

The Declaration on TRIPs and Public Health: A Step in the Right Direction

By Ellen 't Hoen

The fourth WTO Ministerial Conference in Doha affirmed in the Declaration on TRIPs and Public Health the sovereign right of governments to take necessary measures to protect public health. This is an important achievement because it gives clear primacy to public health over private intellectual property and clarifies Members' right to use the TRIPs safeguards. Contrary to proposals of certain developed country Members (see Bridges Year 5 No.7 page 1), the Declaration clearly speaks about 'public health' and does not limit the use of safeguards to crisis situations, HIV/AIDS and pandemics.

The most contentious section of the Declaration was paragraph 4. In a draft presented at the 19-21 September session of the TRIPs Council, a large group of developing countries proposed the following text for it: 'Nothing in the TRIPs Agreement shall prevent Members from taking measures to protect public health.' Some developed countries saw this wording as a new rule that would completely override present TRIPs disciplines in the field of public health. The Harbinson draft submitted to ministers in Doha thus contained alternative text (option 2), which would have limited the use of the TRIPs flexibilities to public health crisis, HIV/AIDS or pandemics. This was clearly seen as limiting Members' rights rather than clarifying them.

Developing countries and public interest NGOs welcomed the Doha compromise because it contained the key principle of primacy of public health over intellectual property rights. 'The TRIPs agreement *does not and should not* prevent members from taking measures to protect public health,' the Declaration says, adding that the Agreement should be interpreted and implemented in a manner 'supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.'

The Declaration gives a clear road map to the key flexibilities within the TRIPs Agreement that can be used to overcome IPR barriers to access to medicines and other measures to protect public health. Governments can decide the grounds for granting compulsory licenses. The discussions in Doha and the Declaration itself make it unambiguously clear that the use of compulsory licenses is in no way confined to cases of emergency or urgency. In Doha, some Members unsuccessfully tried to introduce language that would limit measures such as compulsory licenses to emergency situations or pandemics or certain diseases such as HIV/AIDS. The Declaration leaves Members free to determine what is a national emergency or urgency in which case the procedure for issuing a compulsory license becomes easier and faster.

The Declaration puts the question whether TRIPs authorises parallel imports to bed by stating clearly that 'The effect of the provisions in the TRIPs Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge.'

The Declaration grants least-developed country Members an extra 10-years – until 2016 instead of 2006 – before they must implement the obligation to provide pharmaceutical patent protection. It also refers to the yet-unfulfilled commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2.

One key issue remained unresolved in Doha and that is how to allow another Member to produce for export to a country that has issued a compulsory license but does not have manufacturing capacity. Article 31(f) of the TRIPs Agreement limits manufacture under a compulsory license to 'predominantly for the supply of the domestic market'. Further clarification is necessary to ensure that countries without production capacity can make use of compulsory licensing provisions to the same extent as those who have that capacity. The Doha Declaration acknowledges the problem when it says in paragraph 6: '*We recognise that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPs Agreement. We instruct the Council for TRIPs to find an expeditious solution to this problem and to report to the General Council before the end of 2002.*'

'After Doha, intellectual property has become a bit less private property and a bit more a public good.'

One solution to this problem could be to allow production for exports under an Article 30 exception. This option was proposed by the group of 60 developing countries at the TRIPs Council in September, but did not find its way into the Harbinson draft. In Doha, Peru unsuccessfully tried to bring it back on the negotiating table. An alternative approach to the Article 30 solution would be to amend the text of Article 31(f) so that cross border recognition of a compulsory license becomes possible.

It is not possible to fully predict how the Doha Declaration on TRIPs and Public Health will be used in practice, but commentators have indicated the following:

- the Declaration will play a role in dispute settlement procedures on TRIPs and public health related issues before the WTO. Panels and the Appellate Body will need to take the interpretation given in the Declaration into account;
- at national level, the Declaration will guide governments in implementing legislation that allows to address health needs;
- the Declaration can be used as a checklist in bilateral agreements which include provisions on intellectual property rights; and
- the Declaration should give WTO Members the confidence to make full use of the safeguards, including compulsory licensing to increase the availability of affordable medicines and increase generic competition.

Is it over and done with?

The Declaration gives a strong political message but it will become a useless piece of paper if countries do not enact and implement pro-public health IPR legislation and start using the compulsory license provisions to encourage the availability of more affordable medicines. It would help if the World Intellectual Property Organisation were to adapt its technical advice to countries to give legislative 'hands and feet' to the Doha Declaration on TRIPs and Public Health at the national level.

It also remains to be seen whether the Declaration will have an impact on bilateral or regional negotiations in which developing countries are often pressured to adopt higher levels of intellectual property protection than the TRIPs Agreement requires.

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