

Doha Mandates**Public Health**

"We recognize 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."

(Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health)

Geographical Indications

"With a view to completing the work started in the Council for Trade-Related Aspects of Intellectual Property Rights on the implementation of Article 23.4, we agree to negotiate the establishment of a multilateral system of notification and registration of geographical indications for wines and spirits by the Fifth Session of the Ministerial Conference. We note that issues related to the extension of the protection of geographical indications provided for in Article 23 to products other than wines and spirits will be addressed in the Council for TRIPs pursuant to paragraph 12 of this Declaration."

(Paragraph 18 of the Doha Ministerial Declaration)

Intellectual Property Rights**Prospects for Cancun**

Progress on TRIPs & health will largely depend on whether the US administration can muster the political courage to overcome the pharmaceutical industry's objections to the current draft text. Developing countries are unlikely to make further concessions, as they already regard the current draft as a compromise that is much closer to developed countries' demands than to their own.

Regarding the negotiation of a multilateral register for geographical indications (GI), few believe that the negotiating deadline, i.e. the fifth WTO Ministerial meeting, can be met. Progress can only be expected if the EC waters down its ambition on the register or is prepared to accept a trade-off in other negotiating areas, notably agriculture. The EC, however, has warned that it would not agree on agriculture modalities unless the issue of GI extensions was included in the package (Doha Round Brief No. 2). Given that this issue mainly reflects a US-EC division, developing countries are unlikely to have a major influence on the debate in Cancun.

As is the case with the multilateral register, the deadlock over the extension of additional GI protection to products other than wines and spirits is unlikely to be broken in the TRIPs Council, but might require some bargaining in the agriculture negotiations - possibly at Cancun. The issue also needs to be looked at in the context of implementation concerns in general and the impact a decision to launch negotiations on GI extensions would have on discussions related to other implementation issues (Doha Round Brief No.1).

On issues related to the review of Article 27.3(b), traditional knowledge and biodiversity, it will be up to developing countries as the key *demandeurs* to raise the issue in Cancun. The recent submissions by the African Group and India on behalf of several developing countries will help keep these issues high on the

agenda. Even if no significant progress can be made in Cancun due to the many other negotiating issues up for discussion, developing countries remain confident that there will be further room for debate and agreement at a later stage in the Doha round.

Background

In what many described as an 'historic' development, the TRIPs Council — at the request of the African Group and supported by many developing countries — took up the issue of intellectual property rights and access to medicine in June 2001 at a time when the WTO was coming under increasing criticism for allegedly impeding developing countries' access to life-saving medicines. The subsequent long and difficult discussions culminated in the adoption of the Doha Declaration on the TRIPs Agreement and Public Health in November 2001, in which countries stressed that the TRIPs Agreement did not and should not prevent Members from taking measures to protect public health.

One issue, however, remained unresolved at the Doha meeting, namely how to address the problems countries may face in making use of compulsory licensing if they have insufficient or no pharmaceutical manufacturing capacity. Compulsory licensing refers to the practice by a government to authorise itself or third parties to use the subject matter of a patent without the authorisation of the right holder for reasons of public policy. The perceived need to address this issue arose from concerns related to Art. 31(f) of the TRIPs Agreement, which requires that production under compulsory licensing must be primarily for the supply of the domestic market.

Another highly contentious issue in the TRIPs Council relates to geographical indications (GIs). The mandate in this context is two-fold: Members are currently negotiating the establishment of a multilateral system of GIs for wines and spirits in the special (negotiating) sessions of the TRIPs Council,

Doha Mandates

Non-violation Complaints

"The TRIPS Council is directed to continue its examination of the scope and modalities for complaints of the types provided for under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 and make recommendations to the Fifth Session of the Ministerial Conference. It is agreed that, in the meantime, members will not initiate such complaints under the TRIPS Agreement."

(Paragraph 11.1 of the Decision on Implementation-related Issues and Concerns)

Other Outstanding Implementation Concerns

"We instruct the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this declaration, to examine, inter alia, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension."

(Paragraph 18 of the Doha Ministerial Declaration)

as mandated by the Ministerial Declaration. Furthermore, extensive debate has taken place in the TRIPS Council regarding the possibility of extending the higher level of protection for GIs to products other than wines and spirits, with the EC, Switzerland, Bulgaria, India, Sri Lanka and several other developing countries among the strongest *demandeurs* for GI extension. The issue has also been raised by developing countries as an 'outstanding implementation issue' (Doha Round Brief No. 1).

Mandated Deadlines

- 31 December 2002, Members were to conclude negotiations under para. 6 of the Doha Declaration on TRIPs and Public Health. No new deadline has been set.
- 31 December 2002, the TRIPs Council was to report to Trade Negotiations Committee for "appropriate action" on intellectual property-related implementation issues. No new deadline has been set.
- Fifth WTO Ministerial Meeting (10-14 September, in Cancun, Mexico), conclusion of the negotiations on the multilateral system of notification/registration of GIs for wines and spirits; recommendations on non-violation.

Current State of Play: TRIPs and Public Health

Despite long and intense negotiations, Members have yet to reach consensus on the 'expeditious solution' after failing to meet the 31 December 2002 deadline. At that time, only the US opposed the adoption of a draft Decision — put forward by TRIPs Council Chair Ambassador Eduardo Pérez Motta (Mexico) on 16 December 2002 — due to concerns about the disease coverage of the draft solution. As called for by developing countries, the draft text refers to paragraph 1 of the TRIPs and Public Health Declaration, i.e. "public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics." The draft also covers active ingredients used in the manufacture of medicines, as well as diagnostic kits needed for their use, as proposed in particular by the African Group.

The US rejected this formulation, suggesting instead the inclusion of a footnote that would expand its previously proposed list of diseases from three (HIV/AIDS, malaria and tuberculosis) to 23 and "other epidemics of comparable gravity and

scale", including those that might arise in the future. The US position is also supported by Switzerland, one of the largest exporters of pharmaceutical products. Developing countries, however, strongly rejected the proposal, arguing that it would restrict the mandate given by the Doha Declaration, which refers more generally to "measures to protect public health" (para. 4).

Following the breakdown of the talks in December 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." The interim moratorium, however, only covers HIV/AIDS, malaria, tuberculosis and other infectious epidemics, and will not apply to developed country Members or high-income developing countries (as classified by the World Bank). In a separate statement, the US pharmaceutical industry backed the US initiative. Switzerland and Canada joined the moratorium, saying it would remain valid until a multilateral solution was found in the WTO.

The EC has also declared an interim moratorium, but has not limited it to HIV/AIDS, malaria, tuberculosis and other infectious epidemics. In addition, European governments on 26 May adopted a regulation that aims to facilitate the delivery of medicines to combat HIV/AIDS, malaria and tuberculosis at strongly reduced ('tiered') prices to 76 developing countries. While the EC stressed that the tiered pricing system was not directly related to the ongoing discussions on access to medicines in the WTO, it argued that if countries could obtain medicines through the tiered pricing system, they would not need to invoke compulsory licenses.

Recent Developments

Two extensions of the deadline failed to bridge the gap on the paragraph 6 solutions. At the 24-26 February TRIPs Council session, Members hardly discussed any of the compromise solutions proposed by the Chair or Member countries. At the last scheduled regular session of the TRIPs Council before Cancun, held from 4-5 June, submissions from the African, Caribbean and Pacific (ACP) Group of States and the EC focused more broadly on the implementation of the TRIPs & health declaration. While all speakers, including the US, signalled their interest in finding a multilateral solution on paragraph 6 before Cancun, no progress was made at the session, evoking sentiments of disappointment and frustration amongst developing and several developed countries.

In a 28 May letter to the TRIPs Council Chair (IP/C/W/401), the ACP countries expressed their disappointment with WTO Members' failure to agree on the 16 December draft text, describing the developments in the WTO on this issue as "disheartening". They rejected any attempts to limit the scope of the solution to national emergencies, as proposed by the US, or to involve the World Health Organisation (WHO), as proposed by the EC. The Group urged developed countries to adapt their intellectual property enforcement policies according to the Doha Declaration, and stressed ACP governments' need for assistance to integrate the TRIPs public interest safeguards into their legislation.

The need for technical assistance, in particular from the World Intellectual Property Organisation (WIPO), the WTO and the WHO, was also highlighted by the EC in its 24 June communication, which focused on the implementation of the Doha Declaration rather than on paragraph 6 (IP/C/W/402). Such assistance, the EC noted, was required for developing countries to make the required legislative, administrative or policy adjustments to implement the Declaration. The EC also highlighted the importance of regional cooperation on intellectual property matters as a means of implementing the TRIPs Agreement and the Doha Declaration.

The US is rumoured to be considering a change in its approach to the discussions on paragraph 6, shifting its focus from disease coverage to eligibility. This change reflects the position of the US pharmaceutical industry, which has reportedly called on the US government to limit the use of the paragraph 6 solution to the world's poorest countries and to implement strong measures that prevent diversion of cheap drugs to developed country markets. Developing countries have repeatedly stressed that they would be willing to accept the draft only in its current form and that once the text was re-opened on disease coverage or eligibility, they would also demand changes to other parts of the draft. In particular, Members from economies in transition and high-income developing countries had objected to the inclusion of any categories of countries that were not officially recognised by the WTO.

According to the current draft, all least-developed countries would automatically be eligible as importers, while all other Members would be eligible following a once-off notification to the WTO. The draft text includes a list of countries — i.e. the US, New Zealand, Australia, Switzerland and EC member states —

that have signalled their willingness to not use the system. The decision also notes that other Members have said that, if they used the system, "it would be in no more than situations of national emergency or other circumstances of extreme urgency," without further elaboration on the countries in question.

Multilateral System for GIs

Negotiations on a multilateral system of notification and registration of geographical indications for wines and spirits are taking place in the special (negotiating) session of the TRIPs Council.

Geographical indications identify a good as originating in the territory of a member country, or a specific region within it, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin.

While Members generally agree that the multilateral system should not increase the level of protection that currently exists for covered products, they remain divided over two issues, i.e. "legal effect" — whether Members should be required to protect registered terms — and "participation" — whether those who do not register a term are nevertheless obliged to protect registered terms. A first draft text, circulated by the Chair of the negotiations, Ambassador Eui-yong Chung of Korea on 16 April, sets out various options (labelled A, B and B1 and B2) for a decision.

Option A presented the views of countries such as the US, Canada, Australia, Chile, Argentina, Japan and others, who are seeking a non-binding system that does not require Members to protect registered terms. Rather, the register would function as a database that could be consulted by a Member "when making decisions regarding recognition and protection of geographical indications for wines and spirits." Non-participating Members "shall be encouraged, but shall not be obliged" to use the system as an information source.

In contrast, the European countries favour Option B, which would allow Members to challenge proposed registrations and would require registered terms to be protected in all WTO Member countries, including non-participating Members. This option was further differentiated into B1 proposed by the EC, which envisaged bilateral consultations in case of a challenge, and B2 proposed by Hungary and supported by Switzerland, which suggested settling unresolved challenges by arbitration.

At the last scheduled special session of the TRIPs Council pre-Cancun on 2-3 July, Members failed to make progress on this issue. In his report to the Trade Negotiations Committee (TN/IP/7), the Chair noted that he had been unable to prepare a revised draft with single options as he had hoped. "In the light of the current state of the negotiations in the Special Session and of the Doha Development Agenda as a whole, delegations did not as yet feel in a position to be sufficiently flexible in their positions on the key issues of legal effects and participation to warrant [the Chair] tabling a new draft text at this stage," the report concluded.

Implementation Issues

Non-violation complaints (pursuant to the Implementation Decision):

Non-violation complaints are legal actions that allow Members to bring a dispute to the WTO, based on loss of an expected benefit caused by another Member's actions — even if no WTO agreement or commitment has actually been violated. In the field of intellectual property rights, the potential application of this type of legal action has been controversial due to concerns that countries might use it to bilaterally pressure weaker ones. According to the Decision on Implementation-related Issues and Concerns, Members agreed to not initiate non-violation complaints for two years, while instructing the TRIPs Council to continue its examination of the scope and modalities for such complaints (para. 1.1).

The TRIPs Council had been mandated by the TRIPs Agreement itself to examine the scope and modalities of these complaints and submit its recommendations to the Fourth Ministerial Conference. Members, however, failed to meet this deadline and subsequent discussions have not led to a narrowing of differences. At a consultation in May 2003, the Chair listed four possibilities for a recommendation before the Fifth Ministerial Conference: (1) outlawing non-violation complaints in TRIPs completely, (2) scrapping the moratorium and allowing non-violation complaints even if there were no "modalities", (3) working on "modalities" so that non-violation complaints could be made, and (4) extending the moratorium.

Almost all members favour (1), because they consider non-violation to be an invalid concept in the TRIPs Agreement; and because it could create legal uncertainty as to what the Agreement requires. A few (Canada,

Australia, Japan, Rep. of Korea, Chinese Taipei among them) either favour (1) or are reasonably willing to accept it, while the US and Switzerland have blocked consensus on this option. The US said the moratorium should expire immediately and the question of how non-violation complaints should be handled should be left to the dispute settlement process. Switzerland could accept an extension of the moratorium, but not beyond the next (sixth) Ministerial Conference, and only to agree on possible "modalities".

As no consensus could be reached at the last scheduled regular session of the TRIPs Council, the Chair reported to the Membership that the TRIPs Council was not in a position to make recommendations to the fifth Ministerial Conference at this stage.

Additional protection for GIs (tired 87):

Members continue to be deeply divided over the question of whether to extend the high level of GI protection enjoyed by wines and spirits to other products. As a result, the TRIPs Council has yet to agree on 'appropriate action' on how to address the issue as mandated under paragraph 12.

The discussion on GI extension had effectively blocked progress on other implementation issues under Article 12(b) of the Ministerial Declaration. In contrast to other implementation issues, which have been put forward by developing country Members, GI extensions have also found strong backing from the EC and Switzerland which, along with a number of developing countries including India, Sri Lanka, Thailand and Kenya, have been calling for negotiations on this issue. Their call is strongly opposed by the US, Australia and other Members mainly from the Americas, all of which

are bulk exporters of agricultural products. WTO Director-General Supachai Panitchpakdi's decision to undertake informal consultations on this issue helped to break the deadlock in discussions on other implementation issues, which have now resumed (Doha Round Brief No. 1).

Biodiversity, traditional knowledge and TRIPs 27.3(b) (tired 91 and 95):

Momentum is again building on discussions related to the review of Article 27.3(b) (patentability of life forms), traditional knowledge (TK) and biodiversity, with new submissions received from Switzerland (IP/C/W/400), the African Group (IP/C/W/404) and India on behalf of Brazil, Bolivia, Cuba, Dominican Republic, Ecuador, Thailand, Peru and Venezuela (IP/C/W/403) at the 4-5 June TRIPs Council meeting.

TRIPs Article 27.3(b) allows Members, with certain provisos, to exclude plants and animals other than micro-organisms from patentability.

Both the African Group and the India-led submissions (IP/C/W/404 and IP/C/W/403) stressed the need for a multilateral solution to these issues in the TRIPs Council. The India-led paper reiterated a previous proposal from the signatory countries for amending the TRIPs Agreement to require patent applicants to (a) disclose the source of origin of the biological resource and associated TK; and (b) provide evidence of prior informed consent and benefit-sharing. The African submission called for Article 27.3(b) to be revised so as to prohibit patenting of plants, animals and micro-organisms. On traditional knowledge, the Group proposed to classify TK as a category of intellectual property rights and put forward a draft Decision on TK for adoption by the TRIPs Council.

In contrast to the developing country submissions, Switzerland would like to

see these issues discussed outside the WTO. Specifically, the Swiss submission proposed an amendment to WIPO's Patent Cooperation Treaty that would enable countries to require patent applicants to declare the source of the genetic resources and TK in patent applications. On the CBD-TRIPs relationship, Switzerland noted that the two "can and should" be implemented without conflict and that there was no need to modify the provisions of either.

At the TRIPs Council meeting, the EC noted that the Swiss proposal further developed many of the EC's own ideas, though the EC did not specify whether the issue should be addressed in the WTO or in WIPO. The EC again signalled its willingness to discuss mandatory disclosure of origin requirements as noted in its 'concept paper' submitted in September 2002 (IP/C/W/383). Specifically, the EC had proposed the inclusion of a "self-standing" requirement to include information on the geographic origin of genetic resources and traditional knowledge. Such a requirement, however, should not constitute an additional formal or substantial patentability criterion, the EC added. Thus, failure to disclose should lie outside the patent law, but should, for instance, be regulated by civil or administrative law.

Documents submitted to the TRIPs Council can be found at <http://docsonline.wto.org>, using the document symbols IP/C/W* and TN/IP*.

The TRIPs Council Chair's proposed draft decision of 16 December is available at http://www.ictsd.org/ministerial/cancun/docs/TRIPs_para6_16-12-02.pdf.

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