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Council for Trade-Related Aspects of Intellectual Property Rights

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

Second Communication from the United States

The following is the text of a second communication which was received from the Permanent Mission of the United States on 25 June 2002, and which was circulated as an advance copy for the Council's meeting of 25-27 June 2002.

I. INTRODUCTION

1. We are fully committed to helping countries that are experiencing public health crises find real and comprehensive solutions to these situations. As one element of this effort, we support WTO Members' use of the full flexibility of the TRIPS Agreement to help provide their citizens access to affordable medicines to address these urgent situations.

2. As tangible evidence of our commitment, we are today making a second substantive contribution to the dialogue in TRIPS Council aimed at fulfilling the mandate set out in paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. In our March 14 paper we set out a number of possible solutions to the situation identified in paragraph 6. In this paper we are adding greater specificity to the ideas we tabled in March with the goal of meeting the mandate set forth in the Declaration that the TRIPS Council find an expeditious solution to this problem and to report to the General Council before the end of 2002.

3. We are encouraged by the substantive contributions of other Members toward this common goal and appreciate the communication and cooperation we have had with Members as we developed this second paper. We are heartened that there appears to be an emerging consensus among WTO Members on some of the key elements of a solution, including some we identified as having particular merit in our March communication. While not all issues have been resolved, given the constructive approach taken by many Members we do not see any reason why we should not be successful in finding an expeditious solution by the end of the year. We would be greatly concerned by any suggestion that Members accept that this deadline not be met.

4. In this paper we set forth the fundamental aspects of an expeditious, workable, transparent, sustainable and legally certain solution.

II. NATURE OF THE PROBLEM

5. At Doha Ministers acknowledged the grave public health problems afflicting Africa and other developing and least developed countries, especially those resulting from HIV/AIDS, malaria, tuberculosis, and other epidemics.

6. Paragraph 6 of the Doha Ministerial Declaration on the TRIPS Agreement and Public Health recognizes that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement in order to address these health problems.

7. The situations in which this difficulty might occur and where a TRIPS-based solution might be necessary are likely to be limited. However, given the grave health problems faced by certain developing and least-developing countries we recognize that the consequences could be serious for those encountering the problem. First, difficulty would be expected to arise only in situations where the supply of the pharmaceutical in question has not been provided by the patent holder through normal commercial arrangements or through discount, donation, or other aid programs. A TRIPS-based solution can also only be expected to be effective where Members have, or are provided, the resources necessary to procure pharmaceuticals under the terms of a TRIPS-consistent compulsory licence, which includes the provision of adequate remuneration to the patent holder.

8. In addition, if no patents exist on the needed pharmaceuticals in the Member's territory, that country does not need to grant compulsory licences in order to obtain those pharmaceuticals in its market. If patents do exist, the Member already has flexibility under the TRIPS Agreement to grant compulsory licences. Further, WTO Members are free under a compulsory licence to import the product from a manufacturer in another country so long as there is no patent on the pharmaceutical in question in that other country. Should there be a patent in the other country a compulsory licence would also need to be issued in that country before medicines could be exported. However, we note that there are developing countries that possess the technological capability to manufacture pharmaceuticals, which are not obligated to provide pharmaceutical patent protection until 2005. The expeditious solution the TRIPS Council must devise, therefore, will apply to situations arising no earlier than 1 January 2005.

9. Difficulties could arise, therefore, when a country with insufficient domestic manufacturing capacity and experiencing grave health problems seeks to import a needed pharmaceutical from a manufacturer in a WTO Member where a patent exists on that pharmaceutical. In this situation, it currently would be inconsistent with Article 31(f) for that WTO Member to grant a compulsory licence to its manufacturer to produce the drug solely for export to the country that has insufficient or no manufacturing capacities in the pharmaceutical sector. It is this situation that the TRIPS Council must address. Members have suggested addressing this situation through a moratorium, waiver, amendment, or interpretation.

III. SCOPE OF THE SOLUTION AS SET FORTH IN THE DOHA DECLARATION

10. Paragraph 1 of the Doha Declaration on the TRIPS Agreement and Public Health makes it clear that the public health problems addressed by the Declaration are those gravely afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. Therefore, in establishing the scope of the problems to which the solution should address itself, we encourage Members to reaffirm the Doha Declaration by again:

> ***Recognizing*** **the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, malaria, tuberculosis and other epidemics;**

11. It is clear that the expeditious solution called for in Paragraph 6 of the Declaration is intended to benefit those developing and least-developed country Members that have insufficient or no manufacturing capacities in the pharmaceutical sector. Therefore we encourage Members to further reaffirm the Declaration by:

Recognizing **that some of these Members have insufficient or no manufacturing capacities in the pharmaceutical sector and could face difficulty in making effective use of the compulsory licensing provisions of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in order to address those grave public health concerns;**

12. However, the criterion of capacity established in Paragraph 6 of the Doha Declaration was not defined. To avoid disputes arising once a solution is adopted, Members should establish a procedure to clarify which developing country Members can be considered to have insufficient or no manufacturing capacity in the pharmaceutical sector or at least the factors to be taken into consideration. We would consider all least-developed Members to have insufficient capacity in the pharmaceutical sector.

13. The WTO Secretariat has provided data on capacity in the pharmaceutical sector in certain WTO Members. We are currently evaluating this information to determine what assistance it can provide Members in clarifying what constitutes insufficient or no manufacturing capacity in the pharmaceutical sector.

IV. SITUATIONS TO BE ADDRESSED THROUGH EXPORTS

14. We have suggested preambular language defining the scope of the problems to be addressed by the solution and the Members it is intended to benefit. By once again drawing on the language of the Doha Declaration, we should next consider the situation that will trigger the invocation of the solution.

15. Clearly, the Doha declaration was directed at the needs of developing and least-developed Members. Therefore, it would seem appropriate that the solution be limited to developing and least-developed Members. Failure to do so would undermine what potential there could be under the solution for developing and least-developed Members to expand their pharmaceutical production capacity by supplying other developing and least-developed Members. If the solution were available to producers in the developed world, there might be little opportunity for producers in developing and least-developed Members to supply pharmaceuticals under this mechanism. Therefore, regardless of the mechanism ultimately adopted to implement the solution, we should consider situations in which developing country Members with capacity in the pharmaceutical sector could be released from the restrictions contained in 31(f) to export pharmaceuticals to other developing or least-developed countries with insufficient capacity in the pharmaceutical sector. Pursuant to the Doha Declaration, least-developed countries were provided a further transition on obligations related to pharmaceuticals until 2016 and are thus not bound by Article 31(f) until that time.

16. We feel it would be appropriate for Members, in considering an exception to Article 31(f), to:

Agree that a mechanism[1] shall operate to permit a developing country Member[2] having sufficient manufacturing capacity in the pharmaceutical sector to export needed pharmaceuticals to a developing or least-developed country that:

Is afflicted by a public health problem, especially those resulting from HIV/AIDS, malaria, tuberculosis and other epidemics; and

[1] The exact legal nature of the mechanism has yet to be determined. It could take the form of a moratorium on dispute settlement or a waiver involving TRIPS Article 31(f) for particular countries, or an interpretation, or an amendment.

[2] Least-developed Members have until 2016 to comply with obligations relating to pharmaceuticals.

Has "insufficient or no manufacturing capacity in the pharmaceutical sector";

17. While other approaches might have merit, there is a growing consensus among certain Members in support of using the existing framework of flexibility established in the TRIPS Agreement under Article 31 as a basis for a solution. It would appear there has been consensus from the outset of these discussions that, should a patent exist in the territory of the developing country Member seeking to import medicine, the Member could issue a compulsory licence to authorize such imports.

18. Therefore, in addition to the elements outlined above, we believe it would also be appropriate for Members to specify that a developing country Member seeking to import a needed pharmaceutical that is patented in its territory:

Has authorized, in compliance with the provisions of TRIPS Article 31 (a)-(l), the use of the patent[3]; or

19. However, concern has been expressed about how this solution will apply to Members seeking to import needed medicines that are not under patent in their territory. To address this specific concern, we recommend that, if the needed pharmaceutical is not patented in the territory, Members should specify that an importing country:

Has requested a developing or least-developed Member to manufacture and export the needed pharmaceutical to its territory;

V. TRANSPARENCY

20. All Members appreciate the need for a transparent and efficient WTO-based solution that will provide certainty for those Members addressed by paragraph 6. In devising this solution, we should seek to ensure that it gives Members the opportunity to respond to the grave health problems facing developing and least-developed Members with insufficient capacity in the pharmaceutical sector, including through improved offers by patent holders to supply the country in need. To that end, we recommend that Members taking advantage of this proposal inform the TRIPS Council of actions taken under this mechanism. This will also increase transparency and enable other Members to ensure that the medicines being exported actually reach the intended country and are not diverted into other markets. Members could:

Agree that in authorizing such use or making such a request, relevant Members seeking to import the needed pharmaceutical will inform the TRIPS Council and provide the Council with information enabling interested Members to be responsive in the shortest time possible. Agree that the TRIPS Council shall keep under review the operation and effectiveness of this measure.

VI. ELEMENTS RELATING TO EXPORTING MEMBERS

21. Having touched on the factors Members should take into account in determining what situations should exist in the country seeking to import under this solution, we should consider what steps the exporting developing country Member should undertake in responding to a request from a developing or least-developed country with insufficient capacity in the pharmaceutical sector.

[3] It is further understood that in the event the importing Member owes, in accordance with Article 31, an amount of compensation to the right holder, such amount could take into account any compensation paid to the right holder under the licence issued in the Member country exporting the product.

22. Again, in considering an exception to Article 31(f), Members should:

> **Agree that the developing country Members seeking to export needed pharmaceuticals under this mechanism shall:**
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> > **Authorize use of the patent in compliance with each provision of TRIPS Article 31, except for Article 31(f), including notice to the right holder in conformity with Article 31(b);**

23. All WTO Members should expect that the exporting Member will seek to ensure that the medicines produced in its territory are not diverted from the Member for which they were intended, either by being diverted to other markets or by leaking onto the domestic market of the exporting Member.

24. Therefore, we would consider it reasonable for Members to agree that the exporting country also:

> **Ensure that the entirety of the production is exported to the Member making the request.**

VII. ELEMENTS RELATING TO ALL MEMBERS

25. Having given consideration to the scope of the solution and the elements for determining what situations may give rise to the application of the solution in both importing and exporting Members, we should also give consideration to the contribution Members that are not directly participating in the implementation of the solution in a particular case can make to the overall successful operation of the mechanism.

26. We believe that the TRIPS Council must, as part of any solution, affirm the commitment of all Members to take necessary steps to prevent diversion of the relevant pharmaceuticals into their markets, in order to ensure that the medicines reach the poor for whom they were intended. All WTO Members, consistent with their existing TRIPS obligations, should ensure that means are provided to prevent pharmaceuticals made available under this mechanism from being diverted from the markets for which they are intended.

27. The TRIPS Agreement already requires that Members provide the means for the right holder to prevent entry or sale of such infringing products. For example, Article 28 requires that right holders be able to prevent such entry or sale where a valid patent exists. In addition, at the border TRIPS Article 44.1 requires WTO Members to provide measures to stop infringing imports before they enter the stream of commerce. Article 44.1 provides that "*the judicial authorities shall have the authority to order a party to desist from an infringement, inter alia, to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right, immediately after customs clearance of such goods*".

28. Therefore, we believe it would be appropriate, in order to ensure that the successful implementation of the solution benefits those most in need, that Members:

> **Agree that all Members, consistent with their existing TRIPS obligations, will ensure that means are provided to prevent pharmaceuticals made available under this mechanism from being diverted from the markets for which they were intended.**

VIII. MECHANISM FOR GIVING EFFECT TO THE SOLUTION

Article 31

29. While each option suggested by Members has some merit, at this stage we believe an expeditious, workable, transparent, sustainable and legally certain solution may more likely be achieved through either a moratorium for dispute settlement or a waiver of the obligation in TRIPS Article 31(f). A moratorium or waiver of the obligation of TRIPS Article 31(f) may have several advantages over other options suggested by Members. First, agreement can be reached on a moratorium or waiver much more easily and quickly than on an amendment to the TRIPS Agreement and further delay would be required for Members' formal acceptance. Crafting an amendment on which all Members can agree would delay implementation of the "expeditious solution" beyond the agreed deadline. Should an amendment be adopted, it could prove to be either ineffective or seriously harmful in practice. A further amendment of the Agreement would be required to correct this situation. Finally, if a country begins production for export relying on either an authoritative interpretation or an amendment, its actions could be challenged as being inconsistent with the interpretation or amendment. Because a country would only have full legal certainty after the conclusion of a dispute process - a situation that we would like to avoid - we are concerned that an interpretation or amendment will not deliver the legal certainty and security sought by many WTO Members.

30. In contrast, a moratorium or waiver (and the actions taken under them) would be approved in advance, which would provide the manufacturing country with certainty that its production and export of the product under the waiver will not be subject to challenge.

Article 30

31. Some Members have suggested an authoritative interpretation of Article 30. Article 30 of the TRIPS Agreement permits Members to provide limited exceptions to patent rights "*provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties*". This provision is intended to apply to statutory exceptions already provided for in many countries' laws at the time the TRIPS Agreement was negotiated, situations such as non-commercial experimental use, use aboard vessels temporarily in the territory of a Member, and prior user rights. Interpreting Article 30 to allow Members to amend their patent laws to permit compulsory licences to be granted to authorize their manufacturers to produce and export patented pharmaceutical products to other countries would both unreasonably conflict with the normal exploitation of a patent and unreasonably prejudice the legitimate interests of the patent owner. The limited exceptions to patent rights authorized by Article 30 do not require a government decision in each case. Article 30 contains no requirements for notifying a patent owner of use, for establishing particular terms and conditions, for expiration if circumstances change, or for remuneration to the patent holder. The legitimate interests of third parties, in this case, the people facing health crises in other countries, can be dealt with adequately through the use of either a dispute settlement moratorium or a waiver of Article 31(f).

Summary

32. With certain safeguards, developing country Members having sufficient manufacturing capacity in the pharmaceutical sector should be permitted to export pharmaceuticals to a developing or least-developed country that is afflicted by public health problems, especially those resulting from HIV/AIDS, malaria, tuberculosis and other epidemics, and that lacks manufacturing capacities in the pharmaceutical sector. Where patents exist in the exporting country, the exporting country would comply with each provision of TRIPS Article 31, except for Article 31(f). Further, the exporting country would have to ensure that the entirety of the production under compulsory licence is exported

to the Member making the request. All Members undertake, consistent with existing TRIPS obligations, to prevent pharmaceuticals made available under this mechanism from being diverted from the markets for which they were intended. And finally, the TRIPS Council shall receive information and examine operation of the solution for the benefit of those Members for whom it is intended.

33. Notwithstanding the views we have expressed above, we continue to be willing to consider any proposed solution with respect to Article 31 that is expeditious, workable, transparent, sustainable and provides legal certainty.

34. We fully expect that by the next meeting of the TRIPS Council we will be prepared to offer further substantive contributions to this effort with even greater specificity on the key elements and mechanics of implementing a solution expeditiously by the end of the year.

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