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**Civil Society Groups in South Africa Call on the Companies and Intellectual Property Commission (CIPC) to Immediately Revoke Patents and Reject Patent Applications on Essential COVID-19 Health Technologies in South Africa**

We are writing this letter as concerned patient organisations regarding patents granted to Moderna by the South African Patents office which could block the local production and supply of Covid-19 mRNA vaccines and key therapeutics in South Africa.

The patents on mRNA vaccine technology have been granted to the US company Moderna without substantive examination by the patents office, despite the recruitment and training of at least 20 patent examiners since 2018, yet similar patents have been rejected in China, India, Israel, and South Korea. These patents include a patent with very broad claims covering the method of production of an mRNA vaccine, the other with claims on the gene sequence relevant to mRNA vaccines and one containing broad claims on the method of delivering biological moieties into cells.<sup>1</sup>

These patents granted by your office undermine the efforts of building local vaccine manufacturing capabilities in the country. Initiatives such as the WHO mRNA vaccine technology transfer hub have been established to expedite the production and supply of mRNA vaccines for the African continent including in South Africa, as well as other low- and middle-income countries (LMICs). Building this capability is an important step towards African manufactured vaccines and self-reliance in supply,

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<sup>1</sup> [https://msfaccess.org/sites/default/files/2022-03/Covid\\_TechBrief\\_AC-PHM\\_COVID\\_IP\\_barriers-SA\\_ENG\\_Mar2022.pdf](https://msfaccess.org/sites/default/files/2022-03/Covid_TechBrief_AC-PHM_COVID_IP_barriers-SA_ENG_Mar2022.pdf)

Website: [www.fixthepatentlaws.org](http://www.fixthepatentlaws.org)  
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Fix the Patent Laws is a joint coalition of the Treatment Action Campaign (TAC), Doctors Without Borders (MSF), SECTION27, Cape Mental Health (CMH), Diabetes SA, Epilepsy SA, Health GAP, Marie Stopes South Africa, the Stop Stock Outs Project (SSP), the Schizophrenia and Bipolar Disorders Alliance (SABDA), the South African Depression and Anxiety Group (SADAG), the South African Federation of Mental Health (SAFMH), the South African Non-Communicable Diseases Alliance (SANCD Alliance) and the Cancer Alliance including Advocates for Breast Cancer; amaBele Project Flamingo, Ari's Cancer Foundation, Breast Course 4 Nurses (BCN), Breast Health Foundation (BHF), Cancer Association of South Africa (CANSAs), Cancer Heroes, CanSir, CanSurvive Cancer Support (CanSurvive), Care for Cancer Foundation, Childhood Cancer Foundation of South Africa (CHOC), Gladiators of Hope, Hospice Palliative Care Association (HPCA), Lymphoedema Association of South Africa (LAOSA), Look Good Feel Better (LGFB), Love Your Nuts (LYN), Men's Foundation, National Council Against Smoking, National Oncology Nursing Society of SA (NONSA), Pancreatic Cancer Network of SA (PanCaN), People Living With Cancer (PLWC), the Pink Parasol Project, Pink Trees for Pauline (Pink Trees), Pocket Cancer Support, Rainbows and Smiles, Reach for Recovery (R4R), South African Oncology Social Workers' Forum (SAOSWF), The Sunflower Fund (TSF), VREDE Foundation for Young People with Cancer (Vrede Foundation) and Wings of Hope (WoH).

contributing to the continent's preparedness for Covid-19 variants of concern and future pandemics. The mRNA technology could also potentially serve as a basis for a new generation of vaccines and drugs that could work against a range of deadly diseases such as HIV, malaria and Tuberculosis. The Hub managed to develop its own version of the mRNA vaccine based on publicly available data on the composition of the Moderna Covid-19 vaccine, however these efforts could be derailed as the patents granted in South Africa to Moderna have the potential to impact the Hub's freedom to operate and to impact on future production and supply of any mRNA technology-based vaccines in South Africa.

In addition, patents<sup>2</sup> have been granted to the US company Eli Lilly on one of the key oral treatment options for COVID-19, baricitinib, as recommended by WHO. The granted patent could block generic production and supply of this medicine in South Africa until 2029. The medicine has been sold at high prices by the originator company Eli Lilly, at an amount of R4000 for a treatment course in South Africa yet a treatment course for generics in Bangladesh and in India costs R80.<sup>3</sup>

South Africa and India have championed the calls for a TRIPS waiver of patents on all Covid-19 medical tools to support capable manufacturers in low- and middle-income countries to manufacture and supply the needed tools more freely and independently to mitigate global access inequities to COVID-19 medical tools. After 17 months of negotiation, a draft text of an agreement outlining the terms of such a waiver has been released. This leaked draft text, points to several clarifications on the use of compulsory license to resolve IP challenges countries may face in seeking to manufacture and supply Covid-19 medical tools. However, the CIPC should not view this leaked draft as a solution that mitigates its responsibility to rescind the patents it has currently granted and refuse further patent requests relating Covid-19 medical tool. The text is a draft text and it is uncertain what the final agreement will entail. Furthermore, the text contains serious flaws and limitations that may create further legal risks rather than provide solutions. The draft text does not seek to waive any obligations on any intellectual property, including aspects of Article 39 of TRIPs agreement that concerns the 'protection of undisclosed information' such as manufacturing information that might have been claimed as 'trade secrets' and that are needed to support vaccine production. The text also contains requirements that limit the existing public health flexibilities, such as requesting for listing of all patents when issuing compulsory license. This leaked draft text will not solve South Africa's present domestic challenges caused by patents.

It is imperative for the CIPC to take immediate measures to ensure the protection of local initiatives such as those on developing, producing and supplying mRNA vaccines, to continue their mandate of ensuring access to these lifesaving vaccines.

**We therefore urge the CIPC to immediately take below actions:**

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<sup>2</sup> ZA2010/06000

<sup>3</sup> [https://scholar.harvard.edu/files/melissabarber/files/estimated\\_cost-based\\_generic\\_prices\\_for\\_baricitinib.pdf](https://scholar.harvard.edu/files/melissabarber/files/estimated_cost-based_generic_prices_for_baricitinib.pdf)

- **Review the legal status of all granted patent and pending applications (including divisional applications) to Moderna, immediately rejecting patent applications with long-overdue renewal payments**
- **Revoke all granted patents concerning mRNA vaccines, underlying technologies, raw materials, biological materials, gene sequences, methods or process of production, for the benefit of eliminating the legal risks for the Covid-19 mRNA Technology Transfer Hub established in South Africa**
- **Revoke all granted patents concerning baricitinib, to enable generic production and supply**
- **Proactively monitor all patents and applications concerning key COVID19 medical tools, and consider rejecting and revoking to enable freedom to operate for generic production and supply**
- **Implement the Substantive Search and Examination (SSE) program for all patent applications to avoid patents being easily granted**

**we look forward to your response in 14 working days.**

Yours sincerely

Fix The Patent Laws

