TRIPS FLEXIBILITIES AND DEVELOPING COUNTRIES: ANY HOPE FOR AFRICA IN THE FACE OF PANDEMICS?

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Abstract

The TRIPS Agreement, which came into effect on 1 January 1995, is to date the most comprehensive multilateral agreement on Intellectual Property globally. The areas of intellectual property that it covers are copyright and related rights , trademarks , geographical indications, industrial designs; patents, the layout-designs of integrated circuits; and undisclosed information. There are many Flexibilities available under TRIPs Agreement such as transition period, compulsory licenses, parallel imports, public and non-commercial use of patent, exceptions to patent rights, exceptions from patentability and limit on data protection. Furthermore, one of the aims of the Flexibilities is to permit developing countries to use TRIPS-compatible norms in a manner that enables them to pursue their own public health policies and have access to pharmaceutical products globally. This Paper will address these flexibilities and how Developing Countries can make use of them, in the face of Pandemics that ravage the world. It will also make recommendations for the smooth utilization of the Flexibilities in future Pandemics. Indeed, there is wide consensus on the use of these Flexibilities as mechanisms for the protection of Public health globally.

Keywords:

TRIPS Flexibilities

Though, there is no agreed-upon definition of the term 'TRIPS flexibilities', however, in accordance with a WIPO Document, the term 'flexibilities' means that there are "different options through which TRIPs obligations can be transposed into national law so that national interests are accommodated and yet TRIPS provisions and principles are complied with".

Developing Country

According to the UN, a developing country is a country with a relatively low standard of living, undeveloped industrial base, and moderate to low Human Development Index (HDI). This index is a comparative measure of poverty, literacy, education, life expectancy, and other factors for countries worldwide.

Pandemics

Pandemics are large-scale outbreaks of infectious disease that can greatly increase morbidity and mortality over a wide geographic area and cause significant economic, social, and political disruption

Africa

Africa is the world's second-largest and second-most populous continent, after Asia in both aspects. At about 30.3 million km² including adjacent islands, it covers 20% of Earth's land area and 6% of its total surface area. With 1.9 billion people, it accounts for about 18% of the world's human population.

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Introduction

The origin of these TRIPs flexibilities can be traceable to the UNCTAD Document where Correa[1] spoke of "room to manoeuvre" that TRIPs gives in order to formulate national public policies. The term "room of manoeuvre" was considered too harsh for the diplomatic environment in the United Nations,[2] therefore the WHO's Red Book[3] spoke of "Margins of freedom"[4] Subsequently, in March 2001, the WHO adopted the term "safeguards"[5] The European Communities, in June 2001 spoke of a "sufficiently wide margin of discretion"[6] in reference of the implementation of the TRIPs Agreement. A few months later, in November 2001, in the Doha declaration on TRIPs and Public Health the WHO referred to "the provisions in the TRIPs Agreement which provide flexibility". It was in June 2001, where the WHO, in a document authored by Carlos Correa analyzing the implications of the Doha Declaration, referred to the "flexibilities" of the Agreement.[7] Importantly, the Sustainable development Goals (SDGs), as adopted by the UN General Assembly also refers to the TRIPS flexibilities thus:

> … support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provides access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPs Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade –Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and in particular, provide access to medicines for all.[8]

Today, there is wide consensus on the use of the term "flexibilities" in reference to mechanism and provisions for the protection of public health. Though, there is no agreed-upon definition of the term 'TRIPS flexibilities', however, in accordance with a WIPO Document, the term 'flexibilities' means that there are "different options through which TRIPs obligations can be transposed into national law so that national interests are accommodated and yet TRIPS provisions and principles are complied with".[9]

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1 United Nations Conference on Trade and Development (UNCTAD), The TRIPs Agreement and Developing Countries, U.N.pub.96.II.D.10 (1996) (Prepared for the UNCTAD Secretariat by Carlos Correa, Keith Maskus, J H Reichman and Hanns Ullrich)

2 G Velasquez, *Access to Medicines and Intellectual Property: The Contribution of the World Health Organisation* Research Paper No.47 (Switzerland, South Centre Publication, 2013) p. 5

3 The Red Book came about as a request in resolution 49.14 of 1996 for the Director General to prepare a study on the implications of the TRIPs Agreement to the Drugs Action Plan – DAP- which saw the publication of a document titled: "Globalisation and Access to Drugs: Implication of the WTO/TRIPS Agreement in November 1997. That document was printed, by chance, with a red cover and was referred to as the "red book" even in official correspondence.

4 G Velasquez and P Boulet, *Globalisation and Access to Drugs: Implication of the WTO/TRIPS Agreement* WHO/DAP/98.9, (Geneva, WHO Publication, 1997)

5 WHO Policy Perspectives on Medicines, "*Globalisation, TRIPs and Access to Pharmaceuticals*", No. 3 (Geneva, WHO Publication, 2001) p. 5

6 Communication from the European Communities and their member states to the TRIPs Council (IP/C/W/280), June 12, 2001

7 C Correa, "Implications of the Doha Declaration on the TRIPs Agreement and Public Health", WHO/EDM/PAR/2002.3 (Geneva, A Publication of the WHO, 2002) p. 13

8 Sustainable Development Goals (SDGs), Goal 3, Target 3(b). Resolution adopted by the United Nations General Assembly on 25 September 2015, A /RES/70/1. Available at https://www.un.org/ga/search/view_ doc.asp?symbol=A/RES/70/1&Lang=E accessed on 23rd May, 2023.

9 WIPO (2010), P.11. Available at https://www.wipo.int/meetings/en/doc_details.jsp?doc_id= accessed on 23rd May, 2023.

This concept of flexibility was much discussed at the height of the debate on TRIPs and access to medicines. The HIV/AIDS pandemic afflicting many developing countries, particularly in sub-Saharan Africa fueled the debate, focusing public attention on the manner in which intellectual property protection, as promulgated by the TRIPs Agreement, has an impact on areas of public – making, and in particular public health. In the face of pressures from certain developed countries and pharmaceutical companies which favoured narrow interpretations of the TRIPs provisions and its flexibilities, developing countries in the WTO sought greater recognition for their position that the TRIPs Agreement did provide countries flexibility and discretion. These countries argued that the provisions of the Agreement did not prevent them from adopting measures to ensure access to medicines and to meet other public health needs.[10] Their efforts culminated in the adoption of the Doha Declaration on the TRIPs Agreement and Public Health at the Fourth WTO Ministerial Conference in 2001. Subsequently, the WTO General Council adopted the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health, to address the problem of countries with insufficient or no manufacturing capacity too effectively use compulsory licenses.[11] Thus, there are now three pieces of texts that can be said to delineate the WTO legal framework for the protection of intellectual property rights in the context of countries' right to take measures to protect public health including to promote access to medicines. They are: the TRIPS Agreement; the Doha Declaration and the WTO Decision on Paragraph 6. It may be argued that the Chairman's Statement that accompanies the WTO Decision on Paragraph 6 also has a legal standing in terms of interpretation of the Decision. However, WTO Members have expressed differing views on this point, particularly in the context of the current negotiations for the amendment of the TRIPS Agreement.[12]

TRIPS Flexibilities

There are so many flexibilities available in the TRIPs Agreement which came about as a result of the inability of developed countries to agree to specificities during this period. This was true, for example, on the permissible exceptions and limitations to IPRs contained in Article 13 on copyright and related rights and Article 30 on patents, where loosely-worded phrases that these exceptions should not conflict with normal exploitation of the right and should not "unreasonably" prejudice the legitimate interest of the right holder, based on Article 9(2) of Berne Convention.[13] There are many flexibilities available under TRIPs namely: transition period, compulsory licenses,[14] parallel imports, public and non-commercial use of patent, that is, government use, exceptions to patent rights, exceptions from patentability and limit on data protection. The WTO in adopting the Doha Declaration on TRIPs and public health at the Doha Ministerial Conference in 2001, recognized that although developing countries had the theoretical flexibilities to grant compulsory and use other flexibilities, many of them could not effectively use this policy tool for public health purposes due to insufficient or lack of manufacturing capacity in the pharmaceutical sector. Another concern was the major influence developed countries especially the USA and EU

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10 TRIPS Council submissions from developing countries and the EC to the TRIPS Council Special Session of 20 June 2001, IP/C/W/296 and IP/C/W/280. A Law, *Patents and Public Health: Legalising the Policy Thoughts in the Doha TRIPS Declaration of 14 November 2001* (Nomos Verlagsgesellschaft mbH Publisher: 2008)

11 The Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WTO document WT/L/540/Corr.1, July 25, 2005. Available at https://docs.wto.org>FE_S_S009-DP [Hereinafter TRIPS Council Decision Implementing Paragraph 6 of Doha Declaration] accessed on 23rd May, 2023.

12 Musungu and Oh , "*The USe Of Flexibilities In Trips By Developing Countries Can They Promote Access To Medicines ?* available at https://www.researchgate.net/publication/23777893_The_Use_of_Flexibilities_in_TRIPS_by_Developing_Countries_Can_They_Promot_Access_to_Medicines/link/0912f50c5d9615d053000000/download accessed on 5th June , 2023. P. 90.

13 J Watal, "From Punta Del Este to Doha and Beyond: Lessons from the TRIPs Negotiating Processes" (2011) *WIPO Journal* 3(1), 24-35

14 S M Ford, "Compulsory Licensing Provisions Under the TRIPs Agreement: Balancing Pills and Patents" (2000) 15 *American University International Law Review*, 941-974

have on how developing countries deal with intellectual property and other policies relating to pharmaceuticals due to their economic, political and military power. For this reason, the policies of these developed countries vis-à-vis developing countries with respect to intellectual property and access to medicines are a critical factor that determines how the latter address matters relating to intellectual property, innovation and public health.[15] The debate culminated in the adoption of the Declaration on the TRIP Agreement and Public Health (the Doha Declaration).[16] The Doha Declaration therefore represents a final agreement between the two camps that public health condition the extent to which patent protection is implemented.[17] The Ministers of Members of the WTO expressed their agreement in the following terms:

> We agree that the TRIPs Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPs Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect health and in particular, to promote access to medicine 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 this purpose.

The flexibilities in the TRIPs Agreement can be categorized into two types. The first is time-based, in the form of transition periods, which allow developing and last or least-developed countries extra time in the implementation of their TRIPs obligations while the second type is the substantive flexibilities as provided for in the Agreement.

Transition Periods

Three transition periods are provided for in the agreement, namely: first, the 1995 to 2000 period,[18] at the end of which developing countries were obliged to implement the TRIPs Agreement; and to put into place patent legislation that complied with the minimum standards of intellectual property protection prescribed by the TRIPs Agreement. In terms of patent protection, the critical requirements included the criteria for patentability, the minimum of 20-year protection term and protection for both products and processes in all fields of technology.[19] By the 1st January deadline, the majority of developing countries already had patent legislation meeting these requirements, although this meant a significant change from their previous patent regimes which allowed for shorter protection terms and differentiated treatment for products or sectors.[20] Second, the 2000 to 2005 transition period,[21] which provided an additional period of five years to put in place product patent protection pharmaceuticals or agro-chemicals for those countries without such protection at the entry into force of the Agreement. However, the use of this transition period was subject to certain conditions. Developing countries were required to accept patent applications as of 1995, to keep them in a patent queue "mailbox", and to start processing the applications in 2005.[22] During the mailbox period, developing countries are required to grant exclusive marketing rights for those products for which patents have been filed in the mailbox, where marketing approval the products had obtained in the country and the same product had previously been patented in another

15 Musungu and oh (n39) at viii

16 Doha Declaration on TRIPs Agreement and Public Health, WTO document WT/MIN(01)/DEC/W/2 dated November 20,2001. Available at http://www.wto.org accessed on 23rd May, 2023.

17 Musungu and Oh Ibid P.95

18 Article 65(2) of the TRIPS Agreement

19 Article 27 and 33 of TRIPS Agreement

20 United Nations Conference on Trade and Development (UNCTAD)Report 1996. Available at https://unctad.org/system/files/official-document/wir1996_en.pdf> accessed on 3rd May, 2023.

21 Article 65(4) of TRIPS Agreement

22 Article 70(8)(c) and 70(9) of TRIPS Agreement

country.[23] The third transition period was between 1995 to 2006, after which Least - Developed Countries (LDC) would be required to implement their TRIPs obligations. It is important to mention that this transition period has been extended to 2016 with respect to patents on pharmaceutical products and exclusive marketing rights.[24] Paragraph 7 of the Doha Declaration states that the LDCs Members:

> …will not be obliged, with respect to pharmaceutical products, to implement or imply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until January 1 2016, without prejudice to the rights of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66(1) of the TRIPS Agreement.[25]

While the TRIPS Council Decision implementing Paragraph 7 of the Doha Declaration extends the transition period for pharmaceutical patents until 2016, LDCs are still obliged to implement the rest of their obligations under TRIPs Agreement as of 2006. In order to use this flexibility, those LDCs that have already provided patent protection will have to make the necessary changes to their national laws, to provide for this exemption for pharmaceuticals. However, there is some uncertainty in terms of how countries may act to deal with pharmaceutical patents already granted, as the TRIPS Council Decision does not seem to extinguish existing patent holders' rights under national law. While it has been suggested that an LDC may proclaim its intention to suspend patent enforcement pursuant to the Decision, there is a risk of a claim from a patent holder unless the national law on suspension or non-voluntary use of patents have been properly followed. In addition to these time-based flexibilities or commonly known as transition period, there are substantive flexibilities in the TRIPs Agreement.

Compulsory Licensing

A compulsory license, also referred to as a non – voluntary license, is a license granted by an administrative or judicial body to a third party to exploit a patented invention, without the consent of the patent holder.[26] The grant of the patent rights enables the patent holder to prevent a third party from exploiting his invention. However, when reasons of public interest justify it, national authorities may allow for the exploitation of the patent by a third party without the patent holder's consent or authorization. In such a case, the public interest of ensuring broader access to the patented invention is deemed to be more important than the interest of the patent holder in retaining his exclusive rights. Compulsory license can therefore play a crucial role in ensuring that patent laws are able to meet public health needs, and that patent rights do not unnecessarily hinder or prevent access to affordable medicines.[27]

Rwanda, a country without manufacturing capacities took advantage of the system established by the 2003 Decision[28] to apply for compulsory licensing of the HIV/AIDS drugs manufactured in

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23 Article 7(8)(c) of TRIPS Agreement

24 TRIPs Council's decision of June 2002 (WTO document IP/C/W/25) implementing Paragraph 7 of the Doha Declaration. Available at https://www.docs.wto.org accessed on 3rd May, 2023.

25 TRIPS Council Decision Implementing Paragraph 6 of Doha Declaration(n78)

26 TRIPS Council Decision Implementing Paragraph 6 of Doha Declaration (n78) at p.15

27 Velasquez & Boulet (n21). Also, C Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (Geneva, South Centre, 2000)

28 H P Hestermeyer, "Canadian – Made Drugs for Rwanda: The First Application of the WTO Waiver on Patents and Medicines", (December 10, 2007) 11: 28 ASIL Insight International Economic Law Edition, Available at http://www.asil.org/insights/2007/12/insings071210.html. Also, F M Abbott, "Introductory Note to World Trade Organisation Canada First Notice to Manufacture Generic Drug for Export" (2007) 46 *International Legal Materials* 1127. Also, F M Abbott and J H Reichman, "The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions" (2007) 10 *Journal of International Economic Law*, 921

Canada. Under paragraph 2(a) of the 2003 Decision,[29] Rwanda notified the Council for TRIPS of its intention to import 260,000 packs of HIV/AIDS tri-therapy manufactured by Canadian company Apotex.[30] It also informed the Council of its decision to rely on para.7 of the Doha Declaration[31] and the Council for TRIPS Decision on the Extension of the Transition Period under Article 66 (1) of the TRIPS Agreement for Least-developed country Members for certain Obligations with respect to pharmaceutical products[32] in order to suspend the enforcement of any related patent right.[33]

The examples of developing countries' use of the TRIPS flexibilities are not many, but they are growing. In 2002, Zimbabwe issued a declaration of emergency, which empowered the Ministry of Justice, Legal and Parliamentary Affairs to authorize any government department or third party to use any patented invention for the service of the state. A local producer was authorized to manufacture and supply anti-retroviral (ARV) medicines to government health institutions under the government use license. In 2003, the Malaysian government used the government use provisions of its patent law to allow for the important of generic ARVs from India for use in public hospitals. In 2004, both Mozambique and Zambia issued compulsory licenses for local production of ARVs. In the same year, the Indonesian President also issued a decree authorizing the government use of patent related to two ARVs, empowering the Minister of Health to appoint a pharmaceutical company to undertake local production of these medicines.[34]

In South Africa and Kenya, licenses have been granted to local manufacturers by patent holding companies for the production of ARVs. In South Africa case, the licenses were granted based on a settlement in a competition claim which would make these licenses technically compulsory licenses. In Kenya, the voluntary licenses followed concerted pressure from the government, civil society organization and local manufacturers. Although technically voluntary licenses in that they were negotiated between the patent holding companies and the license company, the political and legal context in this case should be noted. It can be argued in both South Africa and Kenya, the patent holding companies were compelled to enter into voluntary licensing arrangements with local producers, given that national legislation in both countries incorporated a number of the TRIPS flexibilities and there seemed to be sufficient political impetus for their use.[35]

Brazil and Thailand have issued compulsory licenses for *Efavirenz*, a drug used to treat people infected with HIV/AIDS. Thailand overrode Merck & Co.'s patent on *Efavirenz* in December 2006 while Brazil did same in May 2007.[36] Both Thailand and Brazilian governments justified their

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29 Notifications under paragraph 2(a)(ii) of the Annex to the TRIPS Agreement in the amendment would include information on how the Member in question had established, in accordance with the appendix to the Annex to the TRIPS Agreement in the amendment, that it has insufficient or no manufacturing capacities in the pharmaceutical sector.

30 Document IP/N/9/RWA/1, July 17, 2007. Available at https://docs.wto.org>FE_S_S009=DP accessed on 23rd May, 2023.

31 Document WT/MIN(01)DEC/2 dated 14 November 2001. Available at https://docs.wto.org>FE_S_S009=DP accessed on 23rd May, 2023.

32 Decision of the Council for TRIPS of 27 June 2002, Document IP/C/25 dated July 1, 2002. Available at https://docs.wto.org>FE_S_S006=DP accessed on 23rd May, 2023.

33 Gervais Ibid at p. 64

34 S F Musungu and C Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can they Promote Access to Medicines*? Study 4C (Geneva: A Publication of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), 2005)

35 Musungu and Oh Ibid p 102

36 Government of Thailand compulsory license for Efavirenz (Stocrin), the HIV/AIDS drugs still under patent by Merck, details available at http://www.ip-watch.org/weblog/index-php?p=499. The compulsory license of Thailand has a longer duration

action under the provision of TRIPs that "member countries have a right to issue a safeguard measure to protect public health, especially for universal access to essential medicines using compulsory licensing on the patent of pharmaceutical products."[37] They maintained that where a compulsory licensing is issued for "public non-commercial use", there is no requirement to engage in prior negotiations with the patent holder.[38] Article 31(b) of TRIPs, explicitly states that governments do not need to consult with patent holders when issuing a compulsory license for national emergencies or public non-commercial use.

Under the TRIPS Agreement, WTO Members are only limited with regard to the procedure and conditions to be followed in the grant of compulsory licenses. Article 31 sets out the conditions to be met in the grant of compulsory licenses. Although the Agreement refers to some of the possible grounds for compulsory licenses; such as in the case of a national emergency or situation of extreme urgency – such as war, famine, natural catastrophe, and so on. In the case of compulsory licenses for emergencies, the requirement for prior negotiations for a voluntary license is also waived and it should also be reflected in the domestic law.[39] Compulsory License is also granted as a measure to remedy anti-competitive practices – this ground is specifically referred to in the TRIPS Agreement. Where a compulsory license is granted on this ground, the TRIPS Agreement allows for the waiver of certain conditions, including the requirement for prior negotiations for a voluntary license. Article 31(b) provides that the prior negotiation requirement is waived where a compulsory license is granted in the case of an emergency, where it is a public non-commercial use of the patent, or when it is granted to remedy anti-competitive practices and the restriction on exports under the compulsory license.[40] Compulsory license is also granted to enable the use of a dependent patent – this is where a new invention requires the use of a pre-existing patented invention for working and public, non-commercial use of patents. Article 31 refers to "public, non-commercial use", in the context of use of a patent without authorization of the patent holder. Thus, public, non-commercial use may be incorporated as a specific ground for the grant of a compulsory license. However, public and non-commercial use of a patent can also be in the form of the government's right to use patents; that is to say, without the need for a compulsory license. Government-use provisions allow for the use of patents to be 'fast-tracked' as government rights in terms of public and non-commercial use of patents are often procedurally much simpler.

Compulsory license is also granted on grounds of refusal to license – where patent holder has refused, over a reasonable period of time, to enter into a voluntary licensing agreement on the reasonable commercial terms offered by the applicant, the refusal to deal or to license may be a ground for an application for a compulsory license. There is another ground called the public interest – most patent laws provide for grant of compulsory license under the public interest ground but they failed to define the term or provide a non-exhaustive or illustrative list of what may constitute public interest grounds for the grant of compulsory license. Public health and nutrition may fall under this ground in order to ensure availability and affordability of medicines for public use. Adopting the use for a particular does not limit the use of other grounds. Since the permissible grounds are not explicitly defined in the Agreement, it leaves developing countries wide discretion when determining public health sensitive compulsory licensing policies and law. The flexibility to determine the grounds was reaffirmed in paragraph 5(b) of the Doha Declaration on the TRIPS Agreement and Public Health,[41] which states that "[e]ach Member has the right to grant

37 Article 31 of TRIPs Agreement

38 *ibid*

39 Musungu and Oh Ibid at p.17

40 Article 31 (1) of TRIPS refers to the exemption from the requirement of predominant use of the license for the domestic market.

41 TRIPS and Public Health, Ministerial Conference. Fourth Session. Doha, 9-14 November 2001. Available at https://www.wto.org/english/res_e/booksp/ddec_e.pdf [hereinafter Doha Declaration]

compulsory licenses and the freedom to determine the grounds upon which such licenses are granted."

Public, Non-Commercial Use (Government Use) of Patents

The right of the state or government to use patents without the consent of the patent holder is a standard feature of patent laws in many countries. Such use of patents by the government is viewed in common law countries as an eminent domain taking of a license under the patent, and thus, not infringement of the patent.[42] Although the TRIPs Agreement does not refer specifically to government use of patents, it recognizes such use in its references to the concept of public, non-commercial use and of patents "used by or for the government".[43] Analysis of the negotiating history of TRIPs revealed that both compulsory licenses and government use provisions were envisaged. Hence, Article 31 of the TRIPs Agreement is intended to cover non-voluntary use of patents in the form of both compulsory licenses and government use provisions.[44] Many patent regimes provide for government use of patents without the need to grant a compulsory license. In such cases, a determination by a government agency or minister is generally required to attest that the government use is justified and is within the terms of the national law. These government rights are usually framed in broad terms and are often subject to less procedural requirements than are compulsory licenses.

The distinction between government-use provision and compulsory license would lie primarily in the nature or purpose of the use of the patent. In the case of government use, it would be limited to "public, non-commercial purposes", whereas compulsory licenses would also cover private and commercial use. However, the precise meaning of "public, non-commercial use" is not defined in the TRIPs Agreement, which would leave developing countries the policy space to interpret the term. It seems indisputable that the use by a government authority of a patented invention, for example, the purchase of anti-retroviral medicines for distribution through public hospitals without commercial profit would come within the scope of the term. In addition, there may be further flexibility inherent in the term given that there is nothing in the TRIPs Agreement to prevent different ways of defining the term. In this case, the word, "public" could be interpreted as referring to the purpose of the use so that even a private entity charged with exploiting a patented invention for the benefit of the public would also come within the scope of "public, non-commercial use".[45] Referring to both government use and compulsory licensing, the World Bank in its technical guide on procurement of ARVs describes them as "principal means enabling procurement authorities to overcome patent barriers to obtaining lower priced generic medicines and related supplies".[46]

Whilst conditions set out in the TRIPs Agreement[47] are applicable to government use of patents as they do to compulsory licenses, there are important differences that make public and non-commercial use of patents procedurally simpler. A notable difference is the waiver of the requirement for the government or its authorized party too first seek a voluntary license.[48] This

42 Musungu & Oh Ibid p.20

43 Article 31(b) of the TRIPs Agreement

44 J Reichman and C Hazendahl, "*Non-Voluntary Licensing of Patented Inventions: Historical Perspective, Legal Framework under TRIPs and an Overview of the Practice in Canada and the United States of America*" (2002) UNCTAD and ICTSD, Issue Paper No.5, Geneva

45 World Bank, *HIV/AIDS Medicines and Related Supplies: Contemporary Context and procurement – Technical Guide* (World Bank, Washington, D.C. 2004a), World Bank, Global Economic Prospects 2005, (World Bank, Washington D.C. 2004b); UNCTAD and ICTSD, *Resource Book On TRIPs and Development* (Cambridge, Cambridge University Press, 2005)

46 World Bank (2004a) *ibid* at p.90

47 Article 31 of TRIPS Agreement

48 Article 31(b) TRIPS Agreement

waiver provides a considerable degree of flexibility and allows for speedier action. In other words, it allows for the use of patents to be 'fast-tracked', which is of importance when life-saving medicine are required. There is only an obligation to inform the patent holder of the proposed use of the patent, or promptly after such use.

Using the U.S.A. and the U.K system as case study on how public use of patents may be broadly framed, Section 28 of USC of 1498[49], empowers the US government to use patents or authorized a third party to use patents for virtually any public use. Under this statute, the US government does not have to seek a license or negotiate for the use of a patent or copyright.[50] The patent holder is entitled to compensation, but may not have resort to injunctive relief to prevent the use of the patent by the government. The government may only be held liable to the patent owner for payment of the "reasonable and entire compensation" for is non-authorised use of the patent.[51] A similar approach applies in the United Kingdom (UK) with regard to the "Crown use" of a patent, whereby use of a patent "in the service of the Crown" without the prior consent of the patent holder is not considered an infringement of the patent.[52]

Applying the same principle to developing countries, according to Musungu & Oh:

> A significant number of the patent laws reviewed for this study incorporated explicit provisions for government or public use patents. The provisions were generally broadly based on public interest grounds. In many of the patent legislation in the Asian countries, for example, public interest has been defined to include "particular national security, nutrition, health and the development of other vital sectors of the economy", a formulation which reflects the language found in Article 8 of the TRIPs Agreement."[53]

Provisions relating to government rights to use patents in the national laws of Commonwealth countries were generally modelled after the British 1883 Act, which provided for broad powers to the government to "make, use, exercise and vend the patented invention for any purpose for which appears to the government necessary or expedient".[54] In 2002, the Minister of Justice, Legal and Parliamentary Affairs of Zimbabwe issued a notice declaring a period of emergency on HIV/AIDS[55] for the purpose of enabling:

> The State or a person authorized in writing by the Minister to make or use any patented drug, including any antiretroviral drugs, used in the treatment of persons suffering from HIV/AIDS or HIV/AIDS related conditions; and /or to import any generic drug used in the treatment of persons suffering from HIV/AIDS related conditions.[56]

The above declaration was made pursuant to the provision of Section 34 (1) and 35 of the Patent Act. Section 34(1) which provides thus:

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49 28 USC 1498 (1977)

50 Reichman and Hazendahl Ibid

51 Musungu and Oh Ibid p. 21

52 UK Patents Act 1977

53 Musungu and Oh Ibid p. 39

54 Section 65 of Singapore Patents Act 1994 (No. 21 of 1994) as amended by the Patents (Amendment) Act 1995. Also, Para. 20, Part II of the Patent and Designs Act of Nigeria Laws of the Federal Republic of Nigeria CAP P2, Vol. 12, 2010 [hereinafter Nigeria Patent and Designs Act].

55 Declaration of Period of Emergency (HIV/AIDS) Notice 2002, General Notice 240 of 2002, Rules / Regulation of Patent in Zimbabwe to allow the importation and manufacture of generic drugs. [Hereinafter Zimbabwe Declaration of Period of Emergency (HIV/AIDS) Notice 2002]

56 *ibid*

> Notwithstanding anything in this Act, any department of the State or any person authorised in writing by the Minister may make, use or exercise any invention disclosed in any specification lodged at the Patent Office for the service of the State in accordance with this section.

Section 35 provides that "During any period of emergency the powers exercisable in relation to an invention by a department of the State, or a person authorized by the Minister under section thirty four shall include power to make, use, exercise and vend the invention for any purpose which appears to the Minister necessary or expedient …" Sub Section 2 defines a period of emergency as a period beginning on such date as may be declared by the Minister, by statutory instrument, to be commence and end on such dates as may be so declared to be a period of emergency.

In Nigeria, Adewopo argued that the patent system itself has provided the framework for addressing the challenges of access to pharmaceutical medicines.[57] According to him:

> …two important approaches or arguments reinforce the broader application of the patent regime and, in this context, the Patent and Design Act offers significant constitutional and legal rational for government use as patent law mechanism for meeting public health emergencies. These arguments, found in extant health law vis-à-vis the constitutional perspective to the right to health and judicial precedent in the application of government use, complement the existing patent law narrative and provide a strong legal foundation for the adoption of a government use regime in Nigeria.[58]

He went further to argue that from the constitutional and legal standpoint, the right to health of every person in need of basic medical care is provided for in Chapter Two of the Constitution of the Federal Republic of Nigeria 1999 (as amended).[59] Article 17(c) and (d) provides that: "… the health, safety and welfare of all persons [are] safeguarded and not endangered or abused; there are adequate medical and health facilities for all persons." This social objectives provided in the Nigerian Constitution, agrees with the obligations of States under the Universal declaration of Human Rights[60] and African Charter.[61]With respect to the right to health, the power to invoke government use to ensure that needed medicines or vaccines are available to the burgeoning population derives from the exercise of a statutory or executive power under the Patent and Design Act and equally implies an obligation to implement the legal and constitutional rights in the context of the National Health Act.[62] Section 1(1)[63] provides that: "There shall be established for the Federation the National Health System which shall define and provide a framework for standards and regulation of health services".

It is noteworthy that government use of patents as part of the Compulsory License regime is an important part of the history of patent law in Nigeria. Adewopo[64] opines that:

> "Although the introduction of patent law in Nigeria was not particularly intended to foster indigenous inventive activity or local innovation, it took deliberate

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57 A Adewopo, "Access to Pharmaceutical Patents in the COVID-19 Emergency: A Case for Government Use In Nigeria" (2021) *Journal of African Law*, 65 S2, Pp. 259-286

58 *ibid* at p. 274

59 Chapter Two of The Constitution of the Federal Republic of Nigeria 1999 (as amended) as titled "Fundamental Objectives and Directives Principles of State Policy" which is arguably non - justiciable and un-enforcement. *FRN vs Anache; In Re Chief Olafisoye* (2004) 14 WRN 63

60 Article 25 of the Universal Declaration of Human Rights 1948

61 Article 16 of the African Charter of Human and People Rights

62 National Health Act, Act No. 8, No. 145, Vol. 101, Government Notice No. 208 of 27 October 2014

63 *ibid*

64 Adewopo Ibid p. 277

> legislative and judicial interventions to enforce government use as regulatory measure to preserve government's power to override existing patent rights in the public interest. It can conveniently be posited that government patent use is rooted in judicial decisions before the Patent and Design Act came into force.

The Patent and Designs Act replaced the old Registration of UK Patent Ordinance of 1925.[65] The ordinance only enabled patents granted in the UK to be re-registered in Nigeria after three years of the UK grant, with the effect that the registration in Nigeria only conferred rights and privileges granted by the UK law with an extension to Nigeria.[66] In the case of *Rhone SA and May & Baker vs Lodeka Pharmacy*,[67] it was held that Section 46 of the UK Patent Act 1949 regarding patent use by the Crown could not apply the whole of the UK Act to Nigeria, on the ground that the limitations and obligations imposed on the patentee under the provisions did not apply in its entirety to Nigeria. In that case, the British patent was re-registered by the Plaintiff in Nigeria after the patent had been originally granted in the UK. The court issued an injunction against the Defendant based on the view that the provision for the use of patents in the service of the crown under the UK Patent Act, sought to be incorporated into PDA, could not apply to avail the Defendant.

Following the same trend, in the case of *Ciba Ltd vs Lodeka Pharmacy Ltd*,[68] the court in interpreting the provision of the UK Patent Act held that allowing the limitations and obligations imposed on the patentee for the use of the Crown, could not apply as the authority for government patent use in Nigeria in the absence of an express legislative provision that it should so apply. To this extent, government patent use was effectively frustrated by the patentee or the court as the case may be.[69] However, the position changed in the case of *Wellcome Foundation Ltd vs Lodeka Pharmacy*,[70] when the court for the first time upheld government use of patented medicine. This decision could have been influenced by the Patent Rights (Limitations) Act of 1968 which expressly granted the Nigerian government and agencies powers analogous to the powers allowing the use of patents for the service of the Crown in UK. With the coming into force of the Patent and Design Act of 1970, government use of patent was firmly established in Nigeria as an integral part of compulsory licensing regime.

The regulatory framework for compulsory licensing in Nigeria is contained in the first schedule, paragraph 11 of the Patent and Designs Act. The schedule is titled, "Compulsory Licenses and use of patent for service of government agencies". Part I provides for "compulsory licenses" while part II provides for "use of patents for service of government agencies".[71]Compulsory licensing for the use of patents in the service of government makes extensive provisions regarding the range of circumstances or grounds that may apply in the context of exemptions to existing patent rights. Fundamentally, compulsory license and government use in particular remain the most practical way of preventing the abuse of patents and providing remedial access in established circumstances of national emergencies. This is the position when the substantive and administrative character of the framework is considered within the context of the enabling provision of the Patent and Design Act and with due regard to defined emergencies or public interest purposes.[72]

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65 No. 6 of 1925, CAP 182, 1958 Laws of Nigeria and Lagos. A Adewopo, "According to Intellectual Property: A Pro-Development Vision of the Law and the Nigerian Intellectual Property Law and Policy Reform in the Knowledge Era" (2015) *Nigerian Institute of Advanced Legal Studies Journal of Intellectual Property* 1 at 14

66 Sec 6 of Registration of United Kingdom Patent Act, 1925

67 (1965) LLR 9

68 (1968) ALR (Commercial) 352

69 Adewopo Ibid p. 278

70 (1971) All NLR 536

71 Nigeria Patent and Design Act)

72 Adewopo Ibid p. 278

There is no gain saying the fact that Nigeria is a signatory to the TRIPS Agreement since 1995. TRIPS Agreement provides for administrative procedures on the merit of a case in each member states which shall conform to principles equivalent to those set out in the TRIPS Agreement.[73] The above position maintained by Adewopo represent the state of our laws but in reality the level of compliance or implementation is a far cry and leave nothing to desire of those laws. It is important to mention that the right to health as contained in the Nigerian Constitution as discussed by the learned scholar Adewopo remains unenforceable and unjusticiable. Similarly, The Nigerian Patent and Design Act provides for compulsory licensing[74] as a solution to access to medicines and pharmaceutical products in the case of emergency. It provides that:

> … an individual or government agencies may apply for the grant of compulsory license which can only be granted after the expiration of four years from the date the Patent application concerning the invention was lodged, or at the expiration of three years from the date the actual grant of the patent, whichever is applicable in the granting of the license.[75]

The court may vary the terms of a compulsory license if new facts justify the variation or if the patentee is granted contractual license on more favourable terms.[76] A person that has been granted compulsory license shall have all the rights that a patent confers on a patentee under Section 6 of the Patent and Design Act 2004 but with exception not to import the product in question. The grant of compulsory license does not in any way precludes the original patent owner from using or otherwise dealing with the patent as he may deem fit to make.[77] Compulsory license enjoys recognition and approvals by international instruments / agreements and organisations. It discourages increase of price and scarcity of products occasioned by monopolies resulting from the grant of patent. It is true that most developing countries hold patent over critical health, food and agricultural, biodiversity and education materials.[78] With the ravaging effects of HIV/AIDS, tuberculosis, COVID-19 and other health related diseases in most developing countries, compulsory licenses has been considered a viable tool in solving the problem of access to medicines and pharmaceutical products in order to remedy these emergencies and for economic and social benefits of its citizens.

Recommendations:

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"[79] and to take advantage of the TRIPS flexibilities.

It is important for developing countries to develop and promote regional, bilateral or multilateral intellectual property framework that will be responsible to handle issues of public health

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73 Article 49 of TRIPS Agreement

74 Section 11 Nigerian Patent and Design Act, CAP P2, Laws of The Federation (LFN) 2004

75 Section 9(b) *ibid*

76 Section 10 (n142)

77 Part 1, First Schedule to the Patent and Design Act 2004, Also, A S Amaramiro and B G Toby, "Issuance of Compulsory Licenses in Nigeria: Practice and Procedure Under the Patent and Design Act (2016) *UNIZIK Law Journal*,12, Pp. 136-153

78 Amaramiro and Toby Ibid

79 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

challenges as well as support member countries to review national law on intellectual property laws taking into account available TRIPS flexibilities.

Parallel imports and exhaustion of right can also be an important tool to ensure adequate access to medications and pharmaceutical products. The unconditional right of developing countries to determine the way in which exhaustion of rights regimes are applied in their jurisdiction will also improve access by developing countries. However, differential pricing arrangements should not be used to limit the flexibility of TRIPS in any of its provision. In other words, differential pricing should not be prejudicial to the right of Members to make use of the provisions of the TRIPS Agreement such as parallel imports and compulsory licensing.

This paper also suggest that the transitional period outlined in the TRIPS Agreement should be extended to give room for more institutional and infrastructural framework for the enforcement of the provision of the agreement particularly in view of the gap between the developed and developing countries in terms of manufacturing capabilities to tackle the increasing public health challenges. Member countries should be free to implement the provision of the TRIPS Agreement in ways that best accommodate the protection of health policies in national legislation.

Conclusion

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[80] 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.

[80] 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