

**REVIEW OF THE PROVISIONS OF ARTICLE 27.3(b)  
FURTHER VIEWS OF THE UNITED STATES**

Communication from the United States

The following communication, dated 20 September 2000, has been received from the Permanent Mission of the United States with the request that it be circulated to Members.

During the TRIPS Council's discussions under this agenda item, Members raised a number of issues related, both directly and peripherally, to Article 27.3(b). This paper provides the views of the United States regarding these issues.

**1. Micro-organisms**

Some Members have asked about the meaning of the term "micro-organisms", expressing uncertainty regarding what Article 27.3(b) requires to be patentable and what can be excluded from patentability. The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, done at Budapest on 28 April 1977, does not include a definition of the term micro-organism, although it does define other, seemingly unambiguous terms such as "patent procedure", "intergovernmental industrial property organization", and "industrial property office". The Treaty's regulations also do not define "micro-organism". The WIPO Committee of Experts on Biotechnological Inventions and Industrial Property, which met between 1984 and 1988, also did not define the term "micro-organism", although the term was used frequently in the discussions, as is reflected in the reports of the meetings of that Committee. The reason for the lack of definition is reflected in the *Comparative Study of Patent Practices in the Field of Biotechnology Related Mainly to Microbiological Inventions*, dated 20 January 1988, prepared jointly by the European Patent Office, the Japanese Patent Office and the US Patent and Trademark Office. Page 3 of that document contains the following, under the heading "Definition of Microorganism, If Any":

"None of the laws administered by any of the Offices contains a formal definition of the term 'microorganism'. Where definitions are used in either classification definitions or administrative guidelines, the term is defined as a non-exclusive list of organisms which are included within the scope of that term. As noted by the EPO, it does not seem expedient to introduce such a definition as the rapid evolution in the field of microbiology would necessitate its frequent updating."

The principles of international law regarding the interpretation of treaties and international agreements should be used in determining what is meant by the term micro-organism in Article 27.3(b) of the TRIPS Agreement. Articles 31 and 32 of the Vienna Convention on the Law of Treaties require, *inter alia*, that treaties be interpreted "in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in light of its object and purpose".

The Concise *Oxford Dictionary of Current English* defines "micro-organism" as "an organism not visible to the naked eye, *e.g.*, bacterium or virus". That definition should be sufficient to distinguish plants and animals generally from micro-organisms for purposes of the discussion in the TRIPS Council.

To be patentable, a micro-organism cannot be as it exists in nature. The patent granted by the US Patent and Trademark Office, to which India refers in its paper (IP/C/W/161, page 3, paragraph 8), claims a biologically pure culture of streptomyces violaceus which is capable of producing the antibiotic BU-3839T in a recoverable quantity upon cultivation in a culture medium containing assimilable sources of carbon and nitrogen under submerged aerobic conditions. The claim and the specification, when compared to available prior art, make it clear that the invention is new, involves an inventive step, and is capable of industrial application, as required under Article 27.1 of the TRIPS Agreement. What is claimed does not exist naturally. The patent, therefore, is granted for an invention, not merely a discovery. The key to what should be patentable as a micro-organism is not what name is given the biological material on which the invention is based, but is the subject matter claimed; is that subject-matter new, does it involve an inventive step, and is it capable of industrial application. If the subject-matter meets those criteria, Article 27.3(b) requires that it be patentable.

## **2. *Sui Generis* Protection for Plant Varieties**

Article 27.3(b) requires that Members protect plant varieties through patents or an effective *sui generis* system or both. Some Members have asked what would comprise an effective *sui generis* system for plant varieties.

Any law establishing rights in property, whether of real, tangible or intangible property, including the various forms of intellectual property, must have certain characteristics if it is to be effective. First, the nature of the subject-matter must be identified in the law clearly enough to enable those concerned to distinguish what falls within the scope of the law from what is beyond that scope. For example, Section 101 of the US Patent Law establishes rights in "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof". An effective law also must define the characteristics or qualities that particular subject-matter must possess to qualify for protection. Using the US Patent Law again as an example, the standards for determining whether an invention is new and whether the invention is "non-obvious" are spelled out in Sections 102 and 103. An effective law must also establish who is entitled to obtain property rights in particular subject-matter. If particular procedures must be followed to obtain rights in particular subject-matter and fees, if any, must be paid, the nature of these procedures and fees and the legal authority for establishing them must be set out in the law. An effective law must define the rights with respect to particular subject-matter that are acquired by an entitled party. If any limitations are to apply to these legal rights, the law must spell out those limitations and the circumstances under which they will apply. The law must establish the period during which the rights are in force and the circumstances, if any, under which the rights expire early or under which they can be extended. Finally, the legal actions available to the right holder to enforce its rights and the circumstances in which those actions may be taken must also be spelled out, along with the remedies available, unless these are provided for in other laws, such as a code of civil procedure. Any administrative actions or remedies, criminal actions and remedies, or border enforcement provisions can be included in the law or in other laws as appropriate under a country's legal regime.

In the case of *sui generis* plant variety protection, the United States believes that an effective system of protection would apply to plant varieties throughout the plant kingdom. Because the territories of existing and future Members of the WTO cover a substantial portion of the globe, it is in those Members' interests to include as many varieties as possible, since this will encourage investment in developing new plant varieties from among the widest possible range of genera and species. To be entitled to protection, the United States believes that, generally speaking, the variety in question

should be new, *i.e.*, the variety's propagating or harvested material has not been sold or otherwise made available for purposes of exploitation of the variety. The variety should be clearly distinguishable from other known varieties. The variety should also be uniform in that it does not vary beyond what would normally be expected. Finally, the characteristics of the variety should not change through repeated propagation.

An effective *sui generis* system of protection should ensure that protection for plant varieties is granted only to breeders or others specifically entitled either through contract or law of succession. By rewarding those who invest time and resources in development of plant varieties, WTO Members encourage increased investment in plant variety development, which, in turn, ensures an increase in investment in development of varieties suitable for different climates, soil conditions, growing conditions, nutritional needs, cultural preferences, etc. Obviously, to be effective, the procedures to be followed by potential right holders to obtain rights, and any fees that are involved, should be provided for in a comprehensive and transparent way and should apply to foreign nationals on a national treatment basis, as required by Article 3 of the TRIPS Agreement, with a provision, similar to those provided for patents in the Paris Convention, for claiming a priority filing date based on filing in the right holder's own country.

The rights provided should enable the right holder, for a period of at least 20 years from the date rights are granted, to prevent others from commercializing or taking steps to commercialize the protected variety without the authorization of the right holder. Because the development of new varieties of trees and vines understandably requires a longer period of time, and the development of a commercial market likewise requires a longer period than plant varieties that mature quickly, we believe that the period of protection for rights in new varieties of trees and vines should extend for at least 25 years, if breeders are to be encouraged to invest resources in development of such varieties.

The United States believes that certain implied limitations on the rights in plant varieties may be included expressly in an effective *sui generis* system for plant variety protection. If the rights extend only to activities related to commercialization or to commercialization itself, then non-commercial acts, such as those done privately for non-commercial use, experimental use, and use of a variety for the purpose of breeding other varieties would *not* infringe on the rights of the right holder. Stating that expressly in the law would help to prevent unnecessary litigation. The United States also would not consider as a problem a provision in a *sui generis* system for plant variety protection that makes it clear that farmers may save seed from the harvest of a protected variety for purposes of reseedling their own holdings the following year. Such a provision might alleviate concerns that farmers will be subject to infringement suits if they use seed harvested from this year's crop to seed their fields the following year.

Rights in plant varieties should be subject to nullification only if the variety is shown not to meet the standards required for protection or if the right holder, in fact, was not qualified to receive rights. Cancellation should be possible only if a right holder fails to fulfill its responsibilities, laid out thoroughly and transparently under the law, for maintaining rights.

The TRIPS Agreement spells out the legal actions that must be available to the right holder to enforce its rights and identifies the remedies that judicial and administrative authorities with jurisdiction over infringement actions must be able to impose on infringers. Those might be provided in the specific law providing plant variety protection or might be included in other laws such as a code of civil procedure.

### **3. Ethical Considerations**

Several Members have referred to ethical concerns regarding the extent to which private ownership should apply to life forms. Many of these concerns result from a misunderstanding regarding the nature of the rights provided by a patent. As we have noted previously and Article 28 makes clear, a

patent claiming a plant or animal does not represent private ownership of life forms. A patent gives its owner, for a limited period of time, the right to prevent others from taking certain actions in relation to a protected invention. The patent does not give its owner the right to take those actions itself.

In light of some of the interventions made during previous meetings of the TRIPS Council, a point we stressed in our previous paper bears repeating. Holding a patent on an isolated, identified and modified gene does not amount to ownership of the gene itself. A patent claiming an isolated, identified and modified gene taken from a human being certainly would not provide any property rights with regard to the source from which the original gene was obtained.

Excluding particular subject-matter from patentability will not prevent research in particular fields. Research will go forward in any area in which individual scientists and institutions have an interest. The patent system plays a significant, often critical, role in determining whether the broad results of research that promise benefits to mankind are developed into products and processes that will realize those benefits. It is no accident that countries with strong patent systems, where exclusions from patentability are few, are also countries with strong private industries covering the broad range of technology, providing jobs and contributing to the creation of capital that can be invested further. Similar kinds of encouragement can be observed in relation to the development of industries related to other forms of intellectual property as well.

#### **4. Patents Related to Knowledge and Practices of Indigenous People**

Some have criticized the patent system because such systems are formal and require that protected inventions be described in writing, thereby failing to protect knowledge passed along by oral tradition, rather than written text. The Constitution of the United States makes it clear that the purpose of the US patent system is to promote the progress of the useful arts. The US patent law implements that purpose by rewarding inventors with the exclusive rights specified in Article 28 of the TRIPS Agreement, for the limited time specified in Article 33, in exchange for the inventors' disclosure of their inventions in the manner specified in Article 29.1. Every patent issued by the US Patent and Trademark Office and by other patent offices around the world is published, as are most patent applications, making available to the public an enormous body of scientific and technical information of a practical nature. With the advent of the Internet, much of that scientific and technical information is available worldwide with a few clicks of a mouse, thereby providing an extraordinary means for transfer of technology.

Informal systems of knowledge often depend upon face-to-face communication, thereby limiting access to the information to persons in direct contact with one another. The public at large does not benefit from the knowledge nor can the knowledge be built upon. In addition, if information is not written down, that information is completely inaccessible to patent examiners everywhere as prior art when they are examining patent applications. It is possible, therefore, for a patent to be issued claiming as an invention technology that is known to a particular indigenous community. The fault lies not with the patent system, however, but with the inaccessibility of the knowledge involved beyond the indigenous community. The US patent granted for a method of using turmeric to heal wounds, referred to during India's intervention in June 1999 and again in October 1999, is an example of a patent issued because prior art references were not available to the examiner. In that instance, however, the patent system worked as it should. The patent claim was cancelled based on prior art presented by a party that requested re-examination.

Much traditional knowledge is already recorded in databases and print media and it will be important to ensure that patent examiners are made familiar with these resources. The delegation of Switzerland has suggested establishment of a single database in which information regarding knowledge and practices of indigenous communities could be recorded to provide patent examiners around the world with a source of information organized so that it could be searched easily to

determine, in appropriate cases, whether a claimed invention is new and non-obvious. It is our understanding that the Government of India is working to establish a domestic database of traditional knowledge. It will be important to make such information accessible to patent examiners around the world in order to be certain the information can be considered during examinations in appropriate cases.

## **5. The Compatibility of the Provisions of the CBD and the TRIPS Agreement**

Some delegations continue to assert that there is a conflict between the provisions of the Convention on Biological Diversity (CBD) and the TRIPS Agreement but, to date, no examples of such a conflict have been provided. It is difficult to imagine such a conflict in part because Article 22.1 of the CBD, states:

"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 is a principle of international law that countries that are members of various multilateral and bilateral agreements will implement their obligations in a manner that is consistent with the rights and obligations of each of those agreements. Another principle of international law is that, when the provisions of two agreements are mutually exclusive, the provision of the later in time agreement prevails to the extent of the incompatibility. The purposes of the CBD and the TRIPS Agreement are widely disparate, however, and most of the provisions of the two agreements are unrelated in any way. Where there might be a relationship in provisions, the agreements are sufficiently flexible to enable a country that is a member of both to implement the provisions of each in good faith in a non-conflicting and, in some cases, mutually supportive way. There is, therefore, no need to consider amending the provisions of either agreement to accommodate the implementation of the other. In this regard, we note that suggestions that amendment is necessary are always made in the context of the TRIPS Agreement, never in the alternative. We suggest, therefore, that, if a particular country that is a member of both agreements has a question regarding the compatibility with the TRIPS Agreement of a particular method for implementing a provision of the CBD, that country might wish to present its question in writing to this Council so that all WTO Members might benefit from an expression of views on the matter.

## **6. Access to Genetic Resources and Benefit Sharing**

Suggestions have been made in several *fora* that, as a means of ensuring benefit sharing, patent applicants be required to identify in their applications the source of any genetic materials or traditional knowledge used in developing their claimed inventions. Such a system would be a legal and administrative nightmare for all involved and would not ensure that those contributing such resources or knowledge would share in any benefits that might flow from commercialization of any product or process that might be developed from the resource or knowledge.

It is the view of the United States that, to be effective in ensuring a sharing of benefits from providing access to genetic resources or traditional knowledge, obligations must arise at the beginning of the process, not at the point of commercialization. The Preamble of the CBD reaffirms that states have sovereign rights over the biological resources within their territories, including the right to exploit those resources. Exploitation may include granting to others access to those resources on terms and for purposes a sovereign government determines appropriate. The government of a sovereign state, however, needs a legal framework in order to oversee the exploitation of resources so that that exploitation comports with the country's international obligations, is effectively and transparently administered, and ensures that benefits flow to the holders of traditional knowledge where appropriate.

Where access to genetic resources or traditional knowledge is concerned, it is in the interest of the sovereign entity or the indigenous community and the party granted access to make clear from the start the resources or the knowledge to which access is being given and the rights and obligations of both sides in relation to that access, including any provisions for benefit sharing. Such an arrangement is best established by contract prior to the access being granted and an inventory of any genetic resources actually collected or any traditional knowledge acquired. It is the contract giving access that should contain any obligation to identify the source of genetic resources in patent applications claiming an invention based on those genetic resources. It is the contract giving access that should require reference to the agreement establishing prior informed consent for use of the traditional knowledge involved in the development of a claimed invention. As we noted before, questions of court jurisdiction, in the event of disputes, and conditions to be included in any third party contracts authorizing use of acquired resources or knowledge, should also be included in access contracts. Such contracts should, in addition, define terms that are not clear on their face. Provision for such contracts should be included in any sovereign nation's framework for overseeing access to and exploitation of its genetic resources and the traditional knowledge of its indigenous communities.

## **7. Conclusion**

This paper represents the views of the United States on a number of the issues that have been raised in the TRIPS Council's discussions to date. We believe that, if discussion of Article 27.3(b) continues, it will only be productive if other delegations submit papers giving their views of issues they regard as relevant so that those views might be considered in depth. In addition, for discussions of the provisions of Article 27.3(b) to be meaningful, those delegations that have not already done so should provide information regarding their implementation of the provisions of Article 27.3(b), so that a clearer picture can be developed of the operation of the provisions worldwide.

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