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Draft Communication from the European Communities and its Member States to the TRIPs Council

Concept Paper relating to paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health

COMMUNICATION FROM THE EUROPEAN COMMUNITIES AND THEIR MEMBER STATES TO THE TRIPS COUNCIL

CONCEPT PAPER RELATING TO PARAGRAPH 6 OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

I. Introduction

1. Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health recognises 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. Therefore, the Declaration instructs the TRIPs Council to find an expeditious solution to this problem and to report to the General Council before the end of 2002.[1]

2. The European Communities and their Member States (hereinafter "the EC") are committed to continue the efforts they made before and at Doha by co-operating with the other WTO Members in order to reach agreement on such a solution.

3. In this Communication, the EC examine the problem referred to in paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health and explore two possible options for a solution. The EC recognise that other options might exist and are willing to consider any realistic approach on its merits. At this stage, the position of countries which are unable to issue a compulsory licence at all because of an absence of patent protection or because no patents for a given product have been applied for is not addressed in the current proposal. Nevertheless, the EC is ready to consider that issue, too, in the TRIPs Council.

4. As a preliminary remark, the EC wish to point to two important aspects. First, even when manufactured under a compulsory licence, medicines may still be unaffordable for certain segments of the population in poor countries. After all, production of medicines, even by a manufacturer other than the patent holder, always has a cost, and manufacturers have to make a reasonable return on investment if they are to stay in business. Second, any solution that emerges from the discussions in the TRIPs Council will never be a panacea for the problem of access to medicines. It is widely agreed that improving such access requires a mix of complementary measures in different areas. These measures include: public financing of drugs purchases; strengthened health care systems, including the infrastructure for distributing drugs and monitoring their usage; improved information and education; and increased research and development. The discussion within the TRIPs Council should not overshadow these aspects; nor should it divert attention from ongoing international efforts to make medicines available at affordable prices, such as the Global Fund to

[1] The view of the EC is that finding 'an expeditious solution' to this problem means, in effect, that one should be found before the end of 2002.

fight HIV/AIDS, tuberculosis and malaria (GFATM) or the European Commission's own 'Programme for Action'.[2]

II. The problem

II.1 The legal angle

5. During the previous discussions within the TRIPs Council on the link between the TRIPs Agreement and public health, it was argued 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 with regard to patented pharmaceuticals. For such Members, and most developing or least-developed country Members in particular, the right granted by Article 31 of the TRIPs Agreement is of no practical use because, in reality, there is no domestic manufacturer to which such licences can be granted. As a result, they do not enjoy the degree of flexibility or possess the kind of leverage that the ability to issue a compulsory licence can give, and in some circumstances may therefore find it more difficult to obtain substantial price cuts on essential medicines. Finding a solution to the problem posed by their current inability to resort to compulsory licensing could, therefore, benefit these countries in particular and would be in line with the development focus of the new trade agenda.[3]

6. By virtue of the principle of territoriality of patent protection, these Members cannot grant a compulsory licence to a foreign manufacturer, because the patents in both countries are independent of each other. Of course, any WTO member can grant a compulsory licence to *import* a patent-protected product from other countries. There is, however, no guarantee that sufficient supplies will be obtainable on favourable enough terms.

7. These Members could, in theory, rely on *another* Member to issue a compulsory licence to one of its own manufacturers with a view to *exporting* the production under that licence to the Member without manufacturing capacity. In practice, such a solution would in most cases not be workable because Article 31(f) of the TRIPs Agreement stipulates that a compulsory licence should be "predominantly for the supply of the domestic market" of the Member granting the licence. Fulfilling this requirement would be impossible if there were insufficient demand for the domestic market to be able to absorb most of the production. Moreover, in situations of national emergency or other cases of extreme urgency precious time would be lost producing goods which would never be sent to where they were most needed.

II.2 The patent angle

8. The ability to issue a compulsory licence depends of course upon a certain drug being patented, which presupposes that the country has patent legislation in

[2] Communication from the Commission to the Council and the European Parliament – 'Programme for Action: accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction' (COM (2001) 96 final, 21.2.2001).

[3] This paper focuses on the problems faced by developing countries. However, it is worth pointing out that any country may find itself in the position of being unable to manufacture a particular treatment and having to seek supplies abroad. The recent anthrax crisis in North America is a case in point.

place. Therefore, an important element to take into account in assessing the problem in question is the patent situation of pharmaceuticals in developing and least-developed country Members.

9. Most **developing country Members** do provide patent protection for pharmaceutical products. Patents on antiretrovirals, for instance, are in force in several developing countries in sub-Saharan Africa. They appear to be concentrated in countries where pharmaceutical markets are relatively large, such as South Africa or Kenya. In South Africa, for example, 13 out of 15 antiretroviral drugs are patented.

10. The availability of patent protection, though, does not mean that patents have necessarily been granted. Indeed, according to UNAIDS data, most of the medicines used in the treatment of HIV/AIDS are not in fact covered by a patent in the majority of developing countries. The same appears to be true in respect of other major diseases such as malaria and tuberculosis. Another point is that several developing countries[4] have opted for an additional transition period under Article 65.4 of the TRIPs Agreement, which allows them to exclude pharmaceuticals from patent protection until 1 January 2005. Until that date, these countries can legally manufacture generic pharmaceuticals, and *export* them to Members where these drugs are not patented or to Members which have issued a compulsory licence for their import.

11. As far as **least-developed country (LDC) Members** are concerned, Article 66.1 of the TRIPs Agreement provides that the transition period for implementing the Agreement runs until 1 January 2006, while specifying that the TRIPs Council "shall, upon duly motivated request by a least-developed country Member, accord extensions of this period". At the Doha Ministerial Conference, it was agreed, under paragraph 7 of the Doha Declaration on TRIPs and Public Health, that least-developed country Members will not have to implement or apply the TRIPs Agreement's provisions concerning patents and data protection for drugs before 1 January 2016, and the TRIPs Council is instructed to take the necessary action to give effect to this pursuant to Article 66.1 of the Agreement.

12. However, many least-developed country Members already provide patent protection for pharmaceuticals. For example, all 15 Members[5] of the "Organisation Africaine de la Propriété Intellectuelle" (OAPI), most of which are least-developed countries, do provide for patent protection for pharmaceuticals. The same applies to the 14 signatories of the Harare Protocol on Patent and Industrial Designs within the Framework of the African Regional Industrial Property Organisation (ARIPO)[6]. Again, it should be remembered that even where patent protection is available, patents are not necessarily always applied for so that many medicines remain unpatented in a large number of least-developed countries. It is worth noting in passing that access to medicines in countries which do not have patents does not appear any better than in countries which do.

[4] Cuba, Egypt, India, Madagascar, Pakistan, Qatar, United Arab Emirates.
[5] **Benin**, **Burkina Faso**, Cameroon, **Central African Republic**, **Chad**, Congo, Côte d'Ivoire, Gabon, **Guinea**, **Guinea-Bissau**, **Mali**, **Mauritania**, **Niger**, **Senegal**, and **Togo**. LDC Members are in bold.
[6] Botswana, **The Gambia**, Ghana, Kenya, **Lesotho**, **Malawi**, **Mozambique**, **Sierra Leone**, **Sudan**, Swaziland, **Tanzania**, **Uganda**, **Zambia** and Zimbabwe. LDC Members are in bold.

13. At the other end of the spectrum, a few least-developed countries indeed have no patent law at all. These countries, plus those developing countries who have availed themselves of the transition period under Article 65.4, as well as countries which although they have patent legislation have not granted patents for a particular drug, thus have the legal (but not necessarily the physical) possibility of manufacturing generic versions of pharmaceuticals that are still patented in industrialised countries. They could also import them from those Members not yet under an obligation to provide patent protection for pharmaceuticals - although it may not always be easy to find a reliable and affordable source of supplies. It should be borne in mind that generic medicines are not always readily available on international markets and that the prices of branded medicines, even when imported in countries where they are not under patent, remain influenced by the fact that they are patented in their country of origin.

14. We are, therefore, some way off from a situation where all pharmaceuticals are patented in all WTO Members. At the same time, however, it would be false to claim that patents are not a factor to be taken into account, especially in view of the concerns expressed by developing and least-developed country Members.

15. In the light of the preceding paragraphs, the EC remain convinced that the problem identified in paragraph 6 of the Declaration on the TRIPs Agreement and Public Health is one for which an expeditious solution does indeed need to be found. Any such solution, though, should not ignore potential side-effects, which is why close attention will need to be paid to feasibility and to ensuring that the Agreement is not undermined in any way and that adequate safeguards are put in place. Any such solution should also ensure an adequate participation by patent right holders and not affect their capability of offering the drugs needed on better conditions.

III. Possible solutions

16. At this stage, and without in any way excluding other possibilities, the EC consider that there are two possible solutions which merit particular attention:

1) amend Article 31 of the TRIPs Agreement in order to carve out an exception, under certain conditions, to Article 31(f) for exports of products needed to combat serious public health problems and produced under compulsory licences; or

2) interpret the limited exceptions clause of Article 30 of the TRIPs Agreement in a way which would allow production for export, to certain countries and under certain conditions, of products needed to combat serious public health problems.

III.1 Possible amendment of Article 31 of the TRIPs Agreement

17. A first possibility that could be considered by the TRIPs Council is the introduction of an exception to the principle stated in Article 31(f) of the TRIPs Agreement that compulsory licences “shall be authorised predominantly for the supply of the domestic market of the Member authorising such use”.

18. Such an exception clause would state that Article 31(f) does not apply to compulsory licences granted for the purpose of supplying a poor country with a product needed to address serious public health problems. An exception to Article 31(f) already exists under Article 31(k), which states that the former does not apply to compulsory licences "where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive".

19. The objective of the exception clause would be to cover exceptional circumstances, such as those when serious public health problems arise in small economies lacking adequate pharmaceutical production capacity. However, such an exception clause would need to be carefully drafted and hedged around with conditions to prevent abuses and diversion of trade. This is of the utmost importance. Safeguards will be needed to ensure that production pursuant to the proposed exception is not diverted from its destination. Any abuse could open the door to massive circumvention of intellectual property rules, which would seriously impair the legal security of right holders and undermine the basic principles of the TRIPs Agreement.

20. Therefore, three of the most important conditions to be further discussed and refined are :

- the need to provide safeguards against exports to countries which do not face serious public health problems;
- the need to provide safeguards against re-exportation from the country of destination, especially to rich countries, to avoid creating "black markets" for the products concerned; and
- the need to make the system transparent, in order to allow other Members to be informed if a Member makes use of this mechanism.

21. If the exception is not properly limited by such conditions, there could be a risk that any abuse of this exception would undermine confidence in the TRIPs Agreement as well as in initiatives taken to supply medicines at affordable prices to poor countries, and would weaken industry support for any subsequent initiative on access to medicines.

22. An advantage of the approach considered here is that there would be a clear basis, in the TRIPs Agreement itself, for a country to export to a small or least-developed country, in response to a compulsory licence issued by the latter country, products needed to address serious public health problems, whatever the patent situation of the product concerned in the Member in question. Any Member would be free to decide whether or not to incorporate this mechanism in its legislation.

III.2 Possible interpretation of Article 30 of the TRIPs Agreement

23. An alternative approach would consist of interpreting Article 30 of the TRIPs Agreement in a way that would allow a Member to introduce a specific exception in its legislation for the purpose of supplying another country which had granted a compulsory licence for the importation of a specific pharmaceutical product.

24. To this end, WTO Members could adopt a declaration stating that a WTO Member may, in accordance with Article 30 of the TRIPs Agreement, provide that the manufacture, on its territory, of a patented product, without the authorisation of the right holder, is lawful when it is meant to supply another country which has granted a compulsory licence for the import and sale of the product concerned in its territory in order to deal with a serious public health problem.

25. The key to this interpretation lies in the fact that, from a TRIPs point of view, the legal situation pertaining in the two WTO Member countries concerned would not be the same, thereby rendering it possible for a country lacking sufficient manufacturing capacity to give full effect to a compulsory licence on its own territory, without falling foul of the provision in Article 31 that restricts 'other use' to use other than that allowed in Article 30. Thus on the one hand, we would have a country without sufficient manufacturing capacity for pharmaceuticals which, pursuant to Article 31 of the TRIPs Agreement, grants a compulsory licence to an economic operator, authorising him to import and sell a patented pharmaceutical on its territory. On the other hand, we would have another Member which would make use of a limited exception under its patent law (based on Article 30 of the TRIPs Agreement) to allow a producer designated by the destinee of the compulsory licence, to manufacture that product, without the authorisation of the patent holder, for export to the first Member providing a number of conditions were fulfilled.

26. The advantage of this approach would be that it could fit within the flexibility offered by the existing TRIPs Agreement, without there being a need to amend any of its provisions. Here again, it would be left to each Member's discretion to decide whether or not to incorporate an exception based on Article 30 in its own legislation.

27. As with the first option, it should be understood that such an exception can only be considered if it is accompanied by the necessary safeguards to ensure that the product only goes to the Member issuing the compulsory licence. Hence the need for conditions to make sure that the quantities produced in the country of manufacture do not exceed the quantity needed by the country of destination, that production pursuant to the proposed exception is not diverted from its destination, and that a reasonable degree of transparency is maintained. These conditions would, at the very minimum, be that: i) the entirety of the production allowed under the Article 30 exception must be imported by the Member having granted the licence; and ii) the product must be commercialised or distributed solely in the Member having granted the licence, and for the sole purpose for which the licence was issued, and must not be re-exported. Furthermore, both Members involved in the activities outlined above would need to take all necessary measures to avoid trade diversion.

28. These conditions should not be seen as creating burdensome new obligations for Members; instead, they demonstrate the need for the Members concerned to take the necessary measures within the context of their existing administrative procedures, notably in the area of customs, and to provide for legal security and due process.

29. It should also be stressed that any interpretation agreed upon on the basis of Article 30 should be in full conformity with the other relevant provisions of the TRIPs Agreement, and in particular Article 27.1 thereof, with the general principles of treaty interpretation as laid down in the Vienna Convention (as specified in paragraph 5(a)

of the Doha Declaration on the TRIPs Agreement and Public Health), as well as with relevant rulings by WTO Panels and the Appellate Body.

30. Finally, from the **procedural** point of view, if consensus were to be reached in the TRIPs Council for a solution based on Article 31, this could not be implemented until the fifth WTO Ministerial because it would require a proposal to the Ministerial Conference for the amendment of the TRIPs Agreement itself (Article X GATT). For a solution based on Article 30, on the other hand, a three quarters majority in the General Council would suffice (Article IX GATT).

31. The EC would welcome any comments other Members may have, and reserve their final position subject to those comments and to any other proposals that may be tabled on this issue.