

TRIPs and Public Health vs TRIPs and Pandemics?

It looks increasingly certain that WTO Members will adopt a stand-alone statement on the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs) and access to medicines at their Ministerial Conference in Doha, Qatar, in November. While both developed and developing countries have put forward detailed draft proposals for ministers' endorsement, all acknowledge – more or less formally – that the importance of a Ministerial Declaration on TRIPs and health will reside in its political rather than technical content.

The elaboration of such a statement was the central focus of the 19-21 September session of the TRIPs Council, and the political dimension was obvious even in the titles of the texts proposed by the different coalitions: the draft submitted by nearly 50 developing countries was called a *Declaration on the TRIPs Agreement and Health*, while Australia, Canada, Japan, Switzerland and the United States ('Australia + 4') proposed a preamble entitled *Access to Medicines for HIV/AIDS and Other Pandemics* (this was later followed by six operational paragraphs from Canada, the Czech Republic, Japan, New Zealand, Switzerland and the US, i.e. 'US + 5'). The European Commission's compromise contribution was headed *Declaration on TRIPs and Access to Affordable Medicines*.¹

These differences go beyond semantics. The joint developing country draft (see page 3 for further details) sought to ensure that any doubts about the TRIPs Agreement's flexibility with regard to measures taken by developing countries to address access to drugs would be resolved in favour of their sovereign right to protect public health. Its first preambular paragraph affirmed that

The protection and promotion of public health and nutrition is a fundamental obligation and prerogative of the State and that Members retain their sovereign power in this regard.

The corresponding operative part (i.e. 'Ministers declare that') boldly stated: 'Nothing in the TRIPs Agreement shall prevent Members from taking measures to protect public health.'

Quipped one developing country trade diplomat: 'If we get operative paragraph one, we will not even need the rest.' He and other developing country delegates noted that the EC text, which also addressed access to medicines and public health, was 'very close' to their concerns, while the other industrialised country proposals seemed aimed at restricting the Declaration's scope to pandemics such as tuberculosis, malaria and, in particular, HIV/AIDS.

Preambular language in the five industrialised countries' draft would have ministers recognise that 'access to medicines for treatment of HIV/AIDS and other pandemics, such as malaria and tuberculosis' is a major challenge for the global community and

that international organisations, governments, NGOs and private actors have the common responsibility 'to contribute to the promotion of the most favourable conditions for improving access to medicines for treatment of HIV/AIDS and other pandemics.'

The various drafts also showed different interpretations on the extent that other TRIPs provisions should be read in the light of the social and health objectives embodied in Articles 7 and 8.

While the developing country draft Declaration emphasised 'the fundamental importance of the objectives and principles of the TRIPs Agreement', the 'US + five' proposed that each provision of the TRIPs Agreement 'should be read in accordance with customary rules of interpretation of public international law as reflected in the Vienna Convention on the Law of Treaties.' The EC was more specific: 'Each provision of the TRIPs Agreement should, in accordance with Article 31 of the Vienna Convention on the Law of the Treaties, be read in the light of its object and purpose as set out in Articles 7 and 8 of the TRIPs Agreement.'

Unlike the other industrialised country drafts, the EC proposal agreed with developing countries that protection and enforcement of intellectual property rights should contribute to the transfer and dissemination of technology, and noted the need to give least-developed country Members 'maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base.'

The Role of Patent Protection

Developing country delegates consulted for this story were at pains to stress that their draft Declaration was not directed against patents as such but only sought to contain potential adverse effects on public health. In contrast to their over-riding health objective, they saw the US-led groups' proposals as attempts to affirm that patent holders' rights were paramount under the TRIPs Agreement.

The five-country preamble stressed that – rather than patents – 'determinant factors' for improving access to medicines were efficient infrastructure to distribute, deliver and monitor drug usage; research and development particularly targeted at the major communicable diseases of relevance for developing countries; mechanisms to finance drug purchases and affordable pharmaceuticals; and the implementation of effective healthcare systems. It also emphasised that strong intellectual property protection was 'a necessary incentive for research and development of life-saving drugs' and proposed that ministers reaffirm that TRIPs contributes to the availability of medicines.

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Published by the International Centre for Trade and Sustainable Development.

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The EC's proposed preamble also noted that IPRs needed to be adequately protected and proposed a recognition that they serve public health objectives globally. However, unlike the 'Australia + four' paper, the EC acknowledged that intellectual property was 'one of the factors which have a bearing on the price of medicines'. Both texts also expressed concern over drugs made available under tiered pricing schemes or aid leaking back into markets not eligible for lower prices.

Compulsory Licensing and Parallel Imports

Although the details of the texts vary considerably, agreement seems to have emerged that each country is free to determine the grounds for granting compulsory licenses under Article 31. There is more divergence on when Members can forgo seeking prior consent from the rights holder.

Developing countries did not seek to define what would amount to 'national emergency' or 'other circumstances of extreme urgency' that would allow such practices (see para. 4 opposite), but the 'US + five' proposed that

An affected Member's government can declare pandemics of life-threatening communicable diseases such as HIV/AIDS, malaria and tuberculosis, as situations of 'national emergency' or as a 'circumstance of extreme urgency' within the meaning of Article 31(b) of the TRIPs Agreement.

The EC again sought the middle ground:

In the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use, Members may, subject to Article 31(b) of the TRIPs Agreement, grant compulsory licenses without prior efforts on the part of the user to obtain authorisation from the right holder. Epidemics of life threatening communicable diseases can qualify as situations of 'national emergency' or as a 'circumstance of extreme urgency' within the meaning of Article 31(b) of the TRIPs Agreement.

The EC also backed developing countries' point that a compulsory license issued by a Member may be given effect by another Member, which 'may authorise a supplier within its territory to make and export the product covered by the license'. This would allow developing countries that cannot produce generic medicines themselves to licence a company in another country to manufacture a given drug for export to the Member granting the license.

All proponents also agreed (although the 'US + five' draft hedged this acknowledgement with several qualifications) that Members could choose the 'exhaustion regime' – i.e. the legal basis for parallel imports – that best suited their interests (enshrined in TRIPs Article 6, which provides that 'nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights' for dispute settlement purposes).

Some far-reaching points of the developing country draft were not commented on by other Members at the September Council meeting. Among these were paragraphs related to prohibiting the use of bilateral pressure – i.e. threats of sanctions or grant of incentives or other benefits – to prevent developing countries from using TRIPs flexibility to the full (para. 10). Also undiscussed were ongoing differences on developing countries' proposals that Members 'exercise utmost restraint' in initiating and pursuing dispute settlement proceedings with regard to developing countries' measures to protect and promote public health (para. 11), and the extension of transition periods under TRIPs (para. 13).

No formal TRIPs Council sessions are scheduled before the Doha Ministerial, but informal consultations will continue on how to address access to medicines. The draft Ministerial Declaration released on 26 September proposed that 'the issue of the relationship between intellectual property and [access to medicines] [public health] be addressed in a separate declaration.'

¹ All proposals presented at the Council meeting were informal 'non-papers'. The EC draft was withdrawn as it had not been formally cleared by EU members, but sources said the reason was procedural rather than disagreement on its content.



BRIDGES

Between Trade and
Sustainable Development

Published by the International Centre for
Trade and Sustainable Development.

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ISSN 1562-9996

Annual subscription:

US\$225 for OECD country addresses
US\$75 for other countries
Courtesy subscriptions are possible thanks to the support of ICTSD's funders.

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The *BRIDGES* series of publications is possible in 2000-2001 through the generous support of: the Governments of Switzerland (SECO) and the United Kingdom (DFID), the John D. and Catherine T. MacArthur Foundation and the Rockefeller Foundation.

It also benefits from contributions from ICTSD's core funders: the Governments of Finland, Denmark, the Netherlands and Sweden; Christian Aid (UK), IUCN The World Conservation Union, MISEREOR, NOVIB (NL), Oxfam (UK) and the Swiss Coalition of Development Organisations (Switzerland).

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