

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).

At 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 Panitchpakdi 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.”

ACP Countries: Any Disease Restrictions Would Be Unacceptable

The African, Caribbean and Pacific (ACP) Group of States issued a statement to the TRIPs Council (IP/C/W/401) expressing disappointment at WTO Members' failure to agree on a draft text released by former TRIPs Council Chair Eduardo Pérez Motta on 16 December 2002 on paragraph 6 of the Doha Declaration on TRIPs and Public Health. The Group said the draft included "all the key elements" for a solution and reaffirmed its position that "any text that restricts the agreement to a set list of diseases, even involving the WHO in assessing public health concerns, would constitute an unacceptable attempt to restrict ACPs' use of compulsory licensing." It also rejected limiting the application of a paragraph 6 solution to national emergencies and other circumstances of extreme urgency.

The Group stressed that – particularly in view of the outbreak of new diseases such as SARS – finding a "straightforward and easy-to-implement" solution was now a matter of urgency. It urged developed countries to adapt their intellectual property enforcement policies according to the Declaration on TRIPs and Public Health, and stressed the need for assistance to ACP governments to integrate the TRIPs public interest safeguards into their legislation. The ACP also called on pharmaceutical companies "to ensure that their patent policies, practices and lobbying activities are compatible with the Doha Declaration."

EU Focuses on Technical Assistance, Avoidance of Diversion

The need for technical assistance, in particular from the World Intellectual Property Organisation (WIPO), the WTO and the WHO, was also highlighted by the EU, which focused on the implementation of the Doha Declaration rather than on paragraph 6 (IP/C/W/402). Such assistance, the EU noted, was required for developing countries to make the necessary legislative, administrative or policy adjustments to implement the Declaration.

The EU also noted that while voluntary price reductions offered by manufacturers were "one of the most important means to supply low-priced medicines to the poorest populations", it was essential to prevent low-priced products from flowing back to high-price markets. Such trade diversion would "disincentivise companies to engage in differential pricing".

In related news, EU governments on 26 May approved a regulation aimed at encouraging pharmaceutical companies to sell cut-rate AIDS, malaria and tuberculosis drugs to poor African countries. The regulation requires the participating companies to sell the medicines at about a third of their original price. Pills should be in different colours, sizes or shapes from the full-price versions and packaging should be distinctive. The EU will prohibit re-importation of these products from 76 countries, including least-developed and low-income countries, as well as those where HIV/AIDS is particularly prevalent.

US Moving Closer to Compromise?

In December 2002, the US was the only country to reject Ambassador Pérez Motta's draft text due to strong pressure from its pharmaceutical industry, which was concerned that the proposed solution's broad scope (the draft limits neither the diseases the solution would apply to nor the countries that could benefit) would mean losses of market share for patented medicines due to generics manufactured in countries such as Brazil and India.

At the June TRIPs Council meeting, the US again evoked its behind-the-scenes effort to 'build trust' between pharmaceutical companies and developing countries in order for a mutually acceptable solution to emerge. "But we're not there yet," US officials said and no (formal or informal) proposals have been tabled at the WTO so far.

However, at the 'mini-Ministerial' in Sharm El-Sheikh on 21-22 June, the US for the first time hinted that it could drop its insistence that the para. 6 solution be limited to HIV/AIDS, malaria, tuberculosis and "other epidemics of similar gravity." On the other hand, it could try to limit the number of countries allowed to issue compulsory licenses abroad. This possibility was implicit when US Trade Representative Robert Zoellick told Philippine Trade Minister

Manuel Roxas during bilateral talks last May that the US did not consider the Philippines eligible for a paragraph 6 benefits since it deemed the country to have sufficient manufacturing capacity of its own. Developing countries have until now steadfastly refused all solutions that would exclude any of them from benefits.

The TRIPs Council has authorised Chair Vanu Gopala Menon of Singapore to call a special meeting "at short notice if necessary" should ongoing informal consultations on paragraph 6 make progress possible.

On 27 May, President Bush signed into law the United States Leadership Against HIV/AIDS, Tuberculosis and Malaria Act. The Act establishes a new fund within the US Treasury to provide assistance for improving health care delivery systems, hospice and palliative care programmes, and the provision of pharmaceuticals (including antiretrovirals and other pharmaceuticals for the treatment of opportunistic infections) and nutritional support. The US pledged US\$15 billion over five years towards the prevention and treatment of HIV/AIDS at the G8 Summit in early June.

The Act instructs the US Agency for International Development to provide food and nutrition to individuals suffering from HIV/AIDS and their caretakers. This injunction is supplemented by a 'sense of Congress', which notes that "a few of the countries object to part or all of [US food] assistance because of fears of benign genetic modifications to the foods" and states that "United States food assistance should be accepted by countries with large populations of individuals infected or living with HIV/AIDS, particularly African countries, in order to help feed such individuals." While non-binding, the sense of Congress findings' inclusion in the bill could provide a means to pressure governments to accept GM food assistance in return for US-funded AIDS programmes.

The Act also authorises the Treasury to pay US\$1 billion in 2004 to the UN-administered Global Fund to Fight AIDS, Tuberculosis and Malaria and "such sums as may be necessary" from 2005-2008.