WORLD TRADE ORGANIZATION

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Council for Trade-Related Aspects of Intellectual Property Rights

REVIEW OF THE PROVISIONS OF ARTICLE 27.3(B)

SUMMARY OF ISSUES RAISED AND POINTS MADE

Note by the Secretariat

Revision

TABLE OF C42 11.04 TfaBDC BT11 0 0 1 72.024 471.67 Tm[ )]TJETET42 11.04 T1 0 4gSBLE OF

I. INTRODUCTION

1. At its meeting of 17-19 September 2002 the Council for TRIPS requested the Secretariat to periodically update its summary notes on issues raised and points made in the Council's work on three items of its agenda, namely, the review of the provisions of Article 27.3 (b) in IP/C/W/369; the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) in IP/C/W/368; and the protection of traditional knowledge and folklore in IP/C/W/370, not necessarily after every meeting, but when significant new material had been presented. The present document, which replaces IP/C/W/369, responds to this request by including the points that have been made more specifically with respect to the review of the provisions of Article 27.3(b) since the circulation of the original note.

2. This note, like the original note, seeks to summarize the relevant material presented to the TRIPS Council, whether in written or oral form, and lists all the relevant documentation tabled in the Council since 1999. To avoid undue duplication, cross-references to the other two notes or to other sections of this note have been made in certain places. In accordance with the mandate given to the Secretariat, the note only contains issues raised and points made by delegations in the Council for TRIPS. It does not cover the documentation of the Committee on Trade and Environment and of the General Council, unless the relevant paper has also been circulated as a Council for TRIPS document, nor the discussions in the Director

contribute to solving problems in both developed and developing countries in areas such as agriculture, nutrition, health and the environment;[1]

- for this purpose to be adequately met, it is necessary to have international rules for the protection of plant and animal inventions rather than relying on differing national rules;[2]

- patent protection for plant and animal inventions facilitates the transfer of technology and the dissemination of the state-of-the-art research on plant and animal inventions by providing an important incentive for the private sector to conclude licensing agreements and by discouraging confidentiality and trade secret arrangements[3] and, instead, requiring the publication of patent applications on a global basis;[4]

- patent disclosure requirements and the control over exploitation given to the patent owner can facilitate the operation of laws designed to protect public morality, health and the environment.[5]

7.

- the exceptions to patentability authorized by Article 27.3(b) are unnecessary[8] and patent protection should be extended to all patentable inventions of plants and animals;[9]

- Article 27.3(b) should be maintained as it is,[10] with no lowering of the level of protection.[11] The provision is well-balanced, preserving Members' rights and flexibility to decide whether or not to exclude plants and animals from patentability in the light of their specific national interests and needs.[12] With regard to the process to be followed in the review, it has been suggested that this should primarily be one of information sharing on how Members have implemented Article 27.3(b) nationally;[13]

- retain the exceptions, but provide clarification or definitions of certain terms used in Article 27.3(b), especially with a view to clarify the differences between plants, animals and micro-organisms;[14]

- amend or clarify Article 27.3(b) to prohibit the patenting of all life forms, more specifically plants and animals, micro-organisms and all other living organisms and their parts, including genes as well as natural processes that produce plants, animals and other living organisms.[15] It has been argued that the review should provide for unqualified exceptions for exclusions from patentability, along the lines of the general and security exceptions in the other WTO agreements, that recognize the rights of Members to take measures in the public interest, including on ethical and moral grounds, and for the introduction of a universal novelty standard in order to stop piracy of traditional knowledge and other information.[16] It has also been

10. **Since 2002** reference has been made to the mandate contained in paragraphs 12 and 19 of the Doha Ministerial Declaration.[20]

(c) the protection of traditional knowledge;[27] and

(d) the way to make the TRIPS Agreement and the CBD mutually supportive.[28]

13. As a way of moving forward it has been proposed that, where the views of delegations suggest a common understanding, the Council for TRIPS should agree upon a Decision and report the adoption of the Decision to the TNC. The Decision should become operational immediately. It has been stated that 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 it would have to contain a clear commitment to continue the review and finalise it within an agreed time frame. For those areas where there is no common understanding, the Council for TRIPS should continue its work, but should do so within a specific timeframe that addresses the grave concerns of Members on the slow progress with the work programme.[29]

14. In response to this proposal, it has been said that Article 27.3(b) provided considerable flexibility for WTO Members since individual Members were free to exclude from patentability plants and animals and essentially biological processes for the production of plants and animals.[30] By the same token, Members were free to provide patent protection for such subject-matter which some had used to develop a strong biotechnology industry.[31] It has been said that the subject under discussion is evolving and account needs to be taken of developments in the field of biotechnology during the review of Article 27.3 (b)[32]. The need to identify specific demands and to present comprehensive and concrete proposals on the issues under discussion, as a basis for focused and structured discussions, has also been raised.[33]

15. Developing country Members and those from countries in transition to a market economy, which had not already done so, were urged to respond to the Secretariat's illustrative list of questions[34] and submit information to the TRIPS Council on the manner in which they implement the provisions of Article 27.3(b).[35]

20. In regard to the **definition of plants and animals**, it has been suggested that it should be made clear that parts of plants and animals are excludable from patentable subject-matter.[51] In particular, it has been said that there are ambiguities about the meaning of "plants",[52] and that cells, cell lines, genes and genomes should be excluded.[53]

21. With regard to **micro-organisms**, the view has been expressed that there is no scientific or other rationale for distinguishing between plants and animals on the one hand and micro-organisms on the other. Both should not be patentable, since both are living things which can only be discovered and not invented.[54] The view has also been expressed that there is no consensus on the meaning of the term "micro-organism" in the scientific community.[55] For example, it has been argued that the scientific definition of micro-organisms only comprises bacteria, fungi, algae, protozoa and viruses[56] and it has been questioned whether biological material such as cell lines, enzymes, plasmids, cosmids and genes should qualify as micro-organisms.[57] It has also been said that there is no scientific basis for the distinction between plants, animals and micro-organisms.[58]

22. In response, the view has been expressed that the distinctions made in Article 27.3(b) are in accordance with the generally accepted scientific classification of organisms[59] and that the notion of categorising life-forms into plants, animals and micro-organisms is widely accepted in existing international agreements, including the CBD.[60] It has been said that the absence of a definition in the TRIPS Agreement of the term "micro-organism" reflects the fact that the term has not been defined by patent experts anywhere, not even in the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedures. It has also been said that the WIPO Committee of Experts on Biotechnological Inventions and Industrial Property, which met between 1984 and 1988, did not define the term "micro-organism", although the term was used frequently in its discussions. It has been said that the reason for the lack of a 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 text, under the heading "Definition of Micro-organism, If Any":

> "None of the laws administered by any of the Offices contains a formal definition of the term 'micro-organism'. 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."

Thus, it has been argued, patent experts have recognized that any definition that would be agreed upon today would have to be updated later due to the rapid evolution of research in this field.[61] It has been said that, if patent officials operating in more technically expert forums have not considered it

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[51] India, IP/C/W/161.
[52] Kenya, IP/C/M/42, para.120.
[53] Kenya, IP/C/M/28 para. 152; Zimbabwe, IP/C/M/39 para. 111.
[54] Kenya on behalf of the African Group, IP/C/W/163.
[55] Brazil, IP/C/M/29, para. 146; Japan, IP/C/W/236; Switzerland, IP/C/W/284; Venezuela, IP/C/M/29 para. 199.
[56] Zimbabwe, IP/C/M/39, para. 111.
[57] India, IP/C/M/25, para. 70, IP/C/W/161; Pakistan, IP/C/M/26, para. 65.
[58] Kenya on behalf of the African Group, IP/C/W/163.
[59] Switzerland, IP/C/W/284.
[60] Japan, IP/C/M/29, para. 151.
[61] United States, IP/C/M/28, para. 131, IP/C/M/35, para. 222, IP/CM/37/Add.1, para. 210; Singapore, IP/C/M/37/Add.1, para. 218.

appropriate to define the term "micro-organism", it would not be wise for the TRIPS Council to attempt such a task.

23. The question of how WTO Members and, if necessary, a WTO panel should interpret the term "micro-organism" given the absence of a definition has been discussed. One view has been that the principles of international law regarding the interpretation of treaties, in particular Articles 31 and 32 of the Vienna Convention on the Law of Treaties, should be used.[62] The Vienna Convention provides that the basic rule of interpretation is the ordinary meaning of terms in their context and in the light of the agreement's object and purpose. In this regard, it has been said that the dictionary meaning should suffice for distinguishing plants and animals from micro-organisms for the purposes of the TRIPS Council.[63] The *Concise Oxford Dictionary* defines the ordinary meaning of "micro-organism" as "an organism not visible to the naked eye, *e.g.*, bacterium or virus".

24. In response, it has been said that, in interpreting the term "micro-organism", Article 31(4) of the Vienna Convention on the Law of Treaties is more relevant, namely the negotiating history of Article 27.3(b). In this regard, it has been said that negotiators of the TRIPS Agreement questioned, but did not investigate, whether patents would extend to cell-lines, enzymes, plasmids, cosmids and genes and therefore the Agreement contained terms on the meaning of which agreement was not reached.[64] It has also been said that a dictionary reference is not very helpful for dealing with the several "borderline" categories of life-forms that could be classified as either micro-organisms or as plants and animals. Moreover, the view has been expressed that the term is obviously intended to have a special meaning in the context of patentability and the dictionary explanation and example of a

- it should be left to national policy to decide what are patentable micro-

public and morality meaningless for those Members that consider patents on life forms to be immoral, contrary to the fabric of their society and culture and would want to invoke these exceptions in this regard.[85] The minimum that was acceptable in this regard is to clarify that paragraph 3 does not in any manner restrict the rights of Members to resort to the exceptions in paragraph 2.[86]

29. It has been said that ethical and moral matters are not matters for commercial calculations and their force should not be affected by reasoned commercial concerns.[87] Cultural and social values of many societies can

remembered that Article 27.3 (b) is the result of a carefully negotiated balance.[97] The view has also been expressed that biological materials are research ingredients and that patents for these materials should be granted as long as the patentability requirements are met and the commercial exploitation of such living organisms does not go against public order.[98]

D.

to the patent applicant.[121] It has also been said that with respect to gene sequences some Members require the description of a function while others do not.[122]

40. A general point made in relation to the above concerns has been that, if the criteria for patentability have not been properly a

45. With regard to the **question of why plant varieties should be protected**, the point has been

These views and responses made to specific points are elaborated below.

51. The view has been expressed that, in order to be effective, a *sui generis* system of protection should possess the same basic characteristics as those that generally apply in relation to the protection of property rights, whether real, tangible or intangible: the nature of the subject-matter must be identified clearly enough to enable a distinction to be drawn between what falls within and what is

to obtain rights under

have also been expressed about the way in which the issue of farmers' privilege is treated in UPOV 1991; these are summarized in paragraph

- Article 27.3(b) does not bind Members to use UPOV as a model in providing

implementation of Article 27.3(b) have adopted the 1991 Act[208] and that many of those that had originally become signatories to the 1978 Act were in the process of ratifying the 1991 Act.[209]

65. In response, it has been said that, while membership of the 1991 Act of UPOV is increasing, a large number of developing countries are resisting signing the instrument given its limited flexibility as compared with the **1978 Act**. In this regard the view has been expressed that UPOV 1978 allows farmers to save, exchange and, to a limited degree, sell seeds of protected varieties, whereas UPOV 1991 turns these actions into privileges and exceptions, giving the government discretion as to whether to permit farmers to save seeds for use on their own holdings and making it subject to "reasonable restrictions" and the protection of the "legitimate interests" of the breeder. Further, the exception only applies to saved material that has been harvested on the same holdings[210] and not to propagated material.[211]

D. RELATIONSHIP BETWEEN *SUI GENERIS* PROTECTION OF PLANT VARIETIES AND TRADITIONAL KNOWLEDGE AND FARMERS' RIGHTS

67. The view has been expressed that laws and measures on the protection of plant varieties directly affect traditional knowledge and farmers' rights.[221] In this respect, it has been noted that staple or medicinal plants would not qualify for protection under UPOV given their long-standing existence, thus not protecting the traditional knowledge relating to their use.[222] The point has been made that such traditional knowledge has been recognized under a number of international instruments, such as the CBD, the FAO International Undertaking on Plant Genetic Resources, and the OAU model law.[223] The view has been expressed that systems for the protection of plant varieties may support or harm such rights, depending on whether or not the laws and measures strike a balance between the various key interests and whether or not farmers' rights and traditional knowledge are duly recognized and provided for.[224] It has been suggested that the flexibility provided in Article 27.3(b) should therefore be retained and construed consistently with the aforementioned instruments.[225]

other hand can and should be implemented in a mutually supportive way.[234] The view has also been expressed that farmers' rights are part of a much broader issue and are appropriately being dealt with in other organisations, in particular the FAO.[235]

IV. TRANSFER OF TECHNOLOGY

70. In the work of the Council for TRIPS, the issue of the implications of patent protection in respect of life forms and *sui generis* plant variety protection for access to, and transfer and dissemination of, technology has been discussed. This discussion has taken place in a number of contexts, including in relation to developmental matters and the relationship between the TRIPS Agreement and the objectives and provisions of the CBD concerning access to and the transfer of technology. It has been recalled that Article 7 of the TRIPS Agreement includes the transfer and dissemination of technology as one of the basic objectives of the protection of intellectual property rights and the need for measures to effectively operationalize this has been referred to.[236] It has been said that access by the developing world to these important technologies, as well as their capacity to

be considered part of benefit sharing, as was recognized in the work underway in the context of the FAO International Undertaking on Plant Genetic Resources. [243]

ANNEX

DOCUMENTS OF THE COUNCIL FOR TRIPS WITH RESPECT TO THE REVIEW OF THE PROVISIONS OF ARTICLE 27.3(B), THE RELATIONSHIP BETWEEN TRIPS AND THE CONVENTION ON BIOLOGICAL DIVERSITY AND THE PROTECTION OF TRADITIONAL KNOWLEDGE AND FOLKLORE

The reports on the meetings of the Council for TRIPS held during the period January 1999 to January 2006 (IP/C/M/21-35, 36/Add.1, 37/Add.1, 38-40 and 42-49) reflect the work done so far in the Council for TRIPS with respect to three agenda items, namely, the review of the provisions of Article 27.3(b); the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD); and the protection of traditional knowledge and folklore (List A). The substantive

LIST A Records of the work of the Council for TRIPS

LIST B - Members' submissions relating to the agenda items			
Dominican Republic	IP/C/W/429/ Rev.1/Add.3	Request of the Dominican Republic to be added to the List of Sponsors of Document IP/C/W/429/Rev.1	10 February 2005
Colombia	IP/C/W/429/ Rev.1/Add.2	Request of Colombia to be added to the List of Sponsors of Document IP/C/W/429/Rev.1	20 January 2005
2004			
Bolivia, Brazil, Cuba, Ecuador, India, Pakistan, Peru, Thailand, Venezuela	IP/C/W/438	The Relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD), and the Protection of Traditional Knowledge - Elements of the Obligation to Disclose Evidence of Prior Informed Consent under the Relevant National Regime	10 December 2004
United States	IP/C/W/434	Article 27.3(b), Relationship between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore	26 November 2004
Switzerland	IP/C/W/433	Further Observations by Switzerland on its Proposals regarding the Declaration of the	

LIST B - Members' submissions relating to the agenda items			
2003			
African Group	IP/C/W/404	Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement	26 June 2003
Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand, Venezuela	IP/C/W/403	The Relationship between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge	24 June 2003
Switzerland	IP/C/W/400/ Rev.1	Article 27.3(b), the Relationship between the TRIPS Agreement and the Convention on Biological Diversity, and the Protection of Traditional Knowledge	18 June 2003
Switzerland	IP/C/W/400	Article 27.3(b), the Relationship between the TRIPS Agreement and the Convention on Biological Diversity, and the Protection of Traditional Knowledge	28 May 2003
United States	IP/C/W/393	Access to Genetic Resources Regime of the United States National Parks	28 January 2003
2002			

LIST B - Members' submissions relating to the agenda items	
EC	IP/C/W/254

LIST B - Members' submissions relating to the agenda items			
Cuba, Honduras, Paraguay and Venezuela	IP/C/W/166	Review of Implementation of the Agreement under Article 71.1: Proposal on Protection of the Intellectual Property Rights of the Traditional Knowledge of Local and Indigenous Communities	5 November 1999
India	IP/C/W/161	Review of the Provisions of Article 27.3(b) - Communication from India	3 November 1999
African Group	IP/C/W/163	Review of the Provisions of Article 27.3(b) - Communication from Kenya on behalf of the African Group	8 November 1999
Norway	IP/C/W/167	Review of the Provisions of Article 27.3(b) - Communication from Norway	3 November 1999
United States	IP/C/W/162	Review of the Provisions of Article 27.3(b) - Communication from the United States	29 October 1999
1998			
Mexico	Job No. 6957	Non-paper from Mexico: Application of Article 27.3(b)	8 December 1998

LIST C Information on national legislation, practices and experiences			
2006			
Norway	C/M/49, a. 120	Minutes of the Council for TRIPS Meeting	31 January 2006
Peru	C/M/49, as. 81-84	Minutes of the Council for TRIPS Meeting	31 January 2006
2005			
Peru	IP/C/W/458	Analysis of Potential Cases of Biopiracy	7 November 2005

LIST C Information on national legislation, practices and experiences			
2004			
Peru	IP/C/M/45, para. 31	Minutes of the Council for TRIPS Meeting	27 October 2004
Chinese Taipei	IP/C/M/43, para. 58	Minutes of the Council for TRIPS Meeting	7 May 2004
EC	IP/C/M/43, para. 39	Minutes of the Council for TRIPS Meeting	7 May 2004
Norway	IP/C/M/43, para. 54	Minutes of the Council for TRIPS Meeting	7 May 2004
EC	IP/C/M/42, para. 108	Minutes of the Council for TRIPS Meeting	4 February 2004

LIST F - Notes by the Secretariat		
JOB(02)/58	The Relationship between the TRIPS Agreement and the Convention on Biological Diversity - Summary of Issues Raised and Points Made	18 June 2002
	2001	
Job No. 2689 IP/C/W/273	Review of the Provisions of Article 27.3(b): Synoptic Tables of Information provided by Members - Informal Note by the Secretariat	5 June 2001
	2000	
JOB(00)/7517	The Relationship between the Convention on Biological Diversity and the TRIPS Agreement: Checklist of Points Made - Note by the Secretariat	23 November 2000
	1999	
Job no. 2627	UPOV-WIPO-WTO Joint Symposium on the Protection of Plant Varieties under Article 27.3(b) of the TRIPS Agreement: Texts of presentations	7 May 1999
	1998	
IP/C/W/122	Illustrative Questions: Review of the Provisions of Article 27.3(b)	22 December 1998