TRIPs, Biodiversity and Traditional Knowledge

Issues related to biological diversity, patenting of life forms and the protection of traditional knowledge returned to centre stage at the 4–5 June meeting of the Council for Trade-related Aspects of Intellectual Property Rights (TRIPs), which for the past months had focused almost exclusively on health and geographical indications. While Switzerland and the European Union showed willingness to search for solutions, compromise still seems far off on the key issues that have divided the membership since the debate was launched more than four years ago.

Under Article 23.7.(b) of the TRIPs Agreement, WTO Members must provide patent protection to micro-organisms, as well as non-biological and micro-biological processes, while plant varieties must be protected either through patents or an "appropriate *sui generis* system." The article further requires these provisions to be reviewed four years after the date of entry of the WTO Agreement, i.e. in 1999. That review has yet to conclude.

The essential elements of the debate are the following:

- whether life-forms (i.e. plants, animals, micro-organisms and non/micro-biological processes) should be patented at all; and
- whether the TRIPs Agreement should be revised to make it compatible the with the requirements of the Convention on Biological Diversity (CBD) regarding access to genetic resources and the associated traditional knowledge, as well as the sharing of benefits arising from their use.

Members' views diverged on both issues from the start. A large number of developing countries answered the first question by a *no* to patenting of life-forms and the second by a *yes* to revising TRIPs provisions, while most developed countries did the opposite. The Doha Ministerial Declaration instructed the Council for TRIPS 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." The Declaration further noted that in undertaking this work, the TRIPs Council "shall take fully into account the development dimension."

The Council's June 2003 session was first since last September (Bridges Year 6, No.6, page 10) to see a significant discussion on issues related to biodiversity, the patentability of life-forms and traditional knowledge (TK), with new proposals tabled by Switzerland, the Africa Group and India on behalf of Bolivia, Brazil, Cuba, the Dominican Republic, Ecuador, Thailand, Peru and Venezuela.

Developing Countries Call for TRIPs Amendments

Both the Africa Group's and the India-led submissions stressed the need for a multilateral solution to these issues in the TRIPs Council, while also noting that any efforts in the WTO would not preclude work on these issues in other fora. They highlighted the limited progress that has so far been made in WIPO's Intergovernmental Committee (IGC) on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, and noted the limitations of national laws and contracts to prevent biopiracy at the international level.

The India-led paper (IP/C/W/403) 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 (PIC) and benefit-sharing. The submission also addressed a number of arguments against a proposal put forward by the US. By reiterating their proposal, the countries aimed to ensure that this item remains on the agenda and that the proposal would be discussed and adopted as part of the Doha round of trade negotiations.

Similarly, the Africa Group (IP/C/W/404) noted that "any protection of genetic resources and TK will not be effective until international mechanisms are found and established within the framework of the TRIPs Agreement," and described other means such as access contracts and databases as merely "supplementary".

The African submission (IP/C/W/404), however, went considerably further in its scope than the India-led proposal by calling for Article 27.3(b) to be revised so as to prohibit patenting of plants, animals and micro-organisms (least-developed countries made a similar call in their 12 June Dhaka Declaration, see page 19). On traditional knowledge, the Africa 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.

Brazil, Colombia, Cuba, the Dominican Republic, Kenya, Peru and Venezuela were among developing countries that supported one or both papers. China highlighted the contribution of traditional knowledge and called for the TRIPs Agreement to incorporate the CBD principles of sovereignty over resources, prior informed consent and equitable benefit sharing.

In contrast, the US called for traditional knowledge to be removed from the TRIPs Council's agenda. It again stressed that contracts would be more effective than the TRIPs Agreement in ensuring disclosure, PIC and benefit-sharing. While the EU welcomed the Africa Group's flexible approach to *sui generis* protection of plant varieties and agreed that small farmers should have the right to re-use seeds, it nevertheless rejected the call for a ban on patenting of life forms.

Switzerland Wants WIPO Solution

Switzerland 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 but would not oblige them to establish such legislation (IP/C/W/400). However, national law could "foresee that the validity of granted patents is affected by a lacking or incorrect declaration of the source, if this is due to fraudulent intention." Swit-

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zerland also reiterated the "crucial importance" of databases to protect TK. On the relationship between the Convention on Biological Diversity and the TRIPs Agreement, Switzerland noted that the two "can and should" be implemented without conflict and that there was no need to modify the provisions of either

In an October 2002 'concept paper', the EU – like Switzerland – maintained that Article 27.3(b) was flexible enough to accommodate disclosure of origin obligations (IP/C/W/383). The EU agreed to "examine and discuss the possible introduction of a system, such as for instance a self-standing disclosure requirement, that would allow Members to keep track, at the global level, of all patent applications with regard to genetic resources for which they have granted access." The data to be provided by patent applicants "should be limited to information on the geographic origin of genetic resources or TK used in the invention, while such a disclosure requirement should not act, *de facto* or *de jure*, as an additional formal or substantial patentability criterion." The legal consequences of non-compliance with disclosure requirements should lie outside the ambit of patent law, although compensation claims could be filed under civil law or fines be imposed for refusal to submit information or submitting false information (Bridges Year 7 No.3, page 15).

A the Council's June meeting, the EU again signalled its readiness to discuss mandatory disclosure of origin requirements. It did not, however, specify whether the issue should be addressed in the WTO or in WIPO. Several other developed countries, such as Japan, Canada and the US, noted WIPO's technical expertise in this area and proposed that the TRIPs Council await results of the ongoing consultations there.

While acknowledging that the Swiss proposal showed willingness to engage in discussions, one developing country trade source said that restricting the debate to WIPO was unsatisfactory as it would not oblige countries to address biopiracy through intellectual property rights. Several other developing country speakers stressed that work on access and benefit-sharing regarding genetic resources and traditional knowledge should be carried out in the WTO rather than left exclusively to WIPO.

These issues are not expected to figure prominently in Cancun, although some NGOs have launched a petition demanding that ministers adopt the Decision on Traditional Knowledge annexed to the Africa Group's latest proposal. The Chair of the TRIPs Council will brief the Trade Negotiations Committee (scheduled for 14-15 July) on the discussions, and Members will have an opportunity to revert to this agenda item at the TRIPs Council's November meeting.

Geographical Indications: Informal Consultations Continue

Despite strong indications that the EU will continue to insist on linking the reduction of agricultural subsidies to the strengthening of protection for products named after their geographical origins under the TRIPs Agreement, geographical indications were hardly mentioned at the Council's June meeting. WTO Director-General Supachai Panithcpakdi has admitted that the informal consultations he is conducting on the issue have so far yielded scant results. The EU, Switzerland and India, among many others, regard the extension of strong protection to other products than wines and spirits as an 'oustanding implementation issue' subject to the 'single undertaking' negotiations. This view is not shared by 'new world' countries such as Argentina, Australia, Chile and the United States (among others), which fiercely oppose GI extension. Dr Supachai is likely to report to the 14-15 July Trade Negotiations Committee on the results of his latest informal consultations.

Non-violation Complaints: No Recommendation in Sight

Paragraph 11.1 of the Doha Decision on Implementation-related Issues and Concerns instructed the TRIPs Council to continue its study of non-violation and situation complaints and to make recommendations to the WTO's fifth Ministerial Conference. At issue is whether or not to strike out Article 64 of the TRIPs Agreement, which allows Members to challenge through dispute settlement proceedings 'non-violation' cases, i.e. instances where no TRIPs provision has actually been breached but the complainant nevertheless considers that a measure 'nullifies or impairs' its legitimate expectations under the Agreement (see Bridges Year 7 No.2, page 3). No such complaints have ever been filed under Article 64 due to a dispute settlement moratorium set to expire at the Cancun Ministerial Conference. Nearly all Members agree that the Article should either be dropped, or the current moratorium be extended. The US, however, continues to advocate for ending the moratorium in Cancun.

As no consensus could be reached at the last scheduled session of the TRIPs Council before the General Council meets on 24 July to review progress towards Cancun, Chair Vanu Gopala Menon of Singapore concluded that it seemed that he would need to report to the General Council that the TRIPs Council was not in a position to make recommendations to the fifth Ministerial Conference at this stage. He added that this meant that further work might need to take place in the TRIPs Council context in the period between the General Council meeting and the Ministerial Conference.

Access to Medicines Remains Blocked

The June meeting of the TRIPs Council made no progress in breaking the current deadlock on access to medicines. Deadlines were missed in December 2002 and February 2003 for reaching consensus on how countries without the capacity to manufacture pharmaceuticals could still take advantage of compulsory licensing to address public health crises. Despite the lack of measurable process, Members still hope that a solution can be found before the Cancun Ministerial Conference, which desperately needs development-friendly deliverables.

In paragraph 6 of the Doha Declaration on TRIPs and Public Health, ministers recognised that WTO Members with insufficient or no manufacturing capacity in the pharmaceutical sector "could face difficulties in making effective use of compulsory licensing under the TRIPs Agreement" and instructed the TRIPs Council to "find an expeditious solution to this problem and to report to the General Council before the end of 2002."