Hearing on TRIPS and Access to Medicines

European Parliament, Committee on International Trade
Brussels, 18 January 2005

Introductory Statement by Roger Kampf,
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1. Introduction: From the Doha Declaration on the TRIPS Agreement and Public Health to the August 2003 Decision

The TRIPS Council started looking into the possible implications of the TRIPS Agreement for access to medicines well in advance of the Doha Ministerial Conference in 2001. To respond to concerns expressed, the stand-alone Doha Declaration on the TRIPS Agreement and Public Health was adopted at the 4th Ministerial Conference in November 2001. It confirms and clarifies the flexibility in the TRIPS Agreement available to ensure that intellectual property rights are interpreted and applied in a manner supportive of public health. The Declaration also accords least-developed WTO Members an extension of their transitional period until 2016 in regard to the protection and enforcement of patents and rights in undisclosed information with respect to pharmaceutical products. At the same time, it recognises the importance of intellectual property protection for the development of new medicines and reaffirms all WTO Members' commitment to the TRIPS Agreement.

The ability of countries with insufficient or no manufacturing capacities in the pharmaceutical sector to make effective use of compulsory licensing arose during the work on the Declaration. Concerns were expressed about the availability of supply sources from generic producers in other countries to meet the needs of those countries wanting to import under compulsory licenses. At the origin of those concerns is Article 31(f) of the TRIPS Agreement, which explicitly requires that a compulsory license granted by a Member to generic producers shall be "predominantly for the supply of the domestic market" of that Member. Paragraph 6 of the Declaration recognised the problem and instructed the TRIPS Council to find an expeditious solution.

Following intensive work in 2002, a Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health was adopted by the WTO's General Council on 30 August 2003. It waives the obligations:

- of an exporting Member under Article 31(f) of the TRIPS Agreement to the extent necessary for the purposes of production and export of the needed medicines to those countries that do not have sufficient capacity to manufacture them;

- of the importing country under Article 31(h) of the TRIPS Agreement in situations when remuneration is paid in the exporting Member for the same products; and

- under Article 31(f) of the TRIPS Agreement of any developing or least-developed country that is party to a regional trade arrangement at least half of the current membership of which is made up of presently least developed countries.

The system established under the August 2003 Decision provides for the conditions necessary to ensure transparency and requires to have safeguards in place to prevent trade diversion. It takes also care of minimising burdens. For example:

- Notifications required to be made under the system by importing and exporting countries are only for information purposes and are not subject to approval by any WTO body. A country wishing to use the system for importing a pharmaceutical product only needs to conduct a self-verification that it does not have the capacity to manufacture the product and then notify its requirement and the methods and results of its self-verification to the WTO. Least developed countries are automatically assumed not to have such capacity for any pharmaceutical product. Exporting countries have to notify details of the licences granted, but these are countries which can be presumed to have greater administrative and other capacities than the importing Members. Notifications are not required for African countries exporting or importing within the regional trading arrangement;

- As one of the principal safeguards against diversion, the compulsory licensee in the exporting country is required to clearly identify its product as being produced under the system through specific labelling and marking. Since all product have to be marked, labelled and packaged, this cannot be construed to be greatly burdensome. Such procedures should not in general have a significant impact on the price of pharmaceuticals; and

- The requirement to take measures against diversion in the importing countries is confined to reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion. Third countries are required to use the means already available under the TRIPS Agreement to prevent the importation and sale of products produced under the system and not meant for their markets.

All WTO Members are eligible to be importers but some[1] have decided to opt out of using the system altogether to import and others have stated in the General Council before the adoption of the Decision that if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency[2]. All WTO Members are eligible to be exporters in order to produce and export pharmaceutical products to an eligible importing country.

[1] Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America.

[2] Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia agreed that upon their accession to the European Union, they will opt out of using the system as importers. In addition these acceding Members (until their accession) and others, viz. Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, United Arab Emirates, have agreed that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency.

The Decision further envisages an amendment to the TRIPS Agreement; the waivers are to remain in place until such an amendment takes effect.

The Decision was accompanied by a Chairman's statement representing key shared understandings of Members regarding its interpretation and implementation. This statement was designed to provide comfort to those who feared that the Decision was too open-ended and might be abused in a way that would undermine the benefits of the patent system.

2. Use of the System Established under the August 2003 Decision

The WTO Secretariat established a website dedicated to the Decision to ensure transparency of the notifications made. To date, there have been no notifications made to the TRIPS Council of the use of the system.

But there has been a certain amount of activity relating to the grant of compulsory licences. Countries have granted compulsory licences for the importation of anti-retrovirals, but given that the imports were coming from countries that were not yet obliged to provide patent protection for pharmaceutical products, there was no need to use the system. Some others have threatened the use of compulsory licensing, which led to a reduction in prices from the originator companies in certain cases, or to an agreement on voluntary licensing for local production in the country in need of the medicines in other cases.

Can we conclude from the lack of use of the system that it is too complicated and impractical, or, on the contrary, that there was never any real problem ? Both judgements appear premature. It is more likely that the system has not been used so far for the following reasons:

- Traditionally compulsory licences have been very rare and the main effect of the system has been to improve the bargaining power of applicants in obtaining lower prices or voluntary licences. This is usually preferred by the originators and also has an advantage for the applicant since it will generally bring with it the transfer of technology. Recent examples seem to indicate that the preference for voluntary licensing is continuing;

- Exporting countries under the system need to amend their legislation to permit the production of patented medicines for export under compulsory licences. This usually involves primary legislation and inevitably takes time. Only Norway, a country without a significant generic industry, has completed this task. Canada has amended its primary legislation; implementing regulations were published for comment in October and it is expected that the legislative framework is in place in early 2005. As you know, the EC Commission has also tabled a proposal for a Regulation end October, which will soon be discussed in the Council. Finally, Switzerland is expecting to present draft legislation as part of the revision of its patent legislation in the near future;

- Developing countries who had yet to introduce patent protection for pharmaceutical products were required by the TRIPS Agreement to do so by 1 January 2005. Until recently, it was thus possible to import products patented elsewhere from them

without the need to use the paragraph 6 system. As pharmaceutical products progressively come under patent protection in these countries, the need to use the system may become greater.

3. Amendment of the TRIPS Agreement to Replace the Paragraph 6 Decision

Paragraph 11 of the August 2003 Decision called on the TRIPS Council to prepare an amendment to the TRIPS Agreement to implement the Decision with a view to adopting it by June 2004. This amendment is to be "based, where appropriate" on the Decision.

The TRIPS Council took the matter up at its last meeting in 2003, and in all meetings in 2004. All WTO Members continue to be committed to replacing the Decision with an amendment to the TRIPS Agreement. However, due to differences of view on the content, timing and legal form of the amendment, the TRIPS Council agreed at its meeting in June 2004 to extend the timeframe for adoption of an amendment to March 2005. Providing more time does not imply any legal vacuum since the Decision continues to apply until the amendment comes into force.

What are the main issues at stake ? The key question certainly is whether the content of the amendment should track faithfully the deal that has already been struck or whether certain "improvements" could be made. Positions taken so far can be summarised as follows:

- the EC, supported by some others, takes the view that the amendment should be a purely technical transposition of the waiver; the Chairman's statement could be re-read by the Chairman of the General Council at time of the adoption of the amendment so that it has the same status in relation to the amendment as it presently has in relation to the waiver;

- the US seeks to incorporate a reference to the Chairman's statement in the amendment of the TRIPS Agreement, which is seen by many as enhancing the legal status of the Chairman's statement; and

- the African Ministers at their various meetings in the summer insisted on an expeditious permanent solution.

In line with this position, the African Group tabled a proposal on the implementation of paragraph 11 of the Decision at the last TRIPS Council meeting of 1-2 December 2004. This is the first specific proposal put forward in this exercise. While the initiative was welcomed by many developing countries, the proposal was criticized by most developed countries as re-opening the August 2003 Decision, by omitting certain parts of it and modifying the language in some other parts. They reiterated their view that only a "neutral" implementation, faithfully reflecting the deal reached in August 2003, would be acceptable. At this stage, it seems clear that any attempt to re-open the substance of the August 2003 deal may further delay an agreement on the amendment.

The Chair of the TRIPS Council has undertaken to hold intensive consultations prior to the Council's next meeting in early March 2005.

4. Technical Assistance

From the WTO's perspective, it is important to provide technical assistance to importing developing countries so that they feel fully equipped to use the system established under the August 2003 Decision. The WTO is regularly organising regional workshops on intellectual property, of which an important part is focusing on the TRIPS Agreement and public health, and more particularly the implementation of the Decision on paragraph 6. In 2004, seven such workshops were carried out in all regions of the world. In 2005, in addition to further regional workshops, the WTO is organising in Geneva a workshop for IP, trade and public health officials dedicated to the operation of the system. However, the WTO disposes only of limited financial and human resources and therefore attaches importance to technical assistance activities of other organisations, such as WIPO and WHO, as well as to similar efforts by individual countries.

5. Concluding Remarks

The August 2003 Decision by WTO Members signals the fulfilment of the instructions given by Ministers under the Declaration and enables countries without manufacturing capacity to make full and effective use of a major flexibility in the TRIPS Agreement. Hopefully, it will soon be possible to conclude this work by reaching an agreement amongst WTO Members on the amendment of the TRIPS Agreement, which would implement the Decision on a permanent basis.

In the meantime, it is of crucial importance to ensure that the system established under the August 2003 Decision is fully operational and works to the benefit of countries in need of medicines. Major exporting countries, such as the EU, should make all efforts to create the basis for this to happen expeditiously. This will include putting into place the necessary changes in their national legislation, but also making all necessary resources available to provide adequate financial and technical assistance to importing countries.

ANNEX 1

WORLD TRADE ORGANIZATION

WT/L/540
2 September 2003

(03-4582)

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

Decision of 30 August 2003*

The General Council,

Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the "Declaration") and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement and to report to the General Council before the end of 2002;

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in this Decision, the importance of a rapid response to those needs consistent with the provisions of this Decision;

Noting that, in the light of the foregoing, exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products;

Decides as follows:

1. For the purposes of this Decision:

   (a) "pharmaceutical product" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that

* This Decision was adopted by the General Council in the light of a statement read out by the Chairman, which can be found in JOB(03)/177. This statement will be reproduced in the minutes of the General Council to be issued as WT/GC/M/82.

active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included[3];

(b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification[4] to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members[5] and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency;

(c) "exporting Member" means a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.

2. The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph:

(a) the eligible importing Member(s)[6] has made a notification[2] to the Council for TRIPS, that:

(i) specifies the names and expected quantities of the product(s) needed[7];

(ii) confirms that the eligible importing Member in question, other than a least-developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and

(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision[8];

(b) the compulsory licence issued by the exporting Member under this Decision shall contain the following conditions:

(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;

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[3] This subparagraph is without prejudice to subparagraph 1(b).

[4] It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

[5] Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, the Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States.

[6] Joint notifications providing the information required under this subparagraph may be made by the regional organizations referred to in paragraph 6 of this Decision on behalf of eligible importing Members using the system that are parties to them, with the agreement of those parties.

[7] The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

[8] This subparagraph is without prejudice to Article 66.1 of the TRIPS Agreement.

(ii) products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

(iii) before shipment begins, the licensee shall post on a website[9] the following information:

- the quantities being supplied to each destination as referred to in indent (i) above; and

- the distinguishing features of the product(s) referred to in indent (ii) above;

(c) the exporting Member shall notify[10] the Council for TRIPS of the grant of the licence, including the conditions attached to it.[11] The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

3. Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

4. In order to ensure that the products imported under the system set out in this Decision are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

5. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

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[9] The licensee may use for this purpose its own website or, with the assistance of the WTO Secretariat, the page on the WTO website dedicated to this Decision.

[10] It is understood that this notification does not need to be approved by a WTO body in order to use the system set out in this Decision.

[11] The notification will be made available publicly by the WTO Secretariat through a page on the WTO website dedicated to this Decision.

6. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:

(i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least-developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least-developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;

(ii) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of the TRIPS Agreement, including in conjunction with other relevant intergovernmental organizations.

7. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Declaration. To this end, eligible importing Members and exporting Members are encouraged to use the system set out in this Decision in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of the TRIPS Agreement, paragraph 7 of the Declaration and any other relevant work of the Council for TRIPS.

8. The Council for TRIPS shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective operation and shall annually report on its operation to the General Council. This review shall be deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

9. This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration, and to their interpretation. It is also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the present provisions of Article 31(f) of the TRIPS Agreement.

10. Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

11. This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1).

ANNEX 2

EXCERPT FROM THE GENERAL COUNCIL MINUTES – WT/GC/M/82 – MEETING OF 25, 26 AND 30 AUGUST 2003

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

STATEMENT READ OUT THE CHAIRMAN OF THE GENERAL COUNCIL

"29. The Chairman then read out for the record the following statement, which had been forwarded to him by the Chairman of the Council for TRIPS on the approval of the TRIPS Council:

> "The General Council has been presented with a draft Decision contained in document IP/C/W/405 to implement paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. This Decision is part of the wider national and international action to address problems as recognized in paragraph 1 of the Declaration. Before adopting this Decision, I would like to place on the record this Statement which represents several key shared understandings of Members regarding the Decision to be taken and the way in which it will be interpreted and implemented. I would like to emphasize that this Statement is limited in its implications to paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.
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> "First, Members recognize that the system that will be established by the Decision should be used in good faith to protect public health and, without prejudice to paragraph 6 of the Decision, not be an instrument to pursue industrial or commercial policy objectives.
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> "Second, Members recognize that the purpose of the Decision would be defeated if products supplied under this Decision are diverted from the markets for which they are intended. Therefore, all reasonable measures should be taken to prevent such diversion in accordance with the relevant paragraphs of the Decision. In this regard, the provisions of paragraph 2(b)(ii) apply not only to formulated pharmaceuticals produced and supplied under the system but also to active ingredients produced and supplied under the system and to finished products produced using such active ingredients. It is the understanding of Members that in general special packaging and/or special colouring or shaping should not have a significant impact on the price of pharmaceuticals.
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> "In the past, companies have developed procedures to prevent diversion of products that are, for example, provided through donor programmes. "Best practices" guidelines that draw upon the experiences of companies are attached to this statement for illustrative purposes.[12] Members and producers are encouraged to draw from and use these practices, and to share information on their experiences in preventing diversion.
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> "Third, it is important that Members seek to resolve any issues arising from the use and implementation of the Decision expeditiously and amicably:
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> - "To promote transparency and avoid controversy, notifications under paragraph 2(a)(ii) of the Decision would include information on how the Member in

[12] Reproduced as Annex I.

question had established, in accordance with the Annex, that it has insufficient or no manufacturing capacities in the pharmaceutical sector.

- "In accordance with the normal practice of the TRIPS Council, notifications made under the system shall be brought to the attention of its next meeting.

- "Any Member may bring any matter related to the interpretation or implementation of the Decision, including issues related to diversion, to the TRIPS Council for expeditious review, with a view to taking appropriate action.

- "If any Member has concerns that the terms of the Decision have not been fully complied with, the Member may also utilize the good offices of the Director-General or Chair of the TRIPS Council, with a view to finding a mutually acceptable solution.

"Fourth, all information gathered on the implementation of the Decision shall be brought to the attention of the TRIPS Council in its annual review as set out in paragraph 8 of the Decision.

"In addition, as stated in footnote 3 to paragraph 1(b) of the Decision, the following Members have agreed to opt out of using the system as importers: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, The Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, the United Kingdom and the United States.

"Until their accession to the European Union, the Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, the Slovak Republic and Slovenia agree that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency. These countries further agree that upon their accession to the European Union, they will opt out of using the system as importers.

"As we have heard today, and as the Secretariat has been informed in certain communications, some other Members have agreed that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency. These are the following: Hong Kong, China; Israel; Korea; Kuwait; Macao China; Mexico; Qatar; Singapore; the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu; Turkey and the United Arab Emirates."

30. The Chairman then proposed that the General Council take note of the statements and, in the light of the Chairman's Statement he had just read out, adopt the draft Decision contained in document IP/C/W/405 in accordance with the Decision-Making Procedures under Articles IX and XII of the WTO Agreement agreed in November 1995 (WT/L/93).

31. The General Council so agreed.[13]"

[13] The Decision was subsequently circulated as WT/L/540.

ANNEX 3

WORLD TRADE ORGANIZATION

WT/MIN(01)/DEC/2
20 November 2001

(01-5860)

MINISTERIAL CONFERENCE
Fourth Session
Doha, 9 - 14 November 2001

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001

1. We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize 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. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

7. We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement.