Policy Papers on Transnational Economic Law

No. 19

From Doha to Hong Kong – WTO Members Amendment to Make Health Flexibilities Permanent under TRIPS

Sebastian Wolf

TRANSNATIONAL ECONOMIC LAW RESEARCH CENTER

Faculty of Law
Martin-Luther-University
Halle-Wittenberg
Universitätsplatz 5
06099 Halle (Saale)
Germany

Tel.: +49 345 / 55 23149
/ 55 23180
Fax: +49 345 / 55 27201

E-Mail: telc@jura.uni-halle.de
www.telc.uni-halle.de

December 2005

TELC
Transnational Economic Law Research Center

From Doha to Hong Kong – WTO Members Amendment to Make Health Flexibilities Permanent under TRIPS

I. Introduction

With the World Trade Organization to hold its 6th Ministerial Conference in Hong Kong, 13-18 December 2005, its Members approved major changes to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), making permanent a decision on patents and public health originally adopted in 2003. The proposal for a decision on an amendment was reached at the TRIPS Council meeting on 6 December 2005 and was submitted to the General Council for adoption in accordance with paragraph 1 of Article X of the Marrakesh Agreement Establishing the World Trade Organization.

The decision taken in the TRIPS Council and the General Council directly transforms the 30 August 2003 waiver into a permanent amendment of the TRIPS Agreement, being the first such change to a core WTO Agreement since the World Trade Organization came into being in 1995. That temporary waiver, in theory, made it easier for countries exposed to public health emergencies to import cheaper generic versions of patented pharmaceuticals by overriding provisions of the TRIPS Agreement that could hinder exports of pharmaceuticals manufactured under compulsory licenses to countries that are unable to produce them. Although the General Council's approval will not modify the 30 August 2003 agreement, it does provide more legal certainty by making it permanently binding under WTO rules.

Pursuant to paragraph 3 of Article X of the WTO Agreement, the amendment will only take effect once it is ratified by two thirds of the 149 Members. It will now be open for acceptance by the WTO Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference. Pending the necessary ratifications, the temporary waiver will remain the legal basis for trading generic medicines under a compulsory license.

The recent decision is part of a broader WTO initiative to address key issues related to the implementation of the TRIPS Agreement. On 29 November 2005, WTO Members decided to give Least Developed Countries (LDCs) a seven-and-a-half year extension to apply rules protecting intellectual property rights under the TRIPS Agreement based on a request submitted by Zambia on behalf of the WTO's 32 LDC Members. In fact, Article 66.1 TRIPS Agreement provides that LDCs can apply for an extension of the transition period, after which they have to fully apply the TRIPS obligations, originally set to expire on 1 January 2006. The extension

agreed to will prolong the transition period until 1 July 2013, an extension half the duration of the 15 years the LDCs had originally been seeking. The agreement, however, does not apply to pharmaceutical products, which LDCs will not be required to grant intellectual property protection until 2016 as a result of an extension agreed to at the Doha Ministerial.

II. Background

The amendment completes a long troublesome process that began with the Doha Declaration on TRIPS and Public Health in 2001, which in its paragraph 6 had explicitly recognized that developing countries are facing difficulties in making effective use of compulsory licensing. The main problem resulted from the fact that under Article 31 (f) of the TRIPS Agreement, a compulsory license could only be granted predominantly for the supply of the domestic market, thus limiting exports of generic versions of patented drugs and constraining the supply of medicines to countries lacking pharmaceutical manufacturing capacities. Furthermore, paragraph 6 of the Doha Declaration mandated the Council for TRIPS to find an expeditious solution to the problem of compulsory licensing. In fulfilling this mandate, the WTO General Council adopted on 30 August 2003 a Decision on the Implementation of Paragraph 6 of the Declaration on the TRIPS-Agreement and Public Health. The decision allows countries to waive the TRIPS Article 31 (f) constraint of producing under compulsory license predominantly for the domestic market. WTO Members lacking sufficient manufacturing capacities in the pharmaceutical sector are therefore enabled to import generics under a compulsory license subject to the compliance with a number of administrative and procedural requirements in the importing and exporting country. The 30 August 2003 decision was accompanied by a statement form the Chairman of the General Council assuring that the system would not be used as an instrument to pursue commercial policy objectives or to divert medicines produced under compulsory licenses to developed country markets.

The 30 August 2003 agreement however, was always based on the WTO Members' assumption that it would serve as a temporary solution. In particular, paragraph 11 of that decision provided that

> [t]his Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understand-

> ing that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN (01)/DEC/1).

Hence, it was always envisaged that mandating the Council for TRIPS to find a permanent solution would involve an amendment to the TRIPS Agreement.

II. The Amendment

The amendment itself contains three parts: a new Article 31bis, which will be inserted after Article 31 TRIPS, an Annex, which will be inserted after Article 73 TRIPS, and an Appendix.

Paragraph 1 of the new Article 31bis provides that the obligation of WTO Members under Article 31 (f) TRIPS shall not apply to the extent necessary, thus allowing pharmaceutical products manufactured under a compulsory license to be exported to eligible countries lacking sufficient production capacity. Paragraph 3 extends the limited exemption to developing or least developed countries that are party to a Regional Trade Agreement within the meaning of GATT Article XXIV, thereby making it unnecessary to obtain a compulsory license for each member of the RTA that shares the health problem in question. Other paragraphs provide for avoiding double remuneration to the patent-owner or address the issue of non-violation, declaring the Members will not challenge any measure taken in conformity with the amendment.

A further seven paragraphs in the Annex outline the specific terms for using the system and address issues like eligibility, notifications, measures against trade diversion, the development of regional systems to allow economies of scale and annual reviews in the TRIPS Council. The Appendix deals specifically with assessing the pharmaceutical manufacturing capacities in the importing country.

III. A Rushed Decision?

After almost two years of a slow moving debate on the issues relating to the TRIPS Agreement and Public Health, it remains unclear why the WTO Members were so eager to conclude the TRIPS amendment ahead of the Ministerial Meeting in Hong Kong.

Because the 30 August 2003 decision did not set out a fixed time frame for replacing the waiver by a permanent solution, there was no particular need for the amendment at this time. Moreover, the WTO Members have missed several deadlines for reaching a consensus on a permanent solution in the past. Just recently, in October 2005, an impasse became evident on the nego-

tiations as WTO Members appeared far apart on a solution. Developing and developed countries broadly disagreed on the content of a possible amendment and whether to amend the actual body of the TRIPS Agreement or to include the amendment as an annex or footnote to it. In particular disagreements remained concerning the legal status of the Chairman's statement.

Since December 2004, the discussions have centered around a proposal submitted by the African Group which aimed at integrating a modified version of the 30 August 2003 decision into the TRIPS Agreement. In essence, the proposal suggested to eliminate those provisions of the 30 August 2003 agreement, that would be either "redundant in the context of an amendment" or whose "purpose would otherwise be served by other provisions of the TRIPS Agreement". With regards to the statement of the Chair of the General Council the African Group argued, that it was not part of the 30 August 2003 decision and including it in the amendment, would give the statement a legal status which it never had, thereby significantly unbalancing the text. Most developing countries supported the African proposal as a good basis for negotiations.

The subsequent discussions and communications on the African Group submission reaffirmed the well known positions taken by the several WTO Members. Major developed countries strongly opposed the African proposal on the grounds that it did not reflect all the elements of the 30 August 2003 decision. Furthermore the African proposal did not make any reference to the Chairman's statement, which developed countries considered as a substantial safeguard against trade diversion of low-cost medicines into their domestic markets.

From a legal perspective the manner and language in which the amendment is drafted, could significantly impact on whether the Chair's statement is taken into consideration as an instrument for treaty interpretation under the general rule of interpretation (Article 31 of the Vienna Convention on the Law of Treaties) or mere supplementary means of interpretation (Article 32 VCLT). Therefore the concerns of developing countries with regards to 'upgrading' the status of the Chair's statement have a legal background on whether the amendment would result in the statement falling under the criteria of Article 32 VCLT or shifting to meet the criteria of Article 31 VCLT.

Because, until recently developed countries considered the integration of the Chair's statement as a key element in their willingness to agree on an amendment of the TRIPS Agreement, it is most notable that these countries moved away from their original demand as the amendment does not make any reference to the

Chair's statement. In this context in can safely be assumed that both developed and developing countries backed down from their initial positions as a failure to resolve the issue might have adversely affected the Hong Kong Ministerial Conference.

The approval of the TRIPS amendment formally removes one of the most controversial topics from the WTO's current negotiating agenda. As the debate on TRIPS and Public Health threatened to further divide WTO Members in the run up to Hong Kong Ministerial Conference, the agreement can be considered as a positive sign and at least a first contribution to move forward sufficiently to conclude the Doha Round. In order to reflect the recent changes, the draft ministerial declaration has already been updated by adding the following passage to paragraph 34 of the draft text: "In this regard, we welcome the work that has taken place in the council and the decision of the General Council of 6 December 2005 on an amendment of the TRIPS Agreement."

According to WTO Director-General Pascal Lamy the deal "confirms once again that members are determined to ensure the WTO's trading system contributes to humanitarian and development goals as they prepare for the Hong Kong ministerial conference". However, the agreement to amend the TRIPS Agreement cannot belie that after almost two years there has not been a visible progress on other crucial development issues. The success of the Hong Kong Ministerial Conference will therefore in particular depend on the progress on bottleneck issues such as agriculture and non-agricultural market access.

IV. Mixed Public Opinion

Meanwhile the agreement to amend the TRIPS Agreement has been broadly welcomed especially by trade officials and industry based organizations. European Trade Commissioner Peter Mandelson was quoted by saying that "Europe has sent an important signal ahead of the Hong Kong Ministerial". United States Trade Representative Rob Portman praised the agreement as a "landmark achievement that we hope will help developing countries devastated by HIV/AIDS and other public health crises". "The Africa Group and other developing countries made clear that the amendment was something they saw as essential to accomplish before Hong Kong", Portman added, "and we were pleased to work with them to make it happen". Harvey Bale, director-general of the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) declared, that the agreement reached on 6 December, "[…] addresses the needs of countries lacking manufacturing capacity, while also preserving the TRIPS mechanism, which is critical for continuing the innovation essential to addressing the health needs of all

countries. Today's agreement shows that the WTO's multilateral, consensus-based process can work effectively. Hopefully, this success will be replicated in other discussions at the WTO's forthcoming Ministerial Meeting in Hong Kong, to the benefit of the Doha Development Agenda," he added.

However, the 30 August 2003 decision which was originally designed to facilitate production and export of generic medicines, has been harshly criticized by public health groups on the grounds that it was overly cumbersome and inefficient leading to a practically unworkable solution. Yet to date the mechanism has not been used by a single WTO member.

According to a press release by the international humanitarian aid group Médecins Sans Frontières (MSF), "[d]elaying the amendment would have been a far better option, as it would have ensured the possibility of testing and improving the mechanism in practice. This decision shows that the WTO is ignoring the day-to-day reality of drug production and procurement. The amendment has made permanent a burdensome drug-by-drug, country-by-country decision-making process, which does not take into account the fact that economies of scale are needed to attract interest from manufacturers of medicines." MSF therefore urged the WTO to provide evidence by the end of next year demonstrating that the mechanism it is putting in place can bring an end to the negative effects that full TRIPS implementation has on access to medicines.

V. Developed Countries "Opt Out"

Meanwhile the recent changes to the TRIPS Agreement have also raised the public awareness in industrialized countries. In today's closely interrelated and interdependent systems of trade and commerce, all countries are likely to experience public health emergencies, especially in light of a possible outbreak of a pandemic of bird flu and a shortage of medicines needed for treatment.

While there were many problems associated with the 30 August 2003 waiver, one point of the mechanism is of particular concern for developed countries. As part of the decision, a group of 23 developed countries (including all members of the European Union before its enlargement) announced, that they will not use the system as importing countries. Therefore these countries have elected to opt-out of the mechanism, even in cases of a public health emergency or pandemic. A number of other countries announced that they would use the system as importers only in cases of emergencies or extremely urgent situations. As a consequence, none of the countries that have opted-out could obtain generic medicines for stockpiles under a compulsory li-

cense.

Taking into account recent studies by the World Health Organization (WHO), "the world is ill-prepared to defend itself during a pandemic. WHO has urged all countries to develop preparedness plans, but only around 40 have done so. WHO has further urged countries with adequate resources to stockpile antiviral drugs nationally for use at the start of a pandemic". According to the WHO, "[t]wo drugs [...], oseltamivir (commercially known as Tamiflu) and zanamivir (commercially known as Relenza) can reduce the severity and duration of illness caused by seasonal influenza." WHO now estimates that, "at present manufacturing capacity, which has recently quadrupled, it will take a decade to produce enough oseltamivir to treat 20% of the world's population".

However, as the mechanism will be made permanent under the TRIPS Agreement, the question arises if a country's listing in the opt-out footnote results in the said country being permanently barred from importing under the mechanism.

In dealing with eligible importing countries paragraph 1(b) of the Annex to the TRIPS Agreement provides that

> "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification to the Council for TRIPS of its intention to use the system set out in Article 31bis and this Annex ("system") as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system as importing Members and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances of extreme urgency.

In this regard the phrasing that the said members "will not" use the system is of particular importance. The dictionary meaning of "will" refers to an intention. The declaration of intent, however, needs to be distinguished from other commonly used international treaty language like "shall" which goes further than "will" by already implying an obligation. In addition the amendment explicitly states that "a member may notify at any time that it will use the system in whole or in a limited way". Thus, the wording indicates that there are no legal consequences connected with a country's listing in the opt-out footnote.

Even if the wording of paragraph 1(b) of the Annex to the TRIPS Agreement would be found ambiguous in a future dispute before the WTO, this result would not change. WTO jurisprudence frequently refers to the interpretative principle of in dubio mitius, which is widely recognized in international law as a supplementary means of interpretation. According to the Appellate Body, "[w]e cannot lightly assume that sovereign states intended to impose upon themselves the more onerous, rather than the less burdensome, obligation by mandating conformity or compliance with such standards, guidelines and recommendations. To sustain such an assumption and to warrant such a far-reaching interpretation, treaty language far more specific and compelling [...] would be necessary." (Report of the Appellate Body, EC – Hormones, WT/DS26/AB/R, WT/DS48/AB/R, para. 165). In footnote 154 to para. 165 of that decision the Appellate Body further stated that, "[t]he principle of in dubio mitius applies in interpreting treaties, in deference to the sovereignty of states. If the meaning of a term is ambiguous, that meaning is to be preferred which is less onerous to the party assuming an obligation, or which interferes less with the territorial and personal supremacy of a party, or involves less general restrictions upon the parties."

In fact, the WTO members could have easiliy used a phrase explicitly stating that the said countries could never qualify as eligible importing countries. Therefore it can safely be assumed that a country's declaration to opt-out is of no legal relevance. Rather, countries would be free to opt back in as an importing member in case of a national health emergency. This result is also supported by the fact that self determined limitations on a states own sovereignty, like a voluntary declaration to opt-out of the 30 August 2003 system, does not lead to a permanent loss of sovereignty, but can be withdrawn at any time instead.

However, it remains difficult to explain why several developed countries have opted-out as importers. Such a policy would only be beneficial to large pharmaceutical companies that are made immune from generic competition. In either case, the decision to opt-out is likely to marginalize and undermine the legitimacy of compulsory licensing and may be partially responsible for the reluctance of developing countries to actually use the 30 August 2003 mechanism.

Dipl.-Jur. Sebastian Wolf LL.M.oec.int. is a Senior Research Fellow at the Transnational Economic Law Research Center (TELC) at the Faculty of Law, Martin-Luther-University Halle-Wittenberg.