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COMMUNICATION FROM THE EUROPEAN COMMUNITIES AND THEIR MEMBER STATES

The following communication, dated 16 September 2002, has been received from the Permanent Delegation of the European Commission with the request that it be circulated to Members.

REVIEW OF ARTICLE 27.3(B) OF THE TRIPS AGREEMENT, AND THE RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CONVENTION ON BIOLOGICAL DIVERSITY (CBD) AND THE PROTECTION OF TRADITIONAL KNOWLEDGE AND FOLKLORE

"A Concept Paper"

EXECUTIVE SUMMARY

This text addresses the issues dealt with under Paragraph 19 of the Doha Declaration, which instructs the TRIPS Council to continue the review of Article 27.3(b) TRIPS, and to examine the relationship between TRIPS and CBD and the protection of Traditional Knowledge (TK) and folklore, and other relevant new developments. It reflects the EC's stated willingness to commit to this process in a spirit of openness, with the aim of finding ways of interpreting and implementing the TRIPS Agreement in a way to support the objectives of the CBD.

The review of Article 27.3(b)

This review deals, *stricto sensu*, with the patentability of biotechnological inventions and the protection of plant varieties. This subject has an important link with development issues in agriculture, so the development dimension must be fully taken into account.

The European Communities and their member States (hereinafter "the EC") see no reason to amend Article 27.3(b) as it now stands. The TRIPS Agreement allows Members sufficient flexibility to modulate patent protection as a function of their needs, interests or ethical standards. In this connection Article 27.3(b) - in conjunction with Article 27.2 (exclusion from patentability of inventions the commercial exploitation of which is necessary to protect ordre public or morality) and Article 27.1 (patentability criteria) - provides considerable leeway.

The EC have already indicated that they are prepared to discuss certain technical issues related to Article 27.3(b). However, in the EC's view, trying to clarify the definitions of technical terms such as "micro-organism" in the TRIPS Council may not be the best way forward. Firstly, because it would be extremely difficult to agree on precise definitions in that context, and, secondly, because it is questionable whether more precise definitions are really necessary, given that they would reduce the flexibility of WTO Members.

The relationship between the TRIPS Agreement and the CBD

From a legal perspective there is no conflict between the CBD and the TRIPS Agreement. However, it would be wrong to put on end to all discussion by saying that, in the absence of legal incompatibility, there cannot be a problem with the implementation of both Agreements. There is considerable *interaction* between both agreements, so TRIPS and CBD can and should be implemented in a mutually supportive way. The TRIPS Council should focus on ways and means of doing this.

At national level, sound regulation (through legislation or administrative or policy measures) on access and benefit-sharing (ABFS) under the CBD is essential to guarantee legal security for all parties involved and to protect the rights of providers of genetic resources. Further details can be settled through contractual arrangements. Legislation/policy measures and contracts are complementary instruments for ensuring fair implementation of the CBD.

Further synergies between the implementation of these agreements can be worked out at international level by ensuring policy coherence in all forums which deal with issues relevant to the interplay between TRIPS, the CBD and the FAO International Treaty on Plant Genetic Resources for Food and Agriculture. In this respect the Bonn Guidelines on Access to Genetic Resources and Benefit-sharing adopted at the 6th Conference of the Parties in The Hague on 19 April 2002 are an important evolution.

Disclosure of origin

The EC agree to examine and discuss the possible introduction of a system, such as for instance a self-standing disclosure requirement, that would allow Members to keep track, at global level, of all patent applications with regard to genetic resources for which they have granted access. The EC see merit in a system that would ensure transparency and would allow the authorities of countries granting access to their resources to keep track of patent applications linked to the use of these resources.

Under such a system, the information to be provided by patent applicants should be limited to information on the geographic origin of genetic resources or TK used in the invention, while such a disclosure requirement should not act, de facto or de jure, as an additional formal or substantial patentability criterion. Legal consequences to the non-respect of the requirement should lie outside the ambit of patent law.

Protection of TK

Preventive approaches to avoid misappropriation of traditional knowledge and to stimulate the sharing of benefits could be dealt with by the TRIPS Council. We need to explore methods of documenting and sharing information on TK, such as databases and registers, in order to allow patent examiners to take them into account in prior art searches. When TK is used as a basis for further innovations, disclosure of the original TK from which inventions are derived would be an important way of ensuring that holders of traditional knowledge share in the benefits.

The EC support further work towards the development of an international *sui generis* model for legal protection of TK in WIPO. At this stage, the TRIPS Council is not the right place to negotiate a protection regime for a complex new subject matter like TK or folklore. This is an issue where the WTO should ideally be able to build on the work done by the WIPO Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore. Depending on the outcome of the WIPO process, the TRIPS Council will have to determine whether this result warrants further work in the WTO.

Effective sui generis protection of plant variety rights

The absence of a definition of this concept means that Members have a considerable degree of flexibility in determining how their legislation meets the standard of effectiveness, thus allowing them to design a protection regime that is appropriate to their specific national situation. Although the UPOV Convention meets the standard of effectiveness in Article 27.3(b), other protection models may be equally effective.

This paper explores the criteria that any regime establishing rights over plant varieties must fulfil (for example, a clear definition of the protectable subject matter and the conditions for granting protection, the availability of enforcement procedures, etc.).

Farmers' rights and farmers' exemptions

Farmers' exemptions (i.e. exceptions to plant variety rights or patents allowing farmers to save, use, exchange or sell seeds of protected varieties or seeds) can, under certain circumstances, be justified under Article 27.3(b) of the TRIPS Agreement, or under Article 30 of the TRIPS Agreement. The special situation of least developed or developing countries could be addressed by specific exceptions allowing subsistence farmers or small farmers to save, replant, exchange, share and resell seed, provided they do not use the commercial denomination of the variety. Farmers with significant commercial interests should remain subject to more stringent rules.

I. INTRODUCTION

1. Paragraph 19 of the Doha Declaration instructs the TRIPS Council to continue the review of Article 27.3(b) of the TRIPS Agreement, and to examine the relationship between the TRIPS Agreement and the Convention on Biological Diversity (hereinafter called CBD) and the protection of Traditional Knowledge (hereinafter called TK) and folklore (as well as other relevant new developments), both in the context of this review and as part of the work arising from paragraph 12 of the Doha Ministerial Declaration (outstanding implementation points) and the review provided for by Article 71.1 of TRIPS. The recent adoption of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture and of the Bonn Guidelines on Access to Genetic Resources and Benefit-sharing are important relevant new developments which are also dealt with in this document.

2. In the WTO, the relationship between the TRIPS Agreement and the CBD and the protection of traditional knowledge have so far been dealt with exclusively under the review of Article 27.3(b) of the TRIPS Agreement.

3. The Doha Declaration further specifies that, in undertaking this work, the TRIPS Council is to be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and should take full account of the development dimension.

4. The European Communities and their member States (hereinafter "the EC") welcome this broad mandate, because the EC have always been of the opinion that review of 27.3(b) was too narrow a basis for dealing with the wide array of complex issues raised by this review. Also, the EC hold the view that both processes, i.e. the review of 27.3(b) and the examination of the relationship between the TRIPS Agreement and the CBD are, by virtue of their numerous interconnections, inextricably linked. This new mandate arising from the Doha Development Agenda (hereinafter "the DDA") means we can now give this debate more attention.

5. The EC have already expressed a first series of views on the relationship between intellectual property, on the one hand, and biodiversity and TK, on the other, in the communication of

3 April 2001. In this document the EC concluded that the search for solutions to the developing countries' concerns, expressed within the context of the review of Article 27.3(b) of TRIPS, does not necessarily lie within the scope of that Article itself, but may rather be found :

- in developing appropriate instruments to achieve the objectives of the CBD (in particular in particular access to genetic resources benefit-sharing and protection of traditional knowledge) and those objectives of the TRIPS Agreement which, in the view of the developing countries, have not been sufficiently promoted by the developed countries (i.e. the protection of TK, or transfer of technology and know-how);

- in providing technical assistance to developing countries to implement the CBD through sound an effective legislative, administrative and policy measures; and

- through the possible negotiation of measures within the IPR system (in particular in the context of WIPO and the TRIPS Agreement) aimed at facilitating benefit sharing and protecting sovereign access rights (e.g. to insert a provision on the disclosure of origin or to develop protection of traditional knowledge.

6. It was therefore concluded that these issues would be better dealt with within the framework of the new round of trade negotiations as part of a comprehensive package. The DDA now provides for this framework.

7. The EC want to engage in this process in the same spirit of openness so as to find ways of interpreting and implementing the TRIPS Agreement so as to support the objectives of the CBD, like for example the fair and equitable sharing of the benefits arising from the use of genetic resources.

8. To achieve this, the EC believe it might be useful for those countries which have a particular interest in these issues and have specific demands to submit a comprehensive presentation of these demands as a basis for structured and fruitful discussion. The EC are looking forward to receiving concrete proposals from Members who have raised specific concerns in the TRIPS Council.

9. The EC are willing to consider proposals which genuinely reflect the concerns of developing countries, provided these do not affect the substance as well as the balance of rights and obligations laid down in the TRIPS Agreement, and maintain the rights of Members to create a favourable intellectual property environment for research in the area of biotechnology.

10. The EC takes this opportunity to draw the Membership's attention to the fact that specific attention is given to the issues under discussion here in their Action Plan on Life Science and Biotechnology. In particular, Action No. 26 of the Plan foresees that "The Commission and the member States will support the conservation and sustainable use of genetic resources in developing countries and their equitable sharing of benefits arising from their use, inter alia by supporting the development and enforcement of effective measures to conserve, to use sustainably and to provide access to genetic resources and traditional knowledge, as well as to share equitably the benefit arising from them, including income generated by intellectual property protection"[1].

[1] Also, the European Commission financed or co-financed several seminars and workshops on related issues such as :

- The Role of Intellectual Property Protection in the Field of Biodiversity and Traditional Knowledge (Brazil, 2001, co-organised with the Brazilian Institute of Intellectual Property)
- Developing Global Bioresources (London 2002)
- Microbial Biodiversity and Biotechnological Opportunities in the Humid Tropics (Venezuela, 2002).

II. THE REVIEW OF ARTICLE 27.3(B)

11. This review process, which started in 1999, deals *stricto sensu* with the patentability of inventions, including biological material (biotechnological inventions), the protection of plant varieties and possible exclusions to patentability.

12. At the TRIPS Council meeting on 21 March 2000, the Chairman concluded that the Council should proceed in a more orderly, systematic and productive manner by focusing on :

- the link between Article 27.3(b) and development;
- technical issues relating to patent protection under Article 27.3(b);
- technical issues relating to *sui generis* protection of plant varieties;
- ethical issues relating to the patentability of life forms;
- the relationship with the conservation and sustainable use of genetic material;
- the relationship with the concepts of TK and farmer's rights.

These issues call for certain comments.

Link between Article 27.3(b) and development

13. Now that we are in the context of the DDA, the link between Article 27.3(b) and development should be the central theme of our debate. This is emphasised by paragraph 19 of the Doha Ministerial Declaration, which instructs the TRIPS Council to be guided by Articles 7 and 8 TRIPS and to take the development dimension fully into account.

14. The subject matter of Article 27.3(b) - biotechnological inventions and plant varieties - has an important link with development issues in the agricultural sector. Biotechnology offers enormous potential and can play a role in improving the agricultural output, health and the environment of the developing world. It is a sector where intellectual property protection plays an important role because it often requires a considerable amount of high-risk investment.

When determining how to implement Article 27.3(b), it is crucial to assess its impact on the possible development of biotech research.

15. At the same time, it is true that access by the developing world to these important technologies, as well as their capacity to deal with the potential risks associated with these technologies, remains limited. Agricultural technologies, and biotechnology in particular, are therefore an important issue to be tackled in the context of transfer of technology and capacity-building.

Technical issues relating to patent protection under Article 27.3(b)

16. The EC have already indicated that they are prepared to discuss certain technical issues related to Article 27.3(b) (such as for example domestic implementation of Article 27.3(b), issues related to the patentability of inventions including biological material and the protection of plant varieties, possible exclusions to patentability, etc.).

17. Some WTO Members have requested that the TRIPS Council examine and clarify the definition of certain terms used in Article 27.3(b), e.g. "microbiological processes", "essentially

biological processes" or "micro-organisms", in order to make it clearer what can and what cannot be excluded from patentability under Article 27.3(b).

18. In this regard, the EC takes the view that those Members advocating more precise definitions of the technical terms used in Article 27.3(b) should be aware of the difficulties of getting all WTO Members to agree on definitions. It is indeed questionable whether the TRIPS Agreement could or should go into this amount of detail.

19. And it will not be easy to get the TRIPS Council to agree on clarification of these terms, because decisions are made by consensus and the issues are complex. The EC are therefore of the opinion that the TRIPS Council is not the right forum to agree on definitions of technical terms. This could rather be examined in the context of WIPO, which has more expertise on these specific technical issues.

20. Another argument against clarification in the context of the TRIPS Agreement is that the absence of definitions of certain terms gives an element of flexibility, leaving Members some freedom to interpret terms broadly or strictly within reasonable limits.

21. An example of a term that is not defined in TRIPS is the term "micro-organisms". There is also no commonly accepted definition of "micro-organism" in science, international conventions or patent office practices. Nevertheless, the definition of its scope at domestic level is important, as micro-organisms are widely used in the pharmaceutical, chemical or biotech industries and they are the only form of living organism for which WTO Members are obliged to provide patent protection. However, the patentability of micro-organisms depends on whether or not the patentability criteria are met, thus rendering the definition issue less important. As stated, other international conventions fail to provide a definition, e.g. the 1977 Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure.

22. Also there are divergent views among scientists as to what the term "micro-organism" encompasses. But there is some agreement as to its core meaning: "micro-organism" is generally understood to refer to living beings other than plants and animals, i.e. bacteria, fungi, viruses, etc. The *Concise Oxford Dictionary of Current English* (which has been used by WTO panels for interpretation purposes) defines "micro-organism" as an organism not visible to the naked eye, e.g. bacterium or virus. Taking into account the rules of Treaty interpretation, as set out in the Vienna Convention of the Law of the Treaties, and although this is no more than a first step in this process, this definition of the Oxford Dictionary can be considered as providing a standard of reasonableness within which Members can modulate the definition. In this way, WTO Members can determine the scope of what is patentable and what is not.

23. Moreover, microbiology is a fast-moving science, which has led classifications such as "micro-organism" to evolve rapidly. This also raises the question as to whether a more precise definition is really necessary, since it would reduce the flexibility of WTO Members while introducing new uncertainties, given the rapid evolution of knowledge, technologies and applications in the field of microbiology

24. Finally, the task of "review" does not mean that WTO Members are under a duty to agree on an exhaustive definition of each and every term. But rather to see how different Members do for themselves define and apply these terms.

Technical issues relating to sui generis protection of plant varieties

25. The effective protection of plants is an important issue and will be dealt with in Section 5.

26. The review of Article 27.3(b) could be used to clarify the potential benefits and limitations of different national and international schemes for the protection of plant varieties.

Ethical issues relating to the patentability of life-forms

27. The EC acknowledge that issues relating to the patentability of life forms need to be addressed carefully. Different societal values come into play. In fact the TRIPS Agreement does allow Members to take these considerations into account. Article 27.3(b), in conjunction with Article 27.2 (exclusion from patentability of inventions the commercial exploitation of which is necessary to protect ordre public or morality) and Article 27.1 (patentability criteria), already allow Members considerable freedom to modulate the patentability of biotechnological inventions. For instance, the interpretation of the patentability criteria under Article 27.1 may slightly differ from Member to Member, which may lead to certain nuances in approach when distinguishing between an invention and a discovery. This is evidenced by disparities in the legislation and practices of developed countries. It is up to each country to strike the right balance, taking into account economic, ethical and other concerns, without losing sight of the fact that granting intellectual property rights to biotech inventions is one of the key factors for developing domestic skills in this sector.

28. It should be remembered that Article 27.3(b) is the result of a carefully negotiated balance: calls to reopen 27.3(b) in order to change that balance may give rise to counterclaims by other Members to make it compulsory to patent broader categories of biotech inventions, including plants and animals. The EC are in favour of maintaining the current balance of the TRIPS Agreement, which gives WTO Members a large degree of flexibility with regard to patentability of biotech inventions, and therefore see no reason to amend Article 27.3(b) as it now stands.

29. The EC established the scope for the legal protection of biotechnological inventions in Europe in Directive 98/44 of the European Parliament and of the Council on the legal protection of biotechnological inventions. It authorises EC member States to exclude biotech inventions from patentability where their commercial exploitation conflicts with "ordre public" and morality, and includes an illustrative list of inventions excluded from patentability, such as interventions in the human germline, cloning of human beings and the processes referred to or the use of human embryos for industrial or commercial purposes. The EC invites other Members to adopt a similar approach. The EC would welcome further information about the experience of other Members in patenting biotech inventions and dealing with the related ethical aspects.

The relationship with the conservation and sustainable use of genetic material

30. This issue refers to the broad relationship between the TRIPS Agreement and the CBD. Strictly, this issue does not fall within the direct scope of Article 27.3(b), but appropriate solutions will be discussed in the section on TRIPS and CBD below.

The relationship with the concepts of traditional knowledge (TK) and farmers' rights

31. TK is in the EC's view an issue that, strictly speaking, does not fall exclusively within the scope of Article 27.3(b). As a matter of fact, protection of TK is relevant to several other Articles of the TRIPS Agreement which deal with patents, e.g. Articles 27.1 and 29. It is more appropriate therefore to deal with it under a separate heading (Section 4).

32. The issues of **farmers' rights** and farmers' exemptions are directly linked with the intellectual property protection of plants and plant varieties, and will be dealt with in Section 6 of this communication.

III. THE RELATIONSHIP BETWEEN THE TRIPS AGREEMENT AND THE CBD

Interface between two mutually supportive instruments

33. In its Articles 16.2 and 16.5 the CBD acknowledges the need to act in consistency with the adequate and effective protection of intellectual property rights and urges Members to ensure that intellectual property rights are supportive to the CBD. The CBD language relating to intellectual property strikes a fine balance between the need to implement intellectual property protection and the need to ensure that intellectual property rights facilitate conservation and sustainable use of biodiversity and the ABSF principles. It is a fact that the TRIPS Agreement, in its turn, does not refer to the principles of the CBD as regards access to genetic resources and the sharing of the benefits arising from their use. This does not mean, however, that the TRIPS Agreement runs counter to the CBD! There is nothing in the TRIPS Agreement that would prevent the sharing of the benefits arising from intellectual property protection over inventions incorporating genetic resources or the protection of traditional knowledge. At the same time, it is true that the TRIPS Agreement does not provide for direct tools to establish a link between intellectual property protection and compliance with the principles of the CBD.

34. As regards the relationship between the TRIPS Agreement and the CBD, the EC's April 2001 Communication was based upon two basic premises.

35. First, the CBD and the TRIPS Agreement do not conflict with each other from a legal perspective. They have different objectives and do not deal with the same subject matter. There is nothing in the provisions of either Agreement that would prevent a country from fulfilling its obligations under both. The CBD, for example, does not prohibit patents on inventions using genetic material. TRIPS does not prevent signatories to the CBD from exercising their right to regulate access to their genetic resources, to require prior informed consent or to share in the benefits arising from their use.

36. Second, closing the door to any debate on the grounds that, in the absence of legal incompatibility between the two Agreements, there cannot be a problem with the implementation of both Agreements would not be the right attitude. Despite their difference in coverage, there is indeed considerable interaction between the rights referred to in the TRIPS Agreement and the subject matter of the CBD. There are a range of issues for which both Agreements do have implications such as biotechnology, plant varieties, environmental technology relating to conservation and sustainable use, information relating to conservation and sustainable use, traditional knowledge and benefit-sharing.

37. This leads the EC to the view that, with regard to their implementation, the TRIPS Agreement and the CBD should not undermine each other's objectives. They should, accordingly, be implemented in a mutually supportive way.

38. In its implementation, the TRIPS Agreement can in fact be used to support the objectives of the CBD, such as the fair and equitable sharing of the benefits arising from the use of genetic resources. Intellectual property can be a suitable instrument for implementing the CBD. Intellectual property rights can encourage the use of genetic resources by promoting biotechnological innovation. Intellectual property rights generate financial benefits further to commercial exploitation. So, provided that international law (and in particular the CBD), national legislation and contractual arrangements on access and benefit-sharing are fully respected, there is scope for congruence of interests between providers and users, through the use of intellectual property rights, given that the latter contribute to creating benefits stemming from the use of genetic resources in the form of financial returns or access to the relevant technology.

39. Any examination of the link between the CBD and the TRIPS Agreement should, therefore, focus on ways and means of implementing both instruments in a mutually supportive way and on how to create an interface between the two Agreements.

Ways and means of ensuring mutually supportive implementation of both Agreements

40. The first way is at **national level**. It is the duty of the WTO Members and the CBD signatories to honour their commitments under both Agreements at national level. Both Agreements allow for a significant degree of flexibility with regard to their implementation at national level, thus leaving scope for a balance in the way they are applied. These national implementation measures are the primary instruments for ensuring mutually supportive implementation.

41. The CBD must be implemented at national level by establishing the core conditions for access to national genetic resources and determining minimum conditions for benefit-sharing. This implementation may be by legislative, policy and/or administrative measures. Sound regulation is essential to guarantee legal certainty for all parties involved and to protect the rights of providers of genetic resources. The details of each deal can be set out in the contractual arrangements (material transfer agreements) according to "mutually agreed terms".

42. It is important in this context that those Members, which are the most advanced in domestic policy-making with regard to access and benefit-sharing share their experience with other Members of the TRIPS Council.

43. Further synergies between the implementation of both Agreements can also be created at **international level**. First of all, it is important for governments to ensure policy coherence in all forums dealing with issues relevant to the interplay between TRIPS and CBD in order to ensure an integrated approach across institutions (CBD, WTO, WIPO, FAO …). In this context, the granting of observer status to the CBD in the TRIPS Council would play a positive role in creating a clearer appreciation of the links between TRIPS and CBD. The direct relationship of the work of the CBD and that of the TRIPS Council, as expressed in Paragraph 19 of the Doha Ministerial Declaration, makes this observership indispensable.

44. It is also important to underline that legislative, administrative and policy approaches on the one hand and contractual approaches on the other hand should not be set against one another. Multilateral rules, national regulatory or policy measures and contractual arrangements are complementary instruments in securing the principles of the CBD. In this regard, the EC welcome the Bonn Guidelines on Access to Genetic Resources and Benefit-sharing adopted at the 6th Conference of the Parties in The Hague on 19 April 2002 which sets out practical ways and means of implementing the principles of prior informed consent and mutually agreed terms enshrined in Article 15 of the CBD at national level. The Bonn guidelines provide useful elements for Material Transfer Agreements and examples of monetary and non-monetary benefits which could be shared. They are accompanied by a set of recommendations on the role of intellectual property rights in the implementation of access and benefit-sharing arrangements. Their implementation will help to achieve the objectives of access and benefit-sharing and ensure mutually supportive interplay between these principles and intellectual property protection. All stakeholders, governments, scientific and research institutes, companies and indigenous and local communities are invited to implement them.

Disclosure requirements

TRIPS and disclosure of origin

45. A number of Members have expressed the view that the TRIPS Agreement should be amended in order to reconcile or harmonise the Agreement with the CBD (most recently in IP/C/W/356 of 24 June 2002). These proposals are designed to create a direct interface between the

Agreements in the TRIPS Agreement itself by incorporating a requirement into the TRIPS Agreement that patent applicants should disclose the geographical source and origin of the genetic material and the related traditional knowledge used, and produce an official certificate or evidence that domestic laws on access and benefit-sharing of the source country have been respected (evidence of prior informed consent and of fair and equitable benefit-sharing).

46. The TRIPS Agreement does not specifically deal with the disclosure of genetic resources used in an invention. However, Article 29 of the TRIPS Agreement requires that the disclosure of an invention must be in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. This means that, where inventions related to genetic resources are concerned, relevant information must be provided as regards the genetic resource concerned. In certain cases, the geographical origin may be one of the relevant elements of information to be provided to allow "a person skilled in the art" to put the invention into practice, in which case patent applicants are obliged to provide this information. Where the disclosure of that information is not essential to put the invention into practice, there is no such obligation.

47. However, the objective of Article 29.1 (i.e. disclosure in order to allow reproduction of the invention) is different from the disclosure requirement for genetic resources as proposed by certain WTO Members in the context of the discussion on the relationship between the TRIPS Agreement and the CBD (i.e. to facilitate the enforcement of access and benefit sharing requirements) . In most cases, Article 29.1 will *not* require patent applicants to disclose the geographical origin because other elements of information, and/or the deposit of the biological material concerned (as regulated under the Budapest Treaty) would be sufficient to meet the requirements of Article 29.1.

48. In any event, the TRIPS Agreement does not prevent Members from requiring the disclosure of origin in cases where this information is not essential in the meaning of Article 29 TRIPS, or the production of evidence of respect of access and benefit-sharing rules to patent applicants, as long as this requirement does not constitute a patentability criterion and has no bearing on the patentability of the invention or the validity of the patent. Substantive patentability criteria are set out in Article 27.1 of the TRIPS Agreement, while Article 29 lays down obligations that can or must be imposed on the patent-holder in order to check whether the patentability criteria are met. Compatibility with TRIPS depends on the consequences arising from non-compliance. Thus, the concept of making the patentability of an invention subject to the respect of a requirement to disclose the geographical origin of genetic resources used in the invention (in cases where this information is not required under Article 29.1 TRIPS) or of a requirement to provide evidence of the access and benefit sharing rules constitutes a clear step beyond the current provisions of the TRIPS Agreement.

Self-standing disclosure requirements

49. The EC explicitly recognise disclosure of origin of as a principle in the preamble to Directive 98/44 of the European Parliament and of the Council on the Legal Protection of Biotechnological Inventions, although without making it a binding requirement.[2]

50. Of course, no WTO Member is obliged under TRIPS to require or encourage patent applicants to disclose the origin of genetic resources or related traditional knowledge used in an invention where this is not required under Article 29, i.e. a "self-standing requirement" to disclose the geographical origin of genetic resources for <u>all</u> inventions incorporating or based upon such resources. However, because benefits arising from the use of genetic resources are perceived to be generated mainly through the commercial exploitation of inventions derived from biotechnology on the markets of industrialised countries, the interests of those advocating any such requirement are that it should be

[2] Paragraph 27 of the preamble, stipulates that "patent applications should, where appropriate, include information on the geographical origin of biological material of plant or animal origin, if known … this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents".

applied on a world-wide basis. Therefore, the EC acknowledge that it would be more significant if a self-standing requirement were to apply globally rather than only in developing countries.

51. The EC, therefore, agree to examine the possible introduction a system, such as for instance a self-standing disclosure requirement, that would allow Members to keep track, at global level, of all patent applications with regard to genetic resources for which they have granted access.

52. However, the question is how to calibrate such a self-standing disclosure system, especially as regards (1) **the type of information to be submitted by the applicants** and as regards (2) **the legal consequence of failure to disclose**.

53. The EC sees merits in a system that would ensure transparency and would allow the authorities of countries granting access to their resources to keep track of patent applications linked to the use of these resources.

54. Therefore, it is the EC's view that the **information to be provided** by patent applicants should be limited to information on the **geographic origin** of genetic resources or TK used in the invention which they know, or have reason to know. It may indeed happen that a patent applicant is not aware of the country of origin of a genetic resource because it has transited through other countries, research centres, botanical gardens or other ex situ collections. So, when the country of origin is not known, the patent applicant's obligation would be to indicate the research centre, gene bank or entity from which they acquired the resource, it being understood that the disclosure requirement should not act retro-actively. Practical problems that may arise in this respect should not be overlooked, but duly anticipated and taken into account. Moreover, one should not require further evidence with regard to compliance with access and benefit sharing regulations, especially where many countries in the world do not yet dispose of legislation on access to genetic resources and are not in a position to deliver certificates of evidence.[3] Also, one must take into account that requiring patent offices to check compliance with ABFS requirements may well be a very complicated system to manage.

55. Moreover, the EC hold the opinion that such **a disclosure requirement should not act, de facto or *de jure*, as an additional formal or substantial patentability criterion.**[4] Failure to disclose, or the submission of false information should not stand in the way of the grant of the patent and should have no effect on the validity of the patent, once it is granted. Legal consequences to the non-respect of the requirement should lie outside the ambit of patent law, such as for example in civil law (claim for compensation) or in administrative law (fee for refusal to submit information to the authorities or for submitting wrong information). Patent law should not be used to sanction non-respect of domestic access and benefit-sharing requirements through the rejection of the patent application or the invalidation of the patent.

56. Thus, the EC are prepared to enter within the TRIPS Council, into discussions on the introduction of a multilateral system for disclosing and sharing information about the geographical origin of biological material used in all patent applications. However, such a system should have no bearing on the patentability of the inventions concerned or on the validity of these patents, and should not place an unreasonable burden upon patent offices and patent applicants. Requirements of patent

[3] In this context, the Cancun Declaration, adopted on 18.02.2002, in view of the 6th session of the Conference of the Parties to the CBD, by the Like-Minded Megadiverse Countries (Brazil, China, Colombia, Costa Rica, Ecuador, India, Indonesia, Kenya, Mexico, Peru, South Africa and Venezuela) declared that they would seek the creation of an international regime which should contemplate in particular "certification of legal provenance of the biological material, prior informed consent and mutually agreed terms for the transfer of genetic material, as requirements to the application and granting of patents, strictly in accordance with the conditions of access agreed by the countries of origin."

[4] Except in those cases where the disclosure of the geographical origin of the genetic resource is already required under Article 29 TRIPS.

applicants would involve the indication of the geographical origin of genetic resources, which they know, or have reason to know, or, when the country of origin is not known, the research centre, gene bank or entity from which they acquired the resource.

57. Such a system would meet the concerns expressed by a number of WTO Members because :

(1) It would help to prevent misappropriation of genetic resources and related traditional knowledge, i.e. by allowing patent offices to establish novelty more accurately by making more focused searches;

(2) It would help countries providing access to genetic resources to monitor and keep track of compliance with access and benefit-sharing rules as well as with the contractual arrangements between providers and users of genetic resources. It would allow source countries to be informed, through foreign patent offices, of patent applications incorporating genetic resources or traditional knowledge to which those countries, or their local communities, have granted access. This would enable them to check whether patent applicants have respected national rules on access and benefit-sharing and to detect any commercial benefits from the use of genetic resources, thus making sure that source countries get their share of the benefits, by enforcement if necessary.

58. The EC take the view that problems relating to the fact that genetic material originates from more than one country should be resolved through arrangements among the source countries concerned and/or in the context of the CBD.

The FAO International Treaty on Plant Genetic Resources for Food and Agriculture (IT)

59. The relationship between the TRIPS Agreement and the IT has not yet been discussed in detail, due to its recent adoption. The adoption of the IT is an important relevant new development regarding issues related to the patentability of living material. It raises several issues that run in parallel to those raised under TRIPS/CBD.

60. Its provisions regarding IPRs on plant genetic resources covered by a multilateral system call for mutually supportive interpretation of the IT with the TRIPS Agreement and the CBD. As the objectives of the IT will be attained through its close links with the CBD, the conditions for the relationship between the TRIPS Agreement and the IT are similar to the one between the TRIPS Agreement and the CBD. In its Articles 12.3(f) and 13.2.b(iii) the IT acknowledges that access to genetic resources shall be consistent with the adequate and effective protection of intellectual property rights and relevant international agreements. Comparable ways and means to ensure a mutually supportive implementation, as outlined under point 3, will be sought for the IT in its relation to the TRIPS Agreement and the CBD. Currently, a dialogue on the conditions for ABFS is taking place in the context of the IT with an aim to agree on a standard Material Transfer Agreement.

IV. PROTECTION OF TRADITIONAL KNOWLEDGE (TK) AND FOLKLORE

61. As regards the protection of TK and folklore, the EC are actively and constructively participating in the various forums where this issue is being discussed, and in particular the CBD, WIPO and the FAO (IT). The present Communication focuses primarily on traditional knowledge. In this respect, the EC refer to the document entitled "Traditional Knowledge and Intellectual Property Rights" submitted by the EC to the WIPO Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore on 14 June 2002 (WIPO/GRTKF/IC/3/16).

62. There exist three complementary intellectual property approaches to TK:

1. Protection of TK through existing intellectual property rights;

2. Instruments to prevent inappropriate patenting or other types of misappropriation of traditional knowledge and to ensure that benefits stemming from inventions based on TK are properly shared with the providers of that knowledge; and

3. The development of *sui generis* protection.

Protection of TK through existing intellectual property rights

63. Even if it appears difficult to protect all types of TK under existing IP regimes, it may be possible, to a certain extent, to protect certain types of TK or, at least, the way in which it is presented, or products incorporating TK, through existing IP regimes. A number of existing IP standards may potentially be used to this end. This use can take various forms. For more details, see pages 2-3 of WIPO/GRTKF/IC/3/16.

Approaches to prevent inappropriate patenting of TK and to facilitate benefit sharing

64. In many cases, TK is not eligible for patent protection, because it does not, respond to the substantive patentability criteria enshrined in Article 27.1 of the TRIPS Agreement. Some cases have been reported of parties obtaining patent protection merely for copying TK. This amounts to misappropriation of TK and the patent can be challenged for not meeting the patentability criteria. However, it is always preferable to deal with problems before they arise. Also, it must be taken into account that most TK holders do not have the means to engage in litigation that may be costly and time-consuming. Therefore, preventive approaches need to be devised.

65. An effective way of avoiding such practices would be to make sure that TK would always be duly recognised as prior art. Therefore, methods of documenting and sharing information on TK, such as databases and registers, in order to allow patent examiners to take them into account in prior art searches need to be explored. Such databases and registers should be developed with the full participation of the TK holders.

66. The situation is different when TK is used as a basis for further innovations. In many cases, TK serves as a basis or an element in further research and development for use in broader applications. In such cases these innovations are patentable, provided they meet the substantive patentability criteria. But the possibility of obtaining a patent does not override existing legal or contractual requirements to reward TK holders for the use of their knowledge or share the benefits of its use. In this instance, disclosure of origin of TK from which inventions are derived would be an issue. What has been said in this communication as regards disclosure requirements of genetic material also applies, *mutatis mutandis*, to traditional knowledge.

Sui generis protection of TK

67. In their Communication to the TRIPS Council of April 2001 on the relationship between the TRIPS Agreement and the CBD,[5] the EC expressed support for the development of an international model for the legal protection of TK. In this context, the EU also confirmed that it remained open to developing countries' requests to include TK on the agenda of a new round, as the EU had already committed itself to at the Seattle Ministerial in December 1999. This is why the EC welcome the reference to TK in paragraph 19 of the Doha Ministerial Declaration.

68. Certain WTO Members have suggested in the past that they would like to see provisions on TK protection included in the TRIPS Agreement.

[5] IP/C/W/254 (13 June 2001).

69. However, the EC are of the opinion that, at this stage, the TRIPS Council is not the right place to negotiate a protection regime for a complex new subject matter like TK or folklore. This is an issue where the WTO should ideally be able to build on the work undertaken by the World Intellectual Property Organisation (WIPO), where traditional knowledge is now being extensively discussed in the Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore.

70. At this stage it is difficult to anticipate the result of the work of the WIPO Intergovernmental Committee. Nevertheless, it is clear from the EU's perspective that WIPO, as the specialised UN agency responsible for the promotion of IP world-wide, is, from a technical viewpoint, the most suitable forum for tackling the issue of legal protection of TK. There are many complex conceptual and operational problems involved in recognising (collective) rights over TK, and there could well be considerable hurdles to overcome when establishing stringent criteria such as the definition of TK as protectable subject matter, the determination of ownership, the modalities of ownership and the scope of rights related to TK. Folklore is being examined independently from TK in the framework of the WIPO Intergovernmental Committee. Attempts to protect expressions of folklore via intellectual property face similar, if not greater, challenges.

71. Therefore, it seems best to wait for the results of the WIPO Intergovernmental Committee and only then decide whether this warrants further work in the WTO. Depending on the outcome of the WIPO process, it could then be assessed whether the issue need to be taken up by the TRIPS Council. For example, it can be considered how and whether a protection regime for TK could ultimately be made enforceable, for instance through inclusion in the TRIPS Agreement. A separate assessment on the possibility of protecting expressions of folklore could only be made in the light of the outcome of the intergovernmental Committee.

V. *SUI GENERIS* PROTECTION OF PLANT VARIETY RIGHTS

72. The penultimate sentence of Article 27.3(b) TRIPS states that: "Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof". The Agreement gives no further guidance of what is to be understood by "an effective *sui generis* system" and there is no agreed interpretation of this term among WTO Members.

73. The absence of a definition means that Members have a considerable degree of flexibility to determine how their legislation should meet the standard of effectiveness, which allows them to design a protection regime that is appropriate to their specific national situation. Account can be taken, for instance, of the overall agricultural development policy objectives of Members or the need to protect certain rights of small farmers or subsistence farmers (see Section 6).

74. Many countries have enacted specific laws granting exclusive rights to breeders of new varieties of plants so that they can receive a reasonable return on past investments. These rights also provide an incentive for continued or increased investment in the future, and confirm the moral right of the innovator to be recognised as such and his economic right to be remunerated for his effort.

75. A growing number of WTO Members have signed the UPOV Convention of 1978 or of 1991. The Convention requires its signatories to provide protection for new varieties of plants and contains explicit and detailed rules on the conditions and arrangements for granting protection. A plant variety is protected if it is distinct, stable, sufficiently uniform and novel. The Convention also contains rules on the scope of protection, possible restrictions and exceptions, and how protection may be forfeited. The UPOV Convention is an effective, flexible and widely recognised protection model for plant varieties, subscribed by 50 states all over the world. It offers many advantages for its signatories. For instance, it establishes, subject to certain limitations, the principle of national treatment for plant-breeders from other Member States and introduces a right of priority.

76. However, while UPOV 1978 and UPOV 1991 should be considered as meeting the standard of effectiveness under Article 27.3(b) of the TRIPS Agreement, they are not necessarily the only valid "effective *sui generis* systems" for plant variety protection. Other models may exist. Several countries have adopted or are preparing to adopt plant variety protection systems which differ to a lesser or a greater extent from UPOV.

77. In this context, the EC believe that in order to be effective any regime establishing intellectual property rights over a certain subject matter, be it inventions or plant varieties, must fulfil a certain number of criteria. The main criteria are the following :

- the protectable subject matter (i.e. plant variety) must be clearly defined;

- the conditions for granting protection must be clearly defined. In the context of plant varieties, novelty is an essential condition for protection;

- the rights with respect to the protected subject matter need to be clearly spelled out; the right-holder should at least be able to prevent third parties from carrying out certain acts in relation to the protected subject matter over a certain period of time;

- the law must provide for national treatment and most favoured nation treatment; it is logical that Articles 3 and 4 of the TRIPS Agreement apply to plant variety protection as well;

- the procedure to be followed by the breeder to obtain these rights should be spelled out in a detailed and transparent way;

- the necessary administrative organisation needs to be set up to ensure that these rights can be effectively obtained within a reasonable time frame;

- limitations and exceptions to the rights of the right-holder need to be clearly defined; typical examples of such exceptions are experimental use, the right to use a protected variety for further breeding, compulsory licences (in which case Article 31 TRIPS provides a useful yardstick) and certain exceptions to the benefit of farmers (see Section 6 of this paper on farmers' rights and farmers exemptions);

- the period of application of the rights must be determined, but should be sufficient to allow breeders to recover costs and invest in new research;

- the law must provide for legal and institutional implementation procedures to allow the right-holder to enforce his rights and to create an effective deterrent to infringement; the legal actions spelled out in the TRIPS Agreement should be available to the right-holder for this purpose.

VI. FARMERS' RIGHTS AND FARMERS' EXEMPTIONS

78. The term "farmers' rights" is used to refer to very different concepts. For the sake of clarity it is essential to differentiate between basically two different (though closely interrelated) concepts:

(a) "farmers' rights" as a set of measures in recognition of the ancestral role of farmers in developing foodcrop varieties and preserving biodiversity;

(b) farmers' rights as an exception to plant breeders' rights or patents, which, in order to avoid confusion with the former concept, we will further refer to as "farmers' exemptions".

Farmers' rights

79. In its broad sense, the term "farmers' rights" refers to a set of measures in recognition of the ancestral role of farmers in developing foodcrop varieties and preserving biodiversity. These might for instance consist of measures to help support farmers in their conservation and development of agricultural biodiversity and plant genetic resources.

80. The term farmers' right has a specific legal meaning under the FAO IT (see its Article 9). Here, farmers' rights are intended to encourage contracting parties to take specific measures to assist farmers in their role as guardians of biodiversity and to ensure that they share in the benefits of further improvements of plant genetic resources (i.e. giving priority to a funding strategy to the implementation of agreed plans and programmes for farmers in developing countries protection of agriculture-related traditional knowledge etc.). This provision recognises the importance of farmers' rights, but it is left up to the contracting parties to take measures under their national law. Farmers' rights to save, use, exchange and sell farm-saved seed/propagating material (paragraph 3) are not limited by the Article but are subject to the contracting parties' national laws.

81. In their broad meaning, farmers' rights do not directly interfere with the subject of intellectual property rights, the main aim of which is to encourage innovation. Farmers' rights on the other hand are more a matter of retrospective reward to farming communities for their ancestral role in fostering agricultural biodiversity, which is too broad an aspect to be dealt with by the TRIPS Council. It should rather be dealt with by other organisations, particularly the FAO, although some aspects may be considered in the context of traditional knowledge.

82. In this context, it is important to point out that nothing in the TRIPS Agreement prevents Members from taking measures to encourage, support and reward farmers for their role in the conservation and development of agricultural biodiversity and plant genetic resources.

Farmers' exemptions

83. In a more narrow sense, the term "farmers' rights" is also used to refer to exemptions to plant variety right protection or patents on plants or other genetic material allowing farmers to save, exchange or sell seeds of protected varieties or plants, or use them for further multiplication. Farmers' exemptions are thus a derogation - designed to help the farmer - from the scope of protection conferred by a plant variety certificate or a patent.

84. UPOV 91 provides for a right to restrict breeder's rights. The so-called "farmers' privilege" is a form of farmers' exemption, with a clearly circumscribed scope. It allows (but does not oblige) signatories to grant farmers the right to use, for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting the protected variety on their own holdings.

85. EC Regulation No. 2100/94 on community plant variety rights and EC Regulation No. 98/44 on the legal protection of biotechnological inventions both contain a farmers' privilege clause which applies to the main foodcrops (fodder plants, cereals, potatoes, oil and fibre plants), whereby small farmers do not have to pay any remuneration to the right-holders while other farmers are required to pay an "equitable" remuneration, which must be appreciably lower than the amount charged to licensed farmers. The EC consider that these exceptions are justified under UPOV 91 as well as under Article 30 of the TRIPS Agreement.

86. The EC believe that farmers' exemptions can be justified under Article 27.3(b) of the TRIPS Agreement (as an exception to plant variety right protection) or under Article 30 of the TRIPS Agreement (as an exception to patent protection on genetic resources for food and agriculture), depending on the scope of the exception.

87. The farmers' privilege under the UPOV Convention (which gives a farmer the right to freely propagate or multiply protected varieties on his own farm) is designed for economies where farming has become a commercial and quasi-industrial activity performed by a small minority of the population and where plant breeding has become an industrial plant breeder's activity.

88. This could be different for the least developed or developing countries, where all or part of the farming activity is performed on very small farms at subsistence level or where commercial activities of farmers are of limited geographical scope. In these situations, a Member may well create, in its national law, a broader farmers' exemption for the benefit of subsistence farmers, or of small farmers who customarily reuse seed because they lack access to or financial resources for new seed every growing season. This allows them to save, replant, exchange, share and resell seed (to other small farmers), provided they do not use the denomination of the variety or the related trade mark. In any event, the breeder must remain the only one entitled to derive commercial benefit from the new variety. Another option could be to exempt exchanges of seed that take place within the same community or with neighbours, and between farming communities. However, farmers with significant commercial interests should be subject to more stringent rules.

The EC would be happy to discuss these issues further.

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