25

Intellectual property barriers to access to COVID-19 health products in South Africa

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While South Africa has shown admirable leadership at the World Trade Organization, the government has stalled on tabling amendments to the Patents Act 57 of 1978 that would facilitate improved access to vaccines and other health products.

The COVID-19 pandemic has exposed the fragility of local, regional and global health systems and their inability to meet their populations' health needs. South Africa also experienced severe shortages of health technologies, attributable to a lack of institutional capacity, corruption in supply chain management and procurement, inadequacy of local manufacturing capacity, and intellectual property barriers.

This chapter analyses the extent to which intellectual property barriers have impeded the availability, affordability and accessibility of health products, especially vaccines, needed to avert COVID-19 infection. Global initiatives to improve access, such as the COVID-19 Vaccines Global Access facility, the COVID-19 Technology Access Pool, and the waiver of intellectual property rights proposed at the World Trade Organization by South Africa and India, are appraised. A situational analysis of the relevant health product landscape, is also provided. The two-year delay in tabling a Bill to amend the Patents Act, and the limited use of legal flexibilities to circumvent patent and other barriers, are examined.

South Africa experienced significant shortages of diagnostics, personal protective equipment and other products; the country's vaccine acquisition programme lacked urgency; intellectual property rights holders were unable to meet demand for vaccines and their failure to implement technology transfer prevented any prospect of scale-up or local production; and government has stalled on its commitment to patent law reform.

It is recommended that the government urgently give attention to, among others: accelerating its vaccine acquisition and administration; addressing the severely strained health infrastructure; eliminating corruption in procurement contracts and the distribution of supplies; and tabling of a Bill to reform patent legislation.

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Introduction

On 30 January 2020, the Director-General of the World Health Organization (WHO) declared the disease caused by the novel coronavirus (COVID-19) a public health emergency of international concern (PHEIC)[1] – the WHO's highest level of alarm, requiring a commensurate global response. The pandemic has exposed the fragility of health systems and their inability to meet the health needs of populations globally.

South Africa has also experienced severe shortages of personal protective equipment (PPE), *in vitro* diagnostics (IVDs), ventilators, and other medical supplies. Several factors account for this: a lack of institutional capacity, corruption in supply chain management and procurement, inadequate local manufacturing capacity, and the stranglehold of intellectual property (IP) rights (patents, copyright, industrial designs, and trade secrets).

This chapter analyses the extent to which IP barriers have impeded, and continue to impede, the availability, affordability and accessibility of health products for an effective response to the pandemic. An appraisal of some of the global, regional and national initiatives to improve access to health technologies is offered. A situational analysis explores the obstacles to equitable access to health technologies in South Africa, and assesses progress on domestic law reform initiatives.

Global architecture of IP

All inventions, including medicines and medical devices, are protected by patents, a form of intellectual property which gives the inventor the right to exclude others from making or marketing the product for a time-limited period. Before the adoption of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement,[2] countries could fashion their own patent systems by determining whether to grant patents for particular technologies, and the duration of any patent. The TRIPS Agreement established uniformity of rules, such as a minimum 20 years of patent protection for all inventions, including medicines. Such strong protections create monopolies – where a single supplier is free to set any price that the market will bear, in the absence of competition. This enables exorbitant pricing of newer medicines, and of those still under patent. The high prices demanded for antiretroviral drugs only began to drop after the entry of generic competition.[3] IP continues to act as a barrier to accessing health technologies for a variety of conditions.[4]

An intention of the TRIPS Agreement, per Article 7, is to promote knowledge sharing and technology transfer "in a manner conducive to social and economic welfare". However, TRIPS has been criticised for introducing an unbalanced and inefficient IP system[5] that impedes neglected populations' access to essential medicines, and undermines the transfer of scientific knowledge, medical innovations and technologies to the global south. It precludes developing states from using the IP frameworks and practices that were essential to securing economic development in the global north, thus perpetuating a historical injustice.[6] It prioritises private property protection over improving the baseline level of welfare of vulnerable populations in the global south, with research and development (R&D) being directed towards profitable medicines rather than those benefitting vulnerable populations. This imposes an unjust benefit tax on people needing medicines. Joseph Stiglitz states: "It is bad enough that a person has a heart problem, but then to say because someone has a heart problem [they] should also have to pay for heart research is imposing a double penalty".[5]

Significant scholarly work has proposed alternative funding and incentive mechanisms to the IP system as a better means of balancing the rights of inventors to just rewards with the human right to health and to share in the benefits of scientific progress. They include public rather than private ownership of knowledge; awarding prizes rather than patents for medical innovations; and implementing flexible compulsory licensing systems.[7,8,9]

Access advocates have argued for a legally binding R&D convention that addresses the adverse public health impacts of the TRIPS framework more systematically. The recommendations of the UN Secretary General's High-Level Panel on Access to Medicines[10] specifies the kind of IP reforms such a covenant should contain. However, these recommendations have been ignored in high-level policy discussions, including a recent World Health Assembly Resolution on local production.[11]

The reliance on the use of TRIPS flexibilities (which countries can adopt in their national laws) has proven to be futile. Evidence over three decades confirms how complicated this path is for low- and middle-income countries (LMICs), despite the 2001 Doha Declaration on TRIPS and Public Health.[12]

LMICs have been subjected to adverse political and economic pressure when seeking to use compulsory licensing[13] and prevented from doing so by trade agreements that contain even more onerous patent protections than TRIPS. They may lack capacity to institutionalise and enforce these flexibilities speedily, or be subject to competing national, regional and global IP frameworks.[14]

Challenges to an adequate COVID-19 response in South Africa

A November 2020 rapid situational analysis examined barriers and enablers in equitable access to COVID-19 health technologies in South Africa.[15] It included a documentary review and in-depth interviews with government agencies involved in the country's COVID-19 response, civil society and academic stakeholders. The findings highlighted key limitations of the regulatory and financing frameworks, institutional capacity for local manufacturing, and domestic research activities impacting health technology access.

Diagnostics

Shortages of diagnostic kits (reagents, consumables, and cartridges) severely hampered timeous COVID-19 testing scale-up in South Africa during 2020.[16] Despite investing in platform technologies for rapid diagnostic testing for tuberculosis (TB) and HIV, the National Health Laboratory Service (NHLS) was unable to access adequate quantities of COVID-19 test-kits for testing at scale.[15] A combination of patents, trade secrets, and test-kit customisation meant that only the proprietor's test-kits could be used on the testing platforms, preventing rapid testing scale-up. IP holders were unwilling to share know-how, relinquish IP, or grant licences to allow other manufacturers into the market.[17]

Some of these challenges were mitigated by investing in open-source machines that use test-kits manufactured by multiple suppliers and laboratories.[18] The Council for Scientific and Industrial Research (CSIR), jointly developed a molecular test -kit for use on open platforms with a local company, CapeBio.[19]

Ventilators

At the start of the COVID-19 pandemic, South Africa faced significant shortages of the means to provide oxygen therapy needed for severe COVID-19 disease. In April 2020, the National Department of Health (NDoH) reported that only 3 216 ventilators were available nationally, two-thirds of which were located in private health facilities.[20] The Department of Trade, Industry and Competition launched the National Ventilator Project for local manufacturing of 20 000 non-invasive continuous positive airway pressure (CPAP) devices.[21] The availability of open-source designs allowed for local manufacture, enabling scale-up of this critical non-invasive ventilatory support equipment.[15]

Personal protective equipment (PPE)

Hoarding of PPE by high-income countries (HICs) resulted in global shortages[22], exacerbated by uncertainty regarding the regulatory requirements for importing, manufacturing, and marketing of PPE in South Africa. These regulatory requirements initially blocked many local manufacturers from the market.[23]

Decentralisation of PPE procurement by the National Treasury, and the relaxation of procurement rules, resulted in widespread procurement corruption and enabled the importation of substandard products.[24] These factors endangered the lives of healthcare workers, triggering labour action and negatively impacting health service delivery.[25,26]

The South African Health Products Regulatory Authority (SAHPRA) eventually licensed multiple local PPE manufacturers whose processes, products and capacity met quality requirements. SAHPRA maintains that the delays were due, in part, to the submission of incomplete applications.[15]

Vaccines

The South African government had to negotiate four barriers to equitable access to COVID-19 vaccines: global supply shortages, securing financing for procurement, infrastructure weaknesses, and inadequate human resources for health. The decision-making around vaccine procurement and roll-out has been opaque. The for-profit private sector has apparently had a disproportionate influence in these processes compared to civil society. Additionally, the vaccine roll-out, primarily funded by the public fiscus, may be affected by significant cuts to the public health budget.[27,28]

The South African government has committed to making vaccines available free of charge[31] for both citizens and non-citizens.[29] Given the limited options for acquiring vaccines through multilateral mechanisms, the government has engaged in bilateral negotiations with vaccine producers. At the time of writing, it had entered into bilateral deals with AstraZeneca (AZ)/Serum Institute of India (SII) (since withdrawn), Janssen (J&J) and Pfizer – as well as via COVAX and the African Vaccines Acquisition Task Team (AVATT).

When administration of the AZ vaccine was suspended following evidence suggesting poor efficacy against the COVID B.1.351 (Beta) variant, the South African Medical Research Council (SAMRC) embarked on the Sisonke phase 3b implementation study, enabling vaccination of healthcare workers, using clinical trial stock of the J&J vaccine, with SAHPRA approval. For the national roll-out, the NDoH has since procured 31 million doses of the J&J vaccine.[30] The J&J vaccine is administered as a single dose, can be stored at temperatures of between 2-8 degrees Celsius and is best suited to resource-poor settings. In addition, 30 million doses of the Pfizer/BioNTech vaccine have been procured, with more challenging logistical demands (a two-dose regimen and ultra-low temperature storage). This represents a significant improvement on the situation in December 2020, when only 6 million doses had been secured via COVAX.

Reasons for the delay in the national roll-out to the general population included delays in the NDoH securing deals with producers, and a reluctance to commit to procurement in the absence of evidence of efficacy and safety. About 65% of the vaccine doses procured by the NDoH have been via bilateral engagements with vaccine producers, and smaller quantities accessed via AVATT and COVAX.[31]

The financing of South Africa's vaccination efforts remains opaque. The Solidarity Fund (Fund) was launched with pledges amounting to R1 billion.[32] The Fund made a pre-payment of R283 million to COVAX in December 2020[33,34] and contributed R50 million towards the Sisonke study in early 2021.[35] The Fund reported that it would fund "technical assistance to National and Provincial Departments and related human resource capacitation" aimed at promoting the efficacy of the roll-out.[38] A vaccine task team based on a co-funding model between government and medical schemes was established in January 2021 to co-ordinate private sector vaccine financing, as well as procurement, logistics and administration.[36] However, civil society organisations and activists with expertise in advocacy for equitable and affordable access, despite being vocal about corruption and the lack of transparency during the pandemic, are not represented on this structure.

The national fiscus is the primary source of financing for vaccine procurement. In February 2021, the National Treasury announced that R9 billion had been allocated for vaccine roll-out, R6.5 billion of which would be reserved for procurement and distribution of vaccines (in addition to an earlier allocation of R1.3 billion for 2021). An additional R9 billion could be drawn from contingency reserve and emergency allocations. The National Treasury has also allocated R100 million to the SAMRC to be used for 'vaccine research'.[31] Government has described the mass COVID-19 vaccination roll-out as a vertical intervention that will rely on collaboration with the private sector for its success.

Procurement by private entities[37], which would have enabled inequality in access to vaccines with those enjoying access to the private sector being vaccinated ahead of others equally in medical need, has been mooted. Most medical schemes, however, have supported both government's phased approach to vaccination roll-out as well as government's role as sole procurer of the vaccine.[38]

Health system challenges

Equitable access to COVID-19 vaccines has also been impacted by the long-standing under-investment in the physical infrastructure and human resources of the public health system.[39]

Government's stewardship of the vaccine roll-out is consistent with its human rights obligations under the Constitution and the International Covenant on Economic, Social and Cultural Rights (ICESCR) to take reasonable measures to ensure access to healthcare services[40] and to the enjoyment of the benefits of scientific progress without discrimination.[41] The hoarding of vaccines by HICs – 'vaccine nationalism' – is both a violation of the right to enjoy the benefits of scientific progress and the right to health. HICs have extraterritorial obligations[42] to avoid actions that prevent other countries from fulfilling their rights obligations.

These right-to-health commitments are, to some extent, undermined by the R67.2 billion budget cut in public health spending over the next three years, despite the dire need to upgrade healthcare infrastructure to ensure that routine services can be delivered in a dignified manner, particularly in South Africa's poorest provinces.[43–45] Public health budgets are also eroded by unauthorised and irregular expenditures, medico-legal claims from patients harmed by negligence,[46] and poor management. There is also a long-standing shortage of health workers. According to a recent NDoH report, an additional 97 000 health workers will be needed by 2025 to ensure greater health equity, a third of which will be Community Health Workers (CHWs).[47] Despite the additional staffing required for the vaccine roll-out, and the harrowing toll that COVID-19 has taken on health workers[48], government has not indicated any increased financing for health workers' posts, or committed to improving the working conditions of CHWs operating under precarious short-term contracts. Nurses have been threatened with wage freezes, and some financing sources for nursing qualifications have been discontinued.[49] Doctors in Limpopo have threatened industrial action in response to alterations in their service conditions resulting from austerity measures.[50]

Impact of IP protection on the COVID-19 response

Transnational manufacturers holding IP rights maintained tight control of their health-related technology and know-how, which prevented expansion of the pool of suppliers.[51] The declaration of the PHEIC did not supersede the application of IP law. Pharmaceutical companies justify patent monopolies by arguing the need to recover their investment in R&D of new medicines. Although R&D for a new medicine has been claimed to be in the region of US$ 2.6 billion[52], this figure is strongly disputed, as it includes lost 'opportunity' costs, and does not take into account the substantial public funding invested in early research. There is a complete lack of transparency about the actual costs incurred.[53] Even if industry claims were justified, excessive pricing during a pandemic is an egregious abuse of a dominant market position. HICs have provided substantial financial investment in the initial research, with public funding in the region of €86.5 billion (R1.65 trillion) in the development of, and advance market commitments to purchase, COVID-19 vaccines.[54]

Most manufacturers of COVID-19 vaccines are expected to reap considerable profits from vaccine sales. Moderna's advance purchase agreements are worth US$18.4 billion for 2021.[55] The bulk of these will be supplied to HICs, and there is no consideration of equitable access.

The risks associated with new products are routinely passed on to consumers and purchasing countries. Pfizer threatened to withhold its vaccine from several

South American countries unless their sovereign assets, such as embassy buildings and military bases, were pledged as guarantees.[56] In addition, all vaccine manufacturers have required governments to provide no-fault compensation cover for adverse events, including those resulting from negligence or fraud. While a number of HICs have had such schemes, they do not yet exist in LMICs.[57,58] The WHO has established such a scheme only for the countries eligible for donor-funded COVID-19 vaccines, thus excluding South Africa.[59] In April 2021, South Africa published Regulations for such a no-fault compensation scheme.[60]

Global responses to the demand for equitable access

The COVID-19 pandemic has spurred an extensive global response, drawing in multilateral organisations, philanthropic donors and innovative health financing entities. The Access to COVID-19 Tools Accelerator (ACT-A) aims "to speed up an end to the pandemic by supporting the development and equitable distribution of the tests, treatments and vaccines the world needs to reduce mortality and severe disease".[61] The ACT-A is organised in four pillars: diagnostics, treatment, vaccines and health system strengthening, with an overall budget estimated at US$38.1 billion. It has secured US$11.0 billion from donors, less than 30% of its budget, leaving a funding gap of US$22.1 billion for 2021 alone.[62]

The vaccines pillar created the COVAX mechanism, combining domestic financing from HICs and upper middle-income countries (UMICs) with donor-supported financing through the COVAX Advance Market Commitment (AMC) for COVID-19 vaccines for countries eligible for such support. However, UMICs and HICs are not precluded from concluding bilateral agreements with individual vaccine manufacturers, and have so far procured the bulk of available supplies of vaccines, up to three times their requirements. While COVAX has enabled limited access for the AMC recipient countries, it has failed to ensure equitable access to vaccines, in the context of supply constraints. 'Vaccine nationalism'[63] affects the world's poorest countries but has a wider 'knock-on effect' which will prolong the pandemic. It is estimated that "the global economy could lose US$9.2 trillion if developing countries are left behind in the vaccine roll-out".[72]

In cognisance of the potential impact of IP protection on access, the COVID-19 Technology Access Pool (C-TAP) was launched in May 2020 by the WHO, in partnership with the Government of Costa Rica and 40 other countries.[64] C-TAP was meant to build on existing mechanisms to pool IP and other forms of knowledge, clinical data and know-how – working closely with the Medicines Patent Pool and others.[65] C-TAP has failed to attract the needed support from either the health technology industry or major producing countries.[66] This is particularly grievous, given the failure of COVAX to ensure equitable access, and the evident success and broad applicability of the Medicines Patent Pool.[67]

Waiver proposal at the WTO

In October 2020, India and South Africa tabled a proposal at the World Trade Organization (WTO) for the "waiver from the implementation, application and enforcement of Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement in relation to prevention, containment or treatment of COVID-19" (waiver proposal).[68] Such a waiver, which has the support of over 100 member countries, is permitted under WTO rules.[69] HIC delegations have opposed the proposal by resorting to filibustering at the TRIPS Council – repeatedly asking for clarifications on and examples of the abuse of existing IP rights, and refusing to engage with the very detailed and compelling responses provided by the sponsors of the proposal.

While the WHO Director-General has endorsed the waiver proposal, the new WTO Director-General, Dr Ngozi Okonjo-Iweala, has given only qualified support.[70]

Despite a series of both formal and informal meetings of the TRIPS Council, consensus on the waiver proposal remains elusive. The support of the Biden administration for a waiver on vaccines in May 2021 may signal some progress.[71] The proposers have revised their original resolution text to address concerns about the scope and duration of the waiver. Text-based negotiations are expected to take place during 2021.[72]

Local production in South Africa

Limited production capacity in Africa is a major barrier to the scale-up of COVID-19 vaccine supply, exacerbated by export restrictions by producing countries. Ten vaccine manufacturers are located in South Africa, Morocco, Tunisia, Egypt and Senegal.[73] These facilities compound, fill, finish, label and package, rather than manufacture vaccine components. Vaccines which have received regulatory approval are novel technologies, such as mRNA vaccines, adenovirus-vectored vaccines, and protein subunit vaccines, instead of traditional inactivated virus vaccines. In South Africa, Biovac (a public-private partnership) has historically focused on procurement and distribution of vaccines. Aspen Pharmacare has the capacity to compound, fill, finish and package vaccines, and is expected to be a major source of the J&J vaccine.[74] Biovac announced a collaboration with a US-based company to manufacture a second-generation COVID-19 vaccine, undergoing phase 1 clinical trials in South Africa and the US.[75] Recently, Biovac has reached agreement with Pfizer-BioNTech to produce their mRNA vaccine, essentially a fill-and-finish operation expected to deliver more than 100 million doses annually to African countries.[76]

Financing remains a major barrier to the development of production capacity, estimated by Biovac's Chief Executive Officer to cost up to R8.9 billion.[77]

Paralysis on patent amendments, tardiness on transparency and vaccines rollout

While South Africa has shown admirable leadership at the WTO, a lack of political will is evident domestically. The government has stalled on tabling amendments to the Patents Act 57 of 1978 that would facilitate improved access to vaccines and other health products. Cabinet approved a new policy in 2018[78], but no draft Bill has been forthcoming. The policy takes a balanced approach to IP, protecting both the rights of IP holders and the public interest, rooted in the South African Constitution.[79] It recommends the introduction of substantive examination of pharmaceutical patents, as well as the utilisation of flexibilities to ease access, such as strict patentability standards to eliminate patenting of new formulations and new uses of known compounds, and a streamlined and effective compulsory licensing provision.

There are concerns that the government has mismanaged the vaccine procurement process, delaying commitment to the COVAX facility and procurement through bilateral deals. By mid-July 2021, South Africa had managed to deliver just over 5 million vaccine doses.[80] By the end of August, the total exceeded 11 million doses, with approximately 4 million adults fully vaccinated. By contrast, Morocco, with a population of approximately 37 million and ranked lower than South Africa on the Human Development Index[81], had already vaccinated 5.6 million people (or 15%) by March 2021.[83]

Furthermore, there has been a lack of transparency on the terms being negotiated with manufacturers. This has undermined public confidence in the government, potentially contributing to vaccine hesitancy.[82]

Conclusions

While the supply shortages have been due primarily to extraneous factors such as vaccine nationalism and the refusal of patent-holders to share their technology in order to scale up the supply of diagnostics, vaccines and other health products, the government's performance has also been found to be wanting. It is recommended that the government urgently give attention to, among others, the following areas: accelerating its vaccine acquisition and administration; addressing the severely strained health infrastructure; eliminating corruption in procurement contracts and the distribution of supplies; and tabling of a Bill to reform the patent legislation.

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