

Intellectual property protection and public health

Access to medicines and the link to pharmaceutical patents has been on the table for World Trade Organisation (WTO) members since the organisation's ministerial meeting in Seattle in 1999. At the end of August this year, WTO members broke their deadlock over intellectual property protection and public health, agreeing on legal changes to make it easier for poorer countries to import cheaper generics made under compulsory licensing if they are unable to manufacture the medicines themselves. This article looks at the effect the recent decision on "Paragraph 6" will have on improving access to medicines in developing countries.

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Two years after the WTO's Seattle meeting, when ministers met in Doha in November 2001 they were able to conclude a Declaration on the relation between the TRIPS Agreement and public health. This declaration, which stands on its own, separate from the new WTO Development Round that was initiated at Doha, is important for many reasons. Firstly, it is the first time developing countries, with Zimbabwe in the lead, initiated an issue at WTO level that members could react to swiftly. Secondly, it set a badly needed example for the Development Round. Thirdly, and of course most importantly, it brought security to many developing countries in their efforts to develop health policies including provision of patented medicines, for the benefit of their populations.

The Doha Declaration on the TRIPS Agreement and public health recognises the gravity of public health problems in relation to epidemics. Members agreed that the TRIPS Agreement does not, and should not, prevent measures to protect public health and promote access to medicines for all. The most direct effect of the Declaration is that Least Developed Countries (LDCs) will enjoy an additional ten-year period up to 2016, before they have to accept pharmaceutical patents in their legislation. This agreement has subsequently been integrated into TRIPS.

Another issue of utmost importance agreed in Doha is that "each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted" (a compulsory license means that a government issues a decision to the effect that a valid patent is "confiscated" without the patent holder's consent in response to an emergency or other valid reason). WTO members then turned their attention to the issue of the unequal relationship between developed and developing members, in the sense that most of the developing members have no or insufficient manufacturing capacity to produce pharmaceuticals on a national level. This means that these countries are unable to make use of their right to issue a compulsory license since import of the products in question is impossible if a patent in the exporting country is in effect. Export under a compulsory license is prohibited under TRIPS and an exemption from this prohibi-

Will the WTO deal on compulsory licenses for medicines improve access to treatment for disease stricken populations?

tion in order to supply these countries had to be agreed. Members were not able to crack this problem in Doha and referred it back to the TRIPS Council to deal with and conclude before the end of 2002 (the "Paragraph 6 issue").

"Paragraph 6" deal concluded in August 2003

The TRIPS Council did not manage to conclude a solution to the outstanding issue within the set deadline. The EU and other members worked hard on a compromise, which was agreed to by all but one – the US – on December 16, 2002. The US was under heavy pressure from the research based pharmaceutical industry, which feared that the use of compulsory licenses for exports would "open Pandora's Box" in terms of weakened patent protection and therefore insisted on further restrictions in both scope and use. With the next ministerial meeting coming up, this time in Cancún, there was an urgent need, politically, to resolve the "Paragraph 6" issue. The very continuation of the Development Round was in danger and the "Paragraph 6" issue became of central importance. The Decision of the WTO General Council is dated 30 August i.e. just before the Cancún meeting in September.

In short, the Decision states that an importing member, which is an LDC or has notified the TRIPS Council of its intention to use the system and lacks capacity to produce in-country, may issue a compulsory license for the quantity of medicines needed. The exporting country then issues a "back-to-back" compulsory license to meet that need and ensure the entire production, made under the license, is exported to that specific country. It is to be noted that the exporting country pays the obligatory license fee to the patent holder, while the normally poorer importing country is relieved of this.

A set of conditions, notifications and control measures are attached to ensure that the system does not become a regular tool to avoid patent protection and in particular, to ensure that products are not "leaked" to markets other than those for which they were produced. The Decision does, however, recognise the need for free circulation of such products within neighbouring countries which share the same health problem and with whom the importing country has a regional trade arrangement.

This Decision, which can best be described as a political undertaking, needs to be translated into a formal amendment of Article 31 of the TRIPS Agreement, with work starting by the end of 2003 with a view to finalisation by mid-2004. As the system is voluntary on both the importing and exporting side, WTO members are free to use it within the restrictions and conditions set out. National provisions in the patent laws will have to be changed to reflect this agreement. Canada is the first WTO member that has taken this step by proposing an amendment that

Malawi. Sorting drugs in a medical laboratory.

will enable them to export under a compulsory license. It is expected that most members will await the final TRIPS text before they consider their participation. Until this text is negotiated, WTO members have agreed not to initiate dispute settlement proceedings against other members making use of the system.

Compulsory licenses do not ensure access to medicines for all!

A lot of attention surrounded first the Doha declaration and later the process that led to the “Paragraph 6” Decision. But what will it bring in terms of production and increased access to drugs?

The main issue in the WTO Seattle meeting in 1999 was that medicines are largely out of reach due to patents making them extremely expensive. Patented medicines were and are in general more expensive than non-patented drugs. However, we see a trend today whereby prices for certain patented medicines for certain developing markets have dropped considerably. When the discussion on anti-retroviral medicines to treat HIV/AIDS took off some years ago, prices world-wide were as high as \$10,000 per person per year. Now we see certain types of patented anti-retrovirals on sale in poorer markets for \$200. For countries with a health budget per person of \$10 a year, or even less, it is obvious that these prices are still well out of reach.

Many producers consider poorer country markets insufficiently profitable to file a patent. Therefore, these countries are able to produce or import most sophisticated medicines

without the new exemption regarding compulsory licenses. Likewise, countries with no patent legislation in force are free to produce or import. This latter situation applies to LDCs (TRIPS implementation 2016 in respect of pharmaceuticals) and to countries which are not members of the WTO and therefore not party to the TRIPS Agreement.

India, as a developing country benefiting from a specific exemption from awarding patents on pharmaceuticals until 2005, is well placed to supply these countries. We know that exports from India to these countries are limited but slightly improving. The reasons for the slow up-take are, again, lack of funds and local health services.

It is clear that the current Decision on “Paragraph 6” will not on its own significantly improve access to medicines, in particular since the system is complicated and burdensome. It is expected that a handful of countries will explore the route as importing countries in order to make a difference to their populations. These are developing countries of a certain standing i.e. with sufficient funds to buy large quantities and possessing negotiating power to achieve the best possible prices. The exporting countries, on the other hand, have more to win but have to be competitive both when it comes to prices and quality.

In the future, when all developing WTO members have fully implemented the TRIPS Agreement, the picture might have changed and the system to allow export under compulsory licensing might prove more useful in improving access to medicines on a broad basis. Until then, poorer countries with populations suffering from communicable diseases are better off looking for available funding and the lowest possible prices.

Countries with manufacturing capacity, including EU member states, should be encouraged to opt for becoming potential exporting countries under the system. This involves amending their national legislation to legalise export under compulsory licenses so as to be ready to provide if and when needed. This could well be done in anticipation of the formal amendment to the TRIPS Agreement to support the political agreement envisaged in the Decision. ■

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In February 2001 the European Commission adopted the Programme for Action: Accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction (updated on 26th February 2003), which is based on a comprehensive approach to the three major communicable diseases. The Programme for Action focuses on:

- maximising the impact of measures to strengthen health care systems on a national basis,
- increasing “affordability” i.e. seeking to lower the prices of essential medicines,
- identifying ways and means of promoting research into new pharmaceuticals and vaccines to fight these diseases.

The Programme was recently updated by a Commission Communication COM (2003)93.

One of the Commission’s objectives is to improve the affordability of medicines, to ensure that the least developed and low income countries benefit from the lowest possible prices. This includes a sustainable framework for tiered priced products and assurances that these products remain in the markets for which they are intended. The latter problem is addressed in Council Regulation 953/2003 which gives tiered-price medicines sold to developing countries protection against re-importation into the EU.

More information is available at:
http://europa.eu.int/comm/trade/issues/global/medicine/index_en.htm