

### Access to Medicines: WTO Members May Snatch Defeat out the of Jaws of Victory

'We affirm that the Agreement can and 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,' trade ministers stated in the Declaration on TRIPs and Public Health adopted in Doha. Now those very Members are poised to concede defeat on the only point that ministers left for further deliberation: finding a way for countries with insufficient domestic manufacturing capacity to take advantage of the leeway the Declaration provides to Members to use compulsory licensing. The TRIPs Council must find an 'expeditious solution' to this problem and report to the General Council before the end of 2002.

Most developing countries consider fulfilling this mandate as a litmus test of political will to address their concerns in the multilateral trading system, and a key indication of whether the much-touted Doha 'Development' Agenda will ever deliver more than a feel-good phrase. Should the effort fail, the entire negotiations will be seriously affected.

Despite the high stakes, as this issue of Bridges went to press the TRIPs Council had reached an impasse on the question and positions were hardening, as well as diverging further, rather than converging. In an ultimate attempt to reach consensus before the last scheduled General Council meeting of 2002 on 10-11 December, TRIPs Council Chair Eduardo Pérez Motta of Mexico had suspended negotiations on his draft legal text spelling how the mechanism would work in practice in order to allow delegations to seek instructions from capitals.

#### What Was Agreed in Doha

The Declaration on TRIPs and Public Health is widely regarded as the most positive outcome of the Doha Ministerial Conference from the perspective of sustainable development. The result of an unprecedentedly unified developing country effort, the Declaration affirms that the WTO Agreement on Trade-related Aspects of Intellectual Property Rights 'does not and should not prevent Members from taking measures to protect public health.'

It recognises 'the right of WTO Members to use, to the full, the provisions in the TRIPs Agreement' and specifies that each Member has 'the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.' Members also have the right to 'determine what constitutes a national emergency or other circumstances of extreme

urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.'

While some developing countries have advanced pharmaceutical industries capable of making cheap generic versions of patented medicines, many others do not. The only way the latter can acquire such drugs is by importing them from another country that has the capacity to manufacture them. This possibility is compromised, however, by the requirement in TRIPs Article 31(f) that manufacture under compulsory license must be 'predominantly for the domestic market of the Member authorising such use.' It is precisely because ministers recognised the difficulties this obligation could cause for countries without sufficient manufacturing capacity in finding a 'WTO-compatible' supplier, that they instructed the TRIPs Council to 'find an expeditious solution to this problem and to report to the General Council before the end of 2002.'

Meeting in Sydney in mid-November, trade ministers of a dozen WTO Member countries stated their confidence that a solution would indeed be found and affirmed their commitment to meeting the deadline. However, only week later in Geneva it became apparent that a widening gulf separated Members' interpretations of the Doha mandate's scope and coverage.

#### Public Health vs Epidemics

In the Declaration's opening paragraph, ministers recognised 'the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.'

For developing countries, the operative concept here is 'public health' and the diseases specifically mentioned are merely illustrations of the type of medical urgency that could justify the granting of a compulsory license.

Under intense pressure from its powerful pharmaceutical industry, the US is now taking a much more restrictive view. Instead of accepting Doha formulation, it insists that any mechanism allowing the export of generics manufactured under compulsory license must be limited to treatment for AIDS/HIV, malaria, tuberculosis and other 'infectious epidemics of comparable gravity and scale that may arise in the future', as proposed by pharmaceutical CEOs in a letter to US Trade Representative Robert Zoellick.

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Published by the International Centre for Trade and Sustainable Development.

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Echoing this view, US Ambassador Linnet Deily said in November that WTO Members 'should not endanger the progress achieved at Doha and the careful balance that was successfully struck by being diverted away from helping poor countries[...] towards non-epidemic "lifestyle" health issues.'

The focus on grave epidemics only is unacceptable to developing countries, as it would narrow the original Doha mandate considerably. Referring to the Doha commitment to 'promote access to medicines for all', the Africa Group stated on 28 November that 'if discussions continue on the same line as they have been conducted to date, then it is unlikely that the desired solution will be forthcoming, particularly one meant to address the public health problems afflicting Africa.'

While some speculate that the US intransigence could be a negotiating ploy, representatives of the pharmaceutical industry publicly assert that the Administration has assured them that its position on disease coverage is 'the bottom line'. In widely-circulated letters, several members of Congress have urged Mr Zoellick to remain firm on the restrictive language as 'an open-ended or unclear exception to the standards of patent protection would seriously undermine our interests and long-term public health objectives.'

### **Which Drugs and Who Should Benefit?**

The diseases covered are not the only bone of contention. Countries with powerful patented medicines manufacturers are also attempting to limit the type of product that could be manufactured under third party compulsory license. Just as researchers are racing to develop an AIDS vaccine, Japan has proposed to exclude vaccines while the US is trying to limit the availability of compulsory licenses for diagnostic test kits to only those related to AIDS.

Other main points of conflict revolve around which countries would be eligible to import generics under the new arrangement. While Members agree that all least-developed countries would be qualified to issue licenses for manufacture in third countries, the United States, the EU, Japan and Switzerland – so far to no avail – are seeking a commitment from relatively high-income developing/transition countries such as Singapore, Korea, Hong Kong and Hungary not to import generics that override patents from other countries.

### **The Battle over Trade Diversion**

Countries with large research-based pharmaceutical sectors are worried about trade diversion, i.e. the re-export of low-cost medicines from a beneficiary country to OECD members, where they would erode the market share of brand-name drugs. To avoid this to the greatest extent possible, Switzerland and the EU – backed by other major producer countries – are seeking explicit packaging requirements, which developing countries regard as unnecessarily burdensome. As it stands, the Chair's text would impose distinctive packaging only if it is 'feasible and does not have a significant impact on prices'.

Major patented medicine producing countries are also seeking other conditions for the manufacture and export of generics under compulsory license. Among these are that the entire production be exported to the country granting the license, as well as prior notification of the quantity required and the period for which it will be needed. Developing countries retort that it would be impossible to guess beforehand the severity and duration of the public health problem they seek to address.

### **Divisive Legal Questions**

Also at issue is the legal mechanism for allowing the export of medicines produced under compulsory license. The easiest short-term solution would be to agree on a waiver on dispute settlement cases when a Member actually resorts to the mechanism. Most Members are inclined to agree to on such a waiver, but developing countries and the European Union are also seeking a more permanent solution in the form of an amendment to the TRIPs Agreement itself. The US,

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**BRIDGES**

Between Trade and  
Sustainable Development

Published by the International Centre for  
Trade and Sustainable Development.

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Material from *BRIDGES* can be used in other publications with full academic citation.

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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.

The International Centre for Trade and Sustainable Development (ICTSD) is an independent non-profit organisation that aims to contribute to a better understanding of development and environmental concerns in the context of international trade. It upholds sustainable development as the goal of international trade and promotes participatory decision-making in the design of trade policy.

The *BRIDGES* series of publications is possible in 2001-2002 through the generous support of: the Governments of Switzerland (SDC) 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), MISEREOR, NOVIB (NL), Oxfam (UK) and the Swiss Coalition of Development Organisations (Switzerland).

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Japan and Canada are not willing to consider an outright amendment as yet, preferring instead to see the results of the waiver agreement for a so-far undetermined period. Ambassador Pérez Motta has proposed that Members agree on a waiver by the TRIPs and Public Health Declaration's deadline of 31 January 2002 and conclude work on a permanent amendment by the end of next June. To allay developing country fears that the amendment could become a bargaining chip in the Doha Round negotiations, Ambassador Pérez Motta's disputed draft text specifies that negotiations on the text would not be part of the 'single undertaking' launched in Doha.

Another point under intense discussion is compensation to patent holders. TRIPs Article 31(h) requires that the right holder be paid 'adequate remuneration in the circumstances of each case' of unauthorised use of the patented product. Although in situations of 'national emergency or other circumstances of extreme urgency' prior consultation may be waived, compensation must still be provided to the right holder 'taking into account the economic value' of the compulsory license. The Chair's text provides that only the importing country should pay when the product is patented in both the importing and exporting Member countries, but pharmaceutical companies are pushing hard for additional compensation from the producer country in case the importing Member is unable to provide satisfactory payment for the market share lost by the rights owner due to the compulsory license.

### Conflicting Pressures

Brand-name manufacturers are also lobbying hard to make the packaging requirements much more specific, even insisting that the colour and shape of the medicines themselves be different from their patented versions. Shannon Herzfeld, Senior Vice President of the Pharmaceutical Research and Manufacturers of America, said in November that the industry was suspicious of 'the notion that having medicines of a different colour and shape are an impediment to getting medicine', adding that 'people seem[ed] to want a fast passage through Africa up to the lucrative markets in order to confuse people there.'

Harvey Bale of the International Federation of Pharmaceutical Manufacturers Associations summed up the hard-line view in November: 'The proposal as it now stands would allow compulsory licenses to be issued in any country, for any product, for any disease without any review mechanism and without any discipline being imposed. [...] This text will not solve anyone's problems except for the companies in some countries that want to do business forever copying drugs.'

On the other end of the scale, Celine Charveriat of Oxfam International called limiting the scope of an amendment to grave infectious diseases an 'outrageous' attempt to rewrite the Doha Declaration, while James Love of the Consumer Project on Technology said it was 'shocking' on the part of the US and others to exclude asthma, diabetes, cancer and other public health concerns from the amendment's scope.

James Love warned those seeking a broad scope for exports of medicines under compulsory license against 'desperation' regarding the need to find a solution by the end-2002 deadline. Other strategies could be used to achieve the same end, he said, including TRIPs Article 31(k), which requires no prior negotiations with patent holders as compensation could be dealt with through a purely administrative process. Even the source of the trouble, Article 31(f), would not prevent 49 percent of the production under compulsory license from being exported thus allowing 'a fair amount of spill-over for several countries'. In addition, under paragraph 7 of the Doha Declaration on TRIPs, least-developed countries 'can do whatever they need to authorise exports, until 2016 at the earliest. Generic suppliers from anywhere can simply locate factories in these countries. This will do more for technology transfer and economic development in LDCs than anything else in the current drafts on technology transfer.' As a parting shot, he warned delegates against a *Bridge on the River Kwai* scenario, where the bridge gets built even though it helps the enemy.

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Zwischen Handel und Zukunftsfähiger Entwicklung

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