CONFERENCE REPORT

IMPLEMENTATION OF THE
DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH:
TECHNICAL ASSISTANCE – HOW TO GET IT RIGHT

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IMPLEMENTATION OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH: TECHNICAL ASSISTANCE – HOW TO GET IT RIGHT

It has become obvious over the years that IPRs are too important to just be left to IPR specialists.
– Otto Genee, Deputy Permanent Representative, Mission of the Netherlands to the WTO

Introduction

Médecins Sans Frontières (MSF), Consumer Project on Technology (CP Tech), Health Action International (HAI) and Oxfam jointly convened a one-day conference in Geneva on the **Implementation of the Doha Declaration on the TRIPS Agreement and Public Health**, with particular emphasis on **"Technical assistance -- How to get it right."** The gathering came on the heels of a World Intellectual Property Organisation (WIPO) Conference on the International Patent System, at which the questions of access to medicines and the suitability of a 'one size fits all' intellectual property model repeatedly arose. The NGO gathering convened over 200 attendees from 38 countries, including representatives from national and regional patent offices, Permanent Missions to the World Trade Organisation (WTO) and WIPO, UN agencies, academia, industry, philanthropy, and non-governmental organisations (NGOs).

The high attendance at the meeting attested to the growing interest in implementation of the Doha Declaration in the health, trade and intellectual property (IP) policy circles. This historic declaration, made at the November 2001 WTO Ministerial Conference, strongly affirmed that the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."[1] The Declaration clearly outlines all the key flexibilities available in TRIPS, including:

- The right of countries to use compulsory licensing and to determine the grounds on which to grant them,
- The right of countries to determine what constitutes a national emergency or urgency, which can ease the granting of compulsory licenses,
- The right of countries to determine their own parallel import regimes, and
- The right of least developed countries to postpone providing pharmaceutical patents until *at least* 2016, and possibly longer.

As this was the first major international gathering of concerned countries and NGOs since the Doha Ministerial, many participants were eager to make progress towards implementing the Declaration, and to assess what role WIPO, as the UN body charged with developing IP systems worldwide, could play in the process. Major themes of the conference included the nature and quality of WIPO's technical assistance to developing countries, what elements were necessary for appropriate technical assistance, how to address the 'production-for-export' question, and putting compulsory licensing into practice.

In the Spotlight: Assessing WIPO's Technical Assistance

A main focus of many of the conference proceedings was the role of WIPO, and the quality and emphasis of its technical assistance. In particular, participants voiced concerns that WIPO's mandate to strengthen IP protection worldwide may not be consistent with the need for more nuanced levels of IP protection that take into account varying stages of economic development and local conditions in developing countries, especially in light of the crisis in access to essential medicines.

Deputy Director General of WIPO Roberto Castelo gave the keynote address, outlining the organisation's mission as mandated by its Member States and its role in providing legal and technical assistance to developing and least-developed countries under the 1995 WIPO/WTO Agreement on the implementation of the TRIPS Agreement. WIPO has now given technical assistance to 134 developing Member States in a "demystified and very transparent way," according to Castelo. Though emphasizing that ongoing talks between WIPO and governments had to be kept confidential due to the wishes of Member States, he assured

[1] Declaration on the TRIPS Agreement and Public Health, World Trade Organization, WTO/MIN(01)/DEC/W/2, 14 November 2001.

the audience that WIPO's legal advice took into consideration all the flexibilities available in TRIPS. Furthermore, in response to concerns that many developing countries lacked in-depth IP expertise and therefore relied heavily on WIPO advice, Castelo remarked that participants should not underestimate the capacity of national IP offices, and reminded the audience that sovereign states – not WIPO – made final legislative decisions, in accordance with their own political and legal considerations.

However, Professor Frederick Abbott, international IP expert and arbitrator for WIPO, underscored the critical role that WIPO plays when he responded that "it is of course no doubt true that WIPO member governments are sovereign states….however, when we provide technical guidance to least developed countries, most of the government officials in those countries are only vaguely familiar with some of the very technical elements of intellectual property law; and WIPO, of course, has an enormous expertise in this area.…the process of providing technical assistance is a give and take, which involves many subtleties and many different levels and layers of communication."

Victor van Spengler, a legal advisor with MSF in Cambodia, asserted that in his experience, WIPO's draft legislation had not in fact taken into account all the flexibilities available in TRIPS. Cambodia does not yet have a patent law, but WIPO is helping them to draft one as a condition of entry to the WTO. van Spengler found that WIPO had not yet informed Cambodia of the Doha Declaration, nor was the government aware that they are not required to grant patents on pharmaceuticals until 2016. van Spengler also read to the audience an example of text given by WIPO to Cambodia, which disallowed parallel imp ortation completely.

In response to an inquiry about a model law for TRIPS implementation in developing countries, Castelo stated that "we cannot have and we do not have a model law" because "our Member States have different legal basics, according to their cultural structures." Castelo explained that WIPO provided working drafts of legislation on an individual basis instead. Nevertheless, there was strong backing among many participants for WIPO to provide something *like a model law* that would include all the flexibilities available under TRIPS. Later in the conference, William Haddad, a representative from the generic pharmaceutical industry, suggested that "we did have a model compulsory licensing law," referring to Canadian legislation that had been "acceptable for decades to brands and generic" before being dismantled under the North American Free Trade Agreement.

Case Study: Bangui 1999

Catherine Gavin, legal advisor to MSF, presented the Bangui Agreement of the African Organisation of Industrial Property (OAPI) as a case study of WIPO technical assistance. The original 1977 Bangui Agreement, which is binding on all 16 West African Member States of OAPI, was revised in 1999 with the participation of WIPO and the French IP office. This process resulted in what Gavin termed "TRIPS plus plus plus" – that is, IP protection that was much stronger than the minimum level required by TRIPS. For example, Bangui '99 allows parallel importing only among Member States, despite the fact that medicines can often be found at lower prices outside the OAPI region. Gavin presented data showing that one tablet of GlaxoSmithKline's Combivir, a one-pill combination of the two antiretrovirals AZT and 3TC, costs US$1.96 in Togo and US$0.94 in Senegal (lowest price within OAPI region), but only US$0.65 in India. TRIPS does not govern countries' use of parallel importation, as was clarified in Paragraph 5(d) of the Doha Declaration. Therefore, Togo should be allowed to import Combivir from India; however, under Bangui '99 it is restricted to importing from Senegal – at a price that is 45% higher than in India. In addition, Bangui '99 does not allow compulsory licensing for imports and has extended patent protection on pharmaceuticals from 10 to 20 years. In this way, it pushed 12 Member States that are considered least-developed countries (LDCs) to comply with TRIPS many years before it is required.[2] At the time Bangui was revised, LDCs had until 2006 to become TRIPS-compliant; Doha granted them a further extension until at least 2016.

Gavin's presentation prompted several audience responses, including a comment from J.N. Mono Ndjana of the IP office in Cameroon, who insisted that her country had been obliged to instate 20-year patents for medicines by the year 2000 – not 2006 or later – and that the OAPI countries themselves, not WIPO, had made the final decisions on Bangui '99. Furthermore, when asked if WIPO would help to adapt Bangui in light of the Doha Declaration, Castelo responded "in my opinion, this is not necessary….It is totally in line with the Doha Declaration. We should not mix the role of the NGO, where you have a different mandate, a

[2] Of the 16 countries of OAPI, Cameroon, the Republic of Congo, Cote d'Ivoire, and Gabon are considered developing countries, and the remaining 12 (Benin, Burkina Faso, Central African Republic, Chad, Guinea-Bissau, Guinea, Equatorial Guinea, Mali, Mauritania, Niger, Senegal, Togo) are considered LDCs.

different mission – with an international organization, where all Member States are represented…We cannot – we do not have the mandate – to go along with what the Secretariat thinks."

Nevertheless, Falou Samb, of the Senegal Mission to the WTO, made a clear request for assistance at the end of the day when he noted that in OAPI countries "we do face legal challenges in our Bangui agreement, revised in '99 and modified to take into account the TRIPS Agreement….What we need to have, first thing, is sample legislation. What we have was drafted before Doha, now we have to shift from a TRIPS-compliant legislation in our countries to a Doha-compliant legislation. That is what we need from technical assistance."

Technical Assistance: What is Needed?

Several other speakers echoed Samb's call for appropriate technical assistance. For example, Ambassador B.G. Chidyausiku of Zimbabwe stated, "the technical assistance that we have received both from the WTO and from WIPO, has been to developing countries: how do you change your legislation, how do you comply with the TRIPS Agreement? But the question we have never asked ourselves is, how can developing countries benefit from the TRIPS Agreement? At this phase, this is what we should be focusing on."

Martin Khor, Director of the Third World Network (TWN), asserted that "we need that kind of technical assistance that is honest, in favor of the poor and for developing countries," and recommended the publication *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options*, by Carlos Correa, which he called "a response to the wrong kind of technical assistance that was going on."[3] Cecilia Oh, also of TWN, perhaps best summarized the concern of many participants when she said, "at the moment, the emphasis of technical assistance is possibly too much on the legal solutions and possibly too much on the obligations of the TRIPS Agreement."

Reacting to these types of concerns, Castelo noted that "WIPO has not received one complaint from a Member State that it has received wrong technical assistance." However, speaking in a personal capacity, Otto Genee of the Netherlands Permanent Mission to the WTO told the audience, "it doesn't surprise me at all. If he gives technical assistance to the patent offices, of course he will not hear complaints – certainly not if he brings computers with him, and hardware, and other nice goodies. Then, of course, you will not bite the hand that feeds you – that is not so strange."

Overall, serious concerns were raised as to whether WIPO's technical assistance was balanced and appropriate. Nevertheless, at the end of the day Mr. James Quashie-Idun, Director of Cooperation for Development at WIPO, affirmed his organisation's commitment to its Member States and declared that "we are going to take fully into account the Doha Declaration in our technical cooperation." Castelo also informed the conference that WIPO was convening a meeting of LDCs in Dar es Salaam in April, where WTO and WHO would be participating, and at which the Doha Declaration and IP would be discussed.

Implementing Doha Provisions

Later discussions focused mainly on the specifics of the Declaration, including how to resolve the 'production-for-export' issue and put compulsory licensing into practice.

Professor Carlos Correa of the University of Buenos Aires, a pre-eminent world expert on IP, pointed out that the 2016 extension for LDCs was in fact a rather negligible concession, since LDCs represent very small markets and the majority of them already offer patent protection for pharmaceuticals. For example, out of the 30 LDCs in sub-Saharan Africa, only Eritrea and Angola do not currently grant such protection.

Not only did LDCs gain little from the 2016 extension, according to Correa, they also face a serious practical hurdle: Article 31.f of the TRIPS Agreement requires compulsory licenses to be used "predominantly for the supply of the domestic market." This clause may restrict developing countries that *do* have domestic drug production capacity (e.g. India) from exporting sufficient quantities of medicines to those that do not (e.g. Togo), making compulsory licensing a meaningless measure for many LDCs. Correa also pointed out that very little capacity exists in developing countries to produce active ingredients (only a few countries, such as China, India, Brazil, and Thailand, have this capacity.) While many more countries have formulation capacity (i.e. producing pills from active ingredients), a 1992 United Nations Industrial Development Organization study indicated that 60 countries do not have the capacity for either active ingredients or

[3]Correa, Carlos. *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options*. (London: Zed Books and Penang: Third World Network, 2000).

formulation. Cognizant of the problem posed by Article 31.f, Paragraph 6 of the Doha Declaration charged the TRIPS Council to "find an expeditious solution" to this issue by the end of 2002.

Several suggestions have been put forth to the TRIPS Council, including proposals from the European Union and a group of developing countries that focus on either Article 30 or Article 31.f. Keeping in mind that the Doha Declaration instructed the Council to find an "expeditious" solution, Correa opined that the Article 31.f solution would be "cumbersome" because it would require an amendment to TRIPS, and/or amendments in the national legislation of the exporting country; it would also require the granting of compulsory licenses in both the exporting and importing countries, and possibly entail double payment of compensation to the patent holder. According to Correa, Article 30, which allows for general exceptions, would be more expeditious although it would still require an "authoritative interpretation" of TRIPS and amendment of national laws in exporting countries. He pointed out that, in any case, most countries would have to amend their domestic legislation in order to take advantage of the Doha Declaration.

Numerous other speakers emphasized the importance of policy and legal changes at the national level. "One of the problems that we face is that developing countries have been rather passive recipients of systems developed elsewhere…. There has been little adaptation of this system to local conditions," explained Pedro Roffe of UNCTAD. Pornchai Danvivathana, of the Thai delegation to the WTO, echoed Roffe's sentiments when he noted that "it is inevitable that we need amendment to our own laws and that would be impossible if legislators do not understand anything about the TRIPS Agreement or what is in fact underlying – the issue of public health."

Finally, Correa reminded the conference that "while diplomats and we lawyers may devise a very nice legal solution, the solution should also be workable in economic terms. Whatever is the approach followed, there must be sufficient incentive for generic companies to supply markets that may need more quantities of a given medicine at a low price." James Love, Director of CP Tech, underscored Correa's point by explaining that in South Korea, where a patient group is currently trying to get a compulsory license for the anti-leukemia drug Gleevec (imatinib mesylate), the relatively small patient population makes it economically impractical to build a factory to produce the drug. Rather, Love argued that South Korea should be able to import the raw material from India or China, thereby benefiting from economies of scale and comparative advantage – two of the most widely-touted benefits of the international trading system.

There was also discussion of technology transfer as a necessary element to build production capacity for a truly sustainable solution. Matthew Kennedy of the IP Division at the WTO informed the conference that, in order to encourage technology transfer more concretely as outlined in Paragraph 7 of the Declaration, developed country Members were obligated to submit reports to the TRIPS Council by the end of 2002 detailing their efforts to create incentives for technology transfers to LDCs.

Practicing Compulsory Licensing

At the opening of the conference, Dr. Bernard Pécoul, Director of the MSF Access to Essential Medicines Campaign, had reminded the audience that it had been exactly three years since nearly the same coalition of NGOs had organized a meeting on compulsory licensing. Since that conference, compulsory licensing has undergone a dramatic transformation: no longer a pariah, compulsory licensing is now considered an important policy tool in top-level policy circles. No developing country has actually yet issued a compulsory license on a pharmaceutical, but the way is open for compulsory licensing to become the rule rather than the exception.

Compulsory licenses are "an integral part of the patent system to ensure some competition," according to Correa. "If these compulsory licenses do not become an integral part of the system, not only developing countries, but also consumers in developed countries will face a very difficult situation." In light of the importance of implementing compulsory licensing, many participants were eager to see how such measures had been put into force in industrialised countries, particularly in the US and UK.

Dominic Keating, the Intellectual Property Attaché to the US Mission to the WTO, outlined the practice of 'government use' in the US, which is a particular form of compulsory licensing. Keating explained that Article 31.b of TRIPS allows governments to grant compulsory licenses for public non-commercial use, without negotiation. In US practice, government officials can authorize third-party use of a patent without previous negotiation, and patent owners may only sue for "recovery of reasonable and entire compensation" –

they cannot sue to overturn the use of the patent itself.[4] Though government use in the US is common practice, Keating cited a US Supreme Court decision describing the actual use of compulsory licenses as "a rarity." However, others pointed out that it was the credible threat of their use that made them effective, as in the case of Brazil and its negotiations with Merck over antiretrovirals, and the US government with Bayer over ciprofloxacin.

Christopher Garrison, legal advisor to MSF, presented similar measures for protecting the public interest in the UK 'Crown Use' provisions (akin to 'government use'). This legislation allows "any government department, or any person authorised in writing by a government department" to grant the right to use a patent, including "for the production or supply of specified drugs or medicines."[5] The law specifies that such use would not be considered patent infringement. Garrison described a case in 1965 in which the UK exercised the Crown Use provisions to import a generic version of tetracycline from Italy to supply the National Health Service after the patent holder Pfizer had demanded too high a price.[6] Garrison concluded that "the public health of the UK is safeguarded by the '800 pound gorilla' Crown Use powers, which have been used when thought necessary."

From the industry perspective, however, "compulsory licensing is not needed to improve access to quality essential drugs healthcare," according to Dr. Eric Noehrenberg of the International Federation of Pharmaceutical Manufacturers Associations, who had been asked to address the question of compensation models for compulsory licensing. "This debate about compulsory licensing is simply a dead end and discussing about compensation models is truly a non-issue." Noehrenberg instead asked participants to "encourage the governments to take up the offers made by my companies" such as drug donations and discounted pricing.

Nevertheless, Love presented several possible models for compensation to patent holders under compulsory licensing, including a 1917 case in which the US government had created a patent pool in order to circumvent the behavior of two firms that were blocking the use of patents needed to build airplanes for use in World War I. The government had paid patent-holders compensation of about 1% of the market value of the good, which was later reduced to about 0.5%.[7] Love proposed the creation of a similar non-voluntary patent pool for inventions to address essential public health needs, asserting that "Anyone who wanted to show a little leadership could get this show going on the ground, like FDR did in 1917 when the US was faced with a war."[8] Finally, Love presented administrative models that could streamline the compulsory licensing procedure so that it would be fast, simple, and clear.

Another key issue was the spectre of long, expensive legal challenges brought by patent holders if a country attempted to issue a compulsory license. Dr. Christian Wichard of the WIPO Arbitration and Mediation Centre addressed this concern by presenting an alternative process for the adjudication of IP disputes. Wichard described the Alternative Dispute Resolution (ADR) procedure at WIPO, and particularly the successful Internet domain-name dispute resolution process. This process is binding on parties and has successfully settled 90% of cases brought before it, taking an average of two months' time and costing the complainant only US$1500. Wichard felt that ADR would have limited applicability to patent infringement cases since participation was voluntary, but said it might be useful to settle questions of compensation to patent-holders. However, Abbott countered that national governments could make submitting to an ADR process a pre-condition for receiving a patent, and that ADR demonstrated that "one does not need to view legal proceedings as very time-extended, complex, procedural mechanisms." Abbott also saw WIPO's success with domain name disputes as evidence that "there are shorter, simpler ways to adjudicate issues like compulsory licensing. It's possible with political will from WIPO."

The examples provided of compulsory licensing in industrialised countries can inform the efforts of developing countries as they develop their legislation. Ambassador Chidyausiku pointed out, "There is much

[4] See 28 USC 1498
[5] s.55(1) 1977 Act
[6] Pfizer v. MoH 1965 RPC 261 (HL)
[7] The 1% royalty was a payment of $200 on an airplane valued at $20,000. The US government later reduced this payment to $100. (For more on patent pools, see http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf)
[8] FDR stands for Franklin Delano Roosevelt, then Assistant Secretary of the Navy, and later to become President of the United States.

we can learn from countries like the US, where there are useful provisions for broad powers for the US government to exploit compulsory licenses for public benefit…. we can pick a leaf from their experience and see how we can translate this into our particular situation." Dr. Pécoul noted that three years ago, a participant at the compulsory licensing meeting had said, "as a public health worker in the developing world, I feel I am being told 'do what we say, not what we do.'" However, at the conclusion of this meeting, Khor captured the change of mood that had since taken place, when he asked rhetorically, "would the US allow other countries to learn from your experience and do the same thing?"

Conclusions

The gathering revealed much enthusiasm among developing countries for implementing the Doha Declaration in order to improve access to essential medicines for some of the world's poorest people. Technical assistance from WIPO will be a critical element in making this happen. However, serious questions were raised as to whether WIPO's previous technical advice had over-emphasised countries' *obligations* under TRIPS, often at the cost of their rights and interests. Nevertheless, concrete proposals for taking advantage of the Doha Declaration emerged at the conference, including ways to put compulsory licensing into practice and examples of possible model legislation from other countries. It was clear from the broad range of conference participants that intellectual property rights are increasingly of concern – not only to IP specialists – but also to policymakers involved in health, development and trade. This growing interest suggests that critical attention will be trained, not only on the WTO or WHO, but, in the words of Ellen 't Hoen of MSF, "the spotlight is now shifting toward WIPO."[9]

"The question is now, how do we make it effective? How do we make it deliver the medicines to the people? How do we avoid this declaration ending up as a dead letter?"
–Ambassador B.G. Chidyausiku, Zimbabwe, on the Doha Declaration

by Suerie Moon, Médecins Sans Frontières

[9] See Médecins sans Frontières (MSF) Comments on the WIPO Patent Agenda http://patentagenda.wipo.int/rfc/rfc1/0025.html