Open Science, Intellectual Property and the South African mRNA Vaccine Hub

Omowamiwa Kolawole, Caroline B. Ncube, and Jeremy de Beer

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Contents

Authors

Dr. Omowamiwa Kolawole
omowamiwa.kolawole@utoronto.ca
Kolawole is a Postdoctoral Fellow at the Dalla Lana School of Public Health, University of Toronto, and was previously a Postdoctoral Fellow at the SARChI Research Chair in Intellectual Property, Innovation and Development, Faculty of Law, University of Cape Town. Kolawole is an Open AIR Researcher, conducting interdisciplinary research at the intersections of human rights, intellectual property, public health and global health governance.

Dr. Caroline B. Ncube
caroline.ncube@uct.ac.za
Ncube is a Professor in the Department of Commercial Law, Faculty of Law, University of Cape Town, and holds the university's DST/NRF SARChI Research Chair in Intellectual Property, Innovation and Development. Ncube is Co-editor of the *South African Intellectual Property Law Journal,* an Associate Member of the Centre for Law, Technology and Society (CLTS), Faculty of Law, University of Ottawa, and serves on the Open AIR Steering Committee, guiding Open AIR's research on policies, laws and regulations impacting African innovation.

Prof. Jeremy de Beer
jdebeer@uottawa.ca
De Beer is a Professor in the Faculty of Law, University of Ottawa, affiliated to the university's Centre for Law, Technology and Society (CLTS). De Beer is a Senior Fellow, Centre for International Governance Innovation (CIGI), Waterloo, Canada; a Senior Research Associate at the Intellectual Property Unit, Faculty of Law, University of Cape Town; a Visiting Professor at the Trilateral Research Chair in Transformative Innovation, College of Business and Economics, University of Johannesburg; and a co-founder and co-director of Open AIR.

The authors will be grateful for inputs and feedback on the contents of this briefing paper. Please use the authors' email addresses provided above.

Abstract

During, and in the aftermath of, the global COVID-19 pandemic, there were strong calls for more equitable global vaccine access. Among the responses to these calls have been efforts to increase vaccine development and manufacturing capacity in developing-world settings. To this end, the World Health Organisation (WHO) has supported the establishment of an mRNA vaccine hub in South Africa, implemented by a consortium led by Cape Town biotechnology company Afrigen. This mRNA vaccine hub is mandated to develop mRNA vaccines, and to share intellectual property and technology required for their formulation with companies in selected low- and middle-income countries (LMICs). The hub is also mandated to provide training that enables the technology recipients to develop and produce mRNA vaccines. In this briefing paper, which is based on a desktop scoping review of the Afrigen project, we explore the establishment of the hub and some of its key accomplishments and challenges since inception.

Keywords

pandemics, vaccines, COVID-19, mRNA, open science, intellectual property, technology transfer, mRNA vaccine hub, World Health Organisation (WHO), Afrigen, Cape Town, South Africa

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I. Introduction

The COVID-19 pandemic, and the global inequities it exposed and even further widened, led to a renewed call for more equitable bio-medical science and more equitable access to its proceeds (Pilkington et al., 2022). These calls emerged particularly in the context of the 2020–22 international negotiations around the World Trade Organisation (WTO) patent "waiver" (WTO, 2022) and the push for COVID-19 vaccines to be sold to low- and middle-income countries (LMICs) at costs these countries could afford (Sekalala et al., 2021). Some who opposed these measures argued that there was a need for manufacturers to offset the cost of research and development (R&D) and of production (Pitts et al., 2021). This position was countered by those who pointed out that a significant portion of the cost of R&D and production had been shouldered by taxpayers in wealthy countries through their governments, meaning that the R&D and production were not private-sector-only interventions (Lancet Commission, 2021).

In addition, there was the argument that contributors to the understanding of the virus and its variants were not given due recognition and commensurate access to the interventions that stemmed from the discoveries. For example, in the case of the Omicron variant identified in 2020 by South African bioinformatician Tulio de Oliveira at the KwaZulu-Natal Research Innovation and Sequencing Platform (KRISP) at the University of Kwa-Zulu-Natal (UKZN) (Samarasekera, 2022), significant genomic data, crucial to understanding the virus (Tegally et al., 2022), was shared openly with the world. Rather than leading to an acknowledgement of the transformative potential of global genomic pathogen data-sharing, de Oliveira's open science approach resulted in travel bans imposed on travellers from South Africa and other African countries where Omicron was detected (Moodley et al., 2022). This response minimised, and arguably even punished, important intellectual contributions made in the spirit of collaborative international open science—thus potentially leading to a shrinking of the open science space by breeding what de Oliveira has described as an atmosphere of "fear":

> […] it's quite clear, we have suffered very severe discrimination for identifying variants. Even when we don't identify them, the finger is pointed at Africa…As a public health scientist, I think that's the biggest danger—that new pathogens are not quickly identified and transparently shared with the world because of the fear of discrimination. (de Oliveira, quoted in Samarasekera, 2022)

Considerable work is being done by scholars and advocates to contextualise and problematise the disagreements on how, during global pandemics, global health goods (such as vaccines) should be allocated, shared, and/or sold (Rimmer, 2022; see also Kang et al., 2021). This work is spurring new strategic thinking about how intellectual property (IP) regulates international trade and eventual public health outcomes (de Beer & Gold, 2020).

A significant product of the rethinking is the current negotiation process towards a pandemic agreement under the auspices of the World Health Organisation (WHO) (WHO, 2023a). Key elements to be addressed in the agreement include: ensuring equitable global access to pandemic mitigation technologies through sustainable and equitable transfer of technology and know-how;[1] and improving pandemic-related R&D capacities across the globe,[2] built on a foundation of pathogen access and benefit sharing.[3] Both of these core elements can be implemented through harmonised and strengthened national and international regulatory frameworks.[4]

Renewed calls are being made to "leave no one behind" (Omino & Kahumbu, 2022) in the shaping of new and inclusive interventions—including demands for regional solidarity in matters of norm-setting, legislative reform, and development of manufacturing capacity (dos Santos et al., 2022). With respect to manufacturing, there are calls to broaden and fast-track the ability of as many countries as possible to innovate with and produce vaccines. Diversifying local capacity is seen as a practical step to mitigate the current pressure on a small number of countries to manufacture for both their own populations and for the rest of the world, which results in such countries having to make difficult choices around priority and pricing, including choices around free or subsidised provision to countries where prevailing prices cannot be afforded (Sparke & Levy, 2023).

In the context of this push for fast-tracking of local manufacturing capacity, there is widespread agreement on the necessity to explore and promote open science models. One such open science response is the establishment of the mRNA vaccine technology transfer hub in Cape Town, South Africa. The hub was commissioned by the WHO, which positions it as "a sustainable model for mRNA technology transfer to give low- and middle-income countries equitable access to vaccines and other lifesaving health products" (WHO, 2023b). In the international science community, the hub has been positioned as a breakthrough intervention (Maxmen, 2022), capable of disrupting both the global vaccine market and that market's predominant IP rules and structures (Paremoer & Pollock, 2022).

In this briefing paper, which is based on a desktop scoping review, we contextualise the work of the Cape Town vaccine hub vis-à-vis the goals of open science, IP-sharing, and diversified capacity for vaccine development and production.

[1] Article 7, Zero draft of the WHO CA+ for the consideration of the Intergovernmental Negotiating Body at its fourth meeting, A/INB/4/3, 1 February 2023, https://apps.who.int/gb/inb/pdf_files/inb4/A_INB4_3-en.pdf
[2] Article 9, Zero draft.
[3] Article 10, Zero draft.
[4] Article 8, Zero draft.

II. Establishment of the hub

The Cape Town hub is part of a global health initiative to build and spread messenger ribonucleic acid (mRNA) vaccine production capacity across the globe, through what the WHO describes as "spokes" (WHO, n.d.-a). The hub was established as a multilateral node, in contrast with the traditionally bilateral nature of technology transfer (WHO, n.d.-a). The hub seeks to bring together all the necessary aspects of vaccine production technology, expertise, data, training, and, importantly, intellectual property (WHO, n.d.-a). The hub's central goal is to use its collective expertise, resources, and manpower to provide necessary support to LMIC manufacturers seeking to produce vaccines (WHO, n.d.-a). The WHO expectation was that the hub would, first, create mRNA vaccines, and then, second, transfer the knowledge to other spokes (as selected by the WHO in other LMICs), which could then replicate the vaccine production and where possible build on it.

In April 2021, the WHO issued a call for expressions of interest from companies wishing to host the mRNA vaccine hub (WHO, 2021a). As part of its requirements, the selected hub would need to establish its production process at an industrial or semi-industrial level and ensure that it used technology that was free of IP constraints in LMICs—or technology for which the hub had secured the necessary rights, via a non-exclusive licence, to produce, export and distribute the COVID-19 vaccine in LMICs and through COVAX (WHO, 2021a). In line with these conditions, the hub would also need to have applicable skill and expertise; academic/research capacity; available formulation and production technology; and manufacturing capacity.

In South Africa, the South African Medical Research Council (SAMRC) identified the possibility of putting together a consortium for delivery of the hub, through maximisation of South Africa's research and manufacturing expertise and building on existing collaborative networks among the country's scientific research centres across various universities, including: UKZN, the University of the Witwatersrand (Wits), the University of Cape Town, Stellenbosch University, and North-West University (SAMRC, 2021). The work of these universities and their labs was to be crucial for the initial research and development of the vaccine which the hub was to produce.

The South African bid was successful, with the consortium (WHO, 2021b) comprising: the SAMRC; Biovac, which is a vaccine producer partly owned by the South African Government (WHO, n.d.-a); the UN-supported Medicines Patent Pool (MPP) foundation, which provides IP licences for vaccine products and processes (MPP, n.d.); and Afrigen Biologics and Vaccines, a biotechnology company based in Cape Town (Afrigen, n.d.-a), with research support from the scientific research centres at the universities mentioned above.

In June 2021, the WHO announced that the South African bid had been chosen, and that the hub would be mandated to serve all LMICs (WHO, 2021b). The SAMRC expressed confidence in its ability to deliver, with the head of its Grants, Innovation and Product Development Division, Michelle Mulder, stating:

> Our in-house intellectual property (IP) management expertise within the SAMRC Technology Transfer Office, coupled with substantial experience in managing product development funding programs within the broader Grants, Innovation and Product Development (GIPD) Division, and our global product development partnerships place us in an excellent position to coordinate and support this exciting initiative and to assist in delivering a solution for the continent. (Mulder, quoted in SAMRC, 2021)

At UKZN, one of the aforementioned universities participating in the consortium, de Oliveira stated:

> One of the things that South Africa showed the world is that if we work together, we can lead the world in Covid-19 scientific research. We used the same approach of a consortium to help South Africa to win the bid for the WHO Technology Transfer Hub. (de Oliveira, quoted in WHO, 2022a)

Afrigen's Cape Town facilities serve as the consortium's adjuvant production and formulation technology centre, which is said to be the first of its kind in the Southern Hemisphere (Afrigen, n.d.-b). For its part, the WHO works with its international COVAX (COVID-19 Vaccines Global Access) initiative partners and the Africa Centres for Disease Control and Prevention (Africa CDC) to assist the hub, seeking to provide the training and financial support required by the hub (WHO, 2022a).

Financing for the hub has come from various international donors, with France being the first to fund the project. As of April 2023, the hub had received a total USD117 million (WHO, 2023b). Canada initially contributed CAD45 million, and Global Affairs Canada's Director General for Southern and Eastern Africa later pledged a further CAD15 million (Cullinan, 2023a). The European Commission contributed EUR40 million to the hub's establishment, and later provided a further EUR15.5 million targetted at manufacturing capacity (WHO, 2023b).

At the time of its establishment in 2021, the hub was tasked with developing—by the fourth quarter of 2022—its own vaccine and producing batches for clinical trials (WHO, n.d.-a).

III. Development of second-generation mRNA vaccine

At the time of the announcement of the successful South African hub bid, a consortium member, MPP, stated as follows: "The due diligence, which was conducted by both by the Medicines Patent Pool and by WHO, indicates at this moment that there is no IP barrier in South Africa for the production of mRNA vaccines" (MPP, quoted in Furlong, 2021). As indicated by this MPP statement, the initial hope was that there would be no IP issues constraining the hub. The hope was that through engagement and/or political pressure, one or both of the companies holding the IP in the leading mRNA vaccines against COVID-19—Moderna and Pfizer—would cooperate with the hub by licensing their IP and transferring their technology (Tomlinson, 2022).

The WHO made appeals to Moderna and Pfizer to share their vaccine production expertise, but neither responded (Cullinan, 2022). Consequently, Afrigen relied on publicly available information on the Moderna vaccine, selecting Moderna's vaccine over Pfizer's due to Moderna's pledge that it would not enforce its COVID-19-related patents during the pandemic (Cullinan, 2022). Moderna had made this pledge in October 2020 (Moderna, 2020), in response to growing pressure to share its technology (Furlong, 2022), but the commitment was limited to the period of the COVID-19 pandemic. WHO supported the hub's choice of the Moderna vaccine (over Pfizer's) as a template—because the necessary data were in the public domain; the vaccine's refrigeration requirements were less onerous than for Pfizer's vaccine; and Moderna had pledged to halt patent enforcement during the COVID-19 pandemic (Tomlinson, 2022).

By January 2022, starting from the Moderna sequence, the hub had produced a second-generation mRNA vaccine. In an interview with the online *Spotlight* publication, Afrigen CEO Petro Terblanche stated as follows:

> We haven't copied Moderna, we've developed our own processes because Moderna didn't give us any technology. […] We started with the Moderna sequence because that gives, in our view, the best starting material. But this is not Moderna's vaccine; it is the Afrigen mRNA Hub vaccine. (Terblanche, quoted in Tomlinson, 2022)

Terblanche also stated that the hub's vaccine was not the product of "reverse engineering":

> This is not reverse engineering, which implies that we've taken the actual vaccine, analysed that and worked backwards to meet the qualities and the composition of what we have analysed. (Terblanche, quoted in Cullinan, 2022)

Terblanche argued that the new vaccine, based on the sequence of Moderna's Vaccine 1273, was the fruit of "forward integration" (Cullinan 2022). According to Terblanche, the RNA (which is synthesised from DNA) used to develop Afrigen's lab batch of second-generation mRNA vaccine was produced by one of the hub's academic partners, Wits University in Johannesburg, which had the necessary platforms because it had been working on RNA for six years (Tomlinson, 2022).

In March 2022, Moderna pledged to never enforce its COVID-19-related vaccine patents, including outside of pandemic conditions, in the 92 LMICs belonging to the COVAX vaccine distribution mechanism (Tomlinson, 2022). While South Africa is not among those 92 countries, Moderna stated that the South African mRNA hub would also be a beneficiary of the pledge. For its part, Afrigen stated that it did not feel that the Moderna pledge was necessary for the hub's use of the public-domain Moderna sequence (Tomlinson, 2022).

IV. Sharing of intellectual property

In keeping with the Grant Agreement between MPP and Afrigen for the hub, the patent for the second-generation mRNA vaccine created at the hub is held by its inventors, Afrigen. However, the Grant Agreement also specifies that any Afrigen inventions are to be made freely available, via the MPP, to other hubs around the world to aid them in their own local production (WHO, n.d.-a). The Grant Agreement's terms in respect of patent ownership are set out as follows:

> Afrigen hereby grants to MPP a non-exclusive, transferable, sublicensable, irrevocable, fully paid-up, royalty-free, worldwide, license to practice and have practiced the data and the Inventions for the purposes of fulfilling its mission to facilitate the development and equitable access of health technologies in low- and middle-income countries (as defined by the World Bank). […] MPP shall have the right to share the data generated under the Program with WHO for further sharing with any third parties for the purposes of fulfilling its mission to facilitate the development and equitable access of mRNA technologies in low- and middle-income countries.[5]

The hub is also expected to serve as a teaching centre where LMIC manufacturers can come to learn about the new vaccine's formulation and production processes (Aizenman, 2021).

With respect to local production at the various spokes in the mRNA technology transfer network, the WHO committed itself to working with regulatory authorities and governments to secure buy-in for the new products, while also guaranteeing product quality assurance (WHO, n.d.-a). The WHO is using its Global Benchmarking Tool (GBT) as a litmus test for selection of countries to include in the network. The goal is to

[5] Paragraph 8.3, Grant Agreement between MPP and Afrigen, signed 21 January 2022, https://medicinespatentpool.org/uploads/2022/02/Pages-from-MPP-Afrigen-Grant-Agreement-for-web.pdf

work with countries with a "high maturity", as determined by the GBT, while also working to identify strengths and gaps in weaker countries and building plans to help them improve (WHO, n.d.-a).

In the meantime, Afrigen is looking to work up to Phase 3 clinical trials in terms of the "bolar exemption" in South African law (Tomlinson, 2022). Section 69A of South Africa's Patents Act (RSA, 1978) allows generic manufacturers to use patented products to conduct trials that are reasonable for the purpose of obtaining eventual regulatory approval.[6]

The question of commercialised production, however, will depend on the patent status in each country where the vaccine is intended to be used. According to MPP, and its VaxPal patent database,[7] 17 patent applications connected to the Moderna vaccine (the basis of the hub's vaccine) were filed through WIPO's Patent Cooperation Treaty between 2006 and 2021. Filings of this sort could block competitor products, such as that produced by the hub, through to 2041. Of these 17 patent filings, eight were in South Africa, and four of these South African applications were granted, each valid until 2032 (Tomlinson, 2022).

However, the company's more pressing concerns are around its attempts to begin Phase 3 clinical trials, which have been affected by concerns of efficacy. According to Afrigen CEO Terblanche, the company had to cancel plans to start human trials, after it became apparent that the original version of the Moderna vaccine its own vaccine was modelled on was not as effective as Moderna's updated version (Aizenman, 2023).

It is also important to note that while Moderna has pledged not to enforce its COVID-19-related patents in LMICs and has included the South African mRNA hub in that pledge, Moderna's position is discretionary and unenforceable. Moderna has some lingering patent disputes involving its mRNA vaccine (*Reuters*, 2022). Some of its patented mRNA technology has been called into question by competitors Pfizer and BioNTech in response to a patent lawsuit Moderna filed against these two companies (Brittain, 2022). In their counterclaims, Pfizer and BioNTech argued that three of Moderna's patents laid undue claim to Moderna's contribution to mRNA technology, and that Moderna's pledge to waive its patent claims during the pandemic barred it from bringing the claim in the first place (Brittain, 2022). Moderna has also been sued by two other companies, each questioning Moderna's claims to patent ownership (Brittain, 2022).

This uncertainty around Moderna's COVID-19-related patents presents a significant challenge to the IP-sharing and technology transfer objectives of the South African mRNA vaccine hub. According to a representative of Médecins Sans Frontières, Candice Sehoma, "[t]he patents granted to Moderna related to mRNA vaccines may jeopardise the success of the WHO's mRNA Vaccine Technology Transfer Hub as well as the future of self-reliant vaccine production in South Africa" (Sehoma, quoted in Tomlinson, 2022).

The legal regimes of countries, including South Africa, that make up the spokes of the mRNA hub project may become significant factors in the determination of the degree of expansion that is possible based on the hub's initial second-generation vaccine. With respect to the South African patent regime, Afrigen CEO Terblanche has pointed to the fact that while other countries rejected Moderna's patent claims as being too broad, South Africa's regime is "non-examining", meaning that the filed patents were granted without any scrutiny. Terblanche has expressed the fear that other countries in the hub's network could also grant sweeping patents to Moderna that could block the scalability of the hub's achievements (Tomlinson, 2022).

[6] Section 69A, Patents Act No. 57 of 1978, as last amended by Patents Amendment Act No. 58 of 2002, https://wipolex-res.wipo.int/edocs/lexdocs/laws/en/za/za051en.pdf

[7] Since re-named to MedsPaL: https://www.medspal.org

In response, Afrigen is seeking to develop its own versions of some of the patented elements that are integral to the process of producing its own vaccine. The company has also begun developing a new mRNA vaccine with a focus on efficacy against new COVID strains, while finalising the validation of the efficacy of its current version in primates (Aizenman, 2023). It intends to pass on the information on how to produce that version in larger commercial batches to the partner countries to whom it is transferring technology (Aizenman, 2023). Also, another spoke in the WHO's international mRNA technology transfer network, Brazil's Bio-Manguinhos, a public agency, is seeking to produce an entirely new and original mRNA vaccine, which they also intend to share (Aizenman, 2022a).

Afrigen's Terblanche has expressed a willingness to challenge some of Moderna's South African patents in court. First, however, Terblanche says Afrigen will explore avenues for collaboration (Aizenman, 2022b). Moderna's existing patents in South Africa allow it to lay claim to the production of any mRNA vaccines created in the country, at the point of commercialisation (Jerving, 2022b). But such a claim would go against Moderna's pledge to not ever enforce its COVID-19-related patents in LMICs and in respect of the work of the South African mRNA hub (Jerving, 2022b). Also relevant is the fact that Moderna's mRNA technology developed for the COVID-19 vaccine is intended to serve as a platform for creating similar vaccines for other diseases, and yet Moderna's pledge to not enforce its patent claims is limited to only COVID-19-related patents (Jerving, 2022a).

The WHO has selected 14 countries—Argentina, Brazil, Egypt, Kenya, Nigeria, Senegal, Tunisia, Bangladesh, Indonesia, India, Pakistan, Serbia, South Africa, and Vietnam—to be recipients of mRNA technology transfer from the Afrigen hub, beginning with Argentina and Brazil. As of September 2023, representatives of recipient entities in 13 of these selected countries—all except Kenya—had visited the Afrigen hub to receive technology transfer, and a 15th recipient, Ukraine, had been added (Aizenman, 2023).

V. Future of the hub

The goal of the Afrigen mRNA vaccine hub is to be a long-term resource for not just COVID-19 but also other ailments including cancer, Ebola, tuberculosis, HIV-AIDS, and malaria. With respect to malaria, the hub has entered into a vaccine development partnership with BioNTech (Aizenman, 2023), and the hub also has a partnership with the US National Institute of Allergy and Infectious Diseases (NIAID), overseen by the National Institutes of Health (NIH), to develop mRNA vaccines for COVID-19, Ebola, tuberculosis and malaria (Jerving, 2022b). The NIH entered into this partnership despite helping fund and research the Moderna COVID-19 vaccine. (Moderna's patent filings for the vaccine exclude the NIH (Jerving, 2022b), even though NIH scientists collaborated with Moderna on development of the core sequence (Li et al., 2022).)

The success of its second-generation COVID-19 vaccine will depend to some extent on the Afrigen mRNA hub's ability to scale up to commercial production, via receipt of orders for the vaccine. This challenge of generating orders is of particular concern, when considering the failure of the Aspen COVID-19 vaccine to gain traction and buy-in (Cullinan, 2023b). Based in South Africa, Aspen enjoyed government backing as an "African-friendly" vaccine that only required one dose and it did not require ultra-cold storage (Cullinan, 2023b). However, by the time Aspen was licensed to produce and supply its vaccine, Pfizer and Moderna had significantly increased their production and their vaccines had already been adopted by African countries (Cullinan, 2023b).

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For more information about Open AIR, please visit our website, https://openair.africa, or contact one of our programme managers:
ottawa@openair.africa
capetown@openair.africa

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