



## 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 TRIP pursuant to paragraph 12 of this Declaration."*

(Paragraph 18 of the Doha Ministerial Declaration)

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# Intellectual Property Rights

Negotiations on questions related to public health, geographical indications and biological diversity made little progress in the Council for Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) during the first ten months of 2005. Nonetheless, in an attempt to find a solution to the current impasse, discussions on these issues are continuing in the run up to December's WTO Ministerial Conference in Hong Kong.

The most important formal step forward in the TRIPS Council since the launch of the Doha Round was the adoption, on 30 August 2003, of a General Council Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (WT/L/540). The Decision, commonly referred to as the 'waiver', spells out the conditions under which countries without sufficient pharmaceutical manufacturing capacity can use compulsory licenses to import generic versions of drugs still under patent protection. While a number of potential exporter countries have started adapting their domestic laws to reflect the Decision, the likely importing countries have yet to make use of the system. The African Group of WTO Members has submitted a proposal for a permanent amendment (IP/C/W/437) to the TRIPS Agreement (IP/C/W/437), but several (mostly developed) Members argue that it does not accurately reflect the 30 August waiver.

Negotiations are also stalled on the establishment of a multilateral system of notification and registration of geographical indications (GIs) for wines and spirits, as well as on extending the protection the TRIPS Agreement currently grants to wines and spirits to other, mostly agricultural, products. This bitterly divisive issue acquired a higher profile in late October 2005, when the EU linked its latest agricultural tariff cut offer to stronger TRIPS protection for all GIs. The EU also demanded that all GIs be covered by the future multilateral registration system - with legal effects for both participating and non-participating Members. In addition, the EU said it would seek the prohibition of current third party use of a 'limited number' of well-known European GIs (see also Doha Round Briefing Series No. 2 on agriculture).

Despite several new and more specific submissions, discussions on the relationship between the TRIPS Agreement, traditional knowledge and biodiversity-related issues have made no headway due to Members' divergent views on modalities to move the process forward. Contention has focused on the need for a disclosure of origin requirement, mechanisms for access and benefit-sharing, and prior informed consent. At ministerial-level meetings held in early November, India's Minister of Trade highlighted three TRIPS-related issues as "critical to an agreement in Hong Kong": paragraph 6 of the Doha Declaration on TRIPS and Health; the disclosure of origin of genetic resources; and the relationship between the Convention on Biological Diversity and the TRIPS Agreement.

## Mandated Deadlines

- **End March 2005:** Report to the General Council on a solution to compulsory licensing and lack of pharmaceutical manufacturing capacity; partly implemented on 30 August 2003. The deadline for the development of a permanent amendment to TRIPS was extended to 31 March 2005, but this date was missed. Discussions at the last scheduled TRIPS Council in October 2005 failed to reach

*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 Out-standing 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 19 of the Doha Ministerial Declaration)

agreement. The TRIPS Council is now due to reconvene before Hong Kong in an attempt to develop a solution that could be put before the General Council. Separately, informal consultations between the African Group, the US and the EU continue under the Chair's guidance.

- **December 2005 (Sixth Ministerial Conference):** The Council's deadline for reporting to the Trade Negotiations Committee (TNC) on action on outstanding implementation issues under paragraph 12(b) of the Doha Declaration was extended until the Sixth Ministerial Conference in Hong Kong for all issues save the extension of GI protection to other products than wines and spirits. For the extension of GIs, the Chairman of the TNC meeting in September 2005 indicated that, at the insistence of several countries, the issue would be on the agenda for Hong Kong.
- **December 2005 (Sixth Ministerial Conference):** The conclusion of the negotiations on the multilateral system of notification/registration of geographical indications for wines and spirits has had its deadline de facto extended to the Sixth Ministerial Conference.

## TRIPS and Public Health

The relationship between WTO rules on patent rights and access to essential medicines was taken up at the TRIPS Council for the first time in June 2001 at the request of the African Group, supported by a number of developing countries. The subsequent protracted discussions culminated with the adoption of the Doha Declaration on the TRIPS Agreement and Public Health of 14 November 2001 (WT/MIN(01)/DEC/2), which stressed that the agreement did not and should not prevent Members from taking measures to protect public health.

One issue remained unresolved at Doha: how to address the problems that countries with insufficient or no pharmaceutical manufacturing capacity might face in making use of compulsory licensing (paragraph 6 of the Declaration on TRIPS and Public Health). Compulsory licensing refers to the practice by which a government authority permits a third party or a government agency to use an invention without the consent of the patent-holder, although the latter has the right to 'adequate remuneration' contingent upon the circumstances of the case. Many Members felt that TRIPS Article 31(f), which requires production under compulsory licensing to be primarily for the supply of the domestic market, could seriously limit access to affordable medicines for those developing and least-developed countries that are unable to produce generic copies of patented drugs themselves.

### The 30 August Decision and the Chair's Statement

A compromise was finally reached with the adoption of the 30 August 2003 Decision, which temporarily waived Members' obligations under Article 31(f) with regard to the export of pharmaceuticals produced under compulsory license. In theory, the waiver offers an interim solution to countries with no domestic capacity to produce generic copies of patented medicines, but many consider its provisions too cumbersome and politically charged to be of much use to the intended beneficiaries. A large number of its detailed notification and other obligations are aimed at ensuring that imported pharmaceuticals manufactured under compulsory license are not re-exported (for details, see Doha Round Briefing Series Vol. 3 No.5). The waiver remains in force until the TRIPS Agreement is permanently amended.

The Decision was accompanied by a statement (JOB (02)/217) from WTO General Council Chair Carlos Pérez del Castillo noting that the system established by the Decision would be used "in good faith to protect public health" and not as "an instrument to pursue industrial or commercial policy objectives." It detailed further measures aimed at curbing trade diversion, and listed a number of developed and advanced developing country Members who had either agreed not to use the

system as importers at all, or had undertaken to use it only in cases of national emergency or other circumstances of extreme urgency. Recent discussions on the waiver have mainly revolved around the statement's legal status and how it should be reflected in a permanent amendment to the TRIPS Agreement.

### Current State of Play

Discussions on the amendment remained desultory until December 2004, when the African Group proposed a text that built on the 30 August Decision, but did not provide details on the 'trade diversion' issues, with the exception of a paragraph on distinctive packaging. The African Group defended the proposal as an attempt to simplify the use of the mechanism with a view to making it more operational and user-friendly in response to numerous criticisms about the waiver's cumbersome provisions.

The US, the EU, Canada, Japan and Switzerland, among others, continue to insist that any amendment must be a simple 'technical translation' of the Decision. They objected to the African proposal, arguing that it had left out the waiver's sections on notification obligations - such as specifying in advance not only the name but the exact quantity of the drug that the Member sought to import under compulsory license. Many also criticised the proposal's lack of any mention of the Chair's statement. Nigeria and Kenya argued that all of the purported omissions were 'superfluous,' since they were already reflected elsewhere in the TRIPS Agreement.

Several developing countries, including Brazil and India, have welcomed the debate's shift from procedure to substance, and expressed support for the African view that a permanent amendment should be simpler than the waiver, which places considerable administrative burdens on developing country governments. Most recently, at the EU's initiative and under the guidance of the Chair, the African Group, the US and the EU have engaged in informal consultations on an EU proposal, which would keep the original waiver language intact, but omit any reference to the Chair's statement. Several Members - including Switzerland and Malaysia - have expressed support for the process and their willingness to participate. Brazil and India, however, have made strong calls to be included, arguing that consultations organised by the Chair should include all interested parties. As no agreement on the waiver was reached at the final 2005 session of TRIPS Council in October, the Council is to reconvene before Hong Kong in an attempt to develop a permanent or interim solution. No date had been set at the time of writing.

In practical terms, the waiver has already been translated into national legislation in Canada, India, Norway, Switzerland and the EU. Korea's changes to domestic IP law will take effect as of January 2006. Importing countries also need to adopt their legal frameworks to make use of the Decision, but none of them have yet done so; nor has a single eligible country notified the WTO of either its intention to use the system as an importer, or of a specific shortfall of a particular drug.

## Geographical Indications

Geographical indications (GIs), as defined in Article 22 of the TRIPS Agreement, are identifications of the national, local, or regional origin of a product for which "a given quality, reputation or other characteristic... is essentially attributable to its geographical origin." Discussions at the TRIPS Council are conducted along two inter-related tracks: (i) in formal negotiations on a register for GIs denoting wines and spirits; and (ii) implementation-related discussions concerning enhanced protection for GIs that identify other products.

### The Multilateral Register

Paragraph 18 the Doha Declaration requires WTO Members to "negotiate the establishment of a multilateral system of notification and registration of geographical indications for wines and spirits". No discernible progress has occurred in those negotiations due to a profound disagreement over two issues. The first of these

is 'legal effect', i.e. whether registered terms must be automatically protected or whether such protection is voluntary. The second concerns 'participation', i.e. whether the legal effect applies only to those who choose to participate in the system, or whether all WTO Members should be obliged to protect the registered GIs. In September 2005, the Chair of the multilateral register negotiations concluded that "differences appear[ed] to be as large as ever and [had] not narrowed since prior to Cancun."

Argentina, Australia, Canada, Chile, El Salvador, New Zealand and the US, supported by Ecuador, have argued for a GI register what would essentially function as a searchable database, which could be consulted by national intellectual property offices when making decisions on whether or not to grant protection to a given GI for wines and spirits. The register would be voluntary, i.e. Members would be free to choose whether or not to register their GIs. The enforcement of GI protection would remain grounded in national law.

In contrast, the EU and some other European countries would require registered terms to be protected in all WTO Member countries, including non-participating Members. The EU's latest agricultural tariff cut offer repeated this view, adding that the register should comprise all GIs (not only those for wines spirits) and have legal effects for both participating and non-participating Members not having lodged a reservation to the registration of a GI. The submission also suggested that that third party use of a 'limited number' of well-known European GIs should be prohibited.

Some have expressed cautious hope that the impasse over the register could be overcome in the wake of the 15 September 2005 bilateral agreement between the EU and the US to mutually recognise 'names of origin' and 'semi-generic' names for wines. However, French and Italian wine-makers continue to lobby for the rejection of the deal since it permits

certain US producers to continue using names such as Champagne. More importantly, the EU's linking of the register to enhanced protection for all GIs is likely to cause a hardening of the opposition.

For more details on GI extension, see the section on implementation below.

### Biodiversity, Traditional Knowledge and Folklore

Paragraph 19 of the Doha Declaration instructs the TRIPS Council - as part of its review of TRIPS Articles 27.3(b) and 71.1 - to consider the relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD), the protection of traditional knowledge (TK) and folklore. Article 27.3(b) states that WTO Members must provide patent protection over micro-organisms and microbiological processes (such as those used in biotechnology today), but allow countries to exclude plants and animals from their patent laws. Article 71.1 calls for a general review of the Agreement.

Discussions on these issues have largely focused on whether the TRIPS Agreement should be made to require applicants to disclose the country of origin and source of any genetic material/TK used either in the research and development process and/or directly in the invention they seek to patent. This could include providing evidence of (a) prior informed consent (PIC) of the country/community of origin, and (b) how they intend to share the benefits arising from the commercialisation of the invention with the country/community of origin. Developing countries pushing for such amendments include Brazil, Bolivia, Cuba, the Dominican Republic, Ecuador, India, Thailand, Peru and Venezuela, as well as the African Group. In addition to calling for disclosure of origin and evidence of PIC/benefit-sharing, African WTO Members have also proposed to revise TRIPS Article 27.3(b)

so as to prohibit the patenting of plants, animals and micro-organisms, as well as the classification of TK as a category of intellectual property rights.

While some developed countries, such as the EU, Norway and Switzerland, have shown a degree of willingness to address these issues either in the WTO or in the World Intellectual Property Organisation (Switzerland), others, including the US and Japan, remain firmly opposed. They do not see any conflict between the CBD and TRIPS, and argue that patent disclosure requirements would be ineffective with respect to PIC and access and benefit-sharing goals, as well as adding a burden to the patent system.

These fundamentally differing views have led to a long-standing stalemate at the TRIPS Council. In 2005, Brazil and India, along with several other developing countries, made a number of submissions regarding disclosure, PIC and benefit-sharing (IP/C/W/442, IP/C/W/438 and IP/C/W/429). Peru has also taken a strong stance in favour of disclosure requirements - including penalties for non-compliance - as part of the patent system under TRIPS or under WIPO-administered treaties (IP/C/W/441 and IP/C/W/447), citing numerous cases of erroneously granted patents on Peruvian genetic resources and traditional knowledge. In response, the US has argued (IP/C/W/449 and IP/C/W/434) that national laws outside the patent system are the most effective way to ensure prior informed consent and equitable benefit-sharing, which could be arranged through contracts between the provider and the user of the genetic material and/or knowledge. The US has indicated that the suggested additional requirements would be a burden on the patent system and would undermine technological development incentives. Where patents have been granted erroneously, the US has suggested that Members should focus on remedies, including the use of organised databases, information on patentability criteria and post-grant opposition or re-examination systems, as an alternative to litigation.

At the TRIPS Council meetings of 26 and 28 October 2005, Peru introduced a paper (IP/C/W/457) providing an analysis of the benefits that a disclosure requirement could have had in the 'biopiracy' case concerning the Camu Camu plant. India, Brazil, Bolivia, Cuba and Pakistan (IP/C/W/458) provided technical observations on the previous US submission (IP/C/W/449), arguing that a contract-based approach to access and benefit-sharing was insufficient. India and Brazil noted the new level of maturity in the discussions and emphasised that many delegations believed disclosure would be an efficient and workable solution to biopiracy, which could be complemented by the national contract-based approach proposed by the US. In addition, India and Brazil stressed that the TRIPS Council, in its work under paragraph 19 of the Doha Declaration, should be guided by the objectives set out in Articles 7 and 8 of the TRIPS Agreement, fully taking into account the development dimension. Although these meetings failed to yield consensus, many developing country delegations seem determined to move forward on biodiversity-related issues.

On 26 October, India proposed a paragraph for the Hong Kong Ministerial Declaration suggesting that "negotiations shall be undertaken on the relationship between the TRIPS Agreement and the CBD," which would cover *inter alia* "the details of the mandatory requirements on patent applicants to disclose," as well as PIC and benefit-sharing. The proposed paragraph received strong developing country support but raised objections from the US and Japan.

### Implementation Issues

*Non-violation complaints (paragraph 11.1 of the Doha Implementation Decision):* 'Non-violation' complaints are legal actions provided for in Articles XXIII (b) and (c) of GATT 1994 that allow Members to bring a dispute to the WTO based on the loss of an expected benefit caused by another Member's actions even if the actions do not violate WTO law. The purpose of allowing such complaints was to dissuade

countries from altering the negotiated 'balance of benefits' by instituting trade-restrictive but formally GATT-consistent measures. Critics argue that permitting litigation against measures that do not violate WTO rules undermines the predictability of the rules-based trading system. Article 64.3 of the TRIPS Agreement calls for the examination of the scope and modalities for such complaints in the TRIPS context.

The potential application of this type of legal action in the field of intellectual property rights is particularly controversial. The TRIPS Agreement was designed to establish standards for intellectual property protection rather than to protect market access, the main purpose behind GATT Articles XXIII (b) and (c). Moreover, some Members are concerned that countries might use it to bilaterally pressure weaker ones and as such have detrimental effects on issues of high socio-economic importance, such as health, technology transfer or nutrition.

Members agreed in Doha to not initiate non-violation complaints for two additional years (Article 64.2 of the TRIPS Agreement itself had established an initial non-application period of five years). The US is the principal advocate for allowing non-violation complaints in the TRIPS context, while many other countries have proposed removing the possibility of such complaints from the TRIPS Agreement. The 'July Package' explicitly extended the moratorium until the Sixth Ministerial Conference in December 2005. As no progress has been made on a more permanent solution, the moratorium is likely to be further extended in Hong Kong.

*Additional protection for geographical indications (tired 87 of the Compilation of Outstanding Implementation Issues; JOB(01)/152/Rev.1):* Paragraph 18 of the Doha Declaration provides for the TRIPS Council to address the controversial question of whether to extend to other products the protection of GIs afforded by Article 23 to wines and spirits. Bulgaria brought up the issue in the TRIPS Council in April 2003; it was also first to raise it in the context of the agriculture negotiations. Discussions on GI extension have effectively blocked progress on the other implementation issues, which came under the remit of Article 12(b) of the Doha Declaration, i.e. those for which the Doha Ministerial had not provided a specific negotiating mandate.

The EU and Switzerland are the main *demandeurs* for GI extension. They have been joined by a number of developing countries - including India, Kenya, Sri Lanka and Thailand - in calling for negotiations on this issue, although the latter group is not advocating the inclusion of GI extension within the agriculture negotiations. GI extension is strongly opposed by the US, Argentina, Australia and other 'New World' countries that are net exporters of agricultural products, as well as frequent users of 'Old World' GIs for their own food products, such as names of hams or cheeses. The EU's 28 October 2005 agricultural tariff offer formally linked GI protection (including extension) to the agriculture negotiations, thus marking the already divisive issue as a key priority and potential deal-maker or deal-breaker in Hong Kong.

## Parallel Developments

IPRs have been, and continue to be, among the most controversial chapters of bilateral and regional free trade agreements (FTAs), particularly between the US and developing countries. So far, the US has prevailed on its would-be FTA part-

ners to accept a number of 'TRIPS-plus' provisions, including enhanced protection for pharmaceutical test data, which is likely to delay the introduction of generic versions of medicines. Its FTAs also contain routine clauses offering stronger protection to trademarks than GIs, as well as enhanced protection for plant varieties. On the other hand, US has received its first TRIPS-plus requests from Thailand and the Andean Community, both of which have proposed that genetic resources/TK disclosure be made a part of patent filing criteria in their FTAs with the US. This reflects the growing determination of developing countries - despite considerable negotiating challenges - to push for a disclosure requirement at national, bilateral, regional and multilateral levels.

WIPO was recently invited to integrate a more development-friendly approach into its work on elaborating and implementing IP treaties. Based on an original proposition put forward by 14 developing countries, including Argentina and Brazil (WO/GA/31/12), the WIPO General Assembly has established a mechanism to consider the various aspects of the proposal. The Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore (IGC) has also contributed to the recognition of the importance of traditional knowledge, as well as providing a forum for discussion on some of the inherent limitations of the intellectual property system on this issue. Some substantive gains have also been made through the IGC. For example, an amendment was made to the Patent Co-operation Treaty in the minimum documentation list requiring patent offices to consider sources outside of scientific literature, including journals on traditional knowledge.