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BIOTECHNOLOGY AND TRADE: ISSUES CONFRONTING THE WTO

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Abstract

The objective of this paper is to review the relationship between the recent developments in regulations and agreements dealing with GMOs and WTO rules and processes. This paper is not meant to be exhaustive in the sense of addressing all the relevant issues. However, it is intended to be illustrative in that the selection of the topics addressed are intended to show how the current manner in which the WTO operates – particularly with its expanded post Uruguay Round mandate – finds itself at the centre of a number of controversial issues that involve non-traditional trade concerns. Specific attention is paid in the following to the Trade Related Intellectual Property Rights (TRIPS) Agreement, the Sanitary and Phytosanitary (SPS) Agreement, the Technical Barriers to Trade (TBT) Agreement, and the Committee on Trade and the Environment (CTE). The approach is to first briefly describe the relevant provisions of the Agreements or terms of reference of the Committees, and then to provide examples of how biotechnology related issues have emerged.

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(I) INTRODUCTION

In January 1995, the World Trade Organization (WTO) became the successor to the General Agreement on Tariffs and Trade (GATT). The new organization was the result of years of negotiations on improving the system that oversees international trade. Public concern has recently been expressed over the fact that the importance of trade rules in both domestic and global affairs has increased dramatically as a result of the Uruguay Round of negotiations. These negotiations spawned new agreements that extend well beyond border measures and reach deep into domestic regulatory structures affecting regulations as diverse as standards to protect public health, intellectual property rights and the manner in which products should be labelled. The reaction of interest groups within the WTO member countries has on occasion been hostile to say the least, believing that the obligations undertaken by their leaders are not in the public interest.[1]

Building public support for the WTO is perhaps as important today as at any time in the 55-year history of the multilateral trading system. In particular, the eyes of the world will be on the organization as ministers and heads of government meet in Qatar later this year to determine the negotiating agenda for the year 2002 and beyond. In attempting to reach agreement, one of the most potentially charged issues confronting the WTO is how to deal with the interface between existing WTO trade rules, other international treaties, and domestic regulations. One area where tensions run particularly high is in matters relating to the regulation of genetically modified organisms.

[1] There are presently over 140 governments that constitute the membership of the WTO. In what follows, these will be referred to as the WTO members. While the 15 countries of the European Union are individual members, they are represented at WTO meetings (with the exception of the WTO Budget Committee) by the European Commission, which speaks on behalf of the 15 member states.

This sensitivity surrounding discussions relating to biotechnology and regulation derives from the fact that views differ as to the commercial, social, ethical, cultural and religious implications of biotechnology. This is compounded by differing views among scientists as to the risks of biotechnology and among the public as to how the risks should be managed. Also, the depth of concern of those holding these views has increased greatly in recent years. Traditional biotechnology has been around since time immemorial. It involves well know scientific processes and discoveries such as selective breeding and cross-breeding of plants and animals, basic fermentation techniques, and the production of serum and vaccines for human or animal health. The change in public sentiment has come with the development of modern biotechnology techniques made possible with the advance of knowledge regarding genetic and molecular structures. Genetic engineering now permits scientists to change the characteristics of living organisms by transferring the genetic information from one organism, across species boundaries, into another. As such, genetic engineering allows the transfer of genetic material between organisms that would never be able to breed in the natural environment.

It is this modification of the structure of living matter through the transfer of genetic information across the boundaries of species that has led to the most vocal public reactions. For example, the release of living GMOs is thought by some to have potentially disastrous consequences for the environment while for others, the consumption of food derived from GMOs could put the public health at risk. This fear is enhanced by the limited knowledge that modern science has with respect to the future risks associated with products resulting from biotechnological research. Also, even with agreement on the risks associated with a number of aspects of genetic engineering, there are wide differences of opinion as to the degree of precaution that is appropriate in managing these risks. A totally different public concern comes from those that are of the view that many developing countries are rich in genetic material are not adequately rewarded when this resource is tapped, modified genetically and market by companies from the developed world. In their view, the prevailing intellectual property regime does not adequately protect traditional knowledge relating to genetic resources.

A particularly informative case study in enquiring into why the WTO has moved onto centre stage in areas that are of public concern, but would not normally be considered traditional trade subjects, is the manner in which WTO rules could impact on

regulations and treaties relating to genetic engineering. In very broad terms, the issues present themselves under different headings. There are, for example, market access considerations. Are domestic regulations relating to food derived from genetically modified organisms being used for protectionist purposes and disguised restrictions on trade, or as a results of legitimate concerns about public health? There are questions relating to coherence across different treaties. Is the current intellectual property regime the most appropriate to reward indigenous people for information relating to their genetic resources, and are the WTO rules in conflict with those of other multilateral agreements? Environmental considerations also loom large. What are the appropriate restrictions on trade in living modified organisms destined to be released into nature or used for animal food consumption? As will become apparent, there is considerable overlap in all these issues.

The objective of this paper is to review the relationship between the recent developments in regulations and agreements dealing with GMOs and WTO rules and processes. This paper is not meant to be exhaustive in the sense of addressing all the relevant issues. However, it is intended to be illustrative in that the selection of the topics addressed are intended to show how the current manner in which the WTO operates – particularly with its expanded post Uruguay Round mandate – finds itself at the centre of a number of controversial issues that involve non-traditional trade concerns. Specific attention is paid in the following to the Trade Related Intellectual Property Rights (TRIPS) Agreement, the Sanitary and Phytosanitary (SPS) Agreement, the Technical Barriers to Trade (TBT) Agreement, and the Committee on Trade and the Environment (CTE). The approach is to first briefly describe the relevant provisions of the Agreements or terms of reference of the Committees, and then to provide examples of how biotechnology related issues have emerged.

(II) STANDARDS AND PRECAUTION

As incomes and public awareness increase in many countries, so does concern over the protection of public health and the environment. One outcome of this is a growth in mandatory technical regulations, voluntary standards, and conformity assessment procedures for products or processes that could affect either the health of the public or the environment. With more-sophisticated products and production processes, the complexity of regulations has also increased, along with the opportunity for these measures to be used for protectionist purposes. When standards differ between countries, they have the potential to seriously impede trade. In fact, many in the

business community consider dealing with standards in different countries to be the most significant barrier to trade. The same is true of developing countries that fear that excessively high standards will negatively affect their exports.

Concern over the trade implications of standards is expressed in various WTO agreements, in particular the Sanitary and Phytosanitary (SPS) Agreement and the Technical Barriers to Trade (TBT) Agreement. Both of these seek to avoid the use of standards as unnecessary obstacles to trade and encourage the establishment of international standards by international standardizing bodies. Yet they also recognize the sovereign right of each government to adopt whatever standards are appropriate to fulfil legitimate policy objectives, taking into account the risks that non-fulfilment would create

Thus, a particularly important consideration for the maintenance of an open trading system is determining when national standards affecting trade are responding effectively to legitimate societal and environmental concerns. Determining what is "appropriate" in the light of scientific evidence, and what constitutes legitimacy in terms of public preferences promises to be one of the most contentious areas for a variety of public interest groups and trade officials alike. There have, for example, already been serious trade disagreements on appropriate standards for meat treated with hormones or antibiotics.

The relative weight assigned to science and societal choice in the determination of standards – or how "precautionary" to be when managing risk – underpins much of the possible future disagreement over the legitimacy of standards within the context of dispute settlement in the WTO. The precautionary approach notes that in some cases – particularly where the costs of action are low and the risks of inaction are high – preventive action should be taken, even without full scientific certainty about the problem being addressed. In practice this gives governments a fair amount of discretion in setting environmental policy. This issue may well emerge in the WTO as developments in biotechnology proceed. What minimum degree of scientific validation is required for a trading partner to be obliged to accept a standard relating to GMOs as being appropriate? What is the role of "precaution" if there is insufficient scientific evidence to establish a standard relating GMOs but substantial potential consequences to society of not setting such a standard? These questions are being raised in WTO

Committees, such as the SPS and TBT Committees, and it is far from clear which issues are appropriate for which committee.[2]

(I) Sanitary and Phytosanitary Measures

The Agreement on Sanitary and Phytosanitary Measures was an outcome of the Uruguay Round. It applies to measures to protect humans, animals, and plants from additives, contaminants, toxins, or disease-causing organisms in food substances as well as from the spread of disease by pests or by animals or plants.

While the agreement explicitly recognizes members' sovereign rights to take measures that may restrict trade, any such steps must be based on scientific evidence and taken in accordance with the traditional national treatment and most-favoured-nation (MFN) principles of other WTO agreements. Thus, such measures should apply to domestically produced food or local animal and plant diseases as well as to products coming from other countries, without unjustified discrimination among foreign sources of supply. In short, the SPS Agreement requires that potentially trade-restrictive measures be applied to local and foreign products for no other purpose than that of ensuring food safety and animal and plant health, that any such measures do not result in unjustified barriers to trade, and that they be based on scientific evidence. Importing food products derived from GMOs is considered a risk to human health by some; importing living GMOs for release into the environment is also considered a threat to animal and plant health.

Perhaps the most important objective of the agreement is to reduce the arbitrariness of governments' decisions by clarifying which factors to take into account when adopting health protection measures. In particular, measures taken to ensure food safety and animal and plant health should be based on the analysis and assessment of objective and accurate scientific data. Thus, an important question in managing risks to human, animal, and plant life and health, that could be related to GMOs or products derived from them, is deciding on the risk levels and the appropriate standards to adopt to manage the risk.

International standard-setting organizations offer ready-made yardsticks. The SPS Agreement explicitly refers to three such groups whose activities are considered relevant in meeting its objectives: the Codex Alimentarius Commission, a joint effort of the Food

[2] See Matthew Stilwell and Brennan Van Dyke, An Activist's Handbook on Genetically Modified Organisms and the WTO, Centre for International Environmental Law, March, 1999.

and Agriculture Organizaton (FAO) and the World Health Organization; the International Office of Epizootics (OIE); and the international and regional organizations operating within the framework of the FAO International Plant Protection Convention (IPPC). Many WTO members are involved in those fora, and their scientists and health experts participated in the development of these voluntary international standards. There are, however, no similar international standards for GMOs and their products, and therefore no predetermined standards agreed to outside the WTO.

The SPS Agreement allows countries to take measures in cases of emergency where sufficient scientific evidence does not yet exist to support definitive measures. This is how the agreement deals with precaution in an operational sense. Following the bovine scare in 1996 relating to bovine spongiform encephalopathy ("mad cow disease"), and in the absence of sufficient scientific evidence, several emergency bans were introduced. In accordance with the SPS Agreement, however, these could only be provisional. In the long term, governments must conduct scientific risk assessment and adapt their measures accordingly, although there is no determination as to how long "provisional" may be.

Thus, the role of science is important in the SPS Agreement not only for the setting of standards (and deviation from them) but also for precautionary emergency measures. Herein lies the problem for those concerned with the effects on the environment of the release of GMOs into the environment and their use in food products. Many of those concerned with the possible effects of GMOs are not seeking provisional measures in the absence of scientific evidence. In the interface between science and regulation there is the critical question of the manner in which the risk is to be managed: Even with agreement on the assessed risks, WTO member countries have different preferences for the management of risk.

In this context the dispute on meat treated with hormones is particularly instructive for future possible GMO related disputes. The European Union ban on meat products containing hormones went into effect in 1989; it applied to animals treated with hormones in order to promote growth, as the EU maintained that there was a carcinogenic effect associated with human consumption of the hormone-treated beef. When the case was dealt with by a WTO panel, the panelists rejected the EU arguments due to a lack of scientific evidence of a health and safety risk. They concluded this after consulting scientific experts, and there was general agreement on their part that the

hormones posed no risk. Much to their annoyance, the panel did not consider information presented by public interest groups. In the proceedings, international standards played an important role—in particular, the use of the Codex benchmark standard.

The panel also considered whether the precautionary principle could provide justification for the ban in the absence of scientifically based risk assessment. It noted that the precautionary principle was incorporated into the SPS Agreement through the use of emergency measures permitting members to provisionally introduce measures that are not supported by "sufficient" scientific evidence until this evidence is obtained. In the hormone case, emergency measures as such were not under discussion, as the ban did not relate to "provisional regulations." The EU Directive was a definitive regulation.

The panel report was referred to the appellate body, which agreed that the specific wording in the SPS Agreement prevailed over the precautionary principle. However, neither the panel nor the appellate body addressed whether scientific risk assessment and the precautionary principle were potentially at odds. The EU was restricting the importation of hormone-treated beef when scientific risk assessments could not take account of the fear of society toward the potential risk involved. In fact, the appellate body concluded that the precautionary principle awaits confirmation as a customary principle of international law. However, as will be discussed subsequently, the precautionary principle is an accepted pillar of United Nations agreements, including those dealing with biotechnology.

(II) Technical Barriers to Trade

The WTO Technical Barriers to Trade Agreement establishes obligations to ensure that voluntary standards, mandatory regulations, and conformity assessment procedures are not prepared, adopted, or applied with the view or effect of creating unnecessary obstacles to international trade. In line with the concept of proportionality, avoiding unnecessary obstacles to trade means that when preparing a technical regulation to achieve a certain policy objective, the government should choose the approach that has the least restrictive impact on trade.

The agreement encourages WTO members to use, whenever appropriate, relevant standards or conformity assessment guides or recommendations issued by international standardizing bodies as a basis for their own regulations and procedures. The use of

internationally recognized standards is presumed not to constitute an unnecessary barrier to trade. Unlike the SPS Agreement, however, the TBT Agreement does not specifically identify relevant international standards.

Nevertheless, the agreement acknowledges that there are good reasons for mandatory regulations to differ between countries. It states that: "no country should be prevented from taking measures necessary to ensure the quality of its exports, or for the protection of human, animal, and plant life or health, of the environment, or for the prevention of deceptive practices, at the levels it considers appropriate." The agreement also states that standards may differ between countries due to differences in taste or levels of income, as well as geographic and other factors. Thus, legitimate differences can be fully reflected in domestic regulations. Although this offers a high degree of flexibility in the preparation, adoption, and application of national technical regulations, it also raises the question of which differences are "legitimate", what is the criterion that establishes legitimacy and which standards create unnecessary obstacles to trade.

There is little doubt that the TBT Agreement will become increasingly important in future disputes between WTO members as disagreement over the legitimacy of certain technical regulations and standards widens. The public reaction as to the acceptability of GMOs and their products differs greatly across countries and is reflected in very different legislation relating to biotechnology. This is already apparent; the liberal views of countries such as the U.S. and Canada differ significantly from those (mostly EU countries) who are hostile to the cultivation and import of genetically modified organisms and products derived from them. However, there is no agreement on the interpretation of a number of aspects of the TBT Agreement that are important for the regulation of GMOs. In particular, there is no consensus as to the coverage of the agreement for standards and regulations relating to the processes and production methods that produced the product, unless the method of production is "incorporated" into the product (i.e. the production method is evident in the product itself).

In this sense the concept of "like product" is important from genetically modified organisms or their products. As noted, the TBT Agreement commits WTO Members not to discriminate between imported products and sources of supply, nor to discriminate between locally produced goods and imports. In addition, measures taken in accordance with the agreement must be no more trade restrictive than necessary. However, the non discrimination obligation applies to "like products". The same

products must be given the same treatment. The question then begs itself as to whether GMO and non-GMO products are "like" products. In very practical terms, would a compulsory labeling scheme that requires the labeling of only products derived from genetically modified organisms be considered WTO inconsistent on the grounds that GMO derived products are "like" non-GMO products? The manner in which this debate is resolved will have major practical implications in a number of areas of considerable commercial significance; both voluntary and mandatory labelling schemes are covered by the TBT Agreement and the WTO will find itself in the centre of the debate.

Mandatory and voluntary labeling schemes are seen by many as a positive market based response to many of the health and environment concerns surrounding GMOs. Members of the WTO acknowledge, for example, the positive aspects of labelling schemes, the intention of which is to provide consumers with information they require about the manner in which goods have been produced in order for them to identify products that may carry risks for public health or the environment. Members also point to the risks of abuse and impediments to trade of these schemes. [3]

While no case involving a violation of the TBT Agreement through a challenge to GMO labelling has been brought to the WTO panel process yet, problems may well emerge in the future. Storm clouds are on the horizon. In recent meetings of the TBT Committee, the United Sates and Canada expressed concern over the EU regulation on the labelling of food products containing or derived from genetically modified soya or maize. The EU requires foodstuffs and food ingredients containing traces of modified DNA or protein to be labelled as "produced with genetically modified soya/maize." The United States and Canada argued that such labels were unnecessary technical barriers to trade since no scientific reason existed to differentiate between foodstuffs produced with genetically modified crops and "normal" maize/soya. The United States also questioned the feasibility of developing reliable and commercially practical tests for detecting DNA or protein resulting from genetic modification, especially at very low thresholds. The issue at stake is whether GMOs are "like" other products.

[3] It is important to note that like other WTO rules, those contained in the TBT Agreement address the actions of member governments. As a result, purely private labelling programs with no government involvement are unlikely to be considered as subject to the disciplines of the agreement.

It has been speculated that in the event of a dispute, a challenging country will argue that the WTO should use the principle of "substantial equivalence," which compares only selected characteristics of genetically modified food to corresponding non-genetically modified food. According to the logic of "substantial equivalence," if a genetically modified food is equivalent to a traditional food in the characteristics that are important to the consumer - composition, flavour, and texture - then it can also be presumed not to present new safety or nutritional concerns. The "substantial equivalence" test thus sets a low threshold for determining when GMO and non-GMO products are similar.[4]

(III) COHERENCE BETWEEN AGREEMENTS

(I) Committee on Trade and the Environment

The WTO Committee on Trade and the Environment (CTE) reports to the WTO General Council and is mandated not only to address a variety of areas of work relating to trade and the environment, it is also to recommend whether any modifications to the rules of the multilateral trading system are required to permit a positive interaction between trade and environment measures.[5] The CTE includes all WTO members and a number of observers from intergovernmental organizations.

The CTE has a standing agenda, and meets formally at least two times a year and in an informal mode whenever considered necessary. Among other things it addresses. In particular, the relationship between the provisions of the multilateral trading system and trade measures for environmental purposes, including those pursuant to multilateral environmental agreements.[6] An important question under this heading is whether the rules in MEAs that have a bearing on biotechnology (the Convention on Biodiversity and the Biosafety Protocol) are consistent with WTO Member countries obligations. This too raises important questions such as whether the TRIPs Agreement hinders the achievement of the objectives of MEAs (the Biodiversity Convention).

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[4] See Matthew Stilwell and Brennan Van Dyke, An Activist's Handbook on Genetically Modified Organisms and the WTO, Centre for International Environmental Law, March, 1999. The authors note that other tests could be applied more appropriately to determine whether GMO and non-GMO products are like. The traditional WTO test for determining the likeness of products looks at: 1) consumers' tastes and habits; 2) the products' physical characteristics and end uses; and 3) the products' properties, nature and qualities.

[5] According to the Ministerial Meeting of the GATT in Marrakech, held on 14 April 1994, adopted a Decision on Trade and Environment which calls for the establishment of a Committee on Trade and Environment (CTE) open to all Members of the WTO. The Committee on Trade and the Environment (CTE) was established in January 1995.

The CTE is also to consider the relevant provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights as an integral part of its work. A number of recent submissions have enlivened the debate in the CTE[7], at least in part relating to the lack of clarity between WTO rules and MEAs dealing with biotechnology. There is a widely held view that the negotiations surrounding the Bio-safety Protocol proved to be difficult, for example, "precisely because of the lack of clarity with regard to the relationship of the Protocol to the WTO".[8] The following section described two of the relevant agreements and presents examples of points of possible conflict.

(II) Multilateral Agreements

(a) Intellectual Property

The TRIPs Agreement of the WTO provides the most comprehensive multilateral protection of intellectual property rights. Its general goals are contained in its Preamble. They include the reduction of distortions and impediments to international trade, promotion of effective and adequate protection of intellectual property rights, and ensuring that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade. In respect of each of the main areas of intellectual property covered by the TRIPS Agreement, the Agreement sets out the minimum standards of protection to be provided by each Member. Each of the main elements of protection is defined; namely the subject-matter to be protected, the rights to be conferred and permissible exceptions to those rights, and the minimum duration of protection.

While all areas of intellectual property rights protection are addressed in the TRIPs Agreement, the most relevant from the point of view of biotechnology are patents. The TRIPS Agreement requires Member countries to make patents available subject to the normal tests of novelty, inventiveness and industrial applicability. Patents provide for exclusive rights to the patent holder, and are to be provided without discrimination as to the field of technology. The term of patent protection is 20 years from the filing date.

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[6] A number of MEAs have trade-related provisions that raise questions with respect to their WTO conformity. A detailed description of the WTO relevant measures in eleven environment conventions containing trade measures can be found in WTO (19 September 2000).

7 These include, in particular, WTO, Submission by Switzerland (19 October 2000), WTO, Submission by the European Community (19 October 2000); and WTO, Communication from New Zealand, (10 October 2000).

What is important in establishing both equitable and efficient intellectual property rights lies in accepting that the exclusive rights are subject to a number of limitations and exceptions. There are aimed at fine-tuning the balance that has to be found between the legitimate interests of right-holders and of users. For example, with respect to patents, the patent holder should not exploit the patent to the disadvantage of society. Further, the patent holder should be obliged to provide a license (compulsory licensing) if demanding unreasonable terms. As far as exclusions are concerned, members are authorised to exclude from patent protection those inventions which are against public order, morality, human, animal or plant life or health, or those inventions which are likely to cause serious prejudice to the environment.

There are three permissible exceptions to the basic rule on patentability two of which are relevant for the following. First, is for inventions dangerous to human, animal or plant life or health or seriously prejudicial to the environment. The second is that Members may exclude plants and animals other than micro-organisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. Thus, patent protection must be provided for micro-organisms and non-biological and micro-biological processes. Any country excluding plant varieties from patent protection must provide and effective sui generis system of protection.

(b) Convention on Biodiversity

Negotiated under the auspices of UNEP, the Convention on Biodiversity (CBD) was opened for signature in 1992 and entered into force in 1993. The Convention's objectives are the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. The Preamble of the CBD which initially recognises "… the intrinsic value of biological diversity and of the ecological, genetic, social, economic, scientific, educational, cultural, recreational and aesthetic values of biological diversity and its components". The Convention is based on the notion that in accordance with the principles of international law, states have the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure

[8] See, WTO, Submission by Switzerland (19 October 2000). This view is also expressed in WTO, Submission by the European Community (19 October 2000).

that activities within their jurisdiction and control do not cause damage to the environment.

So states have the authority to create legal mechanisms to control their genetic resources, and such access should be with the prior-informed consent of the country providing the genetic resources. The country where the resources reside will also be entitled to a equitable and fair share of the benefits that may arise from the commercialisation of the resources and participate in the scientific researche based on the genetic resources in question.

The fact that the CBD acknowledges that genetic resources have a commercial, economic and scientific value, and entitles Parties providing such resources to have priority access to the results and benefits, on a fair and equitable basis and on mutually agreed terms, means that intellectual property considerations are important to the agreement.

Intellectual property rights protect and enforce the control over information and define who can use the information. They therefore influence the distribution of benefits flowing from their use. It could be argued that intellectual property rights and the protection of biodiversity are conceptually unrelated. However, since the Biodiversity Convention establishes the right of national governments to control the access to genetic resources, and intellectual property rights provide a possible mechanism for controlling the use of information relating to genetic resources, the link is made through the Convention.

An important question then becomes whether the prevailing system of intellectual property protection is supportive of the objectives of the CBD or not particularly the equitable sharing of genetic resources. Views differ widely on this point.[9] There is the assertion, for example, that patenting of seeds, herbs, and traditional processes from developing countries is "biopiracy" and robs the developing world of rightful profits. In this context it is argued that the intellectual property "system" is biased against the interests of developing countries due to the definition of some crucial terms. For example, the view is expressed that the requirement that patents are for products and

[9] A useful distinction between the various schools of thought is provided by Graham Dutfiled in Intellectual Property Rights, Trade and Biodiversity, IUCN and Earthscan Publications, London 2000, pg. 41.

processes which are new, which involve an inventive step, and which are capable of industrial application precludes the granting of patents for many inventions/ discoveries that constitute the traditional knowledge of indigenous people. On the other hand, it favours the patenting of products by multinational corporations, even if their origin is in developing countries. Through the use of modern biotechnology and "gene shuffling" new products can be "invented". Further, while developing country governments can enact strong laws to regulate the conditions under which corporations access domestic resources, few have the legislation in place or the expertise to create it. Additionally, in many instances, developed country patent examiners are not aware of the innovations already made by native peoples and, therefore, grant developed country corporations patents in error. However, due to expense and lack of expertise, developing country citizens cannot challenge patents issued in error.

The more positive approach acknowledges that patents can support the CBD objectives as if corporations are granted patents they will be more willing to invest in natural product research and engage in benefit-sharing arrangements with genetic resource providers. This approach acknowledges that while there are difficulties in reconciling the objectives of the CBD and TRIPs, we can not live in a patent free world and it is better to work in interpreting – and if necessary reforming – existing agreements in an agreed and balanced manner. This approach also envisages implementing domestic legislation that is in conformity with the TRIPS to support the objectives of the CBD.

One example is that the TRIPS Agreement considers the issues on environmental protection in very broad terms. How far this provision would authorise Members to take further action towards environmental protection, even by denying patent protection for some inventions on "environmental" grounds, is still a matter left for future interpretation. It is also not clear if the developed economies will accept that developing countries' use, on grounds of "environmental" protection, of the exception to refuse the granting of patent rights to biotechnological invention, even if the invention is a micro-organism, a non-biological or a microbiological process.

As noted, Members are required to protect micro-organisms, non-biological and microbiological processes and plant varieties. Thus, the wording of the TRIPS Agreement in relation with the protection of biotechnological products or processes is very vague in substance. How a plant or animal could be produced by a process that is not partly or entirely a biological process is still to be determined and does not seem to

be very feasible. It is not yet clear how this will be enforced by the dispute settlement mechanism of the WTO.

Another biodiversity related concern is the provision of property rights protection to genetically modified plant varieties even though their long-term environmental impacts have not been established. The concern here is that the prevailing policy framework enhances incentives to develop seeds that will have a large potential demand. Thus, the focus of seed company research will be on high value crops leading to decreased crop diversity. Also it is argued that the creation of trans-genetic plants with built-in resistance to herbicides could lead to ecological damage with the release of these crops into the nature. The threat to food security comes from protection for innovations associated with the development of new plant varieties which limits the type and number of seeds available to farmers, decreases crop resistance, and increases the likelihood of food shortages and, possibly, famine.

An argument in favour of patent protection of plant varieties is that they could have positive effects on food security. Intellectual property protection for plant varieties provides incentives for farmers to produce new, improved plant varieties and protects innovations made by local farmers, plant breeders, or scientists in developing as well as developed countries to ensure that they have exclusive rights to their innovations. In fact, it is argued that biotechnological innovations hold out the promise to dramatically increase crop yields and viability in developing countries. Using biotechnology, scientists are able transfer specific traits through direct manipulation of the genome of a plant, instead of the conventional plant breeding techniques which involve extensive trial and error. Biotechnology also has allowed for development of new technological solutions in the field of agriculture, for example, frost-inhibiting bacteria, pesticide resistance, or enhancement of the disease resistance of livestock. It is argued that research in this area would be greatly limited if an appropriate system of intellectual property rights was not in place.

However, what is important to consider here is that intellectual property protection does not confer the legitimate right to otherwise regulate products. If a product receives intellectual property protection this does not mean that it has been approved for production, use or marketing. In terms of patent protection for plant varieties, for example, this does not mean that the right holder can automatically produce, use, or market the plant variety. This is the same for the granting of a patent on a

pharmaceutical product; it does not grant an immediate right to market a drug. Rather, a separate review of the drug's safety is typically required before it is introduced widely to the public.

(c) Biosafety Protocol

The CBD also calls for the establishment of biosafety related regulations to "… control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health". The CBD by the wording of this provision broadened the traditionally applied concept of "genetically modified organisms" (GMOs) by using the term "living modified organisms" (LMOs). The Cartagena Protocol on Bio-safety, agreed to in March 2001 and adopted under the auspices of CBD, is the first international legal instrument to deal with biotechnology.

The centre-piece of the Protocol is the Advance Informed Agreement Procedure where a prior notification and consent is required for the export and import of GMOs. These procedures incorporate the principle that States have sovereign rights to control the transfer, handling and use of LMOs, including the right to refuse the importation of LMOs. A central question throughout the negotiation of the Protocol was whether it should cover only those classes of living modified organisms that are released into the environment, or also LMOs that are intended for direct use as food or feed, or for processing. While it was agreed that both classes of living modified organisms would fall under the Protocol's scope, the Protocol's Advance Informed Agreement provisions would only apply to LMOs that are intended for introduction into the environment. Both these procedures have the potential to seriously affect trade flows.[10]

The import decision under the advanced informed consent procedure is to be based on risk assessment that should be carried out in a scientifically sound manner. The lack of agreement among the parties as to the nature and extent of the risk associated with the

[10] As far as LMOs for food or feed or processing are concerned, a clearing-house mechanism has been created to provide an effective link between national authorities where products exported for food, feed, or processing are to be notified to the other party within 15 days. The information to be provided should include details about the producer and the LMO as well as a risk assessment report. The importing party may make their own decision as to the import of the product according to its own domestic regulatory regime for GMOs.

release of living modified organisms is highlighted in differing approaches to the degree of precaution that is appropriate in the management of risk.

After establishing that Parties could take a precautionary approach to restricting imports of LMOs, the challenge remains as to how to put into practice the principle of precaution. As noted above, the potential conflict between the rules of the WTO and MEAs such as the Biosafety Protocol has been under discussion in the CTE. Both the Protocol and the WTO Agreements are international law and an important question is whether there are WTO inconsistent measures contained in the Biosafety Protocol. The answer seems to be in the affirmative, at least as far as the SPS Agreement and its treatment of precaution is concerned.[11]

The objective of the SPS Agreement is to protect human, animal or plant life from food-borne or pest or disease related risks (see above). However, WTO members are obliged to base a measure to restrict trade that could present a risk on sufficient scientific evidence and a risk assessment, or to take measures that are only provisional until the scientific evidence is available. Given the scientific uncertainty surrounding GMOs there are certainly differing views on what constitutes sufficient scientific evidence, and therefore the cover provided by the SPS Agreement to justify the restriction of imported GMOs. While both the Protocol and the SPS Agreement formally provide the right to resort to the precautionary principle in the absence of sufficient scientific evidence, this is not considered to necessarily be a provisional measure in the case of the Biosafety Protocol – whereas in the SPS Agreement it is.

Indeed, it is left unclear how the two treaties are to be read together and which would prevail in the event of an eventual dispute. In what is clearly negotiated language, there is a "savings clause" in the Protocol to "save" both agreements. At the same time, however, it offers little guidance to any future WTO panel that may have to deal with the matter. The Protocol text reads that "this Protocol shall not be interpreted as implying a change in the rights and obligations of a party under any existing international agreement". Thus, WTO rights and obligations stay in tact. On the other hand the next paragraph in the Protocol states that "the above recital is not intended to subordinate this Protocol to other international agreements". This reads that they do not.

[11] See Barbara Eggers and Ruth Mackenzie, "The Cartagena Protocol on Biosafety", Journal of International Environmental Law, 2000.

(IV) FUTURE DIRECTIONS FOR THE WTO

While many regard the current provisions of the WTO to be sufficient and effective in dealing with circumstances surrounding trade in all products, some hold the view that biotechnology is sufficiently unique to require further clarification and/or elaboration of existing provisions in order that they may apply effectively and in a predictable, transparent manner. It is argued that this lack of certainty works to undermine the realization of the full potential of biotechnology by the world's producers and consumers.

To a number of governments, it appears timely for the WTO to engage in a collective exercise aimed at establishing how trade and investment in biotechnology are covered by existing WTO provisions and whether the latter constitute a sufficiently effective regime from the WTO's perspective. Because a number of existing WTO Agreements are of particular relevance to biotechnology, it would be difficult for this exercise to be conducted effectively by any one Committee. It has therefore been proposed that a Working Party be established by Ministers in Seattle with a clear, time-limited mandate to report back to the Steering Body on its findings and possible conclusions. Two such proposals are elaborated below.

Some insight into the future direction of discussions on GMOs in the WTO may come from the preparations for the ministerial meeting in Seattle. Prior to the Seattle meeting, the Government of Canada presented to the General Council of the WTO a proposal for the establishment of a Working Party on biotechnology and the WTO.[12] The Working Party would have a fact-finding mandate to consider the adequacy and effectiveness of existing rules as well as the capacity of WTO Members to implement these rules effectively. One year after its establishment, the Working Party would report on its findings to the Steering Body (to have been be established at Seattle) and provide any conclusions it considered appropriate.

The rationale behind the proposal was that each year, an increasing number of a wide range of agricultural and industrial products, developed through biotechnology, are commercialised and enter into international trade. These activities are not confined to the largest and richest countries but are currently being actively pursued in scores of WTO Members, both large and small, developed and developing, from all regions of

[12] On the 4th of October 1999.

the world. This trend has been forecasted to result in trade of products of biotechnology constituting a significant share of total trade within five years.

According to the Canadian submission, such a Working Party would bring a number of benefits to WTO Members including: providing a transparent process with a common focus and time-frame for preparatory, fact-finding work building on work already underway at the national level in several WTO Members; providing information for those WTO Members not currently engaged in such exercises at the national level; and serving to identify constraints to full implementation by Members of WTO-consistent regulatory systems for biotechnology.

The government of Japan tabled a proposal at the same time as Canada. In the view of the Japanese submission, due consideration should be given to the potential of genetic engineering while evaluating the implications of its application on the environment and human health. The prevailing scientific knowledge and expertise should be considered along with a full awareness of consumers' concerns on the use of genetic engineering. Like Canada, the Japanese government proposed that a forum be established to discuss how regulations relating to GMOs need to be addressed within the context of the WTO agreements. Any examination of GMOs and the WTO should be carried out from a broad perspective including all WTO agreements. A special emphasis was placed on agriculture. The proposed "Examination Group for New Issues including GMOs" should be an independent negotiating group on agriculture and identify topics on food-related matters of GMOs. Possible topics for examination included would be the current situation of Members with regard to their evaluation on the safety of GMOs and the labeling of food containing GMOs; the method of determining the appropriate agenda items for discussion in such a group in the WTO; the appropriate way for the WTO to deal with the contents and outcomes of discussions of other international fora; and, whether the relevant WTO agreements, such as SPS, TBT and TRIPs, which could be related to GMOs matters, are capable of dealing with future concerns.

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