

Access to Medicines Could Become Doha's (only?) Success Story

In the grey landscape of *déjà vu* that characterises the run-up to the WTO's Ministerial Conference next November, the issue of poor countries' access to medicines looks set to provide a bright exception. On 20 June, WTO Member governments for the first time addressed this high-profile problem head-on. In a rare show of unanimity, none of the more than 40 delegates who spoke at the meeting disputed the right of developing country governments to use compulsory licensing of patented medicines to cope with public health emergencies. While interpretations of the latitude offered by the Agreement of Trade-related Aspects of Intellectual Property Rights (TRIPs) varied considerably, all speakers agreed that the HIV/AIDS epidemic in Sub-Saharan Africa, and perhaps other countries, was a 'national emergency' or 'situation of extreme urgency', which could justify the granting of licenses even without seeking the patent-holder's consent.

Two papers provided the backbone for the TRIPs Council's June special discussion. One was submitted by the 30-nation Africa Group together with 26 other developing countries on *TRIPs and Public Health* (IP/C/W/296) and the other by the European Union on the *Relationship between the Provisions of the TRIPs Agreement and Access to Medicines* (IP/C/W/280).

Intellectual Property Rights and Public Health

Developing countries seek a formal confirmation at the Doha Ministerial that 'nothing in the TRIPs Agreement reduces the range of options available to governments to promote and protect public health, as well as other overarching public policy objectives.' While such a confirmation would not necessarily require any changes in the Agreement, it would provide certainty that measures taken under existing provisions will not be subjected to dispute settlement challenges based on a narrow reading of the Agreement or other forms of coercion. Many of the points in the Africa Group's submission are drafted in language that could be used in such a ministerial affirmation.

The Group's statement that 'each provision of the TRIPs Agreement should be read in light of the objectives and principles set forth in Articles 7 and 8' led other speakers to comment on how those provisions related to the overall interpretation of the treaty.

Article 7 states that intellectual property rights protection 'should contribute to the promotion of technological innovation and to the transfer and dissemination of technology [...] in a manner conducive to social and economic welfare, and to balance rights and obligations.' According to Article 8.1, 'Members may, in formulating or amending their laws and regulations, adopt measures to protect public health and nutrition, and to promote the

public interest in sectors of vital importance to their socio-economic and technological development, *provided that such measures are consistent with the provisions of this Agreement* (editors italics).'

The Africa Group, supported by the many developing country delegates who took the floor at the meeting, focused on the *rights* conferred by these articles: 'When intellectual property rights are properly granted and exercised, they may meet their objective of contributing to the development of new medicines. However, there should be a common understanding that confirms the right of governments to ensure access to medications at affordable prices and to make use of the provisions in the Agreement whenever the scope or exercise of IPRs result in barriers to access to medicines.'

The United States, the sturdiest champion of intellectual property protection, emphasised the *obligation* that any measures pursuant to Article 7 or 8, including those to protect public health, must be consistent with other TRIPs provisions. Stressing the importance of patent protection, it argued that, rather than the simple possibility of a royalty, the market exclusivity conferred by patents provided 'the necessary incentive for companies to invest in research to discover, develop and commercialise new products'. Furthermore, because local innovators stood to benefit from the technical details that patent applicants must disclose, the US concluded that, instead of impeding research and development or discouraging competition, patent systems 'actually promote the objective of TRIPs Article 7 by contributing to the promotion of technological innovation and to the transfer and dissemination of technology.' The US also strongly emphasised the role of other factors, such as poor public health infrastructure, in impeding access to medicines.

'Although Articles 7 and 8 were not drafted as general exception clauses, they are important for interpreting other provisions of the Agreement, including where measures are taken by Members to meet health objectives,' the EU wrote. The European Union also stated that intellectual property protection provided 'an essential stimulus for creativity and innovation'. While the TRIPs Agreement had been criticised as 'limiting policy options in

relation to public health concerns', the EU maintained that Articles 7 and 8, special transitional arrangements and other provisions gave Members 'a sufficiently wide margin of discretion in implementing it'.

Compulsory Licensing

Article 31 of the TRIPs Agreement on the use of patented matter without the authorisation of the rights holder sets out a number of conditions that Members must fulfil if they have recourse to such use, but does not itemise the purposes for which

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compulsory licenses may be granted. Among the most important requirements regarding compulsory licenses are the obligation to have – unsuccessfully – sought the patent holder's authorisation 'on reasonable commercial terms and conditions' prior to issuing a compulsory license, and the obligation to provide the rights holder with adequate remuneration if his patent is infringed. However, in cases of 'national emergency or other circumstances of extreme urgency', the requirement to seek prior consent may be waived.

'Members should take the view that the TRIPs Agreement in no way stands in the way of public health protection, and therefore that it should provide the broadest flexibility for the use of compulsory licenses,' developing countries averred. According to the Africa Group's submission, compulsory licenses 'are an essential tool for governments to carry out public health policies, as they may facilitate access to medicines through prevention of abuses of rights, encouragement of domestic capacities for manufacturing pharmaceuticals and in cases of national emergency or other circumstances of extreme urgency, or of public non-commercial use. Nothing in the TRIPs Agreement limits the grounds for governments to issue compulsory licenses.' The EU agreed that Article 7 and 8 justified Members' invoking public health concerns as a reason for compulsory licensing, although Article 31 makes to explicit reference to it.

Despite its general aversion regarding measures that may weaken patent protection, the US recognised that Article 31(b) allowed countries to issue compulsory licences without seeking the right holder's consent in cases of 'national emergency or other circumstances of extreme urgency', but stressed that Article 31 must be read in light of the other provisions of the TRIPs Agreement, including Article 27.1 (obligation to provide patents without discrimination as to the place of invention, the field technology and whether products are imported or locally produced). The US also took issue with the claim that compulsory licenses could be granted to encourage domestic capacities for manufacturing pharmaceuticals: 'Contrary to what some have asserted, compulsory licenses under TRIPs are not intended to be a mechanism for directing industrial development, protecting domestic industries against foreign competitors, or for promoting the now widely discredited economic policy of import substitution.'

Foreign Compulsory Licensing

One of the questions that is likely to be the subject of intense political debate, as well as technical scrutiny of TRIPs language, concerns the possibility to award a compulsory license to a manufacturer in a third country. While the *château* of Article 31 allows governments to authorise 'third parties' to produce goods under compulsory licensing, it does not specify where those third parties should be located. However, Article 31(f) provides that compulsory licensing 'shall be authorised predominantly for the supply of the domestic market'.

Because many developing countries – particularly least developed countries and smaller economies – have limited industrial capacities and very small domestic markets to manufacture medicines locally, the African Group urged a reading of Article 31(f) confirming that 'nothing in the TRIPs Agreement will prevent Members from granting compulsory licenses to supply foreign markets.'

The EU noted that the Agreement did not appear to offer any legal certainty on the issue. 'What can be said is that a WTO Member is free to grant a compulsory licence for the importation of goods which are under patent in its own territory, as long as the imported goods have been produced in a country where they are not patented, or where the term of protection has expired.' The US concurred up to this point, but added that if a drug was protected by a patent in the foreign licensee's home country and the compulsory licensee chose to manufacture it there for export to the licensing country 'a problem [would be] created.'

This arcane-sounding point has wide implications. For instance, at this moment it is possible even for a country that extends patent protection to medicines – South Africa, say – to grant a compulsory license to a manufacturer in another country, such as India, which does not. That manufacturer would produce a generic version

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Dispute Settlement Briefs

- Brazil scored a (conditional) victory in its long-running dispute with Canada over aircraft export subsidies when a WTO panel ruled on 20 June that its export support programme Proex was essentially in line with multilateral trade rules. According to trade diplomats, the still-confidential report found that changes made to Proex in the wake of previous adverse rulings had made it 'on its face' consistent with the Agreement on Subsidies and Countervailing Measures. In the future, however, Brazil should abide by the OECD 'gentlemen's agreement' on export credits, which limits loan repayment terms to ten years at the most and requires such financing to cover no more than 85 percent of the purchase price. Through Proex, the Brazilian government provides low-cost financing for the clients of the aircraft manufacturer Embraer.

In December 2000, the Dispute Settlement Body authorised Canada to impose trade sanctions worth US\$250 million on Brazilian exports, as a compliance panel had determined in July that Brazil's Proex reforms had not gone far enough at that point. However, instead of exercising its trade sanction authority, Canada chose to provide Air Wisconsin a government-guaranteed loan and interest support package worth more than US\$1 billion for the purchase of 75 regional aircraft from Embraer's bitter rival, Montreal-based Bombardier.

This prompted Brazil to seek another dispute settlement panel on loan guarantees provided by Canada's Export Development Corporation, Industry Canada and the Province of Quebec to support the country's regional aircraft industry. The panel is expected to render its verdict in mid-August at the earliest.

Canada claims that, while not necessarily WTO-compatible, the loan it provided to Air Wisconsin – and may yet provide to Northwestern Airlines – exactly mirrors financing arranged by Brazil for Embraer's clients. The June panel findings on the latest Proex reforms may make that claim harder to support.

- A preliminary compliance panel ruling of 22 June found that the US Extraterritorial Income Exclusion (ETI) Act adopted last year to replace the foreign sales corporations (FSC) tax regime still violated the WTO Agreement on Subsidies and Countervailing Measures. The Appellate Body ruled in February 2000 that the tax breaks enjoyed by US corporations under FSC regime amounted to an illegal export subsidy. The replacement legislation was challenged by the EU in November 2000 and, according to trade sources, the interim ruling held that it still provided an illegal subsidy, *inter alia*, because the tax breaks it offers are contingent on export performance (violation on SCM Article 3.1(a)). The ETI Act also violates the national treatment obligation in both the SCM and the GATT because to qualify for tax exemptions, at least 50 percent of the value of the goods must be attributable to US inputs and labour. The US will appeal the panel findings.

While the EU – whose own tax arrangements are vulnerable to similar challenges – has requested authorisation to impose trade sanctions in excess of US\$4 billion, both sides have indicated their willingness to negotiate a solution. In any case, the appeals process is likely to take several months. Should the EU ultimately prevail, the WTO has a further two months to arbitrate the amount of the sanctions.

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of a patented brandname drug and export it to the country that granted the license. However, India and the few other developing countries allowed to postpone full patent protection in some fields of technology under Article 64.4, must extend such protection to all fields, medicines included, as of January 2005. Under a narrow reading of the Article 31(f) requirement that compulsory licenses should be authorised *predominantly for the supply of the domestic market*, it could then become 'TRIPs-illegal' to manufacture generics under a foreign license for export. This would in turn affect the 'client country's' access to affordable drugs.

The EU's submission offered 'another possible interpretation of the Agreement that would allow a Member to issue a compulsory licence to a manufacturer in another country, provided the government of that other country recognised the licence (which it would not be obliged to do under the Agreement), and provided that all the goods manufactured under the licence were exported to the country granting the licence.' The EU added that it was 'far from certain whether such a "permissive" reading of the Agreement would stand scrutiny by a panel or the Appellate Body'.

The US commented that the EU's 'possible interpretation' of the Agreement raised questions that should be addressed in case of 'further discussion of this concept'.

The Special Case of AIDS

While the TRIPs Council discussions on access to medicines are not limited to any particular disease, most speakers at the June meeting singled out the HIV/AIDS pandemic. Whatever their more general views or reservations concerning compulsory licensing, industrialised countries concurred that the proportions that the AIDS epidemic had reached in certain countries could be considered as 'a national emergency or a circumstance of extreme urgency' that would dispense them from seeking the patent holder's consent prior to granting a license to a third party (Article 31(b)). The US put epidemics such as HIV/AIDS within a Member's territory on par with 'war, civil strife or natural disasters for purposes of exercising the waiver authority,' and the EU said that the level of HIV/AIDS infection reported in some developing countries appeared to be a 'very good reason for describing it as a national emergency or as a circumstance of extreme urgency.'

The Next Steps

The debate on access to medicines at the WTO has barely begun. In addition to the topics above, Members will need to address in more depth the difficult issues of parallel imports and the protection of undisclosed test data against 'unfair commercial use', both key concerns for the pharmaceutical lobby in industrialised countries. Developing countries, supported by Norway, are also seeking a moratorium on dispute settlement cases against their health-related IPR measures until all the open questions have been answered.

While it is already certain that ministers will address access to medicines, the format and wording are still under intense discussion. These will now follow two parallel tracks: the General Council special sessions on Doha preparations will focus on the 'political dimension', i.e. Ministerial Declaration language, while the TRIPs Council will continue to explore the legal interpretation of the relevant provisions, such as the meaning or relevance of 'predominantly domestic' or 'anti-competitive practices'.

Due to lack of space, the other outcomes of the TRIPs Council session and other late June WTO meetings will be covered in the next issue of Bridges.