

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

By means of a communication dated 21 June 2002, the following text has been received from the Permanent Mission of Brazil on behalf of the delegations of Bolivia, Brazil, Cuba, China, Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and Venezuela with the request that it be circulated to TRIPS Council Members.

Summary

- Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and Public Health should be read in light of the entire context of the Declaration, as well as of the flexibilities contained in the TRIPS Agreement. In this sense, WTO Members should avoid taking a narrow approach in considering expeditious solutions to the problem recognized in Paragraph 6.
- Solutions based on Paragraph 6 should not be detrimental to the fulfilment of the objective of the TRIPS Agreement of transfer of technology, which is critical to improving manufacturing capacities in the pharmaceutical sector and therefore to ensuring sustainable access to affordable medicines.
- Any WTO Member could face difficulties in making effective use of compulsory licences due to insufficient or no manufacturing capacities in the pharmaceutical sector. Therefore, the solutions envisaged by the TRIPS Council to the problem recognized in Paragraph 6 should not exclude specific categories of countries. In any event, developing countries, in particular least-developed countries, should certainly be among the main beneficiaries of possible expeditious solutions.
- Difficulties of access to public health-related products are not limited to countries with insufficient or no manufacturing capacities where these products are protected by patents. Therefore, the expeditious solutions envisaged by the TRIPS Council should also address situations where no patents exist in the countries in need of access to public health-related products, or cases where economies of scale make domestic production for a particular product impractical or too costly.
- Without prejudice to the possibility of Members seeking additional expeditious solutions to the problem identified in Paragraph 6, the TRIPS Council should recommend an authoritative interpretation of Article 30 of the TRIPS Agreement, so as to recognize the right of WTO Members to authorize third parties to make, sell and export patented public health-related products without the consent of the patent holder to address public health needs in another country.

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

I. INTRODUCTION

1. In Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and Public Health (hereinafter referred to as “Paragraph 6”), Ministers “*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.*” In this sense, Ministers “*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.*”

2. **Paragraph 6 of the Ministerial Declaration on TRIPS and Public Health should be read in light of the entire context of the Ministerial Declaration on the TRIPS Agreement and Public Health.** In Paragraph 4, for instance, Ministers agreed “*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.*” Furthermore, Paragraph 5 of the Ministerial Declaration recognizes some of the existing flexibilities of the TRIPS Agreement, which must be taken into account in considering possible solutions under Paragraph 6.

3. In many situations, the problem of countries with insufficient or no manufacturing capacities identified in Paragraph 6 stems from lack of technological infrastructure and manufacturing capacities in the territory of WTO Members. Consequently, **in considering solutions to the problem recognized in Paragraph 6, Members should bear in mind the need to fulfil and operationalize the objectives and the principles of the TRIPS Agreement.** In this sense, in no way should the envisaged solutions under Paragraph 6 be detrimental to the fulfilment of the objectives of the TRIPS Agreement of transfer of technology. The development of local manufacturing capacities for public health-related products, whenever economically feasible, is critical to ensuring the development of sustainable health policies and access to affordable medicines, particularly in developing countries¹.

¹ In this respect, in June, 2001 developing countries Members already clearly stressed the importance of fulfilling the objectives of the TRIPS Agreement: “*The objective of the **promotion of technological innovation and the transfer and dissemination of technology** places the protection and enforcement of IPRs in the context of the interests of society. Such an objective is essential for the promotion of health policies, as it **encourages the development of domestic production of pharmaceutical products.** Whenever economically feasible, local production of pharmaceutical products is extremely important to ensure that medications are more readily available in the market, and at more affordable prices. Local manufacturing of pharmaceutical products also encourages sustainable access to medications by insulating the price of patented medicines against currency devaluations, as well as supporting the development of local expertise, which is vital in addressing local needs. As mentioned above, these objectives can be obtained by the normal exercise of patent rights. **Where the patent holder fails to meet the objectives of the TRIPS Agreement and of public health policies, however, Members may take measures to ensure transfer and dissemination of technology to provide better access to pharmaceuticals***” (“TRIPS and Public Health - Submission by the African Group, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand and Venezuela”, document IP/C/W/296, Paragraph 20) [emphasis in the original].

II. THE PROBLEM RECOGNIZED IN PARAGRAPH 6 OF THE MINISTERIAL DECLARATION ON TRIPS AND PUBLIC HEALTH

4. **Any WTO Member could face difficulties in making effective use of compulsory licences due to insufficient or no manufacturing capacities in the pharmaceutical sector.** Therefore, the solution to be considered by the TRIPS Council needs not and should not be limited to a specific category of countries – although developing countries, in particular least-developed countries, might figure among its main beneficiaries. Obstacles to granting compulsory licences for the supply of the local market may result from a number of factors. The lack of adequate manufacturing facilities present within the country, for instance, may result from a failure to fulfil the objective of transfer of technology of the TRIPS Agreement. A country with insufficient or no manufacturing capacities may also lack potential licensees that are willing or capable of manufacturing locally. In some countries, capacity to manufacture public health-related products may be owned or controlled by the same companies that hold local patents, and there would be no enterprises interested in taking the role of a compulsory licence supplier. Even in cases where technology may be available, there may be no potential licensees due to lack of economies of scale or other conditions for a viable economic manufacturing. Least-developed country Members generally face particularly dire difficulties in this respect, as there may be no pharmaceutical manufacturing capacities at all in their territories. In light of the above, **each Member shall have the right to determine whether it is in a situation of insufficient or no manufacturing capacities in the pharmaceutical sector.**

5. Logically, difficulties in access to public health-related products are not limited to countries with insufficient or no manufacturing capacities where these products are protected by patents. **Therefore, the expeditious solutions envisaged by the TRIPS Council should also apply to countries where no patents exist.**

III. EXPEDITIOUS SOLUTION TO THE PROBLEM: AUTHORITATIVE INTERPRETATION OF ARTICLE 30 OF THE TRIPS AGREEMENT

6. Within the context of the problem identified in Paragraph 6 of the Ministerial Declaration on the TRIPS Agreement and Public Health, transfer of technology to the country in need may be neither economically feasible nor expeditious enough to ensure access to affordable public health-related products. Consequently, the TRIPS Council should consider expeditious solutions under the TRIPS Agreement to ensure access to public health-related products to countries in need.

7. In this sense, the problem recognized in Paragraph 6 suggests that, among other possible solutions, a producer in a country with manufacturing capacities could be allowed to manufacture, export and sell a patented product, without the consent of the right holder, to supply the country with insufficient or no manufacturing capacities in the pharmaceutical sector.

8. As an expeditious solution envisaged in Paragraph 6 of the Ministerial Declaration on TRIPS and Public Health, **Article 30 of TRIPS² should be interpreted so as to recognize the right of WTO Members to authorize third parties to make, sell and export patented public health-related products without the consent of the patent holder to address public health needs in another country.** Therefore, the acts of making, selling and exporting public health-related products under this circumstance could be recognized as limited exceptions to the exclusive rights conferred by

² Article 30 of TRIPS: “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”

a patent. An authoritative interpretation would confirm that Members may authorize local producers to manufacture, sell and export public health-related products for other countries in need of access to such products. Additionally, in line with the spirit of the “limited” exceptions in Article 30, Members may consider the possibility of establishing appropriate safeguards that would ensure legal predictability in this particular use of the provision, if such safeguards do not have the effect of undermining its practical use, or to prejudice the existing right of countries to use Article 30 of TRIPS in other circumstances.

9. **Such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner.** In the context of the proposed authoritative interpretation of Article 30, the limited exceptions address public health problems outside the territory of the Member and therefore do not conflict with the normal exploitation of the patent. Moreover, the acts of making, selling and exporting patented products by third parties without the consent of the patent owner to countries with insufficient or no manufacturing capacities do not unreasonably detract from the returns ordinarily earned by the patent owner. It should also be noted that the act of exporting is not enumerated among the exclusive rights conferred by the patent in Article 28 of TRIPS. Consequently, they do not unreasonably prejudice the legitimate interests of the patent owner.

10. An authoritative interpretation of Article 30 of TRIPS would have the major advantage of avoiding burdensome procedures related to the grant of compulsory licences in the exporting country. For the importing country, such a solution would leave the freedom to decide on the need to issue or not a compulsory licence for the importer. It would also avoid a dependency by the country in need on the grant of a compulsory licence in the export country. In addition, in situations where the authorization of the limited exceptions under Article 30 is addressed to allow exports to a country where a compulsory licence has been granted or where no patent protection exists, the current text of Article 31(f) would not necessarily amount to an obstacle, as the compulsory licence would be authorized for the supply of the domestic market of the Member authorizing such use – that is, the importing country. Therefore, the limitation of the expression “predominantly” in this context does not affect the acts of making, selling and exporting public health-related products to the country authorizing a compulsory licence to supply its domestic market.

11. Clearly, nothing in the letter and spirit of Article 30 of TRIPS prevents Members from authorizing local producers to make, sell and export public health-related products, without the consent of the patent holder, to address health needs in other countries with insufficient or no manufacturing capacities, as a limited exception under this provision. In light of the mandate to find expeditious solutions to the problem recognized in Paragraph 6, an authoritative interpretation of Article 30 confirming this legal solution would be an important step to ensure legal certainty for all WTO Members. Moreover, in light of paragraph 4 of the Ministerial Declaration on the TRIPS Agreement and Public Health, Article 30 of TRIPS “*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*”.

12. Members should bear in mind that legal solutions based on Article 30 will be best achieved if grounded in economic solutions. In many situations, a public health problem might affect more than a single country (as in the case of – but not limited to – HIV/AIDS, tuberculosis, malaria and several tropical diseases). Therefore, in implementing such solutions, countries may consider establishing economies of scale that would reduce costs of production and thus provide more affordable prices for the beneficiary countries in situations, for instance, where domestic production in small quantities from a compulsory licence for a particularly high-priced product may be impractical or too costly.

13. Finally, it should be stressed that such an interpretation of Article 30 is not exhaustive and is without prejudice to the right of Members to allow other exceptions to the rights conferred by patent under Article 30 of TRIPS in their national legislation.

IV. FINAL REMARKS

14. The TRIPS Council should refrain from considering narrow, burdensome, or ineffective solutions that would ultimately defeat the very purpose of the solution under Paragraph 6. A few Members have mentioned the possibility of considering the imposition of safeguards or conditions to the solution envisaged by the TRIPS Council. Such proposals should be carefully considered. In light of the importance of the possible solutions to alleviate public health problems, **it would be unacceptable to consider safeguards or conditions that in any way would limit either the flexibilities of Members under the TRIPS Agreement or the clarifications established in the Doha Ministerial Declaration on the TRIPS Agreement and Public Health.** Members particularly interested in such safeguards are encouraged to submit concrete proposals for consideration by the TRIPS Council, to the extent they actually reflect legitimate concerns and that the burden of their enforcement is placed on interested parties, such as the patent holder.

15. While an authoritative interpretation of Article 30 is the most effective solution to the problem identified in Paragraph 6, other non-exhaustive solutions could also be contemplated. Merely partial or temporary arrangements, however, such as moratoriums or waivers, would not amount to sustainable or legally predictable solutions.

16. **Other possibilities** for the problem identified in Paragraph 6 might be related, for instance, to **Article 31 (f) of the TRIPS Agreement**, which establishes that compulsory licences “*shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use*”. While this provision contains an in-built flexibility that allows Members to export products under a compulsory licence, the expression “*predominantly*” limits the extent of such exports. In a situation where a Member is willing to grant a compulsory licence in order to grant a local manufacturer the right to supply public health-related products for a country with insufficient or no manufacturing capacities, the imposition of this limitation could result in inefficient production, if there is not enough domestic demand where the compulsory licence has been issued (moreover, the exporting country may not wish its domestic market to be supplied under compulsory licence, yet Article 31(f) effectively requires this as a condition of supplying an export market.). In this case, the TRIPS Council could consider the possibility of an amendment of Article 31 of the TRIPS Agreement, in order to eliminate paragraph (f).

17. Another additional solution based on Article 31 of TRIPS is related to its paragraph (k)³, under which Members are not obliged to apply the conditions set forth in paragraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. Therefore, the limitation of exports under compulsory licences based on Article 31(f) does not apply where the compulsory licence is granted to remedy a practice determined after judicial or administrative process to be anti-competitive. Members may explore the use of such provision of TRIPS as part of the expeditious solutions to the problem envisaged in Paragraph 6. In this respect, the Secretariat could provide to the TRIPS Council a document on the current uses by

³ “Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur.”

Members of Article 31(k) of TRIPS in authorizing the export of products and also to elaborate on the term “or administrative process”, as it relates to Article 31(k). In this study, the Secretariat could also provide the TRIPS Council with information regarding the issue of compensation to patent owners when patents are held in both exporting the importing countries, and on the exhaustion of rights in 31(k) cases.

18. Article 31-based proposals, however, raise a number of issues that might eventually impose restrictions on a solution under Paragraph 6. Those issues include, as the case may be, the need to issue compulsory licences both in the importing and the exporting countries, which is administratively burdensome. The issue of determination of remuneration is another point of concern, as the patent holder should not in any case be entitled to double remuneration, as both compulsory licences would be issued to address essentially the same problem. In this respect, it may be more reasonable to determine compensation in the country where the product is consumed, since the amount of compensation should maintain some relationship with the ability of patients to afford the product.

19. In conclusion, the proposed solution based on an authoritative interpretation of Article 30 is preferable to those based on Article 31, as the former would be administratively less burdensome, involving less steps for implementation.

20. In addition to the fulfilment of the mandate of Paragraph 6, the TRIPS Council should also consider measures under Article 66.2 of the TRIPS Agreement in order to encourage the transfer of technology to least developed countries in order to strengthen local manufacturing capacities in their territories. Therefore, developed country Members should provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base in the pharmaceutical sector. Further, in order to ensure their implementation, such incentives should be monitored under the mechanism to be established by the TRIPS Council in light of the mandate established by Paragraph 11.2 of the WTO Ministerial Decision on Implementation-Related Issues and Concerns.
