

AN APPEAL TO PRESIDENT CYRIL RAMAPHOSA BY ACADEMICS, RESEARCHERS AND TEACHERS TO EXPEDITE THE AMENDMENTS TO THE PATENTS ACT 57 OF 1978, IN LINE WITH THE INTELLECTUAL PROPERTY POLICY PHASE I APPROVED BY CABINET IN MAY 2018

18 May 2020

Dear Honourable President Ramaphosa,

We commend our government's efforts in responding swiftly to the COVID-19 pandemic by the measures already taken to slow down the rate of infections, and to prepare our health facilities for the inevitable demand for beds and health services. But importantly, steps must also be taken urgently to ensure access to COVID-19 health products, both existing and prospective.

We write to you as academics, researchers and teachers from various disciplines who are gravely concerned about the impact of the COVID-19 pandemic on our country and the world. In particular, we are concerned about our ability to provide the essential health products to meaningfully respond to this crisis – the personal protective equipment, diagnostic tests and reagents, ventilators, medicines and vaccines which will be required on a massive, unprecedented scale. More particularly, we are writing because of the urgency of completing the process of amending South Africa's Patent Law to strengthen patentability criteria, to provide for substantive examination of patent applications, and to adopt lawful flexibilities under the WTO TRIPS Agreement to ensure access to medicines for all. That long-delayed imperative is even clearer now as we face high prices and limited supplies of vitally needed COVID-19 health products.

Our sense of urgency stems from the reality that many of the products required already are, or will soon be, protected by patents and other intellectual property, test data and trade secret protections, thereby making them unaffordable to our government for the treatment of all the people in our country. Such protections are the death knell of equitable access to health products.

Under our present patent system, there is no substantive examination of patent applications to ensure that they meet the rigorous criteria for the grant of a patent. This allows pharmaceutical companies to obtain unworthy initial patents and multiple patents on the same medicine thereafter by making small changes, even when such changes are obvious and lack inventiveness. This multiple-patenting strategy, commonly known as 'patent evergreening', results in extending patent monopolies beyond the 20 years required by the WTO trade and intellectual property rules, and blocks the early entry of generic competitors who can expand sources of supply and bring more affordable products to market. Countries like India and Argentina have already taken proactive steps in their legislation to counteract this problem.

Our current patent laws also compromise the security of medicines supply in the country. If patent holders are unable or unwilling to deliver adequate supplies — as we have witnessed recently with the bans on exports of diagnostics by certain countries — we should be able to increase supply through the use of generic products registered in South Africa, which could increase availability and avoid stock outs. It would also enable local manufacturers to scale up the manufacture of the needed health products, thereby also advancing a key industrial policy objective.

Such abuses of patents have restricted, and continue to restrict, access to medicines for millions of our people suffering from TB, cancer, hepatitis and mental health conditions — and will most likely also threaten access to any future COVID-19 related technologies.

We have been there before. We witnessed first-hand how these laws and procedures for protecting patents blocked access to affordable versions of lifesaving antiretroviral medicines (ARVs) for the people needing them. After a lamentable period of delay, South Africa now has the world's largest treatment programme with nearly 5 million people on ARVs, thanks to the availability of generic versions, which reduced the cost of treatment from over \$10,000 per person per year to less than \$.21 per person per day. We watched in desperation as countless lives were lost waiting for affordable prices. Our people should not have to go through that again.

It is precisely for these reasons that your Cabinet wisely approved the Intellectual Property Policy of the Republic of South Africa Phase 1 in May 2018. It is now 2 years since that decision, and we still do not have the relevant legislation before Parliament to ensure that government meets its constitutional obligations to deliver access to health care and the medicines necessary to defeat the current pandemic.

As academics, researchers and teachers at our universities, colleges and other institutions, we have actively participated in that policy-making process, providing comments and technical advice on successive earlier drafts of the policy. We are firmly convinced that the proposed amendments are compliant with international law and advance the right to access health care under our Constitution.

It is therefore imperative that the draft legislation is tabled, through the relevant Minister, as a matter of urgency, subjected to a short period of public comment, processed expeditiously through our legislature, and assented to by the President.

We are also in support of calls that the government take additional proactive, emergency measures to ensure affordable access to COVID-19 health products of assured quality as many countries, both developed and developing, have recently done. For example, the Companies and Intellectual Property Commission (CIPC) could and should be encouraged to adopt a temporary moratorium on the issuance of any patents on COVID-19-related health products for the duration of the pandemic emergency. In addition, the government can and should adopt emergency measures allowing for an automatic or mandatory compulsory licence for public and/or all-sector use with respect to any COVID-19 medical product for which prices are too high or supplies are insufficient to meet our local needs. Such licences should not only address the right to work patents, but also the right to access and use trade secret and confidential business information, especially manufacturing know-how, and where necessary access to clinical trial and other data needed to facilitate registration of licensed medical products. The government could also assure sufficient productive capacity to supply non-predominant quantities of medical products produced under such licences, to neighbouring African countries. Finally, the government could also issue compulsory licences to enable the supply to African countries with insufficient manufacturing capacity, pursuant to Article 31bis of the TRIPS Agreement.

We once again call on you to demonstrate, as you continue to do, the decisiveness and leadership which the people of South Africa have come to expect of you.

Thank you.

Sincerely,

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