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FINAL REPORT: INTERNATIONAL CONFERENCE ON TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS AND THE CONVENTION ON BIOLOGICAL DIVERSITY
SUBMISSION BY THE UNITED NATIONS ENVIRONMENT PROGRAMME

INTERNATIONAL CONFERENCE ON TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS) AND THE CONVENTION ON BIOLOGICAL DIVERSITY (CBD)

Organized by the

African Centre for Technology Studies (ACTS)

and the

United Nations Environment Programme (UNEP)

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On 6-7 February 1999, an International Conference on Trade Related Aspects of Intellectual Property Rights (TRIPs) and the Convention on Biological Diversity (CBD) was carried out at the United Nations Environment Programme's headquarters in Nairobi, Kenya. The conference was opened by the Honorable Francis Nyenze, Minister for Environmental Conservation, Government of Kenya.

Close to sixty participants attended the conference, which featured eighteen national and international speakers who presented and discussed their papers on issues divided into the following sessions:

Overview

The Evolution of the Agreement on TRIPs, P. Drahos, Queen Mary and Westfield College, University of London (UK)

TRIPs and the CBD: Synergies and Conflicts, R. Lettington and R. Manek, African Centre for Technology Studies (Kenya)

It's Now or Never: Grappling with TRIPs in a New Era of Genetic Resources Utilization, E. Peria, South East Asia Regional Institute for Community Education (Philippines)

International and Regional Perspectives

The Crucible Group's Initiative on Intellectual Property Protection, M. Halewood, International Development Research Centre (Canada)

TRIPs and International Relations: The Emerging OAU Position, J. Ekpere, Organization of African Unity (Nigeria)

Review of TRIPs Article 27(3)(b): Perspectives from the World Trade Organization, N. P. de Carvalho, World Trade Organization

The United States of America and the TRIPs/CBD Conflict, A. Ramanna, University of California-Berkeley (USA/India)

TRIPs and Knowledge Systems

Intellectual Property Protection and Traditional Knowledge, G. Dutfield, St. Peter's College & Oxford Centre for the Environment, Ethics and Society, Oxford University (UK)

TRIPs vs CBD: Perspectives on the 1999 Review, R. Vellve, Genetic Resources Action International (Philippines)

Patents for Biotechnology Innovations: New Scope under TRIPs, C. N. Rao, Research and Information System for the Non-Aligned and other Developing Countries (India)

Critical Public Policy and Ethical Considerations

TRIPs and Access to New Technologies: Convergence and Divergence in International Relations, J. Mugabe, African Centre for Technology Studies (Kenya)

The Evolution of Patenting Life Forms: Ethical and Political Considerations, P. Mooney, Rural Advancement Foundation International (Canada)

Conservation, Use and Control of Biodiversity: The Political Ecology of Intellectual Property Rights over Life Forms and Processes, J. A. Gari, University of Oxford (UK)

Access to Genetic Resources and IPRs: Regulatory and Policy Framework in Nigeria, K. Nnadozie, Bioresources Development and Conservation Programme (Nigeria)

TRIPs and its Implications for Access to Genetic Resources Under Article 15 of the CBD, J. Otieno-Odek, University of Nairobi (Kenya)

Emerging Views from Industry

TRIPs and the CBD: An Industry View, K. Becker, Novartis Services AG & the European Chemical Industry Council (Switzerland)

Genomics and the International Economy, J. Kilama, Global Biodiversity Institute & DuPont Agricultural Products (USA)

An East African Private Sector Statement of Position on TRIPs Article 27(3)(b), S. Collins, Monsanto (Kenya)

Emerging Issues

Emerging Issues for the Review of Article 27(3)(b) of the TRIPs Agreement, J. Mugabe, African Centre for Technology Studies (Kenya)

The sessions were chaired by Ms. Norah Olembo, Director, Kenya Industrial Property Office, Mr. Johnson Ekpere, Organization of African Unity, Mr. Dames Otieno-Odek, University of Nairobi, Ms. Ivonne Higuero, Programme Officer, United Nations Environment Programme, Mr. Michael Halewood, International Development Research Centre-Canada, and Mr. Peter Drahos, Herchel Smith Research Fellow, Queen Mary and Westfield College, University of London (UK).

The United Nations Environment Programme (UNEP) is pleased to submit the attached background conference papers for the information of the Intersessional Meeting on the Operations of the Convention. UNEP kindly thanks the authors for the preparation of these documents. The views and interpretation reflected in these documents are those of the authors and do not necessarily reflect an expression of opinion on the part of UNEP.

BIOTECHNOLOGY, TRIPS AND THE CONVENTION ON BIOLOGICAL DIVERSITY

Unedited Draft

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Abstract

When the Trade Related Intellectual Property Rights Agreement (TRIPS) was drafted as part of the Uruguay Round of GATT, provisions were included to allow some flexibility for individual countries to tailor their Intellectual Property Rights laws in respect of living matter. As the TRIPS agreement stands, countries may exclude plants and animals from eligibility for patent protection, though some form of IPP must be devised for new plant varieties. These provisions are subject to a review by the World Trade Organisation's TRIPS Council this year. Some industrialised countries, notably the United States, have indicated that they favour further standardisation of IPR at an international level, including the removal of these provisions and the tighter specification of a regime to protect plant varieties. On the other hand, some developing countries intend to lobby for an extension of the provisions to allow national IPR regimes to exclude *all* life forms from patent protection. Still others believe that the provisions should remain unchanged, at least for the time being.

Whatever the outcome of the review, it will have implications for three related policy areas: the development and implementation of IPR regimes to conform to the international standards established by TRIPS; the international transfer, deployment and development of biotechnology; and, the implementation of the provisions of the Convention on Biological Diversity. This paper examines the relationships between TRIPS, the CBD and international biotechnology transfer, particularly as they impact on developing countries and in light of the potential outcomes of the forthcoming TRIPS review. It argues that, in respect of IPP for biotechnology, changes to IPR legislation should be introduced as part of cohesive national policy regimes rather than in isolation. Many developing countries, especially in Africa, have not yet been able to develop national strategies in the area of biotechnology, but must nonetheless implement new IPR regimes to conform to the terms of the TRIPS agreement. However, any further changes to the TRIPS provisions should be delayed until countries have been able to formulate informed positions according to national needs.

Abbreviations

ARIPO	African Regional Industrial Property Organisation
CBD	Convention on Biological Diversity
DNA	Deoxyribonucleic Acid
DR&SS	Department of Research and Specialist Services (Zimbabwe)
EPO	European Patent Office
GATT	General Agreement on Tariffs and Trade
GEF	Global Environment Facility
GTAC	Gene Therapy Advisory Council
IPP	Intellectual property protection
IPR	Intellectual Property Rights
IUCN	International Union for the Conservation of Nature
PBR	Plant Breeders Rights
PCR	Polymerase Chain Reaction
rDNA	recombinant DNA
R&D	Research and development
RFLP	Restriction Fragment Length Polymorphisms
TRIPS	Trade-Related Intellectual Property Rights
UNCTC	United Nations Conference on Transnational Corporations
UPOV	International Union for the Protection of New Plant Varieties
WIPO	World Industrial Property Organisation
WTA	World Trade Agreement
WTO	World Trade Organisation
ZIPO	Zimbabwe Industrial Property Office

1. INTRODUCTION

This paper has been preparared in anticipation of the 1999 review of patentable subject matter under the Trade-Related Intellectual Property Rights Agreement (TRIPS), a constituent part of the World Trade Organization. TRIPS provides for private ownership of living matter through the granting of patents. At present, this form of protection is only mandatory for micro-organisms. Article 27 Sub-Paragraph 3(b)[1] currently allows both plants and animals to be excluded from patentability at a national level, although novel plant varieties must be protectable under some form of intellectual property protection (IPP) regime. However, these provisions are subject to a review in 1999, notably *before* the deadline for developing countries to implement the terms of TRIPS[2]. The outcome of this review has important implications for two major interrelated areas of concern for both industrialised and developing countries: the development and deployment of modern biotechnology[3] within and across national boundaries, and the conservation and sustainable use of global biological diversity.

The Convention on Biological Diversity (CBD) contains provisions for promoting and regulating the transfer of technology, including biotechnology. Indeed, the negotiations of the Convention, and its eventual provisions, were based around an explicit exchange of resources between countries of the North and those of the South. Biodiversity-rich countries, mainly developing countries in the tropical regions, would provide international access to their genetic resources in return for financial and technological resources from industrialised countries[4]. Biotechnology is clearly an important technology (or, more accurately, a set of technologies) with respect to the Convention in that it provides powerful tools to facilitate biodiversity conservation. These include tissue and cell culture techniques used for both *ex situ* and *in situ* conservation, the rapid development of affordable diagnostics and vaccines for diseases which threaten genetic resources, and generic techniques for analysing and characterising living matter at a genetic level[5]. Many (though not all) of these technologies are the subject of intellectual property protection, where national IPR regimes allow.

The intention of this paper is to clarify the relationships between biotechnology transfer, the TRIPS agreement, and the CBD. Using case study data from Zimbabwe and Ghana, the paper will illustrate the problems for African countries in trying to implement the provisions of TRIPS and the CBD in respect of biotechnology. I will argue that the successful implementation of both TRIPS and the CBD, particularly in countries of sub-Saharan Africa, requires the time and resources to develop national policy regimes which fulfill international obligations under CBD and TRIPS but which also serve national interests in both the short and longer terms.

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[1] For the full text of Article 27, see Appendix 2. Hereafter the sub-paragraph will be referred to simply as Article 27.3(b).

[2] For many developing countries, this deadline is 1st January 2000. Least developed countries have a further 5 years to comply.

[3] The term 'modern biotechnology' is used here to differentiate between traditional fermentation technologies and those biotechnologies which have been developed in the latter part of this century - particularly (though not exclusively), those biotechnologies which involve the analysis and manipulation of DNA. Hereafter, references to biotechnology can be taken to mean 'modern' biotechnology.

[4] See, for example, Svarstad 1994.

[5] For example, the Polymerase Chain Reaction, and RFLP (Restriction Fragment Length Polymorphisms) Mapping.

The paper starts out by outlining some fundamental difficulties in implementing the technology transfer provisions of the CBD as contained in Article 16, and establishing the the implicit relationship between biotechnology transfer and Intellectual Property Rights (IPR) according to the terms of this article. Section 3 goes on to discuss in more detail the development of IPR regimes in industrialised countries in response to rapid technological advancements in the field of biotechnology, and the key issues this has raised for developing countries. Section 4 uses case study data from Zimbabwe and Ghana to illustrate the pressure currently on African nations to implement the provisions of TRIPS with respect to biotechnology in isolation from other related policy issues, and with limited resources. Following from this, the next two sections discuss the importance of retaining the small degree of flexibility offered by TRIPS Article 27.3(b) to tailor IPR for biotechnology-related innovations at a national level. Section 7 attempts to draw together areas of common policy interest between biotechnology, TRIPS and the CBD, and from these identify where implementation of one of these two international agreements may serve to support implementation of the other. Some preliminary conclusions and suggestions for future actions are contained in Section 8.

2. BIOTECHNOLOGY AND THE CBD

Provisions of the CBD that relate to biotechnology are found in several Articles within the text of the Convention[6]. The most obvious link between the CBD and the TRIPS agreement in respect of technology transfer is Article 16 of the CBD[7], which concerns the north-south transfer of proprietary technologies, subject to the existence in recipient countries of 'adequate and effective' intellectual property rights protection. Indeed, Article 16 contains the *only* reference to IPR in the entire text of the Convention. The issues surrounding the implementation of Article 16, particularly in the countries of sub-Sahara Africa, will therefore form the starting point for this paper.

Problems with implementing Article 16

Article 16 of the CBD is, I would argue, a rather neglected provision of the Convention. A review of the outcomes of the Conferences of Parties shows that few substantive decisions on its implementation have emerged[8], and no comprehensive evaluation of its success or otherwise in promoting technology transfer has been carried out. With respect to biotechnology, a brief investigation of the current and past project portfolio of the Global Environment Facility (GEF), the official funding mechanism of the CBD, in the area of biodiversity shows that biotechnology transfer has not been a major objective[9]. Further, a recent review of the effectiveness of the GEF as the Convention's financial mechanism clearly states that the GEF has had no impact on the implementation of Article 16[10].

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[6] Most notably in Articles 16 (Access to and Transfer of technology), 19 (Handling of biotechnology and its benefits) and 8 (In-situ Conservation).

[7] For the full text of this Article, see Appendix 1.

[8] Full reports of COPs and a report of decisions taken at COP4 in 1998 are available on the CBD web site. (URL listed in the References at the end of this paper)

[9] GEF 1996. In fact, the vast majority of projects concentrated on the provisions of Articles 6 (General Measures for Conservation and Sustainable Use) and Article 8 (*In-situ* conservation).

[10] UNEP/CBD 1998 - UNEP/CBD/COP/4/16

There are in many cases institutional barriers to implementing Article 16. Parties to the CBD have generally appointed one specific ministry or other implementing body to be responsible for CBD implementation. In Zimbabwe, for example, this is the Ministry of Mines, Environment and Tourism. Technology acquisition is not necessary within the remit of these bodies, or at least is not a primary function or priority. In Ghana, the institutional arrangement is perhaps more suitable, (or more fortuitous,) with CBD implementation falling under the aegis of the Ministry of Environment, Science and Technology. In Ghana's case, therefore, implementing CBD Article 16 falls more easily into the Ministry's mandate. However, there is still a need to co-ordinate technology needs with several other ministries, notably Health, Food and Agriculture, and Trade and Industry[11]. This point will be returned to in a later section.

Further, there is a problem with the language of the Article, which is extremely vague. In respect of access to technology, Article 16 of the Convention states that such access should be on "fair and most favourable" terms which, in the case of proprietary technology, "recognize and are consistent with the adequate and effective protection of intellectual property rights"[12]. The question of what constitutes "adequate and effective" protection requires negotiation between contracting parties in the transfer of protectable technologies. At present, developed countries generally argue that intellectual property rights regimes, particularly in developing countries, need to be strengthened to facilitate such transfers and promote technological development[13]. However, there is at present so little evidence concerning attempts to implement Article 16 that it is extremely difficult to evaluate the role of increased IPR protection (for example, through TRIPS implementation) in achieving the objectives of the CBD in this respect.

However, there is a great deal of evidence to show that IPRs have become extremely important in the field of biotechnology in industrialised countries. The next section discusses this relationship and its implications for the acquisition of biotechnologies by developing countries.

3. BIOTECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS

Biotechnology is one of the most important areas of the current and future international technology market. The inclusion of Trade-Related Intellectual Property Rights in the Uruguay Round of GATT negotiations was largely at the insistence of industrialised countries who were seeking to protect their comparative advantage in knowledge-intensive generic technologies, notably information technology, new materials, and of course biotechnology. The objective of the TRIPS agreement is to enforce minimum universally applicable standards of IPP in all its member countries. This means, for many developing countries, the introduction of new or revised IPP regimes which allows for the patenting of life forms. The costs of this

[11] As has been done, in fact, in some developing countries, including Brazil and Malaysia. In both countries, cross-sectoral committees have been established to co-ordinate implementation of CBD. In Brazil, the co-ordinating role in respect of individual Articles of CBD have been assigned to specific institutions or appropriately qualified people. I am grateful to Dr. E. Fontes, Brasilian Enterprise for Agricultural Research, Genetic Resources and Biotechnology (EMBRAPA), Brazil and Prof. A.H. Zakri, University Kebangsaan Malaysia, for this information.

[12] UNEP 1992 p33

[13] Mugabe and Clark 1996 p1

will be substantial, and yet the expected return from such investment by way of greater access to protected innovations is very uncertain.

What is the relationship between IPR and technology transfer?

Intellectual Property Rights take different legal forms, including copyright, trademarks, designs, Trade Secrets, Plant Breeders Rights, and patents. Most of the debate on the underlying rationale for IPR concerns patents, which historically have been developed to confer a legal monopoly over the commercial exploitation of new industrial products and processes for a set period of time. Patent protection is therefore often seen as an incentive to invest in research and development which may lead to commercially exploitable innovations[14]. This view has been the subject of extensive debate, which the UNCTC has in the past attributed to insufficient and contradictory empirical evidence on linkages between IPR protection and investment and technology flows[15].

With respect to the protection of IPR for science and research intensive fields such as biotechnology, the technology suppliers argue that the cost of R&D in this field is extremely high, and that unless investors are guaranteed a legally-enforceable monopoly on the commercial exploitation of their innovations, technological development world-wide will diminish. The argument continues that, if stronger IPR adversely affects developing countries in the short term by causing the price of technologies to rise, in the longer term they will gain from the benefits of more technological development[16].

However, several reports exist[17] which show that, whilst links may be found between IPR protection on the one hand and foreign investment and technology flows on the other, the evidence only established that IPR may act as a *disincentive* to invest or transfer technology. None of the reports found a positive link between *strong* IPR protection and *increased* investment or technology flows. In respect of biotechnology transfer to countries in sub-Saharan Africa, my own 1996 study of Zimabwe indicated that the IPR regime had, up to that time, very little effect (positive or negative) on the transfer of biotechnologies to that country[18].

In fact, questions are now being raised as to whether stricter IPR legislation with respect to biotechnology is likely to *hinder* technological progress in this field of technology. The World Bank's 1998 World Development Report cautions that "there is now a risk of excessively strict IPR adversely affecting follow-on innovations... and actually slowing down the pace [of technological development]". The Report goes on to identify patents which cover "not just products but broad areas of technology" and "fundamental research tools" as a particular concern[19]. These issues are especially relevant in biotechnology.

What is 'technology' in respect of biotechnology?

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[14] Phillips and Firth 1990 pp98-99
[15] UNCTC 1990 p3
[16] Bhat 1996 pp206-207
[17] See UNCTC 1990, Mansfield 1994, UNCTAD 1996
[18] Stokes 1998
[19] World Development Report 1998. Cited in Butler 1998

Biotechnology has been defined in many different ways[20], but there is general consensus that biotechnology involves the use of biological material for the development of industrially applicable products and processes. It has also been defined as "*a priori* an interdisciplinary pursuit", in that it draws on knowledge and techniques from a wide range of scientific disciplines[21]. However, biotechnology is a science-intensive field where the distinctions between basic scientific knowledge and technology are very blurred. 'Technology' can be understood to be 'industrially relevant knowledge' which may be variously embodied in, for example, machinery, processes, designs, books (and other printed forms), and people. Therefore, it can be considered that biotechnology may be transferred through education in the scientific disciplines which underpin this technological field, particularly chemistry, microbiology, biochemistry, and chemical engineering. This type of knowledge is mostly in the public domain, and not subject to IPP.

In respect of intellectual property rights, the *applied* definition of biotechnology has been widened further by changes to IPR regimes in some industrialised countries to allow living matter to be protected by patents. Whilst intellectual property rights on living matter is not entirely new in many countries (in that novel plant varieties can be awarded IPP under Plant Breeders Rights), the patenting of life forms was not possible in any country until quite recently. This has major implications for biological resources and diversity, and the controversy surrounding the issue is the reason that Article 27.3(b) was included in the TRIPS agreement.

When is a 'product of nature' a biotechnological 'invention'?

Present patent regimes in northern countries were developed to protect industrial products and processes. Plant Breeders Rights were, until 1980, the only form of IPP for life forms, and these have to date provided a lesser degree of protection than patents. Since a United States High Court ruling in that year which allowed the patenting of a modified micro-organism[22], patent law in the USA and other major countries in biotechnology development has been under continuous review and amendment, often on a case-by-case basis.

The universal criteria of novelty, inventiveness, and industrial applicability, on which eligibility for patent applications are based, had historically precluded patentability of 'discoveries' of nature. Now, interpretation of 'novelty' and 'inventiveness' in patent law, especially in the USA, has been broadened to allow intellectual property protection for even the most fundamental component of life forms (individual genes) and for higher life forms (animals). This has come about not simply because new biotechnologies have allowed the manipulation of living matter in the production of new products: after all, this is what traditional plant and animal breeders do. Rather, it is because of the levels at which such manipulation is now possible, the often wide ranging industrial potential of a single innovation, the long lead times in respect of commercialisation (and recoupment of investment on) the innovation, and high costs involved in its research and development. Patent regimes in many northern countries are still undergoing amendments and interpretation insofar as biological material and processes are concerned, and there is a large degree of

[20] See, for example, Smith 1996 p2 for a list of definitions from various sources.
[21] Smith 1996 p6
[22] the landmark *Diamond vs Chakrabarty* case

uncertainty in establishing the validity of patent applications for biotechnology-related products and processes as a result - this has led to extensive patent litigation in the United States[23].

Concerning the patentability of living matter under exisiting criteria, I would argue that there are two distinct *technical* (as opposed to moral or ethical) issues. The first concerns modified living matter. For example, where a gene sequence occurring in nature has been manipulated to produce a novel gene sequence which does *not* occur in nature, then this would appear to satisfy the 'novelty' and 'inventiveness' criteria for patents. The same applies for modified microorganisms[24], animals, plants and even humans. As long as the modified 'product' has industrial applicability, it would meet the patentability criteria standard to patent legislation across the world. The second issue concerns unmodified living matter. It would seem that unmodified living matter would fail to meet the 'inventiveness' criteria for a patent. Indeed, unmodified plants and animals are *not* considered patentable. However, patenting of unmodified genes and microorganisms is now possible in the United States and the European Union, though new interpretations of the term 'invention'. Genes are in fact very difficult to define, either by their structure or their function, which is often dependent on its environment[25]. Where structure and function can be defined for a particular gene in a specified environment, the gene itself may be regarded as a 'discovery' of nature. However, unmodified genes may now be regarded as 'inventions' according to European Patent Office guidelines, as long as they are "isolated from their surroundings" and have "no previously recognised existence"[26].

The reason for these changes in patent law interpretation is undoubtedly related to one of the underlying objectives of IPR, which is to encourage investment in research by guaranteeing a monopoly on the commercial exploitation of the results. Genes and microorganisms which exist in nature may have important industrial application, but are time-consuming and expensive to search for and isolate. Further, IPR protection for microorganisms is considered to be particularly important because they are easily 'stolen' and their characteristic of being self-replicating means that no understanding of their function is needed for their commercial exploitation[27]. The commercial value of genes and microorganisms lies in the knowledge (or technology) *inherent* in them; that is, the 'technology' to produce a specific protein or perform a specific function. In this sense, they can be seen in, the context of patent law at least, biotechnologies in themselves.

The private ownership of living matter as intellectual property has raised many ethical, socio-economic and legal concerns which are still subject to on-going debate in both industrialised and developing countries. International consensus on the patenting of life forms has not been reached. For several years, innovators in the United States were in dispute with the European Patent Office over the latter's refusal to grant patents on animals. Even now that this issue has been resolved in the European Parliament, and the new European Directive on biotechnology (98/44/EC) specifically allows IPP for animals, one of the EC member countries (The

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[23] Avramovic 1996 p154

[24] as in the above case

[25] for example, the same gene identified in one animal may have an entirely different function in another animal (Kollek 1995:24)

[26] Walden 1995 p183

[27] Bent et al 1987 pp346-9

Netherlands) has recently challenged the legality of this Directive[28]. Further, the issues of IPP for cloning, for human genes and for gene therapy technology is still controversial. How, then, does this affect the attempt to harmonise IPR law at an international level under TRIPS?

How is IPR being developed in response to biotechnology?

IPR regimes in northern countries have been developed over the past two or more centuries in response to, and in harmony with, their industrial, technological and social development. This is still the case, as evidenced by the European Parliament's attempts to balance the interests of technological innovation with social acceptability in the case of animal patents[29], and the refusal to accept this in The Netherlands where the patenting of plants and animals has been opposed by parliamentary amendment[30]. It is interesting to note that, in presenting their case to the European Court of Justice, the Netherlands pleads that the Directive is both in conflict with the provisions of the CBD, and also removes the right for EC member countries to apply Article 27.3(b) of TRIPS to their national patent law[31].

It has been argued that optimal IPR protection should be determined broadly by the level of productive and research capabilities at *national* level, where the greater the level of capabilities, the stronger the IPR regime should be[32]. Frischtak points out that under TRIPS, the standards of protection set are those which are considered the 'minimum' adequate for northern interests, rather than those which are optimal to the national interests of Southern countries[33]. In Ghana, for example, comprehensive and detailed patent legislation was drafted in 1992 which was intended to meet the specific needs of that country at its present stage of technological development. This Act and its associated regulations (1996) only came into force in 1998. However, it now requires extensive amendment to conform to TRIPS.

On this basis, I would argue that the TRIPS agreement may contain an inherent contradiction in its terms. Article 7 of TRIPS states the objectives of the agreement:

> The protection and enforcement of intellectual property rights should contribute
> to the promotion of technological innovation and to the transfer and dissemination
> of technology, to the mutual advantage of producers and users of technological
> knowledge and in a manner conducive to social and economic welfare, and to a
> balance of rights and obligations.[34]

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[28] Emmott 1998

[29] the EC Directive of Biotechnology now makes the patenting of animals permissible as long as the benefits to society outweigh possible suffering of the animal

[30] Bennett 1998 p382

[31] Emmott 1998

[32] Frischtak 1995 pp203-4. He also allows that sectoral differences should be taken into consideration. For example, pharmaceutical innovations are costly to bring to market, but easy to imitate, and there is a perceived need for stronger IPR protection in this sector

[33] ibid, pp200-201

[34] WTA/GATT 1994 Article 7

At the same time, signatories to the World Trade Agreement are compelled to implement the minimum standards of IPR laid out in TRIPS, even where these might conflict with their national interests.

In summary, this section has illustrated that biotechnology is a wide-ranging set of techniques and products which may, according to conceptual interpretation, include genetic resources themselves. Whilst many biotechnologies are already in the public domain, IPR has become a key feature in biotechnological development. Changes to national IPR regimes in response to biotechnology have not been uniform and only a partial consensus has been reached on appropriate levels of IPP for biotechnology and its products, even amongst technologically advanced countries. The provisions of the TRIPS agreement which aim to introduce universal standards of IPR protection for living matter may therefore be seen, at least in respect of biotechnology, as premature. This can only add to the problems of implementing TRIPS in developing countries.

4. IMPLEMENTATION OF TRIPS

Many countries in sub-Saharan Africa must implement the provisions of the TRIPS agreement in national IPR legislation by the start of the year 2000. It is now widely accepted that this will (and does at present) entail large outlays of public resources[35]. In order to then *enforce* the provisions of TRIPS as required by Part III (Enforcement of Intellectual Property Rights) it is evident that a long-term programme of scientific, legal and administrative capacity building must be undertaken. Financial outlays are likely to be considerable. Financial and technical assistance for developing countries to meet their obligations under TRIPS was included as part of the agreement. In Africa, the World Industrial Property Organisation (WIPO) has been providing a range of short training courses, and in-country advice to legislators. It is as yet unclear whether this assistance will be sufficient.

This section presents an overview of TRIPS implementation activities in Zimbabwe and Ghana towards the end of 1998[36], particularly in respect of patents and *sui generis* systems to protect plant varieties. These are the key forms of IPP which might be affected by changes to the existing provisions under TRIPS Article 27.3(b). Both Ghana and Zimbabwe must put their new IPR regimes into place by 1st January 2000. Both have some capacity in advanced biotechnology. Neither country has an explicit biotechnology strategy, although policies for biotechnological development and management have been developed in Zimbabwe through stakeholder consensus in recent years. Where the two countries differ is in their existing IPR regimes and institutional framework for their implementation.

TRIPS implementation in Zimbabwe[37]

The existing 1970 Patent Act in Zimbabwe actually needs very little amendment to conform to TRIPS. It is a relatively simple piece of legislation, where patentability depends only on the standard criteria of

[35] see, for example, UNCTAD 1996

[36] Things tend to be moving very quickly at the moment, therefore it is expected that some of this section will already be out of date.

[37] I am grateful to Mr. W. Nyauchi (Zimbabwe Industrial Property Office), Mr. C. Kiije (ARIPO) and Dr. J. Gopo (Biotechnology Research Institute, SIRDC) for up to date information on Zimbabwe.

novelty, inventiveness and utility and opposition[38] to patentability may only be made on technical grounds or on the basis of fraud. The existing Act therefore allows a great deal of flexibility for interpretation according to national policy. The only part of the Act which requires amendment in order to conform to TRIPS is the provision for compulsory licensing. Even here, the changes required are minimal. Discussions on whether to make other changes to the Patent Act are on-going at present, these discussions forming part of a wider consultation process on the harmonisation of IPR legislation in the country.

Zimbabwe patents are administered by the Zimbabwe Industrial Property Office (ZIPO), which is a non-examining office. Patent applications can be filed with ZIPO in three ways. Direct applications are not subject to a substantive examination, but a brief description of the innovation is published in a weekly journal, and the patent will be automatically awarded three months after this publication should their be no objections notified to ZIPO. Overseas patent applications may also be filed via the Patent Cooperation Treaty. These patents will be subject to a substantive examination at the expense of the applicant, with the examination being carried out at one of five Patent Offices worldwide. Finally, patent applications may be filed through the African Regional Industrial Property Office (ARIPO) under the Harare Protocol (1982)[39]. ARIPO also carry out substantive examinations, either in-house or through other international patent offices. However, final decisions on whether to award a patent rest with the national industrial property office and are therefore, in light of the broad language of the existing Zimbabwe Patent Act, subject to interpretation on a case-by-case basis.

Zimbabwe is not a party to the UPOV (International Union for the Protection of New Plant Varieties) Convention, but has had a Plant Breeders Rights (PBR) Act in place since 1973. The current Act does not comply with the TRIPS agreement in respect of the principle of National Treatment. At present, foreign applications for varieties whose origins are outside Zimbabwe are only considered at the discretion of the Minister of Agriculture[40]. Under a generous interpretation of the Zimbabwe PBR Act, farmers may have extensive rights over the use of saved seed. Article 12 allows for saved seed to be replanted, sold or exchanged with other farmers, or used as a base for breeding new varieties for commercial sale[41]. Whilst the restriction of farmers' rights under either the 1978 or 1991 UPOV Conventions does not technically affect Zimbabwe (as a non-member), the use of the existing Plant Breeders Rights Act to protect genetically-engineered plants may not constitute adequate IPR protection in the eyes of many technology suppliers. This may put more pressure on the government to enhance the patent system to handle IPR for plants.

The Plant Breeders Rights Act in Zimbabwe is administered by the Government's Department of Research and Specialist Services (DR&SS), an umbrella institution for many of the agricultural research institutes in the country. Representatives from the DR&SS and the Zimbabwe Industrial Property Office form part of a cross-ministerial consultative group which is now meeting regularly in an effort to harmonise legislation in support

[38] Any person, or institution, including the State may oppose a patent application

[39] the member states of ARIPO at present are: Botswana, The Gambia, Ghana, Kenya, Lesotho, Malawi, Sierra Leone, Somalia, Sudan, Swaziland, Uganda, Tanzania, Zambia and Zimbabwe. However, Sierra Leone, Somalia and Tanzania are not parties to the Harare Protocol.

[40] Government of Zimbabwe 1974 Article 34

[41] ibid

of TRIPS implementation. Institutions mandated to oversee other forms of IPR such as copyright, together with the customs department and other relevant stakeholders in IPR development are also included in this consultative group. This is an extremely positive initiative, but it should be noted that this process has emerged from previous initiatives in recent years to stimulate debate on IPR development amongst a wide range of stakeholders. In Zimbabwe, these stakeholders include holders of indigenous knowledge such as traditional healers. Several national IPR workshops have been held in Zimbabwe since the signing of the WTA, the most recent being in September 1998. The theme of this workshop was the development of a *sui generis* system for plant protection.

In Zimbabwe, therefore, activities aimed at implementing TRIPS are at an advanced stage and those in the policy arena are taking the opportunity to consider a *sui generis* system which might be used to protect local knowledge. Further, a national biosafety regime has also been established to manage the development of biotechnology in-country and control the imports of biotechnology-related products. This may be important with respect to future developments in IPR, as will be discussed in a later section. Despite all this, opinion in Zimbabwe is still divided on whether more time is needed to properly implement the TRIPS provisions.

TRIPS implementation in Ghana[42]

Before the current Patent Act (1992) and Regulations (1996) came into force in Ghana last year, patent applications in Ghana were covered by a Government Ordinance. This in effect 'rubber-stamped' patent applications where a UK patent had been granted for the innovation. Like Zimbabwe, patent applications could also be filed via ARIPO and the Patent Cooperation Treaty. The new Patent Act is extremely detailed in its terms and provisions, and was obviously carefully drafted to be commensurate with national interests and with the country's stage of technological development. Whilst in principle this could be supported by reference to Article 7 of TRIPS, as described earlier, in practice extensive changes will be required in order for the Act to conform to TRIPS. Changes will be needed in respect of, particularly:

- term of patent award, currently only 10 years with a possible 5 year extension (20 years under TRIPS)
- existing powers of temporary exclusions from patentability (not allowed under TRIPS)
- imported technology requiring a licence (not allowed under TRIPS)
- compulsory licenses awardable where the "working" of a patent is hindered by importation (restricted under TRIPS)
- compulsory licenses awardable for "certain kinds of products" (not allowed under TRIPS)

Ghana does not have a Plant Breeders Rights regime, or a *sui generis* system to cover plants. By November 1998 there had been no progress in this area of TRIPS implementation. This is mainly because the responsibility for overseeing the amendment, development and legislative drafting of the country's entire IPR system lies with the Registrar-General's department. This department simply does not have sufficient resources, despite having a well organised team of drafters and close cooperation with other government

[42] I am grateful to Mrs E. Owiredu-Gyampoh (Acting Registrar General), Accra, and also my colleagues at the Science and Technology Policy Research Institute (STEPRI), Accra, for outlining the current situation in Ghana.

departments and research institutes. A major priority for Ghana was to update their existing (1923) Industrial Designs legislation, given the importance of textile design in Ghana. New legislation is currently being drafted (or drafts reviewed) in the area of copyright, integrated circuits and unfair competition. The Registrar-General's office intends to work closely with the country's Crop Research Institute on the issue of Plant Breeders Rights or a *sui generis* system for plant protection. However, time is running very short, and therefore Ghana may well come under pressure to adopt the provisions of the UPOV Convention wholesale in order to meet the 1st January 2000 deadline.

Under the new Patent Act a Patent Policy Committee was established to bring together expertise from various institutions, including universities and government research institutes. Unfortunately, because the Act only came into force in September 1998, this Committee has not yet become actively involved in IPR development.

Summary

Because of the time constraints imposed for TRIPS implementation, both countries are having to handle amendments to their IPR regimes largely in isolation from other issues related to biotechnology and without being able to take national interests fully into consideration. Zimbabwe is in a more advantaged position, because flexible patent legislation (which is open to some interpretation according to prevailing national policies) and a Plant Breeders Rights Act have been in place for many years. Both pieces of legislation require minimal amendments to conform to TRIPS. Further, Zimbabwe has for several years been actively developing biotechnology policies through consensus amongst stakeholders. These activities have built up expertise within and linkages between stakeholders in biotechnology, which have to an extent mitigated the problems involved in TRIPS implementation. Ghana has had to draft several new pieces of IPR legislation, make extensive amendments to others, and has not yet started work on a *sui generis* system for protecting plant varieties. With less than a year to go before TRIPS implementation, the Registrar-General's Office may come under pressure (possibly even from their WIPO technical advisers) to adopt Plant Breeders Rights which conform to the current UPOV Convention.

5. THE IMPORTANCE OF TRIPS ARTICLE 27.3(b)

It has been noted that the provisions in TRIPS which leave some room for decision making at a national level are generally those on which the two major forces in the Uruguay Round, the European Union and the United States, did not agree[43]. This is certainly the case with respect to Article 27 Clause 3 which covers the patentability of living matter. As this Clause stands at present, it allows member countries of the WTO to exclude plants and animals from patentability, together with "essentially biological processes for the production of plants and animals other than non-biological and microbiological processes"[44]. However, micro-organisms are not excludable under Article 27.3(b), and therefore *are* patentable under TRIPS. Article 27.3(b) further requires that some form of IPP exist at

[43] Ganesan, A.V. 199? p6.

[44] WTA/ 1994 Article 27.3(b). In fact, process patents have not been the subject of much controversy in this context.

national level for new plant varieties, either in the form of patents or by way of a *sui generis* system.

Implications of Article 27.3(b) for patent regimes

The term 'microorganism' is not actually defined within the TRIPS agreement. Microorganisms are generally defined to include unicellular plants and animals (such as algae and protozoa), bacteria, many fungi, and viruses[45]. However, in some patent regimes a wider interpretation of the term is used, to include other biological material which is self-replicating, or can be replicated in a host organism. This definition would include sub-cellular material such as genes, gene sequences and plasmids[46]. At a national level, microorganisms could - technically - be excluded from patentability, or the extent of the patent limited, on one of the following grounds:

- a narrow definition of 'microorganism' which excludes, for example, genes and gene sequences. This in itself would not be sufficient to address fundamental issues of principle on the patenting of life, nor would it necessarily limit patents to microorganisms which are incontrovertibly safe for contained use and release into the wider environment.
- the criterion of inventiveness for organisms other than modified organisms, as discussed in Section 3 of this paper. Unmodified microorganisms have been excluded from patentability in some countries, such as Brazil, on this basis[47].
- the criterion of utility, where the precise industrial use of the innovation is not specified. Alternatively, the patent could be limited to a precisely-specified industrial use of the microorganism (rather than its potential wider applicability). This would avoid potential monopolies on broad areas of technology.
- threat to ordre public or morality, threat to human, animal or plant health, or threat to the environment, as allowed for in Article 27.2. The onus would be on the patent office (or the agency challenging the patent application or award) to prove the case for exclusion on one of these bases. This has proved a problem elsewhere, notably in the Oncomouse case[48] at the European Patent Office.

A major concern for countries wishing to exclude biological material from patentability on any of the grounds listed above is the need for extensive technical and legal expertise to aid decision-making and, possibly, fighting litigation. The issues raised by the patentability of microorganisms illustrates the type of problems which are likely to arise for national IPP regimes should plants or animals be deemed patentable under TRIPS.

Protection of plants under Plant Breeders Rights

Article 27.3(b) requires that plant varieties are protectable as intellectual property either by patents or by an alternative regime. One option is to use a Plant Breeders Rights regime to fulfill this provision. Some countries, notably the USA, have suggested that the provisions of the

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[45] Thain & Hickman 1995 p395

[46] Ganesan, A.V. 199? p11

[47] Correa 1998 p30

[48] the patenting of Harvard University's genetically-engineered mouse, modified to be susceptible to cancer, was opposed on some of these grounds.

existing international agreement for the protection of plant varieties under UPOV should be incorporated into TRIPS, and it is therefore worth outlining the key elements of the UPOV Conventions here.

UPOV was first formed during the 1960s with the aim of harmonising the provisions of Plant Breeders Rights regimes at an international level. The Convention developed to achieve this has undergone several major amendments. The 1978 Act is currently in force in most UPOV member countries, but this will soon be superseded by the 1991 Act, which gives wider rights of protection to the breeder. In fact, the two Acts both restrict the rights of the farmer with respect to propagating material, which cannot (for example) be sold or used repeatedly for the commercial production of another variety. Further, both Acts allow for farmers to replant saved seed from protected varieties, although this is left to the discretion of individual member countries under the terms of the 1991 Act.

The main area of restriction is in the use of a protected variety as a basis for the creation of a new variety, which in turn can be protected by PBRs without the permission of the original breeder. The 1991 Act has constrained this practice to exclude from protection those new varieties which are only minor variants on the original, that is they are "essentially derived" from an existing protected variety. The definition of 'essentially derived' varieties, according to UPOV, are those which are "developed in such a way that they retain virtually the whole genetic structure of the earlier variety"[49]. This affects farmers who wish to take out plant breeders rights on new varieties developed on-farm, and scientists or firms using biotechnology to introduce single genes conferring a novel trait into an existing protected variety[50]. Because of this latter restriction, it is perhaps unlikely that PBRs which conform to the 1991 UPOV Convention will be used to protect transgenic plant varieties.

Most countries in sub-Saharan Africa do not have a Plant Breeders Rights regime[51]. Zimbabwe is one of those which do, although it is not a member of the International Union for the Protection of New Varieties of Plants (UPOV), and its provisions do not conform to those under either the 1978 or 1991 UPOV Convention. It differs mainly in the extent of farmers rights to the use (including resale) of saved seed. However, TRIPS does not at present require any restrictions in this respect. As mentioned earlier, the Zimbabwe PBRs Act only needs amendments in respect of National Treatment to conform to TRIPS. Therefore, countries may consider the introduction of a PBRs regime without becoming a signatory to either UPOV Convention, and without restricting farmers rights over the use of saved seed. It is unlikely that a new PBR regime will either significantly encourage, or protect against, the introduction of new transgenic plant varieties, given the relatively low level of IPP afforded and the potential exclusion of genetically-modified varieties as "essential derivations".

Alternative *sui generis* systems

Plant Breeders Rights are just one option for introducing a *sui generis* system for the protection of IPRs on plant varieties as required by TRIPS. An issue which has merited considerable attention in recent years,

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[49] UPOV 1997

[50] This restriction on new 'varieties' produced using biotechnology is clearly stated in UPOV literature, for example, see the description of "Essential Derivation", UPOV 1997

[51] In fact, PBRs are so far only established in Kenya, South Africa and Zimbabwe (GRAIN 1998)

especially since the coming into force of the Convention on Biological Diversity, is the possible introduction of new IPR regimes to protect the rights of indigenous peoples over their traditional knowledge of plant genetic resources. The option of introducing a *sui generis* system as laid out in Article 27.3(b) of TRIPS, is seen as a potential mechanism for such protection. This opportunity is being promoted by various international organisations, such as IUCN (International Union for the Conservation of Nature)[52], and suggestions for the development of a suitable system are being debated[53]. A detailed discussion of, or comment on, potential models for alternative systems is outside the scope of this paper, which focuses on biotechnology-related innovations. Suffice to say here that biodiversity-rich countries may wish to explore the possibilities of new forms of IPR with a view to both fulfilling their obligations with respect to TRIPS and at the same time introducing effective protection for traditional knowledge and practices. The problem here is that of time, at least in respect of TRIPS implementation[54].

Summary:

The provisions of TRIPS Article 27.3(b) may not ideally suit the interests of many developing countries. The requirement for microorganisms to be patentable may run contra to national interests given the relatively low levels of local technological capabilities in areas of potential application. However, it at least gives the flexibility for countries to avoid tackling areas of great contention (notably, the patenting of modified animals), and gives the opportunity for developing a new IPR regime (in the form of a *sui generis* system) which is consistent with local needs.

6. THE 1999 REVIEW OF TRIPS ARTICLE 27.3(b)

Under Article 71 of TRIPS, the Agreement will undergo a full review in the year 2000, and every two years thereafter. However, the provisions of Article 27.3(b) include a specific review for the sub-paragraph itself in 1999, by the TRIPS Council of the WTO.

Possible outcomes of the 1999 Review

There are various possible outcomes of the review of Article 27.3(b). Mulvaney (1998) lists these, broadly, as:

- the removal of the entire Clause, which would mean that plants and animals must be patentable under national IPR regimes;
- the possible requirement for the provisions of the UPOV Convention to be included as mandatory for plant variety protection under TRIPS;
- the extension of the provisions of Article 27.3(b) to allow for all living matter to be excluded from patentability; and
- maintaining the status quo with regard to Article 27.3(b) - in this case, the clause would come under one of the general TRIPS reviews in the year 2000 or later.

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[52] IUCN 1997

[53] see, for example, The Crucible Group 1994

[54] Of course, there is nothing in TRIPS to prevent later introduction of a sui generis system to protect indigenous knowledge and/or plant genetic resources themselves, which would co-exist with other forms of IPR for plants.

The USA is strongly in favour of the first two possible outcomes[55]. In fact, according to a communication from the USA to the WTO Governing Council, they are the *only* issues on the agenda for consideration in the review of Article 27.3(b)[56]. The EU's stated position is that the review should ensure "that the TRIPS Agreement keeps up with new technological development"[57], possibly an oblique reference to the new EC Directive which now allows for the patenting of animals in Europe. In the light of the current dispute with The Netherlands over the Directive, it is unclear to what extent the EU will support or oppose the USA with respect to removal of Article 27.3(b). Some developing countries, including Cuba, El Salvador, Honduras, Nicaragua and the Dominican Republic, have called for an extension of the exclusion provisions of Article 27.3(b)[58]. Others, such as Egypt, favour the 'status quo' option at this stage[59].

Changes which extend the provisions of 27.3(b)

The main proposal for the extension of provisions relating to patentability is that national patent regimes be free to exclude all living matter from patent protection. This has some obvious advantages, especially for developing countries. First, it would make issues concerning the definition and/or 'inventiveness' of microorganisms redundant and thereby reduce the administrative burden of implementing TRIPS. Second, it would provide a means by which microorganisms (in their broader definition) which carry a potential threat to the environment or human health could be excluded from patentability without resort to the provisions of Article 27.2[60]. This could contribute to the protection of biological diversity, and consequently is favoured by many international environmental organisations such as the Gaia Foundation[61].

However, it is not without drawbacks. The most obvious of these is that this option will inevitably face severe opposition from countries with strong capacities in biotechnology, especially the United States. Confrontation here is likely to reduce developing countries bargaining positions in other areas, and may cause divisions between developing countries. This could happen where countries who are now building capabilities in biotechnology are reluctant to discourage the transfer of basic research and development tools (including, perhaps, genes and gene sequences). Further, countries which are rich in genetic resources may wish to leave a way open to use the patent system to protect some of those resources (including genes) in the future, should other mechanisms (such as Trade Secrets or a novel *sui generis* system) not prove suitable. It should be borne in mind that biosafety regimes may be a more appropriate mechanism for protecting human, animal and environment well-being than a patent regime.

Removal of Article 27.3(b)

Conversely, removal of the provisions to exclude plants and animals from patentability does not favour developing countries, certainly not at

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[55] See, for example, WIPR 1998 and Lourie 1998
[56] Government of the United States 1998
[57] ICSTD 1998
[58] ibid
[59] ibid
[60] implementing the provisions of this clause has some inherent problems, as will be discussed later in this section
[61] Gaia Foundation 1998

present. It would first of all increase the administrative burden on the IPR implementing agencies and increase the required technical and legal resources. Further, it must be questioned whether novel plants and animals, as 'end products' of technological innovation, are in themselves useful to a developing country in respect of building technological capacity. In this respect, removal of this Clause would probably run contra to the provisions of TRIPS Articles 7 (objectives) in many countries. With respect to moral and safety considerations, removal of this Clause is inappropriate at a time when many countries (particularly in sub-Saharan Africa) have not yet established institutions and regulations to deal with potential problems.

Further to this, it has been demonstrated that rejection of a patent application on the grounds provided for by Article 27.2 of TRIPS (especially, ordre public or morality) is in practice very difficult and may be subject to extensive legal battles. The case of Harvard University's Oncomouse case is a good illustration of this. When patentability in the EU was challenged on the basis of morality, the Examining Division of the European Patent Office (EPO) only gave weight to the practical objections lodged, such as potential risk to the environment, and not to the more general ethical principle that evolution was being manipulated[62].

In fact, it is the provision within the recent EC Directive on Biotechnology which allows for the patenting of animals that has been challenged by The Netherlands. This is a good indication that there is by no means a consensus even in the technologically advanced northern countries on this issue. The removal of the provisions in Article 27.3(b) relating to the exclusion of plants and animals from patentability can therefore be opposed purely on the grounds that it is untimely, given the current situation.

Making UPOV provisions a requirement under TRIPS

This is the other potential change which is favoured particularly by the United States. This would not preclude the future development, according to national interests, of a *sui generis* system for locally-relevant intellectual property protection. However, it might remove some of the current impetus to do so, especially given that national resources for IPR protection will be extremely stretched in order to implement the existing requirements of TRIPS. It would certainly remove the option for countries to establish more flexible PBRs legislation in respect of farmers' rights. Further to this, countries which have not already become signatories to the UPOV 1978 Convention would now have to implement the provisions of the stricter 1991 Act[63].

Implementation of UPOV provisions for new plant varieties is unlikely to have any real negative impact at farm level in sub-Saharan Africa (although it almost certainly would in some other developing countries). In most African countries, and for most crops, the market is too small to warrant extensive monitoring by PBRs holders of farmer activities, and/or litigation activities in respect of alleged infringements of intellectual property rights. On the other hand, there do not seem to be any substantial *advantages* to adopting UPOV provisions, except as a quick and convenient

[62] Warren 1998

[63] UPOV had a cut-off date for countries to choose to implement the provisions of the 1978 Act. States had to have started the procedure of accession to UPOV by April 1998 and must complete this process by April 1999 - before the TRIPS review.

way to meet the 1st January 2000 deadline for TRIPS implementation where no alternative regime exists or has been developed.

Maintaining the status quo

The final option, and the one which is widely believed to be the most likely outcome of the 1999 review, is to leave Article 27.3(b) unchanged. It will then, of course, still be subject to discussion and negotiation as part of a future overall review of TRIPS, perhaps as early as next year. So, this option really means 'playing for time' rather than being an endorsement of the Clause as it stands. Time is needed in three major areas. First, the countries of Africa which are obliged to implement TRIPS by the start of the year 2000 are fighting against time to implement the provisions as they stand now. Any substantive changes to Article 27.3(b) just a few months before the 1st January 2000 deadline would in many cases be impossible to implement in time. Even if extra time is allowed for this purpose, changing legislation which has already been established to comply with TRIPS will take up considerable resources at a time when it can ill be afforded. Second, as pointed out by Mulvaney (1998), consultation on TRIPS provisions is needed at local, national and regional levels in order that developing country positions are clarified and can be more effectively argued for. Finally, as has been argued throughout this paper, capacity must be built in African countries for not only the implementation of TRIPS, but also the management and development of biotechnology in a more general sense. The development of such capacity also needs time.

Alternative mechanisms for achieving the same objectives

Biosafety regimes exist in few African countries. Zimbabwe, again, is one country which has already established a regime. Parties to the Convention on Biological Diversity's new Biosafety Protocol (due to be finalised and opened for signature in February 1999) will be obliged to implement its provisions. These will include putting into place procedures for risk assessment of technologies which cross national borders. Biosafety regimes are arguably a more appropriate mechanisms for implementing the objectives of TRIPS Article 27.2 (that is, the exclusion of innovations which threaten ethical values, health or the environment from commercial activities). Once national biosafety regimes have been established, the issues surrounding the revision or removal of Article 27.3(b) will diminish in importance, because alternative mechanisms to implement one of its main objectives (restricting the commercial use of unsafe or undesirable technologies) will be in place. This in turn should give developing countries a stronger position from which to negotiate future changes to TRIPS.

Other policies and institutions related to biotechnology could be developed to serve national or regional interests. For example, even in Zimbabwe, where biotechnology policies have been more extensively developed than elsewhere in Africa and where a biosafety regime is already in place, there is no stated policy on human gene therapy[64]. In Europe, the Gene Therapy Advisory Committee (GTAC) is the mechanism which in reality regulates the deployment of gene therapy innovations. Warren (1998) points out that even where EU legislation might permit the patenting of genetically altered germ-line cells[65], the GTAC currently has an embargo on germ-line gene therapy. Such bodies could be established in Africa, perhaps even at a

[64] I thank Dr. J Gopo of the BRI, Harare, for pointing this out to me as an illustration that much work is still to be done on policy development in that country.

[65] Although it does not allow therapies which use the cells to be patented

regional level, to provide not only a mechanism for *regulating* biotechnology development but also a forum for on-going consultation and debate. National and regional interests are likely to change over time as novel technologies mature (and their effects become more certain or predictable) and newer ones are developed.

Summary and discussion

This section has given an overview of the main options for the 1999 TRIPS Review agenda, together with the main arguments, for and against, and proponents of these. It has been argued that neither the removal of Article 27.3(b) from TRIPS nor the introduction of the provisions of UPOV as requirements in TRIPS implementation are options likely to benefit developing countries. This is probably not a contentious argument from the perspective of African countries. The main issue for the review is therefore whether to negotiate an extension of Article 27.3(b) to allow the exclusion of biological material *other* than plants and animals (or perhaps even all biological material) from patentability, or to leave the Clause unchanged for a further period of time.

The Gaia Foundation has compiled a comprehensive discussion document[66] on the advantages and disadvantages of possible outcomes from the Review, and recommends the introduction of more exclusions to patentability in Article 27.3(b). The document argues that "the opportunity to challenge the existing sub-paragraph as a single issue [rather than as part of a later overall TRIPS review] should not be by-passed"[67]. This paper, on the other hand, argues that this opportunity is ill-timed from the perspective of most developing countries. My own view is that IPR for biotechnology (and for other areas of knowledge also) should not be considered in isolation from other policy issues concerning the technology. Rather, the formulation of appropriate IPR regimes should be undertaken as part of a wider national strategy for technological development. At this time, such cohesive strategies for biotechnology development simply have not been developed by most countries in sub-Saharan Africa.

In summary, the formulation of IPR regimes can be seen as one element in the promotion of technological development. Biotechnology development in general has significant implications for the conservation of biodiversity and the CBD objectives for the preservation of, and equitable benefit-sharing from, indigenous knowledge and genetic resources. Indigenous knowledge and genetic resources themselves may be subject to IPP, where appropriate. Policies for implementing the Convention, for implementing TRIPS, and for managing biotechnology development are therefore inextricably linked. The following section will try to unravel, at least to some extent, this 'tangled web'.

7. TRIPS, BIOTECHNOLOGY AND THE CBD

The WTO's Committee on Trade and the Environment itself indicated, in a 1996 report, the need to clarify the relationship between TRIPS and the CBD[68]. This still not clearly defined, and is subject to change as both the agreements evolve. This section will outline the areas in which links

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[66] Gaia Foundation 1998
[67] ibid
[68] WTO 1997

between CBD and TRIPS are most apparent with respect to biotechnology and discuss issues which may emerge from the review of 27.3(b)

TRIPS and Article 16 of CBD

Returning to the use of the term 'adequate and effective' in Article 16 in respect of IPP for proprietary technologies, there have been no definitive statements from major technology suppliers that implementation of TRIPS will in itself be 'adequate and effective'. The Government of the United States, for example, may not deem TRIPS as 'adequate and effective' unless Article 27.3(b) is removed, plant and animal patents are allowed in national IPR regimes, and UPOV-style Plant Breeders Rights are established. There *may* be a case, therefore, for the CBD's Conferences of Parties to pin down the definition of 'adequate and effective' IPP in Article 16, perhaps through a specific reference to TRIPS implementation. However, this would presuppose that weak IPP is in reality a universal constraint on biotechnology transfer, and also that TRIPS implementation is an appropriate solution for overcoming this constraint. In fact, there is very little documented evidence with respect to the relationship between biotechnology transfer and the IPR regime in recipient countries. This is especially true for biotechnology transferred to developing countries.

Data from a study of biotechnology transfer to Zimbabwe, undertaken in 1996, shows that weak IPR protection has *not* been a major barrier to the acquisition of proprietary technologies in this country[69]. Several transfers of proprietary genes had taken place under simple Materials Transfer Agreements (protected by law of contract) and proprietary techniques such as the Polymerase Chain Reaction[70] are already in use in the country. Several large US and European companies had already taken out biotechnology patents in Zimbabwe[71] by 1996, and enquiries in 1998 showed that this is an accelerating trend. This suggests that overseas technology suppliers are aware that non-legal barriers to *imitation* exist in Zimbabwe which can effectively protect their proprietary technologies[72]. More importantly, perhaps, the study found that most of the biotechnology transferred to Zimbabwe was in the public domain and therefore not subject to IPP. This technology was mostly embodied in the scientists themselves, in the form of relevant scientific knowledge and skills in techniques which had been acquired through education and training. This raises the question of how relevant IPRs - particularly patents - are to the transfer of biotechnology as required by Article 16 of CBD.

On the other hand, the findings from the Zimbabwe study need some qualification. The overall finding was that the majority of scientists and firms consulted had *not* found the existing IPR regime to be a barrier (or indeed an incentive) to biotechnologies required by them. However, this might not hold true for all biotechnologies in all sectors in the future. The response of one firm consulted during the study indicated that rDNA technology in respect of new maize varieties was likely to be an area where stronger IPP might be required to encourage technology transfer. There are two reasons for this. First, maize is the major crop in Zimbabwe, being both the national staple and an export crop. Its vulnerability to climatic and soil stresses, as well as to pests, means that there is a potentially

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[69] Stokes 1998

[70] in fact, IPP for PCR is actually conferred by a patent on *taq*, the enzyme fundamental to the technique

[71] See Stokes, 1998 for details of these patents.

[72] Broadly, the lack of financial, technical and institutional capacity to commercially develop biotechnological innovations

good market for transgenically improved varieties. Second, and in response to this, technological capabilities in maize improvement (in general) and rDNA technology are being built quite rapidly in the country. There is therefore potential for local innovations based on imported technologies to capture at least part of the market from the overseas suppliers.

The overall conclusion from the Zimbabwe case study was that 'adequate and effective' IPR could only be defined according to country specific factors and within this, often, to individual sectors, technologies or applications. Article 16 of CBD, which leaves the definition as the subject of negotiation between technology suppliers and recipient countries, is therefore perhaps better left as it is. Further, countries which are parties to the CBD but not to the WTO may still reasonably expect access to technology under CBD Article 16. However, recognition of TRIPS provisions as 'adequate and effective' IPR in Article 16 might therefore place a potentially undesirable obligation on them (that is, to implement or amend national IPR regimes to conform to TRIPS). This suggests that the relationship between CBD Article 16 and TRIPS will continue to be rather tenuous. Whatever the outcomes of the review of TRIPS Article 27.3(b), it is impossible to generalise about their effects on the implementation of CBD Article 16.

TRIPS and Biosafety

Biosafety can be defined as being "primarily concerned with the potentially undesirable consequences of modern biotechnology for human health and the environment"[73]. Article 8(g) of the CBD requires member countries to establish regimes for the management and regulation of biotechnology. More comprehensively, the CBD's Biosafety Protocol which is due to be finalised and opened for signature in February 1999, specifically concerns the safety aspects of international transfer of biotechnology. However, a debate has emerged in recent years, and this has been especially significant in the drafting negotiations of the Biosafety Protocol, concerning a wider interpretation of the concept of biosafety. This interpretation would include potential ethical and socio-economic impacts of biotechnology development and deployment within the scope of biosafety. Whether a narrow or broad definition is used, a close relationship between biosafety and Article 27 of TRIPS can be established.

The provisions which are most relevant to biosafety in TRIPS are the potential exclusion from patentability of novel plants and animals (Article 27.3(b)) and the potential exclusion from patentability of any inventions whose commercial deployment may threaten public order or morality, or human, animal or plant health, or the environment (Article 27.2). There are two main justifications for these exclusions. The first concerns the commensurability of national IPR regimes with a country's level of technological development, as discussed earlier in this paper. In particular, the import of new technologies and their end products (such as transgenic crops) risks the displacement of locally produced goods from the domestic market. If the potential socio-economic impacts of biotechnology are covered by the CBD's Biosafety Protocol then this will establish a new (and difficult) link between the CBD and TRIPS.

The second justification for excluding certain areas of technology from patentability is the potential threat they pose to health, the environment, and local ethical values. With respect to novel plants, animals and

[73] Essegbey & Stokes 1998

microorganisms there are perceived physical risks and uncertainties concerning both their contained use and more particularly their impact if released into the wider environment. Whilst modified plants and animals may be excluded from patentability under TRIPS (at present), this will not *preclude* their import to, or deployment in, a specific country - it has already been shown by the Zimbabwe case study that lack of strong IPR protection does not necessarily prevent transfer of advanced biotechnology. The same argument can be applied to biotechnology-related inventions which can be excluded from patentability under TRIPS Article 27.2. Implementation of TRIPS cannot therefore cannot effectively protect against the development or import of potentially hazardous technologies into a country. That can only be achieved by establishing an effective biosafety regime.

Regulating the import and/or development of potentially hazardous biotechnologies under a national biosafety regime has further advantages over excluding such technologies from patentability under the provisions of TRIPS Article 27.2. Under TRIPS the onus is on the receiving country to demonstrate that the innovation does in fact pose a threat to the environment, or health, or public morals. In a biosafety regime, permission to import and/or release a given innovation would depend on the demonstration of its safety by (or at the cost of) the technology supplier.

A further advantage is that biosafety regulations do not need to be instituted under legislation in the way that IPRs do, and are therefore more flexible with respect to change. In Zimbabwe's biosafety regime, for example, only a minor legislative amendment was used[74] to legally establish their biosafety regime. National guidelines and a National Biosafety Board regulate biosafety according to emerging knowledge about new technologies and evolving policies. This allows appropriate changes to the regime to be made without trawling legislative amendments through parliament in response to changing conditions. These changing conditions may include increased or decreased public acceptance of biotechnology-related innovations.

The problem for most countries in sub-Saharan Africa is that biosafety regimes are not yet established, and will take time to develop. Until this is achieved, the provisions of TRIPS Article 27.2 and 27.3(b) allow at least a degree of protection in respect of biosafety. To that extent, TRIPS in its present form supports the objectives of the CBD with respect to biotechnology.

TRIPS and the protection of genetic resources as intellectual property

As stated earlier, this paper will not attempt to address the relationship between TRIPS and the protection of indigenous knowledge related to genetic resources. However, with respect to IPRs for biotechnology, the provisions of the CBD raise an important issue concerning the genetic resources themselves. The Convention is the first international instrument to recognise a country's national sovereignty over its genetic resources. In the light of modern biotechnology, these resources include not only diversity of plants and animals, but also microorganisms sub-cellular living matter, including genes. The problem for biodiversity-rich developing countries is that relatively little is known about the extent of these resources, how they could be utilised, or what their 'worth' is in terms of economic or other benefits. There are many cases where genetic

[74] In the form of a Biosafety Amendment to the Research Act of 1986

resources from Africa have effectively become the proprietary technologies of scientists or companies in industrialied companies[75].

The provisions of the CBD aim to ensure that countries which give access to their genetic resources should share in the benefits of any commercially valuable innovation derived from them. Bioprospecting agreements and collaborative research arrangements between suppliers and users of genetic resources are two mechanisms used to achieve these aims. The Convention does not contain any moral or ethical objection to the ownership of life forms as intellectual property, and in this respect is not in conflict with TRIPS in *principle*. In practice, sovereignty and equitable benefit sharing are difficult to achieve given the existing knowledge and other resource gaps between north and south. This raises the issue of the commensurability of IPR with national technological capabilities. As technological capabilities in biotechnology increase, it will become more likely that developing country institutions or individual innovators will wish to protect biological material as their intellectual property. Consideration must be given to this when developing national IPR regimes. Whilst the major benefits from patenting genetic resources will continue to accrue to industrialised countries, there may be more appropriate mechanisms for protecting the interests of developing countries than exclusion from patentability of living matter.

There have therefore been some attempts made by developing countries to include as part of their patent regimes a requirement for the disclosure of the source country of genetic material used in patentable innovations. TRIPS does not explicitly preclude this, but on the other hand does not require it. As a result, industrialised countries are unlikely to incorporate acknowledgement of sources of genetic material in their IPR regimes. Further, no procedures have been developed for using such disclosures to recompense countries providing the genetic resources. This may be one area in which the CBD and the WTO might work together in future.

Synergies between CBD and TRIPS in respect of biotechnology

This section has tried to establish the extent and nature of existing and potential links between the TRIPS Agreement and the CBD in respect of biotechnology. It has been argued that the most obvious link, that which concerns 'adequate and effective' IPP as a precondition of biotechnology transfer in Article 16 of CBD has little practical significance. There is a strong (but probably temporary) link between biosafety in many developing countries and the current TRIPS provisions under Article 27. This will lessen in importance as and when national biosafety regimes are established. For the future, the protection of genetic resources as fundamental tools for biotechnological innovation may become an area in which the CBD member countries should work to enhance the provisions of TRIPS. In this respect, the TRIPS agreement is not supportive of the objectives of the Convention at present.

There are, however, other areas in which synergies between CBD and TRIPS can be identified and be exploited in the national interest. Such synergies can be found in the process of policy formulation to support implemention of the two agreements. In Section 2 it was argued that successful implementation of the provisions of the CBD with respect to technology transfer would depend on cross-sectoral cooperation. In Section 6 it was further argued that in respect of biotechnology, IPR should not be

[75] RAFI describes many of these cases. See RAFI 1994 for details

considered in isolation from other policy issues but rather as part of a national biotechnology strategy. This section has identified key policy areas where there are strong links between biotechnology, genetic diversity, the CBD and TRIPS. The formulation and successful implementation of policies in each of these areas will require:

- scientific, legal, administrative and policy expertise
- cross-sectoral, cross-ministerial, and cross-institutional cooperation
- consultation with 'stakeholders' at local, national and regional levels
- raising of public awareness and stimulation of public debate on key issues

It is clear that the same types of expertise are needed, and could be mobilised, in support of different policy regimes related to biotechnology, the CBD and TRIPS. Similarly, many of the same stakeholders, including ministries and other institutions should be involved in consultations and policy formulation. Linkages built between these stakeholders in support of one area of policy development can be utilised in other areas. Mechanisms devised to inform the public and provide fora for debate can be likewise adopted or adapted by the various policy areas. Synergies between CBD and TRIPS (*viz a viz* biotechnology) at an international level may be relatively weak, but synergies in their implementation at a national level exist and can be exploited. As with other recommendations emerging from this paper, time is a critical factor.

8. CONCLUSIONS

This paper has attempted to analyse the relationships between TRIPS and the CBD in respect of biotechnology. The relationships were found to be complex and policy issues raised by them, notably biosafety and the ownership of life forms as intellectual property, inextricably linked. Conclusions drawn from this study fall broadly into three categories. First are conclusions which relate to the most direct and obvious relationship between CBD and TRIPS, the reference to 'adequate and effective' IPR in support of technology transfer contained in Article 16 of the Convention. Next are issues concerning the wider, evolving relationship between TRIPS and CBD in respect of biotechnology. Last, are immediate concerns for consideration which relate to the forthcoming review of TRIPS Article 27.3(b) and its impact on CBD implementation.

Implemention of CBD Article 16

IPR regimes developed in support of TRIPS implementation will incur substantial costs in the short and medium terms, whereas potential benefits are likely to be long-term. In fact, there is no conclusive evidence that stronger IPR regimes implemented under TRIPS will play a significant role in promoting technology transfer, protecting genetic resources or building technological capacity in Africa. More evidence is required on the links between IPR and technology transfer to African countries, especially with respect to biotechnologies. This, in effect, means monitoring the implementation of Article 16 of the Convention.

Within the context of the CBD, the transfer of biotechnologies can be grouped into three categories:

- technology transfers made in *direct* recompense for access to genetic resources, for example (and primarily) as part of bioprospecting agreements;

- technology transfers arranged as part of GEF-funded projects in the area of bioversity; and
- technology transfers occurring incidental to CBD implementation.

Data on the first two categories should be, at least in principle, relatively easy to collect. GEF project documentation should give a good indication of what transfers have taken place in projects funded by this mechanism. Bioprospecting agreements which are well-known and can be monitored, such as the agreement between Costa Rica and the US-based company Merck, will also be useful for collecting evidence. However, many small-scale north-south collaborations exist, often between university departments, which are unrecorded at national level. Evidence of technology transfer here is more difficult to obtain. Similarly, biotechnologies transferred which are outside the scope of the Convention[76] are rarely recorded in any systematic form

Patent data has sometimes been seen as a suitable indicator of international technology transfer. However, in the current context of biotechnology transfer to Africa, it has several strong limitations. First, biotechnology patents are not easy to identify under present classifications. Biotechnology-related innovations may be patented under any one of a number of classifications[77], so that (potentially thousands of) individual patents under each of these have to be scutinised in order to identify those which are "biotechnology" patents. Second, patent data is only useful for gauging the transfer of *proprietary* technologies. It is biotechnologies which are already in the public domain in northern countries which are often most needed, and acquired. Further, the Zimbabwe study found that other forms of protection (notably, Trade Secrets) had been used to protect proprietary technologies.

Monitoring the implementation of CBD Article 16 requires the development of a suitable methodology. Country case studies would seem to be the most effective way of achieving accurate results. The GEF and the CBD's Conferences of Parties should consider endorsing and supporting such initiatives, especially given that the results may establish a clearer picture of the relationship between TRIPS and the CBD.

CBD and TRIPS

This paper did not set out to consider all aspects of the CBD/TRIPS relationship, but rather focus on the relationship between biotechnology transfer and IPR. However, it found that other policy issues were relevant to, and sometimes inseparable from, this relationship. These are, notably, public awareness, ethical and moral values, the socio-economic impacts of new biotechnologies, health and environmental safety (including the conservation of genetic resources), and protection of the commercial value of indigenous knowledge and genetic diversity.

It was argued that, where one area is debated and/or negotiated in complete isolation from other relevant issues, there is a wide margin for inappropriate decision-making. A good example of this relates to the apparent over-emphasis of some commentators (and perhaps national representatives) on the 'safety' (environmental and moral) provisions of TRIPS, and indeed national IPR regimes. may be taken. This is not to say that these provisions are irrelevant, but, as has been argued elsewhere,

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[76] In fact, most transfers would probably fall under this category. In the Zimbabwe case, *all* transfers did.

[77] For example, pharmaceutical patents, plant patents, biochemistry patents.

patent regimes should not be seen as the "only system of moral regulation" in respect of technological development[78]. Other mechanisms, particularly biosafety[79] regulations and public policy bodies, may be more appropriate. For developing countries, therefore, a priority area for policy development is biological safety.

However, biotechnology presents not only potential threats to the conservation of genetic diversity, but also opportunities to use a wide range of new (often inexpensive and accessible) technologies in support of conservation. This is recognised within the Convention, particularly in the provisions of Article 16 and Article 19 (Handling of biotechnology and distribution of its benefits). IPR for many fundamental building blocks of biotechnological innovations, particularly genes and microorganisms, remains controversial. On the other hand, debate is underway on the potential for new forms of IPR (*sui generis* systems) which could be tailored to protect local and/or national rights over genetic resources. It does appear, then, that IPR may be an appropriate mechanism to achieve the of the CBD objectives in respect of protecting sovereign rights over biological resources and ensuring the equitable distribution of benefits from their utilisation. In future, and in biodiversity-rich developing countries which succeed in building capacity in advanced biotechnology, even gene patents *may* have a positive role to play.

The point here is that biotechnology development, environmental safety, intellectual property rights and conservation of biological diversity are areas of policy which entail considerable overlap. Whilst policy regimes for each area are needed, national strategic planning merits careful consideration of the relationships between these areas. These relationships will generally have both positive and negative potential. Some aspects of the relationships will be stronger than others. This paper, for example, has suggested that the relationship between biotechnology transfer and TRIPS is relatively weak, at least in the African context. On the other hand, there is a potentially strong and positive relationship between the CBD and TRIPS in terms of technical and institutional capacity for their implementation. Examples of this include cooperation and consultation at regional, national and local levels, and the pooling of scientific and legal expertise. The major constraining factor is time, especially given the 1st January 2000 deadline for TRIPS implementation which applies to many developing countries and the need to take a considered position on the forthcoming review of Article 27.3(b) of TRIPS.

The 1999 TRIPS review

The major potential outcomes of the forthcoming review of TRIPS, including the provisions of Article 27.3(b), have been discussed. The United States and possibly other industrialised countries are likely to argue for a complete removal of this sub-paragraph, and/or the introduction into TRIPS of provisions for Plant Breeders Rights which conform those in force under UPOV. I have argued that there is little or no perceived advantage for most developing countries in these proposed amendments. The two main options favoured variously by different developing countries are the extension of

[78] Warren 1998

[79] Of course, biotechnology is not the only technology cover by IPR which may pose threats in this respect. The case of biotechnology is, in many countries, special because of the lack of alternative regulatory methods. Legislation and other regulatory mechanisms are often in place to handle more mature technology (national standards boards, nuclear safety agencies, etc)

the provisions of Article 27.3(b), or its retention as it now stands. Other commentators have made reasonable and well-balanced arguments supporting each of these options[80]. The general hypothesis seems to be that the most likely outcome is a preservation of the status quo. This paper, looking at the issues from the perspective of biotechnology transfer, deployment, development and regulation in (particularly) Africa, suggests that this is probably the most favourable option.

The arguments for extending the provisions of Article 27.3(b) to allow national IPR regimes to exclude living matter (other than plants and animals, which are already covered by the sub-paragraph) are, broadly, twofold. First, novel microorganisms are perceived to be potential threats to health and environmental safety (including bioversity) and in some cases (for example, human genes) the legal protection of their commercial exploitation is morally questionable. I have no argument with this. However, I tend towards the view that IPR legislation is not the most appropriate or effective way to protect physical and moral well-being. With respect to biotechnology, it is clear that the formulation and implementation of national and international biosafety regimes should be an immediate priority.

The second, and in my view, stronger argument in favour of extending Article 27.3(b) is that the existing requirement to allow the patenting of microorganisms largely favours countries with a strong capacity in advanced biotechnology. Most developing countries lack such capacity, and therefore this requirement of TRIPS is not likely to be commensurate with national needs at this stage in their technological development. Again, this is indisputable, and countries *should* be given the flexibility to tailor their IPR regimes accordingly. Unfortunately, opposition to the extension of the provisions of Article 27.3(b) will be strong, if not insurmountable. Even if such a change could be successfully fought for, this would undoubtedly entail substantial concessions[81] elsewhere. The potential political (and probably economic) costs would therefore need to be weighed against the potential benefits of an 'optimal' IPR regime for each individual country. Those benefits depend on what is 'optimal' IPR for a given level of indigenous technological capacity. The level of the benefits logically decreases as technological capacity increases. Developing countries who are actively building capacity in biotechnology have less to gain in terms of benefits than those with no capacity at all, and therefore will be prepared to make fewer concessions to achieve changes to Article 27.3(b). Negotiating an extension of the provisions of Article 27.3(b) would in consequence not have unified support at a consistent level from developing countries. Divisions on this issue could have adverse implications in other areas of negotiation.

A final point on this issue is that many countries are not in a position to decide what would *be* an 'optimal' IPR regime in respect of biotechnology development in their country. Few countries (especially in Africa) have sufficient baseline data, on indigenous biotechnological capabilities and the potential for biotechnology development, to make such an assessment. Again, this is an area which needs to be addressed in many countries. And, again, this paper argues that time is a critical factor. The need for developing countries, especially in sub-Saharan Africa where policy

[80] For example, The Gaia Foundation (1998) argues for an extension of the provisions, as mentioned earlier. Patrick Mulvaney (1998), of the Intermediate Technology Development Group, on the whole favours maintaining the status quo.

[81] Including, perhaps, 'involuntary' concessions such as retaliatory trade sanctions

development in the area of biotechnology is generally at a very early stage, favours maintaining the status quo with respect to Article 27.3(b). Of course, the provisions of TRIPS Article 27.3(b) will be subject to further review as early as next year. I would argue that several years will be needed for even the most technologically advanced African countries to develop and implement appropriate policy regimes to manage biotechnology. If the 1999 Review decides to leave Article 27.3(b) unchanged, but insists on setting a time-scale for further review of its provisions, I suggest that the scheduled TRIPS review of 2004 would be the earliest appropriate time for this.

Time and resources are needed for developing countries to decide, in consultation with their own people and with their neighbouring states where appropriate:

- what opportunities and threats modern biotechnology presents for them;
- how best to exploit the opportunities and minimise the threats; and
- what policies, mechanisms and expertise are needed to achieve this.

Countries need time and resources to build technical and institutional capacity, to stimulate and inform public debate, to address moral and ethical issues, and to formulate a cohesive national strategy for biotechnology development. Policies for the implementation of CBD and TRIPS in respect of biotechnology form a part of this wider policy context and should not be developed in isolation from it. Where policies and legislation *must* be implemented before broad national strategies can be developed, as is the case of TRIPS, these should be as flexible as possible to facilitate future changes[82].

[82] Zimbabwe's Patent Act and Plant Breeders Rights Act may serve as useful models for TRIPS implementation in other African countries.

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Appendix 1

ARTICLE 16 of the CONVENTION ON BIOLOGICAL DIVERSITY

1. Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.

2. Access to and transfer of technology referred to in paragraph 1 above to developing countries shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21. In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights. The application of this paragraph shall be consistent with paragraphs 3, 4 and 5 below.

3. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, 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, where necessary, through the provisions of Articles 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 below.

4. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph 1 above for the benefit of both governmental institutions and the private sector of developing countries and in this regard shall abide by the obligations included in paragraphs 1, 2 and 3 above.

5. The Contracting 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.

Appendix 2

ARTICLE 27 of the TRIPS Agreement

Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3 below, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

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

3. Members may also exclude from patentability:
   (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
   (b) plants and animals other than microorganisms, 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 sub-paragraph shall be reviewed four years after the entry into force of the agreement establishing the WTO

TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS) AND THE CONVENTION ON BIOLOGICAL DIVERSITY: SYNERGIES AND CONFLICTS.

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UNEDITED BACKGROUND PAPER

Introduction

In July 1998 ACTS circulated a proposal to donor agencies and African government representatives suggesting an initiative to examine the nexus between Article 27 (3) (b) of TRIPS and environmental issues, more specifically the Convention on Biological Diversity (CBD). This constitutes an effort to prepare African delegations for the GATT / WTO renegotiation process scheduled to be held in June 1999. The need for such an effort became apparent due to certain policy failures relating to the TRIPs / CBD nexus in Africa. These failures are caused by the lack of a clear understanding and position relating to intellectual property issues in general and in particular how intellectual property protection converges with the conservation, access, control and exchange of genetic resources. Part of this lack of understanding and position has resulted from the handling of WTO matters almost exclusively by ministries of foreign affairs and trade. Thus environmental concerns, if mentioned at all, have been very much in the background of Africa's participation in the WTO. However, many states have expressed concern over these failures and have requested, in fora such as the 4th Conference of the Parties (COP4) to the CBD, actions for their correction. These requests have been followed up by an enthusiastic response to the ACTS proposal. Towards implementing the initiative ACTS will hold various national and regional consultative sessions, commission papers, host an international conference in February, 1999, and ultimately assist African delegates in Geneva with technical support.

The main objective of the initiative is to develop a unified African position on the renegotiation of TRIPS Article 27 (3) (b) in light of the CBD, an objective also identified as a priority by the Organisation of African Unity (OAU). Corollary objectives include: capacity building in the area of protection of indigenous knowledge and rights, access to genetic resources and technology transfer; raising public awareness on the TRIPs/CBD nexus through publications, presentations, technical advice, general debate and discussion; mobilizing and informing regional participation in WTO and CBD processes through the forging of sustainable linkages and political alliances; and finally to identify specific policy options and issues - those that pertain to the region's interests and conditions - to be considered in the revision of TRIPS in 1999. After the said renegotiation conference we strongly feel that it is essential to follow up on the project and thus will prepare a report on the outcome of the review process and the issues that African states should consequently focus on. Further we hope to build a network, consisting of governments and private sector entities working in areas affected by the CBD and TRIPS, whose role is to exchange information and ensure that action is taken towards implementation of the African initiative.

This paper is intended to provide a background to the environmental issues enmeshed within TRIPS Article 27 (3) (b) to facilitate debate, assist in the identification of problems and stimulate the formulation of ideas and policies to address such. Accordingly the paper will first proceed to examine CBD Article 15. This will be followed by a discussion of TRIPS Article 27, and sub-clause (3) (b) in particular. To compliment the discussion of sub-clause (3) (b) there will then be a discussion of *sui generis* options. In conclusion there will be an emphasis on why it is imperative to be prepared for all the implications that the renegotiation encompasses.

The Convention on Biological Diversity (CBD)

The Convention on Biological Diversity, which was opened for signature at the Earth Summit and entered into force in December 1993, is an extremely influential legally binding international instrument, having now been ratified by over 160 countries[1]. The notable exception to this wide endorsement being the United States of America. The CBD has three main interdependent pillars: the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. In ratifying the convention countries have committed themselves to, *inter alia*: developing national strategies and plans for the conservation and sustainable use of biological diversity; identifying and monitoring the components of biological diversity; establishing a variety of measures to conserve biodiversity *in situ*, such as through the creation of protected areas; and establishing a variety of measures to achieve *ex situ* conservation.

One of the central features of the Convention is the establishment of an international regime regulating access to genetic resources. The heart of this regime is embodied in Article 15[2]. The regime itself is not laid out, rather there are a set of guidelines and a requirement for the enactment of national legislation that fits them. A mere handful of countries have enacted legislation or regulations relating to access to genetic resources, these include the Philippines, the Andean Pact countries, India and Malaysia and most of this action has only occurred within the last few years. The final stage of negotiations for the CBD took place in Nairobi in 1992[3] but to date the Kenyan government has not enacted any form of implementing legislation, although initiatives are underway[4].

The area of biological diversity, and genetic resource access in particular, should not be underestimated, its significance to all economies is enormous and it shows great promise for growth. It is estimated that foreign genetic resources have added $3.2 billion to the $11 billion annual U.S. soybean crop and about $7 billion to the $18 billion annual corn crop[5]. This is quite apart from the fact that all of the top 15 crops in the U.S., with annual sales of $50 billion, originally come from foreign sources[6]. Then there is the pharmaceutical industry, which is considered to be one of the U.S.' most internationally competitive industries, where the sale of pharmaceuticals based on traditional medicines alone have been estimated to amount to more than $32 billion annually[7].

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[1] FARNEWS 6/23/97 AIWASAH 12/96 (Westlaw)

[2] Convention on Biological Diversity, Article 15, June 1992.

[3] Convention on Biological Diversity, June 1992.

[4] The Kenyan Government has created an inter-agency committee, which has in turn created an expert working group, with the mandate to draft legislation on access and benefit sharing issues. There is also a process of establishing a working group to produce interim guidelines regulating access to plant germplasm.

[5] CR-140 Cong. Rec. s14046-01. (Westlaw) Letter from Archer Daniels Midland Co. to Congress urging ratification of the CBD.

[6] UNEP, 1992 – quoted in: BIOPOLICY INTERNATIONAL 17- MANAGING ACCESS TO GENETIC RESOURCES at 1 (John Mugabe et al., 1996).

[7] RAFI, 1994 – quoted in: BIOPOLICY INTERNATIONAL 17- MANAGING ACCESS TO GENETIC RESOURCES at 1 (John Mugabe et al., 1996)

The "authority to determine access to genetic resources rests with national governments and is subject to national legislation"[8]. Article 15 (1) of the CBD is arguably the most significant element of the access to genetic resources regime. It's principle of national sovereignty over such resources is a marked break with custom and practice in the field[9], while it is the principle upon which the rest of the regime is based. There have been isolated instances of countries treating genetic resources as protected interests[10], but in general the rule has been that they should be an "unregulated and freely accessible good"[11], on the theory that only such a system can provide research and commerce with all they require[12]. The difficulties with this system have become increasingly apparent as the developing countries have become more assertive on the world stage at the same time that possible uses for genetic resources have multiplied due to technological change. The key areas to this point in time are the pharmaceutical industry and agriculture, both of which are usually significant sectors in developed countries' economies. The great majority of natural components of medicines and of germplasm used to increase the resistance or yield of crops come from developing countries while the bulk of the benefits from such things is realized by developed countries[13]. Particularly in the case of agriculture the inequities often still persist even where a developed country is prepared to share it's discoveries as any technology produced is often not of relevance to the developing country's circumstances. The principle of national sovereignty is thus largely a means by which the developing countries believe they can gain a more equal share in the benefits that their genetic resources are capable of providing[14]. It must be noted that the CBD is not intended to make any reference to the question of property rights which are seen as remaining exclusively in the domestic realm, thus "their resources" refers to the resources within a given state's jurisdiction[15].

Article 15 (2) basically states that Contracting Parties should facilitate access to their genetic resources by other Contracting Parties and that they should also endeavor to remove any restrictions on such access that run counter to the Convention's objectives[16]. This is qualified by the statement that only access for "environmentally sound uses" needs to be facilitated. The use of the word "facilitate" has been used to interpret Article 15 (2) as allowing a degree of room for countries to determine what

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[8] Convention on Biological Diversity, Article 15 (1), June 1992.

[9] A GUIDE TO THE CONVENTION ON BIOLOGICAL DIVERSITY, *IUCN Environmental Policy and Law Paper No. 30* at 76 (Glowka et al. 1994)

[10] The case of the 19th century Chines prohibition of the expert of silkworm larvae is a classic example. ACCESS TO GENETIC RESOURCES - STRATEGIES FOR SHARING BENEFITS, 7 (John Mugabe et al. eds., 1997). There is also Thomas Jefferson's rather famous smuggling of protected rice samples from Italy to America in the 18th century.

[11] BIOPOLICY INTERNATIONAL 17 - MANAGING ACCESS TO GENETIC RESOURCES (John Mugabe et al., 1996)

[12] Glowka et al. *supra* note 9 at 78.

[13] GLOBAL BIODIVERSITY ASSESSMENT (V.H. Heywood ed., 1995)

[14] John Mugabe et al. eds. *supra* note 10 at 7.

[15] Glowka et al. *supra* note 9.

[16] Convention on Biological Diversity, Article 15 (2), June 1992.

policy they will adopt in terms of encouraging or discouraging biodiversity prospecting activities[17].

The customary principle of international law that treaties should not be retroactive is embodied in Article 15 (3). This states that only genetic resources provided by countries of origin, or by those to whom such resources have been transferred from countries of origin under the authority of the CBD, are covered by the Convention[18]. The significance of this largely relates to what is not covered by the Convention, i.e. resources acquired by whatever means prior to the entry into force of the Convention or resources acquired illegally after the entry into force.

A major issue of concern, in this area, to potential source countries is what has come to be known as "bio-piracy"[19]. This operates on two basic fronts. First is the fact that developed countries intellectual property regimes do not take any account of the ultimate origin of genetic material. Thus it is virtually impossible to say what is already housed in the developed countries' ex-situ collections - who's to know what was collected before and what after the entry into force of the Convention? The real sting to this is that the developing countries are required to recognize the force of foreign intellectual property rights under the GATT-WTO/TRIPS regime and thus they may be restricted from utilizing their own resources[20]. The whole system operates rather like the old real property theory that he who utilizes the land owns it and in a world that, at least publicly, now knows we should not be constantly striving to make maximum use of everything it seems a little anachronistic. The issue becomes even more complex as the Convention enters into force at different times for different Contracting Parties depending upon when they acceded[21]. For this reason there is increasing pressure for *ex situ* collections created prior to the CBD to be brought within the ambit of the Convention.

Another problem is that there is no definition of "provided" in terms of an actual moment. Thus if a biodiversity prospector makes use of genetic resources within the jurisdiction of the country of origin have the resources actually been "provided" and is a resource "provided" when a country of origin agrees to it's use, when it is received by the user, or at some intermediate moment?

Finally there is the sanction for those who illegally obtain resources. This is that they have no entitlement to benefit sharing as regards any Contracting Party to whom they pass the resources[22]. This in itself would seem to be a fairly weak, if not negligible, sanction. What might be more convincing is that other Contracting Parties would be likely to be cautious about any future dealings with such an illegal actor.

In Article 15 (4) the Convention requires that access agreements are to be made on the basis of "mutually agreed terms"[23]. This places an affirmative

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[17] John Mugabe et al. eds. *supra* note 10 at 19.

[18] Convention on Biological Diversity, Article 15 (3), June 1992.

[19] FARNEWS 3/31/97 BUSLINE 11 (WESTLAW)

[20] Id.

[21] Glowka et al. *supra* note 9.

[22] Id.

[23] Convention on Biological Diversity, Article 15 (4), June 1992.

burden upon both potential parties of an access agreement to negotiate terms, and even a strict obligation is implied in the use of the word "shall"[24]. There are several issues that arise from this article, the most obvious of which is that international treaties only bind state actors so that until a Contracting Party enacts domestic legislation it will be unable to use the Convention to force the negotiation of terms with private parties. This in itself has ramifications in that in acceding to the Convention a Contracting Party has accepted an obligation to enact domestic legislation. Should it fail to do so within a "reasonable period" it could potentially be liable for any loss of benefits that resulted from its breach of obligation under international law[25].

Another issue related to mutually agreed terms is that the concept of flexible negotiation is implicit and thus a state is precluded from setting rigid guidelines for the conduct and final form of access agreements. This does not, however, preclude a system of minimum requirements such as that used in the Philippines[26].

It should also be noted that the obligation to reach mutually agreed terms only affects relations with Contracting Parties. The consequences of this are that one has no obligation towards a non-member state, an issue of major import when one considers that the United States is the major non-member.

A final issue is that the Convention does not specify with whom one ought to reach mutually agreed terms. Should it be the country of origin's government, a private owner, a private owner subject to government review or should one conclude a tri-partite agreement? [27].

The concept of Prior Informed Consent (PIC) is presented as quite basic to the whole strategy of access agreements and is embodied in Article 15 (5)[28]. In some ways it can be seen as an adoption of what is considered a standard practice in the commercial world, make sure you know what you're getting yourself into and if you have any doubts insure against them. This is achieved through a requirement that potential users of genetic resources provide information to the country of origin prior to the negotiation of any access agreement. Should such information prove to be inaccurate or incomplete then it would constitute a breach of the access agreement process and thus invalidate it, much like the concept of a "meeting of the minds" in contract law. There are several issues which are problematic here, most of which result from the vagueness of the Convention. It's not exactly clear what information needs to be provided and to whom it should be provided. The prevailing view seems to be that users ought to provide details of who they are, the kind and amount of resources they intend to collect, the uses to which they intend to put those resources and the expected results of the research[29].

The information on intended uses and expected results runs into the area which has been most controversial, and has been the main reason given for

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[24] John Mugabe et al. eds. *supra* note 10 at 77.

[25] Id. at 76.

[26] Glowka et al. *supra* note 9.

[27] Id.

[28] Convention on Biological Diversity, Article 15 (5), June 1992.

[29] John Mugabe et al. *supra* note 11.

the U.S. hesitancy to ratify the Convention, which is the question of intellectual property rights (IPRs). Much information regarding uses and expected results from research involving genetic resources falls within what has traditionally been seen as protected information as it gives a strong idea of how somebody intends to conduct their research. However, mounting pressure on the U.S. Senate to ratify the Convention would seem to indicate that western institutions are more afraid of losing access than IPR rights[30].

It is also possible that too detailed a PIC requirement could be attacked as a restrictive practice contrary to the aims of Article 15 (2). Another difficulty is the same as that involved with Article 15 (4), who does one provide PIC information to? The Convention is concerned principally with state actors but there is obvious consideration of private individuals and bodies.

The final problem in this area is yet another incentive for Contracting Parties to enact domestic legislation. PIC is at the discretion of the country of origin so that if they have not enacted legislation requiring it then it cannot be argued that it is necessary[31].

Article 15 (6) is concerned with promoting the "full participation" of both the user country and the country of origin in any research based on genetic resources, where possible in the country of origin[32]. This is phrased in the terms that Contracting Parties "shall endeavor" to achieve such goals, this may or may not be an obligation and as such is taken not to be one[33]. The obvious assumption here is that countries of origin are generally developing while user countries are generally developed and the intention is thus capacity building through the "soft transfer" of technology. Another potential benefit is that joint research programmes are more likely to consider benefits that may be exclusively relevant to developing countries and thus are often missed[34]. This is an article of great potential benefit to the developing world but it is a benefit that may never be realised due to the lack of an affirmative obligation and the developed countries' traditional reluctance to part with any more technical information and expertise than is necessary.

As mentioned in the earlier discussion of national sovereignty over genetic resources the basic issue in Article 15 of the CBD is the question of the allocation of benefits resulting from research related to such resources. This subject is explicitly addressed in paragraph 7 which requires Contracting Parties to undertake any necessary legislative, administrative or policy measures to encourage the "fair and equitable sharing" of any benefits, whether research results or monetary gains. Article 15 (7) also cross-refers to Articles 16 and 19 which bring in the sharing of technology used to utilize the genetic resource[35]. It is this area which developed countries find the most problematic. The reason for this is that the Convention nowhere explicitly states how benefits should be shared and how

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[30] CR-140 Cong. Rec. s14046-01. (Westlaw) Letter from Archer Daniels Midland Co. to Congress urging ratification of the CBD.

[31] Glowka et al. *supra* note 9.

[32] Convention on Biological Diversity, Article 15 (6), June 1992

[33] John Mugabe et al. eds. *supra* note 10 at 82.

[34] Glowka et al. *supra* note 9.

[35] Convention on Biological Diversity, Article 15 (7), June 1992.

far strict requirements by a country of origin could be enforced[36]. It is not so much that the Convention contains such harsh implications but rather that the developed countries are concerned at the possibility of being outvoted by the Developing World Contracting Parties at some future meeting aiming to clarify the area. Having already acceded to the treaty it would be that much more difficult to escape the situation.

The range of possible benefits runs through various types of monetary compensation such as one off payments and royalty agreements through to the transfer of new technology that is developed with the use of the genetic resources. Benefits might not actually be related to the particular research project but could be some other form of technology, as long as the country of origin is receiving a tangible and appropriate recognition of it's position as such.

Another question in this area is yet again the question of who exactly is involved in this benefit sharing process. The implication in the Convention is that this should be left to national policy but there are definite indications that it should be a broad-based policy. One of the Convention's overarching themes is that of conserving biodiversity and to further this end it is likely to be necessary to directly include the local inhabitants of any area from which genetic resources come[37].

Trade Related Aspects of Intellectual Property Rights (TRIPS)

Since the 1970's the developed world has been pushing for a stronger international regime to regulate intellectual property rights than was afforded by the existing instrument in the field, the Paris Convention. Of particular concern has been the fact that the Paris Convention does not provide any requirement for minimum standards of patent rights and neither does it adequately restrict the use of compulsory licenses to circumvent patent restrictions[38]. In the background was also the fact that the Developed World had become increasingly concerned by what it saw as the pirating of its technological achievements by developing countries. The solution came to be seen as consisting of a reduction in global intellectual property protection disparities through the creation of a legally binding, unified international regime[39]. This push culminated in the April 1994 promulgation of the Agreement on Trade Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods of the General Agreement on Tariffs and Trade (TRIPs) by the GATT membership.

The opposite side of the argument was that of some of the developing countries who argued that strict international standards for intellectual property rights would hinder effective technology transfer, and thus limit development opportunities, by failing to recognize varying situations[40]. The members adhering to this position were defeated but the idea is put forward in the preamble to TRIPs:

> *Recognizing* also the special needs of the least-developed country Members in respect of maximum flexibility in the domestic

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[36] John Mugabe et al. *supra* note 11.

[37] Id.

[38] Paris Convention for the Protection of Industrial Property, Article 5 (2) & (4) (1967).

[39] Glowka et al. *supra* note 9.

[40] Id.

> implementation of laws and regulations in order to enable them to create a sound and viable technological base

The embodiment of this recognition is to be found in Article 66. This article allows least developed countries (LDCs) an initial opt out from all but the national treatment and most favoured nation (MFN) elements of TRIPs (Articles 3, 4 and 5). Despite this nowhere in TRIPs is there a recognition of any specific LDC circumstances and / or problems, such as traditional knowledge.

The option is given in Article 1 (1) for more extensive protection than is provided for in TRIPs but only on the condition that such protection does not conflict with any of the Agreement's provisions. This precludes most extensions of patent protection that would benefit LDCs. An example of this problem can be found with most forms of traditional knowledge, protection of which is blocked largely due to the nature of Articles 27 and 29. Further, TRIPs exclusively considers the patent rights of individuals and not those that might be communally held, whether by local communities or a nation as a whole. This is the origin of difficulties such as the W.R. Grace patent issued for Neem derivatives. In Article 29 (1) it is required that a patent applicant reveal sufficient information regarding the invention that a person "skilled in the art" would be able to produce the product or complete the process. Such a clause is standard throughout Developed World intellectual property legislation. This requirement creates problems in that many elements of traditional knowledge are bound up with ceremonial events or are held in sacred trust and thus protection cannot be sought without violating some basic principle of the peoples involved. This choice between protection of one's rights and maintenance of one's principles would seem to be a case of being "stuck between the devil and the deep blue sea".

Article 27 provides both further restrictions on patentability in various areas and the one clause that could be used to create greater flexibility. Article 27 (1) of TRIPs states that:

> patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.

The "inventive step" and "capable of industrial application" requirements are deemed "to be synonymous with the terms 'non-obvious' and 'useful' respectively." These terms are once again standard in Developed World intellectual property legislation. The effect of this is that the developed countries have already extensively litigated a large range of questions related to these terms and thus very specifically defined them. On the other hand most developing countries have barely, if at all, written their intellectual property legislation[41] and have certainly not advanced far with defining the exact meaning of many terms. The tendency in such a situation is for the definitions provided by the Developed World to remain dominant for want of any alternative. This kind of situation means that LDC conditions are not adequately catered for. Traditional knowledge once again provides a good example, it will probably be declared unpatentable on one, or all, of the "new", "inventive step" and "industrial application" standards.

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[41]For instance Kenya's industrial property legislation was hastily drafted in 1989 when it was believed that Kemron would be the wonder drug for HIV/AIDS and it is only now being reviewed and amendments proposed.

Article 27 (2) allows the exclusion from "patentability inventions, the prevention of which is necessary to protect *ordre public* ...including to protect human, animal or plant life or health...". The clause could feasibly be used to prevent the patenting of particular types of knowledge by anybody in a state that decides to enact such a law. The difficulty is with how far one can go to preserve life or health, as the Argentineans found to their cost when they refused to grant patents for pharmaceuticals[42].

It is Article 27 (3) of TRIPs that contains the best options for creating a more flexible, Developing World friendly, system of IPRs. However, due to the fact sub-paragraph (b) is due for review in mid 1999 it also constitutes the greatest potential area of conflict. Sub-paragraph (a) is the simpler of the two sub-paragraphs in that it allows for the exclusion of "diagnostic, therapeutic and surgical methods for the treatment of humans or animals". This derives from the humanitarian idea that it is unethical to restrict such fundamental aids to health and survival. However, what is often overlooked is what is not covered here. It is methods that may be excluded and any hard technology[43] is still required to be subject to protection. This effectively guts the value of Article 27 (3) (a) as regards many methods since knowledge of the method is useless without knowledge of the accompanying hard technology. This is a particularly controversial area with many developing countries traditionally allowing the exclusion of things such as pharmaceuticals from intellectual property protection, as mentioned earlier under Article 27 (2). Despite being a much debated area the countries concerned are not likely to be able to continue with this tradition, particularly after the recent success of the United States in forcing India, among others, to adopt intellectual property protection for pharmaceuticals. This affects things such as traditional knowledge as while a state may exclude the method that is used to employ something such as a traditional medicine, thus preventing it's privatization, they cannot do the same for the actual medicine. Once the relationship between a particular compound and an ailment is known, which will be easy to do since if excluded the method will be in the public domain, a research-oriented company could protect a derivative product against the world. The result of this somewhat paradoxical situation is that a state is unlikely to want to exclude traditional methodology from protection since by doing so it will simply be providing signposts to compounds that may be subsequently protected against the people who facilitated their discovery in the first place. The same sort of risks are also going to be involved with agricultural products. Ultimately all such information is likely to become more restricted and thus less available to those with limited means.

Sub-paragraph (b) of Article 27 (3) represents a compromise between the interests of the Developed and Developing worlds. Its main function is to allow for the prevention of the patenting of life, whether plant or animal. The Developed World has predictably declined to make use of this exception and, led by Europe and the United States, has made moves to explicitly allow for the protection of life forms. On the other hand the Developing World, with it's limited or non-existent research capacity in the area of cutting edge biotechnology, has generally preferred not to provide any

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[42] Bhala and Kennedy, *World Trade Law*, Lexis Law publishing, 1998 at 1175.

[43] "Hard technology" being taken as consisting of things such as machinery, computers, pharmaceuticals etc. This is as opposed to "soft technology" that consists of things such as know how.

protection for life-forms. This means that both methods and products can be kept freely, and more importantly cheaply, available. Like most compromises Article 27 (3) (b) is also at the heart of the controversy surrounding TRIPs. It has been argued that the sub-clause's requirement for the protection of plant varieties by either patent, a sui generis system or a combination of the two simply allows for legal monopolies of what were traditionally common resources. While this may not be a beneficial change it seems that it is one the world must learn to live with. If taken in this light Article 27 (3) (b) potentially provides a useful avenue for the defence of much knowledge. The sub-clause does not expand upon the nature of a sui generis system and thus, so long as some form of protection is provided, one could shape a system in almost any way that one wished. For instance there is no reason why one could not allow for the protection of community resources and knowledge that do not fulfill the requirements of the patent system. There is also no real reason why one could not provide protection through negative rights such as a blanket prohibition on the patenting of endemic resources. The argument for this would simply be that one is protecting the rights of a wider group of people. There would, however, be a fight over this as the Developed World will surely argue that it does not constitute an ***effective*** sui generis system. While such a broad approach to Article 27 (3) (b) seems to be quite permissible the difficulties are twofold. First is the fact that states interested in pursuing such an approach will have to resist tremendous pressure not to. The second is that the sub-clause is due for review in mid-1999. Tension is already building over the polar positions of wanting to abandon Article 27 (3) (b) altogether or dramatically expanding it's scope. Neither of these positions is widely held but what is being put forward is that the sub-clause must be maintained to allow states to take advantage of options such as those discussed above.

Sui Generis Options

As has been discussed earlier the *sui generis* allowance in TRIPS, if used correctly, has tremendous potential for creating a system of biotechnological/biological IPRs that is more suited to Developing World needs. Many Developed countries see Article 27 (3) (b) as stating that if one does not grant patents for plant varieties then one should adhere to the International Convention for the Protection of New Varieties of Plants (UPOV). For this reason there will be some discussion of UPOV as a *sui generis* option. However, there is no explicit requirement to adopt UPOV and thus other options will also be considered, including a suggestion for an original system.

International Plant Variety Protection: The International Convention for the Protection of New Varieties of Plants (UPOV) and Terminator technology

UPOV was established in 1961 and has been revised twice, in 1978 and 1991, since it's inception. The Convention will not be examined in great depth for two reasons. The first is that it does not present great opportunities for the advancement of Developing World interests and the second is that with only thirty seven countries belonging to the Union it is largely an irrelevance[44].

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[44] It is entirely possible that this will change in the near future as there is tremendous Developed World pressure on Developing Countries to join UPOV. For example the US Government's statement of position on the TRIPs review agenda which states that the excision of Article 27(3)(b) and the official recognition of UPOV should

The basic theme of UPOV is that it requires the protection of a new plant variety's original breeder's right to breed and sell that new variety. To fall within the ambit of UPOV a variety must be "new, distinct, uniform and stable"[45]. This presents all sorts of difficulties for varieties developed by traditional or microenterprise methods. To start with it is difficult to tell whether they are new since in many cases they may have been utilized for untold decades, or even centuries. If one manages to get past this requirement one then has to contend with the fact that distinct, uniform and stable do not allow for the prevalent preference of traditional communities for variability and adaptability[46]. There are likely to be a multiplicity of varieties that are only slightly different in their characteristics and which could be altered on as frequent as an annual basis.

However, the key points of interest are the differences between the 1978 and 1991 texts of UPOV. In the 1978 version a farmer was only prevented from commercially selling propagating material from the new variety, there was no restriction on his using saved seed for planting crops in years subsequent to his initial purchase of the new variety[47]. This is particularly important when one considers that approximately 80% of Developing World farmers' seed requirements are met by farm-saved seed[48]. In the 1991 text all use of propagating material is prohibited. The only loophole to this is that Article 15 (2) allows Union members to limit the scope of protection and thus they may allow for farm-saved seed use. The reason that UPOV has concerned itself with this area is that until recently the only way to prevent farm-saved seed use was with hybrid varieties as they naturally produced sterile seeds. This whole area has now largely been superseded by U.S. Patent No. 5,723,765, "Control of plant gene expression", which was granted in March 1998. The so-called "Terminator technology" consists of a gene that can theoretically be inserted into any crop that is propagated by seeds and which will induce sterility in any seeds from the crop[49]. The implications for either a UPOV limitation of use or Terminator technology are tremendous for all Developing World farmers but also have implications for traditional knowledge. If traditional resources are used to produce a new variety of a plant, that plant can be protected against the original providers in a UPOV member state unless the state has invoked the UPOV exception. If the state concerned is not a UPOV member, or has invoked the exception, then Terminator technology can be used to make the whole issue academic. Another worrying element is the fact that the Terminator technology patent allows for the protection of any and all "plant cells, tissues, seeds and whole plants of any species containing the [relevant] genes"[50]. Obviously the introduction of Terminator technology is considered to constitute a sufficiently novel step in and of itself to deserve patent protection. Whatever the exact situation it is clear that a new variety of a traditionally used plant can be protected

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constitute the agenda. This becomes increasingly difficult now that the deadline for joining UPOV 1978 has expired.

[45]UPOV, Article 6 (1).

[46]Posey and Dutfield, Beyond Intellectual Property at 89 (1996).

[47]UPOV, Article 5 (1).

[48]Volker Lehmann, *Patent on seed sterility threatens seed saving* in Biotechnology and Development Monitor No. 35 at 6 (June, 1998).

[49]Id.

[50]Id. at 8.

against use by it's original discoverers. There is another dimension to the Terminator Gene debate with the possible recent discovery of a "Promiscuous Gene" that can transfer itself among species without sexual activity. If this proves to be true it's combination with the Terminator Gene, which has already displayed it's ability to transfer to nearby plants, could prove deadly.

International Plant Variety Protection: The International Undertaking on Plant Genetic Resources

The International Undertaking on Plant Genetic Resources is a curious creature that is not legally binding and has a wide membership[51]. The Undertaking holds that plant genetic resources are the heritage of mankind that should thus be "available without restriction"[52] but at the same time recognizes that such resources are subject to sovereign rights[53] and do not need to be provided free of charge[54]. Not only this but the Undertaking also maintains that it is compatible with the systems of plant breeders' rights called for in UPOV[55]. The seemingly contradictory nature of the Undertaking is undoubtedly the result of an attempt to keep up with international trends that have superseded it and produced the CBD.

The Undertaking could be used to protect Developing World interests through its recognition of sovereign rights or it's recognition of plant genetic resources as the heritage of mankind. The former could be used to prevent alienation of any resources as sovereign rights are universally recognized to be inalienable. The latter could be used as one cannot restrict the use of the heritage of mankind and thus a traditional community would always maintain it's right to utilize such resources. Of course this point would not allow a community to benefit from its resources but at least they would be no worse off than they were initially. The problem is that these two approaches are mutually incompatible. If for no other reason this incompatibility, combined with it's non-legally binding status, should be enough to allow one to disregard the Undertaking as an anachronism. This is, however, another initiative that needs to be watched as the current revisions have been gaining a large base of support and definitely constitute an attempt by the FAO to keep itself at the centre of the debate.

Human Rights Options

If a state wishes it could decide to create it's own *sui generis* system, whether from scratch or based upon an existing system. For this reason it is worth taking a broad view of the options available. Although they might seem to be out of the relevant field, even human rights instruments can be useful. The UN Draft Declaration on the Rights of Indigenous Peoples states in Part II Article 7:

> Indigenous peoples have the collective and individual right not to be subjected to ethnocide and cultural genocide, including prevention of and redress for:...

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[51]One Hundred and Ten states adhere to the undertaking. Glowka et al.*supra* note 9.

[52]The traditional pre-CBD and TRIPs view of these resources. International Undertaking on Plant Genetic Resources, Article 1 (1983).

[53]International Undertaking on Plant Genetic Resources, Annex III Resolution 3/91 (1991).

[54]International Undertaking on Plant Genetic Resources, Annex I Resolution 4/89 (1989).

[55]International Undertaking on Plant Genetic Resources, Annex I Resolution 4/89 (1989).

> b) Any action which has the aim or effect of dispossessing them of their lands, territories or resources;

It is quite clear that traditional knowledge must fall within the realm of the "resources" of indigenous peoples and thus their exclusion from it's benefits could be argued to be a case of "ethnocide and cultural genocide". This has the advantage of preventing any party from defending the use of traditional knowledge and it's derivatives against the original providers. On the other hand it cannot be used to protect the rights of the holders of traditional knowledge against its use by parties outside of the actual state in question and thus it only goes half way towards a real solution[56]. Despite this one could use such an instrument as a part of, or justification for a part of, a more comprehensive *sui generis* system.

Trade Secret protection as a foundation for a *sui generis* regime

Within TRIPs itself there is a section that deserves examination as a possible foundation for a *sui generis* regime: Section 7 Article 39, Protection of Undisclosed Information. In common parlance this is known as trade secrets protection. A trade secret is not a precisely definable asset. It could be information that does not meet the requirements for patent protection or it could be that the holder of such information simply does not want to publicly reveal his knowledge. It is in this flexibility that the potential use of trade secret law to protect biotechnological knowledge lies. Article 39 (1) lays down the requirement that a trade secret be protected but it is in clause (2) that the real protection is iterated:

> 2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices [**(NB)**] so long as such information:
>
> - is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
> - has commercial value because it is secret; and
> - has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.
>
> [**(NB)**] For the purpose of this provision "a manner contrary to honest commercial practices" shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

This area has great potential. A major feature is that the secret is protected for an indefinite term thus allowing it to be kept as part of a community's heritage, a benefit that cannot be afforded by mechanisms such as patent protection. The main benefit of trade secret protection, however, is that no explicit effort is needed to protect the knowledge beyond "reasonable steps under the circumstances...to keep it secret." Thus the burden of registration and it's associated requirements for the proving of

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[56]One could try to argue that the use by parties outside of the state in question still affects the indigenous people's right to make use of their knowledge. However, this is rather weak and can only be approached through the non-legally binding human rights instruments rather than through a combination of human rights instruments supporting a TRIPs based argument.

a process or product are removed. However, there are problems with this. One is that there is some dispute over whether "the person lawfully in control of the information" could be construed as consisting of a group rather than an individual. This is obviously not difficult if a shaman or similar individual is in sole possession of the information but if the information is held community wide, or nationally, it could become a little more awkward. It may be possible to avoid this by claiming that a chief, medicine man, government official or similar individual is the holder of the trade secret and has chosen to reveal it to those members of his immediate community on the understanding that it is a secret. Trade secret law does not preclude the revealing of information, merely its general dissemination. Of course this means that any community must not publicly disseminate the information it possesses. This could be hard to achieve in communities whose tradition is to allow free access to their knowledge. Some redefinition of 'dissemination' is clearly required but since one is advocating the use of trade secret law as a base to build upon, rather than as a wholesale transplant, this should not be difficult.

Another difficulty is that one must establish that the secret protected has commercial value and that such value exists because it is kept protected. This has been put forward as constituting a major stumbling block but if one approaches it from the view of the community concerned, the logical view, it should not be problematic. Even if the knowledge and / or resource is not charged for one could argue that it has commercial value for its users in the sense that it removes the necessity to purchase a replacement from outside. Also if it is used in any form of barter system within the community, or in relations with outsiders, then it is clearly part of a traditional commercial system. The value could be said to exist due to secrecy very easily if it is part of a barter system. However, even within the community it could be said to exist as if it was not secret it could be commercialized to the detriment of the community by outsiders thus resulting in a net loss to the community.

The final problem with trade secret protection is its limited nature. The secret itself is not protected, the law actually constitutes a prohibition on discovering the secret from the holder or someone he has passed it to on the basis that it is a secret. Once the secret is in the public domain or is discovered independently the protection ceases. This leaves a large hole for "bio-piracy" or even genuine revealing of the secret. It also means that a community could be vulnerable due to its lack of detailed knowledge of the situation. They may reveal the information in all innocence and thus destroy their own rights or they may be taken advantage of by a more sophisticated outsider.

What is clear is that trade secret law definitely provides an opportunity for effective protection of knowledge regarding particular resources and it's inclusion in TRIPs means that WTO member states cannot afford to ignore it. At the same time for trade secret law to be truly effective in this role it must be adapted in areas such as what is actually protected. If it could be expanded to protect the actual secret rather than constituting a prohibition on unfair discovery, basically moved away from unfair competition law towards a variety of human rights based patent law, it could provide the ideal solution.

This discussion of *sui generis* options is by no means intended to be exhaustive but rather to illustrate the kinds of options that already exist. Another objective is to stimulate thought about the possibilities for new systems of protection that are more specifically tailored to the

needs of Developing Countries. One need not blindly accept the existing system in its totality.

Conclusion - the Risks of Trade Sanctions

The main reason that Africa needs to be aware of the issues involved with TRIPS Article 27 (3) (b) and its renegotiation is the consequences that await should it not develop a strong position to defend its interests. If TRIPS is altered in a manner that does not serve African interests and countries then cease to observe it rigorously they will open themselves to punitive action by developed countries. A particular example of this is the U.S. 1988 "Special Section 301" provision[57] of the 1974 Trade Act[58] (Special 301).

The United States is quite famous for its various attempts, often successful, to impose its jurisdiction extra-territorially and Special 301 is a classic example. The aim is to provide added protection for U.S. IPR owners in foreign markets.[59] The U.S. Trade Representative (USTR) is required to identify those countries which fail to maintain and enforce adequate IPR protection or that do not provide 'adequate and equitable market access for U.S. IPR owners'[60]. The most extreme offenders are then listed as "priority foreign countries."[61] The definitions are quite broad, and thus extremely powerful:

> if the foreign country denied adequate and effective means under the laws of the foreign country for persons who are not citizens or nationals of such foreign country to secure, exercise, and enforce rights relating to patents, process patents, registered trademarks, copyrights and mask works.[62]

Much the same holds true for the definition of denial of fair and equitable market access:

> if the foreign country effectively denies access to a market for a product protected by a copyright or related right, patent, trademark, mask work, trade secret, or plant breeder's right, through the use of laws, procedures, practices, or regulations which -
>
> (A) violate provisions of international law or international agreements to which both the United States and the foreign country are parties, or
>
> (B) constitute discriminatory nontariff trade barriers.[63]

The implications do not stop here though. Developing countries generally have an exemption from TRIPS compliance until the year 2000 but this is not enough to protect them from listing as a Special 301 Priority Country. In one of the most extreme amendments to Special 301 the USTR has the power to

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[57] Section 1303 of the Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, 102 Stat. 1179 (1988), *codified at* 19 U.S.C. § 2442.

[58] 19 U.S.C. §§ 2411-20.

[59] Bhala and Kennedy *supra* note 42 at 1172.

[60] Id. at 1173.

[61] 19 U.S.C. § 2242(b).

[62] Id. § 2242 (d) (2).

[63] Id. § 2242(d) (3).

list a country as Priority even if it is in compliance with its obligations under TRIPS.[64]

The actual process of a Special 301 investigation is initiated by any interested party[65] by filing a petition with the USTR in response to a foreign country's act, policy or practice that adversely affects the petitioner. The USTR then has a maximum of forty-five days within which to commence an investigation, the exception being if the USTR believes that an investigation would be detrimental to U.S. economic interests and reports such to Congress[66]. Thus proceedings very quickly reach the highest levels of authority in the U.S. Government. Along with this rapid initiation process there is a short time limit for action, the USTR must complete investigations within six months, nine if the case is a complex one[67]. Upon the completion of an investigation that results in unsatisfactory findings negotiations will be undertaken by the USTR to resolve the dispute. If there is no settlement at this point sanctions may be imposed ranging from withdrawal of benefits under existing trade agreements to imposition of punitive duties or import restrictions[68].

This is clearly an extreme piece of legislation but it should not be underestimated because of that fact, the U.S. has been happy to use Special 301, or the threat of it, on a number of occasions. In three cases sanctions have actually been imposed while there are a variety of other cases that have either been settled or are under negotiation[69]. The most famous of the cases involving sanctions was that of 1997 where Argentina lost fifty percent of its benefits under the Generalized System of Preferences because of its failure to provide patent protection for pharmaceutical products[70].

There are a variety of designations at a less extreme point than priority foreign country and the 1997 listings serve as an example of how wide ranging the USTR's interest is[71]:

Priority Foreign Countries	Priority Watch List Countries	Watch List Countries	Growing Concern Countries
Negotiations or action to be taken.	Practices warrant close monitoring	Practices are of "particular concern"	Monitored for possible upgrading
China	Argentina, Ecuador, Egypt, the EU, Greece, India, Indonesia,	Australia, Bahrain, Bolivia, Brazil, Bulgaria, Canada, Chile,	Austria, Cyprus, Czech Republic, Germany, Hungary, Lebanon, Mexico,

[64] Id. § 2242(d)(4). See also Bhala and Kennedy *supra note* 42 at 1174.

[65] 15 C.F.R. § 2006.0 (b) Anybody who has a significant interest affected by a foreign act, policy or practice, e.g. a producer, importer, exporter, trade association or union.

[66] 19 U.S.C. § 2412(a)(2); 15 C.F.R. § 2006.3

[67] 19 U.S.C. § 2414(a)(3)(A)-(B).

[68] Id. § 2411(c).

[69] Bhala and Kennedy *supra* note 42 at 1175.

[70] See *U.S. to cut Argentine GSP Benefits for Failure to Provide Patent Protection,* 14 Int'l Trade Rep. (BNA) 106 (1997).

[71] See Office of the USTR, *Fact Sheet: Special 301 Annual Review* (April 30, 1997). USTR Fact Sheets are available from the USTR's website at http://www.ustr.gov. From Bhala and Kennedy *supra* note 42 at 1175-6.

	Paraguay, Russia and Turkey.	Colombia, Costa Rica, Denmark, Dominican Republic, Guatemala, Honduras, Hong Kong, Ireland, Israel, Italy, Japan, Jordan, Korea, Kuwait, Luxembourg, Oman, Pakistan, Panama, Peru, the Philippines, Poland, San Marino, Saudi Arabia, Singapore, Sweden, Thailand, the United Arab Emirates, Venezuela and Vietnam.	Nicaragua, Qatar, Romania and Uruguay.

Africa is conspicuously absent from this list but that should not provide much reassurance when one examines just how wide ranging the list is.

Special Section 301 is a very good example but is not the only punitive measure provided for in U.S. law and the U.S. is not the only state capable of considering such measures. The lesson is that if Africa does not keep up with the pace of international intellectual property law, and push its common interests forward in that realm, it risks slipping even further behind in the technological race while also exposing itself to extremely damaging trade disputes.