TWN Briefing Paper 17
Third World Network
www.twnside.org.sg
October 2003

The New "Deal" on TRIPS and Drugs: What Does it Mean for Access to Medicines?

by Cecilia Oh

On 30 August 2003, WTO members reached an agreement to allow the export of affordable medicines to countries which lack the means to produce them. Cecilia Oh examines the main provisions of this accord and finds that it may still pose obstacles to the supply of cheap drugs to nations in need.

Background

In November 2001, when Trade Ministers in Doha agreed on a special declaration recognizing the right of countries to take measures to protect public health and promote access to medicines, over and above the obligation to protect intellectual property rights, it was widely acclaimed. The Doha Declaration on the TRIPS Agreement and Public Health enshrined the principles of the primacy of protecting public health and, in particular, promoting access to medicines for all, and that the interpretation and implementation of the TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement would not prevent governments from taking such measures. It was declared a victory for developing countries and civil society organizations that had fought for this right to health. More importantly, it gave hope that developing countries would be able to take concrete steps to make cheaper versions of patented medicines available to the poor and sick in urgent need of them.

The Doha Declaration had confirmed, among others, the right of developing countries to use compulsory licences to override patents on medicines, in order to allow generic drug manufacturers to produce cheaper versions of patented medicines. The Ministers at Doha could not, however, agree on how to solve the problem of how those developing countries without domestic pharmaceutical manufacturing capacity could effectively use the compulsory licences. This became popularly known as the Paragraph 6 problem, named after the paragraph dealing with this issue in the Doha Declaration. The Declaration instructed WTO members to find "an expeditious solution" to this problem by December 2002.

On 16 December 2002, the Chair of the WTO's TRIPS Council came up with a text containing a proposed solution, which was accepted as a compromise by almost all members except the US. The deadline was thus missed. Negotiations then stalled on the proposed solution, known as the December 16 text.

Recently in Geneva on 30 August, WTO members finally adopted the December 16 text, together with an accompanying statement by the Chair of the WTO General Council. Ministers in Cancun will now welcome the "Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health". However, the reception to the Decision may be more muted than that which greeted the Doha Declaration in 2001. Civil society organizations have expressed reservations that the Decision and the Chair's statement represent a compromise that may have the potential of pushing back the gains made at Doha.

The Paragraph 6 Problem

The TRIPS Agreement allows the grant of compulsory licences (CL) to override patents, so that generic manufacturers may produce their cheaper versions of patented drugs. Countries with insufficient or no

Address: 121-S Jalan Utama, 10450 Penang, MALAYSIA **Tel**: 60-4-2266728/2266159 **Fax**: 60-4-2264505
E-mail: twnet@po.jaring.my **Website**: www.twnside.org.sg

domestic manufacturing capacity in pharmaceuticals are faced with a problem because there are no generic manufacturers to produce the drugs domestically. An option for these countries is to grant a CL for the import of such drugs.

However, the supply of drugs for these countries to import may be limited and insufficient because of constraints placed by the TRIPS Agreement on the countries that have the capacity to produce and export the generic versions. The reason is that the TRIPS Agreement (Article 31(f)) requires that the production of generic drugs under a CL be "predominantly for the supply of the domestic market". This restriction would mean that export of drugs produced under a compulsory licence is possible only if the "predominant" portion of the production output has been supplied to the domestic market. This raises the concern that the non-predominant portion may not be sufficient for the needs of the importing country or countries.

The Agreed "Solution"

The "solution" is essentially a waiver of the Article 31(f) limitation on exports, which lifts the requirement of Article 31(f) that pharmaceutical products produced under a CL shall be "predominantly for the supply of the domestic market". With this waiver in force, it means that a predominant portion or even the total amount of production under a CL could be exported to a country that wishes to import. WTO members also agreed to an accompanying statement by the General Council Chair which spells out a number of "key shared understandings" of how the Decision would be interpreted and implemented. The Chair's statement is widely known to be the US' attempt to seek "comfort language" that would assuage concerns of its powerful pharmaceutical lobby that the Decision would allow generic manufacturers to gain a stronger foothold in the profitable pharmaceutical market. The US had, in mid-August 2003, come up with its proposal for a Chair's statement that would enable them to agree to the December 16 text — eight months after the US stalled negotiations by withholding consensus after (almost) all WTO members had agreed to it in December 2002.

After hurried consultations in the few weeks before the end of August, members agreed to the final version of the Chair's statement. The statement confirms the common understanding of members that the Decision should be used in good faith to protect public health purposes, and not for industrial or commercial policy objectives. It also emphasizes the need to prevent diversion of medicines from the markets for which they are intended, elaborating on the trade-diversion-prevention measures that are required to be taken by countries using the Decision.

Will it Work? And How?

The objective of the Decision is to allow for countries wishing to import generic medicines to do so from a foreign generic producer. Where a patent is in force in the importing country on the drug in question, the importing country government will have to issue a CL to enable the import of the generic version of the patented drug. In the exporting country, the patent status of the drug is also relevant: if a patent is in force, then the generic manufacturer would have to obtain a CL to produce the drug and export it.

In countries where there is no patent in force — for example, least-developed country (LDC) members need not allow for drug patents until 2016 — the importing country need not issue a CL. Similarly, in an exporting country where there is no patent in force, the production and export can take place without issue of a CL. However, there are very few countries in this situation, India being a notable exception until 2005, when all countries will have to provide full patent protection. This is the reason why it was of crucial importance that a solution to the Paragraph 6 problem was found quickly.

Therefore, in many cases, two CLs will have to be issued. Under the TRIPS Agreement and confirmed by the Doha Declaration, WTO members have the right to determine the grounds for the grant of compulsory licences. The standard procedural conditions for the grant of CL are set out in the TRIPS Agreement (Article 31), which includes the conditions that an application for a CL should be preceded by a failed attempt to obtain a voluntary licence from the patent holder and the payment of compensation to the patent holder. The Decision now modifies some of these requirements and sets out another set of procedures to be complied with, when the waiver of Article 31(f) is required to allow for generic medicines made in one country to be exported to another.

A Compulsory Licence to Import

So, when a developing country wishes to import generic medicines (and the said medicine is under patent protection in the country), the importing country will have to do the following:
(a) Notify the WTO of its intention to use the solution as an importer (LDCs are not required to notify); the names and expected quantities of the product(s) needed; its confirmation that it has established that it has insufficient or no manufacturing capacity (see (b) below); and its grant or intention to grant a CL.
(b) Establish insufficient or no manufacturing capacity. LDCs are automatically eligible, while other developing countries have to qualify to use the solution. Developing countries have to establish either that: i) they have no manufacturing capacity in the pharmaceutical sector; or that ii) the capacity is currently insufficient for the purpose of meeting its needs. The Decision suggests that countries make this determination themselves, i.e., it is a self-determination test. Developed countries have "opted out" of using the solution and 11 high-income developing countries

say they will only use it in times of emergency, as will the 10 countries seeking accession to the EU. On joining the EU, these countries will not use the solution at all.
(c) Take measures against trade diversion. All importing countries will have to take "reasonable measures within their means" to prevent re-exportation, as "proportionate to their administrative capacities and to the risk of trade diversion". This appears to be an obligation but it is unclear what the consequences of non-compliance or insufficient compliance will be.

A Compulsory Licence to Produce and Export

The importing country will need to locate a generic manufacturer that is willing and able to supply the medicines required. The generic manufacturer will require a CL if the medicine is under patent protection in its country. In theory, any country may grant a CL to its domestic generic manufacturer to produce and export to the importing country. It can be expected, however, that developed-country governments, such as the US, Canada and the EU, will not be granting CLs to their generic manufacturers, given the pressure of their pharmaceutical lobby.

When a government decides to grant a CL, it must notify the WTO of the grant of CL and its conditions, including the name and address of the generic manufacturer, the product, the importing countries and the duration of the CL, as well as the address of the website on which information regarding the product has been posted.

The CL must also be subject to the following conditions: (i) it is only for the amount required by the importing member and must be exported in total to the importing country; (ii) the products produced under CL must be clearly identifiable through labelling or marking (e.g., special packaging, colouring or marking); and (iii) the generic manufacturer is obliged, prior to shipment, to post on a website information on the quantities supplied to each importing country and the distinguishing features of the product.

Procedural Deterrents and the Chair's Statement

These terms and conditions in the Decision are viewed with concern, in that they will be too burdensome and thus act as a disincentive or a barrier against the use of the Decision. This is particularly true of the obligations placed on exporting countries and the generic producers. A generic manufacturer would have to be convinced that it would be worth his while (and be economically viable) to apply for a CL, especially where he would also have to satisfy the conditions of having had unsuccessful negotiations with the patent holder for a voluntary licence and pay the compensation amount.

If granted a CL, the generic manufacturer may go ahead to produce but be subject to the conditions of the CL as stated above. It would appear that the requirements have to be fulfilled anew for each batch of medicines produced under a CL, and for each and every country to which the drug will be exported. There may also be other product-registration and drug-safety (such as proof of bio-equivalence of the generic product) requirements that may have to be satisfied. For these reasons, there are serious concerns that these conditions may deter a generic manufacturer, in terms of the cost implications as well as the bureaucratic red tape.

For prices to be lowered to levels affordable to the majority of the developing-country populations, it would make sense to encourage competition between as many generic manufacturers as possible. Competition from the introduction of generics would also bring down prices of patented medicines; this has been demonstrated in many studies. However, the generic manufacturers would have to be able to achieve economies of scale or cost efficiencies to remain viable. And this would be dependent on large production runs — large enough orders — to stay in business. The measures to prevent trade diversion - in requiring each batch of medicines to be manufactured in different shapes or colours - may prevent this from happening.

Added to these several conditions in the Decision (i.e., the December 16 text) is now another set of conditions contained in the accompanying Chair's statement. This statement, with its "understand-ings", adds to the deterrent effect that hinders or prevents countries from actually making use of the "solution." The Chair's statement has been criticized by civil society organizations as yet another attempt by the US to restrict or limit the effectiveness of an already less-than-perfect solution to the Paragraph 6 problem.

Among the potential problems wth the Chair's statement are the following:
(a) The reference to the Decision not being used for "industrial or commercial policy objectives" would at worst prevent the use of the Decision if it were to result in a expansion of the generic drugs industry or if the generic manufacturers were to make any profit. At best, it adds a layer of uncertainty in terms of how the Decision could be used.
(b) The statement also seems to suggest that generic manufacturers producing for export under the Decision will now have to comply with the requirement for special packaging and/or special colouring or shaping, regardless of its impact on the price of the product. This essentially is a rewriting of the December 16 text, which had stated that this requirement need not be satisfied unless it was feasible and would not have a significant impact on price.
(c) The Chair's statement also establishes a right and mechanism for members to challenge the validity of another member's use of the solution. Whilst it is not clear what the legal implications are, it is feared that these elements would have a "chilling effect" on

countries in their use of the Decision.

The Chair's statement would seem to be the last (and successful) in the series of attempts to restrict the use and effectiveness of the solution. In the early stages of negotiations on the Paragraph 6 problem, the US had sought to put limits on the scope of diseases to be covered under any solution. When this was rejected, an attempt was made to restrict the circumstances in which the solution may be used.

Developing countries also rejected the proposal for a Chairman's understanding that the solution be used only in circumstances of national emergency or extreme urgency. Then, there was the attempt to pressure some countries against using the solution, questioning their eligibility. It had been reported that a number of developing countries have been informed by the US that they are considered ineligible, even though the December 16 text had clearly made eligibility a matter of national decision.

Put it to the Test

It now remains to be seen whether or not developing countries will make use of the solution, and if it will in fact make access to affordable medicines a reality. The Decision will have to be tested as to whether countries will try to use it and whether it can be used successfully. This means that developing-country governments will have to issue the necessary compulsory licences for the import of generic medicines. Generic manufacturers in other countries will have to respond to this call by making applications for compulsory licences to produce and export. In some cases where product patent protection is not yet in force, such as in India, generic manufacturers may produce and export without the need for compulsory licences until 2005.

In the cases where compulsory licences are required, governments will have to issue compulsory licences for production and export by their generic manufacturers to produce and export. Developed-country governments can prove their good faith by granting compulsory licences for export when requested by their generic manufacturers.

The Decision also confirms that it does not prejudice the existing rights and flexibilities available under the TRIPS Agreement, including the extent to which pharmaceutical products produced under compulsory licence can be exported under the present provisions of Art. 31(f). The TRIPS Agreement currently allows export of the non-predominant portion of production under CL (theoretically, anything up to 49% of production) without these additional conditions. Where a CL for remedying anti-competitive practices is granted, the total production output (i.e., 100%) can be exported, without any of the additional conditions specified in the Decision. Therefore, it would appear that where a member seeks to export under these circumstances, it need not meet any of the terms and conditions specified under the Decision. WTO members should therefore explore the means of using these rights and flexibilities as an alternative or in conjunction with the Decision.

The Decision represents only one aspect of the broad framework that the Doha Declaration provides to safeguard against unaffordable prices for much-needed medicines. The Doha Declaration affirms the right of WTO members to employ other measures to facilitate the protection of public health and promote access to medicines. The implementation of these measures in developing countries is far from complete. Therefore, countries should take urgent measures to adopt and adapt their national patent laws, so as to make full use of the flexibilities in the TRIPS Agreement, as affirmed by the Doha Declaration. This includes not only the adoption of rules and guidelines to facilitate the grant of compulsory licences on public health grounds, but also to provide for the appropriate institutional and administrative framework that is necessary for the effective implementation of public-health-sensitive patent laws. There are also other TRIPS-consistent measures, including the use of parallel imports, government-use provisions and exceptions to patent rights, that may be used to mitigate the effects of pharmaceutical patents, and the use of these measures should be properly explored by developing countries as alternatives.

The Doha Declaration also granted the right to not provide for pharmaceutical patents to LDC members until 2016. Therefore, these countries should be cautioned against enforcing or providing for patents on pharmaceutical products until 2016 at the earliest. LDCs should use this flexibility to enable them to structure their patent laws and data protection rules so as to better protect public health and promote access to affordable medicines.

The negotiations leading up to the Doha Declaration and the recent Decision have highlighted the effects of patents on the prices of and access to medicines. The implications of the TRIPS Agreement on public health and access to medicines are now better understood. International public opinion will have to be the judge of whether the declarations and decisions in the WTO have had a real impact on improving people's access to affordable medicines. If it is judged that these have not been effective, it may be that pressures will then begin for more far-reaching changes.

(This paper first appeared as a Briefing Paper of the Third World Network for the 5th Ministerial Conference of the World Trade Organisation (WTO) held in Cancun in September 2003.)

CECILIA OH is a representative and Legal Advisor of the Third World Network based in Geneva.