


IUCN  
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**The TRIPS Agreement,  
Sustainable Development  
and the Public Interest**  
Discussion Paper

Simon Walker



Environmental Policy and Law Paper No. 41

**IUCN**  
The World Conservation Union

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**Simon Walker**

**Center for International Environmental Law**

**IUCN Environmental Law Centre**

**IUCN Environmental Policy and Law Paper No. 41**

**IUCN – The World Conservation Union  
2001**

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# Foreword

This paper by Simon Walker does a fine service helping address the environmental and developmental impacts of patent protection by especially focusing on the global agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The TRIPS agreement emerged from the Uruguay Round of Multilateral Trade Negotiations and establishes the basic global framework for the protection of specified intellectual property creations, including in many forms, creations linked to biology.

The growth of many forms of technology linked to biology has led to a new challenge: to understand the relationship between the field of intellectual property rights, development, and the protection of the environment. This is particularly a challenge as these fields intersect with issues prominent in the Convention on Biological Diversity and under the world trade regime. The growing use and application of wild plants and animals in the laboratory, and interest in traditional applications of the same, has led to a merging, or potential conflict, of interests between environmentalists, traditional users, and modern pharmaceutical and corporate sectors.

To parts of the business world, TRIPS has provided a means to help ensure that their investments in research can reap financial rewards, in order that their products can be globally marketed under patented protection. Without such incentives, we might not be able to produce the medicines and technology that can help raise global standards of living. However, as Walker notes, the times are changing, and there are serious questions about the conditions under which patent protection should be afforded at the international level. Walker notes that products generated from traditional practices, especially in developing countries and many indigenous communities, has meant that intellectual property protection has generated serious concerns pertaining to equity, environment, and health.

To Simon Walker, while the TRIPS agreement serves as an important step in harmonizing international intellectual property systems, it currently fails to properly balance public and private interests, especially in the gap between rich and poor. In this respect, he contends it fails to help build “innovative, ethical, and sustainable societies.” We should all be grateful for a thoughtful paper from which we can debate a serious issue, and for suggesting serious proposals for reform.

*Charles Di Leva*  
*Director, Environmental Law Programme*

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The paper was authored by Simon Walker, and was produced with the assistance of Mark Halle (first IUCN Project Director), Alejandro Iza (second IUCN Project Director), Tina Winqvist (Project Officer), Matthew Stilwell and Catherine Monagle, both of CIEL's European Office. Thanks must also go to David Downes, Graham Dutfield, Dale Andrew and Jorge Corrales for their considerable assistance and encouragement.

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# Executive Summary

## Overview

1. As the shift to a ‘knowledge economy’ continues, the definition of ownership and control of information becomes one of the most important policy issues facing societies. The leading international legal framework for determining rights over information is the World Trade Organization’s (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement). This paper discusses the relationship between the TRIPS Agreement, sustainable human development and the public interest. It examines technical and legal aspects of the Agreement, as well as some of its possible impacts on the environment and the enjoyment of human rights. The paper is designed as a reference for policy-makers in governments, international organizations and civil society. It identifies up-coming decision points, as well as some of the options available to policy-makers seeking to maximize the contribution of intellectual property to the goals of sustainable development.
2. The paper is divided into three sections. The first introduces intellectual property (IP) systems and the TRIPS Agreement. It identifies the traditional role of IP systems in balancing private and public interests as a means to promote innovative, ethical and sustainable societies, and it reviews the controversial insertion of IPRs on the multilateral trade agenda through the TRIPS Agreement. Section two reviews some of the potential impacts of the TRIPS Agreement on issues such as innovation and the dissemination of technology, access to health care, the development and use of biotechnology, and the operation of multilateral environmental agreements, in particular the *Convention on Biological Diversity*. Section three focuses on the review of the TRIPS Agreement and identifies the main negotiating fora, inside and outside the WTO, that are relevant to ensuring that the TRIPS Agreement is interpreted and implemented in accordance with environmental and public interest objectives, as well as obligations under human rights law. It concludes by proposing some options for policy-makers to guide them when reviewing the TRIPS Agreement, and in any future negotiations concerning its interpretation and amendment.

## Section one – Introduction to the TRIPS Agreement

3. The primary justification for granting limited property rights in the form of IPRs is that the grant benefits society by promoting innovation, creation and consumer protection. IP systems have therefore traditionally sought to strike a delicate balance between awarding private property rights to reward innovation with promoting access to the product and promoting the public interest. Increasingly however, this balance between private and public interest is shifting. As ownership of knowledge is becoming a key determinant in defining the “haves” and “have-nots” in modern society, powerful interest groups have stepped-up pressure on governments to implement stronger international protection and enforcement of IPRs. Some groups, in particular some segments of industry, have attempted to give added – and unjustifiable – force to IPRs by promoting them as natural rights without limitation; in other words, rights that have a moral force that somehow is

beyond political challenge. The arguments advanced to support this position assume that a right granted over technology in one State somehow equates with a right of universal coverage. Yet, this development denies the contingent nature of IPRs – governments may, in the interests of their citizens, choose not to grant IPRs, or to define them more narrowly. It also runs counter to a basic premise of IP systems; that any increase in the strength of IPR protection should be clearly justified by associated gains in public welfare.

4. This shift in the balance between public and private interests takes on a new dimension when viewed in the international context. Developed countries – which are traditionally home to the owners of formal technology – have tended to promote IPRs as beneficial to development. At times, developing countries by contrast – which are generally users, but not producers, of formal technology – have criticized IPRs, arguing that they raise prices and restrict access to the new technologies needed for sustainable human development. Despite bitter disputes between developed and developing countries during the Uruguay Round of trade negotiations, minimum standards for the protection and enforcement of IPRs were inserted on the international trade agenda in the form of the TRIPS Agreement.
5. As a direct result of the TRIPS Agreement, the shift in favor of IPR producing companies and countries has accelerated. WTO Members are now obliged to introduce IP standards that in many cases: increase the *scope* of IPR coverage by, for example, removing exceptions for categories of products such as pharmaceuticals; increase the *duration* of coverage; and increase the *geographical coverage* of IPRs. Members have agreed to implement IP systems that are costly, and that are geared towards industrial development, but that fail to protect innovators that are knowledge-rich but economically-poor. Concern has also been expressed that the TRIPS Agreement sits uneasily with the other agreements of the WTO; while the agreements on goods and services strive for trade liberalization, the TRIPS Agreement promotes intervention in the market to protect private property rights.

## **Section two – Possible impacts of the TRIPS Agreement**

6. The practical implications that arise from the implementation of the TRIPS Agreement are examined in Section two. This section explores whether, on the information available, the TRIPS Agreement is meeting its own objectives, including those directed to promotion of technological development and protection of public welfare. For example, while IPRs are generally considered supportive of **technological innovation**, it is doubtful that the TRIPS Agreement alone will be sufficient to promote new investment in developing country innovation, or to promote the informal innovation that is characteristic in many developing countries. At the same time, concerns have been raised that the grant of overly broad patents, for example in the area of biotechnology, and the cross-licensing practices of some corporations, may potentially stifle innovation, even in the countries of the North.
7. Similarly, the capacity for the TRIPS Agreement to promote the **dissemination of technology** is unclear. While proponents of strong IPRs argue that implementation of the TRIPS Agreement will create an enabling environment for technology transfer to developing countries, current trends in technology transfer indicate that the licensing of IPRs is overwhelmingly concentrated in a few developed countries and between a relatively limited number of corporations. Further research is needed to clarify the effects of the use of IPRs on technology transfer.

8. The TRIPS Agreement could also affect the **transfer of technology under Multilateral Environmental Agreements**. Research by the secretariats of the various MEAs suggests that IPRs present both opportunities and barriers to the transfer of environmentally-sustainable technology. While the role of IPRs in technology transfer should not be overstated, it is important that IP systems complement efforts to protect the environment by encouraging the transfer of environmentally-sustainable technology and minimizing the barriers that IPRs might pose to environmental protection. Yet the TRIPS Agreement remains essentially neutral to environmental concerns. Given the immediacy of environmental degradation, promoting the transfer of technology both through the TRIPS Agreement and MEAs is critical.
9. In the area of **health care and access to essential medicines**, implementation of the TRIPS Agreement could help consolidate market control in the hands of a few pharmaceutical companies and increase the price of pharmaceuticals. This may pose serious health risks in cases where essential drugs are needed to respond to diseases such as HIV/AIDS, tuberculosis and malaria. According to the TRIPS Agreement, Members may adopt measures to protect public health and nutrition, including through the grant of compulsory licenses to local companies, as a means of promoting the public interest. Members, however, are often faced by unilateral pressure when seeking to operationalise these measures. Greater consideration needs to be given to the public health aspects of IPRs to ensure that the TRIPS Agreement promotes and does not undermine the right to health.
10. The grant of patents and other **IPRs over biotechnology** has been expanding in spite of the ethical, environmental, economic and legal considerations that suggest moderation in this regard. Under Article 27(3)(b), the TRIPS Agreement requires Members to recognize patents over micro-organisms and microbiological processes for the production of plants and animals but permits Members to exclude plants and animals from patentability. The Agreement also requires Members to recognize either patent or *sui generis* protection for plant varieties. Article 27(2) however allows Members to exclude from patentability, innovations in order to protect animal, plant life or health or to avoid serious damage to the environment.
11. In relation to the **protection of plant varieties**, what constitutes *sui generis* protection for new plant varieties is left undefined by the Agreement. One option is for countries to implement the *International Convention for the Protection of New Varieties of Plants* (UPOV). However, this form of protection has been criticized for focusing too much on the rights of plant breeders, and too little on the rights of those using the seeds – farmers. Members are encouraged to read Articles 27(2) and 27(3)(b) broadly, and to develop national systems that promote not only formal innovation by plant breeders, but also local breeding and the rights of farmers, and protect fundamental human rights, including the rights to food and health.
12. Section two continues with a summary of the on-going debate concerning the **relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD)**. The CBD sets as its objectives the conservation of biological diversity, the promotion of sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the use of genetic resources. Implementation of these objectives requires the protection and use of knowledge relevant to the conservation and sustainable use of biological diversity, including knowledge about genetic material, knowledge in technology,

and knowledge of indigenous and local communities. The allocation of rights over knowledge in the form of IPRs could therefore determine the extent to which the objectives of the CBD are met.

13. First, there are still significant gaps in knowledge concerning the link between the award of private rights over intellectual property and the **conservation and sustainable use of biodiversity**. For example, the TRIPS Agreement obliges Members to introduce protection of new plant varieties, which are essentially property rights awarded to promote the breeding of new varieties. The introduction of new high yielding or easily cultivated species can lead to overplanting of one variety and the loss of others. To the extent that IPRs can be linked to the introduction of monocultures, the IPR systems promoted by the TRIPS Agreement could contribute to a general trend in biodiversity loss and so frustrate obligations under the CBD concerning the conservation and sustainable use of biodiversity. These linkages are, however, complex and there is a need to assess further the relationship between IPRs and the conservation and use of agricultural biodiversity.
14. The requirement to protect new plant varieties could also lead to the establishment of IP systems that promote the innovation of **genetically modified organisms (GMOs)**. As reflected in the negotiation by the international community of the *Cartagena Protocol on Biosafety* in January 2000, GMOs may pose a risk to the environment. In order to avoid future biodiversity loss associated with the introduction of untested GMOs, policy-makers, when considering whether and how to establish protection for plant varieties, should ensure that adequate regulatory systems exist to test and ensure the safety of any new GMOs.
15. Second, questions have been raised about the potential effect of the TRIPS Agreement on the implementation of Article 8(j) of the CBD, including the requirement to recognize the value of the **knowledge, innovations and practices of indigenous and local communities** relevant to the conservation and sustainable use of biodiversity. The standards included under the TRIPS Agreement are generally ill-suited to the protection of the knowledge of indigenous and local communities. The complexity and expense of IP systems required by the TRIPS Agreement may render them difficult for indigenous and local communities to access. IP systems may also allow entities outside indigenous and local communities to appropriate innovations drawn from a community's knowledge, without giving them due compensation. Policy-makers should seek to ensure compatibility between Article 8(j) and national IP systems implementing the TRIPS Agreement through measures such as the requirement of evidence in patent applications of a particular community's prior informed consent over the use of its knowledge.
16. Third, the relationship between the TRIPS Agreement and the provisions of the CBD establishing principles for the **access to and sharing of the benefits from genetic resources** is unclear. Agreements relating to IPRs – for example, royalty-sharing agreements – could provide a means of benefit sharing. There is nothing in the TRIPS Agreement preventing this sort of action. What is lacking, however, is a legal framework to ensure that benefits arising from the use of genetic resources are shared equitably. The international community has established one such framework – the International Undertaking on Plant Genetic Resources (IU) – which protects rights that arise from farmers' past, present and future contribution in conserving, improving and making available plant genetic resources. The IU is currently being renegotiated to bring it into harmony with the CBD, possibly as a legally-binding Protocol to the CBD. Negotiations are focusing on developing the notion of

farmers' rights already contained in the IU, and considering the issue of access on mutually agreed terms to plant genetic resources. The negotiations should be finalized by November 2000. WTO Members should ensure that the interpretation and implementation of the TRIPS Agreement respect farmers' rights, and complement any framework for access to, and benefit sharing from the use of, genetic resources contained in the IU.

17. Finally, the TRIPS Agreement could have an impact on the operation of the CBD as a result of decisions under the **WTO's dispute settlement mechanism**. While the CBD is legally binding, it contains no well-developed enforcement mechanism to address non-compliance by Parties with their commitments. In contrast, TRIPS disputes are subject to the binding decision of the WTO's dispute settlement mechanism. In the case arising out of the implementation of the TRIPS Agreement, a WTO panel may give greater weight to the provisions of the TRIPS Agreement than to those of the CBD. To ensure such disputes are resolved consistently with the CBD's objectives, CBD experts should be included on dispute panels, and involved as independent experts, so that the WTO dispute settlement mechanism is adequately informed of all relevant evidence and jurisprudence.
18. In conclusion, the actual and potential impacts of the TRIPS Agreement on sustainable development and the public interest should not be ignored. The TRIPS Agreement itself states that implementation of its terms should be conducive to economic and social welfare. However, while the Agreement clearly sets out the rights of IP holders, it merely identifies public interest issues without establishing adequate measures and mechanisms by which the public interest can be met. This imbalance is exacerbated by unilateral pressure exerted by some WTO members on others to go beyond the Agreement's requirements. Developing mechanisms to safeguard the public interest, monitor the implementation of the Agreement, and if necessary, to change the Agreement to ensure it meets its objectives, requires coordinated strategy and consistent advocacy by civil society and concerned States.

### **Section three – Review of the TRIPS Agreement**

19. Section three maps the current international fora relevant to IPRs and offers some preliminary ideas about options for change. As a first step towards resolving the complex issues raised by the TRIPS Agreement, this paper recommends: 1) a full and public discussion by WTO Members, in partnership with relevant international organizations, and civil society, of the public interest issues raised by the evolving international intellectual property regime; and 2) a systematic "sustainability review" by WTO Members in the TRIPS Council of the implications of implementing the Agreement for the public interest and sustainable development, as part of the mandated review of the TRIPS Agreement.
20. A number of international fora are considering issues of relevance to the TRIPS Agreement and the public interest. The TRIPS Council is currently reviewing implementation of the Agreement. At the same time, WIPO, the Conference of the Parties for the CBD, the WTO's Committee on Trade and Environment, UNCTAD, the FAO, the Office of the High Commissioner for Human Rights, and the United Nations' Committee on Economic, Social and Cultural Rights are also carrying on discussions that have implications for IP systems. Many of these fora have appeared more willing than the TRIPS Council to discuss the public interest implications of the TRIPS Agreement. Policy-makers should be aware of the discussions in these fora so as to ensure policy coordination.

21. Finally, to assist in policy development, the paper sets out possible ways to: clarify the terms of the TRIPS Agreement; enhance measures for implementing technology transfer; elaborate requirements for the protection of indigenous and local knowledge; and co-ordinate negotiating strategies nationally, regionally, and internationally in order to ensure that the TRIPS Agreement, and the evolving international IPR regime, secure an adequate balance of rights and obligations, and promote, in both developed and developing countries, sustainable development and the public interest.

# Section 1





# Introduction to the TRIPS Agreement

## Introduction

Knowledge is fast becoming the primary resource in economic life. While ‘new technologies’ present tremendous opportunities for human development, the full enjoyment of this potential will depend on who owns technology, and how it is used and disseminated globally.<sup>1</sup> The definition of control over information in the ‘knowledge economy’ is therefore among the most important policy issues facing society.

The leading international agreement establishing standards for the determination of rights in information is the *Agreement on Trade Related Aspects of Intellectual Property Rights* (TRIPS Agreement). The TRIPS Agreement was negotiated during the Uruguay Round of multilateral trade negotiations that established the World Trade Organization. It is the first comprehensive agreement to establish minimum, enforceable standards for the protection of intellectual property rights (IPRs) and, as a result, is a significant step in harmonizing national intellectual property (IP) systems. While the Agreement’s objectives establish that the protection and enforcement of IPRs should balance rights with obligations to the mutual advantage of both producers and users of technological knowledge,<sup>2</sup> the Agreement has been criticized on many levels, in particular for serving to exclude developing countries from participating in the knowledge sector.<sup>3</sup>

This paper takes a critical look at the TRIPS Agreement in the context of its review, scheduled to occur in 2000, and in light of the failed Seattle Ministerial Conference in December 1999. It locates the Agreement within the ongoing debate about the nature and purpose of IPRs, with a focus on IPRs such as patents that cover technology. It explores the potential impacts of IPRs on issues including:

- the innovation and dissemination of technology;
- access to health care;
- the field of biotechnology; and
- the operation of the Convention on Biological Diversity.

This examination suggests that the capacity of the Agreement to meet its objectives is at best unclear. As a result, policy-makers should avoid any further expansion of IP protection under the WTO at this time. It concludes that more detailed empirical research into the effects of IPRs, specifically in relation to developing countries, is needed to ensure that international rules determining the control and use of knowledge will optimize sustainable human development globally.

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<sup>1</sup> United Nations Development Programme (UNDP), *Human Development Report 1999*, United Nations, New York, 1999, p. 57.

<sup>2</sup> The TRIPS Agreement, Article 7.

<sup>3</sup> UNDP, *op. cit.*, p. 57.

## **The role of intellectual property systems in innovative, ethical and sustainable societies**

Intellectual property systems, through the grant of property rights over products, processes, works and signs, have been developed as a means of optimizing innovative and creative activity. Intellectual property rights are generally grouped under two categories: copyright and related rights, and industrial property rights. Copyright protects literary, musical and artistic works such as novels, music scores, films and photographs, as well as technology such as computer programs. Related rights protect theatrical and musical performances as well as sound recordings. Industrial property rights, by contrast, protect technology (in the form of patents over products and processes, industrial designs, and layout design of integrated circuits), trademarks and geographical indications. A trade secret, or undisclosed information, is also a form of industrial property that is protected under many IP systems.

IPRs, such as copyright or patents, reflect a compromise between private and public interests – between the provision of an incentive to private interests to innovate or create, and the desirability of disseminating technology and works to the public at little cost.<sup>4</sup> For example, patents allow technology owners to recoup their investment in research by giving them the power to raise prices and to reduce the supply of technology. Where the technology is particularly innovative, the IPRs might help the technology owner to attain market dominance with resulting effects on competition in the market. On the other hand, at least in theory, the public should benefit from the promotion of a more innovative society in the short term, and in the long term, from having guaranteed access to the technology when the IPRs expire.

Balancing public and private interests is fundamental to ensuring that IP systems achieve their objectives. IPRs such as patents raise the price of a fundamental ingredient in innovation – knowledge – and shift bargaining power from the users to the producers of technology. Consequently, IP systems that grant overly broad protection could undermine technological innovation and have adverse effects on competition.<sup>5</sup> However, IP systems that are too weak could also have adverse impacts on innovation. Weak protection could fail to provide a sufficient stimulus for innovation and could reduce levels of creativity in society. Worse, weak protection might drive innovators to keep new knowledge secret. Reliance on secrecy as a means of adding value to technology could slow innovation and restrict access to technology. In both situations, the public as technology users could suffer.

The balance in many IP systems seems to be shifting too far in favor of technology producers. Negotiations over IPRs have been powerfully influenced by industry lobby groups and are being driven by concerns of trade liberalization and international investment between developed countries. The legitimate technological and developmental objectives of developing countries – generally technology users – are not being given due consideration. This shift in the ownership and control of information, and the resulting boon to private investors, has been called an “information land grab”.<sup>6</sup>

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<sup>4</sup> World Bank, *Knowledge for Development – World Development Report, 1998/99*, Oxford University Press, 1998, p. 33.

<sup>5</sup> Stiglitz, J., *Public Policy for a Knowledge Economy*, Remarks at the Department for Trade and Industry and Centre for Economic Policy Research, London, UK, January 27, 1999.

<sup>6</sup> Boyle, J., “Sold Out”, *New York Times*, March 31, 1996.

<[http://www.wcl.american.edu/pub/faculty/boyle/sold\\_out.htm](http://www.wcl.american.edu/pub/faculty/boyle/sold_out.htm)>.

This shift has been assisted by a change in the discourse surrounding IPRs. IPRs are granted by the State as a means of meeting certain policy objectives: they are “contingent” upon recognition in law, and seek to balance the rights granted to the holder, with those of the broader society. Increasingly, however, certain interest groups are promoting IPRs not as “contingent rights”, but rather as “natural rights” that are inherent to the IPR holder and that have a moral force that makes them somehow free from political challenge.<sup>7</sup> During the 1980’s, for example, the insistence of US industry and the US Government on IPR protection began to take on a moral character.<sup>8</sup> The pharmaceutical industry was particularly vocal in this regard. Much of the rhetoric that helped construct US patent policy at this time used emotive terms such as “piracy” and “theft” when referring to developing countries’ use of technology protected under US IPR laws.<sup>9</sup> These arguments reflected an underlying assumption that a right granted over technology in one State somehow equated with a right of universal coverage. Yet this approach denies that legislatures in different countries, when seeking to maximize the benefits to their society, could choose not to grant certain IPRs or to define them more narrowly. This subtle philosophical restatement of the nature of IPRs has over several decades gradually but successfully swayed the IP debate.

It is time to re-invigorate certain IP systems by re-establishing an appropriate balance between private and public interests, both within and between countries. Doing this will require policy-makers to establish clearly the overarching objectives of their national IP systems. It will require policy-makers, with the help of citizens’ voices, to clarify the technological needs of their country and region. These needs and objectives will change from country to country and are likely to vary between developed and developing countries. In particular, technological objectives must be determined on the basis of a clear evaluation of the ethical, social and environmental needs of societies. The following sections of this paper propose that the TRIPS Agreement, as a significant step in harmonizing international IP systems, fails to achieve a balance of public and private interests that is appropriate to encouraging innovative, ethical and sustainable societies globally.

## **Overview of the WTO Agreement on Trade-Related Aspects of Intellectual Property**

### **The backdrop – international intellectual property law before the TRIPS Agreement**

For centuries IP systems grew and developed sporadically in response to national needs. International agreements concerning IPRs occurred in the later part of the 19<sup>th</sup> Century. In

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<sup>7</sup> The concept of moral rights does exist in some IP systems, but it is limited to copyright law. Moral rights refer to the inalienable right of authors to be acknowledged as the source of a work and to protect its integrity. Moral rights cannot be assigned or licensed, unlike economic rights.

<sup>8</sup> Weissman, R., “A Long Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO legal Alternatives Available to Third World Countries”, *University of Pennsylvania Journal of International Economic Law*, Volume 17, No. 4, Winter 1996, pp. 1069–1125, p. 1086.

<sup>9</sup> See, Easton, T., “Pirated Ideas Cost the United States Billions” *The San Francisco Chronicle*, 6 February 1989.

1873, when the Austrian Government held an international exhibition of inventions at Vienna, many inventors were hesitant to exhibit. They feared that in the absence of protection their inventions might be copied. In response, several diplomatic conferences were held. These culminated in 1883, when 11 States signed the *Paris Convention for the Protection of Industrial Property*.<sup>10</sup> The Convention established rules between the Member States concerning patents, trademarks and industrial designs.

Around the same time, authors and publishers became increasingly concerned that their works were being copied in foreign countries shortly after their original publication. American publishers, for example, were renowned for copying the works, popular with the American public, of English writers such as Byron, Shelley and Dickens.<sup>11</sup> The need for a uniform system of copyright protection at the international level led to the formulation and adoption in 1886 of the *Berne Convention for the Protection of Literary and Artistic Works* – the first multilateral treaty in the field of copyright.

Both Conventions established a minimum set of rules for the international regulation of IPRs. The cornerstone of both is the principle of non-discrimination, known as “national treatment”, which requires each Member State to provide the same level of protection to other Member States as it provides to its own nationals. Beyond this, the Conventions give significant leeway to the Member States to set the standards of protection that are best suited to local conditions. Both Conventions were administered by a Union that, in 1893, became the United International Bureaux for the Protection of Intellectual Property (BIRPI). In 1967, BIRPI became the World Intellectual Property Organization (WIPO). Today, WIPO is one of the 16 specialized agencies of the United Nations and is responsible for the promotion and protection of intellectual property internationally through cooperation among States. WIPO is also responsible for the administration of the various multilateral treaties dealing with the legal and administrative aspects of intellectual property.

The *Paris Convention* and the *Berne Convention* became the two pillars for the international regulation of IPRs. Since their inception, many more States have signed the Conventions, and other Conventions have been negotiated adding to, or strengthening the protection of, trademarks, performers’ rights, industrial designs and plant varieties, to name a few. With the retreat of the old colonial powers, many developing countries became members of the Conventions and encouraged the amendment of provisions to take into account developmental objectives. This stronger developing country voice soon led to the isolation of some developed countries in negotiations.

## **Insertion of intellectual property rights in the trade agenda**

The insertion of IPRs in the trade agenda was a result of significant pressure from developed countries. Several reasons explain their insistence to include IPRs on the trade agenda. Perhaps most significantly, in the 1980’s, trade in counterfeit goods began to impact the US balance of trade, with projected losses to US industry in 1986 estimated at 15% of the US

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<sup>10</sup> The original 11 states were Belgium, Brazil, El Salvador, France, Guatemala, Italy, the Netherlands, Portugal, Serbia, Spain and Switzerland. In 1884, Great Britain, Tunisia and Ecuador signed as well.

<sup>11</sup> Drahos, P. “Biotechnology Patents, Markets and Morality”, *European Intellectual Property Review*, Vol. 21, Issue 9, pp. 441–449.

trade deficit.<sup>12</sup> This led industry to lobby governments in North America, Europe, Japan and elsewhere to remedy the situation. At the same time, the 1980s saw a significant shift in trade composition, with a growing reliance on the export of high technology. The percentage of US exports with a high intellectual property content increased from 9.9% in 1947 to 27% in 1986, highlighting the role of protecting IPRs as a means to protect comparative advantage in high technology goods.<sup>13</sup>

At the same time, some developing countries began to organize themselves as technological competitors to the technology producing countries. Faced with high prices on products in essential areas such as health and agriculture, and reluctance among technology producers to license IPRs, some developing countries amended their IP legislation to relax protection and to allow local enterprises to exploit technology.<sup>14</sup> As a result, several developing countries made some progress in establishing competitive industries. During this period, the globalization of trade meant that IPR holders – traditionally from developed countries – were increasingly interested in marketing in developing countries. Consequently, technology holders were concerned about protecting their ability to compete in these markets. They also became concerned about protecting their traditional markets from the import of “pirated” goods.

While developing countries supported weaker IP systems on the grounds that technology is the common heritage of mankind and is necessary to achieve national developmental objectives, technology producers saw this as free-riding and called for more stringent protection and enforcement of IPRs. Consequently industry, in particular the film and pharmaceutical industries, developed strategies to include IP in the international trade agenda.<sup>15</sup> Alliances such as the International Intellectual Property Alliance, the Union of Industrial Employers’ Confederations of Europe, and the Japanese Federation of Economic Organizations began to lobby governments to take action on the national and international level to remedy the situation.<sup>16</sup> The role of private sector lobby groups, particularly from the pharmaceutical sector, played a significant role in shaping developed country government policy.

Within this context, the US Government began to use unilateral action against countries it perceived were not acting to reduce trade in counterfeit goods. Nationally, the US Government used the Tariff Act (1930) to enable the US International Trade Commission to order the seizure and forfeiture of counterfeit goods upon application by a domestic IPR holder. Similarly, amendments to the *Trade Act* (1974) known as “Regular 301”, “Special 301” and “Super 301” enabled the US Trade Representative to assess the practice of its trading partners, with a view to identifying problem countries, and to eliminating behavior deemed inconsistent with US intellectual property interests through negotiations or through retaliatory measures such as trade sanctions. Some of these measures have had mixed success and have come under

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<sup>12</sup> US International Trade Commission, “Foreign Protection of Intellectual Property Rights and the Effects of US Industry and Trade”, USITC Publication 2065, February 1988, in Evans, G., “Intellectual Property as a Trade Issue: The Making of the Agreement on Trade-Related Aspects of Intellectual Property Rights” *World Competition: Law and Economics Review*, Vol. 18, No.2, December 1994, pp.137–180, p. 144.

<sup>13</sup> *Ibid*, p. 142.

<sup>14</sup> In India, the Government amended the *Patent Act* (1970) withdrawing patent protection for pharmaceuticals and chemicals.

<sup>15</sup> Drahos, *op. cit.*, p. 20.

<sup>16</sup> Evans, *op. cit.*, p. 165.

scrutiny for being contrary to international law.<sup>17</sup> It became increasingly clear that the most effective way of combating the trade in counterfeit goods, and of doing away with unilateral trade action, was to develop multilateral rules over intellectual property within the framework of the international trade agenda.

## **Negotiations on intellectual property rights during the Uruguay Round**

The process of inserting IPRs on the trade agenda began in the early 1970s. In 1973, at the end of the Tokyo Round of trade negotiations, European and US negotiators worked on a draft agreement to combat commercial counterfeiting of trademarked goods.<sup>18</sup> Developed countries used the effects of international markets in counterfeit goods on trade balances to justify the inclusion of IP on the trade agenda. Throughout the 1970s and 1980s, developed countries maintained the pressure to keep IPRs on the GATT agenda so that, by the time the Uruguay Round commenced in 1986, the negotiators had a mandate to develop a multilateral framework of principles, rules and disciplines to deal with trade in counterfeit goods.

The Uruguay Round continued for seven years. The negotiations over intellectual property were delayed by often bitter disputes over the inclusion of an Agreement on IP within the GATT framework, as well as over its form and content. In particular, developing countries, led by India and Brazil, saw the inclusion of minimum standards of IP protection as a legal pretext to “cream off scarce resources in royalty payments”.<sup>19</sup> These countries feared that any such agreement would undermine developing countries’ sovereign power to set national developmental objectives.

The Uruguay Round was characterized by disputes that, at times, almost completely stalled negotiations. Throughout the negotiations, developing countries vehemently contested the jurisdiction of the GATT to deal with matters of intellectual property, insisting that WIPO was the appropriate forum for debate. Some developed countries, by contrast, were eager to move IP negotiations into GATT where their negotiating power was enhanced due to the weaker developing country presence. Developing countries were also concerned that awarding monopoly rights to foreign enterprises would affect their development and insisted on articles for the promotion of technology transfer and for protection against anti-competitive practices.<sup>20</sup> Drafts proposed by India, for instance, set out elaborate anti-trust articles including lists of provisions in licensing agreements that should be considered anti-competitive.<sup>21</sup> The final text included only references to the control of anti-competitive practices and fell short of the proposals made during negotiations.<sup>22</sup>

Slowly negotiators moved towards an agreed text. In particular, concessions to developing countries in negotiations outside the TRIPS arena – specifically in the area of textiles – together with high-level pressure from some developed country governments, helped to push countries to a conclusion. In the context of the depressed state of the world economy in the early 1990s, amongst fears of increasing protectionism, continued unemployment and national debt, the

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<sup>17</sup> *Ibid.*, pp. 150, 153.

<sup>18</sup> *Ibid.*, p. 158.

<sup>19</sup> Cornish, W.R., *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, Sweet and Maxwell, London, 1989, p. 14.

<sup>20</sup> See e.g., the TRIPS Agreement, Articles 7, 8, 40 and 66(2).

<sup>21</sup> Evans, *op. cit.*, p. 173.

<sup>22</sup> See the TRIPS Agreement, Articles 8 and 40.

negotiators concluded the Round.<sup>23</sup> On April 15, 1994 in Marrakech, the Members of GATT signed the Final Act Embodying the Results of the Uruguay Round Of Multilateral Trade Negotiations.

### **Box 1 – Major characteristics of the TRIPS Agreement**

**Objectives.** Article 7, establishing the objectives of the TRIPS Agreement, states that “The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations”.

**Minimum standards.** The TRIPS Agreement establishes minimum standards for the protection of IP. States are free to introduce systems of protection not referred to in the Agreement, for example, to protect informal knowledge, or the rights of indigenous communities. They are also free to set higher standards of protection for existing rights.

**Enforcement.** The Agreement establishes general principles that are applicable to IPR enforcement procedures so that rights’ holders can effectively enforce their rights. In addition, it contains provisions on court procedures, court orders, suspension of custom clearances for goods and criminal penalties.

**Dispute settlement.** The WTO includes a procedure for settling disputes between Members. Any Member can bring proceedings against another Member. A panel of specially appointed trade experts interprets the various agreements of the WTO, including the TRIPS Agreement. Once the panel issues its report, it is adopted unless one of the parties to the dispute appeals the decision or there is a consensus by WTO Members not to adopt the decision. If a party to a dispute fails to abide by a decision of either a Panel or the Appellate Body, the other party can impose trade sanctions on that Member.

**Developing countries’ transitional periods.** While developed countries should have complied with the obligations under the TRIPS Agreement by 1 January 1996, developing countries and countries with economies in transition have until 1 January 2000. Least developed countries have until 2006 to implement the Agreement.<sup>24</sup>

**Built-in agenda** – The TRIPS Agreement includes a built-in agenda of review. Specifically, Article 27(3)(b) provides for the review in 1999 of certain provisions relating to the patentability of plants and animals, and the protection of plant varieties. In the area of geographical indications, Article 23(4) provides that, in order to facilitate the protection of geographical indications for wines and spirits, negotiations shall be undertaken in the TRIPS Council on the establishment of a multilateral system of notification and registration. Preliminary work in this area has already begun. Article 71(1) provides that the TRIPS Council shall review implementation of the whole Agreement from 1 January 2000 and every two years after that.

<sup>23</sup> Evans, *op. cit.*, p. 175.

<sup>24</sup> These dates apply for most but not all obligations.

## **A preliminary critique of the TRIPS Agreement**

A few preliminary observations can be made regarding the final agreed text of the TRIPS Agreement. First, there is an apparent lack of coherence between the TRIPS Agreement and the other WTO agreements. In theory, trade rules are aimed to remove barriers to trade. The Preamble to the Final Act of the Uruguay Round sets “expanding the production of and trade in goods and services” as an objective of WTO Member States. In keeping with this, WTO agreements on goods and services seek to create a liberal trading system under which enterprises from one Member can trade with others under conditions of fair competition. The agreements thus establish rules to reduce barriers to trade and to ensure respect for the principle of non-discrimination among Members. While governments still play a role in ensuring that rules are implemented and enforced, WTO agreements generally seek to reduce and define government intervention in the market.

How then is the TRIPS Agreement justified within this context? Whereas other WTO agreements seek to liberalize trade and promote competitive markets, the TRIPS Agreement requires governments to introduce minimum standards for the protection and enforcement of property rights over products, processes, works and signs. These rights, in practice, grant the rights-holder a degree of control over the market-place. In the case of patents, for example, the rights to prevent competitors from selling, offering for sale, importing and producing technology allow technology holders some control over the market place through setting prices as well as production and import levels. Consequently, while the agreements on goods and services are directed towards “free” trade, the TRIPS Agreement effectively allows technology holders the opportunity to “control” trade.

This double standard in WTO rules is becoming increasingly evident. Whereas many WTO Members (and past dispute settlement decisions) have opposed the use of production and process methods (PPMs) as a grounds for regulating trade by governments, IPRs granted over processes offer technology holders the possibility of using those rights to restrict the import of products, solely on the basis of the processes involved in making the product. So while the WTO agreements restrict the right of Members to differentiate between imported products on the basis of PPMs generally, they also enshrine this right in WTO rules for the benefit of private technology holders on the basis of the rights they hold over PPMs.

Given that IPRs restrict free market competition, it seems difficult to justify their protection through the WTO’s agenda. Dutfield notes that a possible argument could be constructed around this, namely: that a market intervention that permits limited property rights over valuable intangibles might be considered consistent with rules that promote trade liberalization on the basis that the property rights are awarded as an optimal means of achieving public good.<sup>25</sup> The question that remains is whether the TRIPS Agreement does provide an effective model IP system that balances public and private interests optimally so as to achieve its stated objectives of promoting social and economic welfare. Until this can be demonstrated with some certainty, the justification for the presence of the TRIPS Agreement on the agenda for trade liberalization will be unclear.

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<sup>25</sup> Dutfield, G., *Intellectual Property Rights, Trade and Biodiversity – Seeds and Plant Varieties*, Earthscan Publications Ltd in association with IUCN – The World Conservation Union, 2000, p. 18.



In addition to these overarching concerns, a number of other related criticisms have been leveled at the TRIPS Agreement:

1. ***The TRIPS Agreement increases the scope of protection.*** The protection guaranteed under the Agreement expands the level of protection offered under many existing national systems – in time (countries like Australia had to increase protection from 16 years to 20 years from filing); in scope (the TRIPS Agreement covers most inventions in all fields of technology for the first time);<sup>26</sup> and in geographical application (to all WTO Members) – representing a major shift in favor of technology producers.
2. ***The TRIPS Agreement changes the focus of IP protection from individuals to corporations.*** The TRIPS Agreement does not refer at any time to inventors throughout the text. In the Section devoted to patents, the Agreement mentions “patent owners” and “rights holders” but does not refer to inventors as owners of rights. This has been seen as part of a continuing evolution of IP systems that has transformed patent rights from individual rights to corporate assets<sup>27</sup> and further illustrates what has been strongly argued as a shift in the basis of IP systems from promoting and stimulating creative mental labor, to protecting private corporate interests.
3. ***The TRIPS Agreement extends protection beyond previous international levels.*** The TRIPS Agreement requires the introduction of new forms of IP protection for many Members. In WIPO, States have negotiated the UPOV Conventions on plant breeders’ rights and the Washington Treaty on integrated circuits,<sup>28</sup> but relatively few countries are parties to these Conventions. The TRIPS Agreement extends IP coverage for many Members, including over plant varieties and integrated circuits. In addition, in some cases it requires broader protection than is required under existing agreements – such as the obligation to provide copyright protection for certain computer programs and computerized data bases beyond existing obligations under the Berne Convention.<sup>29</sup>
4. ***The TRIPS Agreement fails to protect informal knowledge systems.*** While the TRIPS Agreement includes existing measures to protect integrated circuits, it does not include existing measures for the protection of expressions of folklore such as the WIPO/UNESCO *Special Model Provisions for National Laws on the Protection of Expressions of Folklore Against Illicit Exploitation and other Prejudicial Actions*.<sup>30</sup> In other words, the TRIPS Agreement establishes standards that are relevant to the protection of the commercial property of developed country corporations but does not include models, such as folklore protection or even petty patent protection, that are relatively cheap and easy to access and

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<sup>26</sup> Subject to exceptions – see Article 27, the TRIPS Agreement.

<sup>27</sup> Carvalho, N., “From the Shaman’s Hut to the Patent Office: How Long and Winding is the Road? – II”, *Revista da ABPI*, No. 41, July/August, 1999, pp. 3–17, p. 5.

<sup>28</sup> *The Treaty on Intellectual Property in Respect of Integrated Circuits* (1989).

<sup>29</sup> Finger, J., and P. Schuler, *Implementation of Uruguay Round Commitments: The Development Challenge*, World Bank, p. 20.

<sup>30</sup> The Model Provisions were designed to balance the need to protect expressions of folklore against abuse with the need to encourage the development, dissemination and adaptation of original works inspired by folklore.

appropriate for the informal grassroots innovations of small innovators and local communities in developing countries.<sup>31</sup>

5. ***The TRIPS Agreement favors the technology producers in a few developed countries.*** Statistics documenting levels of international patent applications demonstrate that the users of existing IP systems tend to be interests in a few developed countries.<sup>32</sup> As the TRIPS Agreement constructs a harmonized international IP system that more or less reproduces and builds upon developed country IP systems, it is reasonable to conclude that the main beneficiaries of the implementation of the TRIPS Agreement – at least its provisions relating to patents – will be technology producers in developed countries.

These are serious concerns. While empirical evidence about the impacts of the TRIPS Agreement is still scarce, an initial examination of the theory and the practice of the TRIPS Agreement suggests that there are already problems arising from its implementation. The following sections examine some of these, noting where there is a need for further examination and study in order to gain a more precise understanding of the linkage between the TRIPS Agreement, the IPR systems it requires WTO Members to implement, and broader questions of sustainability and the public interest.

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<sup>31</sup> Although Article 4 of the *Paris Convention* – that deals with utility model protection and inventors' certificates that could be relevant to small-scale innovators including those in developing countries – is included within the terms of the TRIPS Agreement, the enforcement provisions would not apply.

<sup>32</sup> See Dutfield, *op. cit.*, p.58 (noting that 41.78% of patent applications filed in 1997 with the Patent Cooperation Treaty of the WIPO were from US applicants, and 41.93% were from Western Europe).

## **Section 2**



# Possible impacts of the TRIPS Agreement

## Innovation and dissemination of technology

### Innovation of technology

One of the stated objectives of the TRIPS Agreement is to contribute to technological innovation.<sup>33</sup> It is generally agreed that IP protection does so, although to what extent is unclear, and the role of IP systems in stimulating innovative activity should not be overstated. There are many other incentives – from prizes to subsidies and tax credits – that governments use to encourage the private sector to invest in research. For some innovators, the desire to gain a competitive advantage in a leading technological area is incentive enough to innovate.<sup>34</sup> IPRs are thus only one factor contributing to technological innovation. Their impact is likely to change depending on other inter-relating factors, including the level of local research infrastructure, technical education, technological information and finance, the industry involved, the existence of coordinated government technology policy, and so on. Despite the complexity of these inter-relationships, a few observations can be made about the role of IP protection in encouraging innovation.

The contribution of implementing the TRIPS Agreement to innovation in developing countries is questionable for a number of reasons. First, it is unclear whether implementation will significantly increase foreign investment in developing countries for the purposes of research. Some studies suggest that stronger IPR protection will lead to increased foreign direct investment for these purposes. In a study of American, German and Japanese firms in the pharmaceutical, chemical, machinery and electrical equipment sectors, 80% of firms stated that the strength of IPR protection in the host country was an important factor influencing decisions concerning investment in research.<sup>35</sup> Yet, research activities remain focused heavily in developed countries, and strong protection of IPRs alone is not necessarily sufficient to encourage industry to move research facilities from traditional locations. Investment patterns are not particularly encouraging. While foreign direct investment in developing country research rose from 3% in 1989 to 13% in 1995 as a percentage of global investment, a significant amount of this was confined to investment in adapting the technology of parent companies to local conditions as opposed to core research activities.<sup>36</sup>

Second, it is questionable whether the TRIPS Agreement will promote local innovation in developing countries. Innovation relevant to many developing countries is often informal and is undertaken by individuals or local communities in the field who, in many cases, have only limited means. Stimulating informal innovation calls for IP systems that are cheap and easy to

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<sup>33</sup> The TRIPS Agreement, Article 7.

<sup>34</sup> See GRAIN, *Intellectual Property Rights and Biodiversity: The Economic Myths*, The GAIA Foundation, Global Trade and Biodiversity in Conflict, Issue No. 3, October 1998. <<http://www.grain.org/publications/gtbc/issue3.htm>>.

<sup>35</sup> Mansfield, E., *Intellectual Property Protection, Direct Investment and Technology Transfer: Germany, Japan and the United States*, International Finance Corporation Discussion Paper 27, Washington DC, 1995, p. 22.

<sup>36</sup> UNCTAD, *World Investment Report 1997: Transnational Corporations, Market Structure and Competition Policy*, United Nations, Switzerland, 1997, p. 14.

access. The TRIPS Agreement, by contrast, is based on developed country IP systems that seek to promote more technical, formal corporate innovation. Such protection is costly in terms of time and financial resources to acquire, maintain and defend. These costs will, in many cases, hinder the access of economically-poor but knowledge-rich innovators in developing countries from accessing IP systems.<sup>37</sup>

In addition to these questions about the efficacy of TRIPS for developing countries, questions are being raised about the effectiveness of modern IP systems to promote innovation in developed countries.<sup>38</sup> Patents allow their holders to control a key ingredient in research – knowledge. By controlling the use of knowledge, companies can annex areas of research for themselves by claiming patent infringement if a competitor enters the field. In the long run the existing tendency in many developed countries towards over-broad patents could have the paradoxical result of slowing rather than stimulating research.<sup>39</sup> In the US, for example, patent offices regularly grant patents for broad fields of technology, which in turn have the effect of blocking related research activity. The phenomenon of broad patents is most prevalent in the area of biotechnological research. One example is the US patent application by Human Genome Sciences over the whole genetic sequence of bacteria that causes meningitis.<sup>40</sup> If granted, this patent could give its holder the power to restrict, in the US, the development of vaccines and other preventive medicines for meningitis, and possibly other diseases.<sup>41</sup>

Current trends in licensing practices over core research tools also have potentially negative impacts on research. The cross-licensing of IPRs in key areas of technological research such as agriculture and health, together with mergers and acquisitions, are shoring up research activities in the hands of a few corporations to the exclusion of competition.<sup>42</sup> Where exclusive licenses are awarded over core research tools to one company, the research efforts of other firms might be blocked before they even get off the ground.<sup>43</sup>

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<sup>37</sup> Gupta, A., *Securing Traditional Knowledge and Contemporary Innovations: Can Global Trade Links Help Grassroots Innovations?* Honey Bee Perspective, Professor Anil K. Gupta, Ahmedabad, India. Gupta gives the example of the Australian Innovation Patent System that provides product patent protection for a ten year period at low cost but with a limitation on patent claims in the patent application to 5 claims as an example of an effective IPR grant targeted at small enterprises.

<sup>38</sup> See e.g., Thurow, Lester C. “Needed: A New System of Intellectual Property Rights”, *Harvard Business Review*, September–October 1997 and Eisenberg, R.S., “Technology Transfer and the Genome Project Problems with Patenting Research Tools. Risk: *Health, Safety & Environment*, 5, pp. 163–175. <<http://www.fplc.edu/risk/vol15/spring/Eisenber.htm>>.

<sup>39</sup> Hart, D.M., “Antitrust and Technological Innovation”, *Issues in Science and Technology*, Winter 1998 <<http://www.nap.edu/issues/15.2/hart.htm>>. In the US, anti-trust agencies, while recognizing that IPRs can stimulate competition and innovation, have noted that IPRs can extend monopoly power in the area of technological innovation as well as the potential for firms to use IPRs to deny competitors their rightful intellectual property protection. See also “Compulsory Licensing and the Resolution on The Revised Drug Strategy – 51st World Health Assembly. <<http://www.cptech.org/pharm/cl.html>>.

<sup>40</sup> *Ibid.*

<sup>41</sup> See also CUTS, TRIPS, *Biotechnology and Global Competition*, Centre for International Trade, Economics and Environment, Research Report, Jaipur, 1997, p. 9.

<sup>42</sup> *Ibid.*, p. v.

<sup>43</sup> Eisenberg, R., *Technology Transfer and the Genome Project: Problems with Patenting Research Tools*, <<http://www.fplc.edu/risk/vol15/spring/Eisenber.htm>>.

It is important, therefore, to ensure that IP systems do not develop in a way that helps to consolidate control of research in the hands of only a few corporations, and maintains technology in the hands of a relatively small number of private interests. While most developed countries have anti-competition laws to counter the abuse of IPRs, developing countries are left to struggle to implement the TRIPS Agreement, with little guidance on how to regulate anti-competitive practices and to ensure that IPR are used responsibly. Unless corrected, this tendency could ultimately undermine research in developing countries, and reduce rather than stimulate innovation. Deeper consideration must therefore be given to creating an international IP system that balances rights with duties, that shares the benefits of technological innovation equitably between producers and users, and that promotes all forms of innovation, in developed and developing countries alike.

## The dissemination of technology

According to the objectives of the TRIPS Agreement, the protection and enforcement of IPRs should also contribute to the transfer and dissemination of technology.<sup>44</sup> IP systems can promote transfer and dissemination by providing an enabling environment for the licensing of IPRs, although empirical research on whether this is in fact the case is inconclusive.<sup>45</sup> In theory, guaranteed protection of IPRs could encourage risk-averse technology holders to set up joint ventures or wholly-owned subsidiaries in another country through which technology might be transferred. Alternatively, IPR protection can encourage companies to seek technology partners in other countries through the negotiation of licensing agreements. In particular, strong IPR protection could encourage small- and medium-sized companies that lack the resources to set up subsidiaries off-shore and so rely on licensing IPRs to introduce technology to new markets.

Available statistics indicate that developed countries and transnational corporations currently dominate licensing activity and gain most in terms of royalty flows.<sup>46</sup> The United Nations Conference on Trade and Development's (UNCTAD) World Investment Report notes that a high proportion of royalty payments and fee receipts accrue to only a few developed countries. A UNESCO report confirms this, indicating that only 10 developed countries capture 91% of all cross-border technology license fees.<sup>47</sup> Further, technology flows are dominated by a limited number of transnational corporations. The UNCTAD Report noted that 70% of global royalties and license fees flowed between parent companies and their foreign affiliates.<sup>48</sup> While the UNCTAD Report acknowledged small technology flows to developing countries, it concluded that the liberalization of regulatory policies on foreign technology agreements had not been sufficient to bridge the technology gap between developed and developing countries.

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<sup>44</sup> The TRIPS Agreement, Article 7.

<sup>45</sup> See e.g. Mansfield, E., *Intellectual Property Protection, Foreign Direct Investment and Technology Transfer*, International Finance Corporation, Discussion Paper 19, Washington D.C., 1994; Mansfield, E., *Intellectual Property Protection, Direct Investment and Technology Transfer: Germany, Japan and the United States*, International Finance Corporation Discussion Paper 27, Washington D.C., 1995.

<sup>46</sup> UNCTAD, *ibid.*, p. 21.

<sup>47</sup> UNESCO figures cited in GRAIN, *op. cit.*, p. 6.

<sup>48</sup> UNCTAD, *op. cit.*, p. 2.

It remains to be seen the extent to which the TRIPS Agreement will influence patterns of technology transfer. Although those supporting stronger protection and enforcement of IPRs argue that it helps to provide a safe environment for technology transfer, strong IPRs may also increase technology holders' control over technology, and consolidate their influence vis-à-vis the users of technology. Moreover, while the role of IPRs in technology transfer will depend on a mix of political, social, economic, administrative, cultural and legal factors, stronger IPRs could result in barriers to technology transfer in three ways:

1. ***Strong IPR protection can lead to high prices for technology.*** While price depends on a number of factors, IPRs such as patent rights allow their holders to limit competition and thus provide more leeway in price setting. It is difficult to judge the extent to which IPRs influence technology prices. A Swiss Government Report noted the potential for license fees over patented innovations to exclude poorer developing countries from accessing needed environmentally-sound technology.<sup>49</sup> The report also noted that high prices can force these countries to deny themselves technology or know-how, or alternatively, to appropriate IPRs unlawfully.
2. ***Strong protection can allow technology holders to negotiate conditions for transfer that are unfavorable to technology users and may even amount to anti-competitive practices.*** Technology owners may use the influence arising from their exclusive rights to negotiate license terms that unduly restrict the use of technology. They may restrict production levels or severely limit its use geographically. This could, in some cases, undermine attempts by developing country companies to secure a technological foothold in highly competitive global markets.<sup>50</sup> The TRIPS Agreement permits States to restrain anti-competitive practices, but no measures are established to guide States on how to deal with such practices.<sup>51</sup>
3. ***Strong protection can provide technology holders with the means to exclude technology users from accessing technology.*** Technology owners may use IPRs to withhold technology from emerging competitors. While this may be considered a legitimate use of IPRs under the TRIPS Agreement, from the technology-user's perspective the benefits granted to the technology holders may not be adequately balanced with similar public benefits in the form of technology dissemination. By establishing rules that may be used to prevent access to technologies, the TRIPS Agreement could be seen as consolidating global technology

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<sup>49</sup> Inter-Departmental Committee Rio (IDC Rio), *Transfer and Cooperation in the Area of Environmentally-sound Technology*, Final Report of the IDC Rio Working Group "Technology Transfer/Cooperation", Switzerland, 1995, p. 4.

<sup>50</sup> An example of anti-competitive licensing practices is the use of grant back clauses. Grant back clauses are sometimes used to ensure that any technological developments undertaken by the technology user as a result of working the license must be granted back to the technology holder, including the right to claim IP protection over the developments.

<sup>51</sup> The TRIPS Agreement, Article 8 states: "Appropriate measures, provided that they are consistent with the provision of the Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology". Similarly, Article 40(1) states: "Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology" while Article 40(2) states: "Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market".



movements among established technology providers – who could then use their (effective) monopoly rights to restrict the development of competitors in the new markets of the developing world.

It is difficult to judge the extent to which these three phenomena actually occur. At this stage, it is useful to highlight them as possible effects of IPRs on the dissemination of technology.

What then are some appropriate mechanisms to ensure that IPRs are not used to inhibit the transfer and dissemination of technology? Anti-competition law and compulsory licenses have traditionally been used to avoid these sorts of problems. A compulsory license is a license over patent rights that is granted to a third party by authorization of a government authority, irrespective of the will of the patent owner. Generally, a compulsory license will be granted either in the public interest – for example where the license is awarded in the interests of promoting public health, defense or economic development – or in the event of an abuse of patent rights by the owner.

The grant of a compulsory license is governed by Article 31 of the TRIPS Agreement. This article establishes a list of conditions that must be complied with before compulsory licenses may be issued.<sup>52</sup> Some commentators argue that Article 31 holds significant potential for the protection of the public interest in areas of health, nutrition, protection of farmers' rights, and for gaining access to new technologies necessary for development.<sup>53</sup> The use of compulsory licenses to promote the public interests through technology transfer should therefore be explored. However, it should be noted that compulsory licenses do not support technological partnerships between technology holders and users, and are seen by the former as an aggressive remedy. Consequently, compulsory licensing mechanisms should be developed in conjunction with other devices to promote the transfer of technology.

The most explicit provision establishing the responsibility of developed countries with regard to technology transfer is Article 66(2). This Article requires that “developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base”. The TRIPS Council is currently reviewing the action that has been taken by Members to fulfill these responsibilities.<sup>54</sup> While some Members have supplied only examples of technical assistance on implementing the TRIPS Agreement, others have identified incentives to promote technology transfer that conform to the letter and spirit of Article 66(2). A closer analysis of the results of the review once it is complete could help in ensuring the TRIPS Agreement supports technology transfer.

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<sup>52</sup> Article 31 becomes controversial when read with Article 27, which provides “patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether the products are imported or locally produced”. Some WTO Members have read this to mean that the importation of a product embodying technology will amount to local working of the patent. This has provoked criticism from developing countries that point out that the importation of a product embodying technology does not bring the same benefits to the local population – such as increasing technological capacity – as does the domestic manufacture of the product or use of the process.

<sup>53</sup> Dutfield, *op. cit.*, p. 23.

<sup>54</sup> Several countries have responded so far including Austria, Denmark, Finland, France, Germany, the Netherlands, Spain, Sweden, the UK, Ireland, Japan, Australia, New Zealand and the US.

In all likelihood, the effects of the TRIPS Agreement on the dissemination of technology will probably be mixed. However, the role of IPRs in technology transfer should be put in context. Many other factors – some far more relevant than strong IP protection and enforcement – exist that help promote the transfer of technology. Economic and political stability, market size, transparent bureaucratic procedures, the existence of a sound technological infrastructure, access to information on technology needs and availability, and ready finance are all prerequisites to technology transfer which together could well outweigh the existence of TRIPS-style IP systems.

## **The dissemination of environmentally-sustainable technology under MEAs**

The TRIPS Agreement could also affect the implementation of the technology transfer provisions of Multilateral Environmental Agreements (MEAs). The international community has negotiated MEAs to respond to environmental problems such as biodiversity loss, ozone depletion, climate change, desertification, and trade in hazardous waste. Many MEAs include provisions on technology transfer that require developed countries to facilitate and promote the transfer of technology to developing countries. It is unclear to what extent the implementation of the TRIPS Agreement will promote or withhold flows of environmental technology. Empirical research by MEA Secretariats indicates both positive and negative roles for IPRs.<sup>55</sup>

### **Box 2 – CFCs in India**

The *Montreal Protocol* requires, *inter alia*, the phase out of ozone-depleting substances. To this end, the Protocol includes a number of mechanisms to promote technology innovation and dissemination. In particular, it includes an obligation on developed countries to facilitate the transfer of technology to developing countries under “fair and most favorable conditions”.

Some of the most dangerous ozone-depleting substances are of the chlorofluorocarbon (CFC) family. CFCs are used in the refrigeration and air conditioning industry as foam-blowing agents and refrigerants. The most popular replacement of CFCs as refrigerants is HFC-134a. The production of HFC-134a requires the implementation of complex technology which is protected by patents held by transnational companies in the US and Japan. Much of the technology is also undisclosed know-how, protected as trade secrets by the patent owners. As a result, CFC-users in developing countries – faced with the obligation

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<sup>55</sup> See e.g., Intergovernmental Panel on Forests, *Transfer of Environmentally-sound Technologies to Support Sustainable Forest Management: Report of the Secretary General*, Program Element II. c of the Program of Work of the Intergovernmental Panel on Forests, Advanced Unedited Text, 1998, <[gopher://gopher.un.org:70/00/esc/cn17/iff/session2/sgiiic](http://gopher.un.org:70/00/esc/cn17/iff/session2/sgiiic)> which notes patents and other IPRs as important limitations on the transfer and effective use of technology in developing countries. See also, United Nations Framework Convention on Climate Change, *Terms of Transfer of Technology and Know-How – Barriers and Opportunities Related to the Transfer of Technology*, Technical Paper, United Nations, Germany, FCCC/TP/1998/1 which identifies the strengthening of IP laws in Korea in 1990 and the establishment of the Intellectual Property Court in Thailand as examples of government efforts to encourage the private sector to develop local technology and technology transfer.

## Box 2 – CFCs in India (cont.)

of phasing out their CFC production – attempted the negotiation of licenses with the patent and know-how owners of alternative technology in order to stay in business after phase out.

In India, the local refrigeration industry introduced CFCs in the late 1980s. When Indian industry became aware of the requirements to phase out CFC use, they sought licenses over the production of HFC-134a. However, the patent owners either refused, or – according to the Indian CFC producers – required unjustifiably high license fees or export restrictions on HFC-134a.<sup>56</sup> As the Indian companies could not accept such restrictive terms, they turned to innovating alternative technology themselves. While research activities to date have been successful, research is both expensive and time-consuming. The associated delays have delayed the implementation of the HFC-134a technology. Research is made difficult since researchers have to be careful not to infringe the patents of the American and Japanese HFC-134a technology holders. Interestingly, the researchers have themselves protected the results of research with patents.

Although the action of patent owners was a legitimate exercise of their rights over technology, the pursuit of commercial objectives did not assist Indian efforts to implement the *Montreal Protocol* through rapid replacement of CFC production with production of a more environmentally-sustainable alternative. As there was no transfer of HFC-134a technology, this case calls into question the efficacy of developed country obligations to facilitate the transfer of environmentally-sustainable technology under fair and most favorable conditions. Attempts were made by the Indian Government to gain funding from the Multilateral Fund – the funding mechanism of the Protocol. However, these attempts were not successful. While the Fund provides India with finance to cover phase-out of CFCs, it has not funded the research and development nor the implementation of CFC alternative technology such as HFC-134a.

The role that IPRs played in withholding the HFC-134a technology from Indian CFC manufacturers is difficult to assess. The technology relied heavily on know-how that was confidential to the companies. This means that any transfer of the technology would have involved not only licensing of patent rights, but also the transfer of a considerable body of know-how. Thus, even if the technology had never been protected with patent rights, the companies could still have withheld the technology, or set high rates for its transfer. Nonetheless, the existence of patent protection over the HFC-134a technology made the Indian research activities more difficult as they had to ensure they were not infringing the technology holders' rights during their research activities.

Consequently, it might be that, either with or without patent rights over the HFC-134a technology, the technology might have been expensive or effectively withheld. The effect of IPRs on the actual lack of any transfer of technology is difficult to gauge. It can be said

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<sup>56</sup> One CFC producer stated that a technology holder stipulated that a license would be subject to an up-front fee in the range of \$20–\$25million, a figure that the producer considered in excess of a reasonable rate. A UNDP study has noted that Indian industry calculated that the highest possible license fee that would allow a reasonable profit margin for the user would be \$8 million given the price of HFC-134a in 1996 (\$4.5 per kg).

### **Box 2 – CFCS in India (cont.)**

however that the existence of IPRs over the HFC-134a technology was certainly insufficient in itself to promote the transfer of technology consistent with the objectives of both the TRIPS Agreement and the *Montreal Protocol*. As a result, it could be productive for WTO Members to consider the possible alternatives for enhancing the environmental aspects of IPRs by developing a mechanism that would encourage the use of IPRs to meet environmental objectives through promotion of the transfer of technology.

*Source:* Walker, S. *The Use of Intellectual Property Rights in the Transfer of Technology under Multilateral Environmental Agreements*, Study, draft, WIPO, Geneva, 1999. The contents of the case study were drawn from interviews with the concerned parties.

Also, much environmental technology is in the public domain – either because IPR protection has expired, or because protection was never sought in the first place. In these cases, the TRIPS Agreement will have little if any impact on the transfer of technology under MEAs.

The text of the TRIPS Agreement says little about environmental concerns – in spite of its potential to affect the environment.<sup>57</sup> Even accepting the claim that strong IPRs might provide an enabling environment for licensing of technology generally, the TRIPS Agreement does not explicitly seek to promote the transfer of IPR-protected environmental technology. Given the imperative for developed countries to promote technology transfer under MEAs, and in light of pressing environmental problems facing humanity, there is some argument to support the development of an international legal environment that actively promotes the licensing of IPRs over environmental technology. Policy-makers in developed countries may, for example, wish to explore how to implement their obligations relating to technology transfer under Articles 7 and 66(2) of the TRIPS Agreement in a way that complements their obligations to transfer technology under MEAs. The transfer of environmental technology could also be achieved through the inclusion of a duty to transfer environmental technology within a certain time limit, as a requirement of the initial grant of rights. While such measures may contribute to technology transfer, it should be highlighted that technology transfer under MEAs will probably best be achieved with other measures such as private/public sector technology partnerships, and the provision of finance at reduced lending rates.

### **Access to health care**

Article 27(1) of the TRIPS Agreement requires Members to provide patents over all inventions, whether products or processes, in all fields of technology. This broad obligation encompasses a requirement to provide patent protection of pharmaceuticals. This is among the most controversial aspects of the TRIPS Agreement as patents on pharmaceuticals raise fundamental

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<sup>57</sup> Article 27(2) allows Members to exclude from patentability inventions if this is necessary to avoid serious harm to the environment. It is questionable whether such a provision will be interpreted expansively so as to encourage the implementation of MEAs in general or technology transfer in particular. See Drahos, “Biotechnology Patents, Markets and Morality” *op. cit.*, which notes that patent offices are under increasing pressure to adopt liberal attitudes to the grant of patents and to define morality or *ordre public* exceptions narrowly.

questions about life and survival and may conflict with the enjoyment of basic human rights – in particular, the right to health.<sup>58</sup>

Prior to the TRIPS Agreement, most IP systems, in both developed and developing countries, had refused, at some stage in their history, to grant patents over pharmaceuticals – generally in order to fulfill health and developmental objectives.<sup>59</sup> While the effects of the TRIPS Agreement on the health sector in developing countries are unlikely to be uniform, the introduction of patent protection for pharmaceutical products could have the effect of increasing drug prices in those countries where protection had not been offered before.

The prospect of high prices on pharmaceuticals is of particular concern, especially in developing countries. The need to avoid paying high prices for drugs has been a central concern of health strategies in many developing countries. By 1970, for example, India had one of the highest levels of drug prices in the developing world, which it attributed directly to the existence of patents over pharmaceutical products.<sup>60</sup> As a result, India withdrew protection for pharmaceutical products that, together with strong government price regulation, had the effect of radically reducing drug prices.<sup>61</sup> The lack of patent protection also saw the local generic drug industry flourish, producing new drugs within a relatively short space of time of their appearance on the international market without fear of patent infringement suits.<sup>62</sup> This pattern was repeated in many developing countries including Brazil, Argentina, Turkey, Mexico, Taiwan and Egypt,<sup>63</sup> where the lack of patent protection lowered pharmaceutical prices, helped local industry and improved the state of health care generally. Logically, the introduction of patent protection for pharmaceuticals as a result of the TRIPS Agreement should have, at least in some cases, the effect of raising the price of pharmaceuticals.

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<sup>58</sup> See e.g., the *Universal Declaration on Human Rights*, Article 25 which states that “Everyone has the right to a standard of living adequate for the health and well-being of himself and his family, including .... medical care”.

<sup>59</sup> See Salazar, S., “Intellectual Property and the Right to Health”, in WIPO/OHCHR, *Intellectual Property and Human Rights*, A Panel Discussion to commemorate the 50th Anniversary of the Universal Declaration of Human Rights, Geneva, Switzerland, 1999, p.71 which notes that “it was not until 1960 that France introduced protection, with Germany following in 1968, Italy in 1978, and Japan and Switzerland in 1976 and 1977 respectively.”

<sup>60</sup> Drahos, P., “The Universality of Intellectual Property Rights: Origins and Developments”, in WIPO/OHCHR, *Intellectual Property and Human Rights*, A Panel Discussion to Commemorate the 50th Anniversary of the Universal Declaration of Human Rights, Geneva, Switzerland, 1999, p. 19.

<sup>61</sup> While the refusal to protect pharmaceuticals with patents is only one factor that effects drug prices, a comparison of certain drug prices provides a convenient illustration of the benefits of generic production of drugs. The anti-malarial drug Larium currently costs \$37 in the US but only \$4 in India where it is produced as a generic by local industry. Ford, N. and D. Berman, “AIDS and Essential Medicines and Compulsory Licensing”, Summary of the World Health Organization Meeting on Compulsory Licensing of Essential Medical Technologies, Médecins Sans Frontières, Geneva, March 25–27, 1999. <<http://www.cptech.org/march99-cl/report.html>>.

<sup>62</sup> Alam, G., *Impact of the Proposed Changes of IPR on India’s Pharmaceutical Industry*, Centre for Technology Studies, paper prepared for the Indian Council for Research on International Economic Relations and the United Nations Development Programme, India, December 1996.

<sup>63</sup> Rozek, R., R. Berkowitz, “The Effects of Patent Protection on the Prices of Pharmaceutical Products: Is Intellectual Property Protection Raising the Drug Bill in Developing Countries?”, *The Journal of World Intellectual Property*, Vol. 1, No.2, March 1998, pp. 179–243, p. 181.

The effect of patent protection on pharmaceutical prices should be qualified. The World Health Organization's Essential Drug List sets out the drugs it has determined as essential to minimum health care, the majority of which are now off patent. Although patents are favored by the pharmaceutical industry, the therapeutic gains of many patented drugs vary, and the supply of off-patent drugs is sufficient to treat many illnesses.<sup>64</sup> Where there is more than one drug that performs the same treatment, as is often the case, competition between drugs will help to keep price levels down.<sup>65</sup> The role of government price controls, bulk discounts on health services, and reimbursement for health care can also keep a check on the use of patents to inflate drug prices and can be extremely important in ensuring needed drugs are available to the public.<sup>66</sup>

Nevertheless, the TRIPS Agreement could help concentrate more power in the hands of the large pharmaceutical companies, the majority of which are based in only four developed countries – the US, the UK, Switzerland and Germany.<sup>67</sup> Where drugs are patent protected, decisions on pricing will increasingly take place in the executive boardrooms of TNCs, far from the health crises of developing countries. In the case of cures or treatments found for new diseases such as HIV/AIDS, or persistent diseases such as malaria or tuberculosis, decisions on the use of patents over pharmaceuticals could have serious consequences.

### **Box 3 – Access to HIV/AIDS drugs in Thailand**

The most serious health issue facing the world today is the HIV/AIDS pandemic. In countries such as Zimbabwe and South Africa, as many as one in four people are infected with the virus. While researchers have yet to find a cure for the disease, there are an increasing number of treatments that improve both the life expectancy and the quality of life of people with HIV. However, while these treatments are available in developed countries, people in developing countries are denied access to the drugs as a result of high price levels. In Africa, where 26 million of the estimated 33 million people infected with HIV are living, the prices of monthly treatments are hundreds of times average salary levels.

With production of the AIDS drug ddI in Thailand, for example, patent rights that are licensed exclusively to Bristol Myers Squibb ensure that the company controls imports and sales – giving it leeway to set prices to suit its economic objectives, but not necessarily the

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<sup>64</sup> Alam, *op. cit.* Alam notes that the therapeutic value of drugs has steadily decreased since the 1950s.

<sup>65</sup> Many of the new drugs appearing on the market in developed countries are “me too” drugs – drugs that cash in on drugs that have had marketing success but which are sufficiently different not to infringe patents.

<sup>66</sup> In India, for example, the price of drugs has tended to rise as soon as price regulation has relaxed. For example, Roche increased the price of Vitamin A by 40% when price regulation was withdrawn which duly prompted the Government to reintroduce price controls. However it should be noted that regulation is expensive for Governments and therefore ultimately taxpayers which puts effective drug regulation beyond many smaller developing countries. Regulation is also becoming unpopular in a time of small government.

<sup>67</sup> Alam, *op. cit.*

### **Box 3 – Access to HIV/AIDS drugs in Thailand (cont.)**

health objectives of the Thai people. As a result, the Thai Government has been developing strategies to lower prices of ddI as well as other treatments. For example, the Government considered granting a compulsory license of ddI technology as a means of ensuring that there would be at least one affordable, low-tech double therapy combination. The Government's proposed action was consistent with the compulsory licensing provisions under the TRIPS Agreement. The US Government, however, responded by threatening trade sanctions on key exports if the Thai Government did not change its IP laws. In particular, the US pushed for amendments to the Thai patent law that excluded the grant of compulsory licenses over pharmaceuticals as well as to abolish the Pharmaceutical Review Board, the Government body charged with surveying price levels over pharmaceuticals.<sup>68</sup> The Thai Parliament passed amendments in October 1998 abolishing the Pharmaceutical Review Board. However, the Director General of the Department of Intellectual Property maintains the power to override a patent and issue a compulsory license where the patent is deemed not to be locally 'worked' or if the price is considered unreasonably high.

The experience of Thailand and other countries illustrates again the imbalance in the TRIPS Agreement between protecting private rights and promoting the public interest, including the right to health. Not only does the TRIPS Agreement require the implementation of high "minimum" standards for the protection of IPRs, but technology producers are pushing for even stronger protection unilaterally, eroding the already weak acknowledgement of health concerns included in the Agreement. The case illustrates the need for discussion in the TRIPS Council to establish the means to ensure that the TRIPS Agreement is implemented in conformity with other international standards, especially human rights standards, and in particular, the right to health. For example, WTO Members should take measures to ensure that the TRIPS Council repudiates unilateral action on behalf of individual countries that police compliance with the TRIPS Agreement or try to coerce other Members to introduce protection at higher levels than contained in the Agreement.

## **Biotechnology**

### **Introduction**

Ever since the beginning of agriculture, farmers have experimented with plant breeding to develop new varieties of plants that are better yielding or hardier to climatic conditions. The point of departure for modern biotechnology is its reliance on the modification of the basic structures of life – genes. The use of recombinant DNA techniques and the use of tissue culture and *in vitro* techniques have resulted in a whole new range of products that can be produced through biotechnology. Unlike traditional techniques, biotechnology permits genes to be transferred across species boundaries: from scorpions into corn, or from humans into pigs. The genetic modification of organisms raises ethical, environmental, social, economic, as well as legal issues. Given the link between IPRs and the development of biotechnology, the

<sup>68</sup> See Auerbach, S., "Reagan Orders Sanctions Against Thailand, Duty Free Status Removed from \$165 Million in Thai Imports" *The Washington Post*, 21 January 1989, Assavananda, A. "NGOs rally against patent law changes, call on US to stop pressuring Thailand" *Bangkok Post*, 5 September 1998, p. 2.

interpretation and implementation of the TRIPS Agreement, and its possible re-negotiation, could play a significant role in either resolving or exacerbating these issues.

Modern biotechnology is now big business. The costs involved in biotechnological research and the difficulty in controlling access to biotechnology beyond the initial point of sale have highlighted the role of IPRs in biotechnology. The intensive effort that is required to develop new drugs and plants and the uncertainty inherent in biotechnological research make biotechnology an expensive enterprise. Where innovations do make it to market, biotechnological inventions may be easily reverse-engineered by competitors. In many cases, inventions are living organisms that reproduce naturally and so do not need repeat purchases. The ownership and control of technology offered by IPRs guarantees some assurance for innovators against these risks.

The biotechnology sector has been vocal in pushing for IPRs over biotechnology. In developed countries, the protection of biotechnology has developed rapidly. The United States first provided protection for asexually reproduced plant varieties in 1930.<sup>69</sup> For many years, however, the United States did not grant patent protection over other living material as it was considered a product of nature rather than a human invention. In 1980, this was overturned in the landmark case *Diamond v. Chakrabarty*, which held that a patent granted over a genetically modified strain of bacteria capable of degrading components of crude oil was valid.<sup>70</sup> By 1987, the US Patent and Trademark Office (USPTO) was awarding patents over animals. In 1998 for example, the USPTO granted a patent over a mouse that was genetically engineered to be susceptible to breast cancer to help in cancer research. By 1991, the NIH, a US Government research institute, received patent rights over 350 human gene fragments that had been identified by researchers.<sup>71</sup>

While the United States and some other countries actively promote IPRs over life-forms, there are a number of reasons to think carefully about granting IPRs over the products of biotechnology.<sup>72</sup>

1. **Ethical.** While religions generally accept ownership over animals and plants, some religions consider the extension of property rights over all instances of a given structure of living matter morally wrong. Countries should thus be able to develop their IP system that is consistent with respect for their beliefs. Another ethical consideration concerns food security and health. The provision of property rights over biotechnology offers strengthened corporate control over agricultural and health technology thus furthering the purported general shift towards protecting corporate interests over other concerns.<sup>73</sup> Finally, ethical arguments could be raised against patenting on humanist grounds. In the Harvard

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<sup>69</sup> The *Plant Patent Act* (1930).

<sup>70</sup> *Diamond v. Chakrabarty* 477 US 303 (1980).

<sup>71</sup> See Chapman, A. "A Human Rights Perspective on Intellectual Property, Scientific Progress and Access to the Benefits of Science" in WIPO/OHCHR, *op. cit.*, pp. 127-168, p. 141f.

<sup>72</sup> The following breakdown has been adapted from Tansey, G., *Trade, Intellectual Property, Food and Biodiversity: Key Issues and Options for the 1999 Review of Article 27(3)(b) of the TRIPS Agreement*, A Discussion Paper, Quaker Peace and Service, London, UK, p. 18f.

<sup>73</sup> Some commentators have argued however that it is not clear how technology itself can be unethical as it is the use of technology, rather than the technology itself that could face moral condemnation. In this case, governments should determine the moral or ethical limits of research, IP systems being relevant to preventing others from using technology not to the actual uses of technology. Carvalho II, *op. cit.*, p. 5.



Mouse case for example, ethical arguments were raised against patenting on the grounds that mice that had been engineered to be susceptible to cancer would suffer.

2. **Environmental.** The effects on the environment of tampering with the genetic make-up of living matter are largely unknown. It is therefore necessary to carefully regulate and test biotechnological innovation to avoid possibly serious damage to the environment. In the absence of adequate regulatory measures, granting property rights over technology may actively promote innovation without safeguards to avert environmental damage. IP policy-makers should thus take a “wait and see” approach and delay considering whether to extend IPRs over biotechnology until there is a greater appreciation of its environmental impacts.<sup>74</sup>
3. **Economic.** The grant of broad patents over biotechnology in some developed countries, combined with cross-licensing between transnational corporations, could close off research and technology transfer possibilities. The practice in the some developed countries of broad patent applications can give excessive market control to individual corporations.<sup>75</sup> If patenting of biotechnology is extended globally, this could have the effect of further consolidating ownership and control of the biotechnology sector – including seeds, food and pharmaceuticals – in the hands of a few private firms.<sup>76</sup> In this way, rather than stimulate global innovation, IP systems may continue the shift of power away from governments and the public.
4. **Legal.** Much biotechnological research involves the isolation of genes that already exist in nature. The provision of IPRs over this research distorts the basic principle that patents are granted not over “discoveries” but over inventions that are new and involve an inventive step. By contrast, the isolation of a natural substance is more a discovery than an invention and so would normally be considered outside the scope of IP protection.<sup>77</sup> Yet patents are being used to protect many such biotechnological discoveries. The award of patent rights of

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<sup>74</sup> Dutfield examines the linkages between IPRs and the environment due to the innovation and use of crops and agro-chemicals. Dutfield takes the case of genetically modified crops with built-in resistance either to herbicides marketed by the same company or to insect pests. He notes that corporations have a tendency to claim that IPR protection is their incentive to invent which suggests a link between IPRs, and the environmental impact of these products in that they would not exist without the possibility of IPR protection. See Dutfield, *op. cit.*, p. 46f.

<sup>75</sup> In 1992, Agracetus was awarded US patent 5,159,135 for all transgenic cotton. The claim covered any variety of cotton produced by means of any gene transfer technology, giving the company wide control over the research and marketing of genetically modified cotton. In this case, the patent was cancelled after complaints concerning the patent’s breadth made by the US Department of Agriculture, NGOs and others. While this was a case of the patent system righting itself, it should be noted that such litigation can be expensive. See Dutfield, *op. cit.*, p. 26. The case demonstrates some of the undesirable economic effects of patent protection and suggests that there is a need for a re-think of patent examination to avoid the award of broad patents in the first place. The case also suggests that Members that do not currently award patents over biotechnology should exercise caution and think carefully of what means are appropriate for the optimal promotion of biotechnological innovation that includes environmental objectives and curtails excessive economic power of certain commercial interests.

<sup>76</sup> Already, in the agricultural sector, ten of the world’s top seed companies control 40% of the market. See Rural Advancement Foundation International, “RAFI Communiqué”, November/December 1997 in GRAIN, *Ten Reasons Not to Join UPOV*, Global Trade and Biodiversity in Conflict, Issue No. 2, May 1998, <<http://www.grain.org/publications/gtbc/issue2.htm>>.

<sup>77</sup> As one commentator has stated “(m)other nature’s handiwork is never too far away in the case of biotechnological inventions”, Drahos, “Biotechnology Patents, Markets and Morality”, *op. cit.*

biotechnological discoveries – as opposed to innovations – sidesteps this aspect of IP law and permits enclosure of what was previously common property.

## **Obligations under the TRIPS Agreement relevant to biotechnology**

Article 27 of the TRIPS Agreement refers to “Patentable Subject Matter” and states that patents shall be available in all fields of technology. Article 27 includes some exceptions to this general rule, including Article 27(3)(b), which permits WTO Members to:

- exclude plants and animals from patentability;

but requires them to:

- recognize patents over micro-organisms;
- recognize patents for microbiological processes for the production of plants and animals; and
- recognize either patent or *sui generis* protection for plant varieties.

With regard to the protection for plants varieties, Members have the option to:

- provide *sui generis* protection for new plant varieties;
- provide patent protection for new plant varieties; or
- provide both *sui generis* and patent protection for new plant varieties.

With regard to the protection of innovations generally, Article 27(2) allows Members to exclude inventions from patentability to protect *ordre public* or morality, including to:

- protect human life or health;
- protect animal life or health;
- protect plant life or health; or
- avoid serious prejudice to the environment.

Such exclusions must not be made merely on the basis that the exploitation of the invention is prohibited under national law.

## ***Sui generis* protection for plants**

*Sui generis* systems for the protection of new plant varieties refers to systems that are specifically designed for particular subject matter, as opposed to one that is an adaptation of existing IP protection such as patents. The TRIPS Agreement offers no guidelines as to what constitutes a *sui generis* system of plant protection, so Members have significant leeway to develop systems that are best adapted to their particular developmental needs.

One existing system for the protection of plant varieties is established by the *International Convention for the Protection of New Varieties of Plants*, known as UPOV.<sup>78</sup> UPOV provides for protection of plant varieties through the grant of plant breeder rights (PBRs). Plant variety protection (PVB) confers an exclusive right on the plant breeder to exploit a new variety of plant. PBRs are currently granted over new plant varieties that are:

- distinct from existing, commonly known varieties;

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<sup>78</sup> UPOV stands for the Union Internationale pour la Protection des Obtentions Végétales.

- uniform;
- stable; and
- new, in the sense that they must not have been commercialized prior to the date of application.

The UPOV Convention, which came into force until 1968, has been revised in 1972, 1978 and 1991. The 1991 Act (UPOV 91) goes beyond the 1978 Act (UPOV 78) in six main ways (see Box 4) and provides considerably stronger protection to plant breeders than before. UPOV 91 entered into force in 1998, which means that, from April 24, 1998, new parties to the Convention must adhere to the 1991 Act. As of May 26, 2000, 45 States are party to UPOV under one or other of the Acts.

#### Box 4 – Differences between UPOV 78 and UPOV 91

1. **Term of protection.** UPOV 78 requires Members to provide protection to new varieties for a minimum of 15 years (18 years for trees and vines). UPOV 91 requires Members to provide protection for a minimum of 20 years (25 years for trees and vines).
2. **Coverage.** UPOV 78 requires Members to provide protection of as many plant genera and species as possible (minimum of 5 on joining and of 24 after 8 years). UPOV 91 requires Members to provide protection for a minimum of 5 plant genera and species on joining with full coverage of all plant genera and species 10 years later.
3. **Farmers' privilege.** UPOV 78 leaves open the possibility for farmers to practice the age old custom of saving part of their harvest so as to have seed to plant for the following season. Under UPOV 91, governments have a discretion to decide whether or not to permit farmers to save seed for use on their own holdings.<sup>79</sup>
4. **Breeders' exemption.** Under UPOV 78, breeders could modify protected varieties, and provided the new variety is distinguishable from the protected variety, use the new variety without owing any obligation to the original breeder. Under UPOV 91, new varieties that are essentially derived from the protected variety can only be marketed with the agreement of the original breeder.
5. **Scope of protection.** UPOV 78 did not extend PBRs over products such as fruits that are harvested from the protected variety. UPOV 91 extends PBRs over material harvested from a protected variety in certain circumstances.<sup>80</sup>
6. **Double protection.** Under UPOV 78, any species eligible for PBR protection could not be patented. UPOV 91 is silent on this question and countries may choose to exclude plant varieties from patent protection or alternatively offer both patent and plant variety protection.

<sup>79</sup> Significantly, an age-old practice has become an exception to the rights of plant breeders.

<sup>80</sup> Under UPOV 78, someone could take a protected variety to a country where it was not protected, plant it and harvest fruit from it, and then export it to a country where the plant variety was protected – the breeder had no claim to remuneration in this situation. Under UPOV 91, the breeder can claim remuneration. See World Trade Organization, *The Relationship Between the Convention on Biological Diversity (CBD) and the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) with a Focus on Article 27(3)(b)*, Background Note by the Secretariat, 5 October 1999, WT/CTE/W/125, para. 8.

UPOV 91 goes beyond previous standards and shifts the benchmark for establishing plant variety protection in favor of plant breeders. As a result of UPOV 91:<sup>81</sup>

- breeders may gain rights not only in the plant, but over the harvest as well – they may, for example, gain rights not only over the plant but over the sale of its fruit;
- the use of a protected variety in further breeding could be restricted;
- farmers could be restricted in saving seed for their own use; and
- new plant varieties could be doubly protected, through PBRs as well as patent rights.

UPOV 91 should not be seen as the only standard of plant variety protection, nor should UPOV 78 be seen as the only viable alternative to UPOV 91. As implied by the term “*sui generis*”, appropriate mechanisms to stimulate innovation of new plant varieties can be developed on a country-by-country basis, taking into account priorities reflected in national agricultural policy, developed through popular participation, and established with the objective of promoting the fundamental human rights, including the rights to food, health and development.

Under Article 27(3), as it stands, there is still considerable flexibility to introduce a system of plant variety protection that is suitable to local conditions. In the Philippines, for example, plant variety protection legislation that includes farmers’ rights, the breeders’ exemption, as well as plant variety protection that is tailored to the needs of indigenous communities has been drafted.<sup>82</sup> For developing countries, it will be important to maintain the flexibility inherent in Article 27(3)(b) by ensuring that the review does not determine that any one system of plant variety protection becomes the benchmark, to the exclusion of other systems.

### **Some observations concerning Article 27**

1. ***Article 27(2), which excludes innovations from patentability to protect animal, plant life or health or to avoid serious prejudice to the environment, should be broadly applied.*** The scope of the exclusions under Article 27 remains untested, but this provision could be used to ensure that technological innovation is not promoted at the expense of broader objectives of sustainable development. Broad interpretation of similar exceptions under the European Patent Convention Article 53(a) have unfortunately not been adopted in EU jurisprudence. In *Greenpeace UK v. Plant Genetic Systems NV* for example the exclusion was interpreted “as a measure to ensure that patents would not be granted for inventions that would universally be regarded as outrageous” and a contravention of “the totality of accepted norms”.<sup>83</sup> Another case tested the morality of providing patent protection over technology by asking whether the grant would be “abhorrent to the overwhelming majority of the public”.<sup>84</sup> However, this jurisprudence need not be indicative of interpretations of similar provisions under the TRIPS Agreement, and States should be free to develop their own jurisprudence to ensure that their IP system promotes environmental and other public interest objectives.

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<sup>81</sup> Tansey, *op. cit.*, p. 10.

<sup>82</sup> *Ibid.*, p. 11.

<sup>83</sup> [1995] E.P.O.R. 357 at 366.

<sup>84</sup> See *Hormone Relaxin O.J. EPO 6/1995*, 388 in Drahos, “Biotech patents, markets and morality”, *op. cit.*

2. **The exclusions under Article 27(3)(b) should be interpreted broadly.** As already noted, Article 27(3)(b) allows WTO Members to exclude patents over plants and animals and processes that are essentially biological, but requires them to grant patents over micro-organisms and non-biological and micro-biological processes. The interpretation of “micro-organism”, “essentially biological” and “non-biological and micro-biological” will affect the scope of Article 27(3)(b) exceptions. Some commentators have argued that Article 27 requires the *de facto* patenting of biotechnology as biotechnology generally involves the alteration of essentially biological processes by non-biological or micro-biological processes.<sup>85</sup> Similarly, some commentators have recently argued that the term “micro-organism” embraces animal and plant cells and naturally occurring bio-chemical substances such as DNA.<sup>86</sup> However, it should be emphasized that the European Patent Office has declared DNA to be “not ‘life’ but a chemical substance which carries genetic information”.<sup>87</sup> Accordingly, DNA should be considered within the scope of the exclusions under Article 27(3)(b). In light of the ethical, environmental, economic, social and legal reasons against the patenting of biotechnology, Members should clearly define these terms to avoid an interpretation that would lead to the *de facto* patenting of biotechnology. Members should also give careful consideration to the proposals by some countries to exclude life-forms from patentability.<sup>88</sup>
3. **Article 27(3)(b) should be interpreted so as to complement national policies to manage investment in biotechnology.** Many WTO Members may wish to control investment in the biotechnological sector until a proper national regulatory framework on biosafety is developed, and effective national institutions and regulations are in place to monitor the biotechnological sector. Given that IPRs are designed to encourage private sector investment in technological development, the withholding of IP protection over plants and animals could be employed as a check on investment in the biotechnological sector. It will be important to maintain the flexibility in Article 27(3)(b) so as to ensure the context for developing national efforts to provide a sound regulatory framework for biotechnology.
4. **Article 27(3)(b) should be considered in light of States’ obligations concerning fundamental human rights especially the right to food.** The relationship between awarding IPRs over new engineered forms of living material and human rights principles was discussed by the United Nations’ Sub-Commission on the Promotion and Protection of Human Rights in August 1999. In a report entitled “The right to adequate food and to be free from hunger”, the Sub-Commission noted that the merits of IPRs from a human rights perspective become less obvious when IPRs are used by powerful economic entities to control economically weaker producers of food or agricultural products, and to affect the distribution of food. The report concludes that it may be the time for the human rights’ community to consider the potential conflicts arising from IPRs that could seriously jeopardize the right to food. It also expresses concern for farmers’ rights, and states that, whereas commercial interests have recourse to rights such as IPRs, farmers typically have few formal rights and little protection

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<sup>85</sup> See e.g. CUTS, *op. cit.*, p. ii.

<sup>86</sup> See Dutfield, *op. cit.*, p. 22. Dutfield notes that the Intellectual Property Counsel at Novartis has recently argued that animal and plant cells are included in the term micro-organism.

<sup>87</sup> Dutfield, *op. cit.*, p.22.

<sup>88</sup> See, for example, WT/GC/W/302, Communication from Kenya on behalf of the African Group, to the General Council, Preparations for the Seattle Ministerial, The TRIPS Agreement, 6 August 1999.

for their activities.<sup>89</sup> The report is significant as it identifies the linkages between the obligations under the TRIPS Agreement and the long-standing obligations of WTO Members under international human rights law. Drawing these linkages is important as States should be aware of their obligations to implement plant variety protection as required under Article 27(3)(b) in a manner that is compatible with the promotion and protection of human rights.

## **The TRIPS Agreement and the Convention on Biological Diversity**

### **Introduction**

The possibility of the TRIPS Agreement impeding the implementation of the objectives of the Convention on Biological Diversity (CBD) has incited lively discussion at the WTO and the CBD, as well as amongst many organizations in civil society and industry.<sup>90</sup> The link between the two Agreements arises from the importance of protecting various forms of knowledge to the implementation of the CBD. The objectives of the CBD are to (1) conserve biological diversity; (2) promote sustainable use of its components; and (3) achieve fair and equitable sharing of the benefits arising out of the utilization of genetic resources.<sup>91</sup> The Parties to the CBD have agreed to implement these objectives by:

- creating conditions to facilitate access to genetic resources, including through provisions for equitably sharing in benefits from their use;<sup>92</sup>
- recognizing the value of the knowledge, innovations, and practices of indigenous and local communities relevant for the conservation and sustainable use of biodiversity while promoting the wider use of such knowledge, subject to the approval of its holders and the equitable sharing of benefits arising from its use;<sup>93</sup> and
- facilitating the transfer of relevant technology to other Parties.<sup>94</sup>

Implementing the objectives of the CBD therefore relies on the protection and use of knowledge, including knowledge of genetic material, knowledge of technology, or the knowledge of indigenous and local communities regarding biological diversity. Consequently, IPRs, including those required by the TRIPS Agreement, may affect the implementation of the CBD. Unfortunately, however, a lack of clear empirical evidence makes it difficult at this stage to determine conclusively how the rules of the TRIPS Agreement may affect successful implementation of the CBD.

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<sup>89</sup> United Nations, *The Realization of Economic, Social and Cultural Rights: The right to adequate food and to be free from hunger*, Updated study on the right to food, Economic and Social Council, Sub-Commission on the Prevention of Discrimination and Protection of Minorities, Fifty-first session, August 1999, E/CN.4/Sub.2/1999/12, para. 120f.

<sup>90</sup> See *Environment and TRIPS* (WT/CTE/W/8), *Factors Affecting the Transfer of Environmentally-Sound Technology* (WT/CTE/W/22), *The Convention on Biological Diversity and the Agreement on the Trade-Related Aspects of Intellectual Property Rights* (WT/CTE/W/50) and *The Relationship Between the Convention on Biological Diversity (CBD) and the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) with a Focus on Article 27.3(b)* (WT/CTE/W/125).

<sup>91</sup> The CBD, Article 1.

<sup>92</sup> The CBD, Article 15.

<sup>93</sup> The CBD, Article 8(j).

<sup>94</sup> The CBD, Article 16.

Although much technology, especially in the agricultural sector, can have significant environmental impact, the TRIPS Agreement is essentially market-driven, and provides little scope in its operative rules for non-economic social and environmental goals. In the context of current trends in formal research (that demonstrate a shift from public to private funding and an emphasis on profitability rather than other objectives such as sustainability) many people in many countries are concerned that the TRIPS Agreement could conceivably obstruct rather than support the implementation of the CBD.<sup>95</sup> Some of the possible impacts of the TRIPS Agreement on the implementation of the CBD are set out below.

### **Possible impacts of the TRIPS Agreement on conservation and sustainable use of biological diversity**

The use of IPRs can in theory have both positive and negative impacts on biodiversity. One area of concern is that granting patents or PBRs could reinforce a tendency towards monoculture in the agriculture sector. The over-planting of new varieties and the displacement of many traditional varieties are creating areas of monoculture in many countries, and contributing to the loss of biodiversity and local planting techniques.<sup>96</sup> Commentators have rightly suggested that IPRs alone cannot be held responsible for these developments. However, new plant varieties do tend to encourage the displacement of diverse traditional local varieties by a small number of modern varieties.<sup>97</sup> To the extent that IPRs, such as patents and PBRs, can be linked to the introduction of monocultures, the TRIPS Agreement could contribute to the ongoing, rapid loss of agricultural biodiversity.

The TRIPS Agreement could possibly also contribute to biodiversity loss by encouraging the establishment of IP systems that promote the innovation of genetically modified organisms (GMOs). Modern biotechnology is still relatively new and the impact of GMOs on the environment, in particular on biodiversity, is not known with certainty. The protection of the environment therefore demands that GMOs should not be introduced without proper biosafety rules. Encouraging the insertion of biotechnology into the ecosystem without first having effective checks in the form of biosafety regulation could result in biodiversity loss. On 29 January 2000, 130 governments finalized a legally-binding agreement for protecting the environment from the risks posed in the transboundary transport of living modified organisms created by modern biotechnology. The adoption of the *Cartagena Protocol on Biosafety* is a significant advance in meeting the environmental concerns of the international community. However, there are still outstanding concerns regarding implementation of the Protocol. In particular, while the Protocol and WTO agreements should be mutually supportive, it remains to be seen how the relationship between it and the TRIPS Agreement will develop.<sup>98</sup>

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<sup>95</sup> Brenner, C., *Intellectual Property Rights and Technology Transfer in Developing Country Agriculture – Rhetoric and Reality*, OECD Technical Paper, No. 133, Paris, March, 1998.

<sup>96</sup> Acharya, R., "Patenting of Biotechnology: GATT and the Erosion of the World's Biodiversity", *Journal of World Trade*, Vol.25, No.6, December 1991, pp. 71–87, p. 80.

<sup>97</sup> See Kothari, A. and R. V. Anuradha, "Biodiversity, intellectual property rights and GATT Agreement: How to Address the Conflicts?", *Economic and Political Weekly*, (1997), 32, pp. 2817-2820 in Dutfield, G., *op. cit.*, p. 46.

<sup>98</sup> See the *Cartagena Protocol on Biosafety* (2000), Preamble.

## **Possible impacts of the TRIPS Agreement on protecting the innovations and practices of indigenous and local communities**

The knowledge, innovations and practices of indigenous and local communities relevant to biodiversity are protected under Article 8(j) of the CBD. Parties are required to “respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity”. In spite of this provision, such knowledge is under serious threat of erosion, due to a lack of clear principles and means of protection and through the appropriation of this knowledge by outside interests, in particular, pharmaceutical and agro-chemical companies who rely on the store of knowledge held by these communities over genetic resources for research purposes. IP systems, as protectors of knowledge systems, have been criticized for neglecting, and even contributing to, this erosion.

The standards established under the TRIPS Agreement are generally, with some exceptions, ill-adapted to protecting the knowledge of indigenous and local communities under Article 8(j) of the CBD. The TRIPS Agreement has been developed to protect formal knowledge – knowledge that is codified and systematic – but is weak in its protection of informal knowledge that is often unfixd.<sup>99</sup> The nature of much indigenous and local community knowledge places it outside the scope of the protection established under the TRIPS Agreement. For example, indigenous and local community knowledge is often collectively held, making it difficult to determine the appropriate holder of rights; it is in some circumstances intergenerational and so possibly not ‘novel’ for the purposes of patent grant; and it often involves the use of a known substance and so possibly outside the subject matter of patent protection. Further, the allocation of property rights over knowledge can be contrary to some communities’ beliefs.<sup>100</sup>

A major criticism of the IP systems established under the TRIPS Agreement is that the costs involved in accessing them could exclude them as an effective tool to protect the knowledge of indigenous and local communities. IP systems generally involve complex and expensive application procedures and a knowledge of complicated concepts that requires access to expert legal assistance. Even where the protection offered by IP systems could be appropriate to the protection of indigenous and local community knowledge, these costs will often exclude communities from accessing the potential benefits of IP systems.

Members should give careful consideration as to how to ensure the review of Article 27(3)(b) supports and does not undermine the effective implementation of Article 8(j).<sup>101</sup> Developing countries, in particular, have noted concern about the use of patents and PBRs to privatize innovations developed from the knowledge and practices of indigenous and local communities

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<sup>99</sup> Mulvany, P., *TRIPS, Biodiversity and Commonwealth Countries: Capacity Building Priorities for the 1999 Review of TRIPS Article 27(3)(b)*, A Discussion Paper, Paper prepared for the Commonwealth Secretariat and Quaker Peace and Service, London, 1999, p. 9.

<sup>100</sup> See e.g. UNEP, *The Impact of Intellectual Property Rights Systems on the Conservation and Sustainable Use of Biological Diversity and on the Equitable Sharing of Benefits from its Use*, A Preliminary Study, Note by the Executive Secretary, 22 September 1996, UNEP/CBD/COP/3/22, para. 32. For a criticism of the applicability of patent rights to the protection of indigenous knowledge see, Carvalho, N., “From the Shaman’s Hut to the Patent Office: How Long and Winding is the Road?-II”, *Revista da ABPI*, No.41, July/August 1999, pp.3–17, p.3.

<sup>101</sup> Downes, D., *Using Intellectual Property as a Tool to Protect Traditional Knowledge: Recommendations for Next Steps*, CIEL Discussion Paper prepared for the Convention on Biological Diversity Workshop on Traditional Knowledge, Madrid, November 1997, p. 9.



without sharing the benefits. Countries should be free to develop IP systems that accommodate the requirements of Article 8(j), but this could take time. A worst case scenario for the Article 27(3)(b) review – lifting the exception to the patenting of plants and animals, or establishing UPOV 91 as the relevant “effective” form of plant variety protection – could force Members to introduce IPR systems that favor commercial interests and block them from effectively implementing Article 8(j).

To maintain flexibility in Article 27(3)(b), Members should continue to develop the linkages between Article 8(j) and the TRIPS Agreement in fora such as WIPO and the CBD, as well as the WTO’s Committee on Trade and the Environment. Some commentators have also argued that existing IPR systems could be modified or adapted to provide protection of informal knowledge systems that is compatible with Article 8(j). These include the development of *sui generis* systems, the amendment of patent application procedures to require applicants to disclose use of knowledge of local or indigenous communities; the introduction of petty patent protection for informal innovations; and the collection of indigenous and local community knowledge in organized databases or registries.<sup>102</sup>

### **Possible impacts of the TRIPS Agreement on access to and benefit sharing from genetic resources**

Both Articles 8(j) and 15 of the CBD establish principles for the access to and sharing of the benefits of genetic resources.<sup>103</sup> Agreements over IPRs could be relevant as a means of determining benefit sharing arrangements when access is sought to genetic materials. For example, providers of genetic resources could agree with users on access to a share of royalty payments from the use of IPRs over technology derived from the genetic materials. Alternatively, producers and users of genetic material could agree on sharing IPRs over any arising technology. Increasingly, where genetic material is held *ex situ*, the holding institution has developed a detailed IPR policy. This is the case of the Consultative Group on International Agricultural Research (CGIAR), a group that supports 16 international agricultural research centers that hold genetic material *ex situ*, which has developed an IPR policy for use by holding institutions.<sup>104</sup>

There is nothing in the TRIPS Agreement preventing this sort of action. What is lacking however is a framework of legal security that could ensure that benefits arising from the use of genetic resources are shared equitably. Such a framework could involve some form of property rights. Without such a legal framework however, access and benefit regimes will depend on the negotiation of contracts which can be a costly process and which, in themselves, provide no fixed standard ensuring both common and adequate protection. The lack of a systematic framework also allows the appropriation of indigenous and local community knowledge without any way of enforcing adequate benefit sharing. There is already evidence of IP systems, in the US and elsewhere, being used to appropriate the knowledge acquired directly

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<sup>102</sup> In particular, see Gupta, *op. cit.*

<sup>103</sup> Article 15 recognizes the sovereign right of States over their natural resources, and that the authority to determine access rests with national governments. It stipulates that access to natural resources be on mutually agreed terms and subject to the prior informed consent of the party providing the resource, unless otherwise determined by that Party. It calls upon Parties to share equitably the benefits arising from the commercialization of genetic resources with the providing party on mutually agreed terms.

<sup>104</sup> See Brenner, *op. cit.*, and the CGIAR homepage <<http://www.cgiar.org>>.

from indigenous peoples and local communities. Some of these patents were obtained without the knowledge or consent of the people from whom the resources were acquired and without any sharing of the benefits of commercializing the technology.

The Panel of Experts on Access and Benefit sharing, a panel established pursuant to a decision of the Conference of the Parties of the CBD, met for the first time from 4–8 October 1999. The Panel considered the issue of IPRs and acknowledged that IPRs could have some influence on the implementation of access and benefit sharing arrangements. The Panel also believed that IPRs could have a role in providing incentives for users of genetic resources to seek prior informed consent of individuals or communities before using the knowledge for research or other purposes. However, the Panel was unable to come to any conclusions on these issues, and has suggested that the 5th Conference of the Parties, meeting in May 2000, should consider this issue further.<sup>105</sup>

### **Box 5 – Patenting traditional knowledge**

In December 1993, the US Patent and Trademark Organization granted the University of Mississippi Medical Center patent rights over “a method of promoting healing of a wound by administering turmeric to a patient afflicted with a wound”. Turmeric has been used in India for centuries for its medicinal and culinary qualities. The Indian Council for Scientific and Industrial Research (CSIR) launched proceedings against the Medical Center to cancel the patent on the grounds that the patent application failed to meet the novelty requirement. The challenge to the grant was successful, however the case demonstrates the potential for IP systems to appropriate indigenous and local community knowledge but also suggests that IP systems should be amended so as to avoid this form of appropriation without having to chase each patent application that could be derived from indigenous or local community knowledge.

Similarly, in November 1999, the US PTO rejected a patent over the “Ayahuasca” vine – a native plant of the Amazonian rainforest used by thousands of indigenous peoples of the Amazon for sacred religious and healing ceremonies. The rejection of the patent came after the Coordinating Body for the Indigenous Organizations of the Amazon Basin (COICA), the Coalition for Amazonian Peoples and Their Environment and the Center for International Environmental Law requested a re-examination. As a result of the request, the PTO rejected the patent on the grounds that publications describing the plant were “known and available” over one year prior to the filing of the patent application. However, as with the turmeric example, this case highlights the flaws in the patent application procedures and policies that allow the patent applications to proceed in the first place. The case also highlights the ethics of awarding private patents rights over innovations derived from plants or knowledge that is sacred to a cultural or ethical group.<sup>106</sup>

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<sup>105</sup> Convention on Biological Diversity, *Access to Genetic Resources*, Note by the Executive Secretary, Conference of the Parties to the Convention on Biological Diversity, 1 March 2000, UNEP/CBD/COP/5/21 at para. 16.

<sup>106</sup> Downes quoted in a press release “US Patent Office Admits Error, Rejects Patent Claim on Sacred “Ayahuasca” Plant”, *Press Release*, Center for International Environmental Law and Coalition for Amazonian Peoples and Their Environment, November 4, 1999, <<http://204.127.239.82/AyahuascaRejectionPR.html>>.

A framework that has been established as a means of regulating the access to plant genetic resources is the International Undertaking on Plant Genetic Resources (See Box 6). For Member States that choose UPOV 91 as a model for plant variety protection, there could be inconsistencies between protecting rights of plant breeders under UPOV and meeting the objectives of the IU to facilitate access to plant genetic resources and to share benefits derived from its use.<sup>107</sup> For example, the discretion contained in UPOV 91 to decide whether or not to permit farmers to save seed for use on their own holdings might not sit comfortably with obligations under the IU to protect farmers' rights. However, there is no obligation on Members to join UPOV 91. As with the implementation of Article 8(j), States should be given time to determine the most appropriate means of balancing protection of plant breeders' rights with requirements to provide effective access to plant genetic resources. Indeed, as Members such as the Philippines and India implement PBR regimes that are different to UPOV 91, time should be given for other Members to collect information on best practices with regard to protecting plant varieties so as to ensure consistency between the CBD, the IU and the TRIPS Agreement.

### **Possible impacts of the TRIPS Agreement on the transfer of technology under the CBD**

Article 16(5) of the CBD obliges Member States to promote the transfer of environmentally-sound technology. The issues relating to technology transfer have already been addressed, and apply equally here. Of particular relevance is the suggestion of exploring the environmental aspects of the TRIPS Agreement, including the provision of a specific legal regime for the transfer of environmentally-sustainable technology. This could help develop positive links

#### **Box 6 – The International Undertaking**

During the 1980s, many developing countries expressed concern that the plant breeding industry in industrialized countries was seeking IPRs over improved varieties. This led the international community to negotiate the International Undertaking on Plant Genetic Resources for Food and Agriculture (the IU), under the auspices of the UN Food and Agriculture Organization (FAO). The IU establishes a non-legally-binding regime that aims to:

- ensure that the need for conservation is globally recognized and that sufficient funds for this purpose are made available;
- assist farmers and farming communities in all regions of the world in the protection and conservation of plant genetic resources and of the natural biosphere; and
- allow farmers, their communities and countries to participate fully in the benefits derived, at present and in the future, from the improved use of plant genetic resources through plant breeding and other methods.<sup>108</sup>

(Cont.)

<sup>107</sup> Reconciling farmers' rights with PBRs has historically been contentious in relation to the IU. These issues should be resolved – in a forum with expertise relevant to agriculture and a clear sustainable development mandate – before moves are made categorically to define the TRIPS Agreement.

<sup>108</sup> WT/CTE/125, *op. cit.*, para. 11.

### Box 6 – The International Undertaking (cont.)

The IU has been controversial due to its recognition of farmers' rights and its initial rejection of plant breeders' rights.<sup>109</sup> In the IU, farmers' rights were included more as a political effort to counterbalance plant breeders' rights than as a legal concept.<sup>110</sup> A voluntary fund was established to implement farmers' rights by supporting plant genetic conservation and utilization programs, although contributions were insufficient to make it operational.

The initial IU text reflected the concept that plant genetic resources are the common heritage of mankind and made clear that such resources should be preserved, and freely available for use for the benefit of all, including special genetic stocks, a reference that included the proprietary lines of seed breeders.<sup>111</sup> The rejection of plant breeders' rights led many developed countries to indicate their unwillingness to support the IU. As a result, the FAO Member States agreed upon an interpretation of the IU in 1989 stating that plant breeders' rights were not incompatible with the IU.<sup>112</sup>

The international community is currently renegotiating the IU to bring it into harmony with the CBD – possibly as a legally-binding Protocol to the CBD. Negotiations are focusing on developing the notion of farmers' rights already contained in the IU, and considering the issue of access on mutually agreed terms to plant genetic resources, including *in situ* and *ex situ* collections. The positions of negotiators turn on the question of ownership and control. Developing countries are generally wary that free access to germplasm will result in a flow of genetic materials to the plant breeding industry, to be adapted and made subject to IPRs with inadequate sharing of benefits. Developed countries advocate free access to genetic resources, while arguing that germplasm subject to IPRs should be outside the 'free' multilateral exchange system.<sup>113</sup> It appears at this stage of negotiations that farmers' rights will have to be achieved through national legislation. The FAO Conference, at its 30th Session in November 1999, requested that the text of the International Undertaking be finalized for submission to the FAO Council in November 2000.

between the technology transfer objectives in the CBD and Article 7 of the TRIPS Agreement. At the same time, it is generally agreed that much technology relevant to the preservation and conservation of biodiversity is already in the public domain, either because the patents have expired or because IPR protection was never sought in the first place. Measures outside the IP

<sup>109</sup> Resolution 5/89 of the Commission for Plant Genetic Resources of the FAO has defined Farmers' Rights as: "Rights arising from the past, present and future contributions of farmers in conserving, improving and making available plant genetic resources particularly those in the centers of origin/diversity. Those rights are vested in the international community, as trustees for present and future generations of farmers, and supporting the continuation of their contributions as well as the attainment of overall purposes of the International Undertaking", in Dutfield, *op. cit.*, p. 103.

<sup>110</sup> Bragdon, S., *Major Legal Regimes Affecting Plant Genetic Resources: the CBD, the International Undertaking and the TRIPS Agreement*, Paper prepared for the World Trade Forum, Berne, Switzerland, August 27/28, 1999.

<sup>111</sup> The IU, Article 2. See *ibid.*

<sup>112</sup> *Ibid.*, para. 14.

<sup>113</sup> *Ibid.*

system will also be necessary to encourage and facilitate the transfer of technology for the preservation and conservation of biodiversity.

### **Possible impact of the dispute settlement mechanism on the operation of the CBD**

In the event of a conflict between the TRIPS Agreement and the CBD, the conflict may be brought to the WTO's dispute settlement mechanism. While the CBD is a legally-binding agreement, it contains no well-developed enforcement mechanism to ensure that Parties comply with their commitments. In contrast, any dispute concerning the TRIPS Agreement is subject to the binding decision of the WTO's dispute settlement mechanism. Failure to comply with a decision of a WTO panel can leave Members open to retaliation by the other party to the dispute, in the form of wide-ranging trade sanctions. In the event of a dispute, a WTO panel may conceivably give greater favor to the objectives and provisions of the TRIPS Agreement than to those of the CBD.

Nonetheless, some commentators argue that implementing the CBD should take precedence over the TRIPS Agreement. They point to the reference in CBD Article 16(5) that states "(t)he 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".<sup>114</sup> One way to ensure supportiveness would be to include legal and scientific environmental experts on any WTO panel that included interpretations of trade law that could affect the operation of the CBD. Similarly, the submission of *amicus* briefs by interested organizations and experts with expertise in the field of biodiversity protection could be encouraged at dispute hearings. *Amicus* briefs are one way of ensuring that panels are informed of all the relevant facts and law so that decisions affecting biodiversity are well founded.

Similarly, the obligations on States to implement the CBD could be characterized as falling within the exclusions to patenting on environmental grounds in Article 27(2) of the TRIPS Agreement. Members should adopt a broad interpretation of Article 27(2) in the TRIPS Council and in national legislation that would confirm this position. If a wide interpretation of Article 27(2) gains currency, this would lessen the potentially negative impact of any dispute settlement decision concerning patent law, on the operation of the CBD.

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<sup>114</sup> Mulvaney, *op. cit.*, p. 14.

## **Box 7 – Summary of possible impacts of the TRIPS Agreement**

Below is a summary of the main concerns regarding the TRIPS Agreement with respect to the innovation and transfer of technology; consumer access to health; biotechnology; and the conservation of biological diversity under the CBD.

### **Innovation and dissemination of technology**

- There is no guarantee that the grant of IPRs increases investment in research.
- There is little evidence that the grant of IPRs will improve levels of developing country research.
- Broad patents and restrictive licensing practices can be used to block research and stifle innovation.
- IPRs can raise the price of sought-after technology.
- Technology holders can use IPRs to exclude users, especially in developing countries, from accessing technology.

### **Consumer access to health**

- IPRs over health technology may raise the price of pharmaceuticals and restrict the enjoyment of the right to health.
- The TRIPS Agreement could consolidate control of the market in the hands of large pharmaceutical companies.

### **Biotechnology and Article 27(3)(b)**

There are many ethical, environmental, economic, social and legal reasons to restrict the further application of IP systems to the protection of biotechnology and policy-makers must be wary of the potential impact of Article 27(3)(b). In particular:

- IPRs over living resources could detract from national policies to manage investment in biotechnology; and
- The practical operation of Article 27(3)(b) could conflict with fundamental principles of human rights including the right to food.

### **Biological diversity**

- The TRIPS Agreement could contribute to the development of monocultures in agriculture.
- IPRs could promote the innovation and dissemination of GMOs before biosafety rules are effectively implemented as a counterbalance.
- IPRs under the TRIPS Agreement are ill-adapted to protect the knowledge of indigenous and local communities.
- The costs of accessing IP systems as required by the TRIPS Agreement can exclude many indigenous and local communities.
- The TRIPS Agreement does not actively promote the equitable sharing of benefits arising from the use of genetic resources.
- The TRIPS Agreement does not actively promote the transfer of sustainable technology.
- In the case of a conflict of rules between the TRIPS Agreement and the CBD, the dispute settlement mechanism could see rules over IPRs prevailing over the protection and conservation of biological diversity.

## **Section 3**





# Review of the TRIPS Agreement

## Background

Six years on, the inclusion of the TRIPS Agreement on the trade agenda remains a controversial issue. As a result of the Agreement, the shift in favor of the protection of IPR producers and IPR exporting countries has accelerated. WTO Members are now obliged to introduce IP standards that increase the scope of IPR coverage by: removing exceptions for categories of products such as pharmaceuticals; increasing the duration of coverage; and, when viewed collectively, increasing dramatically the potential geographical scope of a holder's rights. The Agreement requires the implementation of IP systems that are costly and geared towards the interests of developed countries, without giving direction on the means to encourage and protect the often knowledge-rich but economically poor innovators in the South.

The Agreement also sits uneasily with the other agreements of the WTO. While the agreements on goods and services strive for trade liberalization, the TRIPS Agreement promotes market intervention in favor of the holders of "private rights". As noted above, Dutfield suggests that market intervention may be consistent with rules that promote trade liberalization where the property rights are awarded as an optimal means of achieving public good, and the TRIPS Agreement itself states that implementation of its terms should be conducive to economic and social welfare. However, while the Agreement clearly sets out the rights of IP holders, it only refers to public interest issues without striking an appropriate balance of rights and obligations by which WTO Members can maximize the public interest.

The preceding review indicates some of the possible impacts of the TRIPS Agreement on innovation and dissemination of technology; health care; food and agriculture; and the conservation and sustainable use of biodiversity. In light of this review the question still remains: what is the justification for maintaining the TRIPS Agreement in its present form within the framework of the multilateral trading system? The profound shift effectuated by the TRIPS Agreement in favor of private interests should not be ignored, and it is time to assert a stronger public voice within IP policy-making.

In spite of the existing gaps in knowledge, the significance of these issues dictates that action should be taken now to ensure that the implementation of the TRIPS Agreement promotes and protects sustainable development and the public interest. Reviewing the TRIPS Agreement, and monitoring and guiding its implementation, will require a coordinated strategy and consistent advocacy by civil society and concerned WTO Members. Environmental, human rights and development dimensions of IP should not be ignored, and fundamental decisions about the evolution of intellectual property rights cannot be left to IP specialists and the national representatives at the WTO alone.

To this end, a full discussion within the TRIPS Council and elsewhere of the public interest implications of the TRIPS Agreement, involving civil society and relevant international organizations is required. Specifically, this paper recommends:

- A full and public discussion by WTO Members, in partnership with other relevant institutions including WIPO, UNEP, UNDP, UNCTAD, the Office of the High

Commissioner for Human Rights and civil society, of the public interest issues raised by the evolving international intellectual property regime; and

- A systematic review by WTO Members of the implications of implementing the TRIPS Agreement for the public interest and sustainable development, as part of the ongoing review of the TRIPS Agreement under Article 71.1, and before starting any possible future negotiations on intellectual property protection.

These discussions should focus on ensuring that the TRIPS Agreement supports innovative, ethical and sustainable societies and the full enjoyment of human rights. As noted in the following sections, achieving these objectives will require coordinated action by civil society and government actors on national, regional and international levels. It will require work across a number of international fora to ensure a coherent approach to the development of the international IPR regime.

To help contextualize discussions about the changes required to the TRIPS Agreement, the following section sets out the work that is already being undertaken in various international fora, including: the WTO TRIPS Council and Committee on Trade and Environment; the World Intellectual Property Organization; the Convention on Biological Diversity; the UNCTAD Biotrade Initiative; the Food and Agriculture Organization; the Office of the High Commissioner for Human Rights; and the Committee on Economic, Social and Cultural Rights. Careful consideration should be given to how work in each of these fora, and others, can contribute to ensuring that the evolution of the international IPR system balances private and public interests, and promotes sustainable human development and the public interest.

## **The current context**

### **The TRIPS Council**

A main focus of the TRIPS Council meetings in 2000 has been the review of national legislation implementing the TRIPS Agreement. Discussion in the TRIPS Council in 1999 did address some equity and environmental issues, although the discussion was preliminary and generally inconclusive. During the TRIPS Council meeting of 21 March 2000, the Chair of the Council suggested the following as a list of issues meriting discussion by WTO Members:

- the implications of intellectual property right protection under 27(3)(b) for the developmental and economic interests of developing countries;
- the exclusions to patentability in Article 27(3)(b), and the definition of terms;
- the provisions on *sui generis* systems in Article 27(3)(b), and their relationship with UPOV;
- ethical questions about the patenting of life-forms;
- prior informed consent and benefit sharing; and
- traditional knowledge and farmers' rights.

So far the discussions have proceeded slowly, and some developed countries have actively opposed discussion of issues on the list. Members have also noted that WIPO has undertaken work programs on emerging intellectual property issues and have suggested that discussion in the TRIPS Council should follow the conclusions of this work. So far, recent discussion in the TRIPS Council has included:

1. **Setting the margins of Article 27.** Discussion in the TRIPS Council has focused on clarifying Article 27 by defining what is meant by “micro-organism”, “essentially biological processes for the production of plants and animals” and “non-biological and microbiological processes”. Another question that has been raised concerns the definition of “inventive step” and novelty under Article 27(1). India, in particular, has been concerned to clarify that the isolation of naturally occurring life forms does not amount to an inventive step for the purposes of the Article. The Africa Group has suggested removing distinctions in the Agreement between plants and animals (which do not require patent protection) and micro-organisms (which do require patent protection). It notes that there is no scientific basis for this distinction and consequently plants and animals, “as well as micro-organisms and all other living organisms and their parts cannot be patented”.<sup>115</sup>
2. **Maintaining the flexibility to implement “effective sui generis system” under Article 27(3)(b).** While some Members including the United States have proposed that UPOV 91 provides an effective *sui generis* system of plant protection, other Members have underlined the inherent flexibility in the TRIPS Agreement and asserted that it clearly does not narrow plant variety protection to only one model.
3. **Clarifying the relationship between the CBD and the TRIPS Agreement.** Members have discussed the relationship between the TRIPS Agreement and access to genetic resources. The Africa Group, for example, has argued that Article 27 should be amended to allow developing countries to meet their international obligations under the CBD and the IU, to satisfy their need to protect the knowledge and innovations of indigenous and local farming communities, and to avoid serious prejudice to the environment through the protection of human, animal and plant life.<sup>116</sup> Similarly, India has proposed to prohibit the granting of patents to those inventions made with foreign genetic material that are inconsistent with Article 15 of the CBD relating to the recognition of sovereignty and access to genetic resources.<sup>117</sup>
4. **Reviewing the TRIPS Agreement under Article 71(1).** In addition to discussions of Article 27(3)(b), the TRIPS Council is mandated in 2000 to undertake a review of the implementation of the TRIPS Agreement under Article 71(1). This review provides Members with an opportunity to undertake a broader examination of the TRIPS Agreement to ensure that it is meeting its public interest objectives as established in Articles 7 and 8 of the Agreement, as well as the overarching commitment by WTO Members, contained in the preamble to the WTO Agreement, to raise standards of living “in accordance with the

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<sup>115</sup> See, Communication from Kenya on behalf of the African Group, *Preparations for the 1999 Ministerial Conference The TRIPS Agreement*, 6 August 1999, WT/GC/W/302. See also, Communication from Kenya on behalf of the African Group, to the Council for Trade-Related Aspects of Intellectual Property Rights, *Review of the Provisions of Article 27.3 (b)*, 8 November 1999.

<sup>116</sup> *Ibid.*

<sup>117</sup> See generally, Communication from India, to the General Council, *Preparations for the 1999 Ministerial Conference, Proposals Regarding the TRIPS Agreement in terms of Paragraph 9 (a)(i) of the Geneva Ministerial Declaration*, 2 July 1999, (WT/GC/W/225). See also, Permanent Mission of Venezuela to the World Trade Organization, *Preparations for the 1999 Ministerial Conference: Proposals Regarding the TRIPS Agreement*, Communication from Venezuela, 6 August 1999, WT/GC/W/282.

objective of sustainable development.” To the extent that the TRIPS Agreement is found to be lacking, Article 71 establishes a mechanism for amending the Agreement.

## **The Committee on Trade and Environment**

The WTO Committee on Trade and Environment (CTE) was established in 1995 to examine the relationship between the provisions of the multilateral trading system and trade measures for environmental purposes, including those pursuant to MEAs. The CTE considers the provisions of the TRIPS Agreement relevant to its work on the environment under Item 8 of its agenda. In relation to TRIPS and IPRs, discussion in the CTE has so far focused on:

1. ***The transfer of environmentally-sustainable technology as required by MEAs.*** While some Members of the CTE assert that the TRIPS Agreement plays an essential role in facilitating access to environmentally-sustainable technology, the Committee has noted that further work is needed to clarify the nature of the relationship between the TRIPS Agreement and MEAs, in particular the CBD. India has identified the TRIPS Agreement as a barrier to the transfer of environmentally-sustainable technology required for the effective implementation of MEAs such as the *Montreal Protocol* (see Box 2).
2. ***The protection of traditional and indigenous knowledge.*** Some Members have argued that the TRIPS Agreement must be reviewed in light of the obligations on States under Article 8(j) of the CBD.

## **World Intellectual Property Organization**

Since 1998, WIPO has undertaken a program that explores emerging intellectual property issues. The proposed program for 2000/2001 covers:

1. ***Protection of traditional knowledge, innovations and creativity.*** The work program includes commissioning a study on customary law and regulatory systems that apply to the protection of informal knowledge; commissioning a feasibility study on the use of IP law or practice to protect informal knowledge; and organizing an annual Round Table on the protection of traditional knowledge for the holders of such knowledge.<sup>118</sup>
2. ***Biotechnology and biodiversity.*** In particular, the program will include an examination of the social, economic and ethical implications of IPRs in relation to the Human Genome Project and the Human Genome Diversity Project and commissioning a study on the IP aspects of access to and benefit sharing in biological resources.
3. ***Protection of folklore.*** The program includes convening several expert meetings to examine alternatives for the development of standards for the protection of folklore at national, regional and international levels; a national pilot project on the documentation, conservation, sustainable use and beneficial commercialization of folklore; and provision of advice on the development and implementation of national laws and systems relevant to the protection of folklore.
4. ***Intellectual property and development.*** The program includes a seminar on the role of IP in economic, social, cultural and technological development and the preparation and dissemination of a study on the role of IP in the transfer of environmentally-sustainable

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<sup>118</sup> The Round Table has already been held in 1998 and 1999.

technology to developing countries with reference to obligations under multilateral arrangements including Article 66(2) of the TRIPS Agreement.

## The Conference of the Parties of the Convention on Biological Diversity

Since 1996, the Conference of the Parties (COP) has considered a variety of issues related to intellectual property at its three meetings, including the recent meeting in Nairobi in May 2000.<sup>119</sup> During this period, the relationship between WIPO and the CBD has also developed, with WIPO actively seeking the experience of the CBD Secretariat for views relevant to WIPO's work on traditional knowledge and intellectual property rights.<sup>120</sup>

1. **Intersessional Meeting on the Operation of the Convention.** In June 1999, the Intersessional Meeting on the Operation of the Convention explored options for access and benefit sharing mechanisms. In this context, the meeting explored the relationship between IPRs, the TRIPS Agreement and the CBD. The meeting recognized the need to ensure mutual supportiveness between the TRIPS Agreement and the CBD and recommended that COP-5 transmit its findings in relation to Article 8(j) to the WTO and WIPO. The meeting also recommended to COP-5 to invite the WTO to acknowledge relevant provisions of the CBD and to take into account that the objectives of the TRIPS Agreement and the CBD are interrelated.<sup>121</sup>
2. **Panel of Experts on Access and Benefit sharing.** The first meeting of the Panel took place in 1999 and focused on mutually-agreed terms and contractual approaches to access to genetic resources; benefit sharing options and mechanisms; access legislation; the concept of prior-informed consent; intellectual property rights; regulatory and incentive measures; and related capacity building. The report of the Panel was adopted by COP-5 in Nairobi, May 2000. Delegations generally supported extending the Panel's mandate and proceeding with the development of international guidelines on access to and the sharing of benefits from genetic resources.<sup>122</sup>
3. **Fifth Conference of the Parties.** IPRs and the relationship between the TRIPS Agreement and the CBD were discussed under Item 23 of the Provisional Agenda – Access to Genetic Resources – at COP-5 in Nairobi, 15–26 May 2000. The COP adopted a decision on access to genetic resources containing three sections: (1) access and benefit sharing arrangements; (2) the relationship between IPRs and the TRIPS Agreement; and, (3) *ex situ* collections acquired prior to the CBD's entry into force and not addressed by the FAO Commission on Genetic Resources.<sup>123</sup> The COP invited Parties to the CBD and relevant organizations to submit information about the role of IPRs in the implementation of access and benefit

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<sup>119</sup> Dutfield, *op. cit.*, p. 97.

<sup>120</sup> See Convention on Biological Diversity, *Access to Genetic Resources*, Note by the Executive Secretary, Conference of the Parties to the Convention on Biological Diversity, 1 March 2000, UNEP/CBD/COP/5/21.

<sup>121</sup> *Ibid.*, Part III.

<sup>122</sup> See Earth Negotiations Bulletin, *Fifth meeting of the Conference of the Parties to the Convention on Biological Diversity, 15–26 May 2000*, Vol.9, No 160, page 10f.

<sup>123</sup> See UNEP/CBD/COP/5/L.26.

sharing arrangements by 31 December 2000. It also invited relevant international organizations to analyze the functioning of IP systems as they relate to access to genetic resources, including the possibility of requiring information on the origin of genetic resources as part of the application procedure for IPRs. Finally, the COP invited the WTO to acknowledge relevant CBD provisions and to take into account the relationship between the CBD and the TRIPS Agreement.

## **The UNCTAD Biotrade Initiative**

The UNCTAD Biotrade Initiative is a joint program of UNCTAD and the Secretariat of the CBD. Its mission is to stimulate trade and investment in biological resources to further sustainable development, in line with the objectives of the CBD. The UNCTAD Secretariat has proposed that the COP of the CBD consider adopting a code of conduct and certification system on bioprospecting.<sup>124</sup> This would mean that products and technology that are developed in compliance with the terms of the code of conduct on bioprospecting would carry an international certification. This system could be included in patent laws by requiring the certification for applications on inventions developed from biological resources. The Initiative will evaluate mechanisms – existing or proposed – that promote the objectives of the CBD. Included in the evaluation will be measures such as “communal intellectual property rights over information concerning uses of components of biodiversity”. It will also undertake market research and policy analysis on technology and traditional knowledge and innovations.<sup>125</sup>

## **The Food and Agriculture Organization**

Negotiations on the International Undertaking have been moving ahead, and a revised text should be submitted to the FAO Council for approval in November 2000. Significantly, broad-based consensus has been reached in the protection of farmers’ rights in the text. The revised text recognizes farmers’ rights, although the development of measures for realizing these rights rests with national governments. At the same time, large parts of the sub-article dealing with the transfer of technology, which has significant implications for IPRs, remain in brackets.<sup>126</sup>

At CBD COP-5, Parties to the CBD urged negotiators of the IU to finalize work on the IU as soon as possible. The COP also affirmed its willingness to consider the IU becoming a legally-binding instrument to the CBD.<sup>127</sup>

## **The Office of the High Commissioner for Human Rights (OHCHR)**

The Special Rapporteur on Indigenous Peoples of the Commission on Human Rights has drafted Principles and Guidelines for the protection of the heritage of indigenous peoples. The draft Principles and Guidelines include articles relevant to IP laws and the operation of the TRIPS Agreement including obligations requiring:

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<sup>124</sup> Dutfield, *op. cit.*, p. 101.

<sup>125</sup> Dutfield also notes that the evaluation will include mechanisms such as the “certification of origin programmes for local suppliers of biological material”, *ibid.*

<sup>126</sup> FAO, *Report on Progress in the Revision of the International Undertaking on Plant Genetic Resources*, FAO Conference, 30<sup>th</sup> Session, Rome, November 12–23, 1999.

<sup>127</sup> See Earth Negotiations Bulletin, *op. cit.*, p. 11, and UNEP/CBD/COP/5/L.26.

- national laws to deny to any person or corporation the right to obtain patent, copyright or other legal protection for any element of indigenous peoples' heritage without adequate documentation of the free and informed consent of the traditional owners for the sharing of ownership, control, use and benefits;
- national laws to ensure the labeling and correct attribution of indigenous peoples' artistic, literary and cultural works whenever they are offered for public display or sale; and
- direct access for indigenous peoples and their representative organizations to all intergovernmental negotiations in the field of intellectual property rights, to share their views on the measures needed to protect their heritage through international law.

The Special Rapporteur will present her report to the Sub-Commission on the Protection and Promotion of Human Rights for approval. The establishment in April 2000 of a Permanent Forum for Indigenous Issues under the Economic and Social Council could give a significant boost to protection of indigenous peoples' cultural heritage, including through the official adoption of the Principles and Guidelines.

## The Committee on Economic, Social and Cultural Rights

The Committee on Economic, Social and Cultural Rights was established in 1985 by the Economic and Social Council to monitor the *International Covenant on Economic, Social and Cultural Rights*.<sup>128</sup> The Committee is comprised of 18 members who are experts with recognized competence in the field of human rights. Members of the Committee are independent and serve in their personal capacity. The primary function of the Committee is to monitor the implementation of the Covenant by States parties, many of whom are also Member States of the WTO. It strives to develop a constructive dialogue with States parties and seeks to determine whether the rights contained within the Covenant are being adequately applied by States parties and how implementation and enforcement of the Covenant can be improved.

The Committee also assists in the interpretation and implementation of the Covenant through issuing General Comments on particular rights contained in the Covenant. General Comments expand on the nature of rights, clarifying the content of the right, the holder of rights, the corresponding duties attached to the right, the duty bearers, as well as clarifying the nature and scope of violations. Already, the Committee has issued General Comments on the rights to food, education and, as recently as May 2000, on the right to health. The Committee will be holding a Day of General Discussion on 27 November 2000 on "The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author" which will focus on the nexus between intellectual property rights and human rights.<sup>129</sup> It is expected that the Committee will use the content of the Day of General Discussion as the basis for issuing a General Comment on Article 15(1)(c).

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<sup>128</sup> The General Assembly adopted and opened for signature the *International Covenant on Economic, Social and Cultural Rights* on 16 December 1966, following almost 20 years of drafting debates. The Covenant entered into force on 3 January 1976. The Covenant contains some of the most significant international legal provisions establishing economic, social and cultural rights, including rights relating to work in just and favorable conditions, to social protection, to an adequate standard of living, to the highest attainable standards of physical and mental health, to education and to enjoyment of the benefits of cultural freedom and scientific progress.

<sup>129</sup> Article 15(1)(c) of the *International Covenant on Economic, Social and Cultural Rights*.

Any General Comment on Article 15(1)(c) issued by the Committee will be important. In particular, a General Comment will assist in clarifying States' obligations with respect to the protection of intellectual property rights within the framework of the international human rights machinery – including ensuring consistency between the grant of IPRs with the promotion and protection of other rights under the Covenant such as the rights to food and health. The Committee will accept submissions from interested individuals and organizations who will also be welcome to attend the Day of General Discussion.

## **Options for change**

An over-riding consideration when reviewing the TRIPS Agreement should be to ensure that the public interest elements of the TRIPS Agreement – those provisions that permit governments to balance private rights with the public interest – are broadly interpreted and applied. In particular, the Article 27(2) exceptions should be interpreted broadly in national laws to ensure that patents are not issued over products and technology that could have adverse effects on the environment or the enjoyment of human rights. Similarly, the provisions on compulsory licensing and anti-competitive conduct should be broadly construed, and developing countries should be given assistance to fully implement these provisions.

While the TRIPS Agreement may potentially have negative impacts on the environment, and the enjoyment of rights to food, health, development and the benefits of scientific advancement, there are ways to reduce these effects that do not rely on the use of IPRs or on modification to the TRIPS Agreement. For example, much technology is already in the public domain. This technology – including environmentally-sustainable or health technology – is not protected and can be more easily accessed by developing countries to meet sustainable development and public interest objectives. Similarly, where technology is protected by IPRs, assistance outside the TRIPS Agreement, such as technology partnerships, might be used to encourage the use of IPRs that can meet public interest objectives. At the same time, once further experience is gained with the TRIPS Agreement – including through the current reviews of Article 27(3)(b) and Article 71(1) – WTO Members may also decide that it is necessary to renegotiate the Agreement to ensure it meets its objectives and to re-establish an appropriate balance between private property rights and the public interest.

The following sections provide some preliminary ideas about options for changing the current shift towards private and away from the public interest that is being facilitated by the evolving international IPR regime, and ensuring that the intellectual property rules established by the TRIPS Agreement benefit WTO Members.

## **General actions**

There are a few general actions that WTO Members that are concerned about the TRIPS Agreement can take to help safeguard their current position and prepare for future discussions in the TRIPS Council and other international institutions.

1. ***Action against the imposition of unilateral measures.*** Members should ensure that the TRIPS Council repudiates bilateral pressure by individual countries to police other countries in their interpretation and implementation of the TRIPS Agreement. Members should



ensure that individual countries do not force other Members to introduce measures that go beyond the requirements of the TRIPS Agreement.<sup>130</sup> See, as an illustration of such action, the US pressure applied to the Thai Government in relation to Thai attempts to access HIV/AIDS drugs – see Box 3).<sup>131</sup>

2. **Empirical research.** One drawback in understanding the impact of the TRIPS Agreement is the lack of empirical research. Policy-makers should encourage international organizations such as WHO, WIPO, UNESCO, the Secretariat of the CBD and FAO to undertake research as part of their work programs. Similarly, national governments should encourage surveys and research into the role of IPRs on national development. The results will help provide the basis for effective implementation of existing international obligations as well as the basis for revising existing, or negotiating new, commitments.
3. **Funding.** Article 67 of the TRIPS Agreement obliges developed countries to provide technical cooperation on request and on mutually agreed terms and conditions in favor of developing and least-developed country Members including in the preparation of laws for the protection of IPRs and the prevention of their abuse. Developing country Members may wish to seek to use these resources to implement those aspects of the TRIPS Agreement – such as rules regarding anticompetitive conduct and compulsory licensing – that safeguards their national interests.

## Clarifications to the terms of the TRIPS Agreement

An opportunity for policy-makers to reassert a public interest voice on the TRIPS agenda will arise in any future renegotiation of Article 27(3)(b).<sup>132</sup> Options include:

1. **Doing nothing.** By maintaining the wording of Article 27(3)(b), Members can continue implementation of patent and plant variety systems without being subject to any new obligations. The present ambiguity provides a level of flexibility for countries to adopt IP systems more relevant to their developmental needs. There is no jurisprudence on the extent of the exclusions under Article 27(3)(b) as yet, so Members have flexibility to interpret its terms to meet national developmental and environmental objectives, a position which conforms with the objectives of the TRIPS Agreement.
2. **Extending exclusions to patentability.** As an alternative, policy-makers could push to extend the exclusions to patentability to include all living organisms. Clearing up the ambiguities over the scope of the exclusions would be the safest way to ensure that life-forms will not be subject to patenting. Pursuing this approach will require careful preparation, as opening the sub-paragraph for renegotiation could raise the possibility of pressure being applied for changes that are disadvantageous to the public interest.
3. **Removing obligations to provide plant variety protection.** Most developing countries have not, until now, considered offering plant variety protection as a priority. The costs involved in implementing new legislation or developing *sui generis* legislation are high and could be directed to other developmental priorities. Removing obligations for plant variety

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<sup>130</sup> Dutfield, *op. cit.*, p. 128.

<sup>131</sup> See Assavananda, *op.cit.*

<sup>132</sup> See Mulvaney, *op. cit.*

protection could be in the interests of developing countries, although again, such an approach must be carefully prepared to reduce risk.

## **Enhanced measures for implementing technology transfer**

As part of any review of the TRIPS Agreement, policy-makers should consider ways of adapting IP systems so that they encourage technology flows that favor developmental and environmental objectives. Policy-makers might consider:

1. ***Strengthening compulsory licensing provisions.*** The compulsory licensing provisions under the TRIPS Agreement are convoluted and restrictive. Policy-makers should encourage the TRIPS Council to streamline and broaden compulsory licensing requirements under the TRIPS Agreement, particularly as a means of accessing health technology. Policy-makers should also ensure that compulsory licenses can be awarded even where technology in the form of products is imported.<sup>133</sup>
2. ***Developing anti-competition laws.*** While Articles 8 and 40 refer to abuses of IPRs that might restrain technology transfer, the TRIPS Agreement is silent on the measures that Members could or should take to prevent these abuses. Policy-makers should encourage discussion in the TRIPS Council concerning the development of international standards that will help prevent abuses of IPRs. Parties could refer to previous attempts to deal with anti-competitive licensing practices, such as the recommendations of developing countries during the Uruguay Round or the International Code of Conduct on the Transfer of Technology that was negotiated, but never agreed, during the 1970s and 1980s at UNCTAD.<sup>134</sup>
3. ***Ensuring patent systems promote innovation.*** Members should ensure that IP laws are clear in their rejection of overly broad claims that could lead to the grant of broad patents and excessive monopolies over areas of research. Members should review patenting requirements and elaborate standards with a view to promoting rather than stifling innovation.
4. ***Ensuring access to patent information for research purposes.*** Article 30 of the TRIPS Agreement ensures that Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner. It is generally agreed that this includes the provision of research exemptions that allow third parties to use information disclosed in patent documents for research purposes without having to seek authorization of the patent owner. Policy-makers should ensure provision in national patent laws that implement research purposes. Developing countries should also make use of the technical assistance programs under Article

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<sup>133</sup> While Article 27 suggests that importation alone is sufficient to show working of technology in a Member State, Article 5A of the *Paris Convention* allows the provision of compulsory licenses in this situation. There could be a conflict between the two Agreements as Article 5A is incorporated in the terms of the TRIPS Agreement by virtue of Article 2. The discrepancy should be resolved, but in favor of the less restrictive provisions of the *Paris Convention*.

<sup>134</sup> See Fikentscher, W., *The Draft International Code of Conduct on the Transfer of Technology*, IIC Studies, Studies in Industrial Property and Copyright Law, Volume 4, Max Planck Institute, Munich, 1980, p.56.

67 of the TRIPS Agreement to introduce state of the art information technology that will help researchers access patent information quickly and cheaply.

5. ***Establishing a Working Group on Technology Transfer at the WTO.*** The call for such a working group has already been made by India.<sup>135</sup> India envisages that a working group will “foster access to technologies; cooperate in the development of scientific and technical resources including the creation and growth of national innovation systems; grant credits for financing the acquisition of technology; provide assistance and cooperation in the development and administration of laws and regulations likely to facilitate [technology transfer]; strengthen the negotiating capacity for transactions; and assist in the protection and commercializing of local innovations”.<sup>136</sup> In addition, the Working Group could be used as a vehicle for promoting the other recommendations in this paper concerning technology transfer.
6. ***Developing new IPR-related mechanisms to encourage MEA technology transfer.*** The context of technology transfer under the Multilateral Environmental Agreements (MEAs) requires a specific legislative framework that will encourage the licensing of IPRs over environmentally-sustainable technology. One possibility could be to offer a new environmental technology transfer grant that included a duty for rights holders to transfer the technology to an organization in the jurisdiction within a certain time frame. Failure to transfer within the given time would involve forfeiture of the IPRs. The duty to transfer could be balanced with wider rights or a longer protection period or could include trade secrets in its scope. Policy-makers should encourage WTO or other relevant organizations such as WIPO and UNEP to develop the environmental aspects of technology transfer further.

## **Elaboration of requirements to protect indigenous and local community knowledge**

Some WTO Members have recently shown some willingness to discuss the protection of informal knowledge. This builds on discussions already taking place in other international and regional fora. The following are some policy objectives to pursue in the TRIPS Council, in other international fora, and at the national level.

1. ***Establishing knowledge databases.*** Policy-makers should give substantial support to the establishment of national and international registries of indigenous and local community knowledge on terms defined by the knowledge holders. Local databases are already being established in some developing countries, and the idea is being studied in various fora such as UNESCO, WIPO, FAO and UNDP. Such registries could support benefit sharing among industry and indigenous and local communities. Support for such databases should be in response to the needs and motivations of the communities concerned. The communities themselves will have to assess the risks of disclosing knowledge first, and then develop the design of such registries and methods of benefit sharing most suited to their needs.

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<sup>135</sup> See Juma, C. (1999), *Intellectual Property Rights and Globalization: Implications for Developing Countries*, Science, Technology and Innovation Discussion Paper, No.4, Center for International Development, Harvard University, Cambridge, MA, USA.

<sup>136</sup> WTO, 1999, “Transfer of Technology”, Communication from India, World Trade Organization, Geneva, in Juma, *ibid.*

2. ***Elaborating the requirements for the award of patents.*** The novelty requirement, for example, should be carefully defined under national laws so as to avoid the misappropriation of traditional knowledge or knowledge that is already in the public domain. Such definitions could involve the inclusion of all public domain knowledge – national and international – within the notion of ‘prior art’ so as to avoid, for example, the use of prior art from a foreign country being used as the basis for a patent application.<sup>137</sup>
3. ***Adapting patent disclosure requirements.*** Commentators have already proposed the inclusion of a requirement to disclose the country and community of origin for genetic resources and informal knowledge used to develop an invention.<sup>138</sup> The proposal could assist in acknowledging the source of knowledge that led to a particular innovation and could assist in developing methods of sharing benefits arising from the marketing of the protected innovation. Failure to disclose relevant information under such a system could also be grounds for revocation of the patent rights. India has already made a proposal to prohibit the granting of patents to those inventions made with foreign genetic material that are inconsistent with the benefit sharing principles of the CBD. Further attention should be focused on this issue within the TRIPS Council.
4. ***Developing sui generis legislation.*** WTO Members should establish national *sui generis* protection systems that are effective in promoting their national agricultural, environmental and developmental objectives. The development of national laws should identify and include the interests of relevant groups such as indigenous peoples, local communities and farmers, within the negotiation and drafting process.
5. ***Developing geographical indications or trademarks.*** Article 23 of the TRIPS Agreement includes protection for geographical indications, specifically in the area of wines and spirits. WTO Members are considering expanding these provisions. Policy-makers should establish programs of consultation with indigenous groups through surveys and workshops with the cooperation of WIPO, UNESCO and the WTO to develop their positions.

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<sup>137</sup> See Dutfield, *op. cit.*, p. 128f.

<sup>138</sup> Downes, *op. cit.*, p. 14.

## Coordinating negotiation strategies

In terms of process, there are a number of strategies that could be adopted to help strengthen the hand of those governments and groups in civil society that are seeking to change the TRIPS Agreement to promote the public interest.

1. ***Coordinating across various international negotiation fora.*** Policy-makers should be aware of the work programs of international organizations such as UNESCO, WIPO, the FAO, the Secretariat of the CBD, the OHCHR and the World Health Organization. The previous section noted a number of developments that are relevant to discussions in the TRIPS Council.<sup>139</sup>
2. ***Coordinating with other national government departments and communities.*** One problem that besets policy-makers is inadequate communication between departments and communities. As negotiations over IPRs touch not only on intellectual property issues, but on environmental, agricultural, health and technological issues, a coordinated policy nationally is important to ensure that a united position is advanced across all regional and international negotiations. Cooperation, particularly among policy-makers and experts in civil society, will help ensure any future negotiations do not result in Members assuming obligations within the WTO that contravene existing obligations to promote and protect human rights and the environment.
3. ***Coordinating with like-minded Members.*** Developing country Members may wish to consider ways to strengthen cooperation with other Members that share similar interests to develop common strategies for negotiations in the TRIPS Council and in other fora. Policy-makers should maximize the benefits of regional policy making blocks such as the Association of South East Asian Nations (ASEAN), the ANDEAN PACT, the MERCOSUR countries and the Organization of African Unity (OAU). Regional negotiating blocks can provide bargaining strength and encourage economies of scale. They may also be useful as a means of pooling resources to develop *sui generis* protection and other systems, such as anti-trust laws, that are suited to national and regional objectives.

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<sup>139</sup> WIPO and UNESCO, for example, have held several regional workshops concerning the protection of folklore. They have also looked at adapting the *Model Provisions for National Laws on the Protection of Expressions of Folklore Against Illicit Exploitation and Other Prejudicial Actions*. The Model Law was developed in the 1980s but has excited only low levels of interest. While the scope of the Law fails to cover medicinal and scientific knowledge, it could still be used as a basis for developing new approaches to IP systems. Policy-makers should also be aware of activities being undertaken in non-IP fora such as the renegotiations of the *International Undertaking on Plant Genetic Resources* currently ongoing at FAO. Finally, the World Health Assembly of the World Health Organization has also been considering intellectual property issues as part of its *Revised Drug Strategy*, including the effects of patents over high drug prices. This information could be helpful in designing national compulsory licensing schemes over essential drugs and coordinating international negotiating positions with regard to the compulsory licensing provisions of the TRIPS Agreement.



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