ACCESS TO DRUGS: IN NEED OF AN EXPEDITIOUS SOLUTION UNDER TRIPS

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Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, adopted in November 2001, mandated the Council for TRIPS to address a problem that will growingly emerge as patents on drugs must be recognized in all WTO members (with the exception of LDCs until 2016). If the patent owner refused to provide a drug on affordable terms and conditions to a Member country, people living there could be simply deprived of treatment as no generic drugs will be available. The Council was instructed to find an 'expeditious solution' by ensuring that Member countries lacking or with insufficient capacity to manufacture the required drugs could import them from alternative suppliers located in other Member countries.

On 30 August, 2003, a Decision (hereinafter 'the Decision') was adopted by the General Council for the implementation of paragraph 6. The Decision was made on the basis of a compromise laboriously reached by the Chair of the Council for TRIPS, and on a 'Statement' by the Chair of the General Council that was demanded by the USA as a condition for accepting the compromise.

The Decision took the form of an *interim* waiver (of paragraphs f) and h) of article 31 of the TRIPS Agreement), which allows Member countries to grant compulsory licenses to export drugs[1] to eligible importing countries, provided that various conditions are met, including the grant of a compulsory license in the importing country, where necessary. The waiver is set to last until the TRIPS Agreement is amended.

One of the conditions for the use of the mechanism created by the Decision is a general notification by potentially eligible countries to the Council for TRIPS of their intention to make such use. After almost four years of the adoption of the Decision, no single notification has been made. No drug has been so far supplied under the mechanism set up by the Decision.

Another requirement to make the mechanism operative is the amendment of the domestic law in the potential exporting countries. With the adoption of the implementing Regulation by the EU in May 2006, a significant number of countries might now grant compulsory licenses for export under the Decision, but only one (India) is a potential supplier of low cost drugs.

In December 2005, WTO Members agreed to incorporate *telle quelle* the Decision into the TRIPS Agreement as article 31*bis*. The amendment is subject to ratification in accordance with WTO rules. Although the deadline for ratification is 1 December 2007, so far only 7 out of 150 Members have done so[2].

The total absence of notifications of the intention to use the system, and the lack of enthusiasm for ratifying the TRIPS amendment may be attributed to different factors. It may be speculated that generics are still available from low cost providers and that the use of the Decision has not been necessary. But developing countries anticipated the problem six years ago and know that concrete cases of lack of supply may emerge at any time as drug patents have become available in all WTO Members (except LDCs, as noted). It may also be argued that prices of drugs are affordable and that agreement has always been possible with patent owners. But five developing countries (Zimbabwe, Malaysia, Mozambique, Zambia, Indonesia, Ghana, Thailand, Brazil) had to grant compulsory licenses to get access to cheaper drugs in the last five years.

The lack of notifications and small number of ratifications may be explained by other factors.

First, the conditions established in both the text of the Decision and the Statement for allowing exports of patented medicines, are hardly compatible with the idea of an 'expeditious' solution (see Box)[3].

[1] The Decision broadly applies to 'pharmaceutical products', including vaccines.

[2] 1. United States (17 December 2005); 2. Switzerland (13 September 2006); 3. El Salvador (19 September 2006); 4. Rep. of Korea (24 January 2007); 5. Norway (5 February 2007); 6. India (26 March 2007); 7. Philippines (30 March 2007). See http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm.

Box: *Conditions for the operation of the 'solution' under paragraph 6*

In order to qualify for importing drugs under this mechanism the following steps must be followed:

(1) unless the prior request of a voluntary license does not apply, an entity in an eligible importing country that has notified its intention of using the Decision, must seek a voluntary license from the patent owner;
(2) failing this, an application for a compulsory license must be submitted and the license be issued by the government in the importing country;
(3) the importing country must assess its manufacturing capacity to produce the medicine locally;
(4) if capacity is lacking or insufficient, it must notify the WTO of its decision to use the paragraph 6 'solution';
(5) the interested importing country or party must identify a potential exporter in a country where the Decision has been implemented;
(6) that prospective exporter must in turn seek a voluntary license on commercially reasonable terms for a commercially reasonable period of time (unless prior negotiation is waived by national law);
(7) if the voluntary license were refused, the potential exporter must seek a compulsory license (to be granted on a single-supply basis) from its own government;
(8) if a license is granted, the exporter will have to develop the chemistry and formulate the drug (when produced by the licensee for the first time), and to investigate the shape, colouring, labelling and packaging of the patent-holder's product in the importing country in order to differentiate the product for export;
(9) the exporter will also need to seek product registration and prove 'bio-equivalence' and 'bio-availability', where required by national law;
(10) if in the importing country exclusivity (as promoted by the USA and EU) is granted with regard to test data submitted for the registration of a medicine, the supplier will have to obtain the data holder's authorisation before using the information, or to develop its own studies about safety and efficacy[4], unless the use of such data is included in the compulsory license;
(11) before shipment begins, the compulosry licensee shall post on a website information about the quantities being supplied and the distinguishing features of the product; and
(12) the exporting Member must notify the Council for TRIPS of the grant of the license, including the conditions attached to it;

The process described in Box 1 must be fulfilled over and over in the exporting country since only the amount necessary to meet the needs of one particular eligible importing Member (except in the case of regional agreements with a majority of LDCs) may be manufactured under the licence, and the entirety of this production shall be exported to the Member that requested the supply.

Notably, such conditions pose legal barriers to the use of tendering procedures. An 'offering for sale' may be regarded as an infringing act (article 28.1 of the TRIPS Agreement) and prevent potential suppliers from participating in tendering procedures without having obtained a compulsory license. But companies cannot be expected to spend their time and money in soliciting a compulsory license when they don't know whether they will be chosen to provide the required product. On its side, the government of the importing country may be reluctant to award a bid to a producer that has not previously obtained a compulsory licence (in the absence of which he will unable to supply the required products).

Second, in order to be effective, a solution to the problem described in paragraph 6 should be economically viable, and not only diplomatically acceptable. The mechanism set out by the Decision fails to provide an effective means for increasing competition and lowering drug prices. The adopted 'solution' is so cumbersome

[3] The following analysis is partially based on Carlos Correa, '*Access to drugs under TRIPS: A not so expeditious solution'*, Bridges, ICTSD, May 1, 2004, available at http://www.ictsd.org/monthly/bridges/BRIDGES8-1.pdf

[4] Of course, this may take years and require a significant investment, thereby preventing any attempt to supply the required medicines at low cost and within a short period.

for potential suppliers that they will hardly be encouraged to use the Decision "because it is so designed that no generic manufacturer would be able or willing to comply with its provisions".[5] In fact, generic producers in the countries that could be potential exporters under the Decision have not shown any interest in bearing the substantial transactions costs involved to eventually supply drugs at low prices to developing countries in need[6].

As noted by Prof. Maskus, although overall needs in the poor nations are immense, 'even if some poor countries in a trade agreement covered by this exception pooled their demands for a particular medicine, the scale may be still too low to become attractive for potential suppliers […][B]ecause the eligible import markets in really small countries will not be large, generic producers may not be interested in producing such small volumes and foregoing chances for economies of scale'[7].

Third, as illustrated by the case of Thailand, developing countries making use of compulsory licenses are subject to political pressures and may also suffer retaliations from the affected companies. Thailand was the first developing country to have granted -after the adoption of the TRIPS Agreement- a compulsory license on a medicine that it is not an anti-retroviral[8].

In sum, the mechanism now incorporated into the proposed article 31*bis* of the TRIPS Agreement has not proven yet to be workable. The multiple conditions required for its application, including political capacity to resist pressures from foreign governments and companies, rather suggest that the Decision is unlikely to lead to a significant increase in the supply of medicines for the poor. Since the waivers adopted under the Decision will remain in force until the Agreement is amended, it seems reasonable to subject the ratification of the amendment to a prior evidence-based assessment of the effectiveness of the mechanism as set up. In such an assessment, other options –such as a straight exception under article 30 of the TRIPS Agreement- should be considered.

Finally, it should be kept in mind that the Decision only addresses *one of the problems* arising in the context of the TRIPS Agreement with regard to public health. The protection conferred on pharmaceutical products will continue to pose significant challenges to public health policies in developing countries, even if the mechanism set up by the Decision would prove to be viable and effective. Difficulties in this area are likely to continue, especially as developed countries seek TRIPS-plus protection via interpretation[9] or the negotiation of bilateral and regional agreements,[10] and as patents on marginal or trivial developments (sometimes called 'ever-greening' patents) are granted – and used – to block or delay generic competition[11] .

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[5] Comments by D. G. Shah, Indian Pharmaceutical Alliance (mail of August 26, 2003, on file with the author).

[6] See the statement by Jeff Connell, spokesman for the Canadian Generic Pharmaceutical Association, regarding the Canadian implementing legislation (*Globe and Mail*, November 19, 2003), and the statement by Greg Perry, President of EGA, regarding the proposed European Regulation (Tuesday, 2 November 2004, available at http://www.egagenerics.com/pr-2004-11-02.htm).

[7] Prof. Keith Maskus on TRIPS, Drug Patents and Access to Medicines-Balancing Incentives for R&D with Public Health Concerns', in K*nowledge economy on the development gateway*, 2003, at http://www.developmentgateway.org/knowledge.

[8] See Ministry of Public Health and National Health Security Office (2007), *Facts and Evidences on the 10 Burning Issues Related to the Government Use of Patents on Three Patented Essential Drugs in Thailand. Document to Support Strengthening of Social Wisdom on the Issue of Drug Patent*, Bangkok.

[9] The USTR and the European Commission, for instance, incorrectly interpret that article 39.3 of the Agreement requires the granting of an exclusive period of protection for data submitted for the marketing approval of pharmaceuticals and agrochemicals.

[10] See, e.g. the US FTAs with Chile, Morocco, Central American countries and Dominicam Republic, Singapore, Colombia and Peru. See, eg., Jean-Frédéric Morin, 'Tripping up TRIPS debates IP and health in bilateral Agreements'**,** *Int. J. Intellectual Property Management, Vol. 1, Nos. 1/2, 2006.*

[11] See, e.g.,Carlos Correa (2001), Trends in drug patenting. Case studies, Corregidor, Buenos Aires.