

## "Patent Games in the Global South" and the Race for COVID-19 Vaccine: Why Nigeria is Lagging Behind and what Needs to be Done

## By:

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As the COVID-19 pandemic rages, there was a global race to develop a vaccine to halt the virus. As of July 2020, over <u>150 candidate</u> vaccines have been developed globally. Of this number, the <u>WHO Landscape of COVID-19 candidate</u> <u>vaccines</u>, of 27 July 2020, shows that 25 of them have reached different stages of clinical evaluation. Nigerian developed vaccine was conspicuously missing from this list. The race has led to the production of vaccines, which are currently being consumed in some parts of the world, while claims to patent monopoly remain a barrier to getting vaccines in most of the global south. Still, Nigeria is not a player in the patent game. However, <u>a vaccine developed by</u> <u>scientists in Adeleke University</u>, Ede, Nigeria is on the list of the 129 candidates at the pre-clinical stage. The vaccine was developed from research funded by Trinity Immunodeficient Laboratory and Helix Biogen Consult, Ogbomosho, Nigeria with roughly N7.8 million (USD20,000).

While this development is commendable, it does not call for much celebration, as the only Nigerian candidate at pre-clinical evaluation stage was developed from private initiative. Further, as the WHO Landscape of COVID-19 candidate vaccines shows, Nigeria is lagging behind in the race for the vaccine and, by implication, the patent game. Why is this so and what needs to be done to change the tide? These questions are important considering that other developing countries such as India, through coordinated government support and private initiatives, have candidate vaccines in advanced clinical trial stage and a number of them in the pre-clinical evaluation stage as at 28 July 2020. Importantly, also, the need to be the first to obtain patent right and priority under the relevant global intellectual property (IP) regime, in order to control the market for COVID-19 vaccine, is a strong propellant for governments' and big pharmaceutical companies' involvement in the race for COVID-19 vaccine.

As if she saw tomorrow, Amaka Vanni already proffered answers to the foregoing nagging questions, and more, albeit within the broad conversation around pharmaceutical patent and access to essential medicines and health technology in the Global South. She undertook this task in her well-researched and exceptionally captivating monograph: Patent Games in the Global South: Pharmaceutical Patent Law Making in Brazil, India and Nigeria (Hart Publishing 2020).

In the book, structured into 7 strong chapters, she critically unpacks, engages and beautifully links the role of states and non-states actors in international patent law-making with the realities of patent legislation and policy formulation, as well as pharmaceutical innovation and R&D in Brazil, India and Nigeria.

The choice of Brazil, India and Nigeria is informed, among others, by the fact that the three states are middle-income countries and strong active voices from the Global South in the global patent law-making fora. However, while Brazil and India can be described as '<u>Rising Middle-IP Powers</u>' (because of the nationalistic and developmental approach in the formulation of their national patent regimes within the global normative standards and the growth of their pharmaceutical industry, among others), Nigeria still lags behind in the "Patent Games in the Global South". Deploying the TWAILIAN theoretical framework linked with the concept of nodal governance, Amaka Vanni explored the history, origin and conceptualization of patent law at the global level and shows how they influenced the construction and implementation of patent law and policy, particularly in relation to pharmaceuticals, in Brazil, India and Nigeria. Specifically, she found that key factors, such as the "colonial experience, development aspirations, the confluence of local politics [including socio-economic considerations] and international political processes that unfolded over time", shaped the interpretation of pharmaceutical patent and patent law-making towards national developmental goals especially in Brazil and India, and to some extent, in Nigeria.

In particular, chapter 6 of Amaka Vanni's book examined patent-law making and the state of pharmaceutical patent in Nigeria. Here, the author discussed the history of the Nigerian patent system from colonial times to the extant regime, and Nigeria's active role in the GATT negotiations and its opposition to the inclusion of IP within the WTO system. She also explored the existing patent regime (Patent and Designs Act) enacted in 1970, the interaction (or not) between other regulatory frameworks relevant to pharmaceutical innovation and the patent mechanism, and the role of players – including civil society organisations (CSOs) and pharmaceutical manufacturing industry in shaping the patent system in Nigeria.

Discussion in the chapter showed that patent law developed in colonial Nigeria out of the Western conceptualization of IP and to serve the interest of foreign innovators, especially multinational pharmaceutical corporations from the territory of the colonial power (Britain). Although the extant patent regime was enacted after independence, Vanni showed that it still continues to promote the interest of foreign innovators, especially multinational pharmaceutical corporations that contrived strategies for the prevention of transfer of relevant technology to their local subsidiaries manned by Nigerians.

Vanni noted, and rightly so, that the extant patent regime is not fit for the purpose of achieving national development since it was developed after the BIRPI (now WIPO) Model Law for developing countries, which was formulated based on Western understanding of IP. In this connection, the book reveals that the patent regime established a mere registry system without effective mechanisms, such as substantive examination of patent claims, which are important in developing local know-how and ensuring technology transfer, especially within the Nigerian pharmaceutical industry.

Worthy of commendation, however, is the fact that the extant patent regime in Nigeria complies with some aspects of the TRIPS Agreement. Nonetheless, it is deficient in its definition of patentable subject-matter, as well as the absence of provisions relating to the Bolar exception and parallel importation which are important TRIPS flexibilities relevant to the promotion of access to essential medicines. Further, the compulsory license regime, as well as other important exceptions, established by the patent regime is subject to certain judicial and administrative bureaucracies, among other conditions, that make implementation a tall order.

Indeed, it would be near impossible to deploy the compulsory license mechanism, and other useful exceptions, such as government use, towards developing the Nigerian pharmaceutical industry largely because of the near absence of local pharmaceutical manufacturing capacity, and the poor state of pharmaceutical innovation and R&D. This is worsened by other factors, as noted by Amaka Vanni, such as the lack of a well-articulated IP policy that links patent and innovation to national development aspirations; the disconnect between relevant regulatory agencies within the innovation system and the patent regime; the improper implementation of other development focused policies such as the indigenisation and import substitution industrialisation (ISI) policies; the absence of nodal networks of CSOs and other players in the pharmaceutical industry for patent regime's reforms; and the huge presence of foreign donor funds for essential medicines in Nigeria.

Drawing from the Brazilian and Indian experiences, Amaka Vanni recommended important legal and policy actions that Nigeria needs to take to encourage technology transfer, develop pharmaceutical manufacturing capacities in Nigeria, and position the industry to be relevant especially in times of public health emergencies, such as the COVID-19 pandemic. Specifically, she canvassed for the development of a patent mechanism that is hinged on the right to health and framed as a health policy tool. Such patent regime, according to Amaka Vanni, must be "cognisant of Nigeria's health challenges and needs as well as its development aspirations". In this connection, the author recommended amendment of the extant patent law to include a substantive examination procedure that ensures participation of the public health sector in the patent grant process in Nigeria.

To be effective, the patent system recommended by Amaka Vanni must be backed by a system that ensures synergy among regulatory agencies operating within the innovation space in Nigeria, particularly with relation to the pharmaceutical industry. Specifically, she suggested a system that reduces fragmentation and policy contradiction among relevant government agencies, and "encourage the development of a cohesive patent regulatory strategy and effective enforcement mechanism". Further, the author makes a case for public investment into research aimed at developing and promoting pharmaceutical innovation. To bring about the necessary changes, Amaka Vanni, makes a case for the development of well-informed and active CSOs in the workings of patent systems within the pharmaceutical sector and the larger innovation ecosystem in Nigeria.

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