DOHA ROUND BRIEFING SERIES

Developments Since the Fourth WTO Ministerial Conference

The International Centre for Trade and Sustainable Development (ICTSD) and the International Institute for Sustainable Development (IISD)

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Intellectual Property Rights

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)

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 medicines in June 2001 at a time when the WTO was coming under increasing criticism for allegedly impeding developing countries' access to 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 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, as mandated by the Ministerial Declaration. Furthermore, extensive debates have 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 EU, 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'.

Mandated Deadlines

- 31 December 2002, Members were to conclude negotiations under para. 6 of the Doha Declaration on TRIPs and Public Health.
- 31 December 2002, the TRIPs Council was to report to Trade Negotiations Committee for "appropriate action" on intellectual property-related implementation issues.
- 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 could not reach consensus on the 'expeditious solution' by the 31 December 2002 deadline. At the 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 — arguing that the solution should apply only to HIV/AIDS, malaria, tuberculosis and other infectious diseases of comparable gravity.

Two extensions of the deadline failed to bridge this gap. The latest setback came on 18 February 2003, when delegates at the TRIPs Council hardly discussed any of the compromise solutions proposed by the Chair or Member countries. Such proposals included a Chairman's statement that would complement the 16 December draft, stating, *inter alia*, that Members regarded the solution as "essentially designed to address national emergencies or other circumstances of extreme urgency." European and

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)

Japanese proposals to involve the World Health Organisation (WHO) or other experts in deciding which diseases the solution would cover were rejected earlier. At an informal ministerial meeting held in Tokyo in mid-February, Brazil proposed shifting the focus from disease coverage to eligible importing countries through involving the WHO in assessing whether countries wishing to use the solution had insufficient manufacturing capacity. This alternative was not brought up at the subsequent TRIPs Council session.

Ambassador Pérez Motta told Members that he was not in a position to propose a new solution and would report to the General Council on discussions held to date. Members remain divided both on the content of the solution and on the way forward. The General Council is expected to provide guidance on whether to:

- press ahead with the quest for consensus prior to the Cancun Ministerial; or
- leave the question for ministers to solve in Cancun; or
- accept the status quo and only return to the issue after the Cancun Ministerial, when it can be addressed independently from the trade-offs implicit in the 'single undertaking' negotiations launched in Doha.

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 EU has also declared an interim moratorium, but has not limited it to HIV/AIDS, malaria, tuberculosis and other infectious epidemics.

Disease Coverage

As called for by developing countries, the 16 December 2002 draft text refers to paragraph 1 of the TRIPs and 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 the draft on the grounds that the disease coverage was too broad. In a last-minute attempt to reach a deal, the US had suggested 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. Developing countries, however, rejected this 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). They also opposed a proposal by the EU that the US could make a statement to the effect of its proposed footnote, which would then be supported by the TRIPs Council Chair as the framework for implementing the solution.

The US position is also supported by Switzerland, one of the largest exporters of pharmaceutical products, which in a press statement released subsequent to the breakdown of negotiations echoed the preferred US wording, namely that "the solution should cover HIV/AIDS, malaria and tuberculosis as well as other epidemics of comparable gravity."

Eligibility

According to the Chair's 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 EU 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." The draft does not elaborate further on these countries, thereby responding to concerns by Members from economies in transition and high-income developing countries that had objected to the inclusion of any categories of countries that were not officially recognised by the WTO.

Permanent Legal Mechanism

With respect to the legal mechanism for the solution, the draft Decision includes a moratorium on disputes regarding any measure taken in conformity with the provisions of a possible waiver. This moratorium would remain in force until an amendment to the TRIPs Agreement has been accepted by all Members. Work on the preparation of such an amendment would start by the end of 2003 with a view to its adoption within six months. These dates would be sooner than the US would prefer, but later than those called for by the EU and the African

countries. Some Members raised the possibility of leaving open the language on a permanent solution, thereby also allowing for a consideration of an authoritative interpretation of Article 30 as called for by Brazil Cuba, China, the Dominican Republic, Ecuador, India, Indonesia, Pakistan, Peru, Sri Lanka, Thailand and Venezuela.

Diversion of Generics

The EU and Switzerland have been the main proponents of strong measures, such as packaging or labelling requirements, to prevent flow-back of generic medicines into developed country markets. Developing countries have stressed that such measures should not be burdensome or delay actions. Some developing countries have further argued that the TRIPs Agreement already contains sufficient safeguards. According to the draft legal language, eligible importing Members would take "reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion" to prevent diversion. The most recent draft includes references to technical and financial co-operation by developed country Members to those importing countries experiencing difficulty in implementing these measures.

Members to which products might be diverted would need to ensure effective legal means to prevent importation. In addition, suppliers are required to distinguish the products covered by the Decision through special packaging and/or special colouring/shaping of the products themselves, "provided that such distinction is feasible and does not have a significant impact on price."

Regional Groupings

The African Group has proposed that 'domestic market' in 31(f) should also refer to customs unions or free trade areas, and that 31(f) should be interpreted to mean that up to 49.9 percent of production could be exported. While the draft Decision allows for the 'domestic market' requirement in Article 31(f) to be waived for regional trade agreements, it sets out clearly which RTAs these rules would apply to, including a requirement that at least half of the membership of the RTA is made up of least-developed countries.

Technology Transfer

Developing countries had called for technology transfer to form an integral part of the paragraph 6 solution. The draft Decision "encourages" Members to use the system set up by the Decision so as to promote technology transfer and capacity building in the pharmaceutical sector, and to pay special attention to these goals in the work of the TRIPs Council, including discussions pursuant to Article 66.2 TRIPs Agreement (technology transfer to least-developed countries).

Multilateral System for GIs

Negotiations on a multilateral system of notification and registration of GIs for wines and spirits are currently underway in the special (negotiating) session of the TRIPs Council. While Members generally agree that the system should not increase the level of protection that currently exists for covered products, they remain divided over whether countries should be obliged to protect the terms in the multilateral system — as advocated by the EU and others — or whether it should be left to each country to decide — as favoured by Australia, Canada, Japan and the US, who envisage the multilateral system functioning essentially as a database. Similar divisions are also apparent with regard to participation in the system. That is, Members disagree over whether the 'voluntary' nature of the system should only mean that the notification and registration of GIs was voluntary, or whether the protection of registered terms should also be voluntary.

Implementation Issues

Non-violation complaints (pursuant to the Implementation Decision): 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). Non-violation complaints are legal actions created under the GATT 1947 (which still exist under GATT 1994) 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 it might enhance the possibility of applying bilateral pressure.

The TRIPs Council has been mandated by the TRIPs Agreement itself to examine the scope and modalities of these complaints and submit its recommendations to the Ministerial Conference for approval five years after entry into force of the Agreement, which would have been the Conference in Doha. Members, however, failed to meet this deadline and discussions since then have not led to a narrowing of differences. All WTO Members with the exception of the US consider that non-violation complaints should not be applicable to the TRIPs Agreement. In this context, various developing countries, including Argentina, Bolivia, Brazil, Colombia, Cuba, Ecuador, Egypt, India, Kenya, Malaysia, Pakistan, Peru, Sri Lanka and Venezuela (IP/C/W/385), put forward a proposal by which the TRIPS Council would recommend to the 5th Ministerial Conference that the violations of the type identified in Article XXIII:1(b) and (c) of the GATT 1994 (non-violation complaints) be determined inapplicable to the TRIPs Agreement.

Outstanding Implementation Issues

Additional protection for geographical indications (tiret 87): In the Compilation of Outstanding Implementation Issues Raised by Members, developing countries had called for the high GI protection enjoyed by wines and spirits to be extended to other products. The Ministerial Declaration instructs Members to address this issue in the TRIPs Council pursuant to Article 12 of the Ministerial Declaration.

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. Champagne, to take a famous example, properly comes only from the Champagne region in France.

The discussion on GI extension has taken up a significant part of the regular TRIPs Council sessions. Switzerland on behalf of 20 developing, developed and transition economy countries has proposed that the additional protection should apply to all GIs and that the multilateral register to be established should include GIs for all products (IP/C/W/353). These countries believe GIs can be used to promote the export of valuable products and prevent misappropriation. They also consider it a matter of fairness that such additional protection not be limited to alcoholic beverages. Those who oppose additional protection are mainly from the Americas plus Australia and New Zealand, all of which are bulk exporters of agricultural products.

As a result of the deep divisions among Members on whether to begin negotiations on GI extensions, the TRIPs Council did not submit a report to the TNC on 'appropriate action' as mandated under paragraph 12. The deadlock is unlikely to be broken in the TRIPs Council but would require some bargaining in the agriculture negotiations. Indeed, several countries, including the EU, Switzerland and Bulgaria, have explicitly linked the GI discussions to the agriculture negotiations in both the TRIPs Council and the Committee on Agriculture.

Biodiversity, traditional knowledge and TRIPs 27.3(b) (tirets 88 and 95): The Doha Ministerial Declaration instructs the TRIPs Council 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 (the review of the Agreement mandated in) Article 71.1"[1] in the context of its work programme "including under the review of Article 27.3(b),[2] the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this Declaration."

In this context, the Council received a submission from a group of developing countries, including Brazil, China, Cuba, the Dominican Republic, Ecuador, India, Pakistan, Thailand, Venezuela, Zambia and Zimbabwe (IP/C/W/356). The submission stressed the need to modify the TRIPs Agreement, arguing that it contained no provisions to prevent biopiracy (illegal access and use) or ensure prior informed consent and the fair and equitable sharing of benefits. To this end, the group proposed several conditions for acquiring patent rights related to biological materials or traditional knowledge (TK), including requirements for patent applicants to disclose the source of origin of the biological resource and associated TK; and evidence of prior informed consent and benefit-sharing.

Most developed countries, including the EU, the US and Japan, generally resist amendments to the TRIPs Agreement, arguing that there is no conflict between it and the Convention of Biological Diversity. The US, in particular, has so far strongly opposed the inclusion of disclosure requirements in patent applications, maintaining that they would be incompatible with the TRIPs Agreement since they would add another substantive condition on patentability beyond those already provided. In a recent submission, the EU has signalled its willingness to discuss the inclusion of disclosure requirements in patent applications, but stressed that such requirements should not constitute an additional formal or substantial patentability criterion.

Other Outstanding Implementation Concerns

Tiret 91: The period given for implementation of the provisions of Article 27.3(b) shall be five years from the date the review is completed.

Tiret 93: The transitional period [before the implementation of the TRIPs agreement is required] for developing countries provided for in Article 65.2 shall be extended; the General Council agrees that the transition period for LDCs shall be extended so long as they retain the status of an LDC.

Tiret 94: Articles 7 and 8 of the TRIPS Agreement to be operationalised by providing for transfer of technology on fair and mutually advantageous terms.

None of these issues have so far been explicitly addressed and/or resolved.

For further details, see Doha Round Briefing No. 1 on Implementation-related Issues and Concerns.

Endnotes

1 TRIPs Article 71.1 mandates that the TRIPs Council review the implementation of the Agreement five years after its entry into force, and at two year intervals thereafter, to see if modifications are necessary.

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

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

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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