Will the TRIPS Amendment on Compulsory Licensing Work?

Cecilia Oh

Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health recognised that developing countries without manufacturing capacity would face difficulties in making effective use of compulsory licensing, but it remains to be tested whether the recent amendment to the TRIPS Agreement will provide an adequate solution to the problem.

The Paragraph 6 problem has been defined thus: since Article 31(f) of TRIPS restricts exports of products manufactured under compulsory license[1], countries without manufacturing capacity dependent on foreign generic producers would have a problem sourcing adequate supplies of generic medicines produced under compulsory license. WTO Members were asked to find an 'expeditious' solution to the problem, but negotiations for the solution could hardly be described as expeditious. On 30 August 2003, WTO Members adopted an interim decision, which waived the restriction under Article 31(f) to permit the production and unrestricted export of generic medicines under compulsory license. It was another two years before the permanent 'solution' could be agreed upon.

While developing countries proposed to correct the flaws they saw in the temporary solution, industrialised countries focused the debate on the legal status of the Statementr read out by the General Council Chairman when the 30 August Decision was adopted. The Statement, supposedly reflecting 'key shared understandings' of Members regarding the solution is a restrictive reading of the solution, which many fear would further hamper its workability. Its doubtful legal status prompted some industrialised countries to try and elevate it by incorporating the Staement into the text of the amendment itself. Developing countries opposed the Chairman's Statement, just as they had done when they negotiated the interim solution. But, the heady mix of political pressure and the fear of a worse deal led to the Chairman's Statement being read out by as the decision to permanently amend the TRIPS Agreement was adopted, just as it had been when the interim solution adopted two years earlier.

It took four years for WTO Members to agree to this permanent solution. In fact, the agreement was simply to convert the temporary solution into a permanent one. Since the text of the amendment does not include the Chairman's Statement, its doubtful status is also preserved.

Will It Work?

According to WTO Director-General, Pascal Lamy, the agreement to amend the TRIPS Agreement "confirms once again that members are determined to ensure the WTO's trading system contributes to humanitarian and development goals as they prepare for the Hong Kong Ministerial Conference". But such pronouncements may be premature when the workability of the solution is still unproven. No use has been made of the 30 August Decision. Since the amendment will incorporate essentially the same system of permitting production and export under compulsory license, it must be asked if the system works.

The system permits countries wishing to import generic medicines, to do so from a foreign producer. Whilst least-developed countries are automatically eligible, developing countries have to establish that either they have no manufacturing capacity or the current capacity is insufficient to meet their needs. Countries make this determination themselves; and the WHO guide on implementing the August 30 Decision observes that this is a matter of self-assessment that is not challengeable by other Members.[2] The system requires the importing country to notify the TRIPS Council. Where the needed medicine is patent-protected in the importing country, the government will have to grant a compulsory license for the import of the generic version of the medicine. Where no patent is in force, the importing country has to provide notification of its intention to use the system.

Whilst much has been made about the amendment allowing poor countries to import generic medicines, the most significant aspect of the system is the ability of generic-producing countries to export generic medicines without the quantitative restrictions. But will generic manufacturers be willing and able to produce and export the needed medicines under the system? The generic manufacturer has to obtain a compulsory license to produce and export, which will only permit the production and export of the quantity required by the importing country. The compulsory license will also require the manufacturer to make the products clearly identifiable through labelling or marking, and notify TRIPS Council of the quantities supplied to the importing countries and the distinguishing features of product.

How to Make It Work?

The workability of the system will depend, in large part, on how the demand-and-supply chain can be linked up. On the demand side, importing countries must be able to indicate their needs. Procurement agencies in these countries must be able to forecast and quantify needed medicines, so that this information can be notified to the TRIPS Council. This notification will be the trigger for necessary measures to be taken on the supply side. Without this indication of demand, it is difficult to see how generic manufacturers will be moved to offer their products for export. In Canada, India and China – where national legislations have been amended to permit the production and export of generic medicines under compulsory license – the law generally requires some indication from the importing country of its intention to permit the import of products manufactured under compulsory license before such a license may be granted.

Generic manufacturers will have to respond by making the necessary applications for compulsory licenses. They will have to be convinced of the economic feasibility of applying for a compulsory license under the circumstances. It has been said that the system is a 'drug-by-

drug, country-by-country, case-by-case system', so that manufacturers will be forced to produce limited quantities under each compulsory license. However, it should be possible for a number of the purchasing countries to co-ordinate their orders, in order that the manufacturers may use a single compulsory license to enable the production and export to more than one country. This method of pooled procurement should be explored, in this context, in order to take advantage of the significant cost and other efficiency savings that can accrue. But it requires a degree of co-operation between participants and shared purchasing needs.

Exporting country governments will have to respond by enabling the grant of compulsory licenses for production and export by their generic manufacturers. This may involve amendments to patent legislation. The initiative taken by Canada, India and, most recently, by China to provide for the grant of compulsory licensing under the system is welcome; given that the concentration of generic manufacturers is in these countries. Governments should demonstrate their good faith by enacting simple and speedy procedures for the grant of compulsory licenses, without unnecessary requirements that may delay the grant of the licenses, or restrictions on the types of pharmaceutical products or diseases.

Importing country governments may have to take the necessary first step by notifying their intention to use the system. Where the product is patent-protected in the importing country, a compulsory license or government use authorisation will be required. Where no patent exists, or where a least-developed country has opted not to grant or enforce pharmaceutical patents until 2016[3], a notification to TRIPS Council of intention to use the system would be sufficient.

What may also be needed is an 'honest broker' (for want of a better word) to link up the various actors in the demand and supply chain. Obvious choices in this regard include UN agencies such as the WHO, UNAIDS and UNICEF, and the Global Fund for the Fight Against AIDS, TB and Malaria. These agencies are well-placed to assist countries in forecasting demand for medicines, identifying potential suppliers of quality assured medicines and have, as their part of their mandate, the achievement of the public health objective – access to medicines.

Put It to Test

It is time for governments and the international organisations to assume the responsibilities, and to make a concerted effort to make the system work. There are now several good reasons to put the system to the test. One reason for not using the August 30 Decision was that developing countries apparently lacked sufficient assurance regarding the 'permanence' of the interim waiver system. Governments were reluctant to revise national legislation due to concern that the final 'solution' might require yet more changes. With an amendment that is substantially the same as the 30 August Decision, there should no longer be concerns on this account.

Second, the post-2005 environment should provide another impetus for countries to test the system. As all new medicines come under the requirement for the 20-year patent protection in all but the least-developed countries, generic suppliers, including those in India, will not be able to reproduce patented medicines without compulsory licensing. This is already the case of medicines such as the second-line HIV treatments. Global efforts, such as the WHO's 3x5 campaign may have helped to put more people on treatment, but it has also increased the need – as resistance inevitably develops – for a switch to second-line or third-line treatments. The generic competition that resulted in the price plunge for first-line ARVs, does not yet exist for the second-line medicines. Current prices of the typical second-line treatments can be 6 to 12 times higher than those of the older first-line medicines.[4] Governments and international organisations will have to develop alternative strategies to ensure the future sustainability of ARV treatment, particularly in low-income countries. Compulsory licensing to permit imports (and local production) of generic second-line ARVs is an obvious option to introduce market competition and reduce prices.

Third, the seemingly imminent avian flu pandemic demonstrates that it is neither easy nor possible to predict future need for medicines, or the quantities in which they may be required. In case of another public health emergency, or pandemic, countries will want to ensure their ability to obtain the necessary treatments in sufficient quantities, at affordable prices. The global debate about access to Tamiflu and the ability of countries to fill national stockpiles have raised questions about the need to ensure multiple suppliers to guarantee availability and affordability.

Change the Rules?

The amendment is expected to come into force in 1 December 2007, WTO Members having set themselves this deadline to have the amendment ratified by the required two-thirds of the membership. This "solution" is here to stay, unless there is a change of heart for the majority of the Members. This seems unlikely, unless there is evidence to demonstrate the workability or otherwise of the system. WTO Members had been congratulated for their unprecedented decision to amend the TRIPS Agreement, which demonstrated their willingness and flexibility to take concrete steps to improve intellectual property rules to ensure the primacy of health. If it is shown that the system does not work, WTO Members may perhaps demonstrate similar willingness to change the rules once again, in the interest of public health.

Cecilia Oh is a technical officer with the World Health Organization. Any views expressed in this article are personal and may not be attributed to the WHO.

ENDNOTES

[1] Article 31(f) restricts exports by providing that compulsory licenses shall be used "predominantly for the supply of the domestic market of the Member authorising such use."

[2] *Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* (2004), Health Economics and Drugs EDM Series No. 16, WHO Geneva

[3] Para. 7 of the Doha Declaration on the TRIPS Agreement and Public Health exempts LDCs from the obligation to protect pharmaceutical patents or undisclosed information until 1 January 2016.

[4] See for example; Médecins Sans Frontières (2005) *Untangling the web of price reductions: A pricing guide for the purchase of ARVs for developing countries*, in UNICEF-UNAIDS-WHO-MSF (2005) *Sources and prices of selected medicines and diagnostics for people living with HIV/AIDS.*