INTELLECTUAL PROPERTY RIGHTS AND PLANT VARIETY PROTECTION IN SOUTH AFRICA: AN INTERNATIONAL PERSPECTIVE

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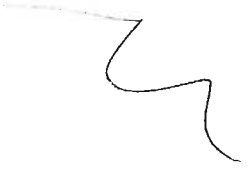

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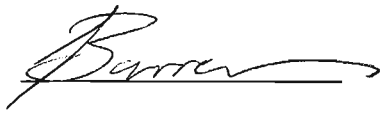
DECLARATION

I, Nadine Lianne Barron, do hereby declare that, unless specifically indicated to the contrary in this text, this dissertation is all my own original work and has not been submitted to any other university in full or partial fulfilment of the academic requirements of any degree or other qualification.

Signed at Durban on 15TH day of September 2003.



ABSTRACT

This work will investigate the implementation of plant variety protection obligations that African states, and in particular South Africa, have to undertake under the various relevant international agreements, especially the Agreement on Trade Related Aspects of Intellectual Property Rights and the Convention on Biological Diversity. The property rights regimes set up in the different international instruments do not necessarily culminate in a coherent whole. While a trend towards the privatisation of plant genetic resources is evident and notable, continuous upholding of the sovereign rights of states over their natural resources is also present. In particular, this work will investigate the question of whether intellectual property rights support or undermine the objectives of the Convention on Biological Diversity. Article 27.3(b) of the Agreement on Trade Related Aspects of Intellectual Property Rights provides for the mandatory patenting of micro-organisms and microbiological processes. This provision has, however, been the source of much controversy and was inserted under the proviso that it be reviewed four years after the coming into force of the Agreement (i.e. 1999). To date, such review has not occurred. Accordingly, it will be argued that the obligation to implement the Agreement on Trade Related Aspects of Intellectual Property Rights in African Member States should be suspended pending the outcome of the review. This work will critically consider the effects that the introduction of patents over plant varieties are likely to have in Africa, focusing on the fulfilment of basic food needs for all individuals and the sustainable management of biological resources in African countries. It will be argued that African states should take advantage of the possibility of devising a property rights system adapted to their needs and conditions and should avoid any system involving the introduction of monopoly or exclusionary rights, such as patents or plant breeders' rights.

ACRONYMS

AU	African Union
Bt	*Bacillus thuringiensis*
BIO	Biotechnology Industry Organisation
CBD	Convention on Biological Diversity
CGIAR	Consultative Group on International Agricultural Research
CIMMYT	International Centre for the Improvement of Maize and Wheat
COP	Conference of the Parties (to the CBD)
CSD	Commission on Sustainable Development
CTE	Committee on Trade and Environment
DEAT	Department of Environmental Affairs and Tourism (South Africa)
DNA	Deoxyribonucleic acid
DOA	Department of Agriculture (South Africa)
ECA	Environment Conservation Act (South Africa)
EIA	Environmental Impact Assessment
ERS	Economic Research Service
ETC	Action Group on Erosion, Technology and Concentration
FAO	Food and Agricultural Organisation (UN)
GATT	General Agreement on Tariffs and Trade
GM	Genetically Modified
GMO	Genetically modified organism
IPRs	Intellectual property rights
ITPGR	International Treaty on Plant Genetic Resources
IUPGR	International Undertaking on Plant Genetic Resources
LMO	Living Modified Organism
LMO-FFP	Living Modified Organism- Food, Feed or Processing
NCFAP	National Centre for Food and Agricultural Policy (US)
NEMA	National Environmental Management Act (South Africa)
OAU	Organisation for African Unity
PBR	Plant breeders' right
PIC	Prior informed consent
PMA	Pharmaceutical Manufacturers Association
PVP	Plant variety protection
RAFI	Rural Advancement Foundation International (Canada)
R&D	Research and development
SAGENE	South African Committee for Gene Experimentation
TNC	Trans-national corporation
TRIPs	Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
UNCED	United Nations Conference on Environment and Development
UPOV	Convention of the International Union for the Protection of New Varieties of Plants
USDA	United States Department of Agriculture
V-GURT	Variety gene use restriction technology
WIPO	World Intellectual Property Organisation (UN)
WSSD	World Summit on Sustainable Development
WTO	World Trade Organisation

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The final submission date for this dissertation happened to fall on 15 September 2003. The World Trade Organisation's fifth Ministerial took place in Cancun from 10 to 14 September. Due to limited time, comments on the WTO meeting do not occur in the body of the dissertation but have been included in a Postscript.

CHAPTER 1

INTRODUCTION

1.1 Outline

The international regime concerning the protection of plant varieties has evolved significantly over the past few decades. The regime is marked by a variety of instruments whose subject matter may differ. For example, the Convention on Biological Diversity (CBD) covers all biological resources, the International Undertaking on Plant Genetic Resources (IUPGR) covers only plant genetic resources and the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) covers intellectual property rights (IPRs). The different agreements belong to different areas of international law, such as environmental law and trade law. Theoretically there is no hierarchy between the different fields of international law. In practice, however, World Trade Organization (WTO) related instruments carry more weight than environmental treaties. This is possibly attributable to the nature of the agreements themselves. Treaties concerning trade tend to be more proactive, whereas environmental treaties tend to be protective.[1] More importantly perhaps, trade sanctions may be imposed in the case of non-compliance with WTO-related agreements.[2] The property rights regimes set up in the different instruments do not necessarily culminate in a coherent whole. While a trend towards the privatization of plant genetic resources is evident and notable, continuous upholding of the sovereign rights of states over their natural resources is also present. Indeed, international law rests on the doctrines of sovereignty and equality of states.

The introduction of plant variety protection (PVP) in African countries is a novelty for all but a few states. Some of the problems they have encountered on the road to developing PVP regimes have been the time pressure forced upon them by TRIPs implementation deadlines and the pressure brought upon them to adopt an existing PVP regime which was formulated predominantly for developed countries.

This work focuses on the implementation of PVP as part of the obligations that African states, and in particular South Africa, have to undertake under TRIPs and the CBD. It will be argued that African states should take advantage of the opportunity of devising a property rights system adapted to their needs and conditions and should avoid any system

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[1] This is perhaps too simplistic. It could be argued that recent developments in international environmental law imply a shift from being merely reactive, such as in the marine pollution conventions concerning the North Sea, the NE Atlantic and the Baltic (1974), to being proactive, such as in the case of the UN Framework Convention on Climate Change (UNFCCC) (1992), which embodies an anticipatory response to the possibility of future global climate change.

[2] An agreement within GATT/WTO facilitates recourse to cross-retaliation for non-fulfillment of specific obligations. That is, countries failing to comply with TRIPs standards could be subject to trade retaliation if the dispute settlement mechanism of the WTO has determined the existence of a case of non-compliance with the TRIPs Agreement. It is important to distinguish between import prohibitions and sanctions. An import prohibition is a ban on a product that has a direct nexus to an environmental harm. A sanction, on the other hand, is a trade ban on unrelated products for the purpose of influencing a foreign country's policies or actions. Both instrument prohibitions and sanctions can be applied by treaty to other parties.

involving the introduction of monopoly or exclusionary rights, such as patents or plant breeders' rights (PBRs). This is due to the fact that the introduction of monopoly rights in agriculture does not seem, from past experience, likely to provide the conditions for the fulfillment of basic food needs for all individuals and the sustainable management of biological resources in African countries.

1.2 Property Rights Over Plant Varieties at the International Level

International environmental law refers to the body of international law relevant to environmental issues.[3] Its growth is premised on the globalisation of environmental problems and concerns, attributable to two crucially interrelated factors: ecological and economic interdependence.[4] The development of international environmental law can be traced through two main phases: the first phase is from the 1972 UN Convention on the Human Environment (the Stockholm Convention), to the 1992 UN Conference on Environment and Development (UNCED)[5]; the second phase is developments that have occurred thereafter.[6] UNCED ('Rio Summit') was a watershed. It placed the environment crisis at the top of the international agenda, and emphasized both the environment and development in a new paradigm of sustainable development. The Rio Summit resulted in the adoption of the UN Framework Convention on Climate Change, the Convention on Biological Diversity, Agenda 21,[7] and the Rio Declaration on the Environment and Development.[8]

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[3] International norms and laws may come about in various ways, the primary sources being: treaties and customary international law. The former are only binding on those that consent to them, originate in a framework of international negotiation over matters of common interest, and result in an agreement which is signed and later ratified by Parties to bring the agreement into force. International customary law, on the other hand, is defined by the Statute of the International Court of Justice as 'general practice accepted as law' by States. Both treaties and international customary law constitute so-called 'hard' law. In contrast, non-binding instruments that lay down guidelines for future actions constitute so-called 'soft' law. 'Soft' law is largely based on international diplomacy and customs. Examples of soft law are the 1972 Stockholm Declaration, the 1992 Rio Declaration and Agenda 21. It is arguable that a number of the principles embodied in the former two agreements have crystallized into 'harder' obligations representing customary law. See The World Bank Group, 'International Environmental Law: Concepts and Issues', (2002), World Wide Web, http://www4.worldbank.org/legal/legen/legen_iel.html

[4] Ibid.

[5] Ibid. Held at Rio de Janeiro (the Rio Summit). This latter period, initiated by the negotiations leading up to the 1992 UN Conference on Environment and Development, is distinguished by concerns for sustainable development and includes the current phase of experimentation with economic, market-based instruments to achieve environmental compliance.

[6] The 1992 OSPAR Convention on Protection of Biodiversity in Maritime Areas, the 1994 Cairo Population Conference, the 1995 UN Straddling Stocks Fisheries Convention, the 1997 Kyoto Conference on Global Warming, the 2000 Amsterdam Conference on Global Warming, the 2002 Johannesburg World Summit on Sustainable Development.

[7] Agenda 21 is a program of action for sustainable development. It deals with plant genetic resources within the context of long-term food security, sustainable agriculture and rural development (Chapter 14). Agenda 21 addresses the conservation of biological diversity (Chapter 15), environmentally sound management of biotechnology (Chapter 16), and the equitable sharing of benefits. It emphasizes conservation *in situ*, and recognizes the importance of the contribution of indigenous and local communities. It is supportive of the CBD, and does not run counter to the CBDs objectives.

[8] It is to be noted that the former two constitute agreements, whereas the latter constitute guidelines.

Several principles of international environment policy[9] were crystallized through the Rio process. Among them are the principles of Precaution, Polluter-Pays, Sustainable Development, Common but Differentiated Responsibility, and Environmental Impact Assessment (EIA). The principle of Common but Differentiated Responsibilities, enshrined in Principle 7 of the Rio Declaration, recognized that the global ecological crisis had to be resolved in an equitable way, through partnership. It acknowledged that developed countries have historically been and are at present more responsible for the degradation of the global environment, have more resources due to the uneven nature of the world's economy, and thus have a proportionately greater responsibility in resolving environmental problems.

Enshrined in Principle 15 of the Rio Declaration, the Precautionary Principle postulates that in cases when serious harm is threatened, positive action to protect the environment should not be delayed until irrefutable scientific proof of harm is available.[10] It is to be noted, however, that there is no universally accepted standard definition of the Precautionary Principle. Nevertheless, there are common elements embodied in the various definitions.[11] In its strongest formulations this principle can be seen to require a reversal of the normal burden of proof, so that a potential actor would need to prove that a proposed activity will not cause harm before it can be sanctioned. Not surprisingly, perhaps, the extension of this principle to conservation has been opposed.[12] The reasons advanced are the absence of agreement as to what constitutes an acceptable threshold at which to apply the principle and shift the burden of proof. Nevertheless, the Precautionary Principle represents an important tool for decision-making which has arguably crystallized into international customary law. It has been endorsed by virtually all recent environmental treaties, including both regional treaties[13] and global environmental treaties.[14] It is therefore possible to argue that the Precautionary Principle

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[9] Some of which were first enunciated in the Stockholm Declaration.

[10] Op cit note 3.

[11] Namely, the vulnerability of the environment and the scarcity of resources necessitates their protection and conservation; science has a limited ability to predict accurately threats to the environment; there is a requirement to remove the burden of proof from those opposing a potentially destructive activity and to place it onto those seeking to promote such an activity; impact assessments should be conducted prior to undertaking a proposed activity; and there is a need to set conservative evidentiary thresholds for taking action. Regarding the last mentioned element, two terms have most often been used to define the threshold; 'threats of serious or irreversible harm' (in the Rio Declaration), and 'unacceptable impacts' (in UN General Assembly Resolution 44/225). These set out the level of risk or harm which triggers a determination that the proposed activities are not compatible with precautionary management. See G. Rose & G. Paleokrassis, 'Compliance With International Environmental Obligations: A Case Study of the International Whaling Commission', in J. Cameron, J. Werksman, and P. Roderick, *Improving Compliance With International Environmental Law* (1996) at 158-159.

[12] Ibid. For example, its extension to fisheries and to whaling has been opposed by major distant water fishing nations and the FAO.

[13] For example, the 1992 Maastricht Treaty on European Union, the 1992 Paris Convention on the North East Atlantic, and the 1992 Convention on the Protection of the Marine Environment of the Baltic Sea Area.

[14] For example, UNFCCC, and the 1995 UN Agreement on Straddling Fish Stocks and Highly Migratory Fish Stocks.

will become a predominant resources management lodestar,[15] and direct the making of conservation measures for common resource management. It is noted in the Preamble to the CBD,[16] and has been incorporated into South African domestic legislation.[17]

CHAPTER 2

INTERNATIONAL AGREEMENTS

2.1 The Convention on Biological Diversity

At the 1992 UNCED in Rio de Janeiro, world leaders adopted the Convention on Biological Diversity. The CBD was opened for signature on 5 June 1992 and entered into force on 29 December 1993. This agreement by the vast majority of the world's governments[18] sets out commitments for maintaining the world's ecological underpinnings at the same time as promoting economic development. Following the Summit, South Africa became a signatory and ratified the CBD on 2 November 1995, binding itself to this international agreement. The CBD is, however, a 'framework agreement' that requires implementation by its parties to give effect to its provisions.[19] The CBD does not deal specifically with the issue of PVP but is of direct relevance to the creation of protection regimes for plant varieties since its scope encompasses all biological resources. Generally, it constitutes the central instrument concerning biodiversity at the international level. In this context, it broadly delimits the rights of states and other relevant actors over biological resources.

The Convention establishes three main goals: the conservation of biological diversity (*in situ* and *ex situ*),[20] the sustainable use of its components, and the fair and equitable sharing of the benefits of the use of genetic resources.[21] It generally affirms the sovereign

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[15] The actual threshold levels for application and management strategies will have to be redefined for each different resource utilization application.

[16] Paragraph 9 of the Preamble to the CBD states that, 'contracting parties noting also that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat.'

[17] Section 2(4)(a)(vii) of the South African National Environmental Management Act 107 of 1998 requires that 'a risk-averse and cautious approach is applied, which takes into account the limits of current knowledge about the consequences of decisions and actions'.

[18] As at 1 August 2003, there were 187 Parties to the CBD, 46 of which were African countries. It is to be noted that the United States of America signed the Convention on June 5, 1993, but has not yet ratified it. Lack of protection of Intellectual Property provisions of the CBD is posited as one of the primary grounds for not ratifying the Convention. However, American companies remain affected by the CBD to the extent that they are doing business with other countries that are member parties or seek access to resources located outside of the United States. See Food and Agricultural Organization, 'Agreement on TRIPs', (2000), World Wide Web, http://www.fao.org/docrep/003/x7355e/X7355e05.htm and The Federalist Society for Law and Public Policy Studies, R. Marzulla, & L. Reifschneider, 'Intellectual Property: The Biodiversity Treaty Challenges Intellectual Property Rights', (2001), World Wide Web, http://www.fed-soc.org/Publications/practicegroupnewsletters/intellectualproperty/ip01

[19] It is a 'framework' agreement also in the more positive sense that it imposes itself on existing law.

[20] The Convention recognizes that *in situ* (local) conservation of biological resources is more sustainable than *ex situ* (gene bank) conservation.

[21] CBD, Art. 1.

rights of states to exploit their own resources pursuant to their own environmental policies,[22] a direct reflection of the principle of permanent sovereignty over natural resources.[23] The sovereign rights of states over their biological resources are limited by the recognition that these resources are a common concern of humankind.[24] The Convention further recognizes both the dependence of local communities on biological resources and the roles that these communities play in the conservation and sustainable use of the resources.[25] It points to the need for equitable sharing of benefits arising from the use of their traditional knowledge, innovations and practices, relevant to the conservation of biodiversity and the sustainable use of its components.[26] Further, it acknowledges the necessity for all parties to recognize and protect IPRs in this field.

The treatment of IPR was a contentious issue in the negotiations on the Convention. Many developing countries argued that the application of existing IPR systems hinders the transfer of technology to the developing world, and unfairly disregards the contributions of generations of farmers to the world's plant genetic resources, which underpin global food security. These countries objected to the expansion of IPR over new crop varieties and other products based on genetic resources, and proposed that the Convention provide for, or authorize, restrictions on IPR. Some developed countries, on the other hand, argued that strong universal protection of IPR would stimulate technology and investment in research and development (R&D) in developing countries, indirectly increasing the incentives to conserve biological diversity. The language on which negotiators eventually agreed does not entirely resolve these differing perspectives on the role of IPR in achieving the Conventions' objectives.[27]

For example, Article 16(5) provides that the Parties, 'recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives'. The use of the term 'may' implies that the negotiators could not agree on whether IPR have a positive effect, a negative effect, or a negligible effect on technology

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[22] Article 3 provides that 'States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies'. This provision repeats Principle 21 of the UN Conference on the Human Environment (UNCHE) of 1972. This doctrine enshrines the principle that national states are sovereign and have equal rights and duties as members of the international community, notwithstanding differences of an economic, social, or political nature.

[23] Art. 15, 'Recognizing the sovereign rights of states over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation'.

[24] The Convention highlights that the conservation of the world's biodiversity is a common *concern* rather than a common *heritage* of mankind. The FAOs' International Undertaking on Plant Genetic Resources, in its present form, similarly reflects this shift in perspective. In this respect, see section 2.6 below, and in particular, footnote 200.

[25] See for example, Article 8(j).

[26] See for example, Article 8(j) and Article 15.

[27] United Nations Educational, Scientific and Cultural Organization, 'Cultural Policy Resources: Issues on Culture and Development', (2002), World Wide Web, http://www.unesco.org/culture/industries/trade/html

transfer or on the achievement of the Convention's objectives generally.[28] It does, however, implicitly accept that conflicts may well arise between IPRs and the CBD and that 'subject to national and international law' these conflicts should be eliminated. Article 16(5) implies that if IPR have an impact on the objectives of the CBD, this is most likely to occur in the context of technology transfer, rather than in the context of conservation and sustainable use.[29] The language of the provision is, however, somewhat broad, implying the potential for influence on any of the Convention's objectives and provisions. Additionally, it is possible that Parties will be required to cooperate in managing the influence of IPR to ensure that it is positive rather than negative.[30]

Article 15 on *Access to Genetic Resources* reaffirms the sovereign rights of states over their natural resources, an established principle of international law. Specifically, it assigns to national governments the authority to determine access to genetic resources. The principle of sovereign rights is mitigated through access and benefit sharing agreements. Least developed countries, mostly of the South, provide a principle source of genetic material, which in turn equips the northern countries' agricultural industries. Recent cries of 'biopiracy' have illuminated the need for equitable sharing of benefits by the providers and exploiters of genetic resources. Under the CBD, prior informed consent (PIC) of both the state and the indigenous and local communities is the standard for ensuring fair and equitable access and benefit sharing agreements.[31] Such PIC to access to genetic resources shall 'be on mutually agreed terms'.[32] The source country providing access to genetic resources must know in advance what will be done with the resource, and what benefits will be shared. Without such an understanding between prospector and supplier there is no true meeting of minds and no fair agreement on benefit sharing. Where a party provides genetic resources to another party, the receiving party 'shall endeavour to develop and carry out scientific research based on [those] genetic resources . . . with the full participation of, and where possible in, [the providing party]'.[33] Prima facie, Article 15 has little to do with information, knowledge or IPRs. It is, however, central to the CBD and to the issues raised by IPRs, strengthening – at least to some degree – the bargaining position of developing countries in relation to developed countries and trans-national corporations (TNCs). This is well understood by a number of countries developing national and regional access/benefit-sharing legislation, such as the

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[28] Ibid.

[29] Indeed, there is great resistance among many people in the private sector to accepting that IPRs have anything to do with the destruction of biodiversity or unsustainable practices. An investigation conducted in Switzerland on the views of firms and universities utilizing genetic resources revealed little support for the need for legislative reforms such as changes to IPR laws in support of the CBD or for any other reason. See G. Dutfield, *Intellectual Property Rights, Trade and Biodiversity,* (2000), Earthscan Publications Limited, United Kingdom, at 34.

[30] Op cit note 27.

[31] CBD. Art. 8(j) and 15(5).

[32] CBD Art. 15(4). The current conventional form of access agreement is the Material Transfer Agreement. In this respect see J.I. Cohen, C. Falconi, J. Komen, & M. Blakeney, 'The Use of Proprietary Biotechnology Research Inputs at Selected CGIAR Centres', (1998), International Service for National Agricultural Research, the Hague, available at World Wide Web, http://www.isnar.cgiar.org/publications/briefing/Bp39.htm

[33] CBD. Art. 15(6).

Andean Community member countries[34] and Costa Rica. The Andean Community's *Common System on Access to Genetic Resources*[35] and Costa Rica's new Biodiversity Law both to some extent subordinate IPRs to access/benefit-sharing regulations.[36]

Similarly, Article 19(1) provides that parties shall take appropriate measures to provide for the effective participation in biotechnological research by parties, especially developing countries, that provide the genetic resources for such research, in such parties where feasible. In general, each party shall take measures '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 [party] providing such resources.'[37] Article 19(2) requires parties to 'take all practicable measures to promote and advance priority access on a fair and equitable basis' for parties providing

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[34] Bolivia, Colombia, Ecuador, Peru and Venezuela.

[35] Adopted by the Andean Community member countries in 1996. The Common System affirms the sovereign rights of member countries over the use and exploitation of their genetic resources as well as the right to determine conditions of access. It then, however, goes further than the CBD by extending sovereign rights to the *derivatives* of these resources. A derivative is defined as a molecule or combination or mixture of natural molecules, including raw extracts of living or dead organisms of biological origin, derived from the metabolism of living organisms. It is therefore not the same as a synthesized product, which is a substance obtained through an artificial process using genetic information or molecules and which may include semi-processed extracts. It appears that isolated bio-compounds could become subject to the claims of Andean Community member states even if the compound has been isolated and patented by a company outside the Andean Community region. It is, however, not certain whether such a measure is TRIPs-compatible.

[36] In April 1998, the Legislative Assembly of Costa Rica passed the *Ley de Biodiversitdad*, or Biodiversity Law. According to Dutfield, 'to date, this is perhaps the most ambitious and elaborate national law to implement the CBD.' See Dutfield, op cit note 29 at 110. The Law's overall objective is to conserve biodiversity, sustainably utilize resources, and distribute fairly the derived benefits and costs (Article 1), but there are thirteen objectives in all. The Law regulates the use, management, associated knowledge, and the fair distribution of the benefits and costs derived from the utilization of biodiversity elements, but with three exclusions (Article 4). These are: (a) human genetic and biochemical material; (b) non-commercial exchanges between indigenous peoples and local communities of biochemical and genetic resources and associated knowledge derived from their practices, uses and customs; and (c) the autonomy of universities with respect to field investigations and teaching for non-commercial purposes. The biochemical and genetic properties of wild or domesticated biodiversity elements are in the public domain (Article 6) and all biodiversity elements per se are subject to the exclusive sovereignty of the State (Article 2). Therefore, while the resources themselves may be owned by the State, private landowners, or local communities, the properties of these elements can be owned by nobody, not even those who discover or are aware of these properties. Articles 77 – 85 are concerned with intellectual and industrial property rights and commence with a statement recognizing the need to protect knowledge and innovations through appropriate legal mechanisms, referring specifically to patents, trade secrets, PBRs, *sui generis* community intellectual rights, copyrights and farmers' rights. Remarkably for a biodiversity law, parameters for the scope of IPR protection permitted by the State are drawn very explicitly and excepted from IPR protection are the following: DNA sequences; plants and animals; non-genetically modified organisms; essentially biological processes for the production of plants and animals; natural processes or cycles *per se*; inventions essentially derived from knowledge associated with traditional biological or cultural biological practices in the public domain; and inventions which, through their commercial exploitation in monopoly form can affect agriculture and livestock processes or products considered basic for nutrition and health of the country's inhabitants. Before awarding IPR protection for innovations involving biodiversity elements, a statement of prior informed consent must be presented to the Technical Office of the Commission. Indigenous peoples and local communities are fully entitled to refuse access to their resources and knowledge for any reason.

[37] CBD. Art. 15(7).

genetic resources, especially developing countries, 'the results and benefits arising from biotechnologies based upon [those] genetic resources . . . on mutually agreed terms'. The implementation of these provisions could involve the development of information that could be subject to patents or trade secrets.

The Convention also provides a broad framework for member states' policies concerning access, development and transfer of technologies.[38] Each party shall take measures 'with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms including technology protected by patents and other intellectual property rights'.[39] The provisions of paragraphs 2 and 5 concerning IPR appear in this context. Article 16(2), on the one hand, provides that technology transfer must be carried out 'on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights'. The phrase 'adequate and effective' is, however, not defined. The precise interpretation of the phrase has been a source of controversy between developed and developing countries, with the former wishing to maintain its competitive technological edge and the latter with a desire to gain access to this technology.[40] Article 16(5), on the other hand, provides that parties, 'recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives'.

The emphasis of Article 8(j) on knowledge and innovations makes it potentially relevant to IPR. It requires each party as far as possible, as appropriate, and subject to its national legislation, to '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'. Much debate has focused on the relationship between IPR and the knowledge and innovations of local and indigenous communities within the terms of Article 8(j). Use of the terms 'knowledge', 'innovations' and 'practices' in addition to 'traditional' is significant.[41] Of more significance, perhaps, is the use of the term 'holders', which arguably implies ownership but minimally seems to indicate the existence of legal entitlements. According to Costa,

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[38] Article 1 of the CBD provides for 'appropriate access to genetic resources'. Article 16(1) requires each party to provide and/or facilitate access and transfer to other parties of technology, including biotechnologies, that are relevant for conservation and sustainable use or that make use of genetic resources and are not significantly damaging to the environment.

[39] CBD. Art. 16(3).

[40] See J. George, & J. Van Staden, 'Intellectual Property Rights: Plants and phytomedicines – past history, present scenario and future prospects in South Africa', (August 2000), *South African Journal of Science* 96, at 435.

[41] There is a tendency to assume that 'traditional' implies any or all of such notions as 'time-honoured', 'historical', 'inflexible' and 'static'. In this context, however, 'traditional innovations' would not be contradictory.

'when the Convention discusses knowledge, innovations and practices and entitles local and indigenous communities to be their *holders*, it links these concepts with the vocabulary for the definition of the proprietor of an intellectual property right.'[42] The Article seems to affirm, then, that the holders[43] have rights over their knowledge, innovations and practices, whether or not they are capable of being protected by IPRs. If they are not capable of being protected by the existing IPR system, there still exists an obligation for governments to safeguard these entitlements through new IPR law or by other legal policy measures. Giving minimal effect to these obligations would involve PIC and observations of codes of conduct.[44] The interpretation that communities have legal entitlements over their knowledge, innovations and practice just as corporations have over their innovations is reinforced by Article 18(4), which affirms the need for Contracting Parties to 'encourage and develop models of cooperation for the development and use of technologies, including traditional and indigenous technologies...' It is trite to say that indigenous and traditional technologies have a role to play in biodiversity conservation. Therefore, there is no justification for assuming that such technologies have a lower status than other technologies relevant to the CBD. Such technologies are in no way less morally entitled to legal protection.

IPRs are also relevant to the implementation of Article 10, which requires parties as far as possible and as appropriate, to integrate considerations of the conservation and sustainable use of biological resources into national decision-making, and to adopt measures relating to the use of biological resources to avoid or minimize effects on biological diversity. These provisions may be implemented to the extent that IPR has an impact on the use of biological resources, for example, through the application of patents to living modified organisms (LMOs). A number of other provisions involving technology, research and sharing of benefits could also relate to IPR, such as Articles 12(c), 17, and 18.[45]

The underlying philosophy of the CBD is that sovereign rights are tempered by providing access to genetic resources in exchange for a share of the benefits. Sharing of the benefits from the use of genetic resources includes 'appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies'.[46] The reference to rights can be understood to include IPR. Thus, technology transfer is highlighted as a method for achieving one of the Convention's three principal objectives and IPR are identified as a significant aspect of technology transfer.

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[42] See S.E. da Silva, 'The protection of Intellectual Property for Local and Indigenous Communities', (1995), *European Intellectual Property Review*, Vol. 17, Issue 11, at 547 [emphasis in original].

[43] Subject to national legislation.

[44] A good example is the International Society for Ethnobiology's 'Code of Ethics and Standards of Practices', and the Biodiversity and Ethics Working Group of Pew Conservation Fellows' 'Proposed Guidelines for Researchers and Local Communities Interested in Accessing, Exploring and Studying Biodiversity'.

[45] While IPR figure prominently in the CBD, the Convention's provisions relating to IPR are framed in broad terms. For example, Article 16(5) states that the parties must cooperate to ensure that IPR promote and do not run counter to the Convention's objectives. This suggests that parties have a general obligation to begin a process of consultation on the issue.

[46] CBD. Art.1.

The introduction of PVP in the context of the TRIPs Agreement cannot be dissociated from the CBD. Indeed, the Convention provides the broad framework within which property rights over plant varieties must fit.

2.2 Agreement on Trade Related Aspects of Intellectual Property Rights [TRIPs] of the World Trade Organization

In the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) in April of 1994, negotiations resulted in the formulation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs).[47] TRIPs was annexed as a condition of membership to the Agreement Establishing the WTO. In the above-mentioned Round, TRIPs was extended to less developed countries, with effect from 1995, in an attempt by the developed countries to create a uniform and global IP regime. This requires developing countries to conform their IP systems to those of developed countries as part of their obligations of membership of the WTO.

The TRIPs Agreement is based in part on a recognition of the dual need to 'promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade'.[48] The Agreement requires all parties to meet certain minimum standards for protecting IPR, defined as including copyrights, patents, plant variety protection, industrial designs, geographic designations, the lay-out design of integrated circuits and trade secrets. The TRIPs Agreement requires WTO members to observe the principles of national treatment[49] and most-favoured nation[50] with respect to IPR. For example, a country could not recognize patents on inventions by its citizens without doing the same for similar inventions by foreign nationals.

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[47] TRIPs took 8 years to conclude, (1986 – 1994). The US argued for its inclusion under pressure from the pharmaceutical industry, representatives of which drafted the basic language for discussion. Developing countries fought against the introduction of IPR into the world trade talks, arguing that different economies required different tools to stimulate innovation and that the imposition of rules to protect monopoly rights in the form of IPR would benefit foreign multinationals more than their own industries. The US won and TRIPs became the third pillar of the world trade regime along with goods and services. See GRAIN, World Wide Web, http://www.grain.org/publications

[48] Preamble, paragraph 1.

[49] The National Treatment principle means that imported and locally produced goods should be treated equally. The same should apply to foreign and domestic services, as well as to foreign and local trademarks, copyrights and patents. The principle of giving others the same treatment as one's own nationals is found in the three main WTO agreements, namely, Article 3 of GATT, Article 17 of the General Agreement on Trade in Services (GATS), and Article 3 of TRIPS. It is to be noted, however, that the principle is handled slightly differently in each of these agreements. Op cit note 27.

[50] Ibid. Most-favoured nation means that every time a Member State improves the benefits that it gives to one trading partner, it has to give the same 'best' treatment to all other WTO members, so that they remain equal. Countries are to grant equal treatment – not more favorable or discriminatory – to goods and services from all WTO members. This principle is found in GATT (Article 1), GATS, and TRIPS (Article 4). Like the national treatment principle, it is handled slightly differently in the three agreements. Some exceptions to the most-favoured nation principle are allowed, albeit under strict conditions. For example, countries within a region can set up a free trade agreement that does not apply to goods from outside the group. Alternatively, a country can raise barriers against products from specific countries that are considered to be traded unfairly.

Some of the most important issues in negotiations concerned patents. The basic definition of patents[51] was never in question. There was, however, considerable disagreement over whether there should be an obligation to make living organisms, particularly plants and animals, patentable.[52] Article 27(3) of the TRIPs Agreement allows members to exclude from patentability 'plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes'. However, 'members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof'.[53] Trade sanctions can be imposed if member states do not conform to TRIPs.[54]

[51] Novelty, inventive step and industrial applicability.

[52] The US wanted full patent protection for all fields of technology, but Europe prohibits patents on plant and animal varieties under the European Patent Convention. A compromise was reached: TRIPs would use the language of European law as a starting point. That language is currently embodied in TRIPs Article 27.3(b) under the provision that countries would review the provision four years after the coming into force of the Agreement, i.e. in 1999. See GRAIN, 'TRIPs Article 27: Patentable Subject Matter', (March 2000), World Wide Web, http://www.grain.org/publications/tripsfeb00-en.cfm. The review of Article 27.3(b) is discussed below in section 2.3.3.

[53] TRIPs Article 27.3(b) states, 'Members may also exclude from patentability . . .plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.'

[54] Trade sanctions appear to be an effective threat. For example, the American Pelly Amendment of 1971 (enacted by the U.S. Congress in response to unsuccessful U.S. efforts to persuade Denmark, Norway and West Germany to comply with the ban on high seas salmon fishing) has, in the absence of any actual sanction, yielded an average success rate of 58 per cent. Additionally, in the negotiations leading up to the establishment of the TRIPs agreement, developing countries (e.g. Argentina, Andean Group countries) who refused to enter into negotiations on standards were repeatedly threatened with trade sanctions in order to obtain changes in their IPRs regimes. Other countries (China, Brazil, India, Taiwan and Thailand) were 'investigated' under the 'Special 301' section of the US Trade Act (which empowers the US government to apply commercial sanctions to countries that are deemed as not respecting adequately the IPRs of US firms). These threats played a strong role in changing the stand of many developing countries on the matter. See South Center, 'Trade-Related Intellectual Property Rights. A New Regime', World Wide Web, http://www.southcentre.org/publications/trips/tripsmaintexttrans-01.htm Those that oppose trade sanctions argue that trade sanctions do not achieve positive environmental results and do not improve the prospects for multilateral solutions. Interestingly, the GATT Secretariat has pronounced that 'negative incentives – in particular, the use of discriminatory trade restrictions on products unrelated to the environmental issue at hand – are not an effective way to promote multilateral cooperation'. See S. Charnovitz, 'Environmental Trade Sanctions and the GATT: An Analysis of the Pelly Amendment on Foreign Environmental Practices', (1994), World Wide Web, http://www.fas.org/irp/news/1995/960826mr.htm

2.3 The relationship between TRIPS and the CBD

2.3.1 COP and CTE analysis of the relationship between the CBD and TRIPS

The relationship between the TRIPs Agreement and the CBD was considered by two intergovernmental forums during 1996: (1) the WTO's Committee on Trade and Environment (CTE) and (2) the Conference of the parties to the CBD (COP).[55] Following 13 official meetings during 1995 and 1996 the CTE adopted its report to the WTO Ministerial Conference that took place in Singapore in December 1996. Item 8 dealt specifically with TRIPs, including its relationship with the CBD. Not surprisingly, perhaps, the conclusions and recommendations of the Report did not draw any firm conclusions or admit any inherent conflicts between conservation of biodiversity and the promotion of 'effective and adequate protection of intellectual property rights'. However, the report did conclude that further work was needed better to appreciate the relationship of the relevant provisions of TRIPs to environmental protection and sustainable development and whether and how these provisions relate to issues such as: 'the creation of incentives for the conservation of biological diversity, sustainable use of its components, the fair and equitable sharing of benefits arising from utilization of genetic resources including the protection of knowledge, innovations and practices of indigenous and local communities'.[56] Discussion is still under way.

2.3.2 Analysis of the relationship between TRIPS and the CBD

Intellectual property rights are important under both the CBD and TRIPs, but the two agreements approach them from markedly different perspectives. Both the CBD and TRIPs allow a significant degree of flexibility in national implementation. This suggests that there is potential for complementary implementation. Some general areas for complementarity have in fact been noted. For example, mutually agreed-upon terms for access to genetic resources could allocate IPR as part of the benefits to be shared among contracting parties. That is, a party could make access to its genetic resources conditional on the receiving parties agreeing to relinquish some or all IPR over products derived from the genetic resources. Alternatively, a party could require the receiving party to carry out joint research with source-country citizens, or to carry out research in the source country as a condition of access. Such IPR could be defined under IPR systems compatible with the TRIPs agreement.

In spite of the flexibility of the CBD and TRIPs, the TRIPs Agreement is in direct conflict with the CBD. The CBD recognizes sovereign rights over biodiversity which contradicts patenting. That is, under the CBD, sovereign rights over genetic resources to farmers and indigenous peoples are recognized,[57] as canvassed above. Under TRIPs, however, such resources, once genetically modified (GM), become the property of the

[55] The acronym COP in this work refers to The Conference of the Parties to the CBD. The COP have had six official meetings to date.
[56] G. Dutfield, 'The WTO, TRIPs and the Biodiversity Convention', (2000), International Institute for Sustainable Development, World Wide Web, http://www.users.ox.ac.uk/~wgtrr/cte4.htm
[57] Article 16(2).

party that carried out the work.[58] National sovereignty implies that countries have the right to prohibit IPRs on biological resources. TRIPs, however, overlooks this right by requiring the provision of IPRs on micro-organisms, non-biological and microbiological process. Clearly, the issue of patent protection for modified life forms raises a number of questions about ownership and control of genetic resources. Complex organisms, which have evolved over millennia in nature, and through the contributions of indigenous peoples, are reduced to their parts. Patenting of genes thus leads to a devaluation of life forms by reducing them to their constituents and allowing them to be owned as private property. This reductionism might be convenient for commercial concerns, but it violates the rights of sovereign nations.

Additionally, national measures to promote technology transfer under Article 16 might raise 'most-favored nation' issues if Convention parties and non-parties were treated differently, and might raise 'national treatment' issues if foreign nationals received less favorable treatment. For example, environmental rules that prohibit certain processes, such as spraying crops with pesticides that cause major harm to surrounding life forms, conflict directly with WTO and TRIPs rules that prohibit distinguishing between products merely by the process that was used to create them.

In considering possible conflicts between certain characteristics or effects of IPRs and achievement of the CBD's three objectives, it is useful to investigate the relationship between IPRs and the conservation and sustainable use of biodiversity.

Assertions have been made that there is a link between the adoption of patents or PBRs and the replacement of diverse agro-ecosystems containing a wide range of traditional crop varieties with monocultures of single agrochemical-dependent varieties.[59] Before analysing this issue, it needs to be pointed out that this is a highly complex topic, and an objective evaluation of the various assertions frequently made both for and against IPRs in this context is difficult to achieve in the current absence of reliable empirical evidence. What must be conceded is that it is unlikely that the erosion of agro-biodiversity can be attributed to a single cause such as IPRs. This is not, however, to say that IPRs do not provide incentives that encourage activities that are prejudicial to biodiversity.

As a starting point it is useful to consider whether IPRs encourage the spread of monocultural agriculture and whether monocultural agriculture in turn contributes to the erosion of biodiversity. According to Reid,[60] there is a strong connection between IPRs and centralised research. Reid notes that the prevailing policy framework for the use of genetic resources for food and agriculture favours 'centralised crop breeding and the creation of uniform environmental conditions, and discourages agro-ecological research or local breeding tailored to local conditions.' Essentially, IPRs enhance incentives to

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[58] E. Masood, 'Biosafety rules will regulate International GMO transfers', (1995), *Nature* 326, 378.

[59] See, for example, The Crucible Group, *People, Plants and Patents: The Impact of Intellectual Property on Trade, Plant Biodiversity, and Rural Society*, (1994), International Development Research Centre, Ottawa.

[60] W.V. Reid, 'Genetic Resources and Sustainable Agriculture: Creating Incentives for Local Innovation and Adaptation', (1992), Biopolicy Series No.2. African Centre for Technology Studies, Nairobi.

develop seeds that will have a large potential demand, and to ensure maximum demand for their products, seed companies tend to focus their research on commonly utilized high-value crops and develop varieties that can be cultivated as widely as possible.[61] The potential biodiversity-erosive effects of this IPR-supported bias towards centralized crop breeding programmes are: decreased crop diversity, decreased special genetic diversity, increased temporal genetic diversity, and increased use of external inputs.

According to Dawkins *et al*,[62] the application of patents to genetic resources that have been engineered accelerates the trend towards monocultural cropping because 'the emphasis on finding and isolating plants with the most marketable traits leads to the decline of other plant species, as only those required to create the new techno-varieties are cultivated. In the U.S. alone, the focus on commercial varieties has already led to the loss of many varieties of plants in seed bank storage.'[63] According to the Independent Panel of Eminent Experts on Ethics in Food and Agriculture,[64] '[m]odern biotechnologies, including the less sophisticated ones such as tissue culture technology, are currently being employed mainly to promote monocultures. For example, oil-palm clones are now spreading in parts of Latin America where various corporations employ this technique, thereby adversely affecting biodiversity.'[65] According to Thrupp,[66] the spread of monocultures is a proximate cause of the erosion of genetic resources (livestock and plants),[67] insect diversity, and soil diversity.[68] The heavy use of agrochemicals and pesticides are also noted as a proximate cause of the erosion of the above-mentioned diversity.

Kothari and Anuradha[69] are of the opinion that IPRs alone cannot be held solely responsible for the loss of agro-biodiversity, but that IPRs are bound to encourage the

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[61] Achieving this objective requires either breeding through selection of genes for maximum adaptability, or introducing the new seeds while also promoting farming practices that reduce environmental heterogeneity.

[62] K. Dawkins, M. Thom, & C. Carr, 'Intellectual Property Rights and Biodiversity', (undated article), Institute for Agriculture and Trade Policy, available at World Wide Web, http://www.rz.uni-frankfurt.de/~ecstein/gen/iatp/ipr-info1

[63] According to a survey of U.S. seed banks, some varieties of non-commercial crops such as chufas, martynia and rampion have been lost entirely. See C. Fowler, & P. Mooney, *Shattering: Food, Politics and the Loss of Genetic Diversity*, (1990), University of Arizona Press.

[64] The Panel of Eminent Experts on Ethics in Food and Agriculture was established by the Director-General of the FAO in accordance with Article VI.4 of the FAO Constitution and Rule XXXV of the General Rules of the Organization, for a period of four years from 1 January 2000. Eight eminent experts were appointed from different scientific and other disciplines to serve on the Panel in accordance with the Terms of Reference established by the FAO. Generally, the eminent experts are to raise public awareness and advise the Director-General on ethical issues in food and agriculture.

[65] See Report of the Panel of Eminent Experts on Ethics in Food and Agriculture, First Session, 26 – 28 September 2000, available at World Wide Web http://www.fao.org/docrep/003/x9600e/x9600e06.htm

[66] L.A. Thrupp, *Linking Biodiversity and Agriculture: Challenges and Opportunities for Sustainable Food Security*, (1997), World Resources Institute, Washinton D.C.

[67] Which leads to disease, increased pests, and a loss of insect diversity.

[68] Which leads to a loss of fertility and a decline in productivity.

[69] See A. Kothari, & R.V. Anuradha, 'Biodiversity, Intellectual Property Rights, and GATT Agreement: Hoe to Address the Conflicts?', (25 October 1997), *Economic and Political Weekly*, Vol. 32, Issue 43, 2814 – 2820.

displacement of a wide range of traditional local varieties in favour of a small number of widely adapted homogenous modern varieties. They highlight one of the lessons of the green revolution, namely, that the development of new varieties by the seed industry is unlikely to match the loss of traditional varieties after these new varieties are introduced.[70] Thus, although it cannot be said that monocultural agricultural systems are inherently biodiversity-erosive, they may cause biodiversity loss if they replace more biologically diverse ecosystems. For example, where a monocultural system produces higher yields per harvest compared to a more polycultural agro-ecosystem, incentives to cultivate more biologically diverse ecosystems may be reduced as a consequence. It is important to note here that various studies document that crop uptake can be driven as much, if not more, by how well farmers believe the crops deliver as by factual data on their real performance. Thus, in the context of yield performance, it is not always necessary for a monocultural system actually to produce higher yields; a belief that this is the case suffices. For example, one study considered an opinion poll of approximately eight hundred farmers in Iowa conducted in 1998 by the Leopold Centre for Sustainable Agriculture.[71] The poll revealed that 53 per cent of the farmers chose genetically modified RR[72] Soybeans because they believed that they produced higher yields than non-GM varieties. Actual data from their farms was analysed. It was found that the farms planting GM soybeans produced lower yields than those planting conventional soybeans.[73] Clearly, most of the farmers were unaware of the negative yield performance of the new soybeans they were growing. The formulation of such erroneous beliefs is most probably attributable to sophisticated marketing on the part of biotechnology

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[70] The Green Revolution began in Mexico in 1944 following the establishment of a plant-breeding station in NW Mexico by the Rockefeller foundation and the Mexican government with the goal of increasing grain yields. The project was headed by Norman Borlaug, who developed a high-yielding wheat plant that won him the Nobel Prize. The term 'Green Revolution' was coined in the 1960s and became a worldwide agricultural movement. With financial inputs from the International Agricultural Research Centres, the new seeds quickly spread across the globe and new strains of various other crops were developed, e.g. rice and corn. However, the Green Revolution was not the complete success in Africa and Asia as it was in other countries. This is because much of the reason why the modern varieties produced more than traditional varieties was that they were more responsive to controlled irrigation and to petrochemical fertilizers. Gains were confined to areas with conditions suited to the Green Revolution technologies – irrigated lands with access to chemical inputs. For example, while Green Revolution rice varieties could achieve yields of 10 metric tonnes per hectare (t/ha) at research stations, in practice, most farmers only got 3-6t/ha. See International Rice Commission, Country Rice Facts, FAO, December 1999. The widespread planting of genetically uniform crops under monoculture conditions rapidly displaced local varieties, which had much greater genetic potential to resist diseases. Pest and disease epidemics quickly overwhelmed the limited resistance potential of the new varieties in various areas, e.g. Zimbabwe. By the 1990s, almost 75 per cent of Asian rice planting areas were sown with the new varieties. The same was true for almost half of the wheat planted in Africa and more than half of that in Latin America and Asia. See D. Kuyek, 'Genetically Modified Crops in Africa: Implications for Small Farmers', GRAIN, (2002), and P. Rosset, J. Collins, & F.M. Lappe, 'Lessons from the Green Revolution', (2000), available at World Wide Web http://www.foodfirst.org/media/opeds/2000/4-greenrev.html.

[71] See L.P. Wessex, 'Low Yields From RR Soybean', (2000), Nebraska University Study, available at World Wide Web, http://www.btinternet.com/~nlpwessex/Documents/gmnebraskasoycomment.htm

[72] Roundup Ready.

[73] To be precise, two years of Nebraska University Institute of Agriculture and Natural Resources research showed that RR Soybeans yield 6 per cent less than their closest non-GM relatives, and 11 per cent less than high-yielding conventional soybeans. This averages to 3 fewer bushel per acre, or 480 fewer bushels on a 160-acre field.

companies. Essentially, however, beliefs are important factors influencing farmers' decisions regarding the adoption of alternative (e.g. monocultural or polycultural) agro-ecosystems. It is important, therefore, to recognise that beliefs may, in some cases, be derived principally from reliance on marketing hyperbole and not objective science.

A further issue that is relevant to an analysis of the relationship between IPRs and the conservation and sustainable use of biodiversity is whether, and to what extent, the increasing production and sale of seed-agrochemical packages – such as transgenic crops sold with pesticides and/or herbicides for which they have built-in resistance – is harmful to biodiversity. The question, in this context, is whether IPRs act as an inducement to companies to produce these kinds of packages.

Although seed companies often produce hybrids and other modern varieties that depend upon applications of agrochemicals,[74] the strongest IPR link appears in the context of genetically modified crops. It is useful at this point to consider the history of genetic engineering. The driving force behind the development of GM crops is the pesticide industry. By the 1990s, the pesticide industry was beset by several major problems. Firstly, it had become increasingly difficult and expensive to develop new pesticides.[75] Secondly, the top selling pesticides were about to come off patent and the TNCs feared that generic producers would reduce prices and take an increasing share of the market.[76] Genetic engineering has great potential to resolve these problems. It provides a new area of science – biology – that companies can turn to for new pesticides,[77] and consequently, new patents. Once the pesticide TNCs understood the potential of GM crops, they bought up all the most advanced biotechnology firms and the world's largest seed companies.[78] By 2001, just six corporations – Aventis, Dow, Du Pont, Mitsui, Monsanto and Syngenta – controlled 98 per cent of the global market for patented GM crops, 70 per cent of the global pesticide market and 30 per cent of the global seed market.[79] The same six

[74] Such as fertilizers, herbicides and insecticides.

[75] In 1991 a new pesticide cost between $40 – 100 million to bring through the regulatory process, whereas, it typically cost under $1 million to bring a new plant variety to market. See H. Hobbelink, *Biotechnology and the Future of World Agriculture*, Zed Books: New Jersey, 1991, p147.

[76] By 1999 off-patent pesticides accounted for 53 per cent of the entire global market and by 2005 are expected to account for 69 per cent, with a market value of $27 billion. See Agrow: World Crop Protection News, 12 February, 1999.

[77] This is because companies can modify crops so that they only grow properly when sprayed with their own pesticides and thereby prevent farmers from using alternative pesticides.

[78] The seed industry has seen consolidation through take-overs and mergers at a frightening pace. In the first wave of acquisitions in the 1960s and 1970s, many large chemical, oil and food corporations acquired many medium and small sized seed companies. Another round of mergers in the 1980s saw many of these chemical, oil and food companies sell their interest in the seed business to agricultural chemical firms and mega-mergers involving the seed giants. In developed countries, the new life science companies that combine crop biotechnology with agro-chemical and seed production dominate the seed industry. For a detailed analysis of selected mergers and acquisitions in the seed industry see C. Thirtle, 'Impact of Terminator Technologies in Developing Countries: A Framework for Economic Analysis', (1999), Appendix 4, at 216, in 'Costs and Benefits to the Livelihoods of the Rural and Urban Poor Arising from the Application of So Called "Terminator Genes" and Similar Technologies in Developing Countries', A Report to the UK Department for International Development Under Contract CNTR 99 8215, 1999.

[79] L.L. Ching, 'Patents on Life Patently Undermine Food Security', (2002), Institute of Science in Society (ISIS), available at World Wide Web http://www.i-sis.org.uk/trips3.php

corporations owned 60.8 per cent of patents granted on rice, 70.8 per cent of patents granted on wheat, 71 per cent of patents granted on maize, 76 per cent of patents granted on soybean and 46.7 per cent of patents granted on sorghum.[80] It is widely accepted that the former three crops, with the addition of potatoes, are the world's most important food crops.[81]

The first crops introduced reflect corporate business strategies. That is, the first generation biotech applications focused on input traits. In 1999, 78 per cent of all the genetically engineered crops planted in the world were engineered for herbicide tolerance[82] and the vast majority were engineered for tolerance to the herbicide Roundup (glyphosate).[83] For Monsanto, the world's leading supplier of Roundup and the owner of most Roundup-resistant GM crops, the GM crops were an effective way to protect sales of its herbicide, which was coming off patent around the world in 2000-2001.[84] Monsanto's patent on the gene for Roundup resistance and all plants containing this gene has many more years to run, and Roundup Ready seed buyers are contractually bound to purchase Roundup herbicide as part of the package. The principle technologies on the market today are herbicide resistant crops and insect resistant crops. The former are engineered to be resistant to the corporation's own brand of herbicide. As a result, the farmer must buy the seed and herbicide as a package. The latter are largely focused on crops engineered with the bacterium *Bacillus thuringiensis* (Bt), a toxin which kills insects which feed on it, but which pests develop resistance to very quickly.[85]

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[80] Ibid. The statistics detailed in this paragraph aim to substantiate the claim that the motivating force behind the development of GM crops is the pesticide industry. The extent to which such statistics can be used to establish whether the high concentration of economic power within the agricultural biotechnology industry either constitutes, or facilitates the creation of, a monopoly is considered below in section 6.3.3.

[81] In 1976, Harlan presented a list of the thirty principal food crops that nourish man. In descending order of annual production in millions of metric tonnes: wheat (360), rice (320), maize (300), potato (300), barley (170), sweet potato (130), cassava (100), grapes (60), soybean (60), oats (50), sorghum (50), sugarcane (50), millets (45), banana (35), tomato (35), sugar beet (30), rye (30), oranges (30), coconut (30), cottonseed oil (25), apples (20), yam (20), peanut (20), watermelon (20), cabbage (15), onion (15), beans (10), peas (10), sunflower seed (10), and mango (10). The four crops at the head of the list were noted as contributing more tonnage to the world than the remaining twenty-six crops combined. See J.R. Harlan, 'The plants and animals that nourish man', (1976), *Scientific American* 235(3):88-97. A more recent analysis did not surface in the writer's search. Further, the moderator of ProMED-plant CIAT Virology Research Unit in Miami, P.K. Anderson, states that, 'I am unaware of an analysis more recent than Harlan's.' See P.K. Anderson, 'Food Security and Emerging Plant Diseases', (1997), ProMED Plant Virology Research Unit, available at World Wide Web, http://www.agnic.org/pmp/1997/fse9707.html

[82] In engineering herbicide resistant crops, the goal is to win a greater herbicide market-share for a proprietary product.

[83] See Kuyek, op cit note 70 at 4.

[84] See R. McNally, & P. Wheale, 'Biopatenting and Biodiversity: Comparative Advantages in the New Global Order', (1996), *The Ecologist,* Vol. 26, Issue, 5, at 222 – 228.

[85] See, for example, D.N. Alstad, & D.A. Andow, 'Managing the Evolution of Insect Resistance to Transgenic Plants', (1995), *Science* 268, 1894-1896; J. Mallet, & P. Porter, 'Preventing Insect Adaptations to Insect Resistant Crops: Are Seed Mixtures or Refugia the Best Strategy?', (1992), Proceedings of the Royal Society of London Series B Biology Science, 250, 165 – 169; F. Gould, 'Potential and Problems with high-dose strategies for Pesticidal Engineered Crops', (1994), Biocontrol Science and Technology, 4, 451-461; and D. Pimentel et al, 'Benefits and Risks of Genetic Engineering in Agriculture', (1989), *Bioscience*, 39, 606-614.

The position of the life-science corporations is that genetic engineering can significantly reduce or even obviate pesticide use. Such reduction is environmentally desirable and has positive implications for biodiversity preservation. However, the statement is both incorrect and unqualified. Subsistence farming, for example, is based on negligible chemical inputs. Indeed, in many cases, subsistence farmers do not utilise agrochemicals at all. Subsistence farming is practiced extensively in developing countries. It is difficult to see, therefore, how genetically modified organisms (GMOs), all of which require chemical inputs and many of which require extensive chemical inputs, can reduce the use of herbicides and pesticides where they replace subsistence farmers' varieties. The statement is clearly directed at industrialised farmers that already utilise chemical inputs. It is interesting at this point to consider Monsanto's claim that, in producing packages of herbicides and pesticides and plants resistant to these particular chemicals, the aim is not to increase herbicide/pesticide use, but to ensure that farmers use *their* herbicides/pesticides.[86] However, even within this context, it is doubtful whether GMOs reduce the use of chemical inputs.[87] In the absence of scientific agreement on the issue, one might question the incentive on the part of biotechnology companies to create varieties that require the use of less agrochemicals. In the writer's view, such incentive is not present. Biotechnology companies engineer crop varieties to be resistant to their particular brand of herbicide or pesticide. To ensure that such varieties require less of the attendant herbicides or pesticides does not make economic sense. The incentive to decrease herbicide and pesticide use corresponds with the incentive to decrease sales and ultimately profits. According to Buttel and Belsky, 'multinational parents of seed companies have larger fertilizer, herbicide, insecticide, and fungible product lines that generally are far more important in terms of total revenue and profit than are seeds . . . accordingly, many agrochemical-based seed company subsidiaries might be hesitant to emphasize plant breeding goals that would threaten fertilizer and pesticide product lines.' Consequently, 'a substantial amount of plant research in private firms has been aimed at developing various types of seed-chemical packages that reinforce rather than threaten sales of agricultural chemicals.'[88] The incentive to incur great financial cost to develop a crop variety that ultimately reduces profits is simply not an incentive of biotechnology companies. The *assertion* that such crops require less chemical inputs, however, does operate to biotechnology companies' benefit. When coupled with clever marketing, such a statement has the potential to override scientific fact and greatly increase sales. It appears therefore that there is greater incentive on the part of biotechnology companies to state that GM crops significantly reduce the use of herbicides and pesticides than there is actually to ensure that GM crops significantly reduce the need for such chemical inputs.

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[86] Op cit note 29 at 47.

[87] It is beyond the scope of this paper to analyze available research concerning whether or not GM crops require the use of more or less herbicides and pesticides. However, the fact that the results of studies remain mixed is instructive and allows one to assert that the introduction of GM crops does not 'significantly' reduce the use of chemical inputs.

[88] See F.H. Buttel, & J. Belsky, 'Biotechnology, Plant Breeding, and Intellectual Property: Social and Ethical Dimensions', (1987), *Science, Technology and Human Values*, Vol. 12, Issue 1, at 31 – 49.

Environmentalists and scientists frequently note that genetically engineered herbicide resistance has negative environmental effects.[89] The most common concerns are: the encouragement of the excessive use of herbicides which may kill other plant varieties and species;[90] the acceleration of the development of resistance among pests;[91] and the creation of the possibility of herbicide resistant genes crossing over to other plants including the weeds being targeted.[92] Concerns are also expressed that increased use of agrochemicals may have serious social impacts, especially in developing countries. These crop-agrochemical linkages can be considered to represent a shift towards capital-intensive agriculture that increases the costs of farming and may therefore be detrimental to small farmers.[93]

The essential question is, however, whether IPRs are responsible for, or facilitate, the production and sale of crop-agrochemical packages. That is, are agrochemicals and crops being sold as packages simply because they are capable of being patented? The life science industry's response is that without IPR protection, they would have no incentive to invent or to innovate. It is difficult to imagine, therefore, that these products would have come into existence without IPRs. A more indirect way that IPRs may encourage such environmentally unfavourable R&D, according to Dutfield, is that IPRs are sometimes said to stimulate industrial restructuring in ways that make such R&D more attractive to industry than it would otherwise be.[94] This idea is supported. As canvassed above, patents over plant varieties increase expectations of seed and agrochemical industry profits and have in the past stimulated a rapid upsurge in acquisitions and mergers between the seed and agrochemical companies.

The WTO imposes IPR modeled on the protection of industrial innovations to grant individual monopolies on living things and rejects the existence of community collective innovations. Contrary to the so-called free trade and trade liberalization principles of the WTO, TRIPs is being used as a protectionist instrument to promote corporate monopolies over technologies, seeds, genes and medicines. Through TRIPs, large corporations use IPRs to protect their markets, and to prevent competition.[95] Excessively high levels of intellectual property protection required by TRIPs have shifted the balance away from the public interest, towards the monopolistic privileges of IPR holders. This undermines sustainable development objectives, including eradicating poverty, meeting public health

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[89] See, for example, M. Lappe, & B. Bailey, *Against the Grain: The Genetic Transformation of Global Agriculture*, (1999), Earthscan Publications Limited, London, and S. Krimsky, & R. Wrubel, *Agricultural Biotechnology and the Environment: Science, Policy and Social Issues*, (1996), University of Illinois Press, Chicago.

[90] See, for example, J. Bell, 'Genetic Engineering and Biotechnology in Industry' (1996), in "The Life Industry: Biodiversity, People and Profits", M. Baumann, J. Bell, F. Koechlin, & M. Pimbert, 31 – 52.

[91] See, for example, R. Jenkins, 'Bt in the Hot Seat' (September 1998), *Seedling*, 13 – 21.

[92] This could create 'superweeds' which would render the herbicide ineffective in the long term, and cause ecological impacts that cannot easily be predicted or reversed.

[93] See S.K. Verma, 'TRIPs and Plant Variety Protection in Developing Countries', *European Intellectual Property Law*, (1995), Vol. 17, Issue 6, at 281 – 289.

[94] Op cit note 29 at 48.

[95] According to the World Intellectual Property Organization, citizens and corporations of industrialized countries hold 95 per cent of the patents in Africa, almost 85 per cent of those in Latin America and 70 per cent of those in Asia. WIPO, data set IP/STAT/1994/B, released November 1996.

needs, conserving biodiversity, protecting the environment and the realization of economic, social and cultural rights.

A good example of the adverse effects of strict IPR protection is the exorbitant prices of medicines, especially for treatment of HIV/AIDS, as a result of the monopoly conferred through patents granted to pharmaceutical companies.[96] This example is well illustrated by a South African case. When the South African government passed the Medicines and Related Substances Control Act 90 of 1997,[97] the US government accused it of failing adequately to protect American drug patents.[98] The US objection was directed at provisions in the Bill[99] which allowed for compulsory licenses[100] and parallel importing.[101] Developing countries have, in the past, been reluctant to resort to

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[96] The excessive levels of IPR required by TRIPs could have a severe impact, especially in the high technology sectors such as pharmaceuticals, working to the disadvantage of developing countries in two main respects: domestic manufacturers wishing to produce and commercialize products covered by patents will be forced into licensing agreements involving royalty payments to patent holders; while R&D activities may be hindered since the TRIPs Agreement is likely to inhibit *reverse engineering*, the process by which research-based industry products are copied and adapted for developing country usage. See G. Velasquez, & P. Boulet, 'Essential Drugs in the New International Economic Environment' (1999), Bulletin of the WHO, 77 (3) 288.

[97] The aim of which was to reduce the price of HIV/AIDS drugs.

[98] C. Oh, 'TRIPs and Pharmaceuticals: A case of Corporate Profits Over Public Health', (September 2000), Third World Network, World Wide Web, http://www.twnside.org.sg/title/twr

[99] Namely, section 15C, which reads as follows, 'The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may – (a) notwithstanding anything to the contrary contained in the Patents Act (57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall not extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent. (b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standard and is intended to have the same proprietary name as that of another medicine registered in the Republic, but which is imported by a person other than the person who is the holder of the registration certificate of the medicine already and which originates from any site of manufacture of the original manufacturer as approved by the Council in the prescribed manner may be imported; (c) prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b)'.

[100] Compulsory Licensing refers to an order by a court or government body that allows any person or the government to use a patent legally without permission from the patent holder in the public interest.

[101] Parallel imports are goods produced genuinely under protection of a trademark, patent, or copyright, placed into circulation in one market, and then imported into a second market without the authorization of the local owner of the intellectual property right. For example, it is permissible for a trading firm to purchase quantities of prescription drugs in Spain and import them into Sweden or Germany without the approval of the local distributor owning licensed patent rights. It is to be noted, however, that these goods are authorized for original sale, and are not counterfeited or pirated merchandize. Thus, parallel imports are identical to legitimate products. Parallel imports generally come about when there is a significant differential in the price for which the goods can be purchased in the exporting country and the price for which the goods can be purchased from the trader holding exclusive trading rights in the country of importation. By reason of this price differential, parallel imports can be traded in at a lower price in the country of importation than that at which the regular goods can be purchased from the trader holding exclusive distribution rights. For further discussion, see O. Dean, 'Copyright v Grey Goods in South Africa, Australia and Singapore', (1994), 111 *SALJ* 746, 747; and K. Maskus, 'Parallel Imports in Pharmaceuticals: Implications for Competition and Prices in Developing Countries', Final report to WIPO (April 2001).

compulsory licensing and parallel importing for fear of trade sanctions.[102] The Pharmaceutical Manufacturers Association (PMA) and 39 drug companies in South Africa, backed by the TNCs and the pharmaceutical lobby in the US, filed a legal challenge to the new law, alleging that it was unconstitutional. Despite considerable pressure exerted on the government and Parliament of South Africa, the Bill was not repealed.[103] The court action instituted by the PMA was withdrawn 'at the doors of the court' and, consequently, neither the legislation nor the objections raised were subjected to legal scrutiny. The South African government's refusal to remove the 'offending' provisions in the Act, and its firm intention to use compulsory licensing and parallel importing in a TRIPs-compliant manner are supported by the writer. This is because section 15C is neither in conflict with the relevant TRIPs provisions,[104] nor is it unconstitutional.[105] In fact, the right of a country to undertake compulsory licensing and parallel importing of pharmaceutical drugs has been reaffirmed in the Doha Ministerial Declaration.[106]

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[102] A report from Medecins sans Frontiers (MSF) details the US government's pressure on Thailand to restrict its use of parallel imports and compulsory licenses. The government of Thailand passed a law banning parallel imports in 1992, under the threat from the US to limit textile imports. In 1999 amendments were made to allow for parallel importing, however, MSF reports that the government of Thailand, this time under threat of high tariffs on imports of wood products and jewelry, passed ministerial regulations to restrict the use of compulsory licenses. Op cit note 98.

[103] It is to be noted that intense campaigning by AIDS activists and health activists globally and particularly in the US may have played a fundamental role in causing the US to retreat from its position and consequently reduce the pressure exerted on South Africa.

[104] Although the use of compulsory licenses is not prohibited in the TRIPs Agreement, it is not specifically referred to. It is submitted, however, that broader provisions (such as Article 7, 8, 30 and 31) sanction its use. Article 7 of the TRIPs Agreement provides that patent rights should not conflict with 'social and economic welfare' objectives of Member States. Article 8(1) provides that 'Members may in formulating or amending either 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 technical development, provided that such measures are consistent with the provisions of this agreement.' Article 8(2) states that 'Appropriate measures, provided that they are consistent with the provisions of this agreement, may be needed to prevent the abuse of [IPRs] by rights holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.' Article 30 allows Member States to include in their patent laws some limited exceptions to the exclusive rights of patent holders, including parallel importation.

[105] Section 79 of the Patents Act allows the Minister of Defense basically to expropriate any invention or patent. The right of the State to expropriate property is derived from section 25(1) and (2) of the Constitution. If the defence and security needs of a country warrant exemption, then public health, even more so, should be exempted from the burdensome requirements of patent protection. In the case of essential medicines, specifically HIV/AIDS drugs, the Minister of Health has the legal and constitutional duty to promote, protect and advance public health. Protecting, promoting and advancing public health through affordable access to essential drugs is a legitimate public purpose and definitely in the public interest. Importantly, the use of compulsory licensing and parallel importing is not contemplated outside of essential medicines.

[106] The Doha Ministerial Declaration was adopted at the Fourth WTO Ministerial Conference in Doha, Qatar from 9-14 November 2001. It is to be noted, however, that despite the agreement reached in Doha specific text concerning the rights of developing countries to protect public health was bracketed (indicating disagreement over text portions) in the *Draft Plan for Implementation* at the on Sustainable Development's fourth Preparatory Committee. See Chapter 7 below, and in particular, footnote 458.

The argument used by TRIPs proponents and the pharmaceutical industries that patent protection is essential to ensure R&D for new drugs warrants analysis. Presently, there is scant evidence to demonstrate that TRIPs-compliant standards of IPR will ensure investment in R&D for diseases of the poor. Of the 1223 new chemical entities developed in the 21-year period between 1975 and 1996, only 11 were for the treatment of tropical diseases.[107] The last major tuberculosis drug was developed 30 years ago, yet tuberculosis remains a major cause of death in many developing countries. There is concern that R&D in the pharmaceutical sector is concentrated on products intended for the lucrative developed country markets. Hence the increased investments for R&D on drugs for impotence, obesity[108] and baldness, instead of on new and more effective drugs for life threatening or poverty-related 'third world diseases', including malaria and tuberculosis.[109]

The pharmaceutical industry and the US Government want the exclusion enumerated in Article 27.3(b)[110] to be deleted, thus forcing the world to accept patents on plants and animals, while the developing countries of the South want the Article to remain in place or even be extended. The problems created by Article 27.3(b) are numerous. Firstly, it sets no parameters for what a *sui generis* system might amount to. Secondly, it does not lay down any guidelines as to what is 'effective'.[111] Thirdly, with its lack of any benefit-sharing mechanism, it offers no remedy to combat biopiracy and is perceived as exacerbating the problem.[112] If it is agreed that IPRs increase commercial benefit, then agreement needs to be reached on the equitable sharing of such benefits. TRIPs does not provide an answer. The CBD, on the other hand, does seek to provide such an answer.[113]

There is a bias ingrained in TRIPs to protect breeders and biotechnologists at the expense of farmers and local communities. Unlike the CBD, TRIPs does not require applicants to consult with local communities or governments concerning patenting compound forms of a natural plant species from the country of origin. Patents on seeds and genetic resources for food and agriculture threaten sustainable farming practices, farmers' livelihoods and food security. Farmers using patented seeds are deprived of their right to use, save, plant and sell their seeds. The imposition of patent rights over biological resources and traditional knowledge unfairly deprive communities of their rights over, and access to, the same resources they have nurtured and conserved over generations. Effectively, centuries of innovation are totally devalued to give monopoly rights on biological resources to those who manipulate genes with new technologies, placing their

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[107] See 'TRIPs, Patents and Access to Medicines: Proposals for Clarification and Reform' (June 2001) Third World Network Briefing Paper, World Wide Web, http://www.twnside.org.sg/title/drugs2.htm

[108] In the US alone, with an estimated 35 million to 65 million clinically obese people, the market for weight reduction pharmaceuticals is huge, and growing all the time. See T. Kahn, 'Prickly Dispute Finally Laid to Rest' *Business Day 1ST Edition*, March 22, 2002.

[109] Op cit note 107.

[110] See footnote 53.

[111] Art. 27.3(b) 'Members shall provide for [PPV's] . . .by an *effective* sui generis system'. (Own emphasis).

[112] TRIPs provides no mechanism for sharing benefits between a patent holder in one country and the donor of material in another country from which the invention is derived.

[113] As is evident in Article 1 (which outlines the Conventions' objectives), and the numerous provisions relating to the equitable sharing of benefits.

contributions over and above the intellectual contribution of generations of indigenous farmers. This contradicts the key principles and provisions of the CBD. The race to patent genes, cells, and deoxyribonucleic acid (DNA) sequences has blurred the crucial distinction between discoveries and basic scientific information, which should be freely exchanged, and truly invented products or processes meriting patent protection.

2.3.3 Review of Article 27.3(b) of the TRIPs Agreement

The provisions of Article 27.3(b) have been under review since 1999, as mandated in the Agreement itself. Developing countries had positive hopes for the 1999 review as it was taking place one year before they were obliged to implement the provision. Developing countries made concrete recommendations for clarification of TRIPs, but these were not acted upon. At the WTO's Third Ministerial Conference,[114] almost 100 developing countries signed proposals to reform TRIPs in respect of biodiversity and indigenous knowledge.[115] The Africa Group of WTO members[116] proposed an extension of the deadline to implement TRIPs Article 27.3(b) in developing countries, so that the review might proceed and conclude properly.[117] Although this proposal was officially tabled, it was not properly deliberated nor decided upon.[118] The deadline for implementation of Article 27.3(b) in developing countries arrived,[119] but no conclusions were drawn from the review process. At the above-mentioned meeting of the General Council, the Chairman advised countries to exercise 'restraint' in dealing with implementation deadlines until the review process is completed.[120] The WTO's Fourth Ministerial Conference in Doha[121] and the World Summit on Sustainable Development (WSSD)[122] in Johannesburg additionally failed to modify Article 27.3(b) in any manner or form. The

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[114] Seattle, 30 November – 3 December 1999.

[115] For a full review of official country positions, see: GRAIN, 'Update on review of TRIPS Article 27.3(b)', (July 2001), World Wide Web, http://www.grain.org/publications/trips-countrypos-en.cfm

[116] The countries enumerated under the Africa group include: Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Central African Republic, Congo, Cote d'Ivoire, Democratic Republic of Congo, Djibouti, Egypt, Gabon, The Gambia, Ghana, Guinea Bissau, Guinea, Kenya, Lesotho, Madagascar, Malawi, Mali, Mauritania, Morocco, Mozambique, Namibia, Niger, Nigeria, Rwanda, Senegal, South Africa, Swaziland, Tanzania, Togo, Tunisia, Uganda, Zambia, and Zimbabwe.

[117] It also enumerated the Africa Group's aspirations of the review that patents on life should be prohibited.

[118] This is because the Conference was 'suspended' without any agreement on where negotiations stood or how they would proceed. One of the major reasons for the breakdown in Seattle's negotiations was the attempt by the U.S. to introduce the environmental issue of the ecological risks of GMOs into the WTO. Developing countries and the European Union wanted it covered by the Biosafety Protocol of the CBD. If Biosafety issues related to GMOs are primarily determined by the free trade rules of WTO, they will be viewed as non-tariff trade barriers. If, on the other hand, the CBD and environmental criteria take precedence, trade rules will have to change to ensure regulation for Biosafety. See V. Shiva, 'Doha: Saving the WTO, Killing Democracy', (4 December 2001), World Wide Web, http://www.ratical.org/co-globalize/QatarShiva.html

[119] 1 January 2000.

[120] Op cit note 52.

[121] Qatar, 9 – 14 November, 2001. It has been suggested by various authors that Doha was chosen as a venue for the WTO's Fourth Ministerial Conference to escape from the popular response of citizens mobilizing on a large scale as they did in Seattle, Gothenburg and Genoa. Op cit note 118.

[122] Johannesburg, 26 August – 4 September 2002. The Johannesburg World Summit on Sustainable Development is discussed below in Chapter 7.

review of TRIPs Article 27.3(b) continues. It is hoped that it will be properly addressed at the WTOs Fifth Ministerial Conference in Mexico in September of 2003.

In June of 2003, the Africa group put forward its latest proposal on the review of TRIPs Article 27.3(b). The proposal commences by highlighting the solutions that the Africa group believes need to be found, sets out possible areas of agreement, and then provides suggestions on how to resolve issues on which common understanding has been lacking. The proposal reiterates the Africa group's reluctance to allow patents on life forms and proposes that Article 27.3(b) be revised to prohibit such. In this respect, the Africa group confirms the notion that patents should only be accepted if they are in the public interest by stating that, 'for plant varieties to be protected under the TRIPs Agreement, the protection must clearly, and not just implicitly or by way of exception, strike a good balance with the interests of the community as a whole.'[123]

The Africa group also tabled a completely new proposal which aims to bring traditional knowledge formally into the ambit of TRIPs. That is, the Africa group want to add to the TRIPs Agreement a whole section on traditional knowledge. Such section would focus on specifying the conditions under which traditional knowledge can and cannot be the subject of IPRs and address how traditional knowledge should be respected and protected in a broader sense. As tabulated in the Africa groups proposal, the proposed section on traditional knowledge currently reads as follows: '[m]embers shall require an applicant for a patent to disclose the country and area of origin of any biological resources and traditional knowledge used or involved in the invention, and to provide confirmation of compliance with all access regulations in the country of origin.' The disclosure of origin and traditional knowledge proposals will now briefly be considered.

It seems trite to say that before research institutions can apply for patents related to biological materials or traditional knowledge they should be required to disclose where they got the materials or knowledge. Without such disclosure it is difficult to see how a patent office could decide whether an invention has occurred or whether the subject matter of the patent is merely an appropriation of pre-existing knowledge. There is, however, no agreement among governments concerning this simple principle, let alone how such requirement would operate. At present, the only available remedy is to challenge the patent in the courts or before the patent office of the country in which the patent was granted. Such remedy is, however, difficult and expensive and is, in most cases, not a practical option. The disclosure of origin requirement has been suggested by developing countries in an attempt to reduce the granting of biopiracy patents. Indeed, developing countries push for such requirement is strengthened by the CBD, which recognises the right of parties to control access to genetic resources and to receive a share in any benefits arising from their commercialisation. Although a requirement of disclosure of origin could make a real difference in reducing biopiracy, it would not solve the problem entirely. Such requirement would not guarantee that local communities that provide resources or knowledge actually receive a fair deal. Proof of their consent would

[123] Africa Group, 'Taking Forward the Review of TRIPs Article 27.3(b) of the TRIPs Agreement', Communication from the Africa Group, WTO, IP/C/W/404, 26 June 2003, at 5, available at World Wide Web, http://docsonline.wto.org

not be required. More importantly perhaps, agreement on a requirement for disclosure of origin could be viewed as a capitulation on the life patenting issue that contradicts the principle of 'no patents on life'.

As noted, the Africa group has issued a concrete proposal on traditional knowledge. The proposal is, however, somewhat contradictory. On the one hand, it tries to set limits on the IPR system as it affects traditional knowledge. For example, it proposes amendments that, firstly, would make the mere existence of traditional knowledge grounds for defeating IPRs,[124] and secondly, prevent IPRs on inventions derived from traditional knowledge unless prior informed consent, benefit-sharing and other access requirements have been met. On the other hand, the proposal defines traditional knowledge as 'a category of intellectual property rights'.[125] This definition, however, contradicts the views of traditional knowledge holders themselves, who – for the most part – regard traditional knowledge as an integral part of their cultural and spiritual lives, not simply as property to be bought and sold. Perhaps recognition of this conflict on the part of the Africa group is evinced through the nature of the measures it proposes for the protection of traditional knowledge. That is, the measures listed are not related to intellectual property protection, but to safeguarding conditions for traditional knowledge holders to continue using and developing their cultural heritage and traditional economic activities without unwanted commercial interference. Further insight into this conflict may be gleaned from the fact that the proposal uses the word 'protection' to refer to both the 'protection' of intellectual property, and the 'protection' of traditional knowledge. In the former case, protection means enforcing private, exclusive economic rights over an invention in order to prevent others from using or reproducing it. In the latter case, protection necessarily implies protecting the whole social, economic, cultural and spiritual context of that knowledge so that it continues to be produced and reproduced. The Africa group proposal, however, uses the term interchangeably.

Framing rights to traditional knowledge as intellectual property and entrusting their development to a body that is primarily concerned with trade and IPRs is dangerous. Indeed, the privatisation of traditional knowledge is one of the major threats to traditional knowledge and not a mechanism to safeguard them. Although there is undoubtedly a need to introduce limits on the use of IPRs on inventions derived from traditional knowledge, and that part of such reform needs to be undertaken within the WTO, there is an even more urgent need to strengthen the protection of traditional knowledge in the broader, non-IPR sense. The latter is, however, not a matter for either WTO or TRIPs, but for intergovernmental bodies such as the UN Human Rights Commission, UN Development Programme, CBD or UN Educational, Scientific and Cultural Organization. The Africa group's proposal on disclosure of origin and traditional knowledge reflects the broad consensus about the need to limit the incidence of biopiracy. However, the limited reforms proposed by the group in this direction could serve to legitimise, expand and strengthen IPRs on life.

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[124] Since novelty, inventiveness and originality will be compromised.
[125] Op cit note 123 at 10.

The decisions taken on the wording of Article 27.3(b) will determine the minimum standards that countries must impose for the protection of IPRs over plants, animals and biological processes. The review is part of a wider process that will determine what choices countries will have over their access to, the sustainable use of, trade in, and benefits arising from the use of plants, animals and biological processes. The outcome of the review will set precedents for future trade and environment negotiations. The impact of this review will affect all negotiations concerning the ownership, development and use of plants and animals, including: the regeneration of the Agreement on Agriculture; negotiations on the implementation of the CBD; and negotiations in the Food and Agriculture Organization (FAO) of the United Nations on the revision of the IUPGR and its submission to the CBD as a possible protocol. A complicating factor is that each of these negotiations is usually handled by different ministries and departments,[126] which can lead to a loss of policy coherence. Discussions are essential between all relevant ministries in order to agree on mutually acceptable negotiating positions and nurture an understanding of the linkages between and implications of all the international negotiations.

The vast majority of developing countries which are members of the WTO have been approaching their obligation to grant IPRs over plant varieties through 'an effective *sui generis* system', and not through patents. Only 21 developing country members of the WTO had PVP legislation in place as at 1 January 2000,[127] leaving 76 WTO members in the South without IPR protection measures for plant varieties. For the purpose of WTO there are 24 least-developed country (LDC) members in Africa,[128] the remaining 21 members being developing countries. Thus, 80 per cent of the African countries which should have implemented Article 27.3(b), had not yet done so by January 2000. It is not only Africa that is in arrears. As of January 2000, 70 per cent of developing countries worldwide that are members of the WTO had not yet fulfilled their obligations in implementing TRIPs Article 27.3(b).[129] The outcome of this review will of necessity have an impact on the drafting of effective *sui generis* legislation.

2.3.4 In the event of a conflict, does TRIPS take precedence over the CBD?

A number of States are Parties to both TRIPs and the CBD, yet are ambivalent regarding which should take priority in the event of conflict between these two agreements – agreeing to the demands of corporations or conserving the world's biodiversity.

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[126] For Example: WTO – Trade; IP – Patent Office; CBD – Environment; FAO – Agriculture.

[127] African States include: Kenya; Morocco, South Africa, and Zimbabwe. South Africa adopted PVP in 1878 when it became a member of the Union for Protection of New Plant Varieties (UPOV, Geneva). Interestingly, Morocco is the only African country that implemented some kind of *sui generis* law on plant varieties specifically for the purpose of TRIPs (1999) as at January 2000. Op cit note 52.

[128] LDCs were granted a longer transition period for implementation of the TRIPs Agreement, extending to 1 January 2006.

[129] This does not, however, mean that countries have been inactive on the legislative front. The progress of national and domestic legislation in Africa is canvassed below in Chapter 3.

The Singapore Ministerial Declaration[130] that was agreed and proclaimed at the WTO's first Conference states that 'each member should carefully review all its existing or proposed legislation, programs and measures to ensure their full compatibility with the WTO obligations'.[131] This implies that where measures to ensure effective implementation of the CBD are found by the WTO to conflict with States' obligations to promote effective and adequate IPR in terms of TRIPs, then such measures would have to be abandoned by the relevant States. The above Declaration needs to be considered in light of the relevant CBD provision[132] which requires States to co-operate, 'subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives'. However, the CTE has not yet confirmed whether or not the TRIPs provisions are supportive of and do not run counter to the CBD's objectives. According to Dutfield,[133] the Singapore Ministerial Declaration is an indication that the international community of States gives priority to the WTO as the main forum for consideration of all trade-related issues including IPR. This is considered a dangerous development as it subordinates environmental concerns to the interests of multinational corporations whose main motivation is profit and not conservation.

Finally, it should be noted that under the Vienna Convention on the Law of Treaties,[134] the agreement that is either later in time or clearer and more specific on the issue will prevail. In the case of the TRIPs Agreement and the CBD, both factors would result in the TRIPs Agreement prevailing.[135] This makes it imperative for developing countries rapidly to organize internally and within regional blocs to ensure that they have a choice over the outcome of the review of Article 27.3(b) of the TRIPs Agreement.

2.4 The International Convention for the Protection of New Varieties of Plants

Although the concept of IPRs as a device for promoting innovation has been around for more than five hundred years,[136] the idea of applying IPRs to plant varieties took another hundred years to emerge. One reason for this was the fact that, until recently, the prevailing paradigms of IPRs precluded their application to living materials. More importantly, perhaps, was the difficulty in segregating[137] and appropriating benefits from their use.[138] This difficulty arose directly from the self-reproducing nature of seed. Once a plant breeder released a new variety to farmers through the sale of seed, he had no

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[130] 13 December 1996.
[131] Paragraph 12.
[132] Article 16(5).
[133] Op cit note 56.
[134] Signed at Vienna on 23 May 1969 and entered into force on 27 January 1980.
[135] Commission on Intellectual and Industrial Property, 'Policy Statement: TRIPs and the CBD: What conflict?', (28 June 1999), World Wide Web, http://www.Iccwbo.org
[136] See F. Machlup, 'An Economic Review of the Patent System', (1958), Sub-Committee on Patents, Trademarks and Copyrights, Committee on the Judiciary, U.S. Senate, Study No. 15, Washinton D.C.: U.S. Government Printing Office.
[137] The difficulties in segregating the benefits flowing from a new plant variety arose because productivity depends on other inputs (e.g. fertilizer, agronomic practices etc.) as well and it is difficult to separate out the contribution of a new variety to productivity.
[138] See T. Swanson, *Global Action for Biodiversity: An International Framework for Implementing the Convention on Biodiversity,* (1997), Earthscan Publications Limited, London.

further control over the use of the variety, as farmers could multiply it themselves. The vast discrepancy between the benefits that could be appropriated privately by the breeder and the total social benefits implied that the market mechanism would fail to produce a socially desirable level of investment or effort in plant breeding. PVP legislation can been seen as an attempt to address the problem of appropriability for self-pollinated varieties.[139]

It was in the 1960s that several European countries enacted PVP legislation. Special laws for PVP were enacted partly because of the technical difficulties in applying the patent system – which was designed for industrial products – to plant varieties, which were thought not to reproduce themselves precisely and whose appearance could vary depending upon the environment in which they were grown.[140] Prior to 1961, while various States provided limited rights to plant breeders, the criteria for grant of rights differed from State to State.[141] Legislation was fragmented and there was no guarantee that the rights a particular country was prepared to grant its own nationals would be extended to the nationals of other states. It was the adoption of the International Convention for the Protection of New Varieties of Plants (UPOV) in 1961 that provided, for the first time, recognition of the rights of plant breeders on an international basis.

UPOV is the only international treaty focusing on plant variety protection. It was first adopted in 1961 by a group of Western European nations with the specific aim of introducing private property rights on plant varieties.[142] The Convention attempted to harmonize the PVP legislation of member countries. It specified as uniform criteria for the protection of new varieties distinctness,[143] uniformity[144], stability[145] and novelty.[146] These criteria reflected the need for identifiability of a variety as a prerequisite for the

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[139] PVP legislation was facilitated by the following developments: firstly, the development of systematic botany, which permitted the unique description of varieties, based on morphological characteristics. This enabled a particular case of plant variety rights to be distinguished from any other case. Improved breeding techniques made it possible to breed genetically uniform varieties, which facilitated the identifiability of individual varieties. This was a key element for the application of IPRs. Secondly, farm size increase coupled with a decline in the number of farmers in developed countries, drastically reduced the transaction costs of enforcing IPRs in relation to farmers. Thirdly, the development of molecular techniques for identification of varieties and their parentage facilitated the enforcement of IPRs in relation to imitators and competitors.

[140] Prior to this, the United States had enacted a Plant Patent Act in 1930 to provide protection to varieties of plant that reproduced themselves asexually; Netherlands enacted the Breeders Ordinance of 1941 which granted a vary limited exclusive right for breeders of agriculturally important species to market the first generation of certified seed; Germany enacted the Law on the Protection of Varieties and the Seeds of Cultivated Plants in 1953, which gave breeders the exclusive right to produce seed of their varieties for the purposes of the seed trade.

[141] Even the concept of 'variety' was not seen in the same light in all States.

[142] Members of the 1961 Act: Belgium and Spain.

[143] That is, distinguishable by one or more characteristics from any other variety whose existence is a matter of common knowledge.

[144] That is, uniform in its relevant characteristics, or homogeneous with regard to the particular feature of its sexual reproduction or vegetative propagation.

[145] That is, the variety is to remain true to its description after repeated reproduction or propagation.

[146] That is, it must not have been offered for sale or marketed, with the agreement of the breeder or his successor in title, in the source country, or for longer than a limited number of years in any other country.

application of IPRs. The Convention required member states to accord the same treatment to nationals of other states as they accorded to their own nationals. Importantly, it defined the scope of the breeders' rights, which extended to production for purposes of commercial marketing of the propagating material of the new plant variety.

UPOV was revised in Geneva in 1978 and 1991.[147] The UPOV Convention of 1978 defines the scope of protection as the breeder's right to prior authorisation for the following acts: production for purposes of commercial marketing, the offering for sale, and the marketing of the reproductive or vegetative propagating material as such of the variety.[148] UPOV 1978 contained two important features that distinguished the protection of plant varieties from patents, namely farmers' privilege and research exemption.[149] The former acknowledged the right of farmers to use farm-saved seed,[150] and the latter provided for the free use of the new variety for creating other new varieties without the breeders' authorisation.[151]

The UPOV Convention of 1991 strengthened the rights of commercial plant breeders. The 1991 UPOV Convention extends the right of the breeder in two ways. Firstly, it increases the number of acts for which prior authorisation of the breeder is required,[152] including all reproduction of the seed of the protected variety. It is to be noted that individual member states may provide for farmers' privilege in their laws as an exception.[153] Reducing farmers' rights to an exception, however, makes it extremely vulnerable to international pressure, industry tactics and arbitrary political decision-making. According to Dutfield, 'there is a strong likelihood that governments will act upon Articles 14 and 15 by further restricting or eliminating farmers' privilege.'[154] Secondly, such acts are not just in respect of the reproductive or vegetative propagating material as with the 1978 version, but also encompass harvested material obtained through the use of propagating material, and so-called 'essentially derived' varieties.[155] Concerning the latter, the 1991 version states that if a new variety is deemed to be essentially derived from a protected variety, the owner of the protected variety enjoys the same rights over the essentially derived variety as if the two varieties are identical. Dhar

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[147] The 1978 Act entered into force in 1981, and the 1991 Act entered into force in April 1998. As at July 15 2003, UPOV had 52 Member States of which 2 are parties to the 1961 Act, 26 are parties to the 1978 Act and 24 are parties to the 1991 Act. See http://www.wipo.org/treaties/documents/english/word/x-upov.doc

[148] Article 5.

[149] Essentially, the UPOV Convention of 1978 disallowed the marketing of the same plant variety in competition with its innovator. It did not disallow breeding activities making use of the new plant variety.

[150] The breeders' right extended only to the production of seed for commercial marketing and consequently the use of farm-saved seed was outside the purview of the breeders' right.

[151] Consequently, the breeder did not attain rights in the genes of his new variety.

[152] Namely, production or reproduction, conditioning for the purpose of propagation, offering for sale, selling or other marketing, exporting, importing, and sticking for the above purposes [Article 14].

[153] According to Article 15, the breeder's right in relation to a variety may be restricted 'in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting . . . the protected variety . . .' The farmers' privilege, therefore, becomes available only as an exception to the breeders' right.

[154] Op cit note 29, para 6, at 28.

[155] Food and Agricultural Organization, 'TRIPS: Article 27.3(b): Related International Agreements', (2001), World Wide Web, http://www.fao.org/docrep/003/x7355e/X7355e05.htm

and Chaturvedi[156] warn that determination of whether a new variety is essentially derived from an earlier one is likely to occur not during the examination but through agreement between breeders or litigation. According to Dhar and Chaturvedi, 'this implies that this critical issue would be settled by the relative strengths of the parties involved, an eventuality that would not favour developing countries like India who have long been involved in major programmes of plant breeding'. While the definition of what constitutes an essentially derived variety is controversial and remains unsettled, the concept is clearly intended to make PVP as close as possible to patents.[157] The entire regulatory process under UPOV 1991 reflects a trend of ever-greater protection of the interests of commercial plant breeders and fewer and fewer rights for traditional farmers.[158] Overall, in the 1991 version, PBRs have become akin to weakened patents and the conceptual distinction between the two is now blurred.

The uniform criteria for the protection of new plant varieties required by UPOV[159] warrant analysis. Firstly, although it is easier and less expensive to acquire a plant variety right than a patent[160] – making it conceivable that local communities could apply for a plant variety certificate – the uniformity and stability requirements mean that only breeders of genetically uniform varieties can use the system. Traditional communities, whose landraces or traditional cultivars may be rich in intra-varietal genetic diversity,[161] are unable to acquire protection because of this genetic diversity. This is not only inequitable, but promotes the breeding of genetically uniform varieties. The requirement of uniformity, therefore, is regarded as being in direct conflict with the aims of the CBD. Secondly, it is sometimes said that the distinctness and novelty standards are too low. In light of the fact that professional breeders are likely to have far greater financial resources, legal expertise and scientific facilities than local communities, there is a danger that traditional cultivars will be misappropriated with minimal, if any, modification. For example, according to the Rural Advancement Foundation International (RAFI),[162] it has uncovered 147 cases of mostly public institutions seeking

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[156] B. Dhar, & C. Chaturvedi, 'Introducing Plant Breeders' Rights in India: A Critical Evaluation of the Proposed Legislation', (1998), *Journal of World Intellectual Property*, Vol. 1, Issue 2, 245 – 262.

[157] In the case of patents the exploitation of an invention which builds upon an earlier invention requires the consent of the patent-holder of the earlier invention.

[158] The rare studies conducted in countries where PVP has been in effect for decades, such as the United States, show that this kind of legal system has resulted in: little impact in terms of stimulating plant breeding; reduced information and germplasm flows from the private to the public sector; a decreased role for public plant breeding and increased seed prices for farmers. See L.J. Butler, & B.W. Marion, *The Impacts of Patent Protection on the US Seed Industry and Public Plant Breeding*, (1985), University of Wisconsin; L.J. Butler, 'Plant Breeders', Rights in the US: Update of a 1983 Study, in J. Van Wijk, & W. Jaffe, *Intellectual Property Rights and Agriculture in Developing countries*, (1996), University of Amsterdam.

[159] Namely, distinctness, uniformity, stability and novelty.

[160] An application for PVP requires the completion of an application form, a description of the variety, and the deposit of propagating material. This material may be used by a government institution to conclusively demonstrate stability and homogeneity through propagation trials.

[161] Due in part to the preference of communities for versatility and adaptability.

[162] RAFI is now known as the Action Group on Erosion, Technology and Concentration (ETC). ETC is an international civil society organization headquartered in Winnipeg, Canada. The ETC group is dedicated to the advancement of cultural and ecological diversity and human rights. The ETC group is also a member of

PBR protection for varieties acquired from the Consultative Group on International Agricultural Research (CGIAR)[163] network.[164] Many of these varieties were landraces that have been subjected to little, if any, additional breeding.

In an official notice sent to African governments in June 1999, UPOV outlined the principal advantages of introducing PVP in Africa in terms of its undertaking: food security, sustainable agriculture, and the protection of the environment and biodiversity. These 'advantages' merit analysis. Firstly, it is to be noted that there is not one provision in the UPOV Convention relating to preservation of genetic resources.

Secondly, the affirmation that the extension of PVP as contained in UPOV 1991 to African countries will enhance food security rests on two crucial assumptions. The first is that hunger is due to a gap between food production and human population density or growth rate.[165] The second is that PVP is the only or the best way to increase agricultural production. If enhancing food security is a goal of UPOV 1991, one must question why there is nothing in the Convention that prioritises legal protection of food crops over industrial crops. In Kenya, not one application filed from the start of its PVP administration up to May 1993 was on a crop important to national food security. In Zimbabwe, as of 1999, over 70 per cent of all applications were on industrial cash crops.[166] In South Africa, as at the end of 1998, a total of 1435 PVP grants had been

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the Community Biodiversity Development and Conservation Programme. The ETC website can be viewed at World Wide Web, http://www.etcgroup.org

[163] The CGIAR is the world's largest international agricultural research network.

[164] See RAFI, 'Aussies pirate other genius?', (1998), Press Release 1 February; RAFI, 'Doing well by doing Little or Nothing?', (1998), A partial list of varieties under RAFI investigation (the names of the varieties are: Goulburn, York, Orion, Caprera, Leura and Denmark); and RAFI, 'The Australian PBR Scandal: UPOV Meets a Scandal "Down Under" by Burying its Head in the Sand', (1998), *RAFI Communique*, January – February, available at World Wide Web http://www.rafi.ca

[165] An analysis of this assumption is beyond the scope of this paper. However, it is to be noted that according to various authors, the real cause of hunger is not lack of food but poverty, inequality, and lack of distribution and *access* to food and land, including the struggles of poor farmers to obtain credit, lack of storage facilities and inadequate infrastructure. The World Bank concluded in an exhaustive 1986 study of world hunger that a rapid increase in food production does not necessarily result in food security. Current hunger can only be alleviated by 'redistributing purchasing power and resources toward those who are undernourished.' Further, that 'enough food is available to provide 4.3 pounds for every person every day: 2.5 pounds of grain, beans and nuts, about a pound of meat, milk and eggs and another of fruits and vegetables.' See F.M. Lappe, J. Collins, & P. Rosset, *World Hunger: Twelve Myths*, (1998), New York: Grove Press; H.R. Herren, 'Potentials and Threats of the Genetic Engineering Technology: Quest for an African Strategy at the Dawn of a New Millenium', International Centre of Insect Physiology and Ecology, 1999; H.Marcos, & C. Moreno, 'Seeds of Discontent: Republic Act 9168 in Perspective', Minda News, 12 August 2002, available at World Wide Web http://www.mindanews.com/2002/08/3rd/vws12mordeno.html, and P. Rosset, J. Collins, & F.M. Lappe, 'Lessons form the Green Revolution', (2000), available at World Wide Web http://www.foodfirst.org/media/opeds/2000/4-greenrev.html. For further information, see S.J. Scanlan, & J.C. Jenkins, 'Military Power and Food Security: A Cross-National Analysis of Less-Developed Countries, 1970-1990', *International Studies Quarterly*, (2001) 45, 159-187, and J.C. Jenkins, & S.J. Scanlan, 'Food Security in Less Developed Countries, 1970 to 1990', *American Sociological Review*, (2001), Vol. 66 (October: 718-744).

[166] These figures indicate that PVP supports the export agricultural industries, which is of particular concern in Kenya and Zimbabwe, where 80 per cent and 70 per cent of the population respectively depends on agriculture for their livelihoods.

made. Half of them were for industrialized crops.[167] In reality, innovations in plant variety development have, for the most part, been profit driven rather than need driven. Food security simply does not factor into this value system. The PVP offered by UPOV 1991 will, in all probability, be applied to high volume crops that offer opportunities for export sales, rather than staple food crops commonly used by Africans. It is difficult to see, therefore, how the adoption of UPOV 1991 by African countries will enhance food security. Even *if* breeders are encouraged to bring whole new species of food crops into cultivation, small farmers will still be worse off if they lose their privilege to replant seeds from their harvested crops. It is essential to note that, in developing countries, the majority of farmers depend on seeds saved from previous harvests to account for their seed needs. It is estimated that African farmers depend on seeds cultivated within their own communities for as much as 90 per cent of their seed needs.[168] Given the vast number of people that rely on the practice of saving seed for their food needs, the consequences that would flow from preventing this practice are devastating.

Thirdly, there is nothing inherent in either the UPOV Convention or national PVP laws that directs plant breeding toward a specific goal. PVP laws in Africa require plant varieties to be distinct, uniform and stable to be eligible for monopoly protection. The latter two requirements incline breeders to develop varieties that have low adaptability, that are suitable for export. They tend to require external inputs to compensate for uniformity. It is noted that, between 1977 and 1997, both Zimbabwe and South Africa tripled their pesticide importation bills.[169] It is also useful to consider which breeders are actually awarded PVP rights. In South Africa, over two thirds of applications came from breeders outside the country.[170]

Uniformity over large areas leads to vulnerability and increases the risk of crop failure.[171] For example, if a particular insect attacks a crop, a naturally diverse variety of the crop has a greater capacity to withstand the invasion. Genetically uniform crops, on the other hand, expose the farming community to a greater risk of crop failure, because if that one strain of the crop fails, the whole crop is likely to fail.[172] If a crop proves susceptible to a

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[167] United Nations Development Program, 'Human Development Report', (1999), World Wide Web, http://www.undp.org/hdro/food.htm

[168] See Food and Agricultural Organization, 'A Synthesis Report of the Africa Region – Women, Agriculture and Rural Development', Prepared under FAOs Programme of Assistance in Support of Rural Women in Preparation for the Fourth World Conference on Women, 1995, available at World Wide Web, http://www.fao.org/docrep/X0250E/X0250E00.htm

[169] FAOSTAT only provides pesticides importation figures. For South Africa this was $34 million in 1977 and $115 million in 1997. See World Wide Web, http://apps.fao.org

[170] GRAIN, 'Plant Variety protection to feed Africa? Rhetoric versus reality', (October 1999), World Wide Web, http://www.grain.org

[171] See V. Shiva, *Tomorrow's Biodiversity,* (2000), Thames & Hudson Limited, London, at 16.

[172] In considering the drawbacks of promoting genetic uniformity, one can look to agricultural history. For example, in the 1970s, T-cytoplasm (a gene that leads to male sterility) had been introduced into approximately 80 per cent of all US corn. When the gene proved susceptible to a leaf disease (caused by the fungus *Helmintosporium maydis*), an epidemic ensued, spreading within four months to destroy crops in 581 counties and 28 states, leading to a 15 per cent reduction in US corn production. According to J. Browning of Iowa State University, 'such an extensive, homogenous acreage of plants . . . is like a tinder-dry prairie waiting for a spark to ignite.' Limited diversity in coffee (*coffea arabica*) likewise led to a termination of all coffee export from Ceylon (the leading coffee producer) in 1985, after it fell prey to a

particular disease or insect, immediate action needs to be taken to prevent the spread of the epidemic, which in many cases involves emergency spraying of pesticides, and in all cases, available infrastructure. It is questionable whether developing countries possess the necessary infrastructure to deal with such an eventuality.[173] Another consequence of genetic uniformity is the resulting organism's poor capacity to adapt to varying environmental conditions. For example, South African biodiversity is very different to that occurring in America. The organisms[174] associated with particular plants as well as the relationship between organisms and the prevailing climatic conditions are accordingly highly specific. As a result, uniform varieties may not perform as well in the vastly varied environments of different countries.

Unfortunately, the option to protect plant varieties under a *sui generis* system is being reduced to compliance with the UPOV Convention, through pressure on developing countries from industrialized countries, the global seed and biotechnology industry, UPOV itself and the WTO Secretariat.[175] Nothing in the TRIPs agreement implies that UPOV is an alternative to patent rights. Indeed, UPOV provides weaker monopoly rights than patents but PBRs are based on exactly the same premises. Further, given that countries can now join only the 1991 version of the Convention which has significantly weakened the exceptions to the rights of breeders contained in the 1978 version, there is no significant difference between patents and the regime offered by UPOV. Not surprisingly, developing countries are attempting to draft their own PVP laws.

2.5 Options for a *sui generis* system

It was noted above that the option to protect plant varieties under a *sui generis* system is being reduced to compliance with the UPOV Convention. It is to be noted, however, that Article 27.3(b) of TRIPs makes no mention of UPOV and permits countries to design their own PVP system. Unfortunately, realistic proposals for non-UPOV PVP systems have been few and far between. This, in addition to the pressure from developed countries, explains why developing countries are joining UPOV. Having said this, the consideration of alternatives to UPOV is important for informed decision-making.

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leaf disease fungus (*Hemileia vastatrix*). Uniformity in European potatoes led to the Irish potato blight in Ireland in 1845 – 1846. Despite the fact that control measures were known at the time (e.g. not to feed diseased tubers to stock without boiling first), one million people died during this period due to starvation and the outbreak of diseases such as cholera and typhus. One and a half million people emigrated, many to the U.S. East Coast. The Mediterranean fruit fly epidemic and the regional citrus canker are similar examples of the widespread crop failure caused by genetic uniformity. See N. Batalion, *Fifty Harmful Effects of Genetically Modified Foods*, (2000), Americans for safe food, Oneonta, N.Y., at 7, and P. Gepts, 'How did plants evolve under domestication? Fate of genetic diversity', (2002), available at World Wide Web, http://agronomy.ucdavis.edu/gepts/pb143/lec15/pb143l15.htm.

[173] However, should such an eventuality arise, the developing country concerned would of necessity be forced to use available finances to bring the situation under control and ensure that its people are fed. The subsistence farmer is even less equipped speedily to obtain input traits, and may, as a result lose her/his entire crop.

[174] That is, insects, micro-organisms and animals.

[175] 'Bulletin 21- NGOs Demand 'Re-thinking' on TRIPs', World Wide Web, http://www.southcentre.org/info/southbulletin/bulletin21/bulletin21-01.htm

WTO States that wish to exclude plant varieties or plants in general from patentability have to provide for the protection of plant varieties by an 'effective *sui generis* system'. As noted, the TRIPs Agreement does not give any details on what such *sui generis* system would have to include. However, minimum requirements for a *sui generis* system would have to be drawn from the context of Article 27.3(b) and the objectives of the TRIPs Agreement itself. For instance, a *sui generis* system must comply with the basic principles of national treatment. Further, a *sui generis* system has to create rights that are legally enforceable – either to exclude others from acts related to protected varieties or to obtain remuneration in respect of at least certain uses of the protected variety by third parties. In order to be 'effective', national *sui generis* legislation must provide for the implementation of juridical procedures for *sui generis* rights holders to execute their rights. Even with these formal requirements, a range of options remain for developing countries to shape *sui generis* systems in compliance with the TRIPs stipulations as well as with their own developmental and ecological demands.

Drafting a *sui generis* system that is consistent with the objectives of the CBD and is TRIPs-compatible involves a careful consideration of the requirements for, and scope of, plant variety protection. The possibility of supplementing the system with non-IPR related provisions or provisions that benefit local communities that support CBD-related objectives should also be explored.

Concerning requirements for protection, Leskien and Flitner[176] suggest a number of alternative requirements. Firstly, the application of a less strict interpretation of uniformity and stability requirements enabling varieties that are bred on farms to have a better chance of protection. Leskien and Flitner go so far as to suggest that these two requirements could be done away with and replaced with a requirement of 'identifiability', which would 'emphasize the legal need to identify the protected subject matter instead of the specific physical properties a plant variety has to have.'[177] Such requirement would enable less genetically uniform new varieties to become eligible for protection, thus taking into account the interests of local communities. Another advantage of this requirement is the possible incentive it would provide to breeders to utilize more genetically diverse germplasm.

Secondly, differentiating between homogenous/uniform varieties and heterogeneous and traditional varieties concerning the extent of rights available.[178] That is, two separate protection and/or certification registers that confer different rights to different levels of

[176] In a paper for the International Plant Genetic Resources Institute (IPGRI) on options for a *sui generis* system, namely, D. Leskien, & M. Flitner, 'Intellectual Property Rights and Plant Genetic Resources: Options for a *Sui Generis* System', (June 1997), International Plant Genetic Resources Institute, Issues in Genetic Resources, Report Number 6.

[177] According to the authors, 'a typical combination of a few characteristics may in many cases suffice for the assignment of a right.' Clearly, this term leaves considerable and explicit flexibility for interpretation. Op cit note 176 at 61.

[178] Op cit note 176 at 62.

uniformity/stability could be established.[179] Here, heterogeneous and traditional varieties could be protected if they are clearly identifiable. However, because broader claims would result, the rights would have to be weaker. By broadening the scope of claims, the possibility of corporate bioprospectors, rather than local communities, promptly submitting applications for discovered landraces arises. This possibility could, however, be negated through a 'certificate of origin' system to safeguard local communities from unauthorised appropriation. Certificates of origin have been proposed by Tobin[180] in order to make the provisions of TRIPs more compatible with the provisions of the CBD. According to this proposal, administrative requirements for filing patent applications based on the use of genetic resources or traditional knowledge should require a sworn statement as to the genetic resources and associated knowledge, innovations and practices of local communities utilised, directly or indirectly, in the R&D of the subject matter of the IPR application, and evidence of PIC from the country of origin and/or local communities.

Concerning the scope of protection, because the protection offered by UPOV 1978 is weaker than that afforded by UPOV 1991,[181] it may be preferable for developing countries to utilise the former version as a model, possibly incorporating protection requirements such as those canvassed above. Upholding farmers' privilege, for example, would decrease possible intrusion on the customary practices of local communities.

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 and informal innovations. Several elements could therefore be added to a *sui generis* system, such as community gene funds,[182] the establishment of mediation procedures (public defender) for the protection of local interests or local communities,[183] and the establishment of local registers.[184] A number of promising model *sui generis* systems have been proposed. A brief analysis of two of these will now be undertaken.

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[179] In the United States, for example, the Plant Patent Act (PPA) for vegetatively propagated varieties, and the Plant Varieties Protection Act (PVPA), for sexually reproduced varieties relate – at least historically – to different standards of uniformity.

[180] B. Tobin, 'Certificates of Origin: A Role for IPR Regimes in Securing Poor Informed Consent', in J. Mugabe, C.V. Barber, G. Henne, L. Glowka, & A. La Vina, *Access to Genetic Resources: Strategies for Sharing Benefits*, ACTS Press, 1997, Nairobi, 329 – 340.

[181] As canvassed above in section 2.4, the UPOV Convention of 1978 merely disallowed the marketing of the same plant variety in competition with its innovator thereby allowing for farmers' privilege and research exemptions. The UPOV Convention of 1991, on the other hand, extends the right of the breeder to all reproduction of the seed of the protected variety and to harvested material obtained through the use of propagating material and essentially derived varieties.

[182] Community gene funds could assist in tracing the genetic material in seeds to a locality which, in turn, could assist in identifying and rewarding the particular community for their conservation and/or development of the genetic material in question. Where the origin of the variety cannot be established, Leskien and Flitner suggest that the funds are used to support *in situ* conservation in areas where biodiversity is particularly threatened. Op cit note 176.

[183] The establishment of a public defender or ombudsman office could be set up at national or international levels to intervene between disputes between governments or companies and local communities.

[184] Local or community registers or even international germplasm tracing registers could assist in the identification of contributors to protected plant varieties and the prevention of unauthorised appropriation.

Butler and Pistorius[185] propose a 'system of remuneration without ownership/property rights.' The system aims: to remunerate innovative plant breeding and provide incentives to encourage the development of novel varieties of plants, thus promoting progress in agriculture in the public interest; to allow farmers (in developing countries) to make use of modern plant genetic resources available in the commercial market, including saving, selling, swapping, multiplication and use for breeding purposes, without violating private property rights; and to provide incentives to preserve, create and enhance biological diversity. Such a system differs from current IPR/PBR systems in two major respects. Firstly, it requires the elimination of 'ownership/property rights' in plant genetic resources; and, secondly, a relaxation of the conditions for the registration of new varieties. According to the authors, 'a system of remuneration without ownership/property rights would be closer to the original idea behind the PBR system.' That is, a contract between the breeder and society rewarding investments in plant breeding. This system is drawn from Dutch law that was in force between 1941 and 1966.[186] Accordingly, this model would require all farmers to pay tax on each crop based on the number of hectares they planted in each crop variety. The funds would then be used to pay plant breeders remuneration for breeding new varieties.[187] Essentially, this model ensures that farmers maintain the freedom to save, sell and use seed for breeding purposes. They would also receive remuneration for their innovative efforts, thereby providing them with incentives to continue to innovate. The authors concede that breeders are likely to be concerned about these freedoms. As regards the concerns of farmers in developing countries, it is noted that they may have little to lose from the inability to enforce exclusive rights over their varieties because of the fact that the majority of seed trade in developing countries occurs in the informal sector.[188]

Leskien and Flitner,[189] propose the 'plant variety seal model,' which would grant the right holder an exclusive right to a seal or certificate for a variety that has fulfilled the requirements laid down in the *sui generis* system.[190] The holder of the seal would have an

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Furthermore, by publishing information on local innovations, their status of novelty expires, and hence, should render them unpatentable.

[185] B. Butler, & R. Pistorius, 'How Farmers' Rights Can be used to Adapt Plant Breeders' Rights', (1996), *Biotechnology and Development Monitor*, Issue 28, 7 – 11.

[186] In the Dutch system, all farmers were levied a small tax on each crop based on the number of hectares that they had in that crop. The fund was used to pay plant breeders remuneration for breeding new varieties. The remuneration was based on the proportion of total hectares planted to the new variety each year, and continued for 25 years. After the seed was released commercially, it could be grown, swapped, multiplied and sold by anyone.

[187] Payment would be based on the proportion of total hectares planted each year for 25 years.

[188] Similarly, concerns on the part of breeders in developing countries are dismissed by the authors on four grounds. Firstly, by enforcing exclusive rights to the original variety its access would be limited, thereby reducing the possibility of it being incorporated into other breeding programmes. Again, since the seed trade in many developing countries is based in the informal sector, and farmers cannot afford the new commercial varieties, it would languish in the market. Secondly, evidence points to the fact that it is probable that most new commercial varieties are superseded by more suitably adapted varieties in a few years. Thirdly, the limits on access to improved varieties provided by the exclusivity of IPRs can be viewed as contrary to the original intent of IPRs. Fourthly, the registration process ensures some form of remuneration to the breeder of the original variety.

[189] Op cit note 176 at 70.

[190] For example, distinctness and identifiability.

exclusive right to use the seal for material of a specified, registered variety in combination with its registered denomination. The difference between a seal and a trademark is not only that the seal would constitute the variety's denomination, but also certify full compliance with the protection requirements as laid down in the *sui generis* legislation when selling, offering, exposing or exchanging seeds of the variety. Essentially, and unlike the acts requiring authorization under UPOV or patent law, the right to use the seal would not relate to the material of the variety as such. That is, 'only the use of the PVP seal in combination with the registered denomination and the material of the variety would be the exclusive right of the holder and those who have obtained that holder's authorization.'[191] Thus, once seed has been sold, either by the seal owner or parties authorized by the owner, there are no further restrictions on the use and sale of the variety. Farmers could therefore continue to save and sell seed. The authors argue that the exclusive right to use the seal 'would still give right-holders a substantial competitive advantage' especially if the protection requirements of the *sui generis* system were adapted to the needs of farmers. In light of the fact that the rights conferred by the seal are not as strong as those provided for under UPOV or patents, Leskien and Flitner suggest that the duration of such rights could be increased. Dutfield is, however, of the opinion that, 'it seems very doubtful that seal holders really could sustain a comparative advantage for any length of time when other breeders (or farmers) can so easily produce and sell the same variety.'[192] This view is supported. The fear is that, if this model were implemented, breeders would respond by creating more genetically uniform hybrids and crops that lend themselves to hybridization. A possible suggestion is to extend the right of the seal holder to prevent others from marketing the protected variety in competition with its innovator.

2.6 International Undertaking on Plant Genetic Resources

In 1983 the FAO Conference established the Commission on Plant Genetic Resources as a permanent intergovernmental forum to deal with questions relating to plant genetic resources. The International Undertaking on Plant Genetic Resources (IUPGR) was adopted as the formal framework for its activities. The undertaking is however a non-legally binding instrument. The Commission is mandated to embrace all components of biodiversity of relevance to food and agriculture.[193]

In the late 1980s and early 1990s, the IUPGR was reinterpreted through resolutions of the FAO Conferences. In 1992, Agenda 21 specifically called for the FAO both to strengthen the Undertaking and to adapt it in line with the CBD. In 1993 the process of revising the Undertaking was begun within the FAO and the Commission adopted a revised Undertaking in July 2001. This then became the International Treaty on Plant Genetic Resources (ITPGR) for Food and Agriculture when adopted by the FAO conference in

[191] Op cit note 176 at 70.
[192] Op cit note 29 at 82.
[193] The undertaking provides for the exploration and collection of genetic resources (Article 3), for conservation *in situ* and *ex situ* (Article 4), the availability of plant genetic resources (Article 5), for international co-operation in conservation, exchange and plant breeding (Article 6), international co-ordination of genebank collections and information systems (Article 7), and for funding (Article 8).

November 2001.[194] The Treaty is essentially an adaptation of the IUPGR and is overseen by the FAO Commission on Genetic Resources.

The Treaty encourages the conservation of plant genetic resources through national and international collections of seeds and plants. Farmer's rights are specifically mentioned and protected in Article 9, which commences by recognizing 'the enormous contribution that the local and indigenous communities and farmers of all regions of the world have made and will continue to make for the conservation and development of plant genetic resources.' The Treaty affirms that the responsibility for the realization of farmers' rights rests with national governments.[195] Article 9.2 then lists various measures that Contracting Parties should[196] take in the protection of farmers' rights, including the right to share equitably in the benefits arising from the use of plant genetic resources.

In line with the CBD, the ITPGR addresses the problem of ensuring access and fair-sharing of the benefits of genetic resources, in this case specifically in the areas of food and agriculture. In common with the CBD the need for financial resources and technical assistance for less developed countries is recognized.

The Treaty has the potential to be an important refinement of the IUPGR, but it may be many years before it is ratified by the requisite 40 states. As at 28 March 2003, only seven states had ratified the Treaty.[197]

The issue of farmers' rights is one of the key elements of the IUPGR. Under Article 15(s),[198] farmers' rights to re-use for propagating the products of the harvest, which they have obtained by planting their own holdings, was considerably limited. A Resolution of the FAO Conference defined farmers' rights as, ' . . . rights arising from the past, present and future contribution of farmers in conserving, improving and making available plant genetic resources, particularly those in centers of origin/diversity. These rights are vested in the International Community, as trustees for present and future generations of farmers, for the purpose of ensuring full benefits to farmers, and supporting the continuation of their contributions'.[199] Thus, the principle of free availability[200] was qualified by recognizing farmers' rights. These rights were intended to recognize and reward the contributions of farmers to the conservation and management of plant genetic resources. This recognition of private property rights implies the right to compensation for access to biological resources.

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[194] As at 28 March 2003, there were 83 signatories to the Treaty. It is to be noted that South Africa has not yet signed the Treaty. For a list of signatories, see World Wide Web, http://www.wikipedia.org/wiki/International_Treaty_on_Plant_Genetic_Resources_for_Food_and_Agriculture

[195] See Article 9.2.

[196] Subject to each Contracting Parties national legislation.

[197] These are: Canada, Eritrea, Ghana, India, Jordan, Malawi, and Sudan. Notably, Canada is the only developed country to have ratified the Treaty. See World Wide Web, http://www.wikipedia.org/wiki/International_Treaty_on_Plant_Genetic_Resources_for_Food_and_Agriculture

[198] Pertaining to optional exception.

[199] Annex II, Resolution 5/89 adopted by FAO Conference, 25TH Session, Rome, November 11-29 1989.

[200] Prior to the resolutions, the IUPGR affirmed the principle that plant genetic resources are a common *heritage* of mankind which should be made available without restriction to anyone, without qualification.

The Commission is specifically required to co-operate with the CBD in the area of genetic resources. The revision of the IUPGR in harmony with the CBD is inevitable in light of advances in biotechnology and pressure for the enactment of stricter IP legislation. Some of the most contentious issues in negotiations have been the drafting of provisions on access to plant genetic resources, farmers' rights, and benefit-sharing regimes.

CHAPTER 3
DEVELOPMENTS IN AFRICA

3.1 Regional Frameworks: Organization for African Unity

Most of the member states of the Organization for African Unity (OAU) - now known as the African Union (AU)[201] - developed national legislation based on a regional model law on 'Community Rights and on the Control of Access to Biological Resources'.[202] The model law was to be utilized as a framework for drawing up national legislation in African States. The model law deals with access to biological resources, benefit sharing, and the rights of farmers and breeders over their knowledge and resources. It is premised on the rejection of patents of life, and its provisions on access to biological resources make it clear that the recipients of biological resources or related knowledge cannot apply for any intellectual property right of an exclusionary nature. The model law focuses mainly on defining the rights of communities,[203] farmers[204] and breeders.[205] The state is to ensure that at least 50 per cent of the benefits derived from the utilization of their resources or knowledge is channeled back to the communities. The positive element in

[201] The AU replaced the OAU on 9 July 2002.

[202] The OAU approved the model law during its Summit of Heads of State and Government in June 1998. All African countries except for 8 signed the model law [Ethiopia; Lesotho; Libya; Mauritania; Rwanda; Somalia; Togo; Tunisia]. As at 27 May 2002, 13 African countries had ratified the Model Law [Botswana; Benin; Burkina Faso; Central African Republic; Congo; Gabon; Ghana; Mali; Niger; Nigeria; Senegal; Sierra Leone; South Africa]. South Africa signed the model law on 17 July 1998, and ratified on 27 November 2000. See Ratification Atlas, 'Country-by-Country Ratification Status Report', World Wide Web, http://www.iccnow.org/html/countryindex.html#africa

[203] Community rights recognized include rights over their biological resources and the right collectively to benefit from their use, rights to their innovations, practices, knowledge and technology and the right collectively to benefit from their utilization. In practice, these rights allow communities the right to prohibit access to their resources and knowledge but only in cases where access would be detrimental to the integrity of their natural or cultural heritage.

[204] These include: the protection of their traditional knowledge relevant to plant and animal genetic resources, the right to an equitable share of benefits arising from the use of plant and animal genetic resources, the right to participate in making decisions on matters related to the conservation and sustainable use of plant and animal genetic resources, the right to save, use, exchange and sell farm-saved seed or propagating material, and the right to use a commercial breeder's variety to develop other varieties.

[205] The noteworthy characteristic of the PBR regime under the model law is the rather broad scope of the exemptions granted. Exemptions to the rights of breeders include the right to use a protected variety for purposes other than commerce, the right to sell plant or propagating material as food, the right to sell within the place where the variety is grown and the use of the variety as an initial source of variation for developing another variety.

the OAU Model Law is that there is a collective effort by a group of countries to pool resources to implement some aspects of the CBD[206] and of the TRIPs Agreement.[207]

In September 2000, African Ministers of Trade[208] invited UPOV and the World Intellectual Property Organization (WIPO)[209] to comment on the model law. What ensued was not comment, but an attempt completely to restructure the model law in order to bring it into line with UPOV and WIPO's intellectual property systems. WIPO noted that the prohibition on patents contained in the model law[210] is inconsistent with TRIPs Article 27.3(b). The WTO further objected to the embodiment of the principle that the collectors of biological resources in Africa are required to assure that they will not apply for patents over such materials or their derivatives,[211] contained in the model law. Underlying this objection is the barrier it poses to the securing of monopolies on such resources or their derivatives. Perhaps the most important objection was WIPO's opposition to the concept that indigenous technology is not transferable to another owner.[212] This concept ensures that no one, including members of a local community, can make exclusive claims over community knowledge or resources. WIPO suggested that local communities apply for patent protection themselves as a solution to the problem. This shows that WIPO, rather than assisting constructively in the development of the model law, attempted to solve the problem utilizing existing global IPR conventions, which are ill equipped effectively to protect indigenous knowledge in Africa. In a Declaration by the OAU/STRC task force, it was stated that 'the WTO-based approach is predatory in nature and runs counter to the aspirations of communities which are in the first place the innovators of biodiversity'.[213] UPOV officials, on the other hand, reworked more than thirty articles of the model law to bring it into line with the standards of their own convention.[214]

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[206] Access to genetic resources and the protection of Indigenous Knowledge.
[207] *Sui generis* protection system for plant varieties.
[208] At a meeting held in Cairo.
[209] WIPO is an intergovernmental organization. It is one of the sixteen specialized agencies of the UN system of organizations. WIPO is responsible for the promotion of the protection of IPR throughout the world through cooperation among states, and for the administration of various multilateral treaties dealing with the legal and administrative aspects of IP. The number of States members of WIPO was over 170 in August 1998. See World Intellectual Property Organization, 'What is WIPO', World Wide Web, http://www.wipo.int/eng/dgtext.htm
[210] The model law rejects patents on life forms as immoral and contrary to the values of African people.
[211] Contained in Article 4.3(e).
[212] The so-called concept of inalienability.
[213] The Organization of African Unity, 'Declaration by the OAU/STRC task force on community rights and access to biological resources', (2001), World Wide Web, http://www.twnside.org.sg/title/oau1-cn.htm
[214] GRAIN, 'Africa's Model Law on Community Rights Under Attack', (2000), World Wide Web, http://www.southcentre.org/info/southbulletin15/southbulletin15-10.htm

3.2 Domestic Frameworks: South Africa

South Africa is a signatory to numerous international environmental conventions,[215] agreements[216] and protocols.[217] As a signatory, South Africa is obliged to adhere to all of the obligations imposed on it in terms of its membership. It is to be noted, however, that a number of international agreements to which South Africa is a party, constitute 'soft' law.[218] Direct consequences of South Africa's membership of international agreements are the development of policies, strategies, national action plans, and implementation plans.[219]

Benefit-sharing is one of the central objectives of the CBD and South Africa's White Paper on the Conservation and Sustainable Use of Biological Diversity, which led to the National Environmental Management: Biodiversity Bill – currently before Parliament for consideration and probable promulgation in 2003 – reflects this. The Biodiversity Bill, however, fails to give adequate consideration to the implementation of this fundamental principle. The Bill requires benefit-sharing arrangements only with holders of traditional knowledge about biodiversity[220] and excludes the sharing of benefits derived from

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[215] Convention on the Conservation of Migratory Species of Wild Animals (Bonn Convention); Convention on International Trade in Endangered Species of Wild fauna and Flora (CITES); Antarctic Treaty; Protocol for the Protection of the Ozone Layer (Montreal Protocol); Convention on Wetlands of International Importance especially as Waterfowl Habitat (Ramsar Convention); Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal (Basel Convention); CBD; International Convention for the Recognition of Whaling (ICRW); Framework Convention on Climate Change (FCCC); Convention concerning the protection of the World Cultural and Natural Heritage (WHC); United Nations Convention to Combat Desertification in those countries experiencing serious draught and/or Desertification, particularly in Africa; Law of the Sea Convention (LOSC); Convention on Conservation of Antarctic Marine Living resources (CCAMLR); Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter, 1972 and its protocol 1996 (London Guidelines); World Conservation Union (IUCN: International Union for the Conservation of Nature and Natural Resources); Convention on Prior Informed Consent (PIC); Agreement for the Implementation of the Provisions of the United Nations Convention on the Law of the Sea 10 December 1982 relating to the Conservation and Management of Straddling Fish Stocks and highly Migratory Fish Stocks; International Commission for the Conservation of Atlantic Tunas (ICCAT); South East Atlantic Fisheries Regional Organization (SEAFRO); Wetlands International; Persistent Organic Pollutants (POPs). See 'National State of the Environment Report - South Africa', (October 1999), World Wide Web, http://www.ngo.grida.no/soesa/nsoer/issues/politic/data.htm The state of South Africa's environment is an issue that is being investigated by the Department of Environmental Affairs and Tourism (DEAT). Accordingly, DEAT and the CSIR have initiated a project to produce the first comprehensive report on the state of South Africa's environment.

[216] Agreement on Trade Related Aspects of Intellectual Property Rights.

[217] The Cartagena Protocol and the Montreal Protocol. The Cartagena protocol was adopted at the fourth COP to the CBD in January 2000. It is to be noted that all countries must have ratified the parent treaty, the CBD, first. For more on the Cartagena Protocol, see section 4.7 below.

[218] Member States are obliged to follow 'hard' law under pain of sanction from the international legal system and community. In contrast, the observance of 'soft' law is dependent on moral suasion or fear of diplomatic retribution.

[219] In all cases, this implies allocation of additional resources, both human and financial, for which donor assistance is often required. Ratification also has indirect consequences for several sectors such as trade, economic development, agriculture, mining, energy, transport and the environment generally.

[220] This is supported by the Bill's rather confusing objective in Article 2(b) that benefit-sharing should be confined only to the commercialisation of traditional uses and knowledge.

biological resources themselves. Effectively, this excludes the diversity of role players that should benefit from bioprospecting agreements[221] as most activities do not use tradtional knowledge to guide screening and collection.

Section 77(3) sets out the requirements for a benefit-sharing agreement.[222] Notably, the Bill does not specifically state that consent to access shall be on mutually agreed terms. However, the National Biodiversity Institute, to be created if the Bill becomes an Act, is assigned bioprospecting functions that go some way towards ensuring that benefit-sharing agreements are conducted on mutually agreed terms.[223]

Prior informed consent is one of the most fundamental principles underpinning provisions relating to access and benefit-sharing in the CBD. The Biodiversity Bill, however, not only excludes this principle, but, in fact, negates it by introducing the following provision: 'The person or community practicing that traditional use or knowledge may not unreasonably refuse to enter into [a benefit-sharing] agreement with a permit holder if that traditional use or knowledge about such indigenous biological resources is in the public domain and not protected by legislation on intellectual property.'[224] In light of the fact that traditional knowledge is not protected by IPRs, this provision could lead to a situation in which consent cannot be refused and could be utilized as a tool to pressurize communities to become parties to agreements against their will.

The possible effects of the review of TRIPs Article 27.3(b) on the provisions of the Department of Environmental Affairs and Tourism's 'Biodiversity Bill' ought not to be ignored. It is arguable that implementation of TRIPs in South Africa should be suspended pending outcome of the review. Realistically, however, the Bill will become an Act in its present form in 2003.

The Plant Breeders' Rights Act 15 of 1976 (PBRA), as amended, gives effect to South Africa's obligations under the UPOV Convention. The purpose of the PBRA is to lay down a system for the granting and registering of rights to breeders of certain varieties of plants.[225] The requisite criteria that have to be met in order for a variety to qualify for a

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[221] Such as local research institutions, conservation agencies, local communities, and National government.

[222] Section 77(3)(b)(i) – (iv) deals with the determination of: the type of indigenous biological resources to which the relevant bioprospecting relates; the area in which such resources will be collected; the quantity that will be collected; and the anticipated profits, revenues or other benefits that may accrue from such bioprospecting. Section 77(3)(c) requires any benefit-sharing agreement to set out the manner and extent to which the traditional use of, or knowledge about the biological resource is to be applied or exploited. Further, s77(3)(d) states that 'any benefit-sharing agreement must detail the manner and extent to which the person or community possessing or practicing knowledge will share in any profits, revenues or benefits'. All benefit-sharing agreement must be submitted to the Minister for approval.

[223] For example, s79(c) states that the institute '*may* facilitate negotiations between the applicant and the other party and ensure that those negotiations are conducted on an equal footing' [own emphasis]. Further, s79(d) states that '*on request by the Minister*, [the Institute] must ensure that the benefit-sharing arrangement agreed upon between the applicant and the other party is equitable' [own emphasis].

[224] Section 77(2).

[225] The Act applies to every variety of any kind of plant, provided that it meets the requisite criteria. For a list of all PBRs granted as at 31 December 2002, see South African Plant Variety Journal, 'Plant Breeders'

plant breeders' right,[226] are novelty,[227] distinctness,[228] uniformity[229] and stability.[230] The period of the right can vary between 20 and 25 years.[231] In essence, the right requires persons who wish to utilise or exploit the relevant plant material to obtain authority to do so by way of license from the right holder.[232] The PBRA provides for compulsory licensing[233] and for possible expropriation of a PBR by the State.[234]

The Plant Improvement Act 53 of 1976, as amended, complements the PBRA by providing a regulatory regime for the distribution and sale of certain plants and propagating material. The Act appoints a Registrar of Plant Improvement, who is, *inter alia*, to register premises from which plant material is sold,[235] and to compile and maintain a varietal list.[236] The latter obligation empowers the Registrar to recognise a variety and enter it into the varietal list, provided that certain conditions are met.[237] The Act also provides for various administrative and enforcement measures. The importance of the Act is that it provides control measures for import and export of plant varieties – and therefore indirectly protects biodiversity.

The Genetically Modified Organisms Act 15 of 1997[238] ('The GMO Act') provides the mechanism to effect South Africa's obligations in terms of the Cartagena Protocol to the CBD.[239] The GMO Act is intended 'to provide measures to promote responsible development, production, use and application of genetically modified organisms'.[240] The

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Rights Valid in the Republic of South Africa as at 31 December 2002', 2002, The Directorate: Genetic Resources, Department of Agriculture, 1 – 50, available at world wide web, http://www.nda.agric.za/docs/pvj2002.pdf

[226] Embodied in section 20(a) – (d).

[227] In terms of section 2(2)(a), a variety is deemed to be new if propagating material or harvested material thereof has not been sold or otherwise disposed of by the breeder for a stipulated period of time.

[228] According to section 2(2)(b), a variety is deemed to be distinct if at time of filing for application for a PBR, it is distinguishable from any other variety of the same kind of plant, the existence of which is a matter of common knowledge.

[229] According to section 2(2)(c), a variety is deemed to be uniform if subject to the variation which may be expected from the particular features of the propagation thereof, it is sufficiently uniform with regard to the variety in question.

[230] According to section 2(2)(d), a variety is considered stable if the characteristics thereof remain unchanged after repeated propagation.

[231] See section 21(a) and (b).

[232] See section 23(1)(a) – (f). The following activities require authorisation from the right holder: production and reproduction (multiplication), conditioning for the purpose of propagation, sale or any other form of marketing, exporting, importing, and stocking for the purposes of production, reproduction and importing.

[233] In terms of section 26(1), a compulsory license may be ranted where a plant breeder unreasonably refuses to grant a license, or where a breeder imposed unreasonable conditions on the issue of such license.

[234] See section 31.

[235] See section 7.

[236] Which is a record of plant material distributed locally and abroad. See section 15.

[237] See section 20.

[238] Introduced by the Department of Agriculture.

[239] The Cartagena Protocol is considered below in section 4.7.

[240] Preamble. The Preamble to the GMO Act clearly subordinates biosafety to the imperative of promoting biotechnology. The objective of the Act is therefore the promotion of the very technology it aims to regulate. It would perhaps have been more appropriate to state that the objective of the Act is to provide for

GMO Act applies in the following cases: the genetic modification of organisms;[241] the development, production, release, use and application of GMOs (including viruses and bacteriophages);[242] and the use of gene therapy.[243] It does not, however, apply to the following techniques: those involving human gene therapy;[244] those in which recombinant DNA molecules or GMOs are not employed;[245] and those in which GMOs are recipient or parental organisms are not employed.[246] Clearly, the provisions of this Act are of little relevance to the protection of plant genetic resources that have not been modified. However, because the GMO Act is directly relevant to both South Africa's biosafety regime and the implementation of legislation promoting IPR protected plant varieties it will be critically assessed in order to determine, firstly, if it constitutes effective biosafety legislation and, secondly, if it regards the protection of the environment and South Africa's people as more important than the interests of multinational biotechnology companies. An analysis of South Africa's GMO Act is important because South Africa is the only African country that has accepted patents over plant varieties and drawn up an Act to provide for the regulation of such organisms. A critical analysis of the inadequacy of this legislation is to be utilised as examples for African countries not to follow should they decide to accept genetically modified organisms.

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comprehensive regulation of biotechnology in order to ensure that the environment, and human and animal health are not harmed.

[241] Section 2(1)(a).

[242] Section 2(1)(b).

[243] Section 2(1)(c).

[244] Section 2(2)(a). This is provided for in the Human Tissue Act 65 of 1983.

[245] Section 2(2)(b). That is, in *in vitro* fertilization in humans and animals; in conjunction, transduction, transformation, or any other natural process; and in any polyploidy induction.

[246] Section 2(2)(c). In mutagenesis; in the construction and use of somatic hybridoma cells; and in cell fusion (including protoplast fusion) of plant cells.

CHAPTER 4

THE GENETICALLY MODIFIED ORGANISMS ACT OF SOUTH AFRICA

4.1 Introduction to the Genetically Modified Organisms Act [15 of 1997] of South Africa

South Africa ranks as the third most biologically diverse country on earth.[247] This diversity, and the environment in general, is threatened by the possible effects of, or risks posed by, genetic modification. The exact nature of these threats is unknown because of a lack of in-depth research into the long-term effects of releasing genetically modified organisms into the environment.[248] Given the unpredictable nature of this technology, and its potential to have a negative impact on the environment, it is wise to proceed with caution.

Prior to biosafety legislation coming into effect in South Africa, the National Department of Agriculture (DOA) authorized 165 applications for releases of genetically modified food crops into the environment under field-trial conditions during the period 1992 - 1999.[249] After the GMO Act came into effect in South Africa,[250] and during the period January 2000 to September 2002, 467 permits were granted for various activities, including general releases, field trials, contained use and commodity imports for human

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[247] This is based upon an index derived by the World Conservation Monitoring Centre, which has calculated an overall diversity index based on species richness for vertebrates and higher plants and richness in endemics. See World Conservation Monitoring Centre (1992). Development of a National Biodiversity Index: A Discussion Paper. This document was lost to the writer due to hard drive failure. In attempting to obtain the document again, the writer ran a search for the 'most biologically diverse country' using the search engine Google. Interestingly, four different countries, namely, Brazil, Colombia, Costa Rica, and Ecuador, were all noted in the various literature as the most biologically diverse country on earth. See World Wide Web, Ancient Forest International, Panacocha Biological Corridor, http://www.ancientforests.org/ecuador/economic.html, which states that, 'Ecuador is the most biologically diverse country on earth'; Travelling Around Costa Rica, http://www.passports.com/feedback/cgi/messages/191.asp, which notes that, 'many experts agree that Costa Rica is the most biologically diverse country on earth'; J.M. Andes Libre, 'GW Bush: Death Stalks Colombia and Venezuela', Earth First Journal, http://www.chiapasnews.ukgateway.net/news/020519.html which states in respect of Colombia that, 'The war and the herbicide spraying by the US endanger the most biologically diverse region on earth'; and CNN, '10% of Amazon Rain Forest to be Preserved by Coalition', http://www.cnn.com/2000/NATURE/05/14/brazil.rainforest/, which states that 'Brazil has long been known as the most biologically diverse country in the world.' Although there were conflicting opinions concerning which country ranks as the most biologically diverse country, South Africa was, in the writer's search, the only country that was noted as the third most biologically diverse country. See World Wide Web, http://www.capestudies.com/page/english/generalinformation/southafrica/; http://www.sn.apc.org/biodiv/bdchp2.htm; http://www.earthsummit2002.org/es/updates/ga/south-africa-ga-55.htm; and http://www.polity.org.za/html/govdocs/green_papers/biodiv1.html?rebookmark=1#2-1

[248] Generally, however, these include risks of increased resistance to herbicides, leading to 'super weed' characteristics; increased use of herbicides; increased pest resistance; toxic effects on biodiversity; development of new viruses; impacts on agricultural crop biodiversity, especially subsistence crop biodiversity; and effects through the unpredictable movements of genes.

[249] M. Mayet, 'Critical analysis of pertinent legislation regulating genetic modification in food and agriculture in South Africa', unpublished paper produced for Biowatch South Africa (May 2001) at 1.

[250] 1 December 1999.

and animal consumption.[251] Not one of these events was preceded by an EIA. The vast majority of permit beneficiaries are foreign multinational biotechnology companies. For example, only 7 per cent of import and export permits granted during the period January 2001 to September 2002, were awarded to local companies. Furthermore, the volume of GMOs imported by local companies during this period amounted to a mere 0.02 per cent of the total volume imported during this period.[252] Instead of emphasizing the importance of assessing potential environmental impacts, the GMO Act promotes the importance of expediting trade in GMOs, primarily to the benefit of foreign multinational biotechnology companies.

This section presents a critical analysis of the EIA provisions contained in the GMO Act within the context of the national environmental management principles and minimum requirements for the investigation, assessment and communication of activities enumerated in the National Environmental Management Act 107 of 1998 (NEMA). It will be argued that, in its present form, the GMO Act does not constitute an adequate biosafety regime for ensuring that GMOs do not cause harm to the environment. The GMO Act does not set out principles and parameters for environmental impact analysis, excludes civil society participation, fails to provide for adequate public participation, and denies the public access to information. Further, it negates the Precautionary Principle, which ought to be the cornerstone for decision-making in regard to biosafety assessment.

4.2 Objectives

The Preamble to the GMO Act subsumes the need for biosafety into the imperative to promote biotechnology. In this regard, the Preamble provides for 'measures to promote the responsible development, production, use and application of genetically modified organisms'. The objective of the Act is therefore the promotion of the very technology it aims to regulate. It would perhaps have been more appropriate to state that the objective of the Act is to provide for comprehensive regulation of biotechnology in order to ensure that the environment, and human and animal health, are not harmed.

While the Act itself is ominously silent as to why GMOs should be promoted, the DOA is not. The DOA echoes the pro-GM lobby's argument that insect and herbicide resistant GMOs are the solution to hunger. The DOA goes so far as to claim that GMOs 'allow us to grow better-quality crops with higher yields while at the same time sustaining and protecting the environment.'[253] Not surprisingly, perhaps, the DOA's website fails to mention any of the concerns raised by scientists about the possible adverse environmental and health risks associated with GMOs. The pro-GM stance of the DOA is also reflected

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[251] See the National Department of Agriculture website at World Wide Web, http://www.nda.agric.za/docs/geneticresources/GMOs.htm

[252] Notably, 66 per cent of GMOs imported during this period were imported from the USA, 20 per cent from Israel, 13 per cent from Argentina, and 1 per cent from Australia, Chile, France and Germany. This information was gleaned from an analysis of the list of permits granted by the NDA. To view the lists, see http://www.nda.agric.za/docs/geneticresources/GMOs.htm.

[253] See A.L. Pole, 'Gene-Pigs of the Multinational Biotechnology Industry', (2002), unpublished paper submitted in partial fulfillment of the academic requirements for the degree of Master of Laws at the University of Natal, Durban, at 9.

in its official newsletter. For example, one article quotes academic and lobbyist, Thomson, as arguing that 'poor nations cannot afford debate on gene altered crops.'[254] Distressingly, the DOA is supporting the promotion of GM crops with taxpayers' money totalling R200 million annually.[255] This clear bias on the part of the DOA invites speculation that the DOA has been influenced by the wealthy biotechnology companies, and has placed the promotion of their interests over and above the duty to prevent or minimise any damage that may occur as a result of the release of GMOs into the environment.

4.3 Regulatory Provisions

4.3.1 Regulatory Authority

The Act establishes, as the key regulatory authority, the Executive Council of Genetically Modified Organisms ('the Council'), which is to consist of not more than eight members, six of whom are required to be officers drawn from six national government departments having an interest in GMOs.[256] The Act requires each member to have knowledge of the implications of GMOs in respect of the sector represented by his/her department. The Council's purpose is to ensure that all activities with regard to the development, production, use, application and release of GMOs are performed in accordance with the provisions of the Act. The Council also acts as an advisory body to the Minister of Agriculture, presumably to aid him/her in setting out regulations.

The Act sets out in detail the powers and duties of the Council.[257] These generally concern the issue of permits to use facilities for the development, production, use or application of GMOs, or for the release of such organisms into the environment.[258] The Council is the key decision-making body for the granting of permits, and takes trade and socio-economic issues into account when making decisions. Glazewski[259] views the establishment of the Council as a welcome development as the Council is an independent body which will make decisions that were previously in the hands of the Department of Agriculture.

4.3.2 Advisory Committee

The Act establishes an Advisory Committee ('the Committee') with which the Executive Council is obliged to consult before granting approvals. The Committee consists of ten members, eight of whom are required to have knowledge in those fields of science applicable to the development and release of GMOs.[260] Two members are from the public sector and are required to have knowledge of ecological matters and GMOs. The

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[254] Ibid.
[255] DOA announcement, SABC television news, 14 July 2002.
[256] See section 3.
[257] Section 5.
[258] Section 5(a).
[259] J. Glazewski, *Environmental Law in South Africa* 1 ed, (2000), Butterworth Publishers: South Africa, at 318.
[260] See section 10 (1)(a).

Committee is essentially an advisory body that bases its decisions on scientific data. The functions of the Committee are set out in detail in the Act.[261] Generally, however, these are to advise the Minister, the Council and appropriate parties on various matters concerning GMOs and to carry out related functions. It replaces the South African Committee for Gene Experimentation (SAGENE), which previously carried out this work, although it did not enjoy any statutory status.

The requirement that the majority of the members emanate from the scientific community could hamper a full and thorough assessment of the implications of the introduction of GMOs into the environment. GMOs interact with the environment in a complex way, requiring a multi-disciplinary approach in order to assess the potential risks. The provisions, and peremptory language, of section 11(1)(d) of the GMO Act may go some way towards remedying this defect, as it allows the Committee to invite written comments from knowledgeable persons on any aspect of GMOs within the Committee's brief. However, the need for a standing and multi-disciplinary panel of experts remains an indispensable requirement.

The inclusion of the phrase 'public sector' is somewhat puzzling. Since government is fully represented on the Council it is questionable why an advisory committee should require further government representation. Of more concern, however, is the question of why civil society participation has been excluded. This is one of the most serious shortcomings of the Act. Mayet believes that this is inconsistent with the tenets upon which South Africa's democracy is built, and also with the principle of public participation in environmental governance advocated by Government policy.[262]

4.3.3 The Registrar

A Registrar, appointed by the Minister in consultation with the Council, is charged with the administration of the Act. The Registrar is empowered to exercise such powers and perform such duties as may be conferred upon or delegated or assigned to him under the Act or by the Council. The Registrar is also authorised to issue permits and carry out certain related functions.[263] The Registrar may, at his discretion, 'fast track' any application for an activity involving GMOs for which a permit had previously been granted. For example, if an import permit has already been granted in respect of the importing of a particular GMO, further imports of the same GMO may be approved without the need for producing a risk assessment for every shipment. However, the Registrar is not obliged to call for an updated risk assessment should the purpose for importation change. Consequently, as public participation[264] is only triggered when an original application for a permit is made, the public will know neither the quantity being imported of the same GMO over a specific period of time, nor the purpose for which the GMO is being imported.

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[261] Section 11.
[262] Op cit note 249 at 17.
[263] Section 9.
[264] See section 4.6 below.

4.4 The Procedure

In terms of section 20(1)(a) of the Act, the Minister is empowered to make regulations regarding the application for and issue of permits. In terms of Regulation 2(1), 'no applicant may import to or export from the Republic of South Africa, or develop, produce, use, release or distribute any genetically modified organism in the Republic of South Africa except in terms of a permit to undertake such activity'.[265] Activities that require a permit have been listed in the relevant Regulations to include: the importation and exportation of GMOs, contained use of GMOs,[266] trial release of GMOs, and general release and marketing of GMOs.[267]

Regulation 2(1) is, however, subject to the provisions of Regulation 2(2) which states that, 'a permit shall not be required for organisms that are used under conditions of contained use in academic and research facilities, and for those organisms specified in table 3'.[268] Table 3 to the Regulations lists GMOs 'that have been cleared for commercial release and/or for food and animal feed only'.[269] This mechanism is meant to serve as an exclusion list to fast-track commercial releases of genetically modified seed, food and animal feed, and to expedite trade in GMOs. Strangely, however, the Table includes virtually all GMOs used in South Africa today.[270] Neither the Act nor the regulations set out a specific decision-making mechanism regarding this category of GMO. It is therefore possible for the decision to be made without public knowledge and participation and, perhaps more importantly, without conducting an EIA, before approval of any GMO. The mechanism created here, as a possible exclusion to the permit requirement, has the potential to render the Act meaningless.

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[265] See RGN 413/20643/1, 26, November 1999. Activity is defined in section 1 of RGN 413/20643/1 as 'work undertaken with regard to the development, production, use and application of genetically modified organisms'.

[266] Section 1 of the GMO Act defines contained use as 'any activity in which organisms are genetically modified or in which such genetically modified organisms are cultured, stored, used, transported, destroyed, or disposed of and for which physical barriers or in a combination of physical barriers together with chemical or biological barriers or both are used to limit contact thereof with the environment'.

[267] Op cit note 265.

[268] Ibid.

[269] Ibid. The organisms listed in Table 3 include: cotton [Line 513], three strains of maize [Mon 180, T25, and T14], and soyabeans [Line 40-3-2].

[270] Op cit note 259 at 320. Notably, the volume of Maize [Mon 180], Cotton [Line 513] and Soyabeans [Line 40-3-2], all of which have been cleared for commercial release, food or animal feed, imported during January - September of 2002 accounted for 9 per cent of total GMOs imported during this period. [See List of permits granted by the DOA during 2002, obtainable from M. Vosges, DOA, Pretoria, (012) 3196253]. It is not possible to determine what proportion of total imports the GMOs listed in Table 3 of RGN 413/20643/1 (1999) account for. This is because the list of permits issued by the DOA group different strains of GMOs under one import permit with one corresponding volume. For example, during January - September 2002, South Africa imported 880 500.019 Million Tons of Maize [Mon 180], Maize [T25], Maize [Bt 11], and Maize [Bt 176]. The former two strains are listed in Table 3 the latter are not. In addition, during the period January - September 2002, South Africa imported 48 360 174.261 Million Tons of White Maize [>1 per cent GMO]. However, the list of permits granted for this GMO details neither the GMOs trait, gene, nor marker gene.

As noted above, a permit is not required for GMOs under contained use conditions in academic and research facilities. Rather, the facilities[271] where the GMOs are being developed, produced, used or applied require registration. However, the requirements for the registration of facilities do not go far enough in ensuring that abuses and circumvention of the stated purpose of the research do not take place.

4.5 Risk assessment and environmental impact assessment

It is internationally accepted that authorizations in relation to GMOs ought to be dealt with on the basis of the Precautionary Principle. This approach is particularly important in dealing with the issues presented by GMOs, where the novelty of the technology and the incredible complexity of the living systems of our planet, make it impossible to predict the consequences of the release of GMOs into the environment with any degree of certainty.

The GMO Act has, however, effectively rendered the application of the Precautionary Principle ineffective by including the following provision: 'lack of scientific knowledge or consensus on the safe use of genetically modified organisms shall not be interpreted as indicating a particular level of risk, an acceptable risk or an absence of risk'.[272] Thus, lack of scientific knowledge or consensus on the safe use of GMOs is not relevant, or should not be taken into account in the assessment of risk. This is directly contrary to the spirit of the Precautionary Principle, which is intended to establish a bias in favour of protecting the environment in situations of scientific uncertainty.

Risk assessments and EIAs are not mandatory in terms of the GMO Act. Rather, the Council has extraordinarily wide discretionary powers to determine when a risk assessment or EIA is required.[273] Regulation 3(1), however, prohibits any person from undertaking 'any activity involving genetic modification unless a suitable and adequate assessment of the risks created thereby to the environment and human health has been made'. At first glance it appears as though this provision obliges the Council to consider the risk or EIA before making a decision regarding the granting of a permit. However, such an obligation exists only where the activity involves 'genetic modification' and not where the activity involves, for example, the release of GMOs into the environment. Consequently, the Council retains its discretionary powers to determine when a risk assessment and EIA are required for all activities excluding the actual genetic modification of an organism.

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[271] Facility is defined in Regulations as 'any place where organisms are being genetically modified under conditions of contained use'. Op cit note 265.

[272] Regulation 3(2).

[273] See section 5(a) which reads 'in order to achieve its objectives, the Council *may* require any applicant for a permit to use facilities for the development, production, use or application of [GMOs] or to release such organisms into the environment, to submit to the Council . . . an assessment of the risk and, *where required, an assessment of the impact on the environment* of such development, production, use, application or release'. [own emphasis] Also, section 5(g) which reads, 'the Council may, after consideration of the risk assessment and, *where required*, the environmental impact assessment referred to in paragraph (a) . . .approve . . . the use of the facilities concerned . . . or the release of genetically modified organisms into the environment'. [own emphasis]

This situation is compounded by the fact that the EIA Regulations promulgated under the Environment Conservation Act 73 of 1989 (ECA) only lists 'the genetic modification[274] of any organism with the purpose of fundamentally changing the inherent characteristics of that organism' as an activity[275] that may have a substantial detrimental effect on the environment and therefore requires an EIA.[276] Consequently, the requirement to undertake an EIA is triggered by the start of the process of genetic modification rather than, for example, the proposed release or import of a GMO. It does not make sense to require an EIA to be conducted prior to the genetic modification of an organism. It is the environmental impact arising from the release of GMOs into the environment that should be investigated and assessed before authorization for such release is granted, and not genetic modification *per se*.[277] The operative words here are 'released into the environment' and not 'genetic modification of an organism'. Although previous drafts of the EIA regulations used the former terminology, the final draft uses the latter. Although the 'release of a GMO into the environment' is not listed as an identified activity, it nevertheless requires a permit,[278] which can only be issued by the Executive Council. As noted, the Council retains discretionary powers to determine when an EIA is required for all activities excluding the actual genetic modification of an organism.

It is argued by the writer that in exercising its discretion the Council is obliged to consider the national environmental management principles enumerated in section 2 of NEMA,[279] which apply throughout the Republic to the actions of all organs of state that

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[274] Although the regulations do not define 'genetic modification', the *EIA Regulations: Draft Guidelines* (1998) issued by the Department of Environmental Affairs and Tourism (DEAT) provides the following definition 'any experimental or industrial technology used to alter the genome of a living cell so that it can produce more or different chemicals or perform new functions; or the manipulations of genes in ways that by-pass normal sexual or asexual transmission'. It is clear from the wording of this section that it applies only to the actual genetic modification of an organism.

[275] See GN 1182 in *Government Gazette* No. 18261 dated 5 September 1997. 'The release of any organism outside its natural area of distribution that is to be used for biological pest control' is also listed as an activity. It is argued that the release of insect resistant GMOs falls within this listed activity. However, it is doubtful whether herbicide resistant and drought resistant GMOs are used for biological pest control.

[276] It is to be noted that a proposal by Makhathini Cotton Farming (Pty) Ltd to develop an irrigated agricultural estate on approximately 2600ha of land on the Makhathini Flats in northern KwaZulu-Natal for the purposes of growing GE cotton and wheat falls under the scope of the ECA regulations and therefore requires an EIA. This is, however, not because the project involves the planting of GMOs, but because it involves the change of land use and the cultivation/use of virgin ground. See Regulations 2(d) and 10 of GN 1182 in *Government Gazette* No. 18261 dated 5 September 1997.

[277] Further, the vast majority of GMOs that are released into South Africa's environment have not been genetically engineered in South Africa.

[278] Regulation 2(1) of RGN 413/20643/1, 26, November 1999.

[279] The National Environmental Management Act was passed in November 1998 and came into force in January 1999. A number of motivations that underlie NEMA are set out in its lengthy Preamble. It converts the constitutional environmental right to more concrete reality, provides the framework to set in place much needed environmental norms and standards, provides a basis for alternate dispute resolution procedures, and emphasizes the public interest in the environment. The Act provides a number of different mechanisms to achieve these ideals. However, the foundation stone of such ideals and of the Act as a whole, is a set of national environmental management principles, contained in section 2, based on the global idea of sustainable development and which apply throughout the Republic in respect of a number of listed criteria. The principles cover a wide spectrum of aspects and include many of the emerging environmental law norms as well as many norms included in the international environmental conventions. The principles are

may significantly affect the environment.[280] A precise interpretation of the words 'may significantly affect the environment' is problematic.[281] However, the use of the term 'may', as opposed to 'will', is important, as it demands compliance with the section 2 principles unless it can be said that an action *will not* significantly affect the environment.[282] This is to be borne in mind by the Executive Council when it considers whether an action may significantly affect the environment.[283] In *Minister of Public Works and Others* v *Kyalami Ridge Environmental Association and Others (Mukhwevho intervening)*,[284] the Constitutional Court considered the meaning of the phrase 'may significantly affect the environment'. The court noted that 'in the circumstances the Kyalami residents have not shown *as a probability* that the establishment of the camp at Leeukop *will* have a significant effect on the environment'.[285] This interpretation is incorrect. The Kyalami residents ought only to have had to prove that the activity in question 'may' have had a significant effect on the environment.

The question as to what is to be regarded as significant then arises.[286] The concept of significance was considered in *High Change Investments (Pty) Ltd* v *Cape Produce Company (Pty) Ltd t/a Pelts Products & 4 Others*.[287] The court noted that 'in light of the Constitutional right a person has to an environment conducive to health and well being, the threshold level of significance will not be particularly high'.[288] This view is supported. The question of what is to be regarded as significant must be seen in the light of the constitutional right to an environment conducive to health and well-being, as well as the

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to guide the interpretation, administration, and implementation of environmental laws. It is to be noted, however, that no guidelines presently exist to assist decision-makers in the interpretation and application of these principles.

[280] Section 2(1). It is to be noted that whilst NEMA requires EIAs to be conducted in respect of activities that may *significantly* affect the environment, the ECA requires EIAs in respect of activities that may have a *substantial detrimental* effect on the environment. NEMA thus adopts a less onerous approach, which encompasses a broader range of activities.

[281] It is argued that the best if not the only, way to determine whether an action may significantly affect the environment is to conduct an EIA.

[282] Even where it is said that an action may not significantly affect the environment, the possibility of such action significantly affecting the environment remains. That is, it may still significantly affect the environment.

[283] In the context of litigation, however, an applicant who wishes to release GMOs into the environment, and avoid compliance with section 2 of NEMA, need not prove that such activity will not significantly affect the environment. Rather, the person who calls for compliance with the section 2 principles must prove that such release may significantly affect the environment. In light of the Precautionary Principle, consideration could be given to reversing the normal burden of proof in this instance. That is, an applicant wishing to release GMOs into the environment would have to prove that such release will not cause harm to the environment in order to escape compliance with section 2 of NEMA.

[284] 2001 (3) SA 1151 (CC).

[285] Paragraph 75. Emphasis added.

[286] The term 'significant' is not defined in NEMA, nor is it clarified in guidelines. Notably, the Constitutional Court in the *Kyalami* case, whilst finding that the Kyalami residents failed to show that the proposed activity would significantly affect the environment, refrained from elaborating on the reason such affects were not regarded as significant. The Court did not, in fact, consider the question of what is to be regarded as significant at all.

[287] Unreported judgement delivered on 20 October 2001 in the High Court of South Africa (Eastern Cape Division), case number 1050/01.

[288] Ibid, at 33.

relevant principles in NEMA. NEMA's definition of the Precautionary Principle, which states 'that a risk-averse and cautious approach is [to be] applied, which takes into account the limits of current knowledge about the consequences of decisions and actions', assumes particular significance at this point. That is, in considering whether an action may significantly affect the environment, the limited ability of science accurately to predict threats to the environment should be borne in mind. It is doubtful whether science can accurately predict threats to the environment arising from the release of a GMO into the environment. If science cannot accurately predict such threats, it cannot be asserted definitively that the release of a GMO into the environment will not significantly affect the environment. It follows that the provisions of section 2 must apply to the release of a GMO into the environment.

Section 2(4)(i) of NEMA provides that the social, economic and environmental impact of activities, including both disadvantages and benefits, must be considered, assessed and evaluated, and decisions taken must be appropriate in the light of such consideration and assessment. It is argued that section 2(4)(i) of NEMA obliges the Council to require an EIA before the release of a GMO into the environment is permitted. According to section 2(1)(c) of NEMA, the principles enumerated in section 2 are to serve as guidelines by reference to which any organ of state must exercise any function when taking any decision in terms of NEMA or any statutory provision concerning the protection of the environment. Thus, any government functionary, who exercises an administrative power (for example, issuing a permit authorizing the release of a GMO into the environment) without substantially complying with the principles contained in section 2, will fall foul of NEMA.[289]

Section 2(3) evinces NEMA's commitment to sustainable development and provides that 'development must be socially, environmentally and economically sustainable'. This is followed by the provision that 'sustainable development requires the consideration of all relevant factors' and elaborates this by a further eight sub-principles.[290] At this point it is interesting to note that various theorists define EIA as a principal tool in environmental decision-making and management aimed at promoting sustainability. For example, Smith[291] defines EIA as 'a process of environmental planning that provides a basis for resource management to achieve the goal of sustainability'.[292] Another definition runs: 'EIA means an examination, analysis and assessment of planned activities with a view to

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[289] Such functionary will also fall foul of section 33 of the Constitution which requires the actions of organs of state to comply with all legislation. Among the remedies which could flow from an action in terms of this section are an interdict, ordering the setting aside of the decision, or a mandamus, ordering that the relevant policy or procedure be applied. See *Van Huysteen and Others v Minister of Environmental Affairs and Others* 1996 (1) SA 283 (C).

[290] These principles are crucial and stipulate internationally emerging environmental norms such as the Precautionary Principle, the Preventative Principle and the Polluter Pays Principle.

[291] L.G. Smith, *Impact Assessment and Sustainable Resource Management*, (1993), Longman: London, at 11.

[292] Further, Sadler defines environmental assessment as 'a systematic process of evaluating and documenting information on the potentials, capacities, and functions of natural systems and resources in order to facilitate sustainable development planning and decision-making in general, and to anticipate and manage the adverse effects and consequences of proposed undertakings in particular'. B. Sadler, *International Study of the Effectiveness of Environmental Assessment*, (1996), at 11.

ensuring environmentally sound and sustainable development'.[293] Failure to utilize a, if not *the*, principal means of achieving sustainability in administrative decision making necessarily renders the whole process suspect, and subject to legal intervention.

Notably, even if the Council were to exercise its powers and require a risk assessment, neither the GMO Act nor the regulations set out the principles or parameters of the risk assessment. This scenario is particularly worrying since section 20(1)(b) of the Act clearly contemplates that the Minister would make regulations 'prescribing the procedure to be followed by an applicant for the purpose of drawing up risk assessments and environmental impact assessments'.[294] Procedures for the purposes of drawing up EIAs need to be promulgated as a matter of urgency. Such procedures should include an evaluation of impacts on, *inter alia*, the environment, livelihood and food security, export trade opportunities, long and short term impacts on indigenous wildlife, implications for development options and the health impact of consuming food containing a cocktail of genes not previously eaten by humans or founding ecosystems.[295]

However, where the Council requires an EIA it would have to comply with the broad procedures enumerated in section 24(7) of NEMA.[296] Section 24(1) of NEMA states that the potential impact on the environment, socio-economic conditions and the cultural heritage of activities that require authorization by law and which may significantly affect the environment, must be considered, investigated and assessed prior to their implementation.[297] It is, however, unclear how this requirement is triggered or who has the power to invoke it. Assuming that this provision applies to GMOs, then it appears as

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[293] *United Nations Environmental Programme Goals and Principles of Environmental Impact Assessment* (1987). This document was significant in setting the tone for the development of the concept of EIA. It outlined the necessity of taking into account the potential environmental effects of resource use and developmental activities. In this respect, 'the first goal set [was]: To establish that before decisions are taken by the competent authority or authorities to undertake or to authorise activities that are likely to significantly affect the environment, the environmental effects of these activities should be fully taken into account'. Goal 1, UNEP Goals and Principles of Environmental Impact Assessment, 17 June 1987, UNEP Governing Council resolution GC 14/25, and endorsed by the General Assembly Resolution 42/184 (1987). Full document in P.W. Birnie, & A.E. Boyle, *International Law and the Environment* (1992).

[294] It is important to note here that section 24(3)(c) of NEMA requires any regulations made in terms of section 24 to comply with section 24(7). Importantly, section 24 empowers every Minister and MEC that is charged with authorizing an activity contemplated in section 24(1) to prescribe regulations laying down the procedures to be followed and the report to be prepared. Consequently, any regulations made in the future concerning the procedure to be followed in respect of EIAs need to comply with section 24(7). However, the present GMO Regulations fall within the scope of section 24(3)(c) and are therefore required to comply with section 24(7). Such compliance is mandatory because NEMA was promulgated and came into effect (January 1999) before the date of commencement of the GMO Act (December 1999). The GMO Regulations do not, however, comply with section 24(7) of NEMA.

[295] Notably, such procedures would have to comply with the principles contained in section 2 and 24(7) if NEMA at a minimum.

[296] Chapter 5 of NEMA, entitled 'Integrated Environmental Management', contains two sections, the first of which sets out the general objectives of IEM (section 23) and the second of which sets out provisions to attain these objectives (section 24). It complements the environmental assessment provisions of the ECA and the EIA regulations promulgated under it by providing broad terms for the IEM philosophy to be applied in the carrying out of environmental assessments.

[297] This encompasses activities under Regulation 1182 of the ECA and any others the Minister may choose to declare.

if the Executive Council, for example, has discretionary powers to invoke this provision if it considers that such activities may significantly affect the environment. Clearly, the provisions of section 24(7) will only be invoked where it has been determined that an activity may significantly affect the environment, and therefore requires an EIA. It is argued that, in view of the limited ability of science to predict precisely how the release of a GMO may affect the environment, it is not possible to assert that such release will not significantly affect the environment. Consequently, before the release of a GMO into the environment is permitted, the provisions of section 24(7) must be complied with.

The DOA does not seem ever to have called for a full EIA.[298] This is attributable to the fact that the Council does not seem to have required the invocation of the EIA provisions.[299] Although the DOA insists that applicants are required to submit risk assessments, information concerning the particulars of such risk assessments have not, to date, been released and are not provided upon request. Notably, if EIAs were being required, the public participation provisions would be invoked. This has, however, not occurred. It is therefore possible to assume, firstly, that the risk assessments provided by applicants have, to date, been regarded as sufficient, and not a single application has warranted a full EIA. Secondly, permits to release GMOs into the environment have been and are being granted without complying with section 24(7) of NEMA.

It is important to note here that the regulations impose very short time limits for the regulators to respond.[300] This means that regulators may have insufficient time to consider any risk assessments that may have been done. The short time-frame is weighted in favour of expediting trade in GMOs rather than ensuring that adequate time is spent on assessing potential impacts on the environment. Furthermore, the Act does not allow the Council to make its decisions based on risk assessments carried out by anyone other than the applicant.[301] This means that, strictly speaking, the Council is unable to base its decision on an independent risk assessment. The Council is, however, obliged to consult the Committee. The Committee must, in turn, invite written comments from 'knowledgeable persons' on any aspect of GMOs within its brief.[302]

The Council may, in considering whether or not to grant a permit for the introduction, use, distribution or release of a GMO, 'consider the socio-economic impact that the

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[298] Personal communication, Michelle Vosges, Assistant Director of GMOs, DOA, (012) 3196253; Professor Richard Fuggle, Environmental and Geographical Science, University of Cape Town, (021) 6502874, Fuggle@enviro.uct.ac.za; Mariam Mayet, Biowatch South Africa, (011) 6460699; Belinda Bowling, Environmental Lawyer, Winstanley Smith & Cullinan Inc, (021) 4257063.

[299] The DOA, in fact, relies on EIAs performed in the country of export. Personal communication, Mr. Preggy Pillay, Chief Plant and Quality Technician, DOA, (031) 3372755/6. This was confirmed by M Mayet, Biowatch South Africa, (011) 6460699, and D Van Staden, Research Department of Pannar, (033) 4139633. Reliance on EIAs performed in the country of export is unsatisfactory for numerous reasons. Essentially, however, it disregards the uniqueness of the receiving environment in South Africa.

[300] That is, for the importation/exportation of a GMO or the contained use of a GMO, a determination must be made within 30 days. For the trial release and general release and marketing of GMOs, a determination must be made within 90 and 180 days respectively.

[301] Section 5(a), read together with section 5(g) of the Act.

[302] Section 11(1)(d).

introduction . . . may have on a community living in the vicinity of such introduction'.[303] Such provision needs to be extended to oblige the Council to take into account the impact of a release of GMOs on traditional crops and technologies[304] and the social and economic costs resulting from the loss of genetic diversity.[305]

4.6 Notification and public participation

Notification refers to the information the applicant is under a legal obligation to supply to the competent authority together with the risk assessment report. The notification process is inextricably linked to public participation insofar as the public should be kept informed of the status of approvals, be furnished with the information supplied under the notification process and be given an opportunity to submit comments. These comments are to be taken into account by the Committee and the Council during the decision-making process. The consultation process is a critically important component of environmental governance and environmental justice.

The Act deals with notification and public participation only in the context of permit applications.[306] Notification must occur prior to an application for a permit. Notification is to be in the form of a standard notice published in the printed media informing the public of the intended release.[307] The notice must contain, *inter alia*, a request that interested parties submit comments or objections in conjunction with the intended release to the Registrar within thirty days from the date of the notice.

The provisions relating to notification and public participation are inadequate. First, the provisions only apply in the context of permit applications. So, for example, because a permit is not required for GMOs under contained use conditions in academic and research facilities, decisions regarding this category of GMOs can be made without public participation and in the absence of public knowledge. This category of GMOs

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[303] Regulation 5(9).

[304] In this respect, regard should be had to section 2(4)(g) of NEMA which states that 'decisions *must* take into account the interests, needs and values of all interested and affected parties, and this includes recognizing all forms of knowledge, including traditional and ordinary knowledge'. [own emphasis] In developing countries, such as South Africa, the socio-economic impact of genetic engineering on farmers' livelihoods is crucial. The ability of farmers, particularly small-scale commercial, organic and subsistence farmers, to control how they use their seed is a question of survival. Traditional farming methods such as multiple-cropping to reduce the risk of crop failure, crop rotation and other ecologically-based technologies for production enhancement, as well as the practice of saving seed from year to year, are thought to account for over 90 per cent of Africa's food requirements. The introduction of genetically engineered subsistence crops is threatening these traditional methods in a number of ways. It is beyond the scope of this paper to detail the threats GMOs pose to traditional crops and technologies.

[305] In this respect, regard should be had to section 2(4)(v) of NEMA which states that sustainable development requires that 'the use and exploitation of non-renewable natural resources is responsible and equitable, and takes into account the consequences of the depletion of the resource'.

[306] See Regulation 6, which deals with public notification of proposed trial release and general release of GMOs.

[307] The publication must be made in at least three newspapers circulating in the area in which the proposed release is to take place.

effectively bypasses the decision-making procedure set out in the Act.[308] The vast majority of international biosafety laws require step-by-step approvals of GMOs.[309] That is, releases of GMOs are approved first for the activity under contained use conditions, then for open field trials and then there is authorization for commercial releases. Authorizations are required for each stage of the process, and every stage of the activity is monitored for risks. Secondly, notification need not be given to the public at large, but merely to those in the area in which the proposed release is to occur. This is not satisfactory as the risks arising from the release of GMOs are of national importance.

Thirdly, the information the applicant is required to furnish is inadequate for the purpose of equipping the public to participate in any meaningful way. The Act provides a right of access only to information regarding the 'evaluation of *foreseeable impacts,* in particular any pathogenic or ecologically disruptive ones'.[310] Thus, the public may be precluded from gaining access to information on the *potential* or *likely* impact and risks posed by the GMO in question to the environment. This right is further tempered. The Council is empowered to determine, in consultation with the applicant, which information will be kept confidential.[311] In fact, the Council is obliged to consult the applicant in order to decide which information should be kept confidential. In addition to this general power to determine what information is to be kept confidential, the Council is further empowered to treat information necessary to protect the IPRs of the applicant confidential.[312] Fundamentally, the risk assessment report itself should be made available to members of the public for critical analysis.[313] The argument that there is a need for secrecy to surround risk analysis as a way of protecting proprietary information in a competitive market has worn thin. Commercial interests should no longer be allowed to trump the rights of the individual (or the well being of the environment). Fourthly, there is no provision for public participation in either the Executive Council, or the Advisory Committee. Lastly, the regulations impose very short time limits for interested and affected parties to respond.[314] As a result, the public is prevented from commenting meaningfully on any permit applications. The time limits need to be extended in order to ensure that the imperative to expedite trade in GMOs does not preclude constructive public participation and the assessment of potential impacts on the environment.

The provisions relating to public participation in the GMO Act do not comply with the national environmental management principles contained in section 2 of NEMA. In this respect, section 2(4)(f) of NEMA requires that the participation of all interested and

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[308] Notably, this loophole is not accounted for and neither the Act nor regulations detail a decision-making strategy for this category of GMO.

[309] Op cit note 249 at 21. See the EU Directive 97/11/EC of 3 March 1997, Norway's Gene Technology Act, and the OAU Model legislation on 'Community Rights and on the Control of Access to Biological Resources'.

[310] Emphasis added. Section 18(2)(c).

[311] Section 18(2).

[312] Section 18(3).

[313] In this respect, the relevant authorities would be well advised to consider section 2(4)(k) of NEMA which states that 'decisions must be taken in an open and transparent manner, and access to information must be provided in accordance with the law'.

[314] That is, 30 days.

affected parties in environmental governance must be promoted, and all people must have the opportunity to develop the understanding, skills and capacity necessary for achieving equitable and effective participation, and that participation by vulnerable and disadvantaged persons must be ensured. Over and above the question of whether or not interested and affected parties have been afforded the opportunity to develop the requisite skills and understanding of GMOs, there remains the question as to whether the participation of interested and affected parties in environmental governance has been promoted. It is argued that it has not. For example, to date four genetically engineered crops have been granted permits for general release.[315] However, none of the permits to release these four crops has undergone any sort of public participation process, EIA, health impact study, or any other meaningful public process before its release. Not a single interested and affected party was identified. Instead, the releases have been shrouded in secrecy.

The lack of publicly available information on what is happening in relation to GMOs makes it extremely difficult to monitor whether or not the existing legislation is being complied with. That is, without access to information, the public is not able to determine whether or not private parties or the DOA are infringing the rights of the public under the Constitution,[316] the GMO Act and its regulations, NEMA, or international conventions to which South Africa is a party. The public is also not in a position to determine the impact of GMOs on the environment in South Africa, or to compare the methodologies used in undertaking and assessing the release of GMOs into the environment with those used in other countries. The situation is exacerbated by the recalcitrant attitude of the National DOA in relation to requests for information. There may in fact be scope for a Constitutional challenge on the grounds of the public's right of access to information held by the State. In this regard the provisions of section 32 of the Constitution[317], and the Promotion of Access to Information Act 2 of 2000 would take precedence over the GMO Act.[318]

4.7 The GMO Act and the Cartagena Protocol to the CBD

4.7.1 History

Article 8(g) of the CBD provides that each contracting party shall, as far as possible and as appropriate, 'establish or maintain means to regulate, manage or control the risks associated with the use and release of LMOs[319] resulting from technology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human

[315] These include Cotton [Line 513], Maize [Mon 180], Maize [NK603], and Soyabeans [GTS 40-3-2].
[316] In particular, section 24.
[317] Relating to access to information.
[318] It is to be noted that Biowatch, a non-governmental organization, has launched an action against the Registrar of the GMO Act, the Executive Council for GMOs and the Minister for Agriculture, in order to gain access to information. Case number 23005/2000.
[319] It is to be noted that, instead of GMO, the term LMO is used, this being the parlance of the Convention. However, because the definition of LMO is largely consistent with that of GMO in the GMO Act, the terms will be used interchangeably in this section.

health.' The basis for doing so was not specifically set out in the Convention, and was left for determination by a protocol at a future date.[320] Negotiation of a Protocol on biosafety commenced after the Convention came into force and was to have been finalized at the sixth meeting of the Biosafety Working Group in Cartagena, Columbia in February 1999.[321] The Protocol was, however, only finally agreed to and adopted in Montreal on 29 January 2000. The major issues of debate in the negotiations concerned the scope of the Protocol,[322] the precautionary principle,[323] the relationship to other agreements,[324] and liability.[325]

The objective of the Protocol is to ensure an adequate level of protection for 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 with a specific focus on transboundary movements.[326] In addition to environmental impacts, human health and socio-economic factors are recognized as valid considerations in determining whether to accept or reject LMO imports. The Protocol deals with, *inter alia,*

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[320] In this respect, Article 19(3) provides, 'the Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, Advanced Informed Agreement, in the field of the safe transfer, handling and use of any LMO resulting from biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity.'

[321] This, however, collapsed as a group of six countries (Canada, Australia, Argentina, Chile, Uruguay) headed by the United States clashed with a coalition formed by the European Union and a bloc of over 100 'like-minded' developing countries. The former favoured a zero-option approach, which would facilitate international trade in LMOs, while the latter united in a call for a comprehensive safety regime. Op cit note 259 at 310.

[322] The central issue here was whether the Protocol should cover a class of LMOs known as LMO-FFPs, LMOs that are intended for direct use as food or feed or for processing. Those opposed to including such LMOs in the Protocol argued that because such LMOs are not intended for introduction into the environment, they pose no threat to biodiversity, and therefore should not be included in the Protocol. Those in favour of including such LMOs in the Protocol argued that it was not possible to ensure that this category of LMO would not in fact be released into the environment, whatever the intention. It was finally agreed that LMO-FFPs would fall under the Protocol's scope and negotiations then focused on whether they would fall under the scope of the Protocol's Advanced Informed Agreement provisions.

[323] After establishing that Parties could take a precautionary approach to deciding what restrictions they might put on the import of LMOs, negotiations turned to the question of how to implement the principle of precaution. Some argued that the Precautionary Principle could be used as an excuse to restrict trade in harmless goods in order to protect domestic producers and, because of this possibility, any restrictions had to be based on sound science and rigorous risk assessment. Others argued that the sound-science argument itself was an excuse to limit the use of an established principle of international environmental law.

[324] The other international agreements in question include the Law of the Sea, international transit and transportation arrangements, and international health agreements that address human pharmaceuticals. Foremost in negotiators minds, however, was the multilateral system of trade rules embodied in the WTO. The concern was what would happen if the trade-related provisions of a multilateral environmental agreement (MEA) was challenged in the GATT/WTO or if a country was challenged for implementing an MEA in a trade-restrictive manner.

[325] Here, the question was whether, and in what form, to create a liability and redress mechanism for any damage resulting from the transboundary movements of LMOs. Proponents argued that if such mechanism were exercised, then by definition there would have been a need for it; if it were never exercised, no harm would result from its inclusion. This argument is strongly supported by the writer. The question of 'whether' was settled by the time of the Montreal meeting, leaving questions of 'how' and 'when' open to negotiators.

[326] Article 1.

establishing an Advanced Informed Agreement (AIA) procedure, setting minimum standards for the use of LMOs as food or feed, risk assessment, risk management, and public awareness and participation.

The Protocol was opened for signature during May 2000, at the fifth Conference of the Parties to the CBD. The required number of fifty Parties was attained on 13 June 2003[327] and, in accordance with the provisions of Article 37 of the Protocol, the Protocol will enter into force on 11 September 2003.[328] As a party to the CBD, South Africa participated actively in the process of negotiating the Protocol. Regrettably, however, South Africa failed to sign the Protocol. Once South Africa ratifies the Protocol the GMO Act will have to be amended substantially to give effect to the Protocol. It is beyond the scope of this paper to deal comprehensively with the extent to which the GMO Act would have to be amended in order to do so. Only the most important issues are discussed here.

4.7.2 The Advanced Informed Agreement (AIA)

The most significant amendment to the GMO Act would be the adoption of the AIA Procedure of the Protocol. The AIA Procedure is the core regulatory mechanism of the Protocol and comprises of three main steps. The first involves certain prescribed and standardized information that must be furnished by either the exporting country or the exporter to the authorities in the importing country.[329] The second step concerns the acknowledgement of receipt of notification.[330] The third step deals with decision-making.

Regarding the application of the AIA Procedure to the importing and exporting of LMOs, the Protocol distinguishes between LMOs that are traded for direct introduction into the environment and those that are 'commodities'.[331] In this respect, the AIA Procedure only applies to the first transboundary movement of LMOs intended for direct introduction into the environment.[332] That is, a particular genetically modified seed, imported for the first time for planting in the open under either field trial conditions or for commercial release, will be subject to the AIA Procedure. The AIA Procedure does not apply outright to subsequent imports of the same LMO. However, in terms of Article 2(4), parties may apply the Procedure to subsequent imports of the same LMO for the same purpose. Article 2(4) affirms the right of a party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in the Protocol, provided that such action is consistent with the party's obligations under international law.

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[327] When Palau ratified the Protocol.

[328] By 1 August 2003, fifty-six parties had ratified the Protocol.

[329] This mechanism is referred to as 'notification' and is set out in Article 8, read together with Annexure I of the Protocol. In terms of Annexure I, the exporting country or the exporter is required to furnish 'a previous and existing risk assessment report consistent with Annex III.' Annexure III deals with risk assessment and contains sections relating to general principles (sections 3 - 5), methodology (sections 7 and 8), and points to consider (section 9).

[330] Contained in Article 9.

[331] That is, LMOs that are intended for direct use as food, feed or processing, or LMO-FFPs. See Article 7(2).

[332] Article 7(1).

In order to implement the AIA Procedure, the GMO Act would have to be amended in the following ways. Firstly, it would have to ensure that the AIA Procedure applies, at the very least, to the first transboundary movement of GMOs intended for direct introduction into the environment. Secondly, it would have to set out the notification procedure in detail, particularly the information that has to be provided, as set out in Annexure I to the Protocol. Thirdly, it would have expressly to set out the risk assessment the importer must conduct. In this regard, the standards contained in Annexure II of the Protocol should be used as a minimum. Fourthly, the current time frames imposed by the GMO Act would have to be revised. As noted above, thirty days is not regarded as sufficient to enable a proper determination of the risks. Fourthly, the Precautionary Principle would have to be redrafted.[333]

4.7.3 Contained use

Article 6(2) creates a special set of provisions for contained use, and provides that, parties may subject LMOs destined for contained use to risk assessment prior to decisions on importing, and parties may set standards for contained use within their jurisdiction.[334] The AIA Procedure, however, does not apply to the transboundary movement of LMOs destined for contained use undertaken in accordance with the standards of the party of import. The AIA Procedure is drafted in ambiguous language and it is not clear whether two different procedures have been created for the trade in LMOs destined for contained use. It appears as if there is a choice, either the AIA Procedure may be used for transboundary movements of LMOs destined for contained use, or the transboundary movement can take place in accordance with the standards set by the importing party. In the latter case, there may be an implied waiver of the AIA Procedure.

The Protocol defines contained use as 'any operation, undertaken within a facility, installation or other physical structure, which involves LMOs that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment.'[335] Mayet opines that this definition is too broad as it encompasses various forms of deliberate releases into the environment.[336]

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[333] The Protocol contains a strong version of the precautionary principle. Although the text does not refer specifically to the 'Precautionary Principle', the preambular reference being to the 'precautionary approach', this does not change the fact that the principle is clearly incorporated in the Protocol. The wording in Articles 10 and 11 is a direct derivative of Principle 15 of the Rio Declaration on Environment and Development. Article 1, (Objective), states that the objective of the Protocol is to be pursued 'in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development.' Article 10(6) states that, 'lack of scientific certainty ... shall not prevent [a] party from taking a decision, as appropriate, with regard to the import of the living modified organism in question....' Similar wording appears in Article 11, which covers the special case of LMO–FFPs. Parties also reaffirm their commitment to the precautionary approach in the preamble.

[334] It is not clear what is meant by 'standards for contained use'. Possible interpretations include the standards that a research institution or other facility must meet before it is allowed to use LMOs under contained-use conditions, and comprehensive biosafety standards for contained use.

[335] Article 3(b).

[336] Including, caged transgenic fish or other aquatic LMOs in open ponds, lakes and marine environments; vaccinations with transgenic viruses and naked nucleic acid vaccines; all forms of gene therapy;

In terms of the GMO Act, GMOs destined for contained use can enter the country without a permit, provided that a risk assessment is conducted in terms of the Act prior to such importation. It appears that, provided the risk assessment embodies some standards for contained use, the provisions of the Protocol will be fulfilled. Thus, the AIA Procedure of the Protocol will probably not apply. This is so because the Protocol contains no express provisions requiring the AIA Procedure to apply to such importation. Further, if exporting countries adopt the Protocol's flawed definition, it will be possible for GMOs destined for contained use in South Africa to be traded as such, but then be deliberately released into the environment in South Africa.

It is imperative, therefore, that the current regulation of imports of GMOs destined for contained use be revised in order to ensure that the AIA Procedure applies to such importation. GMOs imported for use in contained-use conditions should be treated as LMOs intended for direct introduction into the environment.[337] The GMO Act can, however, provide exceptions to this in instances where the GMO in question can clearly not be released into the environment. It is to be noted that the above is in accordance with the Protocol, in terms of which, South Africa would be entitled to establish higher levels of protection.[338]

4.8 Case Study: Syngenta application

On 3 October 2002 Syngenta Seedco (Pty) published two notices in The Star newspaper inviting public comment. One informed the public of a proposed general release of genetically engineered 'Bt11' maize, the other informed the public of proposed field trials for the same Bt11 maize. This application will now be considered as it illustrates just how inadequate the South African process of investigating, assessing and communicating the potential impacts of GM crops is.

The simultaneous application for two activities, testing field trials and general release, does not meet best practice procedures for biosafety and undermines the primary purpose of field trials.[339] The issue of whether or not to proceed with general commercial release should be entertained only after completion of field trials, and any approval or rejection must be based on the evidence from the prior (appropriately contained) field trials. Clearly, simultaneously applying for testing and general release makes a mockery of the whole purpose of field trials. Such application, however, leads one to question whether

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xenotransplantation using transgenic animal organs; open field trials with fencing or other physical barriers; transgenic organisms enclosed in cages or other containers and destined for deliberate release; liquid and solid wastes of transgenic livestock contained in a laboratory; liquid and solid wastes from laboratories creating transgenic organisms for deliberate release. See Mayet, op cit note 249 at 28, and L. Lin, 'The Core Issues in the Biosafety Protocol: An Analysis', (February to March 2000), *Third World Resurgence* Issue No 114 – 115, available at World Wide Web, http://www.twnside.org.sg/title/core.htm

[337] As contemplated by Article 7(2) of the Protocol.

[338] Article 2(4).

[339] The purpose of field trials in the context of GMOs is to assess the GMO for environmental impacts and safety, and to test the efficacy of planting and management strategies intended to prevent cross-pollination and development of insect resistance. The evidence accumulated from each stage should then inform the decision making process in the next stage of release.

field trials are indeed being used to assess biosafety in South Africa. From the above application, it appears not. If this is so then the question as to what data is being used to inform the decision-making regarding general release into South Africa's environment arises. In this respect it is important to note that it is unacceptable to base GMO releases on data gathered in some remote foreign environment, where the conditions of growth and the receiving ecosystem in no way approximate those in South Africa.

The public notices do not adhere to the requirements for open and transparent government, public participation[340] and access to information. With regard to access to information, it will be recalled that the GMO Act and regulations require the applicant to furnish certain information in the public notice. Syngenta, however, failed to furnish the following mandatory information: a description of the inserted genes,[341] identification or description of the maize variety,[342] a description of the receiving environment, and a description of the areas in which the proposed release is to take place. Further, it is difficult to see how Syngenta's statement that 'the safety of humans, animals and the environment has been comprehensively tested and the results presented to the responsible authorities' equips the public to comment on the proposed release.[343] This is because the statement fails to reveal where (i.e. in what country and environment), at what time, and by whom the testing was conducted. If the DOA is relying on data obtained from studies in the USA, the conclusions regarding safety cannot be applied to South Africa.[344] Furthermore, independent review of the studies of Bt maize used by the regulatory agencies of America found that the experimental methodology was often unsatisfactory.[345]

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[340] Syngenta state in the public notice that they 'wish to inform the public of the proposed General Release'. This creates the impression that approval is a *fait accompli* of which the public is merely being informed. Syngenta seems to have forgotten the purpose of the public notice, namely, to notify the public that Syngenta is applying for *permission* for a general release and to give it an opportunity to oppose the application on the basis of any apparent negative impact.

[341] Reference is made to 'a gene', which is in no way descriptive.

[342] The maize has been identified as Maize Bt 11. However, such information does not disclose whether the maize is white maize, yellow maize, or both; nor does it disclose what particular variety of white or yellow maize is involved.

[343] Further, the public notices state that 'no negative impact' on humans, animals or the environment has been recorded despite 'comprehensive testing' for impacts. Reference is then made to 'the set-up of an insect resistance management system'. It is evident from the inclusion of the management strategy that the development of insect resistance is clearly a possibility. This stands in direct contrast to the statement that 'no negative impact(s)' have been recorded.

[344] South African biodiversity is very different from that which occurs in America. South Africa has a very high number of endemic plants, and consequently, the organisms (insects, microorganisms, animals and other plants) associated with these endemics are likely to be highly specific; so too are the ecological relationships between organisms. Given the subtlety and complexity of ecological relationships and South Africa's high levels of species it is not possible to extrapolate with any degree of certainty from research conducted in the USA on organisms occurring there what the potential effects of Bt toxins on local ecosystems will be. Thus, conclusions regarding safety made in other regions cannot be applied to South Africa without considering the particular insects, soil fauna, plants and animals that exist here.

[345] A. Hilbeck, M.S. Meier, & A. Raps, 'Review on non-target organisms and Bt-plants', (April 2000), Report to Greenpeace International, Amsterdam. EcoStrat GmbH, Zurich, Switzerland. For example, tests for toxicity measured acute toxicity while ignoring chronic lethal and sub-lethal toxicity, and multitrophic interactions between plants, herbivores, pathogens and natural enemies were not investigated. Furthermore, a range of reported studies on Bt 11 maize carried out elsewhere have shown that: there are negative effects

The public notice asserts that 'Bt 11 maize has therefore received approval for commercial cultivation in USA, Canada, Argentina, Japan, Switzerland, and Australia/New Zealand'. This is, in fact, incorrect. Bt Maize has not been approved for commercial cultivation in Switzerland or Australia/New Zealand, nor are applications pending.[346] This misrepresentation raises numerous concerns. First, an applicant applying for a GMO release, as owner of the technology to be released, should possess full and precise details of the permits it has been granted in other countries. If such applicant can confuse facts concerning the precise nature of the permits it has been granted, it is entirely possible that further confusion may be expressed in the formulation of the results of scientific tests and trials which, by their very nature, are open to interpretation. Secondly, the public is justified in questioning whether the misinformation was deliberately provided in order to exploit the inadequacies of the GMO Act and to mislead the South African public. Thirdly, the public may question whether or not the misinformation is provided with the knowledge of the very authorities charged with authorizing and controlling the release of GMOs in South Africa. In particular, it would be worth investigating whether Syngenta provided the DOA with similarly false information, and furthermore, what measures the DOA have in place in order to verify information supplied by applicants.

These public notices do not comply with the requirements of open and transparent decision making, the public's right of access to information, or the tenets of effective public participation. This application highlights the manner in which GMOs are being released in South Africa, that is, in secrecy and contrary to the principles of openness and transparency. It also provides insight into, and lends credibility to, the public's reluctance to trust any assurances from the authorities or the applicants regarding the safety, or the extent and results of GMO testing. The Syngenta Maize Bt11 application is the first time that the public has been afforded the opportunity of 'participating' in a decision pertaining to the release of a GMO into the environment. This application's intrinsic flaws, and the impoverished information supplied, cast doubt onto the procedure

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of Bt toxins on non-target insect species, that active Bt toxin could build up in the soil posing a hazard to other soil organisms, and that build-up of insect resistance is a real concern. See D. Saxena, S. Flores, & G. Stotzky, 'Bt toxin is released in root exudates from 12 transgenic corn hybrids representing three transformation events', (2002), *Soil biology and Biochemistry* 34: 133-137; A. Hilbeck, 'Pre-meditated effects of Cry1Ab toxin and protein on the predator Chrysoperla carnea', (1999), *Entomologia Experimentalis Et Applicata* 91(2): 305-316; H. Wandeler, J. Bahylova, & W. Nentwig, 'Consumption of two Bt and six non-Bt corn varieties by the woodlouse Porcellio scaber' (2002) *Basic and Applied Ecology* 3: 357-365; M. Marvier, 'Ecology of transgenic crops', (2001), *American Scientist* 89: 160-167; S.J. Wold, E.C. Burkness, W.D. Hutchison, & R.C. Venette, 'In-field monitoring of beneficial insect populations in transgenic corn expressing a *Bacillus thuringiensis* toxin', (2001), *Journal of Entomological Science* 36(2): 177-187; J.J. Obryeki, J.E. Losey, O.R. Taylor, & L.C.H. Jesse, 'Transgenic insecticidal corn: Beyond insecticidal toxicity to ecological complexity', (2001), *Bioscience* 51(5): 353-361; F. Huang, L.L. Buschman, R.A. Higgins, & W.H. McGaughey, 'Inheritance of resistance to *Bacillus thuringiensis* toxin (Dipel ES) in the European corn borer', (1999), *Science* 284: 965-967; Y-B. Liu, B.E. Tabashnik, T.J. Denney, A.L. Patin, & A.C. Bartlett, 'Development time and resistance to Bt crops', (1999), *Nature* 400: 519; and B.E. Tabashnik, Y-B. Liu, N. Finson, L. Masoson, & D.G. Heckel, 'One gene in diamondback moth confers resistance to four *Bacillus thuringiensis* toxins', (1997), *Proc, Nat, Acad. Sci.* 94: 1640-1644.

[346] Australian Office of the Gene Technology Regulator at World Wide Web http://www.ogtr.gov.au/gmorecord/grlist.htm and Switzerland at World Wide Web http://www.umwelt_schweiz.ch/buwal/de/fachgebiete/fg_biotechnologie/national/odec/registre/index.html

followed in all previous general releases. It is argued therefore, that all previous general releases and field trials authorized by the DOA should be reviewed in a transparent and open process.

4.9 Lessons for Africa

It is argued and demonstrated that the South African GMO Act does not, in its present form, constitute an adequate biosafety regime that ensures GMOs do not cause harm to the environment. Instead, the current Act and its Regulations appear to be designed to facilitate the introduction of GMOs into the environment, favouring the multinational biotechnology companies that stand to profit from the sale of GM seed and attendant agrochemicals. As tersely put by Pole, 'by failing to regulate GMOs adequately, the DOA has allowed the South African environment and public to be used as experimental "gene-pigs" by the biotechnology giants.'[347] Africa is advised to heed the shortcomings of this Act and stand firm against the mounting pressure it faces to accept and implement monopoly rights over plant varieties.

CHAPTER 5

WHY IPRs OVER CROP VARIETIES WILL NOT BENEFIT AFRICA

In considering how IPRs will impact on African agriculture, it is necessary to consider what type of innovation African agriculture needs and who Africa's innovators are. African countries have two kinds of agriculture: one for subsistence and one for export. Subsistence farmers, however, constitute Africa's most important and most capable innovators.[348] Formal sector breeders, from the private and public sectors, remain relatively insignificant. In Uganda, the formal sector supplies only 1 per cent of the bean seed used by farmers. In the Machakos area of Kenya, commercial seed accounts for less than 2 per cent of the cowpea and pigeon pea seed used by the average farmer, neighbours and local markets supply over 17 per cent and the rest is saved by the farmer herself.[349] In the Southern African region, on-farm seed multiplication and farmer-saved seed constitute 95 to 100 per cent of the seed used for sorghum, millet, food legumes, roots and tuber crops.[350] In Zambia, 95 per cent of the millet crop is grown from farmers' seed.[351] Even with a commercial crop like maize, small farmers are typically the main

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[347] Op cit note 253 at 21.

[348] For example, Sahelian farmers produce 2 to 10 times more animal protein per squared kilometre than farmers in Australia and the USA. See P. de Vries, & M.A. Djiteye, 'La Productivite des paturages seheliens. Une etude des sols, des vegetations et de l'exploitation de cette ressource naturelle', (1982), Agricultural Research Paper, PUDOC, Wageningen, at 918.

[349] See A. Gordon, 'Improving Smallholder Access to Purchased Inputs in Sub-Saharan Africa', (2000), Nation Resources Institute, Policy Series No. 7, University of Greenwich.

[350] See W.R. Scowcroft, & C.E.P. Scowcroft, 'Developing a Strategy for Sustainable Seed Supply Systems in Sub-Saharan Africa', (November 1998), Proceedings of the Regional Technical Meeting on Seed Policy and Programmes for Sub-Saharan Africa, Abidjan, Cote d'Ivoire, available at World Wide Web, http://www.fao.org/ag/AGP/AGPS/abidjan/tabcont.htm

[351] See Food and Agricultural Organization, World Wide Web, http://www.fao.org/ag/AGP/AGPS/Abidjan?TA11.gif

suppliers of seed.[352] In Malawi, despite many years of effort by the state seed company and private seed companies, hybrid maize covers no more than 30 per cent of the smallholder area.[353] In Benin, 95 per cent of the agricultural economy is assured by subsistence farmers. In Morocco, smallholder farmers account for 69 per cent of all farmers.[354] In Namibia, 90 per cent of the population in communal farming areas is directly dependant on subsistence agriculture for a living. In Tanzania, smallholders contribute approximately 80 per cent of the value of marketed surplus and 75 per cent of export earnings.[355] Small farmers constitute by far the largest sector of seed breeders in Africa and have cultivated the abundant diversity that sustains the continent's food security.

Traditionally, innovation in African agriculture has proceeded through collective community processes, drawn from customary practices based on sharing. IPRs, on the other hand, are based on a very different culture, where the right to deny access to innovations is supreme. The notion of monopoly rights is completely alien to the traditional process of innovation in African farming communities. Although African communities utilise a wide variety of agricultural practices, they share certain fundamental approaches. As concisely explained by IPR expert Mushita of Zimbabwe,[356] '[i]n the African context, customary law is applied. It does not recognise private property rights but rather community resource rights. All resources belong to everyone and they are regulated by the community's cultural and local knowledge systems and practices. In this sense, farmers have exchanged seed among themselves since time immemorial, passing from neighbour to neighbour, mother to daughter, mother-in-law to daughter-in-law, or even across villages and communities. Even labour is shared for such activities as land preparation, ploughing, planting, processing or threshing and harvesting crops.'

In traditional societies, food security is not just a matter of food production but also of investing in and maintaining good social relations. Exchanging and sharing seed and planting materials takes place on a reciprocal basis, with financial payments being secondary.[357] Here, the basis of exchange is not money, but trust. It is not necessary for reciprocal acts to occur simultaneously in time; in sharing what they have today, their need for seeds will be met tomorrow. In the Philippines, the informal seed system includes farmer-to-farmer exchange or borrowing and other traditional practices of seed and informal sharing during weddings, festivals and village fairs. The bride, for example, brings the local seed to the bridegroom's house after marriage, for planting in the

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[352] See D. Kuyek, 'Intellectual Property Rights in African Agriculture: Implications for Small Farmers', (August 2002), Genetic Resources Action International.

[353] See J. Rusike, & M. Smale, 'Malawi', in M. Morris (ed), *Maize Seed Industries in Developing Countries*, (1998), CIMMYT, at 291.

[354] Op cit note 168.

[355] Ibid.

[356] See personal communication with D. Kuyek, in Kuyek, op cit note 352 at 7.

[357] According to Egziabher and Edwards of the Institute of Sustainable Development in Ethiopia, it is through this 'collective generation, modification, conservation and exchange across generations and communities, that knowledge, technologies and biodiversity become owned and managed by the community, and used by anyone who wants them. Charging money for access is unknown, though reciprocation in kind is a necessary element for the perpetuation of the system.' Op cit note 352 at 7.

couple's field. Tribes exchange seeds during festivals. Seeds are also exchanged as gifts. It is not only seeds that are exchanged, but also local practices for seed selection, preservation and even management of genetic diversity.[358] Butaumocho of the Intermediate Technology Development Group in Zimbabwe provides another example of the role seed plays within the social context. In his community,[359] every farmer has a duty to retain a portion of his or her harvest as seed for the next season. When necessary, seed is obtained from relatives and friends, but it is freely given. The community shares the belief that one should not thank the person who gave you the seed as, in so doing, one would merely be thanking the custodian of the seed, as the true owner is the spirit of the land. Butaumocho notes that, '[t]he idea of royalties is alien in my community. The closest thing to a royalty is the annual offering made to the spirits of the land by every villager as a way of giving thanks.'[360] The seed industry, however, does not share the perspective of African small farmers. Professional plant breeding depends on monopoly rights based on the rationale that plant breeding is expensive and requires an effective cost recovery mechanism.

Another concern that is frequently raised is the extent to which IPRs foster the dependence of developing countries on foreign companies for their seed supply. TNCs dominate applications for PVP and patents in developing countries. At present, nationals of industrialised countries hold 97 per cent of all patents and global corporations hold 90 per cent of all technology and product patents.[361] With their economies of scale and IPR leverage, the fear is that trans-national companies will rapidly take control of the seed industry once IPR rules are set in place. In Kenya, for example, where PVP has been enforced since 1994, 90 per cent of the commercial vegetable seeds are imported from the EU, USA, and Asia.[362] Similarly, over 90 per cent of all PVP applications in Kenya are from breeders that reside outside the country. Even in South Africa, where the domestic seed industry is stronger, the figure is still around 60 per cent.[363]

Africa has a very rich biodiversity. This diversity has been carefully produced, conserved, and analysed over generations by Africa's different ethnic groups. Today, this knowledge and biodiversity is worth billions of dollars to the global seed and pharmaceutical industries, and they are eager to secure monopoly rights over them. With PVP and patents, the seed industry can take farmers' varieties, tamper with them slightly, repackage them in the North, and then demand that farmers pay royalties in order to access them. According to Kamboua,[364] 'by its very essence, patent rights are monopoly rights that are given to individuals and these individuals are from the developed world . . .

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[358] G.T. Castillo, 'Science in the "Eloquence of Everyday Life"', National Academy of Science and Technology (December 2001 issue).
[359] Chundu, Hurungwe District, Mashonaland West Province, Zimbabwe.
[360] Op cit note 352 at 7.
[361] Human Development Report 2000, Human Rights and Human Development, UNDP, New York, 2000, at 84.
[362] J. Shah, 'The Seed Industry in Kenya: An Overview', Presented to the Preparatory Meeting for the Establishment of an African Seed Trade Association, Lillongwe, Malawi, 8 – 10 April, 1999.
[363] J.W. Van der Walt, 'A Review of the South African Seed Industry', prepared for the FIS/ASSINSEL 2001 World Seed Congress.
[364] Namibia's Deputy Director of the Registrar of Companies, Patents, Trade Marks and Designs.

As such, our indigenous biodiversity is then surrendered by way of patent rights to people that are living in other countries.'[365]

It is essential to note that patents are, or should be, granted subject to the public interest.[366] Therefore, before African countries accept, and agree to implement, monopoly rights over plant varieties, they must ensure that the subject matter is deserving of protection and will, in fact, benefit African people. PVP and patents restrict the right of farmers to share, use and save seed from their harvests by extending the breeder's monopoly to the harvest of the farmer's crop.[367] Essentially, PVP and patents violate the spirit of farmers' rights and set a precedent for their elimination. Farmers' rights embody the rights of farmers to conserve, develop, use, control, and benefit from not only local biodiversity but also rural peoples' knowledge systems and technologies.[368] These rights, which cannot be protected by IPRs, form the basis of sustainable agriculture in Africa. Moreover, these rights are directly threatened by the imposition of IPRs in African agriculture.

In Africa, policy-makers are faced with two opposing models of agricultural R&D to choose to support. One is driven by TNCs, mainly in the north and relies upon private monopolies and genetically modified crops. The other is led by farmers, with support from the public sector, and is based on the collective use of knowledge and resources for sustainable agriculture.[369] Africa's small farmers and the seed industry have completely different needs when it comes to supporting their innovation, and IPRs are only designed for one of them. If African governments adopt IPR regimes on agricultural biodiversity, they are choosing to support a corporate model of plant breeding and, subsequently, a reorganisation of agriculture tailored to the interests of multinational seed companies. These seed companies also happen to be the world's largest pesticide and biotechnology

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[365] See L. Machipisa, 'Southern Africa for Renegotiation of UPOV 1991', available at World Wide Web, http://www.twnside.org.sg/title/reneg-cn.htm

[366] Intellectual property law tries to strike a balance between the rights of the creator or owner of an idea expressed in a material form and society in general. The rationale of intellectual property protection is to encourage people to develop ideas that will benefit society by providing them with legal protection for a limited period of time. Protection is limited in duration in order to ensure that society's interests are served. That is, after a period of time, the work becomes part of the public domain. A patent grants a monopoly in the exploitation of a new invention to the discoverer of the invention for a limited period of time in return for a full disclosure of how the patent works. The theory is that the patent seeks to reward the discoverer of a new technology to assist in the development of society and the advancement of technology. While such monopoly protection obviously restricts the dissemination of knowledge, it is supposed to be counterbalanced by the incentive that it provides to innovate. One could say that society 'buys' the invention from the inventor, the price being a monopoly for a limited period.

[367] The issue of denying farmers the right to save and replant seed is considered below in Chapter 6.

[368] See I. Wijayanto (Secretariat of Network on Farmers' Rights), & R. Tjahjadi (PAN Indonesia), 'Indonesia Advances on Farmers' Rights', (December 1998).

[369] It is to be noted that, in many developing countries, the same policy and institutional environment applies to both smallholder and commercial farming. This approach is, however, receiving increasing criticism because of the extreme contrast between the dynamic, well-organised and supported commercial farm sector (located in areas with good soil and high rainfall) and smallholder farming areas. Various authors argue that existing policies are conducive to the former form of production and are not necessarily supportive of the latter. See, for example, C.T. Khombe, P. Tirivanhu, & E. Whingwiri, 'Smallholder Agriculture in Southern Africa', *New Agenda*, Issue 9, First Quarter 2003, 90 – 103.

corporations and they have vested interests in crop uniformity – not the food security of Africa or the well-being of the continent's farmers.

CHAPTER 6

THE RIGHT TO SAVE SEED: THE ETHICS OF A NEW TECHNOLOGY

6.1 The Issues

The issue of preventing farmers from replanting seed, a consequence that flows from both patent and PVP protection of a variety, cannot be ignored. Although countries are theoretically given scope to allow farmers to replant the seed of a patented[370] or PVP[371] protected variety, the concept of preventing farmers from replanting seed is regarded as acceptable. With this in mind, the creation and application of technology that results in seed sterility is not surprising. The construction of this new technology, namely, Variety Gene Use Restriction Technology (V-GURT),[372] is viewed as an extension of an 'accepted' principle and evinces the biotechnology industries' confidence in the global enforcement of preventing the practice of replanting seed. If the issue of preventing farmers from saving seed becomes widely accepted and endorsed uncompromisingly in international law, there will be no grounds for rejecting a technology such as V-GURT technology. It is essential, therefore, that African States stand united in support of farmers' rights to replant seed.

This section will provide a brief analysis of V-GURT technology within an African context. Throughout this section, it is essential that the reader remember that in the industrialised nations very little of farmers' own seed is used, since they are accustomed

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[370] Article 2 of TRIPs states, 'Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or public morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.' Opposition to the patenting of genetically modified organisms on the grounds of morality and ordre public has been expressed by African States on the grounds that releases of GMOs and GE food products may cause ecological damage and be prejudicial to human health or animal welfare. Representatives of many indigenous and traditional societies have condemned monopoly protection of products derived from communally-held resources on the grounds that it is economically exploitive and morally and spiritually repugnant. It seems plausible, than, for patenting life in general to be outlawed on moral or ordre public grounds in countries where such views are especially prevalent. Howver, legal experts tend to assume that TRIPs-compatibility requires governments to apply the exclusion narrowly on a case-by-case basis rather than to broad classes of patents such as life-forms in their broadest sense. Otherwise, such patents would have been specifically outlawed by TRIPs or, at the very least, the option to outlaw them would have been explicitly indicated. Clearly, however, the lack of clarity surrounding Article 27 of TRIPs makes it impossible to predict how the WTOs dispute settlement mechanism will interpret and enforce Article 2.

[371] The position of UPOV on the issue of replanting seeds was considered above in section 2.4.

[372] Variety Gene Use Restriction Technology or 'Terminator Technology', as it has popularly come to be known, alters a fundamental characteristic of seed – its self-reproducing nature. The most important implication of this technology is that farmers cannot save seeds from their crops – they have to purchase new seed from the seed companies at the start of each planting season.

to buying new seed.[373] In the developing countries, on the other hand, the majority of farmers depend on seeds saved from previous harvests to account for their seed needs.[374] Consequently, the factors to be evaluated should be weighted differently. In developing countries the socio-ethical and development policy aspects of the technology play the predominant part in the evaluation.

6.2 Introduction to GURTs

In March 1998 the US Patent Office granted the US patent 5,723,765 on the 'Control of Plant Gene Expression' to Delta and Pine Land Co. and the United States Department of Agriculture (USDA).[375] This patent gives the holders rights for the use of three new gene sequences that block the production of fertile seeds in genetically engineered plants. Shortly after the patent's issuance, RAFI coined the term 'Terminator Technology' to stress one of the likely applications of this technology. In a study conducted by Jefferson[376] for the secretariat of the CBD, the term Genetic Use Restriction Technologies (GURTs) was proposed and is now widely accepted.[377]

Generally, three V-GURT strategies can be identified. The first makes use of induced activation of a disrupter gene. The plant is provided with a disrupter gene that can inhibit embryo formation. This gene is held inactive by a transcriptional blockade. That is, the GURT is dormant until the seed is treated with an inducer chemical. The application of the inducer chemical leads to expression of the disrupter gene in the second-generation seed. As a result, the second-generation seed is sterile.[378] In the second strategy, the breeder/developer applies a chemical in all generations, but stops before selling the seed. Here, a disrupter gene is expressed in the seed by default, resulting in sterile seed. The sterility is prevented by applying the chemical, which provides a restorer protein to safeguard fertility of the seed and reproduction of the variety, when under the control of the developer of the variety.[379] The third strategy concerns crops that produce

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[373] Report of the Swiss Ethics Committee for Non-Human Gene Technology: Ethical Evaluation of 'Terminator' Technology, 6 October 2000, at 9.

[374] As noted, it is estimated that African farmers depend on seeds cultivated within their own communities for as much as 90 per cent of their seed needs. Most of these seed breeders are women, as they produce 70 per cent of the food for use in the region. Op cit note 168. According to M.S Swaminathan, former chair of the United Nations FAOs' Council, notes that, 'over 80 per cent of farmers in India plant their own farm-saved seed.' See M.S. Swaminathan, *Farmers' Rights and Plant Genetic Resources, Biotechnology and Development Monitor*, No. 36, 1998, p6–9. RAFI, 12 May 2000. *Terminator Two Years Later: RAFI Update on Terminator/Traitor Technology*, available at World Wide Web http://www.biotech-info.net/fast_track.html

[375] According to WIPO the patent is pending in more than 78 countries around the world. For example: Australia (AU 9532050), Canada (CA 2196410), the European Patent Office (EP 775212) and South Africa.

[376] R.A. Jefferson, 'CBD Assessment of Genetic Use Restriction Technologies-Expert Paper', (1999).

[377] This paper shall use 'Terminator Technology' and 'GURTs' interchangeably, as is accepted practice.

[378] Put another way, the seeds are fertile, but through the application of a chemical, a dormant 'lethal' gene can be activated. This gene inhibits full seed development. As a consequence, seeds are infertile. For an example of a patent granted for this strategy, see Delta & PineLand/USDA patents, US 5.723.765 and US 5.925.808.

[379] Put another way, a lethal gene is expressed in the seed, resulting in sterility. Breeders can apply a chemical compound that activates another gene to safeguard the fertility of the seed and the reproduction of

vegetatively.[380] Again, a gene blocking growth is expressed by default.[381] However, here, restoration is invoked by the induction of a second gene. Regulation of hormone metabolism and function lies at the basis of this strategy.[382] It is important to note that, although current patent applications apply to plants, GURTs can be built into any organism, including farm animals, fish and forest trees.

A number of technical factors determine for which purposes, on which crops, trees, farm animal and fish breeds, and on which time scale GURTs, will be developed and applied.[383] It is currently not clear in which crop species the application of V-GURTs will be applied and prove feasible. However, GURTs are most likely to be implemented in crops with a high market volume such as wheat, rice, maize, soybeans and cotton.[384] Application of GURT in crop breeding can be expected to precede its applications in the breeding of trees, fish and farm animals, as is reflected in current patent applications.[385] A substantial number of patent applications now describe various GURT concepts and elements. However, due to strong public opposition,[386] corporations have not commercialised V-GURTs, but they still hold patents and are applying for new ones, suggesting that they may still seek to market V-GURT products.

Seldom does an innovation have the potential to alter a product market in such a fundamental way. Given its potential impact, it is understandable that Terminator Technology has attracted a virulent and polemic response from a range of quarters. The independent Panel of Eminent Experts on Ethics in Food and Agriculture, established by the Director-General of the FAO, discussed GURTs in September 2000, and unanimously stated that "'terminator seeds" are generally unethical as it is deemed unacceptable to market seeds whose offspring a farmer cannot use again because the seeds do not

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the variety, but they will stop doing so before selling the seed. For an example of a patent granted for this strategy, see WO9735983/Syngenta and WO 9744465/Monsanto.

[380] For example, root and tuber crops, and ornamentals.

[381] The described method is not only suitable for investment protection, but also for prevention of growth during storage, which is in the interest of growers and consumers.

[382] For an example of a patent granted for this strategy, see WO 9906578/Syngenta.

[383] For an analysis of such technical factors see B. Visser et al, Commission on Genetic Resources for Food and Agriculture, 'Potential Impacts of Genetic Use Restriction Technologies (GURTs) on Agrobiodiversity and Agricultural Production Systems', (2002), Background Study Paper No. 15.

[384] Ibid at 9.

[385] In the writer's search for GURT-related patent applications no applications in the latter domains surfaced. The authors of a study requested by the FAO similarly found no such patent applications. See Visser et al, op cit note 383.

[386] Non-governmental organizations and advocacy groups have strongly opposed such applications, viewing them as a challenge to food security, particularly in developing nations. For example, the world's largest international agricultural research network, CGIAR, banned Terminator Technology from its crop breeding programs; Southeast Asian Regional Institute for Community Education (SEARICE) advised governments to reject V-GURT patent applications; Global Response, an international network for environmental action and education, launched a letter campaign urging the FAO to condemn Terminator Technology, see World Wide Web http://www.globalresponse.org. The Southern African Research and Documentation Centre (SARDC), and the Community Biodiversity Development and Conservation Programme (CBDC), a 15-country consortium of civil society organizations and research institutions devoted to farmer-based plant breeding and community-directed programmes to strengthen the conservation and enhancement of agricultural biodiversity, similarly oppose such patents. The CBDC website can be viewed at http://www.cbdcprogram.org

germinate.'[387] In the same year, the COP to the CBD recommended that, in the current absence of reliable data on GURTs, without which there was an inadequate basis on which to assess potential risks, '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, authorised 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.'[388] Criticism also came from governments. Panama, India, Ghana and Uganda have all announced their intention to oppose 'Terminator Technology'. The government of the United Kingdom, through the Department for International Development, stated that they have given an undertaking 'not to develop, test or use breeding material which incorporates genetic systems designed to prevent seed germination.'[389] Many Southern governments called for tougher action. The Africa Group called on all Parties 'immediately [to] ban the "Terminator Technology" from respective national territories and thus, from the whole of Africa, as intolerable politically, economically and ethically and in terms of safety of plant life, and in the future, be constantly on the look out for unacceptable products of biotechnology.'[390] Action Group on Erosion, Technology and Concentration (ETC), together with hundreds of civil society, farmers' and indigenous peoples' organizations worldwide, has campaigned for a global ban on V-GURT technology.[391] In January of 2003, the Union for the Protection of New Varieties of Plants' expert panel concluded that Terminator Technology 'may have considerable disadvantages for society.'[392]

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[387] It is to be noted that the eminent experts did not, however, furnish reasons for this statement. Op cit note 65, para 5, at 14.

[388] UNEP/CBD/COP/5/23 – Decision V/5, page 88, paras. 20, 21 and 23, available on the CBD webpage at http://www.biodiv.org/decisions/

[389] Department for International Development, 'Genetically Modified Organisms and Developing Countries', (May 1999), DFID Background Briefing.

[390] RAFI News Release, 'COP5 Cops Out', (20 June 2000), available at world Wide Web http://www.biodiv.org/Decisions/COP5/html/COP-5-Dec-05-e.htm

[391] For ongoing initiatives, see World Wide Web http://www.etcgroup.org

[392] UPOV, 'Memorandum Prepared by the Office of UPOV on the Genetic Use Restriction Technologies,' January 10, 2003, at 3. The paper in question, a memorandum prepared by UPOVs Secretariat at the request of member governments of the UN CBD, was presented to an Expert Panel convened by the CBD in Montreal, February 19-21. The memorandum provides a six-page assessment of the drawbacks of Terminator in comparison to PBRs. The US government strongly criticized the memorandum and exerted tremendous pressure on UPOV to remove all critical comments and analysis of the technology. The US succeeded. UPOV bowed to US pressure and replaced the original memorandum with a sanitized and shorter 'Position Paper' that embodies none of the criticisms detailed in the original report. See UPOV, 'Position of the International Union for the Protection of New Varieties of Plants Concerning Decision VI/5 of the Conference of Parties to the Convention on Biological Diversity (CBD),' April 11, 2003, available at World Wide Web http://www.upov.int/en/about/pdf/gurts_11april2003.pdf. According to the UPOV Secretariat, Mr. Makoto Tabata, it was only the US government that raised concerns about the January 10 Memorandum on GURTs. See ETC Group, 'US Government Forces UPOV to Abandon Terminator Critique', 17 April 2003, available at World Wide Web http://www.etcgroup.org. The original UPOV memorandum and the correspondence between UPOV and the US government can be viewed at World Wide Web http://www.etcgroup.org/documents/USAvsUPOV.pdf.

6.3 Analysis of V-GURT Technology

V-GURTs enhance appropriation of the benefits from innovations in seed development. In the first instance, there is no reason to believe that enhanced appropriation is harmful to the interests of farmers. This is because the direct effect of this technique will correspond only to the appropriation of the increased value of the innovations contained within the GURT seed. These technologies merely add an option that did not previously exist. Farmers will continue to have the ability to purchase normally reproducing seed, only it will be without the innovations contained within the GURT seed. The availability of this seed will constrain the price at which GURT seed can be marketed, and it will mean that it will only be the added value of the innovation it contains that will cause it to be valued more highly. Therefore, at first sight, there is no reason to believe that farmers could be made worse off through the introduction of these technologies. However, there are significant indirect effects that may result from the introduction of these technologies. This section will attempt to identify such effects, focusing primarily on the potential economic, social and security impacts of the technology.

Before commencing with the analysis, it is essential to note that the argument that V-GURTs merely add an additional product to the market and therefore are not harmful to the interests of farmers' only holds true if normally reproducing seed remains accessible to farmers and farmers continue to have the choice of purchasing and utilising such seed. Here, V-GURTs need not render normally reproducing seed completely inaccessible in order to constitute a negative consequence. A significant reduction in ease of accessibility suffices. Throughout the following examination, the claim that V-GURTs merely introduce an additional product to the market will be evaluated and the potential for V-GURTs to take away existing traditional farming and cultural practices, biological diversity, social and human rights, and economic independence explored.

6.3.1 Effects on R&D

The effect that the introduction of V-GURTs might have on the entire system of R&D currently existing within agriculture is considered because of the potential of V-GURTs to make a tremendous difference in the rate of diffusion of innovations in developing countries. Farmers tend to utilise all genetic resources available to them for local crop development. Although materials that are derived from formal plant breeding rarely perform as well as traditional varieties, they serve to introduce important new genes such as disease resistant alleles.[393] In the past, innovations in plant varieties have diffused into general use within agriculture over time, even if released as protected varieties, because of the capacity to undertake breeding activities making use of them.[394] V-GURTs, on the

[393] For more information on farmers combining varieties and breeds accessed from formal plant breeding initiatives with their traditional varieties, see J. Hardon, J. Engels, & B. Visser, 'Towards Integration of Policy Frameworks', in *Encouraging Diversity. The Conservation and Development of Plant Genetic Resources*, C. Almekinders & W. de Boef, (2000), Intermediate Technology Publications Ltd., London, 317 – 322.

[394] Publicly funded institutions have in fact placed substantial efforts into ensuring that innovations are diffused across the developing countries. For example, the Consultative Group for International Agricultural Research (CG System).

other hand, capture the value of the innovative characteristics by maintaining control over the plant variety in which they are embedded. As succinctly put by Swanson and Goschl,[395] the 'distinction between the "innovative characteristics" and the "plant variety templates" (on which they are embedded) are categorized as the "software" and the "hardware" components of modern plant breeding activities.' In the past, it was possible for much of the software, developed by private breeders, to diffuse expediently and inexpensively across the developing world via its amalgamation into different hardware. V-GURT varieties, however, cannot be incorporated into traditional varieties. In consequence, the widespread adoption of V-GURTs could terminate a vital source of new genes from formal plant breeding innovations for local crop development.

The development of new varieties in the future may require access to a number of biotechnological processes all patented by different companies.[396] Such development could be negatively affected if the processes of developing useful agronomic traits are licensed from breeders and then bundled with V-GURT technology. For example, the International Centre for the Improvement of Maize and Wheat (CIMMYT) has developed apomictic[397] varieties of maize. If biotechnology companies license the process for producing apomictic varieties from CIMMYT on an exclusive basis and bundle these varieties with V-GURT technology, then, effectively, others will not be able to use apomixes technology. The ability of universities and public sector institutions to license processes often depends on their having a portfolio for cross licensing. Without the ability to cross-license, their 'freedom to operate' would be severely restricted. If the public sector loses its freedom to operate, its ability to generate competitive pressure – so necessary for innovation – will be lost. According to Thirtle,[398] 'unless an efficient system is developed for licensing the component biotechnological processes, there could be a gridlock in the development of new varieties.' IPRs over V-GURT varieties have the potential to stifle, rather than promote, the development of new varieties.[399]

Essentially, with V-GURTs it is entirely within the discretion of the innovator to diffuse its innovation to the rest of the world.[400] It is therefore possible, through the utilisation of

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[395] T. Swanson, & T. Goschl, 'Genetic Use Restriction Technologies (GURTs): Impacts on Developing Countries', *International Journal of Biotechnology*, Vol. 2, Nos. 1/2/3, 2000.

[396] As noted above, it is the patenting of the associated processes of genetic engineering that ensure that companies are able to retain exclusive use of the desirable agronomic traits.

[397] An apomictic variety undergoes reproduction without fertilization.

[398] Op cit note 78, at 183.

[399] Already many International Agricultural Research Centres such as CIMMYT are finding that they cannot work on biotechnology based varietal improvement without licenses for component processes from seed companies.

[400] At this point, the utilisation of compulsory licensing may be mentioned as a possible solution. It is compatible with the TRIPs Agreement (Article 31) for such reasons as the protection of public health and nutrition; promotion of the public interest in sectors of vital importance to socio-economic and technological development, including protection of farmers' rights. A compulsory license over a non-V-GURT variety would allow a developing country to immediately diffuse the variety into subsistence farming. However, a compulsory license over a V-GURT variety would not have the same effect. The innovative characteristics contained within the V-GURT variety would have to be identified and the variety engineered from scratch. For countries without a well-developed biotechnology sector, compulsory licensing over V-GURTs is not a realistic option. More importantly, however, developing countries have, in the past, been reluctant to resort to compulsory licensing for fear of trade sanctions.

IPRs and V-GURT technology, for the rate and extent of diffusion of future innovations in agriculture to occur only under the exclusive control of the developer of the innovation. V-GURTs therefore potentially provide for the elimination of a currently diverse R&D sector.[401] The obvious corollary to the loss of diverse involvement in agricultural R&D is its increasing concentration in a small number of biotechnology firms.

The problem with wholly vesting agricultural R&D within the private sector is that, after a sufficient number of innovations and time have passed, alternative suppliers of plant varieties may be rendered obsolete.[402] The private sector may be able to eliminate the public sector from all breeding activities on account of the need for licenses. The effect of this on countries that are highly dependent on public investment for their plant breeding needs is potentially enormous. The loss of public sector involvement would eliminate the public capacity to direct agricultural R&D towards the crops and pests indigenous to developing countries. Agricultural R&D would then be directed towards those crops and pests dictated by commercial concerns. Another problem that might arise is the lack of incentives for the private sector to diffuse its product widely. Innovations might only be targeted at viable markets and general diffusion disallowed in order to protect those markets. Further, the loss of public sector involvement would eliminate the public capacity to determine the fundamental objectives of agricultural R&D. The future direction of agricultural research would be determined solely by profit-based incentives and market opportunities. There are good reasons for being cautious about exclusive reliance on market-based incentives for giving priority to sustainability and food security.

In a study conducted by Swanson and Goschl, the extent to which innovation will be hindered in developing countries was explored. According to the authors, the impact of GURTs on developing countries depends on a number of factors.[403] In short, for biotechnology capable countries, the impacts of GURTs on R&D are primarily positive because these countries will be able to 'reverse engineer' GURT varieties.[404] For countries that do not possess biotechnology capabilities and receive little investment from

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[401] Comprising of farmers, the public sector, and the private sector.

[402] According to Swanson and Goschl, this would be the case if the alternative suppliers could only acquire the characteristics at high prices, and were thus only capable of supplying substitute varieties. As a result, the farmer might face a small number of suppliers of viable seed and, as a consequence, greatly increased prices for GURT seed varieties. It would then be open to the original developers of GURTs to refuse to license innovations at reasonable prices to potential competitors. Op cit note 395.

[403] Namely, the capability of the developing country to undertake its own biotechnology, the extent to which the developing country has an investment in crops that are amenable to GURTs, and the extent to which the biotechnology capable countries will include the particular developing country into their research strategies.

[404] That is, they will be able to use their biotechnology to relocate the innovative characteristic. For these countries, GURTs merely provide a short-term advantage to the developers of the innovation, possibly of only two to three years. What this assertion fails to take into account is the fact that reverse engineering and the creation of 'generics' is prohibited by the TRIPs agreement. Countries failing to comply with TRIPs standards could be subject to trade retaliation if the dispute settlement mechanism of the WTO has determined the existence of a case of non-compliance with the TRIPs Agreement.

biotechnology capable countries, however, the effects are likely to be negative.[405] These countries rely heavily on the public sector for R&D diffusion and the study notes that there is good reason to be concerned that the rate of diffusion in these countries will slow with GURTs as the flow of plant materials and the level of public funding is restricted.

6.3.2 Economic Impacts

The potential economic impacts of V-GURT varieties is very difficult, if not impossible, to consider in any detail.[406] This is because V-GURT varieties have not been released onto the market and, consequently, data concerning economic impacts are not available. As a result, any analysis must rely on forecasting potential impacts, which again, is difficult in light of the countless variables upon which such impacts are dependent. Having said this, various factors that may influence the economic impact of V-GURT varieties are raised below. Before considering such factors, it is useful to have regard to the economic impact of GE crops in general, as it may provide some indication of what to expect from V-GURT technology. This is because V-GURT technology offers no agronomic benefits in and of itself. It is merely coupled with other innovative modifications. Since there is data concerning the impact of such other modifications, such data is briefly considered below.

The United Kingdom's leading agricultural journal, Farmers Weekly, recently published an article[407] based on a study produced by the US National Centre for Food and Agricultural Policy (NCFAP) claiming the positive economic performance of genetically engineered crops. In the same month, the Economic Research Service (ERS) of the USDA released its extensive analysis of the economic performance of GM crops in the United States of America.[408] The two reports come to startlingly different conclusions. The former hails GM economic success, whereas the latter concludes that 'perhaps the biggest issue raised by these results is how to explain the rapid adoption of GE crops when farm financial impacts appear to be mixed or even negative.'[409] Perhaps insight into these conflicting results can be gleaned by considering who funded the studies. The NCFAP's study was part funded by Monsanto and The Biotechnology Industry Organization (BIO), whereas the ERS study was funded by the USDA.

Research conducted by independent analysts and Universities generally concludes that the uptake of GE crops has a neutral economic impact. For example, a study conducted

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[405] Of the 98 developing countries included in Swanson and Goschl's study, 40 countries fell into this category. Namely, Afghanistan, Bangladesh, Benin, Bhutan, Burkina Faso, Cambodia, Chad, Costa Rica, Ecuador, Eritrea, Ethiopia, Guinea, Guinea-Bissau, Guyana, Haiti, Iraq, Ivory Coast, Kuwait, Lebanon, Lesotho, Madagascar, Malawi, Mali, Mongolia, Morocco, Mozambique, Myanmar, Nepal, Nigeria, Pakistan, Peru, Qatar, Sierra Leone, Sri Lanka, Swaziland, Syrian, Tanzania, Tunisia, Venezuela, and Yemen.

[406] All that can be definitively stated is that because V-GURTs ensure that no seed is saved, biotechnology company profits will increase.

[407] 'Data Shows Economic Success for Genetically Engineered Crops', 12 July 2002, *Farmers Weekly.*

[408] J. Fernandez-Cornejo, & W.D. McBride, et al, 'The Adoption of Bioengineered Crops' (2002), Economic Research Service United States Department of Agriculture.

[409] Ibid at para 1 of 'Interpretation of Results', at 30.

by Duffy,[410] involving a detailed analysis of on-farm financial performance of soybeans and corn in Iowa, concluded that after taking into account the financial costs of all relevant factors,[411] 'there is essentially no difference in costs between the tolerant and non-tolerant fields. Similar to herbicide-tolerant soybeans, Bt corn produced a return essentially equal to the non-Bt corn'.[412] Further, 'the primary beneficiaries of the first generation biotechnology products are most likely the seed companies that created the products'.[413] Studies funded wholly or partly by biotechnology companies, on the other hand, generally conclude that the uptake of GE crops increases financial returns.

If GE crops are not increasing financial return it has to be questioned why farmers are adopting them. The answer seems to be that farmers are receiving benefits from GE crops, albeit non-pecuniary benefits. That is, benefits appear to be more related to greater ease of production and the ability to cover more acres as opposed to an increase in the profits per acre. For example, a farmer may reason as follows: on the one hand, X GE crop seed costs more and yields less, but fields can be practically weed-free, on the other hand, conventional seed of X crop yields better and is less expensive, but weed control is more complex and perhaps more time-consuming. The ease of harvest is an overriding consideration for many producers. The ability to harvest more efficiently and expediently makes farmers more willing to adopt a new technology even if it does not produce clearly superior returns. Here, a primary motivation may be the simplicity and flexibility of the herbicide-tolerant programme,[414] which allows growers to use one product instead of several herbicides to control a wide range of weeds, and makes the harvest easier. The potential of GE crops to reduce management time in supervising production may be a significant factor taken into account by farmers choosing between alternative production systems.[415] There are a multitude of factors that may influence farmers' decisions to adopt GE over non-GE crops, some rational, some perceived. As noted above, for example, GM crop uptake can be driven as much, if not more, by how well farmers believe the crops deliver as by factual data on their real performance.

As canvassed above, the question as to whether GMOs require less agrochemical inputs – thereby decreasing farmer costs – remains unsettled. It is, however, essential to remember that V-GURT technology alone does not affect the use of input traits. An economic analysis of V-GURT technology will therefore focus predominantly on the impact of the

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[410] Associate Director for Iowa State University's (ISU) Leopold Center for Sustainable Agriculture, Professor-in-Charge of the ISU Beginning Farmer Center, and ISU Extension Economist.

[411] For example, seed, herbicides, fertilizer, machinery operations, insurance, and land charge.

[412] M. Duffy, 'Who Benefits from Biotechnology?', (2001), Paper Presented at The American Seed Trade Association Meeting, Chicago, IL, Dec 5-7, 2001, at 8 and 14.

[413] Ibid at 15.

[414] L.P. Gianessi, & J.E. Carpenter, 'Agricultural Biotechnology: Insect Control Benefits', (July 1999), National Center for Food and Agricultural Policy, Washington, DC, available at World Wide Web http://www.bio.org/food&ag/nctap.htm

[415] However, the extent to which the simplicity and flexibility of pest control programmes effect production management time is difficult to measure and quantify from survey data. The ERS/USDA study, in fact considered this, but noted that, '...a meaningful measure of management time dedicated to a particular technology and crop could not be obtained from the data.' Op cit note 408, para 4 of 'Interpretation of Results', at 30.

loss of farmers' privilege and the resulting increase of sales for the biotechnology companies.

The loss of farmers' privilege primarily affects small farmers in developing countries. Repeated cropping of seed from the harvest is of great significance to these farmers. Saving the best grains, roots or tubers from consumption, small-scale farmers' practice of storage and planting developed over centuries into structured local seed systems. Such systems, which are directly linked to the adaptation of the farmers to their agro-ecological and cultural environment are the main agricultural resource for resource-poor small scale farmers in developing countries. As noted, one estimate states that African farmers depend on seeds cultivated within their own communities for as much as 90 per cent of their seed needs.[416] Given the vast number of people that rely on the practice of saving seed for their food needs, the consequences that would flow from preventing this practice are devastating.

For subsistence farmers, the most important source of seed is the farmer's saved seed. This is because the farmer does not have to pay for it, nor does he have to travel to obtain it.[417] If subsistence farmers adopt V-GURT crop varieties, they will not only have to pay for seed that they previously procured themselves, but they will have to pay increased prices for the innovative modifications that the seed contains. Further, such subsistence farmers will also be obliged to purchase the attendant input traits in order for the innovative characteristics to be activated.[418] The vast majority of subsistence farmers simply cannot afford to do this. Another factor that needs to be taken into account is the ease with which subsistence farmers can access seed. In many developing countries, transport infrastructure between the rural and urban areas is poorly developed. As a result, transport is scarce (and in some cases entirely absent) and costly.[419] This will, of

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[416] Op cit note 168.

[417] Additionally, the farmer knows the cultivar he is planting and, in most cases, has confidence in its proven performance.

[418] In light of the fact that traditional farming practices do not generally involve the use of chemical inputs, the adoption of varieties that require input traits will result in the acquisition of an additional weighty expense that subsistence farmers did not previously incur.

[419] In Zambia, for example, many of the feeder roads, linking rural and urban areas are impassable in the rainy season (November to March) and only slightly improved during the dry season. Zambia is a landlocked country consisting of 9 Provinces, each with a Provincial capital that is linked by a main trunk road to Lusaka, the country's capital city. The main trunk roads basically extend from the south to the north (Livingstone to Chililabombwe), the east to the west (Chipata to Mongu) the center to the north-east (Kapiri Mposhi to Nakonde) and spur routes to the North-Western and Luapula Provinces. The trunk roads are maintained by the Department of Roads who fall under the Ministry of Works & Supply. All city and town roads are the responsibility of the city or district councils who fall under the Ministry of Local Government and Housing. In addition to these two categories of roads, are so-called Feeder Roads, which are the vast majority of roads and constitute gravel or dirt roads. There has been a concerted effort to upgrade the main trunk roads with various donor supports being forthcoming in this sector. Unfortunately, the same cannot be said for the feeder roads. Although there has been a certain amount of feeder road rehabilitation the extent of the damage over many years requires a massive injection of funds that are fundamentally not available. A journey from Lusaka to Chifunda in the Eastern province would be something like the following: travel east from Lusaka to the Luangwa Bridge (240km) on a new bituminous road; from the Luangwa bridge to Chipata (Eastern Province Provincial capital) on an old tar road with certain sectors between some of the towns badly potholed. The trunk road between Chipata to

necessity, increase the economic hardship of many subsistence farmers living in the rural areas of developing countries.

If developing countries introduce V-GURT technology, several elements of their regulatory frameworks will require substantial revision and modification.[420] This will of necessity require financial input. There is concern that the existing regulatory framework in developing countries may be simply not adequate to deal with V-GURT technology.[421] For example, quarantine or customs officials may not have the capability to distinguish between V-GURT and non-V-GURT varieties.[422] Ensuring such capability will require both extensive training and access to relevant equipment. Numerous trained personnel and the requisite equipment will have to be stationed at all points of entry into the particular developing country.[423] Wherever the regulatory framework is weak, developing countries will have to deal with the possibility of surreptitious introduction, through informal channels, of V-GURT varieties. If V-GURTs are introduced into developing countries, via formal or informal means, and the technology is not explained to farmers, they may attempt to plant the seeds and lose a whole year's crop production.[424]

If farmers are to be empowered to make choices regarding the adoption or rejection of V-GURT varieties, they must essentially possess the requisite knowledge regarding the effects of such varieties. Financial concerns will, in all probability, play the dominant role in such decisions. It is fundamental therefore that subsistence farmers are informed of such factors as the resulting seeds' sterility, the cost of the particular herbicides and pesticides required for each crop, the locations at which such chemical inputs will be available, the amount of chemicals to apply and the fact that, if they do not apply the attendant chemical inputs, the possibility of crop failure increases dramatically. Generally, there is an overall lack of information on GM crops in many developing countries. In Zambia, for example, the extension services and education system lack the

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Lundazi is in a dreadful state and government is looking at rehabilitating this trunk road. This sector is much worse in the rainy season. From Lundazi you would travel slowly on a feeder road to Kazembe, which is basically only navigable in the dry season. At Kazembe the Lumezi river (a dry river bed in the dry season) will halt any vehicular traffic from around December until May (depending on the rainy season). North and South of Kazembe would be on foot or by bicycle. Throughout the country, the majority of the culverts over the dry river beds (in the dry season) are in a state of disrepair so that these streams become impassable at one time or another during the rainy season (again depending on the severity of the rains), while some become impassable from the outset of the rains. For those who do not own a vehicle, a sizeable proportion of the journey from the rural to the urban areas will have to be done on foot. The result of the poor feeder road system impacts on every aspect of life in the rural area from agricultural inputs to marketing their harvest, education, health as well as accessing basic commodities.

[420] For example, quality control legislation, varietal release and notification procedures, intellectual property rights legislation, policies on export and import of seed, quarantine regulations, approval procedures and marketing regulations for agro-chemicals, and policy governing foreign direct investment in the seed industry.

[421] DFID, 'Costs and Benefits to the Livelihoods of the Rural and Urban Poor Arising from the Application of So Called "Terminator Genes" and Similar Technologies in Developing Countries', A Report to the UK Department for International Development Under Contract CNTR 99 8215, 1999, at 186.

[422] Clearly, such capacity is essential where a country decides not to permit V-GURT varieties.

[423] The lack of developing countries capacity to train persons in biotechnology makes it necessary for such persons to be trained outside the country, which will, of necessity, require increased financial output.

[424] Even where the technology is explained to farmers, mistakes may still be made.

capacity and trained personnel to inform farmers about GM crops. There are no university courses in biotechnology and journalists have scant access to reliable information. In a study conducted by Panos to raise public awareness of GMOs in Zambia it was found that 'small-scale farmers had very low levels of awareness about GMOs.'[425] The study also noted that 'the majority of small-scale farmers had not heard of biotechnology.'[426] Many farmers likened the situation to the period when hybrid maize seeds were introduced into Zambia, where inadequate information prevented them from making informed decisions. Although the high yielding capacity of maize hybrids was highlighted as desirable, farmers noted that these varieties had proved a disaster to food security in the country because of the need to purchase input traits, which they could not afford to do. Another conceivable risk arises in the case of food aid consisting of V-GURT containing seed that is distributed to disaster-struck communities, since relief food supplies are often used as seed. The farmer who plants such seed will not be aware of the consequences.

Subsistence farmers may experience further economic hardship if the V-GURT varieties do not perform. Subsistence farming embodies complexity and diversity, while genetic engineering is based on simplicity and uniformity. As noted, genetically uniform crops expose farming communities to a greater risk of crop failure because if one strain of crop fails, the whole crop is likely to fail. Another consequence of genetic uniformity is the resulting organism's ill suitability to varying environmental conditions. For example, South African biodiversity is very different to that occurring in America. The organisms[427] associated with particular plants as well as the relationship between organisms and the prevailing climatic conditions are accordingly highly specific. As a result, uniform varieties may not perform as well in the vastly varied environments of all countries.

6.3.3 Security Impacts

One of the most serious concerns surrounding V-GURTs is the degree to which their introduction will affect the dependence of developing countries on biotechnology companies. Every dependence reduces individual freedom of choice. The freedom and

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[425] The study consisted of focus group discussions with both small-scale and large-scale farmers in three districts of Zambia, namely, Kabwe, Monze and Mukushi. Notably, these areas were chosen because the researchers possessed limited resources and were more readily accessible. The common problems mentioned by the small-scale farmers were disease, weeds, lack of market, low yields, lack of storage facilities, limited access to land, expensive inputs, limited credit facilities, low prices for agriculture produce, expensive labour, lack of government support, lack of extension support, drought, too much rain (in some cases), thefts and dilapidated road infrastructure. Small-scale farmers said some of the problems did not have solutions because farmers did not have the capacity to buy inputs such as drugs or pesticides. A section of small-scale farmers felt that part of the solution was to revert to cultivating traditional seeds which were resistant to some of the pests. In addition, traditional seeds did not require a lot of artificial fertilisers. Some small-scale farmers resorted to using agro-chemicals in amounts less than recommended by the manufacturers. Panos Southern Africa and the Zambia National Farmers' Union 2001, 'Survey of Zambian farmers' attitudes to Genetically Modified Organisms', (2001), available at World Wide Web http://www.panos.org.uk/environment/gm_food_aid_survey_of_zambian_farmers.htm

[426] Despite such lack of knowledge, such farmers expressed the fear that GMOs would be imposed on them.

[427] That is, insects, micro-organisms and animals.

self-determination of the individual are not limited by V-GURTs as such, but only through a possible increase in monopolisation. The increased trend towards monopolisation in the seed market may result in making not just individual farmers but whole countries dependent on a type of seed and the corresponding chemicals. Here, the hypothetical control of the seed of a whole country through refusing to grant a license also arises.

There is already a general trend towards monopolisation in the seed industry. As detailed in Table 1 below, the six leading biotechnology companies collectively own 70 per cent of all patents granted over the four staple food crops, namely, wheat, rice, maize, and soybeans.[428] The numbers of patents held by the six companies are, however, not equally distributed. Du Pont owns the overwhelming majority, namely, 66 per cent of patents granted to the six companies. Monsanto and Syngenta follow with 11.2 per cent each, and Mitsui,[429] Aventis,[430] and Dow[431] hold the remaining 12 per cent. Tables 2, 3, 4 and 5 detail the global percentage of patents granted over wheat, rice, maize and soybeans respectively.

TABLE 1: PATENTS HELD BY THE SIX LEADING BIOTECHNOLOGY COMPANIES OVER THE FOUR PRINCIPAL FOOD CROPS

COMPANY	WHEAT		RICE		MAIZE		SOYBEAN	
	Number of patents held	Percentage of total granted to six companies	Number of patents held	Percentage of total granted to six companies	Number of patents held	Percentage of total granted to six companies	Number of patents held	Percentage of total granted to six companies
DU PONT	91	76.5%	89	58.6%	105	53.6%	125	78.6%
MONSANTO	8	6.7%	14	9.2%	28	14.3%	20	12.6%
MITSUI	15	12.6%	28	18.4%	0	0%	4	2.5%
SYNGENTA	5	4.2%	11	7.2%	44	22.4%	10	6.3%
AVENTIS	0	0%	8	5.2%	9	4.6%	0	0%
DOW	0	0%	2	1.3%	10	5.1%	0	0%
TOTAL HELD BY COMPANIES	119	-	152	-	196	-	159	-
TOTAL PATENTS GRANTED	168	-	250	-	276	-	209	-
PERCENTAGE HELD BY SIX COMPANIES	-	70.8%	-	60.8%	-	71%	-	76%

[428] Tables 1, 2, 3, 4, and 5 were formulated using information detailed by B. Ayliffe, 'Research for Action Aid on DGENE/GENSEQ database,' in J. Madley, 'Crops and Robbers', (2002), Action Aid, available at http://www.actionaid.org/resources/foodrights/foodrights.shtml

[429] Holding 7.5 per cent.

[430] Holding 2.7 per cent.

[431] Holding 1.9 per cent.

TABLE 2: Global percentage of patents granted over genetically engineered wheat

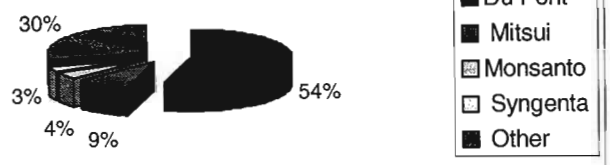


TABLE 3: Global percentage of patents granted over gentically engineered rice

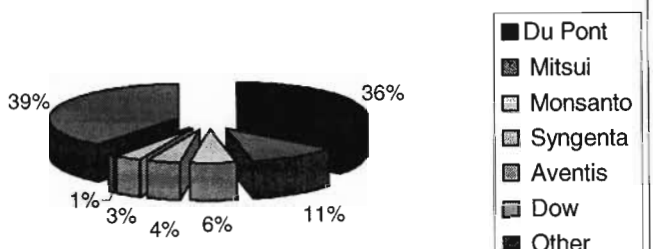


TABLE 4: Global percentage of patents granted over genetically engineered maize

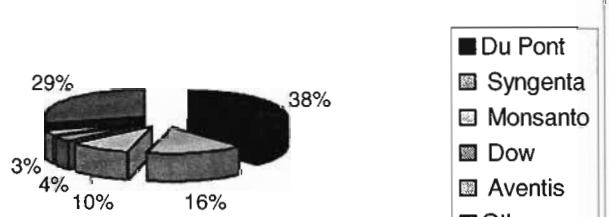
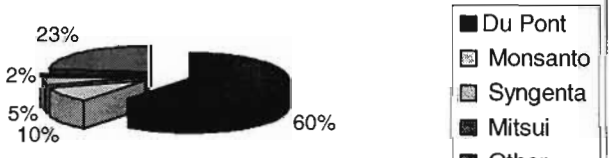


TABLE 5: Global percentage of patents granted over genetically engineered soybeans



Six companies, however, do not constitute a monopoly. Furthermore, the above patent statistics alone are insufficient to lead to a finding of excessive anti-competitive conduct. This is not to say that the current distribution of economic power within the seed industry does not fall foul of the requirements of anti-competition law. The current distribution may indeed be incompatible with such law and one or more of the companies may indeed be guilty of anti-competitive conduct. Such a finding can, however, not come from an analysis of the number of patents held by each company alone.[432] What the above statistics do reveal is that only six companies currently dominate the seed industry. In order to avoid the establishment of a monopoly, these six companies must continue to compete successfully with one another and mergers between such companies must be critically considered by the relevant antitrust and anti-competition institutions before they are authorised.

In light of the large number of mergers that have occurred in the seed industry over the past twenty years, it is fair to state that there is a general trend towards monopolisation in the seed industry. The concern is that biotechnology companies may use their economic leverage to trap farmers in a cycle of economic dependency.[433] In light of the fact that most of the arrangements between seed suppliers and farmers in developing countries will involve extreme inequalities of information and bargaining power,[434] farmers may be forced to enter into agreements that are not in their long-term best interests. According to Swanson,[435] the introduction of V-GURTs into countries without a well-developed biotechnology sector will result in a much higher degree of insecurity arising out of their dependence on foreign firms for an ongoing supply of seeds. According to Visser,[436] 'serious seed security risks can be expected for those already seed insecure farmers who are not able to save their own seed for the next season.' Increased protection of plant varieties facilitates the creation of monopolies. For example, according to a report written for the Association of World Council of Churches-related development organizations in Europe on plant genetic resources and food security, 'the powers given to breeders in the UPOV 1991 mean that monopolies could spread much faster, giving farmers less choice.'[437] Here, it is to be remembered that V-GURTs represent an even more powerful form of protection than offered by the provisions of UPOV 1991.

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[432] In the writer's search, an economic analysis of the six major seed companies, their compliance with anti-competition law, and the possible establishment of a monopoly was not found. Economists lecturing at the University of Natal and the University of Cape Town further informed the writer that such research, to their knowledge, has not been conducted.

[433] For example, farmers may not be able to pay for seeds at the start of a planting season. The seed companies may, in response, be tempted to provide farmers with seeds in exchange for the promise to pay higher prices at the time of harvest – a promise that is often not easily executed. After a few repetitions of this arrangement, farmers could find themselves hopelessly in debt. This example applies only to farmers who intend to sell at least some of their crop and not to subsistence farmers.

[434] For an analysis of the conceptual and practical difficulties presented by situations of this sort, see T.D. Rakoff, 'Contracts of Adhesion: An Essay in Reconstruction,' *Harvard Law review* 96 (1983): 1173.

[435] T. Swanson, 'Costs and Benefits To The Livelihoods Of The Rural And Urban Poor Arising From The Application Of So Called "Terminator Genes" And Similar Technologies, (1999), A Report to the UK Department for International Development, Under Contract CNTR 99 8215.

[436] Op cit note 383, paragraph 4, at 20.

[437] L. Spinney, 'Biotechnology in Crops: Issues for the Developing World', Research Paper for Oxfam GB, (May 1998), available at World Wide Web http://www.oxfam.org.uk/policy/papers.htm

The establishment of a monopoly in the seed industry clearly has the potential to create and perpetuate dependence. However, a further question is to what extent the adoption of V-GURT technology by all biotechnology companies may reduce the ability to choose and thereby create dependence. Selling seed with V-GURT application restricts farmers' freedom and creates dependence only when the product is not available in any other form. Thus, if traditional varieties remain permanently in existence, farmers will retain the ability to choose. However, there is no guarantee that the seeds from traditional varieties will remain in existence indefinitely. Indeed, if V-GURT technology emerges as a truly generic technology capable of implementation in a wide range of crop varieties, there is a strong possibility that it will become the biotechnology industry's vehicle of choice for the protection and delivery of innovations.[438] If all biotechnology companies introduce V-GURT technology, there is a real danger that farmers may no longer have the choice of purchasing normally reproducing seed.[439] At the very least, normally reproducing seed will become harder to access.

Developing countries constitute approximately two thirds of the world's agriculturally productive land area and support about three quarters of its population. Because of the inherent resource limitations, these areas include some of the poorest segments of the world's population who battle for their livelihood from small scale farming systems. Clearly, any conditions that can disrupt small scale farming systems may have devastating long-term implications for household, if not national, and ultimately, international food security.

6.3.4 Social Impacts

The cross-pollination of a V-GURT variety such as maize with traditional maize varieties could render between 5 to 10 per cent of the latter varieties' seed sterile.[440] This would require farmers to save a higher percentage of their seed for replanting. However, the solution of merely saving a higher percentage of seed for replanting is not as straightforward as it appears. Firstly, it assumes that a farmer who grows V-GURT varieties is not accountable for loss suffered by traditional farmers whose varieties have been cross-fertilized by V-GURT varieties. That is, it fails to take account of the fact that rights are being infringed. Secondly, it does not address the social impact that such cross-fertilization could have.

Farmers who grow traditional varieties in close proximity to farmers growing V-GURTs will probably be unaware of the fact that V-GURTs are being grown in nearby fields and, further, will be unaware of the consequences that may ensue should the two varieties cross-pollinate. Should the two varieties cross-pollinate, and a portion of the wild varieties' seed be rendered sterile, the farmer will in all probability not know why this has occurred. He may, in fact, attribute it to a new method that he attempted. The farmer

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[438] Here, the potential of V-GURT technology to prevent R&D in the public sector and promote the establishment of a monopoly must be borne in mind.

[439] That is, farmers may not be able to choose improved agronomic characteristics without also choosing terminator technology.

[440] Op cit note 421 at 14.

would not have expected such outcome and would therefore not have saved additional seed to account for such eventuality. Before the farmer becomes aware of the fact that some of the seed of her traditional variety may be sterile, she may, in accordance with the practice of informal seed distribution, exchange or donate such seed to other persons. If the farmer becomes aware of the nature of V-GURTs his situation is alleviated to the extent that he is now equipped with the knowledge that he must save a larger proportion of the seed for replanting. However, the farmer will not know which seeds are sterile and therefore cannot select only fertile seeds for replanting.[441] Further, the farmer will not be aware of the above statistic, namely, that 5 to 10 per cent of the wild varieties seed may be sterile, and will consequently not know how much additional seed to save. A further factor that must be considered is the potential for on-farm labour and resources to be rendered obsolete. The planting and nurturing of a crop such as maize requires a substantial amount of labour and the application of scarce resources.[442] Yet, 5 to 10 per cent of such labour and resources may be wasted in the event of non-germination. The effect of such labour being incurred unnecessarily is compounded where the farmer is aware that this may be the case at the start of the planting season.

Clearly, the cross-fertilization of traditional varieties by V-GURT containing crops has the potential not only to lead to social unrest, but also to instil and perpetuate a feeling of powerlessness in subsistence farmers. Essentially, the subsistence farmer is not in a position, firstly, to institute legal proceedings and obtain damages for the loss he suffered, and secondly, to ensure that further infringements of his rights do not occur. The subsistence farmer, in this instance, bears the brunt of the new technology and the farmer growing the V-GURT variety is absolved of the obligation to ensure that his variety does not cause subsistence farmers to suffer a loss.

The widespread adoption of V-GURTs may eliminate traditional forms of innovation. The termination of such innovation prevents traditional farmers from improving varieties – which contributes to greater food security. Traditional farmers' active role in farming becomes passive. The opportunity of learning new methods and improving old ones – essentially the opportunity to develop – is not possible with V-GURT varieties. Seeds, and the knowledge associated with them, cannot be passed on within the rich and textured cultural practices of subsistence farmers. Contrary to the philosophy of development, which is adequately captured in the adage 'teach a man to fish', V-GURTs remove the possibility of innovative development and provide, in its place, a system of unsustainable dependence. History tells us that the fundamental driver of economic growth is empowering people to innovate, adapt and diffuse technology. The commercialisation of V-GURT technology, however, does not foster an environment that will unleash human creativity that comes from both traditional and advanced science and technology.

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[441] It is possible, although perhaps not probable, that a farmer may choose to save the very 5 to 10 per cent of infertile seed for replanting.

[442] A hole has to be dug for each seed, a seed placed inside the hole, covered with soil, a bed dug and precious water applied. Many subsistence farmers then burn wood and apply the ash to the seedlings as a fertiliser. As the seedlings start to grow, constant vigilance is required to ensure that the beds remain weed free.

The provisions of intellectual property evolved predominantly out of a western view of knowledge as a commodity owned by an individual, not a community. In the western paradigm, knowledge and technology are regarded as objects and IPRs provide a regulatory framework for establishing ownership and protection of such property. Traditional communities, on the other hand, view knowledge and technology as a fundamental part of life. The material and the abstract are not neatly delineated, and often the knowledge and the natural resource from whence it originated are regarded as one and the same thing.[443] In traditional societies, property is frequently not about ownership, but about custodianship. Knowledge is passed down from generation to generation and becomes an integral part of the communal life of the particular peoples. The thread connecting the original 'owner' of the knowledge is lost in the mists of time rendering individual property concepts futile. V-GURT technology represents the epitome of private property rights. If widely introduced into societies who do not share the western view of knowledge, technology and property, the potential for social conflict may well become a formidable reality.

CHAPTER 7

THE FUTURE

There is a need for fundamental reform of policies and practices at both the international and national levels to achieve sustainable development. The WSSD, held in Johannesburg late in 2002, provided a good opportunity for rethinking such imperatives.

The Commission on Sustainable Development (CSD), acting as the Preparatory Committee (PrepCom) for the WSSD, met for its third session from 25 March to 5 April 2002, at UN headquarters in New York.[444] The purpose of PrepCom III was to consider the *Chairman's Paper*[445] transmitted from PrepCom II, address ways of strengthening

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[443] M. Mankek, & R. Lettington, 'Indigenous Knowledge Rights: Recognizing Alternative World Views', (undated article), available at World Wide Web, http://www.cs.org/publications/CSQ/244.htm

[444] PrepCom I: The CSD held its first session at UN headquarters in New York from 30 April to 2 May 2001. The session adopted decisions on: progress in WSSD preparatory activities at the local, national, regional and international levels, and by Major Groups; modalities of future PrepCom sessions; tentative organization of work during the Summit; provisional rules of procedure; and arrangements for accreditation and participation of Major Groups. PrepCom II: The CSD met for its second session from 28 January to 8 February 2002, at UN headquarters in New York. The session conducted a comprehensive review and assessment of progress achieved in the implementation of Agenda 21, and agreed that the *Chairman's Paper* (A/CONF.199/PC/L.1) would serve as the basis for negotiation at PrepCom III. The PrepCom also adopted its report (E/CN.17/2002/PC.2/L.1), which contains the *Chairman's Summary of the Second Preparatory Session,* the *Chairman's Summary of the Multi-Stakeholder Dialogue Segment,* and the *Proposals for Partnerships/Initiatives to Strengthen the Implementation of Agenda 21.*

[445] The *Chairman's Paper,* at this stage, consisted of nine chapters: Introduction, Poverty Eradication, Changing Unsustainable Patterns of Consumption and Production, Protecting and Managing the Natural Resources Base of Economic and Social Development, Sustainable Development in a Globalizing World, Health and Sustainable Development, Sustainable Development of Small Island Developing States, Sustainable Development Initiatives for Africa, means of Implementation. Delegates submitted amendments to the *Chairman's Paper* and mandated PrepCom Chair Salim to prepare a revised Paper for consideration at PrepCom IV.

institutional frameworks for sustainable development, and to evaluate and define the future role and programme work of the CSD.[446] It was also expected to agree on the text of a document containing the results of the review and assessment as conclusions and recommendations for further action, to be transmitted to PrepCom IV for information. At a minimum, delegates had hoped to produce a broadly agreed upon text. PrepCom III achieved neither objective and thus failed to fulfil its mandate. Notably absent from the *Chairman's Paper* at the conclusion of PrepCom III were recommendations for completion of the mandated review of TRIPs Article 27.3(b), and recognition of the demands from the majority of African countries for the exclusion of genetic resources from patentability.[447] The shortcomings and frustrations at this meeting were attributed to a number of factors, both internal and external to the negotiating process.[448] The general sentiment held by many was that the problems perceived at this session signalled the desperate need to muster high-level political support necessary to ensure Johannesburg's success.[449]

PrepCom IV took place from 24 May to 7 June, at the Bali International Convention Centre in Bali, Indonesia. It started three days earlier than initially scheduled due to the limited outcome of PrepCom III. These days were added for informal consultations and negotiations on the revised *Chairman's Paper.*[450] PrepCom IV had three major goals, agreement on the *Draft Plan for Implementation*, drafting the Political Declaration, and consultations on partnerships.

The negotiations of the *Draft Plan for Implementation* initially took the same direction as during the previous PrepCom in New York. During the first week, the document was

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[446] Delegates discussed the section of the *Chairman's Paper* concerning the 'Protection and Management of the Natural Resource Base of Economic and Social Development' on 28 March. Discussions concerning biodiversity yielded the following proposals: renewed commitment to and implementation of the CBD; multi-stakeholder initiatives for conservation of biodiversity hotspots; implementation of the Convention on International Trade in Endangered Species (CITES); impacts of invasive alien species; conclusion of WIPO processes on intellectual property, traditional knowledge and genetic materials; and access and benefit sharing.

[447] See 'Draft Plan of Implementation for the World Summit on Sustainable Development', World Wide Web, http://www.ukabc.org/wssd4.htm

[448] Including weak political commitment, gaps in institutional memory, poor organization of the PrepCom's work, and a lack of clarity on how the overall process should have been managed to achieve the PrepCom's goals.

[449] Many felt that logistical constraints and lack of direction provided an opportunity for certain delegations to try to circumvent decisions and principles agreed to in Rio, while pushing for language that would make existing multilateral environmental agreements subservient to WTO rules. However, a handful of delegates with experience from the Rio process felt that it was too early to pass judgment on the fate of the WSSD, arguing that what transpired during PrepCom III is an inevitable stage in any multilateral negotiating process, including the Rio preparatory process. For further discussion see International Institute for Sustainable Development, 'Summary of the Third Session of the Preparatory Committee for The WSSD: 25 March – 5 April 2002', The Earth Negotiations Bulletin, Vol 22, No 29. And Type 2 Outcomes - Partnerships/Initiatives, World Wide Web, http://wssd.info/partnerships.html

[450] It is to be noted that the revised *Chairman's Paper* had different names during PrepCom IV. It was called Plan for Action, the Bali Commitment, and the *Draft Plan for Implementation.* At this stage, it included nine chapters of the initial *Chairman's Paper,* and was extended with one additional chapter: the third PrepCom's discussion paper 'Sustainable Development Governance at the International, Regional and National Levels', which was chapter ten.

negotiated in three working groups.[451] The most contentious issues,[452] including biodiversity, were deferred to contact groups that met throughout the session until 5 June. On June 4, PrepCom Chair Salim established a 'Friends of the Chair' group in order to bridge remaining gaps, but even after the high-level ministerial segment, only 71 per cent of the text was agreed, leaving 27 per cent open for Johannesburg.[453] Most of these 27 per cent contentious issues concerned means of implementation[454] and sustainable development governance.[455] Notably, all references to the Precautionary Principle and the principle of Common but Differentiated Responsibilities were bracketed.[456] The final Plan of Implementation, however, made reference to a 'precautionary approach'.[457] In addition, despite the agreement reached in Doha affirming developing countries rights to protect public health and access to medicines, references to such rights in the *Draft Plan* were bracketed,[458] and were deleted altogether from the final Plan of Implementation.

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[451] The consolidated text was considered in Informal Plenary and then taken over by informal-informal ministerial consultations.

[452] Concerning: energy, oceans, biodiversity, finance and trade, good governance, globalization, sustainable development initiatives for Africa, and other regional initiatives.

[453] The United States, European Union and China were satisfied to have reached such agreement. Indonesia was likewise satisfied, but expressed concern about the lack of political will of basically all governments to proceed with higher speed and in a more courageous manner. South Africa also stated satisfaction, noting that Bali left enough substance and flexibility for negotiations in August and September. See M. Berthold, 'The Fourth and Last PrepCom in Bali, Indonesia', (2002), World Wide Web, http://www.worldsummit2002.org/index.htm?http://www.worldsummit2002.org/articles/berthold.htm

[454] Enumerated in Chapter nine of the *Draft Plan for Implementation*, this section contained the following sub-sections: trade and finance, technology transfer, the role of the scientific community, education, capacity building, and information for decision making. The sub-section on trade and finance was the most contentious issue. This sub-section addressed, *inter alia*, issues of debt, implementation of the WTO Doha agreements, and market access, including trade liberalization and elimination of tariffs and subsidies. See P. Doran, et al, 'PrepCom IV – Final Summary ENB 10TH Anniversary 1992 – 2002 Earth Negotiations Bulletin', (2002), The International Institute for Sustainable Development, World Wide Web, http://www.iisd.ca/linkages/download/asc/enb2241e.txt

[455] These were the areas where the United States, Australia, Canada and Japan on the one hand, and China and 130 developing countries on the other hand clashed. China admitted that there were major conceptual differences between these blocks. That until these conceptual misunderstandings were resolved no negotiation of language would be successful. While the United States emphasized the role of national governments and civil society in development, and stressed the need for anti-corruption measures, accountability and further trade liberalization in developing countries, China pointed out the historical responsibility of industrialized countries as former colonial powers, and demanded further assistance without constraints in order to develop adequately. Op cit note 453.

[456] Indicating disagreement over text portions. Bracketing language referring to the principle of Common but Differentiated Responsibilities was supported by the European Union, America, and Japan. Developing countries, on the other hand, questioned whether trade liberalization enhances sustainable development, and demanded a comprehensive environmental assessment on the impacts of GATT and WTO treaties. See Y. Onodera, 'Interim Report from the Bali PrepCom', (2002), World Wide Web, http://www.worldsummit2002.org/index.htm?http://www.worldsummit2002.org/texts/onodera.htm

[457] See for example, Paragraph 103(f) which reads as follows: 'Promote and improve science-based decision-making and reaffirm the precautionary approach as set out in principle 15 of the Rio Declaration on Environment and Development, which states: 'In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation'.'

[458] Paragraph 51 as bracketed read as follows, '[Implement the WTO/TRIPS Agreement as part of the wider national and international action to address public health problems affecting many developing and

Numerous paragraphs in the sub-section on biodiversity conservation were bracketed,[459] including wording proposed by developing countries to ensure fair and equitable benefits derived from biodiversity.[460] However, in the final Plan for Implementation, the following wording was eventually agreed upon: 'negotiate within the framework of the Convention on Biological Diversity, ... an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources.'[461]

The *Draft Plan for Implementation* contains basic contradictions - a direct result of conflicting paradigms being forced into one text.[462] For example, paragraph 18 on globalisation promotes free trade and the Doha agenda. One of the outcomes of Doha was free trade in all environmental goods and services, which includes water. This is in direct conflict with paragraph 4(h) which asks states to promote access by the poor to land, water resources and other agricultural inputs, and promote land tenure modifications that recognize and protect indigenous and common property resource management. If water is a commons, it cannot be commodified. If it is forcibly made a globally traded commodity, it ceases to be a commons.[463] This clash of paradigms is at the heart of the WSSD, its processes, and its documents. It comes as no surprise that, in shifting the process from being people and earth-centred to being corporation and trade-centred, an official directive to the media was issued to remove the term 'Earth' from all references to the Earth Summit at Johannesburg, and only to refer to poverty or development.[464]

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least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria, and other epidemics, while reaffirming that the agreement can and should be Implemented in a manner supportive of WTO members' rights to protect public health and, in particular to promote access to medicines for all, as envisaged in the Declaration on the TRIPS Agreement and Public Health adopted in Doha]'. Op cit note 447. This paragraph was contested by the US in particular, who once again noted the importance of protecting the patent rights of pharmaceutical companies. Op cit note 456.

[459] The five contested issues concerned, a 2005 target to achieve a significant reduction in the current rate of biodiversity loss; benefit sharing from biological diversity by local people, particularly in countries of origin; Mexico's proposal to negotiate the creation of an international regime to effectively promote and safeguard the fair and equitable sharing of benefits from the use of biodiversity and its components; a new proposal to recognize the rights of local and indigenous communities who are holders of, *inter alia*, traditional knowledge; and a new proposal to promote discussions on the relationship between the obligations of the CBD, international trade, TRIPs and the WTO Doha Ministerial, in order to enhance synergy and mutual supportiveness.

[460] Sub-section (o) of the paragraph on Biodiversity Conservation (paragraph 42) as bracketed read as follows, '[negotiate the creation of an international regime to effectively promote and safeguard the fair and equitable sharing of benefits arising from the use of biodiversity and its components;]'.

[461] Paragraph 42(o).

[462] A relevant paradigm is that which inspired the Earth Summit at Rio, Agenda 21 commitments, the CBD and the Convention on Climate Change. Another is that underlying the WTO rules of trade and Trade Liberalization Conditionalities.

[463] See V. Shiva, 'WSSD: World Summit on Sustainable Development or World Summit for Supporting Destruction?', (2002), World Wide Web, http://www.rio10.dk/index.php?a=show&doc_id=807

[464] However, poverty and development cannot be severed from biodiversity, as the vast majority of people depend on land, water and biodiversity for their livelihood. In developing countries environmental movements are a survival imperative for the majority of people whose survival is not ensured by the market economy, but is threatened by its expansion. The disappearance of species, spread of genetic pollution and destruction of water resources are issues which communities at the grassroots level are facing. These are issues where ecology meets economy and the conditions of human survival and development are

Some hope can be gleaned, however, from certain compromises made at the WSSD. For example, negotiation led to resolution of a dispute over the wording of a 'key' paragraph which had, until altered, preferred the WTO over environmental regulations. The revised text states that nations will 'continue to enhance the mutual supportiveness of trade, environment and development.' Omitted was a clause which had added the words 'while ensuring WTO consistency.' [465]

The *Draft Plan for Implementation* contained no recommendations for completion of the mandated review of TRIPs Article 27.3(b). The *Draft Plan* did, however, contain the following broad provision, 'with a view to enhancing synergy and mutual supportiveness, taking into account the decisions under the relevant agreements, promote the discussions, without prejudicing their outcome, with regard to the relationships between the obligations of the [CBD] and of agreements related to international trade and intellectual property rights, as outlined in the Doha Ministerial Declaration'.[466] It is hoped that such recommendation encompasses the mandated review of TRIPs Article 27.3(b). The discussions envisaged in paragraph 42(r) were, however, not entered into during the WSSD as the United States stressed that any calls for a legally binding instrument to promote Biodiversity would have implications on Trade-Related Intellectual Property Rights. Consequently, consideration of such issues are to be left for other fora, such as the WTO. It is essential that the mandated review of TRIPs Article 27.3(b) is undertaken at the next WTO ministerial in Mexico in September 2003.[467] In the review of TRIPs, serious consideration should be given to the following issues. Firstly, in Article 27.3(b), changes should be made to enable member countries to exclude all living organisms and biological materials as well as living processes from patentability. It should be clarified that members have the option of a *sui generis* system for plant varieties that protects traditional knowledge, farmers' rights and local community rights. Secondly, it should be clarified that nothing in TRIPs prevents members from taking measures needed to protect and promote public health. Further, members should be enabled to exclude from patentability medicines needed to treat life-threatening diseases and diseases related to poverty.[468] Lastly, measures for the effective transfer of environmentally sound technology to developing countries should be made operational and binding.

The challenge facing the World Summit was to ensure ecological sustainability in the way the earth's vital resources are used; promote peace and social sustainability in societies plagued by terrorism and war; improve the economic sustainability to people's lives and livelihoods - which are being harmed by economic forces of globalisation and the rules of free trade; and introduce political credibility to systems of governance facing crises of legitimacy and which are seen as instruments of the powerful working against

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determined. Without clean water, fertile soils and plant diversity, economic development will become impossible.

[465] See 'WSSD Conclusions', World Wide Web, http://planetwire.org/details/3254.

[466] Paragraph 42 (r). This provision was adopted in the final Plan of Implementation.

[467] 10 – 14 September, Cancun, Mexico.

[468] The Doha Ministerial Declaration on TRIPs and Public Health is a positive move whereby the right of members to undertake compulsory licensing and parallel imports of pharmaceutical drugs has been reaffirmed.

the weak at global and national levels.[469] It is doubtful whether the World Summit can be considered as having been a breakthrough in the implementation of sustainable development, yet it may in time be seen to have influenced international cooperation. That is, the value of the World Summit and its influence on related discussions in other fora, including the WTO, may lie not in the details of the texts adopted in Johannesburg, but rather in encouraging questioning of the underlying paradigms of globalisation and the legitimisation of anti-globalisation concerns. At this point it appears that the value of the WSSD may be found in its reaffirming of environmental principles (the gradual hardening of 'soft law' into binding customary international law).

CHAPTER 8

CONCLUSION

It is hard to escape the conclusion that a full and thorough review of TRIPs Article 27.3(b) is imperative. As canvassed above, the current text is the result of a compromise between Europe and the USA, with no proper consideration of the interests of developing countries or of the principles embodied in the CBD. Rather than force inappropriate legislation upon developing countries, it is proposed that implementation of the TRIPs Agreement should be suspended until the review is complete. The proposal to suspend implementation in developing countries is arguable on numerous grounds. Firstly, the substantive review of Article 27.3(b) has not been concluded. Secondly, specific demands to amend Article 27.3(b) have not been dealt with. Thirdly, there is strong support for the Africa Group position.[470] Lastly, the ongoing nature of the review of Article 27.3(b) provides developing countries with an opportunity to be proactive.[471]

This proposal does not mean that countries are to abandon efforts to develop appropriate and balanced national systems of rights in the interim. On the contrary, this will provide developing countries with the appropriate time and space to draft effective legislation that properly meets their needs. Protecting biodiversity, promoting its sustainable use, and developing fair and equitable benefit-sharing regimes are objectives that the world will struggle to realise with the TRIPs agreement standing directly in the way.

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[469] Op cit note 463.

[470] Peoples' movements and NGO's, Parliaments, lawyers and academics of Science, worldwide have urged their governments to support the position of the Africa Group. This indicates strong public appeal that should not be ignored, especially on such a sensitive issue as establishing monopoly rights over the basis of the food supply. See for example http://www.twnside.org.sg/title/273bst-cn.htm and, 'Bulletin 21- NGOs Demand re-thinking on TRIPs' http://www.southcentre.org/info/southbulletin/bulletin21/bulletin21-01.htm

[471] Due to the WTO's failure properly to deliberate on the Africa Group's proposals at the Third Ministerial Conference, developing countries may well now have solid grounds on which to challenge the omnipotent reach and under democratic functioning of the WTO, and the way it has served the interests of the industrialized world and its pharmaceutical corporations.

POSTSCRIPT

The Draft Ministerial Text for Cancun,[472] reflects the wide divergences between developed and developing countries. Although the subject of TRIPS and Public Health finds mention in the draft Cancun Ministerial text,[473] there is continuing neglect of the impact of TRIPs on agriculture, food security, farmers' rights and livelihood security. Importantly, the Draft Ministerial text contains no reference to the review of TRIPs Article 27.3(b).

The Doha Declaration made it clear that 'negotiations on outstanding implementation issues shall be an integral part of the Work Programme we are establishing.'[474] It instructed the Council for TRIPs, in pursuing its work program, including the review of article 27.3(b), to examine inter alia the relationship between the TRIPs Agreement, the CBD and the protection of traditional knowledge. It further instructs that, in pursuing this work, the TRIPs Council is to be guided by Articles 7 and 8 of the TRIPs Agreement.[475] The draft Cancun declaration simply ignores these injunctions of the Doha declaration[476]

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[472] Released on 24 August 2003.

[473] Paragraph 3 reads: '[w]e welcome the decision on implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health set out in document [...].' It is to be noted that paragraph 3 of the Draft Ministerial text refers to an annexure. In this respect, the General Council on 30 August adopted the 'Motta Text' (16 December 2002) as the solution to the problem raised in Para 6 of the Doha Declaration on TRIPS and Public Health. The Motta text itself is arguably a compromise document in that it places restrictions on the use of the 'solution' that a compulsory licensee should produce predominantly for the domestic market. The Motta text is now accompanied with a Chairman's statement of understanding which places yet another layer of restrictions. Namely: the solution is to be used to protect public health and not as 'an instrument to pursue industrial or commercial policy objectives'; members 'understand' that the requirement for special packaging and/or special colouring or shaping (to prevent diversion) will not have a significant impact on the price of pharmaceuticals and shall also be applicable to active ingredients; members wishing to use the system have to notify and provide information to the TRIPS Council on how they establish their lack or absence of manufacturing capacity; members may bring 'any matter related to the interpretation or implementation of the decision, including issues related to diversion, to the TRIPS Council for expeditious review, with a view to taking appropriate action', members may also 'utilise the good offices of the Director-General or the Chair of the TRIPS Council' to find a mutually acceptable solution when there are 'concerns that the terms of the Decision has not been fully complied with'. The statement of understanding could make it more difficult, administratively and practically, for developing countries to use the solution. Essentially, however, only time will tell whether the paragraph 6 system actually facilitates the production, export and importation of more affordable medicines.

[474] Paragraph 12.

[475] See note 104.

[476] Paragraph 12 of the Draft Ministerial text for Cancun on 'Implementation' reads: 'We note that, while some progress has been made under the mandates we gave at Doha concerning implementation-related issues and concerns, a number of the issues and concerns raised in this context remain outstanding. We reaffirm the mandates we gave in paragraph 12 of our Doha Ministerial Declaration and our Decision on Implementation-Related Issues and Concerns, and we renew our determination to find appropriate solutions to these issues. We instruct the Trade Negotiations Committee, negotiating bodies and other WTO bodies concerned to redouble their efforts to (resolve these issues), find appropriate solutions as a priority, and we request the Director-General to continue the consultations he has undertaken on certain issues, including issues related to the extension of the protection of geographical indications provided for in Article 23 of the TRIPS Agreement to products other than wines and spirits (and instruct) the General Council (to report on progress to our next Session.) shall review progress and take any appropriate action no later than [...].'

and moves ahead with an agenda that benefits the economies of the industrial countries while being largely oblivious to the interests of the developing world. Essentially, developing countries were promised at Doha that their implementation issues would be addressed if they entered into a new round of negotiations. The Cancun draft text, however, merely reiterates these promises and suggests that another deadline be given.

It was up to developing countries to raise the review of TRIPs Article 27.3(b) in Cancun. In the writer's search,[477] however, discussions on the review of TRIPs were not entered into at the WTO meeting. Furthermore, it appears as though discussions on the Africa Groups' proposal on traditional knowledge were similarly not entered into.[478] It appears that the review of TRIPs has yet again been blocked. This is extremely disappointing. The WTO's failure properly to deliberate on the review of TRIPs does, however, strengthen the argument for a suspension of TRIPs implementation obligations until the review is complete. It can only be hoped that paragraph 12 of the Cancun ministerial text is acted on as a matter of priority and that efforts are not only 'redoubled', but also that the issues are actually 'resolved'.

Circular brackets indicate deleted text. Unlike the text of the Doha Declaration, this text makes no mention of the fact that implementation issues are to be an integral part of the negotiations.

[477] Completed on 14 September 2003.

[478] That is, in the writer's search, no information concerning such discussions surfaced.

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