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Council for Trade-Related Aspects of Intellectual Property Rights

MINUTES OF MEETING

Held in the Centre William Rappard
on 17-19 September 2002

Chairperson: Ambassador Eduardo Pérez Motta (Mexico)

The present document contains the record of the discussion which took place on agenda item C during the TRIPS Council meeting held on 17-19 September 2002. The discussion on the remainder of the agenda items (contained in WTO/AIR/1879) will be recorded and circulated as an addendum to this document.

C. PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

1. The Chairman reminded Members that the Council had to find an expeditious solution to the problem stated in paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health ("the Declaration") and report to the General Council before the end of 2002. He said that it was his understanding that the general view of Members was that the Council should be in a position to make concrete recommendations to the General Council about how this matter should be dealt with by the end of this year. He recalled that, at the last TRIPS Council meeting, the Secretariat had circulated, in document IP/C/W/363, its Corrigendum and Addendum, a thematic compilation of the elements contained in the five written proposals and points made in the discussion at the Council's last meeting, as well as factual information on WTO procedures, practices and experiences with regard to each of the four legal techniques proposed. The Secretariat had now issued an update of document IP/C/W/363 as an informal document JOB(02)/102. It reflected, under each of the headings contained in the original document, first, the various proposals made and, then, the comments made at the informal meeting of 24-25 July 2002. In addition, the Council had recently obtained a non-paper from Switzerland in which Switzerland outlined its view on the key elements listed in document IP/C/W/363 according to the chronological order used in that document (JOB(02)/109).

2. The Chairman proposed to structure the discussion on paragraph 6 using the same format that had been used at the informal meeting in July, namely, to discuss the five principal subjects listed in IP/C/W/363, and repeated in JOB(02)/102, to see if there had been any developments in delegations' thinking on any of these subjects. He reminded Members that these five subjects were: first, scope and coverage (item I.A.); second, conditions (item I.B.); third, legal mechanisms (item I.C.); fourth, measures to facilitate production in countries with presently insufficient manufacturing capacity (item II); and fifth, other proposals (item III). In accordance with the suggestion made at the informal meeting in July, the issue of legal mechanisms would be taken up before the issue of conditions.

3. The representative of Lesotho made a general statement covering all issues on paragraph 6. He highlighted the plight of the people in developing countries suffering from diseases such as HIV/AIDS, tuberculosis and malaria and the problems faced while trying to issue compulsory licences under the TRIPS Agreement to deal with these public health situations. He reiterated that the Declaration did not seek to draw a comprehensive list of diseases and that HIV/AIDS, tuberculosis and malaria were mentioned merely as illustrations. It was his view that transparency in the process would ensure the cheapest prices for pharmaceutical products procured to tackle public health needs. In this respect he said that a national tendering process for procurement by the government, which already existed in most WTO Members, would be helpful. In addition to this, a process of notifying the Council while taking advantage of a solution under paragraph 6 would be important. However, he said that the notification process should not be cumbersome as this would be contradictory to the need for rapid measures to deal with situations of emergency due to public health problems and might result in legally binding TRIPS-plus arrangements. He was of the opinion that this should be avoided as developing countries already faced a big burden in adhering to the TRIPS Agreement. A non-binding commitment to adhere to the principles agreed to by Members should suffice to allay fears of exploitation of the paragraph 6 arrangement for purposes other than those allowed in the Declaration and should be a sufficient safeguard to prevent diversion or re-export of products. On the question of eligible supplying countries, he said that Members must be free to exclude themselves. This was because amendment of national legislation might be necessary or a country might have to issue a complementary licence in order to be able to export to a country that had already issued a compulsory licence.

4. With respect to the legal mechanism, he said that his country supported the provision of a waiver in order to deal with the public health situation referred to in the Declaration. He called for safeguards to be put in place so that the benefits were not made unattainable because of misinterpretation. He said that any waiver should be a multi-year one and that the yearly review should be streamlined as it had been done for the review of the waiver given in respect of the obligation under Article 70.9 of the TRIPS Agreement to least-developed countries. The decision to modify or terminate the waiver must be a decision taken by consensus by the General Council. This would be in consonance with the current WTO Agreement and greatly increased the legal certainty of any arrangement. He also said that under this arrangement a compulsory licence should define a "domestic market" as a group of countries or a specific region, for example, a customs union. This, he said, would allow developing countries to pool their resources and make production more attractive for potential manufacturers. In conclusion, he said that the political mileage of the Declaration should be preserved by finding an expeditious solution that was to be communicated to the General Council by the end of 2002.

5. The representative of the World Health Organization said that he was hopeful that the TRIPS Council would find an expeditious solution by the end of this year to the problem of public health and access to medicines, as instructed by the Doha Ministerial Conference, for those other countries with no or insufficient manufacturing capacity in the pharmaceutical industry. The WHO was committed to helping the TRIPS Council in finding this solution. He drew the Members' attention to a paper published by the WHO on the implications of the Declaration. The paper described a solution to the so-called "paragraph 6 problem" desirable from a public health perspective. In his view, the salient features of this solution included the provision of a stable international legal framework, transparency and predictability of applicable rules, simple and speedy legal procedures in the exporting and importing countries, equality of opportunity for countries in need of medicines, including for products that were not patented in the importing countries, multiplicity of potential suppliers of the required medicines from both developed and developing countries and a broad coverage in terms of public health problems and medicines. He reminded Members that the basic public health principle being followed in the solution was that the people of a country that did not have the manufacturing capacity to produce a needed product should be no less protected by compulsory licences and other provisions and safeguards in the TRIPS Agreement, nor face greater procedural hurdles compared to the people of a country capable of producing the product. The solution, he said, that was most consistent with

this principle was the provision of a limited exception under Article 30. Such an exception would, in his view, meet the mandate of the Declaration and provide expeditious authorization to third parties to make, sell, and export patented drugs and other technologies to meet public health needs.

Scope and coverage

6. The representative of Hungary, speaking on behalf of Bulgaria, Lithuania, and Slovenia, said that the mandate of paragraph 6 of the Declaration should be interpreted in light of the whole Declaration and should not be limited to a particular set of WTO Members or a set of diseases. The aim of the Declaration was to provide flexibility in certain provisions of general applicability and, therefore, the diseases listed in paragraph 1 of the Declaration were merely illustrative and not meant to limit the scope of the Declaration itself in any way. He also said that although paragraph 1 made clear that the Declaration was the result of the initiative of a significant number of developing and least-developed countries that faced severe public health problems, the applicability of the flexibility clarified in the Declaration could not be limited to the countries mentioned in paragraph 1. In his view, the mandate of paragraph 6 was a neutral one and referred only to countries with no or insufficient manufacturing capacity in the pharmaceutical sector and not to any established category of WTO Members. It should not, therefore, exclude those countries that chose not to become developing countries under the rules of the WTO. He pointed out that many countries in his part of the world had comparable or lower manufacturing capabilities than many developing countries in the WTO. He said that it would be socially insensitive, and politically and economically unjustified, to exclude *a priori* a group of countries under the scope of the solution presented under paragraph 6. In this respect, he fully empathized with the position of most developing countries that were opposed to any *a priori* limitation on the scope of beneficiaries on the importing side. He also supported the position that any limitation on potential suppliers, by unnecessary narrowing of sources and limiting competition, would have negative implications for prices. He said that the countries he represented attached great importance to finding an effective and permanent solution under paragraph 6 by the end of 2002 but that it would be extremely difficult for them to be party to any narrow interpretation of the Declaration.

7. The representative of Brazil said that the informal meeting of 24-25 July 2002 had been helpful and had strengthened Brazil's view that an authoritative interpretation of Article 30 would be the most efficient solution, keeping in mind the decision-making process within the WTO and the implementation of the provision itself. He expressed appreciation of the input offered by the representative of the WHO in the form of papers and recognized that the WHO also subscribed to the opinion that an authoritative interpretation of Article 30 would be the most consistent and expeditious solution from the public health point of view.

8. With respect to scope and coverage, he recognized that a great number of countries were against a narrow interpretation of the product coverage in the solution. While he did not intend that the solution cover all products related to public health, it was important not to limit product coverage, for example, only to medicines. As pointed out by his delegation earlier, the active ingredient in medicines should be considered a key product that should be included in the coverage. Countries that did not have access to the active ingredients would necessarily be those countries with no or limited manufacturing capacity. Diagnostic kits were also important products for public health purposes of prevention and treatment and should be included in the coverage. While he would like to arrive at a formulation that would cover different understandings of the product scope and coverage, he preferred a reference to "public health related products". In any case, the reference had to be to a clear range of products necessary to protect and promote public health objectives. In this context, he expressed the view that some constructive ambiguity in the terminology could be useful.

9. Regarding the scope of diseases, he said that his delegation would not support any limitation of the solution to specific diseases. The reference to specific diseases in paragraph 1 of the Declaration should not be interpreted as limiting the scope of the Declaration or of paragraph 6. The

appropriate scope of diseases covered should be a reference to "public health problems" and any reference to HIV/AIDS, tuberculosis and malaria should be taken as non-exhaustive examples.

10. He said that, in principle, his delegation would prefer not to exclude any category of importing Members, although a political decision by a developed country Member not to take advantage of the solution should be respected. As already pointed out earlier, Brazil fully supported the position of the African group that nothing in the Declaration limited the eligible supplying Members to developing or least-developed countries alone. Indeed, he agreed that this would severely limit the efficacy of the solution as not many developing countries had the ability to export. Also the decision by a developed country to "opt out" of the solution could be interpreted in a negative way.

11. Turning to the question of importing countries where the product was not patented, he said that this did not seem to be as controversial and that most Members seemed to be open to the idea that the solution should apply to such countries. Given that patent rules would be inapplicable in such countries, there were no legal restrictions at the national level that would limit the means whereby they got access to pharmaceutical products. Where there was no local manufacturing capacity in such countries, an authoritative interpretation of Article 30 would ensure that the production, sale and export from other countries were made on a legally predictable basis. In this connection he expressed the view that it might be useful to consider the proposal of the European Communities and the United States of notification of the request by the importing country as a way of ensuring legal certainty for the suppliers. Such notification should not, however, be limited only to a developing or least-developed country Member, as suggested by the United States, as any Member could qualify as a potential supplier.

12. With respect to the issue of assessment of insufficient manufacturing capacity, he stressed the point that general horizontal manufacturing capacity in many sectors did not translate into actual manufacturing capacity for specific pharmaceutical products. Therefore, any across-the-board criteria to effectively assess insufficient manufacturing capacities for a country would be extremely difficult. This could result in unnecessary limitations and conditions for the beneficiary countries that might need to make use of the solution. Clarifying the point made by Brazil in the informal session that such an assessment should be made product by product, he said that such an assessment should only be made by the Member concerned and not by other Members of the WTO. He also expressed himself against both the proposals of the United States and Switzerland stressing that to assess eligibility would be burdensome on the TRIPS Council and would make the solution less expeditious. Both proposals would unnecessarily narrow down the scope of potential beneficiary countries and were not in keeping with the wording of paragraph 6 or in the spirit of the Declaration. Brazil appreciated and supported the position of Hungary that the scope of potential beneficiary countries under the solution should not be narrowed down.

13. The representative of Switzerland introduced the non-paper circulated to all the Members in document JOB(02)/109. He said that paragraphs 1 and 6 of the Declaration should be read together and that the scope and product coverage of the solution must be circumscribed as precisely as possible by the context of the Declaration and these two paragraphs. He referred the Members to the non-paper and the thematic compilation put out by the Secretariat for a more detailed approach to this issue. In his view, the broader the range of diseases and products covered by the solution, the greater should be the conditions under which these benefits accrued.

14. With respect to the eligibility of beneficiary importing Members, he again referred to the language in paragraph 1 (developing countries and least-developed countries) and paragraph 6 (countries with insufficient or no manufacturing capacity) as guidelines to determine eligibility. It was in order to actualize this that Switzerland had made three proposals: first, to give a block exemption for least-developed countries without further examination of their manufacturing capacities and to follow a case-by-case approach for all other Members seeking eligibility. Such an examination

would be done not by the TRIPS Council but by the Member itself, based on objective criteria to be decided by the Council with respect to the Member's own manufacturing capacity. Second, to make clear that a paragraph 6 solution, including the modalities and safeguards, should be applicable to products that were not patented by a country that sought eligibility to import. Third, to make clear that in no case should OECD countries benefit from the solution as paragraph 6 was intended for those countries with no production capacities or other, especially financial, means to negotiate fairly with suppliers. He said that Switzerland had no final position on eligibility of potential suppliers but that any decision on this should keep in mind that developing and least-developed countries should have an incentive to enhance their own manufacturing capacities.

15. The representative of the European Communities said that based on the interventions by Members so far a consensus solution could be found to the exception under Article 31(f) only if a literal interpretation of the language of the Declaration, especially in paragraph 1 and paragraph 6, was to be adopted. He felt that since this was the compromise reached last year, it would not be wise to reopen the same debate. As far as extending the scope of products covered, he welcomed the use of the term "constructive ambiguity" by the Brazilian delegate in order to find a desirable solution for this particular problem. With respect to the intervention of the Hungarian representative about the inclusion or exclusion of certain countries, he stressed that the debate concerned developing and least-developed countries as mentioned in paragraph 1. In terms of definition of importing countries, he said that his delegation did not think that there was scope to extend the eligibility beyond low-income developing countries. He was aware of the problem that certain developing countries had higher income than some of the current and potential member States of the European Communities and that a solution would have to be found to this problem.

16. In terms of eligible producing countries a decision had not yet been taken by the European Communities. He recognized some value in the argument that when developing countries did not have manufacturing capacity for a certain product then developed countries might function as suppliers. He felt that the proposal put forth by some developing countries, that they should be allowed to choose from products being produced in developed countries when the product there was of better quality or available at a competitive price, merited consideration. But a good way for a developing country that had long-term goals to improve production capacity to do so would be to negotiate technology transfer and engage in local manufacture of products. Such technology transfer would apply only to those countries without significant production capacities, and not to those developing countries that currently had manufacturing capabilities. In his view predictability was very important when deciding on eligibility based on manufacturing capacity and specific criteria towards this end would be a valuable tool in the debate.

17. The representative of Zimbabwe said that on product coverage and eligibility of importing Members his delegation had nothing new to add to what had already been said in previous meetings. On potential suppliers, he said that Zimbabwe preferred that all WTO Member countries should be included. He concurred with Brazil that if developed countries were allowed to exclude themselves, the solution would be an ineffective one. He noted that a number of developed countries, including Switzerland in its non-paper, had not yet expressed a view on potential suppliers and he awaited their views on this matter with great interest. In spite of the view expressed by Switzerland in section 3 of its non-paper, he said that there seemed to be some openness toward Switzerland being a potential supplier which appeared to be indicated by section 2. Here Switzerland appeared to support a strict regime of safeguards against diversion of products to third countries. He said that this proposal opened the way for other developed countries to agree to being suppliers. He agreed with Brazil's view that the list of diseases in the Declaration was merely illustrative and did not restrict the applicability of the Declaration to only those diseases. To clarify the situation, he said that those countries that opposed the extension of the solution to diseases other than those enumerated in the Declaration should give examples of what diseases they would like to see excluded so that all Members could get a better idea of what they had in mind.

18. The representative of Argentina said that the listing of certain diseases in paragraph 1 of the Declaration should not be taken to be an exhaustive list of public health problems sought to be solved by the Declaration. He quoted paragraph 5(c) of the Declaration that stated that public health crises including those of tuberculosis, HIV/AIDS and malaria and other epidemics could represent a national emergency or other circumstances of extreme urgency and said that this should be taken to be a list of examples that did not exclude other circumstances of public health crises not specifically mentioned. He also drew attention to paragraph 4 of the Declaration which reinforced the right of Members to promote public health and gain access to medicines for all. In this context, Argentina believed that the Declaration was applicable to any national emergency or other situations of extreme urgency and that every Member should be able to decide which situation merited classification as one of extreme urgency.

19. Turning to the document IP/C/W/348 prepared by the Secretariat on the existence or non-existence of patent protection in Members, he said that, although this was a valuable contribution to the debate, it was based only on published sources, referred to only a few diseases and used outdated information. Specifically, the document stated that there was no patent granted, or application pending in Argentina with respect to pharmaceutical products relevant to the diseases enumerated in the Declaration. A report received from Argentina's National Institute for Industrial Property, however, stated that there were, in fact, a significant number of patents in the country related to these diseases, namely, 12 related to HIV/AIDS, three related to malaria and 76 other applications pending. This information clearly showed that the entry of such patented products into the public domain would not take place for some time to come. An important factor to be considered in the context of this document was that the date taken as a basis for compiling the information predated the enforcement of the TRIPS Agreement before which many least-developed countries and some developing countries did not allow patents in the pharmaceutical sector.

20. With respect to the evaluation of insufficient manufacturing capacity, he said that Argentina was against the establishment of new categories of countries in the WTO as any such categorization would be detrimental to the interests of developing countries. Without prejudice to the position of developing countries that would like to decide insufficient manufacturing capacities on their own, he thought that it would be desirable to have certain objective criteria as guidelines for this examination. He, however, took note of document IP/C/W/345 which outlined the difficulty in reaching a consensus on such objective criteria. There were methodological inconsistencies in the information in that document that prevented a comparison of the relative merits or demerits of the criteria suggested. For example, the listing of production values of the pharmaceutical industry in various countries was measured over different periods of time. Even where the period of analysis was the same, the evaluation criteria differed according to the variable under consideration. The same sort of problems were seen in the next three lists as well. He stressed that in the establishment of objective criteria the Council should take note of the dynamic development of the pharmaceutical industry. The data on the world pharmaceutical industry used in the document were based on a UNIDO report of 1992 and appeared to be inadequate to meet the needs of decision-making under paragraph 6 because the industry had undergone substantive qualitative and quantitative changes since that date. Moreover, the period referred to in the document, i.e. 1992–1994, was a period in which many developing countries did not allow either product or process patents for pharmaceuticals. Therefore, any conclusion based on empirical data should refer to data collected after the entry into force of the TRIPS Agreement and any objective criteria would have to take two points into consideration: firstly, the distinction between active ingredients and final products and secondly, the distinction between general manufacturing capacity and specific capacity. Paragraph 6 referred to Members with insufficient or no manufacturing capacity and, in the absence of a distinction being made in the Declaration as to active ingredients and final products, this should be taken to refer to insufficient or non-existent manufacturing capacity for both elements. In other words, only if a country had the capacity to manufacture both elements should it be excluded from the solution since a country that could not produce the active ingredient would still be in a position of strategic dependence. The production of active ingredient should, therefore, be taken as a central link. The information on

foreign trade in document IP/C/W/345 did not give any idea of the degree of dependency of each country on the import of the active ingredients as it referred only to product codes 541 and 542 which related to final pharmaceutical products. It was crucial to also collect and analyse data on products relevant to the sector which were included in the Standard International Trade Classification 51 as the majority of the active ingredients for the pharmaceutical industry fell within this group. Any conclusion reached that did not take into account the trade in active ingredients would be based only on partial information. He said that a correct analysis would reveal the dependence of some developing countries, where the numbers appeared to show a high capacity for independent production, on outside trade in active ingredients. In the case of an epidemic such least-developed countries and even developing countries could face a crisis in production of medicines which might not appear to be the case when looking merely at partial industry information. In addition, with respect to general manufacturing capacity and its interpretation to actualize promotion of public health and access to medicines, it had to be recognized that a country might have technical capacity to produce the pharmaceuticals but it might not be economically viable to do so. Similarly, another country might possess significant general manufacturing capacity but not have the equipment or technical capacity or chemical input for the product or sector required. A solution based on static categories of countries would not be appropriate and the solution agreed upon must be one that could be used at least for all least-developed countries and developing countries. Moreover, document IP/C/W/345 assessed the capacity for innovation by unrealistically and inappropriately saying that a country had innovative capacity simply because between 1961 and 1990 it discovered and marketed, within its country, at least one new chemical entity or product. Any analysis that did not consider the high costs of R&D would be faulty. The bulk of the expenditure on R&D, i.e 85 per cent, was spent in developed countries and this correlated with a concentration there of innovation in chemical products. The Secretariat document needed to be reviewed and revised in order to form an appropriate basis for this debate.

21. The representative of Venezuela also called for an update on IP/C/W/345 as soon as possible. The representative said that a paragraph 6 solution would have to take note of the need for the transfer of technology as well. According to document IP/C/W/345, there were 27 countries with advanced pharmaceutical industries with R&D and innovation capabilities and 14 countries that had the capacity to reproduce therapeutic ingredients and final products. The rest of the world, including Venezuela, only produced final products or did not have a pharmaceutical industry at all. Any solution found under paragraph 6 should, therefore, promote the development of production capabilities in these countries, cover all products related to public health and should not be restricted to the illustrative list. Members should have the ability to decide what constituted a national emergency or other situations of extreme urgency. Turning to the legal mechanisms proposed as a solution, she said that her country preferred an authoritative interpretation under Article 30. The other options, namely a moratorium or a waiver, should not be considered as solutions *per se* but could be complementary to an interpretation of Article 30. A moratorium or a waiver, if agreed upon, should only be applicable for a limited period of time. These proposals were also linked to systems of notification and follow-up process in the WTO which were additional burdens of compliance on developing countries.

22. Referring to the Swiss non-paper, she said that the first paragraph placed a limitation on many developing countries and unduly narrowed the set of beneficiary countries. The first paragraph also drew an inappropriate distinction between diseases that caused public health problems and those that did not. In paragraph 2, a case-by-case approach was recommended by Switzerland to decide on the issue of beneficiary importing countries. The representative of Venezuela said that she did not support such a proposal as it amounted to limitations and unnecessary distinctions. Finally, in her view the last paragraph, part C on legal mechanisms, expressed no intention to ensure access to medicines and promotion of public health.

23. The representative of China said that the product scope provided for in the Declaration was a non-exhaustive one. With respect to beneficiary importing countries, she said that the Declaration

made it clear that developing countries, in particular least-developed countries, should be among the main beneficiaries. She also agreed with the view that paragraph 6 should benefit all Members without further categorization, except those that might opt not to benefit from the solution.

24. Turning to the question of conditions, she said that it was unacceptable to consider safeguards or conditions that would in any way limit either the flexibilities of Members under the TRIPS Agreement or under the Declaration. However, appropriate safeguards that ensured legal predictability in the use of the provision could be considered by China. Such safeguards should not undermine the practicality of the solution or prejudice the existing right of countries to use Article 30 of the TRIPS Agreement. Although technology transfer was not a solution that was expedient enough, the Chinese delegate said that this was indispensable to the solution and, in this respect, she supported the proposal of the African group. She said that developed countries should provide incentives under Article 66.2, as reiterated in the Declaration, to enterprises and institutions in their territories to promote technology transfer to least-developed countries. Such measures would create stable manufacturing capacity in the pharmaceutical sector. As for the proposal of a waiver, she said that, although China did not oppose it, it was impractical to propose that consensus could be achieved on a case-by-case application of the waiver.

25. The representative of Kenya, speaking on behalf of the African group, said that the solution under paragraph 6 should preserve the flexibility of the TRIPS Agreement and should be guided particularly by Articles 7 and 8 of the TRIPS Agreement. The essence of the matter, he said, was the affordability and availability of pharmaceutical products. The solution should be simple, easy to use and economically viable as opposed to a legal solution with additional obligations. Some of the proposals, like moratoria and waivers, were not durable proposals that addressed the lack of manufacturing capacity of countries, especially those in Africa. The representative said that on product coverage or diseases there should be no limitations and that the examples in the Declaration were not exhaustive. He said that with respect to assessment of eligibility and manufacturing capacity, there had been no change in his group's position that this should be done on a product-by-product basis. On the question of suppliers, he said that to restrict potential suppliers to any particular category of countries would not be in keeping with the principles of free and fair trade of the WTO.

26. The representative of Peru said that the proposals presented by Switzerland were restrictive and could not be supported by her delegation. On the question of products to be covered, she was in favour of a broad understanding that included not just medicines, but other products such as surgical equipment, active ingredients, diagnostic kits and other such products. She opposed a restrictive list of diseases and was also against excluding any beneficiary country, especially if it was a developing country. She said that developed countries that would like to exclude themselves should be allowed to do so. On the assessment of manufacturing capacity she said that the Member in question should be allowed to determine its own needs. She also said that no *a priori* exclusion of developed countries as potential suppliers should be enforced as this would undermine availability of pharmaceuticals.

27. The representative of Singapore said that product coverage should include medicines to deal with all public health problems and that limiting product coverage would not be useful. With respect to beneficiary importing countries, the Declaration referred only to countries with no or insufficient manufacturing capacity although this did not preclude a developing country from excluding itself from the ambit of the solution. With respect to those countries where the product was not patented, he said that any mechanism decided upon needed to be made applicable to them. He did not support the use of the World Bank criteria of per capita income as a basis to assess countries with insufficient or no manufacturing capacity and said that it was best to leave the determination of beneficiary importing country status to the individual Members themselves. He felt that laying down broad criteria applicable to all sectors could lead to greater complications in the solution. With respect to eligible supplying countries, he said that all WTO Members should be allowed to be potential suppliers because it would lead to competition and lower drug prices for the importing country.

Turning to the issue of diversion, he said that adequate safeguards should be put in place by both importing and exporting countries. To maintain transparency in procedures, he said that both the TRIPS Council and the right holder of the patented product should be notified. In order to cut down on administrative costs, the same notice could be used for both sets of parties. On the question of legal mechanism, he said that, although a number of proposals had been put forward, it was important to maintain legal certainty as well as the integrity of the TRIPS Agreement itself.

28. The representative of Egypt said that, in his view, the meaning of the term "pharmaceutical products" included medicines, active substances, diagnostic kits, and related technical equipment. He said that paragraph 1 of the Declaration was clearly not meant to be exclusive but only illustrative. With respect to eligibility to benefit from the envisaged solution, he said that any attempt to establish a clear-cut rigid classification of countries would be time-consuming and scientifically irrational as this capacity differed from one country to another and from one product to another. He said that each country should voluntarily decide for itself whether or not to be a part of the solution. Such a determination, he said, should not be a pre-solution requirement but a post-solution assessment by countries facing the type of crisis referred to in the Declaration. He said that the right of each government, particularly those that did not want to be beneficiaries, would be maintained as the consent of the country was required for issuing compulsory licences. Finally, he supported the statement made by Kenya on behalf of the African group.

29. The representative of Malaysia supported the statement made by Brazil on behalf of the group of developing countries for an authoritative interpretation of an Article 30 exception which recognized a limited exception to the rights of patent holders so that WTO Members could authorize third parties to manufacture, sell and export patented products to meet the public health needs of the importing beneficiary country in accordance with the procedure laid out in Article 31 of the TRIPS Agreement. She said that a paragraph 6 solution could form one of the exceptions allowed under Article 30. This provided an expeditious solution as opposed to the time-consuming process of an amendment. The solution should extend to all countries that had insufficient or no manufacturing capacity. Lack of manufacturing capacity did not mean lack of technological infrastructure only. Economies of scale should form an important part of the assessment and a situation might arise in the future where a condition might have to be reversed. Any determination of manufacturing capacity should be carried out by the country itself and any objective criteria set out must follow the principles in paragraph 6. She said that paragraph 1 of the Declaration provided guidance on the extent of product coverage but that it was difficult to define product coverage until the specific public health problem was known. She said that a pre-determined definition would circumscribe the ways to overcome the problem. Also limiting the suppliers to developing countries alone made the solution presented by compulsory licences, ineffective.

30. The representative of Australia said that the Declaration clearly articulated the scope and coverage of the proposed solution as it covered pharmaceutical products needed to deal with HIV/AIDS, tuberculosis, malaria and other epidemics. More detail on the criteria would, however, be necessary to provide certainty to patent holders and recipient countries. During the drafting of the solution, there should be scope to allow for some changes in product coverage. He said that additional products like active ingredients or diagnostic kits could only be included in the agreed criteria if they were related to the specific diseases mentioned. A key safeguard to be included was the limitation in a compulsory licence that the patented product would only be used to deal with the specified diseases. On the question of general eligibility of importing beneficiary Members, he said that, at the very least, the criteria must specify the inclusion of least-developed countries and exclusion of industrialized countries. Developing countries' eligibility was to be decided on manufacturing capability and in this context he said that the Declaration made it clear that each Member had the right to grant compulsory licences and to decide the grounds on which such licences were granted. The final drafting should take special note of the circumstances of those countries that had not granted patents to these products within their own territory. He said that, with respect to assessing manufacturing capacity, objective criteria were necessary but also said that this was a matter

for further discussion. On the question of eligible supplying Members, he said that Australia did not have a final position on the subject.

31. The representative of Canada said that her delegation supported the statement made by the representative of Lesotho on the need to have an illustrative list of diseases. This need, she said, was met by paragraph 1 of the Doha Declaration. She agreed with the proposal presented by Switzerland that least-developed countries should be eligible *per se* and supported the suggestion of Egypt that Members should be able to self-declare as to whether they faced a situation of national emergency and did not have manufacturing capacity. It would be useful, however, to develop objective criteria to help in that determination. On the question of eligibility of suppliers posed by Zimbabwe and Brazil, she said that her delegation had yet to take a final position on the matter, but that this would require legislative changes in Canada and many other developed countries which would contradict the desire for an expeditious solution. She concluded that both developing countries and right holders were an indispensable part of any final solution.

32. The representative of Korea said that, with respect to the scope of diseases covered, the reference in paragraph 1 of the Declaration should be respected. He said that the list was illustrative and that the addition of the term "other epidemics" allowed a certain level of flexibility in determining such cases in the future. At present, he said, work should focus on the diseases mentioned though the flexibility to include other epidemics should be preserved. With respect to product coverage, he said that it should include medicines as well as other materials. In the pharmaceutical sector, production of medicines always included active ingredients and other procedures. He said that such an understanding was effective especially where the patents for active ingredients and other materials needed for production of materials were held by different right holders. Diagnostic kits had a different physical nature from medicines but they should be included too if they were necessary to deal with a national emergency in public health.

33. With respect to beneficiary importing countries, he said that paragraph 6 of the Declaration was drafted to provide a solution to the public health needs of least-developed countries and developing countries and that any solution should necessarily include such countries. On the question of assessment of manufacturing capacity, he said that each Member should be allowed to self-declare. This was because a country that had sufficient manufacturing capacity already had an alternative that was better than that provided under the solution. He supported the development of objective criteria that would guide such self-determination by eligible Members. On the question of eligible supplying Members, he said that he saw no reason to set any *ex ante* limitation on the scope of supplying Members. The decision whether or not to supply the pharmaceuticals requested should be left to the Member that was approached.

34. The representative of Japan said that, with respect to product coverage, this should include only patented products as described in the wording of paragraph 1 of the Declaration. Other comprehensive measures not directly related to paragraph 6 should play an important role in tackling the serious situation. With respect to beneficiary importing Members, he said that no new criteria other than insufficient or no manufacturing capacity should be used to classify Member countries as this would lead to further complications. As for supplying Members, the most eligible countries were those developing countries with sufficient manufacturing capacity. Japan, he said, took this position for three reasons: (a) there were many developing countries with adequate pharmaceutical manufacturing capacities; (b) such developing countries would be in a better position to supply medicines at affordable cost as this was what was required under the solution; and (c) limiting the supplying countries to developing countries would also be an incentive to such countries to further develop their manufacturing abilities.

35. The representative of Norway said that the views of his delegation on scope and product coverage were reflected in JOB(02)/102 put out by the Secretariat. On the subject of supplying countries he said that there was no convincing reason to restrict this to any particular category of

countries. Any country, developing or developed, must be able to respond to a request made by a beneficiary importing Member country. This was the only way to make a solution under paragraph 6 a practical and effective one.

36. The representative of Ecuador said that the flexibility in Articles 7 and 8 of the TRIPS Agreement was the sort needed to find an appropriate solution under paragraph 6. No country was immune to public health problems of great severity, so there was no good reason to restrict the solution under the Declaration to any particular set of countries. Least-developed countries and developing countries should, however, be the major beneficiaries of the solution and every country should be able to decide whether to take advantage of the solution or not. Ecuador, and many other developing countries, lacked manufacturing capacity and a solution should extend to all such developing countries. Coverage should include a broad range and not be restricted only to pharmaceutical products as each country should have the flexibility to decide how to deal with public health problems. As to the source of such products, the country that lacked manufacturing capacity should be able to decide which country to approach. All countries with sufficient manufacturing capacity able to help countries with serious health problems should do so. With respect to the Doha Declaration only the country involved could decide how serious the situation was and there should be no limitation as to the diseases or epidemics being addressed under the solution.

37. The representative of Hungary said that the scope of the solution should not be limited only to patented products that were related to the diseases mentioned explicitly in the Declaration. All products necessary to deal with a public health crisis should be part of the arrangement, including patented products and those that were produced through patented processes. He said that the solution should also be extended to active ingredients and diagnostic kits. Excluding developed countries from potential source countries would limit competition and have an obvious adverse impact on the price at which importing beneficiary countries could obtain the products required. The representative said that restricting the supplying countries to developing Members would not in itself be sufficient incentive for pharmaceutical companies to set up manufacturing units in such countries. In addition to the economic implications of limiting supplier countries, a strong political message would be sent out if developed countries were excluded from the scope of potential suppliers and his country did not want to be party to that message.

38. On the question of assessment of insufficient manufacturing capacity, he said that such examination could only be done on a case-by-case basis by each country. The dynamic nature of the pharmaceutical industry in terms of new drugs and technologies being created, as well as changing geographical patterns of production, should be part of such an assessment under any solution. Given these dynamics, it would not be practical to draw up a list of countries with insufficient manufacturing capacity, which would have to be constantly updated. Against this background, assessment should be made by each country with the help of an indicative set of objective criteria decided upon by the TRIPS Council. On the question of which WTO Members should benefit, he said that neither the World Bank criteria nor the membership of any particular international organization should limit the countries that could benefit from the paragraph 6 solution.

39. The representative of Indonesia said that the Declaration gave a mandate to each country to decide for itself what constituted a public health crisis or a national emergency. Narrow definitions on scope of diseases should, therefore, be avoided. She said that, since it was difficult to define a public health crisis, the product coverage should not be limited and should extend to all related pharmaceutical products and processes, including active ingredients needed to deal with the situation. The eligibility of importing countries was an integral part of paragraph 6 of the Declaration and should not be limited. Public health crises were not exclusive to any particular category of countries and, therefore, it would be ineffective to limit the benefit of the solution under paragraph 6. Developing countries, especially least-developed countries, should be the major beneficiaries of the solution and any country that wanted to exclude itself from being an importing country should be able to do so. On the question of assessing manufacturing capacity, she said that each country should be

able to assess this on their own in relation to particular products but an international standard could be set to allow for this assessment. The elements of such an international standard should include manufacturing capacity to produce active ingredients, technical capability, economic feasibility and economies of scale.

40. The representative of the Czech Republic said that any solution acceptable to all Members would have to be consistent with the architecture of relevant provisions of the TRIPS Agreement itself. Drawing a distinction between different categories of countries at this stage was not going to help solve national emergencies or other extreme situations. An *a priori* exclusion from the solution would not be effective to help Members in such circumstances. A case-by-case approach to assessing manufacturing capacity, based on clear and transparent objective criteria in importing countries, was a very constructive and reasonable approach. Once the criteria and conditions under which paragraph 6 could be invoked, as well as safeguards against abuses and diversion, were decided it would be easier to reach a consensus as to who should have access to the system.

41. The representative of Hong Kong ,China said that on the question of coverage there should be flexibility to decide on the patented products that were related to the pandemic diseases in question. Apart from the pharmaceutical products themselves, it was probable that methods of delivery or diagnostic kits might also be patented and it was reasonable that the scope of a solution should include these. With respect to the beneficiary economies too, there should be flexibility in assessment. It was his opinion that the list of diseases in the Declaration was not an exhaustive one. In the context of the war on terrorism, it was important that flexibility to deal rapidly with any new situation that might arise should be preserved. Regarding the question of lack of capacity, he said that it was important that this should not function as a test. The lack of capacity, being a negative proposition, was always going to be hard to prove. In any case, he agreed that least-developed countries should be included *per se* as having insufficient capacity to manufacture. The representative said that simple, objective criteria should be developed which Members could use for self-assessment. With respect to potential suppliers, he said that only if every country was included could availability and affordability be ensured. He also said, however, that most industrialized countries with advanced intellectual property regimes might be unable to participate in the system because of domestic legal mechanisms and this was not a problem that the Council was able to address in a timely manner. Therefore, although it seemed likely that it was only the developing countries that could function as suppliers, industrialized countries should not be barred from being potential suppliers.

42. The representative of New Zealand said that she took paragraph 1 of the Declaration as a starting-point for any solution under paragraph 6. Although it was broadly recognized that the diseases listed were only illustrative, it was a useful tool to decide upon other diseases of similar magnitude. She said that initially New Zealand was of the view that, at a maximum, least-developed countries and developing countries should be part of the solution under paragraph 6. A number of countries would, however, like to see this reduced and yet others would like to see this increased. She said that Brazil's proposal that a Member could exclude itself if it wanted to, as well as the Swiss suggestion that OECD countries should be excluded, were both acceptable to her delegation. Also, she said, these two proposals were not mutually exclusive and could help in the event that the Council was not able to agree on any other means of recognizing different levels of need for a solution under paragraph 6. She was of the view that the Council should try and develop some broad and objective criteria to help in the self-assessment by Members.

43. The representative of India said that his views were adequately reflected in document JOB(02)/102. He said that he would prefer a broad interpretation of product coverage that would help countries that had insufficient or no manufacturing capacity to develop indigenous production capabilities. To this end, it was necessary for importing countries to have access to the active ingredient at least in the preliminary stages of development of their own industries. He supported the statements of Brazil and of the European Communities and said that "constructive ambiguity" in the

definition of product coverage would help Member countries to deal with public health problems in a comprehensive manner.

44. The representative of the United States said that the documents provided by the Secretariat and Switzerland demonstrated the growing consensus in certain areas among the Members which would help in finding an expeditious solution by the end of the year. The area where there was some commonality were product scope and diseases. He said that he was against an overly narrow interpretation of diseases but, at the same time, it was clear that the language of paragraph 1 was an indication of the gravity and seriousness of the situation of some epidemics that had caused Members to focus on them. The reference to the pharmaceutical sector in this context was not, in his view, a reference to all areas of technology. In this context, he agreed that some constructive ambiguity would be useful in the interpretation. It was more difficult to agree on the countries that were to be included as beneficiaries of such an arrangement. He said that in the run-up to the Declaration, it was clear that least-developed countries, as well as low-income developing countries with insufficient manufacturing capacities in the pharmaceutical sector, were clearly intended to be included within the solution. He agreed with other countries that there was a need to have an objective set of criteria to decide which of the low-income developing countries would be eligible and the circumstances under which they would benefit. For developing countries that had a sizeable generic pharmaceutical capability and possessed the technical capability to produce active ingredients and pharmaceuticals and chose not to do so, it would not be tenable to suggest that they should be equated with the countries for which a solution was being discussed. Such countries were not, in fact, countries with insufficient or no manufacturing capacity in the pharmaceutical sector. The representative said that he was pledging himself, along with other Members, to develop some objective criteria so that countries could assess for themselves if circumstances existed for them to take advantage of the solution. On the question of categories, he underscored the point that, without objective indicators, there would be no legal certainty. Legal certainty was desirable as an assurance for the countries that would be exporters under the provision, as well as for Members in the Council, that the solution would only be used for the purposes for which it was intended. Without such certainty demands for additional safeguards and burdens were going to increase. On the issue of suppliers, he said that to include developed countries would be to reduce opportunities and incentives for domestic or foreign investment and technology transfer to developing countries since, in such a case, markets could simply be supplied from the developed world.

45. The representative continued that he was quite interested to hear that the WHO had taken a specific position and had made a recommendation to the TRIPS Council on how to conclude the paragraph 6 solution. The representative said that, as an active Member of the WHO, he was unaware that any decision had been taken to provide such a recommendation, on behalf of its members, to the Council. He said that he welcomed the report of the WIPO that exposed some of the myths associated with the intellectual property system. He said that, as pointed out in this paper, it was a myth that problems associated with access to health care and life-saving drugs were primarily due to the patent system and that this myth underlay a lot of the positions and assumptions that had been made as part of the debate so far. He welcomed the opportunity for the Council to hear the WIPO's contribution to this debate.

46. The representative of Bolivia said that there seemed to be a consensus among all WTO Members that a flexible, viable and transparent system that provided legal certainty should be developed. The differences arose on the manner in which to reach such a solution. The debate was not on positions but on the most appropriate solution that would help developing countries and other Members of the WTO. He said that the two main solutions proposed in this regard were interpretations under Article 30 or under Article 31. Bolivia was of the opinion that an authoritative interpretation under Article 30 was the one that was likely to cause the least difficulty and cost to developing countries. In this respect his country had co-sponsored the proposal made by Brazil on behalf of a number of developing countries. He said that it was not desirable to have a list of diseases drawn up to limit product coverage. When a country faced a public health crisis or other situation of

national emergency, it should have access to all pharmaceutical products needed, that it could not itself manufacture, to tackle it. It was possible that diseases which were once thought to be eradicated at times came back, and, hence, drawing up a list of diseases was inappropriate.

47. With respect to beneficiary importing countries, he said that every developing country that was facing a public health crisis should be able to benefit from the solution. In this respect, he said that he would like to hear more from the United States delegation on the factors it thought appropriate in order to identify countries that could benefit from the solution. As an initial response to the proposal of Switzerland, he said that he was interested in the self-assessment suggested but would like to hear more about the proposed criteria on which such assessment was to take place. As to supplying Members, he said that what was being discussed were serious public health problems not questions of market access. The universe of potential supplying Members should not be limited and every WTO Member that could help to deal with the public health problems should be able to do so.

48. The representative of Thailand said that dealing with countries other than least-developed countries on a case-by-case approach, as proposed by Switzerland, would only cause further confusion and problems and was not, in fact, an expeditious solution as mandated.

49. The representative of the Philippines said that, on the basis of the discussion so far, an authoritative interpretation of Article 30 seemed to be the most expeditious solution that would also maintain the integrity of the TRIPS Agreement itself. He said that his country, along with many other developing countries, had always maintained that the Declaration should be read and construed in its entirety. While paragraph 6 referred only to insufficient or lack of manufacturing capacity, it was clear that the aim of the Declaration was to deal with public health problems and promote access to pharmaceutical products for all. Clearly, any solution made under this mandate should refer to product coverage for patented products intended to address public health problems, including, but not limited to, those diseases listed in paragraph 1. With respect to active substances and diagnostic kits, he said that he shared the views of other developing countries that any related product that helped protect and promote public health should be included in the product coverage.

50. He said that, with respect to beneficiary importing countries, paragraph 4 of the Declaration affirmed the right of every WTO Member to protect public health and promote access to medicines. The Declaration did not limit this right to a particular set of Members, nor did it qualify those Members who were entitled to promote access to medicines. In fact, he said that the Declaration stated that access to medicines should be promoted for all. Given this mandate, there was no reason to restrict this right to only a few countries. The only limitation on the applicability of the benefits and flexibilities to be provided, he said, was to be found in paragraph 6 itself in that this was to be limited to only those Members with no or insufficient manufacturing capacity in the pharmaceutical sector. It was, however, the prerogative of any country that wished to exclude itself from taking advantage of the solution to do so.

51. In terms of the assessment of insufficient or no manufacturing capacity, he said that each country should be able to carry out this assessment for itself. He agreed with Malaysia that such an assessment should take account not only of technological capability but also of economic viability and economies of scale. Insofar as the eligible supplying Member countries were concerned, there was no limitation provided for in the Declaration and excluding developed countries would limit the sources of medicines that developing countries might need to tackle a specific public health crisis. He recognized the fact that inclusion of developed countries might mean that domestic legislation in such countries might have to be amended. Often such legislation in industrialized countries was more evolved than in developing countries but, he said, a solution under paragraph 6 necessitated such domestic legislative changes.

52. The representative of Sri Lanka said that with respect to product coverage there seemed to be a degree of agreement but the devil lay in the detail and she wanted the term "pharmaceutical

products" to be defined more clearly. She said that document IP/C/W/345 referred to a UNIDO study that used the Standard International Trade Classification (SITC) system to identify products. This system of classification was much more narrow than the Harmonised System (HS) used to identify trading products. The SITC, she said, only referred to finished products whereas the Harmonised System included active ingredients and products that had to be mixed before use. Chapter 3 of the HS also referred to diagnostic kits. Given the desirable and wider scope of the HS system of classification, she said that Members should explore whether this would be acceptable to them.

53. With respect to importing countries, she was disturbed by the allusion that only least-developed countries and low-income developing countries should be eligible to be beneficiaries. Paragraph 6 referred to "smallness" and countries that might have higher incomes might be too small to have their own manufacturing capability. She said that there was a need to include all criteria and not just low-income.

54. The representative of Pakistan said that manufacturing capacity was a dynamic state and that it should therefore be left to each Member to ascertain this for itself. Regarding supplying Members, he supported the statement of the Norwegian delegate and said that he was yet to hear a convincing argument to exclude developed countries from being potential suppliers. He said that the reasoning given that including developed countries would be detrimental to the development of manufacturing capability in developing countries, or in some way stunt their growth, was not a convincing one. It was necessary, in his view, to keep the list of potential suppliers as broad and open-ended as possible.

55. The representative of the Slovak Republic said that he favoured a solution under Article 31(f) of the TRIPS Agreement. Such a solution would facilitate compulsory licensing in order to address public health problems in other WTO Members. It would, he said, also enable Members in need of such products for which they had no or insufficient production capacity to ensure supply under compulsory licensing. As to scope and product coverage, he was of the opinion that it should include pharmaceutical products which were necessary to deal with public health problems afflicting many developing countries, especially HIV/AIDS, tuberculosis, malaria and other epidemics. He said that it should not, however, be limited to these diseases as the list was only an illustrative one. On the scope of diseases, he said that this should be left open-ended and not made definitive. He preferred a case-by-case approval method although beneficiary importing countries could be any WTO Member country and not just least-developed countries and developing countries. It should include low-income Members with no or insufficient domestic manufacturing capacity based on a definition for which further clarification was required.

56. The representative of Djibouti said that a serious question of who was capable of producing a pharmaceutical product and who was not was being treated lightly. He said that the representatives of the United States and of the European Communities had also recognized that there was a large number of countries that were not capable of producing pharmaceutical products. A consensus was required within the framework of the TRIPS Agreement as otherwise problems might be caused in the long term. He said that in the future a country that was of low income might claim to be a beneficiary. Additional criteria like this could, therefore, lead to confusion. There was a committee within the United Nations that decided on the categorization of countries as least-developed countries. He said that the Council should consider setting up a similar committee for classification as otherwise it would be difficult to find consensus on the criteria for deciding which countries should benefit.

57. The representative of Cuba said that, in the Declaration, the term "pharmaceutical products" was to be construed as a generic term that included complementary products and not just the finished products required to deal with a particular public health situation. He said that such situations should not be restricted to those listed in paragraph 6 which were merely representative of extreme cases. However, the coverage of diseases should include all diseases that fell within the scope of interpretation of the principles and objectives of the Declaration. All countries, especially developing

countries, should be potential suppliers and the source countries should not be limited in any way. He said that a transparent solution to the problem was to be found.

Legal mechanisms

58. Turning to the issue of legal mechanisms, the representative of Brazil said that the question of safeguards and conditions was dependent on the legal mechanism chosen. He was of the opinion that an Article 30 interpretation was the most expeditious, least burdensome and legally certain option available. The advantages lay in the procedures necessary in the various WTO bodies as well as in the actual operation of such a solution. He said that the African group, as well as many developing countries, was of the same opinion and, from a public health perspective, the WHO had also supported it as the best solution.

59. He said, however, that an interpretation based on Article 30 was without prejudice to any other possible interpretation of this provision. The discussions on possible conditions and safeguards envisaged under the proposal should not be understood as applicable to other circumstances related to Article 30. This was a provision that allowed for interpretations that could apply to a great number of other situations and the overall flexibility of the provision should not be circumscribed by the interpretation that was being suggested. He said that the Declaration provided a well-defined scope for limited exceptions under Article 30. Such limited exceptions were deviations from legal rules that were constrained within clearly delineated boundaries and such boundaries were a part of the authoritative interpretation being suggested under Article 30. Paragraph 6 allowed for the existence of concurrent limitations under Article 30. Three ways in which exceptions could be limited were as follows: (a) Members, other than those with insufficient or no manufacturing capacity in the pharmaceutical sector, should not be able to invoke the exceptions; (b) the exception was limited to the pharmaceutical sector; and (c) the exception would be confined to patent rights. He said it was important to delineate that the limited exceptions applied only to patent rights as concern had been expressed by a number of stakeholders, as well as other delegations, that there was a danger that the exception might affect other forms of intellectual property, such as copyright.

60. Elaborating on the procedural steps to be taken within the WTO for establishing the authoritative interpretation, he said that the developing countries' proposal had the considerable advantage of not requiring modification to the text of the TRIPS Agreement. This might be an important consideration for some delegations that would not like to see the text changed, although he said he was open to other suggestions that might eventually result in amendments to the TRIPS Agreement. Based on Article IX:2 of the Marrakesh Agreement Establishing the WTO, the General Council would have the authority to adopt an interpretation of Article 30 before the end of the year, in fulfilment of the mandate under paragraph 6. However, he said that solutions based on amendments would require approval by the Ministerial Conference, that was before September 2003. In addition, procedures established under Article X for approval of amendments could delay the entry into force of this solution even further. An Article 30-based solution would have the flexibility to allow Members that did not want to be part of the solution to opt out. The decision whether or not to authorize an Article 30 exception resided necessarily in the country of export. Therefore, an application of the interpretation was within the discretion of the Member making the determination.

61. On the other hand, he said, moratoria or waivers were less advantageous in actual operation as they were too narrow and limited in time to be considered as solutions to problems identified in paragraph 6. In the context of waivers, he said that the absence of legal predictability was a major point of concern. As per Article IX:3 of the WTO Agreement, the Ministerial Conference, on the basis of annual review, might extend, modify or terminate the waiver. The possibility of such a modification or termination provided little incentive to governments to modify their laws in order to accommodate the solution to the problem in paragraph 6. The same element of uncertainty extended to generic manufacturers who could not invest in creating or increasing export capacity in the absence of legal predictability. The legal merits of the proposals based on moratoria or waivers were equally

questionable. In the absence of provisions in the WTO Agreement for authorization of a dispute settlement moratorium, he said that it was unclear as to what procedures would be applied and whether formal changes to the TRIPS Agreement were necessary. Further, he said, a moratorium would only generate legal effects within the WTO. It was unclear if such moratoria would authorize amendments to national legislation. Patent holders seeking to block exports by generics manufacturers under domestic compulsory licence proceedings were not going to be affected by the moratoria or even waivers at the WTO. Such concerns also reflected those expressed by the delegation of Hungary in the last formal session of the TRIPS Council. He concluded that, although there were clear advantages to a solution based on an amendment to Article 30, his delegation was open to other suggestions that were equally expeditious, predictable and sustainable.

62. The representative of Kenya said that he was not inclined toward a temporary moratorium or waiver under Article 31(f), or even an extended waiver, as such a solution was uncertain, unpredictable, and unsustainable. The temporary nature of these solutions would directly undermine the efforts to build a stable environment for the development of domestic manufacturing capacity and long-term plans under the solution envisaged by the Declaration.

63. The representative of the United States said that he joined a number of other countries in supporting the provision of a waiver under Article 31(f) as the most expeditious and legally certain solution. He said that this was most appropriate because the circumstances in the Declaration were precisely the kind of exceptional situation that Article IX of the WTO Agreement intended to address. Waivers, and the actions taken thereunder, were granted in advance and the country of manufacture and export could, therefore, be certain that this would not be subject to challenge in the future. Waivers could be granted for multiple years and many such waivers were, in fact, granted after the Uruguay Round. He said that five such multi-year waivers were granted just last year. A multi-year waiver did provide the legal certainty required for countries to produce and export drugs, otherwise it would be difficult to see why so many waivers had been approved by so many of the WTO Members on previous occasions. Recently, the TRIPS Council had allowed least-developed countries a waiver from having to provide exclusive marketing rights, a solution that was deemed to be legally certain. Waivers, he said could also be granted quickly pursuant to a previously agreed mechanism. There was enough ability in the Council to set up an adequate process of evaluating waiver requests that could function expeditiously. Filing of waivers was not, in itself, a resource-intensive or burdensome exercise but this process could be streamlined and made more efficient. Similarly, a simple and expeditious review process could also be set up as was done in the case for the review under Article 70.9 in June 2002.

64. Replying to the criticism that waivers were not legally certain, he said that any decision to modify or terminate the waiver, as per the Secretariat's clarification, was to be taken ordinarily by consensus in the General Council, which increased the legal certainty of the approach. Any one Member could ensure that an attempt to withdraw or amend a waiver was not successful. Waivers, he said, were also transparent and had the benefit of encouraging competition among those who could respond to the need for medicine, as well as enabling Members to monitor potential product diversion and evaluate if, in fact, this solution was helpful. Finally, the use of a waiver was implementable by the end-of-the-year deadline. He said that he was not aware of any other legal mechanism that had that advantage. In contrast, under the WTO rules, an amendment would not come into place until two thirds of the Members had accepted it. This, he said, was a process that was very likely to take years and not weeks or months. In addition, an amendment would be applicable only to those Members who ultimately implemented it into their domestic laws.

65. The representative of Norway said that the most significant criterion in choosing a solution was legal certainty. On this basis, his delegation favoured an amendment to the TRIPS Agreement. Such an arrangement would ensure that a paragraph 6 solution was not overridden by other substantive provisions of the TRIPS Agreement or the WTO Agreement or the GATT. If the Council should decide to go ahead with an amendment, he said that it would still be inapplicable before

1 January 2003 as the necessary ratifications had to take place. Hence, he said that there was need for an interim solution which, in his opinion, was a waiver. Such a waiver should be available until an amendment of the TRIPS Agreement entered into force.

66. The representative of Australia said that it was important to find an expeditious solution and that for this reason he supported a waiver from among the proposals put forward. While his delegation was open to other options, comments made by various delegations so far had only strengthened his view that a waiver was the best way to move forward. He said that an amendment was not consistent with the expeditious solution required by the Declaration. A waiver could be applied quickly as all Members were aware of the procedures involved and it could be put in place for a long period of time and, further, it could be framed in such a way that a decision not to extend a waiver would require a consensus from all Members. He said that, more importantly, a waiver under Article IX:4 had in-built transparency. This was also supportive of anti-diversion measures under Article 44 of the TRIPS Agreement. It was his view that, for all those reasons, the solution of a waiver did not have to be an interim solution and could be the more permanent one that all the Members were looking for.

67. The representative of the European Communities said that a solution based on an amendment of the TRIPS Agreement was the most sustainable, balanced and workable one. He said that there was a problem with Article 31(f) which should be solved. With a waiver given for a few years, there was the danger that at the end of that period the problem would still remain. The representative said that he would like to deal with the present problem in a lasting way and not have to come back to it time and again. To those delegations that saw the amendment of Article 31(f) as being a cumbersome and lengthy process, he said that he would like to offer more clarifications as to how this would function as the solution under paragraph 6. Just like many other delegations, he too would like to have a political solution and a consensus before the end of the year. The amendment would have to be endorsed at the Ministerial meeting and would require subsequent ratification. In the meantime, he said, there was a need for an interim solution. Given that many Members had already undertaken amendments of domestic legislation to bring them in line with the TRIPS Agreement, the action required following an amendment of Article 31(f) was a relatively minor issue.

68. With respect to an Article 30 exception, he remained concerned that it could lead to an open-ended situation. If Members who would like to see an Article 30 amendment could agree to narrowly defining such an exception and to the conditions and guarantees described in the European Communities' previous communication, he would be willing to discuss this option. He said that he was also willing to consider a waiver or a moratorium as an interim solution but not as a long-term one. The situation was of much greater magnitude and required a solution different to what was suggested for the waiver on exclusive marketing rights. In his view, the waiver approach did not provide the sustainability or the legal certainty necessary.

69. The representative of Canada said that her delegation continued to support the waiver approach. She did not agree with the opinion of the EC representative that the problem was with Article 31 as in her view the problem lay rather in the application of Article 31 by countries that did not have manufacturing abilities and were also facing a public health crisis. She said that the Council was mandated to quickly and expeditiously find a solution that set aside the obligations imposed by the word "predominantly". She said that a waiver would meet all the conditions and concerns raised by the Council. She also said that experience in the waiver granted by the Council to least-developed countries under Article 70.9 showed that a waiver could be both long term and expeditious.

70. The representative of Sri Lanka said that there were problems with the solution of a waiver that would reduce flexibility for many countries. A multi-year waiver under Article IX:4 of the WTO Agreement required annual reviews to be carried out. There was also the question of why collective waivers were chosen instead of individual waivers. In the discussion on these issues it was said that it was because Members could feel pressured to justify that exceptional circumstances still prevailed

that it was decided that waivers would be made collectively. Even with respect to collective waivers, practical experience in the Market Access Committee showed that countries had difficulty in showing that exceptional circumstances continued to exist and the matter had to be negotiated in the Council for Trade in Goods. This resulted in a number of countries being unable to take advantage of the waiver. She concluded that the TRIPS Council had limited experience in collective waivers since the only one granted was the recent one for least-developed countries and its effectiveness had yet to be assessed.

71. The representative of Korea said that a waiver was the most appropriate legal solution for the problem. A waiver was the right legal mechanism to give Members the flexibility required to exclude themselves from WTO obligations due to exceptional circumstances. He said that this was the reason it had been used most frequently in the past. The grant of waivers on a long-term multi-year basis would also provide legal certainty.

72. The representative of Malaysia said that in previous meetings she had indicated her preference for an Article 30 approach. With respect to the proposal on waivers, she said that under Article IX:4 of the WTO Agreement there were a number of conditions that had to be proved before a waiver could take effect, including exceptional circumstances and other terms and conditions. Therefore, it was not a simple solution to the problem of paragraph 6, although it could be expeditious. A long-term multi-year waiver could go on for five to ten years, but after that the situation was uncertain. She did not think that the TRIPS Council, General Council or the Ministerial Conference could extend a waiver for an indefinite period. This meant that the problem would have to be dealt with again. She preferred a long-term and predictable solution to the problem that formed part of the TRIPS Agreement without being subject to continuous review. She supported the statement of Brazil with respect to Article 30 and although a solution under Article 31(f) was also feasible, there could be instances where Members were not part of the paragraph 6 solution and, therefore, a problem of applicability could arise.

73. The representative of Bolivia supported the statement of the Sri Lankan representative and said that in the Council for Trade in Goods, Members had faced considerable problems getting approval for waivers. He said that he would prefer a mechanism that provided legal certainty and would assure countries that if they had a public health crisis they could take steps to tackle this immediately without having to resort to an internal debate in the WTO. He concluded that this was his major concern and the reason why he did not favour a solution based on waivers.

74. The representative of Egypt said that the coordinator of the African group had spoken on behalf of his delegation, but he welcomed the interventions made by Norway and the European Communities on the need for a permanent solution that was not based on a waiver approach.

75. The representative of Peru said that she shared the opinion of a number of delegations on the problems inherent in waivers. She said that the mandate was for a long-term solution and not a short-term solution and that if waivers were decided upon, what was required was a simple procedure that did not have a lot of conditions attached to it.

76. The representative of the Philippines maintained that an Article 30 solution was the most expeditious and legally certain one. He noted that under Article IX of the Marrakesh Agreement a waiver was never granted automatically and that there were, in fact, terms and conditions that had to be met. He said that, from the perspective of a delegation that had participated in the process for the grant of waivers elsewhere in the WTO, such procedures could be very contentious. He said that the debates were prolonged and there was horse trading involved. There was no assurance that the same would not happen in the present case as the waiver being contemplated under paragraph 6 was a blanket one. It was his understanding that waivers were not at all legally certain as they could still be the subject of dispute settlement proceedings as had happened in two cases. The first was the case of a perceived infringement or nullification of benefits arising from the implementation of the waiver

and the second, more relevantly, was when the Member was perceived to be in violation of the waiver conditions. He concluded that waivers did not provide a legally certain and predictable environment as mandated by paragraph 6 of the Declaration.

77. The representative of Singapore said that he was interested in knowing more about the practical aspects of waivers under Article IX:4 of the WTO Agreement and requested the Secretariat to compile information about the applicability of waivers in other areas of the WTO, including in the Market Access Committee, in order to help delegations decide on the appropriate solution.

78. The representative of Nigeria said that he preferred a permanent solution, a need that was not met by waivers even if it did provide an expeditious solution.

79. The representative of Ecuador said that waivers created uncertainty and also promoted the idea of legal non-compliance whereas, in fact, what was being protected was the right of every government to take care of the health needs of its people. Therefore he said that what was required was an amendment under Article 30, recognizing the right of WTO Members to export patented products related to public health.

80. The representative of Indonesia said that the legal mechanism adopted should be simple, not administratively burdensome, speedy as well as legally predictable. Unlike an Article 30 approach, an Article 31 approach was likely to entail legislative changes in national law before becoming operative and was certainly administratively burdensome and required inter-sectoral negotiations. She said that the process was even more cumbersome since intellectual property legislation in a number of developing countries was not yet available in a stable form. Further changes required would lead to confusion in implementation. A survey of 50 countries' intellectual property legislation showed that many of the countries either did not know or only partially used the flexibility afforded by the TRIPS Agreement. In order to avoid repetitive reviews of domestic legislation, she supported an authoritative interpretation of Article 30 as it not only met the above criteria, but was also an expeditious solution. Her delegation did not see waivers as an appropriate solution, either in the short or long term.

81. The representative of the United States supported the request of Singapore that a document be prepared by the Secretariat on the experience of Members on waivers in the WTO. He appreciated the interventions of Bolivia and others that they had experienced difficulties in negotiating waivers, but would like to understand better why those difficulties were experienced in the first place. He felt that the Council had enough flexibility to craft a waiver solution that did not succumb to the pitfalls of other experience on waivers. Although general information on waivers would be useful, he urged Members to consider the possibility that the experiences of waivers in other sectors could be modified, if found to be unacceptable, and adopted if acceptable.

Conditions

82. Turning to the subject of conditions, the representative of Switzerland said that, whatever legal mechanism was eventually adopted, clear and adequate safeguards must accompany any paragraph 6 solution in order to keep such a solution transparent and workable. The number and ambit of modalities and safeguards would have to be proportional to the scope of the solution and the kind of legal mechanism chosen. He said that what was most important for his delegation was safeguards against diversion. Any diversion of the pharmaceutical products would deprive the Members most in need of them. All Members, not only the beneficiaries, should agree to take necessary legal measures, in particular with respect to three aspects: (a) the supplying country should ensure that the manufacturer producing under the legal solution of paragraph 6 only produced the quantity actually needed by the beneficiary country or countries; (b) the entirety of the products should be exported to these beneficiary countries and if the exporting country believed that some of the products should go to its own market then it would need to issue a compulsory licence; (c) no re-

exportation should be allowed to any third country from out of the importing country. In order to assist all Members to prevent diversion without additional rules and burdens, it would be easiest to track these products by way of special labelling, packaging, colouring or shape requirements of the pharmaceutical products delivered under paragraph 6. This requirement could be met in a way that would not entail additional costs to the beneficiaries as it would be carried out by the supplying countries.

83. Turning to transparency, he clarified that he understood this term to mean firstly, that an eligible beneficiary importing Member should be required to make a simple notification of its need of a product to the WTO. This would enable the patent holder to offer the products needed to the country at a reasonable price in the first place. He reminded Members that many products were not patented at all in many countries, and hence the patent holder might not have been involved thus far and that it was important that the right holder be closely involved in order to find a regular commercial solution. His delegation believed that direct delivery by the right holder would always be quicker than any paragraph 6 procedure. Secondly, the exporting Member should notify to the WTO any decision with respect to the export of the pharmaceutical product under the paragraph 6 mechanism. It was the supplying country that had the obligation to notify who the importing Member was, what products were being supplied, and what kind of special labelling was used as a safeguard against diversion. Such obligations would not apply to the beneficiary countries. He added that the right holders should be given the same treatment as that given to all other potential suppliers. In the case of a grant of a compulsory licence, adequate remuneration would have to be paid by the supplier to the right holder. In this respect, he said that a double remuneration in both supplying and receiving countries should be avoided.

84. Finally, on the subject of import duties he said that, although this was not an intellectual property issue as such, such duties constituted an important obstacle to affordable access to pharmaceutical products. He said that in order to make the products more affordable and accessible, beneficiary Members should be willing to lift tariffs on any pharmaceutical product that they imported under paragraph 6.

85. The representative of Japan said that any measure taken under paragraph 6 by a country with no or insufficient manufacturing capacity was an exceptional measure taken because of unexpected situations not anticipated at the time of the Uruguay Round negotiations. It was therefore clear that additional safeguards against diversion were a necessity. As to who should bear the burden of implementation of such additional measures against diversion, his delegation felt this should not fall only on the patent holder. This burden should be shared by all countries, including the importing and supplying countries, taking into account the flexibility of the TRIPS Agreement. He was of the opinion that obligations under Articles 28 and 44 provided a good basis for examination of any additional obligation in this context.

86. The representative of Sri Lanka said that the United States had been a beneficiary of a waiver arrangement for the last 50 years and that the Secretariat, when preparing the document as suggested originally by Singapore, should take note of the GATT waiver granted to the United States on a regulation on ships that was in force before it became a contracting party to the GATT in 1947. This was an exemption from Part II of GATT 1994, i.e Article III to Article XXIII. This was a wide area of exemption and she would like to know more about how this waiver had functioned over the last 50 years.

87. The representative of the European Communities said that there appeared to be widespread agreement in the TRIPS Council on the need for safeguards against diversion. Many, including his own delegation, had also indicated that such measures should be reasonable and proportional. He said that he would like to respond to the question that he was often asked: whether trade diversion was a problem or could be a problem in the future if a system under paragraph 6 was put in place. He said that he would like to bring a case to the attention of the Council, with the understanding that some of

the matters were confidential. Less than two months ago, the Customs department of one of the EC member States seized a consignment of pharmaceutical products patented in the European Communities. The products had been sent by air freight and had been returned to the European Communities by an African company, company A. The destination of the goods was company B, established in the European Communities. The investigation revealed that the medicines had been initially delivered to Africa at preferential prices, or strongly reduced prices, by an agency working in the area of access initiatives. He reiterated the importance of the European Communities' proposal that before compulsory licences were issued, the right holder should have an opportunity to supply the products at a reduced price. Referring again to the investigation, he said that other consignments had taken a variety of routes from five other African countries into the European Communities at different locations. Some of these consignments were impounded in another EC member State. The investigation revealed that the importing company, company B, did not hold the necessary licences to import the product. According to the right holder the packs that were seized in two EC member States constituted only one fifth of the amount that was illegally diverted. The remainder, which eluded the customs authorities, was supplied by company B to a number of parallel traders within and outside the European Communities. The total invoice amount of the product imported by company B in one year amounted to billions of euros. He said that, therefore, it was a matter of concern that a large quantity of medicines headed for developing countries was being illegally diverted. Many of these medicines were sold at low prices under pledges made by companies in the Communities to make medicines available to the world's poorer countries. It was crucial to stop the diversion of these products made available at not-for-profit prices that were then sold for significant profit, at the expense of the health of the people for whom the medicines were originally destined.

88. He continued that, under the measures being considered, the exporting countries should take adequate safeguards to see that all of the quantity that was produced under the compulsory licence went only to the country of destination. The exporting country should prohibit, and take measures to ensure, that there was no trade outside the mandated circuit. The importing country would also have to provide measures to prevent export to other countries. To make such a system workable the authorities should have the power, upon request, or even *ex officio*, to seize products found outside the specified trade circuit. Contrary to what some Members had expressed, Article 44.1 of the TRIPS Agreement did not provide an adequate basis for such an intervention.

89. He supported the point made by the Swiss delegation on the impact of customs duties on the price of medicines in developing countries. He said that the European Communities had carried out a study to assess the duties and taxes on pharmaceutical products to treat major communicable diseases such as HIV/AIDS, malaria and tuberculosis. The study covered 57 countries or about 80 per cent of the developing world. He presented the results with respect only to customs duties although the study itself included other taxes such as VAT. He said that customs duties in these countries varied between 0–35 per cent for compounds as well as for medicines and vaccines. The average customs duty rate constituted between 5–7 per cent of the price of the imported product. However, there was a group of countries, large countries with their own manufacturing capacities of pharmaceuticals, with very high rates. He said that customs duties amounted to one third of the taxes and duties that were normally imposed on pharmaceutical products. He hoped that such countries would consider reducing or eliminating customs tariffs on pharmaceutical products.

90. The representative of Egypt said that the TRIPS Agreement had sufficient safeguards and that there was no need for additional measures. He was open to other measures being proposed as long as they were not administratively burdensome on the beneficiary countries. He said that developed countries were more able, administratively and financially, to protect their borders against diversion. The case raised by the European Communities involved a case of differential pricing rather than compulsory licensing. He, however, recognized that compulsory licensing might increase the frequency of such cases.

91. The representative of Brazil said that there seemed to be flexibility among Members about how best to safeguard the solution envisaged under paragraph 6. He said that narrow and burdensome safeguards would ultimately defeat the purpose of such a solution. The safeguards should not in any way limit the flexibility enjoyed by Members under the TRIPS Agreement or under the clarifications provided by the Declaration. Some of the points raised were, however, legitimate concerns that could ultimately lead to a more efficient solution. Adopting a limited interpretation of Article 30 could be helpful to circumscribe the limitations of the exceptions that were envisaged. He said that the issue of safeguards must always be discussed within the appropriate context. Additional safeguards to those already in the TRIPS Agreement might or might not be necessary according to the legal solution adopted. Specifically it would not be appropriate to consider conditions under a moratorium or a waiver as these were already narrow and limited in scope.

92. He continued that safeguards against diversion were legitimate and that many countries seemed to agree that conditions additional to those established by the TRIPS Agreement were necessary. In this respect he said that he supported the views of the African group and of the United States that Articles 28 and 44.1 of the TRIPS Agreement already provided adequate safeguards. The United States paper did not indicate that there should be additional measures imposed. Referring to the question of labelling, as proposed by the Swiss delegation and some other countries, he said that this might, in principle, be feasible but he would like to revert to it at a later stage. Transparency was another issue on which there was convergence and he said that he was willing to consider any measure that was not burdensome to Members. Again, he said that he doubted the need for transparency measures under a moratorium or a waiver mechanism, given that they were already narrow in scope. In this context, he supported the proposal of New Zealand that conditions imposed should not be a ground for challenging the actions of Members taken in accordance with the solution; they should be helpful in ensuring that the solution benefited those for whom it was intended. The rationale of transparency should increase competition, reduce prices and increase availability for those that had insufficient manufacturing capacity of their own. This should also help the original right holder to have an opportunity to put forward a product at more competitive prices than those which were being considered under a compulsory licence.

93. Turning to the issue of remuneration proposed for the right holder, he said that this was a serious matter especially if related to proposals under Article 31. He supported the statement of many other countries that double remuneration, both from the exporting country as well as the importing country, would not be appropriate as both compulsory licences addressed the same situation. In any event, any compensation should be proportional to the ability of the patients to afford the product.

94. The representative of Hong Kong, China said that measures of transparency as well as safeguards against diversion were both necessary. He said that there should be a way of conveying information to the patent holder and to the Council with respect to the production processes involved, the manufacturer, the exporting and importing parties so that they could be contacted, if necessary. As regards safeguards against diversion, he said that though he saw the need for them, he was concerned that they should not become a burdensome TRIPS-plus obligation. He suggested that the safeguards should be in the form of guidelines, which might even currently be useful to countries that were handling products under differential pricing arrangements. For a solution under paragraph 6, the obligations of the TRIPS Agreement under Articles 8, 44.1, 31, and possibly a modified Article 31(f), were all applicable. Any diverted pharmaceutical product would be an infringing item and he suggested that, if any dispute settlement process arose, the guidelines could then be used as a benchmark. He said that he hoped that a detailed document would be considered by the Council, which would then be used only as a guideline and help in dispute resolution as well.

95. The representative of Norway said that, on the issue of diversion, it was primarily the responsibility of all parties concerned that the products were not diverted and supported the idea that those that produced or marketed the pharmaceuticals should distinguish them by branding, labelling, colouring or such other measures.

96. The representative of Kenya said that the position of the African group with respect to conditions was still the same as summarized in JOB(02)/102.

97. The representative of Malaysia said that her delegation was doubtful whether additional safeguards were necessary as the TRIPS Agreement itself provided adequate safeguards. She said that there were at least ten conditions under Article 31 related to the use of compulsory licences. These were related to usage or the need to obtain authorization, duration, terms and conditions as well as judicial review. Further, Article 44.1 dealt with judicial measures relating to infringing imports. Hence, although her delegation was against diversion, there were adequate in-built safety measures. For example, when a compulsory licence was issued there was usually a contract between the importing country and the exporting Member on the amount to be produced. Any violation of this would naturally be in violation of the terms of the compulsory licence as well as the authority granted under it. Any unauthorized imports and exports would also constitute a violation under the adequate safeguards already provided for in the TRIPS Agreement. The representative said that she did not think there was any difference between a compulsory licence issued under Article 31 and a situation as envisaged under paragraph 6. She wondered if the only difference was that use of the product manufactured beyond the intended purpose of the compulsory licence would mean an infringement of rights under Article 28. She said that, if that were not the case, then remedies against normal infringement of a compulsory licence would be adequately provided for under the TRIPS Agreement. Hence any diversion was also adequately provided for under paragraph 6. She said that the Swiss proposal for special labelling seemed like a good proposal as it was helpful for the enforcement authorities but she was concerned that any such measures would be unduly burdensome or costly.

98. The representative of the United States said that, if a proposed solution under paragraph 6 was formulated under Article 31, then he was of the view that the safeguards therein were adequate. He said that he was very much in support of measures that aided transparency and competition as well as ensuring that products were not diverted away from those most in need. He wanted to respond to the very serious case brought to the attention of the Council by the representative of the European Communities. The possibility of such a situation happening on a larger scale should be kept in mind. He said, however, that such a situation could be addressed by the proposal put forward by his delegation. He also took note of the helpful information in the intervention of Malaysia that production beyond the agreed quantity was an infringement and actionable under the TRIPS Agreement.

99. The representative of Indonesia said that safeguards should be directly related to the kind of solution being considered. She said that if a solution under the TRIPS Agreement itself was being proposed then Articles 28, 31 and 44 provided adequate safeguards. Current measures dealt with potential abuses and, therefore, there was no need for additional safeguards for compulsory licensing under a paragraph 6 solution. She said that in most countries the import, export, production and distribution of pharmaceutical products were highly regulated. This in itself was a safeguard against possible abuses. In this connection, she said that, although it was feasible to carry out measures proposed by Switzerland, they should apply only if a solution under Article 30 was eventually formulated. Nevertheless, she reiterated that safeguards should not impose additional burdens on Members.

100. The representative of Bolivia said that when developing country Members were faced with a public health crisis that required a rapid solution, they would be willing to adopt transparent processes to ensure that the products were delivered to the sectors that needed them most. He said that notification would be the most appropriate method of ensuring such transparency. With respect to safeguards, a subject that was closely linked to that of diversion, his delegation was of the opinion that when specific products were manufactured with a particular use in mind, any other use to which they were put was illegal. In the TRIPS Agreement there were various means of combatting such illegal products.

101. The representative of Thailand said that, unlike other products, pharmaceuticals were restricted goods already as they had to be registered in both the supplying and importing countries, needed import licences and needed to have labels to be put on sale. Therefore he was of the opinion that there was no need for additional safeguards.

102. The representative of China said that she agreed with the opinion of many countries that the safeguards against abuse of compulsory licences and trade diversion in the current TRIPS Agreement were adequate. However, there were almost no rules concerning the double remuneration of right holders and the price of the pharmaceutical products was of fundamental importance under a paragraph 6 solution.[1]

103. The representative of WIPO stated that in June 2002, WIPO had welcomed the opportunity to discuss the TRIPS Agreement and public health and to contribute its knowledge and expertise, gained over the years, to this ongoing debate. At that meeting WIPO had clearly stated that the role of the patent system in developing new drugs and improving on existing ones was fundamental. It was also important to strike a balance between the rights of the patent holder, on the one hand, and the interests of society, on the other. As the United States delegation had already brought to the attention of the TRIPS Council, WIPO had published a brochure last year entitled "Striking a Balance: The Patent System and Access to Healthcare". This was put out as WIPO publication 491, with copies in English, French and Spanish. As the title suggested, the brochure explained the balance in the patent system, namely protecting the works of an inventor, on one side, and on the other side, requiring disclosure of information which would otherwise remain secret from society. Thus the patent system added to the body of technical knowledge available in the world. This form of technology transfer was of primary importance in promoting further R&D in all countries and making available to society the results of innovation and ultimately the end-product.

104. The brochure, she continued, also attempted to clarify some of the commonly held misunderstandings or misconceptions of the patent system. Three of the myths were particularly important to clarify: first, that the problem of access to health care and availability of drugs was primarily due to the patent system. Patents were only one of the factors that influenced access to health care and drugs. In fact, problems arose mainly due to socio-economic factors, including particularly poor national health and social infrastructure. Second, high prices were primarily due to patents as these allowed prices to be kept artificially inflated. In truth, many factors were involved in setting the price of the drug and the patent involved was not necessarily the determining factor. The main factors included cost of research, production, distribution, demand as well as the price of other competing and replaceable drugs. Third, that the patent system was especially unfair to developing countries that faced difficult economic and social problems and that these countries should be exempt from international intellectual property requirements. WIPO believed that an adequate patent system, including protection of intellectual property rights, was beneficial not only to developed countries but also to developing ones. In general, adequate intellectual property systems were a key factor in sustained economic development which ultimately helped to break the cycle of poverty and led to better education, higher standards of living and better health care for everyone. The WIPO brochure had been drafted prior to the Doha Declaration and WIPO was currently in the process of updating it.

105. WIPO believed that clarifying these misconceptions was important and was one example of the demystification of intellectual property. As the Director General of the WIPO had put it, intellectual property was not foreign to any country and belonged to all nations. This referred to the fact that promotion of intellectual property rights was not solely in the interest of one country but was in the interest of every country. WIPO's mandate was to address all issues concerning intellectual property; it was particularly mandated by its 179 Members, through the Convention establishing the WIPO, to promote the protection of intellectual property throughout the world in order to encourage

[1] No comments were made on item II, namely, measures to facilitate production in countries with presently insufficient manufacturing capacity and on item III, namely, other proposals.

creative activity. It was ultimately up to the Members to achieve the proper balance among the various important interests in implementing their various national and international interests. The UN agencies and other intergovernmental organizations existed to help countries in various fields. She reiterated WIPO's commitment to help Members promote intellectual property, particularly in striking a proper balance between intellectual property and public health, taking into account the flexibilities provided in the TRIPS Agreement. WIPO would share its expertise, not just in harmonizing international norms in this area, but also in assisting developing countries in working with other UN agencies and with the WTO and WIPO looked forward to closer cooperation. She also provided information on the upcoming WIPO-UPOV symposium in October 2002 in Geneva in which WIPO and UPOV would be reviewing the coexistence of patents and plant breeders' rights, in light of the developments in the field of biotechnology.

106. The Chairman suggested that the Secretariat be requested to prepare a list of all waivers that had been granted in the WTO and describe the procedures used in reaching agreement on their adoption. He noted that the Council had now reached a point where it was necessary to move to the next phase and try to seek convergence of views and attempt to crystallize them on paper. He indicated that, to this end, he planned to hold informal consultations, in different formats, before the Council's next meeting scheduled for 25-27 November so that a mutually acceptable solution could be found in good time. He assured Members that the process of consultations would be as transparent and open as possible, and that he would keep all Members fully informed through open-ended informal meetings. A first such meeting has been scheduled for Thursday, 17 October, starting at 6 p.m.

107. The Council took note of the statements made and agreed to proceed as suggested by the Chair.