of the provider country or country of origin. [55]

Regional and national responses to the CBD

The implementation of CBD principles has been attempted in a number of regional framework agreements: (i) Decision 391 of the Andean Community on a Common System on Access to Genetic Resources; (ii) the Organization of African Unity (OAU, now African Union, AU) Model Legislation for the Recognition of the Rights of Local Communities, Farmers and Breeders and for the Regulation of Access to Biological Resources; and (iii) the draft Association of Southeast Asian Nations (ASEAN) Framework Agreement on Access to Biological and Genetic Resources. These framework agreements have been developed by regional economic integration organizations in an endeavour to set minimum standards for determining access to genetic resources within a region; to ensure that national access regulations are uniform and consistent with the identified minimum standards; and to strengthen the negotiating capacity of the member countries to the framework agreement.

Article 16 of Decision 391 of the Andean Community[56] provides in Chapter I that '[a]ll access procedures must include the presentation, admission, publication and approval of an application, signature of a contract, issue and publication of the corresponding resolution and a declaratory record of actions linked with such access'. Contractual agreements may be used to establish the specific terms and conditions for ABS in respect of individual genetic resources and associated subject matter, such as derivatives or biodiversity-related TK. Typically, it is required that the terms of the

[53] Brazil, IP/C/M/32, para. 128.
[54] Pakistan, IP/C/M/28, para. 158.
[55] See UNEP/CBD/COP/8/1/Add.2.
[56] Bolivia, Colombia, Ecuador and Peru.

access contract shall comply with the contents of the framework agreement and the national access legislation of the relevant member country of the framework agreement.

In 2001, the Andean Community adopted Decision No. 486, replacing the previous common IP instrument. The patent provision contains the obligation to disclose information to the patent authorities on accessed genetic resources and TK.

The OAU Model Law requires the prior consent of local communities before biological resources can be accessed, as well as the sharing of benefits from the exploitation of those resources.

The draft ASEAN Framework Agreement on Access to Biological and Genetic Resources envisages in Art. 5 that Member States shall provide for access to resources in accordance with the minimum terms and conditions laid down by the Agreement. Article 10 requires the PIC of the Member State genetic resources can be accessed. Article 10 requires that the procedures leading to the grant of PIC at the local level shall provide for the active involvement of indigenous peoples and local communities embodying traditional lifestyles. The PIC process shall respect and comply with the customary laws, practices and protocols of indigenous peoples and local communities and the disclosure of any information pertaining to the access shall be in a language understandable to the local communities.

Article 11 requires for the equitable sharing of benefits resulting from the exploitation of those resources and that 'the ASEAN Member States shall establish legal processes to ensure fair and equitable sharing of benefits arising from the use of such knowledge and resources'.

The countries of Central America[57] are considering a draft Central American Protocol on Access to Biological Resources and Traditional Knowledge, which seeks to create a *sui generis* right where the TK of local communities is utilized in accessing biological resources.

More than 30 countries are in the process of developing national legislation on access to genetic resources and benefit-sharing.[58]

The pioneering national legislation was the Philippines Executive Order No. 247, 'Prescribing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, their By-products and Derivatives, for Scientific and Commercial Purposes, and for Other Purposes', which became law in 1995. The purpose of Executive Order 247 is identified in the Preamble as regulating 'the prospecting of biological and genetic resources so that these resources are protected and conserved, are developed and put to the sustainable use and benefit of the national interest'. This includes the identification and recognition of 'the rights of indigenous cultural communities and other Philippine communities to their traditional knowledge and practices when this information is directly and indirectly put to commercial use'. The Preamble also asserts that 'wildlife, flora and fauna, among others, are owned by the State and the disposition, development and utilization thereof are under its full control and supervision'. However, the State's resource rights are not absolute, in that prospecting is only permitted within 'the ancestral lands and domains of indigenous

[57] Belize, Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua and Panama.

[58] See e.g. Brazil – Medida Provisória, No. 2.052; Costa Rica – Biodiversity Law 1998; India – Biodiversity Act 2002; South Africa – Bill on the Protection of Indigenous Knowledge; Venezuela – Biodiversity Law, 2000.

cultural communities … with the prior informed consent of such communities; obtained in accordance with the customary laws of the concerned community'. Permission for bioprospecting depends on a research agreement between the bioprospector and the government. For an agreement to be granted, a research proposal must be submitted to the government, with a copy submitted to any community that may be affected. At a minimum, the agreement must inform the government and affected communities if a commercial product results from the research, with a provision for payment of royalties to the government and community if commercial use results from any biogenetic resources taken.

This pioneering legislation has been criticized for the complexity of the implementing regulations, with very few research permits being issued.[59]

Under the Brazilian legislation the grant of industrial property rights for a process or product obtained using the genetic heritage is contingent on the observance of a Provisional Measure under which an applicant for those rights is obliged to specify the origin of the genetic material and the associated TK.[60] When there is a prospect of commercial use of TK, a Contract for Use of the Genetic Heritage and Benefit-Sharing regulates *in situ* access to TK and benefit-sharing.[61]

The Indian Biodiversity Act of 2002 provides that

> … no person shall apply for any intellectual property right … in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making such application, provided that if a person applies for a patent, permission of the National Biodiversity Authority may be obtained after the acceptance of the patent but before the sealing of the patent by the patent authority concerned.[62]

The Costa Rican Biodiversity Law provides that

> Both the National Seed Office and the Registers of Intellectual and Industrial Property are obliged to consult with the Technical Office of the Commission before granting protection of intellectual or industrial property to innovations involving components of biodiversity. They must always provide the certificate of origin issued by the Technical Office of the Commission and the prior informed consent.[63]

The Peruvian law provides that 'in the event of access for the purposes of commercial or industrial application, a license agreement shall be signed in which terms are provided that ensure due reward for the said access and in which the equitable distribution of the benefits deriving therefrom is guaranteed'.[64] The licence contract shall include

> …a statement of the compensation that the indigenous peoples receive for the use of their collective knowledge; such compensation shall include an initial monetary or other equivalent payment for its sustainable development, and a percentage of not less than 5% of the

[59] G. Dutfield (2001) *Developing and Implementing National Systems for Protecting Traditional Knowledge: A Review of Experiences in Selected Developing Countries*. UNCTAD, Geneva.

[60] Provisional Measure No. 2186-16 of 2001 Regulating Access to the Genetic Heritage, Protection of and Access to Associated Traditional Knowledge ('Brazilian Provisional Measure') Article 31.

[61] Article 16§4, Brazilian Provisional Measure.

[62] Section 6(1), Indian Biodiversity Act of 2002.

[63] Article 80, Costa Rican Biodiversity Law.

[64] Law No. 27,811 of 2002 Introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples Derived from Biological Resources (Peruvian Sui Generis Law), Article 7.

> value, before tax, of the gross sales resulting from the marketing of the goods developed directly and indirectly on the basis of the said collective knowledge, as the case may be.[65]

As is indicated in Chapter 6, there is a close relationship between national and regional legislation implementing the CBD and legislation providing for the protection of TK.

Model codes and the CBD

Responding to the CBD, the FAO Conference at its 27th session in November 1993 adopted a voluntary International Code of Conduct for Plant Germplasm Collecting and Transfer which had been developed by the Commission on Plant Genetic Resources. The professed aims of the Code were to promote the rational collection and sustainable use of genetic resources, to prevent genetic erosion, and to protect the interests of both donors and collectors of germplasm.

The Code proposes procedures for the request and issue of licences for collecting missions, and guidelines for collectors. It envisages the participation of farmers and local institutions in collecting missions and proposed that users of germplasm share the benefits derived from the use of plant genetic resources with the host country and its farmers. The primary function of the Code was to serve as a point of reference until such time as individual countries established their own codes or regulations for germplasm exploration and collection, conservation, exchange and utilization.

Specifically in relation to farmers, the Code in Art. 14 provides that without prejudice to the concept of Farmers' Rights,[66] users of germplasm

> … should, to benefit the local communities, farmers and the host countries, consider providing some form of compensation for the benefits derived from the use of germplasm such as:
>
> (a) facilitating access to new, improved varieties and other products, on mutually agreed terms;
>
> (b) support for research of relevance to conservation and utilization of plant genetic resources, including community-based, conventional and new technologies, as well as conservation strategies, for both *ex situ* and *in situ* conservation;
>
> (c) training, at both the institutional and farmer levels, to enhance local skills in genetic resources conservation, evaluation, development, propagation and use;
>
> (d) facilitate the transfer of appropriate technology for the conservation and use of plant genetic resources;
>
> (e) support for programmes to evaluate and enhance local land races and other indigenous germplasm, so as to encourage the optimal use of plant genetic resources at national, sub-national, and farmers and community level and to encourage conservation;
>
> (f) any other appropriate support for farmers and communities for conservation of indigenous germplasm of the type collected by the mission; and
>
> (g) scientific and technical information obtained from the germplasm.

[65] Article 27(d), Peruvian Sui Generis Law.
[66] Discussed in Chapter 6.

Also following the coming into effect of the CBD, botanic gardens and herbaria were concerned to obtain directions as to how they might continue to collect and exchange material. In the absence of a clear international consensus, the CBD Unit of the Royal Botanic Gardens (RBG), Kew, headed a project for botanic gardens to develop their own harmonized policy on ABS under the CBD. The group developed a set of non-legally binding Principles and Common Policy Guidelines (CPG) as a guide in developing a more detailed institutional policy. The Principles cover the acquisition, use and supply of genetic resources, benefit sharing, curation, and the preparation of a transparent policy on commercialization.[67]

In relation to the acquisition of genetic resources, the Principles insist that when acquiring resources from *in situ* conditions or *ex situ* collections, PIC be procured on the basis of a full explanation of how the genetic resources will be acquired and used. The Principles require that any benefits arising from the use of genetic resources and their derivatives be shared fairly and equitably with the country of origin and other stakeholders.

5.3 FAO ITPGRFA

Introduction

The free exchange of PGRFA as the common heritage of humankind was embodied in the International Undertaking adopted by the FAO Conference in 1983. The International Undertaking was adopted as a non-binding conference resolution. In subsequent years the principle of free exchange was gradually narrowed by the impact of IPR upon agriculture. Jean Ziegler, the Special Rapporteur on the right to food, observed in his 2004 report that a 'marked paradigm shift has occurred from a system seeking to foster food security on the basis of the free exchange of knowledge, to a system seeking to achieve the same goal on the basis of the private appropriation of knowledge'.[68]

This shift was reflected as early as November 1989 when the 25th Session of the FAO Conference adopted two resolutions providing an 'agreed interpretation' that PBR were not incompatible with the Undertaking. The acknowledgment of plant variety rights obviously benefited industrialized countries, which were active in seed production. In exchange for this concession, developing countries won endorsement of the concept of 'farmers' rights'. A further resolution in 1991 recognized the sovereign rights of nations over their own genetic resources. Agenda 21, promulgated at the Rio Earth Summit in 1992, called for the strengthening of the FAO Global System on Plant Genetic Resources. Resolution 3 of the Final Act to the CBD noted that the access to *ex situ* germplasm collections, such as those maintained by the CGIAR Centres and the realization of Farmers' Rights, were the province of the

[67] F.G. Latorre *et al.* (2001) Results of the Pilot Project for Botanic Gardens: Principles on Access to Genetic Resources and Benefit Sharing, Common Policy Guidelines to Assist with their Implementation and the Explanatory Text. Royal Botanic Gardens, Kew.

[68] Commission on Human Rights, The right to food. Report submitted by the Special Rapporteur on the right to food, Jean Ziegler, in accordance with Commission on Human Rights resolution 2003/25, E/CN.4/2004/10, 9 February 2004, para. 38.

International Undertaking. The 1993 FAO Conference called on member states to harmonize the International Undertaking with the CBD. Negotiations for revision of the International Undertaking to take account of both the CBD and the TRIPS Agreement commenced in November 1994 and were consummated with the adoption of the International Undertaking as the ITPGRFA in 2001.

The objectives of the Treaty are stated in Art. 1 to be 'the conservation and sustainable use of PGRFA and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security'. The term 'plant genetic resources for food and agriculture' is defined in Art. 2 to mean 'any genetic material of plant origin of actual or potential value for food and agriculture'. The term 'genetic material' is defined in Art. 2 to mean 'any material of plant origin, including reproductive and vegetative propagating material containing functional units of heredity'.

Article 10.2 contains the agreement of the Contracting Parties to 'establish a multilateral system, which is efficient, effective and transparent, both to facilitate access to [PGFRA] and to share, in a fair and equitable way, the benefits arising from the utilisation of these resources, on a complementary and mutually reinforcing basis'. The PGRFA to which the MLS applies are some 35 crops and 29 forages which are listed in Annex I and other contributions by resource holders (Art. 11(2)). This is further limited to materials 'under the management and control of the Contracting Parties and in the public domain' (Art. 11(2)). However, the collections of the CGIAR are expressly included in the MLS (Art. 11(5)), but each Centre's collections are to be accessed according to agreements between them and the Governing Body of the PGFRA Treaty on terms which each Centre might negotiate (Art. 15(1)). The Treaty entered into force in June 2004 after the deposit of the 40th instrument of ratification.

Standard MTA (SMTA)

The International Treaty in Art. 12.3 provides that facilitated access to PGFRA is to be provided under MTAs on condition (d) that the recipients 'shall not claim any intellectual property or other rights that limit the facilitated access' to PGFRA, or their 'genetic parts or components', in the form received from the MLS. This, of course, does not prevent IPR being claimed in relation to germplasm which is modified by the recipient. A problematic issue is the extent of modification which must occur before it can be said that the form in which the germplasm was received has changed. In the case of IPR used in a breeding programme, this will be similar to the inquiry in UPOV-derived laws whether a new variety is 'essentially derived' from an existing variety. In the case of the patenting of genetic material derived from germplasm, the question will revolve around the extent of 'invention' which is involved. Given the willingness of patent offices to grant patents, merely for the isolation of useful genetic sequences, the question will arise as to whether the fact of isolation is equivalent to changing the form in which germplasm is received. If the view is taken that this isolated material is in a changed form, this will have the effect of removing useful material from the CGIAR system.

An SMTA was finalized in 2006.[69] The SMTA provides in Art. 4.1 that it 'shall be implemented and interpreted in accordance with the objectives and provisions of the Treaty'. The parties to the SMTA agree in Art. 4.3 that the Governing Body of the Treaty and its MLS (i.e. the FAO) is identified as the third-party beneficiary under the SMTA. Clause 4.4 gives the third-party beneficiary the right to request the information about MTAs into which it enters (Art. 5e) and about transfers of plant genetic resources to other persons (Art. 6.5c) and the right to request samples (Art. 2.3) and the right to receive an annual report detailing the sales of plant genetic resources that incorporate the material supplied under the SMTA by the recipient, its affiliates, contractors, licensees and lessees, for the 12-month period ending on 31 December (Annex 2 paragraph 3).

Including the FAO as the third-party beneficiary puts it in a position to enforce the SMTA. The limited financial resources for legal enforcement actions of many of the institutes, which will be supplying genetic resources under SMTAs, sets up the FAO as a more likely litigant. However, Art. 4.5 preserves the rights of the provider and the recipient from exercising their rights under the SMTA. Although the SMTA seeks to construct a legal basis for the enforcement of rights in relation to germplasm and other materials supplied under its terms, the greater likelihood is that the SMTA will be enforced as a moral obligation. Also recipients who do not abide by the terms of an SMTA are likely to be excluded from the receipt of any further material under the MLS.

Article 5 of the SMTA provides that in the case of transfers from CGIAR Centres these will be subject to the Agreement between the FAO and the Centres under which trusteeship of their collections is conferred on the FAO.

Article 5 requires the provider of material to supply all available passport data and other associated available non-confidential descriptive information.

Article 5(d) provides that access to PGRFA protected by intellectual and other property rights shall be consistent with relevant international agreements, and with relevant national laws.

Under Art. 6.2, the recipient agrees not to claim any IP or other rights that limit the facilitated access to the material provided under the SMTA or its genetic parts or components, in the form received from the MLS. This terminology leaves it open for recipients to obtain IPR in modified derivatives.

A modified derivative is embraced by the concept of 'development'. Article 2 of the SMTA defines 'Plant Genetic Resources for Food and Agriculture under Development' as material derived from the subject matter transferred under the SMTA 'and hence distinct from it, that is not yet ready for commercialization and which the developer intends to further develop or to transfer to another person or entity for further development'. There is no obligation to share monetary benefits arising from the transfer of PGRFA under development.

In the 1980s, CIMMYT devised an information strategy and developed computer software to facilitate the identification of wheat germplasm from different sources. This developed into CGIAR's International Crop Information System

[69] FAO (2006) Report of the First Session of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture, *IT/GB-1/06/Report,* Madrid, 12–16 June.

(ICIS).[70] It defines germplasm under development as a 'breeding line', i.e. an individual plant with specific characteristics 'derived from' germplasm from the MLS, but 'distinct' from its MLS ancestors.

Where a recipient obtains IPR on any products developed from the material supplied under an SMTA, or its components and assigns such IPR to a third party, Art. 6.10 requires that the recipient shall transfer the benefit-sharing obligations of the SMTA, set out in Art. 6.7 to that third party. After the expiry or abandonment of the protection period of an IPR on a product that incorporates the material supplied under an SMTA, the recipient is encouraged by Art. 6.9 to place a sample of this product into a collection that is part of the MLS, for research and breeding.

Under Art. 6.1 of the SMTA, the recipient undertakes that the material shall be used or conserved only for the purposes of research, breeding and training for food and agriculture. Such purposes shall not include chemical, pharmaceutical and/or other non-food/feed industrial uses.

Where the recipient conserves the material supplied, Art. 6.3 provides that the recipient shall make the material and the passport data, and any other associated available non-confidential descriptive information, available under an SMTA.

Where the recipient transfers the material supplied under the SMTA to another person, this must be done under the terms of a new SMTA and the Governing Body has to be notified.

Article 13.1 of the International Treaty recognizes that benefits accruing from facilitated access to PGFRA shall be shared fairly and equitably under this Article. Art. 13.2 envisages that this sharing of benefits include the exchange of technical information, access to technology, capacity building and the sharing of monetary benefits from commercialization. This is sought to be achieved by Art. 6 of the SMTA.

Where a recipient commercializes a product that is a Plant Genetic Resource for Food and Agriculture and that incorporates material supplied under the SMTA, and where such product is not available without restriction to others for further research and breeding, Art. 6.7 provides that the recipient shall pay a fixed percentage of the sales of the commercialized product into the mechanism established by the Governing Body for this purpose in accordance with Annex 2. This Annex requires the recipient to pay 1.1% of the sales of the product unless the product is made available without restriction.

Where research and development is carried out on the material supplied under the SMTA, Art. 6.9 requires the recipient to make available to the MLS all non-confidential information that results from this and the recipient is encouraged to share through the MLS non-monetary benefits that result from such research and development.

Article 7 of the SMTA provides that it shall be governed by 'General Principles of Law', including the UNIDROIT Principles of International Commercial Contracts 2004, the objectives and the relevant provisions of the Treaty, and, when necessary for interpretation, the decisions of the Governing Body. Article 8 provides that disputes arising from the SMTA shall be by negotiation or third-party mediation or where these are unsuccessful, 'by arbitration under the Arbitration Rules of an international

[70] http://www.icis.cgiar.org/icis/index.php/ICIS_History.

body as agreed by the parties to the dispute. Failing such agreement, the dispute shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce. The result of such arbitration shall be binding.'

Under Art. 9.1 of the SMTA, the Provider makes no warranties as to the safety of or title to the material, nor as to the accuracy or correctness of any passport or other data provided with the material, neither does it make any warranties as to the quality, viability, or purity (genetic or mechanical) of the material being furnished and the recipient assumes full responsibility for complying with the recipient nation's quarantine and biosafety regulations and rules as to import or release of genetic material. This is considered in Chapter 7.

The MLS

The International Treaty creates a qualified genetic resources commons. It includes only the PGRFA, which are listed in Annex 1. As the treaty is only binding between countries, the custodians of germplasm collections, such as CGIAR Centres, are encouraged in Art. 15 to place their collections under the Treaty by signing agreements with the Governing Body. The CGIAR Centres had signed agreements with the FAO in 1994, placing the acquisitions to their germplasm collections after that date under the trusteeship of the FAO. A draft model agreement was presented to the Governing Body at its meeting in Madrid, 12–16 June 2006. Article 2 of the draft model agreement made available in accordance with the SMTA PGRFA referred to in Annex 1 of the Treaty collected before and after the coming into force of the Treaty. PGRFA other than that listed in Annex 1 of the Treaty, which are received and conserved by a Centre after the coming into force of the Treaty, are made available for access under Art. 3 of the draft agreement on terms consistent with those mutually agreed between the Centre that receives the material and the country of origin of such resources or the country that has acquired those resources in accordance with the CBD or other applicable laws.

On 16 October 2006, new agreements were signed by the CGIAR Centres[71] together with the Tropical Agriculture and Higher Education Research Centre (CATIE)[72] and the Coconut Genetic Resources Network (COGENT) placing their collections under the supervision of the Governing Body. By these agreements the Centres recognized the authority of the Governing Body to provide policy guidance in relation to their collections. From 1 January 2007, all transfers of PGFRA listed in Annex 1 of the Treaty became subject to the SMTA.

The Second Meeting of the Interim Committee for the International Treaty decided that the priority issues for consideration by the first session of the Governing Body should include the implementation of Art. 6 of the Treaty, which required the Contracting Parties to 'develop and maintain appropriate policy and legal measures that promote the sustainable use of plant genetic resources for food and agriculture'.[73] Access to the genetic resources of the CGIAR by farmers, breeders and national

[71] Now called Future Harvest Centres.

[72] Centro Agronónico Tropical de Investigación y Ensenănza.

[73] *Report of the Second Meeting of the Commission on Genetic Resources for Food and Agriculture acting as Interim Committee for the International Treaty.* CGRFA/MIC-2/04/REP, para. 26.

agricultural research systems (NARS) throughout the world, and the scientific research they undertake, were considered 'one of the major pillars on which present and future world food security rests'.[74] These institutions were therefore identified as major partners of the Governing Body in implementing Art. 6.

As was mentioned above, all of the resources under the MLS will be made available under the SMTA, which constrains the uses to which germplasm may be put. The International Seed Federation (ISF), representing more than 10,000 seed companies, has questioned 'the degree to which the SMTA is acceptable in practice', particularly the duration of restrictions upon the exploitation of accessed material.[75] However, the reported experience of the CGIAR Centres in the first 9 months of 2007 was that of 833 shipments; only three would-be recipients refused to take materials under the SMTA.[76]

Farmers' organizations have also been sceptical about the value of the International Treaty. At the Second Meeting of the Governing Body of the International Treaty held in Rome, 29 October–2 November 2007, farmers' organizations supported by civil society groups called for suspension of the distribution of germplasm under the Treaty.[77] Andrew Mushita of the Community Biodiversity Development and Conservation Network (a network of conservation programmes in 21 countries) described the MLS as 'the greatest case of institutional biopiracy ever seen', describing the Treaty as 'enabling multinational seed companies to impose a legally binding regime that forces the exchange of farmers' seeds without reciprocal benefits'.[78] A Declaration issued by the civil society organizations at the meeting demanded a suspension of the Treaty and the exchange of genetic resources until farmers, all food producers, including indigenous peoples, fisherfolk, herders, nomads, and their organizations were admitted 'to the full range of decisions concerning plant genetic resources and especially the work on the rights of farmers' and 'the revision of any legislation that presents obstacles to the realisation of the rights of farmers, including the rights to reuse, conserve, protect, exchange and sell their seeds'.[79]

5.4 IP and PGRFA

WIPO's involvement with the issue of access to genetic resources commenced in 1999 with a study, commissioned jointly with the UNEP, on the role of IPR in the sharing of benefits arising from the use of biological resources and associated TK. These matters were taken up at the third session of the Standing Committee on the Law of Patents (SCP) in September 1999. The SCP requested the International Bureau to include the issue of protection of biological and genetic resources on the agenda of a Working

[74] FAO, Implementation of Article 6 of the International Treaty etc. IT/GB-1/06/10, para. 17.
[75] ISF, *Position Paper on Plant Genetic Resources for Food and Agriculture* Christchurch, ISF, 2007. www.worldseed.org/Position_papers/PGRFA.htm.
[76] SGRP, Experience of the CGIAR Centres with the implementation of agreements with the governing body, with particular reference to the SMTA. www.planttreaty.org/gbnexx_en.htm, cited in Halewood and Nnadozie, n.7 supra.
[77] GRAIN, 2 November 2007.
[78] Ibid.
[79] Ibid.

Group on Biotechnological Inventions, to be convened at WIPO in November 1999. The Working Group, at its meeting, the following month, recommended the establishment of nine projects related to the protection of inventions in the field of biotechnology. At the third session of the WIPO SCP in September 1999 the delegation of Colombia proposed the introduction into the Patent Law Treaty, proposed as a means of achieving some global harmonization of patent registration procedures, an article which provided that:

1. All industrial protection shall guarantee the protection of the country's biological and genetic heritage. Consequently, the grant of patents or registrations that relate to elements of that heritage shall be subject to their having been acquired or made legally.
2. Every document shall specify the registration number of the contract affording access to genetic resources and a copy thereof whereby the products or processes for which protection is sought have been manufactured or developed from genetic resources, or products thereof, of which one of the member countries is the country of origin.

The Diplomatic Conference, which commenced on 11 May 2000, became bogged down on the question of obliging the identification of source countries in biotechnological patent applications. To facilitate progress on the procedural aspects, the source country question was referred to an expert group for further consideration. In a press release issued on 1 June 2000, WIPO reported that it had also received a mandate to discuss this issue from the COP V meeting in Nairobi and that this request would be referred to its General Assembly in September 2000.

In a note dated 14 September 2000, the Permanent Mission of the Dominican Republic to the UN in Geneva submitted two documents on behalf of the Group of Countries of Latin America and the Caribbean (GRULAC) as part of the debate in the WIPO General Assembly on 'Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore'. The central thrust of these documents was a request for the creation of a Standing Committee on access to the genetic resources and TK of local and indigenous communities.

At the WIPO General Assembly, the Member States agreed the establishment of an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). Three interrelated themes were identified to inform the deliberations of the Committee: IP issues that arise in the context of (i) access to genetic resources and benefit sharing; (ii) protection of TK, whether or not associated with those resources; and (iii) the protection of expressions of folklore.[80] At the first session of the IGC held in Geneva from 30 April to 3 May 2001, the Member States determined the agenda of items on which work should proceed and prioritized certain tasks for the Committee. Principal among these was 'the development of "guide contractual practices", guidelines and model IP clauses for contractual agreements on access to genetic resources and benefit-sharing'.[81]

[80] See WIPO (2000) Matters Concerning Intellectual Property Genetic Resources Traditional Knowledge and Folklore. WIPO Doc, WO/GA/26/6, 25 August 2000.
[81] See WIPO Doc, WIPO/GRTKF/IC/2/3, 10 September 2001, para.1.

At its second session, held in Geneva on 10–14 December 2001, the IGC formulated 'Operational Principles for Intellectual Property Clauses of Contractual Agreements Concerning Access to Genetic Resources and Benefit-Sharing', which suggested sample clauses for bioprospecting contracts.

The third session, held in Geneva on 13–21 June 2002, discussed the development of a database concerning contractual practices and clauses relating to IP, access to genetic resources and benefit-sharing. At this session of the ICG, countries discussed: the formulation of IP clauses in contracts that govern access to genetic resources, and their listing in a database; and the development by WIPO of a technical study on the possibilities to disclose specific information within patent applications.

At its ninth session, the Commission on Genetic Resources for Food and Agriculture (CGRFA) requested 'that WIPO cooperate with FAO in preparing a study on how intellectual property rights may affect the availability and use of material from the International Network and the International Treaty'.[82] In November 2004, WIPO produced a preliminary report,[83] which looked at patent search algorithms with a view to interrogating patent documents to disclose useful information about the effect on availability and use of PGRFA covered by patents. In 2006, WIPO provided a second progress report, which contained a factual description of the international patent landscape surrounding gene promoters relevant to rice.[84] Rice had been selected by FAO and WIPO for the draft patent landscape because of its crucial importance for food security. FAO selected gene promoters as an illustrative technology for the initial set of patent searches and analysis. The report indicated a high level of private ownership and participation concerning these research tools, although no conclusions could be drawn about the legal scope of the patent families identified, and their impact on the freedom of third parties to use the technologies. Similar searches will be undertaken for maize, potato and soybean.[85]

5.5 Interlaken Declaration on Animal Genetic Resources

In 1990, the FAO Council recommended the preparation of a comprehensive programme for the sustainable management of animal genetic resources at the global level. In 1993 the FAO launched its Global Strategy for the Management of Farm Animal Genetic Resources. The Global Strategy contained four elements: an intergovernmental mechanism for direct governmental involvement and policy development; country-based global infrastructure to help nations plan and implement national strategies; a technical support programme aimed at the country level; and a

[82] CGRFA-9/02/REP, para. 31.

[83] WIPO, *Preliminary report on work towards the assessment of patent data relevant to availability and use of material from the International Network of* Ex-Situ *Collections under the Auspices of FAO and the International Treaty.* CGRFA/MIC-2/04/Inf.5, ftp://ftp.fao.org/ag/cgrfa/mic2/m2i5e.pdf

[84] WIPO, *Progress Report on Work Towards the Assessment of Patent Data Relevant to Agricultural Biotechnology and the Availability and Use of Material from the International Network of Ex-Situ Collections Under the Auspices of FAO and the International Treaty: A Draft Patent Landscape Surrounding Gene Promoters Relevant to Rice,* IT/GB-1/06/Inf.17.

[85] WIPO/GRTKF/IC/12/8 (b), para. 39.

reporting and evaluation system to guide the Strategy's implementation, maximize cost-effectiveness and facilitate collaboration, coordination and policy development. In 1995, the CGRFA established the Intergovernmental Technical Working Group on Animal Genetic Resources for Food and Agriculture to formulate, *inter alia*, an internationally agreed framework for the conservation of animal genetic resources.

In 2001, the FAO invited national reports which assessed the contribution of farm animals to food, agriculture and rural development and a list of 'priority actions'. Based on these reports, the first global report on the State of the World's Animal Genetic Resources for Food and Agriculture was drafted, as well as a report on Strategic Priorities for Action for the Sustainable Use, Development and Conservation of Animal Genetic Resources for Food and Agriculture.

These reports were presented to the first International Technical Conference on Animal Genetic Resources for Food and Agriculture in Interlaken, which took place on 3–7 September 2007. This meeting adopted a Global Plan of Action for Animal Genetic Resources and the Interlaken Declaration on Animal Genetic Resources.[86]

The Introduction to the Global Plan of Action states that animal genetic resources for food and agriculture

> … are an essential part of the biological basis for world food security, and contribute to the livelihoods of over a thousand million people … animal genetic resources are crucial in adapting to changing socio-economic and environmental conditions, including climate change. They are the animal breeder's raw material and amongst the farmer's most essential inputs. They are essential for sustainable agricultural production.[87]

The Global Plan of Action provides for the conservation and sustainable use of animal genetic resources, and the fair and equitable sharing of the benefits from their use. The perceived contribution of animal genetic resources concerns the satisfaction of the basic human needs for food and livelihood security through the provision of meat, milk and dairy produce, eggs, fibre, clothes, resources for temporary and permanent shelter, manure for fertilizer and fuel, draught power, hunting assistance and marketable assets.[88]

The Global Plan of Action lists a number of strategic priorities for action. Among these are Strategic Priority 20 to review and develop national policies and legal frameworks for animal genetic resources and to enhance coherence between the various instruments regulating economic development, environmental protection, animal health, food safety, consumer protection, IPR, genetic resources conservation, and access to and equitable sharing of benefits arising from the use of animal genetic resources. Strategic Priority 21 provides for the review of the implications and impacts of international agreements and developments relevant to access to animal genetic resources and sharing the benefits of their use.

The Interlaken Declaration on Animal Genetic Resources in Art. 2 recognizes the sovereign rights of states over their animal genetic resources for food and agriculture. Article 4 commits the signatories to achieve 'the sustainable use, development and conservation of animal genetic resources for food and agriculture'. It also contains a commitment to 'facilitating access to these resources and the fair and

[86] http://www.fao.org/docrep/010/a1404e/a1404e00.htm.
[87] Ibid., at 5.
[88] Ibid., at 7.

equitable sharing of the benefits arising from their use, consistent with relevant international obligations and national laws' with the objective of enhancing world food security, improving human nutritional status and contributing to rural development.

Articles 6–9 of the Declaration contain commitments of the signatories to promote the conservation of animal genetic resources. Article 9 notes that the genetic resources of animal species most critical to food security, sustainable livelihoods and human well-being are the result of both natural selection, and directed selection by smallholders, farmers, pastoralists and breeders, throughout the world, over generations. It states that all countries will need to play their part in conserving these resources as a basis for livestock development, food security and the better nutrition of their rural and urban populations, as well as to sustain their rural communities.

The Declaration in Art. 10 acknowledges that maintaining the diversity of animal genetic resources for food and agriculture is essential to enable farmers, pastoralists and animal breeders to meet current and future production challenges resulting from changes in the environment, including climate change; the necessity to enhance resistance to disease and parasites; and to respond to changes in consumer demand for animal products. Cognisant of the dramatic increase in demand for meat, milk and other animal products, Art. 11 observes that the sustainable use, development and conservation of animal genetic resources for food and agriculture will make a vital contribution to achieving the goals of the Rome Declaration on World Food Security, the World Food Summit Plan of Action, as well as the Millennium Development Goals, in particular Goal 1 – eradication of extreme poverty and hunger – and Goal 7 – ensure environmental sustainability. It notes that the sustainable use, development and conservation of animal genetic resources for food and agriculture make an essential contribution to facilitating the implementation of Agenda 21 and the CBD.

In Art. 18 the signatories recognize that the main responsibility for implementing the Global Plan of Action for Animal Genetic Resources rests with national governments but in Art. 18 acknowledge the essential role of the FAO in supporting country-driven efforts in implementing it.

6 Traditional Agricultural Knowledge and Farmers' Rights

The TK of indigenous peoples throughout the world 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.[1] Examples of TK with an 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.[2] The recent passion for environmental sensitivity in Western countries has resulted in a heightened interest in natural products or 'organic' products. A similarly significant contribution has been made by the knowledge of indigenous peoples and traditional farmers in the development of new crop types and biodiversity conservation. These groups have been an important agency in the conservation of plant genetic resources and the transmission of these resources to seed companies, plant breeders and research institutions. They have not typically been paid for the value they have delivered, whereas breeders and seed companies have resorted to IPR to recover their development expenditures. On the other hand, farmers who utilize improved varieties are obliged to pay for them.

The economic value of biological diversity conserved by traditional farmers for agriculture is difficult to quantify.[3] It has recently been suggested that 'the value of

[1] See Kerry ten Kate and Sarah A. Laird (2000) *The Commercial Use of Biodiversity: Access to Genetic Resources and Benefit*. Earthscan, London; G. McChesney, Biological diversity, chemical diversity and the search for new pharmaceuticals. In: M. Balick, E. Elisabetsky and S. Laird (eds) (1996) *Medicinal Resources of the Tropical Forest: Biodiversity and its Importance to Human Health*. University of Columbia Press, Columbia, 12.

[2] S.A. Hansen and J.W. Van Fleet (2007) Issues and options for traditional knowledge holders in protecting their intellectual property economies. In: A. Krattiger, R.T. Mahoney, L. Nelsen, J.A. Thomson, A.B. Bennett, K. Satyanarayana, G.D. Graff, C. Fernandez and S.P. Kowalski (eds) *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*. MIHR, Oxford, and PIPRA, Davis, CA, 1523.

[3] See e.g. S. Brush (1994) *Providing Farmers' Rights Through In Situ Conservation of Crop Genetic Resources*. University of California, Berkeley, CA.

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' own collections and advanced lines developed in public institutions'.[4] 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 focused upon germplasm derived from wild species and landraces.[5]

TK is particularly important in the development of farming systems adapted to the local conditions, and farming practices. This may enable the utilization of marginal lands, contributing to food security in enabling access to food in remote areas, as in contributing to the management of the environment by preventing erosion, maintaining soil fertility and agro-biodiversity.

Traditional ecological knowledge is claimed to be the basis of sustainable agriculture[6] and by some as underpinning the modern organic farming movement.[7]

6.1 Farmers' Rights under the International Treaty

Farmers' Rights were described in a Resolution of the 1989 FAO Conference as:

> … rights arising from the past, present and future contribution of farmers in conserving, improving and making available plant genetic resources, particularly those in centres of origin/diversity. These rights are vested in the International Community, as trustee for present and future generations of farmers, for the purpose of ensuring full benefits to farmers, and supporting the continuation of their contributions.[8]

The concept of Farmers' Rights was developed as 'a counterbalance to intellectual property rights'.[9] This was a moral commitment by the industrialized countries to reward 'the past present and future contributions of farmers in conserving, improving and making available plant genetic resources particularly those in centres of origin/diversity'. Farmers' Rights were intended to promote a more equitable relation

4 C. Correa (2000) *Options for the Implementation of Farmers' Rights at the National Level*. South Centre, Trade-Related Agenda, Development and Equity Working Papers, No. 8, December, citing Wright (1998) Intellectual property and farmers' rights. In: R. Evenson, D. Gollin and V. Santaniello (eds) *Agricultural Values of Plant Genetic Resource*s. FAO/CEIS/CABI, Wallingford, 228.

5 R. McNeely (2001) 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*. CAB International, Wallingford, 399 at 404.

6 See e.g. R.E. Johannes (1989) *Traditional Ecological Knowledge: A Collection of Essays*. IUCN, Gland; N.M. Williams and G. Baines (eds) (1993) *Traditional Technological Knowledge: Wisdom for Sustainable Development*. ANU, Canberra.

7 IFOAM (International Federation of Organic Agriculture Movements) (ed.) (2007) *Principles of Organic Farming*. IFOAM, Bonn.

8 Annex II, Resolution 5/89 adopted by FAO Conference, 25th Sess., Rome, 11–29 November 1989.

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

between the providers and users of germplasm by creating a basis for farmers to share in the benefits derived from the germplasm they had developed and conserved over time.[10] Farmers' Rights are conceived of as a 'retrospective equity',[11] primarily as the recognition of the moral obligation, rather than an economic incentive.

The first international enactment of Farmers' Rights occurred in the FAO ITPGRFA. The Preamble to the Treaty acknowledges that 'the conservation, exploration, collection, characterization, evaluation and documentation of plant genetic resources for food and agriculture are essential in meeting the goals of the Rome Declaration on World Food Security and the World Food Summit Plan of Action and for sustainable agricultural development for this and future generations'. It also acknowledges that PGFRA 'are the raw material indispensable for crop genetic improvement' and affirms 'that the past, present and future contributions of farmers in all regions of the world, particularly those in centres of origin and diversity, in conserving, improving and making available these resources, is the basis of Farmers' Rights'.

The Preamble outlines that that 'fundamental to the realization of Farmers' Rights, as well as the promotion of Farmers' Rights at national and international levels' are the rights 'to save, use, exchange and sell farm-saved seed and other propagating material, and to participate in decision-making regarding, and in the fair and equitable sharing of the benefits arising from, the use of plant genetic resources for food and agriculture'.

Under Art. 5.1(c), the Contracting Parties agree, subject to national legislation, to promote or support, as appropriate, farmers and local communities' efforts to manage and conserve on-farm their plant genetic resources for food and agriculture and in Art. 5.1(d) to promote *in situ* conservation of wild crop relatives and wild plants for food production, by supporting, *inter alia*, the efforts of indigenous and local communities.

In Art. 9(1) of the Treaty the Contracting Parties 'recognize the enormous contribution that the local and indigenous communities and farmers of all regions of the world, particularly those in the centres of origin and crop diversity, have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agriculture production throughout the world'.

Article 9.2 of the WTO ITPGRFA envisages that 'the responsibility for realizing Farmers' Rights, as they relate to Plant Genetic Resources for Food and Agriculture, rests with national governments' and that national legislation should include measures relating to:

> (a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture;
>
> (b) the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture;

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

[11] S. Brush (1996) Whose knowledge, whose genes, whose rights? In: S.B. Brush, and D. Stabinsky (eds) *Valuing Indigenous Knowledge: Indigenous Peoples and Intellectual Property Rights.* Island Press, Washington DC.

> (c) the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture.

Finally, Art. 9.3 provides that the Article shall not be interpreted 'to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material'.

An assumption of Art. 9 is that the landraces used by traditional farmers are a dynamic genetic reservoir for the development of new varieties and for the transmission of desirable genetic traits. The TK of local and indigenous communities is similarly perceived. Farmers in subsistence systems have tended to utilize a diverse selection of crop species in order to assure their annual harvests and thus to guarantee a minimal level of production and to prevent food shortage. Seed production in many instances has been on the collection of and domestication of locally known, wild varieties. Modern agricultural practices depend on crop species that promote productivity and resistance to disease that can only be maintained with the continuous input of new germplasm. The diversity of landraces and the associated information on their specific qualities contribute invaluable information to formal breeding processes. It has been noted that the loss of biological diversity is paralleled by the loss of TK. Where a plant variety becomes extinct, then the entire body of knowledge about its properties is condemned to irrelevancy.

As a means of remunerating these groups for their past contributions to the development of plant genetic resources for food and agriculture production, there can be little argument, except about the quantum and distribution of this remuneration. Inevitably, any calculation of the equitable share, which traditional farmers and indigenous communities might enjoy under a Farmers' Rights or Traditional Knowledge regime, will be arbitrary. However the IP system is no stranger to arbitrary calculations, thus the 20-year length of a patent term is intended to provide an opportunity for the compensation of all inventors, whatever the area of technology. Similarly, the 25 years exclusivity, which the UPOV Convention provides for new varieties of trees and vines, takes no account of variations in R&D costs between the different varieties.

The principal ways in which plant genetic resources are translated into food and agriculture production is through plant breeding and plant patenting. Standing at the heart of a Farmers' Rights regime is the concept of the equitable benefit sharing of benefits with farmers for their contribution to innovations in plant breeding and plant patenting. It is estimated that about 6.5% of all genetic research undertaken in agriculture is focused upon germplasm derived from wild species and landraces.[12]

Article 9.2 obliges the Contracting Parties to the ITPGRFA 'to take measures', subject to their national legislation to protect and promote Farmers' Rights. The content of these rights is defined in the balance of that provision and embraces the protection of TK, equitable benefit sharing and the right to participate in decision making. The Treaty leaves open the legal context within which Farmers' Rights are to be enacted.

[12] See R. McNeely (2001) 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*. CAB International, Wallingford, 399–408.

To date, the only measure that has been implemented to provide for Farmers' Rights is the International Fund for Plant Genetic Resources, which was envisaged in the Undertaking which preceded the Treaty. This Fund was to operate as a means of capacity building in the field of agricultural biotechnology in developing countries rather than as a reward to individual farmers or farming communities for their contribution to the development or improvement of plant varieties. To date, this fund has not been established because funds were not made available by donor countries.

6.2 Farmers' Rights Defined

A problem with the legislative protection of Farmers' Rights is that there is no accepted definition of the term, or agreement as to how these rights can be realized. To this end, the Farmers' Rights Project was set up at the Fridtjof Nansen Institute in Norway in order to facilitate a common understanding on how Farmers' Rights can be realized under the ITPGRFA and to develop a basis for proposals to the Governing Body of the ITPGRFA on specific measures to be taken to realize these rights.[13] The Project administered an international stakeholder questionnaire survey on the state of Farmers' Rights in 31 countries in Asia, Africa, the Americas and Europe on legislation, policies and implementation as well as perceptions and options for implementation and tasks for the Governing Body.[14] In addition, case studies were conducted in Peru,[15] India,[16] Ethiopia[17] and Norway.[18] As a result of these analyses two approaches to the understanding of Farmers' Rights were identified:[19]

- *The ownership approach*, which refers to the right of farmers to be rewarded for genetic material obtained from their fields which is used in commercial varieties and/or protected with IPR. Access and benefit-sharing legislation and farmers' IPR are suggested as central instruments.
- *The stewardship approach*, which refers to the rights that farmers must be granted in order to enable them to continue as stewards of agro-biodiversity. The idea is that farmers involved in the maintenance of agro-biodiversity should be rewarded and supported for their contributions.

The stewardship approach obtained the greatest support on the basis that as agricultural plant varieties are normally shared among many farming communities, it would be difficult to identify exactly who should be rewarded. Moreover, it was noted

[13] http://www.farmersrights.org/fr-project/index.html.
[14] R. Andersen (2005) *Results from an International Stakeholder Survey on Farmers' Rights*. Background Study 2, FNI Report 9/2005. The Fridtjof Nansen Institute, Lysaker.
[15] M. Ruiz Muller Manuel (2006) *Farmers' Rights in Peru – A Case Study.* Background Study 3, FNI Report 5/2006. The Fridtjof Nansen Institute, Lysaker.
[16] A. Ramanna (2006) *Farmers' Rights in India – A Case Study.* Background Study 4, FNI Report 6/2006. The Fridtjof Nansen Institute, Lysaker.
[17] R. Feyissa (2006) *Farmers' Rights in Ethiopia – A Case Study.* Background Study 5, FNI Report 7/2006. The Fridtjof Nansen Institute, Lysaker.
[18] R. Andersen (2008) *Farmers' Rights in Norway – A Case Study.* Background Study 6, FNI Report 8/2008. The Fridtjof Nansen Institute, Lysaker.
[19] R. Andersen (2006) *Realising Farmers' Rights Under the International Treaty on Plant Genetic Resources for Food and Agriculture. Summary of Findings from the Farmers' Rights Project, Phase 1.* The Fridtjof Nansen Institute, Lysaker.

that the demand for farmers' varieties among commercial breeders is limited, so relatively few farmers would benefit. Also it was noted that the ownership approach could lead to a 'tragedy of the anti-commons' in that farmers could be excluded from the free use of agro-biodiversity, not only by breeders through plant breeders' rights, but also because of competition between farmers.[20]

The Project proposed as a working definition:

> Farmers' Rights consist of the customary rights that farmers have had as stewards of agro-biodiversity since the dawn of agriculture to save, grow, share, develop and maintain plant varieties, of their legitimate right to be rewarded and supported for their contribution to the global pool of genetic resources as well as to the development of commercial varieties of plants, and to participate in decision making on issues that may affect these rights.[21]

6.3 Farmers' Rights in Regional and National Legislation

The OAU Model Legislation for the Recognition of the Rights of Local Communities, Farmers and Breeders and for the Regulation of Access to Biological Resources establishes the concept of 'community intellectual rights', which are 'those rights held by local communities over their biological resources or parts or derivatives thereof and over their practices, innovations, knowledge and technologies',[22] although there are no enforcement consequences flowing from a wrongful appropriation of those rights.

Article 26(1) of the Model Law recognizes the rights of farmers to:

> (a) The protection of their traditional knowledge relevant to plant and animal genetic resources; (b) obtain an equitable share of benefits arising from the use of plant and animal genetic resources; (c) participate in making decisions, including at the national level, on matters related to the conservation and sustainable use of plant and animal genetic resources; (d) save, use, exchange and sell farm-saved seed/propagating material; (e) use a new breeders' variety protected under this law to develop farmers' varieties.

Suggestions have been made in India for a seed tax, where the revenue yield will be distributed through a Community Gene Fund.[23]

6.4 Farmers' Rights under the Interlaken Declaration on Animal Genetic Resources

In 1993, the FAO launched its Global Strategy for the Management of Farm Animal Genetic Resources. One of the outcomes of this process was the Interlaken

[20] Andersen, n.14 at 4.
[21] Ibid., 5.
[22] OAU Model Law, Part 11, Art. 1 (4).
[23] M.S. Swaminathan and V. Hoon (1994) *Methodologies for Recognizing the Role of Informed Innovation in the Conservation and Utilization of Plant Genetic Resources.* CRSARD Proceedings, Madras, no. 9.

Declaration on Animal Genetic Resources, which was adopted on 7 September 2007 at the first International Technical Conference on Animal Genetic Resources of the FAO.[24] Paralleling the promulgation of Farmers' Rights in relation to plant genetic resources for food and agriculture, the Interlaken Declaration in Art. 12 acknowledged the recognition of the signatories of:

> … the enormous contribution that the local and indigenous communities and farmers, pastoralists and animal breeders of all regions of the world have made, and will continue to make for the sustainable use, development and conservation of animal genetic resources for food and agriculture. We further recognize the historic and relevant contribution of all persons engaged in animal husbandry, who have moulded animal genetic resources to meet societal needs. It is their ownership and management of the genetic resources of their livestock that has enabled them to make important contributions in the past. It is this ownership and management that should be ensured for future societal benefits. We affirm that they should participate in the fair and equitable sharing of benefits arising from the utilization of animal genetic resources for food and agriculture. We affirm the desirability, as appropriate, subject to national legislation, of respecting, preserving and maintaining traditional knowledge relevant to animal breeding and production as a contribution to sustainable livelihoods, and the need for the participation of all stakeholders in making decisions, at the national level, on matters related to the sustainable use, development and conservation of animal genetic resources.

The Interlaken Declaration made no specific suggestions for the sharing of benefits but in Art. 15 recognized that 'the transfer of technologies relating to sustainable use, development and conservation of animal genetic resources is essential for world food security' and 'should be facilitated, consistent with relevant international obligations and relevant national laws'. This Article also recognized that the sustainable use, development and conservation of animal genetic resources for food and agriculture required 'the support and participation of farmers, pastoralists and breeders; local and indigenous communities' as well as of the private sector and civil society.

At the Interlaken Conference the participants also adopted the Global Plan of Action for Animal Genetic Resources, which seeks to provide a framework for enhancing management activities in relation to animal genetic resources for food and agriculture through strengthening policies, institutions and building capacity. The FAO's Commission on Genetic Resources for Food and Agriculture will oversee, assess and report on progress in the implementation of the Global Plan of Action.

6.5 International Proposals for the Protection of TK

Introduction

The first international consideration of the protection of TK occurred in a joint UN Educational and Scientific Organization (UNESCO)/WIPO World Forum on the Protection of Folklore, which was convened in Phuket, Thailand, in April 1997. At that meeting the representatives of organizations of indigenous peoples called for the promulgation of an international convention to protect TK. In response, WIPO, in its

[24] http://www.fao.org/docrep/010/a1404e/a1404e00.htm.

1998–99 biennium, instituted a schedule of regional fact-finding missions 'to identify and explore the IP needs, rights and expectations of the holders of traditional knowledge and innovations, in order to promote the contribution of the IP system to their social, cultural and economic development'. Australia was chosen as the first port of call for this expert mission, which visited Darwin and Sydney on 14–18 June 1998, and during 1998 and 1999 similar expert, fact-finding missions visited Peru, South Africa, Thailand and Trinidad and Tobago, and in November 1999 WIPO convened a World Forum on Traditional Knowledge.

Following the failure of the Seattle Ministerial in November 1999, WIPO became the focus of agitation for the inclusion of TK within the international IP regime. In a Note, dated 14 September 2000, the Permanent Mission of the Dominican Republic to the United Nations in Geneva submitted two documents on behalf of the Group of Countries of Latin America and the Caribbean (GRULAC) as part of the debate in the WIPO General Assembly on 'Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore'.[25] The central thrust of these documents was a request for the creation of a Standing Committee on access to the genetic resources and TK of local and indigenous communities. 'The work of that Standing Committee would have to be directed towards defining internationally recognized practical methods of securing adequate protection for the intellectual property rights in traditional knowledge.'[26]

In order to clarify the future application of IP to the use and exploitation of genetic resources and biodiversity and also TK, it was suggested that the Committee could clarify: (i) the notions of public domain and private domain; (ii) the appropriateness and feasibility of recognizing rights in traditional works and knowledge currently in the public domain, and investigating machinery to limit and control certain kinds of unauthorized exploitation; (iii) recognition of collective rights; (iv) model provisions and model contracts with which to control the use and exploitation of genetic and biological resources, and machinery for the equitable distribution of profits in the event of a patentable product or process being developed from a given resource embodying the principles of PIC and equitable distribution of profits in connection with the use, development and commercial exploitation of the material transferred and the inventions and technology resulting from it; (v) the protection of undisclosed TK.

WIPO Intergovernmental Committee

At the First Session of the IGC held in Geneva on 30 April–3 May 2001, the Member States determined the agenda of items on which work should proceed and prioritized certain tasks for the Committee. Principal among these was 'the development of "guide contractual practices", guidelines and model intellectual property clauses for contractual agreements on access to genetic resources and benefit-sharing'.[27]

[25] WIPO Doc. WO/GA/26/9.
[26] Ibid., Annex I, 10.
[27] See WIPO Doc., WIPO/GRTKF/IC/2/3, 10 September 2001, para.1.

By the Fifth Session of the IGC, which met in Geneva on 5–15 July 2003, the following resources, relevant to the issue of food security, had been developed:

- A consolidated survey of the protection of TK through IP laws and an analysis of case studies conducted by WIPO in 1998–99 on the use of IP to protect TK.[28]
- A Draft Toolkit on Intellectual Property Management,[29] which identifies concerns relating to the management of IP arising in the context of documenting TK.
- A compendium of contractual practices and clauses relating to IP, access to genetic resources and benefit-sharing.[30]
- A *Technical Study on Disclosure Requirements Related to Genetic Resources and Traditional Knowledge.*[31] This study reviewed salient aspects of the patent system and of legal mechanisms concerning access to genetic resources and associated TK, and surveyed the responses to a questionnaire circulated to WIPO Member States on patent disclosure requirements.
- Technical proposals, submitted by the Asian group of countries on databases and registries of TK and biological/genetic resources, which were based on the conclusions of the WIPO Asia-Pacific Regional Seminar on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, held in Cochin, India, on 11–13 November 2002.[32]

The seventh session of the IGC, which met in Geneva on 15–19 March 2004, considered Draft Intellectual Property Guidelines for Access and Benefit Sharing Contracts,[33] which sought to provide assistance in the negotiation of contracts for access to genetic resources and related information, including TK, and for benefit-sharing arrangements. The IGC's Draft Technical Study on patent disclosure requirements relevant to genetic resources and TK, which was transmitted for adoption by the COP, proposed a text on modalities for addressing disclosure of information about genetic resources in patent applications.[34] Defensive protection measures relating to IP, genetic resources and TK were considered by the IGC including: the question of the recognition of orally disclosed TK; measures for improving the documentation of genetic resources and TK for use in patent procedures; and methods for improving the understanding of innovations within TK systems for the purposes of patent search and examination.[35]

[28] See WIPO Doc., WIPO/GRTKF/IC/5/8 and WIPO/GRTKF/IC/5/7, which updates and consolidates the information received through the survey WIPO/GRTKF/IC/2/5 and the questionnaires circulated to Member States.
[29] See WIPO/GRTKF/IC/5/5.
[30] See WIPO/GRTKF/IC/5/9.
[31] See WIPO/GRTKF/IC/5/10.
[32] See WIPO/GRTKF/IC/4/14.
[33] WIPO/GRTKF/IC/6/5.
[34] WIPO/GRTKF/IC/6/9
[35] WIPO/GRTKF/IC/6/8.

Substantive PLT

In an endeavour to reach a consensus on substantive patent law issues, a Committee of Experts and WIPO's Standing Committee on Patents (SCP) considered a draft PLT, which had been prepared by the International Bureau of WIPO. The Draft PLT dealt with various procedural aspects of patenting. At the third session of the SCP on 6–14 September 1999, the delegation of Colombia proposed the introduction into the PLT, as a means of achieving some global harmonization of patent registration procedures, an article which provided that:

1. All industrial protection shall guarantee the protection of the country's biological and genetic heritage. Consequently, the grant of patents or registrations that relate to elements of that heritage shall be subject to their having been acquired or made legally.
2. Every document shall specify the registration number of the contract affording access to genetic resources and a copy thereof whereby the products or processes for which protection is sought have been manufactured or developed from genetic resources, or products thereof, of which one of the member countries is the country of origin.

This proposal generated a heated debate about whether, in the first instance, it raised a matter of procedural or substantive patent law. Agreement was eventually reached to defer consideration of this proposal to the occasion of the discussion of a proposed Substantive PLT. The SCP requested the International Bureau to include the issue of protection of biological and genetic resources on the agenda of a Working Group on Biotechnological Inventions, to be convened at WIPO in November 1999. The Working Group, at its meeting the following month, recommended the establishment of nine projects related to the protection of inventions in the field of biotechnology. The Working Group decided to establish a questionnaire for the purpose of gathering information about the protection of biotechnological inventions, including certain aspects regarding IP and genetic resources, in the Member States of WIPO.

An alternative approach to the protection of TK, is its recognition as part of 'prior art'. As prior art it would call into question the novelty and inventiveness of inventions that are the subject of patent applications. The practical difficulty that patent examiners have in identifying relevant TK as prior art arises from the fact that they do not have access to TK information in classified non-patent literature and because there are no effective search tools for the retrieval of such information. The WIPO IGC has begun to address practical measures to establish linkages between IP Offices and TK documentation initiatives.[36] A number of the characteristics of TK present difficulties in identifying the prior art effect of technological information. These include:

(a) The transmission of traditional knowledge through oral communication. This requires the codification and fixation of traditional knowledge into what it is not.

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

(b) Traditional knowledge systems tend to dynamic evolution without necessarily being identified as 'new'.
(c) Traditional knowledge is expressed in local languages and its expression is contingent upon such languages.
(d) The transfer of knowledge from oral into written, printed and electronic forms may involve a cultural, semantic and symbolic transformation of the knowledge, which may affect the value of databases as a tool for the conservation of culture and knowledge.
(e) As knowledge must be in the public domain to be considered as prior art, this may provide some difficulties in those communities where knowledge is to be kept confidential.

The draft Substantive PLT, which was submitted to the fifth session of the WIPO's Standing Committee on the Law of Patents (SCP), held in Geneva on 14–19 May 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.

TRIPS Agreement

A particular contemporary impetus for the formulation of an international position on the protection of TK has been the debate concerning the review of Art. 27.3(b) of the plant variety provision of the TRIPS Agreement. Review of this provision was mandated by the TRIPS Agreement itself, to be completed by the end of 1999. Developing country participants in the review process have suggested the importation into the TRIPS Agreement of the provisions in the CBD, which provide for equitable sharing with indigenous peoples of the benefits of the utilization of traditional medical knowledge.[37] The African Group of countries proposed the inclusion of this issue in the Ministerial Conference to set the agenda for the Seattle Round of the WTO.[38] On 25 July 1999, a federation of Indigenous Peoples groups issued a statement for the purposes of the review, pleading for a legislative structure which 'Builds upon the indigenous methods and customary laws protecting knowledge and heritage and biological resources' and which prevents the appropriation of TK and integrates 'the principle and practice of prior informed consent, of indigenous peoples as communities or as collectivities'. The Statement concluded with an affirmation of the commitment of Indigenous Peoples 'to sustain our struggle to have our rights to our intellectual and cultural heritage and our lands and resources promoted and protected'.

[37] See M. Blakeney (1998/1999) Biotechnology, TRIPS and the Convention on Biological Diversity. *Bio-Science Law Review* 4, 144.
[38] *Communication to the WTO from Kenya, on behalf of the African Group,* WT/GC/W/3026, August 1999.

On 4 October 1999, Bolivia, Colombia, Ecuador, Nicaragua and Peru specifically proposed that the Seattle Ministerial Conference establish within the framework of the Round a mandate:

> (a) To carry out studies, in collaboration with other relevant international organizations in order to make recommendations on the most appropriate means of recognizing and protecting traditional knowledge as the subject matter of intellectual property rights.
>
> (b) On the basis of the above-mentioned recommendations, initiate negotiations with a view to establishing a multilateral legal framework that will grant effective protection to the expressions and manifestations of traditional knowledge.
>
> (c) To complete the legal framework envisaged in paragraph (b) above in time for it to be included as part of the results of this round of trade negotiations.[39]

A communication of 6 August 1999 from Venezuela proposed that the Seattle Ministerial should consider the establishment 'on a mandatory basis within the TRIPS Agreement a system for the protection of intellectual property, with an ethical and economic content, applicable to the traditional knowledge of local and indigenous communities, together with recognition of the need to define the rights of collective holders'.[40]

A practical proposal for the integration of TK with IPR is India's suggestion that material transfer agreements be required where an inventor wishes to use biological material identified by TK. That obligation would be incorporated through inclusion in Art. 29 of the TRIPS Agreement, the requirement that the country of origin of source material be identified in patent applications.[41] Following the failure of the Seattle Ministerial, this agitation for the inclusion of TK within the international IP regime shifted to WIPO, until it was picked up again at the Doha Ministerial.

Article 19 of the November 2001 Doha Declaration instructed the Council for TRIPS, in pursuing its work programme concerning both its review of Art. 27.3(b) and its general review of the implementation of the TRIPS Agreement under Art. 71.1, 'to examine, *inter alia*, the relationship between the TRIPS Agreement and the CBD, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to Art. 71.1'.

Following the Doha approach, amendments have been proposed to the TRIPS Agreement (Art. 29*bis*) which would require WTO Members to oblige patent applicants to disclose the source of any TK and evidence of compliance with legal requirements in the source country of PIC for access and fair and equitable benefit sharing arising from the utilization of the TK.[42] The African Group of Countries have proposed that as part of the review of Art. 27.3(b), TK should be protected as a 'category of intellectual property rights'.[43] The scheme of protection they proposed would include the grant of rights to local or traditional communities concerning: (i) respect for those communities on the commercialization of TK; (ii) PIC to the use

[39] WT/GC/W/362 12 October 1999.
[40] WT/GC/W/282.
[41] WT/GC/W/147.
[42] Discussed in A. Tabman and M. Leistner (2008) Analysis of different areas of indigenous resources. In: S. von Lewinski (ed.) *Indigenous Heritage and Intellectual Property: Genetic Resources, Traditional Knowledge and Folklore*, 2nd edn. Wolters Kluwer, Alphen aan den Rijn, 59 at 166.
[43] IP/C/W/404, 26 June 2003.

of that TK; (iii) full remuneration; and (iv) the prevention of unauthorized third parties from utilizing that TK and incorporating that TK into any article or product.

Debate is still continuing within the TRIPS Council as to whether it has a mandate to amend TRIPS by the inclusion of an Art. 29*bis* or whether that discussion is to be confined to the implementation of the existing text.[44]

The CBD

The Rio Declaration in Principle 22 stated that 'Indigenous peoples and their communities … have a vital role in environmental management and development because of their knowledge and traditional practices'. Chapter 26 of Agenda 21 detailed the relationship which conference participants recognized between indigenous peoples and their lands. The Agenda, at para. 26.3(a), required governments:

> to establish a process to empower indigenous peoples and their communities' through measures that include:
>
> - recognition of their values, traditional knowledge and resource management practices with a view to promoting environmentally sound and sustainable development;
> - enhancement of capacity-building for indigenous communities based on the adaptation and exchange of traditional experience, knowledge and resource-management practices, to ensure their sustainable development;
> - establishment, where appropriate, of arrangements to strengthen the active participation of indigenous peoples and their communities in the national formulation of policies, laws and programs relating to resource management and other development processes that may affect them.

The Preamble to the CBD recognized the

> … close and traditional dependence of many Indigenous and local communities embodying traditional lifestyles on biological resources, and the desirability of sharing equitably arising from the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity and sustainable use of its components.

Article 8(j) of the Convention required each signatory

> … subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.

The provisions of Art. 8(j) require implementation through national legislation. It is expressed to be subject to national legislation, in order to preserve legislation on this subject, which predates the CBD.

[44] See WTO Secretariat, *The Protection of Traditional Knowledge and Folklore: Summary of Issues Raised and Points Made*, IP/IC/W/370/Rev.1, 9 March 2006.

The Ad Hoc Open-ended Inter-Sessional Working Group on Art. 8(j) and Related Provisions of the CBD was established by decision IV/9 of the COP to the CBD. It held its first meeting in Seville, Spain, on 27–31 March 2000. This Working Group has been developing an international regime on access and benefit sharing. At the fourth meeting of the Working Group, held on 23–27 January 2006 in Granada, it identified five elements to be considered for inclusion in the international regime, namely:

(i) Measures to ensure compliance with prior informed consent of indigenous and local communities holding traditional knowledge associated with genetic resources, in accordance with Art. 8(j);
(ii) Disclosure of origin/source/legal provenance of genetic resources and associated traditional knowledge in applications for intellectual property rights;
(iii) Recognition and protection of the rights of indigenous and local communities over their traditional knowledge associated to genetic resources subject to the national legislation of the countries where these communities are located;
(iv) Customary law and traditional cultural practices of indigenous and local communities;
(v) Code of ethics/code of conduct/models of prior informed consent or other instruments in order to ensure fair and equitable sharing of benefits with indigenous and local communities.[45]

Considerable progress is still required before agreement can be reached on an international regime on access and benefit sharing. At the eighth meeting of the COP in Curitiba, 20–31 March 2006, much of the text of the proposed regime remains unresolved and within square brackets. In relation to TK, the following text is before the parties:

> (a) [Parties may consider developing, adopting and/or recognizing, as appropriate, [international,] national and local *sui generis* [models] [systems] for the protection of traditional knowledge, innovations and practices associated to genetic resources, [derivatives and products]];
>
> (b) [Subject to its national legislation,] Parties [should] [recognize and protect the rights] [respect, preserve and maintain knowledge, innovations and practices] of indigenous and local communities and [ensure] [encourage] the equitable sharing of benefits arising from the utilization of such knowledge, innovations and practices [regarding benefit-sharing derived from their traditional knowledge associated with genetic resources, [derivatives and products,] subject to the national legislation of the countries where these communities are located [and to applicable international law];
>
> (c) [[Users [Parties] should comply with the prior informed consent of indigenous and local communities holding traditional knowledge associated with genetic resources, [derivatives and products] in accordance with Art. 8(j) of the Convention on Biological Diversity, subject to national legislation of the country where these communities are located [and to applicable international law]];
>
> (d) [Access and benefit sharing arrangements relating to traditional knowledge should be implemented in the context of national ABS regimes.][46]

[45] UNEP/CBD/COP/8/1/Add.2, 26, 1 March 2006.
[46] Ibid., Annex 1.

6.6 Regional and National Agreements for the Protection of TK

One of the difficulties for both the international organizations and regional and national legislatures in providing for the protection of TK is that subject matter of protection is 'highly diverse and dynamic' such that 'it may not be possible to develop a singular and exclusive definition of the term'.[47]

Access to TK in violation of requirements of PIC is defined as an act of misappropriation; the Draft African Regional Intellectual Property Organization (ARIPO)/Organisation Africaine de la Propriété Intellectuelle (OAPI) Framework for an African Instrument on the Protection of Traditional Knowledge defines the term 'traditional knowledge' as

> … the content or substance of knowledge that is the result of intellectual activity and insight in a traditional context, and includes the know-how, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge that is embodied in the traditional lifestyle of a community or people, or is contained in codified knowledge systems passed between generations. It is not limited to any specific technical field, and may include agricultural, environmental or medical knowledge, and knowledge associated with genetic resources.[48]

The Draft Legal Instrument for South Asian Association for Regional Cooperation (SAARC) Countries on Protection of Traditional Knowledge defines the term 'traditional knowledge' as

> … the content or substance of knowledge that is the result of intellectual activity and insight in a traditional context, and includes the know-how, skills, innovations, practices and learning that form part of traditional knowledge systems, and knowledge that is embodied in the traditional lifestyle of a community or people. It is not limited to any specific technical field, and may include agricultural knowledge and knowledge associated with genetic resources or other components of biological diversity.[49]

In advance of the development of an international regime to protect TK, a number of countries apply existing IP laws to protect TK.[50] Laws opposed to wrongful misappropriation or unfair competition have been suggested as particularly useful in this regard. The concept of misappropriation evolved under unfair competition law, in some countries through the evolution of the common law. A US Supreme Court has developed a misappropriation doctrine under tort law, holding a person liable for the taking of publicly disclosed or disseminated intangible objects where that intangible was developed through substantial investment and where such taking caused damage to its original holder.[51] Misappropriation laws have been identified as particularly useful in protecting the investment in developing intangible goods, which

[47] WIPO (2001) *Intellectual Property Needs and Expectations of Traditional Knowledge Holders: WIPO Report on Fact-Finding Missions on Intellectual Property and Traditional Knowledge (1998–1999).* WIPO, Geneva.

[48] Article 1.2, draft ARIPO/OAPI Instrument.

[49] Article 2.1, draft SAARC Instrument

[50] See WIPO/GRTKF/IC/9/INF/5.

[51] *International News Service v. Associated Press* 248 U.S. 215 (1918).

are otherwise ineligible for traditional intellectual property protection'.[52] Misappropriation has been identified by the IGC as a particularly useful basis for the protection of TK.[53]

Most national *sui generis* laws for TK protection apply the principle of PIC.[54] Access to TK in violation of requirements of PIC is defined as an act of misappropriation in the Draft Framework for an African Instrument on the Protection of Traditional Knowledge and the Draft Legal Instrument for SAARC Countries on Protection of Traditional Knowledge.[55] The draft African instrument prohibits the

> … commercial or industrial use of traditional knowledge without just and appropriate compensation to the recognized holders of the knowledge, when such use has gainful intent and confers a technological or commercial advantage on the user, and when compensation would be consistent with fairness and equity in relation to the holders of the knowledge in view of the circumstances in which the user acquired the knowledge.[56]

The draft African Model Legislation provides that protection shall not affect the traditional systems of access, use or exchange of biological resources and access, use and exchange of knowledge and technologies by and between local communities. The sharing of benefits based on the customary practices of the concerned local communities is also not affected neither does it extend to persons who are not living in the traditional and customary way of life relevant to the conservation and sustainable use of biological resources.[57]

The Draft SAARC Framework also provides that TK protection

> … should not adversely affect (i) the continued availability of traditional knowledge for the customary practice, exchange, use and transmission of traditional knowledge by traditional knowledge holders; and (ii) the use of traditional medicine for household purposes, use in government hospitals, or for other non-commercial public health purposes.[58]

Interestingly, the TK law of Portugal limits its definition of TK to that associated to local plant varieties:

> Traditional knowledge is all the intangible elements associated to the commercial or industrial use of local varieties and other endogenous material developed by local communities, collectively or individually, in a non-systematic manner and that are inserted in the cultural and spiritual traditions of those communities, including, but not limited to, knowledge relating to methods, processes, products and denominations that are applicable in agriculture, food and industrial activities in general, including handicrafts, trade and services, informally associated to the use and preservation of local varieties and other endogenous and spontaneous material that is covered by the present law.[59]

[52] R.Y. Fujichaku (1998) The misappropriation doctrine in cyberspace: protecting the commercial value of 'hot news' information. *University of Hawaii Law Review* 20, 421 at 439, cited ibid., at p.61.
[53] WIPO/GRTKF/IC/9/INF/5 at para 31.
[54] See e.g. Brazil, Costa Rica, India, Peru, the Philippines and Portugal; see WIPO/GRTKF/IC/5/INF/4, Annex I.
[55] Article 5.3(ii), Draft ARIPO Instrument; Article 7.3(b), draft SAARC Framework.
[56] Article 5.3(iv), draft ARIPO/OAPI Instrument.
[57] Article 2, African Model Law.
[58] Article 7*ter*, draft SAARC Instrument.
[59] Decree Law No.118 of 2002 Establishing a Legal Regime of Registration, Conservation, Legal Custody and Transfer of Plant Endogenous Material ('Portuguese Sui Generis Law'), Article 3(1).

Under the Portuguese TK law, all TK shall be protected against reproduction or commercial or industrial use, subject to being identified, described and registered in the Register of Plant Genetic Resources.[60]

Under the legislation of Brazil, TK must be related to the genetic heritage, belong to an indigenous or local community, and have real or potential value, in order to be eligible for protection.[61] Similarly, under the TK law of Peru, protection is granted where the knowledge must have been developed and preserved collectively[62] and relates to biological diversity and is developed by indigenous peoples,[63] provided that it is not in the public domain.[64]

Key to regional and national legislation is the principle of benefit-sharing. The draft ARIPO/OAPI Instrument states that 'commercial or industrial use of traditional knowledge should be subject to just and appropriate compensation for the benefit of the traditional holders of the knowledge'.[65] The draft SAARC Framework provides that commercial or industrial use of TK without just and appropriate compensation shall be a prohibited act of misappropriation.[66] The Brazilian Provisional Measure provides that 'the benefits arising from economic exploitation of a product or process developed from … associated traditional knowledge … shall be shared in a fair and equitable way between the contracting parties'.[67]

Under the Indian Biodiversity Act the term 'benefit-claimers' – i.e. the list of those stakeholders who are entitled to benefit-sharing – includes 'creators and holders of knowledge and information relating to the use of such biological resources, innovations and practices associated with such use and application'.[68]

The Preamble to the Peruvian Sui Generis Law states that 'this instrument will form the basis for the fair allocation of the benefits generated by the use of this material', i.e. autochthonous plant genetic material and provides that 'in the event of access for the purposes of commercial or industrial application, a license agreement shall be signed … in which the equitable distribution of the benefits deriving therefrom is guaranteed'.[69]

As this legislation demonstrates, TK protection measures have to be coordinated with legal frameworks regulating access to genetic resources, particularly where protection of TK is linked to the application of the principle of PIC to access and use of certain TK elements associated with genetic resources.

[60] Article 3(2), Portuguese Sui Generis Law.
[61] Provisional Measure No. 2186-16 of 2001 Regulating Access to the Genetic Heritage, Protection of and Access to Associated Traditional Knowledge ('Brazilian Provisional Measure') Article 7.II and 8.
[62] Law No. 27,811 of 2002 Introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples Derived from Biological Resources (Peruvian Sui Generis Law), Article 2(b).
[63] Article 2(a), Peruvian Sui Generis Law.
[64] Article 42, Peruvian Sui Generis Law.
[65] Article 7.1, draft ARIPO/OAPI Instrument.
[66] Article 7*bis*, draft SAARC Framework.
[67] Article 24, Brazilian Provisional Measure.
[68] Section 2(a), Indian Biodiversity Act.
[69] Article 27(c), Peruvian Sui Generis Law.

6.7 Indigenous Peoples and the Protection of TK

Indigenous communities consider that their TK is holistically linked with their custodianship of the genetic resources on their land and, indeed, their rights of self-determination.[70] Indigenous peoples have themselves called for either the creation of a *sui generis* IP regime or the modification of existing patent and copyright laws to confer rights upon indigenous peoples in both their genetic resources and TK. The Rio Earth Summit of 1992, which produced the CBD, coincided with the United Nations Year of Indigenous Peoples. A number of conferences of indigenous peoples in 1992 issued declarations and statements affirming the IPR of indigenous peoples, and interpreting and elaborating the IP issues raised in the Biodiversity Convention. Principal among these were: the Penang Conference of February 1992, which promulgated the *Charter of the Indigenous-Tribal Peoples of the Tropical Forests (CITP)*; the World Conference of Indigenous Peoples on Territory, Environment and Development, held at Kari-Oca, Brazil, in May 1992, which issued the *Indigenous Peoples Earth Charter*; and the First International Conference on the Cultural and Intellectual Property Rights of Indigenous Peoples, held in the Bay of Plenty Region, New Zealand, in June 1993, which issued the *Mataatua Declaration on the Cultural and Intellectual Property Rights of Indigenous People*.[71]

Typical of these declarations was the Declaration Reaffirming the Self-Determination and Intellectual Property Rights of the Indigenous Nations and Peoples of the Wet Tropics Rainforest Area, issued at the Julayinbul Conference on Intellectual and Cultural Property, held at Jingarrba, in the Daintree Forest region of North-Eastern Australia on 27 November, 1993. Clause 5 of the Declaration asserted:

> That the intellectual property of the Indigenous Nations and Peoples of the Wet Tropics region includes and has always included the ability to discover and make what they deem appropriate use of new knowledge derived from their total environment: such as the discovery of new genotypes and the right to control subsequent use of and access to the genetic make-up within the flora and fauna of the forests.

The Final Statement issued by the *South Pacific Regional Consultation on Indigenous Peoples' Knowledge and Intellectual Property Rights*, held in Suva, Fiji, in April 1995, declared 'the right of indigenous peoples of the Pacific to self-governance and independence of our lands, territories and resources as the basis for the preservation of indigenous peoples' knowledge'. Article 1 of the Final Statement sought a treaty to declare the Pacific region 'a life forms patent-free zone'. Article 2 called for 'a moratorium on bioprospecting in the Pacific' and urged indigenous peoples not to co-operate in bioprospecting activities until appropriate protection mechanisms are in place. Article 7 urged the 'strengthening of indigenous networks and encouraged the UN and regional donors

[70] See A. Taubman (2008) Genetic resources. In: S. Von Lewinski (ed.) *Indigenous Heritage and Intellectual Property: Genetic Resources, Traditional Knowledge and Folklore*, 2nd edn. Wolters Kluwer, Alphen aan der Rijn, 180 at 185.

[71] Some 15 declarations and statements are listed in G. Dutfield (2002) Indigenous peoples declarations and statements and equitable research relationships. In: S.A. Laird (ed.) *Biodiversity and Traditional Knowledge: Equitable Partnerships in Practice*. Earthscan, London, 228.

to continue and support discussions on indigenous peoples' knowledge and intellectual property rights'.

On 25 July 1999, a federation of indigenous peoples groups issued a statement for the purposes of the review of Art. 27.3(b) of the TRIPS Agreement. The Statement commences with the observation that 'Humankind is part of Mother Nature, we have created nothing and so we can in no way claim to be owners of what does not belong to us. But time and again, western legal property regimes have been imposed on us, contradicting our own cosmologies and values.' It expresses concern that Art. 27.3(b) 'will further denigrate and undermine our rights to our cultural and intellectual heritage, our plant, animal, and even human genetic resources and discriminate against our indigenous ways of thinking and behaving'.

The Statement drew the distinction between private proprietorial rights and: 'Indigenous knowledge and cultural heritage [which] are collectively and accretionally evolved through generations…The inherent conflict between these two knowledge systems and the manner in which they are protected and used will cause further disintegration of our communal values and practices.'

The Statement pleaded for a legislative structure which 'Builds upon the indigenous methods and customary laws protecting knowledge and heritage and biological resources' and which prevents the appropriation of TK and integrates 'the principle and practice of prior informed consent, of indigenous peoples as communities or as collectivities'.

This Statement was picked up by a submission of Cuba, Honduras, Paraguay and Venezuela to the TRIPS Council,[72] which stated that these countries 'consider it fair to recognise the specific contribution of indigenous and tribal peoples and local communities to the cultural diversity and social and ecological harmony of mankind'.

One of the results of the International Decade of the World Indigenous Peoples (1995–2004) was the promulgation, by the UN General Assembly on 13 September 2007 of a Declaration on the Rights of Indigenous Peoples. Article 31 of the Declaration provides that:

> 1. Indigenous peoples have the right to maintain, control, protect and develop their cultural heritage, traditional knowledge and traditional cultural expressions, as well as the manifestations of their sciences, technologies and cultures, including human and genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs, sports and traditional games and visual and performing arts. They also have the right to maintain, control, protect and develop their intellectual property over such cultural heritage, traditional knowledge, and traditional cultural expressions.
>
> 2. In conjunction with indigenous peoples, States shall take effective measures to recognize and protect the exercise of these rights.

The Declaration, which is binding in morality only, was supported by 143 countries with four countries voting against it[73] and 11 abstaining.[74]

[72] *Proposal on the Protection of the Intellectual Property Rights of the Traditional Knowledge of Local and Indigenous Communities*, WT/GC/W/362, 12 October 1999.

[73] Australia, Canada, New Zealand and the United States.

[74] Azerbaijan, Bangladesh, Bhutan, Burundi, Colombia, Georgia, Kenya, Nigeria, Russian Federation, Samoa and Ukraine.

Some national legislation has linked the recognition of the rights of indigenous peoples with their custodianship of TK and genetic resources. Thus for example, the Indigenous Peoples' Rights Act of the Philippines of 1997 provides that Indigenous Peoples

> … shall have the right to special measures to control, develop and protect their sciences, technologies and cultural manifestations, including human and other genetic resources, seeds, including derivatives of these resources, traditional medicines and health practices, vital medicinal plants, animals and minerals, indigenous knowledge systems and practices, knowledge of the properties of fauna and flora, oral traditions, literature, designs, and visual and performing arts.[75]

6.8 Remunerating Farmers and TK Owners

Benefit sharing regimes were discussed in the previous chapter and mention was made above of the unconsummated attempts to establish an International Fund for Plant Genetic Resources. One practical attempt to establish a fund to remunerate traditional farmers for the contribution which they made in conserving useful germplasm was the GRRF, sought to be established by UC Davis. This arose out of the episode described in the previous chapter when the University patented a disease resistance gene, *Xa21*, which was contained in a rice type developed by IRRI from a landrace identified and conserved by traditional farmers in Mali. The GRRF was established as a mechanism to share financial benefits with Mali and other source countries involved in future developments by funding Fellowships for scholars from those source countries.

The negotiations for the establishment of this fund disclose some of the difficulties involved in calculating a reasonable share of benefits for farmers and traditional communities. UC Davis proposed that companies marketing products based on *Xa21* should make payment in the form of a royalty of a certain percentage of sales of the products. However, from the companies' perspective, *Xa21* would only make a small contribution to the genome and desirable traits of any new crop variety developed, so they were not prepared to make an open-ended royalty payment and settled for a single lump sum payment.[76] As has been mentioned above, given that many commercial crops include sometimes a large number of source materials, the quantification of benefits to be shared with source countries is often going to be a difficult task. Similarly, only a minute proportion of research will lead to a successful commercial product for the companies, so any payment will necessarily be a rough estimate. In the case of a university or research institute seeking access to countries for the purposes of bioprospecting, the payment will often be a pragmatic estimate which will secure them the appropriate access.

[75] Section 34, Republic Act No 837, An Act to Recognize, Protect and Promote the Rights of Indigenous Cultural Communities/Indigenous People, Creating a National Commission of Indigenous People, Establishing Implementing Mechanisms etc.

[76] US$52,000 in the case of the first company, and US$30,000 in the case of the second company see K. ten Kate and A. Collis (1999) The Genetic Resources Recognition Fund of the University of California, Davis. Submission to the Executive Secretary of the Convention on Biological Diversity by the Royal Botanic Gardens, Kew, 1999, at 10.

7 Intellectual Property Aspects of Genetically Modified Organisms and Food Security

7.1 Introduction

Biotechnology proponents, especially in the areas of food and agricultural production, assert its ability to deliver increased food security.[1] This is to be achieved not only through higher-yielding crops and improved animal husbandry techniques, but also through a catalogue of other improvements, which include the introduction of disease resistance, the enhancement of micronutrient levels, the development of resistance to inhospitable conditions, the introduction of vitamins and the removal of allergens.[2] Opponents of biotechnology are sceptical about the role of biotechnology in increasing food security;[3] they point to the threats it poses to sustainable development,[4] to agricultural and environmental biodiversity and to public health;[5] they counsel caution about the 'not yet well known risks of gene technology'.[6] Oxfam has observed that although the share of transgenic crops grown in the developing

1 See e.g. C. Ives, B. Bedford and K. Maredia (1998) The agricultural biotechnology for sustainable productivity project: a new model in collaborative development. In: C. Ives and B. Bedford (eds), *Agricultural Biotechnology in International Development* 1, 2; Nuffield Council on Bioethics, *Genetically Modified Crops: The Ethical & Social Issues*, esp. chap. 4, http://www.nuffield.org/bioethics/publication/modifiedcrops/index.html.

2 Nuffield Council on Bioethics, n. 1 supra, Overview.

3 Press Release from Non-Government and Farmers' Organisations, Food for All – Farmers First in Research, Global Forum on Agricultural Research, 22 May 2000: 'The root cause of hunger is not a lack of technology, but rather pervasive social economic and political inequalities and injustices, which prevent the poor to [sic.] having access to the abundance that surrounds us.' See also K. Barrett and G. Flora (2000) *Genetic Engineering & the Precautionary Principle: Information for Extension*. Science & Environmental Health Network, chap. 2.

4 See e.g. J. Kloppenberg and B. Burrows (1996) Biotechnology to the rescue? Twelve reasons why biotechnology is incompatible with sustainable agriculture. *The Ecologist* 26, 61.

5 See e.g. Barrett and Flora, n. 3 supra. Interestingly, given the arguments of the pro-GM camp, one of the often-cited risks to public health is the possibility of the development of new allergens.

6 Press Release from Non-Government and Farmers' Organisations, n. 3 supra.

world has been increasing, coverage is almost exclusively confined to 'a small number of relatively prosperous, export-oriented countries – and a small number of commercial crops'.[7]

From the perspective of food security it has been observed that 'rather than focussing on improving yields in marginal lands, nearly all research into GM crops is going into improving food-processing qualities, transport durability, appearance and shelf-life – traits favouring sales in Northern niche markets rather than meeting food needs in the South'.[8] Further, it is noted that GM crops are developed with large-scale agricultural techniques in mind, with a view to obtaining a financial return on R&D and patenting expenses.[9] Again this favours farming methods in the North, rather than the small-scale cultivation of the South.

The relationship between genetic engineering and patenting is also condemned as the basis for the extension of 'control over the biological wealth and the traditional knowledge of the gene rich developing countries'.[10] Overlaying and incorporating all this is enormous consumer concern about GMOs, especially where they occur in food or are used in food production.[11]

Studies of the economic impacts of GMOs upon agriculture indicate differences between developing countries.[12] Institutional factors such as national agricultural research capacity and the IP infrastructure have been identified as critical determinants of the level of economic benefits.[13] The principal studies which have been made have focused on the cultivation of GM cotton in China and Argentina.[14] The principal study of a GM food crop in a developing country is Argentine experience with soybeans. Paradoxically, the enthusiastic embrace of GM soybean by Argentine farmers is attributable to Monsanto's failure to patent its soybean invention in Argentina.[15] As is discussed below, this enthusiasm might be curbed if Monsanto is able to enforce its patent in those countries to which Argentinian soya is exported.

7 Oxfam (2002) *Rigged Rules and Double Standards: Trade, Globalisation and the Fight against Poverty.* Oxfam, Oxford, 223.

8 J. Oram (1999) The TRIPS Agreement and its implications for food security. International FamineCentre, Cork, http://www.recrea.f9.co.uk/biopatents.htm.

9 See M. Kropiwnicka (2005) Biotechnology and food security in developing countries. The case for strengthening international environmental regimes. *ISYP Journal on Science and World Affairs* 1, 45.

10 D. Sharma, Conquests by Patents. *Pakistan Observer*, 22 August 1999, quoted in G. Downes, *Implications of TRIPS For Food Security in the Majority World, Dublin, Comhlámh Action Network*, October 2003, 23.

11 This concern has been much greater in Europe, e.g. than it has been in the USA. For a discussion of the differences in consumer perceptions on different sides of the Atlantic Ocean, see Nuffield Council on Bioethics, n. 1 supra, chap. 5.

12 See T. Raney (2006) Economic impact of transgenic crops in developing countries. *Current Opinion in Biotechnology* 17 1.

13 D. Byerlee and K. Fischer (2002) Accessing modern science: policy and institutional options for agricultural biotechnology in developing countries. *World Development* 30, 913; D. Zilberman and G. Graaf G (2005) IPR innovation and the evolution of biotechnology in developing countries. *Quarterly Journal of International Agriculture* 44, 247.

14 See e.g. J. Huang, R. Hu, C. Pray, F. Qiao and S. Rozelle (2003) Biotechnology as an alternative to chemical pesticides: a case study of Bt cotton in China. *Agricultural Economics* 29, 55; M. Qaim and A. de Janvry (2003) Genetically modified crops, corporate pricing strategies, and farmers' adoption: the case of Bt cotton in Argentina. *American Journal of Agricultural Economics* 85, 814.

15 M. Qaim and G. Traxler (2004) Roundup Ready soybeans in Argentina: farm level, environmental and welfare effects. *Agricultural Economics* 32, 73.

One of the problems for policy makers in deciding how much latitude to allow to the genetic modification of food crops is that there is a lack of consensus among scientists and agronomists as to the harmfulness or safety of GMOs. At one end of the spectrum are those who oppose any interference with the 'intrinsic integrity' of plant genomes.[16] At the other end are those who point out that genetic engineering merely replicates the results of spontaneous genetic alterations.[17]

The concerns that have been expressed with GMOs range generally across issues concerned with health, environmental protection and ethics. In response to these concerns, national, regional and international regulatory structures are emerging. At the international level, the principal regulatory structures are those established under the WTO and the CBD. The principal WTO Agreements which affect the area of biotechnology regulation are the SPS Agreement and the TBT Agreement. The particular initiative under the CBD that concerns itself with biotechnology is the Cartagena Protocol on Biosafety.

7.2 WTO SPS Agreement

The significance and operation of the SPS Agreement were addressed by the WTO panel and Appellate Body in the US/EU Beef Hormone dispute.[18] In this case, the panel and the Appellate Body held that an EU ban on trade in beef from any source containing artificially administered growth hormones violated the SPS Agreement.

Despite its first recital '*[r]eaffirming* that no member should be prevented from adopting or enforcing measures necessary to protect, human, animal or plant life or health', the SPS Agreement is essentially concerned with placing limitations on the introduction of such measures. Consistently with the approach of other WTO Agreements, these limitations flow from the Agreement's concern to ensure that the measures in question are, in the words of the first recital, 'not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between Members … or a disguised restriction on international trade'.[19] Further limitations arise from the requirements of Art. 2 that any SPS measures be 'necessary',[20] be 'applied only to the extent necessary'[21] to protect human, animal or plant life or health, and be based on scientific principles and evidence.[22]

[16] E.T.L. Van Bueren, P.C. Struik, M. Tiemens-Hulscher and E. Jacobsen (2003) Concepts of intrinsic value and integrity of plants in organic plant breeding and propagation. *Crop Science* 46, 1922; E.T.L. Van Bueren and P. C. Struik (2005) Integrity and rights of plants: ethical notions in organic plant breeding and propagation. *Journal of Agricultural & Environmental Ethics* 18, 479.

[17] W. Arber (2004) Biological evolution: lessons to be learned from microbial population biology and genetics. *Research in Microbiology* 155, 297, cited in K. Ammann (2007) Reconciling traditional knowledge with modern agriculture: a guide for building bridges. In: A. Krattiger, R.T. Mahoney, L. Nelsen, *et al.* (eds) *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices.* MIHR, Oxford, and PIPRA, Davis, CA, 1539.

[18] *EC – Measures Concerning Meat & Meat Products (Hormones)*, Panel Reports: Case WT/DS26/R/USA, 18 August 1997 & Case WT/DS48/R/CAN, 18 August 1997; Appellate Body Report: WT/DS26/AB/R & WT/DS48/AB/R, 16 January 1998.

[19] See SPS Agreement, Art. 2.3.

[20] SPS Agreement, Art. 2.1.

[21] SPS Agreement, Art. 2.2.

[22] SPS Agreement, Art. 2.2.

Sanitary and phytosanitary measures are defined in Annex A of the SPS Agreement as:

> Any measure applied:
>
> (a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;
>
> (b) to protect human or animal life or health within the Territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;
>
> (c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
>
> (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.
>
> Sanitary or phytosanitary measures include … packaging and labelling requirements directly related to food safety.

As may be seen, the focus of this definition is on measures concerned with pests, diseases, additives, contaminants and toxins. While it may be argued that GMOs are not always (or even typically) disease carrying, disease causing or otherwise toxic, it is likely that any measure that has the purpose of restricting the use of GMOs in foodstuffs or as part of food production would fall within the definition of an SPS measure. It seems that this would be true whether the motivation for the measure was human or animal health or safety, or the protection of the environment. The conclusion that measures in relation to GMOs are likely to fall within the SPS Agreement may be regarded as being reinforced by the Appellate Body in the *Beef Hormones* case. In that case, the European Communities argued that the level of protection which it had introduced in relation to growth hormones in beef cattle could not be compared with levels of protection in relation to naturally occurring hormones:

> Science and the regulatory practices of Members do not treat man-made risks, such as the risks created by hormones used for growth promotion, and naturally-occurring risks, such as those arising from the presence of hormones in meat, milk, cabbage or broccoli, in the same way. The *SPS Agreement* applies only to man-made risks because the naturally-occurring hormones in meat and other foodstuffs are not 'contaminants and toxins' within the meaning of the *SPS Agreement*.[23]

While the Appellate Body did not adopt the wide distinction drawn by the European Communities between natural and man-made risks, it agreed that 'there is a fundamental distinction between added hormones (natural or synthetic) and naturally-occurring hormones in meat and other foods'.[24] One might deduce from this that the element of human intervention might constitute an additive, contaminant or toxin within the meaning of the definition in Annex A of the SPS

[23] Appellate Body Report: WT/DS26/AB/R and WT/DS48/AB/R, para. 32.
[24] Ibid., para. 221.

Agreement. Applying this in the biotechnology area, human manipulation of the genetic structure of a plant or animal is likely to be regarded as being capable in some cases of constituting an additive, contaminant or toxin. Accordingly, a measure in relation to such a GMO may fall within the definition of SPS measures in Annex A.

An important role of the SPS Agreement is the harmonization of acceptable sanitary and phytosanitary measures across Member states. Article 3.1 requires members to base their sanitary or phytosanitary measures on any existing standards, guidelines or recommendations. The incentive to emulate, but not exceed, such standards, guidelines or recommendations is provided in Art. 3.2, which deems measures that conform to international standards to be necessary. Article 3.2 provides that measures conforming to international standards, guidelines or recommendations will be presumed to be consistent with both the SPS Agreement and with the GATT. According to the Appellate Body in the *Beef Hormones* decision, Art. 3 of the SPS Agreement distinguishes between three types of measures: firstly, measures 'conforming' to international standards; secondly, measures 'based on' international standards; and thirdly, measures which result in a higher level of protection than provided for in international standards. The first and second class of measures are permitted, but only the first class of measures obtains the benefit of the presumption in Art. 3.2. The third class of measures will be permitted only if they comply with the principles of risk assessment laid down in Art. 5, which is discussed below.

The standards, guidelines or recommendations envisaged in Art. 3 are to be set under the auspices of the relevant international organizations. Article 3.4 identifies the Codex Alimentarius Commission, the International Office of Epizootics and the organizations operating under the International Plant Protection Convention as being of particular relevance in setting such standards. More specifically, Annex A, paragraph 3 defines the international standards, guidelines and recommendations as the following:

(a) for food safety, the standards, guidelines and recommendations established by the Codex Alimentarius Commission relating to food additives, veterinary drug and pesticide residues, contaminants, methods of analysis and sampling, and codes and guidelines of hygienic practice;
(b) for animal health and zoonoses, the standards, guidelines and recommendations developed under the auspices of the International Office of Epizootics;
(c) for plant health, the international standards, guidelines and recommendations developed under the auspices of the Secretariat of the International Plant Protection Convention in cooperation with regional organizations operating within the framework of the International Plant Protection Convention; and
(d) for matters not covered by the above organizations, appropriate standards, guidelines and recommendations promulgated by other relevant international organizations open for membership to all Members, as identified by the Committee.

The Codex Alimentarius Commission (CAC) in 1991 considered the Report of the joint FAO/WHO Consultation on the Assessment of Biotechnology in Food

Production and Processing as Related to Food Technology[25] and endorsed its conclusions and recommendations. One of the conclusions of this joint consultation was that '[t]he use of these [modern biotechnological] techniques does not result in food which is inherent [sic.] less safe than that produced by conventional ones'.[26] A further Joint FAO Expert Consultation on Biotechnology and Food Safety held in 1996 noted that '[s]ince globalization interconnects raw material production to processing and consumers of all regions of the world, it is imperative that proper safety assessments be made of food produced by rDNA technology world wide'.[27]

The principle of equivalence established in Art. 4 requires importing members to accept different sanitary or phytosanitary measures as being equivalent to their own measures where the 'exporting Member objectively demonstrates to the importing Member that its measures achieve the importing Member's appropriate level of sanitary or phytosanitary protection'.[28] The principle of equivalence has food security implications in generating the possibility for trade conflicts over SPS measures. Where the importing member objects to the SPS measures put in place by the exporting member then the alternative to attempting to establish equivalence where this looks likely to be a problem is to make the counter argument that the importing member's standards exceed what is 'necessary' and are thus inconsistent with both the SPS Agreement and the GATT. By way of prelude to such a claim, Art. 5.8 permits any member that believes that its actual or potential exports are constrained by an SPS measure introduced by another member to require that member to explain the reason for the imposition of the measure in question. This applies where the importing member's standards are higher than those that are internationally accepted and where there is not yet any internationally accepted standard. There is a particular problem where there is not yet any internationally accepted standard and an importing member has established strong precautionary measures. This might be likely in cases where scientific evidence on health risks is inconclusive. Measures designed to limit biotechnological food and plant products might very well fall within this description.

SPS measures that are not conforming to or based upon international standards[29] must be based upon a risk assessment 'as appropriate to the circumstances'.[30] The principles of risk assessment laid down in the SPS Agreement require members to take into account risk assessment techniques developed by international organizations, as well as scientific and economic factors.[31] The scientific factors are

[25] World Health Organization (1991) *Strategies for Assessing the Safety of Foods Produced by Biotechnology: Report of a Joint FAO/WHO Consultation.* WHO, Geneva.

[26] Codex Ad Hoc Intergovernmental Task Force on Foods Derived From Biotechnology, Matters Referred to the Task Force by the Codex Alimentarius Commission and Other Codex Committees. CX/FBT/00/2, January 2000, Appendix 1 to Annex 1 (Paper produced for Joint FAO/WHO Food Standards Programme).

[27] Ibid., Appendix 2 to Annex 1.

[28] See also SPS Agreement, Art. 6.3: Exporting Members claiming that areas within their territories are pest- or disease-free areas or areas of low pest or disease prevalence shall provide the necessary evidence thereof in order to objectively demonstrate to the importing Member that such areas are, and are likely to remain, pest- or disease-free areas or areas of low pest or disease prevalence, respectively…

[29] SPS Agreement, Art. 3.1–3.3.

[30] SPS Agreement, Art. 5.1.See also, Arts 2.1 and 3.3.

[31] SPS Agreement, Art. 5.1–5.3.

stated in an open-ended list as follows: 'available scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases or pests; existence of pest- or disease-free areas; relevant ecological and environmental conditions; and quarantine or other treatment'.[32] The relevant economic factors to be taken into account are stated in a definitive list as follows: 'the potential damage in terms of loss of production or sales in the event of the entry, establishment or spread of a pest or disease the costs of control or eradication in the territory of the importing Member; and the relative cost-effectiveness of alternative approaches to limiting risks'.[33] Having taken all these factors into account, Members are required to exercise proportionality, that is SPS measures must not be 'more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility'.[34] The relevant risks that are to be assessed using this multifarious criteria are risks to human, animal or plant life or health.

The SPS Agreement recognizes that there may be cases where scientific evidence is not sufficient and permits provisional adoption of provisional SPS measures 'on the basis of available pertinent information'.[35] Two possible sources of such information are the international organizations and the SPS measures applied in the same area by other members.

It is evident from the comments submitted to the Codex Ad Hoc Intergovernmental Task Force on Foods Derived From Biotechnology that there is considerable international concern, and not necessarily a great amount of consensus, about the issue of risk assessment.[36] For example, Hungary, Mexico, New Zealand, Singapore and Switzerland all noted the need for clear principles of risk assessment in Codex Guidelines. In its comments, Consumers International noted:

> A … major subject of discussion of the Task Force should be to define what [is] a 'core data set' or minimum amount of scientific information that should be reviewed in order to assess the safety of an engineered food. Perhaps the most difficult aspect of such a core data set will be the scientific studies that would be needed to screen for unexpected genetic, biochemical, immunological and toxicological consequences of genetic engineering. The crude compositional analysis of engineered foods, required as part of a 'substantial equivalence' approach is not sufficient enough to look for such problems. The Task Force should investigate what alternative methods may be used to more accurately look for unintended consequences of genetic engineering.[37]

Consumers International also called for an examination of what 'other legitimate factors' might be taken into account in risk analysis.[38] As possible candidates for 'other legitimate factors', it suggested: environmental impacts; food security and agricultural

[32] SPS Agreement, Art. 5.2.
[33] SPS Agreement, Art. 5.3.
[34] SPS Agreement, Art. 5.6.
[35] SPS Agreement, Art. 5.7.
[36] Codex Ad Hoc Intergovernmental Task Force on Foods Derived From Biotechnology. Consideration of the Elaboration of Standards, Guidelines or Other Principles for Foods Derived from Biotechnology. CX/FBT 00/4, Part I, February 2000.
[37] Ibid., 17.
[38] Ibid., 18–19.

sustainability; the precautionary principle; animal welfare considerations, consumer choice; and ethical and religious considerations.[39]

Risk assessment was at the heart of the *Beef Hormones* decision. The Appellate Body concluded that the European Communities' risk assessment process had not been sufficient to support the measures in question.[40] It stated that

> It is essential to bear in mind that the risk that is to be evaluated in a risk assessment under Art. 5.1 is not only risk ascertainable in a science laboratory operating under strictly controlled conditions, but also risk in human societies as they actually exist, in other words, the actual potential for adverse effects on human health in the real world where people live and work and die.[41]

This meant that, contrary to the panel, the Appellate Body took the view that non-science factors should be included in any risk assessment. In the context of the *Beef Hormones* case that meant, in particular, that the risks of potential abuse in the administration of drugs was an appropriate factor to include in the risk assessment.[42] This was because the studies relied upon as forming the risk assessment were not sufficiently specific: they dealt with the carcinogenic effects of the hormones in question in general. 'They do not focus on and do not address the particular kind of risk here at stake – the carcinogenic or genotoxic potential of the residues of those hormones found in meat derived from the cattle to which the hormones had been administered for growth promotion purposes.'[43]

One of the questions raised in the *Beef Hormones* case was the role of the precautionary principle, if it exists, in the interpretation of the SPS Agreement. The European Communities argued that Arts 5.1 and 5.2 should be read in the light of the precautionary principle with the result that it should be entitled to take a cautious approach to risk assessment. In particular, it argued 'that it is not necessary for *all* scientists around the world to agree on the "possibility and magnitude" of the risk, nor for *all* or most of the WTO Members to perceive and evaluate the risk in the same way'.[44]

The Appellate Body although not authoritatively defining the status of the precautionary principle in international law, stated four principles governing the relationship between the SPS Agreement and the principle.[45] Firstly, the precautionary principle does not justify measures otherwise inconsistent with the SPS Agreement. Secondly, while the precautionary principle is reflected in Art. 5.7, this does not mean that Art. 5.7 exhausts the application of the precautionary principle to the SPS Agreement. Thirdly, a panel that is considering whether or not there is 'sufficient scientific evidence' for a measure (within the meaning of Art. 2.2) should 'bear in mind that responsible, representative governments commonly act from perspectives of prudence and precaution where risks of irreversible, e.g. life-threatening, damage

[39] See also the Comments of the International Association of Consumer Food Organizations, ibid., 25–26.
[40] Appellate Body Report: WT/DS26/AB/R and WT/DS48/AB/R, para. 208.
[41] Ibid., para. 187.
[42] Ibid., para. 206.
[43] Ibid., para. 200.
[44] *Beef Hormones*, Appellate Body Report, n. 18 supra, para. 121.
[45] Ibid., para. 124.

to human health are concerned'.[46] Finally, the precautionary principle does not displace ordinary principles of treaty interpretation. On the basis of these principles, the precautionary principle, even if it exists, was held not to exculpate the European Communities from their failure to comply with Arts 5.1 and 5.2.

Relevant to the issue of food security is the impact of the SPS Agreement to developing countries. The fifth recital to the SPS Agreement recognizes:

> … that developing country Members may encounter special difficulties in complying with sanitary or phytosanitary measures of importing Members, and as a consequence in access to markets, and also in the formulation and application of sanitary and phytosanitary measures in their own territories, and desiring to assist them in their endeavours in this regard …

The sentiment expressed in this recital is realized in the Agreement by provisions on technical assistance and special treatment. Article 9.1 contains a general provision whereby members agree to facilitate technical assistance to other members, especially developing country members. Such technical assistance is defined to include assistance to allow members to comply with SPS requirements of other members 'in the areas of processing technologies, research and infrastructure, including in the establishment of national regulatory bodies, and may take the form of advice, credits, donations and grants, including for the purpose of seeking technical expertise, training and equipment'. Article 9.2 is expressly directed towards assistance to developing countries and requires importing members 'to consider' technical assistance to developing countries to promote market access for that developing country.

7.3 WTO TBT Agreement

To a considerable extent the TBT Agreement reflects the provisions and obligations found in the SPS Agreement. Accordingly, the general obligations under the Agreement are to ensure that technical barriers (which are comprised of technical regulations, standards and conformity assessment procedures) are subject to national treatment and most-favoured nation (MFN) obligations[47] and that they do not create 'unnecessary obstacles to international trade'.[48] It also contains provisions on harmonization[49] and equivalence,[50] notifications[51] and the establishment of enquiry points,[52] and special provisions for developing countries.[53]

[46] Ibid., para. 124.
[47] TBT Agreement, Art. 2.1 (technical regulations); Art. 4 and Annex 3, para. D (standards); Arts 5.1.1, 7, 8 and 9 (conformity assessment procedures).
[48] TBT Agreement, Art. 2.2 (technical regulations); Art. 4 and Annex 3, para. E (standards); Arts 5.1.2, 7, 8 and 9 (conformity assessment procedures).
[49] TBT Agreement, Art. 2.6 (technical regulations); Art. 4 and Annex 3, para. G (standards); Arts 5.5, 7, 8 and 9 (conformity assessment procedures).
[50] TBT Agreement, Art. 2.7 (technical regulations); Arts 6, 7, 8 and 9 (conformity assessment procedures).
[51] TBT Agreement, Art. 2.9–2.12 (technical regulations); Art. 4 and Annex 3, paras J, L–Q (standards); Arts 5.6–5.9, 7, 8 and 9 (conformity assessment procedures).
[52] TBT Agreement, Art. 10.
[53] TBT Agreement, Art. 12.

The TBT Agreement applies to three types of measures: technical regulations, standards and conformity assessment procedures. Each of these types of measures is defined in Annex 1.[54] A 'technical regulation' is defined in paragraph 1 as a:

> Document which lays down product characteristics or their related processes and production methods, including the applicable administrative provisions, with which compliance is mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

A 'standard' is defined in paragraph 2 as a:

> Document approved by a recognized body, that provides, for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, with which compliance is not mandatory. It may also include or deal exclusively with terminology, symbols, packaging, marking or labelling requirements as they apply to a product, process or production method.

Finally, a 'conformity assessment procedure' is defined in paragraph 3 as:

> Any procedure used, directly or indirectly, to determine that relevant requirements in technical regulations or standards are fulfilled.

Bearing in mind that most, if not all, measures concerning the characteristics, processes and production methods of biotechnological products are likely to be covered by the SPS Agreement, it seems that the particular application of the TBT Agreement in the biotechnology area will be with respect to labelling or marking requirements. Such requirements explicitly fall within the definitions of technical regulation and standard, the main difference between the two being that the former are mandatory requirements whereas the latter are not. Whether mandatory or recommended, the issue of labelling, especially eco-labelling, has been a hotly contested one within the WTO. Traditionally, the issue of eco-labelling, in general, has been one of the bones of contention between the developed and developing countries.[55]

7.4 CBD Cartagena Protocol on Biosafety

One of the results of the CBD was that the COP, by its decision I/9 of 9 December 1994, decided to establish an open-ended ad hoc group of experts to consider the necessity for a biosafety protocol, setting out appropriate procedures for the safe transfer, handling and use of living modified organisms (LMOs). At the various meetings a draft text was formulated for adoption by the COP. By the conclusion of its sixth meeting, the Working Group had still been unable to present a consensus text for adoption. The countries were divided into two groups. The majority group, comprising some 120 countries, wanted an agreement based on the precautionary principle, under which a lack of scientific certainty of adverse environmental harm would not

[54] TBT Agreement, Art. 1.2.

[55] See S.P. Subedi (1999) Balancing international trade with environmental protection: international legal aspects of eco-labels. *Brooklyn Journal of International Law* 25, 373.

be used as an excuse to postpone legislation. On the other side was the Miami Group, comprising Argentina, Australia, Canada, Chile, USA and Uruguay, which sought controls based on sound scientific knowledge.[56] Informal consultations on reviving the negotiations took place at meetings in Montreal in June 1999 and Vienna in September 1999.

Dissatisfied with progress in relation to the formulation and enforcement of IPR, the USA had previously had a marked success in conferring a jurisdiction in this area upon the WTO.[57] In anticipation of the WTO's Seattle Ministerial Conference, the USA also sought to shift the biosafety issue to within the WTO's mandate. In a communication dated 27 July 1999, the USA recommended that trade in agricultural biotechnology products was a matter for the WTO.[58] This position was endorsed by Japan, which called for the formation of a GMO negotiating group within the WTO.[59]

The failure of the Seattle Ministerial Conference in November 1999 was attributed in part to political demonstrations on the subject of GMOs. This failure formed the backdrop to the resumption of negotiations on a biosafety protocol. Informal consultations were held in Montreal on 20–22 January 2000, followed by a Resumed Extraordinary Meeting of the COP to Finalise and Adopt A Protocol on Biosafety, on 24–28 February. The Miami Group had maintained its adherence to the precautionary principle at this meeting, but in the face of the opposition of the EU and the developing countries the formal negotiation period concluded without the conclusion of an agreement. However, the following day, the USA withdrew its opposition to permit the adoption of a protocol. The agreed text of the Biosafety Protocol was opened for signature at UNEP headquarters in Nairobi on 15–26 May 2000, on the occasion of the Fifth COP.

Applying the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, Art. 1 envisages that the objective of the Protocol is

> … to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of LMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements.

To this end, Art. 4 expressly applies the Protocol to 'the transboundary movement, transit, handling and use of all LMOs that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health'.

'Living modified organism' is defined in Art. 3(g) as 'any living organism that possesses a novel combination of genetic material obtained through the use of

[56] See C. Tapper, 'Biosafety Protocol – the outlook for renewed negotiations: 20 Jan 2000. www.ds.dial.pipex.com/ukfg/Ukabc/catagena.htm.

[57] See M. Blakeney (1995) Intellectual property in world trade. *International Trade Law & Regulation* 1, 76.

[58] WTO, *Negotiations on Agriculture, Measures Affecting Trade in Agricultural Biotechnology Products* (4 August 1999, WT/GC/W/288).

[59] WTO, *Proposal of Japan on Genetically Modified Organisms (GMOs)* (12 October 1999, WT/GC/W/365).

modern biotechnology'. 'Modern biotechnology' is defined by Art. 3(h) as 'the application of: (a) *in vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or (b) fusion of cells beyond the taxonomic family', both of which 'overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection'.

Excluded from the Protocol by Art. 5 is the transboundary movement of LMOs, which are pharmaceuticals for humans 'that are addressed by other relevant international agreements or organisations'. Article 6 excludes the transit of LMOs through the territory of a signatory and the transboundary movement of LMOs 'destined for contained use undertaken in accordance with the standards of the Party of import'. 'Contained use' is defined in Art. 3(b) to mean 'any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment'.

Article 2.2 requires that parties shall 'ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health'. To this end Art. 2.1 requires that 'each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol'.

Article 8.1 provides that 'the Party of export shall notify, or require the exporter to ensure notification to, in writing, the competent national authority of the Party of import prior to the [first] intentional transboundary movement of a living modified organism' for intentional introduction into the environment of the country of import.[60]

A party that makes a final decision regarding domestic use of a LMO that may be subject to transboundary movement for direct use as food or feed, or for processing is required by Art. 11.1, to inform the parties through the Biosafety Clearing House, within 15 days of making that decision.

The precautionary principle is included within Art. 10.6, which provides:

> Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question … in order to avoid or minimize such potential adverse effects.

Pursuant to Art. 12.1, a Party of import may, at any time, 'in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health, review and change a decision regarding an intentional transboundary movement'. The Party is required to communicate this decision to any notifier, as well as to the Biosafety Clearing-House, setting out the reasons for its decision. Also a party of export, or a notifier may request the Party of import to review a decision, where there is

[60] Importing the provisions of Cartagena Protocol, Art. 7.1.

considered to be either a change in circumstances, which could influence the outcome of the risk assessment upon which the decision was based, or where additional relevant scientific or technical information has become available. Article 12.3 requires the Party of import to respond in writing to such a request within 90 days, setting out the reason for its decision.

Under Art. 13.1 a party of import may, provided that 'adequate measures are applied to ensure the safe intentional transboundary movement' of LMOs , specify in advance to the Biosafety Clearing-House:

> (a) Cases in which intentional transboundary movement to it may take place at the same time as the movement is notified to the Party of import; and
>
> (b) Imports to it to be exempted from the advance informed agreement procedure.

Risk assessments under the Protocol are required by Art. 15 to be carried out in a 'scientifically sound manner', in accordance with Annex III and taking into account recognized risk assessment techniques. The risk assessments under the Protocol are to be based, 'at a minimum, on information provided in accordance with Art. 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health'.

Annex III requires a risk assessment to be 'carried out in a scientifically sound and transparent manner', taking into account 'expert advice of, and guidelines developed by, relevant international organizations'.[61] The lack of scientific knowledge or consensus is not to be interpreted 'as indicating a particular level of risk, an absence of risk, or an acceptable risk'.[62] Assessments are to be carried out on a case-by-case basis.[63] Risks associated with LMOs or processed materials that are of LMO origin, 'containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology', are to 'be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment'.[64]

Parties are obliged, under Art. 16.1 to 'establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms'. Pursuant to Art. 16.2, these measures are required to 'be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import'.

Under Art. 16.3, each Party is required 'to take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment to be carried out prior to the first release of a living modified organism'. Where an unintentional transboundary movement occurs, Art. 17 requires each Party to take appropriate measures to notify affected or

[61] Cartagena Protocol, Annex III, para. 3.
[62] Ibid., para. 4.
[63] Ibid., para. 6.
[64] Ibid., para. 5.

potentially affected States, the Biosafety Clearing House and relevant international organizations. The notification is intended to be sufficiently detailed to enable States to determine appropriate responses and to initiate emergency measures.

As part of the general risk management process, Art. 16.4 requires each Party to ensure that any LMO, whether imported or locally developed, 'has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use'. Parties to the Protocol are required by Art. 16.5 to cooperate with a view to identifying LMOs or specific traits of LMOs 'that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health'; and to take appropriate measures in relation to the treatment of such LMOs or their specific traits.

Article 18 requires LMOs that are subject to intentional transboundary movement to be handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards. Parties are obliged, under Art. 18.2, to require that documentation accompanying LMOs that are intended for direct use as food or feed, or for processing, clearly identifies that they 'may contain' LMOs and are not intended for intentional introduction into the environment, as well as providing a contact point for further information. Where LMOs are destined for contained use, they must be identified as such, and the documentation must specify the requirements for their handling, storage, transport and use, as well the contact point for further information and the name and address of the consignee of the LMOs. LMOs that are intended for intentional introduction into the environment of the Party of import must be clearly identified as such, and the identity and relevant traits of LMOs identified, along with any requirements for the safe handling, storage, transport and use, the contact point for further information, and the name and address of the importer and exporter. Also Art. 18.2 requires that, in the case of LMOs intended for intentional introduction into the environment of the Party of import, the documentation contains a declaration that the movement is in conformity with the requirements of the Protocol.

Article 18.3 sets the scene for the development of international standards with respect to the matters covered by Art. 18. It obliges the COP to 'consider the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices, in consultation with other relevant international bodies'.

A Biosafety Clearing-House is established under Art. 20 as part of the clearing-house mechanism referred to in Art. 18.3 of the CBD. The role of the Biosafety Clearing-House is, first, to facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, LMOs and, secondly, to assist Parties to implement the Protocol. The Biosafety Clearing-House is designed to provide access to information made available by the Parties that is relevant to the implementation of the Protocol and also to provide access to other international biosafety information exchange mechanisms.

In the implementation of the Protocol, Art. 26 permits Parties to take into account 'socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities'. Article 26.2 encourages the Parties 'to cooperate on research and information

exchange on any socio-economic impacts of living modified organisms, especially upon indigenous and local communities'.

7.5 Biosafety Liability and Food Security

As we saw in the discussion of *Monsanto Canada, Inc and Monsanto Company v Percy Schmeiser and Schmeiser Enterprises*[65] and *Monsanto Co. v McFarling*,[66] the introduction of genetic engineering to plant development has introduced the possibility of patent infringement for farmers who save patented seed. Another problem that the arrival of this proprietary technology has caused is that seed breeders and farmers might be liable for any biohazards that may result from the use of this technology. As a general rule, under the laws of most countries, farmers are liable for the damage caused by dangers emanating from their land and that affects neighbouring properties. The principal causes of action that might be relevant are: negligence, nuisance and trespass. A separate cause of action is the liability, which might arise out of the contractual relationship between the supplier of germplasm and its acquirer.

A separate issue, which has important implications for food security, is the use of patented Genetic Use Restriction Technologies (GURTs), which are impugned for the substantial adverse environmental impacts which they might produce.

It should be noted that the supply of GM germplasm by a CGIAR Centre under the SMTA, promulgated under the International Treaty on Plant Genetic Resources for Food and Agriculture, is governed by Art. 9.1, which provides that the Provider

> … makes no warranties as to the safety of or title to the Material, nor as to the accuracy or correctness of any passport or other data provided with the Material. Neither does it make any warranties as to the quality, viability, or purity (genetic or mechanical) of the Material being furnished. The phytosanitary condition of the Material is warranted only as described in any attached phytosanitary certificate. The Recipient assumes full responsibility for complying with the recipient nation's quarantine and biosafety regulations and rules as to import or release of genetic material.

Thus the liability for the use of GM germplasm from this seed is likely to be imposed upon the farmer recipient.

Legal liability arising from the possible contamination by GM crops of organic or other 'GM-free' crops under tort law was comprehensively examined by the Saskatchewan Court of Queens Bench in *Larry Hoffman and others v Monsanto Canada Inc and Bayer Cropscience Inc*.[67] The plaintiffs in this case claimed damages to organic grain farmers allegedly resulting from the development and commercial introduction into Canada of GM canola by the two defendants. The nature of the damage suffered by the plaintiffs was the loss of the principal foreign markets for organic grain: the USA, Japan and Europe.

It was not disputed that in-field trials were conducted in Canada between 1990 and 1994 by AgrEvo Canada, the predecessor of Bayer Cropscience (BCS) for a gene,

[65] 2001 FCT 256.
[66] 302 F.3d 1291 (Fed. Cir. 2002).
[67] 2005 SQKB 225.

which, when inserted in canola, renders the plant resistant to glufosinate ammonium-based herbicides such as Liberty, a herbicide marketed and sold by BCS. Approval for the unconfined release of 'Liberty Link' canola was granted by the Canadian Food Inspection Agency in 1995. In 1996 Monsanto had been granted approval for the sale of its RuR canola. By 2003 approximately 70% of all canola grown in Western Canada was either a RuR or Liberty Link variety.

Canola in general, and RuR and Liberty Link varieties in particular, are open-pollinated. As a result, there is inevitable pollen drift as a result of wind and cross-pollination can occur with non-GM ('conventional') canola grown nearby. This can result in the production of GM seeds in conventional canola, which can, in turn, result in GM progeny. Volunteer plants of GM canola can also result in fields where canola is not grown at all as a result, *inter alia*, of spillage of GM canola seeds from passing trucks, or from neighbouring farmland where GM crops are cultivated. The resulting presence of GM canola or canola seed on cultivated land where it is not intentionally cultivated was referred to by the plaintiffs as 'contamination of the environment'. The term, 'adventitious presence' was proposed by the defendants. This also included mechanical mixing during the harvesting, processing, handling and storage of seed and grain.

A critical factor in the decision by the court to disallow the plaintiffs' claims was the determination by the Canadian Food Inspection Agency that the GM canolas were not harmful. The damage alleged to organic grain farmers was 'solely the damage resulting from loss of use of canola as an organic crop or for cleanup costs for fields "contaminated" by GM canola, due to standards imposed by organic certifiers or by foreign markets or individual customers for organic products'.[68]

The legal bases of the plaintiffs' claims were that the defendants were liable in negligence, nuisance, trespass and for breach of statutory duty.

Negligence

Liability for negligence occurs where a legal duty to act as a reasonable and prudent person exists and is breached, and the breach of duty causes damages to others or their property. The principal elements of the tort of negligence are: (i) the defendant must owe a duty of care to the plaintiff; (ii) the defendant causes damage to the plaintiff; and (iii) that damage was reasonably foreseeable. With respect to GM crops a negligence claim could be brought by a person claiming personal damage based on an allergic response to food products containing GMOs. Negligence has been claimed in cases involving the contamination of organic crops by GM crops.

In *Larry Hoffman and others v Monsanto Canada Inc and Bayer Cropscience Inc*,[69] the court was not prepared to find a duty owed by the defendants (developers and marketers of GM canola) to the plaintiffs (organic grain farmers in Saskatchewan) to prevent or to minimize the extent of adventitious presence of their respective GM canola varieties

[68] Ibid. at para.22.
[69] 2005 SQKB 225.

on the plaintiffs' farmland or in their crops. The principle of law which the Court applied was that laid out by the House of Lords in *Anns v Merton London Borough Council*.[70]

In *Anns*, Lord Wilberforce explained the test for negligence in the following terms:

> First one has to ask whether as between the alleged wrongdoer and the person who has suffered damage there is a sufficient relationship of proximity of neighbourhood such that, in the reasonable contemplation of the former, carelessness on his part may be likely to cause the damage to the latter – in which case a *prima facie* duty of care arises. Secondly, if the first question is answered affirmatively, it is necessary to consider whether there are any considerations which ought to negate, or to reduce or limit the scope of the duty or the class of person to whom it is owed or the damages to which a breach of it may give rise.[71]

It should be noted that the *Anns* principle defines the law of negligence in Canada and New Zealand, but it has been rejected in Australia and England. In Australia in *Pyrenees Shire Council v Day,*[72] the High Court advocated the three-stage test, which is now generally applied in England.[73] That test involves firstly, foreseeability; secondly, the existence of a relationship between the parties of 'proximity' or 'neighbourhood'; and finally, a consideration of policy to determine whether it is 'fair, just and reasonable' to impose the duty of care in question.

Applying *Anns* Case, the Saskatchewan court was not prepared to find that the defendants were in a sufficiently proximate relationship to the plaintiffs that it could be said that a duty of care was owed. Mere foreseeability of loss was not sufficient under the law of negligence to establish a *prima facie* duty of care. Of course, in a CGIAR Centre or NARS context, there is a proximate relationship with client farmers, so that liability in negligence is a possibility if the seed supplied to those clients results in their exclusion from relevant markets.

The Court held that the plaintiffs had alleged facts sufficient to support a finding that it was reasonably foreseeable that release of the defendants' GM canola into the general environment would result in the adventitious presence of GMOs in the plaintiffs' crops and fields. The defendants' GM canola varieties were open-pollinated varieties, which, due to the 'natural' process of cross-pollination can pollinate conventional canola conferring genetic modification upon the seed of the formerly conventional canola. However, the Court found that what was missing from the plaintiffs' claim was any specific allegation that the loss and damage to organic farmers (namely loss of the use of canola as a marketable organic commodity and loss of canola for use in crop rotation, plus the clean-up costs and loss of use of fields as a result of GM canola volunteers) was foreseeable.

The Court noted in addition that there were policy considerations that, in accordance with the second leg of the test in *Anns* Case, would bar or limit the imposition of the duty of care alleged on the defendants. First, both defendants received approval of the federal government for the unconfined release of their GM canola varieties prior to their release. Thus the imposition by the courts of a duty of

[70] 1978] A.C. 728 (H.L.).
[71] Ibid., at 751–752.
[72] (1998) 192 CLR 330 at 419–420.
[73] See *Caparo Industries Plc v Dickman* [1990] 2 AC 605; *X (Minors) v Bedfordshire County Council* [1995] 2 AC 633; *Marc Rich & Co AG v Bishop Rock Marine Co Ltd* [1996] AC 211.

care not to release these substances into the environment would therefore appear to be in conflict with express governmental policy. Further, the alleged damage was not of physical harm to the plaintiffs' crops, but arises from the alleged inability to meet the requirements of organic certifiers or of foreign markets for organic canola. There was no allegation that GM canola was unhealthy or caused detrimental physical problems to humans or plant life.

A similar result to that in *Hoffman v Monsanto* was the decision of the US District Court for the Eastern District of Missouri in *Sample v Monsanto Co.*[74] The plaintiffs argued that farmers, such as themselves, who did not grow GM crops 'lost revenue because the European community rejected Monsanto's genetically modified products and boycotted all American maize and soybean as a result'.[75] The plaintiffs brought an action for negligence against Monsanto for introducing the non-GM seeds into the market. Monsanto moved for summary judgment, arguing that the economic loss doctrine barred negligence claims that are not based on physical injury to persons or property.

The Court ruled that, as the plaintiffs did not sustain physical contamination or injury to their property, the economic loss doctrine precludes recovery of damages.

A different approach to negligence, producing an opposite result, was the Australian High Court decision in *Perre v Apand Pty. Ltd.*[76] The defendant had provided defective potato seed to Sparnons, commercial growers of potatoes and other vegetables. The seed caused an outbreak of bacterial wilt in Sparnons' potato crop. The plaintiff owned farms near the Sparnons' land and sold potatoes in the lucrative Western Australia market. Their potatoes were not directly affected by potato wilt, but legislation of Western Australia prohibited the import of potatoes that were grown within 20 km of a bacterial wilt outbreak. The plaintiffs therefore lost the most lucrative market for their potatoes.

At trial and in the Court of Appeal, the plaintiffs were unsuccessful, these Courts holding that, as the plaintiffs had suffered no physical damage, their claim was for pure economic loss and was not recoverable. The High Court of Australia ruled that where a defendant knows or ought reasonably to know that its conduct is likely to cause harm to the person or tangible property of the plaintiff unless it takes reasonable care to avoid that harm, the law will *prima facie* impose a duty on the defendant to take reasonable care to avoid the harm.[77] The loss to the plaintiffs was on the facts clearly foreseeable and they were known to be a vulnerable class. As McHugh J. pointed out, imposing a duty of care on the defendant in this case did not expose it to indeterminate liability, nor did it unreasonably interfere with the defendant's commercial freedom, because it was already under a duty to the Sparnons to take reasonable care to avoid the very risk complained of.[78]

In *Hoffman v Monsanto*, the Court sought to distinguish *Perre v Apand* on the ground not only that it was concerned with pure economic loss, which was not recoverable in Canada, but that unlike the situation in *Perre v Apand* imposing a duty on the

[74] 283 F.Supp.2d 1088 (E.D.Mo.2003).
[75] Ibid. at 1091.
[76] (1999), 164 A.L.R. 606.
[77] Ibid. at para. 68.
[78] Ibid. Para. 103.

defendants would expose them to a 'liability in an indeterminate amount for an indeterminate time to an indeterminate class'.[79]

The possibility of harm emanating from GM crops was considered recently by the US Court of Appeals for the Ninth Circuit in *Geertson Seed Farms and others v Forage Genetics, Inc and Monsanto Company and Others*.[80] This was not a tort action, but concerned decisions by the Animal and Plant Health Inspection Service (APHIS), a division of the US Department of Agriculture (USDA), concerning the environmental impact of RuR lucerne. APHIS had initially classified the GM lucerne as a regulated article under the National Environmental Policy Act (NEPA). After being petitioned by the manufacturer it had made a finding of no significant environmental impact and unconditionally deregulated the lucerne.

In its Environmental Assessment, prepared in accordance with NEPA and its implementing regulations, APHIS explained that lucerne is pollinated by insects, primarily bees, and that insect pollination has been documented as occurring up to 2 miles from the pollen source. However, with regard to the threat of possible genetic contamination of non-genetically engineered lucerne, it explained that the National Organic Program mandates buffer zones around organic production operations, the size of which are decided by the organic producer and the certifying agent on a case-by-case basis. The Environmental Assessment concluded that it was therefore unlikely that RuR lucerne would have a significant impact on organic farming.

In May 2007, the District Court had granted the plaintiffs a permanent injunction to prohibit all future planting of RuR lucerne, as well as the harvesting of any RuR lucerne seed already planted, pending the completion of an environmental impact statement (EIS) and a new decision on deregulation. APHIS agreed that any future planting should be subject to certain conditions, including requiring isolation distances from other crops and requiring certain harvesting conditions to minimize gene flow to non-genetically engineered lucerne seeds. The District Court found that genetic contamination had occurred. Monsanto and its licensee, Forage Genetics, appealed the injunction, arguing it was too broad.

On appeal, the Court considered the principles of law that applied to the grant of a permanent injunction. It noted that applying these principles, an injunction did not 'automatically issue' when a NEPA violation is found and said that it was required to 'engage in the traditional balance of harms analysis'. With respect to harm, the court found that genetic contamination of organic and conventional lucerne had already occurred, and it had occurred while Monsanto and Forage Genetics had contractual obligations in place. It held that such contamination was irreparable environmental harm because contamination cannot be reversed and farmers cannot replant lucerne for 2–4 years after contaminated lucerne has been removed.

The Appeal Court agreed with the District Court that the harm to growers and consumers who wanted non-genetically engineered lucerne outweighed the financial hardships to Monsanto and Forage Genetics and their growers.

The courts also agreed that in considering the public interest, while recognizing that agricultural biotechnology has social value, they held that it would be in the public interest to enjoin the expanded use of RuR lucerne before its impact was

[79] 2005 SQKB 225 at para. 73.
[80] 2008 U.S. App. LEXIS 18752.

studied, because failing to do so could potentially eliminate the availability of non-genetically engineered lucerne.

A dissenting judgement in the Appeal Court noted that the facts were sharply disputed by the parties, including a dispute as to the risk of genetic contamination that could occur while APHIS prepared the EIS.

Actions based on the rule in *Rylands v Fletcher*

The principle of law set out in *Rylands v Fletcher*[81] was propounded in the case where Fletcher was mining coal on land adjacent to land owned by Rylands, who operated a mill. Rylands, who had no knowledge of the mining operation on the adjacent land, built a reservoir to supply water for the mill. The reservoir gave way and flooded the mining site. The House of Lords outlined the elements of this cause of action as: (i) the defendant has made a non-natural use of its land; (ii) the defendant brought onto his land something which was likely to do mischief if it escaped; (iii) the substance in question escaped; and (iv) damage was caused to the plaintiff's property or person as a result of the escape.[82]

In *Hoffman v Monsanto* two different allegations were made in relation to the *Rylands v Fletcher* claim, the first relating to the growing of GM canola in confined field plots in 1990–1994 and the second relating to the escape of genetic material from the fields of conventional farmers growing varieties of Liberty Link or RuR canola after its commercial release.

The Court ruled that regardless of whether one considers GM canola a 'dangerous substance', or the field trials for GM canola an 'unnatural' or 'non-natural' use of land, it was not reasonably arguable that the commercial release and sale of RuR canola seed and Liberty Link canola seed constituted an 'escape' of a substance, dangerous or otherwise, from property owned or controlled by the defendants in the sense of 'escape' required by the rule in *Rylands v Fletcher*. Thus the pleadings did not disclose a reasonable cause of action based on the rule in *Rylands v Fletcher*.[83]

Nuisance

The tort of private nuisance is concerned with conditions or activities that cause physical injury or damage to land or that interfere with the use or enjoyment of land. The common law has distinguished between activities or conditions that cause physical injury or damage to another's land from activities and injuries that interfere with the use or enjoyment of land, without actual physical damage.

In *Hoffman v Monsanto*, the plaintiffs took the position that there had been physical damage to the land of organic farmers and to organic crops as a result, at least, of the presence of invading GM volunteer plants. The defendants argued that the damage alleged was not caused by the release of GM canola at all, but by the actions of third

[81] (1866), L.R. 1 Ex. 265; (1868), L.R. 3 H.L. 330.
[82] (1868), L.R. 3 H.L. at 339.
[83] 2005 SQKB 225 at para. 97.

parties who had promulgated the standards affected by the inevitable adventitious presence of GM canola and by the decisions of individual organic farmers to seek to adhere to those standards. Secondly, the defendants pointed out that agricultural activity in Saskatchewan generally involves the production of open-pollinating crops, that the release of GM canola was subject to federal approval and that the growing of GM canola was widespread and was therefore a 'usual and ordinary' activity. The Court, however, noted that the crops and land of organic farmers was effectively contaminated by the presence of GM canola and that it was not 'plain and obvious that they cannot succeed in showing that the damage or interference they have alleged constitutes a legal nuisance'.[84]

The defendants argued that they could not be liable unless the alleged nuisance emanated from land they occupied or controlled. The Court noted that although it is true that nuisance is typically a claim by one landowner or occupier against his neighbour, in Canada responsibility for private nuisance is not restricted to the occupiers of adjoining lands. However, as with the negligence claim, the Court considered that the damage suffered by the plaintiffs was caused by the European legislation, rather than by the introduction of GM canola.

A nuisance claim in relation to GM maize was considered by the US District Court in Illinois in *In re StarLink Corn Products Liability Litigation, Marvin Kramer v Aventis CropScience USA Holding Inc*.[85] The plaintiffs in that case sought to bring a class action claim against the defendant manufacturer and creator of GM StarLink maize. It was alleged that StarLink had contaminated the entire maize supply in many states resulting in increased farming costs and depressed maize prices. The genetic modification of StarLink maize caused it to produce a protein (Cry9C) toxic to certain insects and containing several attributes similar to known human allergens. Accordingly, the defendant had obtained only qualified approval for release for use for animal feed, ethanol production and seed increase by the Environmental Protection Agency (EPA) under the Federal Insecticide, Fungicide, and Rodenticide Act. The EPA prohibited its use for human consumption and imposed on the defendant manufacturer stringent requirements of warning and monitoring to ensure implementation of mandatory segregation methods in the cultivation, harvesting, handling, storage and transport of StarLink maize, including a mandatory 660-foot 'buffer zone' around StarLink maize crops. It was alleged that the defendant had failed to comply with the EPA requirements resulting in the cross-pollination and commingling of StarLink with non-StarLink maize.

The plaintiffs' actions included private nuisance, alleging that the defendant created a private nuisance by distributing maize seeds with the Cry9C protein, knowing that they would cross-pollinate with neighbouring maize crops. The defendant moved to have the claim dismissed as disclosing no cause of action, arguing that they could not be liable for any nuisance caused by StarLink maize because they were no longer in control of the seeds once they were sold to farmers.

The Court first ruled that the cross-pollination of a crop from neighbouring land constituted nuisance as the StarLink maize was not considered fit for human

[84] Ibid., para. 110.
[85] (2002), 212 F. Supp. 2d 828 (U.S. District Court, N.D. Illinois).

consumption.[86] On the question of whether liability in private nuisance could extend to a manufacturer after the point of sale, the Court relied on the American Restatement para. 834, stating that one can be liable in private nuisance 'not only when he carries on the activity but also when he participates to a substantial extent in carrying it on'. The question was what counted as 'participation to a substantial extent' in carrying on the nuisance beyond the point of sale. It was clear that the general rule was that liability for nuisance could not be imposed on the manufacturer in these circumstances. However, the Court pointed to a number of cases in which the normal pattern of nuisance liability (imposed on a neighbouring land owner or occupier) had been extended. In the case of some manufacturers, the liability had been extended on the basis of foreseeability of the harm alleged coupled with some malfeasance on the part of the manufacturer. In this case, it was alleged that the defendant had itself violated the EPA's mandates in failing to warn adequately of the need for segregation and to enforce farmers' compliance with the EPA requirements. The Court concluded 'All parties who substantially contribute to the nuisance are liable. The unique obligations imposed by the limited registration arguably put Aventis in a position to control the nuisance.'[87]

In *Hoffman v Monsanto* the court distinguished the *StarLink* decision on the grounds that it was not alleged that contamination of organic crops by GM canola was harmful per se or that it rendered the organic crops unfit for consumption or otherwise harmful. Nor was it alleged that the defendants failed in any way to conform to the requirements imposed on them. Indeed, it will be recalled that they had received federal approval for the unconfined release of the GM canola varieties. Thus there were no facts alleged in this case that could support a finding that the defendants substantially caused the nuisance alleged.

Trespass

To sustain a cause of action in trespass, the plaintiffs must establish intentional and direct interference with another's possession of land, usually an unauthorized entry upon another's land. It has been suggested by a number of scholars that planting a crop which, several months later, produced pollen that was carried by the wind onto a neighbour's property would not be a sufficiently 'direct' interference to satisfy the requirements of trespass to land.[88] In *Hoffman v Monsanto*, the plaintiffs alleged that the defendants had released a self-propagating and proliferating product into the environment, without any, or in the alternative, inadequate, controls that they knew, or ought to have known, would eventually trespass on lands farmed by organic farmers. The plaintiffs cite authorities that suggested that a defendant should be liable in trespass when he has deliberately placed a contaminant (oil, soot, pesticide, etc.)

[86] Ibid., at 841.
[87] Ibid., at 847.
[88] R.A. Repp (2000) Biotech pollution: assessing liability for genetically modified crop production and genetic drift. *Idaho Law Review* 36, 585; C. Flood (2003) Pollen drift and potential causes of action. *Iowa Journal of Corporate Law* 28, 473; T.N. Vollendorf (2001) Genetically modified organisms: someone is in the kitchen with DNA – Who is responsible when someone gets burned? *Mississippi College Law Review* 21, 4.

that natural forces such as wind or water has then carried onto neighbouring land. However, the Court noted the authority of a number of English and Canadian cases, which required more direct interference with land for trespass to be established. The Court ruled that the commercial marketing and sale of GM canola seed that subsequently finds its way onto the land of another was not an action sufficiently direct to constitute trespass. It was only after conventional farmers grew GM canola varieties and with the intervention of natural processes (or because of the actions of others who have processed or handled the seed) that the GM canola genes could find their way onto the land of organic grain farmers. This was insufficiently direct to lay at the door of the defendants. However, harvesting a crop where the spread of seed to adjoining fields is an immediate consequence of the harvesting could satisfy the directness requirement.

Breach of statutory duty

Most countries have introduced environmental legislation or legislation, based on the Cartagena Protocol, to deal with the impacts of GM agriculture. A number of countries have also adopted GM labelling laws. Breaches of this legislation could render a defendant criminally liable, as well as liable for a civil action for breach of statutory duty.

Biosafety legislation

Typically two approaches or 'regulatory styles' have been identified in national legislation implementing Cartagena: (i) a process-based approach (exemplified by the EU regulatory system); and (ii) a product-based approach (exemplified by the USA) focusing primarily on the end-use of the product rather than on the production process.[89] A UN University study, published in February 2008,[90] has observed that in practice, many national regulatory systems and international instruments appear increasingly to reflect a 'mixed' approach, subjecting GMOs and GM products to both general and specific safety rules and standards.

The UN University study listed the following biosafety legislation.

AFRICA Forty countries had ratified or acceded to the Cartagena Protocol on Biosafety.[91] A Model Law on Biosafety was developed under the auspices of the Organization for African Unity in 2001.[92] Member States were urged to use the

[89] See C. Dunlop (2000) GMOs and regulatory styles. *Environmental Politics* 9, 149.

[90] Sam Johnston, Catherine Monagle, Jessica Green with Ruth Mackenzie, *Internationally Funded Training in Biotechnology and Biosafety: Is it Bridging the Biotech Divide?* United Nations University Institute of Advanced Studies, Yokohama, February 2008.

[91] Including Algeria, Benin, Botswana, Burkina Faso, Burundi, Comoros, Congo, Cote d'Ivoire, Djibouti, Gambia, Ghana, Guinea, Lesotho, Liberia, Madagascar, Mali, Mozambique, Niger, Nigeria, Rwanda, Senegal, Seychelles, Sierra Leone, Sudan, Swaziland, Tanzania, Togo. See http://www.unep.org/biosafety/.

[92] The text of the Model Law is available at: http://www.africabio.com/policies/MODEL%20LAW%20ON%20BIOSAFETY_ff.htm.

Model Law in drafting their national legal frameworks for biosafety in order to create a harmonized Africa-wide biosafety system.[93]

ASIA AND PACIFIC By December 2007, 37 countries in the region had ratified or acceded to the Cartagena Protocol on Biosafety.[94] In addition, ASEAN nations have adopted non-binding guidelines which provide guidance for biosafety regimes in the absence of a national biosafety framework.[95]

CENTRAL AND EASTERN EUROPE By December 2007, 20 countries in the region had ratified or acceded to the Cartagena Protocol.[96] With the exception of Romania, no country permits the commercialization of GMOs. Bulgaria, Croatia and Romania have adopted GMO legislation. Eight countries in the region are Member States of the European Union and subject to its GMO legislation.[97]

LATIN AMERICAN AND THE CARIBBEAN Legislation in this region has tended to lag behind the introduction of GM agriculture. For example, in Brazil it was estimated that 5 million hectares of GMO crops were grown, but it was only in late March 2005 that Parliament passed a biosafety law that allowed for the legal commercial planting of GM crops. The UN University study notes that the regulatory environment across the region is variable.[98] Some countries, such as Brazil, have broad-based biosafety legislation in place, covering transgenic plants, animals, microorganisms, as well as bioethics and biotechnology. Others, such as Chile, Paraguay, Uruguay and Colombia, have regulations that apply only to plants. Twenty-five countries in the region have ratified or acceded to the Cartagena Protocol on Biosafety.[99]

Some representative examples of national legislation are considered below.

[93] Decision on the Report of the Interim Chairperson on the Africa-wide Capacity Building in Biosafety, Doc. EX/CL/31(III) (Decision on the Third Ordinary Session of the Executive Council of the African Union, 4–8 July 2003, Maputo).

[94] Bangladesh, Bhutan, Cambodia, China, Cyprus, Democratic People's Republic of Korea, Fiji, India, Indonesia, Islamic Republic of Iran, Japan, Jordan, Kiribati, Kyrgyzstan, Lao People's Democratic Republic, Malaysia, Maldives, Marshall Islands, Mongolia, Nauru, Niue, Oman, Palau, Papua New Guinea, Philippines, Qatar, Republic of Korea, Samoa, Saudi Arabia, Solomon Islands, Sri Lanka, Syrian Arab Republic, Tajikistan, Thailand, Tonga, Viet Nam, Yemen. See www.cbd.int.

[95] The guidelines can be accessed at http://binas.unido.org/binas/regulations/ASEANGuidelines.pdf. UNIDO, United Nations Industrial Development Organization.

[96] Albania, Armenia, Azerbaijan, Belarus, Bulgaria, Croatia, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Republic of Moldova, Romania, Serbia, Slovakia, Slovenia, The Former Yugoslavia, Republic of Macedonia and Ukraine. See www.cbd.int.

[97] Czech Republic, Estonia, Hungary, Latvia, Lithuania, Poland, Slovakia and Slovenia.

[98] Johnston *et al. Internationally Funded Training in Biotechnology and Biosafety: Is it Bridging the Biotech Divide?* United Nations University Institute of Advanced Studies, Yokohama, February 2008, 29.

[99] Antigua and Barbuda, Argentina, Bahamas, Barbados, Chile, Costa Rica, Dominica, Ecuador, El Salvador, Grenada, Guatemala, Peru, Saint Lucia, Suriname, Venezuela. See www.unep.ch/biosafety/news/htm.

AFRICA

Algeria National biosafety legislation in Algeria is an order by the Ministry of Agriculture and Rural Development no. 910 dated 24 December 2000, which forbids the import, production, distribution, marketing and use of GM plant material. It provides that 'the import, distribution, marketing and use of plant material, which was subject to an artificial transfer of genes from another organism belonging to a different species, e.g. from a bacterial gene, is forbidden'. 'Plant material' is defined in article 13 of law 87-17 dated 1 August 1987 as 'living plants or living parts of plants including buds, grafts, scions, tubers, rhizomes, cuttings, shoots and seeds for multiplication or reproduction purposes'. Scientific institutions and some research bodies may be authorized by the phytosanitary authority represented by the Ministry of Agriculture and Rural Development's Directorate for Plant Protection and Technical Control for analysis and research purposes and upon request, 'to introduce, hold, carry and use, under previously defined conditions, genetically modified plant material'.

Benin Decree no. 2004-293 of 20 May 2004 established the National Biosafety Committee (NBC), which is responsible for the management of GMOs. Under the law, the importation or placing on the market of a GMO requires the authorization of the Minister in charge of the environment.

Botswana The Biosafety Act 2006 establishes the Biosafety Authority Board (BAB) which is responsible for licensing of the use and handling of products of modern biotechnology, including: the intentional introduction into the environment; import or placing in the market; export; and transit of GMOs.[100] Under s. 57 of the Act, a person is guilty of an offence if they undertake 'modern biotechnology activities without a licence'. Under s.59 of the Act, a licence holder for contained use is guilty of an offence if they unintentionally release GMOs into the environment.

The Gambia The African Model Law for the Protection of the Rights of Local Communities, Farmers and Breeders and, for the Regulation of Access to Biological Resources is proposed for adoption in the Gambia.[101] It is proposed that no applications for patents covering life forms or biological processes shall be entertained.[102]

There is no unitary legislation in the Gambia that addresses the issues of safe transfer, handling and use of GMOs. However the Plant Importation and Regulation Act of 1936 provides the regulatory framework for the importation and exportation of plants, seeds, soil, manure or other plant packaging materials. The Act specifically empowers the head of the Agricultural Pest Management Unit (APMU) of the Department of State for Agriculture (DOSA) to provide import and export permits to all importers and exporters of plants or plant products intended for commercial, private or public use.

[100] Biosafety Act 2006, s.35.
[101] National Environment Agency (NEA), Development of National Biosafety Framework for the Gambia, February 2005, http://www.unep.org/biosafety/files/GMNBFrep.pdf.
[102] Ibid., para. 2.2.6.

South Africa The Genetically Modified Organisms Act 1997, implemented in 1999, established the Executive Council for GMOs, charged with approving imports and release of GMOs. Draft Regulations Governing the Labelling of Foodstuffs Obtained Through Certain Techniques of Genetic Modification have been issued by the Department of Health.[103]

ASIA AND PACIFIC

Australia Licences are required under the Federal Gene Technology Act 2000 (Cth), as well as State Moratorium Legislation before a deliberate release of a GM crop into the environment may take place. The person planting the crop must have the authority of a licence to do so issued by the Gene Technology Regulator.[104] The Gene Technology Regulator engages in a risk assessment before granting a licence, which requires the consideration of the risks posed to health or safety of humans and to the environment and the long- and short-term potential of the GMO to be harmful to other organisms and its ability to transfer, spread, or persist in the environment.[105] Unless satisfied that the risks are insignificant or able to be managed, a licence cannot be granted.

On the question of liability, securing the approval of the Gene Technology Regulator would be equivalent to the government approvals in *Hoffman v Monsanto*, which excluded the defendants from liability. On the other hand it has been pointed out that if it had been intended that the legislation was to operate in this way, it would have been easy enough to say so in the legislation. Consequently the courts should be slow to create an immunity by implication.[106] Secondly, the risk assessment carried out by the Regulator excludes the economic consequences (which include damage to property) of introducing the GM crop into the environment from the risk assessment process, which is limited to the risks to human health and the environment.[107]

China In 2001 China enacted a framework Regulation on the Safety Control of Agricultural GMOs, with the aim of protecting human, animal and plant health and the environment. Subsequently, three implementing regulations were issued on Biosafety Evaluation, Import Safety, and Labelling. The Regulation on Biosafety Evaluation establishes procedures for handling applications for GM cultivation and sets up an advisory body – the Biosafety Committee – and a decision-making body – the Biosafety Administration Office, under the Ministry of Agriculture (MOA) – to handle applications. Applicants must provide information on risk assessment. GMOs are classified into four classes depending on their potential danger to human and animal health and to the environment. The Regulation on Safety of Imports entered into force on 20 April 2004. The Regulation establishes the requirements that should

[103] Government Notice No. 366, 4 May 2001, http://www.africabio.com/policies/GMlabellingE.htm.
[104] Gene Technology Act 2000 (Cth) s 50.
[105] See S. Mascher (2003) Sowing the seeds of discontent? Australia's New Gene Technology Act. *Journal of Environmental Law & Practice* 12, 341.
[106] See M. Stallworthy (2003) Environmental Liability and the Impact of Statutory Authority. *Environmental Law* 15, 3.
[107] M. Lunney and R. Burrell (2006) *A Farmer's Choice? Legal Liability of Farmers Growing Crops*. ACIPA, Canberra, 25.

be met to obtain authorization to import GMOs. Requirements vary according to the intended purposes of the imports, i.e. research, release into the environment, or processing. A 270-day approval procedure applies before the first import of a specific GMO takes place. Applications must be accompanied by a safety assessment carried out in the country of origin of the GM material. The Regulation on Labelling applies to five GMOs: soybean, maize seeds, rapeseeds, cotton seeds and tomato seeds, as well as to products thereof.

India The Genetic Engineering Approval Committee (GEAC) under the Department of Environment, Forests and Wildlife is responsible for approval of proposals relating to release of genetically engineered organisms and products into the environment, including experimental field trials and Guidelines for Toxicity and Allergenicity Evaluation of Transgenic Seeds, Plants and Plant Parts. The Review Committee on Genetic Manipulation (RCGM) in the Department of Biotechnology (DBT) is responsible for monitoring safety-related aspects in respect of ongoing research projects and activities involving GMOs and laying down procedures restricting or prohibiting their production, sale, importation and use.

The Consumer Protection Act of 1986 provides protection to a consumer against the 'marketing of goods and services which are hazardous to life and property'. A defect in a product is defined as 'any fault, imperfection or shortcoming in the quality, quantity, potency, purity or standard which is required to be maintained by or under any law for the time being in force or under any contract, express or implied, or as is claimed by the trader in any manner whatsoever in relation to any goods'.[108]

The liability for parties is, again, arguably low because the approval by GEAC for commercialization of the crops would mean that the varieties have passed the necessary tests for food safety.

Japan In June 2003, Japan promulgated 'The Law Concerning the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms'. The law establishes an approval system for the use of LMOs and includes requirements for exports of LMOs.[109]

New Zealand The main regulatory requirement for new crops is the Hazardous Substances and New Organisms Act 1996. This Act was amended in 2003 to provide for civil liability to arise in relation to a new organism where: (i) the developing, field testing, importing or releasing of a new organism was done in contravention of the Act; (ii) possessing or disposing of any new organism imported, manufactured, developed or released in contravention of the Act; or (iii) failing to comply with any controls relating to a new organism imposed by an approval under the Act or specified in any regulations under the Act.[110] It is irrelevant whether the person intended the breach or was exercising reasonable care at the time of the breach.

[108] See Section 2(f) of the Consumer Protection Act 1986.
[109] WTO document G/SPS/N/JPN/107, Committee on Sanitary and Phytosanitary Measures, *Notification from Japan*, 25 September 2003.
[110] See http://www.mfe.govt.nz/issues/organisms/law-changes/liability.html.

Philippines Regulations on the Importation and Release into the Environment of Plants and Plant Products Derived from the Use of Modern Biotechnology, Administrative Order No. 8, April 2002, require all GM products to undergo a safety assessment carried out by regulatory bodies of the Department of Agriculture (Bureau of Plant Industry and Scientific Technical Review Panel). As of 1 July 2003, release into the environment and imports of GMOs need authorization.

Thailand Thailand adopted Biosafety Guidelines in 1992 for laboratory work and field work and planned release. The Thailand Biodiversity Center was established in 2000. It is responsible for the implementation of biosafety legislation. In 2001, Thailand banned all GM field experiments and has restricted GM imports by banning the import of 77 plants.[111]

EUROPE

UK In the UK the Environmental Protection Act 1990 (UK) Part VI, Genetically Modified Organisms (Deliberate Release) Regulations 2002 (UK) has been enacted to comply with the requirements of EC Directive 2001/18/EC on the Deliberate Release of GM organisms into the environment. Where the release is for non-commercial or research and development purposes (a Part B release), the Department for Environment, Food and Rural Affairs (DEFRA) must decide whether the safety conditions set out in the regulations implementing Directive 2001/18/EC are established. Advice is taken from the Advisory Committee on Release to the Environment (ACRE). For commercial releases (Part C releases) the approval process requires the authorization of the European Commission and Member States under the Directive.[112] Directive 2001/18/EC must be read in light of Directive 2004/35/CE dealing with 'Environmental Liability with regard to the prevention and remedying of environmental damage'.

Directive 2004/35/CE does not grant private parties a right to compensation as a consequence of environmental damage or of an imminent threat of such damage.[113] Recital 14 of the Directive declares that it does not apply to cases of personal injury, to damage to private property or to any economic losses. As far as private civil liability is concerned, failure to comply with licensing requirements will be strong evidence of negligence and the receipt of the appropriate regulatory approvals will be strong evidence that reasonable care has been used in relation to the release.

The interaction between environmental protection legislation and the plant varieties legislation was considered in *R. v Watson (On the application of) v Secretary of State*

[111] Simonetta Zarrilli (2005) *International Trade in GMOs and GM Products: National and Multilateral Legal Frameworks*, UNCTAD, Policy Issues in International Trade and Commodities, Study Series No. 29, UNCTAD/ITCD/TAB/30, 20.

[112] See Estelle Brosset (2004) The prior authorisation procedure adopted for the deliberate release into the environment of genetically modified organisms: the complexities of balancing community and national competences. *European Law Journal* 10, 555; Sara Poli (2004) The overhaul of the European legislation on GMOs, genetically modified food and feed: mission accomplished. What now? *Maastricht Journal of European and Comparative Law* 11, 13.

[113] Directive 2004/35/CE Article 3(3).

for Environment, Transport & Regions & Anor.[114] Under Part VI of the Environmental Protection Act 1990, GM seed may not be released into the environment, that is to say sown and grown on, without a consent issued by the Secretary of State for the Environment, Transport and the Regions under section 112 of the Act. Sharpes, a firm of seedsmen, had developed a GM strain of maize seed known as T25. They wished to have a seed trial conducted so that if plants grown from the seed demonstrated the qualities required by Schedule 2 of The Seeds (National Lists of Varieties) (Amendment) Regulations 1982, the seed could be listed in the National List published in the *Plant Varieties and Seeds Gazette*, published under the Plant Varieties Seeds Act 1964. Inclusion of a plant or seed in the National List is an aid to marketing it in the UK. Accordingly Sharpes made application for T25 to be included in the list. The Ministers arranged that the National Institute of Agricultural Botany (NIAB) should conduct a trial on land it occupies for the purpose of such trials at Totnes in Devon. However, because T25 seeds were GMOs to which the provisions of Part VI of the Environmental Protection Act 1990 apply, they could not be released into the environment, that is to say sown and grown on, without a consent issued by the Secretary of State for the Environment Transport and the Regions under section 112 of the Act. Before a consent could be given, the Secretary of State had to be satisfied, pursuant to sections 108 to 112, that release would be safe. The Secretary of State was satisfied and granted a consent to Sharpes.

What was not realized when the consent was given was that the Applicant, whose farm was in the same area as NIAB's land, was an organic farmer and that a question could arise whether a crop of organic maize grown by him could be pollinated by pollen from the T25 plants. The Applicant was a member of the Soil Association, which certifies organic crops. For a farmer who holds himself out as selling produce that is organically grown, if he does not have this certification of his crop its commercial value is seriously depreciated. The Applicant knew of the trial of T25 which was taking place and was warned by the Soil Association that if there was a risk of pollination from it, his own crop certification of it would be withdrawn. Faced with this warning the Applicant sowed his own crop, but at a point as far away as he could sow it from the land on which T25 was being grown – 2 km away, in fact. No question of risk to the Applicant's crop arose if the T25 plants were not allowed to flower. The question was taken up with the Secretary of State. He decided that it was appropriate to take a decision nearer the time as to whether the crop should be allowed to flower. He took advice from ACRE and decided to allow the trial to continue and not to prevent the plants from flowering.

The Applicant sought an order requiring the Secretary of State to prevent the crop from flowering. The Secretary of State has sought the advice of ACRE on this matter. That advice stated that as the applicant's maize crop had been planted at a site approximately 2 km from the nearest GM maize, ACRE consider the amount of cross-pollination was likely to be zero.

On this basis the Court ruled that the Secretary of State's decision was not open to challenge.

[114] [1998] EWHC Admin 737.

LATIN AND CENTRAL AMERICA

Argentina The Secretariat of Agriculture, Livestock, Fisheries and Food (SAGyP) is responsible for the overall regulation of the use of transgenic organisms in field tests, unconfined releases and commercial applications, under Resolutions n. 656 (1992), 837 (1993), 39 and 57 (2003) of SAGyP. The National Advisory Committee on Agricultural Biotechnology (CONABIA), as advisor to SAGPyA, provides science-based environmental risk assessment on the requests for authorization. Once a transgenic plant has been sufficiently field-tested, the applicant may request that the crop be 'flexibilized', i.e. approved for unconfined planting for certain specified uses (export, pre-commercial multiplication pending variety registration, etc). CONABIA's risk assessment for flexibilization evaluates the transgenic crop's potential hazards for human health and for the environment.[115]

Guidelines for food safety approval have been developed by SENASA (National Service of Health and Agrofood Quality). Requests for commercialization are reviewed by CONABIA, which provides an approval or denial recommendation to SAGPyA. If the commercialization approval is granted, the applicant is responsible for the safety of the GM food as well as for monitoring its quality and consistency. The Directorate of Agri-Food Marketing (DNMA) determines which GM crop varieties seed companies can sell to Argentine farmers. The applicant must apply to INASE (National Seed Institute) for a New Variety Registration. For pest-protected and herbicide-tolerant crops, commercialization requires specific authorization from SENASA.[116]

Brazil In October 2003 the Federal Government introduced a draft law aimed at amending former legislation on GMOs (i.e. Brazilian Biosafety Law n. 8974, 1995). The draft law (Biosafety Law PL 2401/2003) was approved by the Chamber of Deputies in February 2004 and was approved by the Federal Senate in October 2004, subject to amendments which must be approved by the Chamber of Deputies. Under the draft law the Ministries of Health, Agriculture and the Environment have the prerogative to authorize the release of GMOs into the environment and their placing on the market. However, their decisions may be reversed by the National Council for Biosafety (CNBS), which will take the final decision in case of diverging opinions. The National Technical Biosafety Committee (CTNBio), within the Ministry of Science and Technology, is fully responsible for scientific research on GMOs, developing standards, carrying out risk assessment and assessing the safety of GMOs.

NORTH AMERICA

Canada In *Larry Hoffman and others v Monsanto Canada Inc and Bayer Cropscience Inc* plaintiffs alleged that the defendants were responsible for adverse environmental effects in breach of The Environmental Management and Protection Act, 2002, S.S. 2002, c. E-10.21 (EMPA, 2002) and that they had failed to obtain an environmental assessment under The Environmental Assessment Act, S.S. 1979-80, c. E-10.1 (EAA).

[115] http://siiap.sagyp.mecon.ar/.
[116] http://www.senasa.gov.ar/.

The Court noted that this legislation applied only to discharges of substances that may cause an adverse effect, and did not apply to discharges authorized by governments or government agencies (as was the release of GM canola).[117]

Section 23 of the EMPA imposes civil liability on any person (a term that includes a corporate body) who proceeds with a 'development' (a term defined in s. 2 (d)) for which ministerial approval is required without obtaining that approval. Section 8 of the Act requires ministerial approval before any person proceeds with any 'development' unless a specific exemption is sought and obtained. Failure to comply with this section results in civil liability, under s. 23. The section makes the person who proceeds with the development without approval liable to any other person who has suffered loss, damage or injury as a result of the development without proof of negligence or intention to inflict loss, damage or injury. Further, the section imposes the burden of proving that any loss, damage or injury was not caused by a development on the person who proceeds with the development without ministerial approval.

In *Larry Hoffman and others v Monsanto Canada Inc and Bayer Cropscience Inc*, the statement of claim alleged that the defendants tested, developed and commercially released GM canola to be grown on a widespread basis in Saskatchewan and that they did not obtain ministerial approval before doing so. The court did not consider that the testing, development and commercial release of GM canola constituted a 'development' within the meaning of the Act.

> In particular, the plaintiffs do not allege that GM canola is likely to have an effect on any unique, rare or endangered feature of the environment …; that the activities would likely substantially utilize any provincial resource; or that they would cause the emission of pollutants or by products that require handling and disposal in a manner not regulated by any other Act or regulation … It is not in my view plain and obvious that the plaintiffs could not prove that the development of GM canola caused widespread public concern because of potential environmental changes or that it is (or was) likely to have a significant impact on the environment, particularly given the relatively broad definition of 'environment' in s. 2(e).

Of course in situations where the testing or release of GM seed is likely to cause 'widespread public concern' then the EMPA might be applicable.

USA Based on the approach that GM products are essentially an extension of conventional products, the US Government has made use of existing laws to ensure the safety of GM products. The current system was delineated under the 1986 Coordinated Framework for Regulation of Biotechnology. Under the Framework, agencies that were responsible for regulatory oversight of certain product categories or for certain product uses are also responsible for evaluating those same kinds of products developed using genetic engineering.

The Food and Drug Administration (FDA) is responsible for food and feed safety; within the USDA, the APHIS is responsible for assessing the environmental safety of GM crops; and the EPA is responsible for development and release for GM plants with pest control properties.

[117] 2005 SQKB 225 at para. 165.

The laws currently used to regulate the products of modern biotechnology are the Plant Protection Act (PPA), the Federal Food, Drug, and Cosmetic Act (FFDCA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the Toxic Substances Control Act (TSCA). Under the 1992 FDA 'Statement of Policy: Foods Derived from New Plant Varieties', developers have the responsibility to ensure that the foods they offer to consumers are safe and comply with all applicable requirements. In 2001, the FDA issued a proposed rule and a draft guidance document concerning food developed through biotechnology. The proposed 'Pre-market notice concerning bioengineered foods' would require, on a mandatory basis, the submission to the agency of data and information regarding plant-derived bioengineered foods that would be consumed by humans or animals, to be made at least 120 days prior to the commercial distribution of such foods. The draft guidance on labelling will assist manufacturers who wish to voluntarily label their foods as being made with or without the use of bioengineered ingredients.[118]

7.6 Genetic Use Restriction Technologies (GURTs)

Technological aspects

On 3 March 1998, the USDA and the Delta & Pine Land Company were registered as assignees of a US patent 'to control plant gene expression'.[119] This technology allowed plant breeders to modify crops so that, after germination, they would produce sterile seed. This technology was first known as the 'Technology Protection System', after which it has become known as GURT. GURT is a broad term that refers to any use of an external chemical inducer to control the expression of any genetic trait of a plant.[120]

There are two types of GURTs: (i) v-GURTs: where the use of a crop variety is controlled through genetically induced seed sterility; and (ii) t-GURTs: where the use of a trait, such as disease resistance or early ripening, is controlled. GURTs use a chemical-sensitive genetic switch (responsive, for example, to alcohol or the antibiotic tetracycline) linked to a gene for an enzyme which activates a toxin gene. In the t-GURT system when the toxin gene is switched on, it becomes active in the late stage of seed formation to prevent it germinating.[121]

Pat Mooney, member of the organization formerly known as Rural Advancement Foundation International (RAFI), now known as the Action Group on Erosion, Technology and Concentration (ETC Group), has coined the term 'Traitor

[118] US FDA, Center for Food Safety and Applied Nutrition: Voluntary labelling indicating whether foods have or have not been developed using bioengineering, January 2000, available at: www.cfsan.fda.gov/~dms/guidance.html.

[119] See U.S. Pat. No. 5723765.

[120] ETC Group, Communique, Issue #79 'Terminator Technology – Five Years Later' (May/June 2003). http://www.etcgroup.org/documents/TermCom03.pdf

[121] See J.T. Odell, J.L. Hoopes and W. Vermerris (1994) Seed-specific gene activation mediated by the Cre/lox site-specific recombination system. *Plant Physiology* 106, 447–58. For a critique of technological issues see: H. Daniell (2002) Molecular strategies for gene containment in transgenic crops. *Nature Biotechnology* 20, 581–586.

technology' to describe GURTs as a whole and 'Terminator technology' to describe v-GURTs.[122]

Advantages

It has been suggested that the primary purpose of GURTs is for seed companies to prevent seed saving.[123] Also, it overcomes the cost, expenditure of time and unpredictability of patent litigation.[124] As a corollary to this argument, where an IP regime might be ineffective, GURTs could provide an alternative safeguard to investment in the development of new plant varieties by life-sciences firms. A valuable function has been suggested for v-GURTs in reducing the possibility of genetic pollution from GMOs. The risk of GMOs cross-pollinating with wild species would be reduced by the sterility of any cross-pollinated offspring. The National Research Council in the USA has commended v-GURTs as an effective method of confining gene flow.[125]

Non-viable seed produced on v-GURT plants will reduce the propagation of undesirable volunteer plants, which are those which grow on their own, rather than being deliberately planted. Volunteers often grow from seeds that are wind borne, dropped by birds or inadvertently mixed into compost. Unlike weeds, which are unwanted plants, a volunteer may be encouraged once it appears, being watered, fertilized, or otherwise cared for, because of its superficial resemblance to a cultivated crop. For example, in the case of canola, which is a recently domesticated plant, two undesirable traits that persist in wild species are weak seed dormancy and seed shattering. As a result of these traits, large numbers of seeds can enter the soil after cropping and return as volunteer plants. Volunteer plants can become an economic problem for larger-scale mechanized farming systems that incorporate crop rotation.

Environmental effects

A comprehensive analysis of the potential environmental effects of v-GURT plants was undertaken by the Ad Hoc Open-Ended Inter-Sessional Working Group on Art. 8(j) which met in Montreal, 10–14 November 2003. The main environmental concern about v-GURT plants is that they could cross-pollinate with non-GM plants, either in the wild or on the fields of farmers who do not adopt the technology. This cross-pollination could reduce yield in the subsequent year due to occurrence of sterile seeds in neighbouring stands. This outcrossing was said by the Working Group to be of particular concern where ecological niches and wild relatives exist locally,

[122] See e.g. RAFI (1998) Terminator technology targets farmers. Communique, www.etcgroup.org.

[123] Sina Muscati (2005) Terminator technology: protection of patents or a threat to the patent system? *IDEA* 45, 477, at 481.

[124] Kojo Yelpaala (2000) Owning the secret of life: biotechnology and property rights revisited. *McGeorge Law Review* 32, 111, at 172.

[125] Committee on Genetically Modified Pest-Protected Plants, National Research Council (2000) *Genetically Modified Pest-Protected Plants: Science and Regulation.* National Academy Press, Washington DC, at 90.

particularly in the centres of origin of a crop.[126] The Working Group also suggested that the application of GURTs might produce low quantities of autotoxic compounds in seeds or other tissues, which may negatively impact non-target organisms (e.g. birds, insects and soil biota).[127] It was also speculated that GURTs might negatively impact the food chain and affect human health due to the additional traits, such as the transfer of allergenicity genes and the transfer of antibiotic resistance. The Working Group noted that if GURTs are perceived as a reliable and efficient technology for the environmental containment of transgenic seed, their promotion might prevent or reduce further research on gene containment alternatives at a legal and biological level.[128]

It has been urged that these possible negative effects of GURTs should be seen in the general context of the evolution of new plant types.[129] Our major food crops are the result of selective breeding and adaptation by farming communities through the repetitive selection of desirable traits. The resultant crops can only thrive by the application of specific agricultural practices. They would probably not survive in nature. Furthermore, a number of our major crop types are hybrids, which were produced by the crossing of highly inbred plant types. Hybrid vigour tends to decrease substantially with each successive planting. In this regard an analogy can be drawn with GURTs.

It is urged[130] that to analyse the environmental impacts of GURTs, account has to be taken of the three principal types of agriculture systems: (i) highly industrialized agriculture, characterized by wide-scale use of a limited number of species and improved varieties, fertilizers, crop-specific pesticides, chemical seed treatments, irrigation and a high degree of mechanization; (ii) intermediate agriculture systems, including partial adoption of mechanization and other inputs; and (iii) traditional subsistence agriculture, with diverse locally adapted varieties, often diverse crop–livestock enterprises, limited external inputs and low adoption of improved varieties. In the first category, farmers are most receptive to practices which will enhance the value of their crops. To be acceptable to this group, GURTs would have to be tied to some added value aspect such as increased yield. If this is achieved, then the large-scale use of GURTs is going to have a significant environmental effect, because of the large geographical area in which they will be used. Farmers in the second category will have more limited access to external inputs for financial reasons. For this reason, GURTs would be expected to have a lower acceptance among these farmers, however, if taken on by some farmers, might have an environmental impact upon their neighbours. The subsistence agricultural sector is not likely to be offered GURT varieties by seed companies because of their limited financial capacity and because GURTs are not directed to meet the environmental conditions of this limited seed market.

126 UNEP/CBD/SBSTTA/9/INF/6, Annex I.

127 Ibid.

128 Ibid.

129 Richard A. Jefferson, Don Byth, Carlos Correa, Gerardo Otero, Calvin Qualset, Technical assessment of the set of new technologies which sterilize or reduce the agronomic value of second generation seed, as exemplified by U.S. Patent No. 5,723,765, and WO 94/03619. Expert paper, prepared for the Secretariat (SSBTA) on 30 April 1999, available at http://www.biodiv.org/sbstta4/docs-e.html.

130 Ibid., para. 134 ff.

The extensive agitation against GURTs has been by commentators concerned about their impact in developing countries. As is indicated above, this is not likely to be the market in which this seed technology is to be sold. Of course, if this market was penetrated, the v-GURT varieties could displace the more robust traditional varieties that are better resistant to environmental changes, resulting in increased food insecurity.

At this stage, it has been suggested that insufficient scientific data exists on the likely environmental effects of GURTs from genetic pollution.

Economic effects

In farming systems that are dependent upon saved seed, genetically engineered sterility will have a direct impact upon the livelihoods of such farmers. Where GURTs displace local varieties of crops, not only would genetic erosion occur, as was a feature of the Green Revolution, but the loss of the ability for such farmers to save seed will confer market power upon seed companies, who can then raise seed prices, which will undermine the profits of farmers.

It is also suggested that GURTs might tend to concentrate breeding efforts in the private sector and result in fewer options for smallholder farmers and indigenous and local communities, rather than widening breeding efforts to broaden the genetic base of crops through the stimulation of participatory crop breeding.[131]

Morality issues

As a technological appropriation method, GURTs are not constrained to provide the balance of societal and individual benefits sought to be secured by IP systems. For example, disclosure of technological information is part of the bargain that justifies the limited patent monopoly and equitable benefit sharing is a characteristic of the CBD, and the possibility of seed-saving is built in to the UPOV system. As was seen above, it might well have been the existence of these balances which encouraged the development of GURTs.

The potential economic and environmental effects of the v-GURT technology raises the question whether a patent on v-GURT may be refused, or cancelled, on the basis of morality or public order grounds. Thus Art. 27.2 of the TRIPS Agreement provides for the exclusion 'from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment…'. The language of this exception has yet to be tested in a food security context.

[131] UNEP/CBD/SBSTTA/9/INF/6, Annex I.

Registration history

As was mentioned above, the Terminator patent was that registered in 1998 by the USDA and the Delta & Pine Land Company.[132] The involvement of the USDA has been explained as part of the US Government's concern to protect the IP of its agri-businesses in overseas markets. A USDA spokesman has apparently explained that the technology is to be 'widely licensed and made expeditiously available to many seed companies' in order 'to increase the value of proprietary seed owned by US seed companies and to open up markets in Second and Third World countries'.[133] Nine weeks after the registration of the Terminator patent, Monsanto announced the intended purchase of Delta & Pine, but this proposed merger was unsuccessful. In October 2005, a patent for the control of plant gene expression was obtained by D & PL Technology Holding Company and the USDA at the European Patent Office[134] and in Canada[135] relying on the priority of the US patent. The EPO and Canadian patents claimed a genetic modification process that enables a characteristic such as sterility or enhanced growth to become active in a plant only when the plant is treated with an external chemical and reaches a certain stage of growth. The patent application indicated that the preferred way the technology could be used would be to create seeds which, when matured into fully grown plants, become sterile and produce seeds that will not germinate, which would help to avoid 'accidental reseeding, escape of the crop plant to areas outside the area of cultivation, or germination of stored seed'.

In March 2004, Syngenta obtained a US patent for an invention concerning 'a method of controlling sprout formation in plants and parts thereof including vegetative storage organs'.[136] This invention was applicable to the germination of potatoes and tubers. In July 2005, Monsanto Technology LLC filed a patent application in the USA,[137] and in October in Australia,[138] Europe[139] and under the PCT[140] for an invention entitled 'plant regulatory sequences for control of gene expression'. Similarly entitled applications were filed by the Australian Commonwealth Scientific and Industrial Research Organization in Australia,[141] Japan,[142] Europe and the USA.[143]

[132] See U.S. Pat. No. 5,723,765 – Control of plant gene expression.
[133] Quoted in Rural Advancement Foundation International, US patent on new genetic technology will prevent farmers from saving seed. RAFI press release, 11 March 1998.
[134] EP 775212B.
[135] CA 2196410.
[136] US 6700039.
[137] US2003131375.
[138] AU2005222559.
[139] C12N15/82B.
[140] C12N15/82; C12N15/82; (IPC1-7): C12N15/00.
[141] AU2005211538.
[142] JP2005323615.
[143] US2005250208.

NGO agitation

As was mentioned above, ETC (formerly RAFI) has led the NGO opposition to terminator technology. A Ban Terminator organization has been established and a Ban Terminator campaign was launched by a consortium of Canadian-based civil society organizations.[144] In October 1999, in response to opposition to GURTs, Monsanto had publicly pledged not to commercialize Terminator seeds. Its CEO, Robert Shapiro, had written an open letter to the Rockefeller Foundation, stating, 'I am writing to let you know that we are making a public commitment not to commercialize sterile seed technologies, such as the one dubbed "Terminator"'.[145] However, concern was raised by the Ban Terminator campaign early in 2006 that Monsanto had modified its position in which it did 'not rule out the potential development and use of one of these technologies in the future. The company will continue to study the risks and benefits of this technology on a case-by-case basis.'[146] Although Monsanto in an email to the director of this campaign of 27 February 2006 stated that 'we stand by our commitment to not use genetic engineering methods that result in sterile seeds. Period',[147] the ETC Group expressed concern that 'the company's pledge leaves the door open and does not rule out future development of the technology'.[148] As is indicated below, submissions made by representatives from Canada, Australia and New Zealand at the *Ad hoc* Open-ended Intersessional Working Group on Art. 8(j) which met in Granada on 23–27 January 2006 and at COP 8, called for future research on v-GURT technology on a case-by-case basis.

International efforts

In response to the registration of the first terminator patent, the CGIAR on 30 October 1998 accepted the recommendation of the 8th meeting of its GRPC that it adopt a statement concerning the 'terminator gene technology'. The recommendation was based on the 'recognition of concerns over potential risks of its inadvertent or unintended spread through pollen; the possibilities of the sale or exchange of non-viable seed for planting; the importance of farm saved seed, particularly to resource poor farmers; potential negative impacts on genetic diversity; and the importance of farmer selection and breeding for sustainable agriculture'. Noting that the CGIAR's science exists to serve the poor, it decided that its centres 'would not incorporate into their breeding material any genetic systems designed to prevent seed germination'.

[144] ETC group, Inter Pares, National Farmers Union, and USC Canada. See, *Ban Terminator*, 25 March 2006 at www.banterminator.org

[145] Ban Terminator, News Release, 21 February 2006, www.BanTerminator.org

[146] Ibid.

[147] E-mail from Diane Herndon, Director of Public Policy, Monsanto, to Lucy Sharratt, Ban Terminator Campaign, copied to Hugh Grant, CEO Monsanto Company. Judith Rodin, President, The Rockefeller Foundation. Gordon Conway, Chief Science Advisor, UK Department for International Development, and Former President, The Rockefeller Foundation, reproduced on ETC website, 2 March 2006, www.etcgroup.org.

[148] Ibid.

At the 36th meeting of the Second Committee (Economic and Financial Issues) of the UN General Assembly (UNGA), on 10 November 1998, a draft resolution was introduced, on behalf of the States members of the UN that are members of the Group of 77 and China, addressing issues pertaining to the CBD, including the evolution and patenting of 'terminator' technologies. Following consideration by the Committee, a resolution on the CBD was adopted by the 53rd session of the General Assembly, which called upon governments, in cooperation with the COP of the CBD, 'to use science-based analysis to study and monitor closely the evolution of new technologies to prevent possible adverse effects on the conservation and sustainable use of biological diversity, which might have an impact on farmers and local communities'.[149]

Because of its perceived impact upon biological diversity and upon the agricultural practices of traditional farmers, the subject of GURTs has been taken up by the COP of the CBD, which entered into force on 29 December 1993. Article 8(j) of the CBD provides that its parties will, subject to their national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biodiversity; promote their wider application with the approval and involvement of knowledge holders; and encourage the equitable sharing of benefits arising from the utilization of such knowledge.

At its fourth meeting, the COP, in May 1998, paragraph 10 of its decision IV/6, requested the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) to consider and assess, in the light of contributions to be provided by Parties, other Governments and organizations, 'whether there are any consequences for the conservation and sustainable use of biological diversity from the development and use of new technology for the control of plant gene expression, such as that described in US patent 5723765, and to elaborate scientifically based advice to the COP'.

At its fifth meeting the COP, in decision V/5, Section III made lengthy reference to GURTs, based upon the advice of the SBSTTA. At paragraph 23 of this Section the COP recommended:

> … that, in the current absence of reliable data on genetic use restriction technologies, without which there is an inadequate basis on which to assess their potential risks, and in accordance with the precautionary approach, products incorporating such technologies should not be approved by Parties for field testing until appropriate scientific data can justify such testing, and for commercial use until appropriate, authorized and strictly controlled scientific assessments with regard to, inter alia, their ecological and socio-economic impacts and any adverse effects for biological diversity, food security and human health have been carried out in a transparent manner and the conditions for their safe and beneficial use validated. In order to enhance the capacity of all countries to address these issues, Parties should widely disseminate information on scientific assessments, including through the clearing-house mechanism, and share their expertise in this regard.[150]

[149] A/RES/53/190.
[150] http://www.biodiv.org/decisions.

The moratorium on the use of GURTs until such time as relevant scientific assessments could be obtained has been reiterated as recently as COP 8 in March 2006.

In paragraph 25 the COP indicated that the scientific assessments should address the ecological, social and economic effects of GURTs taking into account such information, as available, as:

> (a) The molecular biology information available; (b) The genetic constructs and inducers used; (c) Effects at the molecular level, such as site-specific effects, gene-silencing, epigenesis and recombination; (d) Potential positive applications of the variety-specific genetic use restriction technologies on limiting gene flow, and possible negative impacts of genetic use restriction technologies on small populations of threatened wild relatives.

Section III also encouraged Parties and Governments to identify ways and means to address the potential impacts of GURTs on the *in situ* and *ex situ* conservation and sustainable use, including food security, of agricultural biological diversity and to take into account the necessity 'to ensure the safety of human health, the environment, food security and the conservation and sustainable use of biological diversity'.[151]

The COP also invited relevant organizations 'to study the impact of technologies on the protection of intellectual property in the agriculture sector, and its appropriateness for the agricultural sector'.[152]

At the sixth meeting of the COP an Ad Hoc Technical Expert Group (AHTEG) on the potential impacts of GURTs on Smallholder Farmers, Indigenous and Local Communities and Farmers' Rights was established. Several meetings of the SBSTTA considered the AHTEG. The tenth meeting of the SBSTTA met in Bangkok on 7–11 February 2005, prefatory to COP 8. It noted the recommendation of the Art. 8(j) Working Group which recognized that 'GURTs present complex issues that require further scientific research and studies as well as the evaluation of potential impacts on the basis of the precautionary approach, and notes the range of their potential socioeconomic impacts'.[153] The SBSTTA recommended that the COP reaffirm its Decision V/5 section III (GURTs) and invited parties to:

- respect the right of farmers and indigenous and local communities to use, save and exchange their farm-saved seeds; and
- undertake further research and studies on potential impacts of GURTs, including on a case-by-case risk assessment basis with respect to different categories of GURTs subject to the precautionary approach.

The fourth meeting of the *Ad hoc* Open-ended Intersessional Working Group on Art. 8(j) and related provisions of the CBD met on 23–27 January 2006, in Granada. The Working Group reaffirmed the CBD's de facto moratorium on GURTs. However, at the insistence of Australia, it was agreed that further research and studies on potential impacts and other aspects of GURTs be undertaken on a case-by-case risk assessment basis.

[151] Ibid., decision V/5, Section III, paras 25–26.
[152] Ibid., decision V/5, Section III, para. 22.
[153] UNEP/CBD/WG8J/4/L.8.

The Working Group invited WIPO, UNESCO and the UN Commission on Human Rights to undertake studies on granted and pending GURTs patents, and on the ethical and spiritual consequences of GURTs.[154] COP 8 was also recommended to urge parties and others to:

- promote technology transfer and capacity building for risk assessment;
- support smallholder farmers and indigenous and local communities in the application of the COP decision on GURTs; and
- promote and facilitate the full and effective participation of indigenous and local communities in all future discussions on GURTs under the CBD.

In anticipation of COP 8, the European Parliament on 16 March 2006 passed a resolution urging the European Commission and Member States to take note of the 'moratorium on the field-testing and marketing of V-GURT technology' in Decision V/5, section III, taken by COP 5 in 2000.[155] Clause 3 of the resolution stated that 'the requirements of the global moratorium on the field-testing and marketing of V-GURT technology with regard to, inter alia, the ecological and socioeconomic impact and any adverse impact on biological diversity, food security and human health, have not been met'. Reflecting NGO concerns, this resolution asserted in recital K that 'the use of genetic engineering to produce sterile seeds would force farmers to purchase new seed each season and could therefore threaten food security, in particular in developing countries, and … such genes could contaminate non-GM crops as a result of cross-fertilisation and accidental mixing'.

Clause 4 of the resolution urged the European Commission and the Member States to 'reject any proposals to undermine the moratorium on the field-testing and marketing of so-called terminator technologies set by CBD Decision V/5 through a "case-by-case" assessment or approval of Genetic Use Restriction Technologies' and to 'defend robustly an EU policy to require that no open-air growing of crops involving Genetic Use Restriction Technologies can be permitted until thorough research on ecological and socio-economic impacts and on any adverse effects for biodiversity, food security and human health has been carried out in a transparent manner'.

By consensus, the COP 8 negotiators at Curitiba reaffirmed the COP 5 Decision V/5, section III requesting a moratorium on the field-testing and marketing of v-GURT technology. Malaysia, speaking on behalf of the G77 and China, were reported to have objected to the reference to case-by-case risk assessment, because it would potentially allow field tests.[156]

Conclusion

As a patentable technology, v-GURTs are subject to the express limitations of the morality clause contained in most patent statutes. The protection of food security has

[154] UNEP/CBD/WG8J/4/L.8, 30 January 2006.
[155] P6_TA-PROV(2006)0098.
[156] ETC Group: UN Upholds Moratorium on Terminator Seed Technology, 31 March 2006.

not yet been tested as a ground of morality objection to patentability. Another ground, which has developed in the USA as a gloss on the statute, is the patent misuse doctrine. Under this doctrine a patent licence will be struck down if it extends beyond the term of the underlying patent, because it attempts to extend the patent owner's exclusive right beyond the term of protection that Congress has granted.[157] It can be argued that v-GURTs are an impermissible means to extend the term of the patent, since even after the patent over a v-GURT seed or method has expired, seed companies can still enjoy a monopoly over the seed, since farmers are obliged to continue buying the seed, particularly in the absence of saved viable seed.

In the UK, a patent misuse doctrine can be argued through an application of the reasoning in *Interlego v Tyco*,[158] where the Judicial Committee of the Privy Council was concerned with an attempt to enforce through copyright law designs that had expired under the Registered Designs Act. Lord Oliver reprimanded the plaintiff for seeking to extend its IPR, in effect, for perpetuity.[159]

Of course, if patent law proves to be problematic for the protection of v-GURTs, seed developers can resort to trade secrecy protection. In *Pioneer Hi-Bred International v Holden Foundation Seeds*,[160] the US Court of Appeals for the Eighth Circuit held that the genetic composition of proprietary seed was protectable as a trade secret. This was because of the seed developer's expenditures on research and development and the preservation of confidentiality.[161] A similar approach was taken by the Supreme Court of Queensland in *Franklin v Giddings*,[162] which held that the genetic information contained within the budwood of early ripening nectarine trees was proprietary information which was protectable in a breach of confidence action.

An underlying concern about terminator technology is its impact upon market concentration. Because of the expense of this research, the sector is becoming one in which fewer companies are able to participate. Terminator technology has been identified as a development which may accelerate market concentration in the field of agricultural research by reducing access to plant genetic resources through the imposition of licence fees which might be beyond the research budgets of public sector institutions.[163] It may ultimately be the case that through competition laws countries can ensure freedoms of choice and operation in the agriculture sector.

[157] Eg *Dawson Chemical Co. v Rohm & Haas Co.* 448 U.S. 176 (1980), at 180; *Brulotte v Thys Co.* 379 U.S. 29 (1964).

[158] *Interlego A.G. v Tyco Industries Inc.* [1989] A.C. 217.

[159] Ibid. at 255–256.

[160] *Pioneer Hi-Bred International v Holden Foundation Seeds* 35 F.3d 1226 (8th Cir. 1994).

[161] Ibid. at 1236.

[162] [1977] Qd. R 72.

[163] T.M. Swanson and T. Goeschl (2002) The impact of GURTs: agricultural R&D and appropriation mechanisms. In: Swanson, T.M. (ed.) *Biotechnology, Agriculture and the Developing World: The Distributional Implications of Technological Change.* Edward Elgar, Cheltenham, 60–61.

8 Geographical Indications and Food Security

8.1 Introduction

It would be convenient to hypothesize that the legislation which sought to protect the commercial reputation of traders in discrete geographical localities (principally in Europe) evolved into the modern system for the prohibition of false and misleading GIs. However, the origin of GI legislation can be traced back to French statutes to protect the competitive advantage of wine producers.[1] The mediaeval legislation of Bordeaux conferred two privileges upon the wine producers of south west France. Firstly, the *privilège de la descente* prohibited the transportation by river through Bordeaux of wines produced outside the region until 11 November of each year. With the icing up of rivers consequential upon the onset of winter, this gave the local wines a competitive advantage in gaining access to the lucrative Northern Europe markets. The justification for this restriction was stated to be to provide an opportunity for the authentication of the wines of the region.[2] As will be seen below, a similar duality exists in relation to the modern justification of GI laws in which a concern with the authentication of the origin of products cohabits with a concern to preserve the competitive advantage of local producers.

The second category of privilege was the *privilege de la barrique*, which restricted for use only for the wines of Bordeaux a barrel (barrique) of prescribed dimensions, which meant that wines from the region were better packaged and travelled more cheaply than wines from competing regions. By a statute of 1764 seeking to prevent the illicit use of the Bordeaux barrique, each had to be branded with the name and

[1] See A. Richard (1918) *De la protection des appellation d'origine en matièe vinicole, Bordeaux, Imprimeries Gounouilhou*, referred to in William van Caenegem (2003) Registered geographical indications. Between intellectual property and rural policy – Part II. *Journal of World Intellectual Property* 861.

[2] Richard, n.1 supra at 50, van Caenegem, n.1 at 862.

parish of origin of the wine grower.[3] The barrique brand can be seen as a precursor of the registered GI.

In seeking to resist the resist the abolition of its privileges at the time of the French Revolution, Bordeaux raised a number of the arguments, which have characterized the modern debate on GIs. Firstly, it argued that the privileges were essential for guaranteeing the authenticity of the crus (vintages) and, secondly, that as the land of the region was not suitable for other agricultural pursuits, viticulture had to be protected through the maintenance of these privileges. Relevant to the issue of food security, both the protection of consumers and the maintenance of the rural economy are advanced as justifications for the protection of GIs.

It has been observed that 'it is a matter of historical irony' that notwithstanding the ancient provenance of GIs, current developments in the institution are a local reaction to the industrialization and globalization of agricultural production, where the global marketplace provides opportunities for the diversification of agricultural products and foodstuffs.[4] Given the dominance of industrialized countries regarding access to knowledge, medicines and the distribution of transgenic plant products, the protection of GIs has gained a certain moral authority that weighs in favour of developing countries having access to knowledge while at the same time having the freedom to exploit their available knowledge.

Interestingly, despite their vehement opposition to the TRIPS Agreement, leading developing countries, such as India and Brazil, now espouse GIs, at the launch of the Doha Round, as the best available means exploiting their TK. The Hong Kong Ministerial Declaration of November 2005 affirmed the 'central importance of the development dimension in every aspect of the Doha Work Programme'. Ambitious claims associating the protection of GIs with economic development are now made by those developing countries that support the international protection of GIs. It is put forward as a means of sustaining rural communities by helping to guarantee food security for those without cash incomes, helping to mitigate natural environmental disasters and protect biodiversity.[5]

8.2 GIs and Food Security

In signalling the association between product quality and origin, the GI provides both a trade benefit in generating market appeal 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.[6] A 2005 study states that in the EU, the price difference between Protected Designation of Origin (PDO) and

[3] Arrêt de la Cour du Parlement concernant la police des vins, 18 July 1764.

[4] See G. Evans and M. Blakeney (2006) The protection of geographical indications after Doha: quo vadis? *Journal of International Economic Law* 9, 573.

[5] See UNDP (2004) Environmental Mainstreaming Strategy, A strategy for enhanced environmental soundness and sustainability in UNDP policies, programmes, and operational processes, June, at 8: http://www.undp.org/fssd/docs/envmainstrat.doc.

[6] See e.g. 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 (2004) *Geographical Indications and Property Rights: Protecting Value-Added Agricultural Products*. MATRIC Briefing Paper 04-MBP 7, May, Iowa State University.

Protected Geographical Indication (PGI) products and similar products without such designations is on average 10–15%.[7]

The first preamble to the 2006 EC Regulation on the protection of GIs and designations of origin for agricultural products and foodstuffs[8] declared: 'The production, manufacture and distribution of agricultural products and foodstuffs play an important role in the Community economy.'[9] Thus today in the EU the 640 GIs and designations of origin for foodstuffs, and over 4200 registered designations for wines and spirits, together generate a turnover of more than €40 billion annually.[10] Similarly, the second 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.

In recent years, the use that the EU has made of GIs as a tool to consolidate the reputation and market niche of certain agricultural products has been supplemented by the motive to use GI protection as a 'potential political and economic "counterweight" to the threat that subsidies reduction and increased market access commitments could represent to its agricultural production'.[11] The protection of GIs is seen as a means of changing the EU's Common Agricultural Policy (CAP) to one with a focus on quality rather than quantity. The CAP aims to create better-paid employment in rural areas and to motivate young people to continue to be involved in agricultural activity through the generation of premium prices. An illustrative example is the result of the protection of 'Lentilles vertes du Puy', which is said to have increased the production of lentils from 13,600 quintals in 1990 to 34,000 quintals in 1996 and 49,776 quintals in 2002, the number of producers almost tripling from 395 in 1990, to 750 in 1996, and 1079 in 2002.[12] It is estimated that France has 593 GIs registered under the general EC rules, for wines and spirits and for foodstuffs, generating €19 billion for 138,000 agricultural enterprises and that Italy's 420 GIs generate a value of €12 billion and give employment to more than 300,000 Italians.[13]

The role of GIs in 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

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

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

[9] For a recent analysis of European GIs legislation, see L. Bently and B. Sherman (2006) The impact of European geographical indications on national rights in Member States. *Trade Mark Reporter* 76, 1.

[10] See O'Connor and Company, n. 7 supra at 3.

[11] D. Vivas-Eugui and C. Spennemann, The treatment of geographical indications in recent regional and bilateral free trade agreements. UNCTAD/ICTSD Project on Intellectual Property and Sustainable Development, 24.

[12] O'Connor and Company (2005) Ibid., 4.

[13] Ibid., at 7.

> 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.[14]

The agro-food industry is characterized by the production of standardized 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. The evidence from Europe is that the success of policy measures promoting GIs has resulted from the careful implementation of effective marketing, pricing and distribution strategies.[15] European surveys indicate that consumers are prepared to pay a premium price for regional products, where origin and quality have a positive relationship.[16] Examples of recently developed agricultural markets which illustrate the marketing potential of GIs for developing countries are the growth of the global organic market which is said to account for between 1% and 3% of the global food market[17] and the growth of the European Fair Trade market. A GI-type option, which has been proposed in the USA, is the creation of Farmer Owned Brands (FOB), as a means of creating value for farm produce.[18] This is an attempt to create brand appeal by the collective effort of farmers producing a homogeneous product originating in a particular area. One possibility that has been identified for FOBs in the USA is beef originating from packing plants located along Interstate 80, which apparently has a particular appeal for Japanese consumers.[19]

The GI has 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.[20]

It has been suggested that the traditional agricultural knowledge of traditional farmers and indigenous people could be protected through GIs.[21] Addor states that 'GIs are based on collective traditions and a collective decision-making process; they reward traditions while allowing for continued evolution; they emphasize the

[14] F. Fischler (2004) Quality food, CAP reform and PDO/PGI. Speech delivered at the Congress Fondazione Qualivita, Siena, 17 April.

[15] See D. Rangnekar (2004) *The Socio-Economics of Geographical Indications, A Review of Empirical Evidence from Europe*. Issue Paper No. 8, Geneva, International Centre for Trade and Sustainable Development (ICTSD), May, 16.

[16] D. Barjolle and B. Sylvander (2000) PDO and PGI Products: Market, Supply Chains and Institutions. Final Report, FAIR 1-CT95-0306. European Commission, Brussels, June; M.L. Loureiro and J.J. McCluskey (2000) Assessing consumer response to protected geographical identification labelling. *Agribusiness* 16, 309; A. Tregear (2002) Final Report on 'Link between origin labelled products and consumers and citizens'. Contract QLK5-2000-0593. European Commission, Brussels, July.

[17] See E. Millstone and T. Lang (2003) *The Atlas of Food: Who Eats What, Where and Why?* Earthscan, London.

[18] D.J. Hayes, S.H. Lence and A. Stoppa (2003) *Farmer Owned Brands? Briefing Paper 02-BP 39.* Center for Agricultural and Rural Development, Iowa State University, March (Revised).

[19] This beef is apparently favoured by Japanese consumers because of its flavour, being typically produced from calves that are grain fed for as long as 6 months. Ibid., 20.

[20] See M.A. Echols (2008) *Geographical Indications for Food Products: International Legal and Regulatory Perspectives*. Kluwers, Alphen aan der Rijn, 8.

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

relationship between human efforts, culture, land, resources and environment'.[22] As the overwhelming majority of the food-insecure population of the world lives in rural economies, any benefit that a system of GIs can secure is going to be very significant.

In the area of biotechnological patenting, the role which a GI law might play is illustrated by the recent dispute between the Indian Basmati rice marketing authorities and a US corporation that 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.[23] Had a GI 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 PVP for strains of chick peas that had been developed from Indian stock and that were sought to be registered with Indian names.[24] Ultimately, this dispute was resolved without litigation, but could have been settled in the context of GIs.

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 TK in the field of agricultural plant genetic resources offers the potential of 'appropriate flanking policies'.[25]

8.3 Definitions

Because of the diverse ways in which the protection of GIs has evolved under national laws, there is no generally accepted terminology. The following are the conventional definitions, which can be found in the literature on GIs:[26] 'Indication of Source' refers to a sign that indicates that a product originates in a specific geographical region; 'Appellation of Origin' refers to a sign that indicates that a product originates in a specific geographic region only when the characteristic qualities of the product are due to the geographical environment, including natural and human factors; and 'Geographical Indication' includes both of the above concepts.

For the purposes of the discussions of reform proposals in April 2001 by the TRIPS Council, the WTO Secretariat adopted the term 'indications of geographical origin' to designate the different expressions used by WTO Members to protect geographical origin of products.[27] A GI is a generic description, which is applicable

[22] F. Addor (2003) Geographical Indications – Where Now After Cancun? Paper presented at OriGIn, 2nd Meeting, Alicante, 27–28 November, 2.

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

[24] See M. Blakeney (1998) Intellectual property rights in the genetic resources of international agricultural research institutes – some recent problems. *Bioscience Law Review* 1, 3.

[25] See S. Biber-Klemm, T. Cottier, P. Cullet and D. Szymura-Berglas (2005) The current law of plant genetic resources and traditional knowledge. *Traditional Knowledge on Plant Genetic Resources for Food and Agriculture*. CAB International, Wallingford, 57–81.

[26] See e.g. A. Conrad (1996) The protection of geographical indications in the TRIPS Agreement. *Trade Mark Reporter* 86, 11 at 13–14.

[27] See Note by the WTO Secretariat IP/C/W/253, dated April 2001, on 'Review under Article 24.2 of the application of the provisions of the section of the TRIPS Agreement on geographical indications. Summary of the responses to the checklist of questions (IP/C/13 and Add.1)'.

by all traders in a particular geographic location to goods which emanate from that location. A trademark is a sign that distinguishes the products of a specific trader from those of its competitors. Thus it is not likely to be descriptive and it cannot be generic.

The right to protect a GI 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, GIs are monitored and protected by producer associations from the relevant region.

Unlike trademarks, GIs are not freely transferable from one owner to another, as a user must have the appropriate association with the geographical region and must comply with the production practices of that region.

8.4 International Protection of GIs

Paris Convention for the Protection of Industrial Property, 1883

The first multilateral agreement, which included 'indications of source or appellations of origin' as objects for protection by national industrial property laws, was the Paris Convention. Under Art. 10(1) of the Paris Convention, provision is made for seizure upon importation of goods bearing false indications of the source of goods or the identity of the producer.

Under Art. 10(2), any

> … producer, manufacturer, or merchant whether a natural person or legal entity, engaged in the production or manufacture of or trade in such goods and established either in the locality falsely indicated as the source, or in the region where such locality is situated, or in the country falsely indicated, or in the country where the false indication of source is used, shall in any case be deemed an interested party.

Article 10*bis* also afforded protection against false or misleading indications of source as a means of repressing unfair competition.

Included under the definition of unfair competition are any acts which create confusion, or allegations, the use of which in the course of trade are liable to mislead the public, as to the nature, the manufacturing process, the characteristics, the suitability for their purpose, or the quantity, of goods.

Madrid Agreement for the Repression of False or Deceptive Indications of Source of Goods, 1891[28]

The original form of Paris Convention prohibited the use of false GIs. A number of signatory nations proposed a more comprehensive form of regulation for what was considered to be a significant IP abuse. The 1891 Madrid Agreement concerning the protection of GIs was their response. Article 1 provided that all goods 'bearing a false

[28] The Madrid Agreement was adopted in 1891 and revised at Washington (1911), The Hague (1925), London (1934), and Lisbon (1958). It was supplemented by the Additional Act of Stockholm (1967).

or misleading indication' to signatory country, or to a place in that country 'shall be seized on importation'. However, this agreement failed to attract the accession of significant trading nations such as the USA, Germany and Italy. A threshold problem with this agreement, and with subsequent revisions, was the inability of nations to exempt GIs that had become generic within their borders.

International Convention on the Use of Appellations of Origin and Denominations of Cheeses (Stresa Convention), 1951

The parties to the Stresa Convention, which are some of the cheese producing countries of Europe,[29] 'pledge themselves to prohibit and repress within their respective territorial confines the use, in the language of the state or in a foreign language, of the "appellations d'origine", denominations and designations of cheeses contrary to the principles stated in Arts 2 to 9 inclusive'. The Convention, which entered into force on 1 September 1953, applies to all specifications that constitute false information as to the origin, variety, nature or specific qualities of cheeses, which are stated on products that might be confused with cheese. The term 'cheese', according to Art. 2.1 of the Convention, is reserved for 'fresh and matured products obtained by draining after the coagulation of milk, cream, skimmed or partially skimmed milk or a combination of these', or by 'products obtained by the partial concentration of whey, or of buttermilk, but excluding the addition of any fatty matter to milk'.

Article 3 provides that the appellations of origin of those cheeses 'manufactured or matured in traditional regions, by virtue of local, loyal and uninterrupted usages', which are listed in Annex A are exclusively reserved to those cheeses, 'whether they are used alone or accompanied by a qualifying or even corrective term such as "type", "kind", "imitation" or other term'. Annex A lists: Gorgonzola, Parmigiana Romano, Pecorino Romano and Roquefort.

Annex B lists a number of designations for cheese, which are prohibited by article 4.2 for products that do not meet the requirements provided by contracting parties in relation to 'shape, weight, size, type and colour of the rind and curd, as well as the fat content of the cheese'. Listed in Annex B are Asiago, Camembert, Cambozola, Danablu, Edam, Emmental, Esrom, Fiore Sardo, Fontina, Gruyére, Pinnzgauer Berkäse, Samsöe and Svecia.

The Stresa Convention came into force prior to the EEC Treaty and its regime providing for the free movement of goods. In the *Deserbais* case,[30] the ECJ held that the EEC Treaty did not affect the duty of a Member State to respect the rights of non-member countries under the prior agreement. Similarly, in the *Cambozola* case,[31] the ECJ ruled that the free movement of goods principle was subordinated to the Stresa Convention and Council Regulation (EEC) No 2081/92 permitting the registration and enforcement of rights in relation to designations of origin.

[29] The Stresa Convention was ratified by Austria (12 June, 1953); Denmark (2 August 1953); France (20 May 1952); the Netherlands (29 October 1955); Norway (31 August 1951); Sweden (27 January 1951) and Switzerland (5 June 1951).

[30] [1988] ECR-4907, 22 September 1988.

[31] [1999] ECR 1, 4 March 1999.

Lisbon Agreement for the Protection of Appellations of Origin and their Registration, 1958[32]

The Lisbon Agreement established an international system of registration and protection of appellations of origin. It adopted the French definition of appellation of origin by restricting the protected indications to cases in which the quality and characteristics of a product are 'due exclusively or essentially to the geographical environment, including natural and human factors'.

The Agreement provided for the registration, at the International Bureau of WIPO, of appellations of origin which are 'recognized and protected as such, in their country of origin'. Countries are thus free to adopt their own system of designating appellations, either by judicial or administrative decision, or both. Once registered, a GI is protected in other member nations. The countries have to ensure that any kind of usurpation or imitation is prohibited under their laws. Finally, the Agreement provides that no genetic indication can be deemed generic in any other country, as long as it is protected in its country of origin.

The Lisbon Agreement failed to attract support from more than a few nations. One problem was that accession was confined to those nations that protected appellations of origin 'as such'. Thus, states which protected this form of IP under unfair competition or consumer protection laws were locked out. Also the Agreement did not make exception for GIs which had already become generic in member states.

WIPO proposals

In 1975, WIPO issued a Draft Treaty on the Protection of Geographical Indications. The Draft Treaty provided for the protection both of appellations of origin and GIs. Unlike the Lisbon Agreement, it did not require signatories to have domestic laws for the protection of appellations of origin. In 1990, WIPO issued a memorandum asserting the continuing need for a treaty on this subject.[33]

In 1975, WIPO also issued a Model Law on GIs for adoption by developing countries. The Model Law defined 'appellation of origin' as

> The geographical name of a country, region, or specific place which serves to designate a product originating therein, the characteristic qualities of which are due exclusively or essentially to the geographical environment, including natural factors, human factors, or both … any name which is not that of a country, region or specific place is also considered a geographical name if it relates to a specific geographical area, when used in connection with certain products.

The Model Law also defined 'indication of source' as 'any expression or sign used to indicate that a product or service originates in a country or region or a specific place'. This would embrace symbols such as an Egyptian pyramid or the Eiffel Tower, as well as the birds and animals associated with a place.

[32] This agreement was concluded in Lisbon on 31 October 1958. It was revised in Stockholm in 1967 and amended in 1979.

[33] WIPO (1990) The Need for a New Treaty and its Possible Contents. WIPO doc., GEO/CE/1/2.

The Model Law establishes a system for the registration of appellations of origin and includes an optional provision permitting national courts to determine whether particular terms are generic. Upon registration, appellations are only protected if used by producers of products carrying on business in the area described by the appellation and only if their products possess the essential characteristics associated with the appellation.

Finally, the Model Law provided that:

> It shall be unlawful to use, in the course of trade, a registered appellation of origin, or a similar name, with respect to the products specified in the Register or similar products, even if the true origin of the products is indicated, or if the appellation is in the form of a translation or is accompanied by terms such as 'kind', 'type', 'make', imitation', or the like.

The memorandum issued by WIPO in 1990, asserting the continuing need for a treaty on this subject, has not been taken up by the WIPO Committee of Experts on the International Protection of Geographical Indications.

TRIPS Agreement

Section 3 of the TRIPS Agreement covers six topics: (i) definition and scope of a GI; (ii) minimum standards and common protection provided for GIs corresponding to all kinds of products; (iii) the interrelationship between trademarks and indications of origin; (iv) additional protection for GIs for wines and spirits; (v) negotiation and review of section III on GIs; and (vi) exceptions to the protection of GIs.

Article 22 defines GIs 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.

This definition expands the Lisbon Agreement concept of appellation of origin to protect goods that merely derive a reputation from their place of origin without possessing a given quality or other characteristics due to that place. Also, under the TRIPS Agreement, a GI to be protected has to be an indication, but not necessarily the name of a geographical place on earth. Thus, for example, 'Basmati' is taken to be an indication for rice coming from the Indian sub-continent, although it is not a place name as such. The indication has to identify goods as originating in the territory of a Member, a region or a locality of that territory. This definition also indicates that goods to be protected should originate in the territory, region or locality to which it is associated. This suggests that licences for the use of GIs cannot be protected under the TRIPS Agreement.

The TRIPS definition permits Members to protect GIs of goods where the quality, reputation or other characteristic of goods are attributable to their 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'. Thus, for example, the use of symbols such as the Eiffel Tower or the Statue of Liberty to infer an association with France or the USA, or the use of a language or script to evoke an erroneous connotation of origin would fall within this prohibition.

The TRIPS Agreement does not specify the legal means to protect GIs. This is left for Members to decide.

Article 22.2 also prohibits any use that 'constitutes an act of unfair competition' under Art. 10*bis* of the Paris Convention. The ambit of Art. 10*bis* is extended to a GI '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, to 'refuse or invalidate the registration of a trademark which contains or consists of a GI 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'.

Cognizant of the fact that for most countries the protection of GIs will be an innovation, Art. 24.4 exempts from this form of protection trademarks that have been 'applied for or registered in good faith' or where the rights to the trademark 'have been acquired through use in good faith' either before the implementation of the TRIPS provisions, or before the GI is protected in its country of origin.

Article 24.7 provides that a Member may provide that any request made under the section in connection with the use or registration of a trademark must be presented within 5 years after the adverse use of the protected indication has become generally known in that Member, or after the date of registration of that trademark, provided the registration has been published and 'provided that the geographical indication is not used or registered in bad faith'.

Similarly to the analogous provision in most trademark laws, Art. 24.7 preserves 'the right of a person to use, in the course of trade, that person's name or the name of that person's predecessor in business, except where such name is used in such a manner as to mislead the public'.

Finally, Art. 24.9 provides that there is no obligation under the TRIPS Agreement to protect GIs 'which are not or cease to be protected in their country of origin, or which have fallen into disuse in that country'.

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

These provisions give GIs for wines and spirits stronger protection than that provided in Art. 22 for all products. For some countries, this additional protection is regarded as an unacceptable discrimination against all other products and they have agitated for an extension of that protection to all kinds of GIs.

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 GIs, 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 constitutes to be a very legalistic approach. They believe that this provision permits negotiations to extend the additional protection for GIs for wines and spirits to all kinds of products.

In order to facilitate the protection of GIs 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 GIs which has been under preparation since 1974.

GI disputes under the TRIPS Agreement

A number of WTO Members argued that the EU scheme for the protection of GIs was TRIPS-deficient in a number of areas. For example, the statement of the USA to the WTO on the WTO trade policy review of the EU expressed the concern that 'foreign persons wishing to obtain protection for their GIs in the EU itself face a non-transparent process that appears to come into some conflict with the EU's TRIPS obligations' and that 'EU rulemaking processes are often perceived by third countries as exclusionary, allowing no meaningful opportunity for non-EU parties to influence the outcome of regulatory decisions'.[34] On 1 June 1999, the USA requested consultations with the EC pursuant to Art. 4 of the *Understanding on Rules and Procedures Governing the Settlement of Disputes* (DSU) and Art. 64 of the TRIPS Agreement regarding EC Council Regulation (EEC) No. 2081/92 of 14 July 1992 on the protection of GIs and designations of origin for agricultural products and foodstuffs.[35] The USA and the EC held consultations on 9 July 1999, and thereafter, but these and following consultations failed to resolve the dispute.

In view of the global markets at stake in the agricultural and food processing sectors, the USA and Australia became so concerned at the systematic discrimination its trademark owners faced in enforcing their rights against European registered GIs that it invoked the WTO dispute settlement procedure.[36] On the 18 August 2003, the

[34] WTO Trade Policy Review of the European Union, Statement by the United States to the WTO, 24 July 2002, http://www.state.gov/e/eb/rls/rm/2002/12242.htm

[35] *European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, WT/DS174/1.

[36] In 2002, the USA had expressed the concern that 'foreign persons wishing to obtain protection for their GIs in the EU itself face a non-transparent process that appears to come into some conflict with

USA and Australia requested the establishment of a WTO dispute settlement panel to review the consistency of the EU Regulation 2081/92 with the rules of the TRIPS and GATT Agreements.[37] The USA and Australia argued that the EU scheme for the protection of GIs failed to comply with TRIPS in three chief respects.

Firstly, they claimed the EC Regulation was discriminatory and in violation of the national treatment obligations and the MFN obligations in Arts 3 and 4 of the TRIPS Agreement and Arts I and III of the General Agreement on Tariffs and Trade 1994. The TRIPS Agreement requires that Members accord MFN treatment to the GIs of fellow Member States and national treatment to the GIs of their citizens. The USA and Australia argued that Regulation 2081/92 does not provide the same treatment to other nationals and products originating outside the EC that it provides to the EC's own nationals and products, does not accord immediately and unconditionally to the nationals and products of each WTO Member any advantage, favour, privilege or immunity granted to the nationals and products of other WTO Members, diminishes the legal protection for trademarks, does not provide legal means for interested parties to prevent the misleading use of a GI, does not define a GI in a manner that is consistent with the definition provided in the TRIPS Agreement, is not sufficiently transparent, and does not provide adequate enforcement procedures.

As a result of the alleged violation, when US holders of GIs such as Florida Oranges and Idaho Potatoes sought registration under the EC Regulation, they were subject to a requirement of reciprocity and equivalence. Although expressed to be 'without prejudice to international agreements' Art. 12 states that the Regulation 'may apply to an agricultural product or foodstuff from a third country provided that:

> (a) the third country is able to give guarantees identical or equivalent to those referred to in Art. 4,
>
> (b) the third country concerned has inspection arrangements and a right to objection equivalent to those laid down in this Regulation,
>
> (c) the third country concerned is prepared to provide protection equivalent to that available in the Community to corresponding agricultural products for foodstuffs coming from the Community.

Secondly, they claimed that the grant of exclusive rights in the use of the mark provided by virtue of TRIPS Art. 16.1 require Member States to make available to earlier trademark owners rights against GIs. The USA argued that the Regulation was inconsistent with the exclusivity of the trademark owners' rights under Art. 16.1 of the TRIPS Agreement because it does not ensure that a trademark owner may prevent uses of GIs which would result in a likelihood of confusion with a valid prior trademark.[38]

the EU's TRIPS obligations' and that 'EU rulemaking processes are often perceived by third countries as exclusionary, allowing no meaningful opportunity for non-EU parties to influence the outcome of regulatory decisions'. WTO Trade Policy Review of the European Union, Statement by the United States to the WTO, 24 July 2002, http://www.state.gov/e/eb/rls/rm/2002/12242.htm.

[37] See documents WT/DS174/20 and WT/DS290/18.

[38] See variously, United States' first written submission, paras. 137–140, 170; United States' first oral statement, paras. 42–43.

Thirdly, they argued that Regulation 2081/92 was inconsistent with the EC's obligations under Art. 24.5 of the TRIPS Agreement, since the Regulation failed to provide sufficient protection to pre-existing trademarks that were similar or identical to a GI.

Food exporters in the USA were concerned that GIs should not be given precedence over trademark rights. The issue was one of priority between a coexisting GI and a trademark and whether the principle of first-in-time, first-in-right should be enforced as it is in the trademark law of the USA. In contrast, in the EU trademarks are required to coexist with GIs. Under European law a trademark owner's rights cannot prevail over a third party using a duly registered GI in accordance with honest business practices.[39] As a result, private trademark suits brought by US litigants against European-owned GIs might well result in the US trademark owner having to forfeit valuable rights to priority and exclusivity. Thus, trademark wars over the competitive European market for beer had seen US trademarks 'Budweiser' and 'Bud,' subject to termination in various Member States of the EC because the European law holds 'Budweiser' and 'Bud' to be GIs for beer from the Czech Republic.[40] The cancellation of the Budweiser and Bud trademarks for beer in Europe caused unease among US trademark owners. The obstacles to registering US certification marks as GIs in Europe gave rise to further uncertainty about the security of protection and conditions of competition.

The USA and Australia claimed that the EU Regulations imposed two requirements that contravened the national treatment principle contained in Art. 2(2) of the Paris Convention as incorporated by Art. 2.1 of the TRIPS Agreement: (i) the requirement that enterprises seeking to register GIs possessed a commercial establishment in the EU; and (ii) the requirement that GIs located in the territory of a WTO Member outside the EU could only be registered if that Member had adopted a system for GI protection that was equivalent to that in the EC and provided reciprocal protection to products from the EC.

The Panel Report in the dispute was adopted at a meeting of the Dispute Settlement Body on 20 April 2005.[41] Concerning the discriminatory conditions regarding the registration of foreign GIs and requirement for reciprocity of protection, the Panel decided in favour of the USA and Australia. Pursuant to Art. 19.1 of the DSU, the Panel recommended that:

> (a) The European Communities bring the Regulation into conformity with the TRIPS Agreement and GATT 1994.
>
> (b) The European Communities could implement the above recommendation with respect to the equivalence and reciprocity conditions, by amending the Regulation so as

[39] *Gerolsteiner Brunnen GmbH & Co. v Putsch GmbH* (Case C-100/02).

[40] The battle over the right to the name 'Budweiser' has pitted the world's largest brewer, Anheuser-Busch of the USA, against the 'boutique' Czech brewer Budejovicky Budvar. The latter, based in the Czech town of Ceske Budejovice (also known as Budweis), claims it has been brewing a beer under the name since the 13th century, although the American beer has gained broader international reputation in recent years. See WTO (1999) Preparations for the 1999 ministerial conference – Agreement on TRIPS: Extension of the additional protection for geographical indications to other products. Communication from the Czech Republic. WT/GC/W/206.

[41] WT/DS290/R.

for those conditions not to apply to the procedures for registration of GIs located in other WTO Members.

In an affirmation of the GI as IP, the Panel endorsed the European principle of their coexistence with all but the most famous of prior trademarks. The Panel found that Art. 14(2) of the Regulation was a 'limited exception' permitted by Art. 17 of TRIPS because it only allows use by those producers who are established in the geographical area on products that comply with the specification.

On the critical issue of whether the nationals of other WTO Members were accorded less favourable treatment than the EC's own nationals, the Panel ruled that the conditions in the Regulations modified the effective equality of opportunities to obtain protection with respect to IP in two ways. Firstly, GI protection was not available in respect of geographical areas located in third countries which the Commission had not recognized. It was confirmed that the European Commission had not recognized any third countries. Second, GI protection under the Regulation could become available if the third country in which the GI is located entered into an international agreement with the EU. For the Panel, both of those requirements represented a significant 'extra hurdle' in obtaining GI protection which did not apply to geographical areas located in the EC. The significance of the hurdle was taken to be reflected in the fact that currently no third country had entered into such an agreement or satisfied those conditions.[42] Accordingly, the Panel found that the equivalence and reciprocity conditions modified the effective equality of opportunities with respect to the availability of protection to persons wishing to obtain GI protection under the EU legislation, to the detriment of those wishing to obtain protection in respect of geographical areas located in third countries, including WTO Members. This was held to be less favourable treatment.[43]

The Panel noted that whilst the Regulation did not prevent a foreign national from producing goods within the territory of the EC, the different procedures that applied to foreign nationals compared with those of the EU were perceived as disadvantageous to the nationals of other Members.

Review of the TRIPS Agreement

The Council of TRIPS was obliged under Art. 24.2 to conduct a review of the operation of the GIs provisions within the first 2 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. Prior to the Seattle Ministerial, a submission by Turkey of 9 July 1999 proposed the extension of the multilateral register beyond wines and spirits;[44] this was endorsed as the African group of countries requested that the protection of GIs be extended 'to other products

[42] See e.g. European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products And Foodstuffs – complaint by the USA, WTO Doc WT/DS174/R, 15 March 2005, para 7.139.

[43] Ibid., at para 7.141.

[44] WTO Doc No WT/GC/W/249, 13 July 1999.

recognizable by their geographical origins (handicrafts, agro-food products)'.[45] This proposal was also taken up by Cuba, Czech Republic, Dominican Republic, Honduras, India, Indonesia, Nicaragua, Pakistan, Sri Lanka, Uganda and Venezuela. At the TRIPS Council meetings in 2000, the President sought to separate the discussion of Art. 23.2 from 24.2 to avoid confusion. A response to this suggestion was a proposal from Bulgaria, the Czech Republic, Egypt, Iceland, India, Kenya, Liechtenstein, Pakistan, Slovenia, Sri Lanka, Switzerland and Turkey that the extension of GIs to products other than wines and spirits be included as an extension of the built-in agenda.[46] This issue has also been 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 register for wines and spirits, as well as the extension of GI protection beyond wines and spirits. The principal protagonists in negotiations are the EC, which favours an expanded international regime, and the USA, which argues that the current TRIPS and trademark protections are sufficient.

In opposition to the proposals for an extension of the protection of GIs for wines and spirits under TRIPS to all products, on 29 June 2001, a communication was sent to the TRIPS Council by Argentina, Australia, Canada, Chile, Guatemala, New Zealand, Paraguay and the USA.[47] The Communication pointed out that proposals for the extension of the TRIPS wines and spirits provisions to all products had insufficiently addressed the costs and administrative burdens of this extension. However, Clause 18 of the Doha Declaration has expressly opened the possibility of the extension of the additional protection, through a multilateral system of registration, to products other than wines and spirits and countries are currently exploring the cost impacts and other practicalities of the extension.

In June 2005, the EC submitted a proposal to amend the TRIPS Agreement to provide global protection for GIs in a multilateral system of registration.[48] This proposal seeks to bring international protection for GIs into conformity with the EU where a Community-wide system for their registration is considered an indispensable part of agricultural policy, serving both to preserve the incomes of small to medium-size producers and to guarantee the sustainability of the rural economy. Given the fact that it possesses over 700 registered GIs,[49] sophisticated institutional infrastructure

[45] *Preparations for the 1999 Ministerial Conference the TRIPS Agreement Communication from Kenya on Behalf of the African Group.* WTO Doc WT/GC/W/302, 6 August 1999.

[46] WTO Doc. IP/C/W/204/Rev.1.

[47] WTO Doc. IP/C/W/289.

[48] The EC proposed amending Section 3 of the TRIPS Agreement with a view to extending the regime of protection today available for GIs on wines and spirits to GIs on all products ('extension'); and in addition a proposal for the inclusion of an annex to the TRIPS Agreement establishing a multilateral system of notification and registration of GIs. World Trade Organization, General Council, Trade Negotiations Committee, Council for Trade-Related Aspects of Intellectual Property Rights, Special Session on Geographical Indications, Communication from the European Communities 14 June 2005, WT/GC/W/547, TN/C/W/26, TN/IP/W/11. See earlier submissions of the EC, 22 June 2000, IP/C/W/107/Rev.1 with respect to the register; and submission of 2002 in respect of the extension, IP/C/W/353, 24 June 2002.

[49] 'Since 1993, more than 700 names, designating inter alia over 150 cheeses, 160 meat and meat-based products, 150 fresh or processed fruits or vegetables and 80 types of olive oil, have

and technical prowess, the EU in Europe is exceptionally well placed to leverage the benefits of an expanded international system of GI protection. On the other hand, the USA and its supporters largely endorse the *status quo* favouring voluntary multilateral registration and the choice of the means of protection – whether by special system or the established trademark system – left to national discretion.

The EC submission set out provisions for a centralized register that would be compulsory and have legal effect.[50] The EC proposal aimed at preserving each WTO Member's prerogative to determine whether a certain sign, indication or geographical name does indeed meet the TRIPS definition of a GI. [51]

Opponents of the EC proposal – the USA, Argentina, Australia, Canada, Chile, Ecuador, El Salvador and New Zealand – opposed the extension of GIs protection, taking the position that the international protection of GIs is adequate as it stands and that such a drastic development would only serve to undermine future gains in market access for non-European food and agricultural products.[52] Concern has also been expressed about the additional costs and administrative burdens of implementing a distinct system of GI protection in addition to the TRIPS obligations. They advocated a system of voluntary notification and registration with no obligation to protect registered GIs.

The opposition between the USA and EU demonstrates that in relation to GIs at least there is not a simple North–South divide between the old industrialized and the developing worlds. Newly industrializing and leading developing countries such as India, China and Kenya are well placed to take advantage of IP protection afforded agricultural GIs. Other developing countries, however, may lack either the agricultural tradition related to place or the financial means to enforce the worldwide protection of their GIs.

It should be acknowledged that some academic commentators regard 'the assertions on the part of the EU and other nations with vested interests in a worldwide regime of vigorous GI protections – such as Switzerland – that such a scheme would aid developing countries in expanding their economies by ensuring the maintenance of knowledge bases related to the growth and manufacture of traditional indigenous products are unfounded and inherently flawed'.[53] By this they mean that mere registration of a GI will not create a premium price; investment is required in

been registered in this context. The Commission has also received over 300 further applications for the registration of names and/or amendments to specifications from Member States and third countries'. Proposal for a Council Regulation on the Protection of Geographical Indications and designations of origin for agricultural products and foodstuffs, Commission of the European Communities, Brussels, 5.1.2006, para.3.

50 Communication from the European Communities. The communication, dated, is being circulated to the General Council, to the TNC and to the Special Session of the Council for TRIPS at the request of the Delegation of the European Commission. (TN/IP/W/11) of 13 June 2005. This new proposal maintains the level of ambition of the EC as regards both 'extension' and the multilateral register of GIs, as contained in its earlier proposals in documents IP/C/W/107/Rev.1 (on the GI register) and IP/C/W/353 (on 'extension').

51 Paragraph 3.2(a).

52 See Communication from Argentina, Australia, Canada, Chile, Ecuador, El Salvador, New Zealand and the USA, TN/IP/W/9, 13 April 2004.

53 A. Kur and S. Cocks (2007) Nothing but a GI thing: geographical indications under EU law. *Fordham Intellectual Property Media & Entertainment Law Journal* 17, 999 at 1011, citing J. Hughes (2006) Champagne, Feta, and Bourbon: the spirited debate about geographical indications. *Hastings Law Journal* 58, 299 at 369–373.

advertising and promotion. The advantage of the GI system in this regard is that it provides a mechanism for the aggregation of promotional expenditure on the part of agricultural producers and in developing countries can be supported by the national agricultural marketing authorities.

8.5 National Systems for the Protection of GIs

As was mentioned above, the TRIPS Agreement leaves to WTO Members some discretion in how to implement their GIs obligations. National approaches have been divided between *sui generis* legislation and a modification of existing trademark laws. Additionally regional agreements, such as the North American Free Trade Agreement and the Cotonou Accord,[54] as well as bilateral trade agreements,[55] impose GIs obligations on parties. In general terms, two approaches are taken to the protection of GIs. *Sui generis* laws have been promulgated by the EU, France and India. The majority of countries have protected GIs through trademark laws. Both types of laws are considered below.

Sui generis laws

Europe

The protection of GIs across the European Economic Area became an early feature of the European Commission's agricultural policy. The formation of the EC enabled the Commission to make the international protection for GIs an integral part of the Common Market's rural policy. The aim of Council Regulation 2081/92 on the protection of GIs and designations for agricultural products and foodstuffs noted in its seventh recital that:

> … there is diversity in the national practices for implementing registered designations of origin and geographical indications … a Community approach should be envisaged … a framework of Community rules on protection will permit the development of geographical indications and designations of origin since, by providing a more uniform approach, such a framework will ensure fair competition between the producers of products bearing such indications and enhance the credibility of the products in the consumers' eyes.

It has been suggested that despite the strong position taken by the EU on GI protection there is variation among the individual EU Member States concerning their enthusiasm for this system of IP protection.[56] France, Italy and Spain are identified as the nations that were instrumental in establishing the EU's current GI regulatory scheme.[57] To their numbers in supporting vigorous GI protection have been added the Eastern European nations which have recently joined the EU as Member States. It has been suggested that the Northern European nations 'with

[54] Agreement between the EU and countries of Africa, the Pacific and the Caribbean.
[55] E.g. EU–South Africa Agreement (1999) and the various FTAs made by the USA.
[56] A. Kur and S. Cocks, n.53 supra, at 1006.
[57] J. Hughes, ibid., at 318.

weaker agricultural heritage such as Germany' have remained 'disinterested with, and even wary of, strong GI protection'.[58] Whether or not this distinction can be drawn, it emphasizes from a food security perspective, the role which GIs protection might play in agricultural policy.

The first national legislation on GIs was the French Law of 6 May 1919 concerning *Appellations d'Origine*.[59] This law defined the characteristics with which wines and spirits had to comply for the application of an appellation and provided for the delimitation of regions to which appellations attached. The Law of 30 July 1935 provided for a generalized system of *Appellations d'Origine Contrôlée* (AOC) under the supervision of a committee, which from 1947 became the Institut National des Appellations d'Origine (INAO). Until 1990, the INAO was responsible only for wines and spirits, but following European legislation concerned with the protection of GIs and designations for agricultural products and foodstuffs, the jurisdiction of the INAO was extended to these items.

Under the French legislation, the registration of an appellation is initiated by a local syndicate. This is examined by the INAO which consults with the relevant regional committee and then the national committee concerned with the products in question. Following the receipt of experts' reports the committee will then decide on whether to approve the application. A delineation committee will determine the definition of the terroirs (soils) within the proposed AOC. This will be incorporated within a draft decree, which is submitted to the Minister for Agriculture for promulgation. The supervision of the decree is undertaken by the INAO.

Inspired by the French legislation, the EC promulgated a series of regulations binding on all member nations of the EU dealing with designations for wines[60] and spirits,[61] foodstuffs and agricultural products[62] and mineral waters.[63] Some modification to these regulations occurred as a result of the WTO Dispute Panel determination on GIs.

The European regime provides for the protection of 'designations of origin' or 'geographical indications' and that have not become generic. To qualify as a PDO or PGI, a product must comply with specifications for describing the 'principal physical, chemical, microbiological or organoleptic characteristics' of the product, and also describe the geographic area from which it originates that gives rise to the product's unique qualities.[64] In the case of a product originating from an EU Member State, a party seeking to register a GI must file an application for registration with the relevant authorities in the Member State. In the case of a product originating from a country

[58] Kur and Cocks, n.53 supra at 1006, citing Ibid., at 344.

[59] See N. Olszak (2001) *Droit des Applellations d'Origine et Indications de Provenance*. Éditions TEC & DOC, Paris.

[60] Commission Regulation 753/2002, arts. 28–33, 2002 O.J. (L 118) 1, 14–18 (EC); Council Regulation 1493/1999, On the Organisation of the Market in Wine, arts. 50–53, 1999 O.J. (L 179) 1, 27–29 (EC).

[61] Council Regulation 1576/89, Laying Down General Rules on the Definition, Description, and Presentation of Spirit Drinks, 1989 O.J. (L 160) 1 (EC).

[62] Council Regulation 2081/92, On the Protection of Geographical Indications and Designations of Origin for Agricultural Products and Foodstuffs, 1992 O.J. (L 208) 1 (EC), *superseded* by Council Regulation 10/2006, On the Protection of Geographical Indications and Designations of Origin for Agricultural Products and Foodstuffs, 2006 O.J. (L 93) 12 (EC).

[63] Council Directive 80/777, 1980 O.J. (L 229) 1 (EC), *amended* by Council Directive 96/70, 1996 O.J. (L 299) 26 (EC).

[64] Council Regulation 510/2006, art. 4, 2006 O.J. (L 93) at 15.

that is not a member of the EU, a party seeking GI registration must file an application with the EU Commission, either directly or through the relevant authorities in the applicant's country. In the case of applications originating in EU Member States, the competent authorities in the appropriate member state conduct an initial examination of the application, following a second assessment by the European Commission. Where a product originates from outside the EU, the European Commission is the examining authority.

Following these assessments, the PDO or PGI application together with the specifications are published in the *Official Journal of the European Union*. For a period of 6 months following the date of publication persons with a legitimate interest may object to the application. Following successful registration, the regulation permits producers in the geographical region identified in the specification to identify their products as 'PDO' or 'PGI'.

Registration prohibits any exploitation of the registered indication, by persons or enterprises from outside the area. Prohibited is:

> (a) any direct or indirect commercial use of a name registered in respect of products not covered by the registration in so far as those products are comparable to the products registered under that name or insofar as using the name exploits the reputation of the protected name;
>
> (b) any misuse, imitation or evocation, even if the true origin of the product is indicated or if the protected name is translated or accompanied by an expression such as style, type, method, as produced in, imitation or similar;
>
> (c) any other false or misleading indication as to the provenance, origin, nature or essential qualities of the product, on the inner or outer packaging, advertising material or documents relating to the product concerned, and the packing of the product in a container liable to convey a false impression as to its origin;
>
> (d) any other practice liable to mislead the public as to the true origin of the product.

This prohibits not only food products from outside the region from using the geographical name, but also denies use of the name to products within the region that do not meet the standards set forth in the application. Furthermore, the prohibition as to 'any misuse, imitation or evocation, even if the true origin of the product', prevents the use of PDOs and PGIs in conjunction with qualifiers such as 'style' or 'method'. EU Member States may allow continued use of these qualifiers for a transitional period of 5 years, if the products had previously been marketed in such a manner for at least 5 years and the true origin of the product is clearly labelled.[65] However, this exception may not lead to the marketing of products freely on the territory of a Member State where such expressions are prohibited.

Perhaps most significantly, the Regulation prevents any protected name from becoming generic. Although a designation may be altered, or even lost, as a result of changes in technology or processing techniques, it cannot be lost as a result of changes in understanding or usage of the protected name.[66] Because of the general unfamiliarity of agricultural communities in developing countries with the concept of GIs, many of the products they produce will have become generic. This was arguably

[65] Art. 13(4).
[66] Art. 13(3).

the case in Europe, for example with the name Feta for cheese. Greece had sought the registration of 'Feta' as a PDO for 'salted white cheese traditionally produced in Greece, from sheep's milk or a mixture of sheep's milk and goats' milk coming exclusively from the regions of Macedonia, Thrace, Epirus, Thessaly, Central Greece, Peloponnese and Lesbos'. Although a majority of the Member States had asked the Commission to include the name 'Feta' on the list of generic names which it was preparing, the Commission had taken the view that 'Feta' was not disqualified from registration on this ground. It had relied on a market survey conducted in Greece, which concluded that Feta was recognized as a GI in that country. The ECJ ruled that it was not permissible for the Commission to minimize the importance to be attached to the situation existing in the Member States other than the State of origin and that account must be taken of the existence of products which are legally on the market and have therefore been legally marketed under that name in Member States other than the State of origin by which registration is applied for. Thus as the Commission did not take due account of all the factors which the Art. 3(1) of the basic regulation required it to take into consideration, the ECJ ruled that the contested regulation had to be annulled to the extent to which it registered the name 'Feta' as a PDO.

Under European law, food processing and packaging are considered to be part of a PDO and an infringement will occur if these activities are conducted outside the registered area. For example the grating and packaging of 'Grana Padano', in France, rather than the registered Italian agricultural region was an infringement,[67] as was the sale by Asda Stores Ltd, which operated a chain of supermarkets in the UK, of ham bearing the description 'Parma ham', purchased pre-sliced from a corporation outside the Parma region, on the ground that they were contrary to the rules applicable to the registered PDO 'Prosciutto di Parma'.[68]

As a matter of general practice, infringement actions in relation to GIs concern either: (i) wrongful use of a PGI or a PDO, in which case an action will be brought by the entity responsible for preserving the integrity of the GI; or (ii) in relation to a misleading use of a GI.

Once the PDO or PGI has been awarded, production is monitored and assessed against the Regulation and the specifications by certifying bodies inspecting production or distribution plants, taking samples, inspecting business records or requesting information. Codes of Practice are usually formulated by producer associations to ensure specifications are complied with.

According to Regulation 510/2006, a prior PDO or PGI application takes priority over a trademark for a product of the same type or use where registration of the trademark could lead to confusion or exploitation of the name's reputation. Therefore the trademark application must be refused or invalidated. However, if a trademark has been applied for, registered or established by use in good faith within the EU before the designation of origin or GI is protected at national level or the application is submitted to the Commission, the mark can continue to be used. A GI cannot be registered if it would be likely to mislead the consumer where there is a pre-existing trademark of strong reputation and length of use of the trademark.

[67] Case C-469/00.
[68] Case C-108/01.

India

India protects GIs under the Geographical Indications of Goods (Registration and Protection) Act 1999, which introduces a registration system. An application for registration of a GI can be made by an association of persons or producers or any organization or authority, representing the interests of the producers of the concerned goods. GIs are defined in similar terms to the TRIPS Agreement. A producer of the goods in respect of which a GI has been registered may apply to the Registrar for registration as an authorized user of the GI. The Registrar will determine whether such person is a producer of relevant goods and register him as an authorized user.

The Indian GI system was introduced to protect Darjeeling tea, and the Tea Board of India has applied for the registration of the words 'Darjeeling' and 'Darjeeling logo' under the Act.[69] The Tea Board of India was established under the Tea Act 1963. It monitors cultivation, processing, promotion and sale of Darjeeling tea and certifies the origin of exports.

Thailand

Thailand enacted a *sui generis* GI law – the Act on Protection of Geographical Indications B.E. 2546 (2003) – on 28 April 2003. A GI is defined in s.3 (1) as 'name, symbol or any other thing which is used for calling or representing a geographical origin and can identify the goods originating from such geographical origin where the quality, reputation or other characteristic of the goods is attributable to the geographical origin'. The first GIs registered under the Thai law are: Pomelo from Nakorn Chaisri, Tamarind from Petchaboon and Hom Mali rice from Surin.

The Thai enactment of GI protection supplements its 'One Tambon,[70] One Product (OTOP)' programme. This programme seeks to promote locally made and marketed products for each Tambon. The standards of the products will be approved by the Thai Industrial Standards Institute to ensure that the quality of the community products would be widely accepted. Typically, OTOP products are fabrics and textile products, artistic creations, processed food, fruits and drinks, utensils, wickerwork and fermented spirits.[71]

Trinidad and Tobago

The Geographical Indications Act No. 20 of 1996, as amended by Act No. 18 of 2000 adopted by Trinidad and Tobago, is substantially based on the draft model law prepared by WIPO. It uses a TRIPS-style definition of GI; interested parties may prevent the use of indications in a manner which would mislead the public, or that

[69] S.C. Srivastava, *Protecting the Geographical Indication for Darjeeling Tea.* Managing the Challenges of WTO Participation, Case Study 16, http://www.wto.org/english/res_e/booksp_e/casestudies_ e/case16_e.htm.

[70] A Tambon is an administrative division in Thailand.

[71] P. Tanasanti, Geographical Indication protection and promotion in Thailand, www.wipo.int/edocs/mdocs/geoind/en/wipo_geo_bei_07/wipo_geo_bei_07_www_81772.doc.

would be contrary to honest business practices within the meaning of Art. 10*bis* of the Paris Convention.

Following registration, only producers carrying on their activity in the geographical area specified in the Register shall have the right to use a registered GI in the course of trade, with respect to the products specified in the Register, 'provided that such products possess the quality, reputation or other characteristic specified in the Register.'[72]

Trademark laws

UK

Protection against the wrongful appropriation of GIs is found in the English tort of passing-off. A recent authoritative definition of this term, by the House of Lords, occurred in a case where an English alcoholic drinks manufacturer was sought to be enjoined from using the name 'Advocaat' to describe his product, as this drink was typically associated with a traditional recipe of eggs and brandy, developed by Dutch manufacturers, and was accused of passing off.[73] The elements of the tort were identified by Lord Diplock as involving a misrepresentation made by a trader in the course of trade to prospective or ultimate consumers of goods or services supplied by him that is calculated to injure the business or goodwill of another trader, which causes actual or probable damage to the plaintiff.

The principal development of passing-off law in relation to GIs occurred with the Spanish Champagne case,[74] which formed the basis of protection for Champagne not only in England but also other common law jurisdictions. The question the court had to consider in that case was whether use of the term 'Spanish Champagne' could be used in relation to a sparkling wine not produced in the French Champagne District. The suit was instituted by one of the French Champagne houses on behalf of themselves and all other persons who produce wine in the Champagne District and supply such wine to England and Wales. The plaintiffs alleged that wine produced by the Champagne houses and supplied by them to England and Wales was a naturally sparkling wine produced in the Champagne District by a process of double fermentation from the grapes grown in the Champagne District and that it was long known to the trade and public throughout the UK as Champagne and has as such acquired a high reputation. They alleged that any member of the trade or public in the UK ordering Champagne or seeing wine advertised or offered for sale as Champagne, would expect the wine so ordered, advertised or offered for sale, to be a naturally sparkling wine produced in the Champagne District from grapes grown in the Champagne District and no other.

The trial judge observed that:

> The region in which the Champagne vineyards are found is about 100 miles east of Paris around Rheims and Epernay, where there is a chalky, flinty soil and the climate is subject to extreme variations of heat and cold. It appears that these factors give to the wine its

[72] Geographical Indications Act No. 20 of 1996, Art. 11.
[73] *Erven Warnink B. V v J. Townend & Sons (Hull) Ltd* 1980 R.P.C. 31.
[74] *Bollinger (J) v Costa Brava Wine Company Ltd* (1959) 3 All ER 800.

> particular qualities. Since 1927 the Champagne Viticole District has been strictly limited by law, and only certain vineyards are allowed in France to use the name 'Champagne'. Wines produced from these vineyards are sold as 'Champagne', but goodwill has also become attached to the names of the shippers, or 'brand names' as they are called. The wine is a naturally sparkling wine made from the grapes produced in the Champagne District by a process of double fermentation which requires a considerable amount of care.

He ruled that it was established that 'Champagne' in England meant the product produced in the Champagne District of France by the plaintiffs and the other growers and shippers in that district.

This decision was followed by the 'Sherry case',[75] in which Spanish Sherry producers claimed exclusive rights in the mark 'Sherry', which they derived from the Jerez district of Spain. They sought to enjoin the use of the mark, 'British Sherry'. The court found that the term 'Sherry' was indeed a GI, but that the plaintiffs were disqualified from a remedy because they had acquiesced for a long time in the use in the English market of marks such as 'Australian Sherry' and 'South African Sherry'.

The Scotch Whisky case[76] was the third in the line of English cases on protecting GIs. The questionable practice was the export of Scotch whisky to Ecuador where it was to be resold under the labels 'White Abbey' and 'Scottish Archer' Scotch whisky after being admixed with local cane spirit. The evidence in the case disclosed that there were two basic types of Scotch whisky: that made from malted barley only, and grain whisky which is made from malted barley together with unmalted barley in varying proportions. These whiskies were produced by two different processes: the pot-still process for malt whisky and the patent or Coffey Still process for grain whisky. Almost all of the whisky sold to the public is blended whisky, where a number of malt whiskies are blended with a number of grain whiskies to produce the whisky sold to the public under brand names. The formula for each brand is secret. There was evidence that there were no blenders of Scotch outside of Scotland and England. The court held that producers of Scotch fell within the principle enunciated in the *Spanish Champagne* case and were entitled to have upheld the description of their product as 'Scotch whisky'.

Similar results were obtained by the Scotch Whisky manufacturers in passing off cases in South Africa, in *William Grant v Cape Wine & Distillers*.[77] The court held that a blend of Scotch Whisky with local spirit, together with advertising material showing a Scotsman in full Highland dress and carrying the slogan 'ten years in Scotland makes all the difference' was actionable. In *Long John International v Stellenbosch Wine Trust*,[78] the court enjoined the sale of a product called 'Ben Nevis Scotch Whisky Liquer' with a Scottish theme to the label. The drink actually consisted of whisky distilled with water and sweetened with sugar.

In *Taittinger v Allbev*,[79] the Court of Appeal was concerned with the use of the name 'Elderflower Champagne' for the use of a soft drink. Despite the unlikelihood of English consumers thinking that the Champagne houses of France were now involved

[75] *Vine Products Limited & Others v Mackenzie & Company Limited & Others* (1969) R.P.C. 1.
[76] *John Walker & Sons Ltd.v Henry Ost & Company Ltd* (1970) 2 All ER 106.
[77] (1990) 3 S.A.897.
[78] (1990) 3 S.A.897.
[79] [1994] 4 All ER 75 CA.

in the production of soft drinks, the Court took the view that the international significance of appellations of origin prevented their misuse, even in an apparently innocuous context.

USA

The USA protects GIs within the scope of its trademarks law. This is done mainly through certification marks established under the Lanham Trademark Act of 1949. A certification mark is a 'word, name, symbol or device' which conforms to specifications laid down by the owner. The specifications may concern place of origin and/or methods of production.

In addition, GIs can be protected under US law as collective marks. A collective trademark can be granted to the members of a 'collective' for use by its members. The following certification trademarks have been registered in the USA: 'Napa Valley Reserve' and 'Ohio river valley' for wines, 'Idaho' for potatoes and 'Vidalia' for onions, 'Real California Cheese' for cheese and 'Washington' for apples and 'Pride of New York' for various agricultural products.[80] The leading US case involving the enforcement of a GI as a certification mark is *Community of Roquefort v William Faehndrich, Inc.*[81] This case held that the designation 'Roquefort' was not a generic designation of blue cheese and that the owner of the certification mark was entitled to prevent the use of the mark on all cheeses not made in the French city of that name.

Despite the negotiating position the USA has taken in the WTO on GIs, similarly with the EU, the USA has incorporated GI protection in its bilateral free trade agreements (FTAs) seeking protection for 'Tennessee Whiskey' and 'Bourbon' and GI protection is also included in the NAFTA. In the latest FTAs, the GI sections provide for a dual GIs/trademarks system of protection, e.g. FTAs with Chile and Morocco.

People's Republic of China

The People's Republic of China (PRC) protects GIs under a law concerning Measures for the Registration and Administration of Collective Marks and Certification Marks. On 16 May 2005, Provisions for the Protection of Products of GI were promulgated by the General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ), which is responsible for the administration of GIs in China. Regulations for the administration of the law came into force on 1 February 2008.

On 31 August, China and the EU entered into an agreement for the reciprocal recognition of selected GIs. Ten Chinese products: Dongshan White Asparagus, Guanxi Honey Pomelo, Jinxiang Garlic, Lixian Yam, Longjing Tea, Longkou Vermicelli, Shaan'xi Apple, Zhenjiang Vinegar, Pinggu Big Peach and Yancheng Crayfish were agreed to be recognized in the EU. Ten EU products to be registered in China are: West Country farm cheddar, white Stilton cheese/blue Stilton cheese,

[80] L. Beresford (1999) The protection of Geographical Indications in the United States of America. Paper presented at Symposium on the International Protection of Geographical Indications. WIPO, Geneva.

[81] 303 F. 2d 494 (CA 2 1962).

Scottish farmed salmon, Prosciutto di Parma, Grana Padano, Pruneau d'Agen/ Pruneaux d'Agen mi-cuits, Roquefort, Comté, Sierra Mágina and Priego de Córdoba.

8.6 GIs and the Protection of TK

In the absence of an international regime to protect TK, existing categories of IP have been called in aid.[82] A more optimistic assessment of the potential for GIs to protect TK is made by Marion Panizzon and Thomas Cottier in their study: 'Traditional Knowledge and Geographical Indications: Foundations, Interests and Negotiating Positions'.[83] They observed that:

> Traditional Knowledge (TK) and Geographical Indications (GIs) share a common element insofar as they both protect accumulated knowledge typical to a specific locality. While TK expresses the local traditions of knowledge, GIs stand for specific geographical origin of a typical product or production method. GIs and TK relate a product (GIs), respectively a piece of information (TK), to a geographically confined people or a particular region or locality.

Similarly, in its Review of Existing Intellectual Property Protection of Traditional Knowledge,[84] the IGC Secretariat observed that:

> Geographical Indications as defined by Art. 22.1 of the TRIPS Agreement and appellations of origin, as defined by Art. 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.[85]

Three examples provided by the Secretariat of TK protected by GIs are: 'Cocuy the Pecaya' liquor from Venezuela, and 'Phu Quoc' fish sauce and 'Shan Tuyet Moc Chau' tea, both from Vietnam.

A concern for the authentication of traditional culture in the face of the economic, psychological and cultural threat from alien sources is often cited as a reason for the protection of TK. [86] A related concern is that expressed in a number of contemporary European GI disputes, where the producers of 'Rioja' wine,[87] 'Grano

[82] See chap. 6 supra.
[83] S. Biber-Klemm and T. Cottier (2006) *Rights to Plant Genetic Resources and Traditional Knowledge: Basic Issues and Perspectives*. CAB International, Wallingford.
[84] WIPO/GRTKF/IC/3/7, 6 May 2002.
[85] Ibid., para 40.
[86] A. Jabbour (1982) Folklore protection and national patrimony: developments and dilemmas in the legal protection of folklore. *Copyright Bulletin* XVII, No.1, 10 at 11–12, cited in M. Blakeney (2000) Protection of traditional knowledge under intellectual property law. *European Intellectual Property Review* 251–261.
[87] Case C-47/90.

Padano' cheese[88] and 'Parma' ham[89] have successfully insisted on their exclusive right to process these products within the relevant geographic region, in order to preserve the quality and authenticity of these products.

The support, maintenance and development of TK systems are built into most national GI regimes. Various consortiums of producers have been established both to monitor and promote production in conformity with the registered GI, as well as to secure protection. In a number of countries which are promoting the establishment of GIs as a marketing tool, the establishment of producers' consortia is being promoted.

[88] Case C-469/00.
[89] Case C-108/01.

9 Competition Aspects

9.1 Competition

At the heart of the concerns about IP and food security is the concern that food security is too important to be a hostage to private rights. However, as is discussed below, the proprietization of agricultural innovations has resulted in the concentration of the plant breeding industry in the hands of a few 'biogopolies'.[1] IP laws have facilitated this market concentration since those laws confer statutory monopoly rights upon the owners of those categories of intellectual creation which have been recognized as IP. This statutory monopoly was intended to provide an incentive for creativity through the provision of an opportunity for the exclusive commercial exploitation of the relevant invention, plant variety, design, trademark or copyrighted work. However, the IP monopoly is part of the armoury of business and can be used to exclude competitors from markets and to generate the market power to oblige farmers to deal exclusively with rights holders and to subject themselves to a variety of other restraints.

There is, of course, an inherent conflict between the exclusivity of IPR and the freedoms sought to be guaranteed by competition law. IP law is content to allow mild distortions in competitive market conditions to realize long-term benefits. Competition law is used in developed countries as a means of limiting the harmful effects of IPR. Their competition laws are used to prevent price fixing by rights holders and predatory activities arising from a dominant market position. Developing countries tend not to have the same array of competition laws or agencies to deal with abusive conduct.[2]

[1] P. Drahos (2002) *Information Feudalism*. Earthscan, London, chap. 10.

[2] See C. Correa (2007) *Intellectual Property and Competition Law: Exploration of Some Issues of Relevance to Developing Countries*. ICTSD IPRs and Sustainable Development Programme Issue Paper No. 21, International Centre for Trade and Sustainable Development, Geneva, at 1.

An illustration of the way in which the objectives of competition law and IP law were reconciled in an agricultural context occurred in the ECJ determination in *L.C. Nungesser KG and Kurt Eisele v Commission of the European Communities*.[3]

This case concerned licences entered into between the two German applicants and the Institut National de la Recherche Agronomique (INRA), which had developed certain new varieties of hybrid maize seeds. The applicants were licensees of exclusive propagating and selling rights over those seeds and they were obliged to produce no more than a certain percentage of the seed sold to farmers in the FRG, the balance was required to be imported only from INRA. The exclusivity of these rights and the obligation to deal exclusively with INRA raised the question of whether these licences have the effect of preventing or distorting competition in breach of European competition law.

The ECJ noted that the exclusive licence concerned the cultivation and marketing of hybrid maize seeds which were developed by INRA after years of research and experimentation and were unknown to German farmers. On this basis, the Court considered the exclusivity to be justified because the risk involved in launching the new variety would not otherwise have been assumed by the applicants. The Court noted that 'such a result would be damaging to the dissemination of a new technology and would prejudice competition in the community between the new product and similar existing products'.[4]

However, in relation to the obligation to deal exclusively with INRA, the Court held that absolute territorial protection manifestly went beyond what was 'indispensable for the improvement of production or distribution or the promotion of technical progress'.[5] The Court commented that it was influenced by the fact that the case concerned 'seeds intended to be used by a large number of farmers for the production of maize, which is an important product for human and animal foodstuffs'.[6]

9.2 Market Concentration

The propertization of genetic resources has resulted in the concentration of proprietary biotechnologies in a few corporations.[7] Jean Ziegler, the Special Rapporteur on the Right to Food of the Human Rights Council, has observed a 'marked paradigm shift has occurred from a system seeking to foster food security on the basis of the free exchange of knowledge, to a system seeking to achieve the same goal on the basis of the private appropriation of knowledge'.[8] The history of pharmaceutical patenting was characterized by the cartelized use of patenting as a tool of competition

[3] Case 258/78.
[4] Ibid., para. 57.
[5] Ibid., para. 77.
[6] Ibid.
[7] See e.g. A. Wells (1994) Patenting new life forms: an ecological perspective. *European Intellectual Property Review* 3, 111; W. Lesser (1998) Intellectual property rights and concentration in agricultural biotechnology. *AgBioForum* 1, 56.
[8] Human Rights Council, *Report of the Special Rapporteur on the Right to Food, Jean Ziegler.* A/HRC/7/5, 10 January 2008, para. 44.

and market protection.[9] Since the modern 'life sciences' companies were largely spun off from the pharmaceutical patenting industry, they share in this tradition.

In its 1998 report on EC Regulation of Genetic Modification in Agriculture, the Select Committee of the British House of Lords warned of the problem of cartels and monopolies in the agrochemical/seed sector, pointing out that the degree of consolidation was already much greater than in the pharmaceutical sector. The Nuffield Council in its 1999 report on bioethics and GM crops observed that there were 'six major industrial groups' who between them control most of the technology which gives the freedom to undertake commercial R&D in the area of GM crops.[10] In 2000, it was reported that five companies controlled 60% of the pesticide industry, 25% of the world's seed market and almost 100% of GMOs.[11] In 2002 Monsanto alone was said to control in excess of 90% of the global market for GM seed.[12] Thus in South Africa, Monsanto was said to control 100% of the national market for GM seed, 60% of the hybrid maize market and 90% of the wheat market.[13]

A 1997 study by Krattinger on the development of insect resistance in crops indicated that the then six major company groups held about 60% of the 410 patents that related to the *Bt* gene and *Bt* pesticide technology.[14] The effect of this concentration of patent ownership was to enclose research on the manipulation of cry proteins, which have selective application to the various agricultural pests.

The development of this market concentration is attributed to the Green Revolution, which involved the application of large quantities of fertilizers and herbicides.[15] Given the impact of market concentration on the development of agriculture, it is probably not surprising that the two principal features of the biotechnological revolution are the development of seeds with the genetic traits of resistance to insects and herbicide tolerance.

The concentration of proprietary technologies in the hands of a relatively small group of Northern life-sciences companies, has been exacerbated by the grant, by patent offices of over-broad patent claims, resulting in what Heller and Eisenberg[16] have described as the 'biomedical anticommons tragedy'. The current low thresholds for protection applied by the US and the European patent offices mean that the courts are becoming the arbiters of patentability, as the revocation of the Neem and

[9] See P. Drahos, n.1 supra, 149ff; G.M. Dutfield (2002) *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History.* Ashgate, Aldershot and Brookfield, VT.

[10] These are: Agrevo/Plant Genetic Systems, ELM/DNAP/Asgrow/Seminis, Du Pont/Pioneer, Monsanto/Calgene/Delkalb/Agracetus/PBI/Hybritech/Delta and Pine Lane Co., Novartis, Zeneca/Mogen/Avanta. Nuffield Council on Bioethics (1999) *Genetically Modified Crops: The Ethical and Social Issues*, para. 3.36.

[11] J. Meek (2000) Beginners guide to gene patents. *Guardian*, 15 November, 11, quoted in G. Downes (2004) TRIPS and food security: implications of the WTO's TRIPS Agreement for food security in the developing world. *British Food Journal* 106, 366.

[12] C. James (2002) Global status of commercialized transgenic crops: 2002. International Service for the Acquisition of Agri-Biotech Applications (ISAAA) Briefs, No. 27.

[13] ActionAid (2003) *GM crops – Going Against the Grain*, see www.agribusinessaccountability.org/pdfs

[14] A.F. Kratinger (1997) Insect Resistance in Crops: A Case Study of *Bacillus thuringiensis* (Bt) and its Transfer to Developing Countries. ISAA Briefs, Ithaca, New York, No 2.

[15] See M. Kropiwnicka (2005) Biotechnology and food security in developing countries. The case for strengthening international environmental regimes. *ISYP Journal on Science and World Affairs* 1, 45.

[16] M.A. Heller and R.S. Eisenberg (1998) Can patents deter innovation? The anticommons in biomedical research. *Science* 280(1 May), 698.

Turmeric patents demonstrate. The argument for raising the threshold for protection can be justified on the basis that it will result in greater predictability and certainty for the bioscience industry, ensuring that those inventions which deserve protection are protected and that this protection is less likely to be subsequently challenged in court. The re-opening of the Neem and Turmeric patents are cited as examples of courts being forced to reconsider the liberality of patent offices.[17] On the other hand, they may be considered to be examples of the necessity for patent offices to have access to data on TK as part of the state of the art.

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 undertaken. For example, to what extent will the dominance of private corporations in biomedical and agricultural research direct that research towards Northern concerns such as away from Southern health problems[18] and Southern food priorities.[19] The Assistant Director General of the FAO has stated that 85% of all plantings of transgenic crops are soybean, maize and cotton, modified to reduce input and labour costs for large-scale production systems, but not designed 'to feed the world or increase food quality'.[20] It has been estimated that only 1% of research and development budgets of multinational corporations is spent on crops of interest to be useful in the developing world.[21] Almost entirely neglected by these corporations are the five most important crops of the poorest, arid countries – sorghum, millet, pigeon pea, chickpea and groundnut.[22]

An analogy may be drawn with biomedical research where to deal with the lack of commercial interest of companies to conduct research into poor peoples' diseases, e.g. schistosomiasis and malaria or diseases with small number of sufferers, 'Orphan Drugs' legislation has been introduced, which provides incentives for private sector research into these diseases. Incentives under this legislation include market exclusivity for limited periods, fiscal incentives, subsidies and preferential access to public sector research funding. It has been suggested that 'orphan crops' legislation can be adopted in the same way to stimulate research and development for orphan crops as a means of stimulating research on crops of importance to national food security.[23]

[17] See O. Das (2000) Patenting and the ownership of genes and life forms. The Indian experience. *The Journal of World Intellectual Property* 3, 577; R. Prakash (2000) WTO rules. Do they conserve or threaten biodiversity? *The Journal of World Intellectual Property* 3, 155.

[18] J. Watal (2000) Pharmaceutical patents, prices and welfare losses: policy options for India under the WTO TRIPS Agreement. *The World Economy* 23, 733.

[19] J. Alston, G. Pardey and J. Rosenboom (1998) Financing agricultural research: international investment patterns and policy perspectives. *World Development* 26, 1045.

[20] L.O. Fresco (2003) *Which Road Do We Take? Harnessing Genetic Resources and Making Use of Life Sciences, a New Contract for Sustainable Agriculture*, www.fao.org/ag/magazine/fao-gr.pdf.

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

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

[23] C. Spillane (1999) *Recent developments in biotechnology as they relate to plant genetic resources for food and agriculture.* Commission on Genetic Resources for Food and Agriculture, Background Study Paper No 9, 34.

The design of GM seeds has involved the development of vertical integration between the producers of seed, herbicides and food processing systems, with a view to creating power in a number of related markets.

As in other areas of technology, an impetus for mergers and cartelization was to obtain access to patented technologies. Thus the acquisition of Agracetus by Monsanto enabled the acquirer access to its patent for transgenic cotton.[24]

Of course cartelism is an ancient means for a competitor to fix prices. Drahos refers to the private antitrust action brought by US and international farmers against Monsanto and its co-conspirators alleging the use of patents to fix prices and restrain trade in the GM maize and soybean seed markets.[25]

A problem with the development of oligopolization in the agri-food industries is that competition law, like IP law, is formulated and enforced nationally. The USA and European antitrust authorities examine competitive impacts in their own markets rather than considering such impacts in developing country world markets. For this reason, it has been suggested that there is 'obvious need here for a global antitrust policy that considers competitive impacts in all markets'.[26]

9.3 IP and Innovation

The conventional wisdom is that one of the principal justifications for IP protection is that such protection is required as an incentive to innovation, investment and technology transfer. This wisdom is reflected in Art. 7 of the TRIPS Agreement, which 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…'. However, even in industrialized countries, the evidence that patenting is a prerequisite for or a facilitator of economic development is equivocal. In his celebrated 1959 study of the patent system in the USA, Fritz Machlup concluded that 'no economist on the basis of present knowledge, could possibly state with certainty that the patent system, as it now operates, confers a net benefit or a net loss upon society'.[27] Since that time, a number of empirical studies have been undertaken to ascertain the industrial significance of patent protection. In his celebrated 1971 study, Firestone found that competition was reported by US firms as the principal factor influencing R&D expenditure.[28] More recently, the UK Commission on Intellectual Property Rights (CIPR), in its report *Integrating Intellectual Property Rights and Development Policy*,[29] noted the complexity of evaluating the available evidence on the impact of IPR regimes on developing, or developed countries. It concluded that 'in most low income countries, with a weak scientific and technological infrastructure, IP protection at the levels mandated by TRIPS is not a significant

[24] G. Monbiot (2002) Patent nonsense. *Guardian,* 12 March, 253, cited by G. Downes (2003) *Implication of TRIPS for Food Security in the Majority World.* Comhlámh, Cork, 27.

[25] Drahos (2002), n.1 supra at 165, referring to *Biotechnology Law Report* 19, 357.

[26] J.H. Barton (2003) *Nutrition and Technology Transfer Policies.* UNCTAD/ICTSD, Geneva, July, 24.

[27] F. Machlup (1959) *An Economic Review of the Patent System.* Study No. 15 of the US Subcommittee on Patents Trademarks and Copyrights, 85th Congress, 2d Sess., 79.

[28] O.J. Firestone (1971) *Economic Implications of Patents.* University of Ottawa Press, Ottawa.

[29] CIPR, London (2002).

determinant of growth'. Keith Maskus suggests that the literature discussing the extent to which stronger IPR influence foreign investment, licensing behaviour and the transfer of technology can reach only tentative conclusions, because of weaknesses in data or methodology.[30]

In a study published in 1986, Edwin Mansfield inquired among a random sample of 100 firms from 12 industries in the USA, about the proportion of their inventions introduced between 1981 and 1983, which would not have been commercially developed if patent protection had not been available.[31] He discovered that there were sectoral differences in attitude to IP protection. In the pharmaceutical and chemical industries, patent protection was considered essential for the commercialization of about one third of inventions. In the petroleum, machinery and fabricated metal products industries, the proportion was between one tenth and one fifth. Mansfield found industrial property protection to be considered of little significance in the electrical, office equipment, motor vehicle, instrument, primary metals, rubber and textile industries. Despite the misgivings of Maskus about the methodological limitations of such studies, it is now agreed that there are sectoral differences in the significance of patenting for innovation.

Studies of the incidence of patenting in the USA trace a gradual increase from the period 1976–1996, when the total number of patent applications in the USA grew at an average annual rate of 1.8% to the period 1986–1996, when patenting grew at 3.5% annually.[32] This growth is attributed to the pro-patent shift associated particularly with the establishment of the specialized Court of Appeals for the Federal Circuit.[33] This growth was particularly rapid in high tech industries, for example, 9.3% in biotechnology, 11.0% in semiconductors and 11.2% in software.[34]

A simplistic application of the incentive thesis may suggest that this growth of patenting is a reflection of the growth of innovation. However, a qualitative analysis of these patents might suggest otherwise. The breadth of the patents which are granted has important implications for innovation. A broad patent grant may be justifiable to permit inventors to appropriate returns on fundamental research, by receiving some of the value of later commercial applications. On the other hand, broad patent grants may deter firms from engaging in research in the area of the patented invention, and from searching for improvements in the patented invention.[35]

The critical question is to pitch the breadth of protection to balance the incentives, particularly between the primary innovator and a later inventor who introduces improvements to the original invention.

[30] Keith E. Maskus (2003) *Transfer of Technology and Technological Capacity Building.* Bellagio Series on Development and Intellectual Property, 18–21 September.

[31] E. Mansfield (1986) Patents and innovation: an empirical study. *Management Science* 32, 173.

[32] Michael Noel and Mark Schankerman (2006) *Strategic Patenting and Software Innovation.* Paper No. CEPDP0740: August, http://sticerd.lse.ac.uk/dps/ei/EI43.pdf.

[33] Adam Jaffe and Josh Lerner (2004) *Innovation and Its Discontent*s. Princeton University Press, Princeton, NJ.

[34] B. Hall and R. Ziedonis (2001) The patent paradox revisited: an empirical study of patenting in the semiconductor industry, 1979–1995. *RAND Journal of Economics* 32, 101.

[35] R. Mazzoleni and R.R. Nelson (1998) The benefits and costs of strong patent protection: a contribution to the current debate. *Research Policy* 27, 273 at 275.

9.4 Biotechnological Patenting and Innovation

The important question for us in a food security context is the extent to which IP protection provides an incentive for agricultural innovation. It has been suggested that broad patents in the biotechnology field may have greater potential to impede innovation than in other industries. For example, 'molecular modification' is a common practice in the pharmaceutical industry, but it is suggested that it is much more difficult to 'design around' treatments that depend on a particular gene sequence or gene fragment.[36]

For example, patents have been granted over ESTs, which are fragments of DNA that can be used as tools to search for full-length genes. A typical EST is 400–500 nucleotides in length compared with a typical gene of 2000 to 25,000 nucleotides in length. Thus a number of ESTs may be patented on the same gene. A researcher wishing to use the full-length gene, the patentee, would need to first obtain a licence from the owners of the EST patents.[37]

The impact of biotechnological patenting will have different impacts in the research continuum. It has been noted that start-up biotechnology firms may need patents on their upstream discoveries in order to attract investors, whereas for pharmaceutical companies patents are needed not to raise capital but to ensure effective commercial exploitation of their products.[38]

A critical question in the field of biotechnological patenting is whether the growth of patenting inhibits research. The OECD has lamented the 'conspicuous absence of rigorous economic studies' that explore the impact of gene patents on research'.[39] The Report of the OECD Working Party on Biotechnology identified a number of issues concerning the possible adverse impact of gene patents on research, including blocking patents or overly broad patents; increases in secrecy and a slower pace of research; increased research and transaction costs; and increased litigation involving public research organizations.[40]

It has been stated that 'a web of proprietary claims now envelops the transfer and use of patented agricultural biotechnologies, thereby limiting the freedom to operate of public and private agencies alike'.[41] These claims include: (i) parent germplasm in the form of individual plant varieties; genes controlling tolerance of biotic and abiotic stresses, and increased content of beneficial components such as oil, proteins, vitamins, and minerals, or decreased content of harmful traits such as allergens; and (iii) enabling technologies that include methods of transformation of plant cells by

[36] Alissa K. Lipton, *Biopharmaceuticals: The Patent System and Incentives for Innovation*, text at no. 233, http://leda.law.harvard.edu/leda/data/641/Lipton.html#fnB234, citing Sandy M. Thomas, M.M. Hopkins and M. Brady (2002) Shares in the human genome—the future of patenting DNA. *Nature Biotechnology* 20, 1185.

[37] Molly A. Holman and Stephen R. Munzer (2000) Intellectual property rights in genes and gene fragments: a registration solution for expressed sequence tags. *Iowa Law Review* 85, 735, 764.

[38] Australian Law Reform Commission (2004) *Genes and Ingenuity: Gene Patenting and Human Health*, ALRC 99, chap. 17, http://www.austlii.edu.au/au/other/alrc/publications/reports/99/index.html.

[39] Organisation for Economic Co-operation and Development (2002) *Genetic Inventions, Intellectual Property Rights and Licensing Practices: Evidence and Policies*, 82.

[40] Ibid., 12–15.

[41] C. Nottenburg, P.G. Pardey and B.D. Wright (2002) Accessing other people's technology for non-profit research. *Australian Journal of Agricultural and Resource Economics* 46, 389 at 391–92.

insertion of a gene coding for a specific characteristic into plant cells, promoters that are used to control expression of the gene in plants, genes serving as selectable markers to determine which plant cells have been successfully transformed, and gene silencing or regulating technologies.[42]

As a consequence, access to many agricultural biotechnologies involves access to a package of technologies, often from various sources. Indeed part of the impetus for the merger activities in the agri-biotechnology field has been for companies to secure access to proprietary technologies.[43] The market concentration identified above in relation to categories of food crops is matched by concentration in relation to the ownership of proprietary technologies.

For example, it has been noted that plant transformation technologies, such as particle bombardment, *Agrobacterium* technology and the most widely used selectable markers and promoters for cereal transformation are controlled by a small group of companies with a web of cross-licences.[44] A 1999 study showed that the top seven firms controlled three-quarters of patents on transformation technologies and genetic materials, together with close to all of the germplasm patents.[45]

A particular problem in the field of biotechnological patenting is the grant of over-broad patents, which can chill the vigour of research and innovation because of concerns about infringement, or because downstream inventors are obliged to seek licences from upstream inventors. Main impact of over-broad patenting upon research is identified in the area of research tools. In biotechnology, patentable research tools may include: (i) research techniques such as the Cohen–Boyer techniques (for gene-splicing) and the polymerase chain reaction (PCR) methodology (for DNA amplification); (ii) research products such as Taq polymerase (used in PCR) and restriction enzymes (used in cloning), combinatorial chemistry libraries; and (iii) genetic materials, cell lines, monoclonal antibodies, reagents, animal models, growth factors, drugs and drug targets, clones and cloning tools, methods, laboratory equipment and machines, databases and computer software and genetic materials that are targeted in research, e.g. genes for receptor proteins used in designing new drugs or vaccines, ESTs and SNPs, which can be targets of research or used to target other genetic materials.[46] The most important research tools are 'fundamental research platforms that open up new and uncharted areas of investigation'.[47] In the hands of a single patentee, these could sterilize disparate areas of research. For example, Barton suggest that patents on some foundational research tools can 'pre-empt large areas of medical research and lay down a legal barrier to the

[42] Ibid.

[43] G.D. Graff, G.C. Rausser and A.A. Small (2003) Agricultural biotechnology's complementary intellectual assets. *Review of Economics and Statistics* 85, 349.

[44] E. Binenbaum, C. Nottenburg, P.G. Pardey, B.D. Wright and P. Zambrano (2003) South–North trade, intellectual property jurisdictions, and freedom to operate in agricultural research on staple crops. *Economic Development and Social Change* 51, 309 at 315.

[45] See Graff n.43 supra.

[46] See National Institutes of Health Working Group on Research Tools (1998) *Report of the National Institutes of Health (NIH) Working Group on Research Tools.* www.nih.gov/news/researchtools/index.htm.

[47] See A. Rai (2002) Genome patents: a case study in patenting research tools. *Academic Medicine* 77, 1368, 1369.

development of a broad category of products'.[48] Patented stem cell lines are an example of fundamental research platforms which have a significant impact upon research trajectories.

A positive point to note in relation to food security is that very few of the patented agri-biotechnologies have been registered in developing countries, which leaves them with a degree of freedom to operate (FTO). Problems would arise primarily in situations where products are exported into markets where IPR have been registered.

9.5 Licensing

Licensing of proprietary goods or technologies could have anti-competitive effects where competitors agree to divide markets, fix prices or limit output or where the licence has an exclusionary effect, e.g. where it excludes other potential licensors of substitutable IP; or facilitates the licensee's accumulation of market power in competing technologies. Art. 40 of the TRIPS Agreement identifies that 'some licensing practices or conditions pertaining to IPR which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology'. It permits WTO Members to specify 'in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market'.

Listed in Art. 40.2 of the TRIPS Agreement as anticompetitive practices which may be the subject of national legislation are 'exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing'.

Exclusive grantback conditions occur where the licensee agrees to extend to the licensor of technology the exclusive right to use any improvements by the licensee in the technology; this may adversely affect competition by substantially reducing the licensee's incentive to engage in research and development. This is probably more relevant to agricultural researchers than it is to farmers. Similarly, restraints on challenges to the validity of IPR are going to be more relevant for agricultural researchers than for farmers in developing countries.

Exclusive dealing will occur when a farmer or technology licensee is prevented from licensing, selling, distributing or using products that compete with those of the original supplier. A considerable body of case law has developed on the indirect methods used to effect exclusive dealing restraints, such as obligations to acquire minimum quantities of product, which have the effect of foreclosing the acquisition of competing products, or the rigorous enforcement of best endeavours clauses, which have the effect of preventing practical access to competing technologies, goods or services. A form of exclusive dealing which is generally regarded as a separate genus is an agreement to supply a product or technology on the condition that the licensee acquires another product or line of products from the supplier. Tying is a stratagem adopted by suppliers with market power in one product, which is used to extort competitive advantages in the market for the tied product, in which the significant

[48] J. Barton (2002) Research tool patents: issues for health in the developing world. *Bulletin of the World Health Organization* 80, 121, 122.

advantage of market power may not exist. The existence of a statutory monopoly such as that conferred by a patent, copyright or trade secret may be the basis for the market power, which permits the tying in of other supplies. As we have seen, seeds are increasingly being engineered to require the tie-in of herbicides, which are often supplied by the same corporate group as the seed supplier. This effectively excludes farmers from acquiring herbicides from competitors of the seed supplier and is considered to be exclusive dealing.

A study by UNCTAD on Control of Restrictive Practices in Transfer of Technology Transactions (1982) identified as unduly restrictive conditions in technology licences which obliged licensees to acquire 'additional technology, future inventions and improvements, goods or services not wanted by the acquiring party, or unduly restricting sources of technology, goods or services as a condition for obtaining the technology required' when these ties were not required to secure the quality or performance of products produced pursuant to the licence. Also the provisions in a licence which require the making of payments or the imposition of other obligations following the expiration of IPR may be considered impermissibly restrictive, as well as restrictions imposed upon a licensee after the expiration of the licence term.

Access to proprietary research tools will depend upon the availability and terms of licences granted by patent holders to researchers. The OECD Report suggested that research tool patents on occasion make 'collaboration and communication with other researchers more difficult'.[49] This may be through the imposition of high licence fees or because of the transaction costs and administrative delays and burdens in negotiating licences. Eisenberg observed that 'there seems to be a widely-shared perception that negotiations over the transfer of proprietary research tools present a considerable and growing obstacle to progress in biochemical research and product development'.[50]

On occasion, licence agreements for the use of research tools may contain reach-through provisions, which give the patent holder rights over discoveries made by licensed researchers who utilize the research tools. For example, licences of the Bio-Rad gun, used by researchers to shoot DNA coated pellets into cells, required licensees to make commercial applications of their research available to Bio-Rad. Such reach-through rights may prejudice researchers' later technology transfer and commercialization prospects, as potential commercial partners are likely to demand that IP be unencumbered by competing interests.

It is not uncommon for patent holders to charge lower fees for academics, compared with commercial researchers. However, these lower prices may carry a number of ancillary obligations. For example, genetic materials may be made available to academic researchers on condition that they undertake not to seek IP rights over these materials or derivatives. The licensor may seek priority in the commercial exploitation of research products and may seek to control the publication of research results.

The Nuffield Council on Bioethics in a 2002 report indicated that there was insufficient evidence to assess any negative effects on research from the patenting of

[49] OECD (2002) n.39 supra, 14.

[50] R. Eisenberg (2001) Bargaining over the transfer of proprietary research tools: is the market failing or emerging? In: R. Dreyfuss, D. Zimmerman and H. First (eds) (2001) *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* 223, 225.

research tools it is producing.[51] A review conducted in 2003 for the United Kingdom Department of Health concluded the evidence was limited and anecdotal.[52]

The Australian Law Reform Commission noted that 'the current position may change, particularly if patent holders become more active in enforcing patent rights'.[53]

An example which has been given of a company blocking applications of its proprietary technology is the difficulty that the Centre for Legumes in Mediterranean Agriculture, a university-based research centre (CLIMA) in Australia, has had in commercializing the transgenic lupin cultivar, which it developed with tolerance to the herbicide 'Basta'. Apparently it was unable to reach agreement with Agrevo (now Aventis), the developers of Basta.[54]

As was the case with securing access for developing countries to anti-HIV/AIDS drugs, it must be possible for food security reasons to differentiate between categories of acquirers of patented technologies. In the case of poor farmers growing crops, such as plantain, cassava, yams and cowpea, which are not exported but consumed in the producing country, it is feasible to make proprietary technologies available at a low cost.[55]

Responding to the HIV/AIDS crisis, the TRIPS Agreement was amended to permit developing countries to license foreign producers to supply patented pharmaceuticals in situations of 'national emergency or extreme urgency'.[56] Given the contemporary food security crisis, patented agricultural biotechnologies could be treated in a similar way with the availability of compulsory licensing on reasonable terms to secure access to biotechnologies that are essential to deal with food security problems.

9.6 Patent Thickets

The increase in patenting in the biotechnological and other high technology industries has led to the development of 'patent thickets', which are defined as an overlapping set of patent rights requiring that those seeking to commercialize new technology obtain licences from multiple patentees. The US Federal Trade Commission in its 2003 hearings on the interface between patent policy and competition policy[57] noted in particular the development of a patent thicket in the software

[51] Nuffield Council on Bioethics (2002) *The Ethics of Patenting DNA* [5.40].

[52] W. Cornish, M. Llewelyn and M. Adcock (2003) *Intellectual Property Rights (IPRs) and Genetics*.

[53] ALRC n.38 supra at 12.80.

[54] E. Binenbaum *et al.* (2003), n.44 supra at 314.

[55] See E. Binenbaum and B. Wright (1998) On the significance of South-North trade in IARC crops. Report of the CGIAR Panel on Proprietary Science and Technology, SDR/TAC:IAC/98/7.1; IARC, International Agricultural Research Centres.

[56] See J.H.J. Bourgeois and T.J. Burns (2002) Implementing Paragraph 6 of the Doha Declaration on TRIPS and Public Health: the waiver solution. *Journal of World Intellectual Property* 5, 835; E. Noehrenberg (2003) TRIPS, the Doha Declaration and Public Health. *Journal of World Intellectual Property* 6, 379; F. Ismail (2003) The Doha Declaration on TRIPS and Public Health and the negotiations in the WTO on Paragraph 6: Why PhRMA needs to join the consensus! *Journal of World Intellectual Property* 6, 393.

[57] Federal Trade Commission (2003) *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy.* FTC, Washington DC, October 2003.

industry, with 'potentially dozens or hundreds of patents covering individual components of a product'.[58]

The leading empirical studies focus on the semiconductor industry. Hall and Ziedonis demonstrate that patenting in this industry rose sharply in the 1990s, suggesting the creation of patent thickets in that industry.[59] Ziedonis concludes that the incidence of patenting is a measure of the fragmentation of patent rights.[60] Similarly Nagaoka and Nishimura concluded that a firm in an industry in which there is extensive cross-licensing and in an industry with higher patent thickets has a higher propensity to patent its inventions.[61]

The US Federal Trade Commission in its 2003 hearings on the interface between patent policy and competition policy observed that defensive patents may have negative implications for innovation. It reported that some companies have diverted resources from R&D to fund their defensive patenting programmes and to cover legal expenses.[62]

Additionally, dealing with the owners of the thicketed patents will often involve prohibitive transaction costs and will impose research hold-ups as patent owners are identified and dealt with. Paradoxically, Noel and Schankerman observe that by increasing the transaction costs of R&D, patent thickets provide an incentive for firms to patent defensively, since a firm's bargaining power is raised by more patents to trade in patent disputes.[63] With the consequential increase in patents, transaction costs will rise as the complexity of negotiating multilateral licences is increased.

However, Bessen suggests that even in situations where there are no transaction costs or research holdups, some companies aggressively seek to build large patent portfolios for the purpose of extracting benefits from competitors.[64] A phenomenon that has been identified is that negotiations are undertaken on the basis of portfolios of patents, rather than on individual patents.[65]

9.7 Patent Thickets and Biotechnological Innovation

The original research on patent thickets was Heller and Eisenberg's 1998 study on the 'Anticommons in Biomedical Research'. Their classic formulation was that:

> By conferring monopolies on discoveries, patents necessarily increase prices and restrict use – a cost society pays to motivate invention and disclosure. The tragedy of the anticommons refers to the more complex obstacles that arise when a user needs access to

[58] Ibid., at 342.
[59] B.H. Hall and R.H. Ziedonis (2001) The patent paradox revisited: an empirical study of patenting in the U.S. semiconductor industry, 1979–1995. *RAND Journal of Economics* 32, 101–128.
[60] R. Ziedonis (2003) Don't fence me in: fragmented markets for technology and the patent acquisition strategies of firms. *Management Science* 50, 804.
[61] S. Nagaoka and Y. Nishimura (2006) An empirical assessment of the effects of patent thickets, July. http://www.sussex.ac.uk/Units/spru/events/ocs/viewpaper.php?id=32
[62] USPTO, FTC, n.57 supra, at 347.
[63] Michael Noel and Mark Schankerman (2006) Strategic Patenting and Software Innovation. Paper No CEPDP0740, August. http://sticerd.lse.ac.uk/dps/ei/EI43.pdf.
[64] OECD n.39 supra, at 12, refers to IBM as an example of a corporation which aggressively seeks to build large patent portfolios with a view to extorting benefits from competitors.
[65] Hall and Ziedonis (2001) n.59 supra.

> multiple patented inputs to create a single useful product. Each upstream patent allows its owner to set up another tollbooth on the road to product development, adding to the cost and slowing the pace of downstream biomedical innovation.[66]

Heller and Eisenberg had speculated that the lowering of patenting standards had encouraged the growth of patent thickets around both DNA sequences and fragments of DNA, which raised difficulties for biotechnological innovators, first through the privatization of upstream research and secondly, through the introduction of excessive transaction costs. For example, a proposal by the IRRI, to make available to poor farmers protein and vitamin-enhanced 'Golden Rice', ran into the problem of some 70 patents over various enabling technologies and gene sequences.[67] This problem was resolved when AstraZeneca acquired the commercial rights to 'Golden Rice' and licensed the inventors to enable the distribution of the rice on a royalty-free basis to farmers earning less than $10,000 per year and living in developing countries, leaving the company free to explore commercial prospects for the technology.[68]

9.8 Patent Pools

An alternative to cross-licensing as a means of negotiating patent thickets is the creation of patent pools. This is an arrangement among multiple patent holders to aggregate their patents, which are shared by members of the pool and made available on standard terms to non-members of the pool. The analogy is usually made between patent pools and collective rights organizations which manage copyrights. One of the first patent pools was formed in 1856 by a group of five sewing machine manufacturers as a means of resolving their patent infringement disputes with each other. Similarly in 1908, the four pioneers of the motion picture industry pooled their patents to avoid infringement litigation.

This stratagem appears to have recommended itself to innovators in areas of newly emerging technologies. Thus a patent pool for the distribution of shared royalties was formed in 1997, by the ten companies who developed and sought to utilize the MPEG-2 compression technology standard. In 1998 and 1999, patent pools were established for the inventions that were essential for DVD-Video and DVD-ROM standard specifications.

Patent pools have been suggested as a means of securing access to essential medicines. WHO's Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) suggested that pooling 'could be most useful for technologies particularly relevant to developing countries, because the lack of strong market incentives may enable agreements that would otherwise be more difficult to

[66] M. Heller and R.S. Eisenberg (1998) Can patents deter innovation? The anticommons in biomedical research. *Science* 280, 280, 698 at 699.

[67] R.D. Kryder, S.P. Kowalski and A.F. Krattiger (2000) The Intellectual and Technical Property Components of Pro-Vitamin A Rice (*Golden* Rice): A Preliminary Freedom-to-Operate Review. ISAAA Briefs no. 20. International Service for the Acquisition of Agri-Biotech Applications, Ithaca, New York.

[68] N. Tait and M. Wrong (2000) Deal offers free GM rice to poor farmers while rich have to pay. *Financial Times* (London), 16 May, reproduced by AgBiotech Infonet, http://www.biotech-info.net/deal_offers_free_rice.html.

engineer'.[69] For example, WHO has established the 'SARS[70] IP Working Group', to develop a patent pool for a SARS vaccine. Similarly, UNITAID, an international drug purchase facility, established on the initiative of Brazil, Chile, France, Norway and the UK to facilitate access to drugs and diagnostics to fight AIDS, malaria and tuberculosis in developing countries, has proposed the establishment of the UNITAID Medicines Patent Pool. This will focus on the patents required for anti-retroviral HIV/AIDS treatments.

The UNITAID Medicines Patent Pool will operate by seeking voluntary contributions of relevant patents by the patent holders to the Patent Pool for use in countries not designated as high-income by the World Bank.[71] In cases where the UNITAID Medicines Patent Pool failed to obtain voluntary licences, it would seek non-exclusive open compulsory licences from appropriate WTO members.

Underpinning the creation of a patent pool for essential medicines are the facts of: the high cost of patented medical products, particularly when marketed under monopoly conditions; restrictions on innovation and adaptation of proprietary medicines and devices to adapt to differing viral strains, changing immunities, related infectious diseases, local health system conditions and local patient customs; the necessity for access to economies of scale.

9.9 Patent Pools and Biotechnological Innovation

A study commissioned by the USPTO has suggested that patent pools are a solution to the problem of biotechnological patent thickets.[72] Questions of public health and nutrition could be considered sufficiently crucial for the government to mandate the creation of patent pools, as the US did in 1917 to secure access to aircraft patents. The USPTO study referred to the creation of the Manufacturer's Aircraft Association, because the two major patent holders, the Wright Company and the Curtiss Company, were blocking the development of new aircraft at the time of the First World War.

Similarly Ebersole *et al.* proposed the establishment of patent pools as a means of securing access to diagnostic genetics.[73] In 2001, the American College of Medical Genetics (ACMG) had sought to establish a standard for determining which mutations of a disease were significant and should be tested. Problems have been identified where diagnostic tests have been patented by different parties or where multiple patents have been secured for similar tests. For example, a number of diseases can be correlated to a genetic variation (SNP) within an individual. Where the relevant SNP or a fragment has been patented by multiple patentees, navigating the patent thicket can become prohibitive. Ebersole *et al.* give the example of patent thickets over

[69] World Health Organization (2006) Commission on intellectual property rights, innovation and public health. *Public Health: Innovation and Intellectual Property Rights.* WHO, Geneva, 68.

[70] SARS=Severe Acute Respiratory Syndrome.

[71] See Médecins Sans Frontières (2006) *Intellectual Property Rights and Medicines Procurement: Patent pools.* Note for consideration by the Ministry of Foreign Affairs (France) and UNITAID, June.

[72] J. Clark, J. Piccolo, B. Stanton, K. Tyson (2000) *Patent Pools: a Solution to the Problem of Access in Biotechnology Patents?* USPTO, Washington DC, December 5.

[73] T.J. Ebersole, M.C. Guthrie and J.A. Goldstein (2005) Patent pools as a solution to the licensing problems of diagnostic genetics. *Intellectual Property and Technology Law Journal* 17, 6.

multiplex tests, which permits the simultaneous testing of 25 mutations identified by the ACMG.[74] Patent pools are suggested as a means of dealing with these thickets. The suggestion that genomics might be too diverse a field to sustain patent pools[75] is met by the observation of Ebersole *et al.* that diagnostic genetics tends to be suitably focused for pooling.[76] The members of a diagnostics genetics patents pool would be those patent holders who have essential and complementary patents on specific genetic mutations. The pool would be administered by a body such as the ACMG. The incentives for participation by patentees would be their participation in an industry standard, mediated by a respected organization such as the ACMG and the FTO within the pooled patents, as well as the prospect of higher revenues from participation in the pool.

9.10 The Impact of Competition Law upon Patent Pools and Cross-licensing

The creation of patent pools was originally seen as an impermissible use of IPR beyond what was required to incentivize innovation. The hostility of competition law to patent pools was reflected in the US Supreme Court decisions in *Standard Sanitary Manufacturing Co. v United States*[77] (1912) and *Hartford-Empire Co. v United States*[78] (1945), which struck down these patent pools on the grounds that they were devices to fix prices. The pro-competitive effects of patent pools, particularly in dealing with the transaction costs caused by impenetrable patent thickets, caused the US Department of Justice and the Federal Trade Commission to issue *Antitrust Guidelines for the Licensing of Intellectual Property* (IP Guidelines).[79] The IP Guidelines indicate that anticompetitive effects may also occur if the pooling arrangement deters or discourages participants from engaging in research and development which is more likely 'when the arrangement includes a large fraction of the potential research and development in an innovation market'.

The Australian Competition and Consumer's Commission (ACCC) follows the US approach in finding that patent pools and cross-licensing arrangements could have either positive or negative implications for competition. The ACCC noted the potential for price fixing, market sharing, or agreements among competitors without any possible pro-competitive justification. It suggested that patent pools would be less likely to raise competition concerns if:

- they combine complementary patents;
- licensing arrangements do not restrict access to the pool's technology by competitors, potential entrants, or third parties; and

[74] Ibid., 7.
[75] Ibid at n.59 supra.
[76] n.73 supra, at 10.
[77] 226 US 20 (1912).
[78] 323 US 386 (1945).
[79] http://www.usdoj.gov/atr/public/guidelines/ipguide.htm.

- pooling arrangements do not facilitate sharing or access to competitors' commercially sensitive information in the relevant or downstream markets.[80]

[80] ACCC submission to Australian Law Reform Commission report on Genes and Ingenuity: Gene Patenting and Human Health, ALRC 99, 2004, http://www.austlii.edu.au/au/other/alrc/publications/reports/99/index.html.

10 Intellectual Property and Agricultural Research

10.1 Agricultural Research and Food Security

Agricultural research plays a significant role in ameliorating food insecurity. Where the fruits of the research assist poor farmers in increasing their productivity this lowers food prices for consumers, which raises real incomes for farmers, rural labourers and the urban poor in the neediest communities.[1] As food staples are the main source of nutrients in the diets of the rural poor, agriculture research, by increasing output, will contribute to improving health through greater consumption.[2] The reduction of food prices will increase the real incomes of the poor, not only allowing them to consume more and better food, but also other essential goods and services, such as housing, education and healthcare.[3]

During the mid-1990s, public-sector institutions accounted for in excess of 90% of the expenditure on agricultural research in developing countries.[4] However, this expenditure is declining at a time when private-sector investment in agricultural research is increasing worldwide. This growth is occurring in the private sector and is directed toward those crops and technologies that benefit farming in industrialized countries and which are profitable enough to guarantee adequate returns on investment in research.[5]

[1] See R.S. Meinzen-Dick, A. Adato, L. Haddad and P. Hazell (2003) *Impacts of Agricultural Research on Poverty: Findings of an Integrated Economic and Social Analysis.* EPTD Discussion 49 Paper 111/FCND Discussion Paper 164. IFPRI, Washington DC.

[2] C.E. Pray and A. Naseem (2003) *The Economics of Agricultural Biotechnology Research*. ESA Working Paper No. 03-07 June, 1.

[3] M. Lipton (2001) Reviving global poverty reduction: what role for genetically modified plants? *Journal of International Development* 13, 823.

[4] P.G. Pardey and N.M. Beintema (2001) *Slow Magic: Agricultural R&D a Century After Mendel.* Technical Report 36, Agricultural Science and Technology Indicators. IFPRI, Washington DC, table 4.

[5] D.J. Spielman and K. von Grebmer (2004) *Public–private Partnerships in Agricultural Research: An Analysis of Challenges Facing Industry and the Consultative Group on International Agricultural Research*. EPTD Discussion Paper No. 113. IFPRI, Washington DC.

The proprietization of enabling technologies, as well as genetic resources, raises concerns about the capacity of the public agricultural research system to fulfil its mission in contributing to the elimination of food insecurity. Added to the expense of research are the various transaction costs involved in creating and defending IPR. The public goods institutions like the CGIAR research centres are not in a very strong position, either to participate in this research or to appropriate its fruits. A contrast may be drawn between the $25 million spent by the CGIAR on research in 1998 compared with the $1.26 billion invested by Monsanto alone.[6] Although the CGIAR Centres have a decisively important role in agricultural research of relevance for food security, their research budgets are continuing to decline, particularly in times of financial instability.

The domination of private corporations in agricultural research has meant that Northern agricultural priorities and business plans have come to dominate innovation and the identification of food priorities. The innovations undertaken by these corporations have focused upon large-scale agricultural methods, based on the development of herbicide- and pesticide-resistant varieties of wheat, maize, canola and cotton. Hardly any of the newly engineered seeds that appear on the market 'are designed to meet the food needs of the rural poor or to enhance the productivity of smallholder farmers'.[7] Almost entirely ignored by the private sector, because of the low return on investment, is research on the so-called orphan crops: rice, tropical maize, wheat, sorghum, millet, banana, cassava, groundnut, oilseed, potato, sweet potato and soybean.

It has been suggested that the public sector is being squeezed out of applied research by private organizations that are intent on creating a 'basic research agenda for the benefit of corporations'.[8] On the other hand, as we saw in the previous chapter, 'in biotechnology and agriculture it is likely that much research will end up as an international rather than public good and that it will be distributed according to complex licensing structures'.[9]

10.2 Consequences of the Green Revolution

Although the Green Revolution technologies of the three decades from 1970 led to substantial reductions in poverty and improved food security, particularly in Asia, the intensification of agriculture and the reliance on irrigation and chemical inputs led to environmental degradation, increased salinity and pesticide misuse. With crop intensification, incidences of pests and diseases have increased with the concomitant negative impacts upon yields.[10] Despite the very substantial gains, wheat and rice

[6] P. Pardey and M. Beintema (2001) n.4 supra, 19; http://www.ifpri.cgiar.org/pubs/fps/fps36.pdf.

[7] Oxfam (2002) *Rigged Rules and Double Standards: Trade, Globalisation and the Fight Against Poverty*. Oxfam, Oxford, 32.

[8] G. Tansey (1999) *Trade, Intellectual Property, Food and Biodiversity. Key Issues and Options for the 1999 Review of Article 27.3(b) of the TRIPS Agreement*. Quaker Peace and Service, London, 10.

[9] P. Drahos (2002) The rights to food and health and intellectual property in the era of 'biogopolies'. *European Intellectual Property Review* 134.

[10] P. Pinstrup-Andersen and M.J. Cohen (2001) Modern biotechnology for food and agriculture: risks and opportunities for the poor. In: G.J. Persley and M.M. Lantin (eds) (1999) *Agricultural*

yields have now begun to stagnate in the face of population increases.[11] Green Revolution technologies also had little impact on the millions of smallholders living in rainfed and marginal areas, where poverty is concentrated. There are few incentives for private R&D on the food crops, livestock, fisheries and aquaculture systems important for food security and poverty reduction in rural Asia.[12] In Asia, private sector investments in the rural sector and related R&D have concentrated on export commodities.[13]

Modern biotechnology has been identified as bringing new possibilities for achieving the sustainable increases in agricultural productivity that will be necessary to meet the projected demands for food by growing populations. This technology is looked to for the development of high-yielding varieties which can be used by the previously ignored farming communities.[14]

10.3 Public–Private Collaboration

Given the shift of enabling technologies and proprietary materials into private hands, as well as the decline in public sector funding, agricultural research institutes are looking increasingly to collaboration with the private sector. Partnerships can offer private firms access to farmers and resources in emerging markets; the chance to wield constructive influence in the development of legal and regulatory regimes; opportunities to participate in important local, regional and global forums; and prospects to improve corporate profiles.[15] For example, in June 2000, Monsanto made its mapping of the rice genome available to researchers in return for their research data.[16] This was advantageous to Monsanto as it gained access to data from researchers in widely dispersed climatic areas, while improving its international reputation. Researchers obtained access to cutting-edge scientific knowledge. This example also illustrates the fact that public–private partnerships sometimes improve the capacity of researchers to address problems in agriculture that cannot be solved by a single actor. Public–private collaboration can also assist institutions to identify redundant research.

At a meeting convened by CIMMYT in Tlaxcala, Mexico, in late 1999, between the private sector, major public research institutes in the developing world, multilateral donor agencies, academia and the CGIAR, the future roles of the public and private sectors in agricultural research were explored. Participants in the Tlaxcala Forum agreed that the future pattern of private R&D on maize and wheat was likely to focus on investments in developing technology and information resources in genomics and biotechnology, and in developing new crop varieties in areas of expected profits. The public sector was expected to concentrate on the crop needs of

Biotechnology and the Poor: Proceedings of an International Conference on Biotechnology, Washington DC, 21–22 October. CGIAR, Washington DC, 2001.

11 P.L. Pingali, M. Hossain and R.V. Gerpacio (1997) *Asian Rice Bowls: The Returning Crisis?* CAB International, Wallingford.

12 Asian Development Bank (2001) *Agricultural Biotechnology, Poverty Reduction and Food Security*. ADB, Manila.

13 Ibid., at 3.

14 Ibid., at 75.

15 See Meinzen-Dick, n.1 supra at 3.

16 See http://www.rice-research.org/.

developing countries, biological resource conservation and pre-breeding (i.e. research to produce elite breeding materials that researchers can use to develop varieties adapted to local farmers' conditions).

It was agreed that public–private sector alliances were critical to ensure that biological and information technologies are adapted in ways that enable resource-poor farmers to benefit from improved agricultural productivity, profitability and sustainability. However, despite the enthusiasm expressed at Tlaxcala for public−private collaboration in the field of agricultural research, the results have been disappointing. This is attributed to the differing incentives of the actors in public–private partnerships.[17] On the one hand the private sector is interested in research where profits are realizable in the short term, whereas for the public sector, profits are not a priority.

Also it has been observed that the transactions costs in public–private partnerships are excessive, often including the legal expenses associated with the formulation of memoranda of understanding, confidentiality and non-disclosure agreements, MTAs and licences.[18] The difference in the respective cultures of public and private partners also adds transaction costs; this is particularly the case for public agencies with limited experience dealing with the private sector. However, most research institutes have established a technology transfer office or officer. Within the CGIAR, a Central Advisory Service on Intellectual Property has been established to provide IP advice to CGIAR Centres.[19] A number of collaborative institutions have been established by public–private partners. These include: the Golden Rice Humanitarian Board (Syngenta, the International Rice Research Institute and the Rockefeller Foundation); the Insect-Resistant Maize for Africa project (Syngenta, the Kenyan Agricultural Research Institute (KARI) and CIMMYT), which have been established to manage some of the complexities of public–private relationships.

It should be noted that these solutions may generate unintended negative consequences, because of cultural differences between the two sectors. Public agricultural research institutes attract staff at low salaries compared with the private sector, since those institutes offer staff an opportunity to make a contribution to developing countries. Public–private collaborations with multinational corporations and controversial technologies are problematic for some staff and have attracted negative criticism by NGOs and the media. The CGIAR established a Committee of Non-governmental Organizations (the NGO-C) in order to get input from civil society. Its October 2002 meeting in Manila was accompanied by protests by civil society and farmers' organizations. At the meeting the NGO-C announced that it would freeze its participation because of CGIAR's failure to deal with the alleged discovery of GM contamination at CIMMYT. Equally disturbing was the 'increasing influence and membership from the Gene Giants … Syngenta [and] Novartis'.[20] These particular problems are not so relevant to university research institutes as they are keen to secure access to cutting-edge technologies.

[17] See Spielman and von Grebmer, n.5 supra at 6.
[18] Ibid., at 21.
[19] http://www.cas-ip.org/.
[20] ETC Group, Trouble in Paradise: Civil Society Denounces CGIAR for Denial of GM Contamination in Mexican Centre of Genetic Diversity, 31 October 2002, http://www.etcgroup.org/en/materials/publications.html?pub_id=181.

The pressing importance of dealing with food insecurity may overcome the political difficulty, which some in the public sector may have in dealing with the 'Gene Giants' in much the same way the HIV/AIDS crisis has enabled developing countries to reach an accommodation with 'Big Pharma'. IPR can mediate this situation. The patentability of modern agricultural technologies such as genes, gene constructs and enabling technologies has allowed corporations the opportunity to recover their investment in R&D through sales and licence revenues in developed country markets. This is a similar situation as applied in the case of HIV/AIDS drugs where the business plan of pharmaceutical companies is predicated on recovering their costs in developed country markets. This leaves those companies able to make HIV/AIDS drugs or relevant technologies available in developing countries at very low costs, provided measures are in place to prevent the export of those drugs between markets.

A similar business model applies to agricultural technologies, where companies seek their primary remuneration in developed country markets, leaving those technologies available at low cost in developing countries. The Golden Rice project is an example of the utilization of technologies for the production of vitamin- and protein-enriched rice for poor farmers comprised of technologies and genetic material which had been exploited in different industries, such as brewing and pharmaceuticals in developed countries. The development of new products, such as orphan commodities at affordable prices for the poor, will inevitably involve greater private and public sector cooperation.

Applying this market segmentation approach, it may be possible to limit the use of private sector proprietary technologies according to those crops or crop varieties that are produced or consumed primarily by poor farmers or to localities predominantly populated by poor farmers or limiting use to those crops that are consumed domestically and not exported.[21]

Agricultural research in the USA was promoted by the establishment of Land Grant Colleges, which were created in the late 1800s to advance teaching and research in agriculture.[22] The land grant system began in 1862 with the Morrill Act, which gave States public lands provided the lands be sold or used for profit and the proceeds used to establish at least one college that would teach agriculture and the mechanical arts. The Second Morrill Act, passed by Congress in 1890, provided for annual appropriations to each State to support its land grant college. This legislation was enacted at a time when more than half of the US population lived on farms, and 60% of the labour force was employed in agriculture. Traditionally, discoveries in public research institutions and agricultural universities were treated as public goods and flowed freely to farmers and businesses. With the growth of the US economy, most colleges of agriculture were transformed into universities and expanded their activities beyond teaching and research in agriculture. Another significant impact upon the system has been the reduction in federal funding at a time when the biotechnology revolution has increased the expense of agricultural research and the possibility of protecting agricultural innovations through patenting.

[21] See D. Byerlee and K. Fischer (2001) Accessing modern science: policy and Institutional options in developing countries. *IP Strategy Today* 1, www.biodevelopments.org/ip/ipst1n.pdf.

[22] See Committee on the Future of the Colleges of Agriculture in the Land Grant University System (1995) *Colleges of Agriculture at the Land Grant Universities. A Profile.* National Academy Press, Washington DC.

Educational funding policy was also influenced by the belief that innovations created by government-sponsored research were under-commercialized, by universities accustomed to a ready supply of public funds. These factors drove the passage of the Bayh–Dole Act, which was designed to encourage universities to license their inventions to the private sector, thereby encouraging commercial use. Universities hoped that the exploitation of their IP would help make up funding shortfalls. The Stevenson–Wydler Act allowed federal research laboratories to exercise the same privileges.

The US example has been imitated in many other countries, including in the developing world.[23] An unintended consequence of the attempt to stimulate entrepreneurship in publicly funded research institutes is that applied research is promoted at the expense of theoretical analysis. Also, the funding authorities and donors are increasingly expecting research institutes to generate their own research funds by commercializing their innovations. In this environment, agricultural researchers are going to behave the same way as the private sector and focus their attention on lucrative Northern crops, rather than those of significance for poor farmers.

10.4 Open Source Licensing

A suggestion, which is in the course of exploration, is the dissemination of biotechnology in a non-proprietary fashion through open source licensing, which places innovations in the public domain. This idea, which has been inspired by the open source software movement, is a means of overcoming the difficult and expensive access to proprietary technologies.[24] Various software licence models exist for emulation. The most popular among these are reciprocal licences, which allows the user to modify and redistribute a software program at will with the obligation to make relevant downstream technologies available to all including the original licensor, under the same terms as provided by the original licence. This is designed to make any downstream innovations available to all.

Among the life-sciences open source-style licences listed by Hope[25] are a Canadian proposal for a General Public License for plant germplasm, the international haplotype mapping (HapMap) project, the Biobricks Foundation, Tropical Diseases Initiative (TDI), Science Commons and Biological Innovation for Open Society (BIOS). However, as Hope points out, the software example is not easy to transpose to the biotechnology context, because of the complexity of biotechnologies, compared with copyrights.[26]

Until recently, the Centre for the Application of Molecular Biology to International Agriculture (CAMBIA), a non-profit organization based in Australia, undertook

[23] See G.D. Graff (2007) Echoes of Bayh–Dole? A survey of IP and technology transfer policies in emerging and developing economies. In: A. Krattiger, R.T. Mahoney, L. Nelsen, J.A. Thomson, A.B. Bennett, K. Satyanarayana, G.D. Graff, C. Fernandez and S.P. Kowalski (eds) *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*. MIHR, Oxford and PIPRA, Davis, CA, 169.

[24] See J. Hope, Open source licensing, in ibid., 107.

[25] Ibid., at 115.

[26] Ibid.

research in molecular biology in agriculture directed at the needs of developing countries and also developed patent and technology databases. One of these, the Patent Lens, is an open access, open source, integrated informatics platform of worldwide patent data with tools to make patents and patent landscapes more transparent and navigable, and to explore paths leading to fair and equitable innovation capabilities.[27] CAMBIA has prepared a model licence 'BiOS (Biological Open Source)' as a 'legally enforceable framework' to enable the sharing of the capability to use patented and non-patented technology, which may include materials and methods, within a dynamically expanding group of those who all agree to the same principles of responsible sharing, a 'protected commons' under which subscribers 'agree not to assert IP rights against each other's use of the technology to do research, or to develop products either for profit or for public good'.[28]

As part of CAMBIA's BiOS initiative has been its establishment of 'BioForge' as a prototype protected commons of enabling technologies in biotechnology available for use in improvement and new innovations through specially constructed BIOS licences.[29] It is an Internet-based platform of tools to allow scientists in diverse locations to find out about and work together with those who are positioned to apply their research. For example, CAMBIA makes available the 'TransBacter™' method of gene transfer for plants using bacterial species outside the extensively patented genus *Agrobacterium*. Similarly, 'GUSPlus™' is made available as a new reporter gene for use in molecular biology, with GUSPlus vectors for checking transformations and screening transformants, and special vectors for use with TransBacter strains. This is made available as an alternative to the beta-glucuronidase (GUS) enzyme from *E. coli*, which was considered to have a number of problems.

10.5 Public Intellectual Property Resource for Agriculture

An open source development in the field of agricultural research is the establishment of the Public Intellectual Property Resource for Agriculture (PIPRA). This was established as a collaboration promoted by the Rockefeller and McKnight foundations between currently 40 public and/or private non-profit agricultural research institutions,[30] to promote access to agricultural technologies developed by those institutions for both 'humanitarian and neglected commercial purposes'.[31] An immediate impetus for the formation of PIPRA was the difficulty confronting the Golden Rice project in securing access to the various blocking patents.

PIPRA's primary strategies to improve access to agricultural technologies are to:

- provide an IP clearinghouse for access to public-sector patented technologies;
- provide a resource for the analysis of patented technologies for implementation of specific projects;

[27] http://www.patentlens.net/daisy/patentlens/patentlens.html.
[28] http://www.bios.net/daisy/bios/mta/license-intro.html.
[29] http://www.cambia.org/daisy/cambia/4292.html.
[30] http://www.pipra.org/en/about.en.html.
[31] R.C. Atkinson, R.N. Beachy, G. Conway, F.A. Cordova, M.A. Fox, K.A. Holbrook, *et al.* (2003) Public sector collaboration for agricultural IP management. *Science* 301(5630), 174.

- develop gene transfer and gene-based-trait technologies that have maximum legal FTO;
- manage pools of public sector technologies to promote availability and reduce transaction costs associated with the transfer of rights to patented technologies; and
- support the development of IP management best practices and capacity enhancement in developing countries.[32]

Another PIPRA programme involves building an IP database, currently accessing approximately nine million patents. The goal of the database is to inform public sector researchers about their freedom to bring new products to market and to find 'ways to invalidate patents and minimize the chances of patent blocking'.[33]

10.6 Non-assertion Covenants

A form of transaction which is of the same genus as open source is the non-assertion covenants (NAC) by which permission is granted by a rights holder to third parties to use the IPR, which they would otherwise infringe. The NAC was developed in 2006 in the context of open-source software, when a number of major software companies announced that they would not seek to enforce any of their patents concerning certain Web-based applications.[34] The Massachusetts Institute of Technology (MIT), the Max Planck Gesellschaft zur Förderung der Wissenschaften e.V. and the Whitehead Institute for Biomedical Research introduced NACs to the field of biotechnology, when they announced that they would not assert their patents against companies that sell or use DNA vectors that induce production of small interfering RNA endogenously, 'provided that such vectors are only used for research purposes, and provided that the RNA that mediates RNA interference is not isolated from the transformed cells'.[35]

An NAC may take the form of an agreement between two or more parties or it may take the form of a public statement, such as when Monsanto in 2000 offered access to researchers to its map of the rice genome.

10.7 Defensive Publication

Another way in which IP rights can be placed in the public domain can be through defensive publication, which precludes patenting or PVP by others by destroying the novelty or inventiveness of an innovation.[36] This can be done through the advance publication of an invention or by the filing of a provisional patent application.

[32] R.T. Mahoney and A Krattiger (2007) The role of IP management in health and agricultural innovation. In: A. Krattiger, R.T. Mahoney, L. Nelsen, *et al*., n.23 supra, at 3.
[33] R. Eiss, K.E. Hanna and R.T. Mahoney, Sharing the art of IP management', ibid., 63 at 75.
[34] See A. Krattiger, The use of nonassertion covenants: a tool to facilitate humanitarian licensing, manage liability, and foster global access, ibid., 739.
[35] http://www.web.mit.edu/tlo/www/industry/nonassert_statements.html.
[36] See S. Boettiger and C. Chi-Ham, Defensive publishing and the public domain. In: A. Krattiger, R.T. Mahoney, L. Nelsen, *et al.* n.23 supra, at 879.

Publication is broadly interpreted by most patent offices to mean any printed or web document which is freely available to the public. IBM uses its *Technical Disclosure Bulletin* as a means of defensive publishing.[37] An empirical study in 2008 by Henkel and Pangerl[38] found that defensive publishing is widely practised, with more than two-thirds of the firms they sampled in Europe, making use of it either through publication in specialist journals and on specialist web sites as well as through peer-reviewed journals, public notice boards and company-owned journals. They also found that patent applications were sometimes used for the sole purpose of creating prior art.[39] The legal test of what has to be disclosed is sufficient detail for a person skilled in the art to be able to make and use the invention after reading the disclosure.

Henkel and Pangerl found four categories of motives to choose defensive publishing over patenting and secrecy: (i) the patent (if granted) is of limited value because the invention is protected by complementary assets or because the patent would be costly to enforce; (ii) it is less costly than patenting; (iii) to preserve FTO is crucial where there is a risk that a competitor may patent; and (iv) there is uncertainty about patentability.[40]

A problem with defensive patenting is that some broad patents may incorporate some technologies, which may not be placed in the public domain. The example is given of Monsanto's claim to the plant transformation method using *Agrobacterium*, which means that all patents in which the claims specifically depend on this transformation method are blocked by the patent.[41]

Patenting provides an opportunity to segment the market of technology users, by field of use or geographic area of use. For example, the UC Davis patent over the *Xa21* gene, concerned with resistance of plants to bacterial blight, may be licensed for use by rice farmers in Asia, but not by tomato growers in the Northern Hemisphere.

A provisional patent application is an informal type of patent application which is permitted in some countries for the purpose of establishing a priority filing date and providing inventors with one additional year to prepare and file a formal application. The provisional patent application does not require all the formal aspects of a patent application, such as the full claims. All that is required is a written description of an invention, a disclosure of an invention and of the best mode of the invention, and any drawings necessary for understanding or performing the invention.[42]

[37] A search of the US Patent database from 1996 to 2001 reveals almost 10,000 patents that cite the *IBM Technical Disclosure Bulletin* as prior art; B. Barrett (2001) Defensive use of publications in an intellectual property strategy. *Nature Biotechnology* 20, 191.

[38] J. Henkel and S. Pangerl (2008) *Defensive Publishing. An Empirical Study.* DRUID Working Paper 08-04, Copenhagen, Danish Research Unit for Industrial Dynamics.

[39] Ibid., at 3.

[40] Ibid., at 2.

[41] The example is given of US Patent No. 6,369,298 assigned to Pioneer Hi-Bred International, Inc. for the transformation of sorghum in which the claimed technology depended on the *Agrobacterium* transformation method, requiring a licence from Monsanto. See ibid., at 885.

[42] See R.L. Cruz, Provisional patent applications: advantages and limitations. In: A. Krattiger, R.T. Mahoney, L. Nelsen, *et al.*, n.23 supra at 900.

11 Assessment of the Relationship between Intellectual Property and Food Security

11.1 Policy Perspective

The role of IP in eliminating food insecurity has to be placed in its proper policy perspective. Development experience since the 1950s attributes rural poverty and food insecurity in developing countries to development strategies that overlooked the importance of the development of the agricultural sector, particularly the production of staple foods.[1] Thus the enhancement of food security in developing countries requires a package of policies that address the supply, distribution and consumption aspects of the food chain. The FAO has noted that the policy options available to poor countries are constrained by a number of factors including: (i) limited resources for public spending programmes; (ii) the dilemma between remunerative prices for producers and prices that a large number of poor households can afford, thus making the option of border protection less attractive, despite high bound tariffs; (iii) major constraints on foreign exchange availability leading to pressure to boost production of export crops.[2]

As was seen in Chapter 1 of this volume, a new Green Revolution is called for to deal with the current food security crisis. It has been reported that by 2020 'cereal production will need to increase by 41%, meat by 63% and roots and tubers by 40% … without any significant expansion of agricultural area'.[3] However, it is important to bear the negative results of that first revolution in mind, particularly the decline of soil fertility resulting from the excessive use of fertilizers, pollution caused by the excessive use of pesticides, as well as the growth of salinity and the water-logging of

[1] FAO (2000) *The State of Food and Agriculture: Lessons from the Past 50 Years*. FAO, Rome.

[2] FAO (2001) *Incorporating Food Security Concerns in a Revised Agreement on Agriculture*. FAO Round Table on Food Security in the Context of The WTO Negotiations on Agriculture, 20 July, Discussion paper no. 2.

[3] C. Spillane (1999) *Recent Developments In Biotechnology as they Relate to Plant Genetic Resources for Food and Agriculture*. FAO Commission on Genetic Resources for Food and Agriculture, Background Paper No. 9, April, 49.

soils.[4] Even if these environmental impacts can be circumvented, the economic impacts must also be borne in mind. Increases in yields were accompanied by reductions in farm income, through the expense for farmers of purchasing chemical inputs and the reduction of selling prices in glutted markets. The new Green Revolution which is prophesied involves the use of GM crops. There is not yet strong evidence that GM cops will effect a Green Revolution in developing countries. The latest studies indicate 'positive, but highly variable, economic returns' to adopting transgenic crops in which 'institutional factors such as national research capacity, intellectual property rights, environmental and food safety regulatory capacity, trade regulations and the existence of functioning input markets are crucially important determinants of the level and distribution of gains'.[5]

New agricultural technologies should contribute to food security through increasing the aggregate supply of food. To this end, policies are required to promote agricultural research which could contribute to food security in developing countries, particularly in relation to orphan crops. Where IP could make its greatest contribution is in the incentivization of beneficial agricultural innovations. Historically, the strongest incentives have been those arising from the marketing of hybrid seeds, which provide higher yields, with the commercial benefit to the seed marketer that the seeds of the offspring cannot be used by the farmer because these seeds do not breed true-to-type. As is discussed above, the evidence for incentives to breeding research for crop plants is limited and in developing countries, it is even more questionable whether PVP and patenting will be useful in encouraging a national seed industry. Barton suggests that a developing country 'is probably best-off adopting minimum compliance with TRIPS, which requires at least some form of *sui generis* protection for plants – although there is the possibility that a number of nations with similar agricultural conditions could combine their markets in some way that encouraged private investment. Moreover, use of UPOV-style laws might help in commercializing varieties developed by the public sector.'[6]

The question of whether a developing country will adopt a *sui generis* PVP system or a patent-based system, to comply with Art. 27.3(b) of the TRIPS Agreement (unless that Agreement is amended along the lines suggested in the communication to the TRIPS Council of the African Group)[7] will depend upon the technological sophistication of agricultural research in that country. Where agricultural research involves classical plant breeding, PVP would be the likely route. Where, however, a country has developed a capacity for microbiological research, then patenting becomes an option. In both countries the form of protection which is adopted will depend upon the nature of the registration facilities that are available. For a PVP system, facilities for test breeding are required. For patenting appropriate examination facilities will be required. In both cases there is the possibility for regional co-operation. This is probably more advanced in relation to patenting where there are

4 See V. Shiva (1991) *Violence of the Green Revolution, Third World Agriculture, Ecology and Politics*. Third World Network, Delhi and ZED Books, London; G.S. Dhaliwal and V.K. Dilwari (1991) Impact of the Green Revolution on environment. In: B.S. Hansra and A.N. Shukra (eds) *Social, Economic and Political Implications of Green Revolution in India*. Classical Publication, New Delhi.

5 T. Raney (2006) Economic impact of transgenic crops in developing countries. *Current Opinion in Biotechnology* 17, 1.

6 J. Barton (2003) *Nutrition and Technology Transfer Policies*. UNCTAD/ICTSD, Geneva, August, 11.

7 WTO Doc., 1P/C/W/404, 20 June 2003.

regional patent offices, or the availability of international searching for PCT members. The EU provides an example of the regionalization of PVP, through the Community Plant Variety Rights Office.

As for the protection of traditional knowledge and the necessity to address the misappropriation of genetic resources, progress has been very slow. On 23 October 2008, after 13 sessions of the WIPO IGC, the negotiating parties agreed on the importance of these subjects but failed to agree on the best ways to achieve progress. They were divided between legally binding measures preferred by most developing countries and non-binding measures and further research preferred by developed countries. At present, the way forward, which has been proposed by the African group of countries, is the formation of three taskforce groups: on traditional cultural expressions, traditional knowledge and genetic resources. The first two groups should address the definitions and subject matter of protection, exceptions and limitations and duration, PIC and moral/economic rights to knowledge, beneficiaries and *sui generis* options for protection.[8] The taskforce group on genetic resources should examine the development of disclosure requirements and alternative proposals for dealing with the relationship between IP and genetic resources. The African proposal stressed that the work of this taskforce group must be carried out 'without prejudice to work in other international fora'. Participation in each of these fora will require the enhancement of the negotiating capacity of developing countries.

11.2 Recommendations for Action

Policy capacity building

The TRIPS Agreement recognizes in its preamble 'the underlying policy objectives of national systems for the protection of IP, including developmental and technological objectives' and the 'special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base'. The TRIPS Agreement in Art. 7 declares that the protection and enforcement of IPR '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'. The TRIPS review processes in general require the development of an IP policy capacity on the part of developing and least-developed Members of the WTO. The food technology debate and the question of access to new technologies is a complex and multi-dimensional issue in which IP is usually a vital component.

Article 8.1 of the TRIPS Agreement indicates that 'Members may, in formulating or amending their law 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 this Agreement'. The scope of this provision

[8] http://www.ip-watch.org/files/africaproposalintersessional.pdf.

remains to be charted and it counsels a multi-disciplinary approach. Indeed, in addition to law, the formulation of IP and food security policy has now to accommodate considerations of economics and finance, science and technology, ethics and philosophy, medicine, agriculture and culture. As IP policies are currently being formulated by international and inter-governmental organizations as diverse as the WTO, WIPO, FAO, CBD, UNCTAD, UNEP, UNESCO and WHO, developing countries and LDCs that have to engage with this process have to construct IP policy capacity in the areas of: public health (patenting, confidential information, compulsory licensing, parallel importation); food security (patenting and plant variety protection); agricultural research (access to proprietary enabling technologies, development of IP assets; genomics and bio-informatics, bio-prospecting and access to genetic resources); agricultural trade (patenting, plant variety protection, GIs); general trade (trademark protection, piracy and counterfeiting, border control of IP rights); technology transfer (approval of technology transactions, technology packaging, control of restrictive licences, remuneration); the impact of digital technologies (copyright and computer programs, software patenting, communication technologies, domain names, ecommerce, encryption and technological controls, reprographic technologies, electronic rights management); enforcement of IP rights (civil litigation, judicial adjudication, criminal enforcement, alternative dispute resolution, jurisdictional issues); traditional knowledge and folklore; establishment and management of IPRs (patent examination and searching, registration of rights, compulsory licensing).

In all countries, there is a plethora of government ministries and public institutions that have to deal with public policy issues raised by different parts of IP. This has two implications: first, the various ministries, e.g. trade, industry, agriculture, health, justice and education, bring their own competencies and biases to the subject, with the result that conceptions of IP become muddled; and secondly, in developing countries and LDCs, experience in the formulation and implementation of IP policy is limited and generally not available across the entire spectrum of ministries. The construction of IP policy capacity in developing countries and LDCs so that they can engage more effectively in IP dialogues in the various national, regional and international fora is imperative. The focus of this initiative would be not on fostering knowledge on IP as the end, but on advancing approaches to IP that can serve central public policy ends such as food security, fostering innovation, creativity, development and the public diffusion of knowledge and ideas. This initiative would support the emergence of IP policy leaders in developing countries and LDCs committed to poverty reduction, equity and fairness to engage in the: (i) design and implementation of appropriate domestic policies; and (ii) process of international IP standard-setting.

A capacity building initiative could be undertaken with the establishment of a global, self-sustaining network of developing country experts, policy makers and scholars who would engage at the national and international level in IP agricultural policy debates with an eye to advancing the public policy interests of developing countries and LDCs, and in particular the interests of the poor, ethical considerations and development in those countries. This network could be envisaged as a twinning arrangement between institutions in developing countries and LDCs, which would help develop an approach to training and leadership development that provides an alternative to existing capacity building efforts. The initiative would not be focused simply on legal understanding and implementation of existing IP laws, but on

evaluating them, formulating food security policies relevant to national and local circumstances. The network would:

- facilitate the establishment of regional and national IP-agri policy networks in the South;
- identify the substantive and policy priorities of different regions and potential participants;
- develop criteria to guide a needs assessment, both of potential trainers and beneficiaries, for each aspect of capacity building in IP and food security policy;
- develop criteria for use in identifying beneficiaries, mentors and partners that have a record of commitment to the public interest and the desired commitment to engaging in IP and food security policy debates from a public interest perspective;
- become an international medium for the effective exchange of information in the rapidly developing IP food security policy world; and
- provide effective mentoring for IP food security policy experts in the South.

Implementation of the FAO ITPGRFA

Of particular institutional significance for the guarantee of food security is the ratification and implementation by countries of the FAO ITPGRFA and, in particular, the implementation of the Treaty's provisions relating to the refusal of IP protection of any material transferred in the framework of the multilateral system, together with the implementation of Farmers' Rights at the national level.

The use of the SMTA which has been developed under the Treaty, in particular its provisions restricting the availability of IPR in germplasm, will preserve the accessibility of that germplasm for future crop development.

Implementation of the informed consent and benefit-sharing principles of the CBD

The principle of informed consent in relation to the bioprospecting activities of enterprises, as well as the sharing of benefits resulting from the exploitation of those resources with source communities, should be adopted. This support could be seen to be an equitable trade-off for the costs incurred by developing countries in adopting the TRIPS IP regime and could be manifested: (i) in implementing the informed consent and benefit-sharing principles of the CBD; and (ii) in including benefit sharing and informed consent within Art. 27.3(b) of the TRIPS Agreement.

Recognizing the rights of source countries where IP rights are obtained over biological materials

As the various 'biopiracy' episodes indicate, developing countries perceive that the TRIPS regime requires rebalancing to reflect the economic interests of countries at all levels of development. The recognition of the rights of source countries in relation to biological material which is patented or over which PVP rights are obtained is something which has assumed great political significance. In so many areas, developing countries are in the position of supplicants for aid, but the biodiverse circumstances of developing countries, particularly in the tropics, places them in a position where they can be the providers, rather than the recipients of resources. Furthermore, developing countries that are obliged to assume the costs of implementing the comprehensive system of IP protection mandated by TRIPS would be in the position of receiving something from that system, if the rights of source countries were recognized in the international IP system.

As a matter of practical significance, it is often difficult to identify the source of plants and plant derivatives where genetic material may come from numerous sources, some of which may no longer be identifiable because of the lack of documentation and the length of time between its acquisition and its use in breeding programmes. The formulation of a workable country of origin system should also be an objective of international negotiations.

Recognition of the protection of traditional agricultural knowledge

As was mentioned in the introduction above, since its creation in 2001, WIPO's IGC has made limited progress towards legislative proposals for the protection of traditional knowledge. The proposal for further gaps has been criticized as an excuse for maintaining the glacial progress as 'member states involved in the process over the years … must know the gaps in protection by now!'[9] However, a more substantial criticism of the IGC process was the failure to include the WIPO Indigenous Caucus in the IGC's consultations.[10] The least that can be urged is that the requirements of the UN Declaration on the Rights of Indigenous Peoples be complied with, namely that 'Indigenous peoples have the right to participate in decision-making in matters which would affect their rights, through representatives chosen by themselves in accordance with their own procedures, as well as to maintain and develop their own indigenous decision-making institutions'.

One of the reasons for the slowness in producing a negotiating text for the protection of traditional knowledge may be the fact that this subject has been raised in a number of international fora and is being considered by a number of international and intergovernmental organizations. As a consequence each organization will defer to the experience of others, or at least of WIPO, where a lack of progress has been noted. The development of a negotiating text on traditional knowledge is something which could be undertaken by the proposed IP policy network, mentioned above.

[9] M. Goffe (2008) Sabotage. http://tkcommunity.blogspot.com/, October 17.
[10] See J. Gibson, Indigenous boycott at WIPO, ibid.

Protection of GIs for agricultural products

It has been suggested that GIs may be of particular interest to those developing countries which have, or might be able to achieve, a comparative advantage in agricultural products and processed foods and beverages. Of course, these benefits have to be weighed against the expense of enforcement actions, as well as the expense of protecting the geographical indication in the country of origin. Those countries which have mature GI systems could usefully assist in the preparation of case studies and cost analyses of the likely impact of introducing a registration system.

EU assistance, in particular, would also be useful in exploring with developing countries and LDCs the way in which a policy on GIs could be integrated with the formulation of rural policy in the context of sustainable food security.

As with the protection of traditional knowledge, the IP policy network mentioned above could lend its support to the proposal to extend the multilateral register for the geographical indication of wines envisaged within the context of the negotiations under Art. 24 of the TRIPS Agreement, to agricultural and other products.

Technology transfer in support of food security

The relationship between the TRIPS Agreement and development has been raised narrowly in the contexts of the implementation of the Agreement and more transcendentally in the context of the human rights to health and nutrition. Capacity building is required in developing countries to enable them to deal with the impacts of IPRs upon biotechnological research. Reference has been made above to capacity building in relation to the formulation of IP policy. Professor Jackson has proposed the establishment of a Genetic Resource and International Trade Institute 'to provide technical assistance training and research on genetic resources management and the rapidly changing policy environment to developing countries'.[11]

Article 66.2 of the TRIPS Agreement requires developed country members to 'provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base'. Article 67 provides for 'technical and financial cooperation in favour of developing and least-developed country Members' on request and on mutually agreed terms and conditions, 'in order to facilitate the implementation' of the TRIPS Agreement. The technical cooperation envisaged in Art. 67 includes 'assistance in the preparation of laws and regulations on the protection and enforcement of intellectual property rights as well as on the prevention of their abuse, and shall include support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel'.

A survey by UNCTAD identifies two broad but overlapping categories of technology-related provisions in international instruments: (i) standard setting to protect proprietary technology (e.g. the TRIPS Agreement and regional agreements

[11] L. Jackson (2000) Agricultural biotechnology and the privatization of genetic information: implications for innovation and equity. *The Journal of World Intellectual Property* 3, 825.

such as NAFTA, European Union, Andean Group and ASEAN legislation); and (ii) direct measures for transfer of technology to developing countries and LDCs (e.g. CBD).[12]

The CBD in Art. 16 provides for access to and transfer of biotechnology. In the case of developing countries, Art. 16.2 provides that this access to and transfer of technology shall be provided and/or facilitated under fair and most favorable terms, including on concessional and preferential terms where mutually agreed. Each Contracting Party agrees in Art. 16.4 to 'take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology … for the benefit of both governmental institutions and the private sector of developing countries'.

Article 17.1 of the CBD requires the Contracting Parties to facilitate 'the exchange of information, from all publicly available sources, relevant to the conservation and sustainable use of biological diversity, taking into account the special needs of developing countries' and specifies in Art. 17.2 that this exchange of information shall include 'exchange of results of technical, scientific and socio-economic research, as well as information on training and surveying programs, specialized knowledge, indigenous and traditional knowledge as such'.

Article 18 of the CBD provides that the Contracting Parties shall 'promote international technical and scientific cooperation in the field of conservation and sustainable use of biological diversity, where necessary, through the appropriate international and national institutions'. In promoting such cooperation, Art. 18.2 requires that 'special attention should be given to the development and strengthening of national capabilities, by means of human resources development and institution building' and Art. 18.4 envisages the promotion of cooperation in the training of personnel and exchange of experts and Art. 18.5, the 'establishment of joint research programs and joint ventures for the development of technologies' relevant to the objectives of the CBD.

There is not much evidence that these provisions have been implemented by developed countries in any systematic way. However, in a number of developing countries, these technology transfer obligations are tied in to the conditions for the grant of bioprospecting licences. In Costa Rica, 'InBio' has been set up as a public entity to allow Costa Rica to gain access to biotechnology assets in the form of technology licences, while providing access to Costa Rica's biotechnology assets and genetic resources, for commercial interest. This provides a first model of a method to utilize biotechnology IP assets in a fair, comprehensive and consultative manner. A number of universities and public research institutes in both developing countries and in more technically advanced countries have established technology transfer units to disseminate research results.[13] Very often the focus of the technology transfer office is to evaluate the research efforts of the institution and to identify commercial partners that will license the technology and assist in the commercialization of research findings.

[12] UNCTAD (2001) *Compendium of International Arrangements on Transfer of Technology: Selected Instruments*. UNCTAD/ITE/IPC/Misc.5, UNCTAD, Geneva, iv.

[13] See M. Blakeney (2002) Intellectual property, biological diversity and agricultural research in Australia. *Australian Journal of Agricultural Research* 53, 127–148.

Support should be provided by industrialized countries to technology transfer for the conservation of landraces and traditional food crops both *in situ* and *ex situ* in developing countries and LDCs. This technology transfer could be focused upon the food security requirements of developing countries.

A particular area of assistance could be in the development of best practices for bioprospecting, in which technology transfer is built into technology transfer licences as a condition of access to genetic resources.

Plant variety protection

As part of countries' obligations to introduce PVR protection, whether as a UPOV-style statute, or as *sui generis* legislation, the preservation of the right of farmers to save and exchange seed should be supported, as well as the maintenance of the exception from liability of research utilizing protected varieties. The compatibility between the systems for the protection of plant varieties and patents should be maintained by ensuring that the patenting of the genetic components of plants does not extend to the patenting of plants themselves, thereby compromising food security and undermining the research exception in PVP laws.

Clearing house mechanism

The establishment of the clearing house mechanism within the CBD should be supported as an initiative for the provision of information about IP applications concerning PGRFA worldwide. The development of a global mechanism for exchanging and integrating information on plant genetic resources would have the effect of reducing the loss of biodiversity and promoting the fair and equitable sharing of benefits. This would also facilitate the exploitation of genetic resources by developing countries and dealing directly with a traditional knowledge stakeholders and source countries through the mechanism would lower transaction costs. The mechanism would perform a number of useful functions: (i) the repository for national and community registers of indigenous knowledge, which would be maintained under strict obligations of confidentiality; (ii) a catalogue of knowledge and innovations, available for sale or licensing, as well as identifying that traditional knowledge which is unavailable; (iii) a register of legal experts who are available to assist indigenous and traditional communities in such negotiations and in evaluating research proposals; (iv) representing the stakeholders in national government and intergovernmental negotiations; (v) monitoring the use, e.g. patenting of traditional knowledge; (vi) a dispute resolution facility between stakeholders; (vii) promulgating industry bioprospecting standards, and contract terms; and (viii) engaging in awareness-raising activities.

As to whether the clearing house mechanism should function as a private organization or be part of a government or intergovernmental structure, it has been

urged that a private global bio-collecting society should be established to keep it outside inter-governmental politics.[14]

Agricultural research and innovation

Options for the provision of biological materials and enabling technologies for agricultural research have been discussed in Chapter 10. The World Bank has been urged to 'continue to build bridges between available biotechnology tools and their application for the improvement of crops and livestock in developing countries'.[15] Strategies to strengthen public–private partnerships and corporate investments in international agriculture, including the establishment of competitive funding schemes to encourage research links between advanced research institutes, both in the North and the South, with the CGIAR have been urged.[16]

The shift of funding away from the public agricultural research sector and away from the food crops of importance for developing countries points up an urgent need to attract increased investment in rural agricultural economies by promoting small agribusiness enterprises. The establishment of the PIPRA to promote access to agricultural technologies was discussed in Chapter 10. Another model is the Latin American Agribusiness Development Corporation (LAAD) which links finance and agricultural companies with small entrepreneurs in the rural areas, assisted by loans from the US Agency for International Development (USAID). This initiative could be created on a regional or sub-regional basis to secure investment funds from the philanthropic donor community and from the corporate sector which will be managed in harmony with local conditions.[17]

Establishment of a World Agriculture Organization

Krattiger has suggested that the agricultural research centres of the CGIAR be merged into a World Agricultural Organization with a mandate to 're-focus its attention on two strategic areas: the poorer developing countries with weak agricultural research and extension programs, and crops of specific importance to resource poor and subsistence farmers'.[18] He suggests that this will deal with the 'top heavy'

[14] See P. Drahos (2000) Indigenous knowledge, intellectual property and biopiracy: is a global bio-collecting society the answer? *European Intellectual Property Review* 22, 248.

[15] J.H. Dodds, R. Ortiz, J.H. Crouch, V. Mahalasksmi and K.K. Sharma (2001) Biotechnology, the Gene Revolution, and proprietary technology in agriculture: a strategic note for the World Bank, no. 2. *IP Strategy Today*.

[16] Ibid.

[17] See also Anatole Krattiger's proposal for an 'Investment Company for Development,' which would provide business investment services to local entrepreneurs, small companies, and university researchers in order to facilitate the acquisition and transfer of innovations from the laboratory to the market as well as from multinational companies to poorer rural areas. A.F. Krattiger (2002) Public–private partnerships for efficient proprietary biotech management and transfer, and increased private sector investments. A briefings paper with six proposals commissioned by UNIDO, No 4. *IP Strategy Today*. www.biodevelopments.org/ip/index.htm.

[18] A.F. Krattiger, 'How can intellectual property rights contribute to the food security of an increasingly globalized world while meeting the demands of farmers and breeders? http://www.infoagrar.ch/ipr-symposium/documents/Paper_Krattiger.pdf, 7.

institutional structure of the CGIAR and its limited research budget in comparison with the corporate sector.[19] The establishment of a new organization would permit the 'channelling' of existing technologies to the specific needs and priorities of the least developed countries and regions and 'would negotiate with technology owners and seek licences with the right to sublicense on a crop-by-crop, market-by-market, or technology-by-technology basis.'[20]

There are of course a number of major obstacles in achieving this result. Each of the CGIAR centres has its own constitution and headquarters agreement with its host country which may circumscribe the disposition of their germplasm collections and other property. It already has a centralized IP office[21] and a centralized food policy office.[22] Arguably the FAO already exists to provide a developing country perspective in matters of agricultural policy.

[19] Ibid.
[20] Ibid.
[21] Central Advisory Service on Intellectual Property, http://www.cas-ip.org/.
[22] Bioversity International, formerly the International Plant Genetic Resources Institute (IPGRI), http://www.bioversityinternational.org/.

Select Bibliography

ActionAid (1999) *Patents and Food Security*. ActionAid Briefing Paper, no. 5. ActionAid, London.

Adcock, M. and Llewelyn, M. (2000) Micro-organisms, Definitions and Options Under TRIPS. Paper prepared for a Discussion Meeting hosted by the Quaker UN Office – Geneva and the International Centre for Trade and Sustainable Development, 23 November.

Addor, F. and Grazioli, A. (2002) Geographical indications beyond wines and spirits – a roadmap for a better protection for geographical indications in the WTO TRIPS Agreement. *Journal of World Intellectual Property* 5, 865–897.

Ampofo, K.K.K. (1996/99) Enabling implementation of intellectual property protection in developing countries under the TRIPS Agreement: the role of the World Bank and the World Trade Organisation. *University of Ghana Law Journal* 20, 26–61.

Andersen, R. (2005) *Results from an International Stakeholder Survey on Farmers' Rights*. Background Study 2, FNI Report 9/2005, The Fridtjof Nansen Institute, Lysaker, Norway.

Andersen, R. (2006) *Realising Farmers' Rights Under the International Treaty on Plant Genetic Resources for Food and Agriculture. Summary of Findings from the Farmers' Rights Project, Phase 1*. The Fridtjof Nansen Institute, Lysaker, Norway.

Anuradha, R.V. (2001) IPRs: implications for biodiversity and local and indigenous communities. *Review of European Community and International Environmental Law* 10, 27–36.

Asian Development Bank (2001) *Agricultural Biotechnology, Poverty Reduction, and Food Security. A Working Paper.* ADB, Manila, May.

Barton, J. and Berger, P. (2001) Patenting agriculture. *Issues in Science and Technology* 17, 43–50.

Benbrook, C. (2007) Principles governing the long-run risks, benefits and costs of agricultural biotechnology. In: McManis, C.R. (ed.) *Biodiversity and the Law: Intellectual Property, Biotechnology and Traditional Knowledge*. Earthscan, London, pp. 149–167.

Biber-Klemm, S. and Cottier, T. (2006) *Rights to Plant Genetic Resources and Traditional Knowledge: Basic Issues and Perspectives.* CAB International, Wallingford.

Biggs, S. (1998) The biodiversity convention and global sustainable development. In: Kiely, R. and Marfleet, P. (eds) *Globalisation and the Third World*. Routledge, London, pp. 113–140.

Binenbaum, E., Nottenburg, C., Pardy, P.G., Wright, B.D. and Zambrano, P. (2003) South–North trade, intellectual property jurisdictions, and freedom to operate in agricultural research on staple crops. *Economic Development and Cultural Change* 51, 309–336.

Blakeney, M. (1997) Bioprospecting and the protection of traditional medical knowledge. *European Intellectual Property Review* 6, 296–303.

Blakeney, M. (1999) Ethnobiological knowledge and the intellectual property rights of indigenous peoples in Australia. In: Blakeney, M. (ed.) *Intellectual Property Aspects of Ethnobiology*. Sweet & Maxwell, London, pp. 83–100.

Blakeney, M. (1999) The international framework of access to plant genetic resources. In: Blakeney, M. (ed.) *Intellectual Property Aspects of Ethnobiology*. Sweet & Maxwell, London, pp. 1–22.

Blakeney, M. (2000) Intellectual property in agriculture. In: O'Brien, L. and Henry, R.J. (eds) *Transgenic Cereals*. American Association of Cereal Chemists, St Paul, MN, pp. 277–301.

Blakeney, M. (2000) Plant variety protection, international agricultural research and exchange of germplasm: legal aspects of the new *sui generis* regimes. In: Padolina, W. (ed.) *Plant Variety Protection of Rice in Developing Countries. Impacts on Research and Development*. IRRI, Los Banos, Philippines, pp. 9–22.

Blakeney, M. (2001) Intellectual property and agriculture: the issue of biotechnology. In: McMahon, J.A. (ed.) *Trade & Agriculture. Negotiating a New Agreement?* Cameron May, London, pp. 349–379.

Blakeney, M. (2001) Intellectual property rights and global food security. *Bio-Science Law Review* 4, 127–140.

Blakeney, M. (2001) Proposals for the international regulation of geographical indications. *Journal of World Intellectual Property* 4, 629–652.

Blakeney, M. (2001) Intellectual property aspects of traditional agricultural knowledge. In: Blakeney, M. and Drahos, P. (eds) *IP in Biodiversity and Agriculture: Regulating the Biosphere*. Sweet & Maxwell, London, 29–52.

Blakeney, M. (2002) Intellectual property aspects of traditional agricultural knowledge. In: Evenson, R.E., Santaniello, V. and Zilberman, D. (eds) *Economic and Social Issues in Agricultural Biotechnology*. CAB International, Wallingford, pp. 43–60.

Blakeney, M. (2002) Agricultural research: intellectual property and the CGIAR system. In: Drahos, P. and Mayne, R. (eds) *Global Intellectual Property Rights. Knowledge, Access and Development*. Palgrave Macmillan, London, pp. 108–124.

Blakeney, M. (2002) Protection of plant varieties and farmers' rights. *European Intellectual Property Review* 24, 9–19.

Blakeney, M. (2002) Intellectual property, biological diversity and agricultural research in Australia. *Australian Journal of Agricultural Research* 53, 127–148.

Blakeney, M. (2004/05) 'Terminator' technology: a technological fix for an IP problem? *Bio-Science Law Review* 7, 229–236.

Blakeney, M. (2004) International proposals to regulate intellectual property rights in plant genetic resources. In: Evenson, R.V. and Santaniello, V. (eds) *The Regulation of Agricultural Biotechnology*. CABI, Wallingford, pp. 35–52.

Blakeney, M. (2004) Bioprospecting and biopiracy. In: Ong, B. (ed.) *Intellectual Property and Biological Resources*. Marshall Cavendish, Singapore.

Blakeney, M. (2005) Stimulating agricultural innovation. In: Maskus, K.E. and Reichman, J.H. (eds) *International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime*. Cambridge University Press, Cambridge, pp. 367–390.

Blakeney, M. (2006/07) The role of competition in biotechnological patenting and innovation. *Bio-Science Law Review* 9, 95–101.

Blakeney, M. (2007) Plant variety protection, international agricultural research, and exchange of germplasm: legal aspects of sui generis and patent regimes. In: Krattiger, A., Mahoney, R.T., Nelsen, L., Thomson, J.A., Bennett, A.B., Satyanarayana, K., Graff, G.D., Fernandez, C. and Kowalski, S.P. (eds) *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*. MIHR, Oxford, pp. 401–418.

Blakeney, M. (2007) Biotechnological patenting. Law, ethics and science. In: Ghidini, G. and Cavani, G. (eds) *Brevetti E Biotecnologie*. Luiss University Press – Pola s.r.l, Rome, pp. 21–35.

Blakeney, M. (2007) Auditing intellectual property rights by public research institutes. In: Westkamp, G. (ed.) *Emerging Issues in Intellectual Property. Trade, Technology and Market Freedom: Essays in Honour of Herchel Smith*. Edward Elgar, Cheltenham, pp. 14–34.

Blakeney, M. and Egelyng, H. (2001) Plant variety protection in Asia: some issues of implementation and implications for germplasm exchange networks. In: Blakeney, M. and Drahos, P. (eds) *IP in Biodiversity and Agriculture: Regulating the Biosphere*. Sweet & Maxwell, London, pp. 85–100.

Blakeney, M., with Lightbourne, M. (2005) Geographical indications, traditional knowledge and basmati rice. In: O'Connor, B. (ed.) *Agriculture in WTO Law*. Cameron May, London, pp. 349–376.

Blakeney, M., Kulkarni, R.S.K., Reddy, C. and Rao, A.M. (2008) Intellectual property rights and protection of agbiotechnological inventions. In: Kole, C. and Abbott, A.G. (eds) *Principles and Practices of Plant Genomics*. Science Publishers, Enfield, NH, pp. 465–485.

Bragdon, S. (2003) Major legal regimes affecting plant genetic resources. In: Cottier, T. and Mavroidis, P.C. (eds) *Intellectual Property: Trade, Competition, and Sustainable Development*. World Trade Forum, Vol. III. University of Michigan Press, Ann Arbor, MI, pp. 441–453.

Brush, S.B. (1994) *Providing Farmers' Rights Through* In-situ *Conservation of Crop Genetic Resources*. Background Study Paper No. 3. Commission on Plant Genetic Resources, First Extraordinary Session, Rome.

Brush, S.B. (ed.) (2000) *Genes in the Field. On-Farm Conservation of Crop Diversity*. Lewis Publishers, Rome.

Brush, S.B.P. (1995) In situ conservation of landraces in centers of crop diversity. *Crop Science*, 35, 346–354.

Bugos, G.E. and Kevles, D.J. (1992) Plants as intellectual property: American practice, law, and policy in a world context. *Osiris* 7, 75–104.

Butler, L.J. and Marion, B.W. (1983) *The Impacts of Patent Protection on the US Seed Industry and Public Breeding*. University of Wisconsin, Madison, WI.

Buttel, F.H. and Belsky, J. (1987) Biotechnology, plant breeding, and intellectual property: social and ethical dimensions. *Science, Technology, and Human Values* 12, 31–49.

Carvalho, N.P. de (2000) Requiring disclosure of the origin of genetic resources and prior informed consent in patent applications without infringing the TRIPS Agreement: the problem and the solution. *Washington University Journal of Law & Policy* 2, 371–401.

Carvalho, N.P. de (2003) From the shaman's hut to the Patent Office – in search of effective protection for traditional knowledge. *Washington University Journal of Law & Policy* 17, 111–186.

CIDSE (International Co-operation for Development and Solidarity) (2000) Bio patenting and the threat to food security, Part 1 – Bio patents: A Christian and development perspective. CIDSE, Brussels.

CIPR, *Integrating Intellectual Property Rights and Development Policy*. Report of the UK Commission on Intellectual Property Rights, CIPR, London.

Cohen, J., Falconi, C., Komen, J. and Blakeney, M. (1998) *The Use of Proprietary Biotechnology Research Inputs at Selected CGIAR Centres*. CGIAR, The Hague.

Cohen, J. Blakeney, M. and Crespi, S. (1999) Intellectual property rights and agricultural biotechnology. In: Cohen, J. (ed.) *Managing Agricultural Biotechnology. Addressing Research Program Needs and Policy Implications*. CAB International, Wallingford, pp. 209–227.

Correa, C. (2000) *Options for the Implementation of Farmers' Rights at the National Level*. T.R.A.D.E. Working Paper No. 8. South Centre, Geneva.

Correa, C.M. (2000) *Intellectual Property Rights, the WTO and Developing Countries. The TRIPS Agreement and Policy Options*. Third World Network, Penang.

Correa, C. (2001) *Traditional Knowledge and Intellectual Property – Issues and Options Surrounding the Protection of Traditional Knowledge – A Discussion Paper*. Quaker United Nations Office, Geneva.

Correa, C.M. (2003) *Establishing a Disclosure of Origin Obligation in the TRIPS Agreement*. Quaker UN Office, Geneva.

Correa, C.M. (2005) *The Politics and Practicalities of a Disclosure of Origin Obligation*. Occasional Paper 16. Quaker United Nations Office, Geneva.

Correa, C.M. (2007) *Trade Related Aspects of Intellectual Property Rights. A Commentary on the TRIPS Agreement*. Oxford University Press, Oxford.

Conway, G. (1997) *The Doubly Green Revolution: Food for All in the Twenty-First Century*. Penguin Books, Harmondsworth.

Cottier, T. (1998) The protection of genetic resources and traditional knowledge: towards more specific rights and obligations in world trade law. *Journal of International Economic Law* 5, 555–584.

Crosby, A. (1986) *Ecological Imperialism: The Biological Expansion of Europe, 900–1900*. Cambridge University Press, Cambridge.

Crucible Group (1994) *People, Plants and Patents: The Impact of Intellectual Property on Biodiversity, Conservation, Trade and Rural Society*. International Development Research Centre, Ottawa.

Crucible II Group (2000) *System-Wide Information Network on Genetic Resources of the CGIAR, Seeding Solutions*, Vol. 1. International Plant Genetic Resources Institute (IPGRI), Dag Hammerskjöld Foundation, Rome.

Crucible II Group (2001) *Seeding Solutions*, Vol. 2. *Options for National Laws Governing Access to and Control Over Genetic Resources*. IPGRI, IDRC, DHF, Rome.

Cullet, P. (2001) Property rights over biological resources – India's proposed legislative framework. *Journal of World Intellectual Property* 4, 211–230.

Cullet, P. (2005) *Intellectual Property Protection and Sustainable Development*. LexisNexis, New Delhi.

Cunningham, E.P. (1999) *Recent Developments in Biotechnology as they Relate to Animal Genetic Resources for Food and Agriculture*. CGRFA Background Study Paper No. 10. FAO, Rome.

DEFRA, Food Chain Analysis Group (2006) *Food Security and the UK: An Evidence and Analysis Paper*. DEFRA, London, December.

Dhar, B., Chaturvedi, S. and Anuradha, R.V. (2001) *Regime of Intellectual Property Protection for Biodiversity: A Developing Country Perspective*. RIS, New Delhi.

Dodds, J.H., Ortiz, R., Crouch, J.H., Mahalasksmi, V. and Sharma, K.K. (2001) Biotechnology, the gene revolution and proprietary technology in agriculture. A strategic note for the World Bank. *IP Strategy Today*, No. 2.

Downes, D. and Laird, S.A. (1999) *Innovative Mechanisms for Sharing Benefits of Biodiversity and Related Knowledge – Case Studies on Geographical Indications and Trademarks*. UNCTAD Biotrade Initiative, Geneva.

Downes, G. (2003) *Implications of TRIPS for Food Security in the Majority World*. Comhlámh Action Network, Cork, October.

Doyle, J.J. and Persley, G.J. (1996) *Enabling the Safe Use of Biotechnology: Principles and Practice*. Environmentally Sustainable Development Studies and Monographs Series No. 10. World Bank, Washington DC.

Drahos, P. (2000) Indigenous knowledge, intellectual property and biopiracy: is a global bio-collecting society the answer? *European Intellectual Property Review* 22, 245–250.

Drahos, P. with Braithwaite, J. (2002) *Information Feudalism: Who Owns the Knowledge Economy?* Earthscan, London.

Echols, M.A. (2008) *Geographical Indications for Food Products: International Legal and Regulatory Perspectives*. Kluwer Law International, Alphen aan den Rijn.

Evans, G. and Blakeney, M. (2006) The protection of geographical indications after Doha: Quo vadis? *Journal of International Economic Law* 9, 573–614.

Falcon, W.P. and Fowler, C. (2002) Carving up the commons – Emergence of a new international regime for germplasm, development and transfer. *Food Policy* 27, 197–222.

FAO (1995) *Agricultural Biotechnology in the Developing World*. FAO Research and Technology Paper No. 6. FAO, Rome.

FAO (1996) *Investment in Agriculture: Evolution and Prospects*. World Food Summit Technical Background Document No. 10. FAO, Rome.

FAO (1999) Biotechnology Development and their Potential Impact on Trade in Cereals. Report of the Joint Session of the 28th Session of the Intergovernmental Group on Grains and the 39th Session of the Intergovernmental Group on Rice, Rome, 22–24 September.

FAO (1999) *Global Strategy for Farm Animal Genetic Resources*. FAO, Rome.

FAO (2001) *The State of Insecurity in the World: Food Insecurity: When People Live With Hunger and Fear Starvation*. FAO, Vienna.

Fowler, C. (1994) *Unnatural Selection: Technology, Politics and Plant Evolution*. Gordon & Breach, Yverdon.

Fowler, C. (2003) The status of public and proprietary germplasm and information. *IP Strategy Today*, No. 7.

Fowler, C. and Hodgkin, T. (2004) Plant genetic resources for food and agriculture: assessing global availability. *Annual Review of Environmental Resources* 29, 10.1–10.37.

Funder, J. (1999) Rethinking patents for plant innovation. *European Intellectual Property Review* 21, 551–577.

Garforth, K. and Ainslie, P. (2006) When worlds collide: Biotechnology meets organic farming in *Hoffman v. Monsanto*. *Journal of Environmental Law* 18, 459–477.

Garforth, K. and Frison, C. (2007) *Key Issues for the relationship between the Convention on Biological Diversity & the International Treaty on Plant Genetic Resources for Food and Agriculture*. Occasional Paper 2. Quaker International Affairs Programme, Ottawa, July.

Gervais, D. (2003) *The TRIPS Agreement: Drafting History and Analysis*, 2nd edn. Sweet & Maxwell, London.

Girsberger, M.A. (1999) *Biodiversity and the Concept of Farmers' Rights in International Law Studies in Global Economic Law*, Vol. 1. Peter Lang Publishing Group, Bern.

Glowka, L., Burhenne-Guilmin, F. and Synge, H. (1994) *A Guide to the Convention on Biological Diversity*. IUCN, Gland.

Glowka, L. (1998) *A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources*. IUCN, Gland.

Gonzalez-Pelaez, A. (2005) *Human Rights and World Trade. Hunger in International Society*. Routledge, London.

Graff, G. and Zilberman, D. (2001) Toward an intellectual property clearinghouse for agricultural biotechnology. *IP Strategy Today*, No 3.

Graff, G.D., Cullen, S.E., Bradford, K.J., Zilberman, D. and Bennett, A.B. (2003) The public–private structure of intellectual property ownership in agricultural biotechnology. *Nature Biotechnology* 21, 989–995.

Halewood, M. and Nnadozie, K. Giving priority to the commons: the International Treaty on Plant Genetic Resources for Food and Agriculture. In: G. Tansey and T. Rajotte (eds) (2008) *The Future Control of Food. A Guide to International Negotiations and Rules on Intellectual Property, Biodiversity and Food Security*. Earthscan, London, pp. 115–140.

Hamilton, N. (1993) Who owns dinner: Evolving legal mechanisms for ownership of plant genetic resources. *Tulsa Law Journal* 28, 587–646.

Hansen, S.A. and van Fleet, J.V. (2003) *A Handbook on Issues and Options for Traditional Knowledge Holders in Protecting their Intellectual Property and Maintaining Biological Diversity*. American Association for the Advancement of Science (AAAS), Washington DC.

Hardon, J.J., Vosman, B. and van Hintum, Th.J.L. (1994) *Identifying Genetic Resources and their Origin: The Capabilities and Limitations of Modern Biochemical and Legal Systems*. Commission on Plant Genetic Resources, Background Study Paper No. 4, Rome.

Hawtin, G.C., Engels, J. and Siebeck, W. (1997) International plant germplasm collections under the Convention on Biological Diversity – options for a continued multilateral exchange of genetic resources for food and agriculture. In: Hoagland, K.E. and Rossman, A.Y. (eds) *Global Genetic Resources: Access, Ownership, and Intellectual Property Rights*. Natural Science Collection, Washington DC, pp. 247–262.

Hawtin, G. (2003) Management of plant genetic resources in the CGIAR: problems, prospects and the quest for equity. In: Cottier, T. and Mavroidis, P.C. (eds) *Intellectual Property: Trade, Competition, and Sustainable Development*. The World Trade Forum, Vol. III, Ann Arbor, MI; University of Michigan Press, pp. 425–440.

Helfer, L. (2001) *Legal Study on Intellectual Property Rights in Plant Genetic Resources*. FAO, Rome.

Hendrickx, F., Koester, V. and Prip, C. (1993) Access to genetic resources: a legal analysis. *Environmental Policy and Law* 23, 250–258.

Hennessy, D.A. and Hayes, D.J. (2000) Competition and tying in agricultural and seed markets. *Review of Agricultural Economics* 22, 389–406.

Hobbelink, H. (1991) *Biotechnology and the Future of World Agriculture*. Zed Books, London.

International Food Policy Research Institute (1997) *The World Food Situation: Recent Developments, Emerging Issues, and Long-term Prospects*. International Food Policy Research Institute, Washington DC.

Jackson, L.A. (2003) Agricultural biotechnology and the privatization of genetic information, implications for innovation and equity. *Journal of World Intellectual Property* 3, 825–847.

Jaffé, W. and Wijk, J. (1995) *The Impact of Plant Breeders' Rights in Developing Countries: Debate and Experience in Argentina, Chile, Colombia, Mexico and Uruguay*. Directorate General International Cooperation, Ministry of Foreign Affairs, The Hague.

Jefferson, R. (2006) Science as social enterprise: the CAMBIA BiOS Initiative. *Innovations: Technology, Governance, Globalization* 1, 13–44.

Joly, P. and deLooze, M. (1996) An analysis of innovation strategies and industrial differentiation through patent applications: the case of plant biotechnology. *Research Policy* 25, 1014–1027.

Kate, K. ten and Laird, S.A. (1999) *The Commercial Use of Biodiversity – Access to Genetic Resources and Benefit-Sharing*. Earthscan, London.

Khor, M. (2002) *Intellectual Property, Biodiversity and Sustainable Development: Resolving the Difficult Issues*. Zed Books, London.

Kloppenburg, J.R. (2004) *First the Seed: the Political Economy of Plant Biotechnology, 1492–2000*, 2nd edn. University of Wisconsin Press, Madison, WI.

Kloppenburg, J.R. Jr and Kleinman, D.L. (1988) Seeds of controversy: national property versus common heritage. In: Kloppenburg, J.R. Jr (ed.) *Seeds and Sovereignty – The Use and Control of Plant Genetic Resources*. Duke University Press, Durham, NC.

Kongolo, T. (2001) New options for African countries regarding protection for new varieties of plants. *Journal of World Intellectual Property* 4, 350–371.

Kothari, A. and Anuradha, R.V. (1999) Biodiversity and intellectual property rights: can the two co-exist? *Journal of International Wildlife Law and Policy* 2, 204–223.

Krattinger, A. (2002) Public–private partnerships for efficient biotech management and transfer and increased private sector investment. *IP Strategy Today*, No. 4.

Krattiger, A., Mahoney, R.T., Nelsen, L., Thomson, J.A., Bennett, A.B., Satyanarayana, K., Graff, G.D., Fernandez, C. and Kowalski, S.P. (eds) (2007) *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices*. MIHR, Oxford, and PIPRA, Davis, CA.

Kryder, R.D., Kowalski, S.P. and Krattiger, A.F. (2000) The intellectual and technical property components of pro-vitamin A rice (Golden Rice™): a preliminary freedom-to-operate review. ISAAA Brief 20, Ithaca, New York.

Laird, S.A. (2002) *Biodiversity and Traditional Knowledge. Equitable Partnerships in Practice*. Earthscan, London.

Lang, T. and Heasman, M. (2004) *Food Wars: The Global Battle for Mouth, Minds and Markets*. Earthscan, London.

Lappé, M. and Bailey, B. (1998) *Against the Grain: Biotechnology and the Corporate Takeover of Your Food*. Common Courage Press, Monroe, ME.

Laurie, G.T. (1997) Intellectual property rights and the interests of indigenous peoples. *Lesotho Law Journal* 10, 107–126.

Lee, D.R. and Barrett, C.B. (eds) (2001) *Tradeoffs or Synergies? Agricultural Intensification, Economic Development and the Environment*. CAB International, Wallingford.

Leskien, D. and Flitner, M. (1997) *Intellectual Property Rights and Plant Genetic Resources: Options for a* Sui Generis *System*. International Plant Genetic Resources Institute, Rome.

Lesser, W.H. and Masson, R.T. (1983) *An Economic Analysis of the Plant Variety Protection Act*. American Seed Trade Association, Washington DC.

Lettington, J.L. and Nnadozie, K. (2003) *A Review of the Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore at WIPO*. Trade-Related Agenda, Development and Equity (T.R.A.D.E.) Occasional Papers 12. South Centre, Geneva, December.

Lewinski, S. Von (ed.) (2008) *Indigenous Heritage and Intellectual Property. Genetic Resources, Traditional Knowledge and Folklore*, 2nd edn. Wolters Kluwer, Alphen aan den Rijn.

Llewelyn, M. (2003) Which rules in world trade law: patents or plant variety protection? In: Cottier, T. and Mavroidis, P.C. (eds) *Intellectual Property: Trade, Competition, and Sustainable Development*. The World Trade Forum, Vol. III, Ann Arbor, MI; University of Michigan Press, pp. 303–339.

McConnell, F. (1996) *The Biodiversity Convention: A Negotiating History*. Kluwer Law International, London.

McManis, C. (ed.) (2007) *Biodiversity and the Law. Intellectual Property, Biotechnology and Traditional Knowledge*. Earthscan, London.

Mannion, A.M. (1995) *Agriculture and Environmental Change: Temporal and Spatial Dimensions*. John Wiley and Sons, London.

May, C. (2000) *A Global Political Economy of Intellectual Property Rights: The New Enclosures?* Routledge, London.

Meinzen-Dick, R.S., Adato, A., Haddad, L. and Hazell, P. (2003) *Impacts of Agricultural Research on Poverty: Findings of an Integrated Economic and Social Analysis*. EPTD Discussion 49 Paper 111/FCND Discussion Paper 164. International Food Policy Research Institute, Washington DC.

Mgbeoji, I. (2001) Patents and traditional knowledge of the uses of plants: is a communal patent regime part of the solution to the scourge of biopiracy? *Indiana Journal of Global Legal Studies* 9, 163–186.

Mishra, J.P. (2000) Biodiversity, biotechnology and intellectual property rights – implications for Indian agriculture. *Journal of World Intellectual Property* 3, 211–224.

Mishra, J.P. (2001) Intellectual property rights and food security – the efficacy of international initiatives. *Journal of World Intellectual Property* 4, 5–25.

Mogollon-Rojas, I.D. (2002) The preservation of local biodiversity inheritance and indigenous people's knowledge proprietorship in the Venezuelan and Andean community legislation. *Journal of World Intellectual Property* 5, 535–543.

Mooney, P.R. (1979) *Seeds of the Earth: Private or Public Resource?* Canadian Council for International Cooperation and International Coalition for Development Action, Ottawa.

Mooney, P.R. (1996) The parts of life: agricultural biodiversity, indigenous knowledge, and the role of the third system. *Development Dialogue. Special Issue*, 1–2. Dag Hammarskjöld Foundation, Uppsala.

Moore, G. and Tymowski, W. (2005) *Explanatory Guide to the International Treaty on Plant Genetic Resources for Food and Agriculture*. IUCN, Gland.

Nesta, M.G. (2001) Food security and international trade law, an appraisal of the World Trade Organization approach. *Journal of World Trade* 35, 449–468.

Nuffield Council on Bioethics (1999) *Genetically Modified Crops: The Ethical and Social Issues*. Nuffield Council on Bioethics, London.

Odek, J.O (1994). Bio-piracy: creating proprietary rights in plant genetic resources. *Journal of Intellectual Property Law* 2, 141.

Oguamanam, C. (2006) *International Law and Indigenous Knowledge. Intellectual Property, Plant Biodiversity and Traditional Medicine*. University of Toronto Press, Toronto.

Oram, J. (1999) The TRIPS Agreement and its implications for food security. International Famine Centre, Cork, September. www.recrea.f9.co.uk/biopatents.htm.

Overwalle, G. van (1999) Patent protection for plants: a comparison of American and European approaches. *IDEA – The Journal of Law and Technology* 39, 143–193.

Oxfam International (2008) What agenda now for agriculture? A Response to the World Development Report 2008. Available at www.oxfam.org.uk/resources/policy/trade/bn_wdr2008.html.

Paarlberg, R.L. (2000) *Governing the GM Crop Revolution: Policy Choices for Developing Countries*. IFPRI Food, Agriculture, and the Environment Discussion Paper 33. International Food Policy Research Institute, Washington DC.

Pinstrup-Andersen, P., Pandya-Lorch, R. and Rosegrant, M.W. (1999) *World Food Prospects: Critical Issues for the Early Twenty First Century*. International Food Policy Research Institute, Washington DC.

Petit, M., Fowler, C., Collins, W., Correa, C. and Thornström, C. (2000) *Why Governments Can't Make Policy. The Case of Plant Genetic Resources in the International Arena*. CGIAR, Washington DC.

Persley, G.J. (1990) *Beyond Mendel's Garden: Biotechnology in the Service of World Agriculture*. CAB International, Wallingford.

Pistorius, R. and van Wijk, J. (1999) *The Exploitation of Plant Genetic Information: Political Strategies in Crop Development*. CAB International, Wallingford.

Prakash, S. (2000) WTO rules – do they conserve or threaten biodiversity? *Journal of World Intellectual Property* 3, 155–165.

Rangnekar, D. (2000) *Intellectual Property Rights and Agriculture: An Analysis of the Economic Impact of Plant Breeders' Rights*. Actionaid UK, London.

Rangnekar, D. (2002) *Geographical Indications: A Review of Proposals at the TRIPS Council*. UNCTAD/ICTSD Capacity Building Project on Intellectual Property Rights and Sustainable Development, Geneva.

Rangnekar, D. (2002) R&D appropriability and planned obsolescence: Empirical evidence from wheat breeding in the UK (1960–1995). *Industrial and Corporate Change* 11, 1011–1029.

Reichman, J.H. (2000) Of *green tulips and legal kudzu*: repackaging rights in subpatentable innovation. *Vanderbilt Law Review* 53, 1743–1798.

Reichman, J. (2000) The TRIPS Agreement comes of age: conflict or cooperation with the developing countries? *Case Western Reserve Journal of International Law* 32, 441–470.

Rosell, M. (1997) Access to genetic resources: a critical approach to Decision 391 'Common Regime on Access to Genetic Resources of the Commission' of the Cartagena Agreement. *European Community & International Environmental Law Review* 6, 274.

Scoones, I. (2002) *Agricultural Biotechnology and Food Security: Exploring the Debate*. IDS Working Paper 145, January.

Sell, S.K. (2003) *Private Power, Public Law: The Globalization of Intellectual Property Rights*. Cambridge University Press, Cambridge.

Serageldin, I. (1999) Biotechnology and food security in the 21st century. *Science* 285, 387–389.

Serageldin, I, and Collins, W. (eds) (1998) *Biotechnology and Biosafety*. World Bank, Washington DC.

Serageldin, I. and Persley, G.J. (2000) *Promethean Science: Agricultural Biotechnology, the Environment and the Poor*. Consultative Group on International Agricultural Research, Washington DC.

Setyawati, I. (1996) Environmental variability, IK and the use of rice varieties. *Indigenous Knowledge and Development Monitor* 4, 11–13.

Shiva, V. (1994) Farmers' rights and the Convention on Biological Diversity. In: Sanchez, V. and Juma, C. (eds) (1994) *Biodiplomacy – Genetic Resources and International Relations*. African Centre for Technology Studies, Nairobi, pp. 107–118.

Shiva, V. (1999) *Monocultures of the Mind: Perspectives on Biodiversity and Biotechnology*. Zed Books, London.

Shiva, V. (2001) *Protect or Plunder*. Zed Books, London.

Spielman, D.J. and Grebmer, K. Von (2004) *Public–Private Partnerships in Agricultural Research: An Analysis of Challenges Facing Industry and the Consultative Group on International Agricultural Research*. EPTD Discussion Paper No. 113. International Food Policy Research Institute, Washington DC.

Spillane, C. (1999) *Recent Developments in Biotechnology as They Relate to Plant Genetic Resources for Food and Agriculture*. Background Study Paper No. 9, Commission on Genetic Resources for Food and Agriculture, April.

Stenson, A.J. and Gray, T.S. (1999) *The Politics of Genetic Resource Control*. St Martin's Press, New York.

Straus, J. (1987) The relationship between plant variety protection and patent protection for biotechnological inventions from an international viewpoint. *International Review of Industrial Property and Copyright Law* 18, 723–737.

Straus, J. (1998) The Rio Biodiversity Convention and intellectual property. *International Review of Industrial Property and Copyright Law* 24, 602–615.

Subramanian, A. (2002) Proprietary protection of genetic resources and traditional knowledge. In: Hoekman, B. Mattoo, A. and English, P. (eds) *Development, Trade and the WTO: A Handbook*. World Bank, Washington DC, pp. 382–389.

Swaminathan, M.S. (ed.) (1995) *Farmers' Rights and Plant Genetic Resources – Recognition & Reward*. Macmillan, Madras.

Swanson, T. (1997) *Global Action for Biodiversity – An International Framework for Implementing the Convention on Biological Diversity*. Earthscan, London.

Tansey, G. (1999) *Trade, Intellectual Property, Food and Biodiversity: Key Issues and Options for the 1999 Review of Article 27.3(b) of the TRIPS Agreement*. Quaker Peace and Service, London.

Tansey, G. and Worsley, T. (1995) *The Food System – A Guide*. Earthscan, London.

Tansey, G. and Rajotte, T. (eds) (2008) *The Future Control of Food. A Guide to International Negotiations and Rules on Intellectual Property, Biodiversity and Food Security*. Earthscan, London.

Taubman, A. (2008) Genetic resources. In: Lewinski, S. Von (ed.) *Indigenous Heritage and Intellectual Property: Genetic Resources, Traditional Knowledge and Folklore*, 2nd edn. Wolters Kluwer, Alphen aan der Rijn, pp. 181–292.

Thrupp, L.A. (2000) Linking agricultural biodiversity and food security: the valuable role of agrobiodiversity for sustainable agriculture. *International Affairs* 76, 283–297.

Tomasevski, K. (ed.) (1987) *The Right to Food through Applicable International Law*. Martinus Nijhoff Publishers, Dordrecht.

Tzotzos, G.T. and Skryabin, K.G. (2000) *Biotechnology in the Developing World and Countries in Economic Transition*. CAB International, Wallingford.

UPOV (2005) *UPOV Report on the Impact of Plant Variety Protection*. UPOV, Geneva.

Vellvé, R. (1992) *Saving the Seed: Genetic Diversity and European Agriculture*. Earthscan, London.

Verma, S.K. (1995) TRIPS and plant variety protection in developing countries. *European Intellectual Property Review* 17, 281–289.

Vorley, B. (2003) *Food Inc. Corporate Concentration from Farm to Consumer*. UK Food Group, London.

Watal, J. (2001) *Intellectual Property Rights in the WTO and Developing Countries*. Oxford University Press, New Delhi.

Weis, T. (2007) *The Global Food Economy: The Battle for the Future of Farming*. Zed Books, London.

Wijk, J., van, Cohen, J.I. and Komen, J. (1993) *Intellectual Property Rights for Agricultural Biotechnology: Options and Implications for Developing Countries*. ISNAR Research Report No. 3. International Centre for National Agricultural Research, The Hague.

Wilkinson, J. and Castelli, P. (2000) *The Internationalisation of Brazil's Seed Industry: Biotechnology, Patents and Biodiversity*. ActionAid, Rio de Janeiro.

Williams, N.M. and Baines, G. (eds) (1993) *Traditional Technological Knowledge: Wisdom for Sustainable Development*. ANU, Canberra.

WIPO (2001) *Intellectual Property Needs and Expectations of Traditional Knowledge Holders. WIPO Report on Fact-finding Missions on Intellectual Property and Traditional Knowledge 1998–1999*. WIPO, Geneva.

WIPO/UNEP (2002) Case Study One – Mali. In: *The Role of Intellectual Property Rights in the Sharing of Benefits Arising from the Use of Biological Resources and Associated Traditional Knowledge – Selected Case Studies*. WIPO/UNEP, Geneva.

WIPO (2003) *Descriptions of National and Regional Experiences with Existing Sui Generis Measures and Laws for the Protection of Traditional Knowledge*. WIPO, Geneva.

Woodend, J.J. (1994) Biotechnology for cash crops of developing countries: opportunities, prospects and threats. *Genetic Engineering and Biotechnology Monitor* 1, 75–81.

Wuger, D. and Cottier, T. (eds) (2008) *Genetic Engineering and the World Trade System: World Trade Forum*. Cambridge University Press, Cambridge.

Yamin, F. (2003) *Intellectual Property Rights, Biotechnology and Food Security*. IDS Working Paper 203, September.

Zarrilli, S. (2001) International trade in genetically modified organisms and multilateral negotiations: a new dilemma for developing countries. In: Francioni, F. (ed.) *Environment, Human Rights and International Trade*. Hart Publishing, Oxford, pp. 39–86.

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