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The WTO TRIPS Agreement, the Right to Health and Access to Medicines in Africa

1. Introduction

There is no gainsaying the fact that access to affordable medicine is an issue that continues to elicit a considerable degree of concern all over the world albeit the effects of the problem are evidently more devastating in the developing countries. The international patent regime under the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement) is seen as a major part of the global access to medicine problem. Patents are exclusive ownership and exploitation rights granted in respect of inventions possessing a degree of novelty, some scintilla of inventiveness over what is already known and having significant utility value². Prior to the advent of the TRIPS Agreement, most developing countries did not extend patent protection to pharmaceutical products. As a consequence, in those developing countries that either excluded pharmaceuticals from patenting or did not yet have a patent system in force, and that had indigenous manufacturing capacity, generic firms were able to enter the market and sell medicines at considerably lower prices than the originator pharmaceutical companies, whilst also driving prices of the original drugs down by the competitive force they exerted in the market.³ However with the advent of TRIPS, all WTO countries became bound to grant patents for pharmaceuticals to meet their obligations under TRIPS⁴. The TRIPS patent regime has therefore made it extremely difficult and nigh impossible for countries to use the types of measures that were formerly available to them to address the access to medicine problem.

In Africa where both communicable and non-contagious diseases continue to take an ominous toll on the health of people, the access to medicines problem is a very significant one. The problem of access to affordable medicines in Africa is undoubtedly not one that was solely occasioned by the TRIPS Agreement. As a matter of fact, a study conducted in conjunction with the African Union shows that the reasons for lack of access to essential medical products in the continent *'have to do with trade agreements, market size, drug pricing, intellectual property and competition within the pharmaceutical industry as well as with a progressively dying R&D pipeline, the financing of R&D pharmaceutical production, procurement and supply issues, the failures of health systems in many poor countries and regions'*.⁵ Whilst there are a number of international and regional conventions, including the

¹ The Author is an LL.M (Thesis) Candidate at the School of Law, University of Tasmania. I will like to acknowledge with thanks the valuable comments and feedbacks from my supervisors, Prof Dianne Nicol and Dr. Jane Nielsen, on the draft of this paper.

² See William Cornish & David, Llewelyn, *Intellectual Property: Patents, Copyright, Trade Marks And Allied Rights*, (London Sweet & Maxwell, 6th ed, 2007) 179

³ Elena Ghanotakis, 'How the US Interpretation of Flexibilities Inherent in TRIPS affects Access to Medicines for Developing Countries' (2004) 7(4), *Journal of World Intellectual Property* 563, 565

⁴ Elena Ghanotakis, *supra* at 566

⁵ Council on Health Research for Development (COHRED) and New Partnership for Africa's Development (NEPAD), *Strengthening Pharmaceutical Innovation in Africa*, (2009) 58-59

African Charter on Human and Peoples Rights, recognising the right to health as a fundamental right, the enforcement of the right to health remains highly illusory in Africa.

The aim of this paper is to consider the extent to which the TRIPS patent regime has exacerbated the access to medicines problem in Africa and the flexibilities that are available within TRIPS to address the problem. It examines the significance of the right to health to the debate and highlights the need for African nations to form a common front under the African Union to address this problem.

2. The TRIPS Agreement and Access to Medicines in Africa

For African nations, as it is with other countries in the Global South, one of the most significant public health problems is the availability of affordable treatment and medicines especially for people who are HIV-positive.⁶ Access to affordable anti-retroviral drugs is not the only significant health problem in Africa; it is only representative of a much broader problem – access to essential medicines. According to the WHO World Health Statistics 2010⁷, lack of resources (access to medicine) is one of the major challenges in the global efforts to achieve the health-related Millennium Development Goals (MDGs adopted by world leaders under the auspices of the United Nations and fashioned to drastically reduce poverty and substantially improve human development all over the world)⁸ with less than 5 years to the 2015 deadline. The 2010 World Health Statistics shows that in the WHO African Region, where the HIV prevalence among adults continues to be the highest in the world, only 45% of pregnant women in need in low-income countries received HIV treatment, while in the WHO European Region, where HIV prevalence amongst adults is much lower, 94% of pregnant women in need in low income and middle income countries had access to medicine. The fact that only 45% of pregnant women who constitute the priority group in the distribution of HIV drugs in poor countries, where quite a significant proportion of the infected persons hardly have the means of getting to the major distribution centers, inexorably, shows that access to medicine is a serious challenge in the African continent. The situation is even more disheartening having regards to the fact that the few people who receive the drugs are primarily supplied through the efforts of organizations like the WHO, non-governmental organisations and sometimes, foreign aid- suppliers which are anything but regular.

It has been argued that the difficulty with access to medicines in developing countries has nothing to do with patent protection under the TRIPS Agreement but with problems such as the absence of free trade and effective economies of scale.⁹ There is however a connection between patents on pharmaceuticals, which empowers patent holders to set high prices for

⁶ See Erika George, 'The Human Rights to Health and HIV/AIDS: South Africa and South-South Co-operation to Reframe Global Intellectual Property Principles and Promote Access to Essential Medicines' (2011)18 *Indiana Journal of Global Legal Studies* 168

⁷ WHO World Health Statistics 2010/ <http://aidsdatahub.org/en/whats-new/287-all-data-alerts/598-who-2010-world-health-statistics-2010> (Accessed 27-07-11)

⁸ UN Secretariat, United Nations Millennium Declaration, General Assembly Resolution 55/2 (Doc. A/RES/55/2 adopted 8 September 2000)

⁹ Nuno Pires de Carvalho, *The TRIPS Regime of Patent Rights* (Kluwer Law International, 2nd edition, 2005) 337

their products, and the availability of these drugs in poor countries where most people cannot afford to pay for expensive drugs from their earnings.¹⁰ A very good instance of the effect of the TRIPS patent regime on access to medicines is the sequence of events that followed the enactment of the South African Medicines and Related Substances Control Amendment Act No. 90 1997 which actually empowers the South African government to use parallel importing and compulsory licensing to create generic versions of drugs patented by several US companies. Following the enactment of the law, South Africa was placed on the US trade sanction 301 Watch List and a patent infringement suit was commenced against the South African government by the Pharmaceutical Manufacturer's Association (PMA) and 39 pharmaceutical companies.¹¹ The crux of their argument was that the South African law was discriminatory against pharmaceutical patents and therefore inconsistent with TRIPS Article 27 which requires that patents be made available without discrimination as to the field of technology.¹² These however incensed a lot of AIDS and human rights groups globally and the public pressure they generated resulted in the termination of the suit by the pharmaceutical companies and an executive order from the US that supported the use of compulsory licenses for sub-Saharan Africa.¹³

In a similar vein, the US government hinted that it might parallel import or issue a compulsory licence for Ciproflaxin (an anthrax antidote) should Bayer (the patentee/manufacturer) refuse to sell the drug below market costs following the circulation of anthrax contaminated letters in the US sometime in 2001.¹⁴ The fact that the US had little compunction in threatening to grant compulsory licensing for an anti-anthrax drug in the wake of the 2001 Al Qaeda attack on New York¹⁵ eloquently shows that an unchecked patent protection regime can be a significant public health problem for not only the poor countries but even developed countries. At the same time it shows that the flexibilities are there to alleviate some of the potential hardships caused by patents if there is the political will to do so.

3. The TRIPS Flexibilities

The TRIPS Agreement gave some succour to developing country members in that it allowed them not to extend patent protection to areas of technology not originally patentable in their territories until 2005.¹⁶ With respect to least developed countries, the Agreement gave

¹⁰ Rachel Roumet, 'Access to Patented Anti – HIV/AIDS Medicines: The South African Experience' [2010] *European Intellectual Property Review* 137

¹¹ Ibid

¹² P Drahos with J Braithwaite, *Information Fedalism, Who Owns the Knowledge Economy?* (The New Press, New York, 2002) 6

¹³ See N Ansari, 'International Patent Rights in a Post-Doha World' (2002) 11 *International Trade Law Journal* 57, 61

¹⁴ See Ansari above n13, 63; Keith Bradsher, A Nation Challenged: The Cost ; Bayer Agree to Charge Government a Lower Price for Anthrax Medicine, *New York Times*, Oct. 25, 2001 at B7

¹⁵ Cornish & Llewelyn above n 2, 295

¹⁶ Agreement on Trade-Related Aspects of Intellectual Property Rights, Article 65 (4)

them up to 2005 to comply with its substantive provisions.¹⁷ In response to the global outcry for more flexible standards in the interest of public health, the TRIPS council adopted the Doha Declaration in 2001 and the Implementation Decision in 2003 to address this issue.

With the adoption of the Doha Declaration in 2001, least developed countries are further exempted from complying with the TRIPS patent regime and protection of undisclosed information until 1 January 2016.¹⁸ This, however, provided little in the way of guaranteed access to medicines in such countries as they substantially lack the necessary manufacturing capacity for producing generics and are no longer able to import them from generic producers like India or China as they are unable to manufacture generic versions of medicines that have been patented post-TRIPS.

The TRIPS Agreement does contain certain flexibilities enabling countries to take certain measures in national interest and which arguably have the effect of preventing an abuse of the patent system¹⁹ albeit the scope of the flexibility is largely qualified. The basic flexibilities guaranteed by TRIPS in relation to patents are found in Articles 6 (exhaustion of rights and parallel importation), 8 (dealing with measures to protect national interests and prevent abuse of intellectual property rights), 27 (2) & (3) (exceptions from patentability), 30 (exceptions to the rights conferred) and 31 (compulsory licensing). A detailed discussion of these flexibilities is however not within the purview of this paper.

Access to affordable medicine in Africa is, however, a big problem not only as a result of under-utilisation of the TRIPS flexibilities but also because other means of checking the abuse of patent rights such as economies of scale, anti-trust regulation and technology transfer are not concepts that are being effectively utilised in many if not all parts of the continent.

4. The Human Rights Dimension to the Debate

Access to medicines is undoubtedly a significant component of the right to health²⁰ and about two billion people have been reported to lack access to essential medicines all over the world.²¹ Intellectual property rights are also human rights as they are recognised as such in a number of international conventions.²² The question that thus arises from this is

¹⁷ Agreement on Trade-Related Aspects of Intellectual Property Rights, Article 66

¹⁸ Doha Ministerial Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/Dec/2, adopted on 14 November 2001, paragraph 7

¹⁹ See Nielsen & Nicol 'Pharmaceutical Patents and Developing Countries: the Conundrum of Access and Incentive' [2002] *Australian Intellectual Property Journal* 13 pg 21

²⁰ Erika George, 'The Human Rights to Health and HIV/AIDS: South Africa and South-South Co-operation to Reframe Global Intellectual Property Principles and Promote Access to Essential Medicines' (2011) *Indiana Journal of Global Legal Studies* 18, 168

²¹ UN Human Rights Council (H.R.C.), Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, 11th Sess., P 14, U.N. Doc. A/HRC/11/12 (Mar.31, 2009) (by Anand Grover)

²² Article 27 of the Universal Declaration of Human Rights provide that everyone has the right to the protection of the moral and material interests resulting from any scientific, literary and artistic production of which he is the author. Similarly, by Article 15 of the International Covenant on

whether certain human rights are superior to others and, putting it in more specific terms, whether the right to health is superior to property rights? It has been eloquently argued that the right to health is a basic right vital to a minimally adequate standard of living and therefore should assume eminence over rights that are based on wants or desires.²³ However, it is equally arguable that property rights are fundamental and vital to adequate standard of existence although it is not easy to reach a consensus on this point.²⁴ There is, however, no gainsaying the fact that relying on the right to health can produce real legal and institutional outcomes and there are a number of cases where health has actually been secured through rights.²⁵

The preamble to the Constitution of the World Health Organization (WHO) declares that the 'enjoyment of highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.'²⁶ The Universal Declaration of Human Rights of 1948 states that 'everyone has the right to a standard of living adequate for the well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services.'²⁷ In a similar vein, the International Covenant on Economic, Social and Cultural Rights of 1966 provides that States shall recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.²⁸

Economic, Social and Cultural Rights, states contracted to recognise the right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary and artistic production of which he is the author.

²³ Rajshree Chandra, 'The role of national laws in reconciling constitutional right to health with TRIPS obligations: an examination of the Glivec patent case in India' in Thomas Pogge, Matthew Rimmer and Kim Rubenstein (eds), *Incentives for Global Public Health: Patents Law and Access to Essential Medicines* (Cambridge University Press, 2010) 381.

²⁴ See Philippe Cullet, 'Human Rights and Intellectual Property Protection in the TRIPS Era', (2007) *Human Rights Quarterly* 29, 403, 405

²⁵ See Katherine G. Young, 'Securing health through rights' in Thomas Pogge, Matthew Rimmer and Kim Rubenstein (eds), *Incentives for Global Public Health: Patents Law and Access to Essential Medicines* (Cambridge University Press, 2010)

²⁶ Constitution of the World Health Organisation (signed in New York on July 22 1946)

²⁷ Universal Declaration of Human Rights, UN Doc A/810 (1948) Article 25

²⁸ International Covenant on Economic, Social and Cultural Rights, Article 12(1). Article 12(2) of the Covenant further provides that states shall take necessary steps for the provision for the still-birth rate, infant mortality and the healthy development of the child; the improvement of all aspects of environmental and industrial hygiene; the prevention, treatment and control of epidemic, endemic, occupational and other diseases;

and the creation of conditions which would assure to all medical service and medical attention in the event of sickness. Other international conventions recognizing the right to health are:

- a. The International Convention on the Elimination of All Forms of Racial Discrimination (1965): art. 5 (e) (iv);
- b. The Convention on the Elimination of All Forms of Racial Discrimination against Women (1979): arts. 11 (1) (f), 12 and 14 (2) (b);
- c. The Convention on the Rights of the Child (1989): art. 24
- d. The International Convention on the Protection of Rights of All Migrant Workers and Members of their Families (1990): arts. 28, 43 (e), and 45 (c);
- e. The Convention on the Right of Persons with Disabilities (2006); art. 25

The right to health is recognised in many regional instruments and not less than 115 national constitutions.²⁹ The African Charter on Human and Peoples' Rights also recognises the right of every individual to attain the highest state of physical and mental health and all states parties to the convention are enjoined to protect the health of their people and to ensure they receive medical attention when they are sick.³⁰ The right to health is linked to the right to life and the right to economic, social and cultural development which is recognised under the International Covenant on Civil and Political Rights.³¹ Human rights can be used to justify liberal interpretation of the TRIPS flexibilities in a way that will sufficiently empower countries to adopt measures in national interests and in the interest of public health. It has been argued that human rights '*establish an absolute minimum standard for the protection of a dignified life for every human being, with a particular emphasis on the most marginalized and vulnerable among them*'.³² Whilst it has been eloquently argued that intellectual property rights are natural human rights and recognised as such by the Universal Declaration of Human Rights³³, the fact that IP rights are essentially based on economic considerations is an undeniable fact.³⁴ Thus, given the economic foundations of intellectual property rights, they arguably differ substantially from natural rights, such as the right to life/health, which are significantly essential not only for the well-being of man but even his existence. It is thus recommended that where economic rights conflict with natural rights, a balance must be struck and that balance must be one that best protects the dignity of human life.

It is therefore very possible to secure health through recourse to human rights.³⁵ African countries can take advantage of all the flexibilities currently allowed by the TRIPS Agreement and interpret the Agreement as a whole in a way that will favour the availability of drugs in the continent. Bold steps can be taken in implementing the TRIPS flexibilities as done by India³⁶, Thailand³⁷ and South Africa before the TRIPS Doha Declaration. If such

²⁹ See Office of the United Nations High Commissioner for Human Rights, (OHCHR), The Right to Health. Fact Sheet No 31, Geneva, OHCHR June 2008, pg 10

³⁰ African (Banjul) Charter on Human and Peoples' Rights, OAU Doc. CAB/LEG/67/3 rev. (Adopted in 1981, entered into force in 1986) Article 16

³¹ International Covenant on Civil and Political (Adopted in 1966, came into force in 1976) Article 1

³² Hans Morten Haugen, 'Human Rights and TRIPS Exclusion and Exception Provision' (2009) *Journal of World Intellectual Property* 11, 345, 359

³³ Robert J. Gutowski, 'The Marriage of Intellectual Property and International Trade in the TRIPS Agreement: Strange Bedfellows or a Match Made in Heaven?' (1999) *Buffalo Law Review* 47, 713,745

³⁴ See L.T.C Harms, 'A Few Negative Trends in the Field of Intellectual Property Rights' (2009) *European Intellectual Property Review* 31(11) 540, 541

³⁵ See Katharine G. Young, 'Securing health through rights' in Thomas Pogge, Matthew Rimmer and Kim Rubenstein (eds), *Incentives for Global Public Health: Patents Law and Access to Essential Medicines* (Cambridge University Press, 2010) 381

³⁶ See Rajshree Chandra, 'The role of national laws in reconciling constitutional right to health with TRIPS obligations: an examination of the Glivec patent case in India' in Thomas Pogge, Matthew

actions are challenged for infringing intellectual property rights, African states can justify the measures taken by relying on international human rights laws and the African Charter on Human and Peoples' Rights which all impose an obligation on states to secure the health of their citizens.

5. Access to Medicines in Africa: The Role of the African Union

The objectives of the African Union Commission (AU) include establishing the necessary conditions for the continent to play its rightful role in the global economy and in international negotiations whilst working with relevant international partners in the eradication of preventable diseases and the promotion of good health on the continent.³⁸ The AU has taken certain steps to address the issue of access to affordable medicine in Africa. African Heads of State and Government adopted the Abuja Declaration and Framework of Action on HIV/AIDS, Tuberculosis and Other Related Infectious Disease (ORID) at a Special Summit in 2001.³⁹

The enactment by South Africa of the Medicines and Related Substances Control Amendment Act of 1997 and the stiff opposition to it by the US actually paved the way for the adoption by the WTO of the Doha Declaration on TRIPS and Public Health in Doha, Qatar in November 2001.⁴⁰ The African Group, working as African, Caribbean, and Pacific Ministers (ACP) equally played a very significant role in negotiating the text of the Implementation Decision on Paragraph 6 of the Doha Declaration on TRIPS and Public Health adopted by the WTO in August 2003.⁴¹

Indeed, the policy position of the AU, taken by 55 African Ministers of health during the Abuja Summit in 2001 and the 2005 Gaborone Declaration, is 'to pursue, with the support of our partners, the local production of generic medicines on the Continent and make full use of flexibilities within the Trade Related Aspects of Intellectual Property Rights (TRIPS) and Doha

Rimmer and Kim Rubenstein (eds), *Incentives for Global Public Health: Patents Law and Access to Essential Medicines* (Cambridge University Press, 2010) 381

³⁷ See Jonathan Burton-Macleod, 'Tipping Point: Thai compulsory licenses redefine essential medicines debates' in Thomas Pogge, Matthew Rimmer and Kim Rubenstein (eds), *Incentives for Global Public Health: Patents Law and Access to Essential Medicines* (Cambridge University Press, 2010) 406

³⁸ See The African Union Constitutive Act (Adopted in 2000, came into force in 2001) Article 3(i) & (n)

³⁹ African Union Secretariat, African Summit on HIV/AIDS, Tuberculosis and other Related Infectious Diseases Abuja Nigeria 24-27 April 2001, 'Abuja Declaration on HIV/AIDS, Tuberculosis and Other Related Infectious Disease (Doc No. OAU/SPS/Abuja/3; see also African Union, Special Summit of African Union on HIV/AIDS, Tuberculosis and Malaria (ATM) Abuja, Nigeria, 2-4 May 2006, 'Universal Access to HIV/AIDS, Tuberculosis and Malaria Services by a United Africa by 2010 (Doc No. Sp/Assembly/ATM/3(I), pg1

⁴⁰ See Peter Drahos with John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?*, (The New Press, 2002) 6 – 8

⁴¹ See Communication from the African, Caribbean and Pacific Group of States (ACP), WTO Doc. IP/C/W/401 (May 28, 2003); Frederick M. Abbot, 'The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health' (2005) *American Journal of International Law* 99, 331

Declaration on TRIPS and Public Health.⁴² The AU in line with this objective adopted the Pharmaceutical Manufacturing Plan for Africa in 2007. The Pharmaceutical Manufacturing Plan for Africa recommended that a Technical Committee be established with a mandate to conduct a detailed study of the implications of local production of pharmaceuticals in Africa.⁴³ The Technical Committee -which was made up of North Africa (Egypt and Libya), West Africa (Ghana, Nigeria and Senegal), Central Africa (Burundi, Cameroon and Gabon), East Africa (Kenya and Ethiopia) and Southern Africa (South Africa and Angola) - noted that whilst African countries South of Sahara import 90% of their medicine needs from outside the Continent (mainly India and China), local production of affordable medicines with quality, efficacy and safety will only be possible by African countries working together to achieve this objective.⁴⁴

6. The African Union and Options for Facilitating Access to Medicines in Africa

Although the African Union Commission has made laudable efforts in addressing the access to medicine challenge in Africa, much more still has to be done to effectively address the situation. Some options that can be explored to address the problem are highlighted below.

6.1 Local Production of Drugs

The AU has expressed its firm commitment to local production of generic drugs on the continent. According to the AU Pharmaceutical Manufacturing Plan for Africa adopted in 2007, no single country in the continent, whatever its size or economic development, is fully self-sufficient in the production of pharmaceuticals. Local production is particularly desirable because apart from the economic benefits to local industry, local production will enhance the affordability of drugs and make it easier to have access to drugs that are particularly difficult to import, such as intravenous drips, which are mostly in liquid form.⁴⁵ However, having regards to the challenges of many African countries such as political instability, poor economy and lack of sufficient technical expertise, it may not be easy for governmental collaborative efforts even at regional level to achieve the international standard for primary pharmaceutical production. Local primary production will be easier to achieve if African governments can harness their resources under the auspices of an umbrella body such as the AU to establish pharmaceutical plants for each region in the continent. Only South Africa has a limited primary production capacity in Africa (that is capable of producing Active Pharmaceutical Ingredients) and the AU's approach seem to place more emphasis on national and regional efforts.⁴⁶ However a continent wide collaboration under the AU for every region in Africa is likely to be a more effective solution to the problem.

⁴² African Union Secretariat, Gaborone Declaration, Doc. CAMH/Decl.1(II) 3 (10 – 14 October 2005)

⁴³ African Union Secretariat, Draft Pharmaceutical Manufacturing Plan for Africa Doc. CAMH/MIN/7(III), 6 (10 – 13 April 2007)

⁴⁴ African Union Secretariat, Progress Report on the Pharmaceutical Manufacturing Plan for Africa Doc. MIN/Sp?AU?CAMH3/2, 12 (MAY 17, 2008)

⁴⁵ See Tatum Anderson, 'Tide turns for drug manufacturing in Africa' (2010) *The Lancet* 375(9726) 1597, 1598; <http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2810%2960687-3/fulltext> (Accessed 27-08-11)

⁴⁶ See Council on Health Research for Development (COHRED) and New Partnership for Africa's Development (NEPAD), *Strengthening Pharmaceutical Innovation in Africa*, (2009) 58-59

6.2 Incorporation of TRIPS Flexibilities into National Laws

Many African countries are yet to incorporate the provisions of the TRIPS Agreement, especially its flexibilities, into their national laws. For such countries, it will be difficult to take advantage of TRIPS flexibilities such as compulsory licensing if this is not provided for in their national laws. For instance, a recent study conducted in Tanzania, reveals that the non-inclusion of TRIPS flexibilities in Tanzanian law is one of the factors hindering access to essential medicines in the country as the range of generics local manufactures can produce is limited.⁴⁷

Compulsory licensing is a process whereby the government grants a license allowing either the government or a third party to produce the patented product or use the process without the authorization of the patent holder.⁴⁸ The TRIPS Agreement allows for compulsory licensing (which it refers to as use without authorisation) subject to an extensive list of conditions. In summary, these conditions provide that each case must be considered on its merits, there must be an unsuccessful negotiation with the patent holder, the WTO must be informed of the grant, the use of the product must be limited to the purpose for which the license is granted, products manufactured under the system must be predominantly for the supply of domestic market, the compulsory license shall be non-exclusive and non-assignable, right holder must be adequately remunerated, the compulsory license shall be subject to judicial review and there are also restrictions on the use of second patents to protect the interest of the first patent holder.⁴⁹ However, as a result of these conditions, a number of commentators have argued that the TRIPS regime for compulsory licensing is very cumbersome, time consuming and expensive⁵⁰.

In response to the global outcry for more flexible standards in the interest of public health, the TRIPS Council adopted the Doha Declaration in 2001, paragraph 6 of which affirms the '*right of WTO members to use to the full, the provisions in the TRIPS Agreement which provide flexibility for the purpose of protecting public health in particular promoting access to medicine for all*'.⁵¹ This was followed by the adoption of the Implementation Decision on Paragraph 6 of the Doha Declaration on TRIPS and Public Health in 2003. The basic purport of the Implementation Decision is to empower countries with little or no pharmaceutical manufacturing capacity to import essential drugs through compulsory licensing.⁵² The

⁴⁷ Mhamba RM and Mbrigenda S 'The drugs industry and access to essential medicines in Tanzania' (*EQUINET Discussion Paper Series 83*, 2010) Training and Research Support Centre, SEATINI, Rhodes University, EQUINET: Harare

⁴⁸ Holger Hestermeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, (Oxford University Press 2007) 239

⁴⁹ See Article 31 of the TRIPS Agreement

⁵⁰ Chian Kee, 'Efficiency, equity and ethics: Examining the policy behind compulsory licensing and access to medicines in developing countries' (2007) *Australian Intellectual Property Journal* 18, 39, 62; Katri Paas, 'Compulsory Licensing Under the TRIPS Agreement – A Cruel Taunt for Developing Countries?' [2009] *European Intellectual Property Review* 609

⁵¹ See Rachel Roumet, 'Access to Patented Anti – HIV/AIDS Medicines: The South African Experience' [2010] *European Intellectual Property Review* 137

⁵² See Frederick M. Abbot, 'The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health' (2005) *American Journal of International Law* 99, 317; Report to the General Council of the Council for TRIPS Annual Review of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WTO Doc. IP/C/57

Implementation Decision, which has been incorporated into the Protocol Amending the TRIPS Agreement, applies only to pharmaceutical products and it allows countries with little or no manufacturing capacity in the pharmaceutical sector to import drugs under a compulsory license.⁵³ The Decision therefore waives the requirement of TRIPS Article 31(f), which states that products made under compulsory licenses must be predominantly for domestic markets.⁵⁴

Whilst both the country exporting and the importing country are required to grant compulsory licenses under the system if the product is patented in both,⁵⁵ only the country exporting to the member without manufacturing capacity is bound to remunerate the patent holder to avoid a situation whereby the right holder receives double remuneration.⁵⁶ Although any WTO members is entitled to import under this decision, 23 developed countries have voluntarily indicated that they will not use the system to import, 11 more indicated they would only use the system to import in national emergencies or other circumstances of extreme urgency and with effect from 2004 when the EU became a WTO Member, another 10 members have been added to the list.⁵⁷

The Protocol Amending the TRIPS Agreement, which seeks to incorporate the August 2003 Implementation Decision into TRIPS, was adopted on 6th December 2005 in the interest of public health. The amendment will come into force upon acceptance by two thirds of the all WTO Members.⁵⁸ Once the amendment comes into force, it will take effect with respect to those who have accepted it while the waiver will continue to apply for others until they accept the amendment⁵⁹. The WTO has 153 Members⁶⁰ and so far only 34 Members have accepted the amendment.⁶¹

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http://docsonline.wto.org/GEN_highLightParent.asp?qu=&doc=D%3A%2FDDFD%2FDOCUMENTS%2F%2FIP%2FC%2F57%2EDOC%2EHTM&curdoc=4&popTitle=IP%2FC%2F57 (Accessed 19/07/11)

⁵³ Mathew Kennedy, 'When Will the Protocol Amending the TRIPS Agreement Enter into Force?' (2010) *Journal of International Economic Law*, 13 (2), 459

⁵⁴ Paragraph 2 of the Decision on the Implementation of Paragraph 6 of Doha Declaration on the TRIPS Agreement and Public Health; Annex to the Protocol Amending the TRIPS Agreement, Article 31bis (1) (WTO Doc No. WT/L/641)

⁵⁵ See Paragraph 2 (a) (iii) of the Decision on the Implementation of Paragraph 6 of Doha Declaration on the TRIPS Agreement and Public Health; paragraph 2 (a) (iii) of the Annex to the TRIPS Agreement; Paragraph 2 (c) of the Decision on the Implementation of Paragraph 6 of Doha Declaration on the TRIPS Agreement and Public Health; paragraph 2 (c) of the Annex to the TRIPS Agreement

⁵⁶ See Paragraph 3 of the Implementation of Paragraph 6 of Doha Declaration on the TRIPS Agreement and Public Health; Annex to the Protocol Amending the TRIPS Agreement, Article 31bis (2) (WTO Doc No. WT/L/641)

⁵⁷ See WTO Factsheet on TRIPS and Pharmaceutical Patents, September 2006, http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm#importing (accessed 09/08/11)

⁵⁸ See Article X (3) of the Agreement Establishing the World Trade Organization

⁵⁹ See Article X (5) of the Agreement Establishing the World Trade Organization

African countries also need to accept the Protocol Amending the TRIPS Agreement. Whilst the flexibilities in TRIPS might not be the best solution to the global access to medicine challenge, Africa need not deprive herself of the little flexibility the international framework currently allows. More importantly, African countries should form a common front to reject TRIPS-plus agreements, which have the effect of eroding the little flexibility allowed by the TRIPS Agreement. The reason why this can occur is because TRIPS only sets minimum standards and increasingly the level of protection is expanding beyond the TRIPS minima through bilateral trade agreements.

6.3 The need for effective competition policies

One major challenge with the enforcement of intellectual property rights in Africa is the fact that most African countries have a very weak or even no framework for competition law which strives to ensure static efficiency by preventing the abuse of a dominant position and enhancing the entry of new competitors for the benefit of consumers.⁶² Indeed, competition law/anti-trust regulation is a significant weapon for the abuse of intellectual property in the United States.⁶³ The AU has to make the need for African countries to develop strong competition policies one of its priorities.

6.4 Technology Transfer

Technology transfer is one of the incentives included in the TRIPS Agreement for developing countries.⁶⁴ Lack of technical expertise and the need for technology transfer have been identified as significant issues for local production of drugs in the AU Pharmaceutical Manufacturing Plan for Africa. Technology transfer is undoubtedly an expensive venture and one that the least developed states may find particularly difficult. This is another area where a collaborative effort is urgently needed and the AU is best positioned to facilitate this.

6.5 Establishing a Continental Free Trade Zone

As earlier noted, the emphasis of the AU is currently on Regional Economic Communities (REC) to facilitate the free movement of goods. The TRIPS Agreement states that nothing in the Agreement shall be used to address the issue of exhaustion of intellectual property

⁶⁰ See Understanding the WTO: The Organization: Members and Observers, available at http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (accessed 11/07/11)

⁶¹ WTO, TRIPS and Public Health: Members accepting amendment of the TRIPS Agreement, http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (Accessed 22-08-11)

⁶² Tu Thanh Nguyen, *Competition Law, Technology Transfer and the TRIPS Agreement: Implications for Developing Countries* (Edward Elgar Publishing Limited, 2010) 34

⁶³ See Richard A. Eipstein and F. Scott Kieff, 'The Licensing of Intellectual Property: Questioning the Frequency and Wisdom of Compulsory Licensing for Pharmaceutical Patents' (2011) *University of Chicago Law Review* 78, 71, 85

⁶⁴ See Duncan Matthews, 'TRIPS Flexibilities and Access to Medicines in Developing Countries: The Problem With Technical Assistance and Free Trade Agreements' [2005] *European Intellectual Property Review* 420

rights.⁶⁵ Generally, intellectual property rights are exhausted after first sale by the right owner or with his consent although this is usually confined to first sales within the country covered by the right.⁶⁶ There are three basic types of exhaustion of rights to wit: national exhaustion, regional exhaustion and international exhaustion.⁶⁷ National exhaustion requires that the exclusive rights of an IP holder become exhausted once goods are put in the market within a country's national borders, regional exhaustion regards the exclusive rights as exhausted with the first sale in a regional market such as the EU and the AU, whilst international exhaustion requires that rights are exhausted with the first sale in any market.⁶⁸ The import of Article 6 of the TRIPS Agreement is to recognise the legitimacy of international exhaustion of rights which means the importation into a country of products protected by intellectual property rights can occur without the risks of patent infringement once the product has been put on the market legitimately in any country.⁶⁹

However, Africa as a continent can have a regional trade agreement or an African Economic Community.⁷⁰ As there is no single developed country in the continent, a regional trade agreement covering the whole of Africa will make it easier for drugs imported under a compulsory license in one African country to move to any other country in the continent without being subject to the constraints imposed by the TRIPS Agreement on the exportation of drugs imported under compulsory licensing.⁷¹ It will also mean that intellectual property rights are exhausted with the first sale of IP products in any market in the continent.

Pending the time Africa can start full local pharmaceutical production for the continent, the AU should look at developing a trade agreement for the United Nations African region to facilitate the circulation of drugs imported into the continent under the TRIPS compulsory licensing scheme whilst enhancing the use of the exhaustion of rights doctrine.

7. Conclusion

For a continent that is being highly affected by one of the most dreaded diseases of the 21st century as well as other epidemics, the need for access to affordable medicines can hardly be over-emphasised. Health is not only essential for the complete well-being of the

⁶⁵ Article 6 of the TRIPS Agreement

⁶⁶ Cornish & Llewellyn, above n2, 43

⁶⁷ Duncan Matthew and Viviana Munoz-Tellez, 'Parallel Trade, A User's Guide' in IP Handbook of Best Practices (2007) 1432

⁶⁸ *ibid*

⁶⁹ Carlos M. Correa *Trade Related Aspects of Intellectual Property Rights: A Commentary on TRIPS Agreement* (Oxford University Press 2007) 79

⁷⁰ The AU Treaty Establishing the African Economic Community was adopted in Abuja, Nigeria on 3 June 1991 and came into force on 12 May 1994. Article 6 of the Treaty provides that the African Economic Community shall be established gradually in six (6) stages of variable duration over a transitional period not exceeding thirty-four (34) years.

⁷¹ See Paragraph 6(i) of the Decision on the Implementation of Paragraph 6 of Doha Declaration on the TRIPS Agreement and Public Health; Annex to the Protocol Amending the TRIPS Agreement, Article 31bis (3) (WTO Doc No. WT/L/641)

populace; it is also linked to programmes in development.⁷² According to the 2010 UN Human Development Report⁷³, Sub-Saharan Africa has the highest incidence of multidimensional poverty in the world⁷⁴ with the region particularly found to possess the lowest Human Development Index indicators of any region.⁷⁵ Access to affordable medicines is therefore intimately linked with Africa's developmental goals and the AU, in line with its cardinal objectives of economic integration, the eradication of preventable diseases and promotion of good health, is best positioned to harness the support and resources needed to safeguard the right to health in Africa. The TRIPS flexibilities and other international human rights law safeguarding the right to health must therefore not only be implemented into domestic law in all African Union countries but must also be put into practical effect.

⁷² See Johanna Gibson, *Intellectual Property, Medicine and Health: Current Debates* (Ashgate Publishing Limited, 2009) 77

⁷³ UNDP Secretariat, Human Development Report 2010 available at http://hdr.undp.org/en/media/HDR_2010_EN_Complete_reprint.pdf (Accessed 29- 11- 11)

⁷⁴ *Ibid* at 97

⁷⁵ *Ibid* at 30