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# CANCUN SESSION OF THE PARLIAMENTARY CONFERENCE ON THE WTO

Cancún (Mexico), 9 and 12 September 2003

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*Organised jointly by the Inter-Parliamentary Union and the European Parliament with the support of the Mexican Parliament*

Item 5(b) of the provisional agenda

## THE TRIPS AGREEMENT AND PUBLIC HEALTH

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### **I. Basis of the TRIPS Agreement**

1. The TRIPS Agreement (Agreement on the Trade-Related Aspects of Intellectual Property Rights), which constitutes annex 1C of the Marrakech Agreement establishing the WTO, is to date the most complete multilateral undertaking in the area of intellectual property. This agreement, which deals with patents, copyright and trademarks, recognises notably the patent holder's monopoly over rights of sale for a long period. At the Doha Conference, the ministers agreed that provisions should be made for special interpretation of this agreement in the particular context of public health.

2. The issue of access to medicines for the poorest countries was at the centre of the deliberations at the Doha Conference. It became a kind of rallying point for consideration of the specificities of developing countries and their integration in a globalised world. It also influenced, in large measure, their support for the principle of a new round of international trade negotiations.

3. The stakes involved are very high indeed. According to the World Health Organization (WHO), a third of the world population, i.e., around two billion people, do not have access to essential medicines. Yet the health situation of developing countries is critical, due mainly to the AIDS epidemic which affects 42 million persons throughout the world, the majority of whom are in Africa, and 90% of whom have no medicines. The magnitude of this problem justifies making available to them pharmaceutical products which are currently out of their reach because of their market price. It is estimated that some 6.8 million persons are affected by the AIDS virus in West Africa. At the price set on the European market, treating these populations would cost €6 billion a year, a far cry from the €500 million which the countries concerned allocate each year to their health budgets.

4. It is worth mentioning why this problem, which *a priori* belongs to the domain of public health, solidarity and humanitarian aid, became directly entangled in international trade negotiations.

5. The problem arises from the TRIPS Agreement which governs the protection of intellectual property rights at the global level, reform of which had been included in the Doha Agenda. This agreement establishes rights for holders and mechanisms for guaranteeing those rights. The regulation applies *inter alia* to medicines and covers the fixing of sale prices. Developing countries, which now make up the majority of WTO Members, had very high expectations of developed countries regarding the relaxing of related international rules.

6. The deliberations held at the Doha Conference focused therefore on finding a legal solution acceptable to all aimed at reducing the price of medicines by authorizing the exemption of duties without prejudice to the financial gains used to foster research.

## II. The Doha Declaration

### (a) Asserted principles

7. At the end of the Conference, the parties adopted a separate declaration on public health and the implications of the TRIPS Agreement on access to medicines.

8. This declaration underscores the imperative of public health which justifies governments using the “flexibilities” provided for therein, particularly resorting to **compulsory licences** in emergencies. Having established that, the text is fairly similar to prevailing Western laws. In fact, the same flexibility to grant compulsory licences exists, for example, in French and American law. Where a genuine reason exists for circumventing patent protection, a country can grant a manufacturer a compulsory licence to manufacture duty-free medicines. Depending on the national legislation on intellectual property in force, this decision may take the form of a law or regulation. The patent holder is either involved in the negotiation or informed only in an emergency and receives in exchange financial compensation, even if only partial.

### (b) The difficulty with implementation

#### Authorisation to manufacture generic medicines

9. An agreement in principle was reached in Doha which acknowledged the need to assist developing countries in combating the three fatal pandemics of AIDS, malaria and tuberculosis. Considering, to quote the Secretary General of the United Nations, Kofi Annan, “*that rules regulating intellectual property must not act as a barrier to the promotion and protection of public health*”, **it grants emerging countries the right to reproduce medicines patented in developed countries**. Such an authorisation benefited the big emerging countries such as India, Thailand, Brazil and South Africa, who have laboratories and the scientific capabilities to produce those substances. However, the agreement sidelined the poorest countries which do not possess the technical production capacity although they are often the ones which are most affected by the diseases in question.

10. Indeed, although the WTO accepted the **manufacture** of medicines for local use, it was against the **marketing** of generic medicines and by extension, its export outside the domestic market mainly because of opposition from the big pharmaceutical groups. These groups fear that the export of low-cost substances to Third World countries would divert trade towards developed countries and result in losses which would dry up the funds they earmark for research and development.

#### Problems associated with exporting generic medicines

11. Aware of the gridlock, WTO Member Countries discontinued the principle of a rendez-vous clause to the end of 2002. The TRIPS Council was entrusted with the task of finding a legal solution to this problem.

12. For a time, this commitment was respected as a second agreement was concluded on 15 November 2002 in Sydney among 24 governments, in addition to the European Union, who met in a WTO Mini-Ministerial.

13. The agreement should authorise certain countries to manufacture and export to “countries which need them the most” the generic medicines used for “diseases of an epidemic proportion” on a case by case basis. Albeit clumsy and complicated in terms of implementation, it should guarantee the poorest countries access to generic products at an acceptable price and avert the risk of re-export to other countries. However, the process was incomplete as the matter of determining **which medicines** were covered by the agreement and **which countries** could benefit remained unresolved; besides which, agreement of WTO Members on the mechanism as a whole also had to be obtained.

14. The TRIPS Council and the WTO General Council met on 20 December 2002, and noted the obvious opposition of the United States and the absence of a consensus on the text which had been proposed four days earlier by the Ambassador of Mexico who is Chairman of the TRIPS Council. No headway has been made since despite a second attempt, albeit unsuccessful, at a compromise at the Mini-Ministerial in Tokyo in mid February 2003.

### III. Breakdown in negotiations

#### (a) Ambiguity of the Doha mechanism

##### Vague definitions

15. Agreed upon in the closing turmoil of a difficult Conference, the Doha text was an eminently political declaration, whose overall aspect made its translation into a legally binding instrument a delicate balancing act.

16. This can be observed from the first article which expressly mentions three diseases, namely: AIDS, tuberculosis and malaria and “other epidemics”. This phrase, which referred to anthrax, for example, given the events of that time, could today include severe acute respiratory syndrome (SARS), which hit Asia hard before spreading to the rest of the world. In the French version, the word “*épidémies*” supports the notion of contagion while in English *epidemics* could also include diabetes or mental illness. From the very outset, therefore, the text was vague regarding the mechanism, perhaps deliberately so, and this bred misunderstanding among the various Member States.

17. Indeed, developing countries have insisted on retaining the “Doha spirit”, considering that the mechanism’s scope of application was unlimited and could pertain to any pathology. Other partners, however, such as the United States, had a more restricted notion of the diseases to be considered. The same vagueness of language is found in Article 4 which mentions “*public health crises*” without actually defining what they are. The same is true of Article 5C which confers on all countries the right to report, of their own volition, such a crisis situation in order to extricate themselves from the obligations of the TRIPS Agreement.

##### Uncertain legal basis

18. To implement the exception mechanism, two distinct provisions of the TRIPS Agreement can be used, but the choice of legal basis carries different consequences.

19. **Article 30** authorises very limited exceptions to the regulation of patents, which could be applied to medicines. In conformity with this text, Members may provide limited exceptions to the exclusive rights conferred by a patent, 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.

20. The advantage of taking this route would be to perpetuate the regimen applicable to medicines by adding an interpretative provision limited to these products. The procedure in itself is simple but the pharmaceutical

industry considers it dangerous, particularly since patent law is applied directly by national tribunals and not by WTO itself.

21. **Article 31** outlines the mechanism of compulsory licences. Pursuant to this article, the granting of compulsory licences and the use by public authorities of the object of a patent without authorisation of the right holder are allowed, but are subject to conditions aimed at protecting the legitimate interests of the right holder. It provides, in particular, for the following cases:

- Not to grant such licences unless the proposed user has made efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time;
- To grant the right holder adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation;
- To provide for judicial review or other independent review by a distinct higher authority.

22. By using Article 31 as the basis for action, the right to export generic medicines outside the national territory could be foreseen. The downside to this solution is that it sets into motion complex procedures which require a consensus and which have but a limited effect in time, one year, in principle. Furthermore, it will mean re-opening WTO's most fragile agreement which protects the interests of industrialised countries, and which developing countries are legally ill-equipped to handle.

23. The decision as to which of these two bases should be used has not been made. Developing countries, supported by WHO and non-governmental organisations (NGOs) are in favour of the Article 30 solution, considering that it is more in keeping with the "Doha spirit". The United States, the European Commission and the pharmaceutical industry opt for Article 31, which, in their view, follows "Doha to the letter". The Member States of the Union are divided between the two options, France having long supported the Article 30 route. However, it should be noted that neither of the solutions is entirely satisfactory.

## **(b) Opposing theories**

### **Positions presented**

24. The deliberations centred mainly on the list of diseases concerned and the countries likely to use the emergency procedure.

#### *Diseases targeted*

25. The United States were for imposing a short list of 25 diseases by retaining the notion of communicable diseases. To that end, they blocked any move towards a compromise by the stipulated deadlines and provoked a severe reaction from certain developing countries which refused to move away from the text drafted at Doha, which does not impose any limitations regarding pathologies.

26. During these negotiations, the European Union displayed a great willingness to bring the negotiations to a successful conclusion but that proved insufficient as no decision was reached. It proposed, in particular, drawing up a tentative list of 22 diseases which could be extended in consultation with WHO depending on eventual health situations. However, this proposal was rejected. The idea of drawing up a list, moreover, is perhaps not the best solution for it always carries the risk of being incomplete. For example, in the version presented on 20 December 2002, the list included mumps but not leprosy.

#### *Beneficiaries*

27. After tense deliberations, it would appear that a consensus has been reached on the list of countries likely to resort to the mechanism. The problem lay in the fact that certain countries categorised as "developing", such as Singapore, enjoyed a level of economic growth which did not justify access to the preferential mechanism.

28. Henceforth, developing countries will be broken down into three categories as follows:

- "*low-income countries*" with no industrial production capability (approximately 40);
- "*middle-income countries*" whose situation can be evaluated on a case by case basis; and
- "*high-income countries*" which can withdraw voluntarily from the preferential mechanism.

### Concerns of the pharmaceutical industry

29. The position taken by pharmaceutical laboratories, particularly French ones, is not one of outright hostility towards granting special facilities to developing countries. In fact, they themselves manufactured for poor countries certain medicines which, although they are not generic, did drop the price of treatment by 85 to 90%. However, the fact still remains that these medicines are three times more expensive than their generic counterparts. Moreover, it should be highlighted that a large number of products used in developing countries are no longer covered by the term of protection afforded to patents and this therefore, is the real problem affecting essentially the treatment of AIDS.

30. Nevertheless, these laboratories stress that the real difficulty, in their view, has more to do with the organisation of **screening, administration and follow-up**, which are still woefully inadequate in the countries affected, than with the actual price of medicines. It is not enough to send medicines on site virtually free of charge to be efficient. Dispensaries and medical equipment are also necessary so that patients can receive information and be monitored to ensure that the treatment is being used properly. Very conclusive partnership trials conducted by laboratories with certain African countries, such as Uganda, showed how important this type of monitoring is.

31. Furthermore, manufacturers remain cautious over the risks of diverting the trade in medicines towards rich countries. They have pointed out that a tritherapy treatment costs around €10,000 per year per patient while the generic form of the same treatment costs a mere €200. It is not difficult, therefore, to gauge the financial interest of resale at a high price of an unpatented medicine. True this risk remains limited in France because of the social security mechanisms in place there, but the situation is far less controllable in other European countries and even in the United States where the social security coverage of citizens is based on less favourable structures.

32. Finally, manufacturers consider that the failure of the current negotiations is due to a lack of trust between the partners. The developing countries feel that the rich countries fail to keep their word and developed countries fear an unjustified circumvention of procedures if a health crisis is not actually one of **urgency**. To address this situation, some suggest *ex post* verification, a task which would be entrusted to the WTO Council for TRIPS. This body could be charged with verifying, once the crisis is over, the actual nature and gravity of the crisis with possible assistance from the World Health Organization. If it is found that the situation was exaggerated and the actual circumstances were blown out of proportion, the rights of the patent holder could then be reinstated.

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33. In the meantime, until a solution is found, the licensed medicine-manufacturing countries such as the European Union, the United States, Switzerland and Canada, have ended the moratorium and have pledged unilaterally to refrain from taking the matter to court. In light of the fact that developing countries are not bound to uphold the TRIPS Agreement until 2005, continuing to supply them with generic medicines at present will not constitute a violation of international law.

34. Nevertheless, the concerns of developing countries remain over the forthcoming period and they await a lasting and legally viable solution. If the situation remains at a standstill up to the opening of the Cancun Conference, it is not wholly impossible that developing countries will draw conclusions that will not be conducive to a calm meeting. Doubtless, this matter will not influence the successful conclusion of the negotiations on agriculture or any other matter, but it will certainly affect the overall mood of the ministerial meeting.