Compulsory licenses for the exportation of generic versions of patented pharmaceutical products: A complete and permanent solution by the World Trade Organization?

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Abstract

The WTO General Council adopted on December 6th, 2005, the "Decision on the implementation of paragraph 11 of the General Council Decision of 30 August 2003 on the implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health". This adoption will result in a new protocol, leading to the first ever amendment of the TRIPS agreement. This protocol may offer a permanent solution to the problem of WTO member states which face difficulties in addressing their urgent public health problems because they lack the production capacity for pharmaceutical products to address public health problems.

Key words: Public health; WTO-TRIPS; patents; compulsory licences; development.

Introduction

On December 6th, 2005, the World Trade Organisation (WTO) announced a permanent solution to the so-called "paragraph 6 problem" used to identify the situation of – mainly – developing countries which do not have the production capacity in the pharmaceutical sector allowing them to make use of compulsory licences. This announcement is good news, because a consensus on this subject is likely to be celebrated in the future as the main success of the run-up to the Ministerial Conference of the WTO in Hong-Kong, held on December 13 to18th, 2005. Moreover, the provisional solution contained in the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health of 30 August 2003, which was not used by any country until now, may become more operational with the inclusion of the solution in the TRIPS agreement. The latter will certainly provide it with more legal certainty and allow WTO member States to adapt their legislation on the basis of a solid legal instrument.

1 Background

The decision of the General Council of December 6th, 2005, deals with the problem of countries that do not have sufficient capacity to produce pharmaceutical products themselves. When such countries face public health crises, how can they help their inhabitants receive the medicines, or, more generally speaking, the pharmaceutical products they need, in order for the disease they suffer from to be treated?

This issue is part of the more general discussion on access to medicines. How can the poor people in developing countries get access to the pharmaceutical products and medical treatments, if they lack the means to pay for them?

The subject was first taken to the WTO TRIPS Council in the year 2000 already, where the group of African countries (also commonly called the African Group) requested that the TRIPS Council deal with the issue of the HIV/AIDS pandemic, especially in Africa. Difficult negotiations led to the adoption of the Declaration on the TRIPS agreement and public health on 14 November 2001, at the Doha Ministerial conference. The main goal of this Declaration was to clarify the use of possible instruments such as exceptions to patent rights – that existed in the TRIPS Agreement – in order to facilitate access to patented products to address public health crises. The Doha declaration was actually nothing really new, but helped give confidence to developing countries, that they were allowed to apply some flexibility when addressing their to public health challenges. These flexibilities include in particular the following:

- In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement is to be read in the light of the object and purpose of the TRIPS Agreement as expressed, in particular, in its objectives and principles.
- Each WTO Member State has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.
- Each Member State 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.

Each Member State is free to establish its own regime of exhaustion without challenge, subject to the most favoured nation and national treatment provisions of Articles 3 and 4 TRIPS.

2 The problem of export under a compulsory licence

The Declaration did remind Member States of their right to issue compulsory licences, but, according to article 31 (f) of TRIPS Agreement, these may be delivered only "predominantly for the supply of the domestic market". Hence a country with no or insufficient manufacturing capacity in the pharmaceutical sector could not make any use of this provision, nor could it import products made under a compulsory licence in another WTO Member State, unless the latter had produced predominantly for its own territory and exported a (smaller) part of its production.

Paragraph 6 of the Declaration on the TRIPS agreement and public health recognized this problem, and requested WTO Member States to "find an expeditious solution to this problem and to report to the General Council before the end of 2002".

The provisional solution was found on 30 August, 2003 with the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.

3 The solution

The Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health allows WTO member states which have a production capacity in the pharmaceutical sector to derogate from the obligation contained in Article 31(f) TRIPS mentioned above. They may issue compulsory licences for the production and export of generic versions of patented pharmaceutical products to Member States lacking this manufacturing capacity and facing public health problems. Any patented pharmaceutical product needed to address a public health problem may be exported under this system. Diagnostic kits are expressly included. Covered diseases include typically HIV/AIDS, tuberculosis and malaria, but also any other disease causing a public health problem. Importing countries may be least developed countries, where production capacity for pharmaceutical products is deemed to be lacking. Any other WTO member state that deals with a public health problem may import pharmaceutical products under a compulsory license, as long as the state can demonstrate a lack of capacity to produce the needed pharmaceutical product. On the other side, any member state, which has that production capacity, may act as exporting country.

Measures must however be taken in order to make sure that the system is not abused and that products reach those countries really in need. In particular, the importing country will have to notify the TRIPS Council with the name and the quantity of products necessary to face the public health problem it meets; if the importer is not a least developed country, a confirmation is requested, according to which it lacks production capacity for the particular pharmaceutical product; if the product is patented in the importing country, a confirmation is needed, mentioning that a compulsory licence has been, or is going to be, granted.

Under a compulsory licence for export, exporting countries may produce and export only the quantity of products necessary to meet the needs of the eligible importing member state and the entire production under such a licence is then to be exported to that member. The products shall have to be clearly identified by a special colouring and/or labelling, and the information on the above conditions shall be made publicly available on a web-site (which can be the WTO website). Appropriate measures shall be taken to prevent trade diversion. General conditions of adequate remuneration shall also be respected, whereas the value of the license shall be calculated taking into account the economic value to the importing country of the use authorized in the exporting country. In case patents exist in both the exporting and the importing member states, no double remuneration shall be necessary: the condition of adequate remuneration in the importing country shall be waived. Finally, measures in favour of economies of scale and local production shall be encouraged, in particular where least developed countries are at stake. So will technical cooperation and technology transfer.

4 The amendment: Technical or not technical?

The August 2003 Decision on the implementation of Paragraph 6 however still had to become an amendment of the TRIPS Agreement in order to be final and provide all the legal certainty member states need to implement it. Work on such an amendment was initiated by the end of 2003 with a view to its adoption within six months.

With one and a half years delay, the WTO member states now have a solution which gives them the legal security they need. That was not an easy task: Paragraph 11 of the August 2003 Decision mentioned that the amendment was to be based, *where appropriate*, on its content. These terms were interpreted in different ways. For some delegations, mainly representing industrialised countries, the discussions had to remain purely technical, meaning that the consensus found on 30 August 2003 was not to be touched at. The only question was to know how, technically, to incorporate the decision into the TRIPS Agreement, without making it unreadable. Only conditions existing already in the TRIPS Agreement did not need to be repeated for the implementation of the Decision, but all the new rights and obligations resulting from the Decision and the General Council's Chairperson Statement had to be incorporated in the TRIPS Agreement. The industrialised countries feared that a reopening of the discussions may destroy the very delicate balance of rights and obligations that was achieved in previous negotiations.

Other delegations, mainly developing countries, interpreted the terms *where appropriate* more broadly, in the sense that some obligations, which seemed too burdensome, could be rediscussed and possibly left aside from the amendment.

5 The General Council Decision of 6 December 2005

The General Council Decision of 6 December 2005 includes a protocol for the amendment of the TRIPS Agreement, which contains the elements of the August 30, 2003 Decision. It is open for ratification by Members until December 2007, a date that may be extended by a decision of the Ministerial Conference. The protocol will then take effect accordingly to the procedure foreseen in the WTO Agreement (paragraph 3 of Article X).

The TRIPS Agreement, upon entry into force of the Protocol, shall be modified by the insertion of a new Article 31*bis* after article 31 and by inserting an Annex at the end of the TRIPS Agreement. With the new Article 31*bis* and the Annex, all rights and obligations included in the August 30 2003 Decision have been maintained. The General Council Chairperson's statement made at that time, and which allowed the consensus to be reached, is not included in writing in the protocol, but has been made orally again on 6 December by the current General Council's Chairperson. That gives it exactly the same – unclear – value as it had until now. An inclusion in writing would have given it, at least psychologically, more weight than it really had. Leaving it totally aside would also have been wrong, as it was an important element leading to the consensus found in 2003. Its reading at the General Council meeting probably provided just the right balance.

Finally, an appendix is attached to the annex, which includes indications on the way to assess the lack of production capacity in the pharmaceutical sector in the importing country. This appendix corresponds to the annex to the 2003 Decision, which dealt with the same issue.

Conclusion

The adoption of the General Council's Decision of 6 December 2005 must be welcomed. It provides more legal certainty, allowing WTO Member States to incorporate the decision into their national legislation and to import (respectively export) generic versions of pharmaceutical products that are still under patent protection. It may help them address their public health problems more effectively. As regards public health issues, a coherent and balanced system of rights and obligations is now avai-

lable for existing pharmaceutical products. The use of the system will hopefully prove that it is not as complicated as it seems to some at first sight.

Footnotes:

1. Doc. WT/L/540, and General Council Chairperson's statement of 30 August 2003.
2. Doc. WT/MIN(01)/DEC/2 of 20 November 2001.
3. Ibidem, in particular paragraphs 4 and 5.
4. See note 2.
5. Some Member States have stated that they will not make use of the system as importers (OECD countries). Some advanced developing countries have indicated that they would make use of it only in case of emergency.
6. Article 31 (h) TRIPS.
7. Paragraph 11 of the Decision.
8. The incorporation of the entire text of the August 2003 Decision into article 31 TRIPS would have rendered the latter unusually long and complicated. The same is true for its incorporation in a footnote to article 31 TRIPS.
9. Implementation of paragraph 11 of the general council decision of 30 august 2003 on the implementation of paragraph 6 of the Doha declaration on the trips agreement and public health; Proposal for a Decision on an Amendment to the TRIPS Agreement, doc. IP/C/41.
10. See the "Protocol amending the TRIPS Agreement" in doc IP/C/41