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An Analysis of the Effect of Pharmaceutical Patent Laws on Access to Medical Care

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Abstract

Most developing countries have their public health goals compromised by poor access to essential drugs. One of the causes of this has been attributed to strict patent law regimes. This challenge is acute in developing countries because less than 10 percent of drugs are patented. Developing countries are also handicapped by inadequate access to research facilities and the technological know-how needed for local production with regard to pharmaceutical. This essay is concerned with setting out guidelines for acceptable patents in such a way that public health is not compromised. This work finds that there is need to determine the effectiveness and efficiency of the laws laid down by local and international statues, and whether or not such laws in place are sufficient. The need to distinguish patent protection for both processes and products is also highlighted. This is monumental as process patents provide only protection in respect of the technology and methods of manufacture.

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1.0.0 Introduction

Patent right is about the most prominent and encompassing intellectual property right that has emerged in recent times. It has been rightly adjudged as an incentive to holders such as pharmaceutical patent holders which if properly harnessed can spur speedy economic growth. It is based on the premise that pharmaceutical patent holders who have invested time and efforts in the production of pharmaceutical goods and allied services are entitled to exclusive rights to them. This right is however sprinkled with the need to balance other competing interests such as those of the public health care system. The framework for this essay is to build awareness for policy makers and independent legal regulators of the health sector of the impact of "international trade agreements for countries, leading to effective participation in international regional negotiations"[1] In this way nations, especially the developing ones will be aware of their options in implementing such agreements. This will lead to better incorporation of safeguards in such polices, legislations and practices within the national legal framework. This paper will highlight some of the challenges that confront those seeking for patent protection, the public health issues arising from granting certain patents which infringe on human rights of the individual, as well as thoroughly examine the existing legal framework to accommodate such patent rights in a balanced manner.

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[1] World Health Organisation (WHO), 'Access to Medicine Intellectual Property Protection: Input on Public Health' *WHO Drug information*, Vol. 19, No.3, 2005

2.1.0 Public Health Being a Right from a Human Right Point of View

An examination of the conceptual framework in which the debate over access to drugs is taking place, especially the intellectual property angle as epitomised in the context of the Trade Related Aspects of Intellectual property rights Agreement (TRIPS) is necessary. This reveals how much the human rights debate can make in the sharp divide between intellectual property and human rights. There is always a need to balance the rights of humans alongside the right of intellectual property owners. [2]

In furtherance to this, Walter Kalin and Jorg Kunzil [3] assert that the essence of human rights is to ascertain who the human right duty bearers are and who the real holders of the human rights are. Though this paper is essentially not on human rights, but the views of these authors are important because the authors believe that obligations to people who are holders of human rights are part and parcel of international legal instruments. The highest bearing burden of obligation is the 'state'. This is because:

> The state is accountable for the conduct of all its organs, irrespective of the higher or subordinate status of the organ concerned or of whether it exercises legislative, executive or judicial functions.[4]

The set of human right rules that apply to the individual entails more than the right not to get killed. It also involves access to basic necessities of life such as food and shelter. More so, there should be freedom from health problems, some of which are caused by

[2]Phillipe Cullet, "Patent and Medicines: the Relationship between TRIPS and the Human Right to Health" *International Affairs* 79 1 (2003) 139 – 160

[3]Walter Kalin and Jorg Kunzli, *The Law of International Human Rights Protection* (Oxford University Press, 2009) pp. 303 -309

[4] International Law Commission (ILC) draft Articles on State Responsibility 'Report of the ILC on its fifty – third session (2001), UN Doc A/56/100, Supplement No 10 (Official Records of the General Assembly)

epidemics and other endemic breakouts. This is more pertinent and obvious where people cannot afford basic drugs and necessities to assure their health and survival.[5] The right to an adequate standard of living and right to health then becomes also an economic issue which are tied to the dignity of the human person. These are enshrined in such international treaties like the International Covenant on Economic, Social and Cultural Rights of 16th December, 1996. (ICESCR)[6]

2.2.0 Access to Medicines as a Moral and Human Obligation

While the pharmaceutical industry is an inevitable link in the duty of corporate responsibility to promote human rights, the two ends of the relationship are at polar opposites in terms of output. Human beings need drugs and medicines for optimal health and well -being to carry out their basic activities in society. Though drug producers are instrumental in promoting a basic level of human welfare, the goal of major pharmaceutical corporations is geared by profit. The human right angle of the equation comes in to question the rationale and moral justification for passing these costs by the international community to the developing world and other less positioned consumers through "artificially high" prices to offset what they perceive as their sunk cost. Pharmaceuticals have not always been on the patent list of most countries. In nations such as Norway, Finland and Spain, pharmaceuticals were not included on their patent lists before 1995.[7] Patents are given only for work that is innovative, new idea, method or step of a process which can be

[5] Walter Kalin and Jorg Kunzli, *The Law of International Human Rights Protection* (n.3)

[6]International Covenant on Economic, Social and Cultural Rights of 16th December, 1996. (ICESCR)Articles 11 and 12

[7]M. Morgan Medicines for the Developing World: Promoting Access and Innovation in the Post TRIPS Environment; Anna. Lanoszka, 'The Global Politics of Intellectual Property Rights and Pharmaceutical Drug Policies in Developing Countries' *International Political Science* Vol. 2 181 -1

duplicated through the industrial process and has industrial applicability.[8] Patent protection is not automatic; they are valid only in countries where protection is applied for through the proper channels.

It must be noted that many international conventions do not specifically mention the right to health. This is to be gleaned from other provisions.[9] The ICESCR provision is to ensure environmentally sanitary working spaces, human and satisfactory working conditions.[10]

ICESCR qualifies the right to health as 'availability' of not only quantitative, but also qualitative public health, which of necessity must include the availability of drugs and other medical inputs. The most important parameter seems to *be* 'Non-discriminatory "accessibility" for all, with consideration to disadvantaged groups, to health services and health-related information throughout the territory of a state party.'[11]

According to the Human Rights Committee, discrimination may be explained by highlighting the situation whereby a measure is formulated in '*neutral terms'* without making provision for divergent situations that may be prominent in other climes. Such compliance with such insensitive measures indirectly wreaks havoc on the economies and lifestyles of the people in those other climes.

[8] S. Sterckx, 'Patents and Access to Drugs in Developing Countries: an Ethical Analysis' *Developing World Bioethics*, Vol. 4(1):58-75, 2004

[9]Universal Declaration of Human Rights of 10th December 1948, UDHR Art. 25; African Charter on Human and People's Rights , (Banjul Charter) of 27 June 1981(ACHPR) art 16; CERD ART 5 (e)(iv); Convention on the Elimination of all Forms of Discrimination against Women of 18th September 1979 (CEDAW) art 12; Conventions on the Rights of Persons with Disabilities of 13 December 2006, (CRPD) art 25; Preamble to the Constitution of the World Health Organization (WHO).

[10] ICESCR, Art. 7 and 12

[11]*Purohit and Moore v The Gambia*, Communication No. 241/2001 (2003), para 80; ACmHR (American Commission of Human Rights)

They are termed discriminatory because they are not backed up with strong objectives that can be justified on moral grounds.[12]

The European Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine has asserted and continually maintains the principle that 'the interests of human beings have primacy over those of scientific research and guarantees non -discriminatory access to health care of appropriate quality.'[13] Invariably, this can be analysed to mean that though pharmaceutical companies have to conduct research to come out with meaningful drugs, such scientific research must be tailored along the line of alleviating human suffering to be meaningful.

2.3.0 The Role of Research and Development

Research by multinationals often entails harm to individuals in less developing countries or some form of exploitation. This scenario plays out especially when the big pharmaceutical companies conducting the research are from highly industrialized nations and when they choose to conduct the research in developing countries. It is encouraging to note that human right principles are now being resorted to by such nations in a bid to protect themselves from exploitation.[14] Apart from exploitation, research should also be

[12] HRCttee, *Althalmmer et al v Austria*, Communication No. 998/2001 (2003), para 10.2.; see also European Court of Justice (ECJ) , Case C- 184/89 *Nimtz vFreie and Hansestadt Hamburg*9199): ECJ Case C-360/90 *Arbeitswohfahrt der Stadt Berlin Ev v Boetel*, (1992).

[13] The European Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine of 4April 4, 1997

[14]Lybecker, Kristina Marie. 2000. Counterfeit Pharmaceuticals: Product Piracy and the Transition to Stronger Intellectual Property, <http://www.lebow.drexel.edu/lybecker/piracy.doc>. Macklin Ruth. 'Bioethics, Vulnerability and Protection.' *Bioethics* 17(5-6): 472-487, 2003

carried out in a manner that promotes the dignity of the human person.[15]

In view of the various changes that may occur in terms of human rights violations, the Vienna Declaration implores states to be cautious about human right obligations when they enter into international covenants in the areas of intellectual property and trade liberalisation.[16] This is to avoid disparity with the Declaration which states that 'human rights and fundamental freedoms are the birthright of all human beings, their protection and promotion the first responsibility of governments.'[17]

3.0.0 Legal Framework and Policies Supporting Possible Health Principles in the Context of Access to Medicines

Given the immense importance to nations, public health principles are a priority as well as facilitating full access to medicines. As such they are supported by national and international legal and policy instruments, including the Constitution of the World Health Organization (WHO).

3.1.0 National and international legal and policy instruments

Since private persons or entities also form part of the 'state' if they are empowered to carry out public functions.[18] It therefore behoves on holders of pharmaceutical patents to exercise authority and use

[15]The European Convention for the Protection of Human Rights And Dignity of the Human Being with Regard To The Application Of Biology and medicine. (n.18)
[16] Article 1 of the Vienna Declaration and Programme of Action, 25th June, 1993, UN Doc. A/CONF. 157/24 (Part 1)
[17] Ibid
[18] ILC draft Articles on State Responsibility, Art 5: Conduct of persons or entities exercising elements of governmental authority.

of their patents rights in such a way that promotes the public good. [19]

Where they do not do so, the state cannot absolve itself of complicity for such misconduct or be heard to say that the duty was delegated.[20] It is to prevent anomalies and to ensure a balance in the need of patent holders to recoup their costs and make profits, and the urgent steps necessary to curb epidemic outbreaks that governments intervene through legislations to promote easy access to healthcare for all. Thus nation states or member nations have a duty to adopt only international legislations that seek a balance between the interests of the patent regime and the populace. This is because an international organisation breaks international law if it adopts decisions "that bind members to commit an act that would be internationally wrongful if committed by the international organization".[21]

Authors such as Kolawole,[22] Lanoszka and Morgan[23] opine that Member states should seek for guidance from legal authorities and guidelines laid out by such international organisations like WHO, World Bank, while commensurate efforts should also be made to resist legislation that impede and hinder broad access to medicines. The TRIPS legislation, though of immense importance and highly

[19]Walter Kalin and Jorg Kunzli, *The Law of International Human Rights Protection* (n.3)

[20] ECtHR, Costello – Roberts v The United Kingdom, Series A, No 247 – C (1993), para 27, concerning corporal punishment of a child attending a private school.

[21] ILC draft Articles on State Responsibility, Art 15 (n.18)

[22] Kolawole, Abimbola Omolara Dahunsi, Patent rights and essential medicines in developing countries: is access compromised for innovation in Nigeria? *Journal of Medicine and Medical Sciences* Vol. 3(3) pp. 130-134

[23]M. Morgan, Medicines for the Developing World: Promoting Access and innovation in the post TRIPS environment; Anna. Lanoszka, The Global politics of intellectual property rights and pharmaceutical drug policies in developing countries. *International Political Science* Vol. 2 181 -197

regarded in the international community, does have some provisions that while promoting a 'trade free zone' indirectly impedes access to drugs, This is paramount especially as it impacts individuals living with HIV AIDS in places in Nigeria and Columbia.[24]

3.1.1 The Trade - Related Aspects of Intellectual Property Rights (TRIPS)

The importance of the TRIPS Agreement lies in the fact that it introduced global minimum standards for protecting and enforcing nearly all forms of Intellectual Property Rights (IPRT). It is to be noted that of particular importance is that it included those for patents. Though over 40 countries as at the time negotiations began did not grant patents for pharmaceutical products, by virtue of their membership of the WTO and TRIPS, they had to adopt into their laws minimum standard of protection for pharmaceutical products. Though the TRIPS Agreement is very clear on the legal requirement for intellectual property protection, it does have some tendency to incorporate societal and welfare inclined goals.

> TRIPS first remind signatory states that the intellectual property rights regime in place should contribute to the promotion of technological innovation and to the transfer and dissemination of technology in a manner conducive to societal and economic welfare.[25]

Also, because the issue of parallel imports' is fully discussed under TRIPS, most member states have the freedom to decide whether to take advantage of lower prices of drugs in other nations. One area of great discourse since the adoption of the TRIPS agreement has been in the area of patents on medicines. This is because patents grant exclusivity for the duration of the patent term and result in patent

[24] Ibid
[25] Article 7of the TRIPS Agreement.

holders having control over the production, supply, distribution and, by virtue of exclusivity, price. [26]

3.1.2 The Doha Declaration

Also of critical importance to this essay is the Doha Declaration by the WTO (World Trade Organisation) in Qatar in November 2001, which enables nations to take initiatives during a health crisis despite the existence of strict patent regimes in place.[27]

Authors like tHoen[28] are of the opinion that government induced generic competition would be the best strategy of lowering drug prices. Recent research has shown that the mere threat of introducing such drugs is enough to lower cost of patent protected essential drugs. The important role of legislation here would be to see that standards are maintained and that whatever little advantage that generic drugs might have alongside patent protected drugs is not subsumed under exorbitant R&D expenses.[29]

The influence of intellectual property has always been to protect patents and other owners of intellectual property rights. The Doha Declaration came up in 2001 as a nexus to bridge the gap between the terms of the application principles of public health by governments and the terms of the Agreement on Trade-Related

[26]Frederick M. Abbott, 'First Report (final) to the Committee on International Trade Law of the International Law Association on the subject of Parallel importation" *Journal of International Economic Law* 1, 1998, p.607

[27] WTO'S Fourth Ministeral Conference in Doha Qatar, in November 2001; see also Markus Nolff, "Paragraph 6 of the Declaration on the TRIPS Agreement and Public Health and the decision of the WTO regarding its implementation: An expeditious solution?" at 298, 86 J.PAT. & TRADEMARK OFFICE. SOC'Y 291 (2009)

[28] E. tHoen, TRIPS, Pharmaceutical patents and access to essential medicines: Seattle, Doha and Beyond. (ANRS collection Scences socials etSida, Le publieu, 2003) 39 - 69.

[29] Ibid

Aspects of Intellectual Property Rights (TRIPS).[30] This agreement, initiated by the World Trade Organization in 2001 was to ameliorate the stringent nature of the TRIPS agreement with regard to access to affordable medicines.

> In particular, concerns had been growing that patent rules might restrict access to affordable medicines for populations in developing countries in their efforts to control diseases of public health importance, such as HIV, tuberculosis and malaria.[31]

The foreseeable challenge that most developing countries with growing populations may not be able to afford patented drugs is the reason that such developing nations had not implemented the terms of the TRIPS Agreement.[32] In order to alleviate this concern related to the exercise of patent rights and importation, the manner of implementation of such patents over drugs is no longer so stringent.[33]

3.1.3 The Committee on Economic, Social and Cultural Rights (ICESCR)

There is a veritable link between patents, access to drugs and even the price which such drugs are made available especially to people who cannot afford them. Most developing countries find a way to go around such policies.[34] To meet the objective of availability,

[30]World Health Organisation (WHO), Access to Medicine intellectual property protection: Input on Public Health (n.1)

[31] WTO'S Fourth Ministeral Conference in Doha Qatar, in November 2001 (n.27)

[32] Ibid.

[33] Carlos M. Correa, 'Intellectual Property Rights and the use of Compulsory Licences: Options for Developing Countries' Working Paper no.5 (Geneva: South Centre 1999)

[34]Jean O. Lanjouw, "The introduction of pharmaceutical product patents in India: Heartless exploitation of the poor and suffering?" NBR Working Paper no.6366 1999, cited in Phillipe Cullet (n.2)

accessibility and non-discriminatory access to health, states are required to effect legislation and perhaps take legal action against obstruction of the right to health by private actors.[35] Such anti health practices may chiefly involve access to health facilities, and perhaps discrimination against people with contagious diseases, and other disadvantaged groups.[36]

Therefore, it suggested that a minimum standard of health care must ensure that laws which can compel patent owners to make drugs available in emergencies are incorporated into domestic law.

> Where this minimum content is not realized, 'the Committee on Economic, Social and Cultural Rights considers there to be a violation of ICESCR, Article 12, unless the state can show that the required minimum standard has proved unattainable despite heavy investment of its resources and recourse to international assistance.'[37]

The manner in which the international community can render assistance is through influencing trade policies especially as it pertains to patent regulations with regard to pharmaceutical products. The ICESCR exerts influence over party states, in a form of reciprocal monitoring to prevent third parties from unruly practices in their home states.[38] A form of diplomacy and political strength to achieve this is to appeal to the terms of the Charter of the United Nations.

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[35] Ibid

[36] Ibid

[37] Walter Kalin and Jorg Kunzli, (n.3) p.318

[38] Ctteee ESCR, (European Committee of Social Rights) General Comment No 14(2000), para 39. See also the report of the Special Rapporteur on the right to health of March 2004, Mission to the World Trade Organization, UN Doc E/CN, 4/2004/49/Add. 1, para 11, cited in Walter Kalin and Jorg Kunzli, (n.3) ibid, p.319

3.1.4 Legal Regulation by TRIPS, Through Efforts to maintain Public Health Treatment Programmes and Balance Patent Rights.

The World Trade Organization has been in the forefront to cushion the unique position of non-drug producing nations, and other developing nations when it comes to making such product come at an affordable price. This is facilitated by its agreement on the Trade Related Aspects of Intellectual Property rights (TRIPS) to find a way around the barriers posed by patent rights. Some authors like Wesley Cann find that an in-depth study of the TRIPS Agreement reveals provisions for developing countries to have access to essential drugs despite strict patent regimes at the international level. These provisions are found in articles 8, 27, 30, 31 and 73.[39]
Article 7 of TRIPS provides that:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Among such methods is to facilitate importation of drugs from cheaper sources and compulsory licensing to aid generic

[39]See Wesley A. Cann, Jr. 'On the relationship between intellectual property rights and the need of less developed countries for access to pharmaceuticals: creating a legal duty of supply under a theory of progressive global constitutionalism." 25 U.PA.J.INT"LECON.1.755, 808-826(2004)5 cited in Angela Anderson, "Global pharmaceutical patent law in developing countries – amending TRIPS to promote access to all" (Hosted by the Berekley Electronic Press) htpp://law.bepress.com/expresso/eps/1109

production.[40] In the US, for example, for ease of doing business and to encourage generic production of drugs, generic firms can file an Abbreviated New Drug Application (ANDA) in speedy time, and with minimal filing fees.[41]

Paragraph 6 of the Doha Declaration on TRIPS and public health states as follows:

> We are committed to helping countries that are experiencing public health crises. We want to find a real solution to problems that prevent Members from being able to address health problems associated with access to pharmaceuticals. We want all Members to be able to use the full flexibility of the TRIPS Agreement to help provide their citizens access to affordable medicines in times of crises. An important practical implication of this belief is that it forces competitors to adhere to strict manufacturing guidelines, greatly affecting global drug supply. TRIPS, then, is a legal framework that creates standards that protects these works[42].

4.0.0 Governments and Role of Legislation in Developing Nations.

Patent protection has some challenges, especially when it comes to not only protection of the product but also adequate supervision to ensure not just quantity but also quality. The lack of enforcement of the laws covering patents in the pharmaceutical industry and inadequate penalties in terms of unauthorised reproduction of those

[40] WTO(2006). Intellectual Property (TRIPS) fact sheet-Pharmaceuticals.http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm01_e.htm

[41] U.S. Congressional Budget Office, 'How increased competition from generic drugs has affected prices and returns in the pharmaceutical industry' (Washington DC: US Government printing office , 1998)

[42]Paragraph 6 of the DOHA Declaration on the Trips Agreement and Public Health, World Trade Organization

products is also noteworthy of correction. The legal Umbrella provided by Trade Related Aspect of Intellectual Property Rights (TRIPS)[43] and other policy instruments affords absolute protection of the product.[44] TRIPS establish minimum standards for all forms of intellectual property rights. Under the terms of TRIPS Agreement, members of the World Trade Organisation must adopt and enforce strong, strong non-discriminatory minimum standards of Intellectual property protection The need to adequately supervise pharmaceutical products has led to the emergence of legal regulation of pharmaceutical patents through TRIPS and other policy instruments. Such guidelines have insisted that as a condition for permitting the sale or marketing of pharmaceutical products, the drug related pharmaceutical industries;

> ….submit data demonstrating the safety, quality and efficiency of their product. The TRIPS Agreement requires that WTO Members protect undisclosed test data, submitted to drug regulatory authorities for the purpose of obtaining marketing approvals, against unfair commercial use.[45]

The impact of this approach is that the pharmaceutical originator is granted exclusive rights over their test data. As such, when it comes to registering generic products, approval must be gotten from the originator if reliance is to be made on their test data.

The old approach was that generic product producer only needed to rely on original test data already in place by the originator. Though the test data block may impede introduction of other generic products for a while, in the long run, it ensures that when such

[43] Trade Related Aspects of Intellectual Property Rights TRIPS
[44] World Health Organization (WHO), (n.1)
[45] Ibid.

generic products come into the market, after the exclusivity period, their quality and safety is assured.[46]

The limited scope of protection accorded to patents in developing countries compared to most western nations as well as lack of concerted efforts in research and development has led to a seemingly downward slope in the pharmaceutical industry in such countries. This anomaly has led to a dependence on imported drugs and other pharmaceutical accessories.

The ultimate goal of inculcation of international regimes must be geared towards continuous monitoring and analysis of access to essential medicines, as well as compliance with new trends and developments.[47] This will serve as a platform for governmental agencies, legislatures of nation states to take a cursory look at the existing framework and make necessary adjustments.

One of the major characteristics of the emerging international economic order is the treatment of intellectual property rights (IPRT). The impact that this will have on developing countries is uncertain, especially with the participation of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) which is certain to impact their economies.[48] Governments in many developing nations, have no subsidised health insurance schemes. Therefore, they have to go the extra mile to put in place domestic Legislations that will enhance their access to drug to fulfil their societal obligations.

Article 8 of TRIPS makes the provision: "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the

[46] Ibid.
[47] Ibid
[48] Anna. Lanoszka, (n.23)

public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement."

It is concise to say that access to public health is very vital to a countries 'socio-economic and technological development' as a workforce that has vitality is more productive in the workplace. So TRIPS empowers Governments to take adequate measures to 'to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.'[49] Some of these practices relate to elongation of patent periods as well as hoarding of information by patent right holders. This will be contrary to the provision of TRIPS, that holders will provide 'information concerning the applicants corresponding foreign applications and grants.'[50] When it comes to foreign applications, complexity of transfer technology should be minimal to enhance use.

4.1.0 Role of Government on Access to Drugs when Epidemic is in Developing Nations.

The role of patents and the incentives which it affords are extremely crucial for funding of research and development of new medicines. Most of the pharmaceutical drugs come from developed nations, and because developing nations account for manufacturing a minimal amount of pharmaceutical products globally, the developing countries are import dependant on those countries who are producers. It becomes difficult for less developed countries to generate enough funds for research. Another fall out of import dependency is that new products cannot be tailored to fight diseases peculiar to developing countries such as malaria or HIV. Such

[49] Ibid.
[50] Article 29 sub 2 TRIPS

products when they become available are at very exorbitant costs to allow the patent holders recoup their investments. Then also, the situation is not helped by the fact that TRIPS has provided for very long duration of patent protection for such new products.[51]

4.1.2 Governments Role and Measures Needed to Contain Contagious Diseases and other Health Emergencies in Developing Nations.

i) HIV Epidemic

The Affordability of essential medicines became the focus of the international public with the rise of the HIV pandemic and need to provide antiretroviral therapy for millions of people. This is because when 'patent-protected antiretroviral treatments were first introduced, the cost was over US$ 10 000 per patient per year, putting them out of reach of the vast majority of HIV patients in developing countries where over three billion people live on less than US$ 2 a day.' At the Ministerial conference held in Doha in 2001, the matter of compulsory acquisition of licenses was addressed to ascertain the credibility or otherwise of such topics as compulsory acquisition of licenses from patent owners, when placed alongside intellectual property protection over new medicines and continued inventive interest in research by substantive holders.[52] A compulsory license is a government license that enables people other than the patent holder to copy patented or copyrighted products and processes. Governments can issue them if a patent owner abuses their rights by, for example failing to offer their produce on the market, or offering it at a price that is too high for potential buyers to afford. Competitors can then produce the product or use the process under

[51]World Health Organization (WHO), (n.1)
[52] DOHA Declaration on the Trips Agreement and Public Health, World Trade Organization (n.42)

government license without fear of prosecution.[53] But adequate compensation must be paid to the patent owner upon such compulsory acquisition.[54]

It was the consensus that despite TRIPS, exorbitant prices of medicines heavily impeded the efforts of government with enormous public health concerns such as those resulting from HIV/AIDS, tuberculosis, malaria. As such, the TRIPS Agreement, while protecting the intellectual property regime, 'does not and should not prevent members from taking measures to protect public health.'[55]

There was a need to have a systematic approach to reducing the HIV epidemic. Therefore many pharmaceutical companies volunteered to reduce or give discounts on the prices of drugs to cushion the impact of the epidemic in developing countries.[56] Apart from discounts, some other pharmaceutical companies volunteered to supply generic versions at much reduced costs. This not only led to increased competitiveness between the companies, but also enabled more generic manufactured drugs into the market.[57]

Most African nations such as South Africa are ravished by AIDS. The issue of affordable drugs to fight the endemic is a thorny issue for countries such as the US who oppose the efforts of the South African government to provide drugs at affordable prices. It is the consensus that laws put in place by major drug manufacturers and exporters such as the US, impoverish developing nations.[58]

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[53]Bonita de Boer, 'TRIPS, AIDS and Generic Drugs'. *AVERT ORG*. Jan. 19 2005

[54] Article 31 TRIPS

[55] Ibid.

[56] Bonita de Boer, (n.53)

[57]Ibid

[58] R. Weissman, "AIDS Drugs for Africa." Multinational Monitor 20(September1999): 9-14.

While the momentum favours an upsurge of supply of antiretroviral drugs to nations like Uganda to fight the high rates of HIV Infection, unguarded and unprofessional use of such drugs could lead to incidences of drug resistance from indiscriminate use. It **becomes** necessary that such indiscriminate use should be curtailed by supervised.[59] The answer to this issue will be to send in health care professional to ensure that specifications for effective use are properly adhered to.

4.1.3 Role of Government on Access to Drugs when Breakout is in Developed Nations.

Sometimes, health authorities may have an impending epidemic on their hands involving highly pathogenic diseases such as Avian flu which would require them to surmount all obstacles in a bid to protect the populace.[60]

When there is a breakout in a developed society likes the US, the approach to use of drugs which have a patent tag is different from that of developing nations. The first pre-requisite to effectively tackle the epidemic is to have enough supplies to block the occurrence. For example during the outbreak of anthrax attacks, there was a dilemma concerning the availability of ciprofloxacin to treat those who had been exposed to it. As with most medicines that were patent, it was in short supply, and the price was out of reach of most people.

The initial response by the health authorities in US and Canada was to make a generic version of the drug. This would have crashed the price of the drug. In the end, to avoid attendant legal dilemma, the

[59]Ruairi Brugha, "Antiretroviral Treatment in Developing Countries: the Peril of Neglecting Private Providers." British Medical Journal; International Edition 326(7403) of 2003: 1382.

[60]KWT Tsang, 'H5N1 influenza pandemic: contingency plans.' Lancet, 2005; 366:533–534.

US and Canada negotiated with the patent owner for reduced prices and regular supply.[61] It is exactly to avoid situations like this that inventors are urged to give full disclosure of their products so that generic or other innovative versions can be made available to the public at lower costs.[62]

4.1.4 The Position of the Pharmaceutical Industry on Effective Patent Protection as an Incentive for Continued Research and Development (R&D)

Developed nations often push for the same level of patent protection to apply to both developed and developing nations. – they argue that patents " create more certainty of potential profits at the end of the research cycle and decrease the risk of investment[63]" This is especially as the pharmaceutical industry invests heavily in R&D – close to about 11 – 18 percent of sales. It also fuels innovations needed to bring about much new products through R&D.[64]

The pharmaceutical industry is the benefactors of a large number of patents granted in many countries. This is as a cushion to enable them recoups their investments for years of innovative research effort by granting them exclusivity over the drugs produced.

In order to continue to carry out their research activities and make reasonable returns on investments, most of these patented drugs reach the markets at highly exorbitant costs. This often leads to a

[61]E. tHoen, TRIPS, Pharmaceutical patents and access to essential medicines: Seattle, Doha and Beyond. (n.28)

[62]*Free World Trust v Electro Sante Inc.*, [2000] 2 S.CR. 1024, *Whirpool Corp. v Camco Inc.*, [2000] 2S.C.R. 1067, 2000 S.C.C 67, *Graham v John Deere Co*., 383 U.S. 1, 5-9 (1965).

[63] Sahar Asiz, 'Linking Intellectual Property Rights in Developing Countries with Research and Development, Technology Transfer and Foreign Direct Investment Policy: A Case Study of Egypt's Pharmaceutical Industry.' 10 *ILSA .J.INT'L & comp*.l.1, 5 (2003).

[64] Ibid.

conflict of roles for government as they are placed in a position to abide by internal conventions as regards patents such as those laid down by TRIPS, WTO, and the urgent needs to make drugs available to the populace at affordable prices.

While the aim of the pharmaceutical industry is to recoup its investments, the priority of most governments is to make healthcare affordable. On a very practical level, the incentives supposedly given to pharmaceutical industries by the intellectual property framework is regarded as contributory to high cost of healthcare and stifling to innovation.[65]

In most developed nations, patent rights, connotes the right to exclude others from making, using or selling an invention until the expiration of the term granted[66]As such, there have been concerted efforts by the pharmaceutical companies to further extend the period of monopoly granted to them on patented products. The end result of this will be to keep such drugs out of the reach of those who desperately need them, but cannot afford them.[67]

In South Africa for example, the government's initiative to totally overhaul the pharmaceutical industry by making access to generic drugs easier through a more flexible intellectual property regime was resisted by the pharmaceutical companies. [68]Needless to say,

[65]John H. Barton " Intellectual Property Rights and Innovation' in Nicholas Imparato ed. *Capital for our time: the economic, legal and management challenges of intellectual capital* (Stanford , CA: Hoover Institution Press, 1999) pp. 123 at 132

[66] R.A. Bouchard, R.W. Hawkins, R. Hagtvedt and J. Sawani, 'Empirical analysis of Drug approval-drug patenting linkage for high value pharmaceuticals' (2010) *Northwestern Journal of technology and intellectual property* Vol.8 No.2, p. 175

[67] L. Adedeji, 'Patenting and the pharmaceutical industry' The Lawyer's Chronicle: The magazine for the African Lawyer, available on-line at <the lawyers chronicle.com>

[68] T. Motsoeneng, South Africa slams big pharma in generic drugs row, (Reuters 2014)

the governments in places were pharmaceutical products thrive such as India and Brazil brazenly continue their fight to hack down prices, albeit at the risk of going against their international trade obligations under the WTO.[69]

The jurisdiction of India accounts for one great source of generic products, which makes the Indian drug landscape relatively cheaper to access when compared to most other patented drugs in the western world.[70]

Another area that the pharmaceutical companies want to exert control over is the issue of 'parallel imports' of patented drugs. This refers to a situation where patented drugs can be mass produced at a cheaper cost from another country with great savings on such parameters as labour and energy costs. Not only are such generic versions cheaper to produce, but they are also subjected to rigorous testing and approval by the regulatory authorities, before they are introduced into the market once the original patent expires.[71]

These pharmaceutical companies exert so much pressure on governments of their home countries to put in place regulations, litigation and sanctions that will be handed out to countries who engage in such parallel imports. In reality, many countries are reluctant to use these due to fear of sanctions and litigations from drug companies and their home governments, as well as lack of technological ability.[72]

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[69]Ibid

[70] M. Chen, 'Patents against People: How Drug Companies Price Patents out of Survival.' (2013) *dissent*.

[71]Oxfam,'Patents Versus Patients: Five Years after Doha Declaration' Available at www.oxfam.org; F.M. Abbott, 'WTO Medicine Decision: world pharmaceutical trade and the protection of Public Health' *The Am. J. Int. Law.* 99; 317-358

[72] Anna Lanoszka, (n.23)

4.2.0 Amending National Laws to Ensure Numerous Pharmaceutical Suppliers in order to Beat Down Costs and Avoid Monopolies.

i) Generic drugs.

Though a number of potential exporting countries have amended national laws to incorporate and enable the production of generic drugs, such production is hinged on the proviso that there must be evidence of a well-founded domestic manufacturing capacity.[73] More so, the TRIPS Agreement stipulates that productions under compulsory licences must be for use in the domestic market. However, this aspect of the matter has been resolved by the WTO who has given more flexible regimes. Domestically produced drugs can be exported provided the national legislations of the home country support it. This will aid such countries in exporting such generic versions drugs to other needy jurisdictions.[74]

This may not be a palatable solution to the manufacturing industry, as they may see mass production of generic versions as pitching into their markets at cheaper prices, and thereby reducing their profit margins. It also highlights the different possible interpretation of the dual role of the TRIPS Agreement in carrying out its different obligations. Parallel imports of medicines and provisions enacted on compulsory licences remains a contentious issue that needs to be further addressed.

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[73] Paragraph 6 of the DOHA Declaration on the Trips Agreement and Public Health, World Trade Organization (n.42)

[74] ; Roger Thurow and Scott Miller, "Empty Shelves: As U.S. Balks on Medicine Deal, African Patients Feel the Pain --- Big Drug Makers, Protecting Their Patents, Seek Limits To a Global Trade Accord --- Searching for Insulin in Chad." *Wall Street Journal* - Eastern Edition (June 2) 2003: A1.

It is suggested that in "the case of generic drugs, compulsory licenses can be issued because of the high (and for developing nations often unaffordable) prices charged by the major pharmaceutical companies for their products.[75]"

> TRIPS emphasizes a property rights approach whereby private "owners" of the inventions can restrict access on the basis of commercial considerations. As a consequence, higher prices for pharmaceuticals and other healthcare inventions can prevent low-income consumers in developing countries from obtaining life-saving medications and equipment. Many developing countries, however, lack the necessary financial resources and have not yet developed appropriate rules to deal effectively with the challenges presented by the TRIPS Agreement.[76]

A sure change is imminent as Canada has initiated actions geared towards exporting drugs to developing countries. It is anticipated that more producing countries and other corporate patent owners will follow suit.[77]

Conclusion and Recommendations

The general consensus is to have a more human outlook of the pharmaceutical industry. The way to upgrade the ability of consumers to access drugs is to set reasonable prices based on the economic reality of each country. This is because, among other things, though TRIPS is based on the idea that artists, entrepreneurs

[75] Bonita de Boer, 'TRIPS, AIDS and Generic Drugs' (n.53)
[76]Anna Lanoszka, (n.23)
[77]Ann Silversides, "No Turning Back on Cheap AIDS Drugs for Poor Nations, U.N. Vows." *CMAJ: Canadian Medical Association Journal* 169(10): 1067, 2003; BrianVastag, "Alarm Sounded on Fake, Tainted Drugs: 'Some Wholesalers are a Weak Link in a Dangerous Chain.' *Journal of the American Medical Association* 290(8): 1015-1017, 2003

and inventors have a legal right to protect profits derived from their ideas, there should also be a middle ground, that considers the germane conditions and medical emergencies that may arise in less developed countries.

In order to achieve its public health goals, the governments of member states to the TRIPS and other policy instruments may formulate policies which are in contrast to maximising profit goals of pharmaceutical companies. At all times there should be a balance between the industry and government. This is to encourage continued research into new drugs and to assure investors that they can always recoup monies geared towards research.

The level of private sector intervention in research and development needs to be increased, so that many more upcoming inventors will have the adequate support to carry out inventive activities. Governments in developing nations can partner with the corporate bodies by informing them of tax reliefs. This genre or group includes practitioners in the traditional cadre who are custodians of manners of combining herbs and leaves to take care of every day ailments such as malaria, coughs and colds, treating burns as well as skin diseases, that have been passed down from generation to generation. Such traditional practitioners need the necessary assistance to have their products well packaged with dosage instructions. This will enable them to be patented and easily recognised and accepted in the international market.

Government of countries that need better access to drugs or who need to rapidly develop their local drug output will have to put in better efforts. Such efforts will be needed in assuring the transfer of technology from foreign countries. This is a major prerequisite for

an appreciable change in properly increasing the drug quotient and output. [78]

> The manner in which Instead, developing countries in Central America, Africa and 'South African Customs Trade Area' are pressured into making bilateral and regional Free Trade Agreements (FTA) with the United States of America (USA) which often include more stringent patent rights conditions than TRIPS; limiting use of compulsory license and extending patent life. These are called 'TRIPS plus' agreements and negates the spirit of the Doha declaration[79]"

For now, the implementation of TRIPS is seen as a factor in reducing access to drugs and thereby jeopardizing people's right to health.[80] This appears to be unacceptable under the ESCR Covenants and countries in this situation would be expected to give priority to their human rights obligations. In this context, the more worthy or commendable solution would be to do that which makes medicines more accessible at a cheaper cost to the generality of the population.

Although the WTO has gone to great lengths through appendage legislations to TRIPS, and Doha Declaration to improve access to drugs, by dissecting patent laws at the international level, all it seems to have done is to make drugs more readily available to meet epidemic or crisis situations that could cripple a nation's public health. The issue of disparity in terms of developing needs of developed and developing nations is hardly addressed. As such

[78]Anna Lanoszka, (n.23)

[79]C.M. Correa, 'Implications of bilateral trade agreements.' *Bulletin of World Health Organisation* 84 (5)399-404, 2006; C. Bloiun, Trade Policy and Health: conflicting interests to policy coherence. *Bulletin of World Health Organisation*, 85(3)169-173, 2007.

[80]Phillipe Cullet , (n.2)

there is an *obvious* need for a more relaxed patent criteria or regime in less developed nations.[81]

[81]Ibid