

### 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

While some progress has been made since Doha on questions related to intellectual property rights, a number of issues remain outstanding. The main developments relate to the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs) and public health, but discussions on geographical indications and biodiversity-related issues have hardly advanced at all.

The biggest step forward in the TRIPs Council was the adoption of the 30 August 2003 Decision on the *Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health* (WT/L/540). The Decision 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 some countries have started changing their domestic laws to reflect the Decision, the African Group of WTO Members has proposed an amendment (IP/C/W/437) to the TRIPs Agreement that differs substantially from the Decision itself.

Virtually no headway has been made in negotiations on a multilateral register of notification and registration of geographical indications (GIs) for wines and spirits since Cancun. Talks are also deadlocked on extending the strong protection TRIPs currently grants to wines spirits to other (mostly agricultural) products. The July Package (WT/L/579) instructs the Director-General to redouble efforts in this regard, and sets a July 2005 deadline for 'any appropriate action' by the General Council.

Despite new submissions, little progress has occurred on the relationship between the TRIPs Agreement, traditional knowledge and biodiversity-related issues.

### Mandated Deadlines

- **End of 2002:** Report to the General Council on a solution to compulsory licensing and lack of pharmaceutical manufacturing capacity; partly implemented on 30 August 2003.

- **End of 2002:** Report to the Trade Negotiations Committee on action on outstanding implementation issues under paragraph 12(b) of the Doha Declaration. The July Package extended the deadline until the Sixth Ministerial Conference (2005 in Hong Kong) for all issues save the extension of strong geographical indications protection to other products than wines and spirits, on which the Director-General must report to the Trade Negotiations Committee and the General Council by May 2005 so that the Council can take any appropriate action no later than July 2005.
- **Fifth Ministerial Conference** (2003 in Cancun): Conclusion of the negotiations on the multilateral system of notification/registration of geographical indications for wines and spirits; 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 countries with insufficient or no pharmaceutical manufacturing capacity might face in making use of compulsory licensing (para. 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-

## 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)

holder. The patent-holders are to receive '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, did not address the concerns of developing and least-developed countries that could not produce such drugs and thus needed to import them.

### The 30 August Decision

A compromise was finally reached on 30 August 2003. The Decision drafted by TRIPS Council Chair Pérez-Motta offers an interim 'solution' by waiving Members' obligations under Article 31(f) with regard to the export of pharmaceuticals produced under compulsory license, but sets a large number of conditions for both exporting and importing countries. Some of the most important ones are detailed below.

### Importing Countries

A country seeking to import generic copies manufactured under compulsory license must notify the TRIPS Council of its intention to use the system. Most importantly, it must notify the Council of the name and expected quantity of the product needed, as well as confirm (unless it is a least-developed country) that it lacks the domestic capacity to manufacture the product. The importing country must also confirm that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence. The exporting country may only manufacture the specific quantity of the product notified to the WTO, and must export the total production to the importing country, which must in turn take 'reasonable measures' to prevent re-exportation.

Eligible importing countries comprise all least-developed WTO Members, as well as "any other Member" that has made the notifications described above. However, EU members and most other OECD countries have formally agreed to 'opt out' of using the system as importers, while Hong Kong, Israel, Korea, Kuwait, Macao, Mexico, Qatar, Singapore, Taiwan, Turkey and the United Arab Emirates will only use it in "situations of national emergency or other circumstances of extreme urgency". According to the Doha Declaration on TRIPS and Public Health, each Member has "the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted", as well as the right to "determine what constitutes a national emergency or other circumstances of extreme urgency".

### Exporting Countries

Both production and export are subject to stringent conditions largely intended to prevent cheap copies of patented drugs (or active ingredients) from being diverted to developed country markets. For instance, products made under the license must "be clearly identified as being produced under the system [...] through specific labelling or marking. Suppliers should distinguish such products 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."

In addition authorities in the exporting country must notify the TRIPS Council of the grant of the licence, including the conditions attached to it, such as the name and address of the licensee, the product(s) for which the licence has been granted, the quantity for which it has been granted, the country to which the product is to be supplied and the duration of the licence. Before shipment, the 'licensee' (i.e. the manufacturing company) must post on a website the quantities being supplied to each destination and the distinguishing features of the product(s).

All Members must ensure the "availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets".

### The Chair's Statement

The Decision was accompanied by a statement (JOB (02)/217) from WTO General Council Chair Carlos Pérez del Castillo intended to soothe the fears of those concerned that the Decision would be used to undermine patent protection. The statement noted 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 also stressed the need to avoid trade diversion, noting that "special packaging and/or special colouring or shaping [for drugs produced under compulsory license] should not have a significant impact on the price of pharmaceuticals".

### Current State of Play

While the 30 August Decision was without doubt a diplomatic success, the biggest challenge is its implementation. So far Canada, India, Norway, and the EU are the only exporting countries in the process of integrating the Decision into their national legislation. Importing countries also need to adopt legal frameworks to make use of

the Decision. Many developing and least-developed countries will need more and better technical assistance for this. Indeed, several of these countries, as well as civil society health activists, have expressed serious doubts over the Decision's practical value, arguing that the procedures are so cumbersome that they will never be used. Not a single eligible country has so far notified the WTO of either its intention to use the system as an importer, or a specific shortfall of a particular drug.

The Decision specifies that it will only remain valid until a permanent amendment to the TRIPS Agreement replacing its provisions takes effect. The TRIPS Council was to have adopted the amendment by mid-2004, but the deadline was missed and extended to March 2005. Discussions on the subject remained weak until December 2004, when the African Group, including all African WTO Members, proposed a text for the permanent amendment. The text differed substantially from the Decision in that it omitted all references to 'trade diversion' and to measures that Members using the system must take to avoid it, with the exception of a paragraph on distinctive packaging. It also left out sections on notification obligations – including the requirements that would-be importers specify the name of the drug and the quantity they expect to need, as well as have the inadequacy of their pharmaceutical manufacturing capacity specified. In contrast, such obligations are central to the patent law changes necessary to comply with the Decision itself.

Members including the US, the EU, Canada, Japan and Switzerland criticised the African proposal, arguing that it sought to re-open negotiations on the content of the Decision. Most developed country and some developing countries insist that any amendment must simply be a 'technical translation' of the Decision. They also want it to reflect the Chair's statement, which the African proposal neglected. Nigeria and Kenya countered that all of the purported omissions were 'superfluous,' since they were already reflected elsewhere in the TRIPS Agreement. Many developing countries, including Brazil and India, welcomed the debate's shift from procedure to substance, but indicated that they would need more time to study the proposal carefully.

Prior to the African proposal, discussions had been largely technical, with Members arguing over whether the amendment should take the form of a footnote referencing the Decision and

the Chair's statement, or a change to the actual body of the TRIPS Agreement.

## The Wines and Spirits Register

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."

TRIPS Article 23.4 provides for negotiations in the TRIPS Council "concerning the establishment of a multilateral system of notification and registration of geographical indications for wines eligible for protection in those Members participating in the system". This mandate was reiterated in the Doha Declaration, and negotiations are currently underway in the special (negotiating) session of the TRIPS Council.

While Members generally agree that the multilateral system should not increase the existing level of protection for covered products, they remain divided over two issues, i.e. 'legal effect' – whether registered terms must be protected or whether such protection is voluntary; and 'participation' – whether such legal effect applies only to those who choose to opt into the system, or whether participation and its corresponding obligations extends to all WTO Members.

### State of Play

In April 2004, Argentina, Australia, Canada, Chile, El Salvador, New Zealand and the US, supported by Ecuador, submitted a 'joint proposal' (TN/IP/W/9) to clarify previous submissions (TN/IP/W/5 and 6). They would like the GI register to function as a searchable database that would provide national intellectual property offices with information on the GI rights claimed by producers in other WTO Member countries when making decisions on the GIs 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.

Objecting to this approach, European countries, supported by Bolivia, noted that if Members could not challenge a term internationally, a database would be unreliable and not 'facilitate' protection. They would require registered terms to be protected in all WTO Member countries, including non-participating Members. The EU has also proposed bilateral consultations in the event of a challenge, while Hungary and

Switzerland have suggested settling unresolved challenges by arbitration.

The supporters of the 'joint proposal' countered that the European approach, which would allow Members to challenge proposed registrations and require registered terms to be protected in all WTO Member countries, would oblige Members' to extend protection beyond that currently required under TRIPS. In contrast, supporters of the European approach believe that a system that allows Members to opt out would be 'plurilateral' rather than 'multilateral', while the system they propose would facilitate compliance with existing obligations rather than increase them. Hungary noted that even the 'joint proposal' could be regarded as 'TRIPS-plus' as it would require a notification that does not currently exist.

Under the 'implementation concerns' heading, the extension of GI protection to other products, mainly in the agriculture sector, is a major demand of European and some developing countries (see 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 microorganisms and microbiological processes, such as those used in biotechnology today, but allows countries to exclude plants and animals from their patent laws. Article 71.1 calls for a general review of the Agreement.

Just prior to the Cancun Ministerial in September 2003, discussions in the TRIPS Council focused on submissions received from Switzerland (IP/C/W/400), the African Group (IP/C/W/404) and India on behalf of Brazil, Bolivia, Cuba, the Dominican Republic, Ecuador, Thailand, Peru and Venezuela (IP/C/W/403). 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. The India-led paper proposed 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 revising Article 27.3(b) so as to prohibit the patenting of plants, animals and

micro-organisms. The African Group also proposed to classify TK as a category of intellectual property rights and put forward a draft decision on TK protection for adoption by the TRIPS Council.

In contrast, Switzerland wanted these issues to be discussed outside the WTO. Specifically, the Swiss submission proposed amending the World Intellectual Property Organisation's (WIPO's) Patent Co-operation Treaty to enable countries to require patent applicants to declare the source of any genetic resources and TK in patent applications. On the CBD-TRIPS relationship, Switzerland noted that the two could "and should" be implemented without conflict and that there was no need to modify the provisions of either. The EU, for its part, has been debating whether to address this issue in the WTO or in WIPO. Based on a concept paper submitted to TRIPS Council in 2002 (IP/C/W/383), the EU was thinking of making a concrete proposal on disclosure of origin to the WIPO Inter-Governmental Committee (November 2004). However, the proposal could not be submitted for want of consensus within the EU itself.

### State of Play

The September 2004 TRIPS Council meeting considered a proposal (IP/C/W/429) by Brazil, India, Pakistan, Peru, Thailand, and Venezuela to advance discussions on the relationship between the TRIPS Agreement, biodiversity issues and traditional knowledge, with a particular emphasis on disclosure requirements of the source and country of origin of genetic resources. The proposal focused essentially on how disclosure requirements could improve patent examination, arguing that improved patent examination would in turn prevent situations where patents based on traditionally-used herbal remedies were granted without provisions to ensure that revenues flow back to the communities where the genetic material was sourced. The proposal acknowledged that other processes for improving patent examination had been proposed, but maintained that they either lacked cultural sensitivity or were voluntary and thus provided no legal security. Therefore, the proposal suggested a "legally binding obligation to disclose the source and country of origin of biological resource and/or traditional knowledge". It also proposed penalties for non-compliance and wrongful disclosure, suggesting that the patent application process could be suspended or other penalties imposed. If non-compliance was discovered after a patent had been granted, the patent could be revoked, or the rights could

be transferred back to the original sources. The proposal would have the burden of proof lie with the patent applicant, and noted that the disclosure obligation could be introduced into the TRIPS Agreement through an amendment.

Members remained locked in their positions, so no substantive progress was made.

The September proposal followed a broader proposal made by a number of developing countries in March 2004 (IP/C/W/420), which put forward a checklist of issues to cover in the negotiations on biodiversity, traditional knowledge and folklore. This approach – which was not supported by the US or Japan – would have discussions proceed with a focus on three clusters of issues: disclosure of origin, evidence of prior informed consent and benefit-sharing.

### Implementation Issues

*Non-violation complaints (para 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 at Doha to not initiate non-violation complaints for two additional years (Article 64.2 of the TRIPS Agreement itself had set out an initial non-application period established of five years). They also instructed the

TRIPS Council to continue its examination of the scope and modalities for such complaints. Even though discussions on this issue took place in Cancun, as well as during the preparation of the July Package, no agreement has been reached. The July package explicitly extended the moratorium until the Sixth Ministerial Conference in December 2005.

*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 geographical indications afforded by Article 23 to wines and spirits. Bulgaria brought up the issue in the TRIPS Council in April 2003; it has also been raised in the context of 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.

Although the EU and Switzerland have been joined by a number of developing countries including India, Kenya, Sri Lanka and Thailand in calling for negotiations on this issue, the first two are the only Members advocating the inclusion of GI extension within agricultural negotiations. Their call is strongly opposed by the US, Australia and other 'New World' countries that are net exporters of agricultural products.

### Parallel Developments

It is important to be aware of some parallel developments are likely to impact the ongoing TRIPS negotiations,

First, bilateral and regional free trade agreements (mostly between developed and developing countries) have introduced an ever-increasing number of TRIPS-plus standards for intellectual property protection. These agreements include the Central American Free Trade Agreement (CAFTA; an agreement between the US and five Central American countries), US-Morocco, US-Australia, and ongoing negotiations between the USA and Colombia, Ecuador, Peru, Thailand and the countries of the Southern African Customs Union (SACU). The impact of such TRIPS-plus standards on public health has been the subject of much debate, as has the relationship of these regional agreements with the WTO, since some argue that they un-

dermine some of the flexibilities in the TRIPS context, including the Doha Declaration on TRIPS and Public Health. The 30 August Decision runs the risk of being undermined by bilateral and regional agreements.

Second, the protection of pharmaceutical test data has become an important issue. The test data that patent-holding pharmaceutical companies provide to regulatory authorities in order to receive marketing and sanitary approval for newly developed drugs is useful to generic pharmaceutical manufacturers, since they can use it when getting their copies of the drugs onto the market. Protecting access to such data thus increases the time it takes for generic drugs to reach the market (and in doing so, impairs competition). Thus, data protection effectively functions as an additional layer of

IP protection. Minimum standards for test data protection have been integrated in US free trade agreements with Singapore, Morocco, Chile and the five CAFTA countries. Longer data-exclusivity periods will undoubtedly have a significant impact on the performance of generic industries and as a result on access to essential drugs in developing countries, and thus needs to be taken into account when negotiating the implementation of the Doha agenda.

Third, WIPO has recently been mandated to integrate a development-friendly approach into its work on elaborating and implementing IP treaties. Based on a proposition put forward by Argentina and Brazil (WO/GA/31/12) during the WIPO Assemblies in September 2004, the WIPO Secretariat has agreed to look into the relationship of its work with respect to specific de-

velopment concerns such as public health and technology transfer. WIPO's technical assistance programme has been under similar scrutiny.

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](http://www.ictsd.org/ministerial/cancun/docs/TRIPs_para6_16-12-02.pdf).

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