Access to COVID-19 Treatment, International Intellectual Property Protection and Nigerian Bilateral Investment Treaties: Patent Protection and Compulsory Licencing

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Introduction

Leading public health experts suggest that we will still continue to live in some form of public distancing rules until we have advanced an effective treatment for Covid 19.[1] Given that the serious economic hardship[2]and social cost[3] of measures taken to stop the spread of Covid 19 could have upsetting consequences for Nigerians, one can appreciate the significance of developing effective medicine for Covid 19 treatment as soon as possible. Due to the full

onslaught of Covid 19 globally, it is not surprising that publicly funded projects, [4] private-public partnership[5] and pharmaceutical industries[6] are making efforts to develop an effective treatment. The key question is whether Nigerians will be able to access medicines for Covid 19 treatment once treatments have been developed. Under international law and international investment treaties, this is primarily a matter for intellectual property (IP) protection for such treatments.

This post explains options for Nigerian government to facilitate access to Covid 19 treatment under WTO TRIPS Agreement and Nigerian bilateral investment treaties (BITs), taking into account commitments for IP protection under TRIPS Agreement and Nigerian BITs. In the first part, it considers obligations under TRIPS Agreement that offer patent protection for existing and future Covid 19 treatment, and how that is likely to affect access to affordable Covid 19 treatment in Nigeria. The second part considers obligations under Nigerian bilateral investment treaties (BITs) that offer patent protection for Covid 19 treatment, and how they affect access to affordable medicine for Covid 19 treatment.

Impact of intellectual property rights protection on access to affordable Covid-19 treatment in Nigeria

Under Articles 27 and 28 of TRIPS Agreement,[7] WTO Members must make patents available for any new invention that are capable of industrial application, granting patent holders exclusive exploitation rights. This applies to pharmaceutical products that are new, inventive and have industrial application. My main argument is that while we expect drugs developed for Covid 19 treatment to be patentable in Nigeria and most high-income countries by pharmaceutical companies, patent rights will not serve as a barrier to access affordable Covid 19 treatment. This is because many potential patent holders recognising the unprecedented effect of Covid 19 will likely licence the treatment widely on affordable terms, especially in middle and some low-income countries such as Nigeria.

Assuming a patent is granted for Covid 19 treatment in Nigeria, the question that will arise will be to what extent should patent holders be allowed to profit

from their inventions, and to what extent should the society limit the rewards they can obtain in order to take care of other social concerns such as public health in Nigeria? The fact that Covid 19 has an unprecedented effect globally, we can assume that patent holders will be under immense pressure to licence widely. Although at the heart of recent debate over patented pharmaceutical drugs have been their price, some pharmaceutical companies have already shown willingness to licence their patent drugs for Covid 19 treatment widely. [8] Overall, we should expect voluntary licencing to be the norm.

If that is not the case, international law generally allows the Nigeria government to grant compulsory licences to respond to national health emergency in the country. For instance, in this case, the outbreak of Covid-19 in Nigeria. The grant of compulsory licences is supported by international law relating to IP, which generally allows countries to grant compulsory licences under the conditions of Article 31 of the TRIPS Agreement. In summary, this enables authorities in a state to allow another entity to produce and sell the patented invention without the authorisation of the patent holder, subject to adequate compensation and usually after unsuccessful efforts to obtain authorisation from the patent holder.

However, the requirements for prior negotiations may be waived in the case of national emergency. While it is certain that addressing the Covid 19 pandemic would satisfy the issuing of compulsory licences, all WTO members agreed on the Doha Declaration on TRIPS and Public Health that countries have 'the right to determine what constitutes a national emergency…it being understood that public health crisis, including those relating to HIV/AIDs tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency'[9] Moreover, the UN have advised African countries to demand urgent access to medicines IP for Covid 19 treatment,[10] while United States[11] and Israel[12] show their willingness to issue compulsory licences for IP medicines for Covid 19 treatment.

In the event Nigeria has insufficient or no manufacturing capacity to produce the relevant treatment domestically the special mechanism[13] now incorporated in a new Article 31bis of TRIPS[14], is designed to enable countries with insufficient manufacturing capacity to nevertheless benefit from

compulsory licencing to facilitate access to affordable Covid 19 treatment. In summary, the system allows the exporting country to issue a compulsory licence solely for the purpose of exports to an eligible importing country that has made a notification to the WTO[15] about its insufficient manufacturing capacity. Given the unreasonably high global necessity for Covid 19 treatment once a vaccine is developed, it is easy to imagine that Nigeria will find their own manufacturing capacity to be insufficient[16], therefore might ask other countries to help produce sufficient supplies for them. The system should apply to a wide range of relevant medicines used in the treatment of COVID 19.[17] However, despite the usefulness of the system, it is not difficult to imagine that countries with sufficient manufacturing capacities for vaccines are initially going to prioritise their own population before manufacturing for export to Nigeria.[18]

Access to Covid-19 treatment and intellectual property protection in Nigerian bilateral investment treaties:

Secondly, although BITs do not stand in the way in case Nigeria wants to rely on compulsory licences to ensure access to affordable medicine for Covid 19 treatment, they become complicated when the granting of compulsory licences is prejudicial to international pharmaceutical company patent holder. In a foreseeable scenario, the patent holder could potentially bring an action to challenge any Nigerian government's compulsory licence measures under relevant BITs between Nigeria and the home country of the patent holder, using the investor-state dispute settlement mechanism (ISDS).

Learning from the past, government measures to protect public health have come under challenge in ISDS claims. For instance, in 2010 the Canadian government's measure banning chemicals detrimental to public health was met with ISDS proceedings.[19] In 2013, the invalidation of two drug patents of a US pharmaceutical company by Canada was also met with ISDS proceedings.[20] In these cases, the tribunals were tasked with deciding whether Canada complied with the investment treaty commitments when placing a ban on the harmful chemicals and invalidating the patents. In addition, the scope of protection for IP brought much international attention by a case brought by a group of international pharmaceutical companies against South Africa where

there were clashes between over IP rights, public health concerns and obligations of South Africa under the TRIPS Agreement.[21] Even though the right of South African government to take measures such as compulsory licencing prevailed due to pressure brought by NGOs, this case shows the potential for IP rights under TRIPS, despite its apparent flexibilities, being utilised as a mechanism for enforcing IP rights at the expense of public health. There will not be any difference in the case of Nigerian BITs. So, international pharmaceutical companies could use the IP protection of these BITs to enforce IP rights.

As such, any compulsory licences granted by Nigerian government may fall within the scope of more than 20 BITs entered between Nigeria and home countries of foreign corporations.[22] For instance, Article 1 of Netherlands-Nigeria BIT provides 'that the term investment shall comprise of any kind of asset and more particularly, and though not exclusively; rights in the field of intellectual property such as patents…' [23]These BITs seek to promote cross-border investment flows by requiring states to provide certain standards of protection and treatment to foreign investors. Generally, the standards of protection and treatment that might be invoked before ISDS tribunals for measures such as compulsory licences include right to compensation for indirect expropriation, right to full protection and security and right to fair and equitable treatment.[24] In the first part, this post considered obligations under the TRIPS Agreement to offer protection to international pharmaceutical companies holding patents for existing and future Covid 19 treatment, and how that is likely to affect access to affordable treatment in Nigeria. It showed how voluntary licenses and compulsory licenses can ensure that international patent law does generally not serve as a barrier for access to affordable Covid 19 treatment in Nigeria.

This part, however, looks at options in Nigerian BITs that ensure access to affordable Covid 19 treatment in Nigeria. A review of Nigerian BITs indicates the presence of express provisions such as non-discriminatory measures of general application adopted aimed at safeguarding public health and safety[25] can be considered consistent with the Nigerian government's obligations under the BIT. Another significant provision provides that expropriation does not apply to issuance of compulsory licences granted in relation to intellectual property

rights provided such actions are consistent with international law on intellectual protection (TRIPS Agreement).[26] These provisions confirm that some Nigerian BITs are without prejudice to the rights, obligations and flexibilities that contracting parties have under these BIT. The primary question concerns the applicability of these provisions to our Covid 19 scenario. Can the Nigerian government rely on these provisions, arguing that compulsory licencing to access affordable Covid 19 treatment is necessary for protecting public health in the country?

The guidance from tribunals addressing this issue suggests that exception provisions such as these are not totally self-judging but rather requires a balancing of factors including the significance of the public interest protected by that measure.[27] However, the severity of the Covid 19 pandemic and its far-reaching consequences across the globe, plus the clarifications of the Doha Declaration that public health crisis, including epidemics can represent a national emergency, arguably support an application of these provisions. This means that the appropriate use of these provisions by the Nigerian government would ordinally not give rise to liability under the BIT, even if international pharmaceutical companies have been negatively affected.

Even in the absence of express exception provisions in Nigerian BITs, it can be arguably said that compulsory licence measures represent a valid exercise of the Nigerian government's police powers provided the measures are proportional and non-discriminatory. As a general matter, compulsory licencing in this scenario can arguably be said to be proportional and reasonable in relation to their goal. Hence, Nigerian BITs cannot serve as a barrier for access to affordable Covid 19 treatment in Nigeria. For example, in *Philip Morris v Uruguay*[28], the tribunal found that the anti-smoking polices by Uruguay restricting the advertisement and packaging of cigarettes with a view to protect public health in fulfilment of its national and international obligations to protect public health were not arbitrary but rather an effective means to protect public health. The tribunal concluded that the measures were a valid exercise of Uruguay's police powers for the protection of public health, as such did not constitute a breach of Uruguay's obligations under the BIT.

The principle of necessity under international law can be another justifiable

ground for the Nigerian government to grant compulsory licences to access affordable Covid 19 treatment if it negatively affects a foreign pharmaceutical company.[29] The Nigerian government can invoke certain risk of grave harm to the population to justify granting compulsory licences to address a threat to life such as Covid 19, and provided that they are no other reasonable way to deal with the threat.[30] As a general matter, compulsory licencing to access essential and affordable drugs can arguably be said to be the only way to deal with an epidemic such as Covid 19.

Concluding remarks

It is evident that the Nigerian government could rely on a number of provisions in international IP law and its BITs to grant compulsory licences to access essential and affordable treatment for Covid 19, which aim to limit substantive IP protection under the IP laws and BITs. Such provisions are important to providing the government with regulatory latitude to deal with public health concerns such as Covid 19, provided the appropriate use of these provisions. In addition to BITs and IP laws, the Nigerian government can rely on the international law principle of necessity to justify taking measures such as compulsory licencing, yet the successful use of this principle depends on satisfying various conditions. Meanwhile, applicability of the customary doctrine of police powers to the claims arising under BITs has been accepted. This means that ISDS tribunals should thus attach normative propriety to state regulation in an epidemic.

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[2] See Emeka Onyekwena and Mma Amara Ekeruche, ‘Understanding the impact of the COVID-19 outbreak on the Nigerian Economy’ https://www.brookings.edu/blog/africa-in-focus/2020/04/08/understanding-the-impact-of-the-covid-19-outbreak-on-the-nigerian-economy/ accessed 24 April 2020.

[3] Nigeria: Protect Most Vulnerable in COVID- 19 Response https://www.hrw.org/news/2020/04/14/nigeria-protect-most-vulnerable-covid-19-response accessed 24 April 2020.

[4] UK provides funding support for Covid-19 vaccine programme https://www.pharmaceutical-technology.com/news/uk-covid-19-vaccine-funding/ accessed 21 May 2020.

[5] AstraZeneca gets $1bn from US BARDA to support Covid-19 vaccine https://www.pharmaceutical-technology.com/news/astrazeneca-us-support-covid-vaccine/ accessed 21 May 2020.

[6] Jaimy Lee, 'These 23 companies are working on corona virus treatments or vaccines-here's where things stand' https://www.marketwatch.com/story/these-nine-companies-are-working-on-coronavirus-treatments-or-vaccines-heres-where-things-stand-2020-03-06 accessed 21 May 2020.

[7] Part II- Standards concerning the availability scope and use of Intellectual Property Rights https://www.wto.org/english/docs_e/legal_e/31bis_trips_04c_e.htm accessed 24 May 2020.

[8] AbbVie Partnering with Global Authorities to Determine Efficacy of HIV Drug in Treating COVID-19 https://news.abbvie.com/news/press-releases/abbvie-partnering-with-global-authorities-to-determine-efficacy-hiv-drug-in-treating-covid-19.htm accessed 24 April 2020.

[9] Declaration on the TRIPS agreement and public health (adopted on 14 November 2001) 5c.

[10]United Nations Economic Commission for Africa https://www.uneca.org/sites/default/files/PublicationFiles/briefing_paper_on_trade_policies_19_290820.pdf accessed 24 April 2020.

[11] How Covid-19 Could Spur The Gov't to Seize Patents https://www.law360.com/articles/1258140/how-covid-19-could-spur-the-gov-t-to-seize-patents?nl_pk=5b03a094-2168-4217-a36c-371a5a80d20c&utm_source=newsletter&utm_medium=email&utm_campaign=special accessed 24 April 2020.

[12] Israel Defies AbbVie IP to Import Generic Drugs for COVID-19 https://www.law360.com/articles/1255079/israel-defies-abbvie-ip-to-import-generic-drugs-for-covid-19 accessed 24 April 2020.

[13] See Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm accessed 25 May 2020.

[14] See Amendment to the TRIPS Agreement https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm accessed 25 May 2020.

[15] See Notifications by importing WTO members https://www.wto.org/english/tratop_e/trips_e/public_health_notif_import_e.htm accessed 24 May 2020.

[16] See Nigeria relies heavily on drug imports. Why this is worrying in the time of COVID-19 https://theconversation.com/nigeria-relies-heavily-on-drug-imports-why-this-is-worrying-in-the-time-of-covid-19-134562 accessed 20 May 2020.

[17] See Annex and Appendix to the TRIPS Agreement para 1a. https://www.wto.org/english/docs_e/legal_e/31bis_trips_annex_e.htm accessed 21 May 2020.

[18] Paul Brackley, 'AstraZeneca to begin supplying 100million doses of Covid 19 vaccine to UK from September-if trials succeed' https://www.cambridgeindependent.co.uk/business/astrazeneca-to-begin-supplying-100-million-doses-of-covid-19-vaccine-to-uk-from-september-if-trials-succeed-9110892/ accessed 24 May 2020.

[19] *Chemtura Corporation v Government of Canada*, UNCITRAL, Award (2 August 2010).

[20] *Eli Lilly and Company v The Government of Canada*, UNCITRAL, ICSID Case No UNCT/14/2, Award (16 March 2017).

[21] See James Harrison, *The Human Rights Impact of the World Trade Organisation* (Hart Publishing, 2007) pp 157-158

[22] To access Nigeria BITS see Investment Policy Hub https://investmentpolicy.unctad.org/international-investment-agreements/countries/153/nigeria accessed 23 April 2020.

[23] *Agreement Between the Kingdom of the Netherlands and the Federal Republic of Nigeria for the Promotion and Protection of Investments* (signed 2 November 1992, entered into force 1 February 1994)

[24] Ibid, Arts. 3 and 6.

[25] See, eg, *Agreement Between the Government of the Federal Republic of Nigeria and the Government of the Republic of Singapore for the Promotion and Protection of Investments* (signed 4 November 2016) Art 28 (b).

[26] Ibid, Art. 5(5); see also *Agreement Between the Canada and the Federal Republic of Nigeria for the Promotion and Protection of Investments* (signed 6 May 2014) Art 10(5).

[27] See Okechukwu Ejims, 'African Regional Investment Agreements: Neutralising a Threat to Non-communicable disease Control Policies', Manchester *Journal of International Economic Law,* 2020, 17(1): 18

[28] *Philip Morris band Sarl (Switzerland), Philip Morris Products SA (Switzerland) and Abal Hermanos SA (Uruguay) v Oriental Republic of Uruguay*, ICSID Case No ARB/10/7, Award (8 July 2016).

[29] See 'Federia Paddeu and Freya Jephcott, COVID-19 and Defences in the law of State Responsibility : Part II' https://www.ejiltalk.org/covid-19-and-defences-in-the-law-of-state-responsibility-part-ii/ accessed 25 May 2020.

[30] Ibid.

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