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Intellectual Property Rights, Pharmaceutical Patents and Public Health: Adopting Compulsory and Government Use Licences in COVID-19 Emergency

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INTRODUCTION

As the season of the new coronavirus (COVID-19) pandemic unfolds, policy makers and leaders have continued to grapple with one of the world's most recent public health challenges. Within weeks of the outbreak in Wuhan, China, the sheer human and material cost in many countries in terms of the rate of transmission and attended death has been overwhelming.[1] As at 15 April 2020, the World Health Organisation (WHO) has reported a total of 1,914,916 confirmed cases and 123,010 deaths worldwide, with rising numbers, defying attempts to flatten the curve.[2] By all means, the pandemic has exacted enormous pressure on public health policies and systems, raising far-reaching political, economic, social and technological questions and uncertainties on global welfare and prospects of cure.[3] If COVID-19 impact has been most severe in most of the best of health care systems, one can only imagine the impact on countries which has been paying lip service to the health sector. At the core of these questions is the issue of intellectual property rights (IPRs) arising from emerging medical and technological innovations that would attend to finding the much-needed curative vaccines, drugs and diagnostics that would finally stem the tide. This would largely shape the rapidly evolving COVID-19 era. If there was ever another moment to affirm the agelong precept that 'invention is the mother of necessity', it is now!

United in the commitment to the containment of the virus, the trend has been for many small and big corporate enterprises and brand owners to convert their production lines into making critical items such as hydroalcoholic gels, face masks gloves and other items for health workers and patients and donated same in order to address shortages that had arisen from the outbreak. Clearly, this concerted effort, joined by private individual donations, has largely

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[1] See Johns Hopkins Mortality Analyses, https://coronavirus.jhu.edu/data/mortality See also NCDC Updates at https://ncdc.gov.ng/diseases/sitreps/?cat=14&name=An%20update%20of%20COVID-19%20outbreak%20in%20Nigeria

[2] See WHO Situation Report-86 dated 15 April 2020 accessed at www.who.int/docs/default-source/coronaviruse/situation/reports/20200415-sitrep-86-covid-19pdf accessed on 15 April 2020

[3] See the IMF Policy Tracker which summarizes the key economic responses governments are taking to limit the human and economic impact of the COVID-19 pandemic. The tracker includes 193 economies at https://www.imf.org/en/Topics/imf-and-covid19/Policy-Responses-to-COVID-19

facilitated established preventive protocols.[4] In our local environment, social media has been awash with displays of innovation in locally fabricated machines and equipment in varying designs and functional utility, including home-based herbal therapies and combinations, all targeted at COVID-19 prevention, treatment and management. Some of these products could be subject of trademark and other IPRs but this is not the focus of this discourse. The ultimate global innovative test is in the cure that only vaccines, protected by patents, would deliver on the global market. As the crucial question, it has significant implications on the ability of the global public health care systems to fulfil one of its most critical objectives of delivering medicines accessible to the population especially in the developing and sub-Saharan countries like Nigeria with underdeveloped health care and innovation ecosystems. How best can public expectation be achieved; expectation to safeguard public health and ensure adequate access to affordable medicines during and after emergencies? How can the demands of IPRs meet the challenging public health emergencies such as presented by COVID-19 pandemic? This short article briefly discusses the need to integrate IPRs policies the promotion of public health particularly relating to access to pharmaceutical patents through the adoption of the important compulsory licences instrument for COVID-19 related health care. The socio-economic importance of this instrument available under patent law and practice provides the rationale for considering them at this time.

INTEGRATING IPRs POLICIES IN COVID-19 - RELATED HEALTH CARE

Perhaps, more than anything else in global history, public health emergencies have confronted the integrity of patent system. As we have witnessed so far, this time, it is COVID-19 and the race for vaccines to save the world. While it would appear that IP lawyers and policy makers across jurisdictions are familiar with the protracted narratives between IPRs, in particular pharmaceutical patents and public health in the context of access to affordable medicines in health emergencies particularly brought about by the HIV/AIDS pandemic in the 80s and 90s,[5] COVID-19 pandemic realities pervade every sector of the global population with a suspicious gaze at the nuances of a much trodden IPR-public health debate. In the annals of pandemics, COVID-19 reminds the global community of the unfinished IPR-public health imperatives that any emergent COVID-19 related patents and technologies should resolve without delay. Medical experts would instruct that in the world of infectious disease and with all the epidemics which have confronted man, the state-of-the-art vaccines have been the dominant model. COVID-19, regardless of its origin and the conspiracy theories surrounding it, is not an exception. With the global race for the COVID-19 vaccines among the big pharmaceuticals, patent and health policies must align to adequately regulate the scope of rights and obligations that would govern patent protection for and use of the vaccines.

Essentially, patents afford the privilege of incentivising new innovation for the benefit of society. That goal is achieved through the grant of monopoly for a limited period in order to

[4] Due to insufficient understanding of the full nature of the new coronavirus, some of the well- known measures adopted across many countries include testing, tracing, social distancing, isolation & quarantine and in many cases lockdowns. See WHO Interim Recommendation of 1 April 2020 on regular soap hand washing, sanitizing at file:///C:/Users/PC/Downloads/who-interim-recommendation-on-obligatory-hand-hygiene-against-transmission-of-covid-19.pdf.

[5] See IPRs, Public Health and Pharmaceutical Industry: Issues in the Post-2005 TRIPs Agenda in *Intellectual Property Rights, Legal and Economic Challenges for Development*, Edited by Mario Cimoli, Giovanni Dosi, Keith Maskus, Ruth L Okediji, Jerome H Reichman & Joseph S Stiglitz, Oxford Press, 2014, 219-241.

sustain the engine of innovation that should drive development. This underlining essence of patent is coterminous to public health objectives but involves a complex dynamic of IP as an innovation policy that is not antithetical to the promotion of public interest, including public health. Patents, including pharmaceutical patents, are granted in Nigeria under the Patents and Designs Act (PDA) provided they are new, involve an inventive activity and capable of industrial application as the basic substantive requirements under most patent law.[6] While pharmaceutical and biotech companies as the vital parts of health care ecosystem, have traditionally produced drugs for protecting human health, they are commercial entities which utilise the patent rights they hold as the incentive which allows them to make profit on their research and development (R & D) investment and to maintain the cycle of innovation.[7] The concern has been in maintaining the right balance between the imperatives of private and public interests inherent in the whole enterprise for promoting public health. This concern often comes to the fore in periods of health emergencies like the current COVID-19 experience, which has called for the development of new or existing vaccines under patents that must be paid for one way or the other by the global community.

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) which regulates global trade in IPRs engages two core legal instruments in its functional relevance to public health and facilitates access to essential and affordable medicines, namely compulsory license (CL) and government use. Between the Article 27.1 standard guiding patents including pharmaceuticals and the substantive exception clauses across the agreement, TRIPs arguably maintains a global patent regime or imbalances, as it were, which has always courted controversy in the different sets of circumstances or applications across both the developed and developing countries. TRIPs flexibilities construct and as patent law's exceptions and limitations provide the organic framework to bypass patent exclusive rights in making patented products and processes available without the risk of infringement. Although, TRIPs as 'a minimum standard' agreement has witnessed considerable ambivalence both in its rigidities and flexibilities generally and with respect to its relationship with public health, for example, with the 80s and 90s global outcry over the HIV/AIDS pandemic that necessitated the clarification of the 'Doha Declaration on TRIPs and Public Health' in 2001,[8] the aforementioned instruments have remained the standard legal and policy measures adopted by most patent systems for accessing pharmaceutical patents without the voluntary permission of the patentee. This helps to meet diverse public interests, particularly public health emergencies, among others, which is particularly useful for many developing countries with low or non-existent manufacturing capacity. The range of grounds include emergency or extreme urgency, anti-competitive practices, public non-commercial use and dependent patents to be determined by national laws.[9] With the 'countries' right to determine what constitutes national emergency or circumstance of extreme emergency', application of compulsory licences and government scheme is consistent with TRIPs, taking into account necessary competition and trade considerations such as parallel import.

[6] CAP 344, Laws of the Federation of Nigeria, 2004. See section 1(1).

[7] For discussion of the monopoly of patent rights and Pharmaceutical industry in Nigeria, see Bankole Sodipo, *Piracy and Counterfeiting, GATT, TRIPS and Developing Countries*, Kluwer Law International, 1997, 83-118, 199-201

[8] See the Doha Declaration, 2001, Article 4.

[9] See article 31, TRIPs. See also note 5. For the arguments over whether the ground is limited to emergency or not, see Cynthia M Ho, A New Approach to Compulsory Licence Conundrum, in Patent Law in Global Perspective (Ruth L Okediji & Margo A Bagley, Oxford University Press, 2014, 485-513

Evidently, Nigeria satisfies the condition of a country with low income and low manufacturing capacity generally and in the pharmaceutical industry. Consistent with TRIPs, the Nigerian patent regime makes room for the utilisation of the twin instruments or mechanisms of CL and use of patent for the service of government agencies (government uses), which are essentially non-voluntary licences for the use of patented invention for public purposes. From the standpoint of limitation to patent,[10] both types of licences are the enduring patent instruments for the overall purpose of making patented products and processes available, but for certain defined circumstances, it would ordinarily constitute infringement of patent. More specifically, they facilitate access to drugs that would be unavailable due to lacking manufacturing capacity and the same time expensive. They can therefore be used to engage access to COVID-19 vaccines in Nigeria, when available, to save patients' lives. In the present circumstance, the instruments present important legal and policy options available to health policy makers and practitioners to ensure prompt and adequate supply of COVID-19-related vaccines for the welfare of millions of Nigerians over time.

There are reports of development and clinical trial of potential treatment and vaccines specifically for COVID-19 by top pharmaceutical and research corporations. Prominent are Eli Lilly, which has developed *Barvicitinib* by artificial intelligence (BenevolentAI) with Incyte; *Remdesvir* by Gilead, '*Kaletra'* by Abbvie, *interfero-beta* and *ritonavir/lopinavir*, including the well-known *chloroquine* and *hydrochloroquine*, among others.[11] The World Health Organisation (WHO) has indicated a multi-country 'solidarity' clinical trials of these vaccines in order to develop a global data.[12] There are also reports of countries which have adopted a combination of CL and government use and other extra-ordinary measures ahead of the release of vaccines under their respective patent laws to make the vaccines available for their citizens in the prevailing COVID-19 pandemic and possible shortages in global supply. With patents on these vaccines, although the pharmaceuticals have expressed their intention to waive their patent rights in public interest, the issue of the ability of many of the developing and less developed countries to provide access to the vaccines without government intervention remains a big question. For example, Israel, Germany, France, Chile, Australia, Canada, Ecuador, among others, have invoked their respective patent statutes to authorise appropriate CL and government use licensing regulation and now well positioned to assure access for their COVID-19 patients and citizens ahead of time.[13] In the raging pandemic, these countries, by March 2020, have issued CL and/or government patent

[10] Section 11, First Schedule, PDA

[11] For report of a potential treatment with Baricitinib by Eli Lilly and Incyte using artificial intelligence (BenevolentAI) approaching clinical test, see www.clinicaltrialsarena.com/news/eli-lilly-to-study-baricitinib-for-covid-19-treatment/ accessed 14 April 2020. (According to Daniel Skovonsky, President of Lilly Research Laboratories "Lilly is moving at top speed and using all available resources to help fight this pandemic. Developing potential therapeutic medicines for COVID-19 is part of our vital and humanitarian mission. To be successful, we must combine resources, data and expertise with government, academia and other companies. We look forward to seeing the results of *Banitinib* clinical trials").

[12] See www.sciencemag/news/2020/03/WHO-launches-global-mega-trial-four-most-promising-coronavirus-treatment. Accessed 15April 2020.

[13] See www.iam-media/coronavirus/the-key-COVID19-compulsory-licensing-development-so-far accessed on 13 April 2020.

use instruments to permit supply COVID-19 vaccines during national health emergency.[14] Many more will certainly issue in the course of the pandemic.

CASE FOR COMPULSORY AND GOVERNMENT PATENT USE LICENSING REGULATION

Against this background, it is advised that the Nigerian government, perhaps for the first time in the history of public health emergencies, considers the adoption of these statute-based non-voluntary instruments, in particular, government patent use under the PDA for the supply of COVID-19 vaccines to Nigerians. As at mid-April 2020, Nigerian statistics in terms of the country level epidemic trajectories appear relatively slower compared with other countries but the curve has not flattened. The contagion across borders has awakened countries to the menace of the pandemic requiring swift and effective response by utilizing available pre-emptory and extra-ordinary legal, regulatory and administrative measures for importing or making vaccines once approved available for public use.[15] While the instruments are similar in nature, they may be different in operation and/or applications in different patent systems.[16] For example, while CL is not subject to judicial process in some patent systems, it is in some others like Nigeria. Their suitability in the present circumstance ahead of the supply of COVID-19 vaccines in Nigeria is important. There is however a concern with respect to the use of non-voluntary (compulsory) licensing in Nigeria with low pharmaceutical manufacturing capacity. CL are more effective in countries that can manufacture drugs locally. The Protocol Amending the TRIPS Agreement addresses this problem by allowing countries like Nigeria to issue CL for drugs to be imported from overseas under a TRIPS CL framework. Giving effect to the TRIPS framework may require the incorporation of the TRIPS flexibilities in this regard into the Nigerian national law. This involves a broader discussion of the patent and access to medicines challenge for COVID-19 and the mechanics of this instrument, which is outside the intended scope of this short paper. Suffice to state that, in the convergence between the Nigerian patent and public health policy and regulatory system, government use would be better suited specifically to promote and guarantee access to COVID-19 vaccines. This conclusion is arrived at when the substantive and administrative character of the scheme is considered.

Within the framework of non-voluntary licence, the relevant schedule of the PDA makes provision including the grounds, for CL and use of patent for service of government agencies under separate Parts of the same schedule.[17] They are like, as it were, two sides of the same coin. Under Part 1 of the Schedule, the grounds for CL are that the patented invention being capable of being worked in Nigeria having not been so worked; the existing degree of working of the patented invention in Nigeria does not meet on reasonable terms the demand for the product; working of the patented invention in Nigeria or prevented by importation of the patented article; by reason of the refusal of the patentee to grant licences on reasonable terms, the establishment or development of industrial or commercial activities in Nigeria is

[14] Ibid. Dated 18 March 2020, Israel was reported as the first country to grant compulsory license on COVID-19. The instrument allows import of a generic version of *Kaletra* (HIV drug) produced by AbbVie from India for treatment of coronavirus for 'national defence purposes' under the Patent Statute.

[15] For example, there is a report of the President of Ukraine offering $1million USD to any scientist in the country who develops a COVDI-19 vaccine. See www.tellafrica.com.ng

[16] See Adebambo Adewopo, Public Health, Access to Medicines and the Role of Patent System in Nigeria, NJIP, Maiden Edition, November 2011, 164.

[17] See First Schedule pursuant to section 11, PDA. Part 1 of the First Schedule is titled 'Compulsory Licenses and Use of Patent for Service of Government Agencies' and provides for Compulsory Licences while Part 2 provides for 'Use of Patent for Service of Government Agencies'.

unfairly or substantially prejudiced.[18] With respect to government use of patent for service of government agencies, the grounds include; efficient prosecution of any war in which the Federal Republic may be engaged; maintenance of supplies and services essential to the life of the community; securing a sufficiency of supplies and services essential to the wellbeing of the community; promoting the productivity of industry, commerce and agriculture; fostering and directing exports and reducing imports from all or any countries and for redressing the balance of trade; generally ensuring that the whole resources of the community are available for use and are used in a manner best calculated to serve the interest of the community. [19]

As part of the features of CL, an application by a person can only be made after expiration of 4 years after filing of patent application or 3 years after patent grant whichever expires last, which suggests that public health emergencies, in the case of COVID-19 pandemic, would have to wait for 3 or 4 years depending on the relevant scenario to apply to court before supply of vaccines can be ordered under compulsory patent license in Nigeria. However, government use fills the gap, in substance and in operation, for meeting the key objective of promoting access to medicines in health emergencies. Clearly, government use provision will save more time in relation to the use of non-voluntary licences in public emergencies for which access to pharmaceuticals is sought, although the only reported decision on compulsory licence for government use for supply of a pharmaceutical drug prior to the PDA, did not involve public health emergency.[20] Under this scheme, the Minister, when satisfied that it is in public interest, can authorize any person to purchase, make, exercise or vend any patented article or inventions for the service of a government agency without reference to court.[21] The period of the emergency, which is defined as any period of emergency however

[18] See para.1, First Schedule, PDA for the grounds for issuing CL, which are only granted by the court upon application by a person. The grounds are the following; that the patented invention being capable of being worked in Nigeria have not been so worked; the existing degree of working of the patented invention in Nigeria does not meet on reasonable terms the demand for the product; working of the patented invention in Nigeria or prevented by importation of the patented article; by reason of the refusal of the patentee to grant licences on reasonable terms, the establishment or development of industrial or commercial activities in Nigeria is unfairly or substantially prejudiced.

[19] See para.20 with respect to government use. The grounds include; efficient prosecution of any war in which the Federal Republic may be engaged; maintenance of supplies and services essential to the life pf the community; securing a sufficiency of supplies and services essential to the wellbeing of the community; promoting the productivity of industry, commerce and agriculture; fostering and directing exports and reducing imports from all or any countries and for redressing the balance of trade; generally ensuring that the whole resources of the community are available for use and are used in a manner best calculated to serve the interest of the community.

[20] See *Rhone Poulenc SA & May & Baker v. Lodeka Pharmacy* [1965] LLR 9 (Where the pharmaceutical preparation under the name 'Largactil' under the plaintiff's patent was supplied by the defendant to the Federal Ministry of Health pursuant to use for the services of the crown. The plaintiff's alleged infringement of its patent and took the action to enforce its right to distribute the drug to the general public. The defendant contended that plaintiff's patent was not infringed as it applied to the drug pursuant to government use and not for use by the public and therefore was not in dimunition of plaintiffs right as the patentee with the right to import and distribute the drug to the public. The court upheld the plaintiffs claim and issued an injunction against the defendant based on the view that the provision for use of patent for the service of the crown under UK Patent Act 1949 (s.46(1)) sought to be incorporated into the Patent Act by s.6, which conferred patent rights and privileges as though the patent had been issued in the UK with an extension to Nigeria, could not apply the whole of the UK Act to Nigeria. Based on that, the provision on any use of patented invention for the use of the crown could not apply to avail the defendant.

[21] See note 19. It is important to note that government use may be issued before or after relevant patent has been granted, or before or after the doing of the acts in respect of which the authority is given (in other words having retroactive effect); or whether or not he is authorised directly or indirectly by the patentee to make, use or exercise or vend the relevant article or invention.

declared or notified by or on behalf of government. Government in the circumstance may be State or Federal or their respective agencies. This is not to say that CL, by its juridical nature, is altogether inapplicable, however time is of the essence. The fact that CL is court-granted by itself implies it may be subject to the delays and other vagaries of the judicial process. It can be used in combination with government use within the context of the enabling provision of the PDA and with due regard to the defined public interest purposes.

From the practical standpoint of patent law, the concrete urgency in invoking the powers to issue the CL for use of government under the PDA is vital to the effort of promoting access to affordable COVID-19 vaccines in record time and without any delay. The adoption of government use model therefore provides the instrument which helps to guarantee the supply of needed vaccines and drugs for Nigerians, given the apparent lack of manufacturing capacity and affordability for patented medicines that will accompany the release of COVID-19 vaccines thereby safeguarding public health in the challenging time. It affords the government to exercise the powers to fulfil one of the primary objectives of its public health obligations as enshrined in the National Health Act. The Act for the first time established the National Health System,[22] and in some respect, due to its novel provisions, the Act, has been reputed, as if it confers the 'right to health'.[23] This above context underscores the functional role of patent system in the development of health system in the context of facilitating access to essential medicines. As health sector has not always enjoyed any appreciable or much less significant share of the domestic budget in most sub-Saharan African countries, heavy reliance on aids and global compassion has been the most convenient option, whether in normal times, national emergencies or pandemics such as COVID-19.

In Nigeria,[24] the persistently inadequate allocation to health well below the recommended standards or benchmarks has resulted in the poor state of health care infrastructure. This fact became evident in the wake of COVID-19 pandemic, where donations, private and public intervention funds and stimulus packages were immediately generated to cushion its socio-economic impact, provide palliatives, upgrade existing medical facilities and other make-shift COVID-19 facilities were hurriedly built in Lagos, Abuja and other towns.[25] In the context of

[22] See section 1, National Health Act 2014. The Act provides the legal framework for the regulation, development and management of Nigeria's health system, provides 'for persons living in Nigeria the best possible health services within the limit of available resources' and 'protect, promote and fulfil the rights of the people of Nigeria to have access to health care services', among other objectives.

[23] See section 20, National Health Act 2014 (provides under subsection 1 that 'a health care provider, health worker or health establishment shall not refuse a person emergency medical treatment for any reason'. Subsection 2 provides that a contravention of the provision is an offence punishable by a fine of =N=100,000.00 or 6 months imprisonment or both).

[24] A holistic 5-year review of budgetary allocation to health form 2014-2018 shows 33.938b, 347.26b, 353.54b, 380.16b and 528.14b respectively regarded as a far cry from global and continental level standard. See yourbudgIT.com/wp_content/uploads/2019/02/FEDERAL-GOVERNMENT-2018-final.pdf. accessed 18 April 2020.

[25] See N500 billion COVID-19 Intervention Fund, see guardian.ng/news/fg-seeks-nass-approval-for-n500b-covid-19-intervention-fund/ reported 5th April 2020. See also N50 billion Targeted Credit Facility (TCF) Stimulus Packages for households and micro, small & medium enterprises (MSMEs) see www.ripplesnigeria.com/10-things-you-need-to-know-to-access-cbns-n50b-covid-19-intervention-fund/ reported 14 April 2020. See House of Representatives proposal for Emergency Economic Stimulus Bill 2020, inter alia, to provide tax rebates, deferment of residential mortgage payment by individual contributors to national housing scheme for 180 days, waiver of import duties on medical goods, see www.news.bloombergtax.com/daily-tax-report-international/insight-covid-19-pandemic-nigerias-fiscal-and-ecpnomic-measures reported 10 April 2020 accessed 16 April 2020

public health, as CL has found usefulness across the developed, developing and less developed countries for meeting pricing and production gaps in health emergencies, it has become patent law's ready handmaiden for sustaining health care systems and the need to commit significant domestic funding to meeting the legal, moral and constitutional obligations of government to fulfil critical needs for health and human development. This further justifies the public interest imperatives of limiting patent's exclusive rights through the use of CL to assist in promoting access to essential medicines and vaccines in period of emergencies.

RECOMMENDATION AND CONCLUSION

In the discharge of government's duty to safeguard life and wellbeing of the society in health emergencies, the centrality of legal regulation to preserve public health and safety has been demonstrated through the previous issuance of COVID-19 regulations, which specifically related to lockdown measures by federal and respective state governments pursuant to the Quarantine Act.[26] With the global search for vaccines and the need for government to further prepare for urgent supply of vaccines for Nigerians during the emergency, patent law's CL mechanism for government use serves to reinforce existing regulation to meet the pressing public health needs that Nigerians will eventually face in order to access COVID-19 vaccines when released. In the present COVID-19 pandemic where vaccines are not yet available, CL for government patent use is needed to ensure immediate and affordable supply of the new patents as well as generics, once they are released. If government, like every government in different countries, has found it important to develop the existing economic intervention initiatives to cushion the economic impact of COVID-19 on citizens, the issuance of CL as a regulatory measure is even more crucial in the current COVID dispensation to enable citizens access low-cost vaccines.

In the present circumstances, both the Federal government and various State governments are urged to issue appropriate legal instrument/gazette pursuant to the enabling provision of PDA for compulsory licences and use of patent for service of government agencies for the 'maintenance' and 'sufficiency' of 'supplies and services' 'essential to the life and wellbeing of the community' as it relates to approved COVID-19 related vaccines in Nigeria.[27] The concurrence of patents, as a Federal matter in the exclusive legislative list and health in the concurrent list within the legislative competence of both Federal and State government, is reinforced by the provision of PDA which expressly confers the powers to make regulation for compulsory and government use licenses for emergencies, among other purposes on both the Federal and State governments and their agencies, including voluntary agency hospitals wholly or partly maintained by government by way of grant in aid or otherwise.[28] As the world draws closer to the 'magic' vaccines, this regulatory action is necessary to consolidate the legal and moral rationale for government's intervention including appropriate funding to save millions of lives that will be lost where the vaccines, whether or not under patents, are unavailable or unaffordable to the Nigerian public.

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[26] See COVID-19 Regulations No 1 & 2020 respectively dated 30 March & 13 April 2020 made pursuant to the Quarantine Act, CAP Q2 LFN 2004 issued by the President M Buhari.

[27] The recommended regulation under the title: COVID-19 (Compulsory Licenses and Use of Patents for Service of Government Agencies) Regulation 2020, Patents and Designs Act, 1965) can be issued under the powers and authority of the President and respective State governors.

[28] See section 23, First Schedule, PDA