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ASSESSING THE CONTRIBUTIONS OF THE EC AT THE WTO IN FACILITATING ACCESS TO
AFFORDABLE HIV/AIDS MEDICINES IN AFRICA

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1 Introduction

The Acquired Immune Deficiency Syndrome (AIDS) is one of the most compelling public health crises of modern times and the long term evolution of the epidemic remains uncertain. This is because there is no cure for the malady. Many people are living with HIV/AIDS. At the end of 2007, they were an estimated at 33.2 million.¹ The number of people with HIV has continued to rise with Africa remaining the global epicentre.² Vulnerable groups have been hardest hit by the epidemic. 75 per cent of young women aged between 15-24 years live with HIV/AIDS in sub-Saharan Africa and this trend is on the rise in other regions where females represent an increasing proportion of people with HIV/AIDS.³ HIV/AIDS related diseases account for 500 million or more illnesses and 6 million deaths every year. Furthermore, the incidence of HIV/AIDS is disproportionately high among groups that already suffer from a lack of human rights protection and who also experience discrimination which is widely criminalised.⁴

Although it is evident that HIV/AIDS has reached endemic proportions, there is no binding international legal framework on HIV/AIDS specifically. The right to health has however been dealt with extensively in International jurisprudence.⁵ In order to achieve the highest attainable standard of health countries must ensure the prevention, treatment and control of epidemic, endemic occupational and other diseases.⁶ In April 2001, the African Union met to discuss the challenges of the AIDS scourge on the African continent. This led to HIV/AIDS being categorised as a “State of Emergency” in Africa. The efforts led to the Abuja Declaration on HIV/AIDS, Tuberculosis and other infectious diseases.⁷ In addition, in 2001, the World Health Organisation (WHO) adopted Resolution WHA 10, urging member states to make every effort to provide the highest standard of treatment for HIV/AIDS in a progressive and sustainable manner.⁸

On its part, the United Nations (UN) General Assembly has issued two declarations on HIV/AIDS. The first in 2001 gave rise to the Global Fund to Fight AIDS, Tuberculosis and Malaria in 2002. The second declaration issued in 2006 reaffirmed the commitments made in the first

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¹ UNAIDS, UNAIDS REPORT ON THE GLOBAL AIDS PANDEMIC 6 (2007).

² *Id.*

³ Global Fund, The Status and Impact of the three diseases, at <<http://www.theglobalfund.org/EN>> (Accessed on 20 August 2006).

⁴ There are high levels of the criminalization of drug use, sex work and homosexuality. The criminalization of these various aspects has contrived to drive the practices underground and to increase the infection rate amongst these marginalized groups. See Mindy Jane Roseman and Sofia Gruskin, *HIV/AIDS and Human Rights in a nutshell*, Program in International Health and Human Rights, Francois Xavier Bagnoud Centre for Health and Human Rights: Harvard School of Public Health and International Council for AIDS Service Organizations.

⁵ See Article 25 of the Universal Declaration of Human Rights (1948) Article 12 of the International Covenant on Economic, Social and Cultural Rights (1966) Also see General Comment No 14 Of the Committee on Economic Social and Cultural Rights.

⁶ See Article 12 of the International Covenant on Economic Social and Cultural Rights (1966)

⁷ See Abuja Declaration at <http://www.rbm.who.int/docs/abuja_declaration.pdf>

⁸ See the 54th World Health Assembly Agenda Item 13.6 Scaling Up the Response to HIV/AIDS WHA54.10, 21 May 2001.

declaration and encouraged the approach of prevention, treatment, care and support which included the removal of barriers on access to essential medicines.⁹ Although declarations of the United Nations are not legally binding documents they represent clear statements by governments on what they have agreed should be done to address HIV/AIDS.

The major specific guidelines on UN Resolutions have dealt extensively with access to medicines for people afflicted by the HIV/AIDS scourge. This is because people living with HIV/AIDS need access to essential medicines¹⁰ in order to survive. The medicines are commonly known as Anti Retroviral medicines (ARVs). There are a variety of ARVs and each serves a specific purpose. For instance, some of the drugs prevent or defer the replication of the virus in the host's body. Antiretroviral treatment is the difference between life and death for the millions of people who are HIV positive.¹¹ Although millions of people who live with HIV/AIDS in developing countries need immediate access to affordable antiretroviral medicines, the majority of them especially those in Africa are living and dying without medicines that have dramatically extended lives in the USA and Europe.¹² The HIV/AIDS pandemic has garnered a lot of attention as a result of the fact that many developing countries cannot afford expensive ARVs. In addition their frustration is further compounded by the fact that they can not produce cheaper generic versions.¹³

The problems that poor countries face in terms of access to medicines are often blamed on the World Trade Organization rules on intellectual property rights or TRIPS. The TRIPS Agreement that was endorsed in 1995 covers basic principles, standards on the use of patent enforcement and the dispute settlement mechanism in an event of irreconcilable differences.¹⁴ It has always been fraught with implementation problems due to the inherent tensions between the holders of Intellectual Property rights (IPRs) and the majority of member states that seek to use patented medicines¹⁵ to combat ongoing epidemics such as HIV/AIDS. This apparent décalage of interests has always created an enormous North-South chasm because the major holders of patent rights come from the industrialised North while on the other hand the greatest numbers of victims come from the less developed South.¹⁶ The two sides have differing interests. While the South needs access to affordable life saving medicines, the North's interests are more focused on the profitable proprietary pharmaceutical companies¹⁷ that research develop and produce patented medicines.¹⁸

⁹ Political Declaration on HIV/AIDS 60/262 Resolution adopted by the UN General Assembly 15 June 2006 at <<http://data.unaids.org/pub/Report/2006>> (Accessed on the 20 August 2006).

¹⁰ Essential Medicines are those that satisfy the priority needs of the population. From a public health perspective access to essential drugs depends on a rational selection and use of medicines, sustainable financing, affordable supply systems and reliable health systems. For more on essential medicines especially in relation with HIV/AIDS see Technical Cooperation Activities Information from Intergovernmental organizations. WHO Doc IP/C/W/305/Add3 at <<http://www.who.int/medicines/organisationood/techcoo.shtml>> (Accessed 12 June 2006).

¹¹ Since April 2002, the WHO has recognized ARV drugs as essential medicines. WHO, *12 Model list of Essential Medicines* (April 2002).

¹² Six Million people living with HIV/AIDS in developing countries need immediate access to affordable medicines or they will die within 2 years. WHO, *A Commitment to Expanded Access to HIV/AIDS Treatment*, 1 <http://www.who.int/hiv/pub/arv/who_hiv_2002_24.pdf> (December 2002). See Jane Glavao, *Access to antiretrovirals in Brazil* <<http://image.thelancet.com/extras/01art9038web.pdf>> (5 November 2002).

¹³ A generic drug is a pharmaceutical product intended to be biologically equivalent with an originally patented product. It is often manufactured without a license from the originator company. Source: Websters Medical Dictionary (2005). See also, Oxfam International, *TRIPS and Public Health: The Next Battle* (2002).

¹⁴ WTO, *Overview of the TRIPS Agreement*, A more detailed overview of the TRIPS Agreement available at <http://wto.org/english/tratop_e/trips/e/intel_ehtml> (Accessed 20 August 2006).

¹⁵ A patent is an exclusive right granted for an invention which is a product or process that provides a new way of doing things.

¹⁶ Philip McCalman, *The Doha Agenda and Intellectual Property Rights*, A study on Regional Integration and Trade: Emerging Policy Issues for Selected Developing Member Countries 2-4 (October 2002).

¹⁷ Pharmaceuticals have been consistently ranked as the most profitable sector in the Fortune 500 rankings for the past 3 decades. The top ten US drug makers increased their profits by 32 per cent from 38 billion dollars in 2000 to 37 billion dollars in 2001. See Scott Gottlieb, *Drug Companies Maintain Astounding Profits*, 324 BRITISH MEDICAL JOURNAL 1054 (4 May 2002)

The patent system is built on the premise that patents provide an incentive for innovation by offering the patent holder an exclusive right to exclude others from using the patented product without the consent of the patent owner. With the absence of competition, the patentee is able to set higher prices during the period of protection usually pegged at 20 years. Although these tensions existed at the signing of the TRIPS Agreement, they were brought to the forefront by the HIV/AIDS epidemic in the 2000/2001.

This paper discusses some of the major contributions that have been made by the European Community in promoting access to affordable medicines, *a fortiori*, HIV/AIDS medicines in Africa. It examines some of the contributions that have had a positive impact for access for African countries (2). In addition it treats some of the positions that have been adopted over the years by the EC that could have been detrimental for poor countries in accessing cheap medicines (3). A number of conclusions follow (4).

2 Positive Aspects of EC Actions at the WTO Level

The EC has been engaged in a number of positive actions related to intellectual property (IP) that have an impact on the public health concerns of developing countries and LDCs. Its backing of the Doha Declaration statement on public health and its support for the changes that culminated in the amendment of the TRIPs Agreement in 2005 are some of the contributions worth mentioning. Other important actions of the EC have involved efforts to fight counterfeit products including pharmaceutical products. In addition, its backing for a differential pricing system for pharmaceutical products for poorer countries has been an innovative approach. It also supported the use of compulsory licensing for those countries that find it necessary to use the same for their public health exigencies. What is more, its technical cooperation contributions for developing states and LDCs in the field of intellectual property rights (IPRs) have been commendable. Finally, the Community's stances on trade diversion as well as its backing for regional integration on patent related issues are some of the steps that have positive fallouts for poorer countries. These various elements are now addressed one apiece.

2.1 EC support for the adoption of the Doha Declaration

The Doha Declaration was the outcome of the WTO Ministerial Meeting that was held in the United Arab Emirates (UAE) in November 2001.¹⁹ The Declaration contained specific statements on various issues. One of such issues with a separate declaration was the Declaration on the TRIPs Agreement and Public Health (DTAPH).²⁰ The DTAPH was the culmination of discussions that had been started within the TRIPs Council by the African Group. The spokesperson for the Group at the time was the representative of Zimbabwe (Ambassador Boniface Chidyausiku) who also doubled as Chair of the TRIPs Council.²¹ The EC²² and Brazil (acting on behalf of many developing countries and LDCs)²³ had also submitted important documents on the issue prior to the June 2001 Council meeting. Zimbabwe and many third world countries were of the opinion that “the Ministerial Conference in Qatar in November 2001, will be an opportunity to demonstrate Members’ commitment and contribution to preventing further deaths and saving lives through

¹⁸ Brook Baker, *Analysis and Response to WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health*, United Nations Millennium Goals Project Task Force 5: *Infectious Diseases and Access to Essential Medicines*, Sub Group Access to Essential Medicines (2003).

¹⁹ Ministerial Conference, Fourth Session, Doha, 9-14 November 2001, Adopted on 14 November 2001.

²⁰ Declaration on the TRIPs Agreement and Public Health, WT/MIN(01)/DEC/2, adopted on 14 November 2001.

²¹ Council for TRIPs, Special Discussion on Intellectual Property and Access to Medicines, IP/C/M/31, 18-22 June 2001.

²² IP/C/W/280.

²³ IP/C/W/296.

facilitating easier access to medicines at affordable prices.”²⁴ The sub-stratum of its proposal was that “Members issue a special declaration on the TRIPs Agreement and access to medicines at the Ministerial Conference in Qatar, affirming that nothing in the TRIPs Agreement should prevent Members from taking measures to protect public health.”²⁵ Zimbabwe recalled the plight of the young South African (Nkosi Johnson); the situation of the 11 million preventable deaths each year and the scourge of HIV/AIDS in developing countries. It demanded a) an extension for the transition period for developing countries respecting patent protection; b) the adoption of a moratorium on dispute settlement to allow Members to adopt measures that are protective of public health; and c) the placing of a moratorium on dispute settlement specifically on developing countries that take action to promote public health.²⁶ The EC was quite supportive of the move and referred to its efforts made to address the problem of public health concerns in third world countries. These mainly included actions within the framework of the G7, the Round Table and Action Plan of 2000 and its partnership with the WHO. In addition, it reiterated the significance of a European Council Resolution of 14 May 2001 that stressed the elements of affordability, research and development.²⁷

The discussions all led to the adoption of the special declaration on public health as had been requested by Zimbabwe. The declaration contained 7 paragraphs. Paragraph 1 restated the broad awareness of the issue by the Members: “We recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.”²⁸ The Ministers were quite keen to stress the fact that the TRIPs Agreement should be regarded as being part of the solution to the issue. Members were equally cognizant of the importance of maintaining the famous balance that goes to the very heart of the IP system: “We recognize,” they affirmed, “that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.”²⁹

The very core of the Zimbabwean proposal was contained in paragraph 4 which was basically a recognition that the “TRIPs Agreement does not and should not prevent Members from taking measures to protect public health ... [It] 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.”

A clear commitment was also made in terms of allowing countries in need to use compulsory licenses as deemed appropriate.³⁰ In a significant way, the Members also noted that states will reserve the right to determine what constitutes a national emergency or case of extreme urgency with the understanding the diseases such as HIV/AIDS, tuberculosis, malaria and other epidemics may come under such a narrow category.³¹ They also reiterated the spirit of Article 6 of the TRIPs Agreement the purport of which is to allow the state the right to determine the nature of the exhaustion of IPRs which they judge convenient for their systems.³²

In one of the statements, the Members also emphasized the need for technical cooperation to be fostered and that developed countries should assist LDCs with regard to technology transfer.

²⁴ IP/C/M/31, ¶¶ 2 and 3.

²⁵ *Id.*

²⁶ *Id.*, at 6.

²⁷ *Id.*, at 7.

²⁸ DTAPH, ¶ 1.

²⁹ DTAPH, ¶ 3.

³⁰ *Id.*, ¶ 5(b).

³¹ *Id.*, ¶ 5(c).

³² *Id.*, ¶ 5(d). The demands included in this paragraph in terms of the extension of the transitional period for the implementation of patent rights for pharmaceutical products for LDCs was effected in 2002: General Council Decision: Extension of the Transition Period Under Article 66.1 of the TRIPs Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products, IP/C/25, 1 July 2002, ¶ 1. See also the Decision on of the General Council: Least-Developed Country Members – Obligations Under Article 70.9 of the TRIPs Agreement with Respect to Pharmaceutical Products, WT/L/478, 12 July 2002, ¶ 1.

They also extended the transitional period during which LDCs are expected to adhere to the TRIPs Agreement in terms of patent protection for pharmaceutical products.³³

Paragraph 6 contained specific terms aimed at addressing a crucial issue that has come to be known as the paragraph 6 problem. The problem emanated from the wording of Article 31(f) of the TRIPs Agreement that allows for the authorization of other use of IP products (without the consent of the patent holder) for the predominant supply of the domestic market. This basically meant that countries that have the capacity to use compulsory licensing for instance in the mass provision of vital drugs such as ARVs could only do so to (mainly) meet the demand of the domestic market. Export of such consignments to foreign countries that are in need ought to be minimal or very limited.³⁴ In addressing this issue Contracting Parties “recognized 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.”³⁵ They also mandated the Council for TRIPs with the task of finding a speedy solution to the problem and report to the General Council before the end of 2002.

This was an important milestone in dealing with the problem posed in paragraph 6 of the Doha Declaration and such a solution was only reached because most of the states, notably the African states and also the EC made it possible to bring the issue to the limelight. The DTAPH was such a vital document that it has actually been regarded as a legal text with important forensic implications.³⁶

2.2 EC's contributions in reaching the Decision of 30 August 2003

In a bid to address the paragraph 6 problem, Members started negotiations within the TRIPs Council that were geared at reaching a solution that was acceptable to both the rich and poorer countries. The negotiations proved tough. In the first instance some of the Members like the EC initially expressed preference for a TRIPs Article 30 solution. However the Community later retracted from this approach and declared its intention to go with the broader fray of the Members who expressed a predilection for a TRIPs Article 31 solution. The essence of the Article 31 solution was modification of Article 31(f) in a manner that will reflect the needs of countries that had a public health problem yet lacked sufficient capacity to deal with the issue. The modification would allow those with sufficient capacity to go beyond the TRIPs requirement of manufacture aimed “predominantly” for the domestic market. It should be noted that paragraph 6 of the DTAPH made it clear that the TRIPs Council had to report a solution to the General Council by the end of 2002. This deadline later proved unrealistic because of the reservations that the US expressed in terms of the scope of the medicines as well as the number of countries that could benefit from such a waiver of Article 31(f) obligations. The US as well as other Western countries was equally concerned that if introduced such a waiver system for Article 31(f) would lead to abuse as some Members may actually seek to use the initiative for commercial purposes. After much debate and clear assurances that were later included in the statement of the Chairman of the General Council, the US succumbed. The EC was very instrumental in helping to allay the fears of the US and thus securing the eventual agreement on the decision on the paragraph 6 problem.³⁷

³³ *Id.*, ¶ 7.

³⁴ F.M. Scherer and Jayashree Watal, *Post-TRIPs Options for Access to Patented Medicines in Developing Countries*, in *The WTO, INTELLECTUAL PROPERTY RIGHTS AND THE KNOWLEDGE ECONOMY* 367, 355-381 (Keith Maskus ed., 2004).

³⁵ DTAPH, ¶ 6.

³⁶ KATHARINA GAMHARTER, *ACCESS TO AFFORDABLE MEDICINES: DEVELOPING RESPONSES UNDER THE TRIPs AGREEMENT AND EC LAWS 153 AND 157* (2004).

³⁷ Decision of the General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health*, WT/L/540, 1 September 2003. (Hereafter, the Decision). For an upbeat albeit cautious assessment of the potential positive fallout of the Decision in terms of access to medicines for a broad array of diseases in developing countries see, Frederick Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and*

The provisions of the 30 August 2003 Decision were important as they waived the obligation of Article 31(f) and also put in place a dispute settlement moratorium on those countries that sought to depart from the strict wording of Article 31(f) in a bid to meet public health concerns. The paragraphs of the Decision, which remain in force, are worth examining.

Firstly, the preamble recalled the nature of the paragraph 6 problem and noted that exceptional circumstances existed that warranted deviations by means of waivers from the obligations encoded in Articles 31(f) and 31(h) of the TRIPs Agreement with regard to pharmaceutical products.

Paragraph one presents the scope of eligible products; importing Members and exporting Members. In terms of the scope of the products these mainly relate to any patented product; product manufactured via a patented process and importantly, diagnostic kits necessary for using the product in question.³⁸ In as much as the scope of the importing Members is concerned, the Decision makes clear that all LDCs are eligible to use the system. In addition, any other Member may put the system into operation provided that this is done in a “limited way” meaning “only in the case of a national emergency, or other circumstances of extreme urgency or in cases of public non-commercial use.”³⁹ The meaning of exporting Member denotes those using the system described in the Decision to manufacture pharmaceutical products for export to the eligible importing Members.⁴⁰

The second paragraph provides an elaborate description of the *modus operandi* of the mechanism understood as the “system” contained in the Decision. The provision is to the effect that exporting Members can issue compulsory licenses for the manufacture of pharmaceutical products for use in eligible importing Members, under very strict conditions to be adhered to by both the importing and exporting Members. The eligible importing Member has to notify the TRIPs Council of its intention to use the system and such notification has to specify the names and quantities of the product needed;⁴¹ justification (if the importing Member is a non-LDC) that it has no or insufficient manufacturing capacity to produce the products needed⁴² and finally a confirmation that (in case the pharmaceutical product is patented in its territory) it has granted a compulsory license pursuant to Article 31 of the TRIPs Agreement.⁴³ In addition, the importing Member has to put in place secure and reasonable measures to stem trade diversion of products imported under the system. In equal measure, the importing Member has to avert re-exportation of the products imported under the system.⁴⁴ Developed countries pledged that they will assist importing LDCs or developing countries that lack the capacity to implement such measures to do as much.⁴⁵

The exporting Member has to meet very onerous conditions when it issues a compulsory license for purposes of compliance with the Decision. First a compulsory license can only be issued for the production of a specified quantity that meets the need of the eligible importing Member who has made a notification of its needs to the Council of TRIPs.⁴⁶ Second, the Decision also requires

the Protection of Public Health, 99 AMERICAN JOURNAL OF INTERNATIONAL LAW 322-323, 358, 317-358 (2005) (concluding that although “[the] adoption of the Decision shows that the WTO can address important issues of social concern ... [the] WTO’s effectiveness can be better assessed if, and when, developing countries actually use the Decision to address their public health needs.”).

³⁸ *Id.*, ¶ 1(a).

³⁹ *Id.*, ¶ 1(b). Many WTO Members declared that they will not use the system. They include Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany Greece, Iceland, Ireland, Italy, Japan, Luxemburg, The Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, UK and US. In all the EC 15 Members noted they will not use the system: see footnote 3 to the Decision.

⁴⁰ *Id.*, ¶ 1(c).

⁴¹ *Id.*, ¶ 2(a)(i).

⁴² *Id.*, ¶ 2(a)(ii).

⁴³ *Id.*, ¶ 2(a)(iii).

⁴⁴ *Id.*, ¶ 4.

⁴⁵ *Id.*

⁴⁶ *Id.*, ¶ 2(b)(i).

that products produced under the license have to be clearly identified as being produced under the system. This has to be done by means of specific labelling or marking. In addition, the suppliers of the product are obliged to distinguish the exported products via “special packaging and/or special colouring/shaping of the products themselves” to the extent that the marking used for the distinction be “feasible and does not have a significant impact on price.”⁴⁷ Third, the Decision stipulates that prior to the commencement of shipping of the needed consignments of the products the licensee has to post on a website specific pieces of information, to wit, the quantities being supplied and distinguishing features of the product.⁴⁸ Finally the Decision provides that “the exporting Member shall notify the Council for TRIPs of the grant of the licence, including the conditions attached to it. The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity (ies) for which it has been granted, the country (ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.”⁴⁹ As revealed in chapter four, these conditions are reflected in EC Regulation 816/2006 on the application of the August 2003 Decision of the WTO.

Paragraph three makes provision for the award of “adequate remuneration” in the event of the use of a compulsory license in the exporting country. The “adequate remuneration” condition is in line with the requisites of Article 31(h) of the TRIPs. The remuneration will be paid in the exporting country taking into account “the economic value to the importing Member of the use that has been authorized in the exporting Member.” To the extent that remuneration for the products exported under a compulsory license is paid in the exporting Member, the requirement for such payment in the importing Member will be waived.⁵⁰

While paragraph five sets out a generic safeguard provision for all Members to avoid diversion and re-exportation of the products imported under the system, paragraph 6 is a crucial statement that is very relevant for regional trade agreements (RTAs) such as SADC.⁵¹ One of the crucial aspects of paragraph six as mentioned above is that if half of the Members of an RTA is made up of LDCs then the requirements of Article 31(f) shall be waived. SADC is composed of eight LDCs and six developing countries. This means that SADC non-LDCs can make use of the waiver of Article 31(f) and such states may also be excused from the obligation of providing justification of the need for the system as elaborated under paragraph 2(a)(ii). This of course means that the SADC Group EPA on the other hand, cannot take advantage of such a provision mindful

⁴⁷ *Id.*, ¶ 2(b)(ii).

⁴⁸ *Id.*, ¶ 2(b)(iii).

⁴⁹ *Id.*, ¶ 2(c).

⁵⁰ *Id.*, ¶ 3.

⁵¹ Paragraph 6 states:

With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products;

(i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of the Member under Article 31(f) of the TRIPs Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory license in that Member to be exported to the markets of those developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;

(ii) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of the TRIPs Agreement, including in conjunction with other relevant intergovernmental organizations.

of the fact that the majority of the members of SADC Group EPA are members of the Southern African Customs Union (SACU) that are developing and not least-developed countries.

The Decision also stipulates that Members will need to make more effort in order to foster transfer of technology in the pharmaceutical sector.⁵² A specific review mechanism is provided for under the Decision.⁵³ Finally it makes it clear that the solution provided for by the system is only a temporary solution and that the waivers of the Article 31(f) and 31(h) obligations shall become permanent once the permanent amendment of the TRIPs Agreement takes effect in Member States.

One element that marked the Decision was that it was accompanied by a Statement from the Chair person of the General Council, Ambassador Carlos Pérez del Castillo. The Statement was regarded as representing “several key shared understandings of Members regarding the Decision.”

In the Statement he sought to allay the fears of those who believed that the Decision could be abused thereby undermining patent protection. He stated that the system has to be used in “good faith to protect public health” and that the system will not be used as an “instrument to pursue industrial or commercial policy objectives.”⁵⁴ Although the Decision had positive aspects for developing countries and LDCs, the Statement clawed back some of the gains of the Declaration by making the conditions for the use of the system much stricter. For instance, importing Members are required under the Decision to only show a confirmation of need and a justification of the same. However, the Statement stated that such states have to show how they established the deficiency expressed. In addition the Decision, limited any oversight on the developments regarding the use of the system to annual reviews. The Statement goes further and actually makes provision for a frequent scrutiny of developments (notifications) of the system during all TRIPs Council meetings. Furthermore, the Statement also gives way for the possibility of “expeditious review” that can be conducted by the TRIPs Council at any time. Moreover, it made an to the option that a Member who has reservations as to the operation of the system to make use of the good offices of the Director General of the WTO. Finally the Statement included an attachment that contained examples of distinctive labelling which some Western pharmaceutical companies have been using in schemes akin to that provided for by the Decision. These included, amongst others, GlaxoSmithKline’s use of different outer packaging for its HIV/AIDS medicines (combivir, epivir and trizivir) supplies to developing countries and Merck’s use of differentiated packaging and labelling of its ARV crivivan.⁵⁵

In spite of these claw back requirements that were included in the Chair person’s Statement, the Decision was hailed in many quarters as a watershed in WTO’s history. The WTO Director General, Supachai Panitchpakdi (as he then was) declared that the Decision “proves once and for all that the organization can handle humanitarian as well as trade concerns.”⁵⁶ Some analysts welcomed the so-called balanced nature of the Decision. They argued that “... it sets up a balanced and flexible mechanism, which provides for a workable framework to allow for exports of medicines produced under a compulsory license, while adequately addressing concerns on trade diversion.”⁵⁷ But this position was not universal. Indeed one commentator has submitted that “[t]he involvement of the WTO – or any other international organization – in granting a compulsory licence had never been heard of. Thus, the involvement of the WTO in granting compulsory licences, not only results in the surrender of sovereignty but it also establishes a set of obligations beyond the TRIPs

⁵² *Id.*, ¶ 7.

⁵³ *Id.*, ¶ 8.

⁵⁴ WTO News, The General Council Chairperson’s Statement, 30 August 2003 (hereafter, the Statement), at http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm.

⁵⁵ *Id.*

⁵⁶ WTO News, *Decision Removes Final Patent Obstacle to Cheap Drug Imports*, Press/350/Rev.1, 30 August 2003, at http://www.wto.org/english/news_e/pres03_e/pr350_e.htm.

⁵⁷ Paul Vandoren and Jean Charles Van Eeckhoutte, *The WTO Decision on Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health*, 6 JOURNAL OF WORLD INTELLECTUAL PROPERTY 782, 779-793 (2003).

Agreement, that is, a TRIPs-plus obligation ...”⁵⁸ It has also been contended that the system and strict conditions provided for in the Decision is burdensome for non-producing developing countries.⁵⁹

Although the EC spasmodically adopted a cautious approach during the negotiations leading to the adoption of the Decision, it nevertheless joined hands with most of the developing world in securing a solution. In the TRIPs Council meeting on 4-5 June 2003 the representative of the EC noted that the Community “... was willing to work with other Members with a view to finding a formula that would restore the confidence among Members while leaving unaffected the scope of the Declaration and the scope of the diseases covered.”⁶⁰ The EC was quite instrumental in defusing the deadlock that had earlier curtailed efforts to meet the 2002 deadline due to the fact that the US was keen on maintaining a narrow scope of diseases as well as the beneficiaries to be eligible for purposes of the system. So the EC “... worked with a view to reconciling the almost irreconcilable positions of the outer ends of the spectrum.”⁶¹ Other hard issues that had to be negotiated included the nature of remuneration in the event of a use of compulsory licenses.⁶² At issue was the question whether or not remuneration had to be paid both in the exporting and importing countries. Negotiations led to the conclusion that remuneration need not be paid in the importing developing country or LDC so long as it has been paid in the exporting Member.

2.3 EC backing for the 2005 TRIPs amendment

The Decision states that the system of the waiver which it provides is temporary and that the TRIPs Council has to initiate work on the preparation of an amendment to the TRIPs Agreement that will serve as a permanent solution. The amendment has to be based “where appropriate”⁶³ on the Decision and on the understanding that it is not part of the broader Doha negotiations.⁶⁴ Between 2004 and end of 2005 important negotiations took place in the TRIPs Council in order to decide on the content, form and timing⁶⁵ of the amendment of the TRIPs Agreement – which had to be the first modification ever of a WTO covered agreement. In broad terms, most third world countries preferred a complete modification of the Decision if it had to be regarded as the basis for the amendment. A majority of the developed countries preferred the option of using a footnote as a means of amending the TRIPs Agreement – the idea being that most if not all the provisions of the Decision together with the entirety of the Chairman’s Statement would become binding as part of the TRIPs Agreement. Argentina dismissed the option of using the footnote.⁶⁶ It also resisted the notion that the Statement of the Chairman had to be integrated as part of the permanent solution in the proposed amendment.⁶⁷ For Argentina, the Statement could not be part of the amendment because “... to introduce it would establish a bad precedent amounting to a disguised amendment to the provisions of the TRIPs Agreement through unilateral instruments, which were not generated by one of the contracting parties and which did not constitute an agreement between parties.”⁶⁸ The July meeting ended in a deadlock. When the Council resumed discussions in September, the African

⁵⁸ K.M. Gopakumar, *The WTO Deal on Cheap Drugs: A Critique*, 7 JOURNAL OF WORLD INTELLECTUAL PROPERTY 108, 99-113 (2004).

⁵⁹ Duncan Matthews, *TRIPs Flexibilities and Access to Medicines in Developing Countries: The Problem with Technical Assistance and Free Trade Agreements*, 11 EUROPEAN INTELLECTUAL PROPERTY REVIEW 422, 420-427 (2005).

⁶⁰ IP/C/M/40, 22 August 2003, ¶ 28.

⁶¹ Paul Vandoren, *Médicaments sans Frontiers? Clarification of the Relationship Between TRIPs and Public Health Resulting from the WTO Doha Ministerial Declaration*, 5 JOURNAL OF WORLD INTELLECTUAL PROPERTY 12, 5-14 (2002).

⁶² See GAMHARTER, *supra* note 36, at 180.

⁶³ As discussed below the extent to which the amendment had to be based on the Decision became a major apple of discord in the TRIPs Council negotiations that led to the permanent amendment of Article 31(f).

⁶⁴ The Decision, ¶ 11.

⁶⁵ IP/C/M/43, 8 March 2004, ¶ 86.

⁶⁶ IP/C/M/44, 19 July 2004, ¶ 80.

⁶⁷ *Id.*, ¶ 82.

⁶⁸ *Id.*, ¶ 84.

Group, through the representative of Nigeria came up with a proposal for an Article 31bis to specifically address the problem of public health.⁶⁹ Most developing countries hitherto were poised to accept the proposal of Nigeria pursuant to further discussions. The EC on its part was initially abrasive and dismissive of the African Group proposal noting as it were that Members ought to avert opening any negotiations on substantive issues. Its representative noted that the EC's preferred option was "... a change in the body of the TRIPs Agreement to the effect that a new exception was created to Article 31(f)."⁷⁰

At the TRIPs Council meeting held on 1-2 December 2004 Nigeria unveiled the full version of its draft proposal on the revision of Article 31. For Nigeria, Article 31 had to change to Article 31(1) and the Decision of 2003 had to be Article 31(2). Third world countries such as Argentina, Brazil, China, Cuba, India, Kenya, Malaysia and the Philippines,⁷¹ amongst others, backed the African Group's proposal as contained in the statement of the Nigerian representative. The EC like the US disagreed with the African Group on the proposal.⁷²

During the TRIPs Council meeting held on 8-9 and 31 March 2005 the representative of Nigeria (on behalf of the African Group) noted that the earlier proposed solution of adding a subparagraph to Article 31 remained the best approach "... which left no doubts about the legality of the amendment."⁷³ He went on to allay the fears of some developed countries, that the important parts of the Decision would be maintained under the African proposal. The sections that had to be removed included redundant and self-eliminating provisions such as paragraphs 1(b), 6(ii), 8, 9 and 11.⁷⁴ The other category of provisions that had to be eliminated, according to the Nigerian representative were those the purpose of which was served by other provisions of the TRIPs Agreement such as those on enforcement and the extant provisions of Article 31. This entailed that paragraphs 2(a)(i-iii), 2(b)(i-iii) and 2(c) had to be removed.⁷⁵ He equally proposed the elimination of paragraph 4 on re-exportation. This action was based on the fact that the patent holder would have adequate alternatives to prevent re-exportation of products manufactured under the system.⁷⁶ For the African Group the most important part of preventing diversion rested with third countries and this aspect could be adequately covered by Article 31(2)(d) of the African Group proposal which incorporated elements of paragraph 5 of the Decision with slight modifications to include the main elements of paragraph 4.⁷⁷

The EC adopted a cautious approach regarding the African proposal and maintained that any amendment had to be a purely technical exercise rather than a window of opportunity to reopen discussions on substantive parts of the Decision. In a short gun fashion the EC representative proposed that the Chairman should continue consultations on the issue with the aim of producing a text consisting of a technical adaptation of the Decision. This in reality meant throwing cold water on the African proposal.⁷⁸

The EC castigated the African Group approach as a cheery-picking exercise that essentially redrafted the Decision.⁷⁹ It noted that some of the changes proposed by the African Group were bogus. For instance it took issue with the product coverage of the African Group proposal. The EC disagreed with the fact that the African proposal included the words "amongst others" in terms of describing the product range. This, the EC argued, broadened the scope of products in paragraph 1 of the Decision in "an unacceptable manner" to the extent that "products" could cover not only

⁶⁹ IP/C/M/45, 21 September 2004, ¶ 66.

⁷⁰ *Id.*, ¶ 68.

⁷¹ *Id.*, ¶¶ 112, 122, 134, 111, 113, 119, 125 and 115, respectively.

⁷² *Id.*, ¶ 114 and 117.

⁷³ IP/C/M/47, 3 June 2005, ¶ 106.

⁷⁴ *Id.*, ¶ 107.

⁷⁵ *Id.*, ¶ 108.

⁷⁶ *Id.*, ¶ 109.

⁷⁷ *Id.*

⁷⁸ *Id.*, ¶ 124.

⁷⁹ *Id.*, ¶ 125.

medicines but vaccines as well.⁸⁰ In addition, the EC was concerned that paragraph two had been substantially changed and that the standard or threshold for justification of need that had to be furnished by an importing Member had been diluted and weakened.

The EC also raised issues respecting the African Group Proposal regarding paragraph 3 which basically limited the payment of compensation by the importing rather than exporting Member. The EC equally believed that the African Group proposal had weakened the obligation to restrict diversion and re-exportation under paragraphs 4 and 5.⁸¹ For the EC, the changes which the African Group was proposing regarding paragraph 6 were simply not acceptable because the proposal ejected two vital aspects, namely, reference to the principle of territoriality of patent rights and establishment of regional patent systems. In terms of paragraph 7 changes, the EC noted that rather than addressing the real issue that pertained to public health the African Group had used their proposal as a means of securing technical cooperation which did not, at the time, constitute the real issue on the table. Finally the EC took issue with the fact that the African Group simply cut off the provision in the Decision regarding annual reviews of the operation of the system.⁸²

In the face of the challenge to the African Group proposal Argentina mounted a strong defence of the position of the African Group. On the issue of the scope of change open to the negotiators, it argued that “[n]othing in paragraph 11 of the Decision required a transposition without changes. It merely asked for the amendment to be based on the appropriate parts of the Decision.”⁸³ The Kenyan representative also derided the approach of the EC which was that of a complete rejection of the African proposal – something which, as Kenya noted, no other delegation had done.⁸⁴

The representative of Rwanda presented a poignant intervention on how many people were dying while negotiators toyed on specious and spurious redundancies in the Decision. For her it was preposterous that all the EC could do was offer strictures of the African Group proposal – strictures that were bereft of any real alternatives. She reiterated the fact that the matter was very serious for Africa and that Members should delay no further with futile bickering over useless technicalities of form or content of the amendment. The key issue had to be about saving lives, period.⁸⁵ For her African countries wanted a “permanent, sustainable, secure and predictable solution” to the paragraph 6 problem.⁸⁶

In the same spirit the representative of Zambia noted that the issue was not a procedural debate “... but an emergency with social and economic implications on which the well-being and lives of millions of its people depended.”⁸⁷ Argentina, which had been forceful against the positions of developed countries, added that the Decision had been conceived as an ephemeral solution and that nothing in the provisions forfeited the option of introducing critical changes in the amendment.⁸⁸

Speaking on behalf of the ACP Group, the representative of Benin also backed the African Group proposal.⁸⁹ The representative of Lesotho reminded Members that the Decision had been taken mainly to address the plight of AIDS patients blighted by HIV. For Lesotho, the amendment provided an opportunity for WTO Members to show compassion. These calls were not sufficient to appeal to the compunction of most developed Members. The EC, Switzerland and the US dismissed the African Group proposal.⁹⁰ The discussions were slated to end by March 2005 but it went on

⁸⁰ *Id.*

⁸¹ *Id.*, ¶ 127.

⁸² *Id.*, ¶ 128.

⁸³ *Id.*, ¶ 140.

⁸⁴ *Id.*, ¶ 160.

⁸⁵ *Id.*, ¶ 191.

⁸⁶ *Id.*

⁸⁷ *Id.*, ¶ 194.

⁸⁸ *Id.*, ¶ 195.

⁸⁹ *Id.*, ¶ 196.

⁹⁰ *Id.*, ¶¶ 216, 214 and 210, respectively.

through the year and a solution was finally reached and incorporated as the final amendment in December 2005. The amendment was adopted by means of a decision of the General Council which in turn alluded to the use of a protocol that contained the main parts of the amendment. It is expected that the protocol will be open for Members to accept it by December 2007.⁹¹

On the issue of the form of the amendments Members adopted a two track approach: the insertion of Article 31bis after Article 31 and the integration of the Annex to the TRIPs Agreement at the end of the same, that is, after Article 73.⁹² The insertion of Article 31bis was by means of an annex to the Protocol Amending the TRIPs Agreement.⁹³ The annex (and adjoined appendix), mainly imported *mutatis mutandis*, the provisions of the Decision.

Like in the case of the Decision of 2003 the Chair person of the General Council at the time of the adoption of the amendment (Kenyan Ambassador Amina Mohammed, as she then was) reiterated the fact that Members should avert acts of diversion and re-exportation.⁹⁴ She equally noted that States were proscribed from using the system for commercial purposes. Her Statement included a list of countries that have made clear they will opt out of the system provided for by the

⁹¹ Amendment of the TRIPs Agreement, Decision of 6 December 2005, WT/L/641, 8 December 2005 (hereafter, The Decision), ¶ 2.

⁹² Protocol Amending the TRIPs Agreement, Amendment of the TRIPs Agreement, Decision of 6 December 2005, WT/L/641, 8 December 2005 (hereafter, The Attachment).

⁹³ Article 31bis provides as follows:

1. The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory license to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.
2. Where a compulsory license is granted by an exporting Member under the system set out in this Article and the Annex to this Agreement, adequate remuneration pursuant to Article 31(h) shall be paid in that Member taking into account the economic value to the importing Member of the use that had been authorized in the exporting Member. Where a compulsory license is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall not apply in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.
3. With view to harnessing economies of scale, for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products: where a developing or least developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory license in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question.
4. Members shall not challenge any measures taken in conformity with the provisions of this Article and the Annex to this Agreement under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.
5. This Article and the Annex to this Agreement are without prejudice to the rights, obligations and flexibilities that Members have under the provisions of this Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration on the TRIPs Agreement and Public Health (WT/MIN(01)/DEC/2), and to their interpretation. They are also without prejudice to the extent to which pharmaceutical products produced under a compulsory license can be exported under the provisions of Article 31(f).

⁹⁴ WTO News, *Chair person's Statement, December 2005*, 6 December 2005, http://www.wto.org/english/news_e/news05_e/trips_319_e.htm.

amendment.⁹⁵ Other states noted their intention of using the system only in situations of national emergency or extreme urgency.⁹⁶

Although the amendment has been praised by the WTO Director General, Pascal Lamy,⁹⁷ it is noteworthy that the discussions that took place in the TRIPs Council in the run-up to the amendment revealed certain fundamental deficiencies. This was so particularly in relation to the manner in which some developed countries advocated for development (higher life expectancy levels) in developing countries and LDCs, yet at the same time, adopted inflexible approaches to the issue of the amendment. The example and strategies of the EC were revealing because outside the WTO setting (as seen in the next chapter) the Community had been thought to be an advocate for the development concerns in poor countries. But its interventions during the TRIPs Council meeting raised more questions than answers.

That said, there could be several explanations as to why the EC had to adopt such a hard line position on the issue of a permanent amendment to Article 31. On the one hand it could have been concerned that giving in so easily to the kind of emendations proposed by developing countries for a substantial amendment would have been setting a precedent that revisions of the TRIPs Agreement could be done with ease. Yet this is exactly the kind of development that Members would have striven to avert so as not to open a Pandora's Box or floodgate of future demands for amendments of covered agreements each time Members had to grapple with given challenges. On the other hand, the EC could also have been concerned for its pharmaceutical sector because of the challenges from strong generic concerns in countries such as Brazil, China, Malaysia and India, all of which ardently and trenchantly defended the proposal of the African Group. So while one may question the approach of the EC in terms of the stances adopted during the TRIPs Council discussions one also has to put the issue into context because in such circumstances critical issues and jobs are often on the line.

Despite the difficult compromises that had to be made, a solution was finally arrived at through the permanent amendment and that was good news for countries in need of the system. The ball is now in their court to use the Decision to provide the needed ARVs and other medicines for their patients.

2.4 EC's strong stance on counterfeit products

The EC has adopted a very strong position on counterfeit products. Besides the damage that such products cause in terms of distorting trade they also pose the danger of being extremely harmful in the case of pharmaceutical products. This is because most of the products are usually fake medicines with insufficient or no active ingredients. What this usually does is to embolden or fortify viral strains of particular diseases. The issue of counterfeit products hedges a general concern that some developing countries have raised regarding the quality of the drugs that are exported to third world countries under the guise of donations or tiered pricing. During the negotiations that led to the adoption of the amendment of the TRIPs Agreement the Nigerian Delegation, on behalf of the Commonwealth of Nations had raised the issue of the low quality of medicines as a bane to efforts of developing countries in dealing with public health challenges.⁹⁸ In the same light Jamaica made reference to the results of a study carried out by the WHO “... showing that between 50 to 90 per cent of samples of anti-malarial drugs failed the quality control test and that more than half of the anti-retroviral drugs did not meet international standards.”⁹⁹ The EC was quick to respond to these

⁹⁵ Australia, Canada, the European Communities and its Members, Iceland, Japan, New Zealand, Norway, Switzerland and the United States.

⁹⁶ Hong Kong, China; Israel; Korea; Kuwait; Macao; China; Mexico; Qatar; Singapore; the Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu; Turkey and the United Arab Emirates.

⁹⁷ WTO Press Release, *Members OK Amendment to Make Health Flexibility Permanent*, Press/426, 6 December 2005.

⁹⁸ IP/C/M/47, ¶ 119.

⁹⁹ *Id.*, ¶ 138.

statements regarding the quality of the medicines that are exported to countries of need. Its representative stated that:

To ensure that patients from countries in need benefit from the same level of safety, quality and efficacy as European patients, the competent authorities in the EC would be entitled to deliver a scientific opinion for medicinal products for supply outside the European market.¹⁰⁰

Such measures are critical because in recent years events such as the contamination of Libyan children with HIV as well as the recall of viracept¹⁰¹ from the market by Roche have raised questions about the quality of products and services that are often offered third world countries by Western altruistic concerns. That being said, the EC has, of late, endeavoured to adopt a very firm position on the issue at the WTO level. At a TRIPs Council meeting held on 14-15 March 2006 the EC presented a series of documents on the enforcement of IPRs.¹⁰² It raised concerns of counterfeit products of many items including “common goods” such as medicines, the seizures of which had augmented by 200 per cent.¹⁰³ It revealed that criminal groups were now deploying advanced tactics to avert the wrath of the law. The EC representative also showed a fake anti-malarial drug to convey his message. He proposed more stringent transshipment controls and added that these controls should be made part of the discussions within the TRIPs Council.¹⁰⁴ The Swiss representative alluded to the fact that notable amongst the main counterfeit products in the world were ARVs. But like in most issues within the WTO it soon became an altercation between the developed and developing nations. While the US and Switzerland sided with the EC, Argentina and Brazil took the more cautious option of resisting the introduction of the issue as a permanent item in TRIPs Council meetings.¹⁰⁵ On its part, China adopted a more direct position, hoping as it were, that “... the European Communities would not open a Pandora’s Box, which would be disastrous for the ongoing Doha Round negotiations and other work of the organization.”¹⁰⁶ But the issues are so critical that in such cases one would have expected Members to tone down the rhetoric and deal with the substance of the problem which in recent years has helped to compound rather than assuage the public health challenges for developing countries and developed countries alike.

2.5 EC support for differential pricing

The use of differential pricing as revealed in chapter four has been one of the landmarks in EC’s approach in helping countries in need to access affordable medicines. The basic ideas behind the differential or tiered pricing system is that pharmaceutical companies are encouraged to provide needed and essential medicines at lower prices to LDCs and countries where the need has been expressed. Although the approach is good because it is based on the volition of the pharmaceutical companies¹⁰⁷ and because it also eases access to life-saving medicines, it has been criticized because it can easily be abused by free riders who desire to divert the products for purposes of re-exportation back to the rich markets. The problem is succinctly formulated by Scherer and Watal in these terms

[Wholesalers] in a low-price country direct supplies through international trade channels to nations in which the manufacturer is attempting to maintain high prices, undermining the high prices (and their contribution to research and development expenditures) in the

¹⁰⁰ *Id.*, ¶ 130.

¹⁰¹ *Global Business Briefs: Roche Holding AG*, THE WALL ST. J. 10 (7 June 2007).

¹⁰² IP/C/W/448, IP/C/W/468, and IP/C/W/471. IP/C/M/50, 14-15 March 2006, ¶ 111.

¹⁰³ IP/C/M/50, ¶ 114.

¹⁰⁴ *Id.*, ¶¶ 116 and 117.

¹⁰⁵ *Id.*, ¶¶ 127 and 128.

¹⁰⁶ *Id.*, ¶¶ 130-135.

¹⁰⁷ See EC intervention in the TRIPs Council meeting: IP/C/M/40, ¶ 32. See also GAMHARTER, *supra* note 36.

wealthier nations and, if quantitatively substantial, in inhibiting the manufacturer's willingness to supply at low prices in the low-income nation.¹⁰⁸

This and other reasons explain why in general terms, pharmaceutical companies are not quite keen on the approach.¹⁰⁹ However, it must be noted that differential pricing makes sense in situations where trade diversion and run-away tendencies of parallel trading are controlled.

2.6 EC approach to the use of compulsory licensing in countries of need

Aside from the TRIPs amendment, voluntary licensing is a vital tool for the reproduction of patented products with the consent of the patent holder. In the absence of such consent and where the need so dictates, compulsory licensing can be reverted to, to the extent that the right holder is accorded equitable and fair remuneration. So the use of compulsory licensing need not necessarily be bad for the holder because remuneration has to be provided. In addition, the use of such a license helps in assuaging a situation of public need. But the use of the compulsory licensing has been limited in countries where one would have thought are in need of the system set in the 2003 Decision. As at the time of writing, only the Rwandan Government through its Centre for the Treatment and Research on AIDS (TRAC) has made a notification under the system. In the document announcing the decision by Rwanda to use the system its permanent representation in Geneva noted that "Based on Rwanda's present evaluation of its public health needs, we expect to import during the next two years 260,000 packs of TriAvir, a fixed-dose combination product of Zidovudine, Lamivudine and Nevirapine ... manufactured in Canada by Apotex, Inc. However, because it is not possible to predict with certainty the extent of the country's public health needs, we reserve the right to modify the foregoing estimate as necessary or appropriate."¹¹⁰

The example of Rwanda shows that contrary to the interventions of Kenya and Pakistan in TRIPs Council meeting of 16 June 2004, the system could be used by developing countries and that the conditions set are not as burdensome as they averred.¹¹¹ The use of compulsory licensing is just not universally appreciated.

In a caustic criticism of such licenses, Rozek and Rainey argue that the use of such licenses "... demonstrates a lack of respect for IPRs and destroys the incentives for pharmaceutical firms to invest resources to conduct research and development ... It imposes costs on the national governments faced with having to improve and monitor the products produced by the licenses."¹¹² They further note that: "Compulsory licensing shifts the balance in favour of free-riders (copiers) seeking instant access to technologies, and it destroys the incentives of the innovator ..."¹¹³ In the same light, the pharmaceutical companies have been firm in their defence against advocates of a system that is more open to licensing methods. One of the leaders of the International Federation of Pharmaceutical Manufacturers Association has taken a clear position on this issue: "... the commercial interests of copy producers in some mid-to high-income countries have hijacked this process. These interests have turned the debate away from AIDS drugs for poor countries, instead of trying to deform this process into promoting copies of all drugs for all countries, including industrialized countries."¹¹⁴

¹⁰⁸ Scherer and Watal, *supra* note 34, at 370.

¹⁰⁹ Arvind Subramanian, *The Aids Crisis, Differential Pricing of Drugs, and the TRIPs Agreement: Two Proposals*, 4 JOURNAL OF WORLD INTELLECTUAL PROPERTY 325, 323-336 (2001).

¹¹⁰ TRIPs Council, Notification Under Paragraph 2(a) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health IP/N/9/RWA1, 19 July 2007.

¹¹¹ IP/C/M/44, ¶¶ 91 and 115.

¹¹² Richard P. Rozek and Renee L. Rainey, *Broad-Based Compulsory Licensing of Pharmaceutical Technologies: Unsound Public Policy*, 4 JOURNAL OF WORLD INTELLECTUAL PROPERTY 464, 463-480 (2001).

¹¹³ *Id.*, 469.

¹¹⁴ Eric Noehrenberg, *TRIPs, the Doha Declaration and Public Health*, 6 JOURNAL OF WORLD INTELLECTUAL PROPERTY 380, 379-383 (2003).

However, this position is not the rule. To the extent that compulsory licensing accelerates the provision of affordable medicines to poor countries (with the explicit provision of fair remuneration and diversion controls), their use makes economic and social sense. Indeed Abbott contends that: “From the standpoint of developing and least-developed WTO Members, a restriction on compulsory license for export will frustrate their capacity to effectively address access and affordability issues.”¹¹⁵

2.7 EC policies on technical cooperation in the area of IPRs

As noted earlier, Article 67 of the TRIPs Agreement is on technical cooperation and provides term to the fact that developed countries should accord assistance to developing and least developed countries in the form of IPRs. It is noteworthy that in all the important events that have taken place in the TRIPs Council ranging from the 2003 Decision to the 2005 amendment, the Members have, on each occasion, made provision for the extension of assistance to LDCs and developing countries in terms of fostering their capacity in this area. Technical cooperation in the form of technical assistance in the realm of expertise has been deemed critical if poor states are to be able to address IP enforcement nightmares such as diversion. At the TRIPs Council meeting of August 2003 the representative of the EC was quick to note that technical cooperation was “key to an effective implementation” of the Doha Declaration.¹¹⁶ He expressed the commitment of the EC to fully integrate the Doha Declaration into the EC trade policy “... especially with regard to technical assistance for the implementation of the TRIPs Agreement.”¹¹⁷ The EC further reiterated the salience of technical cooperation in the field of IPRs when its representative stated that technical assistance was needed in LDCs to incorporate the Doha Declaration into IP policies and practices. He also proposed that the TRIPs Council should direct the WTO Secretariat to make sure that the WTO-World Intellectual Property Organization (WIPO) Joint Initiative on Technical Assistance in the field of IPRs for LDCs should effectively address the public health dimension. The EC also proposed that the WHO should equally be closely involved in this process.¹¹⁸

Although the provision of technical assistance by rich countries may make sense, some commentators have recently expressed scepticism regarding the motives behind such assistance, counselling developing countries to be more circumspect in terms of what they accept and from whom.¹¹⁹ However, it is widely recognized that developing countries and LDCs need more money and human resources assistance to overcome their access problems.¹²⁰ To that extent the contributions of the EC are worthwhile.

2.8 EC efforts in curbing the incidence of trade diversion

When medical products that are direly needed in a given importing country are diverted to other countries where consumers have a better purchasing power trade diversion is at play. When it happens efforts geared at price diminution are thereby compromised. Trade diversion in the field of pharmaceutical products almost always results in the re-exportation of affordable drugs back to some developed or richer developing countries. The effect of trade diversion is that it leads to a reduction of the availability of the medicines in the markets where they are badly needed. This in turn leads to an upward push in the prices. The issue of trade diversion was raised by the EC in the TRIPs Council meeting of 22 August 2003. While welcoming the concerns of the EC, Kenya was quick to note that the issue of trade diversion need not be overburdened and overstretched because “... most of the diseases that were under discussion were not prevalent in the countries that had the capacity and

¹¹⁵ Frederick M. Abbott, *The TRIPs Agreement, Access to Medicines, and the WTO Doha Ministerial Conference*, 5 JOURNAL OF WORLD INTELLECTUAL PROPERTY 26, 15-52 (2002).

¹¹⁶ IP/C/M/40, ¶ 28.

¹¹⁷ *Id.*, ¶ 35.

¹¹⁸ IP/C/M/42, 18 November 2003.

¹¹⁹ Abbott, *supra* note 115, at 40.

¹²⁰ Noehrenberg, *supra* note 114, at 381.

technology to produce the medicines.”¹²¹ In the EC’s repost it stated that instances of trade diversion had taken place in 2002 where products that were subject to tiered pricing left the EC for a developing country but were re-exported back to the original EC country of export. He added that the example was not unique and that the onus was on the recipient countries to ensure that the medicines stayed within their borders.¹²²

2.9 EC’s backing for regional integration in the IP field

The Decision of 2003 and the amendment of 2005 all make it explicit that there will be an advantage for countries that are part of an RTA for purposes of Article XXIV of the GATT or for purposes of the Enabling Clause. In Africa IP cooperation is more enhanced in West and Central Africa within the framework of the *Organization africaine de la propriété intellectuelle* (OAPI).¹²³ What makes the OAPI stand out is the fact that its rules are directly applicable in the Member States.¹²⁴ In the English speaking parts of Africa a number of countries have also teamed up to form the African Regional Intellectual Property Organization (ARIPO).¹²⁵ Neither OAPI nor ARIPO are recognised at the WTO as GATT Article XXIV or the Enabling Clause-related organizations. None of the African regional organizations has a mandate for cooperation in the area of IPRs. This is one of the main reasons which SADC has forwarded as a pretext in abstaining from any IP-related negotiations within the framework of the EPA. However, as noted above there are advantages that SADC Members may avail themselves of if they took IP issues as important aspects of their development that warrant a place in the EPA negotiations. But the concern that most developing countries often have, and rightly so, is that most of the North-South bilateral or regional arrangements have been platforms on which developed countries incorporate TRIPs-Plus obligations in their ties with the developing countries or LDCs. That being said, TRIPs itself is an agreement that only provides for minimum standards and states are aware of this. There is room to impose tighter obligations than those agreed by TRIPs at bilateral or regional level.

The EC has been forthright in its support for the use of patents and also compulsory licences within regional frameworks. During the TRIPs Council meeting of 22 August 2003, the representative of the EC stressed the importance of regional cooperation in view of implementing the TRIPs Agreement and the Doha Declaration. Backing a regional patent system he argued: “In particular, the regional patent system, coupled with a centralized system of regional compulsory licensing schemes, would be instrumental in overcoming possible constraints stemming from the principle of territoriality and independence of patents.”¹²⁶ Abbott has also argued that regional patent systems are likely to be beneficial for the development prospects of developing countries.¹²⁷

¹²¹ IP/C/M/40, ¶ 36. See also EC intervention in TRIPs Council meeting of November 2003: IP/C/M/42, 18 November 2003, ¶ 136.

¹²² *Id.*, ¶ 52.

¹²³ The 16 members are Benin, Burkina Faso, Cameroon, the Central African Republic, Congo, Côte d’Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal, Chad and Togo. The headquarters of OAPI is in Yaoundé, Cameroon.

¹²⁴ Agreement Revising the Bangui Agreement of 2 March 1977, on the Creation of the African Intellectual Property Organization, Bangui, 24 February 1999: http://www.oapi.wipo.net/doc/en/bangui_agreement.pdf.

¹²⁵ The 16 members include Botswana, the Gambia, Ghana, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Somalia, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe. ARIPO has 14 observer countries: Angola, Algeria, Burundi, Egypt, Eritrea, Ethiopia, Liberia, Libya, Mauritius, Nigeria, Rwanda, Seychelles, South Africa and Tunisia. The headquarters of ARIPO is in Harare, Zimbabwe. For more on ARIPO see <<http://www.aripo.org/articles.php?Ing=en&pg=14>>

¹²⁶ IP/C/M/40, ¶ 33.

¹²⁷ See Abbott, *supra* note 115, at 39. See also Vandoren and Van Eeckhoute, *supra* note 57, at 790; Tshimanga Kongolo and Folarin Shyllon, *Panorama of the Most Controversial Intellectual Property Issues in Developing Countries*, 6 EUROPEAN INTELLECTUAL PROPERTY REVIEW 262, 258-268 (2004); Matthews, *supra* note 59, at 426; Gamharter, *supra* note 36, at 24.

Although some of the positions adopted by the various WTO States have generated heated discussions and in certain cases led to the exchange of very obtrusive language between delegations in Geneva, reason has always triumphed with the adoption of the 2003 Decision and the 2005 Amendment of TRIPs. However, some of the approaches of the Community on a number of issues have been patently controversial.

3 Controversial Positions of the EC in Terms of Access Debates at the Global Level

A number of EC strategies on the question of access to affordable HIV/AIDS medicines in developing countries have given life to many controversies. Such positions or strategies include the approach adopted by the EC in the row between the Government of South Africa and a group of pharmaceutical companies; and the insistence by the EC and other developed countries that the Chair person's Statement had to be fully incorporated as part of the final amendment to the TRIPs Agreement. Other aspects that have been laden with controversies include EC's insistence, alongside other developed countries, that there should be a strong system for test data protection. The use of supplementary protection certificates in the EC has also raised eyebrows within the circles of generic manufacturers. What is more, although TRIPs-Plus requirements in North-South bilateral agreements and RTAs such as the EPA may not be a cause for concern such TRIPs-Plus arrangements could well be helping in undermining the multilateral framework for IP protection given the inconsistencies that may be imported into the multilateral trading IP system.

3.1 EC position regarding the controversy surrounding pharmaceutical companies in South Africa

In 1997 the South African Government adopted a Medicines and Related Substances Amendment Act (the Medicines Act). Amongst others, the critical innovations introduced by the Act included a mandate authorizing the Minister for Health to issue a compulsory license to import cheaper drugs in cases of public health emergencies. In addition, the Act allowed for the use of parallel trade in attenuating the impact of high prices of medicines that are needed by the population. Many multinational pharmaceutical companies that were based in South Africa (amongst which were EC based firms) brought a case against the Government of President Nelson Mandela before a Pretoria High Court in South Africa in 1998. The drug companies mainly relied on the South African Patent Act of 1978 and the South African Constitution as the bases of their claims.¹²⁸ The row was presented by many non-governmental organizations as a ploy by the big pharmaceutical industry with its huge profits poised to deprive poor South Africans of essential ARVs medicines. In April 2001 and before the court had the opportunity to provide a verdict, the companies decided, with good reason, to withdraw their complaint and let sleeping dogs lie due to what was first amounting to a public relations disaster for the companies. The EC like the USA did not come out with a clear position in favour of the plight of the Government of South Africa. Indeed the US Government initially abjured efforts by the South African Government to introduce the amendment to the Medicines Act.¹²⁹ By failing to take a clear stance on the issue, the EC failed to provide the leadership needed to pressurize the big pharmaceutical companies as the NGOs had done.

¹²⁸ See Tshimanga Kongolo, *Public Interest Versus the Pharmaceutical Industry's Monopoly in South Africa*, 4 JOURNAL OF WORLD INTELLECTUAL PROPERTY 609, 609-627 (2001). For more on the approach used by the South African Government in terms of provision affordable medicines through the use of parallel importation see, Shubha Ghosh, *Pills, Patents, and Power: State Creation of Gray Markets as a Limit on Patent Rights*, 53 FLORIDA LAW REVIEW 789-829 (2001).

¹²⁹ Robert L. Ostergard Jr., *The Political Economy of the South Africa United States – Patent Dispute*, 2 JOURNAL OF WORLD INTELLECTUAL PROPERTY 879, 875-888 (1999).

3.2 EC's position on the full integration of the Chairman's Statement into the amendment

The discussion that marked the debates within the TRIPs Council for the greater part of 2004 and 2005 related to the form that the amendment would take. Incidental to this issue was the legal validity of the Statement of the Chair person of the TRIPs Council. Most developed countries led by the EC, Switzerland and the US (with minor variations of positions) supported the fact that the Chair person's Statement reflected a shared understanding by the WTO Members and that it should be fully integrated into the amendment with full legal effect. Most developing countries and LDCs took issue with this approach. It is worth recalling that the Statement constituted assurances by WTO Members to the pharmaceutical industry and other IP right holders that the system provided for in the 2003 Decision was not to be used in an abusive manner for instance, for commercial purposes.

The debate was rather outlandish and almost futile. It was outlandish because the Statement was simply an expression of intent by the Members to behave in a specific way. It was not a result of a negotiation as the Decision had been.¹³⁰ As Argentina argued: "At no stage had the Chairman or the Members construed the Statement as being part of the Decision, but rather as an instrument which would facilitate a consensual decision on the Decision."¹³¹ It was a unilateral verbalization of the determination of the States not to abuse the system. The discussion was almost futile to the extent that paragraphs two and three of the Decision had provided for very strict guidelines to control the types of products that could be eligible for purposes of the Decision. Without bickering over the issue a permanent solution to the paragraph 6 problem in the form of an amendment could have been secured earlier. Although the EC finally decided against the elevation of the legal status of the Statement,¹³² its initial position on the issue was ambiguous, at best.

3.3 EC stance on the protection of test data

Protection for undisclosed information is generally provided for in Article 39 of the TRIPs Agreement. This should not pose any problem to the extent that it curtails unfair commercial use of such data. However, the protection of test data often allows research based pharmaceutical corporations to conceal vital information from generic companies even when the term of protection expires. In this way research-based companies can be able to limit competition when the product comes into the public domain. Developed countries have broadly backed this form of protection that fosters the interests of their companies. This approach has not served consumers (mainly in LDCs and developing countries) well. One of the overall negative impacts of the use of test data exclusivity has been that of dampening the zeal of innovation because pharmaceutical companies find it more interesting and profitable to use such an approach to technically extend their patents on blockbuster drugs rather than engage in innovative research for the production of new medicines.¹³³

3.4 The use of supplementary protection certificates (SPCs)

SPCs are used by patent owners in the EC to prolong the period during which they can exercise exclusive rights over the patented product before it falls into the public domain. In most cases the SPC extends the period of patent protection by five years. Like the issue of test data exclusivity SPCs have the effect of extending the patent protection time. In this manner they limit the time range within which competitors may come into the market leading to an inordinate increase of

¹³⁰ As Sell has noted, the Statement had the imprimatur of Pfizer's Chairman E.O. Hank McKinnell and that of the Office of Karl Rove, President Bush's Deputy Chief of Staff charged with Policy (as he then was). See Susan K. Sell, *TRIPS-Plus Free Trade Agreements and Access to Medicines*, 28 LIVERPOOL LAW REVIEW 49, 41-75 (2007).

¹³¹ IP/C/M/44, 16 June 2004, ¶ 82.

¹³² IP/C/M/47, 8-9 March 2005, ¶ 129.

¹³³ Karin Timmermans, *Intertwining Regimes: Trade, Intellectual Property and Regulatory Requirements for Pharmaceuticals*, 8 JOURNAL OF WORLD INTELLECTUAL PROPERTY 69-70, 67-74 (2005).

prices. This is because SPCs may actually foster the power of a pharmaceutical monopoly to determine market prices due to limited competition.

3.5 TRIPs-plus obligations

TRIPs-plus obligations as their name indicate contain legal requirements that go beyond what is required under the provisions of the TRIPs Agreement.¹³⁴ They have not been common in EC's RTAs involving developing countries but they are common in US' FTAs with developing countries. TRIPs-plus obligations need not be bad for development but they pose a problem because they could engender inconsistencies in the multilateral framework.

4 Conclusion

HIV/AIDS is a serious problem for developing and least developed countries especially for African states that are afflicted by the malady. There are various facets in the possible response to the disease. Prevention, testing and education against stigma are vital components of the riposte which, by necessity, has to be holistic. But more importantly, focusing on the access component is also vital from a prevention perspective. This is because when effective vaccines are discovered to stem the virus, access will also be a key issue.

This paper has focused on the treatment component of access to medicines. In doing as much it has dwelt more on the trade related aspects of medicines that are dealt with at the WTO. The WHO, UNAIDS, WIPO, the UN amongst others. Attention was placed on the WTO mindful that it is the international body that has the mandate to decide on the modalities of the use of patent rights. Emphasis on the WTO is not an indication that the other international bodies are playing a lesser role on the issue of access.

The positive role of the EC at the WTO was examined. It was noted that the EC backed forward looking initiatives such as the Doha Declaration, tiered pricing, the use of compulsory licensing to deal with a health emergency amongst others. It was also asserted that although Community has been constructive on the access debate at the WTO, it also took certain stances that could have diluted the positive contributions made. Some of the stances such as its approach on extended patent protection and interpretation of WTO rules on test data protection could be ameliorated so in a manner that is more coherent with its ambition to assist poor countries provide affordable HIV/AIDS treatment to their populations.

¹³⁴ Matthews, *supra* note 59, at 420.