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ARTICLE

THE VIABILITY OF PATENT-RELATED FLEXIBILITIES IN PROMOTING BIOTECHNOLOGY RESEARCH AND INNOVATION FOR IMPROVED FOOD SECURITY AND PUBLIC HEALTH IN NIGERIA

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Abstract

While patent laws are expected to play a crucial role in incentivising investments in research and innovation in all fields of technology, their application to biotechnology has remained a sensitive issue for developing countries because biotechnology impacts food security, public health and other critical aspects of human life. Particularly, the notion that the application of existing patent standards to biotechnology impedes access to innovations and follow-on research in developing countries such as Nigeria is well established in the literature. This led to calls for the adoption of patent flexibilities, particularly as embodied in the TRIPS, as a counterbalance to the defects in the patent system in relation to biotechnology. Therefore, this paper probes the viability of patent-related flexibilities in fostering access to and innovation in biotechnology in Nigeria, with particular reference to public health and food security. The paper shows that their implementation in Nigeria and other developing countries is not tenable for various reasons, including lack of political will, fear of trade retaliation and low technological capacity. As a result, it advocates for the adoption of alternative approaches to research and innovation in biotechnology, such as open science, in order to facilitate need-driven research and access to innovation in biotechnology in Nigeria.

Keywords: Biotechnology, patent flexibilities, food security, public health, Nigeria.

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1.0 Introduction

Biotechnology has significant roles to play in agriculture, health, and other critical aspects of human life. In terms of agriculture, the application of biotechnology has the potential to, among others, improve crop and animal productivity and nutritional qualities, contributing to governments' efforts to eradicate hunger and malnutrition and improve food security in developing countries. Regarding health, biotechnology also promises to bring about quicker diagnostic tests, a broad range of therapeutic products, novel drugs, and vaccines for improved public health in Nigeria and other developing countries. However, while a number of explanations have been offered for the extension of patent protection to the field of biotechnology, including incentivising investment in biotechnology research and innovation, the notion that biotechnology patenting poses some peculiar challenges to nutrition, food security, access to medicine and public healthcare in developing countries is well established in existing literature.[1] In particular, the monopoly rights conferred on patent owners significantly impede access to and use of biotechnological innovations, such as seeds and vaccines, which are priced out of the reach of the poor, most of whom are in developing countries. It is this concern and others that led to the call for temporal waiver of intellectual property rights during the pandemic.

Quite often, adopting the flexibilities under the existing regimes on intellectual property rights is proposed as a counterbalance to the negative effects of protecting biotechnology research and innovation.[2] In fact, since the COVID-19 pandemic, there has been renewed interest in the use of flexibilities,[3] with the African Union declaring explicitly that the barriers posed by

[1] For instance, CM Correa, JI Correa and B De Jonge, 'The Status of Patenting Plants in the Global South'. (2020) 1 *The Journal of World Intellectual Property* 121, 122 – 123 <https://doi.org/10.1111/jwip.12143> accessed 06 February 2024; United Nations Secretary-General and Co-Chairs of the High-Level Panel, 'Promoting Innovation and Access to Health Technologies' (Report of the United Nations Secretary-General's High-Level Panel on Access to Medicines, 2016) <http://www.unsgaccessmeds.org/s/UNSG-HLP-Report-FINAL-12-Sept-2016.pdf> accessed 24 February 2024.

[2] United Nations Secretary-General and Co-Chairs of the High-Level Panel, 'Promoting Innovation and Access to Health Technologies', pp.22-26 (discussing TRIPS flexibilities in relation to the existing gaps in health technology innovation and access).

[3] E 't Hoen, 'COVID-19 and the Comeback of Compulsory Licensing', Medicines Law & Policy (23 March 2020) <https://medicineslawandpolicy.org/2020/03/covid-19-and-the-come-back-of-comulsory-licensing/> accessed

intellectual property rights as regards timely access to affordable pharmaceutical products could be addressed through the use of the flexibilities captured in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), 1994 (as amended) and the Doha Declaration on the TRIPS Agreement and Public Health, 2001.[4]

In light of the above, this paper examines the viability of patent-related flexibilities in fostering access to and innovation in biotechnology in Nigeria, with particular reference to public health and food security.[5] While the World Intellectual Property Organisation (WIPO) identified four clusters of flexibilities,[6] the discussion in this paper focuses on those measures that reduce or limit the exclusive nature of patents, such as compulsory licensing, research or experimentation exception and parallel importation, provided under the TRIPS Agreement and the Nigerian patent law to determine their suitability for addressing the access and innovation gaps within the context of biotechnology in Nigeria. It finds that the patent flexibilities do not provide adequate safeguards for developing countries like Nigeria and, therefore, argues for the adoption of open and collaborative approaches to biotechnology research and innovation to ensure public health and food security in Nigeria.

2.0 PATENT-RELATED FLEXIBILITIES

Flexibilities, also known as safeguards or checks, are legal mechanisms countries adopt to mitigate the impact of the monopoly rights granted to intellectual property owners, including

13 February 2024; Médecins Sans Frontierès (MSF). 'MSF Calls for No Patents or Profiteering on COVID-19 Drugs, Tests, and Vaccines in Pandemic' Press Release (27 March 2020) <https://msfaccess.org/msf-calls-no-patents-or-profiteering-covid-19-drugs-tests-and-vaccines-pandemic> accessed 13 February 2024; African Union and Africa Centres for Disease Control and Prevention, 'Africa's Leadership in COVID-19 Vaccine Development and Access' (Communique for the Virtual Conference Held on 24 – 25 June 2020). <https://africacdc.org/wp-content/uploads/2020/07/Commumique-from-vaccine-conference-ENG.pdf> accessed 13 February 2024.

[4] African Union and Africa Centres for Disease Control and Prevention, 'Africa's Leadership in COVID-19 Vaccine Development and Access'.

[5] United Nations Secretary-General and Co-Chairs of the High-Level Panel, 'Promoting Innovation and Access to Health Technologies', pp.22-26 (discussing TRIPS flexibilities in relation to the existing gaps in health technology innovation and access).

[6] WIPO, 'Advice on Flexibilities under the TRIPS Agreement' <https://www.wipo.int/ip-development/en/policy_legislative_assistance/advice_trips.html> accessed 29 February 2024.

excessively high product prices.[7] From a globalised perspective, the term 'TRIPS flexibilities' is often used. This refers to the policy spaces available for countries to meet their obligations under the TRIPS Agreement.[8] According to WIPO, the aim is to allow the least-developed and developing countries to employ TRIPS-compatible norms in such 'a manner that enables them to pursue their own public policies, either in specific fields like access to pharmaceutical products or protection of their biodiversity, or more generally, in establishing macroeconomic, institutional conditions that support economic development'.[9] This opens up the question of whether patent-related flexibilities offer the Nigerian government the opportunity to improve food security and public health in the context of biotechnology research and innovation.

2.1 Compulsory Licensing

Compulsory licensing is considered 'the first and the most critical' tool under the intellectual property system.[10] Compulsory licensing permits the use of a protected work, invention or plant variety by a third party or government without the consent of the right holder, often to serve

[7] Health Action International, 'TRIPS Flexibilities and Access to Medicines: A European Approach' (2019) <https://haiweb.org/wp-content/uploads/2019/06/HAI-TRIPS-Brochure.pdf> accessed 29 February 2024.

[8] Ibid.

[9] WIPO, 'Advice on Flexibilities under the TRIPS Agreement'.

[10] M El Said and A Kapczynski, 'Access to Medicines: The Role of Intellectual Property Law and Policy' (Working Paper prepared for the Third Meeting of the Technical Advisory Group of the Global Commission on HIV and the Law, 7 – 9 July 2011) 6 <http://clok.uclan.ac.uk/12962/1/ACCESS-TO-MEDICINES-THE-ROLE-OF-INTELLECTUAL-PROPERTY-LAW-AND-POLICY%20%284%29.pdf> accessed 29 February 2024; Similarly SF Musungu, 'The TRIPS Agreement and Public Health'. In Correa C.M and Yusuf A.A (Eds), *Intellectual Property and International Trade: The TRIPS Agreement* (2nd Edition, Kluwer Law International, The Netherlands 2008) 227, 229 (maintains that compulsory licensing is crucial 'both for improving access to essential medicines as well as facilitating the development of innovative capacities and R&D, especially in developing countries'.); However, some contributors have argued that the use of compulsory licensing will impede the development of new technologies, particularly in the field of biotechnology. - Biotechnology Innovation Organisation, 'BIO Strongly Opposes Compulsory Licensing Legislation'. <https://www.bio.org/media/press-release/bio-strongly-opposes-compulsory-licensing-legislation> accessed 30 January 2024; Sumikura, K. 'Intellectual Property Rights Policy for Gene-Related Inventions: Toward Optimum Balance between Public and Private Ownership'. In Castle D. (eds.) *The Role of Intellectual Property Rights in Biotechnology Innovation* (Edward Elgar Publishing, Cheltenham, 2009) 83. (asserting that the frequent application of compulsory licensing rights could discourage efforts to develop new drugs and diagnostic methods').

specific public interest by enhancing access.[11] The substantive legal instrument on patenting in Nigeria, which is the Patents and Designs Act, 1970, and the TRIPS Agreement set out the preconditions for the use of a patented invention without the consent of the right holder.[12] Generally, compulsory licences are granted on a non-exclusive basis and require payment of adequate remuneration to the right holder.[13] Sometimes, the government may use the threat of compulsory licensing to improve local production or to achieve price reduction, particularly from right holders who may find the discounted price more rewarding than the royalty on compulsory licensing.[14]

The principle of compulsory licensing forms an important part of the discourse on biotechnology protection, especially in relation to patents. In this vein, it is important to state that the TRIPS Agreement, 1994 (as amended) in Article 31, sets out more elaborate conditions limiting the use of compulsory licensing under the patent law as compared to other forms of intellectual property rights. For instance, in light of Article 31(b) of the TRIPS Agreement, 1994 (as amended), compulsory licensing may only be invoked after the proposed user must have made attempts to obtain a voluntary license from the patentee on reasonable commercial terms and conditions, and such attempts have not been successful within a reasonable period of time.[15] While this condition may be waived in cases of national emergency or extreme urgency or cases of public non-commercial use, Article 31(f) of the TRIPS Agreement, 1994 (as amended) further limits the grant of compulsory licensing to mainly domestic use. As a result, many developing countries expressed concerns that the conditions in Article 31 of the

[11] Section 11 and first Schedule to the Nigerian Patents and Designs Act 1970, and Article 31 of the TRIPS Agreement 1994 (as amended).

[12] Ibid.

[13] Paragraphs 6(c) and 8 of the First Schedule to the Patent and Designs Act 1970 and Article 31(d) and (h) of the TRIPS Agreement, 1994 (as amended).

[14] Reportedly, the governments of Brazil, United States, and some African countries have used this strategy to achieve price reduction or encourage local production of patented health technologies. United Nations Secretary-General and Co-Chairs of the High-Level Panel, 'Promoting Innovation and Access to Health Technologies', p.23.

[15] Under the Nigerian patent law, the use of patented inventions by the government need not be preceded by any attempt to secure a voluntary licence - paragraph 20 of Part II, First Schedule, the Nigerian Patents and Designs Act 1970.

TRIPS Agreement, 1994 (as amended) pose significant challenge to the attainment of improved public health and food security due to their low technology manufacturing capacity.[16]

Given the devastating health conditions in developing countries and practical problems of technology manufacturing capacity, particularly in the biomedical industry, the Doha Declaration on the TRIPS Agreement and Public Health of 2001 clarifies that member countries of the World Trade Organisation are free to determine grounds upon which to grant compulsory licenses other than in emergency situations. In the same vein, members have the right to determine what circumstances may constitute national emergency or extreme condition.[17] Even more significantly, in light of paragraph 6 of the Doha Declaration, 2001, the members reached a further decision in 2003 to waive the provisions of Article 31(f).[18] This is in order to promote access to health technologies by permitting member countries to produce drugs under a compulsory licence for the purpose of exporting to countries facing public health problems but lacking manufacturing capacity in the pharmaceutical sector.[19] The waiver was in 2005 transformed into a Protocol amending the TRIPS Agreement by inserting Article 31*bis* after Article 31 of the TRIPS Agreement.[20] With the Protocol entering into force on 23 January

[16] United Nations Secretary-General and Co-Chairs of the High-Level Panel, 'Promoting Innovation and Access to Health Technologies', p.23.

[17] Paragraph 5(b-c), the Doha Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) 2001 <https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_TRIPS_e.htm> accessed on 30 January 2024.

[18] Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Decision of the General Council, WT/L/540 and Corr.1, 2003) <https://www.wto.org/english/tratop_e/TRIPS_e/implem_para6_e.htm> accessed on 30 January 2024 (also described as Paragraph 6 Decision - United Nations Secretary-General and Co-Chairs of the High-Level Panel. 'Promoting Innovation and Access to Health Technologies', p.233).; The World Trade Organisation (WTO), 'TRIPS: Factsheet - Amendment to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)' <https://www.wto.org/english/tratop_e/TRIPS_e/TRIPSfacsheet_e.htm#:~:text=An%20amendment%20to%20the%20WTO's,force%20on%2023%20January%202017.&text=The%20amendment%20was%20formally%20built,since%20the%20Organisation%20was%20created.> accessed on 30 January 2024.

[19] Ibid.

[20] Amendment of the TRIPS Agreement (Decision of the General Council, 6 December 2005) <https://www.wto.org/english/tratop_e/TRIPS_e/wtl641_e.htm> accessed on 30 January 2024.

2017,[21] the new Article 31*bis* of the amended TRIPS Agreement gives full and permanent legal effect to the special compulsory licensing system proposed in the Paragraph 6 Decision of 2003.[22]

While the Doha Declaration and amendment to the TRIPS Agreement create some form of legal certainty regarding the use of compulsory licensing in addressing public health challenges in least developed and developing countries, it remains unclear to what extent it can be invoked in the aspect of agricultural biotechnology. Notwithstanding, it is important to state that food security concerns such as hunger and starvation can also constitute a valid ground for the issuance of compulsory license.[23] But its usefulness may be called into question given that similar challenge besetting the biomedical field particularly in terms of insufficient or low manufacturing capacity also ploughs the agricultural biotechnology industries in developing countries including Nigeria. Should food security considerations not get the same attention as health pursuant to the recent TRIPS amendment?

Biotechnology inventions such as genetically modified foods have the potential to combat certain food security concerns including famine and plant diseases by genetically improving seeds. However, due to production time, the use of compulsory licensing to provide fast reliefs in circumstances of emergency or extreme urgency may be questionable. In other words, giving the duration from sowing and harvesting a food crop, compulsory licensing may not serve a lifesaving purpose.[24] It is instructive to note that lack of food may also constitute many severe

[21] World Trade Organisation (WTO). 'WTO IP Rules Amended to Ease Poor Countries' Access to Affordable Medicines'. (News, 23 January 2017) <https://www.wto.org/english/tratop_e/TRIPS_e/implem_para6_e.htm> accessed on 30 January 2024.

[22] Article 31bis(1) of the TRIPS Agreement, 1994 (as amended) provides thus: 'The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s)….'; See also the annex to the TRIPS Agreement, 1994 (as amended).

[23] World Trade Organisation (WTO), 'TRIPS: Factsheet - Amendment to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)', states that 'while there has been particular attention to use of compulsory licensing for pharmaceuticals, it can also apply to patents in any field'.; Also, paragraph 20 of the First Schedule to the Nigerian Patent and Designs Act 1970 identifies the promotion of agriculture, among other purposes for which the government may use compulsory licensing, particularly in times of emergency.

[24] Agering I, 'Why Compulsory Licensing of Genetically Modified Food will not be a Possible Way of Fighting World Hunger' (2007) 31

health conditions if not immediately addressed. These may in turn require the invocation of compulsory licensing for drugs.

2.2 Research and Experimental Use Exemption

The research and experimental use exemption also allows the use of a subject matter of intellectual property right for research or experimental purposes during the term of protection without the consent of the right holder.[25] In practice, this legal doctrine forms the basis upon which patented inventions are not only used in further research but also in experiments for purposes of obtaining regulatory approval for generic products before a patent expires.[26] The regulatory exception is also known as the 'early working' or 'Bolar' exemption' within the patent system.[27] While there is no express provision with regard to the research and experimental use exemption in the Nigerian Patents and Designs Act, 1970, the very general wording of Article 30 of the TRIPS Agreement, 1994 (as amended), provides legal backing for the exception to patent.[28]

However, the scope and limits of application remains generally unclear especially in terms of the early working of patented inventions by generic producers. This is because the application of the Bolar exception has historically been commonly associated with the pharmaceutical industry. In this regard, it is worth noting that developing countries such as India, Brazil and South Africa have in recent times called for a technology-neutral or a general non-industry specific approach to the use of the Bolar exception. This, in particular, is due to the link between

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<http://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.993.87&rep=rep1&type=pdf> accessed on 30 January 2024.

[25] World Health Organisation (WHO), World Intellectual Property Organisation (WIPO) and World Trade Organisation (WTO), *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade* (2nd Edition, World Health Organisation (WHO), World Intellectual Property Organisation (WIPO) and World Trade Organisation (WTO), Geneva, Switzerland 2020) 234.

[26] Ibid.; W Cornish, D Llewelyn and T Aplin, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights* (5th Ed., Sweet & Maxwell, London 2003) 255.

[27] Bolar exception is a term derived from the United States' case of *Roche Products Inc. v Bolar Pharmaceuticals Co* (1984) 733 F. 2d 858 (Fed Cir).

[28] CM Correa, 'Patent Rights'. In Correa C.M and Yusuf A.A (Eds), *Intellectual Property and International Trade: The TRIPS Agreement* (2nd Edition, Kluwer Law International, The Netherlands 2008) 227, 244; The World Trade Organisation case of Canada — Patent Protection of Pharmaceutical Products WT/DS114/R (2000) <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm> accessed on 30 January 2024.

Bolar exceptions and compulsory licensing, as it is believed that early working of patented inventions by generic producers improves a country's ability to effectively utilize compulsory license provisions.[29]

Overall, in facilitating access to and use of patented inventions, the research and experimental use exemption has the potential to speed up the scientific research and technological development processes, as well as access to both new and generic products in the aspects of biomedical and agricultural biotechnology. This is of particular importance to the advancement of food security and public health in Nigeria and other developing countries.

2.3 The Exhaustion Doctrine

The exhaustion doctrine presupposes that a right holder cannot exercise legal control over the further distribution or resale of protected products after consenting to the first sale or entry into the market.[30] This doctrine also known as 'first sale doctrine' provides the basis for parallel importation which in relation to this study means a third party can without the consent of the right holder import or buy a subject matter of intellectual property protection from another country or market where the right holder or licensee must have sold the product, taking advantage of price difference. It is significant to note that parallel importation relates to genuine and not counterfeit products, in that the relevant products are first put on the market by the right holder or his licensee.[31] As a result, the right holder must have had the opportunity to

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[29] Statements Contained in Council for Trade-Related Aspects of Intellectual Property Rights - Minutes of meeting - Held in the Centre William Rappard on 21 September 2020. – Addendum. 46-53 <https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?DataSource=Cat&Query=%40MeetingId%3d150028&Language=English&Context=ScriptedSearches&languageUIChanged=true#> accessed on 30 January 2024.

[30] World Health Organisation (WHO), World Intellectual Property Organisation (WIPO) and World Trade Organisation (WTO), *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade*, p.246; SF Musungu, 'The TRIPS Agreement and Public Health'. In Correa C.M and Yusuf A.A (Eds), *Intellectual Property and International Trade: The TRIPS Agreement,* p.428

[31] World Health Organisation (WHO), World Intellectual Property Organisation (WIPO) and World Trade Organisation (WTO), *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade*, pp.181-182; SF Musungu and C Oh, 'The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?' (A Study Commissioned by the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH), 2005) 30. <http://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf> accessed on 30 January 2024.

receive payments on first sale. While opponents of parallel importation often suggest that it will result in the inflow of counterfeits, it is difficult to identify the link between the two (parallel imports and counterfeit), especially as counterfeits are not legitimate and a question of market surveillance.[32]

Article 6 of the TRIPS Agreement affirms the legality of the exhaustion of intellectual property rights generally, with member countries being entirely free to define their domestic regime for exhaustion of rights without any challenge, subject only to the non-discriminatory principles of national treatment and most-favoured-nation treatment.[33] In this regard, a country can opt for an international, regional or national exhaustion regime. Under the international exhaustion regime, parallel importation is permissible from anywhere in the world.[34] In other words, the right to further distribution or resale is considered to have been 'internationally' extinguished once the product legitimately enters the market in any country.[35]

As for regional exhaustion regime, it means the right with regard to the relevant product is exhausted only within a particular region or regional market. Hence, the right holder can in this situation prevent the parallel importation of the product from outside the specific region within which the country employing regional exhaustion regime falls.[36] Where it is the national

[32] SF Musungu and C Oh, 'The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?', p.30 (pointing out with particular regard to medicine that 'the issue of counterfeits, which relates to market surveillance is applicable whether products are locally produced or imported, and whether they are branded or generic. With or without parallel imports, substandard and counterfeit drugs may get into the market so long as the system of market surveillance is weak').

[33] This was reaffirmed from the public health perspective by paragraph 5(d) of the Doha Declaration on the TRIPS Agreement and Public Health 2001; World Health Organisation (WHO), World Intellectual Property Organisation (WIPO) and World Trade Organisation (WTO). *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade*, pp.247 – 248, provides further discussions on international, regional and national doctrine of exhaustion.

[34] Ibid.; Q Nguyen Nhu, 'Parallel Trade of Patented Pharmaceuticals: A Discussion from Developing Country Perspective' (2011) 4 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1767823> accessed on 30 January 2024.

[35] Ibid.

[36] Ibid.; European Commission, 'Notice to Stakeholders: Withdrawal of the United Kingdom and EU Rules in the Field of Exhaustion of Intellectual Property Rights' (Brussels, 25 June 2020) 3. <https://ec.europa.eu/info/sites/info/files/brexit_files/info_site/exhaustion-ip-rights_en.pdf> accessed on 30 January 2024; Article 5 of the ECOWAS Competition Rule of 2008.

exhaustion regime that is adopted by a country, the right of the holder is exhausted only with regard to products that have legitimately entered the domestic market.[37] This in effect prohibits parallel importation.

In general, while protecting the interest of right holders by ensuring that they receive remuneration for their intellectual efforts, the exhaustion regimes, to varying degrees, promote the free movement of patented inventions. This has significant implications as regards the ability of developing countries to access patented biotechnological inventions that could be relevant to the issues of public health and food security. Thus, a critical question for developing countries such as Nigeria is, what exhaustion regime should be adopted? In this regard, many scholars hold the view that the international exhaustion regime facilitates greater access to low-priced products, particularly pharmaceuticals and food, making it the best option for developing countries.[38] It is believed that besides the increase in distribution and availability of products through parallel imports, right holders are forced to lower the prices of their own products in competition with parallel importers who are able to buy the products from low-price markets and resell at prices lower than what the right holders are offering in a particular country.[39] Similarly, as in the case of compulsory licensing, it is also suggested that 'sometimes just the threat to undergo parallel imports suffices to persuade right owners to lower prices'.[40]

However, it is argued, particularly by pharmaceutical companies, that parallel importation 'denies them adequate protection of their patent rights and prevents them from recouping the costs of pharmaceutical development'.[41] In this regard it may be safe to argue that, having received payment for the first sale, a right holder should not be heard complaining about

[37] Ibid.

[38] E Bonadio, 'Parallel Imports in a Global Market: Should a Generalised International Exhaustion be the Next Step?' (2011) *European Intellectual Property Review*, 33(3), 153, 155.; Also, Q Nguyen Nhu, 'Parallel Trade of Patented Pharmaceuticals: A Discussion from Developing Country Perspective', p.7, asserts that 'an international regime of exhaustion seems to be a better fit for developing countries'; the UK Commission on Intellectual Property Rights report recommending the adoption of an international exhaustion regime by developing countries and Least Developing Countries particularly to facilitate access to medicines.- UK Commission on Intellectual Property Rights, 'Integrating Intellectual Property Rights and Development Policy', 119, 122.

[39] E Bonadio, 'Parallel Imports in a Global Market: Should a Generalised International Exhaustion be the Next Step?', p.155.

[40] Ibid.

[41] Q Nguyen Nhu, 'Parallel Trade of Patented Pharmaceuticals: A Discussion from Developing Country Perspective', p.1.

recoupment of costs. Yet, the promotion of international exhaustion regime among developing countries raises the question whether lower-priced products can indeed be found on the markets of developed countries. This in light of the suggestions by multinational companies that, compared to developed countries, products on the markets of developing countries are low-priced, and thereby questioning the appropriateness of the international exhaustion regime for developing countries. Also, it is argued that parallel importation may discourage differential or preferential pricing of protected products on the basis that lower-priced products for developing countries could enter higher-priced markets of developed countries. Thus, it is believed that the fear of parallel importation of low-priced products into developed countries could lead private companies to desist from supplying low-priced products or ensure to eliminate differential prices by increasing the prices in developing countries.[42]

In light of the above circumstance, it would seem more rational for developing countries to consider adopting national exhaustion regime rather than international exhaustion regime. This is because it is believed that the national exhaustion regime would serve as an incentive for right holders as they would be entitled to restrict parallel imports.[43] But, the foregoing arguments can be countered by the fact that most developed countries have specific rules in place prohibiting the importation of differentially-priced products, particularly as they relate to pharmaceuticals.[44] In their study of prices of pharmaceuticals in developing countries, Schweitzer and Comanor considered whether parallel imports could be seen as a barrier to differential pricing.[45] They concluded that parallel importation 'is not a major threat to either manufacturers' revenue or to price discounts. Not only is the evidence of such effects weak, but various mechanisms are available to governments and manufacturers alike to ensure that drugs can be sold at lower prices in less-developed countries'.[46]

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[42] SF Musungu and C Oh, 'The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines?' p.30.

[43] Ibid.

[44] Ibid.; The United Kingdom Commission on Intellectual Property Rights. 'Integrating Intellectual Property Rights and Development Policy', p.41 (it is pointed out that the United States and the European Union already have in place mechanisms preventing parallel importation. It, however, noted that developing countries must also act to prevent the exportation of products under differential pricing schemes).

[45] SO Schweitzer, and WS Comanor, 'Prices of Pharmaceuticals in Poor Countries are Much Lower Than in Wealthy Countries' (2011) 30(8) *Health Affairs*, 1553-1561.

[46] Ibid, p.1559.

Importantly, it could further be argued that the exhaustion doctrine, especially in relation to public health and food security, is not always a question of price only. A right holder may not be able to satisfy the public needs of a country in terms of production and distribution of the subject matter of intellectual property rights protection. In this case, a country adopting a national exhaustion regime will be foreclosed from relying on parallel importation to get the relevant products from any available market. While the regional exhaustion regime may provide greater flexibility compared to the national exhaustion regime, it may not be of significant benefits for developing countries in relation to the challenges of public health and food security. Particularly, in the case of Africa and the African regional blocs such as the Economic Community of West African States (ECOWAS), there appears to be common problems especially, in terms of the countries' poor technological and manufacturing capacities. Thus, it is questionable whether there would be significant variances in product distribution and prices among the (regional) markets, the key drivers of parallel import.

Within the Nigerian context, the wording of section 6(3)(b) of the Nigerian Patents and Designs Act, 1970, seems to suggest a national exhaustion regime by providing that a patent right 'shall not extend to acts done in respect of a product covered by the patent after the product has been lawfully sold in Nigeria….'[47] This contravenes Article 5 of the ECOWAS Competition Rule of 2008, which prohibits any form of restrictive trade or business activities among member states and, in effect, establishes a regional exhaustion regime at the minimum. In 2018, the Nigerian government enacted the Nigerian Federal Competition and Consumer Protection Act. Section 59(2) of the Nigerian Federal Competition and Consumer Protection Act, 2018, which is *impari material* with Article 5 of the ECOWAS Competition Rule, 2008, among other things, considered unlawful, any act or agreement that divides existing 'markets by allocating customers, suppliers, territories or specific types of goods or services'. In addition, the Nigerian Federal Competition and Consumer Protection Act 2018 contains other elaborate provisions, the overall purpose of which is to encourage competition in 'any market'. Significantly, sections 63 and 64 of the said Act prohibit agreements that seek to establish minimum prices

[47] In contrast see section 11(4) (a) of the Ghanaian Patent Act, 2003 (Act 657) (as amended) <http://www.wipo.int/wipolex/en/text.jsp?file_id=223078#LinkTarget_507> accessed on 30 January 2024; Section 43(1)(a) of the Namibian Industrial Property Act, 2012 (Act No. 1 of 2012) <http://www.wipo.int/wipolex/en/text.jsp?file_id=482098> accessed on 30 January 2024.

for the resale of goods and services in Nigeria, including patented goods and goods made by patented processes.

It is important to bear in mind that while the Nigerian Federal Competition and Consumer Protection Act, 2018, *prima facie* suggests the adoption of an international exhaustion regime in Nigeria, section 167(12) of the Act offers quite a restrictive definition of 'market'. It provides that every reference to the term 'market' in the Act 'is a reference to a relevant market in Nigeria for goods or services'. Such a restrictive definition is clearly incompatible with Nigeria's obligations under the ECOWAS Competition Rule, 2008, notwithstanding the similarity between section 59(2) of the Nigerian competition law and Article 5 of the ECOWAS competition rule. To reconcile this issue, the Nigerian government would need to clearly define the exhaustion regime it is adopting, preferably an international regime, taking into cognisance the obligations of Article 5 of the ECOWAS Competition Rule, 2008. Furthermore, the inconsistencies between the competition law and the Nigerian patent law also call forth the need for amendments explicitly establishing the international exhaustion principle in Nigeria.

3.0 LIMITATIONS OF THE PATENT FLEXIBILITIES

As reflected earlier, the low technological capacity of developing countries such as Nigeria continues to impede the effective use of the TRIPS flexibilities. Also, there appears to be a general lack of political will among developing countries like Nigeria toward adopting and enforcing the flexibilities available within the TRIPS Agreement in their domestic laws and to advance national interests. In addition, exceptions and limitations such as compulsory licensing do not necessarily guarantee that biotechnology would be available at a much lower price than that of the right holder.[48] With particular regard to the application of the legal doctrines of compulsory licensing and Bolar exception, there is a high chance that the patent specification submitted for the grant of a patent over a biotechnological invention does not disclose sufficient and enabling information about a patented invention.

Similarly, the research exemption is also of limited value in that the commercialisation or entry to the market of any resulting technology would still require the authorisation of multiple patent

[48] G Dutfield, *Literature Survey on Intellectual Property Rights and Sustainable Human Development* (UNCTAD, 2003).

owners whose patents cover the underlying inventions used to create a new one.[49] The problems associated with license negotiation, including the monopolistic attitude of right holders and huge transaction costs, especially where multiple right owners are involved, as is often the case in the field of biotechnology, are well known.[50] Evergreening, a phenomenon whereby patent holders extend the period of market exclusivity of their patented inventions and delay the entrance of generic or competing products through the filing of multiple and often successive patent applications on minor and insignificant improvements,[51] also renders the research and experimentation exemptions ineffective.

The above situations are exacerbated by the proliferation of bilateral and regional free trade agreements (FTAs) between developed countries such as the United States and Japan on the one hand and developing countries on the other. These FTAs often include 'TRIPS-plus' provisions imposing more stringent regimes on patent and other intellectual property rights while restricting governments' use of flexibilities.[52] Besides, there is evidence suggesting the use of political and economic pressure or threats of retaliation by some developed countries and Multinational Corporations (MNCs) to deter developing countries from employing any of the TRIPS flexibilities and exceptions discussed above.[53] This is exemplified by the 1999 case of *PMA v. The President of the Republic of South Africa,* involving a consortium of multinational pharmaceutical companies who sought to block amendments to the South African Medicines Act in 1997 that would expand access to medicines in South Africa through the use of TRIPS flexibilities. The Office of the United States Trade Representative also placed South Africa on its section 301 'Watch List', strongly pushing for a repeal of the law. The legislative amendment also led to a suspension of South Africa's duty-free treatment under the United

[49] VV Kumari, RK Sastry, MS Chandrana and TK Srivastava, 'Managing Intellectual Property in Collaborative Way to Meet the Agricultural Challenges in India' (2017) 22(2) *Journal of Intellectual Property Rights*, 55, 58. <http://docs.manupatra.in/newsline/articles/Upload/0CF368BB-B0A6-4E7A-A2E7-B54C6CE1BCA2.pdf> accessed on 30 January 2024; Section 2(3) of the Nigerian Patents and Designs Act, 1970.

[50] Ibid.

[51] United Nations Secretary-General and Co-Chairs of the High-Level Panel, 'Promoting Innovation and Access to Health Technologies', p.5.; World Intellectual Property Organisation. 'Patent Landscape Report on Ritonavir' (suggesting the existence of evergreening practices with regard to the Ritonavir drug).

[52] UN Secretary-General and Co-Chairs of the High-Level Panel, 'United Nations Secretary-General's High-Level Panel on Access to Medicines Report: Promoting Innovation and Access to Health Technologies', pp.25-26, provides examples of TRIPS-plus provisions.

[53] Ibid.

States Generalized System of Preferences program in 1998. Reportedly, this case was, in fact, one of the key factors that brought about the global dialogue on the potentially negative impact of intellectual property rights on public health, which climaxed in the adoption of the Doha Declaration on TRIPS and Public Health in 2001.[54]

Significantly, mindful of the race by developed countries to secure medical products including doses of COVID-19 vaccines for their populations even before the completion of clinical trials, during the pandemic, developing countries raised questions as regards the adequacies of TRIPS flexibilities, in terms of timely access and affordability.[55] Of particular concern are the provisions of Article 31*bis* of the TRIPS Agreement, 1994 (as amended). As explained above, the said Article 31*bis* was introduced in 2017 to address the continuing public health challenges of developing and least-developed countries linked to their inability to use the TRIPS flexibilities due to insufficient or lack of manufacturing capacity. While a member country of the World Trade Organisation could use the compulsory licensing system to produce pharmaceuticals for another member that has insufficient or lacks manufacturing capacity, there are various terms which must be complied with.[56] These include the need for the 'eligible importing member' to make prior notification to the Council for TRIPS, proof that the member lacks or does not have sufficient manufacturing capacity and specification of the names and expected quantities of the pharmaceutical product(s) in question, among others. For a pandemic

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[54] South African Statement on Intellectual Property and the Public Interest: Regulatory Review Exception (Contained in Council for Trade-Related Aspects of Intellectual Property Rights - Minutes of meeting - Held in the Centre William Rappard on 27 February 2018 – Addendum) 48 <https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?DataSource=Cat&Query=%40MeetingId%3d150028&Language=English&Context=ScriptedSearches&languageUIChanged=true#> accessed on 21 January; The Problem Statement to South Africa Proposed Draft Intellectual Property Policy of the Republic of South Africa Phase I 2017 (South Africa Department of Trade and Industry Notice 636 of 2017) (Government Gazette, No. 41064, 25 August 2017) 321 <http://www.gpwonline.co.za/Gazettes/Gazettes/**41064**_25-8_NationalGovernment.pdf> accessed on 30 January 2024; For other case examples see UN Secretary-General and Co-Chairs of the High-Level Panel. 'United Nations Secretary-General's High-Level Panel on Access to Medicines Report: Promoting Innovation and Access to Health Technologies', pp.24-25.

[55] 'Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19'. (IP/C/W/669, Being Joint Communication from India and South Africa to the Council for Trade-Related Aspects of Intellectual Property Rights, 2 October 2020) <http://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=Q:/IP/C/W669.pdf> accessed on 13 February 2024; E 't Hoen, 'Remdesivir Developed Country Price Announced'.

[56] Article 31*bis* and the annex to the TRIPS Agreement, 1994 (as amended).

such as COVID-19 requiring timely access to affordable pharmaceuticals, it is believed that all the terms are in themselves barriers, making the process for the importation and exportation of pharmaceuticals available and being developed for COVID-19 cumbersome and lengthy. Consequently, developing countries such as India and South Africa called for a temporal waiver of the TRIPS standards on patents and copyrights, among others, in relation to the prevention, containment or treatment of COVID-19.

Beyond COVID-19, which, as agreed generally, is a global pandemic, it is important to reiterate that the TRIPS flexibilities do not address one of the significant challenges fuelling the innovation and access gaps, particularly in the field of biotechnology. This is due to the failure of the existing globalised intellectual property standards to incentivise research and innovation that would address the specific health and food security needs of developing countries such as Nigeria.[57] As discussed in some literature, the patent system mainly fosters market or profit-driven research and innovation.[58] Given their low purchasing power, products and processes relevant to challenges affecting mainly developing countries such as Nigeria are rarely researched.[59]

4.0 OPTIONS FOR BIOTECHNOLOGY RESEARCH AND INNOVATION

Due to the inadequacy of patent flexibilities, the government and actors in the biotechnology industry must explore alternative research models and innovations to promote the sharing and disclosure of research results while engendering collaboration. Some of the options available in this regard are patent pooling, clearinghouses, and the emerging concept of open science, which is eliciting a growing interest among pharmaceutical companies, government and international organisations such as the United Nations Educational, Scientific and Cultural

[57] From the public health perspective, it is particularly pointed out that 'compulsory licenses alone do not present an answer to the issue of access to medicine in developing countries because they cannot be effective in addressing those neglected diseases such as HIV/AIDS, malaria and tuberculosis and for which the main problem is still lack of adequate incentive to produce effective drugs'. - E Ferrara, 'Access to Medicine: Patent, Price Regulation and Prizes' (2013) ILSP L. J., 14, 16.

[58] United Nations Secretary-General and Co-Chairs of the High-Level Panel, 'Promoting Innovation and Access to Health Technologies', pp.7 – 8; World Health Organisation (WHO), World Intellectual Property Organisation (WIPO) and World Trade Organisation (WTO), *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade*, pp.151 – 153.

[59] Ibid.

Organization (UNESCO). A patent pool is defined as 'an agreement between at least two patent owners to group their patent rights relating to a specific technology and to license the rights to use these patents to each other and to third parties, subject to certain conditions such as the payment of royalties'.[60] Clearinghouses, on the other hand, are mechanisms whereby owners and users of goods, services and information are matched through networks or institutions that facilitate the exchange of information and technical and scientific cooperation.[61] Meanwhile, open science is a concept increasingly being used to reflect the convergence of the diverse open and collaborative practices in science, including open source, open access and open data. It aims to make 'scientific knowledge openly available, accessible and reusable for everyone, to increase scientific collaborations and sharing of information for the benefits of science and society, and to open the processes of scientific knowledge creation….'[62]

The foregoing mechanisms have the potential to foster research and facilitate access to relevant innovations in the field of biotechnology. Their applicability to biotechnology research and development in Nigeria requires an in-depth investigation which the pages of this paper do not permit.

5.0 CONCLUSION

The impact of patent standards on biotechnology research and innovation in developing countries such as Nigeria, particularly in relation to food security and public health, remains a sensitive issue that continues to generate debates in international forums such as the World Trade Organisation. While the adoption of patent flexibilities is advocated to counterbalance the inherent defects with the application of the patent regime to biotechnology research and innovation, this paper shows that their implementation in Nigeria and other developing countries is not tenable due to lack of political will, fear of trade retaliation and low technological capacity, among others. This calls for the exploration of alternative approaches

[60] World Health Organization (WHO), World Intellectual Property Organization (WIPO) and World Trade Organization (WTO). *Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade*, p.118.

[61] van Zimmeren E, et al. "Patent pools and clearinghouses in the life sciences." *Trends in biotechnology* vol. 29,11 (2011): 569-76.

[62] United Nations Educational, Scientific and Cultural Organization (UNESCO) Recommendation on Open Science, 2021. <https://unesdoc.unesco.org/ark:/48223/pf0000379949> accessed 20 Jun 2023.

to research and innovation in biotechnology, such as open science, in order to facilitate need-driven research and access to innovation in biotechnology in Nigeria.