



CENTER FOR INTERNATIONAL ENVIRONMENTAL LAW

REVIEW OF ARTICLE 27.3(B)

BY

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I. INTRODUCTION

This paper sets out views relating to the review of the provisions of Article 27.3(b). It provides a number of specific comments on the issues arising as part of the review, organized under the following three items of the chairman's list proposed during the TRIPS Council meeting held on 21 March 2000:

- the link between the provisions of Article 27.3(b) and development;
- technical issues relating to *sui-generis* protection of plant varieties; and
- the relationship to the conservation and sustainable use of genetic material as required in the Convention on Biological Diversity.

The paper also responds to the views expressed by some developed countries on issues arising as part of the Article 27.3(b) review.

II. THE LINK BETWEEN THE PROVISIONS OF ARTICLE 27.3(B) AND DEVELOPMENT

In our view, the Article 27.3(b) review should take into careful consideration the trade and development implications of Article 27.3(b) for developing countries, in line with the decision of WTO Members at the General Council Meeting of 7 February 2000, which provides that "The General Council also agreed that mandated reviews should address the impact of the agreements concerned on the trade and development prospects of developing countries."

While some WTO Members have highlighted the benefits to them of a strong intellectual property protection over life-forms, the benefits of such an approach for many developing countries remains to be demonstrated. Set at an appropriate level, intellectual property rights may encourage investment in research, promote early disclosure of new developments, and spur the creation of technology. If too strong, however, they risk imposing costs that exceed benefits, reallocating power from the users to the producers of technology, shifting resources from the public to the private domain, and ultimately retarding effective market competition, investment and technological innovation.

The appropriate level will vary significantly for different countries, and countries that are not currently leaders in an area of technology may choose a lower level of protection in order to maximize benefits to their society and economic development. In the area of intellectual property rights over life-forms, developing countries are fundamentally concerned about the implications for their economic, developmental and other interests.

As custodians of over 80% of the Earth's biodiversity, developing countries have a responsibility to ensure that intellectual property systems help ensure that genetic resources are used efficiently, and their benefits distributed equitably. As approximately 97 percent of all intellectual property rights are owned in industrial countries, the TRIPS Agreement, by consolidating an international framework for the protection and enforcement of intellectual property rights, has entrenched a new division of the benefits of intellectual property between the predominantly industrialized country

producers of technological knowledge, and its users that are often located in developing countries. In the following sections, we note our general concerns relating to the impact of strong intellectual property protection on the trade and development prospects of developing countries in the areas of investment, innovation and competition in markets relating to genetic resources.

A. Investment

Some developed countries have argued that strong intellectual property rights will promote the investment of time and money in the development of the results of research into products and processes that benefit society. Intellectual property protection over life forms may, however, have mixed implications for both the level and the nature of investment received by developing countries.

First, patents are only one determinant of investment, and other factors, including domestic technological capacity, availability of research infrastructure, and the existence of a skilled labor force, will be important. The practical experience of many developing countries illustrates that strong intellectual property protection may be neither necessary nor sufficient for the development of new industries: some countries with strong patent protection have received little investment, while others with little or no protection have received significant investment, suggesting that other factors may play a more important role.

Indeed, it seems that the development of the biotechnology industry in some developed countries has been spurred at least as much by subsidies, as by intellectual property protection. In the context of services, the issue of subsidies is being negotiated in the GATS Rules Working Group to identify their trade distortive effects in the services sector. Obviously, research and development subsidies and governmental support can have a major effect on the biotechnology industry, and in related areas such as agro-industry, chemical, food, and pharmaceutical production. This type of subsidies must be studied and analyzed to identify any distortive effect in trade, and in the development and transfer of technology. It would be interesting to receive from developed country Members, information about the nature and extent of subsidies given to firms investing in the biotechnology sector.

Second, while some intellectual property protection may attract investment, the granting of broad basic patents may constitute a barrier to ongoing investment in related research and development. In the area of medical biotechnology, for example, broad patents on fundamental research processes may undermine the opportunity for investment in follow-on research. Firms that want to develop new products must negotiate for numerous licenses with firms that have patents on various steps in the research process.

Finally, it seems likely that, while strong patents may have succeeded in some developed countries in encouraging research and development, for developing countries that are now competing against established market dominance, a more flexible system of intellectual property protection over life-forms that promotes the development of domestic industries may be preferable.

B. Innovation

Like the relationship between intellectual property protection and investment, the existence of a positive relationship between strong intellectual property rights over life-forms and innovation in the area of plant and animal biology remains unclear.

First, in many developing countries, innovation in plant and animal biology exists without enforceable intellectual property rights over life-forms. Innovation is often informal and is undertaken by individuals or local communities in the field. In these cases, the stimulation and promotion of informal innovation calls for flexible *sui generis* systems that are cheap and easy to access. By contrast, the high costs involved in acquiring, maintaining and defending patents may exclude these economically poor, but knowledge rich, innovators.

Second, in many industrialized countries the role of strong patent systems in promoting innovation is being questioned. Strong patents, and patent portfolios may block follow-on research activities. As noted, rather than using patents to develop products or processes that benefit society, firms may stockpile numerous and interlocking patents to stifle innovation by competitors, and to support patent infringement litigation. The phenomenon of broad patents is most prevalent in the area of biotechnological research, where patents may distend “horizontally” to cover many varieties or “vertically” to cover unimproved germplasm.

Third, the tendency in some industrialized countries towards over-broad patents requires firms to waste a disproportionate portion of revenues on patent litigation rather than on research and development. In the long run this tendency could dramatically slow rather than stimulate research, and imposes undue costs of individuals and small and medium sized investors that cannot afford to entertain costly legal proceedings.

Finally, to the extent a “strong” patent system may encourage innovation, it may not do so in the areas needed to promote the economic and developmental interests of developing countries. The shift in emphasis from public sector research towards private sector research affects the nature of new products that are being developed. Private firms have sought patents over new developments in biotechnology – such as “terminator technology”, and the genetic “tie-in” of seeds and pesticides – that are designed as much to increase market control and to reduce competition, as to improve productivity. Similarly, in the area of pharmaceutical biotechnology inadequate funding is dedicated to solving the problems of the world’s poor, such as tropical diseases, while significant resources are expended to create “life-style” drugs for wealthy consumers.

C. Competition

Intellectual property rights may occasionally serve as a tool to enhance competition. However, the tendency in some industrialized countries towards over-broad patent claims, the strategic use of patent portfolios by firms to prevent competition by similar but non-infringing products, combined with continued blurring of the lines between invention and discovery, is intensifying the risk of anti-competitive impacts. These impacts are occurring in many key markets for developing countries,

with particularly important impacts on trade and development, particularly in the areas of agriculture and medicine.

Patents over life-forms have become an important strategic tool for agricultural and medical biotechnology firms that are seeking to consolidate their dominant competitive positions through mergers, acquisitions and strategic alliances, and through the vertical and horizontal integration of international markets. Horizontal integration in both the agricultural and medical industry is occurring at an unprecedented rate, and the top 10 corporations in the pharmaceutical, seed and agrochemical markets now account for approximately 36, 40 and 82 percent of their respective global markets. Vertical integration is similarly consolidating the control of a few global firms. In the agricultural industry, for example, the vertical integration of seed, agrochemical, food processing, and food distribution markets has given a handful of firms located in industrialized countries disproportionate control over the world's food system.

In addition to horizontal and vertical integration, there is a tendency for most powerful firms in agricultural, medical and other related industries to cross-link across traditional industry boundaries in the development of "life" industries. One single life firm now ranks simultaneously as the world's largest agrochemical corporation, second seed and plant breeding firm, third pharmaceutical corporation, and the ninth ranking animal pharmaceutical corporation. Ownership of plant and animal genetic material by firms of this kind is likely to have a significant impact on which companies and people have access to new technologies – including those in the developing world.

The implications of the consolidation of these industries to the welfare of citizens in developing countries – their access to food, health and nutrition – suggests that careful consideration should be given to the relationship between strengthened intellectual property rights, competition in these industries, and the economic and developmental interests of developing countries. These factors deserve careful consideration by WTO Members in the context of the review of Article 27.3(b).

III. TECHNICAL ISSUES RELATING TO SUI-GENERIS PROTECTION OF PLANT VARIETIES

Article 27.3(b) requires Members "to provide for protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof". This article does not establish what is considered by WTO Members to be an effective *sui generis* system, or the elements that should be included in such a system. Many options, wide interpretations and variable results could therefore be a normal part of any outcome in the national implementation of this obligation.

The United States' paper on Article 27.3(b) addresses what, in their view, should be the content of a *sui generis* system. It describes in detail the features of the U.S plant variety law and, it seems, the UPOV 1991 system. The features described go beyond what is required by the terms of the TRIPS Agreement. Rather, the provisions give individual Members significant flexibility to define the content of their *sui generis* systems. Indeed it is implied in the term *sui-generis* that Members will adopt different approaches to the protection of plant varieties. The only requirement is that these systems are "effective" as required in Article 27.3(b).

The word “effective” is defined in the Oxford English Dictionary to mean “producing a desired or intended result”. “Effective” must also be interpreted in light of its context, and the object and purpose of the TRIPS Agreement. This includes the objectives and principles of the TRIPS Agreement embodied in Articles 7 and 8. To be effective, therefore, a *sui-generis* system must “contribute to the promotion of technological innovation and to the transfer and dissemination of technology ... in a manner conducive to social and economic welfare, and to a balance of rights and obligations” (Article 7). Additionally, an effective *sui-generis* system should be consistent with the principles of the Agreement, including the right of members to “adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development” (Article 8).

For many developing countries, the agricultural sector is vital to their socio-economic development, and to protecting health and nutrition. Any interpretation of effective *sui-generis* system should therefore provide these Members with sufficient flexibility to achieve these goals, in light of the particular national circumstances. The existence of a *sui generis* option also permits the inclusion of any measures and regulation necessary to promote specific national objectives including food security, bio-safety, farmers’ rights, and protection for traditional knowledge, etc.

Finally, Article 27.3(b) does not imply in any manner the use of UPOV 78 or 91 acts systems. When requirement to protect plant varieties was included in Article 27.3(b) the use of the wording choice “*sui generis* system” rather than UPOV system was not accidental. The recognition that Members wished to retain significant flexibility as to how they protect plant varieties, and to what ends, resulted in the adoption of accommodating language in Article 27.3(b).

IV. THE RELATIONSHIP TO THE CONSERVATION AND SUSTAINABLE USE OF GENETIC MATERIAL UNDER THE CONVENTION ON BIOLOGICAL DIVERSITY

A number of developing countries have argued that no examples of conflict between the CBD and the TRIPS Agreement have been provided. The examples of actual and potential conflict, however, are numerous. Many of these have been addressed in previous statements by developing countries to the TRIPS Council. The United States has raised a number of principles of international law in response to our concerns of conflict. We briefly respond to these below.

A. The CBD and the TRIPS Agreement have overlapping coverage and address similar issues

A prerequisite for a conflict between treaties is that they address the same subject matter. The United States has argued that “the purposes of the CBD and the TRIPS Agreement are widely disparate, however, and most of the provisions are unrelated in any way”. Similarly, the EC has argued that the two agreements “have different objectives, they do not deal with the same subject matter and they are of a different legal nature”. In response to these views, we offer the following points.

First, the purposes and objectives of the two agreements are not as disparate as has been suggested. The EC has narrowly characterized the objectives of the TRIPS Agreement as seeking to “set minimum standards of intellectual property protection within WTO members and to ensure that states make available to rights holders judicial and/or administrative procedures to enforce their intellectual property rights.” Arguably, the objectives of the TRIPS Agreement, as expressed in its preamble and Articles 7 and 8 (and reflected in the preamble of the WTO) are broader than this, and more closely related to those of the CBD.

Second, both agreements *do* address the subject matter of intellectual property. The TRIPS Agreement establishes minimum standards for the protection and enforcement of intellectual property rights. The CBD includes a number of specific references to intellectual property rights (Articles 16.2 and 16.3). It also contains the more general statement that parties must ensure that intellectual property rights do not run counter to the objectives of the CBD (Article 16.5). Whereas the TRIPS Agreement establishes a *general* framework requiring the protection and enforcement of intellectual property rights, the CBD deals with intellectual property rights in the *specific context* of the conservation and sustainable use of biological diversity.

Third, both agreements also deal in some way with the components of biological diversity. The CBD has as its fundamental goal the conservation and use of the components of biological diversity. The TRIPS Agreement, in turn, requires in Article 27.3(b) that some intellectual property protection be granted over some genetic resources. That these two agreements address the same subject matter is also illustrated by the ongoing debate in the TRIPS Council, and the numerous papers developed by the CBD’s Conference of Parties on the relationship between the protection of intellectual property rights and the protection of biological diversity.

B. Language in the TRIPS Agreement and the CBD do not prevent or resolve conflicts

Some developed countries have referred to Article 22 of the CBD in relation to conflict between the two agreements. Article 22 addresses the relationship between the CBD and certain other international conventions, and provides that “the provisions of this Convention shall not affect the rights and obligations of any Contracting Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity.”

It seems clear from this provision, that it was intended to address the relationship between the CBD and “existing” international agreements, and not with future agreements, which should be addressed under any specific provisions on conflict contained in those agreements, or according to principles of international law regarding the relationship between treaties. Indeed, the view that Article 22 does not define the relationship between the two agreements seems to have been accepted, at least implicitly, by the European Communities, which have stated that “neither treaty specifies that it is subject to the other. The CBD and the TRIPs Agreement do not expressly refer to each other.” Notably, the TRIPS agreement does not contain any conflicts provisions relevant to the CBD.

C. Principles of international law relating to a conflict of treaties

The United States has argued that when the provisions of two agreements are mutually exclusive, the provisions of the later in time agreement prevail to the extent of the incompatibility. The “later in time” rule, however, is only one of a number of principles of international law applying in the event of a conflict between treaties. Another rule provides that the more specific treaty prevails, even if it is earlier (*lex specialis derogat lex generalis*) (the special law derogates from the general law).

The general view is that this rule applies where there is a conflict of treaties on the same subject matter. To the extent that obligations in the CBD and the TRIPS are on the same subject matter – relating, for example, to the application of intellectual property rules to life-forms – and those in the former are more specialized than those in the latter, it may be argued that the more specific rules apply.

In light of uncertainty about the application of rules about conflict of treaties, the approach suggested by India of avoiding a legalistic view is to be preferred, and resolution of conflicts between the CBD and the TRIPS Agreement will likely only be resolved satisfactorily through a cooperative approach as suggested in the CBD itself in Article 16.5, which provides:

The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of the Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.

D. The obligations of signatories to the CBD

Countries that have signed but not ratified a treaty retain some obligations under international law. In particular, the principle of good faith reflected in Article 18 of the Vienna Convention may apply to signatories of the CBD, requiring them to refrain from acts which would defeat the object and purpose of a treaty it has signed the treaty or has exchanged instruments constituting the treaty subject to ratification, acceptance or approval, until it shall have made its intention clear not to become a party to the treaty. As a principle of customary international law, this would also bind those countries that are not a party to the Vienna Convention.²

In the present case, the inappropriate implementation of a subsequent treaty (such as the TRIPS Agreement) in a manner that defeats the express object and purpose of another treaty such as the CBD (e.g. Articles 1, 8(j) and 15 obligations on access and

² Article 18 of the Vienna Convention was held to be a rule of customary international law by the EU Court of First Instance in Case T-115/94, *Opel Austria GmbH v Council* [1997] ECR II-0039, at paras 77-78. Its status as customary international law has also been accepted by the United States. See *Digest of United States Practice in International Law*, 1979, at 692-3, cited in R E Dalton, 'The Vienna Convention on the Law of Treaties: Consequences for the United States' (1984) 78 *ASIL Proceedings* 276, at 278. See generally J S Charme, 'The Interim Obligations of Article 18 of the Vienna Convention on the Law of Treaties: Making Sense of an Enigma' (1991) 25 (71) *The George Washington Journal of International Law & Economics* 255-257, at 74-85.

benefit sharing) could arguably constitute and “act which would defeat the object and purpose of a treaty”. Similarly, all signatories to the CBD should, in accordance with their obligation of good faith, give positive consideration to formal requests by the CBD Secretariat for observer status in the TRIPS Council and other WTO bodies. The participation by the CBD Secretariat would increase transparency, assist in developing mutual understanding between the two conventions, and help to maximize the joint contribution of these institutions to promoting the economic, social and environmental interests of their Parties and Members.