The Biosafety Protocol and its Socio-Economic Consequences

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Resumen

La biotecnología (BT) se está constituyendo en una fuente importante de numerosos cambios socieconómicos y ecológicos, a medida que ingresamos en el siglo XXI. El público escucha, casi a diario, opiniones divergentes que van desde aquellas que proclaman a la BT como la salvadora de la especie humana, hasta aquellas otras que la consideran como causa de una destrucción ambiental total. Los gobiernos enfrentan dificultades para diseñar políticas apropiadas que permitan regular todos los aspectos de las BT, desde los protocolos de investigación hasta las pruebas experimentales, la protección de la propiedad intelectual, las licencias ambientales, la salud nutricional y el comercio internacional.

El nivel de incertidumbre ambiental existente sobre los productos de la BT ha determinado que, además de las posibilidades de impactos negativos provenientes de los movimientos interfronterizos de los organismos genéticamente modificados (OGM), se reconoce la urgencia de un acuerdo internacional para regular el comercio de estos OGM. Un Protocolo de Bioseguridad sería un acuerdo ambiental internacional encargado de diseñar una estrategia normativa internacional exhaustiva para la protección de la biodiversidad, así como de establecer reglas para manejar los riesgos ambientales de los movimientos interfronterizos de los OGM.

El Protocolo tendría implicancias fundamentales, tanto para las tecnologías involucradas como para el comercio internacional. Sería el primer acuerdo internacional importante que utilice en forma explícita, el "principio precautorio," para controlar el comercio de productos que han sido producidos empleando una tecnología específica, la BT. El presente trabajo pretende hacer un análisis socioeconómico crítico del Protocolo, en los temas relacionados con la agrobiotecnología y la biodiversidad.

Abstract

Biotechnology (BT) is a major source of numerous socio-economic and ecological changes and consequences as we are entering the 21st century. The public is almost daily confronted with conflicting stories that encompass the entire spectrum from BT being proclaimed as humankind's saviour to it being the cause of our ultimate environmental destruction. Governments have difficulties designing appropriate policies to regulate all aspects of BT from research protocols, to testing, to protection for intellectual property, to licensing for release into the environment, for food safety and for international trade.

Given that there is a certain level of environmental uncertainty associated with the products of BT in addition to the possibilities of negative impacts arising from trans-boundary movements of genetically modified organisms (GMO), the urgency for an international agreement to regulate trade in GMOs was recognized. The Biosafety Protocol is such an international environmental agreement that is charged with devising a comprehensive international regulatory approach to the protection of biodiversity and to establish rules to manage the environmental risks of trans-boundary movements of GMOs.

The Protocol has major implications both for the technology addressed in the Protocol and for international trade. It is the first major international agreement to use the "precautionary principle" explicitly to allow the restriction of trade in products because they were produced using a specific technology, namely BT. This paper intends to provide a critical socio-economic assessment of the central issues addressed in the Protocol in regards to agro biotechnology and biodiversity.

1. BIOTECHNOLOGY AND BIOSAFETY: THE ISSUES

The international civic community has recognized since quite some time that any successful strategy of ecological sustainable economic development (SD) has to balance the conflicting interests of conventional economic advancement with ecosystem health. The emergence of biotechnology (BT) in recent decades is one area where these divergent positions of commercial interests of corporations and nations with environmental concerns became apparent. The fast expanding international trade in genetically modified organisms (GMOs) -particularly, the use of BT in food production- has provoked growing consumer opposition and gave rise to public regulatory resistance in several countries, in particularly in the European Union (EU). These tougher regulations on the release of GMOs into the environment have generated accusations by GMO-exporting nations of unfair international trade barriers. For instance, the USA, the largest exporter of GMO-products, has criticized on several occasions the EU for its adherence to the precautionary principle (PP) in controlling GMOs, and is considering this persistence as being in direct contradiction with the WTO's science-based approach to risk-assessment (Falkner 2000).

In awareness of these conflicting interests, the international agreement of the so-called Cartagena Protocol on Biosafety (BSP) in January 2000 has been regarded by the international community as an important leap forward in that this BSP establishes a regulatory framework which attempts to reconcile economic interests with environmental concerns with respect to the fast-growing global BT-industrial complex.

This article focuses on BT and the resulting socio-economic and environmental issues caused by the application of this technology in the agrifood industrial complex, as the main area where BT has become most controversial since its commercial application leads to widespread releases of GMOs into the ecosystem and thus poses a potential threat to biological diversity, while integration of its products into the human food chain may produce adverse consequences on human health.

2. THE BIOSAFETY PROTOCOL IN A SKETCH

The application of agricultural BT in food production is a source of additional international trade disputes, where exporting countries of GM-crops and food products are disagreeing with those countries that insist to uphold stricter regulations on GM-imports for safety purposes for human health and the environment. At the international level, the BioSafety Protocol, as a multinational environmental agreement (MEA), is an attempt to provide a

scheme for managing the environmental risks of transboundary movements of living genetically-modified organisms (LMOs). Although the BSP has predominantly an environmental orientation, it also contains provisions that have significant repercussions for international trade in LMOs[1]. The Preamble of the BSP, however, remains ambiguous with respect to the linkage between the Protocol and other international agreements, in particularly, the WTO, by stating:

- "*Recognizing* that trade and environment agreements should be mutually supportive with a view to achieving sustainable development,
- *Emphasizing* that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreement,
- *Understanding* that the above recital is not intended to subordinate this Protocol to other international agreements" (Parts of the Preamble).

The "recognizing" statement provides no guidance in the situations when trade and environmental issues are clashing, i.e., when they are not "mutually supportive", while the "emphasizing" and "understanding" statements appear to contradicting each other. The "emphasizing" statement may give rise to the impression that a country may refer to the WTO regulations in case of a dispute over international trade in LMOs, while the "understanding" phrase apparently implies an escape clause from WTO regulations. Thus, this (intentional) failure in clarity may lead to significant challenges for the implementation of the BSP as it seeks to find a compromise between environmental and trade objectives (Vogler and McGraw 2000: 133-35).

The negotiation process of the BSP, which involved 138 countries, stretched over several years and was concluded in Montreal on January 29, 2000. The Protocol, which has to be ratified by at least 50 nations before it becomes a new accepted MEA, outlines the regulations regarding transboundary movements of GMOs (including transit, handling, and use) intended for release into the environment and for those destined for the food chain[2].

According to the BSP a "living GMO" is "any living organism that possesses a novel combination of genetic material obtained through the process of modern biotechnology" (Article 3, sec. g).

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1. The BSP focuses actually only on the **unintended** environmental consequences of agrifood BT. However, it could be argued that the **intended** consequences of BT represent a more severe environmental threat, namely through the creation of monocultures which lead to a decline of biological diversity (Kloppenburg 1988 and Müller 2000).
2. The USA, the largest industrial producer of GMOs, was relegated to observer status in the negotiations of the BSP, since it has not ratified the Convention of Biological Diversity, and thus, is formally not obliged to follow the terms of the BSP.

The overriding objective of the BSP is to establish a regulatory framework for national governments to examine –and possibly to deny– the transboundary movement of LMOs within their jurisdictions. The centre of this scheme is the application of the "Advanced Informed Agreement" (AIA) of article 7. This article outlines differentiated procedures for the *first* intentional transboundary movement of LMOs for intentional introduction into the environment of the importing country (e.g., seeds for propagation, seedlings, fish for release) and LMOs for "direct use as food, feed or for processing" (LMOs-FFP), as stated in articles 7(3) and 11(1). The AIA procedure refers to the former category of LMOs and it includes rules regarding notification, acknowledgement of receipt, decision-making, and consent–orrefusalof the importing country (Articles 7 to 10, and 12). In the case of LMOs-FFP, the exporting country has to obtain approval from the importing country. Within 15 days, the importing country has to make a final report concerning the import of the LMOs-FFP and is obliged to notify the exporting country through a BioSafety Clearing House with the pertinent information about the traits and evaluation results (Article 11(1)). Based on these results regarding the environmental risks, determined through a science-based risk assessment procedure, the importing country decides whether to approve or disapprove the shipment of LMOs-FFP.

The BSP calls this process "AIA", which only applies to LMOs to be released into the environment, and it appears quite uncomplicated. The BSP, however, includes two provisions that may become the basis of conflict in the future. The first one (Article 26) points out that a country may –in its assessment process of LMOs– also include *socio-economic* factors (e.g., the impacts on local farming communities) provided that these decisions remain consistent with the country's other international obligations. The second provision refers to the so-called "Precautionary Principle" (PP) of Article 1, whereby a country does not have to establish comprehensive scientific certainty to prevent imports of LMOs that the country suspects to have adverse impacts on its biodiversity and human health (Phillips and Kerr 2000: 65).

At present, however, there is no experience with these provisions, and thus, it remains uncertain how countries exporting and importing LMOs are anticipating these two provisions to function. Being aware of the references in the Preamble to other international agreements and obligations, it is quite probable that in a case of conflict, any import restriction which did not comply with a process of scientific risk assessment will be viewed as inconsistent, and thus, in violation with WTO obligations[3].

3. Under the "Agreement on the Application of Sanitary and Phytosanitary Measures" (SPS) under the WTO, a country may impose a temporary restriction on imports, but the country is obliged to make serious efforts and to provide scientific evidence to uphold its decision.

The negotiations of the BSP intended to centre this Protocol predominantly on environmental risks. With this objective in mind, since the transboundary movements of LMO-FFP, i.e. commodities, are not considered to pose an environmental threat to the environment, they are actually exempt from the AIA-procedure. Exporting countries, however, have to identify clearly that their shipment of LMO-commodities "may contain" LMOs (Article 18 (2a)) and importing countries have the option to determine whether to import or not these commodities, provided their decisions are based on proper procedures of scientific risk assessment. In addition, LMOs intended for "contained use" (e.g., for research purposes) and LMOs in transit with destination to other countries are also exempt from the AIA-requirements.

Although the BSP is supposedly an MEA and not just a trade agreement, the fact that it stresses economic activities, namely export and import transactions, makes it actually to a specialized international trade agreement for trade in LMOs. As such, this Protocol has the potential to shape beneficially the international trade relationships in at least two aspects. The first one is that the application of AIA-procedures will contribute to increased transparency and standardized procedures by reducing trade impediments in the market of LMOs. The second aspect refers to enhanced trade fairness, since all countries have to apply generally accepted scientific risk assessment procedures for determining the risk that may exist to biological diversity and human health originating from LMOs, irrespectively of their domestic or foreign origin.

Too little time has elapsed since the successful conclusion of the negotiation of the BSP, and therefore, it would be premature to make an attempt to evaluate with finality if the Protocol represents a major step forward (or not) in reconciling environment and trade with respect to the use of BT. Initial reactions from the representatives of the "Miami-Group". Australia, Argentina, Canada, Chile, Uruguay, and USA welcomed the agreement as allowing sustained market access and upholding WTO-obligations. The EU-countries, the Third World Network and NGOs are considering the inclusion of the PP and the provisions of socio-economic factors as major accomplishments.

Obviously, the BSP does not offer solutions for all concerns of the marketplace and the society. For instance, the USA, the world largest producer of LMOs, has not ratified the CBD and, consequently, it is not a party of the BSP either. Most developing countries are confronted with serious implementation problems due to their limited capacities and/or little or no expertise with domestic biosafety regulations. In addition, the BSP provides no or only limited financial resources for protection against any adverse environmental impact of agricultural BT in developing countries' research and development, transfer,

handling, testing, use and disposal of all LMOs. These tasks become the responsibility of the individual country. Finally, the BSP does not address socio-economic, ethical, and consumer concerns in any detail and many important issues were left out altogether or for future negotiations, like e.g., a dispute-solving mechanism, liability issues, the functioning of the Biosafety Clearing House, and capacity building for developing countries[5].

3. SEEDS OF DISCORD

At the centre of potential conflicts are the different perceptions and divergent social-economic values associated with the benefits and risks of agrifood BT. USA companies are stressing the alleged numerous gains from genetic engineering for the world food production, such as increased yields and enhanced pest resistance of GM-crops, and downplaying the potential risks to humans and the environment. In contrast, the countries of the European Union (EU) are in favour of a more careful approach with respect to the use of BT by questioning the necessity for more intensive methods of industrial agriculture, and consequently they emphasize the application of the "Precautionary Principle" (PP). Since most DCs are neither economically nor scientifically in the position to establish their own BT research facilities, nor are able –for whatever reason– to attract international BT-research investment on a sufficient scale to satisfy their national needs, they were supportive to adopt the BSP with the expectations that the Protocol would enhance their regulatory power against foreign BT-companies. They feared that implicitly the Protocol would be more interested in trade in biotechnological commodities than in setting up and enforcing stricter and more comprehensive biosafety standards. Thus, besides the environmental issues, the DCs are also concerned about the socio-economic consequences of the Protocol[5]. The DCs' concern appears to be paramount about the dominance of foreign companies in BT-R&D, commercialisation and international trade which may lead to the potential outcome for the DCs to lose control over their own agricultural sector if they permit GM-crops to get intermingled with their agricultural crops and genetic diversity. In addition, their anxiety is further heightened by the existence and enforcement of the WTO's regime of intellectual property rights (IPR), which compel DCs to adopt ICs' rules and standards into domestic legal infrastructure. This fact provides foreign companies with powerful mechanisms to patent genetic resources that previously have been used unrestricted by local farmers, and thus, it heightens the fears of increased dependence on ICs. In what follows, this article will focus mainly on two potential seeds of discord, namely on the PP and on the socio-economic consequences of IPR.

4. For a detailed discussion of the BSP see e.g., Vogler *et al.* 2000, and Phillips *et al.* 2000.
5. Falkner presents a general discussion about international trade and agricultural BT (Falkner 2000).

3.1 The Precautionary Principle

The PP, as incorporated in the articles of the Protocol, is a major seed of discord that may hamper the Protocol's successful implementation. The problem arises from the lack of clarity and consensus about a generally accepted definition of the PP. The PP is supposed to be applied in cases when scientific evidence is not sufficiently conclusive to determine and set a desired level of protection, but at the same time the decision makers are under pressure to adopt measures for the protection of human health and/or environmental quality. In context with LMOs, this would be the case when e.g., a risk assessment analysis is in progress, or when unique problems arise regarding quality and/or quantity risk factors, or when there is indecision as to what kind of risk management measures should be employed. For example, such a situation would be present with respect to choosing control instruments intended to contain microbiological danger, where it is complicated or difficult to conduct a risk assessment analysis due to uncertainty. Therefore, where grave danger looms, tight control measures might be selected despite the lack of sufficient scientific justification: e.g., decision-makers may have to utilize far-reaching control methods in an outbreak of the infamous foot-and-mouth disease for cattle. Thus, a tentative definition of the PP emerges as a principle that is linked to **uncertainty** in the risk assessment or difficulties in determining the **scale** of the risk, and intends to cope with uncertainty and/or with inconclusive scientific proof. Differently stated, if **undisputed** scientific evidence exists, then there is no justification to invoke the PP[6].

The PP was initially established in European environmental law during the late 1970s at the national and international levels and since the early 1990s, it is incorporated into the environmental law of the EU. Primarily, the minimum standards of conventional environmental law had the purpose of protecting humans and the environment against hazards and to control actual damages: thus, it was reactive. In contrast, contemporary environmental law extends beyond these objectives by incorporating preventive perspectives, i.e., to prevent adverse impacts, such as to avoid actual environmental and health problems before they arise and, thus, to minimize the risk to humans and environmental quality as far as possible. The PP, however, has an even more extended range: besides this "short-term" aspect of preventing environmental damages, the PP encompasses also a "long-term" aspect, which is associated with the conservation/preservation of ecosystem functions and the obligation towards the sustainable use of natural resources in accordance with the paradigm of sustainable development. In economic and legal terms, **precaution** and **prevention** are not synonyms; the latter term implies to be more restrictive, i.e., to prevent

6. Streinz discusses in detail –mainly from a legal perspective– the PP and its application in various areas, such as public security, food law, and environmental law (Streinz 1998).

environmental danger and/or damages, while precaution is more comprehensive and includes in addition also future-oriented elements, such as foresight and prudence[7]. Within the EU, the PP is not only a dominant element of any environmental policy, but it is also an integral part of prevailing environmental law. Examples of its application are the Ozone Convention, Ocean dumping, transboundary movements of waste (Streinz 1998: 420).

USA government and companies are objecting to the European application of the PP because –according to them– the PP is derived from the assumption that GMOs are **new** goods and **not** just an extension of their counterparts found in natural environment and, therefore, may have adverse impacts. Consequently, the PP places a burden on decision-makers not to approve and/or release GMOs until there is conclusive evidence that they do not pose any threat to anyone and/or anything. The US-decision-makers adopt the opposite position: they regard GMOs as an extension and/or improvement of their natural counterparts and conclude, that these "improved" and/or "altered" products are harmless to humans, other species, and the environment. From this perception follows that the USA assume that the European authorities do not follow exclusively scientific procedures and that they are permitting other factors, e.g., ethical, political, etc. to intervene, and hence give in to pressure of interests groups to influence the policy-making process and its implementation. Consequently, the USA declines to accept the EU's PP as a legitimate intervention to restrict international trade within BSP, WTO, and other agreements (Perdikis 2000: 51-65).

Whose perception is correct? Are the EU and DCs only self-serving for the purpose of restricting foreign access to their markets? Or, are the USA just a spokesperson for their companies' commercial interests?

Some social scientists, besides the US proponents of BT, are expressing reservation against the PP on conceptual and pragmatic grounds. They regard the EU's approach to adhere to the PP as

> ...mired in a system that is biased against release and has neither transparency nor due process. Thus, it is open to political interference and capture by vested interests". .."The 'precautionary principle' is popular with environmental groups internationally because of its bias against changes to the status quo. It is an understandable position for people with strongly held preferences for environmental protection but it is a poor basis for public policy (Gaisford *et al.* 2001: 59-60).

7. Nottingham identifies in context with GMOs twenty areas where concern has risen and where the PP should be applied (Nottingham 2002).

In rebuttal to the statement above, which regards the "PP as a trade barrier", it can be said that the EU legislation restricts equally US and EU producers, but actually it establishes a bias against its own industrial interests. EU companies are very critical of EU legislation, since the BT industry foresees short- and long-run implications on both profitability and the capacity to set up production facilities and to initiate R&D activities in this potentially lucrative area. Consequently, some EU companies raise the possibility to relocate their research to the USA and/or other BT-friendly countries. Thus, the statement is invalid that EU companies intend to seek protection behind the PP. Other social scientists even anticipate that the PP may even have an anti-technology bias and may result in not approving new biotechnological innovations, because speculative risks are always present. (Gaisford, et al. 2001: 61).

The above quotation is correct in pointing out that consumer associations and environmental groups are supporting the use of the PP[8]. The opinion polls about the public attitude to GM food products, conducted by the European Public Concerted Action Group, confirmed that a large majority of those surveyed —namely, 74 percent— want GM food products clearly identified and labelled, an additional 60 percent would like to see public consultation regarding new BT development, and 53 percent felt that existing regulations were insufficient to safeguard human health and environmental quality (Perdikis 2000: 59).

The PP is also challenged on conceptual grounds. The US attitude towards the PP would be reasonable and logical if, e.g., the issues of GMOs could be settled by appealing to science. The problem here is that science cannot provide unequivocal evidence and certainty regarding the absence of any long-term adverse impact of GMOs. While some scientific studies raised doubts about the long-term health safety for humans of consuming GM food products, others questioned those results. In any case, the display of public disunity among scientists on such a vital issue does not contribute to the consumers' confidence, and rather weakens the further the role of scientists as "judges" about "what is safe, and what is not". Therefore, it is not surprising that consumers are no longer convinced that more scientific evidence is required before judgements can be passed about human and environmental health impacts (Fraver *et al.* 1996). The outbreak of the "foot-and-mouth-disease" in the EU may serve as an illustrative example.

A further issue concerns the validity of risk assessment. In general, when a new product is introduced on the market, it is customary to proceed with a general risk assessment

8. An UK-opinion poll, conducted in 1998, compiled the following results: 77 percent of the public surveyed would like all GM food products and crops banned, while 61 percent stated that they would not like to consume them. Opinion polls with similar results were conducted in other EU countries (Perdikis 2000: 59).

analysis, which also includes a risk assessment regarding the environmental safety of this product. Risk assessment implies that there exists a statistical probability distribution for the existence of certain events. In case, however, where there is no —or only marginal— information available, then it is also impossible to assign any statistical probability values, because one is operating under uncertainty. This is the conventional distinction between risk and uncertainty. The latter situation seems to be relevant when considering GMOs, a situation where there is limited information available regarding any -beneficial and/or adverse- short- and long-term consequences, and thus, it is impossible to determine any risk probability. Under such a situation of uncertainty, a prudent decision maker will have difficulties to rely upon some nebulous scientific report as a basis for judgement. Therefore, if risk cannot be assessed reliably then it is undisputed that it is prudent and legitimate for non-scientific institutions, such as NGOs, not only express their own opinion, but also to determine what kind of political decision/action should be taken, i.e. a case for invoking the PP. While this view may not be widely accepted, it is nonetheless an ethical, responsible, and legitimate position (Perdikis 2000: 60).

In conclusion, despite its vagueness, the PP is acknowledged at least "in principle" in various areas of national and international policies, agreements, and environmental law, although its application still leads to controversy. The PP should be invoked in situations of recognized uncertainty after a risk assessment has been executed but failed to produce conclusive and unequivocal results, and yet the existence of serious hazards cannot be ruled out, and, therefore, the decision-maker should proceed "with caution". Indeed

> (...) to determine the situations which justify the application of the precautionary principle, and, if it is decided to do so, to determine the extent of 'caution' are *political decisions* (italics added by author), even if they may be partly based on scientific evidence. ....In the field of the protection of the environment as well as in the fields of health protection (...) science often is not able to say if a line of causality exists or not. Just for these cases (...) because neither the risk nor the exclusion of any risk can be proved whereas absence of evidence is not evidence of absence—, the precautionary principle has been developed and is necessary (Streinz 1998: 421).

Certainly, such a wide principle is open to potential abuse, particularly, when

> (it) can be shaped to support any cause, when the protagonists are arguing about a future which does not exist except in their imaginations. (*Ibid.*, p. 421).

3.2 The Controversy over Intellectual Property Rights

Can or should a living being be patented? A substantial majority of ICs is responding affirmatively. These ICs, spearheaded by the U.S.A., are urging DCs to establish schemes for protecting (private) intellectual property rights (IPR) on all inventions. Thus, issues concerning property rights in general on global genetic resources are now gaining importance in national and international policies, as various negotiations e.g., for the Convention on Biological Diversity, for WTO, or BSP, have indicated, and as respective implementation activities and continuing revision negotiations are persistently demonstrating. It seems that proponents of a worldwide patent system have succeeded in their negotiations by obliging the WTO to accept the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). DCs were granted a grace period until 2005, at the latest, to incorporate the granting of patent rights "for any invention, product or process, in all technological fields" (TRIPS, Art. 27, sec. 5) into their respective domestic laws.

In what follows, the article focuses on some socio-economic and environmental issues which the implementation of IPR provisions may have, in particularly for local communities in DCs[9]. The outcome of these implementations, however, depends upon the domestic policy objectives of each respective country with respect to biodiversity prospecting and conservation. For instance, if a DC has decided to set up an industry of BD prospecting and to participate in this area in international trade, then establishing a patent system of IPRs would be compatible with this domestic economic objective. In contrast, if BD prospecting by foreign companies is generating conflicts with the traditional and cultural consumers and/or producers of biological resources or indigenous products, then the advancement of IPRs may have potentially adverse impacts. Here, in this article, the focus is "biased" towards DCs, which have traditionally resisted any type of foreign competition on larger segments of their domestic markets and trade.

3.2.1 The Conventional Economic Arguments about IPR

Modern technology is predominantly "intellectual" rather than physical in essence. The development and production of new sources of materials, energy substitutions (like solar energy), electronics, pharmaceuticals and BT are examples of this trend, i.e., technologies with a substantial component of intellectual content. From an individual entrepreneur's perspective, the decision to invest in conservation and supply of genetic resources depends upon profit expectations, i.e., these decision-makers will only implement their investments if they can expect to obtain a substantial proportion of the socio-economic value generated

9. For a detailed discussion of IPRs see Bhat (1996), de la Perriere and Seuret (2000: 90-111) and Gaisford *et al.* (2001: 35-52).

by their investments. Thus, to generate a continuous flow of intellectual innovations, entrepreneurs who commercialize such innovations want to be rewarded and expect a legal system in place —a system of IPR protection— so that they will be able to appropriate the financial returns from their investments.

In addition, there are other aspects of the BT-R&D process where similar issues of profit appropriation arise associated with the supply of genetic resources/products. The absence of property rights on genetic resources does not raise the issue of profit appropriation. Instead these issues concern the **value of information and knowledge products** that are generated by utilizing genetic resources. These information products may include the discovery, analysis and/or decoding of genetic and biochemical linkages, properties and/or substances that are embodied in the genetic resource, and the knowledge and know-how created by processing this new information. In contrast to the development and production of a more conventional commodity, e.g. textiles or airplanes, the problem of generating information and knowledge is a time-consuming —not always successful—, and therefore costly, process but transmitting or imitating these outcomes is relatively simple and inexpensive. Thus, the generation of BT information contained in genetic resources, and further generation of information and knowledge on how to apply it in processes for the production of commercially-successful goods, is quite costly. But once the information and knowledge are generated and applied, imitating these results is quite reasonably inexpensive because this information becomes almost a public good. ICs, therefore, argue that IPR have to be established and respected to provide a reasonable return to the entrepreneurs who take the financial risk for investing in BT (Janssen 1999: 318). If not, according to conventional economic wisdom, there will be insufficient incentives to invest, resulting in a socially sub-optimal amount of investment in innovative BT activities. However, conferring IPR on products or as copyright to companies will lead to the creation of monopolies, and thus, depending upon market conditions, will lead to higher rates of return on their investments. While these returns are rewarding the inventors, they also are imposing a burden on the society as a whole in form of excessively high prices and smaller quantities supplied during the duration of their patents and preventing the dissemination of innovations.

In principle, a socially responsible IPR system attempts to strike a balance between these conflicting objectives: rewarding innovation and disseminating new ideas, i.e., it becomes a question of what is the **appropriate scope** of the protection of intellectual properties (Ordover 1991). The scope of IPR, therefore, encompasses at least two aspects: **breadth** and **duration.** A socially optimal policy has to find a compromise between the two aspects of optimal duration and breadth of the exclusive IPR such as a patent and/or copyright. The **breadth** of an IPR deals with the aspects of how similar a competing invention can be

without violating the patent for the initial invention. A competing invention may display functional similarities, i.e., it may show properties of a substitute in a certain production process (horizontal similarity), or it may refer to sequential stages of invention in a specific production process (vertical similarity) (Jansen 1999: 319-20).

The **duration** of an IPR relates to the length of the time period between its registration and expiration, e.g., a patent. The optimal length of time for such an IPR, again, requires a compromise between stimulating innovations and discouraging dissemination. Certainly, the decision is invention-dependent. The ongoing debate about public control and regulation of BT centres mainly on the issue of breadth of IPR; however, the solution to this issue is clouded by mingled arguments on economic efficiency, equity, and ethics.

In addition, in the legal domain there exists no single worldwide IPR-system. In reality the IPR systems of various countries reflect their particular historical and cultural heritage about ownership of ideas and knowledge. For instance, many DCs do not acknowledge IPR protection for BT-innovations, and yet at the same time, they are exposed places for BT-research activities from ICs. However, without appropriate IPR-protection, ICs may shy away from these countries due to fear that emerging competitors of DCs may pirate away ICs' profits with the consequence of reducing further investment in BT-R&D in DCs[10]. Furthermore, critics from DCs have pointed out that IPR provide patent-holders of ICs with a monopoly in advanced technologies. They argue, because of this, their socio-economic advancement may be impeded, since IPR deny them access to new technologies. Even if DCs were granting IPR, they claim that this will not support investment in indigenous technology because many DCs lack the most elementary prerequisites, such as financial funds, research institutions, and/or sufficient number and quantity of scientific and technical staff (Shiva and Holla-Bhar 1993).

The application of IPR-schemes to genetic resources faces additional particularities in contrast to those innovations and technologies in other more conventional sectors of the economy. Genetic resources identified as commercially useful are commonly located in habitats of DCs whereas companies claiming IPRs to those genetic resources are frequently companies from ICs. Thus, to guarantee a sufficient supply of those genetic resources from DCs for these foreign companies is equally important as IPR protection for ICs. Therefore, this situation requires policies and institutions to assure not only the interests of companies using genetic resources, but also to protect the interests of those people living in these habitats who ultimately exercise control over their continuous existence, i.e., equity

10. The resolution of this issue requires empirical evidence.

considerations have to be observed. The existing international agreements do not provide sufficient incentives for conservation of biological diversity (Müller 2000).

IPR are also criticized on ethical and fairness considerations (Shiva 2001). Throughout history, biological resources, technologies and the knowledge associated with them has been treated as international heritage and were freely traded between individuals and regions, contributing to the enhancement of well-being of everyone. Opponents of IPRs demand that ICs should also provide free access to BT generated from the use of these genetic resources and knowledge obtained from DCs. In DCs, the livelihood of a large segment of their population depends upon the use of these plants and animals and on indigenous technology based on them as part of their daily routine. Consequently, it is considered as unethical to patent any form of life and technology related to those resources. Some critics of IPR to genetic resources even consider their establishment and enforcement as

> (...) a new era of colonialism in which not only are we re-colonized as a people, but all life forms are colonized (Shiva 1997: 132).

3.2.2 Consequences of TRIPS

The Agreement on Trade Related Aspects of Intellectual Property Rights (or TRIPS), administered by the WTO, outlines rights and obligations in various areas of IPR (patents, copyrights, trademarks, industrial designs, geographical indicators, trade secrets, and others) which must be enacted by all member countries of WTO[11]. TRIPS will force ultimately all countries to establish IPR for technologies that they previously have excluded from their domestic legal system, in particular it will urge DCs to protect agrochemicals, pharmaceuticals, and plant varieties for the first time. Thus, TRIPS can be viewed as an extension (or imposition) of IPR-legal institutions of ICs upon the domestic legal system of DCs (Braga 1996). In this sense, TRIPS is an extremely intrusive system, allowing WTO members actually no scope in establishing their own IPR regime, tailored for their specific socio-economic needs. In reality, DCs cannot simply select certain aspects of IPR that they consider as essential for their national interests. Instead it is an "all or nothing package" which also includes life patenting. Furthermore, TRIPS combines the enforcement of IPR in member states with the WTO dispute settlement mechanism, i.e., if a member state strays off the WTO-regulations, then sanctions may be imposed against the "offending" state. In conclusion, countries have a single "choice" in terms of IPR and life patenting laws: to adopt or reject the rules of WTO – actually, there is **no** choice at all for any single DC.

11. For a detailed interpretation and analysis of TRIPS, see Williams (2000) and Correa (2000).

This IPR regime is drawing sustained criticism, in particularly from DCs, which assume that TRIPS will cost them more than they may gain from it. TRIPS is being viewed as using a "one-size-fits-all approach" to IPR by ignoring the apparent differences between economies of ICs and DCs. Moreover, since DCs' societies are more dependent on production that is based on the utilization of biological resources for agricultural production, any regime that gives rights over these resources is viewed as a direct threat to the survival of DC populations. This prevailing sentiment is the dominant argument against a regime that intends to establish patent protection on life forms and biotechnological products and processes.

Several TRIPS provisions are distinctly different from existing patent rules in DCs and therefore, will restrict the manner local people and farmers have traditionally used biological resources and their products. Article 27 of TRIPS, the centre of controversy, reflects the main intension of the IPR regime for patenting under WTO. This complex article can only be discussed here in a very sketchy manner. The WTO, following the dominant paradigm of neo-liberal economics, defines IPR and patent as purely **private rights** in the preamble of TRIPS. This new interpretation represents a subtle, and yet politically far-reaching shift from the traditional "balance of rights" between private inventors and a wider public interest, which was reflected in both domestic and international IPR systems. This view of defining IPR as exclusive private rights stresses the reality that by enforcing TRIPS many countries may be forced into protecting the commercial interests of foreign companies, irrespective of policy preferences of their own population and the resulting potential socio-economic conflicts (Williams 1999: 72).

Article 27.1 of TRIPS bestows a "catch-all" patent protection for any technology and/or process in all fields of technology.

Article 27.2 specifies for member countries the "exemptions" of specific inventions from their patent systems if they might conflict with public order, morality, or pose a serious threat to the environment. These "exemptions" provide the illusion that there exists a broad scope for countries to deny patent protection for plant varieties and/or modified animals. In reality, these "exemptions" are there for **purely cosmetic** purposes[12].

Article 27.3(b) is the only section of the TRIPS agreement which outlines the regulations referring to biological resources, including plants, animals and micro-organisms and BT. It reads:

12. According to Williams, any attempt to avoid biotechnological patenting according to these "exemptions will be expediently dealt with by the dispute settlement mechanism" (Williams 2000: 72).

> Members may also exclude patentability of plants and animals other than micro-organisms, and essentially biological processes for the production of plants and animals other than non-biological and micro-biological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system.

A superficial perusal of this article may give rise to the impression that individual countries could exercise a substantial degree of discretion with respect to granting or refusing life patents. Part of the problem, namely the proper understanding of the correct meaning of this sub-paragraph, results from the unsuccessful intention to combine IPR laws with a new technology, thus it is not astonishing that this paragraph draws a lot of criticism because of its linguistic and technical inadequacy (Barton 1995). The term "essentially biological processes" refers only to the non-patentability of traditional breeding methods, and **not** to biotechnological processes. Consequently, TRIPS provides no protection to those inventors/breeders producing plants by methods of selectivity and cross-breeding, but insists that the patenting of plant varieties and animals be allowed if they are the results of bio-engineered or micro-biological processes. These biotechnological methods are **not** considered to be traditional methods of breeding plants, or biological processes.

The true strength (and threat) of this paragraph is embodied in the stipulation that nations have to permit patentability of micro-organisms and micro-biotechnological processes. These two components of this sentence's patent provisions alone give an enormously wide scope for international patent rights over biotechnological products and processes (i.e., they include modified plants, animals and lower organisms). These micro-organisms, such as bacteria and viruses, are in the centre of BT-R&D and provide BT with the major means of culturing, cloning, delivering, and transferring genetic information.

Many opponents of article 27.3(b) anticipate that the most disturbing impacts of this sub-paragraph may result from the provisions to allow protection of plant varieties by means of patents or by establishing a sui generis system, or a combination of both[13].

Plant Breeders Rights (PBRs) have been used throughout the 20ies century for the protection of pant varieties, which have been bred for the agricultural systems of ICs. The plant variety has to satisfy a certain set of criteria of genetic distinctness from competing varieties, uniformity, and stability over successive generations, to be awarded plant variety protection. PBRs are solely available for crops and plant varieties, which are genetically uniform, such monocultures and hybrids, and not for diverse crops bred to meet local environmental

13. A sui generis system is a system of legal right specifically adapted to "inventions" which are different from standard IPR-protection schemes such as patents and copyrights.

conditions and nutritional requirements in DCs. Thus, they do **not** fulfil the agricultural demands of DCs.

Whatever system of sui generis IPR, DCs may eventually settle for (do they really have a choice?), it is quite obvious that PBRs and patents are establishing legal and economic incentives to breed biological uniformity and are contributing to the decline of biodiversity. In addition, IPR will restrict the rights of local farmers and communities to utilize biological resources. Such IPR provisions may also force farmers saving patented seeds for the following year from the current year's crop either to compensate the patent holders or to buy new seeds annually. The exchange of seeds between farmers, generally done at quite reasonable prices particularly in traditional communities, would then become illegal! This exchange is also an important method by which biological diversity is diffused and maintained. Free access to seed is of paramount importance for the global agricultural economy and for global food security: the seeds are the most basic means of survival for farmers in DCs. The maintenance and non-exclusivity of traditional knowledge linkages is very relevant for sustaining food security at both the domestic and international levels. Thus, patents impose rights of an industrially-oriented knowledge system and would therefore suppress traditional knowledge and curtail DCs' farmers to save and exchange seeds. Or, seen from a different perspective, the distinction between traditional and industrially-oriented knowledge is somewhat an artificial one, namely when the contribution of DCs' agri-biodiversity to the final products of plant BT (or, modern plant breeding in general) is considered over a longer time span. If seed companies could provide evidence that their engineered varieties and monocultures were independently developed and have no linkage to knowledge systems that characterize sustainable agriculture and traditional and indigenous farming, then there could be a case in favour of rewarding their efforts by IPR protection. The reality is different: the vast majority of arable food crops used in ICs is derived from varieties of plants that have been developed over centuries by DC farmers (Juma 1989, Kloppenburg 1988). Thus, patents will exercise an unjust function in the appropriation of ethno-botanical knowledge and biological resources of DCs. As it is the situation with modified plant varieties, the presence of patents for ethno-botanical resources will disguise/hide the knowledge systems of DCs. At risk is not only the future sustainability of traditional and indigenous knowledge, which can become extinct within one generation if its use is restricted, but the potentially large profits that appropriation confers to the patentees —a violation of equity considerations[14].

14. Some estimates point to annual values on medical plants used by ICcompanies (sometimes referred to as bio-piracy) of $32 billion, and the value of "undiscovered" DC-plant-based pharmaceuticals in topical forests is put at $150 billion. These resources could become eventually patented products and re-sold to the countries of origin: what a travesty of equity and fairness (Williams 2000: 75).

Thus, TRIPS provisions for plant variety protection can be viewed as an attempt to impose corporate control over international agriculture by establishing private property rights for scientific knowledge as applied to plants and other species. IPR can be appropriated irrespective of the contribution of indigenous and traditional knowledge to international agri-biodiversity. The continued plundering of these biological resources for the purpose of producing genetically uniform plants simply illustrates the lack of fairness and equity of the global flow of plant germplasm (Kloppenburg 1988: 15).

In sum, the TRIPS agreement is a joint-product of the international system of patent rights for BT products and processes, and the growing economic dominance of the BT lobby based in ICs. It is revealing that the WTO contains no antitrust provisions by which dominating companies, resulting from IPR, can be controlled. It appears that industrial concentration will be a continuing trend of TRIPS life-patenting laws and empirical evidence shows that the BT-sector (agrochemicals, food processing, healthcare, pharmaceuticals, and plant breeding) is characterized by a long period of restructuring, which includes mergers and acquisitions. Evidently, the life-patenting system will be employed to control the relevant knowledge foundation of BT and, thereby, to maintain and/or to enforce the economic dominance of this sector worldwide by a system of exclusive IPR. Therefore, farmers from DCs wishing to compete with BT companies are at a disadvantage. Regretfully, patents will fail to stimulate plant breeding of a truly meaningful manner, since product diversity will not be conducive to increased biological diversity. Life patents will adversely impact on cultures and social communities in the area of agricultural production, and will undermine indigenous and traditional knowledge arrangements that have sustained biodiversity and provided a secure food supply in DCs.

CONCLUSION

The acceptance of the BSP can be viewed as an attempt to reduce the conflict potential between environmental interests and trade issues. The Protocol, however, does not set international standards by which to judge and/or to assess environmental impacts of agricultural BT. Recognizing that BT may have "huge potential for humans", the Protocol's intention instead may be to empower individual countries with an internationally-accepted regulatory framework for assessing biosafety of trade in GMOs. Importing countries have the option to foster trade in GMOs or to err on the side of caution, and these decisions will reflect the differences in social values among nations with respect to the trade-offs between environmental risk and uncertainty vis-à-vis economic opportunities. Thus, the

biosafety controversy is clear evidence that societal values with regard to human health and environment will continue to compete with economic interests on the international trade agenda.

TRIPS and the extension of IPRs to life forms will enforce and globalize companies' reach over BT-products and processes, whilst generating an infrastructure of accumulation, which is founded on knowledge control. TRIPS will also extend these corporations' interests to areas of human life and production where IPRs were previously either considered to be inappropriate or ethically unacceptable. TRIPS establish a new system of rights for seeds, plant varieties, animals and human genetic information. The adverse impacts of TRIPS are very likely to be disproportionately larger for DCs and the world's underprivileged communities.

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