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The Trips Agreement and Access to Medicine and Pharmaceutical Products by Developing Countries: Any Hope For Africa?

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I. Introduction:

Infectious diseases such as HIV/AIDS, respiratory infections, Ebola, bird flu, cancer and most recently COVID-19 have continued to kill people in their numbers daily the world over, with higher mortality rate in developing countries, particularly in Africa. The predominant reason for the deplorable situation in developing countries is the lack of access to medical and pharmaceutical products as well as adequate cutting edge technology in management of such ailments.[3] However, there is an interplay between access to medical and pharmaceutical products, information on health and general wellbeing of the people. In assessing the level of access to information on health both preventive and curative, it is important to consider the educational standard of the people. There is no need saying the fact that the educational attainment of the population has also come under strain. This has occurred despite an improvement in access to educational facilities at all levels. According to 'Organisation for Economic Co-operation and Development' (OECD) report[4], "the educational system has become so ineffective and inefficient; that the quality of education has been compromised at all levels.[5] Although the literacy rate has increased, this is of little consequence in the face of the overall decline in the quality of education.[6] Low educational attainment has contributed to a decrease in access to medical, pharmaceutical products and vaccines, productivity in the economy, high fertility rates and a worsening situation in the nutrition and health status of the population.[7]

On the other hand, the evolution of intellectual property has generated a variety of supporting theories and an array of legal tools to help solve the multifaceted problems in our society such as the issue of access to medicine and pharmaceutical products. These legal tools find application particularly in open economies where there is competition. However, the tools of intellectual property are designed to stimulate private activity, chiefly the investment of funds in support of the research for development of innovation and creative expression. The development of new technology inherently bears greater risk than other commercial activity.

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[3] C Rao, A D Lopez and Y Hemed, "Causes of Death" **In:** D T Jamison, R G Feachem, M W Maggoba, *et al*'(eds)' "*Disease and Mortality in Sub-Saharan Africa*, 2nd Edition (Washington DC: The International Bank for Reconstruction and Development / The World Bank, 2006) Chapter 5

[4] Organisation for Economic Co-operation and Development (OECD), *Innovating Education and Educating for Innovation: The Power of Digital Technologies and Skills*(OECD Publication, 2016)

[5] N S Okoroma, "Educational Policies and Problems of Implementation in Nigeria (2006) 46 *Australian Journal of Adult Learning*, 2, 244-263

[6] A E Gakusi, "African Education Challenges and Policy Responses: Evaluation of the Effectiveness of the African Development Bank's Assistance" (2010) 22 *African Development Review*, 1, Pp. 208-264. A publication of the African Development Bank Group, available at https://www.afdb.ord>afdb.

[7] A Bhalla, *et al*, "Globalisation and Sustainable Human Development: Progress and Challenges for Malawi" United Nations Conference on Trade and Development/United Nations Development Programme (UNCTAD/UNDP) Occasional Paper, UNCTAD/EDM/Misc.129, 2020 at P. 68-69

Thus, through reduction of risk, these legal tools stimulate greater investment in innovation process;[8] such as in the medical and pharmaceutical field. In recent years, the issue of intellectual property protection has been 'married' to international trade and other areas of human life. Unfortunately for some countries, this has converted intellectual property into a matter of trade confrontation.[9]Also, considering its core objectives and the overlapping nature and interference of intellectual property in other area of human development, it calls to question the ability of intellectual property to establish an overarching principle in the resolution of the ever increasing human needs like in the area of medicines and pharmaceuticals.

It is considered that a fairly open trading system will be important to gaining the benefits of robust intellectual property protection because without openness, strong intellectual property protection could produce tendencies toward less competition, whether because of trade restrictions, market size problems or other similar conditions in a closed economy.[10] Similarly, that the institutionalization of the human development principles in the conceptualization of intellectual property is the way to go in solving the human development challenges particularly in the era medicines, human needs and in the face of epidemic or pandemics.

TRIPs Agreement is part of the World Trade Organisation[11] system, negotiated during the Uruguay Round trade negotiations between 1986 to 1994. It emerged as one of three multilateral agreements laying the fundamental framework under which the WTO operates. The TRIPs Agreement which set out minimum standards for the protection of intellectual property rights, such as; copyrighted literary, artistic works and computer programmes, including patents for pharmaceutical and agricultural products as well as trademarks, geographical indications of origin, trade secrets, industrial designs and unfair competition, and other related issues.[12] Second, TRIPS mandated a detailed set of enforcement procedures, that is to say, rules of judicial and administrative conduct for all states.[13] Third, it established speedy and tough dispute -settlement machinery within the WTO framework, which in the end, leads to the possibility of cross-collateral trade sanctions for non-compliance with the agreed minimum standards of intellectual property protection.[14] These core mandates of TRIPs come under serious public scrutiny in the light of the human development concerns particularly as it concerns it effect in assisting developing countries to overcome or deal with issues of human development such as access to medicines, health and pharmaceutical products. In examining this critical area of concerns, Articles 27, 65, 66, 70 and 73 of TRIPs Agreement are subject of public debates and international discourse by scholars, governmental institutions and Non-Governmental Organisations (NGOs).

Article 27 provides that patent be available in all fields of technology, based on the criteria of novelty, industrial "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the term "non-obvious" and "useful" respectively.[15] Article 65 provides for the transitional arrangement for a period of four years from the date of coming into force the application of the TRIPs Agreement while Article 66 provides for a period of ten years for Least Developed Countries Members to apply and implement the provisions of the agreement. Article 70 provides for protection of existing subject matter and does not give rise to obligations in respect of acts which occurs before the date of application of the Agreement for the Member in question and Article 73 provides for security exceptions where Members are allowed to take any action which it considers necessary for the protection of its essential security interests inter alia taking in time of war or other emergency.

Apart from public policy objectives on health, the other set of challenges facing the international intellectual property system during the past decade related to its ability to address broader public interest considerations and development concerns.[16] The minimum standards for intellectual property protection,

[8]R M Sherwood, "The TRIPs Agreement: Implications for Developing Countries" (1997) 37 *IDEA: The Journal of Law and Technology*, 491-552 at 492

[9]*ibid*

[10]*ibid*

[11] WTO.

[12]The Agreement on Trade Related aspects of Intellectual Property, Annex 1C of Marrakesh Agreement Establishing the World Trade Organisation, signed in Marrakesh, Morocco on 15 January 1994 (Hereinafter referred to as TRIPS Agreement), Article 9-39; J H Reichman, "The TRIPS Agreement Comes of Age: Conflict or Cooperation with the Developing Countries" (2000) 32 *Case W. Res. J. Int'l L.*, 442-470

[13]Articles 41-61 TRIPS Agreement

[14]Article 63-64 of TRIPs Agreement; Also, Understanding on Rules and Procedures Governing the Settlement of Disputes, April 15, 1994, WTO Agreement, Annex 2, 33 I.L.M. 1226 (1994); R C Dreyfuss and A L Lowenfeld, "Two Achievements of Uruguay Round: Putting TRIPs and Dispute Settlement Together" (1997) 37 *VA. J. Int'l L.*, 275

[15]Footnote to Article 27 of the TRIPS Agreement

[16] A A Latif, "Change and Continuity in the International Intellectual Property System: A Turbulent Decade in Perspective" (2011) *W.I.P.O. J.* 3(1) 36

including pharmaceutical patents, as set out in the TRIPs Agreement does not allow for differentiation between products that are merely consumer goods and those that are life-saving such as medicines, pharmaceutical products and vaccines. The TRIPS Agreement has the singular aim of harmonising intellectual property standard globally. This has led to patent practices that maintain medicines and pharmaceutical products at artificially high prices in the poorest countries. Such practices did not take into consideration the human development component.

From the above stated facts, the traditional view of TRIPS as an instrument to promote innovation and incentives for creators or inventors no longer holds true in the light of the shifting geopolitical, social and economic dynamics which seems to define the new multilateralism in international relations. A multilateralism system where human development appears to progressively emerge as a strong influential factor on trade and development policy.[17] Consequently, it is the interest of this paper to examine the human development implications of TRIPs Agreement to developing countries as it relates to the issues of access to medicine, health and pharmaceutical products. In examining this concept, the legal and institutional framework for the protection of the right to health and access to medicine and pharmaceutical products will be examined.

II. Right to Health, Access to Essential Medicine and Pharmaceutical Products

The Right to Health has been proclaimed by the Commission on Human Rights,[18] as well as in the Vienna Declaration and Programme of Action of 1993 and other International instruments.[19] The UN Committee on international Economic, Social and Cultural Rights – the treaty body responsible for implementing and monitoring International covenant on Economic, Social and Cultural Rights (ICESCR) – has published a General Comment No. 14 to ICESCR[20] that outlines the content of the international right to health. It addresses the content of the right to health and the implementation and enforcement of the right to health. It also provides remedies for individual parties who have been denied the human right to health. General Comment No. 14 begins with some observations about the normative content of the right to health. It states that: "the right to health is not to be understood as a right to be healthy and that the right to health contains both freedoms and entitlements". The General Comment No. 14 specifies the freedoms and entitlements as follows:

The freedoms include the right to control one's health and body, including sexual and reproductive freedom, and the right to be free from interference, such as the right to be free from torture, non-consensual medical treatment and experimentation. By contrast, the entitlements include the right to system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.[21]

General Comment No. 14 then observes that the right to health extends not only to timely and appropriate health care but also the underlying determinants of health, such as access to safe and potable water and adequate sanitation, an adequate supply of safe food, nutrition and housing, healthy occupational and environmental conditions, and access to health-related education and information, including on sexual and reproductive health.[22] Furthermore, General Comment 14, provides that the health care system of a state party must have certain institutional characteristics to realize the right to health. These include the availability, accessibility and quality of needed health care services and facilities. "Availability" means that the state party has sufficient facilities and services for the population given the country's state of development. "Services" include those that affect the underlying determinants of health, such as safe and portable drinking water. "Accessibility" to health care facilities and services include the four dimensions: non-discrimination, physical

[17]B Janamanchi, "TRIPS and Developing Countries: Towards a New IP World Order? (2017) 31 *The International Trade Journal*, 5, Pp. 471-482

[18]Non Discrimination in the Field of Health, Resolution 1989/11, UNE(01)/R3 (45th Session: 1989, Geneva) Symbol IE/CN.4/RES/1989/11, Adopted at 46th Meeting, March 2, 1989. In: Commission on Human Rights: Report on the 45th Session, 30 January – 10 March 1989 E/1989/20-E/CN.4/1989/86.-1989.p.48-49. (ESCOR,1898,Suppl.no.2).

[19] The Principles for the Protection of Persons with Mental Illness and for the Improvement of Mental Health Care adopted by the UN General Assembly in 1991 (resolution 46/119) and the Committee's general comment No. 5 on persons with disabilities apply to persons with mental illness; the Programme of Action of the International Conference on Population and Development held at Cairo in 1994.

[20] UN Committee on Economic, Social and Cultural Rights (CESCR), General Comment No. 14: The Right to the Highest Attainable Standard of Health (Article 12 of the Covenant), 11 August 2000, E/C.12/2000/4, available at https://www.refwoorld.org/docid/4538838d0.thml Accessed April 28, 2022 [Hereinafter General Comment 14]

[21]General Comment 14 (n17)

[22] The Declaration and Programme for Action of the Fourth World Conference on Women held in Beijing in 1995. Available at httpa://www.un.org>Beijing >Declaration>pdf (Hereinafter the Beijing Declaration) contain definition of reproductive health and Women's Health respectively.

accessibility, economic accessibility (affordability), and information accessibility; while "acceptability" means that services and facilities must be respectful of medical ethics and culturally appropriate as well as being designed to respect confidentially and medically appropriate and food quality.[23]

It is generally accepted that pharmaceutical products cannot be regarded as ordinary goods or products. In the first place this is because consumers are not in a position to judge, for example, the quality of drugs, hence the need for a monitoring and surveillance system ensured by the State. Secondly, this is because drugs play a significant social role, in that, they are an integral part of the realization of a fundamental human right – the right to health. That is why they are classified as essential goods, and the emphasis that they have to be accessible for all people.[24] The concept of accessibility is very important. It means that policies pursued must aim to make drugs available for all who wish to have them, and at affordable prices. If the objective is accessibility, then the best possible supply must be ensured. This objective coincides with the general objective of the General Agreement Tariffs and Trade (GATT) seeking to eliminate barriers to trade so that consumers have the greatest possible access to all the goods available in the world.[25]

The trend in access to medicines, particularly in poor countries, provides the evidence for policies in global health to increase access at all stages of the process from setting research priorities for the development of new drugs, to manufacturing, pricing, marketing, and distribution.[26] The impact of TRIPs was beginning to be felt by developing countries, particularly in Africa and other less developed countries in the 1990s, just as the devastating effect of HIV/AIDS pandemic deepened.[27] Prices of life-saving medicines were no longer within the reach of the people even as they became more urgently indispensable to preserve lives. Efforts made by certain developing countries, like Thailand, Brazil and South Africa during this period, to ensure access to medicines for their people by invoking the flexibility provisions of the TRIPs Agreement were opposed by pharmaceutical companies.[28] South Africa and Brazil came under pressure for introducing or maintaining legal provisions concerning compulsory licensing in their patent laws, rules on parallel importation and price regulations of medicines which were considered incompatible with WTO by the USA and EU. Responding to the position of South Africa, about 40 pharmaceutical companies in South Africa supported by the USA and EU brought a case against the South African government,[29] for enacting the 1997 Patent Law.[30] The Pharmaceutical companies were challenging Sections 15c and 22c of the South African Patent Law permitting the South African government to use both parallel importation and compulsory licensing respectively in the wake of the HIV/AIDS pandemic in the country. This case provoked global outcry on inadequate access to patented medicines in poorer countries, particularly HIV/AIDS medicines in the sub-Saharan Africa, and international campaign in support of South Africa which forced the Pharmaceutical Association of South Africa to withdraw the case in 2001.[31]

Similarly, Brazilian Patent Law permits the use of compulsory licensing.[32] Article 68 provides thus:

A patent owner shall be subject to the grant of compulsory license of his patent if the rights there from are exercised in an abusive manner or if the patent is used in abuse of economic power, as proven by an administrative or judicial decision pursuant to the provisions of the law.

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[23]General Comment 14 (n17)

[24] G Velasquez and P Boulet, *World Health Organisation Action Programme on Essential Drugs, Globalisation and Access to Drugs – Perspectives of the WTO/TRIPS Agreement* (Geneva: WHO Publication, 1999) Health Economic and Drugs DAP Series No.7 (Revised) WHO/DAP/98.9 [Hereinafter Globalisation and Access to Drugs, WHO-DAP 1999 Revised]

[25]*ibid*

[26]S P Marks, "Access to Essential Medicines as a Component of the Right to Health" **In:**A Clapham and M Robinson (eds), *Health: A Human Rights Perspective* (Harvard University Press, 2009) Pp. 82-101

[27] S K Verma, "TRIPs Agreement and Access to Medicines" (2011) *Political Science and Medicine Journal* Pp. 75 - 105

[28]*ibid*

[29]*Pharmaceutical Manufacturers' Association of South Africa vs. President of the Republic of South Africa*, Case No. 4183/98 (filed February 18, 1998), available at http://www.fordham.edu/law/faculty/patterson/tech&hr/materials/pharmace.txt.

[30] Medicines and Related Substances Control Amendment Act, No.90 (1997) Laws of South Africa

[31]E T' Hoen, "TRIPS, Pharmaceutical Patents and Access to Essential Medicines" (2002) *Chicago JIL*, 3 at 31; E Durojaye, "Compulsory Licensing and Access to Medicines in Post Doha Era: What Hope for Africa? (2008) *LV Netherlands Int'l Law Review* (NILR) 33-71, at 41 and "Access to Medication in the Context of Pandemics such as HIV/AIDS, Tuberculosis and Malaria" Commission on Human Rights Res. 2004/26, UN Doc. E/CN.4/2004/127 (April 16, 2004), available at http://ap.ohchr.org/documents/E/CHR/resolutions/E-CN_4-RES-2004-26.doc

[32] Article 68 Industrial Property Law Act No. 23 (1998) Laws of Brazil

A threat by the Brazilian government to invoke this law to ensure access to HIV/AIDS medications for its citizens led to the filing of a petition by the United States of America (USA) before the WTO panel opposing the action of the Brazilian government. In June 2001, the USA requested consultations with Brazil under the WTO dispute settlement mechanism. The US argued that allowing compulsory licenses for failure to work locally is inconsistent with Article 27.1 of TRIPs. However, the dispute was subsequently settled bilaterally and the case withdrawn but before the withdrawal, the Brazilian government had forced pharmaceutical companies to reduce prices of patented HIV/AIDS drugs in that country.[33]

In 2015, the international community adopted the Sustainable Development Goals (SDGs), a set of 17 goals to be achieved by 2030.[34] Goal 3 – which committed to "ensure healthy lives and promote well-being for all ages" – proposed a range of targets from addressing non-communicable diseases to substance abuse to environmental health. Imbedded in the fulfillment of Goal 3 was the target to end the epidemics of AIDS, tuberculosis, malaria, and neglected tropical diseases, and to combat hepatitis, water-borne diseases, and other communicable diseases. Goal 3 also called for the achievement of universal health coverage, greater investment in research and development of medicines for communicable and non-communicable diseases, and access to affordable essential medicines.[35]

According to WHO, Essential Medicines are those that, "'satisfy the priority health care needs of the population" and "are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford.[36] The issue of essential medicine is as it relates to public health. Every society, culture and civilization has had to battle diverse diseases including those which are transmissible and self-propagating. Public health was birthed by the community efforts at combating diseases.[37] Historically, the idea that epidemics were divine judgments for the wickedness of mankind held sway. However, with the passage of time, this belief gave way to the reality that pestilence and diseases are often due to natural causes, such as climate and physical environment.[38] Consequently, epidemics or pandemics can be handled or tackled with available medicines, medical technologies and pharmaceutical products. This can be achieve by having access to these health products using the human development standards or index.

By strengthening the international level of patent protection, TRIPs has impacted significantly the access to life saving pharmaceutical manufacturing capacities and are afflicted with pandemics. Also, on countries that were until now dependent on the importation of life-saving drugs at low process from countries that provided no patent protection to pharmaceuticals. In other words, TRIPs intensified the problem of access to essential medicines at affordable prices in the developing countries.[39] According to World Health Organisation (WHO), one out of three persons on earth lacks access to essential medicines.[40] Looking at this statistics vis-à-vis the issue of HIV/AIDS, approximately 3 million people died from HIV/AIDS in 2001, 2.3 million of these deaths occurred in Sub-Saharan African. Nearly 1.7 million people worldwide died from tuberculosis in the same year and there had been as many as 10.2 million new cases in the developing world living with HIV/AIDS need access to treatment now. Of an estimated 40 million people living with HIV/AIDS globally, approximately 95% live in developing countries.[41]

[33]Joint Communication of Brazil-United States, June 25, 2001.

[34] Transforming Our World: The 2020 Agenda for Sustainable Development" UN Report A/RES/70/1. Available at sustainabledevelopment.un.org. Accessed November 2, 2021

[35] United Nations (UN), "Goal 3: Ensure healthy lives and promote well-being for all at all ages" SDGs fact sheet. Available at http://www.un.org/sustainabledevelopment/health/.

[36] World Health Organisation, "Essential Medicines: Definition" Available at http://www.who.int/medicines/services/essmmedicines_def/en. Also MDG Task Force, Millennium Development Goal 8: Delivering on the Global Partnership for Achieving the Millennium Development Goals. MDG Gap Task Force Report 2008 (New York: United Nations, 2008) at 36

[37] J A Dada, *Public Health Law in Nigeria* (Calabar, University of Calabar Press, 2021) at p.9

[38] Dada (n34)

[39]Verma, (n23)at P. 75-106

[40] WHO Bulletin (2004), p. 61, "The World Medicines Situation" WHO/EDM/PAR/2004.5

[41] Treating 3 million by 2005: Making it Happen – the WHO Strategy (Geneva, World Health Organisation: 2003) at 3; E Cameron, "Patents and Public Health: Principle, Politics and Paradox" Inaugural British Academy Law Lecture held at the University of Edinburgh, 19 October 2004, available at ,<http://www.law.ed.ac.uk/script/newscript/home.htm>

III. The Debate on the Implication of TRIPs and Access to Essential Medicine and Pharmaceutical Products in International Discourse

The current international debate on the implications of intellectual property, especially the TRIPs Agreement on access to essential medicines and pharmaceutical products came into limelight in 1997 with the attempt by the US government to force the revision of the South Africa's Medicine and Related Substance Amendment Act[42] and the subsequent filing of a legal challenge against that law by South Africa Pharmaceutical Manufacturers Associations. Thereafter, particularly in the run up to the fourth session of the WTO Ministerial Conference in Doha, developing countries were pitted in a bitter debate against developed countries over the interpretation and scope of the flexibilities in the Agreement and the use of these flexibilities to improve access to essential medicines.[43] Responding to the global outcry on inadequate access to patented medicines in poorer countries, particularly HIV/AIDS medicines in the sub-Saharan African, and on the case brought by 40 pharmaceutical companies against South African government on its parallel import regime,[44] the WTO Secretariat took the unusual initiative of co-organising with the WHO Secretariat a workshop on Differential Pricing and Financing of Essential Medicines in Norway in April 2001.[45] In a related development, a week before this workshop, in a TRIPs Council meeting, a new item for discussion was included in the Council's agenda, namely; intellectual property and access to medicines, following a request by Zambia on behalf of the African Group requesting a special discussion, which was accepted by all and which took place in June 2001.[46] Significantly, further work in the WTO on the issue of differential pricing was not accepted by many developing countries, stating that this subject should fall to other intergovernmental organisations, such as the WHO. A substantial group of developing countries, including the African Group, submitted a joint proposal at TRIPs Council meeting for a special declaration on the TRIPs Agreement and access to medicines, which formed the basis of the Doha Declaration.[47]

According to Ellen 'T Hoen,[48] the Non-Governmental Organisations (NGOs) have played a key role in drawing attention to provisions of TRIPs that can be used to increase access to medicines. One such provision pertains to compulsory licensing, which enables a competent government authority to license the use of an invention to a third party or government agency without the consent of the patent holder. The right holder, however, according to Article 31 of TRIPs retains intellectual property rights and "shall be paid adequate remuneration" according to the circumstances of the case. After the meeting of March 1999 at the Palais des Nations in Geneva organised by Consumer Project on Technology, Health Action International on issue of compulsory pricing and access to medicine and pharmaceutical products, the group of NGOs organized another conference in Amsterdam on increase access to essential drugs in a globalized economy which brought together participants from about 50 countries on the eve of the Seattle WTO Ministerial Conference. The statement drawn up at the conference "Amsterdam Statement" focused on establishing a working group in the WTO on TRIPS and access to medicines, considering the impact of trade policies on people in developing and least developed countries, and providing a public health framework for the interpretation of key features of WTO agreements.[49]

From the Amsterdam Statement, the working group was to address questions related to the use of compulsory licensing to increase access to medicines, mechanisms to allow for production of medicines for export markets to a country with no or insufficient production capacity, patent barriers to research, and overly restrictive and anti-competitive interpretations of TRIPS rules regarding protection of health registration data. In addition, the working group was to examine "burden sharing" approaches for R & D that permit countries to

[42] Act No. 90 of 1997

[43] S F Musungu and C Oh, "The Use of Flexibilities in TRIPs by Developing Countries: Can They Promote Access to Medicine? Study 4C, Commissioned by the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), August 2005

[44] Abandoned finally in April 2001, http://www.ncbi.nlm.nih.gov/pubmed/11837037 Accessed May 9, 2021. Also WHO and WTO, Agreements and Public Health: A Joint Study by the WHO and the WTO Secretariat (Geneva: 2011), P.17 available at http://www.wto.org/english/res_e/booksp_e/who_wto_epdf accessed May 9, 2021

[45] J Watal, "From Punta Del Este to Doha and Beyond: Lessons from the TRIPs Negotiating Processes" (2011) 3*WIPO Journal*, 1, 24 at 28

[46]*D* Gervais, *The TRIPS Agreement – Drafting History and Analysis* (London: Sweet & Maxwell, 2008) at 44

[47]*ibid*

[48] E T' Hoen, TRIPS, Pharmaceutical Patents and Access to Essential Medicines: A Long Way from Seattle to Doha" (2002) *Chicago Journal of International Law*, 3, 1, 6, Pp. 27-46. Also, E T' Hoen, "TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond" (2003) available in https://msfaccess.org>Docs

[49]*ibid* at p.46

consider a wider range of policies instruments to promote R & D and to consider the practical burdens on poor countries of administrating patent systems. The Amsterdam Statement also urged national governments to develop new and innovative mechanisms to ensure funding for R & D for neglected diseases. The Amsterdam Statement has served as a guide for the work of NGOs and other advocates on TRIPS and public health.[50]

Though public health and access to medicines did not form part of the official agenda in Seattle in the way it would two years later in Doha but the issue of the use of compulsory licenses for drugs appearing on the list of essential drugs of the WHO[51] which are patented drugs in certain countries with high cost or price of a drug in general used to exclude a drug from the WHO Essential Drug List. This proposal could have limited the use of compulsory licensing, rather than making sure it became a useful tool to overcome access barriers, such as prohibitive pricing, caused by patent abuse. A number of international institutions and UN agencies contributed to the debate on access to medicines and looked into the consequences of stronger intellectual property protection as a result of TRIPS for developing countries.[52]

The Discussion on the subject matter of Intellectual Property and Access to Medicines was centered on two main issues: firstly, the interpretation and application of the relevant provisions of the TRIPs Agreement with a view of clarifying the flexibility to which Members were entitled under the Agreement; and secondly, the relationship between the TRIPs Agreement and affordable access to medicines. The Council received two papers on the matter, one from the European Communities and other from developing countries led by the African Group.[53] The European Council proposal expressed the view that Article 31 was a necessary safeguard to guarantee legal security but at the same time was flexible enough to accommodate cases of national emergency and other situations of extreme urgency. Also, the absence of explicit reference to public health in Article 31 did not prevent WTO Members invoking public health as a reason for granting compulsory licenses. In view of the European Communities, Article 30 should not be interpreted to allow any substantial or unjustified curtailment of patent rights, but at the same time it was flexible to accommodate certain, non-discriminatory exceptions.[54] On the other hand, the developing countries focused in their joint presentation were on the clarification of TRIPs flexibilities and how the Agreement can guarantee use of these flexibilities to improve access to medicines and pharmaceutical products.

The public health community first raised concerns about the consequences of globalization and international trade agreements with respect to drug access during the 1996 World Health Assembly. A resolution on the Revised Drug Strategy (RDS) set out the WHO's medicine policy.[55] The WHO resolution on the RDS requested the WHO in paragraph 2(10) "to report on the impact of the work of the World Trade Organisation with respect to national drug policies and essential drugs and make recommendations for collaboration between WTO and WHO, as appropriate." This resolution gave the WHO the mandate to publish, in 1998, the first guide with recommendations to Member States for implementing TRIPS while limiting the negative effects of higher levels of patent protection on drug availability.[56] The United States and a number of European countries unsuccessfully pressured the WHO inn an attempt to prevent publication of the guide[57] because at that time, the WHO's involvement in trade issues was highly controversial.

The emphasis on public health needs versus trade interest was seen as a threat to the commercial sector of the industrialised world. For example, in 1998, in response to the draft World Health Assembly's resolution on the RDS and in reference to "considerable concern among the pharmaceutical industry," the European Directorate General for Trade (DG Trade) of the European Commission concluded: "No priority should be given to health over intellectual property considerations."[58] However, subsequent resolutions of the World Health Assembly have strengthened the WHO's mandate in the trade arena. In 2001, the World Health

[50]*ibid*

[51] Common Working Paper of the EC, Hungary, Japan, Korea, Switzerland and Turkey to the Seattle Ministerial Declaration3 (Nov. 29, 1999) available at http://europa.eu.int/comm/trade/2000_round/friends.pdf

[52]Hoen (n45)

[53]*ibid*

[54]*Gervais* (n43) at 44

[55]World Health Organisation: Revised Drugs Strategy Resolution. World Health Assembly Resolution WHA 46.14, 1996. 101st Session Agenda item 9 EB101.R24. Available at https://www.apps.who.int>handle

[56] G Velasquez and P Boulet, *Globalisation and Access to Drugs: Perspective on the WTO/TRIPS Agreement*, 2nd Edn. (WHO Publication, 1999)

[57] P Benkimoun, Agressions et menaces contre un responsible de l'OMS defeseur de l'acces du Tiers-monde aux medicaments. Le Monde, Aug 23, 2001 cited by t' Hoen (n28) at p.48

[58] European Commission (DGI): Note on the WHO's Revised Drug Strategy, Doc. No 1/D/3/BW D, 98, Oct. 5, 1998

Assembly adopted two resolutions in particular that had a bearing on the debate over TRIPS.[59] The resolutions addressed the need to strengthen policies to increase the availability of generic drugs; and the need to evaluate the impact of TRIPS on access to drugs, local manufacturing capacity, and the development of new drugs. As a result, the WHO's work programme on pharmaceuticals and trade now includes the provision of policy guidance and information on intellectual property and health to countries for monitoring and analyzing the effects of TRIPS on access to medicines.[60]

Between 1997 and 1999, pursuant to World Health Assembly resolutions,[61] Drug Action Programme (DAP) carried out a series of activities involving pharmaceuticals and trade. Among the activities was the analysis and dissemination of information regarding the effect of trade agreements on health, advising States to guarantee access to medicines under such agreements, and participation in international conferences on the relation between trade and public health. During the second half of the 1990s, DAP incorporated human rights into the work of the WHO regarding access to drugs as a part of the right to health. In the year, 2000, the Committee on Economic, Social and Cultural Rights stated that access to essential medicines is a vital element of the right to health,[62] which was supported by a series of resolutions of the United Nations Sub-commission and Commission on Human Rights.[63] In 2001, both the UN General Assembly[64] and the World Health General Assembly[65] supported this stance. The publication of the "Red book" on Globalisation Access to drugs: Implications of the WTO/TRIPS Agreement" anticipated what the Doha Declaration later came to recognise as the right of the WTO members to fully exploit flexibilities contained in the Agreement in order to protect public health.[66]

3.2 TRIPS and Public Health – The Doha Declaration

In November 2001, members of the WTO sought to restore a balance by adopting the Doha Declaration on TRIPS and Public Health. Paragraph 4 of the Doha Declaration states that the TRIPS Agreement:

[c]an 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. In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for the purpose.

On December 6, 2005, WTO Members finally concluded its access to medicines negotiations when the General Council adopted a Protocol Amending the TRIPS Agreement[67], by imposing certain conditions. The main conditions that were imposed are the following:[68] An entity in the importing country (a country with insufficient or no drug manufacturing capacities) must seek a voluntary licence from the patent holder. If efforts to obtain a voluntary licence fail, a compulsory licence must be applied for and the compulsory license must be obtained in the importing country. The importing country, unless it is a LDC, must demonstrate that it has sufficient capacity to produce the drug locally. The importing country must notify TRIPS Council if it decides to use para.6 of the Doha Declaration.[69] The interested importing country or entity must identify a potential exporter. That potential exporter must first try to obtain a voluntary license on commercially reasonable terms for a commercially reasonable period of time. If such a voluntary license is refused by the patent holder, the

[59] World Health Organisation: Scaling up Response to HIV/AIDS. World Health Assembly Resolution WHA 54.10, 2001. And World Health Organisation, WHO Medicines Strategy. World Health Assembly Resolution WHA 54.11, 2001

[60]World Health Organisation: Technical Cooperation Activities: Information from Other Intergovernmental Organisations. WHO Doc No IP/C/W/305/Add.3, Sept 25, 2001

[61]E 't Hoen, "The Revised Drug Strategy: Access to Essential Medicines, Intellectual Property, and the World Health Organisation" **In:** G Krikorian and A Kapczynski (Eds) *Access to Knowledge in the Age of Intellectual Property* (New York, Zone Books Publication: 2010)

[62] Committee on Economic, Social and Cultural Rights, General Comment No. 14, The Right to the Highest Attainable Standard of Health, 2000, E/C.12/2000/4, para.43.

[63] Sub-Commission on the promotion and protection of human rights, Globalisation and its Impact on the full enjoyment of all human rights, 2001, E/CN.4/sub.2/Res/2001/5

[64] United Nations General Assembly, Declaration of Commitment on HIV/AIDS, 2001, A/RES/S-26/2, para.15

[65]WHO Medicines Strategy, 54th World Health Assembly, WHA 54.11, Agenda Item 13.8, 21 May 2001. Available https://apps.who.int>WHA55.

[66]F Antezana and X Seuba, *Thirty Years of Essential Medicines: The Challenge* (Barcelona, Ed. Icaria, Milenrama: 2008) at P.42

[67]Decision of 6 December 2005 (WT/L/641). Available https://docs.wto.org.

[68]Gervais (n43)at p.66

[69]Doha Declaration on TRIPS and Public Health, WT/MIN(01)/DEC/2, Ministerial Conference 4th Session 9-14 November 2001, adopted on the 14 November 2001. Available at http://www.wto.org

potential exporter must seek a compulsory license from its own government. If a compulsory license is granted, the exporter must then formulate the drugs and investigate the shape, colouring, labelling and packaging of the patent holder's product in the importing country, in order to differentiate the product for export. The exporting country must notify the TRIPS Council of the grant of the licence and its conditions. The exporter has to seek product registration and prove bio-equivalence, when required by national law in the importing country. If in the importing country, date exclusivity is granted, the exporter will have to obtain authorization from the owner of the data to use them, or he will have to develop his own toxicity and efficacy studies (unless the use of the data is included in the compulsory licence) and before shipment of the drug starts, the holder of the compulsory license for exportation must post information on a website about the quantities that will be supplied and the distinguishing features of the product (colour and so on).

The Agreement requires all WTO Member States to grant patents for pharmaceutical products or process inventions for a minimum of 20 years. Although social benefits may arise from patent protection through the discovery of new drugs, the TRIPS standards derive from those of industrialised countries and are not necessarily appropriate for all countries' level of development. Public health concerns should therefore be considered when implementing the Agreement.[70] The Agreement leaves Member States certain amount of freedom in modifying their regulations. The terms invention and discovery are not defined in the Agreement, yet how they are defined could have important implications in the biotechnological field. The Agreement says that Member States may provide limited exceptions to the patent holder's exclusive rights in their laws. National public authorities may be allowed, within the conditions laid down in the Agreement, to issue compulsory licenses against the patent owner's will when justified by the public interest. The agreement does not prohibit parallel imports. These restore price competition for patented products by allowing the importation (without the holder's consent) of identical patented products which have been manufactured for a lower price in another country. Member States must be aware of these possibilities when they amend their legislation. Each country's strategy in regard to globalisation of drug production and distribution will have to be incorporated into its national pharmaceutical policy, a component of national health policy.[71]

IV. Access to Medicines and Pharmaceutical Products in Africa: Lessons from India

The implementation of this principle in developing countries indicates an almost equal number of patent laws that incorporated specific provisions allowing for parallel importation, and those that did not make specific reference to parallel importation or exhaustion principle. This may be because the legal basis of parallel importation has historically been established through case law.[72] In many cases, national laws provide for the explicit derogations to the exclusive rights of the patent holder, to allow for parallel imports. In terms of the use of parallel import for public health purposes, an example is found in South Africa Legislation which enables the Minister to "prescribe conditions for the supply of more affordable medicines"[73] and in this context determine that the patent rights related to a medicine has been exhausted once the said medicine has been put to the market. Regulation issued under the Act specified the condition for parallel importation of medicines into South Africa, and provide that "parallel importation" means the importation into South Africa of a medicine protected under patent and or registered in South Africa that has been put onto the market outside of South Africa by or with the consent of the patent holder. The regulations and guideline provide procedures under which a parallel importer must obtain a permit to undertake importation, these procedures are intended to assure that parallel import medicines are duly approved and registered by the Department of Health.

In Kenya, parliament passed into law the industrial property Act 2001 in June 2001, and the Act came into force by notice on May 1, 2002.[74] According to Musungu,[75] the drafting of a new Industrial Property Act in Kenya generated considerable discussion and debate on the need to incorporate the TRIPS flexibilities aimed at promoting affordability and availability of essential medicines, the incorporation of the international exhaustion principle. The previous Kenya regime had prohibited parallel imports, and the appropriate amendments were

[70] G Velasquez and P Boulet, *World Health Organisation Action Programme on Essential Drugs, Globalisation and Access to Drugs – Perspectives of the WTO/TRIPS Agreement* (Geneva: WHO Publication, 1999) Health Economic and Drugs DAP Series No.7 (Revised) WHO/DAP/98.9 [Hereinafter, Globalisation and Access to Drugs, WHO-DAP 1999 Revised]

[71]Globalisation and Access to Drugs (n67)

[72]Musungu and Oh (n39) at p. 28

[73] Section 15(c) of the Medicines and Related Substances Control Amendment Act No. 90 of 1997 Laws of South Africa

[74] Section 1 Intellectual Property Act 2001 and Legal Notice No. 53 of 2002 of 12 April 2002

[75] S Musungu, "Industrial Property Act 2001 and Access to Essential Medicine in Kenya" **In:***Access to ART and other Essential Medicines in Sub-Saharan Africa: Intellectual Property and Relevant Legislations* (New York, UNDP: 2007)

made to adopt the international exhaustion regime. A key focus of the debate was on the effects of patents on process of essential medicines and the need to incorporate public health safeguards aimed at promoting affordability and availability of essential medicines in Kenya.[76]

The process attracted considerable public attention both in Kenya and abroad, particularly since it was taking place whilst WTO Members were engaged in a similar debate over the use of TRIPS flexibilities to ensure access to medicines at the TRIPS Council. Civil society organisations, particularly the Kenya Coalition for Access to Essential Medicines (KCAEM) – a broad coalition of public health, trade and development organisations and individuals – had played a critical role in the legislative process in Kenya, by actively campaigning for the incorporation of public health safeguards in the law.[77] With regards to parallel importation, the Intellectual Property Act 2001 adopts the international exhaustion principle, which is a departure from the national exhaustion approach under the Industrial Property Act 1989.[78] Section 58(2) of the 2001 Act on limitation of patent rights now provides that: "[T]he rights under the patent shall not extend to acts in respect of articles which have been put on the market in Kenya or in any other country or imported into Kenya." This text as it stands in the 2001 Act, contemplates the importation of any products put on the market abroad legitimately including products put on the market under a compulsory license. This interpretation is supported by Regulation 37 of the Intellectual Property Regulations which clarifies that the limitation on the rights under a patent in section 58(2) extends to acts in respect of articles that are imported from a country where the articles were legitimately put on the market. Legitimacy of products in this context only implies compliance with the national laws applicable in those foreign markets.

The Indian position on the implementation of the TRIPS Agreement particularly as it relates to Access to medicine and pharmaceutical products is very important for our consideration. The role of the Indian pharmaceutical industry as a producer of affordable generic medicines and, in particular, antiretroviral medicines, received wide recognition when the Indian company Cipla, offered its generic version of the antiretroviral triple therapy at US dollars of 350.00 per patient per year.[79] This offer has been credited with triggering significant reductions in prices of anti-retroviral triple therapy, which had been largely unaffordable for most of the HIV patients in the developing world.[80] The Indian Pharmaceutical industry supplied 70% of the bulk drugs (active pharmaceutical ingredients) and 80% of formulations in the country. This would make India one of the few countries and possibly the only developing country in the world that has come this close to achieving so-called self-sufficiency in medicines. The availability of lower-cost human resources with specialist technical knowledge, coupled with the large domestic market for pharmaceuticals provided India with the important pre-conditions for economic viability of pharmaceutical productions.[81]

A study of pharmaceutical industry of India carried out by Dhar and Rao for the United Nations Conference on Trade and Development (UNCTAD)[82] posits the view that the development of the pharmaceutical industry in India is the result of successful, active policy interventions by the government.[83] The study identified crucial factor in the development of the technological capability of the Indian pharmaceutical industry has been the existence of an enabling policy and legal environment as well as policy initiatives undertaken by the Indian government. In the 1970, the government of India established an incentive scheme for domestic producers, the promotion of research and development, and an enabling patent protection regime.[84] The incentive scheme included a price control regime aimed both at ensuring the availability of affordable medicines and providing incentives for domestic producers. A local content policy encouraged the production and use of active pharmaceutical ingredients, and controls were placed on the imports of active ingredients and intermediaries so as to foster an increase in the downstream capacities. Secondly, research and development was

[76]*ibid* at Pp. 28-29
[77]*ibid*
[78] Chapter 509 Laws of Kenya (now repealed)
[79]Reuters: "Indian Firm Offers AIDS Cocktail for $1 a day", 9 February 2001
[80] B Dhar & C Rao, *Transfer of Technology for Successful Integration into the Global Economy: A Case Study of the Pharmaceutical Industry in India* (Geneva, UNCTAD: 2002)
[81]*ibid*
[82]Dhar & Rao (n233)
[83]*ibid*
[84] S Chaudhuri, "Generic Competition, Price Control and Affordability of Drugs in India" (2003) Working Paper No. 478/2003, Indian Institute of Management Calcutta, Calcutta. Also, S Chaudhuri, "Trips and Changes in Pharmaceutical Patent Regime in India", (2005) Working Paper No. 535/2005, Indian Institute of Management Calcutta, Calcutta

strongly promoted,[85] in particular through public-funded research and development facilities. It encouraged the more knowledge-based and research-intensive production of active pharmaceutical ingredients over that of formulation production. Foreign firms were also required to make minimum investments in research and development (R & D) facilities in India, and to re-invest part of their turn over in local R & D facilities. Finally, the domestic patent law was crafted with a view to encouraging innovations in the context of limited technological capabilities and financial resources.[86]

The prevailing intellectual legislation in India post-independence was the Patents and Design Act of 1911, which was only modified after a long period of debate. The amendments were largely based on the recommendations of two Patent Enquiry Committees which examined the country's patent system and concluded that the country had not derived much benefit from the previous or the then existing systems, and made recommendations designed to make the patent system an effective catalyst of industrial and economic growth.[87] The resulting Patents Act 1970 (which came into effect in 1972) is considered a landmark in the industrial development of India. It was designed to preserve the continuing interest of the investor in his creation, the social interest in encouraging research, the consumers' interest in enjoying the fruits of inventions at reasonable cost and the creation of conditions for the acceleration and promoting of the economic development of the country.[88] Three aspects in the Act affected the pharmaceutical industry, namely: the grant of process patents only; a relatively short term of protection (the term of protection for a process patent was five years from the date of the sealing of the patent or seven years from the date of application, whichever was shorter) and automatic "licenses or right" that could be issued three years after the granting of the patent to enable the exploitation of a process patent, on terms mutually agreed between the patent holder and the license.[89]

The absence of product patents in the field of pharmaceuticals, food, insecticides and chemicals in India facilitated reverse engineering and the development of alternative processes for the manufacture of products patented elsewhere. Although the "weak" patent regime may not have encouraged foreign investors to patent in India – with some implications for foreign investment in the pharmaceutical sector – it allowed Indian firms to find alternative processes for the manufacture and production of pharmaceuticals.[90] The adoption of a process patent regime, as opposed to product patent regime, to encourage the technological advancement and the growth of industries is supported by evidence of the policy and patent regimes adopted by several developed countries when their industries were at a nascent stage. For example, chemical substances and pharmaceutical products remained unpatentable in developed countries, such as, Germany, Italy, Japan and Switzerland until well into the 1970s and pharmaceutical products were not patentable in Canada and Spain until the 1990s.[91] In taking advantage of the TRIPs transition period and establishing the complementary policy environment, India has similarly encouraged the development of its domestic pharmaceutical sector.

As the Indian economy liberalized in the 1990s, modifications were introduced to the policy regime aimed at de-regulating the industry. Two key elements in the revised policy environment affected the pharmaceutical industry: first, the removal of restrictions on the use of imported active pharmaceutical ingredients and on formulation production; and secondly, narrowing of the scope of price control mechanisms (price controls would no longer apply to new drugs developed through indigenous R & D). The Patent Act of 1970 had been amended by the Patent (Amendment) Act 1999, and again by the Patents (Second Amendment) Act 2002, in order to fulfil the TRIPS obligations, including the establishment of the mailbox facility and the 20-year patent protection term. According to Chaudhuri[92]Patent amendments in India, after the TRIPs Agreement came into force, can be characterized in three stages as follows: first, as required under the Article 70(8), India provided the mailbox facility, to allow the filing of pharmaceutical product patent applications during the 10-year from 1995-2005. During this period, a regime for the grant of Exclusive Marketing Rights

[85] As set out in India New Drug Policy of 1978 cited in V Motkuri and R N Mishra, "National Drugs Policy Face-off: Some Notes Justifying the Regulations and Drugs Price Control Regime in India (2018) Available at https://www.researchgate.net?3286.

[86]Musungu (n228) at p. 10

[87]A G Z Hu and P L Peng, "Patent Rights and Economic Growth: Evidence from Cross-Country Panels of Manufacturing Industries (2009), Available at https://www.wipo.int>mdocs

[88]*ibid* at p. 19-23

[89]Musungu (n228) at p.10

[90] Dhar & Rao (n223) at p.6-7

[91] H Chang, *Global Economic Development and the Role of the State* (Penag, Third World Network, Zed Books: 2003), p. 273-298

[92]Chaudhuri (2005) (n237) at p. 4-5

(EMRs) was also instituted. EMRs were to be granted to those applications that fulfil the criteria of having been granted a foreign patent and having successfully obtained marketing approval in India.[93]

After the expiration of the transition period for developing countries on the 1st day of January 2000 and the beginning of implementation of the TRIPS obligations, India changed her patent law with an impact on pharmaceuticals, it included the establishment of 20 years patent protection term for all patents and the abolition of licensing of right system. Provisions relating to the grant of compulsory licenses were also amended to comply with the conditions for the grant of compulsory license as set out in Article 31 of the TRIPs Agreement – including the restrictions on export under compulsory license and the payment of adequate remuneration in case of a grant of compulsory. India is now required to provide for full patent protection, both product and process, in all fields of technology including pharmaceuticals as of 1ST January 2005. The mailbox applications will now have to be assessed. If an application meets the TRIPS Agreement standards of patentability, as interpreted and implemented under the national law, a patent would be granted for the remainder of the patent term, calculated from the application filing date in India.[94]

The latest amendments to the Patents Act of 1970 are found in the Patents (Amendment) Act 2005, which received the presidential assent on 4th day of April 2005. The objective of the amended Act was intended to bring India in compliance with the TRIPs Agreement after the end of the transition period in 2005.[95] One of the most significant aspects of the Act is the introduction of a product patent regime in India and the provisions relating to the patentability criteria. The 2005 Amendment Act contains a number of provisions relating to the patentability of pharmaceutical products. First, the Act defines a "pharmaceutical substance" that is patentable as one that means "any new entity involving one or more inventive steps".[96] The Act also substituted the definition of "inventive step" with "a feature of an invention that involves a technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art".[97] It was observed that whilst the definition specifies that "a technical advance or economic significance" is required to meet the criterion of inventive step, the use of the word "or" dilutes the criterion for patentability, as it would enable the determination of inventive step on the basis of economic significance alone.

Section 3 of the Act provides that the "mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy or the mere discovery of any new property or new use of a known substance or mere use of a known process … unless such known process results in a new product or employs at least one new reactant" would not be considered to be a patentable invention. The provision is further explained by a note stating that:

For the purposes of this clause, salts, esters, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy."[98]

This provision is intended to prevent "evergreening" of patents by not allowing the "mere" discoveries of a new form of a new use of a known substance or mere use of a known process, to be patentable. However, it is not clear how the provision will be interpreted because the use of the word "mere" is ambiguous and may cause difficulty in interpretation of the provision. Furthermore, the phrase "unless they differ significantly in the properties with regard to efficacy" in the explanatory note would have the effect of negating the intention of the provision by diluting step requirement, and thus potentially allowing for evergreening.[99]

An obvious concern in the context of the introduction of the patent regime in India is the future of domestic generic production and export.[100] The Act contains provisions which relates to the grant of patents for the mailbox applications and the grant of compulsory licenses and exports under compulsory licenses. The Act provides that after a patent is granted in respect of an application in the mailbox, no infringement proceedings may be instituted against generic manufacturers who continue to manufacture the product covered under the patent, so long as specified conditions are met. Thus, the production of the generic versions of the now-patented

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[93] C Grace, *The Effect of Changing Intellectual Property on Pharmaceutical Property on Pharmaceutical Industry Prospects in India and China* (London, DFID Health System Resource Centre, 2004)

[94] Musungu and Oh (n39) p. 11

[95] The amendment is deemed to come into effect on 1st January 2005 except for Section 37(ii)(a) and (b), Section 41, 42, 47, 59 to 63 and 74 of the India Patent (Amendment) Act 2005

[96] Section 2(h) *ibid*

[97] Section 2(f) *ibid*

[98] Explanatory note to Section 3 *ibid*

[99]"A Critical View of the New Indian Patent (Amendment) Act 2005", by the Access to Medicine and Treatment Campaign (AMTC), Alternative LAW Forum and Lawyers' Collective HIV/AIDS Unit, March 2005. Available at http://archives.healthdev.net/af_aids/msg01715.html

[100]Grace (n246) at P. 13

medicine can continue, provided that three conditions are satisfied, namely: that the generic manufacturer had been producing and marketing the product prior to 1st January 2005; that the manufacturer has made significant investment for such production and marketing; and that a reasonable royalty is paid to the patent holder. This provision, which has been variously referred to as a system of "automatic compulsory licenses" or "prior use rights" will, in theory, ensure the continued production of currently available generic medicines. However, a number of issues will still require clarification, including the definitions of "significant investment" and "reasonable royalty". There is concern that the requirement of significant investment may be open to differing interpretations. Similarly, in the case of reasonable royalty, guidelines may be necessary to reduce uncertainty.[101] The India law now allows for compulsory license to manufacture and export patented pharmaceutical products to any country with insufficient manufacturing capacity. It also clarifies that where a compulsory license is granted to remedy anti-competitive practices, the licensee shall also be permitted to export the product.

India has successfully put to use the flexibilities provisions provided for by the TRIPS Agreement and that to a greater extent have significantly solved the problem of access to medicines and pharmaceutical products. Regrettably, these flexibilities provided for in the TRIPS Agreement have not been effectively put to use both by individuals and government in most developing countries like Nigeria even in the face of serious emergencies like the recent outbreak of COVID-19 and the quest for vaccines. The reason for this failures may be as result of lack of institutional framework for the implementation and enforcement of the TRIPS Flexibilities provisions. In Nigeria some government regulatory agencies or institutions have functions which can be utilized to enforce the provisions of TRIPS Agreement, such as, the Nigerian Copyright Commission (NCC) saddled with the responsibility to regulate copyrighted works, the Nigerian Intellectual Property Office (NIPO), National Office for Technology Acquisition and Promotion (NOTAP), National Agency for Food and Drug Administration and Control (NAFDAC), The Consumer Promotion Council, Standard Organisation of Nigeria (SON). However, the standard of operation of these agencies have been compromised as they fall short of international best practices and operations.

Having regards to the above stated position, Viljeon and Precious in their work[102] emphasized the need to declare HIV/AIDS pandemic particularly in Southern Africa countries as an emergency as it remains the epicenter of the disease globally. According to them, Southern Africa accounts for thirty-four percent of all global AIDS death. They also considered the non-compliance with the greater involvement of people living with HIV/AIDS as the researchers working with and on this issues are. Against this background, they sort for a more feasible human right based approached to the issue of HIV/AIDS as a dire issue public emergency and not to be perceived as being overly individualistic in nature.[103] Similarly, the recent outbreak of COVID-19 pandemic has called to question the implementation and interpretation of the Article 73(b) of TRIPS which provides for "Members essential security interests".[104] Correa, the Executive Director of South Centre in April 2020 wrote an open letter for the provisions of Article 73(b) to be invoked and COVID-19 should be declared an issue of national and international security emergency to allow for access to pharmaceutical and medical products and technologies to prevent and treat this pandemic. The emergence of COVID-19 pandemic is adjudged to constitute an emergency to all intent and purposes.[105] There is no denying the fact that COVID-19 has been so declared as a matter of international emergency but access to medicines and pharmaceutical products has not been as a matter of right but it has been an issue of international politicking and negotiations. The WHO raised a cry that the manufacture, allocation and distribution of the approved COVID-19 vaccines have been characterized with large scale of complexities and vices such as corruption, nepotism, favouritism, et cetera which has hindered access of safe and effective COVID-19 vaccines by the population, including the most vulnerable and marginised groups[106] which the developing countries are the worst hit.

5. Conclusion

In the final analysis of the subject of TRIPS Agreement and human development, particularly as it relates to the issue of access to medicines and pharmaceutical products, in the face of ever increasing issues of

[101] Musungu and Oh (n39) at P. 13

[102] F Viljeon and S Precious (Eds) *Human Rights Under Threat: Four Perspective on HIV, AIDS and the Law in Southern Africa* (South Africa: University of Pretoria Law Press, 2007) Pp. 1-12

[103]*ibid*at p. 23

[104] C Correa, "COVID-19 Pandemic: Access to Prevention and Treatment is a Matter of National and International Security" Available at https://www.southcentre.int./wp-content/uploads/2020/04/COVID-19-Open-Letter-REV.pdf>

[105]Adewopo (n125) at p. 281

[106]United Nations Office on Drugs and Crime (UNODC) Report, "COVID-19 Vaccines and Corruption Risks: Preventing Corruption in the Manufacture, Allocation and Distribution of Vaccines". Available at https://www.unodc.org>policy_paper_on_covid-19_vaccines_corruption_risks.pdf

national and international public health emergencies such as HIV/AIDS, Ebola, Monkey Pox, COVID-19 pandemics amongst others, the use of TRIPS flexibilities can be an important tool enabling access to affordable medicines, pharmaceutical products and promoting human development. Universal reality has always raised the concern about maintaining the right balance between the imperatives of private and public interests inherent in the enterprise of promoting public health. This conflict arises mostly in area of preventing abuse of patent rights particularly in the case of pharmaceutical patents and in facilitating access to pharmaceutical products, medicines and medical technologies in the face of global health emergencies.[107]

Developing countries have always been badly affected by global health emergencies because of their lack of manufacturing capacity of pharmaceutical products to meet the medical need of their people. The TRIPS flexibilities therefore, provides the organic framework to bypass exclusive patent rights without risk of infringement and has been utilized to meet diverse public interests, on the grounds of emergency or extreme urgency, anti-competitive practices, public non-commercial use or government use as determined from time to time by national laws. Developing countries should therefore avail themselves of the widest scope in terms TRIPS flexibilities particularly taking advantage of compulsory license and non-commercial or government use of patent. Beyond the knowledge of this exemptions, it is important for developing countries to incorporate explicit provisions of the TRIPs Agreement as confirmed by the Doha Declaration knowing that the provisions of the agreement does not automatically translate into the national regimes, and it will be necessary for specific legal provisions to be enacted in the national laws[108] as well as establishing the legal framework to its enforcement. Beyond leveraging on the provisions of the TRIPs Agreement flexibilities in the face of ever increasing health emergencies, it is important for developing countries to take measures to set up research and development project or programmes with the aim of establishing indigenous bio-medical innovations or institutions with the capacity for technology transfer and assimilation to meet the emerging health needs of the people.

V. Recommendations

The intellectual property protection of medicines and pharmaceuticals products will continue to pose significant challenges to public health particularly in developing countries. The reason for this problem is the intrinsic nature of public health and the human development needs or concerns. Also, the inability of intellectual property system to adequately balance the conflicting interest between intellectual property and public health and human development. Third, the inability of intellectual property to bridge the ever widening gap between the developed countries seeking higher standard of intellectual property protection via TRIPS interpretation, or negotiations of bilateral and regional agreements and the developing or least developed countries are seeking for more flexibilities in the enforcement of TRIPS. It is suggested that an amendment to TRIPs Agreement should be made to elaborate a permanent solution to the problem affecting countries with limited or without manufacturing capacities in the field of medicine and public health.

The intellectual property system seems to build upon the assumption that a patent owner is legitimised to prevent access to product under his control, even in the presence of compelling humanitarian reasons like the outbreak of epidemic or pandemic. This is certainly not consistent with the Doha Declaration on the TRIPs Agreement and Public Health. Consequently, it is recommended that countries should be encouraged to develop disciplines or policies to deal with such refusals in the context of the "essential facilities doctrine"[109] and to take advantage of the TRIPS flexibilities.

The experiences of the prevalence of HIV/AIDS epidemic and the COVID-19 pandemics have highlighted the tensions between intellectual property rights and public health interests and the devastating effect in developing countries. This public health concerns calls to question the preparedness of developing countries to tackle these challenges and the need to develop and strengthen health innovation systems in developing countries. This can be done through policies that support health research systems and a local incentive structure that focuses on research on local health solutions to this challenges. Also be developing health innovation system such as biomedical research capacities and local manufacturing capabilities.

The issue of public health is consider all available legal standard and international instruments are human rights which cannot in any way be undermined by the provisions of TRIPS. Consequently, each provision of TRIPS should be read or construed in the light and importance of the fundamental nature of the right to public health and access to medicine and pharmaceutical products. This can be achieve by encouraging the protection of intellectual property rights, particular patent protection to encourage the development of new

[107]Adewopo (n125) at P. 269

[108] C Correa, *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement* (Geneva, South Centre: 2002) at P.18

[109]J Taladay and J Carlin Jr., "Compulsory Licensing of Intellectual Property under the Competition Laws of the United States and European Community" (2002) *George Mason Law Review*, 10, 3, at 443

medicines and pharmaceutical products as well as the international transfer of technology to promote the development of manufacturing capacities of pharmaceuticals products without any restraining policies on access by developing countries.

The position of India in the aspect of implementation and enforcement of the TRIPS Agreement as well as balancing the competing needs of her populace accessing public health care and pharmaceutical products. Accordingly, the India institutional and legal framework is recommended for other developing countries to adopt. This will involve developing strong governmental policies and monitoring agencies to ensure compliance with the best international standard and will curb corruption and counterfeiting and ensure effective transfer of technology.

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