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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

*This document has been prepared under the Secretariat's own  
responsibility and without prejudice to the positions of Members  
and to their rights and obligations under the WTO*

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## 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-General's consultative process on outstanding implementation issues. The relevant documentation is listed in the Annex to this note. It is referred to in the footnotes which reflect the sources for the points made in the compilation. In many cases, the same point has been made more than once; the footnotes do not purport to contain references to all such occasions.

3. It is emphasized that this note is an attempt to summarize the work done so far. By its very nature, it cannot include a full reflection of all the interventions made and documents submitted. It is structured around the issues raised rather than the positions of individual Members. Therefore any reader wishing to appreciate fully the position of a particular Member should consult the statements made and any papers submitted by that Member.

4. This note is divided into three major sections. The first concerns issues relating to the patent provisions of Article 27.3(b), the second concerns issues relating to the *sui generis* protection of plant varieties and the third concerns issues relating to the transfer of technology. There is also a final section which provides information on national legislation, practices and experiences with respect to this agenda item.

## II. ISSUES RELATING TO THE PATENT PROVISIONS OF ARTICLE 27.3(B)

5. After summarizing some general points made about the patent provisions of Article 27.3(b), this section summarizes points made with regard to the scope of the exceptions to patentability permitted under Article 27.3(b), the ethical exceptions to patentability permitted under Article 27.2 and the way in which the conditions of patentability provided for under Article 27.1 apply to plant and animal inventions.

### A. GENERAL ISSUES

6. One general issue that has been discussed is the **case for and against providing patent protection for plant and animal inventions**, especially from a development perspective. One view has favoured a broad provision of patent protection for such inventions, for the following reasons:

- plant and animal inventions, as well as other biotechnological inventions, should be accorded adequate patent protection, in the same way as inventions in other fields of technology, in order to promote private sector investment in inventive activities that

contribute to solving problems in both developed and developing countries in areas such as agriculture, nutrition, health and the environment;<sup>1</sup>

- 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;<sup>2</sup>
- 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<sup>3</sup> and, instead, requiring the publication of patent applications on a global basis;<sup>4</sup>
- 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.<sup>5</sup>

7. Another view that has been expressed is that patents on life forms give rise to a range of concerns, including in regard to development, food security, the environment, culture and morality:<sup>6</sup> These include:

- concerns relating to the implications of patent protection in the field of plants for access to, and the cost, re-use and exchange of, seeds, by farmers, as well as concerns about the displacement of traditional varieties and depletion of biodiversity;<sup>7</sup>
- concerns relating to the grant of excessively broad patents, which do not fully meet the tests of patentability and the consequent problems of "bio-piracy" in respect of genetic material and traditional knowledge and of the costs and burdens associated with the revocation of such patents;
- another area of concern has been the view that present international arrangements, which it has been said protect the interests of innovators but do not adequately protect the countries and communities that supply the underlying genetic material and traditional knowledge, need rebalancing, in particular to make the principles of the CBD in regard to prior informed consent and benefit sharing more effective.

8. Some of these points, especially the last two, are elaborated in the Secretariat summary notes on the relationship between the TRIPS Agreement and the CBD and the protection of traditional knowledge and folklore.

9. The suggestions that have been made for **what action might be taken by the WTO** in regard to the patent provisions of Article 27.3(b) in light of the mandated review can be grouped in the following categories:

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<sup>1</sup> Japan, IP/C/M/32, para. 142; Switzerland, IP/C/M/30, para. 161 and IP/C/W/284, para. 4; United States, IP/C/M/39 para. 114, IP/C/M/42, para. 109; China, IP/C/M/37/Add.1 para. 201.

<sup>2</sup> Singapore, IP/C/M/25, para. 80.

<sup>3</sup> Australia, IP/C/M/24, para. 83.

<sup>4</sup> Australia, IP/C/M/24, para. 83; Canada, IP/C/M/25, para. 91; European Communities, IP/C/M/25, para. 72; Japan, IP/C/M/29, para. 150; Switzerland, IP/C/M/30, para. 161.

<sup>5</sup> Switzerland, IP/C/W/284.

<sup>6</sup> India, IP/C/M/25, para. 70, IP/C/M/24, para. 80; Kenya, IP/C/M/28, para. 143.

<sup>7</sup> Kenya, IP/C/M/28, para. 145, IP/C/M/40, para. 106.

- the exceptions to patentability authorized by Article 27.3(b) are unnecessary<sup>8</sup> and patent protection should be extended to all patentable inventions of plants and animals;<sup>9</sup>
- Article 27.3(b) should be maintained as it is,<sup>10</sup> with no lowering of the level of protection.<sup>11</sup> 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.<sup>12</sup> 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;<sup>13</sup>
- 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;<sup>14</sup>
- 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.<sup>15</sup> 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.<sup>16</sup> It has also been suggested that the Article should be amended to prohibit the patenting of inventions based on traditional knowledge<sup>17</sup> or those that violate Article 15 or other provisions of the CBD.<sup>18</sup> It has been suggested that the obligation of developing countries to implement Article 27.3(b) should take effect five years after the completion of the review of this provision.<sup>19</sup>

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<sup>8</sup> United States, IP/C/M/29, para. 185.

<sup>9</sup> Singapore, IP/C/M/29, para. 169; JOB(00)/7853, para. 6.

<sup>10</sup> Australia, IP/C/M/28, para. 152; Canada, IP/C/M/25, para. 91, IP/C/M/40, para. 113; China, IP/C/M/37/Add.1, para. 201; Korea, IP/C/M/26, para. 70; European Communities, IP/C/M/43, para. 40.

<sup>11</sup> Japan, IP/C/M/32, para. 142; Singapore, IP/C/M/32, para. 139; IP/C/M/29, para. 169; Switzerland, IP/C/M/30, para. 161; European Communities, IP/C/M/43, para. 40.

<sup>12</sup> Brazil, IP/C/M/26, para. 61, IP/C/M36/Add.1, para. 199; Switzerland, IP/C/M/32, para. 123, IP/C/M/30, para. 161. Mexico, IP/C/M/26, para. 76; United States, IP/C/M/37/Add.1, para. 209; Switzerland, IP/C/M/40, para. 70; Canada, IP/C/M/40, para. 113; European Communities, IP/C/M/43, para. 40.

<sup>13</sup> Japan, IP/C/M/28, para. 162; Canada, IP/C/M/40, para. 111; European Communities, IP/C/M/44, para. 42; Australia, IP/C/M/44, para. 44.

<sup>14</sup> Brazil, IP/C/M/30, para. 156 and 183, IP/C/M/25, para. 94; India, IP/C/M/26, para. 55; Peru, IP/C/M/29, para. 175; Thailand, IP/C/M/25, para. 78; Zimbabwe, IP/C/M/36/Add.1, para. 201.

<sup>15</sup> India, IP/C/M/29, para. 163, IP/C/W/161; Kenya, IP/C/M/28, para. 146, IP/C/M/40, para. 109; Kenya on behalf of the African Group, IP/C/W/163; Zimbabwe, IP/C/M/39, para. 111, IP/C/M/40, para. 75; Bangladesh, IP/C/M/42, para. 103.

<sup>16</sup> Kenya, IP/C/M/28, para. 141, IP/C/M/40, para. 109.

<sup>17</sup> India, IP/C/M/25, para. 70; Kenya, IP/C/M/40, para. 109.

<sup>18</sup> India, IP/C/W/196; Kenya, IP/C/M/40, para. 107.

<sup>19</sup> Kenya on behalf of the African Group, IP/C/W/163.

10. **Since 2002** reference has been made to the mandate contained in paragraphs 12 and 19 of the Doha Ministerial Declaration.<sup>20</sup> This broad mandate has been said to be a more appropriate basis for dealing with a wide array of issues raised in the review.<sup>21</sup> Reference has also been made to Article 7 and 8 of the TRIPS Agreement, the development dimension in the Doha Declaration contained in paragraph 19 and the objective of sustainable development contained in paragraph 6 and the recitals of the WTO Agreement.<sup>22</sup> The link between Article 27.3(b) and development has been said to be the central theme of debate in the context of the Doha Development Agenda.<sup>23</sup>

11. Concern has more particularly been expressed that the review of Article 27.3(b) of the TRIPS Agreement that started in 1999 has not yet been finalised. In order to finalise the review in a manner that would reflect a good overall balance for all Members, it has been proposed that areas of possible agreement could be identified. It has been suggested that these include the recognition:

- (a) of Members' right and freedom to determine and adopt appropriate regimes to protect plant varieties by an effective *sui generis* system, including non commercial use of plant varieties and the system of seed saving and exchange as well as selling among farmers;
- (b) that the TRIPS Agreement and the CBD should be implemented in a mutually supportive and consistent manner;
- (c) that the TRIPS Agreement, being a minimum standards agreement, does not prevent Members from protecting traditional knowledge;
- (d) of the importance of documentation of genetic resources and traditional knowledge to help better patent examination.<sup>24</sup>

12. It has also been suggested that in areas where a common understanding did not yet exist, further work was needed in the TRIPS Council, including on:

- (a) the proposal to eliminate patent availability for all life forms, including elimination of the current TRIPS obligation to patent micro-organisms and microbiological and non-biological processes for the production of plants and animals;<sup>25</sup>
- (b) recognition of the need to adopt definitions to clarify certain terms in Article 27.3(b);<sup>26</sup>

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<sup>20</sup> African Group, IP/C/W/404, p.1; Australia, IP/C/M/40, para. 134, IP/C/M/43, para. 44; Brazil, IP/C/M/40, para. 132; Canada, IP/C/M/40, para. 133; China, IP/C/M/43, para. 56; European Communities, IP/C/W/383, para. 1; India IP/C/M/40, para. 83, 129; Malaysia, IP/C/M/43, para. 40; New Zealand, IP/C/M/43, para. 45; Switzerland, IP/C/M/40, para. 69, IP/C/W/400/Rev.1, para.1; United States, IP/C/M/40, para. 131; Zimbabwe, IP/C/M/36/Add. 1, para. 200, IP/C/M/39, para. 111,112, IP/C/M/40, para. 80; China, Colombia, Cuba, Dominican Republic, Kenya, Peru, Venezuela, IP/C/M/40, para. 135; European Communities, IP/C/M/44 para. 28.

<sup>21</sup> European Communities, IP/C/W/383, para. 4.

<sup>22</sup> European Communities, IP/C/W/383, para. 3; Kenya, IP/C/M/40, para. 106; Zimbabwe, IP/C/M/36/Add.1, para. 200, IP/C/M/39, para. 112.

<sup>23</sup> European Communities, IP/C/W/383, para. 13.

<sup>24</sup> African Group, IP/C/W/404, p. 2; Zimbabwe, IP/C/M/36/Add.1, para. 201.

<sup>25</sup> African Group, IP/C/W/404, p. 3.

<sup>26</sup> Zimbabwe, IP/C/M/37/Add.1, para. 197.

- (c) the protection of traditional knowledge;<sup>27</sup> and
- (d) the way to make the TRIPS Agreement and the CBD mutually supportive.<sup>28</sup>

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.<sup>29</sup>

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.<sup>30</sup> 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.<sup>31</sup> 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)<sup>32</sup>. 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.<sup>33</sup>

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<sup>34</sup> and submit information to the TRIPS Council on the manner in which they implement the provisions of Article 27.3(b).<sup>35</sup> This would enable the Council to conduct the review under Article 27.3(b) on the basis of Members' experiences with implementing the provisions related to patents on life forms and *sui generis* protection of plant varieties.<sup>36</sup>

16. The more specific suggestions made regarding the relation between the Convention on Biological Diversity (CBD) and the protection of traditional knowledge and folklore are dealt with in the Secretariat summary notes on those two matters (IP/C/W/368/Rev.1, IP/C/W/368/Rev.1/Corr.1) and (IP/C/W/370/Rev.1).

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<sup>27</sup> African Group, IP/C/W/404, p. 4.

<sup>28</sup> African Group, IP/C/W/404, p. 5.

<sup>29</sup> African Group, IP/C/W/404, p.6; Zimbabwe, IP/C/M/36/Add. 1, paras. 200-201, IP/C/M/40, paras. 74-80.

<sup>30</sup> Canada, IP/C/M/40, para. 113; Switzerland, IP/C/M/40, para. 70; United States, IP/C/M/37 Add.1, para. 209; European Communities, IP/C/M/43, para. 40.

<sup>31</sup> United States, IP/C/M/37/Add.1, para. 209.

<sup>32</sup> Singapore, IP/C/M/37/Add.1, para. 218.

<sup>33</sup> European Communities, IP/C/W/383, para. 8, IP/C/M/44, para. 28.

<sup>34</sup> Chairperson, IP/C/M/28, para. 173, IP/C/M/30, para. 186; IP/C/M/32, para. 122; Canada, IP/C/M/40, para. 111, 113. The Secretariat's illustrative list of questions is contained in IP/C/W/273 and Rev.1. The responses by Members to these questions are listed in List D of the Annex to this document.

<sup>35</sup> United States, IP/C/M/39, para 113.

<sup>36</sup> Canada, IP/C/M/40, para. 111, 113.

B. SCOPE OF EXCEPTIONS TO PATENTABILITY IN ARTICLE 27.3(B)

17. Issues have been raised regarding the scope of the exceptions, including the **definition of the terms** used, in Article 27.3(b). It has been argued that the absence of clear definitions could pose problems of legal uncertainty as regards the scope of patentability under Article 27.3(b),<sup>37</sup> and that it is necessary to define the terms at both the national and international level.<sup>38</sup> The difficulty to get WTO Members to agree on definitions should not deter the Council from developing precise definitions of certain terms.<sup>39</sup>

18. In response, the view has been expressed that it is difficult to get all WTO members to agree on definitions as decisions are made by consensus and the issues involved are complex. Doubt has been expressed whether the TRIPS Council should study and clarify the issue of micro-organisms, as, in case of a dispute, this would hand the interpretation of these definitions to the DSB, including the Appellate Body, and this would not be desirable.<sup>40</sup> It has further been argued that the absence of definitions at the international level affords Members flexibility in the use and interpretation of these terms,<sup>41</sup> whereas a clear definition of the term micro-organism is important at the national level, as this is the only form of living organisms for which Members are obliged to provide patent protection and which are widely used in the pharmaceutical, chemical and biotechnology industries.<sup>42</sup> It has also been said that the more important issue with respect to micro-organisms is whether or not the patentability criteria are met.<sup>43</sup> The view has also been expressed that the term "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 define and apply these terms.<sup>44</sup>

19. Regarding the question whether **WIPO or the WTO is the right forum** to discuss such definitions, it has been questioned whether the TRIPS Agreement could or should go into this amount of detail.<sup>45</sup> It has been stated that WIPO rather than the TRIPS Council is the right forum to agree on technical definitions, as they have more expertise.<sup>46</sup> In response, it has been pointed out that the WTO membership is more or less replicated in WIPO, and that with regard to technical expertise the WTO can enlist the services of experts at WIPO to arrive at specific definitions.<sup>47</sup> It has also been said that there is no intention on the part of Members advocating precise definitions to diminish or erode any flexibilities that Members have in respect of the meanings that they currently attribute to any of those terms,<sup>48</sup> as such flexibilities also provide protection against unilateral pressure to take on higher commitments than those in the TRIPS Agreement.<sup>49</sup> However, specific meanings could be agreed upon while preserving reasonable flexibilities.<sup>50</sup>

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<sup>37</sup> Brazil, IP/C/M/29 para. 146; Pakistan, IP/C/M/25 para. 88., Kenya, IP/C/M/28 para. 141-146; Mauritius on behalf of the African Group, IP/C/W/206; Zimbabwe, IP/C/M/36/Add.1 para. 201.

<sup>38</sup> Zimbabwe, IP/C/M/37/Add.1, para. 198.

<sup>39</sup> Zimbabwe, IP/C/M/37/Add.1, para. 197.

<sup>40</sup> Peru, IP/C/M/37/Add.1, para. 217.

<sup>41</sup> European Communities, IP/C/W/383, para. 20.

<sup>42</sup> European Communities, IP/C/W/383, para. 21.

<sup>43</sup> European Communities, IP/C/W/383, para. 21.

<sup>44</sup> European Communities, IP/C/W/383, para. 24.

<sup>45</sup> European Communities, IP/C/W/383, para. 18; United States, IP/C/M/37/Add.1, para. 210.

<sup>46</sup> European Communities, IP/C/M/37/Add.1, para. 200, IP/C/W/383, para. 19; United States, IP/C/M/37/Add.1, para. 210.

<sup>47</sup> Peru, IP/C/M/37/Add.1, para. 217, Zimbabwe, IP/C/M/37/Add.1, para. 199.

<sup>48</sup> Zimbabwe, IP/C/M/37/Add.1, para. 199.

<sup>49</sup> Peru, IP/C/M/37/Add.1, para. 217.

<sup>50</sup> Zimbabwe, IP/C/M/37/Add.1, para. 199.

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.<sup>51</sup> In particular, it has been said that there are ambiguities about the meaning of "plants",<sup>52</sup> and that cells, cell lines, genes and genomes should be excluded.<sup>53</sup>

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.<sup>54</sup> The view has also been expressed that there is no consensus on the meaning of the term "micro-organism" in the scientific community.<sup>55</sup> For example, it has been argued that the scientific definition of micro-organisms only comprises bacteria, fungi, algae, protozoa and viruses<sup>56</sup> and it has been questioned whether biological material such as cell lines, enzymes, plasmids, cosmids and genes should qualify as micro-organisms.<sup>57</sup> It has also been said that there is no scientific basis for the distinction between plants, animals and micro-organisms.<sup>58</sup>

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<sup>59</sup> and that the notion of categorising life-forms into plants, animals and micro-organisms is widely accepted in existing international agreements, including the CBD.<sup>60</sup> 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.<sup>61</sup> It has been said that, if patent officials operating in more technically expert forums have not considered it

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<sup>51</sup> India, IP/C/W/161.

<sup>52</sup> Kenya, IP/C/M/42, para.120.

<sup>53</sup> Kenya, IP/C/M/28 para. 152; Zimbabwe, IP/C/M/39 para. 111.

<sup>54</sup> Kenya on behalf of the African Group, IP/C/W/163.

<sup>55</sup> Brazil, IP/C/M/29, para. 146; Japan, IP/C/W/236; Switzerland, IP/C/W/284; Venezuela, IP/C/M/29 para. 199.

<sup>56</sup> Zimbabwe, IP/C/M/39, para. 111.

<sup>57</sup> India, IP/C/M/25, para. 70, IP/C/W/161; Pakistan, IP/C/M/26, para. 65.

<sup>58</sup> Kenya on behalf of the African Group, IP/C/W/163.

<sup>59</sup> Switzerland, IP/C/W/284.

<sup>60</sup> Japan, IP/C/M/29, para. 151.

<sup>61</sup> 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.<sup>62</sup> 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.<sup>63</sup> 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, cosmid and genes and therefore the Agreement contained terms on the meaning of which agreement was not reached.<sup>64</sup> 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 bacterium or virus do not necessarily concern patentable micro-organisms.<sup>65</sup>

25. With regard to what action should be taken in the WTO on the treatment of micro-organisms, the following views have been expressed:

- micro-organisms, like other biological and living organisms, should be excluded from patentability.<sup>66</sup> In the event that living organisms remain patentable, a provision should be incorporated into the TRIPS Agreement to the effect that patents must not be granted without the prior consent of the country of origin in order to affirm its compatibility with the CBD and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA);<sup>67</sup>
- the coverage of the term "micro-organisms" should be clarified, in particular so as to exclude cell-lines, enzymes, plasmids, cosmid and genes;<sup>68</sup>
- individual Members should determine and apply the term in their national jurisdictions in accordance with Article 1.1 of the Budapest Treaty<sup>69</sup> and not seek to define the term. Patent experts have a fairly clear idea of the term but the issue is complex and therefore it is better left to each Member's patent offices and experts to determine;<sup>70</sup>

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<sup>62</sup> United States, IP/C/W/209.

<sup>63</sup> Japan, IP/C/M/29, para. 151; Korea, IP/C/M/32, para. 140; Switzerland, IP/C/M/30, para. 163, IP/C/W/284; United States, IP/C/M/35, para. 222, IP/C/M/28, para. 131, IP/C/W/209.

<sup>64</sup> India, IP/C/M/25, para. 70.

<sup>65</sup> Brazil, IP/C/M/29, para. 146; India, IP/C/M/30, para. 168.

<sup>66</sup> Kenya, IP/C/M/28, para. 152; Bangladesh, IP/C/M/42, para. 103.

<sup>67</sup> Bangladesh, IP/C/M/42, para. 103.

<sup>68</sup> Kenya, IP/C/M/28, para. 152.

<sup>69</sup> Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure and Regulations, done at Budapest on 28 April 1977 and amended on 26 September 1980.

<sup>70</sup> Korea, IP/C/M/35, para. 225.

- it should be left to national policy to decide what are patentable micro-organisms;<sup>71</sup>
- it has also been said that it is important to consider what approach has been taken in each Member's legal framework and that such a flow of information would be useful for a collective understanding of the nature of the terms under discussion and for clearing up concerns or grey areas.<sup>72</sup>

26. With regard to **non-biological and micro-biological processes**, concern has been expressed that Article 27.3(b) incorporates specific obligations on the patenting of such processes but does not define these terms.<sup>73</sup> It has been suggested that artificial distinctions between essentially biological processes on the one hand and microbiological and non-biological processes on the other hand should be removed<sup>74</sup> or clarified.<sup>75</sup> The view has been expressed that micro-biological processes are biological processes and should be treated in the same manner as other biological processes in the TRIPS Agreement.<sup>76</sup>

#### C. ETHICAL EXCEPTIONS TO PATENTABILITY AND ARTICLE 27.2

27. It has been said that the criteria and rationale for what could and could not be excluded from patentability on the grounds that inventions are contrary to *ordre public* or morality, including on grounds of protection of life and health of humans, animals and plants, should be examined in the review given the direct link to Article 27.3(b).<sup>77</sup> It has been suggested that the following specific concerns should be taken into account: those relating to public health, restrictions on research materials<sup>78</sup>, limitations on competition as in the case of gene use restriction technologies (GURTs),<sup>79</sup> human rights, agricultural security, bio-piracy, traditional knowledge and farmers' rights<sup>80</sup> and the concern that the current provisions of Article 27.3(b) did not prevent the abuse of patent systems.<sup>81</sup>

28. The view has been expressed that patenting of life forms is in itself unethical and harmful and therefore should be unconditionally prohibited. Article 27.2 is not sufficient for this purpose as the conditions it imposes on action to protect *ordre public* or morality are unnecessary and cumbersome,<sup>82</sup> for instance that the commercial exploitation of the invention must also be prevented.<sup>83</sup> The qualifications included in Article 27.2 amount to redefining morality for Members.<sup>84</sup> The view has also been expressed that patents on life forms make the exceptions in Article 27.2 for protecting *ordre*

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<sup>71</sup> India, IP/C/W/161.

<sup>72</sup> Australia, IP/C/M/29, para. 190; United States, IP/C/M/39, para. 113; Canada, IP/C/M/40, para. 111.

<sup>73</sup> India, IP/C/M/24, para. 8.

<sup>74</sup> Kenya, , IP/C/M/28, para. 146.

<sup>75</sup> Brazil, IP/C/M/29, para. 146; Zimbabwe, IP/C/M/39, para. 111.

<sup>76</sup> Kenya, on behalf of the African Group, IP/C/W/163; Zimbabwe, IP/C/M/39, para. 111.

<sup>77</sup> Australia, IP/C/M/28, para. 152; Brazil, IP/C/W/228; Ecuador, IP/C/M/30, para. 184, IP/C/M/25 para. 87; India, IP/C/M/28, para. 127, IP/C/M/25, para. 70; Kenya, IP/C/M/28, para. 143, IP/C/M/40, para. 109; Mauritius on behalf of the African Group IP/C/W/206; Norway, IP/C/M/25, para. 76; Pakistan, IP/C/M/24, para. 86; South Africa, IP/C/M/25, para. 79.

<sup>78</sup> Kenya, IP/C/M/28, para. 141; Mauritius on behalf of the African Group, IP/C/W/206; Zimbabwe, IP/C/M/39, para. 112.

<sup>79</sup> India, IP/C/M/28, para. 126.

<sup>80</sup> Brazil, IP/C/W/228.

<sup>81</sup> Zimbabwe, IP/C/M/39, para. 112.

<sup>82</sup> Kenya, IP/C/M/28, para. 143, IP/CM/40, para. 105; Zimbabwe on behalf of the African Group, IP/C/M/40, para. 75.

<sup>83</sup> India, IP/C/W/161.

<sup>84</sup> Kenya IP/C/M/28, para. 143, IP/CM/40 para. 105.

*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.<sup>85</sup> 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.<sup>86</sup>

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.<sup>87</sup> Cultural and social values of many societies cannot countenance the appropriation or marketing of life in any form or at any stage. The preponderance of such inherent values in particular countries is a matter for democratic domestic legislative process to determine and not for the WTO whose trade mandate is narrow and insufficient to decide on these matters.<sup>88</sup>

30. In response, the view has been expressed that Article 27.2 adequately takes into account ethical concerns as far as patent law is concerned and that other ethical issues have to be addressed and dealt with in other laws, such as on the protection of the environment, public health or animal welfare.<sup>89</sup> In this regard, the point has been made that patents do not guarantee the patent holder unfettered exploitation of the patented invention. Such exploitation is subject to the national law of the Member in question, including on matters of ethics, animal welfare, bio-safety etc. A Member might legitimately enforce its national law to prohibit patentees from exploiting patented inventions for various reasons, including ethical ones. There is no need to exclude inventions from patentability in order to prevent their exploitation.<sup>90</sup> Moral and ethical concerns relating to the research into life-forms and the exploitation of the results of that research are better legislated on directly rather than through patent laws.<sup>91</sup> It has been said that, in fact, excluding particular subject-matter from patentability will not in itself prevent either research or exploitation of such technology.<sup>92</sup> Instead, it could make it more difficult to control, for example by encouraging secrecy.<sup>93</sup> It has also been said that discussion on this issue is difficult because the moral and ethical concerns expressed by some Members about patenting life forms have not been specified.<sup>94</sup>

31. In response, it has been said that, while it may be possible to restrict undesirable research by other means, it has to be taken into account that patents have an incentive effect on research and development. Therefore, restriction of the grant of intellectual property rights can be a tool to discourage research contrary to ethical, cultural or religious standards.<sup>95</sup>

32. The view has also been expressed that Article 27.3(b) already allows Members considerable freedom with regard to the patentability of biotechnological inventions and that it is up to each Member 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 biotechnology inventions is one of the factors for developing domestic skill in this sector.<sup>96</sup> Further it has been said that it should be

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<sup>85</sup> African Group, IP/C/W/404, p. 2; Zimbabwe, IP/C/M/39, para. 115.

<sup>86</sup> African Group, IP/C/W/404, p.4.

<sup>87</sup> Kenya, IP/C/M/40, para 105.

<sup>88</sup> Kenya, IP/C/M/40, para 105.

<sup>89</sup> European Communities, IP/C/M/25, para. 73; Japan, IP/C/W/236; Switzerland, IP/C/M/30, para. 162, IP/C/W/284; United States, IP/C/M/30, para. 176.

<sup>90</sup> Japan, IP/C/M/29, para. 153.

<sup>91</sup> United States, IP/C/W/162.

<sup>92</sup> United States, IP/C/W/209.

<sup>93</sup> Switzerland, IP/C/W/284.

<sup>94</sup> United States, IP/C/W/162.

<sup>95</sup> Brazil, IP/C/W/228.

<sup>96</sup> European Communities, IP/C/W/383, para. 27, IP/C/M/43, para. 40; United States, IP/C/M/39, para. 113.

remembered that Article 27.3 (b) is the result of a carefully negotiated balance.<sup>97</sup> 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.<sup>98</sup>

D. CONDITIONS OF PATENTABILITY IN ARTICLE 27.1 AND PLANT AND ANIMAL INVENTIONS

33. The way in which the basic criteria for patentability set out in Article 27.1, namely novelty, inventive step (or non-obviousness) and industrial applicability (or usefulness), should be applied in the case of micro-organisms and micro-biological processes and other plant and animal inventions that may be patentable under national law has been discussed. In this regard, the view has been expressed that the lack of clear definitions of the conditions for patentability has left grey areas, in particular with respect to the definition of the term "invention" and the scope of patentable micro-organisms and microbiological or non-biological processes.<sup>99</sup> Leaving the issue purely to the discretion of Members could give rise to a number of concerns.<sup>100</sup>

34. Another view is that it should be left up to the domestic laws and practices of the national patent offices to define these matters.<sup>101</sup> That freedom constitutes part of the flexibilities in the TRIPS Agreement.<sup>102</sup>

35. One issue raised has been the use of **unduly low thresholds for novelty, inventive step and industrial applicability**. It has been said that the lax criteria applied by some Members is undermining the patent system as a whole.<sup>103</sup> Concern has been expressed that some patent offices either do not have appropriate procedures or reward their examiners on the basis of the number of patent applications handled, thereby encouraging examiners to be less than careful in granting patents.<sup>104</sup> In this context it has been said that over-broad patents can restrict access to genetic material and restrict or raise the cost of research, thus giving rise to questions of compatibility with the CBD.<sup>105</sup>

36. The issue of the distinction to be made between **discoveries and inventions**, and, in particular, what is required to satisfy the test of **inventive step** (or non-obviousness) has been raised. It has been said that, by stipulating the patenting of micro-organisms and micro-biological processes, the TRIPS Agreement violates the basic tenet of patent law that, while discoveries are not patentable, inventions are.<sup>106</sup> It has also been said that there is need for a clearer understanding of which stages of research into genetic resources, including genetic parts and components, constitute "discoveries" and which ones fulfil the requirements of being an invention.<sup>107</sup> A specific point that has been made in this connection relates to the patenting of genetic materials in their natural state.<sup>108</sup> It has been argued that some Members define inventions to include discovery of naturally occurring matter, or the mere

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<sup>97</sup> Canada, IP/C/M/40, para. 112.

<sup>98</sup> China, IP/C/M/37/Add.1, para. 201.

<sup>99</sup> India, IP/C/W/161; IP/C/M/28, para. 128.

<sup>100</sup> India, IP/C/M/28, para. 126.

<sup>101</sup> Venezuela, IP/C/M/29, para. 199.

<sup>102</sup> European Communities, IP/C/M/43, para.40; United States, IP/C/M/37/Add.1, para. 209, IP/C/M/39 para. 113.

<sup>103</sup> Brazil, IP/C/W/228.

<sup>104</sup> Brazil, IP/C/M/29, para. 146, IP/C/W/228; India, IP/C/M/28, para. 126.

<sup>105</sup> Brazil, IP/C/M/25, para. 94, IP/C/W/228.

<sup>106</sup> Kenya on behalf of the African Group, IP/C/W/163, Mauritius on behalf of the African Group, IP/C/W/206; Zimbabwe, IP/C/M/39, para. 112.

<sup>107</sup> Malaysia, IP/C/M/32, para. 143; Cuba, IP/C/M/40, para. 118.

<sup>108</sup> Brazil, IP/C/M/29, para. 146; India, IP/C/M/25, para. 70; Kenya, IP/C/M/28, para. 141; Kenya on behalf of the African Group, IP/C/W/163; Peru, IP/C/M/29, para. 175; Zimbabwe, IP/C/M/39, para. 112.

isolation of such matter, and that this has led to patents on life forms found in their natural state and on research materials.<sup>109</sup> It has been questioned whether the mere act of isolation of genetic material from its natural state would satisfy the test of non-obviousness or of the inventive step.<sup>110</sup> The view has been expressed that the negotiating history of the TRIPS Agreement shows that the negotiators were not able to agree that the task of isolating a bacterium would satisfy the inventiveness test.<sup>111</sup> It has also been said that, however costly it may be today to isolate a micro-organism, in many instances it may correspond better to a mere discovery than to an invention.<sup>112</sup> Members should be able to limit the grant of patents in respect of micro-organisms to those that had been transgenetically modified and satisfy the requirements of patentability.<sup>113</sup>

37. In response, it has been said that mere discoveries, not involving human intervention, are not considered patentable subject-matter.<sup>114</sup> Examples have been given to illustrate the point, relating to ores, natural phenomena, chemical substances or micro-organisms found in nature. Life-forms in their natural state would not satisfy the criteria for patentability in the TRIPS Agreement.<sup>115</sup> It has been elaborated that if, however, naturally occurring things, such as chemical substances or micro-organisms, have been first isolated artificially from their surroundings in nature they are capable of constituting an invention. It has also been said that the subject-matter of a patent has involved sufficient human intervention, such as isolation or purification, and if the isolated or purified subject-matter is not of a previously recognized existence, then it is considered an invention.<sup>116</sup> Plants, animals or micro-organisms and other genetic resources would have to be altered by the hand of man or produced by means of a technical process to satisfy the criteria of patentability.<sup>117</sup>

38. In regard to **novelty**, it has been argued that universal novelty should be introduced in order to deal with piracy of traditional knowledge.<sup>118</sup> It has been said that some members define novelty in a manner that does not recognize information available to the public through the use of oral traditions outside their domestic jurisdictions.<sup>119</sup> This point is more fully discussed in the Secretariat's summary note on the protection of traditional knowledge and folklore. In regard to the patent obligations on micro-organisms in the TRIPS Agreement the point has been made that the mere fact that a micro-organism or a gene has existed in nature does not mean that it has become known to the public and ceases to be "new" for patent purposes.<sup>120</sup>

39. It has been questioned whether some patents claimed over micro-organisms adequately fulfil the requirements of **industrial applicability** as the usefulness of the inventions is often unclear even

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<sup>109</sup> Kenya, IP/C/M/28, para. 141.

<sup>110</sup> India, IP/C/M/29, para. 161; Zimbabwe, IP/C/M/39 para. 112.

<sup>111</sup> India, IP/C/M/29, para. 161.

<sup>112</sup> Brazil, IP/C/W/228.

<sup>113</sup> Brazil, IP/C/W/228.

<sup>114</sup> Japan IP/C/M/29, para. 151, IP/C/W/236; Switzerland, IP/C/M/30, para. 164.

<sup>115</sup> Japan, IP/C/M/29, para. 151; Switzerland, IP/C/M/30, para.164; United States, IP/C/M/28, para. 131, IP/C/M/25, para. 71, IP/C/W/209.

<sup>116</sup> Australia, IP/C/M/24, para. 83; European Communities, IP/C/W/254; Japan, IP/C/M/29, para. 151, IP/C/W/236; Malaysia, IP/C/M/30, para. 179; Switzerland, IP/C/M/30, para. 164; United States, IP/C/M/29 para. 186.

<sup>117</sup> European Communities, IP/C/W/254; Japan, IP/C/M/29, para. 151, IP/C/W/236; Switzerland, IP/C/M/30, para. 164; United States, IP/C/M/29, para. 186; United States, IP/C/M/37/Add.1, para. 209.

<sup>118</sup> Kenya, IP/C/M/40, para. 109.

<sup>119</sup> India, IP/C/M/28, para. 126; Kenya, IP/C/M/28, para. 141; Zimbabwe, IP/C/M/39, para. 112.

<sup>120</sup> Japan, IP/C/W/236.

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

40. A general point made in relation to the above concerns has been that, if the criteria for patentability have not been properly applied, the patent system provides for opposition and revocation procedures to remedy such situations.<sup>123</sup> In response, concerns have been expressed about the financial and other resource costs and delays involved in keeping track of such patents and using such procedures, especially where pre-grant opposition is not possible.<sup>124</sup>

41. There has been some discussion on the **patenting of genes** and, more specifically, DNA sequences. It has also been said that there appeared to be a number of different views among Members on the granting of patents in regard to DNA sequences<sup>125</sup>: it is sufficient to discover a certain sequence of the DNA; it is necessary also to describe the function of the DNA sequence; a distinct diagnostic and therapeutic application should also be identified for the particular DNA sequence. In the discussion, it has been said that a gene, if isolated and purified from the originating biological material, should be considered to be an invention as it is a particular kind of chemical substance. This is because micro-organisms and genes could be characterised in the patent claims by their structure, by parameters or by other appropriate means.<sup>126</sup> In response it has been said that, while in some cases the biological material is also a chemical, as in the case of artificial enzymes, and hence could be patentable as a chemical, the TRIPS Agreement does not require genes to be patentable, since they are parts of living organisms, except if they also qualify as a micro-organism that is patentable under the national law.<sup>127</sup>

42. The role of the correct application of patentability criteria, organized databases and effective post-grant opposition procedures in preventing erroneously granted patents has also been discussed in the context of the relationship between TRIPS and the CBD and in the context of the protection of traditional knowledge and folklore. The point is therefore discussed in more detail in the two summary notes on these topics (IP/C/W/368/Rev.1, IP/C/W/368/Rev.1/Corr.1) and (IP/C/W/370/Rev.1).

### III. ISSUES RELATING TO THE *SUI GENERIS* PROTECTION OF PLANT VARIETIES

43. This section is concerned with the issues that have been raised and points made with regard to the provision of Article 27.3(b) relating to the *sui generis* protection of plant varieties. After summarizing points made on some general issues, the section then describes the views that have been expressed about: first, what are the elements of an effective *sui generis* system; second, the relationship between the TRIPS provision and the International Union for the Protection of New Varieties of Plants (UPOV) Convention, and, third, the relationship with traditional knowledge and farmers' rights.

#### A. GENERAL ISSUES WITH RESPECT TO PLANT VARIETY PROTECTION

44. This sub-section deals with the general issues raised in the discussion on the protection of plant varieties including whether or not such protection should be accorded and whether or not the provisions contained in Article 27.3(b) are balanced or need to be amended.

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<sup>121</sup> Brazil, IP/C/W/228; Zimbabwe, IP/C/M/39, para. 112.

<sup>122</sup> Pakistan, IP/C/M/26, para. 64.

<sup>123</sup> Switzerland, IP/C/M/30, para. 164.

<sup>124</sup> India, IP/C/W/161.

<sup>125</sup> Pakistan, IP/C/M/26, para. 64.

<sup>126</sup> Japan, IP/C/M/29, para. 151, IP/C/W/236.

<sup>127</sup> India, IP/C/W/161.

45. With regard to the **question of why plant varieties should be protected**, the point has been made that such protection allows development of new technological solutions in the field of agriculture.<sup>128</sup> It encourages the easy introduction of new varieties and ensures that breeders continue breeding effectively.<sup>129</sup> More particularly, the point has been made that improvements in agricultural biotechnology have resulted in the design of new plants through direct manipulation of the genome of a plant rather than reliance upon conventional plant breeding techniques that involve a trial and error process. Advances in the area include the development of new crops with higher productivity and yields and with disease resistance.<sup>130</sup> Further, it has been said that strengthening plant varieties protection ensures a more efficient agricultural sector.<sup>131</sup>

46. On the other hand, concerns have been expressed that the protection of plant varieties can have an adverse impact upon the fulfilment of the national goals of developing countries, in particular in regard to food security, health, rural development and equity for local communities whose traditional knowledge systems have produced staple varieties, including varieties that have medicinal and biodiversity value.<sup>132</sup> It has been suggested that plant variety protection could lead to excessive dependence on foreign commercial breeders, and that such persons could not always be relied upon.<sup>133</sup> Concern has also been expressed about the possible adverse implications for the cooperative relationships among neighbouring farmers that are common in developing countries and the difficulty of traditional farmers in having the capacity or education required to use the system to protect their own interests.<sup>134</sup> The view has further been expressed that although the TRIPS Agreement is not to apply to least-developed countries until 2006,<sup>135</sup> and 2016 with respect to pharmaceutical products, the imposition of patenting requirements on some least-developed countries is imminent through bilateral arrangements.<sup>136</sup>

47. With respect to the question as to whether provisions in the TRIPS Agreement relating to the protection of plant varieties strike the right **balance between right holders and other interests** that are involved, two views have been expressed:

- Article 27.3(b) provides a certain degree of flexibility to Members in deciding on the most effective means of *sui generis* protection for plant varieties and that the status quo should be maintained;<sup>137</sup>
- while preserving the flexibility in Article 27.3(b), clarification of the term "effective *sui generis* system" is needed<sup>138</sup> and Members should confirm and lock in, by way of a decision, a common understanding that Members have the right and freedom to determine and adopt appropriate regimes.<sup>139</sup> Members should also confirm a

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<sup>128</sup> Japan, IP/C/M/29, para. 152, IP/C/M/40, para. 98; United States, IP/C/W/162.

<sup>129</sup> Japan, IP/C/M/40, para.98.

<sup>130</sup> Japan, IP/C/M/29, para. 152, IP/C/M/40, para. 98; United States, IP/C/W/162.

<sup>131</sup> Norway, IP/C/M/43, para. 52.

<sup>132</sup> Mauritius on behalf of the African Group, IP/C/W/206; Peru, IP/C/M/29, para. 175; Zimbabwe, IP/C/M/36/Add.1, para. 201; Kenya, IP/C/M/40, para. 108.

<sup>133</sup> Kenya, IP/C/M/28, para. 145.

<sup>134</sup> India, IP/C/M/28, para. 125.

<sup>135</sup> On 29 November 2005, the Council for TRIPS extended the transition period under Article 66.1 for least-developed country Members until 1 July 2013 (IP/C/40).

<sup>136</sup> Bangladesh, on behalf of LDCs, IP/C/M/42, para. 102.

<sup>137</sup> Brazil, IP/C/M/29, para. 147; European Communities, IP/C/M/35, para. 214; Egypt, IP/C/M/25, para. 92; Malaysia, IP/C/M/29, para. 206; Mexico, IP/C/M/26, para. 76; Peru, IP/C/M/29, para. 175; Venezuela, IP/C/M/29, para. 200; Thailand, IP/C/M/42, para. 115.

<sup>138</sup> Brazil IP/C/W/228; India, IP/C/M/25, para. 70; Kenya, IP/C/M/28, para. 146, Kenya on behalf of the African Group, IP/W/163; Thailand, IP/C/M/25, para. 78; European Communities, IP/C/M/35, para. 214.

<sup>139</sup> African Group, IP/C/W/404, p.2; Zimbabwe, on behalf of the African Group, IP/C/M/40, para.79.

common understanding that regardless of what *sui generis* system is adopted for protecting plant varieties, non-commercial use of plant varieties, the system of seed saving and exchange as well as the 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.<sup>140</sup>

48. Specific suggestions for possible clarifications that have been made are:

- reference could be made to the UPOV Convention in Article 27.3(b);<sup>141</sup>
- a footnote should be inserted after the sentence on plant variety protection in Article 27.3(b), stating that any *sui generis* law for plant variety protection can provide for: (i) the protection of innovations of indigenous and local farming communities in developing countries, consistent with the CBD and the International Undertaking on Plant Genetic Resources<sup>142</sup>; (ii) the continuation of traditional farming practices including the right to save and exchange seeds, and sell farmers' harvest; and (iii) the prevention of anti-competitive rights or practices which threaten the food sovereignty of developing countries, as is permitted by Article 31 of the TRIPS Agreement;<sup>143</sup>
- provisions permitting specific exceptions to plant variety rights should be included in the TRIPS Agreement covering, as a minimum, farmers' rights,<sup>144</sup> in particular to sow and share harvested seed of a protected variety, communities' rights and compulsory licensing where plant varieties are not available on reasonable commercial terms, in times of national emergency and in cases of public non-commercial use.<sup>145</sup>

49. The views that have been expressed in response to these suggestions are set out in the discussion below.

#### B. "EFFECTIVE *SUI GENERIS* SYSTEMS" OF PROTECTION

50. The question has been raised as to what constitutes an "effective" system of *sui generis* protection for plant varieties for the purposes of Article 27.3(b). In this respect, two views have been expressed:

- there are specific criteria available to judge the effectiveness of a *sui generis* system;<sup>146</sup>
- the TRIPS Agreement does not specify criteria by which to judge whether a *sui generis* system is effective and therefore this should be left to Members to decide.<sup>147</sup>

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<sup>140</sup> African Group, IP/C/W/404, p.3.

<sup>141</sup> European Communities, IP/C/M/25, para. 74.

<sup>142</sup> See also the International Treaty on Plant Genetic Resources for Food and Agriculture (2001) adopted on 3 November 2001 in Rome. See <http://www.fao.org/ag/cgrfa/itpgr.htm>.

<sup>143</sup> Kenya on behalf of the African Group, IP/C/W/163.

<sup>144</sup> Peru, IP/C/M/37/Add.1, para. 217; Zimbabwe, IP/C/M/40, para. 79; Malaysia, IP/C/M/40, para. 128.

<sup>145</sup> Thailand, IP/C/M/25, para.78.

<sup>146</sup> United States, IP/C/W/209.

<sup>147</sup> India, IP/C/M/25, para. 70; Zimbabwe, IP/C/M/36/Add.1, para. 201; African Group, IP/C/W/404, p.2; Kenya, IP/C/M/40, para. 108.



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 beyond the scope of the law; who is entitled to obtain property rights must be established; the circumstances in which the rights exist and the limitations that apply must be spelt out; the period during which the rights are in force and the circumstances, if any, under which the rights expire early or under which they can be extended must be specified; and the legal action available to the right holder to enforce its rights along with the remedies available must be indicated, unless these are provided for in other laws such as a code of civil procedure.<sup>148</sup>

52. In regard to the **subject-matter that should be protected**, the view has been expressed that such subject matter should be clearly defined<sup>149</sup> and for a *sui generis* system to be considered effective, protection should apply to all plant varieties throughout the plant kingdom.<sup>150</sup> It has been pointed out that, unlike the English and French versions of the text of the TRIPS Agreement, the Spanish version, which is as authentic as the English and French versions, makes it clear that all plant varieties are to be protected.<sup>151</sup> In response, the point has been made that Article 27.3(b) only speaks of a *sui generis* system without providing specific details as to the plant varieties that should be protected.<sup>152</sup> Further, it has been pointed out that some existing *sui generis* systems, such as in the UPOV, which appear to be considered effective models given their long-standing use, do not require protection of the entire plant kingdom.<sup>153</sup>

53. In regard to **the conditions for granting protection**, the view has been expressed that these should be clearly defined.<sup>154</sup> It has been suggested that, in order to be eligible for protection, a variety should be: new, i.e., the variety's propagating or harvested material should not have been sold or otherwise made available for purposes of exploitation of the variety; it should be clearly distinguishable from other known varieties; it should be uniform in that it does not vary beyond what would normally be expected; and the characteristics of the variety should not change through repeated propagation.<sup>155</sup> In response it has been said that the suggested determinants of entitlement to protection, namely novelty, distinctiveness, uniformity and stability, go beyond the determinants contained in existing models. For example, under the UPOV system, novelty is strictly speaking not a criterion. Further, protection under the International Undertaking on Plant Genetic Resources for Food and Agriculture<sup>156</sup> or the CBD may entitle a farmer's variety to protection, even though such a variety might not be new.<sup>157</sup>

54. In regard to **the rights with respect to the protected subject matter**, the view has been expressed that, 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 and the law should provide for national treatment and most favoured nation treatment.<sup>158</sup> With respect to **who is entitled**

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<sup>148</sup> United States, IP/C/W/209.

<sup>149</sup> European Communities, IP/C/W/383, para. 77.

<sup>150</sup> Uruguay, IP/C/M/28, para. 132.

<sup>151</sup> Uruguay, IP/C/M/28, para. 132.

<sup>152</sup> Peru, IP/C/M/32, para. 128.

<sup>153</sup> India, IP/C/M/29, para. 162; Thailand, IP/C/M/25, para. 78.

<sup>154</sup> European Communities, IP/C/W/383, para. 77.

<sup>155</sup> United States, IP/C/W/209.

<sup>156</sup> See also the International Treaty on Plant Genetic Resources for Food and Agriculture (2001) adopted on 3 November 2001 in Rome. See <http://www.fao.org/ag/cgrfa/itpgr.htm>.

<sup>157</sup> India, IP/C/M/29, para. 162.

<sup>158</sup> European Communities, IP/C/W/383, para. 77.

**to obtain rights** under a *sui generis* system of protection for plant varieties, the view has been expressed that an effective system should ensure that protection for plant varieties is granted only to breeders or others specifically entitled to protection either through contract or law of succession.<sup>159</sup> In response, it has been said that this would mean that, for example, farmers' rights that have arisen through tradition and not through contracts or succession cannot be protected.<sup>160</sup> In turn, it has been said that this would not prevent Members from protecting farmers' rights through other means; it only meant that such protection would not be an obligation under the TRIPS Agreement.<sup>161</sup>

55. In regard to **limitations and exceptions to the rights of the right-holder** it has been suggested that these should include experimental use, the right to use a protected variety for further breeding, compulsory licences and certain exceptions to the benefit of farmers.<sup>162</sup> It has also been argued that regardless of what *sui generis* system is adopted for protecting plant varieties, non-commercial use of plant varieties, the system of seed saving and exchange as well as the 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.<sup>163</sup> In this regard the scope of farmers' privilege and the breeders' exemption has been discussed. While the view has been expressed that these exceptions provide for a balance between the interests and needs of plant breeders and farmers<sup>164</sup> and may ensure biodiversity in accordance with the CBD,<sup>165</sup> it has also been said that it is not clear that there is a commonality of views on the definition of these terms. With regard to the **breeders' exemption**, it has been said that it allows breeders to freely use plant varieties protected by plant breeders' rights in their breeding activities.<sup>166</sup> However, the question has been raised as to whether it is clearly understood that breeders are able to innovate around protected varieties without overly restrictive or prohibitive compensatory conditions in favour of the holders of rights in such varieties.<sup>167</sup> In response, the view has been expressed that the breeders' exemption as contained in the UPOV Convention adequately deals with this concern.<sup>168</sup>

56. With regard to **farmers' privilege**, it has been stated that this allows farmers to replant on their own holdings propagating material of protected plant varieties that they have harvested on their own holdings.<sup>169</sup> It has been said that the issue of whether remuneration must be paid in relation to the exercise of the farmers' privilege is left to the national legislator.<sup>170</sup> In response it has been said that the farmers' privilege should not be limited to saving and re-planting the material only on a farmer's own holdings.<sup>171</sup> It has been said that the TRIPS Agreement would leave scope for certain farmers' exceptions both under patent and plant varieties protection law, provided they are limited to subsistence and small farmers and as long as the commercial interests of plant breeders are protected. While farmers who had an activity on a commercial scale should not benefit from farmers' exceptions, there is room for discussion regarding certain categories of farmers in developing countries.<sup>172</sup> Views

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<sup>159</sup> United States, IP/C/W/209.

<sup>160</sup> India, IP/C/M/29, para. 162.

<sup>161</sup> Switzerland, IP/C/M/30, para. 166, IP/C/W/284.

<sup>162</sup> European Communities, IP/C/W/383, para. 77.

<sup>163</sup> African Group, IPC/W/404, p.3.

<sup>164</sup> Japan, IP/C/W/236; Switzerland, IP/C/W/284; Norway, IP/C/M/43, para. 52.

<sup>165</sup> Kenya, IP/C/M/28, para. 142; Norway, IP/C/M/43, para. 52.

<sup>166</sup> Switzerland, IP/C/W/284.

<sup>167</sup> Mauritius, on behalf of the African Group IP/C/W/206.

<sup>168</sup> Switzerland, IP/C/W/284.

<sup>169</sup> European Communities, IP/C/M/25, para. 74; Switzerland, IP/C/M/29, para. 179; United States, IP/M/25, para. 71, IP/C/W/162.

<sup>170</sup> Switzerland, IP/C/W/284.

<sup>171</sup> Kenya, IP/C/M/28, para. 145; African Group, IPC/W/404, p.3.

<sup>172</sup> Canada, IP/C/M/40, para. 114; European Communities, IP/C/M/37/Add.1, para. 214, IP/C/M/43, para. 38; Norway, IP/C/M/43, para. 52.

have also been expressed about the way in which the issue of farmers' privilege is treated in UPOV 1991; these are summarized in paragraph C.61 below.

57. In regard to **the period of application of the rights**, the view has been expressed that this should be determined, but should be sufficient to allow breeders to recover costs and invest in new research.<sup>173</sup> In this regard, it has been suggested that the right holder should, for a period of at least 20 years from the date rights are granted, be entitled to prevent others from commercializing or taking steps to commercialize the protected variety without the authorization of the right holder. A period of 25 years should apply in relation to new varieties of trees and vines given that the development and commercialisation of such new varieties requires a longer period of time than that for other plant varieties.<sup>174</sup> In response it has been said that the suggested term of protection of at least 20 years, which applies to patents in Section 5 of Part II of the TRIPS Agreement, does not apply to plant variety protection. Effective *sui generis* models, such as the UPOV system, may have a different term of protection.<sup>175</sup>

58. In regard to the **procedures to be followed by potential right holders to obtain rights**, the view has been expressed that such procedures and any fees involved, should be provided for in a comprehensive and transparent way<sup>176</sup> and should apply to foreign nationals on a national treatment basis, as required by Article 3 of the TRIPS Agreement, with a provision for claiming a priority filing date based on filing in the right holder's own country similar to that applicable to patents in the Paris Convention.<sup>177</sup> In response it has been said that *sui generis* models that reflect the practice of reciprocity rather than national treatment should not be deemed to be lowering the level of protection or the effectiveness of the *sui generis* system.<sup>178</sup>

59. With regard to the **enforcement of rights** and it has been suggested that, to create an effective deterrent to infringement, the law should provide for legal and institutional implementation procedures.<sup>179</sup> In this regard, the view has been expressed that effectiveness depends upon the enforceability of a right within a national legal system.<sup>180</sup> More particularly, it has been suggested that the legal actions that must be available to a right holder to enforce rights and the remedies that judicial and administrative authorities must be able to impose on infringers should be those that are currently provided for in the TRIPS Agreement.<sup>181</sup>

60. The view has also been expressed that what can constitute "effective protection" as it relates to the protection of plant varieties, under the TRIPS Agreement, is left to Members to determine<sup>182</sup> and that the review should clarify that *sui generis* systems are domestic laws adopted to protect plant varieties within the context of important domestic goals and other relevant international obligations.<sup>183</sup> In this respect, the view has been expressed that the concept of a "*sui generis*" system is inconsistent with a prescription of rights and duration or even models to be imposed on all WTO Members.<sup>184</sup> As a fair balance between the interests involved may vary between countries and over time, it is the responsibility of each Member to create a system that gives sufficient protection for the parties

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<sup>173</sup> European Communities, IP/C/W/383, para. 77.

<sup>174</sup> United States, IP/C/W/209.

<sup>175</sup> India, IP/C/M/29, para. 162.

<sup>176</sup> European Communities, IP/C/W/383, para. 77.

<sup>177</sup> United States, IP/C/W/209.

<sup>178</sup> India, IP/C/M/29, para. 162.

<sup>179</sup> European Communities, IP/C/W/383, para. 77.

<sup>180</sup> India, IP/C/M/25, para. 70.

<sup>181</sup> United States, IP/C/W/209; European Communities, IP/C/W/383, para. 77.

<sup>182</sup> Kenya, IP/C/M/28, para. 142; Kenya highlighting African Group submission, IP/C/M/25, para. 75; Zimbabwe, IP/C/M/36/Add.1, para. 201.

<sup>183</sup> Kenya, IP/C/M/40, para. 109.

<sup>184</sup> Kenya, IP/C/M/28, para. 142.

involved.<sup>185</sup> The view has also been expressed that the standards for patents might not necessarily be applicable, particularly for countries that have opted to create a *sui generis* system rather than relying upon patents or a combination of systems including patents.<sup>186</sup>

C. RELATIONSHIP BETWEEN THE TRIPS REQUIREMENT TO HAVE AN EFFECTIVE *SUI GENERIS* SYSTEM AND THE UPOV CONVENTION

61. Views have been expressed as to whether the systems of plant variety protection provided for under UPOV constitute effective *sui generis* systems for the purposes of Article 27.3(b). One view has been that, while it is recognized that the TRIPS Agreement does not specifically call for a UPOV model to be followed, UPOV does provide for an effective *sui generis* system as required by Article 27.3(b).<sup>187</sup> Several arguments have been made to support this view and in favour of widespread use of UPOV:

- the UPOV system is the most favourable for encouraging development of new plant varieties in all WTO Members' territories;<sup>188</sup>
- with respect to concerns that have been expressed about the impact of the UPOV system on farmers and plant breeders especially in developing countries, the UPOV system is flexible enough to allow Members to adequately address such concerns through, for example, the farmers' privilege and the breeders' exemption;<sup>189</sup>
- recognizing the difficulties associated with the creation and administration of *sui generis* systems for the protection of plant varieties, the most efficient and rapid way to implement Article 27.3(b) would be to rely on existing harmonised plant variety systems with possible adaptations to ensure special national needs;<sup>190</sup>
- lack of a uniform system like UPOV could reduce market access for small plant breeders and biotech developers because maintaining protection in other markets would be more time consuming and costly;<sup>191</sup>
- the uniformity provided by the UPOV system would facilitate trade in new plant varieties;<sup>192</sup>
- a growing number of countries have signed on to UPOV and the number of protected varieties under UPOV is increasing.<sup>193</sup>

62. In response, the view has been expressed that a reference to UPOV would not be appropriate,<sup>194</sup> for the following reasons:

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<sup>185</sup> Norway, IP/C/M/43, para. 51; IP/C/W/293.

<sup>186</sup> India, IP/C/M/29, para. 162, Thailand, IP/C/M/42, para. 115.

<sup>187</sup> European Communities, IP/C/M/25, para. 74; Japan, IP/C/W/236, IP/C/M/40, para. 98; Switzerland, IP/C/M/30, para. 166; United States, IP/C/W/162; Uruguay, IP/C/M/28, para. 132.

<sup>188</sup> United States, IP/C/M/30 para. 175.

<sup>189</sup> Japan IP/C/W/236; Switzerland, IP/C/M/32, para. 123; Norway, IP/C/M/43, para. 51.

<sup>190</sup> European Communities, IP/C/M/25, para. 74.

<sup>191</sup> United States, IP/C/M/37/Add.1, para. 210.

<sup>192</sup> United States, IP/C/M/37/Add.1, para. 210.

<sup>193</sup> European Communities, IP/C/M/37/Add.1, para. 212; Japan, IP/C/M/40, para. 98.

<sup>194</sup> Norway, IP/C/M/25, para. 76.

- Article 27.3(b) does not bind Members to use UPOV as a model in providing protection for plant varieties, although UPOV may be an important point of reference.<sup>195</sup> More particularly, Members are free to choose a model other than UPOV, such as those based on FAO's International Undertaking on Plant Genetic Resources or the CBD, if they so desire.<sup>196</sup> The appropriate and beneficial approach is to have systems of protection that can address the local realities and needs.<sup>197</sup>
- incorporation of a reference to UPOV into Article 27.3(b) could damage the delicate balance already established in that provision;<sup>198</sup>
- there is no authoritative interpretation as to whether UPOV satisfies the requirements contained in Article 27.3(b);<sup>199</sup>
- UPOV is premised on the protection of plant breeders in industrialized countries rather than the needs of users in developing countries, although the 1978 Act of UPOV allows the recognition of farmers' privilege to re-sow farm-saved seeds.<sup>200</sup>

63. In response, it has been said that the reason why a reference to UPOV does not appear in Article 27.3(b) is because of its limited geographic coverage at the time the TRIPS Agreement was being negotiated.<sup>201</sup> While there may be *sui generis* systems for the protection of plant varieties other than UPOV that meet the requirements of Article 27.3(b)<sup>202</sup> and may be equally effective<sup>203</sup>, such systems would have to be judged on their merits on a case by case basis.<sup>204</sup> It has also been said that Members may implement a minimum set of standards in order to meet their TRIPS obligations.<sup>205</sup>

64. Differing views have been expressed on the merits of the various UPOV conventions and their relationship to the TRIPS Agreement. In regard to **UPOV 1991**, one view has been that it achieves a proper balance of rights and obligations which work to the benefit of all countries and that UPOV 1991 provides the most appropriate system and level of protection.<sup>206</sup> In this regard, the point has been made that the 1991 Act of UPOV does not permit contracting parties to limit the eligibility for protection of varieties by species of plant. This means that newly developed varieties of species of plant that would not have been eligible for protection under the 1978 Act are now eligible for protection under the 1991 Act. However, under UPOV 1991, contracting parties can limit rights so as to permit farmers to save seeds harvested from their own plantings for replanting in subsequent years.<sup>207</sup> The point has also been made that most Members that responded to the questionnaire on the

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<sup>195</sup> Brazil, IP/C/M/30, para. 183, IP/C/M/25, para. 94; India, IP/C/W/161, page 4; Malaysia, IP/C/M/37/Add.1, para. 202, IP/C/M/29, para. 206, IP/C/M/25, para. 83; Mexico, IP/C/M/26, para. 76; Singapore, IP/C/M/30, para. 172; Zambia, IP/C/M/28, para. 147; Zimbabwe, IP/C/M/36/Add.1, para. 201; African Group, IP/C/W/404, p.2.

<sup>196</sup> Brazil, IP/C/M/30, para. 183; India IP/C/W/161; Zambia, IP/C/M/28, para. 147; Zimbabwe, IP/C/M/36/Add.1, para. 201; African Group, IP/C/W/404, p.2.

<sup>197</sup> African Group, IP/C/W/404, p.3.

<sup>198</sup> Brazil, IP/C/M/26, para. 60.

<sup>199</sup> India, IP/C/M/25, para. 70; Thailand, IP/C/M/25 para. 78.

<sup>200</sup> India, IP/C/W/161.

<sup>201</sup> Switzerland, IP/C/M/25, para. 82.

<sup>202</sup> Switzerland, IP/C/M/30, para. 166; United States, IP/C/W/162.

<sup>203</sup> Brazil, IP/C/M/37/Add.1, para. 208; European Communities, IP/C/M/37/Add.1, para. 212, IP/C/M/43, para. 38, Norway, IP/C/M/43, para. 53.

<sup>204</sup> Switzerland, IP/C/M/30, para. 166; United States, IP/C/W/162.

<sup>205</sup> Canada, IP/C/M/40, para.114.

<sup>206</sup> European Communities, IP/C/M/25, para. 74; Switzerland, IP/C/M/24, para. 79; United States, IP/C/M/25, para. 71, IP/C/W/162.

<sup>207</sup> European Communities, IP/C/M/25, para. 74; United States, IP/C/M/25, para. 71, IP/C/W/162.

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

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<sup>210</sup> and not to propagated material.<sup>211</sup> The terminator technology and poverty in developing countries renders the exceptions in UPOV 1991 meaningless.<sup>212</sup> Since the food security of local communities in most developing countries depends largely on their saving, sharing and replanting seeds from the previous harvest, the possibility of having to pay fees for engaging in such activities, as is permitted under UPOV 1991, would negatively affect small rural producers and result in social imbalances.<sup>213</sup> The result would be food insecurity and dependence on commercial breeders abroad for seeds.<sup>214</sup> Further, UPOV 1991 limits exhaustion of the right to sell or otherwise market plant varieties made within the national territory of the contracting party concerned, which might disturb the negotiated balance struck by Article 6 of the TRIPS Agreement.<sup>215</sup> The view has been expressed that, from the perspective of developing country Members, the 1978 UPOV Act remains a useful reference for discussions, even if that instrument is no longer open for membership.<sup>216</sup> Legislation based upon UPOV 1978 should be regarded as providing effective protection for plant variety rights for the purposes of Article 27.3(b).<sup>217</sup>

66. In response it has been stated that the farmers' exemption can be justified under Article 27.3 (b) as an exception to plant variety protection or under Article 30 of the TRIPS Agreement as an exception to patent protection on genetic resources for food and agriculture, as the case may be.<sup>218</sup> There is no need to change the wording of the TRIPS Agreement to allow the national legislator to introduce the farmers' privilege in national patent laws.<sup>219</sup> Least-developed and developing countries whose farming activities are limited to small farms at subsistence level or where commercial activities of farmers are of limited geographical source, could create within their national laws broader farmers' exemptions for the benefit of subsistence farmers or small farmers who customarily reuse seed because they lack access to financial resources for new seeds every growing season.<sup>220</sup>

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<sup>208</sup> Switzerland, IP/C/M/24, para. 79; United States, IP/C/M/24 para. 76.

<sup>209</sup> Switzerland, IP/C/M/24, para. 79.

<sup>210</sup> Kenya, IP/C/M/28, para. 145.

<sup>211</sup> Kenya, IP/C/M/40, para 108.

<sup>212</sup> Kenya, IP/C/M/40, para 108.

<sup>213</sup> Brazil, IP/C/W/228.

<sup>214</sup> Kenya, IP/C/M/40, para 108.

<sup>215</sup> Brazil, IP/C/W/228.

<sup>216</sup> Brazil, IP/C/M/26, para. 60.

<sup>217</sup> Mexico, IP/C/M/25, para. 90.

<sup>218</sup> European Communities, IP/C/M/37Add.1, para. 213, IP/C/W/383, para. 86; Brazil, IP/C/M/37/Add.1 para. 208.

<sup>219</sup> Switzerland, IP/C/W/400/Rev.1, para. 22; Bangladesh, IP/C/M/42, para. 102; European Communities, IP/C/M/42, para. 108.

<sup>220</sup> European Communities, IP/C/M/37/Add.1, para. 214, IP/C/M/40, para. 94, IP/C/M/42, para. 108, IP/C/M/43, para. 38, IP/C/W/383, para. 88; Malaysia, IP/C/M/40, para 128.

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.<sup>221</sup> 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.<sup>222</sup> 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.<sup>223</sup> 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.<sup>224</sup> It has been suggested that the flexibility provided in Article 27.3(b) should therefore be retained and construed consistently with the aforementioned instruments.<sup>225</sup> More particularly, the view has been expressed that the protection of plant varieties should recognize the contribution of farming and indigenous communities to genetic resource conservation and enhancement,<sup>226</sup> should be equitable and should ensure biodiversity.<sup>227</sup>

68. In response, the view has been expressed that, although the TRIPS Agreement does not specifically determine the subject matter to be protected by the *sui generis* system of protection and does not define the term "plant variety", the results of commercial plant breeding are likely to be the primary subject matter to be protected by a *sui generis* system, taking into consideration the overall objectives of the TRIPS Agreement.<sup>228</sup> Reference has been made in this respect to the definition of the term "plant variety" contained in Article 1(vi) of the 1991 Act of the UPOV Convention.<sup>229</sup> Nevertheless, it has been stated, the TRIPS Agreement does not preclude Members from implementing a *sui generis* system of protection for farmers' varieties or so-called "landraces," which generally have characteristics that differ from commercial plant varieties and might, therefore, require their own system of protection.<sup>230</sup>

69. It has been stated that Members are free to protect farmers' rights as defined in Article 15.2 of the draft for a revised International Undertaking on Plant Genetic Resources for Food and Agriculture,<sup>231</sup> but that the farmers' rights currently defined in the International Undertaking cover plant genetic resources and not plant varieties.<sup>232</sup> Furthermore, the definition of farmers' rights is not specific enough to be "an effective *sui generis* system" as required by Article 27.3(b) of the TRIPS Agreement. Therefore, the view has been expressed that national legislation would have to further define farmers' rights in order to satisfy the requirement of "an effective *sui generis* system" under Article 27.3(b).<sup>233</sup> It has been said that the provisions of the International Undertaking and the CBD, on the one hand, and the TRIPS provisions regarding *sui generis* protection of plant varieties on the

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<sup>221</sup> Mauritius on behalf of the African Group, IP/C/W/206.

<sup>222</sup> Kenya, IP/C/M/28, para. 145.

<sup>223</sup> Kenya, IP/C/M/28, para. 145; Mauritius on behalf of the African Group, IP/C/W/206; Zimbabwe, IP/C/M/36/Add.1, para. 201.

<sup>224</sup> Mauritius on behalf of the African Group, IP/C/W/206; Zimbabwe, IP/C/M/36/Add.1, para. 201.

<sup>225</sup> Kenya, IP/C/M/28, para. 145; Mauritius on behalf of the African Group, IP/C/W/206;.

<sup>226</sup> Zambia, IP/C/M/28, para. 147; Zimbabwe, IP/C/M/36/Add.1, para. 201.

<sup>227</sup> Kenya, IP/C/M/28, para. 142.

<sup>228</sup> Switzerland, IP/C/W/284.

<sup>229</sup> Switzerland, IP/C/W/284.

<sup>230</sup> Switzerland, IP/C/M/30, para. 166, IP/C/W/284.

<sup>231</sup> The International Treaty on Plant Genetic Resources for Food and Agriculture (2001) adopted on 3 November 2001 in Rome deals with Farmers' Rights in its Article 9.

<sup>232</sup> Switzerland, IP/C/W/284.

<sup>233</sup> Switzerland, IP/C/W/284.

other hand can and should be implemented in a mutually supportive way.<sup>234</sup> 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.<sup>235</sup>

#### 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.<sup>236</sup> It has been said 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 technology and biotechnology in particular are therefore important issues to be tackled in the context of transfer of technology and capacity building.<sup>237</sup>

71. In the discussion, one view has been to put emphasis on the concern that intellectual property rights in respect of life forms and genetic material could impede access to, and raise the cost of technology in this area, by virtue of the exclusive rights given to right holders to prevent others from using the protected technology. It has been said that the issue of whether and how IPRs such as patents and plant breeders' rights lead to the relocation of investment, transfer and dissemination of technology and research and development in developing countries needs to be examined.<sup>238</sup>

72. In response, it has been said that full implementation of TRIPS provisions, including those in Article 27.3(b) by developing countries, would build confidence among investors, both domestic and foreign, stimulating investment in innovative and creative businesses in these countries.<sup>239</sup> It has been said that where technology is in the hands of the private sector, it can be transferred most effectively through market mechanisms such as licensing and that for licensing agreements adequate intellectual property protection is an important premise. Experience shows that the benefits to recipients and users of technology exceed the cost of acquiring that technology and that they can in time themselves become producers of follow-up technology.<sup>240</sup> The importance of the patent system for discouraging secrecy and its disclosure requirements for facilitating the dissemination of technological and scientific knowledge has already been referred to.<sup>241</sup>

73. Concern has been expressed that excessively broad patent rights in the area of biotechnology may impede the use of micro-organisms and genetic material by others for research purposes.<sup>242</sup> In response, it has been said that the TRIPS Agreement leaves scope to WTO Members to provide for exclusions from patent rights to allow use for research purposes and that this is also the case for *sui generis* plant variety protection, as made clear by the breeders' exception required under UPOV 1991. The point has been made that this access to protected technology for research purposes should

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<sup>234</sup> Switzerland, IP/C/W/284.

<sup>235</sup> European Communities, IP/C/M/35, para. 215.

<sup>236</sup> Mauritius on behalf of the African Group, IP/C/W/206.

<sup>237</sup> EC, IP/C/W/383, para. 15.

<sup>238</sup> Mauritius on behalf of the African Group, IP/C/W/206.

<sup>239</sup> United States, IP/C/W/257, IP/C/M/29, para. 184.

<sup>240</sup> Japan, IP/C/W/236.

<sup>241</sup> Switzerland, IP/C/W/284.

<sup>242</sup> Brazil, IP/C/W/228.



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.<sup>243</sup>

74. In regard to benefit sharing, reference has been made to the requirements in the CBD regarding the provision of access to and transfer of technology to developing countries, especially that which makes use of genetic resources that they have provided. This discussion is summarized in the note on the relationship between the TRIPS Agreement and the CBD.

## **V. INFORMATION ON NATIONAL LEGISLATION, PRACTICES AND EXPERIENCES**

75. At its meeting in December 1998, the Council for TRIPS invited Members that were already under an obligation to apply Article 27.3(b) to provide information on how the matters addressed in this provision were treated in their national law. Other Members were invited to provide such information on a best endeavour basis. A questionnaire was circulated by the Secretariat in document IP/C/W/122 and an alternative questionnaire was circulated by Canada, the European Communities, Japan and the United States in document IP/C/W/126. The information provided by Members in response has been summarized by the Secretariat in the synoptic tables in document IP/C/W/273 and document IP/C/W/273/Rev.1. Since the preparation of that document additional responses have been received from Moldova and Peru, which are listed in the Annex to this document.

76. The following Members have made submissions or comments on their national legislation, practices or experiences in the discussions in the Council for TRIPS: Australia<sup>244</sup>, Canada<sup>245</sup>, China<sup>246</sup>, European Communities,<sup>247</sup> India,<sup>248</sup> Peru,<sup>249</sup> Switzerland<sup>250</sup> and the United States.<sup>251</sup>

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<sup>243</sup> European Communities, IP/C/W/254. This process came to an end with the adoption of the International Treaty on Plant Genetic Resources for Food and Agriculture on 3 November 2001.

<sup>244</sup> Australia, IP/C/W/310.

<sup>245</sup> Canada, IP/C/M/40, para. 112, 114.

<sup>246</sup> China, IP/C/M/37/Add.1, para. 201; IP/C/M/37/Add.1/Corr.1.

<sup>247</sup> European Communities, IP/C/M/37/Add.1, para 213, IP/C/W/383, para. 29.

<sup>248</sup> India, IP/C/W/198.

<sup>249</sup> Peru, IP/C/W/441; IP/C/W/441/Rev.1; IP/C/W/447.

<sup>250</sup> Switzerland, IP/C/W/400/Rev.1, para. 21.

<sup>251</sup> United States, IP/C/M/37/Add.1, para. 211; IP/C/M/39, para. 114.

## **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 discussions in the Council for TRIPS on these issues have been recorded in the reports of the meetings held from August 1999 to January 2006 (IP/C/M/24-35, 36/Add.1, 37/Add.1, 38-40 and 42-49).

Other documents that have been made available include:

- Members' submissions relating to specific issues. Over the period December 1998 to November 2005, 51 papers have been submitted by Members or groups of Members (List B).
- Information on national legislation, practices and experiences provided by eight Members (List C)
- Responses to the questionnaire on Article 27.3(b) from 25 Members (List D).
- Information provided on work in intergovernmental organizations (List E).
- Notes by the Secretariat on relevant issues under discussion in the Council for TRIPS (List F).

| <b>LIST A – Records of the work of the Council for TRIPS</b> |   |                                   |
|--|---|-----------------------------------|
| IP/C/M/21-35, 36/Add.1, 37/Add.1, 38-40 and 42-49            | Minutes of the Council for TRIPS Meetings | 22 January 1999 - 31 January 2006 |

| <b>LIST B - Members' submissions relating to the agenda items</b>                   |                  |   |                  |
|---|------------------|---|------------------|
| <b>2005</b>   |                  |   |                  |
| Bolivia, Brazil, Colombia, Cuba, India, and Pakistan                                | IP/C/W/459       | The Relationship between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge - Technical Observations on US Submission IP/C/W/449  | 18 November 2005 |
| Peru  | IP/C/W/458       | Analysis of Potential Cases of Biopiracy  | 7 November 2005  |
| United States   | IP/C/W/449       | Article 27.3(b), Relationship between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore   | 10 June 2005     |
| Peru  | IP/C/W/447       | Article 27.3(b), Relationship between the TRIPS Agreement and the CBD and Protection of Traditional Knowledge and Folklore  | 8 June 2005      |
| Switzerland   | IP/C/W/446       | The Relationship between the TRIPS Agreement and the CBD, and the Protection of Traditional Knowledge and Folklore and the Review of Implementation of the TRIPS Agreement under Article 71.1   | 30 May 2005      |
| Brazil, India   | IP/C/W/443       | The Relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge: Technical Observations on Issues Raised in a Communication by the United States (IP/C/W/434)           | 18 March 2005    |
| Bolivia, Brazil, Colombia, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand | IP/C/W/442       | 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 Benefit-Sharing under the Relevant National Regime | 18 March 2005    |
| Peru  | IP/C/W/441/Rev.1 | Article 27.3(b), Relationship between the TRIPS Agreement and the CBD and Protection of Traditional Knowledge and Folklore  | 19 May 2005      |
| Peru  | IP/C/W/441       | Article 27.3(b), Relationship between the TRIPS Agreement and the CBD and Protection of Traditional Knowledge and Folklore  | 8 March 2005     |

| <b>LIST B - Members' submissions relating to the agenda items</b>          |                        |   |                   |
|--|------------------------|---|-------------------|
| 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   |
| <b>2004</b>  |                        |   |                   |
| 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 Source of Genetic Resources and Traditional Knowledge in Patent Applications  | 25 November 2004  |
| Bolivia  | IP/C/W/429/Rev.1/Add.1 | Request from Bolivia to be added to the List of Sponsors of document IP/C/W/429/Rev.1   | 14 October 2004   |
| Brazil, Cuba, Ecuador, India, Pakistan, Peru, Thailand and Venezuela       | IP/C/W/429/Rev.1       | Revised Version of Document IP/C/W/429 and Request from Cuba and Ecuador to be added to the List of Sponsors  | 27 September 2004 |
| Brazil, India, Pakistan, Peru, Thailand and Venezuela                      | IP/C/W/429             | Elements of the Obligation to Disclose the Source and Country of Origin of Biological Resources and/or Traditional Knowledge Used in an Invention   | 21 September 2004 |
| Switzerland  | IP/C/W/423             | Additional Comments by Switzerland on its Proposal Submitted to WIPO Regarding the Declaration of the Source of Genetic Resources and Traditional Knowledge in Patent Applications  | 14 June 2004      |
| Bolivia  | IP/C/W/420/Add.1       | Request of Bolivia to be added to the List of Sponsors of Document IP/C/W/420   | 5 March 2004      |
| Brazil, Cuba, Ecuador, India, Peru, Thailand and Venezuela                 | IP/C/W/420             | The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD) - Checklist of Issues   | 2 March 2004      |

| <b>LIST B - Members' submissions relating to the agenda items</b>  |                      |  |                 |
|--|----------------------|--|-----------------|
| <b>2003</b>  |                      |  |                 |
| African Group  | IP/C/W/404           | Taking Forward the Review of Article 27.3(b) of the TRIPS Agreement  | 26 June 2003    |
| Bolivia,<br>Brazil, Cuba,<br>Dominican Republic,<br>Ecuador,<br>India, Peru,<br>Thailand,<br>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/<br>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 |
| <b>2002</b>  |                      |  |                 |
| European Communities and member States   | IP/C/W/383           | 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 | 17 October 2002 |
| Peru   | IP/C/W/356/<br>Add.1 | Request of Peru to be added to the List of Sponsors of Document IP/C/W/356   | 1 November 2002 |
| Brazil, China, Cuba,<br>Dominican Republic,<br>Ecuador,<br>India,<br>Pakistan,<br>Thailand,<br>Venezuela,<br>Zambia and Zimbabwe | IP/C/W/356           | The Relationship between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge  | 24 June 2002    |
| United States  | IP/C/W/341           | Technology Transfer Practices of the US National Cancer Institute's Departmental Therapeutics Programme  | 25 March 2002   |
| <b>2001</b>  |                      |  |                 |
| Australia  | IP/C/W/310           | Communication from Australia: Review of Article 27.3(b)  | 2 October 2001  |

| <b>LIST B - Members' submissions relating to the agenda items</b> |              |  |                   |
|---|--------------|--|-------------------|
| EC  | IP/C/W/254   | Review of the Provisions of Article 27.3(b) of the TRIPS Agreement: Communication from the European Communities and their Member States  | 13 June 2001      |
| Norway  | IP/C/W/293   | Communication from Norway: Review of Article 27.3(b) of the TRIPS Agreement: The Relationship between the TRIPS Agreement and the Convention on Biological Diversity   | 29 June 2001      |
| Switzerland   | IP/C/W/284   | Communication from Switzerland: Review of Article 27.3(b): The View of Switzerland   | 15 June 2001      |
| United States   | IP/C/W/257   | Communication from the United States - Views of the United States on the Relationship between the Convention on Biological Diversity and the TRIPS Agreement   | 13 June 2001      |
| <b>2000</b>   |              |  |                   |
| Brazil  | IP/C/W/228   | Review of Article 27.3(b) - Communication from Brazil  | 24 November 2000  |
| India   | IP/C/W/195   | Communication from India   | 12 July 2000      |
| India   | IP/C/W/196   | Communication from India   | 12 July 2000      |
| India   | JOB(00)/6091 | Non-paper by India: Issues for Discussion under the Review of the Provisions of Article 27.3(b) of the TRIPS Agreement   | 5 October 2000    |
| Japan   | IP/C/W/236   | Review of the Provisions of Article 27.3(b) - Japan's View   | 11 December 2000  |
| Mauritius   | IP/C/W/206   | Communication from Mauritius on behalf of the African Group  | 20 September 2000 |
| Singapore   | JOB(00)/7853 | Non-paper by Singapore - Article 27.3(b)   | 11 December 2000  |
| United States   | IP/C/W/209   | Review of the Provisions of Article 27.3(b) - Further Views of the United States - Communication from the United States  | 3 October 2000    |
| <b>1999</b>   |              |  |                   |
| Andean Group  | IP/C/W/165   | Review of the Provisions of Article 27.3(b) - Proposal on Protection of the Intellectual Property Rights Relating to the Traditional Knowledge of Local and Indigenous Communities - Communication from Bolivia, Colombia, Ecuador, Nicaragua and Peru | 3 November 1999   |
| Canada, EC, Japan and the United States                           | IP/C/W/126   | Review of the Provisions of Article 27.3(b) - Communication from Canada, the European Communities, Japan and the United States   | 5 February 1999   |
| Brazil  | IP/C/W/164   | Review of the Provisions of Article 27.3(b) - Communication from Brazil  | 29 October 1999   |

| <b>LIST B - Members' submissions relating to the agenda items</b> |              |   |                 |
|---|--------------|---|-----------------|
| 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 |
| <b>1998</b>   |              |   |                 |
| Mexico  | Job No. 6957 | Non-paper from Mexico: Application of Article 27.3(b)   | 8 December 1998 |

| <b>LIST C – Information on national legislation, practices and experiences</b> |                         |  |                   |
|--|-------------------------|--|-------------------|
| <b>2006</b>  |                         |  |                   |
| Norway   | IP/C/M/49, para. 120    | Minutes of the Council for TRIPS Meeting   | 31 January 2006   |
| Peru   | IP/C/M/49, paras. 81-84 | Minutes of the Council for TRIPS Meeting   | 31 January 2006   |
| <b>2005</b>  |                         |  |                   |
| Peru   | IP/C/W/458              | Analysis of Potential Cases of Biopiracy   | 7 November 2005   |
| India  | IP/C/M/48, paras. 57-59 | Minutes of the Council for TRIPS Meeting   | 15 September 2005 |
| Norway   | IP/C/M/48, para. 81     | Minutes of the Council for TRIPS Meeting   | 15 September 2005 |
| Peru   | IP/C/W/447              | Article 27.3(b), Relationship between the TRIPS Agreement and the CBD and Protection of Traditional Knowledge and Folklore | 8 June 2005       |
| Peru   | IP/C/W/441/ Rev.1       | Article 27.3(b), Relationship between the TRIPS Agreement and the CBD and Protection of Traditional Knowledge and Folklore | 19 May 2005       |
| Peru   | IP/C/M/47, paras. 16-23 | Minutes of the Council for TRIPS Meeting   | 3 June 2005       |
| Peru   | IP/C/W/441              | Article 27.3(b), Relationship between the TRIPS Agreement and the CBD and Protection of Traditional Knowledge and Folklore | 8 March 2005      |
| Australia  | IP/C/M/46, para. 63     | Minutes of the Council for TRIPS Meeting   | 11 January 2005   |

| <b>LIST C – Information on national legislation, practices and experiences</b> |                                |  |                   |
|--|--------------------------------|--|-------------------|
| <b>2004</b>  |                                |  |                   |
| Peru   | IP/C/M/45,<br>para. 31         | Minutes of the Council for TRIPS Meeting   | 27 October 2004   |
| Chinese Taipei   | IP/C/M/43,<br>para. 58         | Minutes of the Council for TRIPS Meeting   | 7 May 2004        |
| EC   | IP/C/M/43,<br>para. 39         | Minutes of the Council for TRIPS Meeting   | 7 May 2004        |
| Norway   | IP/C/M/43,<br>para. 54         | Minutes of the Council for TRIPS Meeting   | 7 May 2004        |
| EC   | IP/C/M/42,<br>para. 108        | Minutes of the Council for TRIPS Meeting   | 4 February 2004   |
| United States  | IP/C/M/42,<br>para. 110        | Minutes of the Council for TRIPS Meeting   | 4 February 2004   |
| <b>2003</b>  |                                |  |                   |
| Norway   | IP/C/M/40,<br>paras. 87-88     | Minutes of the Council for TRIPS Meeting   | 22 August 2003    |
| Norway   | IP/C/M/39,<br>para. 121        | Minutes of the Council for TRIPS Meeting   | 21 March 2003     |
| Peru   | IP/C/M/38,<br>para. 245        | Minutes of the Council for TRIPS Meeting   | 5 February 2003   |
| United States  | IP/C/W/393                     | Access to Genetic Resources Regime of the United States National Parks   | 28 January 2003   |
| <b>2002</b>  |                                |  |                   |
| India  | IP/C/M/37/<br>Add.1, para. 253 | Minutes of the Council for TRIPS Meeting   | 8 November 2002   |
| New Zealand  | IP/C/M/37/<br>Add.1, para. 248 | Minutes of the Council for TRIPS Meeting   | 8 November 2002   |
| Peru   | IP/C/M/36/<br>Add.1, para. 204 | Minutes of the Council for TRIPS Meeting   | 10 September 2002 |
| United States  | IP/C/W/341                     | Technology Transfer Practices of the US National Cancer Institute's Departmental Therapeutics Programme - Communication from the United States | 25 March 2002     |
| <b>2001</b>  |                                |  |                   |
| Australia  | IP/C/W/310                     | Communication from Australia: Review of Article 27.3(b)  | 2 October 2001    |
| Peru   | IP/C/W/246                     | Communication from Peru: Peru's Experience of the Protection of Traditional Knowledge and Access to Genetic Resources                          | 14 March 2001     |
| <b>2000</b>  |                                |  |                   |
| India  | IP/C/W/198                     | Protection of Biodiversity and Traditional Knowledge - The Indian Experience   | 14 July 2000      |



| <b>LIST D - Information on Review of the Provisions of Article 27.3(b)</b> |                          |   |                   |
|--|--------------------------|---|-------------------|
| <b>2004</b>  |                          |   |                   |
| Moldova  | IP/C/W/125/Add.24        | Review of the Provisions of Article 27.3(b) - Information from Members - Addendum               | 26 January 2004   |
| <b>2002</b>  |                          |   |                   |
| Lithuania  | IP/C/W/125/Add.23        | Review of the Provisions of Article 27.3(b) - Information from Members - Addendum               | 22 July 2002      |
| <b>2001</b>  |                          |   |                   |
| Czech Republic   | IP/C/W/125/Add.8/Suppl.1 | Review of the Provisions of Article 27.3(b) - Information from Members - Supplement             | 18 September 2001 |
| Thailand   | IP/C/W/125/Add.22        | Review of the Provisions of Article 27.3(b) - Information from Members - Addendum               | 10 August 2001    |
| Hong Kong, China   | IP/C/W/125/Add.21        | Review of the Provisions of Article 27.3(b) - Information from Members - Addendum               | 10 July 2001      |
| Estonia  | IP/C/W/125/Add.20        | Review of the Provisions of Article 27.3(b) - Information from Members - Addendum               | 2 July 2001       |
| <b>2000</b>  |                          |   |                   |
| Iceland  | IP/C/W/125/Add.19        | Review of the Provisions of Article 27.3(b) - Information from Members - Addendum               | 17 July 2000      |
| <b>1999</b>  |                          |   |                   |
| Slovak Republic  | IP/C/W/125/Add.18        | Review of the Provisions of Article 27.3(b) - Information from Members - Addendum               | 27 July 1999      |
| Norway   | IP/C/W/125/Add.17        | Review of the Provisions of Article 27.3(b) - Information from Members - Addendum               | 19 May 1999       |
| South Africa   | IP/C/W/125/Add.16/Corr.1 | Review of the Provisions of Article 27.3(b) - Information from Members - Addendum - Corrigendum | 25 May 1999       |
| South Africa   | IP/C/W/125/Add.16        | Review of the Provisions of Article 27.3(b) - Information from Members - Addendum               | 21 April 1999     |
| Switzerland  | IP/C/W/125/Add.15        | Review of the Provisions of Article 27.3(b) - Information from Members - Addendum               | 13 April 1999     |
| Morocco  | IP/C/W/125/Add.14        | Review of the Provisions of Article 27.3(b) - Information from Members - Addendum               | 20 April 1999     |
| Australia  | IP/C/W/125/Add.13        | Review of the Provisions of Article 27.3(b) - Information from Members - Addendum               | 16 March 1999     |
| Canada   | IP/C/W/125/Add.12        | Review of the Provisions of Article 27.3(b) - Information from Members - Addendum               | 12 March 1999     |
| Poland   | IP/C/W/125/Add.11        | Review of the Provisions of Article 27.3(b) - Information from Members - Addendum               | 12 March 1999     |
| Slovenia   | IP/C/W/125/Add.10        | Review of the Provisions of Article 27.3(b) - Information from Members - Addendum               | 16 February 1999  |
| Korea  | IP/C/W/125/Add.9         | Review of the Provisions of Article 27.3(b) - Information from Members - Addendum               | 16 February 1999  |
| Czech Republic   | IP/C/W/125/Add.8         | Review of the Provisions of Article 27.3(b) - Information from Members - Addendum               | 16 February 1999  |
| Japan  | IP/C/W/125/Add.7         | Review of the Provisions of Article 27.3(b) - Information from Members - Addendum               | 12 March 1999     |

| <b>LIST D - Information on Review of the Provisions of Article 27.3(b)</b> |                  |   |                  |
|--|------------------|---|------------------|
| Romania  | IP/C/W/125/Add.6 | Review of the Provisions of Article 27.3(b) - Information from Members - Addendum | 16 February 1999 |
| United States  | IP/C/W/125/Add.5 | Review of the Provisions of Article 27.3(b) - Information from Members - Addendum | 20 April 1999    |
| European Communities   | IP/C/W/125/Add.4 | Review of the Provisions of Article 27.3(b) - Information from Members - Addendum | 10 February 1999 |
| Zambia   | IP/C/W/125/Add.3 | Review of the Provisions of Article 27.3(b) - Information from Members - Addendum | 10 February 1999 |
| New Zealand  | IP/C/W/125/Add.2 | Review of the Provisions of Article 27.3(b) - Information from Members - Addendum | 12 February 1999 |
| Hungary  | IP/C/W/125/Add.1 | Review of the Provisions of Article 27.3(b) - Information from Members - Addendum | 16 February 1999 |
| Bulgaria   | IP/C/W/125       | Review of the Provisions of Article 27.3(b) - Information from Members            | 3 February 1999  |

| <b>LIST E - Information on the work of intergovernmental organizations</b> |                  |   |                 |
|--|------------------|---|-----------------|
| <b>2002</b>  |                  |   |                 |
| UPOV   | IP/C/W/347/Add.3 | Review of the Provisions of Article 27.3(b), Relationship between the TRIPS Agreement and the Convention on Biological Diversity and Protection of Traditional Knowledge and Folklore | 11 June 2002    |
| UNCTAD   | IP/C/W/347/Add.2 | Review of the Provisions of Article 27.3(b), Relationship between the TRIPS Agreement and the Convention on Biological Diversity and Protection of Traditional Knowledge and Folklore | 10 June 2002    |
| CBD  | IP/C/W/347/Add.1 | Review of the Provisions of Article 27.3(b), Relationship between the TRIPS Agreement and the Convention on Biological Diversity and Protection of Traditional Knowledge and Folklore | 10 June 2002    |
| FAO  | IP/C/W/347       | Review of the Provisions of Article 27.3(b), Relationship between the TRIPS Agreement and the Convention on Biological Diversity and Protection of Traditional Knowledge and Folklore | 7 June 2002     |
| <b>2001</b>  |                  |   |                 |
| WIPO   | IP/C/W/242       | Statement by the World Intellectual Property Organization (WIPO) on Intellectual Property, Biodiversity and Traditional Knowledge   | 6 February 2001 |

| <b>LIST E - Information on the work of intergovernmental organizations</b> |                  |   |                  |
|--|------------------|---|------------------|
| <b>2000</b>  |                  |   |                  |
| UNCTAD   | IP/C/W/230       | Document Prepared by the UNCTAD Secretariat for the Expert Meeting on Systems and National Experiences for Protecting Traditional Knowledge, Innovations and Practices which took place from 30 October to 1 November 2000 in Geneva: Outcome of the Expert Meeting | 14 December 2000 |
| International Bureau of WIPO   | IP/C/W/218       | Document Prepared by the International Bureau of WIPO for the Meeting on Intellectual Property and Genetic Resources, which took place on 17 and 18 April 2000 in Geneva: Intellectual Property and Genetic Resources - An Overview                                 | 18 October 2000  |
| International Bureau of WIPO   | IP/C/W/217       | Document Prepared by the International Bureau of WIPO for the Roundtable on Intellectual Property and Traditional Knowledge, which took place on 1 and 2 November 1999 in Geneva: Protection of Traditional Knowledge: A Global Intellectual Property Issue         | 18 October 2000  |
| <b>1999</b>  |                  |   |                  |
| CBD  | IP/C/W/130/Add.1 | Review of the Provisions of Article 27.3(b) - Information from Intergovernmental Organizations - Addendum   | 16 March 1999    |
| FAO  | IP/C/W/130/Add.2 | Review of the Provisions of Article 27.3(b) - Information from Intergovernmental Organizations - Addendum   | 12 April 1999    |
| UPOV   | IP/C/W/130       | Review of the Provisions of Article 27.3(b) - Information from Intergovernmental Organizations  | 17 February 1999 |

| <b>LIST F - Notes by the Secretariat</b> |  |                  |
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| <b>2003</b>                              |  |                  |
| IP/C/W/273/Rev.1                         | Review of the Provision of Article 27.3(b): Illustrative List of Questions Prepared by the Secretariat - Revision                  | 18 February 2003 |
| <b>2002</b>                              |  |                  |
| IP/C/W/370                               | The Protection of Traditional Knowledge and Folklore - Summary of Issues Raised and Points Made                                    | 8 August 2002    |
| IP/C/W/369                               | Review of the Provisions of Article 27.3(b) - Summary of Issues Raised and Points Made   | 8 August 2002    |
| IP/C/W/368                               | The Relationship between the TRIPS Agreement and the Convention on Biological Diversity - Summary of Issues Raised and Points Made | 8 August 2002    |
| JOB(02)/60                               | The Protection of Traditional Knowledge and Folklore - Summary of Issues Raised and Points Made                                    | 18 June 2002     |
| JOB(02)/59                               | Review of the Provision of Article 27.3(b) - Summary of Issues Raised and Points Made  | 18 June 2002     |

| <b>LIST F - Notes by the Secretariat</b> |   |                  |
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| 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     |
|  | <b>2001</b>   |                  |
| Job No. 2689<br>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      |
|  | <b>2000</b>   |                  |
| 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 |
|  | <b>1999</b>   |                  |
| 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       |
|  | <b>1998</b>   |                  |
| IP/C/W/122                               | Illustrative Questions: Review of the Provisions of Article 27.3(b)   | 22 December 1998 |

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