

TRIPs Council Gets Another Opportunity to Solve Manufacturing Capacity Problem

On 10 February, the WTO's General Council agreed to give Members another week to forge consensus on the circumstances under which countries unable to copy patented medicines themselves could import such drugs from abroad without violating the provisions of the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs). This was the second extension to the Doha-mandated deadline of 31 December 2002.

At issue is finding an 'expeditious solution' to the problems countries may face in making use of compulsory licensing (i.e. allowing the use of a patent without the consent of the rights-holder under certain conditions) if they have insufficient or no pharmaceutical manufacturing capacity of their own. The principal point of contention is the scope of diseases for which drugs produced under compulsory license could be exported to Members without manufacturing capacity. Article 31(f) of the TRIPs Agreement requires countries to limit such production 'predominantly' to the supply of their domestic markets (see page 1).

Prior to the 10 February meeting, Members seemed headed for a recognition that consensus was out of reach. However, the General Council decided to give another chance to TRIPs Council Chair Ambassador Pérez Motta of Mexico, who stated that he had sensed "a certain momentum towards finding a solution" in recent days and felt that it was "important that advantage should be taken of this". He requested the General Council to provide "an additional period for further deliberations in capitals and consultations in Geneva", adding that he aimed to have "something more concrete" to report by the end of the TRIPs Council meeting scheduled for the week of 18 February.

Conditional Support Despite Doubts over Legal Status

The solution Ambassador Pérez Motta is trying to broker would consist of adopting the 16 December draft (which the US rejected) together with a Chairman's statement recognising the importance of patent protection in providing incentives for pharmaceutical innovation and the right of governments to protect public health. In a key passage, it would also note that WTO Members regard the solution as "essentially designed to address national emergencies and other circumstances of extreme urgency."

While a number of both developed and developing countries are inclined to accept this formulation, many have concerns over the legal standing of the proposed statement. The US may reject it if ongoing consultations with industry show that manufacturers consider the statement too weak for comfort. Kenya, on the other hand, is worried that a binding legal status would limit the right of governments to determine what constitutes a public health problem. Médecins sans Frontières has already issued an open letter to WTO Members urging them to reject the statement (see page 4).

The Long Road Toward Non-Consensus

In the final hours of the 2002 negotiations, the US suggested the inclusion of a footnote expanding its previously proposed list of diseases from three (HIV/AIDS, malaria and tuberculosis) to 23 plus "other epidemics of comparable gravity and scale", including those that might arise in the future. Developing countries rejected this proposal, arguing that it would restrict the mandate given by

the Doha Declaration, which – according to their interpretation – acknowledges Members' right to address 'public health problems' and only points to the three diseases as examples of such problems afflicting many developing and least-developed countries.

On 10 January, the European Union put forward a proposal, which included a list of 'at least' 22 infectious diseases, mostly endemic in African countries. The EU suggested that the list could be further expanded based on advice from the World Health Organisation (WHO) which, when requested by a Member, should "give advice on the occurrences in an importing Member or the likelihood thereof, of any other public health problem". The WHO's advice on whether a disease was covered by the solution would prevail in case of a dispute. EU Commissioner Pascal Lamy pointed out that trade officials had neither the credibility, nor the capacity or the competence to determine what constituted a public health problem. "When there's too much mistrust in the game, then you have to call on a third party, and the WHO is a trusted party," he said.

On the brink of an impasse, the TRIPs Council now has a third chance to fulfil its Doha mandate on public health.

Objecting to any narrowing of the scope of the Doha Declaration on TRIPs and Public Health, the Africa Group, Brazil and India rejected the EU proposal as a basis for further negotiations at an informal TRIPs Council session on 5 February.

A late proposal from Japan – also advocating a list-based approach – was rejected as well. Like the EU, Japan suggested that Members approve 22 diseases as examples of public health problems to which the 'solution' would apply 'at minimum'. Rather than naming the WHO directly, the proposal would allow the TRIPs Council to confirm 'as necessary' the inclusion of other diseases with the advice of outside experts, also 'as necessary'. Kenya said the proposal was unacceptable as only the government had the right to decide what constitutes a public health problem in a given country.

Declining to comment on these proposals, Deputy US Trade Representative Peter Allgeier focused on the need to rebuild the confidence of the pharmaceutical industry, which had been shaken by attempts to interpret the Declaration in a way 'other than what was intended' in Doha.

Members Close to Admitting Impasse on Disease Coverage

On 5 February, many Members appeared ready to concede that consensus on disease coverage would not be found. Although concerned about the consistent trend of developed countries' falling short of fulfilling the development-related mandates adopted in Doha, the majority of developing countries made it clear that they would prefer no 'solution' at all to accepting an additional decision that would limit the disease coverage. One Latin American delegate noted that additional time to reach consensus would only make developing countries more vulnerable to bilateral pressure, and thus possibly splinter the united front they had presented since June 2001 when the Africa Group took the lead in placing the issue on the Doha Ministerial agenda.

South Africa, 'wholeheartedly' supported by Norway, believed that it was time to focus energy on other core issues in the negotiations, as continued discussions on the scope of the

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paragraph 6 solutions were a waste of time with little hope for consensus in sight. Efforts to address TRIPs and health should rather focus on working with the pharmaceutical industry directly in an effort to appease concerns that the 16 December draft decision could weaken intellectual property protection. The need to build confidence was also acknowledged by Chile and Bulgaria, while Thailand echoed South Africa's view that efforts to settle the disease coverage of the solution were 'non-starters'.

Health Activists and Industry Slam Proposals

Research-based pharmaceutical companies – which generally view the compromise proposals as too broad – were particularly alarmed at the thought of putting decision-making power in the hands of the WHO, which they claimed had in the past been hostile to drug companies' interests. In contrast, health activists have been strongly critical for opposite reasons. According to James Love from the US-based Consumer Project on Technology, the EU proposal showed that it might be time to take the medicines issue out of the WTO, which was "clearly out of its depth", and to hand it over to the WHO. Médecins sans Frontières, which also deemed the EU proposal 'unacceptable', has now called on WTO Members to reject Ambassador Motta's proposed statement (see box).

Moratorium in Force, for Now

Following the breakdown of the talks in 2002, the US announced that it would not challenge any WTO Member "that breaks WTO rules to export drugs produced under compulsory license to a country in need". This moratorium covers patented pharmaceutical products needed to treat HIV/AIDS, malaria, tuberculosis and other infectious epidemics, as well as HIV/AIDS diagnostic test kits (IP/C/W/396). It does not, however, apply to high-income developing countries (such as Singapore and Korea, for instance). The US also attached a number of conditions to the moratorium, including measures to prevent diversion, requirements to inform the TRIPs Council of the grant of the licence, and an opportunity for the patent holder to supply the needed product.

Expressing sympathy with the overall US position, Switzerland has joined the moratorium, which is to remain valid until a multilateral solution is decided in the WTO. The EU has also agreed to an interim moratorium (not limited to HIV/AIDS, malaria, tuberculosis and other infectious epidemics), stressing however that this is "a purely stop-gap, temporary measure" which does not provide a stable permanent solution.

What Next?

While Ambassador Pérez Motta noted after the 5 February meeting that discussions on disease coverage were back at the stage they had been before the Doha Ministerial meeting in November 2001, his statement to the General Council was more optimistic. The issue is likely to be addressed at the next "mini-Ministerial" on 14-16 February in Japan and then at the TRIPs Council, scheduled for 18-21 February. Some sources, however, see no solution emerging until the Cancun Ministerial Conference next September.

For a comprehensive overview of the background, issues, positions and progress in 2002, please see *Doha Round Briefing on Intellectual Property Rights*, available at the ICTSD website <http://www.ictsd.org>.

**MSF Open Letter to WTO Members
on Ambassador Motta's Draft Statement on Paragraph 6**

"We urgently call upon the WTO Members to reject this statement for the following reasons:

- Paragraph 6 was never meant to only address national emergencies or other circumstances of extreme urgency, whether "essentially" or otherwise. The objective of paragraph 6 was to ensure that countries without production capacity could make effective use of compulsory licensing which is a key TRIPs safeguard. Anyone who claims otherwise is re-writing the history of the Doha negotiations.
- The adoption of this text would mean that countries without the possibility to produce medicines are at a major disadvantage over countries that do have the capacity. The Doha declaration confirms the right of countries to issue compulsory licenses in paragraph 5 (b): *Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.*
- The proposed Chairman's statement would constitute two different classes of Members. First class Members with manufacturing capacity will be able to use compulsory licensing to address whichever public health problems they have identified. Second class Members without manufacturing capacity will be able to use compulsory licensing to address public health problems only in case of a national emergency or other circumstances of extreme urgency.
- The proposed text would indicate that the 'solution' cannot be used for the production and purchase of products meant for the prevention of an emergency. How long would a country attempting to prevent an outbreak of an infectious disease by vaccinating have to wait? It is unacceptable that a subset of developing countries may only provide pharmaceutical care after a public health situation has gone out of control.
- There is a near absence of innovation for diseases that affect people in developing countries. [...] The financing of the research and development of new medicines for neglected diseases will require additional and alternative global approaches. To therefore hail the importance of the IP system for the development of new drugs for people in developing countries might not be entirely appropriate in this context.
- Let no delegation be under the illusion that a Chair's note, reflecting an agreement amongst all negotiating parties, can have no legal effect. The Chair would not be making the note if it had no legal effect and there are grave grounds to worry that under the Vienna Convention it could be held to have legal effect. If the Motta text were used outside emergency situations, the exporting Member would open itself to dispute settlement for breach of its obligations under Art. 31(f) TRIPs.
- We therefore propose that the Members of the WTO take into consideration the following alternative wording for the Chair's statement:

Delegations have made it clear that they see the system that is being established under this proposed solution as being designed to promote access to effective treatments to address public health problems afflicting countries with insufficient or no manufacturing capacities in the pharmaceutical sector as called for in paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health."

Extracts from the 8 February letter to WTO Members from Ellen 't Hoen, Campaign for Access to Essential Medicines, Médecins sans Frontières.