



## **Removing intellectual-property barriers from COVID-19 vaccines and treatments for people in South Africa**

Intellectual property (IP) barriers can undermine access to medicines. The COVID-19 pandemic provides a stark example, with limited access to COVID-19 medical tools like vaccines and treatments in South Africa due in part to IP barriers. This briefing paper highlights the present and emerging IP barriers for COVID-19 vaccines and treatments, and provides an analysis of policy and legal changes that are required to address them in the South African context and beyond. These include reforms of South Africa’s national patent laws, use of compulsory licenses, revocation of lapsed and unmerited patents, and rejection of patents related to COVID-19 medical tools. At the global level, the South African government together with the Indian government, has taken the lead in proposing a waiver from certain IP rules at the World Trade Organization (WTO), and all countries should support this proposal. In addition, patent-holding companies should refrain from seeking or enforcing patents in South Africa on COVID-19 medical tools and should share their technologies to enable increased manufacturing and greater access.

### **IP barriers impact access to COVID-19 medical tools**

The concentration of IP on lifesaving health technologies in the hands of powerful multinational pharmaceutical corporations contributes to many low- and middle-income countries (LMICs) being subjected to a charity- and monopoly-based model. They are left to rely primarily on donations and importation of medical tools – which are usually insufficient for the needs for their populations – instead of being self-reliant in production and supply. Present and emerging evidence<sup>1</sup> suggests that a monopoly-based model of developing, producing and supplying lifesaving medicines poses a critical structural barrier contributing to inequity in accessing COVID-19 medical tools, including vaccines and treatments.

The extensive portfolio of existing and emerging patents, non-patent IP and other exclusivities comprise a legal minefield for alternative producers seeking to develop, produce and supply COVID-19 medical tools to increase access.<sup>2,3</sup> Patent barriers preventing price-lowering generic

production and supply are a long-standing concern for access to medicines — a concern widely experienced in the HIV/AIDS epidemic, as well as in the struggle for access to affordable treatments for hepatitis C, tuberculosis (TB), cancer and other diseases.

## Opportunities and challenges of addressing IP barriers in South Africa

To address barriers and uncertainties caused by IP on lifesaving medical tools, it is important for governments to consider all policy options and make use of legislative reforms that prioritise health, and to tackle corporate monopolies that can hinder access options for people in need.<sup>4</sup>

In the COVID-19 pandemic, MSF has held the position that major IP barriers related to all components and materials needed for production and supply of lifesaving medicines, vaccines and diagnostics for the pandemic, should be removed domestically and globally to increase access. At the international level, in response to these needs, the South African government, together with the Indian government and many LMICs, have been leading a proposal to enable countries to temporarily waive certain IP rules under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO). This proposal for a TRIPS waiver, if adopted, could provide an opportunity for countries, including South Africa, to promptly address the present and emerging IP challenges on COVID-19 medical tools, and to mitigate the shortcomings of national and international IP rules in responding to the pandemic.<sup>5</sup> The proposal is supported by more than 100 countries. However, as of January 2022, a number of high-income economies including the UK, Switzerland and European Union states continue to oppose the adoption of the waiver.

The TRIPS agreement provisions enable countries to incorporate flexibilities in their national IP laws to protect health and access to medicines. Yet, many LMICs, including South Africa, face both technical and political challenges in implementing the full range of flexibilities to ensure that access to medicines is prioritised.

There are several key issues with the current patent law system in South Africa that hinder access to more affordable medicines in the country:<sup>6</sup>

1. Patent applications are not subjected to a substantive examination before granting, and there are lax patentability criteria. As a result, a large number of low-quality patents have been granted for lifesaving medicines. Many of these patents do not represent genuine innovation, and their existence contributes directly to shortages or the high prices of the medicines. For example, South Africa granted very broad patent claims to Moderna related to mRNA vaccine technology that were rejected in other countries, such as in Japan, Israel and South Korea, due to lack of technical merits (Annex 1). These broad claims do not warrant patent protection in South Africa. If substantive

examination and reform of the patentability criteria are implemented in South Africa, such claims can be examined, challenged and rejected.

2. There is no expedited and efficient administrative procedure to enable the public and civil society organisations to challenge unmerited patents and applications before the patent office. The current law provides only a lengthy procedure to challenge patents before the judicial court and this hampers public scrutiny, as the legal costs are prohibitive for civil society and the public.
3. The current provisions on compulsory licenses are insufficient to support their rapid issuance for government use. South Africa has not ever issued a compulsory license.

Civil society organisations, such as the Fix the Patent Law coalition (FTPL), have analysed these issues and advocated for reforms to facilitate access to medicines in South Africa.<sup>7,8</sup> The government has recognised the need for reforms to the patent law system, as outlined in the National Intellectual Property Policy issued in 2018.<sup>9</sup> However, many of the provisions relating to access to medicines have yet to be implemented.

The current pandemic situation and concrete IP barriers on COVID-19 medical tools in South Africa highlight the urgent need to accelerate the law reform process alongside the pursuit of the TRIPS waiver at the international level.

### Example of patents on COVID-19 mRNA vaccines in South Africa

At least three mRNA vaccine patents have been granted in South Africa to one foreign company, Moderna. These patents will only start expiring in 2034. These include one patent with very broad claims covering the method of production of an mRNA vaccine,<sup>a</sup> one with claims on the gene sequences relevant to mRNA vaccine,<sup>b</sup> and one containing broad claims on the method of delivering biological moieties into cells that is useful for production.<sup>c</sup> Notably, several equivalent patents in other countries have been withdrawn or abandoned by Moderna or rejected by national patent offices including in Australia, Canada, China, India, Israel, Japan, Mexico, Singapore and South Korea (Annex 1). Moderna has additional patent applications pending with South Africa's patent office, including some with long-overdue renewal payments.<sup>d</sup>

Contrary to some claims<sup>10</sup> that IP issues are not barriers to access to COVID-19 vaccines in countries in Africa, these patents and applications pose barriers to production and supply of mRNA vaccines by alternative developers in South Africa. Particularly, they create uncertainties for any outputs of the COVID-19 mRNA Vaccine Technology Transfer Hub in South Africa,

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<sup>a</sup> South Africa patent ZA 201403783B, expiring in 2034, is equivalent to WO 2013/090648 A1, PCT/US2012/069610

<sup>b</sup> South Africa patent ZA 201402547 B is equivalent to WO 2013/052523 A1 (PCT/US2012/058519)

<sup>c</sup> South Africa patent ZA 201403666 B is equivalent to WO 2013/090648 A1, PCT/US2012/069610

<sup>d</sup> For instance, the two divisional applications ZA 201503620 A and ZA 201503621 A

established in collaboration with the World Health Organization (WHO), to facilitate transfer of technologies and promote production of mRNA vaccines in Africa.<sup>11</sup> Although the Hub continues working on research and development (R&D) for the time being, the patents granted to Moderna could create a chilling effect and legal risks of potential patent disputes for entities that acquire technologies from the Hub and intend to take the products to market.

Moderna announced in October 2020 that it would not enforce its patents related to COVID-19 mRNA vaccines during the pandemic,<sup>12</sup> but also created uncertainty at the time by stating that the pandemic might end within a year.<sup>13</sup> Moderna's strategy is to retain decision-making power, being able to declare themselves when the pandemic is over, so it can enforce its patent and decide who gets vaccine supplies first and at what prices. Under increased pressure, Moderna announced that it would build its own mRNA production plant in an African country.<sup>14</sup> This is not a step in the right direction in terms of the demand for full access to, and transfer of, technology in order to support local production and supply, and increase self-reliance on the African continent. Under the proposed model, Moderna retains full control on production and supply.

As the patent landscape for the mRNA platform and related technologies used to produce mRNA vaccines continues to evolve, the legal uncertainties for production and supply may increase. Research has identified a complex portfolio of patents attached to an mRNA technology platform owned by multiple entities.<sup>15</sup> An example of patents that could potentially block production of mRNA vaccines is for the special delivery system with lipid nanoparticles (LNP) required to produce mRNA vaccines. Some of the broad patent applications on LNP, such as in WO/2021/030701 sought by company Acuitas,<sup>16</sup> could hinder production of current and future mRNA vaccines that need to use this system, if granted.

### Example of patents on COVID-19 medicines in South Africa

Baricitinib, a Janus kinase (JAK) inhibitor previously approved for treating rheumatoid arthritis, has been recently included in the WHO COVID-19 treatment guideline,<sup>17,18</sup> with a strong recommendation for treatment of severe and critical COVID-19 patients, to suppress the overstimulation of the immune system. Baricitinib is widely patented in several countries,<sup>19</sup> including South Africa,<sup>e</sup> India and Brazil (Annex 2). The patents on the medicine, held by Eli Lilly, expire in 2029, but the term could be extended if evergreening<sup>f</sup> patent applications are granted.

The cost of production of baricitinib has been estimated to be as low as US\$0.14 per tablet (\$1.78 per treatment course for 14 days). However, Eli Lilly's list price of \$1,109 per 14-day treatment in the US is 555 times of the cost-based estimated generic price (\$2.00).<sup>20</sup> Indian

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<sup>e</sup> South African patent ZA 2010/06000, granted with expiry in 2029, is equivalent to WO/2009/114512, PCT/US2009/036635.

<sup>f</sup> Evergreening is a tactic by which a company files for additional patents on small changes to existing drugs, thereby lengthening their monopoly and blocking affordable generic products.

generic companies have made the medicine available for \$0.41 per tablet — about 100 times lower than Eli Lilly’s price of \$44 per tablet for the supply in India.<sup>21</sup> Other countries such as Bangladesh have also developed generic versions of baricitinib.<sup>22</sup> However, Eli Lilly’s patent monopoly on baricitinib in South Africa impedes access to these lower-cost generic versions in the country. Eli Lilly signed a voluntary license with a few generic manufacturers in India for baricitinib, but limits the territorial coverage of the license to India and specifically excludes supply from India to other countries, including South Africa.<sup>23,24</sup>

An oral antiviral treatment, nirmatrelvir in combination with ritonavir,<sup>g</sup> produced by the US pharmaceutical corporation Pfizer, recently received emergency use authorisation by the US Food and Drug Administration (FDA) for early treatment of people with mild-to-moderate COVID-19 who are at increased risk of developing severe disease.<sup>25</sup> However, Pfizer’s limited supply has already been almost fully secured by high-income countries through advanced purchase agreements, while generic versions are not widely available.<sup>26</sup>

Pfizer has recently applied for at least one primary patent<sup>h</sup> on nirmatrelvir in several countries, including LMICs such as Cuba, Peru and Russia.<sup>27</sup> This may block generic production and supply until at least 2041 in countries where the patent is granted. In a voluntary license signed between Pfizer and the Medicines Patent Pool, Pfizer has explicitly stated its plan of pursuing patents in South Africa and other countries.<sup>i</sup> Also, the geographic territory for supply under the voluntary license only covers the public market in South Africa,<sup>j</sup> meaning a producer can only supply generic versions of the medicine to government, UN, NGO or other public programmes, and not to the private healthcare sector, which could limit access for some people.

A number of generic manufacturers have started working on producing active pharmaceutical ingredients and finished formulations. Particularly, a generic company in Bangladesh has already independently developed a generic version of nirmatrelvir/ritonavir outside of the voluntary license, benefiting from the fact that as a Least-Developed Country, Bangladesh is exempt from trade requirements to implement IP rules on medicines.<sup>28</sup>

South Africa has existing generic production capacity that could produce medicines such as baricitinib and nirmatrelvir/ritonavir. Given the present and emerging patent barriers and the limitations of voluntary licenses as mentioned above, removing any IP barriers and

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<sup>g</sup> In 2020, AbbVie announced its decision to abandon and withdraw remaining patents on ritonavir globally, following a compulsory license issued by the government of Israel on lopinavir/ritonavir. <https://www.keionline.org/32503>; <https://medicineslawandpolicy.org/2020/03/covid-19-and-the-come-back-of-compulsory-licensing/>.

<sup>h</sup> WO2021/250648, PCT/IB2021/057281, [https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2021250648&\\_cid=P21-KYKG6Y-34775-1](https://patentscope.wipo.int/search/en/detail.jsf?docId=WO2021250648&_cid=P21-KYKG6Y-34775-1)

<sup>i</sup> Appendix 2 of the Pfizer-MPP license: <https://medicinespatentpool.org/licence-post/pf-07321332>

<sup>j</sup> Appendix 3 of the Pfizer-MPP license: <https://medicinespatentpool.org/licence-post/pf-07321332>

uncertainties is important to facilitate local production and diversified supply of generic COVID-19 therapeutics, to help ensure uninterrupted and more affordable access.

## Recommendations to remove IP barriers on COVID-19 medical tools in South Africa

### 1. All countries should support the efforts to immediately adopt the TRIPS waiver for COVID-19

To remove all major IP barriers rapidly in a pandemic, the immediate adoption and implementation of the TRIPS waiver provides a critical option for South Africa and other countries.

### 2. South Africa should take immediate actions to remove IP barriers domestically

The South African government should use existing domestic legal and policy options as a matter of urgency. These include:

- a. **Issue a compulsory license for government use of COVID-19 vaccines and medicines to cover granted patents, pending and evolving patent applications, and the requirement to disclose manufacturing know-how:** Although the current provisions on compulsory licensing under South Africa's patent law contain shortcomings, South Africa legally has the right to allow use of patented technologies. IP barriers on COVID-19 medical tools provide a justifiable ground for South Africa to consider issuing its first compulsory license for government-use.
- b. **Review pending and evolving patent applications of COVID-19 vaccines and medicines.** The patent office should also proactively monitor the legal status of pending and evolving patent applications related to pandemic vaccines and medicines, such as those related to mRNA vaccines and to nirmatrelvir, as well as those pending applications with overdue payments, and consider rejecting or terminating them.
- c. **Review voluntary licenses on COVID-19 vaccines, medicines, diagnostics and other medical technologies.** With limited voluntary-license terms such as those offered by Pfizer, the freedom to produce and supply more affordable generic medicines can be restricted. Problematic voluntary-license terms need to be reviewed, including those segmenting South Africa's markets and restricting geographic scope of supply, thus impacting access in the country.
- d. **Provide strict substantive examination on all patents, especially those related to COVID-19 medical tools.** Upon publication of the IP policy in 2018, it was understood

that South Africa will prioritise substantive examination of pharmaceutical patents, as a critical step towards the full-fledged substantive examination system in the country. The current access challenges to COVID-19 medical tools provide a unique opportunity for South Africa to concretely put in place a mechanism so that patents concerning COVID-19 medical tools will not be so easily granted and will be subject to strict examination.

- e. **Immediately publish the draft amendment of the patent law act for public consultation and accelerate the law reform process.** The IP policy published in 2018 clearly affirmed the objective of safeguarding public interests. The COVID-19 access crisis demonstrates how the current patent law of South Africa does not provide sufficient and effective safeguards against patent claims that impede access to medicines. There is no excuse to further delay the reform process.

### 3. Moderna should withdraw its patents on mRNA vaccine technology in South Africa and share its technology and know-how with the WHO Technology Transfer Hub.

As shown in Annex 1, Moderna has withdrawn or abandoned their equivalent patents in multiple countries including some high-income countries, such as Canada and Australia. Moderna should immediately withdraw these patents and applications in South Africa, and transfer its technologies to the WHO COVID-19 mRNA Vaccine Technology Transfer Hub. As the mRNA vaccine of Moderna was primarily publicly funded, the US government, which provided the primary funding support to Moderna, should leverage all power and options to request the company to share its technology and know-how with the WHO Technology Transfer Hub.



## Annex 1: Preliminary patent landscape of Moderna's COVID-19 mRNA vaccine in South Africa<sup>29</sup>

PCT number	Description	Legal status in South Africa	Legal status in select jurisdictions
WO 2013/090648 A1 PCT /US2012 / 069610 (Moderna Therapeutics)	Method of producing a polypeptide of interest in a mammalian cell or tissue, the method comprising, contacting said mammalian cell or tissue with a formulation comprising a modified mRNA encoding the polypeptide of interest. Use of a modified mRNA encoding polypeptide of interest in the manufacture of a medicament for use in a method of producing a pharmacologic effect in a primate comprising contacting said primate with a composition comprising a formulated modified mRNA encoding a polypeptide of interest.	ZA 201403783 B (granted, last renewal paid on 12.10.2021)  Divisional applications: - Div. ZA 201503620 A (pending, fee overdue) - Div ZA 201503621 A (pending, fee overdue)  <b>Note: broad claims covering all mRNA vaccines</b>	Australia (all lapsed) - AU 2012352180 A1 - AU 2016231503 A1 - AU 2018207584 A1 Canada (all abandoned) - CA 2 859 387 A1 - CA 3 018 046 A1 China - CN 104114572 A (rejected) - Div. CN 110201187 A (pending) India - 4286/DELNP/2014 (abandoned) Israel - IL 232749 D0 (rejected) New Zealand - NZ 625987(abandoned) - NZ 724458 (pending) - NZ 741438 (pending) Singapore (all abandoned) - SG 11201402666W A - SG 10201604896T A South Korea - KR 10-2014-0102759 A (rejected)
WO 2012/045082 A2 PCT/US2011/054636 (Moderna Therapeutics)	Compositions and methods for delivering biological moieties such as modified nucleic acids into cells to modulate protein expression. Such compositions and methods include the use of modified messenger RNAs, and are useful for production of proteins.	ZA 201303161 B (granted)  ZA 201403666 B (div of ZA 2013/03161) (granted)  Note: claims 18 and 20 of ZA 201403666 B are very broad and not granted in other countries	Australia - AU 2011308496 (lapsed) - AU 2017202958 (lapsed) Brazil - BR 1120130078626 A2 (withdrawn) Canada - CA 2813466 A1 (pending) - CA 2821992 A1 (abandoned) China (all withdrawn) - CN 103429606



			<ul style="list-style-type: none"> <li>- CN 104531671</li> <li>- CN 104531812</li> </ul> <p>India</p> <ul style="list-style-type: none"> <li>- IN2861/DELNP/2013 (withdrawn)</li> </ul> <p>Japan</p> <ul style="list-style-type: none"> <li>- JP 2013-543381 (refused)</li> </ul> <p>Mexico</p> <ul style="list-style-type: none"> <li>- MX/a/2013003681 (abandoned)</li> </ul>
WO 2013/052523 A1 PCT/US2012/058519 (Moderna Therapeutics)	An isolated polynucleotide encoding a polypeptide of interest, comprising: (a) a sequence of n number of linked nucleosides or nucleotides comprising at least one modified nucleoside or nucleotide as compared to the chemical structure of an A, G, U or C nucleoside or nucleotide, (b) a 5' UTR comprising at least one Kozak sequence, (c) a 3' UTR, and (d) at least one 5' cap structure.	ZA 201402547 B (granted, paid renewal on 25-08-2021)	<p>Brazil</p> <ul style="list-style-type: none"> <li>- BR 11 2014 007852 1 A2 (pending)</li> </ul> <p>China</p> <ul style="list-style-type: none"> <li>- CN 103974724 B (granted)</li> <li>- CN 110511939 A (pending)</li> </ul> <p>EPO</p> <ul style="list-style-type: none"> <li>- EP 2 763 701 B1 (lapsed)</li> <li>- EP 3 492 109 B1 (granted and opposed by BioNtech, Sanofi)</li> <li>- EP 3 682 905 A1 (pending)</li> </ul> <p>India</p> <ul style="list-style-type: none"> <li>- IN 2839/DELNP/2014 A (abandoned)</li> </ul> <p>Singapore</p> <ul style="list-style-type: none"> <li>- SG 10201602654S A (pending)</li> <li>- SG 11201401196W A (abandoned)</li> </ul>

## Annex 2: Preliminary patent landscape of baricitinib<sup>30,31,32</sup>

PCT Publication/ Application	Description	South Africa patent status	Filed in	Granted in
WO/2009/114512 PCT/US2009/036635  (Incyte Corporation) <sup>k</sup>	Arthritis, rheumatoid and COVID-19 (treatment)	ZA 2010/06000 (granted), expiry in 2029	Albania, Bosnia and Herzegovina, El Salvador, Guatemala, Honduras, Pakistan, Paraguay, Thailand, Trinidad and Tobago, Tunisia, Uruguay, Venezuela	Algeria, Argentina, Armenia, Australia, Azerbaijan, Brazil, Canada, Chile, China, Colombia, Costa Rica, Dominican Republic, Eurasian Patent Office, European Patent Office, India, Indonesia, Japan, Kazakhstan, South Korea, Malaysia, Mexico, Morocco, New Zealand, Nigeria, North Macedonia, Panama, Peru, Philippines, Russia (term extended to 2033), Serbia, Singapore, South Africa, Tajikistan, Turkey, Ukraine, United Arab Emirates, United States, Uzbekistan, Vietnam
			<b>Rejected under appeal:</b> Ecuador, Egypt	
			<b>Withdrawn in:</b> Belarus, Kyrgyzstan, Moldova, Turkmenistan	

<sup>k</sup> Baricitinib (INCB28050) was first developed by the Incyte Corporation and licensed to Eli Lilly. See: <https://investor.lilly.com/news-releases/news-release-details/lilly-and-incyte-announce-collaboration-development-and>

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