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AFRICA REGIONAL WORKSHOP ON WTO NEGOTIATIONS

31 August – 2 September 2005

Cape Town, South Africa

Trade Brief

WTO Negotiations on Intellectual Property

Implications for Developing Countries Moving Into Hong Kong

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HOSTED BY TRALAC AND COMMONWEALTH SECRETARIAT

Table of Contents

1 Introduction: A history of the TRIPs Agreement

For an agreement which was initiated as a response to developed country dissatisfaction with the inadequate protection afforded to technological inventions by World Intellectual Property Organization (WIPO)[1] treaties, the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) has come a very long way. The introduction of intellectual property into the realms of the WTO has been mired in controversy well before the launching of the Uruguay round of negotiations in 1986. Developing countries and Least Developed Countries (LDCs) at the time, were insistent that they were not ready to enter into commitments around intellectual property because there had not been enough reseach conducted into whether or not a regime of stringent intellectual property protection would be beneficial or detrimental to the interests of developing contries. Two decades later, the debate as to whether stringent intellectual property protection assists or hinders the interests of developing countries remains an unconcluded one.[2]

The TRIPs Agreement is the most comprehensive multilateral agreement on Intellectual property (IP) yet cocuuded and its area of substantive application includes copyrights, trade marks, geographical indications, industrial designs, layout designs of integrated circuits, patents as well as related issues such as technology transfer and technical assistance. The TRIPs Agreement is meant to provide a minimum standard of protection with countries opting to provide more stringent protection in municipal law.[3] Although all of the various substantive areas covered by the TRIPs Agreement are important to developing countries, the most contentious for African countries to date have been issues around patents and traditional knowledge. Issues around copyright have become more contentious in recent times, more partuularly as they pertain to

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1 See page 3 of the UNCTAD-ICTSD "Resource Book on TRIPs and Development", Cambridge University Press, 2005, available online at: http://www.iprsonline.org/unctadictsd/docs/RB_%20part1.1_corrected_update.pdf

2 See for instance the divergence of views on the topic based on studies conducted by various experts and stakeholders for the World Health Organization's Commission on Intellectual Property Rights and Public Health (CIPH), available online at: http://www.who.int/intellectualproperty/studies/en/

3 This is an option that has been taken up by a hand full of developed countries.

access to learning materials. However, the most controversial aspect of the TRIPS agreement for developing countries in general and the Africa Group in particcular remains the public health dimension.

The final text of the agreement was generally regarded as a delicate balance between protecting the rights of innovators against piracy, thereby encouraging further innovation on the one hand, and the rights of (particularly developing country) consumers who, very often, were not in a position to afford product prices being demanded by patent holders. It is with this in mind that a number of safeguards and flexibilities were inserted into the agreement as a way of achieving the balance between the innovator's rights and the conumer's interests. These safeguards include compulsory lincesing, parallel importation, the early working/bolar exception and more ambiguous exceptions allowing for the divergence from TRIPs provisions in the event of public interest concerns, non commercial public use national security and a host of simialr reasons. Article 30 alone, by virtue of its broad application could be the conduit for a vast network of exceptions. It prodives that::

"*Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.*"

From the entry into force of the TRIPs Agreement in 1995 until the Doha Ministerial Meeting in November 2001, there remained a marked difference in opinion between developed and developing countries over the use of flexibilities and safeguards contained in the agreement which would allow signatories of the agreement to continue to pursue sustainable development objectives. A prime example of the level of disagreement that existed is illustrated by the complaint brought before the Dispute Settlement Body (DSB) of the WTO by the United States (US) against Brazil due to a

dispute which arose over a provision of Brazilian law [4] which was only dropped after the countries reached an agreement amid massive local and international lobbying pressure against brand name pharmaceutical companies.[5]

The TRIPs Agreement has become one of the most poignant examples of the complexities that accompany Special and Differential (S&D) Treatment for developing countries and LDCs. S&D provisions such as extended grace periods by which TRIPs compliance must be achieved, or the 20 year exemption in respect of pharmaceutical patents granted to LDCs are meant to create policy space and to prevent detrimental consequences to a country's development such as the inability to afford essential medicines necessary to combat diseases that are endemic in parts of the developing world. Yet, practice shows that these S&D provisions are seldom used by developing countries without acrimonious debate as to the policy space created by the provisions of the TRIPs Agreement.

2 The Doha Declaration on TRIPs and Public Health and the 30 August 2003 Agreement [6]

There are several reasons cited by health authorities for the slow uptake of antiretroviral (ARV) drugs and other essential medicines for tuberculosis and malaria, ranging from the stigma still associated with HIV/AIDS, ineffective health care delivery systems, a lack of qualified health care practitioners, and the un-affordability of essential medicines,

4 More particularly, Article 68(1) of the Brazilian Patent Law which provides that which provides that if a patented product is not manufactured in Brazil within three years of the issuance of the patent, the Brazilian government can compel the patent holder to license a competitor.

5 Refer to "United States Drops WTO Case Against Brazil Over HIV/AIDS Patent Law" (June 26, 2001). Copyright 2001 by The Bureau of National Affairs, Inc. online report of the dispute is available online at: http://www.cptech.org/ip/health/c/brazil/bna06262001.html

6 Section two of this paper draws heavily from a previous **tralac** Trade Brief entitled "TRIPs and Public Health: The Unresolved Debate" , Trade Brief 2/June 2005 available online at: http://www.tralac.org/scripts/content.php?id=3716

especially where there are no generic equivalents. Furthermore, the cost of essential medicines remains out of the reach of most developing country residents. The drastic decline of the price of ARVs over the past few years is attributable to a number of factors, such as the now famous case of the Pharmaceutical Manufacturers' Association v The President of the Republic of South Africa[7], the decision of the Brazilian government to threaten to issue compulsory licenses in the event that negotiations for licenses with brand name pharmaceutical companies were unsuccessful, generous donations of ARVs by pharmaceutical companies often brokered by philanthropic organizations and the ability of countries like India to continue producing generic versions of brand name drugs without complying to the TRIPs Agreement.

The other important factor relates to developments at the WTO since the landmark Doha declaration on TRIPs and Public Health, which in some ways was a very significant turning point for developing countries in negotiations on the topic. The declaration clarified, once and for all, the increasingly dogged debate around the ability of developing countries to issue compulsory licenses where necessary, in the interests of public health. The Declaration on TRIPs and Public Health again re-iterated the entitlement of countries to take what ever steps were necessary if in the public interests of their citizens. Paragraph 4 of the Declaration read as follows:

"*We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement 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.*" [8]

7 On 30 October 1997, the South African Parliament passed the Medicines Control and Related Substances Amendment Act 90 of 1997, which contained provisions including Section 15C which appeared to allow a Minister of State, discretionary powers to parallel import essential medicines from countries where the patented drug was available at a more affordable rate. As a response, the Pharmaceutical Manufacturers' Association (PMA) lodged a court application to prevent the Act coming into operation *inter alia*, because of what it perceived to be the unfair wide-ranging powers which could be improperly used. After intense domestic and international lobbying, the PMA withdrew its application. The withdrawal of the case opened the door for generic drug companies to negotiate voluntary licenses in South Africa for ARVs.

8 See WT/MIN(01)DEC/2. The complete Declaration is available electronically at: http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.doc

While this was a significant step, the reality remained that most African countries do not have sufficient drug manufacturing capacity to produce sufficient enough essential medicines for their populations. The matter of options available for countries with no or insufficient manufacturing capacity was referred to the TRIPs Council for further negotiations and a solution. For that reason, a deadline was set for the end of 2002 by which a solution for countries with no or insufficient manufacturing capacity were able to access essential medicines. The now infamous paragraph 6 of the Declaration read as follows:

" We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002."

After protracted and often acrimonious negotiations with several self imposed deadlines missed at the TRIPs Council, the 30 August WTO General Council Decision[9] was announced a few days before the Cancun Ministerial meeting. The Decision constitutes a waiver of the requirement contained under Article 31(f) of TRIPs that production of pharmaceuticals produced under compulsory license must be predominantly for the domestic market. This expressly allows developing countries with no or insufficient manufacturing capacity to import generics produced under compulsory license subject to the compliance with a number of rather complicated technical requirements such as providing notification on the specific drugs and the exact quantity needed; arranging for different physical specifications for medication that was to be consumed in these countries; and implementing measures to prevent re-exportation of drugs meant for developing countries to more lucrative markets.

Whilst initially, there was great hope for the operation of the Decision with the Director General being quoted as saying:

9 WT/GC/M/82. The Decision is available online in its entirety at: http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm

"*The final piece of the jigsaw has fallen into place, allowing poorer countries to make full use of the flexibilities in the WTO's intellectual property rules in order to deal with the diseases that ravage their people*."

Regrettably, the 30 August mechanism has not been used by a single WTO member to date, with the reasons for its non-use including:

a) The administratively cumbersome procedures and requirements leading to a practically unworkable solution, more so for developing countries;

b) Fears at a local level that the issuing of compulsory licenses might have an adverse impact on foreign direct investment (FDI) or even on donor aid; and

c) The lack of capacity at a domestic level to completely comply with the 30 August Decision. As a practical example, a number of countries have expressed doubts about the ability of customs officials to prevent re-exportation.

There is also a great deal of debate and controversy over the role of the Chairman's statement which was read together with the decision. The Chairman's statement contains a number of additional pre-conditions which are not contained in the 30 August Agreement. Developing countries have continued to argue vehemently that the chairman's statement does not constitute part of the 30 August Decision while developed countries insist that the Chairman's statement not only should be read as a contextual guide to the Decision, but should also be incorporated into any permanent solution that is reached by the parties (as the Decision is regarded as a temporary waiver).

3 Article 27.3(b) and Traditional Knowledge

Article 27 of the TRIPS Agreement defines which inventions governments are obliged to make eligible for patenting, and what they can exclude from patenting. Inventions that can be patented include both products and processes, and they generally cover all fields of technology. The TRIPs Agreement requires a review of Article 27.3(b) and this

is currently taking place. There are four primary issues of contention at the TRIPs Council at present:

a) How to apply the existing TRIPS provisions on patenting biotechnological inventions and whether at all, life forms should be patentable;

b) The meaning of effective "*sui generis*" protection for new plant varieties (i.e. alternatives to patenting such as the 1978 and 1991 versions of the UPOV convention);

c) How to deal with traditional knowledge, folklore and genetic material, and the rights of the communities where these originate. Central to this question is how to prevent improper patents from being granted and to what extent existing TRIPs provisions can be used to protect traditional knowledge and folklore; and

d) How to implement the TRIPs Agreement and the Convention on Biological Diversity (CBD), whether patent applications should have to disclose the source of the traditional knowledge or genetic material and possible methods of sharing benefits with local communities when inventors in other countries have rights to inventions based on material obtained from the locality

The two most fiercely argued points as far as developing countries in general and the Africa group in particular are concerned, are over the issues of 'disclosure of origin' and the patenting of life forms and '*sui generis*' protection to be afforded to plant varieties in order to protect the interests of local farmers. Developing countries have been lobbying for a disclosure of origin so that patent applicants are required to disclose the country of origin of the biological resources and traditional knowledge used in the inventions as well as proof that the patent applicant received "prior informed consent." The patent applicant should also be able to prove that there is some benefit sharing taking place. While issues around the patenting of life forms and traditional knowledge have been placed on the negotiating agenda through Paragraph 19 of the Doha Declaration, the relevant portions of which read as follows:

" *We instruct the Council for TRIPS, in pursuing its work program including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement*

under Article 71.1 and the work foreseen pursuant to paragraph 12 of this declaration, 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. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension."

The pace of negotiations has been frustratingly slow exacerbated by the different for a (WIPO and the CBD) where the interlinked matters are being discussed.

4 The emergence of 'TRIPs Plus' Provisions in bilateral Trade agreements

There has been a marked shift in the negotiation priorities and tactics of both the US and EU in recent years, more so after the failed Seattle Ministerial of 1999. The EU is in the process of concluding a number of economic Partnership Agreements (EPAs) with the African, Caribbean and Pacific (ACP) countries while the European Free Trade Association (EFTA) is in the process of concluding an FTA with the Southern African Customs Union (SACU) members[10] The US has already concluded Free Trade Agreement (FTA) negotiations with Morocco and has been involved in negotiations with SACU since July 2003. The subject matter of most bilateral trade agreements freely extends beyond the traditional trade negotiating agenda of the WTO and encompasses the so-called 'new generation' trade policy issues.

The US in particular, has been able to obtain bilateral concessions that appear to extend well beyond the pace of the negotiations taking place at the TRIPs Council and which may prove to be contrary to both the Doha Declaration on TRIPs and Public

10 The SACU countries comprise of Botswana, Lesotho, Namibia, South Africa and Swaziland.

Health as well as the 30 August Decision. Specific official objectives of the US include the establishing of standards in SACU similar to those contained in domestic US provisions as well as those found in the Patent Co-operation Treaty, the Copyright Treaty and the Phonograms Treaty of WIPO. Other stated objectives include the obtaining of commitments from SACU countries to strengthen their domestic enforcement procedures as compensation measures of right holders for infringements of intellectual property rights and to provide for criminal penalties under the laws of SACU countries that are sufficient to have a deterrent effect on piracy and counterfeiting.[11]

On the basis of concerns raised during the Free Trade Area of the Americas (FTAA) negotiations[12], some of the more damaging 'TRIPs plus' provisions that may find their way into the text of a bilateral FTA involving the US:

a) A limitation on the circumstances under which compulsory licenses on pharmaceutical patents may be issued by individual SACU governments;
b) Extending the minimum period of patent protection to beyond the 20-year requirement of TRIPs consequently delaying the introduction of generic pharmaceuticals;
c) A new responsibility given to drug regulatory authorities (most of whom have a limited expertise of patents) to consider the patent status of drugs before granting marketing authorization to manufacturers of generics;
d) The limiting of data on pharmaceutical tests to drug regulating authorities, which generic companies traditionally rely on to prove the efficacy and safety of their products; and
e) The potential restriction of parallel imports to limited geographical configurations which may prevent SACU countries from sourcing generics from the cheapest global supplier.[13]

11 Refer to the letter sent to Senate.

12 As raised in a 'Doctors without borders' document accessible at: http://www.doctorswithoutborders.org/publications/reports/2003/FTAA_Advocacy.pdf

13 For an authoritative discussion on the emergence of TRIPs plus provisions in bilateral negotiations and the implications for public health, see Abbott, Frederick, 2004. 'The Doha Declaration on the TRIPs Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements'. Occasional Paper 14, Quaker United Nations Office available at: http://www.geneva.quno.info/pdf/OP14Abbottfinal.pdf

Recent reports are that after several months of stalled discussions over issues including intellectual property, the negotiations are likely to be re-started in the second half of September 2005.[14] Another potential impact of the FTA is that it would see Lesotho losing the important waiver granted to LDCs of not having to comply with the provisions of TRIPs until 2016, in violation of Paragraph 7 of the Doha Declaration on TRIPs and Public Health.

5 Outstanding issues going into Hong Kong

Developments in negotiations at the TRIPs Council have been stalled in the past few months primarily because of the interlinked nature of the negotiations. There are now recent signs that there may be concessions granted on the issue of geographical indications (a sensitive priority area for the EU) in exchange for concessions on agriculture. However, recent attempts by a host of developing countries to have the important issue of the link between the TRIPs Agreement and the CBD brought into the negotiation framework for Hong Kong appeared to have been largely unsuccessful. So while the issue of a registry for Geographical Indications (GIs) is currently on the negotiation table, the issue of disclosure of origin is accorded corresponding importance on the negotiation table. The disclosure of origin issue has been extensively debated in recent months, with new papers submitted to the June meeting of the TRIPS Council. Sources have been quoted as saying that they expect a positive outcome in line with the Doha Agenda. There also appears to be a growing feeling that the forum where the debate is most advanced is at the WTO. While consensus is still far from being reached over the disclosure of origin issue, indications are that the matter is open for discussion by the various negotiating parties

On intellectual property and public health issues, several problems remain with the 30 August Agreement. First and foremost, the notification mechanism (perhaps for reasons mentioned earlier) remains unused by developing countries. While there is no doubt that

14 http://bilaterals.org/article.php3?id_article=2526

the mere existence of the declaration has led to decreased prices for essential medicines, it is clearly too cumbersome to be regularly used. While negotiations for a permanent solution continue, it remains extremely important that the permanent solution be made more workable. The validity of the chairman's statement remains a bone of serious contention between developed and developing countries. The Chairman's statement was meant to be a way of consoling developed countries that were concerned that the decision might end up being abused to produce essential medicines for commercial use. Now, the real possibility exists that the statement will be incorporated into a permanent solution which would result in an even more unworkable mechanism as far as developing countries are concerned. Despite extended consultations throughout July with the various parties, TRIPs Council Chairman and Korean Ambassador Choi Hyuck, was unable to obtain a breakthrough of the deadlock. A deadline has been set for the next TRIPs Council meeting on 25 and 26 October and it remains to be seen whether a break though will be achieved just before the Hong Kong ministerial as was the case before Cancun, or whether the public health debate will once again, play a role in the outcome of another Ministerial Meeting.

6 Bibliography

1 WTO website on TRIPs and Public Health:

URL: http://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm

2 Carlos Correa, 'Establishing a Disclosure of Origin Obligation in the TRIPs Agreement, Ouaker United Nations Office Occasional Paper 12, August 2003

URL: http://www.geneva.quno.info/pdf/Disclosure%20OP%2012.pdf

3 Fredrick Abbott 'The Rule of Law and the problem of asymmetric Risks in TRIPs', Bridges Monthly Report, September- October 2003

URL: http://www.ictsd.org/monthly/bridges/BRIDGES7-7.pdf

4 William New, 'Push For IP Deals Continues In Lead-Up To WTO Ministerial' IP-Watch, 9 August 2005

URL: http://www.ip-watch.org/weblog/index.php?p=86&res=1280&print=0

5 CP-Tech, "statement of dispute between the US and Brazil" February 2001

http://www.cptech.org/ip/health/c/brazil/CPTstatement.html

6 Abbot, Frederick M. 2004 The Doha Declaration on the TRIPs Agreement and Public Health and the contradictory trend in bilateral and regional free trade agreements. Occasional Paper 14, Quaker United Nations Office. (online). http://www.geneva.quno.info/pdf/OP14Abbottfinal.pdf