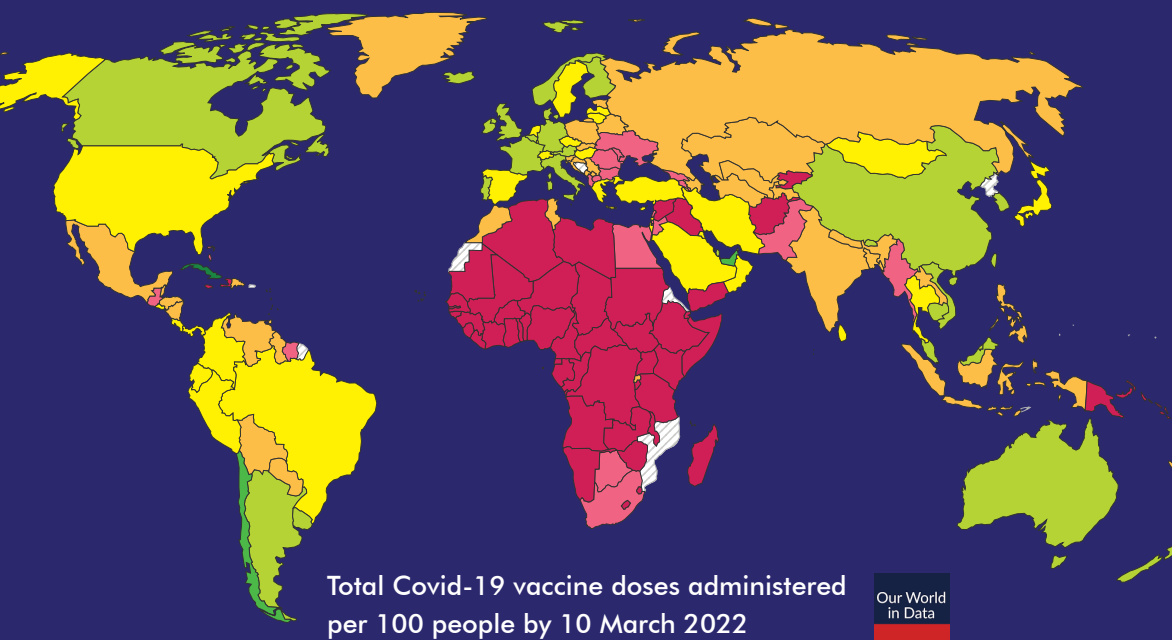


Pandemics and the illumination of “hidden things”

Lessons from South Africa on the global response to Covid-19

B.K. Baker and F. Hassan

Covid-19’s silver lining? The WHO mRNA Technology Transfer Programme for the Global South Overcoming IP Barriers is central to the South-South Innovation and Access Goals of the WHO mRNA Technology Transfer Programme



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Adaption of *World in Data*. Image shows Total Covid-19 vaccine doses administered per 100 people, as of 11 March 2022 (two years since the WHO declared Covid-19 a “pandemic”).

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Covid-19's silver lining? The WHO mRNA Technology Transfer Programme for the Global South Overcoming IP Barriers is central to the South-South Innovation and Access Goals of the WHO mRNA Technology Transfer Programme

**Brook K. Baker
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Background

Despite early warnings, (Kashyap, 2020) (Hassan, 2021) intellectual property protectionism and vaccine nationalism defined the Covid-19 pandemic response (Hassan et al., 2021) resulting in vaccine apartheid. As early as December 2020, activists warned that nine out of 10 people in poor countries were set to miss out on Covid-19 vaccinations. Indeed, as late as April 2023, nearly three-fourths of people in high-income countries were vaccinated whereas only 59% of people in lower- and middle-income countries

had received a first dose (Mathieu, 2023). Vaccination rates in low-income countries were dramatically lower.

Exclusive market control and gross nationalism resulted in more than 18 months of artificially-restricted supplies of essential Covid-19 vaccines and other health technologies, needlessly high prices, breath-taking pandemic profiteering (Allen, 2022) and grossly inequitable global distribution (PVA, 2021).

Existing intellectual property laws and global intellectual property rules (WTO Agreement on TRIPS, 1994) permit companies and vaccine innovators to use patents, data protection, trade secrets, and other intellectual property protections / barriers to exclude competition and to prevent alternative, qualified vaccine manufacturers from offering additional supplies, lower prices, and more equitable distribution (Baker, 2021a) (Hassan, 2020).

Not satisfied with existing prices already many multiples over estimated costs of production, (Public Citizen, 2021) (Kis, 2020) in 2023 Pfizer and Moderna are expected to raise vaccine prices four-fold to US\$110-\$130 per dose for private sector sales in the US as public sector purchases dwindle (Silverman, 2023).

As discussed in earlier chapters here, early on in the pandemic, certain rich country governments, especially the US, invested billions to accelerate and de-risk Covid-19 vaccine research and development, clinical trials, and expanded manufacturing capacity (Global Health Centre, 2021) (Baker & Koons, 2020) (Lalani, 2023). Although these countries could have insisted on technology transfer, fair pricing, and equitable distribution requirements on their public investments, they neglected to do so and instead attached only one condition: Subsidised vaccine manufacturers preferentially supply initial stockpiles of Covid-19 vaccines to them. Other rich countries also hoarded vaccine supplies early in the pandemic via advance purchase agreements. This meant that many people in low and middle-income countries simply waited for Covid-19 vaccines throughout 2021 and beyond. Many low and middle-income countries did not have timely access to a first shot, and while they waited countries such as the US and Europe administered second and in some cases, booster shots to their populations (Johnson et al., 2021) (Mathieu, 2023).

Vaccine innovators expanded their production capacity to a limited extent through partnerships and contract manufacturing agreements (Baker, 2021b) but this was still insufficient to meet global need. Meanwhile, major vaccine producers largely boycotted or undermined voluntary technology sharing/transfer initiatives, including the WHO's Covid-19 Technology Access Pool (C-TAP), the MPP, and the Access to Covid-19 Tools Accelerator (ACT-A), which were meant to increase access to Covid-19 tools such as tests, medicines and vaccines. As a consequence, these firms denied technology transfer requests from multiple qualified producers (Dalberg, 2021).

Paradoxically, the same pharmaceutical representatives that originally scoffed at the idea of allowing voluntary licences to independent vaccine producers later touted industry's alleged commitment to "voluntary measures" in their Berlin Declaration (International Federation of Pharmaceutical Manufacturers & Associations, 2022).

Still, one early response in October 2020 to address the need for meaningful and timely technology transfer was the proposal by the governments of India and SA at the WTO to adopt a temporary waiver of multiple intellectual property rights, such as patents, trade secrets/confidential information, copyright, and industrial design on Covid-19-related medical technologies for the duration of the pandemic. The proposition became commonly known as the "TRIPS Covid-19 waiver" proposal. This proposal was preceded by an important submission by the SA government in July 2020 warning of the dangers of hoarding knowledge and the need to relax international intellectual property rules during the pandemic (Hassan, 2022) (Vawda et al., 2022a) (Vawda et al., 2022b) (Hassan et al., 2022) (HJI, 2022) (Yu, 2023) (Public Citizen, 2022) (SA Government, 2020) (Balasubramaniam, 2020) (Proposal by the African Group et al., 2001) (MSF, 2017).

Pharmaceutical companies and front-runner vaccine manufacturers lambasted the TRIPS Covid-19 waiver proposal and actively lobbied US and European governments to block it (Fang, 2023). Ultimately, developed countries — led by Germany, Switzerland, the UK and the EU — prevented any decision on the

waiver proposal for approximately 20 months, and were enabled to do so by the WTO secretariat. The US initially opposed the waiver but then announced limited support for a vaccine-only approach in May 2021 (Office of the US Trade Representative, 2021).

The WTO membership finally acceded to a highly watered down and ineffectual version of the original proposal, known as the “TRIPS Covid decision” in June 2022, that mainly focused on overcoming a limitation affecting exports to developing countries by means of compulsory licences on patents but does nothing more substantial (WTO, 2022).

The SA government has tried to put a positive spin on the woefully insufficient and defective TRIPS Covid-19 decision. Still, the decision does virtually nothing to expand Covid-19 vaccine access now, though proponents at the WTO continue to try to extend the decision to the more promising areas of access such as diagnostics and therapeutics. Unfortunately, the six-month time period within which to decide on whether to include the latter had been postponed indefinitely at the time of writing (Patnaik, 2022). Simultaneously, the US Trade Representative requested a 10-month study by the US International Trade Commission on whether the US should also support the extension of the decision to include therapeutics and diagnostics too.

Another response — the pandemic’s potential “silver lining” and the subject of this and another companion article in this Compendium — is the establishment of the WHO mRNA Technology Transfer Programme with its “mRNA Hub” in SA and at least 15 country “Spokes”, or local manufacturers in Global South countries (now called “partners”). The Programme (Hub and Spokes) as of January 2023 is shown in Figure 5. (Note: The Programme was initially established on a Hub and Spoke model but is now referred to as a partnership; we will use the original terms only for convenience.)

The mRNA Hub — regarded as a “radical plan” to reduce dependency by the South on the North (Maxmen, 2022) — was established by the WHO in May of 2021 after a year-long unsuccessful effort to convince Moderna, Pfizer/BioNTech, and other pharmaceutical companies to share knowledge and vaccine

technologies in the middle of a devastating global pandemic. It is one of the most important and innovative approaches to reduce dependency on Global North countries that have fuelled gross inequity in global pandemic responses.

Crucially, it has to succeed for the people of Africa, Latin America and the broader Global South to realise the advantages of open science research, and the fruits of scientific progress and its applications. Not surprisingly, companies such as Moderna have not explicitly committed to cooperating with the mRNA Hub. Instead, Moderna’s CEO, Stéphane Bancel, in an interview with the *Financial Times* in 2021 likened the Hub’s work to a “fake luxury handbag” (Smyth et al., 2022).

In addition to setting up the Hub and selecting Spoke partners, the Hub has also begun training of the workforce from several Spoke countries (Brennan, 2022).

mRNA Technology Transfer Hub Programme (“Hub and Spokes”)

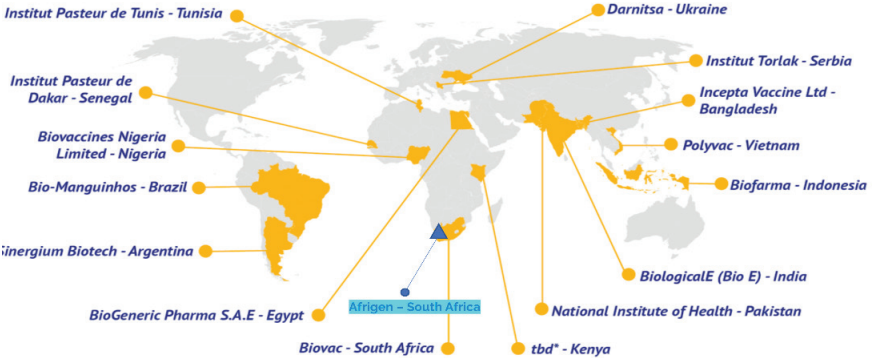


Figure 5: The WHO’s mRNA Technology Transfer Programme is based at its “Hub” in Cape Town, SA but is set to engage in technology transfer with a broad network of other local producers in the Global South or “Spokes” to produce mRNA vaccines.

It should be noted that intellectual property rights still guard Covid-19 mRNA vaccines and many of their components, and their (intellectual property) breadth and duration threaten efforts to develop independent mRNA manufacturing capacity (Li et al., 2022). A database established by the MPP— a Geneva based organisation that facilitates voluntary licences — shows a complex web of patenting by several entities. This includes component and finished product rights holders with many patents in SA, other Spoke countries, and countries that could potentially import future vaccines made by the mRNA Hub and its Spokes (MPP Pool, 2022a). But despite Moderna's intransigence, and at times arrogance, the Hub still has grand ambitions for both innovation and access.

On the innovation front, the mRNA Hub and its Spokes have contractually committed to pursuing improved mRNA vaccines and therapeutics, optimising manufacturing, and adapting mRNA to address unmet health needs, particularly with respect to infectious and other diseases that disproportionately affect their countries, including HIV, TB, malaria, and neglected diseases. The Hub and Spokes have also agreed to share back all such relevant innovations with each other, creating a virtuous circle of reciprocal and wide sharing of the benefits of scientific progress and its applications.

The sharing will not only include patentable inventions but also information and data, and complex, commercial-scale manufacturing know-how. In terms of enhancing equitable access, it is expected that the Hub and Spokes will not only serve their domestic populations with earlier, expanded and more certain sources of supply, but that they will also supply regional and global markets on fair and equitable terms. Unlike the mRNA Hub in SA, certain country Spokes or partners that are led by companies that are 100% state owned (for example, Brazil) are not required to also ensure commercial and for-profit success (they are set up as not for profit). Fiocruz, the lead Brazilian partner, is not only a highly capable R&D and technology transfer centre for Latin America (PAHO, 2021), it is also developing a new self-amplifying RNA (saRNA) technology and is fully committed to sharing its technology with partner organisations and other countries (Aizenman, 2022).

Ultimately, the SA and Brazilian partners could help to

diversify and democratise biopharmaceutical manufacturing in all regions of the world and potentially enable more affordable, reliable, and equitable access to mRNA and saRNA vaccines and therapeutics for this and other pandemics. The Programme could revolutionise the way diseases affecting the poor and vulnerable are researched, especially in the fields of HIV, TB, the deadly childhood illness, Haemophilus influenzae type b and perhaps even cancer.

Preliminary comments about the SA mRNA Hub

Governance

The governance framework of the Programme is slightly unclear, raising questions on the part of civil society recently. The names of the SA mRNA Hub's steering committee were eventually shared in late 2022 by the MPP after civil society raised concerns about the lack of information sharing around key details related to the Programme's general and SA -specific "governance". As of July 2022, the mRNA Hub's steering committee — now and since formally called the Scientific and Technical Review Committee — consisted of:

1. Marie-Paule Kieny - Chair of the Governance Board of the MPP and Chairperson of the Committee
2. Mmboneni Muofhe - Deputy DG at SA Department of Science and Innovation
3. Michel de Wilde - Independent vaccine research and development expert
4. Nicaise Ndembi - Senior Science Advisor at the Africa Centres for Disease Control and Prevention
5. Marion Gruber - Vice President Public Health and Regulatory Science AIDS at the International AIDS Vaccine Initiative
6. Nadia Tornieporth - Professor of Clinical Research and Pharmacovigilance at the Hannover University of Applied Sciences and Arts in Hannover, Germany

According to the MPP , the Committee acts “as the advisory body” for the Programme, on areas such as:

- project directions, including the technology(ies) to pursue the design of the preclinical and clinical evaluation plans as needed for technologies to be developed;
- the regulatory pathway for technologies;
- allocation of flexible funds, and approval of disbursements of funds by the MPP consistent with terms provided in relevant funding agreements; and
- other issues of critical importance to the successful accomplishment of the goals of the mRNA Programme.

It is unclear whether each Spoke country (or other country partners to the Programme) also has a similar steering committee and who serves on those. Similarly opaque is what relationship these bodies, if they exist, have with the mRNA Hub in SA and the above Committee. In other words: Does this Committee make decisions for all the Spoke or partner countries too? If not, who does?

In respect of SA, and the Hub that is based in Cape Town:

- Only one person representing the SA government from the Department of Science and Innovation, is on the Programme’s Scientific and Technical Review Committee. The Programme is effectively run by the MPP and WHO and its main “steering” committee is chaired by a person who is not from the Global South.
- The SA Presidency and the country’s Ministries of Health, Trade, Industry and Competition have no formal representation. In addition, the Department of Science and innovation’s practical and political coordination with the Department Trade, Industry and Competition is unclear.

We are unaware of the details of how the remaining Spoke countries are included in decision-making of the Programme.

So far, there is no elected civil society representation on the Committee. In September 2022, the MPP indicated that a process to select a civil society representative was being developed (Communicated by MPP at 2nd Civil Society Forum: mRNA Technology Transfer Hub Programme, September 2022), but it has not yet been publicised or implemented. Moreover, it is unclear how one permanent civil society representative will fulfil the mandate of representing civil society across approximately 15 diverse countries.

Meanwhile, the “model” mRNA Technology Transfer Spoke Agreement Template and Agreements are now available online (MPP, 2022a). In January 2023, the MPP’s General Counsel reported that 10 Agreements have already been signed and it summarised the Spoke licences as follows: (MPP, 2022a) (note: Brazil has not yet signed this agreement in part because of its competing saRNA technology platform)

1. Freedom to Operate: The MPP and WHO will not guarantee freedom to operate at country level but will provide an intellectual property landscape analysis detailed at country level. The confirmation of actual status and scope of patents / claims filed and/or granted in the country in each Spoke’s responsibility.
2. MPP grant of licence to Spoke:
 - The MPP grants to each Spoke a non-exclusive licence to technology transfer packages to develop and commercialise “products” based on the technology.
 - The MPP agrees to grant to each Spoke non-exclusive rights to data/inventions developed by other Spokes and any other sublicensable rights it obtains through other mRNA Hub agreements (for example, through South African Medical Research Council grantees).

The patent wars: Risks and mitigation

Moderna's obstructionist and misleading conduct

The SA mRNA Hub, and the Spokes and their host countries cannot rely on the goodwill and misleading promises of Moderna to moderate its mRNA IP empire. In a largely cynical offer with illusory benefits, Moderna had promised not to enforce its patents on the Covid-19 mRNA vaccine in low and middle-income countries for the duration of the pandemic (Moderna, 2020). Moderna has subsequently updated its commitment to “equitable access” and publicly affirmed “that its intellectual property will not create a barrier to Covid-19 vaccine distribution ... by Afrigen Biologics”, although subsequent statements have cast doubt on this declaration (Roelf & Steenhuisen, 2022). A non-enforcement pledge on Covid-19 vaccine patents, even if enforceable and non-revocable, will not create a freedom to operate with respect to non-Covid-19 vaccines.

Emphasising the importance it places on its patent rights, Moderna recently sued Pfizer and BioNTech (Moderna, 2022) in the US for patent infringement, showing Moderna's willingness to defend its patents and seek royalties/ financial compensation. Pfizer has responded by countersuing (Brittain, 2022). In addition, to the best of our knowledge, these cases are alongside at least seven other legal cases involving intellectual property claims on the mRNA technology and Moderna, the US government and other US-based biopharmaceutical companies.

Throughout the pandemic, Moderna has steadfastly refused to share underlying, trade-secret protected know-how that is essential to commercially scale production of the vaccine. It does so despite multiple requests from the mRNA Hub, medicine access activists and even the US government (Meyer, 2022) (Malpani & Maitland, 2021) (Baumgaertner, 2021), which had financed most of Moderna's research and development expenses, via the US National Institutes of Health. This funding included the costs of clinical trials and investments in expanded manufacturing capacity.

Moderna and the biopharmaceutical industry, more broadly, have

justified their refusal to share technology developed with public support and with public scientists on spurious grounds, claiming alternately — and inconsistently — that technology transfer was “too hard”. The pharmaceutical industry made these claims even as it transferred technology to favoured contract manufacturing partners. Similarly, it argued that it was “too busy” to conduct technology transfers and that there were “no qualified alternative producers” although researchers identified 120 potential manufacturers (MSF, 2021).

It also claimed without any basis that other producers could not manufacture “quality vaccines” and would “waste and disrupt component supplies and supply chains”. In addition, despite initial decisions to supply only high-income countries almost exclusively, (Robbins, 2021) Moderna, Pfizer and industry trade groups began to vociferously claim that global supplies were “sufficient” and that there was “no need for additional capacity”, despite very delayed and sporadic access to mRNA vaccines in low and middle-income countries (Johnson et al., 2021).

Moderna also revealed its true intentions in calls with investors — basically arguing that the mRNA technology platform was the foundation of its plan to maintain “monopoly control” over future applications of mRNA technology to develop vaccines and treatments for other conditions, including “gold-mine” cancer medicines.

Although this discussion has focused on Moderna, this is equally applicable with respect to Pfizer and BioNTech.

Moderna’s refusal to license or share its technical knowledge and manufacturing know-how with the SA mRNA Hub and others has necessitated a much longer timeline for the SA mRNA Hub to independently develop its own technical and manufacturing know-how, which it plans to share on an incremental basis with its partners, thereby accelerating their capacity to bring identical mRNA products to the market.

Steps needed to extend freedom to operate and to create viable export/import markets

The SA Hub is currently working with the initial freedom to operate to research, develop, and register a clone of Moderna's mRNA Covid-19 vaccine under SA's so-called Bolar or early working exception to patent protections. This exception contained in section 69A(1) of the Patents Act allows SA scientists to work with and on the patented product to produce quantities for clinical trials, to continue to work to independently develop commercial scale manufacturing processes and know-how to satisfy Good Manufacturing Practices requirements, and thereafter to file for regulatory approval in SA and other countries.

Still, the SA mRNA Hub's ability to actually research and market non-Covid-19 vaccines or future therapeutics may be highly constrained by existing intellectual property protections.

Even the ability of the SA mRNA Hub to sell a new or improved heat-stable Covid-19 vaccine might be constrained if Moderna does not formalise its verbal offer not to enforce its patents. Likewise, the mRNA Hub's work would be jeopardised if Moderna revokes the same pledge although we would argue that it can no longer unilaterally withdraw this offer given its public statements (Contreras, 2022) including submissions made in its legal papers in its recent claim against Pfizer in the US courts (*Moderna v Pfizer Inc, BioNTech, 2022*). In paragraph 23 of Moderna's Complaint for Patent Infringement, the company references the WHO's COVAX initiative that sought to guarantee access particularly to the world's poorest 92 countries, writing:

Critically, however, and to further its belief that intellectual property should never be a barrier to access, as part of this announcement, Moderna committed to never enforce its patents for any Covid-19 vaccine used in the 92 low and middle-income countries in the GAVI COVAX Advance Market Commitment ("AMC"). **This includes any product manufactured outside the AMC-92 countries, such as the WHO's project in SA, with respect to Covid-19 vaccines destined**

for and used in the AMC-92 countries. Although they have continued to use Moderna’s intellectual property, Pfizer and BioNTech have not reached out to Moderna to discuss a license..... (Emphasis added).

Not only will the mRNA Hub in SA potentially be constrained, but other countries might be limited as well by their own domestic patent laws and Moderna’s global patent landscape. We say this because Moderna has filed and is expected to continue to file mRNA-related patent applications in multiple low and middle-income countries, especially those with manufacturing capacity. Admittedly, it has not filed its basic mRNA Covid-19 vaccine patent in all the countries that are part of the Programme, nor has its broader underlying mRNA technology patent application been widely filed or granted in countries, although this broader patent has regrettably already been granted in SA (without patent examination). (As a bit of good news, the saRNA vaccine technology being developed by Fiocruz might “work around” Moderna’s patents and thus have more freedom to operate.)

Nonetheless, Moderna has already indicated intentions to research and develop mRNA vaccines for multiple other conditions, including cancer, cardiovascular and respiratory infectious diseases (Tong, 2022) — as have other mRNA vaccine originators. It is inconceivable that Moderna will not seek extensive patent protection for those new products.

Moderna is also initiating plans to develop its own regional manufacturing capacity that might “compete” with the Programme. Moderna has already entered into “sweetheart” deals in several countries — including Kenya — whereby it has promised governments that if they co-invest in the facility, Moderna will in turn preferentially supply the host country (Moderna, 2023). And here, of course, Moderna will continue to control the quantity and price of what it produces.

On the other hand, whilst aware of the full extent of Moderna's conduct and actions, the SA government has regrettably not shared its plan to protect the mRNA Hub in SA through legislative and executive action, which the Constitution of SA — we argue — would permit and indeed require. The SA government's inaction comes despite health justice and activist groups requesting that it intervenes.

This absence of clear planning could be the net result of the SA government — from the Presidency to key government ministries and departments — not being central in the design and decision-making of the Programme itself. Alternatively, and even worse, the SA government may not have the political will to stand up to Moderna and other right holders or to the rich countries that support them nor the funders of the Programme (ironically, most of the European funders to the Programme blocked SA's request for the TRIPS waiver - see above). SA officials may also be deterred by the potential backlash as embodied by trade threats that have materialised in the past with respect to efforts to increase access to life-saving medicines (Fisher & Rigamonti, 2005).

This is a worrying and immediate risk because recently, the MPP stated that while it designed and set up the mRNA Hub and Spokes (the Programme) in multiple countries: the “MPP and WHO will not guarantee FTO (freedom to operate) at country level but will provide an IP landscape analysis detailed at country level. The confirmation of actual status and scope of patents/claims filed and/or granted in the country *is each Spoke's 'responsibility'*” (emphasis added) (MPP, 2023).

This means that the SA government — here the Department of Trade, Industry and Competition — is in receipt of such an intellectual property landscape (discussed above and below) and knows full well the risks for the mRNA Hub from an intellectual property point of view. Still, to date, the department has been unable to or been unwilling to take any executive action against Moderna and others to actually protect the mRNA Hub's work.

We ask: Is it simply awaiting the forbearance and benevolence of Moderna?

During December 2022 the HJI requested the Minister of

Department of Trade, Industry and Competition in SA to provide any details about how it plans to protect the mRNA Hub (executive action). The Ministry provided a vague and non-committal response.

This clarification of individual country responsibility ultimately to assure freedom to operate (to override patent barriers) means that if countries where the Partners are located are unable — or are unwilling — to take the necessary steps to safeguard the freedom to operate, then the promise of the model may be compromised with resulting negative impacts on mRNA vaccine supply, price, and availability.

Under these circumstances, government action will be required in each place as follows:

- Each country with blocking patents will need to muster the political will to issue compulsory or government use licences on pending or granted component, process, and product patents to ensure freedom to operate.
- Host countries might also need to issue compulsory licences that permit export of finished mRNA products to other countries.
- Governments, including SA, must promptly amend their patent laws to allow mandatory or presumptive compulsory licences on key biopharmaceutical products, processes, and manufacturing components. Such reform should not be limited to mRNA products only, though those products may be key to global health in the future.
- In order to guarantee freedom to export/import and to expand markets so as to achieve economies of scale, importing countries facing patent barriers might also need to grant compulsory licences to mRNA Hub and Spoke producers.
- Because countries often face intense pressure from high-income countries and Big Pharma when they act unilaterally, it would be preferable for SA, with the partner countries and other low and middle-income countries to issue compulsory licences on a co-ordinated basis in order to aggregate a viable market for the Programme.

A key question for the Programme being “successful” is: Who ultimately will control the intellectual property and will countries be willing to adopt and use compulsory and government use

licences and limited exceptions on patents, data protections, and trade secrets? Will innovations be declared global public goods and be shared beyond the mRNA Hub's formal Spoke partners, and who will make decisions about technology sharing beyond the mRNA Hub and Spokes?

These decisions are complicated by the fact that not all the Spokes nor the SA mRNA Hub have 100% state-owned partners — they largely have commercial partners. For SA for example: Local firms and Hub partners Afrigen and Biovac are not 100% state-owned although publicly funded universities and a statutory research body, the South African Medical Research Council, are also involved in the product research phase. It should be noted that while the list of Hub and Spoke partners is publicly available, the respective percentage of state ownership for each entity in the Hub and in Spoke countries, if applicable, is not yet known (MPP, 2022b).

The mRNA Hub's technology transfer / sharing licences

At present, the now public mRNA Technology Transfer Spoke Agreement Template only has one firm access-performance requirement for the Spokes, although it does impose quality assurance and regulatory requirements. Pursuant to paragraph 4.5, in the event of a public health emergency of international concern, mRNA Hubs are obligated to supply 10% of their output to the WHO or public sector agencies at cost-of-manufacture plus 20%. However, there are no direct requirements concerning fair pricing for the remaining 90% of production and no requirement to distribute equitably to other countries.

There will be distributed manufacturing and perhaps an expectation of more affordable pricing and equitable distribution, but there are no contract terms to that effect. Instead, in the case of SA, Afrigen with others have focused on trying to achieve market entry and sustainability by having diversified product lines beyond mRNA vaccines and therapeutics, and by entering into advance agreements with governments and entities such as GAVI and UNICEF to guarantee that the mRNA Hub and its Spokes will

become preferred suppliers (GAVI, 2022). These efforts to ensure commercial sustainability make sense for profit-dependent private enterprises — and maybe for industrial policy, but deference to the logic of private markets also risks compromising some of the potential access goals of the mRNA Hub to help ensure adequate supplies, affordable prices, and equitable distribution.

Specific steps needed in SA

The WTO TRIPS decision has not been domesticated in SA nor has the fully drafted Amended Patents Act (enacting many of the long-promised TRIPS-flexibility patent law reforms) been tabled in the Parliament of SA as promised by the Minister of Trade, Industry and Competition, Ebrahim Patel, who is in charge of this portfolio. These long-awaited patent law reforms in SA could have benefited the mRNA Hub if adopted sooner but nevertheless, still could — if passed in the near future. If these reforms are undertaken, they would:

- help avoid future unwarranted patents being granted (by requiring patent examination pursuant to stringent eligibility and disclosure requirements and pre- and post-grant opposition procedures); and
- expand the grounds and simplify processes for the issuance of compulsory and government-use licences.

This is important because in 2021 several broad patents on mRNA technology platforms were granted to Moderna by SA's Companies and Intellectual Property Commission without any substantive patent examination and without any opportunity for pre-grant opposition, including to the best of our knowledge: ZA 201403783 B, ZA 201303161 B, ZA 201403666 B (div of ZA 2013/03161), ZA 201402547 B. These patents were not examined for compliance with SA's patentability criteria, and organisations and groups acting in the public interest were precluded from opposing the patents before they were granted, as is the case with all patent applications currently. Similar patents have been rejected in other countries or withdrawn by Moderna's representatives there.

In addition to domesticating the WTO TRIPS decision and amending the Patent Act, the SA government will need to take concrete steps to file for compulsory licences as needed to overcome

present and future patent barriers to existing and emerging mRNA vaccines and therapeutics. Showing a determination to act may provoke reluctant acquiescence by Moderna and others, but if not, actual compulsory licences must be pursued.

Conclusion

The mRNA Hub's decision to develop its own commercial manufacturing and quality control know-how overcomes the trade-secret/know-how barriers. Still, the mRNA Hub, its Spokes, and the countries they will seek to supply will continue to face patent barriers that must also be overcome. SA and other low and middle-income manufacturing countries and importers must consider coordinated compulsory licensing campaigns to create sustainable markets for mRNA vaccines and medicines — especially for conditions other than Covid-19.

Moderna and other transnational biopharmaceutical companies in the mRNA space are expected to patent new uses of mRNA vaccines and therapeutics broadly and to resist voluntary licensing. In light of this, SA and other low and middle-income countries will have to resort to so-called involuntary measures to create the freedom to operate for manufacture and for export/import. The long-delayed SA patent law reform would go a long way to clear the path for needed compulsory licences in SA, but Spoke countries may also need similar reform. It is important to emphasise, however, patent barriers in import market countries will also need to be overcome to aggregate viable and sustainable markets for new mRNA vaccine manufacturers.

The SA government and especially the Department of Trade, Industry and Competition, Department of Science and Technology, the Presidency, the mRNA Hub and its partners — particularly the WHO and MPP — cannot continue to act as if intellectual property barriers are not real. When the mRNA Hub was conceptualised and set up in SA — in assessing the patent and legal landscape — they should have anticipated that they also need to prepare for overcoming these real intellectual property barriers even as they advanced this exemplary experiment in South-South collaboration to make mRNA vaccines and therapeutics global public goods.

Political, legislative, and executive inaction now will contribute to challenges down the road and potentially undermine the mRNA Hub's work. It is a huge risk for the SA government not to act promptly when for over two years the President of SA especially, on behalf of Africa, advocated for the lifting of intellectual property rules in the Covid-19 pandemic and championed vaccine equity calling for more and especially South- South cooperation (Fabricius, 2022).

The pandemic has clearly shown that the “benevolence” of Big Pharma is a misnomer, and that the potentially unenforceable pledges or charity of Moderna or any other pharmaceutical company is a ruse that cannot be relied upon. It behoves the Global South to act now, and act decisively, starting with the SA government and the multiple partners to the mRNA Hub based in SA. It is certain that vibrant civil society campaigns can and should be undertaken to convince governments hosting the mRNA Technology Transfer Programme to engage in domestic and co-ordinated action to ensure its success.

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