

## TAKING FORWARD THE REVIEW OF ARTICLE 27.3B OF THE TRIPs AGREEMENT

### Communication from the Africa Group

This communication from the Africa Group aims to assist in finalising the longstanding issues relating to the review of provisions of Article 27.3(b) of the TRIPs Agreement. To this end, the communication first indicates the solutions that the Africa Group considers need to be found, secondly it sets out possible areas of agreement on issues that have arisen, thirdly it provides suggestions on how to resolve issues that for the moment members have not been able to reach a common understanding on, and then suggests the way forward.

#### **I. The solutions required**

The Africa Group is concerned that the review of Article 27.3(b) of the TRIPs Agreement has not been finalised having started way back in 1999. The Group urges all delegations to positively respond to the instructions to the Council for TRIPs from the 4<sup>th</sup> Session of the Ministerial Conference in paragraphs 12 and 19 of the Declaration. The deadline of December 2002 within which the review was to be finalised and this reported to the Trade Negotiations Committee (TNC) “for appropriate action” has passed. This should be of concern to all delegations especially given that deadlines in other areas of the work programme have similarly passed without concrete results. The review should continue until all the issues are resolved while at the same identifying the issues on which agreement is available.

The requirement to protect plant varieties should not in any manner undermine, but should support, the right of Members to protect important public policy goals relating to food security, nutrition, the elimination of rural poverty, and the integrity of local communities. In this regard, there is no basis for requiring Members to adopt inappropriate regimes for protecting plant varieties.

The protection of genetic resources and traditional knowledge particularly those originating from developing country Members, is an important means of addressing poverty and is rightly a matter of equity and due recognition for the custodians of the genetic resources and the traditional knowledge. It is also a matter of law in the context of protecting cultural rights as well as of

preserving the invaluable heritage of humankind that biological diversity and traditional knowledge constitute.

Any protection of genetic resources and traditional knowledge will not be effective unless and until international mechanisms are found and established within the framework of the TRIPs Agreement. Other means, such as access contracts and data bases for patent examinations, can only be supplementary to such international mechanisms, which must contain an obligation on Members collectively and individually to prohibit, and to take measures to prevent, the misappropriation of genetic resources and traditional knowledge.

Patents on life forms are unethical and the TRIPs Agreement should prohibit them, through modifying the requirement to provide for patents on micro-organisms and on non-biological and microbiological processes for the production of plants or animals. Such patents are contrary to the moral and cultural norms of many societies in Members of the WTO. They make the exception in Article 27.2 for protecting ordre public and morality, which Members that consider patents on life forms to be contrary to the fabric of their society and culture, and to be immoral, and which they would otherwise invoke, meaningless in this regard.

The relation between the TRIPs Agreement and the Convention on Biological Diversity as well as the International Treaty on Plant Genetic Resources is properly a matter on which the Vienna Convention may provide helpful guidance. However, the debate must go beyond this purely legal context and substantively deal with the crux of the issue raised within the framework of the review.

In this regard, the Group believes that for purposes of the review of Article 27.3(b) the issue raised is that the TRIPs Agreement at the moment has gaps in the sense that it has not provided adequate and equitable means to prevent patents mainly in developed Members that have amounted to and resulted in the misappropriation of genetic resources and traditional knowledge mainly from developing Members. A solution needs to be found, therefore, in the context of the TRIPs Agreement. In this sense the discussion should focus on how to improve the TRIPs Agreement, as a substantive subject. Any manner that the provisions of the Convention on Biological Diversity may facilitate this work should be used, provided that the result does not put Members in a position of breaching their obligations or forfeiting their rights under the Convention on Biological Diversity and the International Treaty on Plant Genetic Resources.

## **II. Possible areas of agreement**

The Africa Group welcomes the interest that delegations have shown in the review of Article 27.3(b) to date as demonstrated in the various communications and statements. On its part, the Group is keen to take the process forward in a constructive manner and to finalise the review in a manner that reflects a good overall balance for all Members. In doing so, however, the Group recalls that the General Council and the Declaration of the 4<sup>th</sup> Session of the Ministerial Conference in paragraph 19, equally highlighted that the development implications for developing and least developed Members must be integral to the review of the TRIPs Agreement.

In this context, the Africa Group wishes that delegations confirm a common understanding in the following areas:

(a) Members have the right and the freedom to determine and adopt appropriate regimes in satisfying the requirement to protect plant varieties by effective *sui generis* systems. In this regard, and for purposes of illustration, such regimes may draw upon the International Treaty on Plant Genetic Resources, the Convention on Biological Diversity, the 1978 Act of the Convention of UPOV, and the African Model Legislation on the Protection of the Rights of Local Communities, Farmers and Breeders and the Regulation of Access to Biological Resources. The appropriate and beneficial approach is to have systems of protection which can address the local realities and needs. The “African Model Legislation on the Protection of the Rights of Local Communities, Farmers and Breeders and the Regulation of Access to Biological Resources” is one example of a *sui generis* system, which has been developed to provide appropriate and effective protection for the rights and knowledge of farmers, as well as indigenous peoples and local communities, in a manner that suits the circumstances of Africa and possibly other developing Members.

(b) Regardless of what *sui generis* system that is adopted for protecting plant varieties, non commercial use of plant varieties, and the system of seed saving and exchange as well as selling among farmers, are rights and exceptions that should be ensured as matters of important public policy to, among other things, ensure food security and preserve the integrity of rural or local communities. While the legitimate rights of commercial plant breeders should be protected, these should be balanced against the needs of farmers and local communities, particularly in developing Members. Any *sui generis* system should enable Members to retain

their right to adopt and develop measures that encourage and promote the traditions of their farming communities and indigenous peoples in innovating and developing new plant varieties and enhancing biological diversity.

(c) Both the TRIPS Agreement and the Convention on Biological Diversity as well as the International Treaty on Plant Genetic Resources should be implemented in a mutually supportive and consistent manner. In this regard, Members retain the right to require, within their domestic laws, the disclosure of sources of any biological material that constitutes some input in the inventions claimed, and proof of benefit sharing.

(d) Traditional knowledge and inventions of local communities should be protected under appropriate regimes, on the understanding that the TRIPs Agreement provides only minimum standards and does not prevent Members from adopting additional areas of protection. In this regard, it is important to develop mechanisms for ensuring equity in relation to the use of genetic resources and traditional knowledge through appropriate international arrangements and mechanisms to supplement domestic laws and measures.

(e) It is important to identify and document genetic resources and traditional knowledge as a way of assisting searches and examinations for novelty and inventive step, and equally important as a mechanism for ensuring equity and promoting economic and social development in the use of genetic resources and traditional knowledge.

In this exercise of finding solutions to concerns raised by Members under Article 27.3(b), co-operation with all relevant international and civil society organisations is vital. Special consideration should be given to fully engaging indigenous people and local communities in developing any mechanisms relating to traditional knowledge; in any case provision must be made for respecting their concerns over the knowledge they are custodians of.

### **III. Areas without common understanding**

#### **Patenting life forms**

One area where delegations have yet to reach common understanding concerns the possibility under Article 27.3(b) for members to grant patents on micro-organisms and on non-biological and micro-biological processes for the production of plants or animals.

The Africa Group maintains its reservations about patenting any life forms as explained on previous occasions by the Group and several other delegations. In this regard, the Group proposes that Article 27.3(b) be revised to prohibit patents on plants, animals, micro-organisms, essentially biological processes for the production of plants or animals, and non-biological and microbiological processes for the production of plants or animals. For plant varieties to be protected under the TRIPs Agreement, the protection must clearly, and not just implicitly or by way of exception, strike a good balance with the interests of the community as a whole and protect farmers' rights and traditional knowledge, and ensure the preservation of biological diversity.

In any case, the Council for TRIPs must ensure that the exceptions for ordre public or morality in paragraph 2 of Article 27 are not rendered meaningless by any provisions in its paragraph 3(b) through requiring Members to do what is otherwise contrary to ordre public and morality in their societies. The barest minimum in this regard, would be to clarify that paragraph 3(b) does not in any manner restrict the rights of Members to resort to the exceptions in paragraph 2.

#### **Patenting of micro-organisms, and non-biological and microbiological processes**

As pointed out above, the Africa Group has consistently raised serious concerns about patents on life forms and research tools and on the basis of these concerns the Group has maintained that there should not be a possibility, within the framework of the TRIPs Agreement, of patents on micro-organisms as well as on non-biological and microbiological processes for the production of plants and animals.

It is the view of the Group that the distinction drawn in article 27.3(b) for micro-organisms, and for non-biological and microbiological processes for the production of plants or animals, is

artificial and unwarranted, and should be removed from the TRIPs Agreement, so that the exception from patentability in paragraph 3(b) covers plants, animals, and micro-organisms, as well as essentially biological processes and the non-biological and microbiological processes for the production of plants or animals.

### **Misappropriation of genetic resources and traditional knowledge**

A third area without common understanding concerns the international mechanisms that should be adopted within the framework of the TRIPs Agreement to protect genetic resources and traditional knowledge. This issue is important for the Africa Group and other developing Members due to the misappropriation of these resources. The misappropriation has mainly taken the form of obtaining patents in, mostly, developed Members inconsistently with the will of the custodian communities and the countries that have sovereignty over the resources.

Subject to the need for the WTO to find solutions within its own framework as indicated below, the Africa Group believes that access contracts can be useful in regulating the activities of researchers and other gatherers. However, this utility will be effective only within the countries themselves in accordance with the domestic law enforcing the contracts.

The Group believes further that data bases for patent offices, which can be used in examining patent claims to determine whether they meet the requirements of novelty, inventiveness and usefulness, can also be helpful in minimising misappropriation of resources. But it must be noted that such data bases are still far from complete and documentation is still an ongoing process. And, such efforts would still not amount to effective international mechanisms requiring every member individually and collectively, as enforceable international obligations, to prohibit and take measures to prevent the misappropriation of the resources. The problems to be addressed among others are, that in applying the test of prior art certain domestic laws do not recognise certain (unwritten) forms of traditional knowledge, that it may be far too costly for local communities and some developing Members to seek remedies in domestic courts abroad, and that international solutions are needed quite urgently given the ongoing nature of the problem.

Nevertheless, such efforts – contractual access clauses and data bases on traditional knowledge – are being undertaken in the context of WIPO in a manner that suits the functioning of WIPO. Ongoing work in WIPO could not possibly be a good reason for delaying or putting off work in

the WTO. First, any conclusions reached in WIPO do not automatically become applicable in the WTO, which would have to start its own processes afresh. But even this optimism that WIPO work could be relevant to the WTO in areas of interest to developing Members, may not be borne out by experience so far. Work in other international organisations, particularly regarding the Convention on Biological Diversity and the International Treaty on Plant Genetic Resources, has not automatically translated into the WTO, though relevant. Secondly, it is the assessment of the Africa Group that work in WIPO on genetic resources and traditional knowledge has been very slow, and that it would therefore not be appropriate to defer action under the mandate on Article 27.3b, which has a time frame, until WIPO completed its work. In WIPO at the moment, the possibility of an international instrument to protect traditional is still far, while the problem of misappropriation of genetic resources and traditional knowledge continues unabated. Rather, it would appear sensible that all international organisations whose work has a bearing on genetic resources and traditional knowledge should seek to find international solutions. Coherence would then be in terms of sharing information and ensuring harmony in the instruments. This was clearly demonstrated recently when the International Treaty on Plant Genetic Resources took its place in the family of international instruments.

The WTO must on its part find measures that are in line with its unique way of functioning, particularly in regard to the manner that rights and obligations of members are spelt out and breaches of obligations addressed. The WTO Agreement, as a single undertaking, provides for compulsory obligations on members, which are enforceable in accordance with the Dispute Settlement Understanding. A solution to the concerns relating to patenting that constitutes a misappropriation of genetic resources and traditional knowledge, should similarly take the form of obligations that are enforceable within the WTO framework.

Against this background, the Africa Group suggests that the Council for TRIPs should consider adopting a Decision on Protecting Traditional Knowledge as set out in annex 1 to this communication. The Decision could be subject to a review that would take future developments into account.

### **The relation between the TRIPs Agreement and the Convention on Biological Diversity**

The Africa Group recognises that delegations do not hold the same view on how the Vienna Convention can assist reconcile the relevant obligations of the TRIPs Agreement and the

Convention on Biological Diversity. In light of the several communications from Members on this subject, the Group is willing to further engage with delegations to find a solution.

It is the view of the Group that the major issue to be addressed, within the context of the review of Article 27.3(b), is how to fill in the gaps that have been perceived in the TRIPs Agreement. Although the Convention on Biological Diversity has important provisions related to the perceived gaps, the Council for TRIPs should squarely address the question on its own merits and find appropriate solutions. Appropriate solutions in this regard, given the nature of the rights and obligations under the TRIPs Agreement, should be in the nature of international mechanisms that similarly confer rights and obligations upon every WTO Member.

The rights should protect genetic resources and traditional knowledge from misappropriation. This should be done, naturally, through requirements for equity for the custodians of the genetic resources and the traditional knowledge. The obligations should require every Member to prohibit and take measures to prevent misappropriation of genetic resources and traditional knowledge. This should be done through requirements for disclosure of the source of the genetic resources and traditional knowledge involved in the claimed inventions, and for a demonstration of compliance with the applicable domestic procedures in the Member where the genetic resources and traditional knowledge originate.

Compared to other alternatives, Article 29 of the TRIPs Agreement seems to be the most suitable for an appropriate modification to contain these rights and obligations, by including the requirements for equity, disclosure of the community of origin of the genetic resources and traditional knowledge, and a demonstration of compliance with applicable domestic procedures. These requirements would formalise what in the view of the Group should be expected of all such patent applications. Given the failure of certain domestic systems to prevent patents that constituted a misappropriation of genetic resources and traditional knowledge, these requirements would be useful in preventing or minimising the repetition or even the increase of such cases.

The Group suggests that Article 29 be modified by adding the following as paragraph 3:

3. Members shall require an applicant for a patent to disclose the country and area of origin of any biological resources and traditional knowledge used or



involved in the invention, and to provide confirmation of compliance with all access regulations in the country of origin.

#### **IV. Way forward**

The Africa Group believes that the Council for TRIPs would do well to show results for its work so far and to take steps to resolve any outstanding issues.

Regarding the issues where the views of delegations suggest a common understanding, the Council for TRIPs can agree upon a Decision and report the adoption of the Decision to the TNC. The Decision would immediately become operational. This communication has set out the areas where delegations may wish to consider agreeing upon a common understanding. However, such a Decision would have to be worthwhile in terms of adequately addressing most of the issues that have arisen in the review so far, and further the Decision would have to contain a clear commitment to continue the review and finalise it within an agreed timeframe.

For those areas where there is no common understanding, the Council for TRIPs should continue its work but doing so within a specific time frame that addresses the grave concern of delegations on the slow progress with the work programme. The important tasks that the Council for TRIPs should focus on should include a Decision on protecting traditional knowledge and the amendment to paragraph (b) to prohibit patents on life forms. The annex to this communication contains a draft for a Decision on traditional knowledge that could be a basis for further discussion.

Annex

Draft

## DECISION ON TRADITIONAL KNOWLEDGE

1. This Decision, adopted as a result of the review of Article 27.3(b), shall be an integral part of the TRIPs Agreement.

2. Rights given effect and to be protected by all Members

(a) Traditional knowledge is a category of intellectual property rights hereby recognised and protected in accordance with this Decision. Members shall protect and enforce rights in respect of traditional knowledge in accordance with the provisions of this Decision. Members may adopt sui generis systems for more extensive protection.

(b) In co-operation with all relevant international and civil society organisations particularly associations of local communities and traditional practitioners, the WTO shall prepare and adopt programmes for the development and review, as may be necessary from time to time, of the protection of traditional knowledge and enforcement of rights conferred under this Decision in respect of traditional knowledge.

(c) The rights relating to traditional knowledge that shall be protected include, in relation to any local community or traditional practitioners, the right for such community or practitioner to:

(i) respect for their will and decisions on whether or not to commercialise their knowledge

(ii) respect and honour of any sanctity they attach to their knowledge,

(iii) give prior and informed consent for any access and any intended use of their knowledge,

(iii) full remuneration for their knowledge,

(iv) prevent third parties from using, offering for sale, selling, exporting, and importing, their knowledge and any article or product in which their knowledge is input, unless all the requirements under this Decision have been met.

(d) The existence of traditional knowledge in any form or at any stage shall defeat the novelty and inventiveness requirements for purposes of patents and originality for purposes of copyrights under any laws of all Members.

(e) Where:

(i) traditional knowledge has been a lead to the invention,

(ii) any invention that qualifies for patentability has derived at any stage from traditional knowledge,

(iii) any invention is based on in situ genetic resources of any Member,

then, no intellectual property rights shall be granted or protected in any Member unless the requirements on access to genetic resources under the Convention on Biological Diversity have been fully complied with.

(f) Members shall require in their laws that any intellectual property rights granted in breach of this Decision shall, without any further requirements as to procedure other than this provision, be cancelled forthwith. No intellectual property rights shall be granted or protected without due recognition of the traditional knowledge involved in accordance with this Decision. In accordance with this paragraph, Members shall provide for the ex-officio cancellation of any intellectual property rights that breach this Decision.

#### 4. Documentation of Traditional Knowledge and Local Communities

(a) Members may document traditional knowledge in their territories and designate a competent authority to continually carry out this exercise. Members may also maintain registers of local communities and traditional practitioners for administrative purposes, but non-

registration shall not prejudice the rights of any local community or traditional practitioner under this Decision.

(b) Members may make appropriate arrangements for the establishment and maintenance of electronic and other registers on traditional knowledge that shall be public documents subject to reasonable regulations they may put in place, and for applications from any local communities or traditional practitioners to the competent authority to register their traditional knowledge.

(c) Local communities and the competent authorities shall have an exclusive right in perpetuity to any information that is documented or entered in the register, to prevent any access or use they have not expressly authorised or any application that is inconsistent with the rights of local communities and traditional practitioners under this Decision.

## 5. Institutional Arrangements

(a) The Committee on Traditional Knowledge and Genetic Resources is hereby established.

(b) Its functions shall include:

(i) developing and reviewing this Decision and any other instruments,

(ii) overseeing and making recommendations on the protection of traditional knowledge and enforcement of the rights of the Members,

(iii) following activities and developments in relevant regional and international intergovernmental organisations,

(iv) providing forums for dialogue on traditional knowledge, and

(v) conducting studies and making recommendations to Members and relevant organisations on protection of traditional knowledge under the provisions and within the framework of other international and regional instruments.

(c) Every Member shall establish a competent authority and a central enquiry point to provide information and carry out designated functions arising from this Decision.

## 6. Meaning

(a) Traditional knowledge includes, but is not to be limited to, knowledge systems, innovations and adaptations, information, and practices of local communities or indigenous communities as understood within the territory of the Member, relating to any type of medicine or cures, agriculture, use and conservation of biological material and diversity, and any other aspect of economic, social, cultural, aesthetic or other value.

(b) Traditional knowledge is not static but continues to evolve, and its nature relates to the manner it develops rather than to its antiquity.

(c) For purposes of this Decision, traditional knowledge includes folklore unless the context requires otherwise or it is provided otherwise; and local communities includes indigenous peoples subject to definitions that Member may adopt within their domestic laws.