

Council: The 5<sup>th</sup> Ministerial Conference of the World Trade Organization

Topic: The Agreement of Trade Related Aspects of Intellectual Property Rights (The TRIPS Agreement) and its implications on Public Health

Date: 6/3/2003

Sponsors: The African Group, the Federative Republic of Brazil, Canada, the People's Republic of China, Republic of India, the European Communities and the United States of America

Co-sponsors: The Republic of Cuba, Japan and the United Mexican States.

1. Recalling article 7 and article 8 of the TRIPS agreement,
2. Referring to paragraph 4 of the Doha Declaration and the 16<sup>th</sup> of December Proposals of
3. the Chairman of the council for Trade Related Aspects of Intellectual Property
4. Rights –here and after TRIPS,
5. Emphasizing those public health problems that developing countries and Least
6. Developed Countries –here and after LDCs- face should be taken into consideration,
7. Expressing our full commitment for implementing the TRIPS agreement,
8. Believing in the assistance of international organizations contributing in the 5<sup>th</sup>
9. Ministerial Conference of the World trade Organization,
10. Keeping in mind the highly need of flexible access to medicines,
11. Aware of the different conflicting point of views of paragraph 6 of the Doha
12. Declaration,
- 13.
14. Hereby, we the Ministers of the member states of the World Trade Organization
15. 1) Approve the following definitions;
16. A) “Pharmaceutical product” means any patented product, or product
17. manufactured through a patented process of the pharmaceutical sector needed
18. to address the public health problems in eligible importing members. It is
19. understood that active ingredients necessary for its manufacture, and diagnostic
20. kits which their patents have expired, needed for its use would be included;
21. B) “Exporting member” means a member using the system explained in this
22. Declaration manufacturing pharmaceutical products for, and exporting them to
23. an eligible importing member –as explained later in this Declaration;
24. 2) State that the role of the World Health Organization –here and after known as WHO-
25. concerning this problem will include:
26. A) Determining which World Trade Organization members shall be considered
27. as eligible importing members, through a report from the secretariat of the
28. WHO, noting that this report:
29. (i) Should determine the names and quantities of the pharmaceutical
30. products needed by the country,
31. (ii) Should be based on the following conditions:
32. - The burden of disease in that country;
33. - The public health expenditure in the national budget of this country;
34. B) Monitoring the commitment of the World Trade Organization members to
35. the following:
36. (i) The commitment to the report presented by the WHO
37. (ii) Their commitment to avoid trade diversion;
38. 3) Agree on the following procedures to avoid trade diversion:

39. A) Special labeling or marketing for the pharmaceutical product,  
40. B) Monitoring the behavior of the eligible importing members towards the  
41. usage of the imported pharmaceutical products by WHO and other international  
42. organizations;
43. 4) Approve the following joint programs between the WHO/United Nations Conference  
44. on Trade and Development- here and after UNCTAD:
45. A) Differential Pricing:
46. (i)The patent owner shall provide this program by 50% of the determined  
47. quantity of pharmaceutical product by the WHO report previously mentioned,  
48. at the Break-even Price;
49. (ii) LDCs shall pay the subsidized price under these conditions:
50. - This price is determined according to the per-capita purchasing power of  
51. the importing country;
52. - This price shall be above the equivalent price of the generic medicine;
53. (iii) In the case that the payments of the importing country purchase a lower  
54. amount than is stated in the WHO report, Non Governmental Organizations  
55. specially (Oxfam, Red Cross, Medicines Sans Frontiers) are to pay the  
56. difference;
57. B) Generic Medicine Support:
58. (i)The exporting member (producer of the generic medicine) should provide  
59. this program by the other 50% of the determined quantity of pharmaceutical  
60. product;
61. (ii) Noting that the price of the generic product shall be paid by the importing  
62. country;
63. (iii) Allocating the gained net profit of the eligible exporting countries as  
64. follows:
65. - 50% given to the patent owner;
66. - 25% given to the eligible exporting country (producer of generic  
67. medicines);
68. - 15% given to LDCs to promote technology transfer in the pharmaceutical  
69. sector;
70. - 10% given to the exporting member to improve Research and  
71. Development (R&D) in the pharmaceutical sector and this would be  
72. controlled by the UNCTAD;
73. 5) Reaffirm that this system shall function in the following procedure:
74. A) This program shall be applied by the end of the transitional period given to  
75. the developing countries to implement the TRIPS Agreement that is January  
76. 1<sup>st</sup> 2005,
77. B) At the first year the supply of the pharmaceutical product shall be divided  
78. equally between the 2 previously mentioned programs,
79. C) An annual gradual increase of 4.545% of providing the pharmaceutical  
80. product in the first program (differential pricing) to reach 100% supply of  
81. patented drugs at the end of the transitional period given to the LDCs to  
82. implement the TRIPS Agreement, which is January 1<sup>st</sup> 2016;
83. 6) Insure that these 2 programs are only applied in the emergency cases as defined by  
84. the WHO report;
85. 7) Take note of that after the year 2016 the differential pricing program would only be  
86. applied in emergency cases;
87. 8) Remind all members that the first program may harm developing countries with  
88. generic pharmaceutical industry;
89. 9) Call upon the UNCTAD to provide developing countries which have generic  
90. pharmaceutical industries a program of capacity building project under the following  
91. conditions:
92. A) Providing an adequate percentage of their national budget to promote  
national Research and Development (R&D) programs;

93. B) Monitoring the usage of the 10% of the gained profit given to them as stated  
94. in clause 4.B of this Deceleration;
95. 10) Consider the 50% given to the patent owner previously mentioned shall be  
96. considered as adequate compensation to patent owner for the usage of the  
97. pharmaceutical product;
98. 11) Hope that the eligible exporting member provide the council for TRIPS by true  
99. financial statements;
100. 12) Approve the following amendments to the TRIPS Agreement:
101. A) Amending Article 31 sub-paragraph (f) to read as follows:  
102. “Any such use shall be authorized predominantly for the supply of the domestic  
103. market and the free trade area market that the member authorizing such use is a  
104. member at”;
105. B) Deleting Article 31 sub-paragraph (h) that reads as follows: The right holder  
106. shall be paid adequate remuneration in the circumstances of each case taking  
107. into account the economic value of authorization;
108. 13) Establish the committee of the TRIPS and public health under the direct supervision  
109. of the Council for TRIPS;
110. 14) Note that the composition and tasks of this committee are identified in Annex I  
111. attached to this Deceleration.

## Annex I

1. Realizing the importance of the issue of TRIPS and Public Health,
2. Stressing the need of having a specialized sub-committee for the TRIPS and Public
3. Health,
4. Recalling the establishment of the sub-committee of the TRIPS and Public Health in
5. clause 12 of this declaration,
- 6.
7. We the Ministers of the member states of the World Trade Organization:
8. 1) Approve the following composition of the sub-committee:
9.       A) All World Trade Organization member states,
10.       B) Granting the observership status to UNCTAD, WHO, World Intellectual
11.       Property Organization;
12. 2) Affirm the following tasks of the sub-committee:
13.       A) Ensuring that all funds allocated for Research and Development (R&D), and
14.       technological transfer are properly used and they are achieving the purpose
15.       they are meant to achieve.
16.       B) Notifying all World Trade Organization members of the following:
17.           (i) The recommendations of WHO's report which determines the eligible
18.           importing member & the basis of the public health crises & the supply of
19.           medicines are properly allocated;
20.           (ii) Informing the Council for TRIPS of the compulsory license issued by the
21.           exporting member;
22.       (C) Monitoring the commitment of all WTO members to combat trade
23.       diversion;
24.       (D) Electing a fact finding committee in the case of the suspicion of any
25.       violation of the notification presented to the council or any other principles of
26.       this council taking into considerations the demands of the harmed party;
27.       (E) The composition of this Fact finding committee, shall as follows: a
28.       representative of the following organizations WTO, WHO and UNCTAD;
29.       (F) This fact finding committee shall submit its report to the Dispute Settlement
30.       Body (DSB) of the World Trade Organization;
31.       (G) Deciding what free trade area which the member authorizing the
32.       compulsory license is a party in, according to the amended article 31.f in this
33.       declaration, on case by case basis;
34. 3) Stress that this committee would meet on weekly basis.