AUTHORS:
Fernando dos Santos[1]
Caroline B. Ncube[2,3]
Marisella Ouma[4,5]

AFFILIATIONS:
[1]Faculty of Law, Eduardo Mondlane University, Maputo, Mozambique
[2]DSI-NRF Research Chair: Intellectual Property, Innovation and Development, Department of Commercial Law, University of Cape Town, Cape Town, South Africa
[3]Department of Commercial Law, University of Cape Town, Cape Town, South Africa
[4]Head of Legal, Central Bank of Kenya, Nairobi, Kenya
[5]Visiting Lecturer, MIP Programme, Africa University, Mutare, Zimbabwe

CORRESPONDENCE TO:
Caroline Ncube

EMAIL:
caroline.ncube@uct.ac.za

DATES:
Received: 13 Nov. 2021
Revised: 11 Apr. 2022
Accepted: 12 Apr. 2022
Published: 31 May 2022

HOW TO CITE:
Dos Santos F, Ncube CB, Ouma M. Intellectual property framework responses to health emergencies – options for Africa. S Afr J Sci. 2022;118(5/6), Art. #12775. https://doi.org/10.17159/sajs.2022/12775

ARTICLE INCLUDES:
☒ Peer review
☐ Supplementary material

DATA AVAILABILITY:
☐ Open data set
☐ All data included
☐ On request from author(s)
☐ Not available
☒ Not applicable

GUEST EDITOR:
Jonathan Jansen

KEYWORDS:
intellectual property, TRIPS Agreement, TRIPS Waiver, COVID-19, pandemics, emergencies

FUNDING:
South African Department of Science and Innovation, South African National Research Foundation (grant no. 115716)

Intellectual property framework responses to health emergencies – options for Africa

We debate whether intellectual property (IP) protection of medical products and devices required to prevent, treat and contain COVID-19 should be waived, as proposed by South Africa and India, under the World Trade Organization (WTO)'s Agreement on Trade-related aspects of Intellectual Property Rights (TRIPS Agreement). We discuss existing public policy mechanisms under the TRIPS Agreement and how these have been implemented at national level in Africa, and find that these have proven inadequate and that they have been sub-optimally implemented. We then consider the TRIPS Waiver proposal which has been tabled due to the inadequacy of existing mechanisms and outline the EU's counter proposal which is founded on existing mechanisms. Both proposals have served at multiple WTO council meetings and would have been the subject of the 2021 WTO Ministerial Conference, which was postponed and is now set to be held in June 2022. Meanwhile, the proposal has been the subject of negotiations between India, South Africa, the EU and the USA ('the quad') and, as of May 2022, has been opened for consideration by all Members. Whatever the outcome of WTO deliberations, African states must take necessary national IP regulatory reforms and cooperate at sub-regional and continental level to improve access to medical products and devices to meet their citizenry's healthcare needs.

Significance:

- There is need for a sustainable and comprehensive intellectual property framework that is responsive to health emergencies. Existing public policy mechanisms have not proven effective.
- Adaptation and innovation are required at the international norm-setting level as evidenced by the two in-progress proposals for a TRIPS Agreement waiver and for an International Treaty on Pandemics. Both are contested and may only actualise in the medium to long term.
- In the context of such uncertainty and delay, timely action should be taken at national level, through legislative reform coupled with necessary manufacturing capacity, which will be boosted by cooperation between African states.

Introduction

Since late 2019 the world has been confronted with an economic and health emergency caused by the COVID-19 pandemic. A multiplicity of responses is required, including an intellectual property (IP) law and policy framework ('regulatory') approach, which is the focus of this article and which will be of interest to IP scholars and practitioners and also to those engaged in efforts to develop COVID-19 vaccines, diagnostics and therapeutics. The article centres on Africa for two reasons. First, by mid-2021 some parts of the world had accessed and administered vaccines that enabled a return to economic and other activity, whilst the developing world, particularly Africa, remained in the grip of lockdown necessitated by lack of access to vaccines and the corollary rampant rise of COVID-19 infections, illness and deaths. For example, on 2 July 2021 it was reported that 'only 1% of people in low-income countries ha[d] received at least one dose'[1]. Second, no doubt spurred by its vulnerability, Africa has taken a leading position in seeking IP regulatory solutions at global level. South Africa and India proposed a waiver of the implementation, application or enforcement of the sections dealing with copyright, industrial designs, patents and protection of undisclosed information in the Agreement on Trade-related Aspects of IP (TRIPS Agreement). This proposal (TRIPS Waiver proposal) gained the support of more than 50% of the World Trade Organization (WTO) member states, including the 55 members of the African Union (AU). The proposal has been the subject of extensive deliberation at the WTO and was on the agenda at its 12th Ministerial Conference, initially scheduled for 30 November – 3 December 2021, but postponed to June 2022. It has been further negotiated between South Africa, India, the USA and the European Union (EU), the so-called 'quad negotiations' from which a text was leaked in March 2022[2]; the official text was later published by the WTO on 3 May 2022 for consideration by all WTO members[3]. This text is not considered in this article. There are also calls for a Treaty on Pandemics under the auspices of the World Health Organization (WHO) which will bring up IP as the Treaty protects devices, products, medicines and technologies required to fight pandemics, but the treaty will not focus on IP; the Treaty therefore falls outside the scope of this article and will be only briefly discussed. Medicines and product regulatory aspects are also not discussed in detail. This article focuses on IP laws and policies ('IP regulatory responses').

Previous international responses: Doha, TRIPS Waiver and amendment

IP rights (IPRs) were introduced into the world trade arena after the Uruguay Round of negotiations under the General Agreement on Tariffs and Trade.[4] The TRIPS Agreement, which establishes the minimum standards of protection for IP within the framework of the WTO, came into effect on 1 January 1995. WTO Members were obliged to fulfil their obligations within a certain period, with further transition periods being dependent on the status of a country as a developing country or a least developed country (LDC) as elaborated below. The TRIPS Agreement covers trade-related aspects of IP such as copyright and related rights, trademarks, patents, geographical indications, layout designs of integrated circuits and undisclosed information. It introduced obligations for enforcement which

include administrative procedures, civil and criminal sanctions, border measures and dispute settlement mechanisms at international level. Existing international treaties such as the Berne Convention for the Protection of Literary and Artistic Works (*Paris Act of 1971*, as amended in 1979) and the Paris Convention for the Protection of Industrial Property, left the issues of enforcement to the individual member states. Its preamble recognises the competing interests in protection and enforcement of IP and the need for a secure conducive social and economic environment.[5] Under Article 8.1, Members may adopt measures that they deem necessary to protect public health and nutrition. Developing nations and LDCs have found it very challenging to access essential medicines and other pharmaceutical products, more so in the face of the HIV/AIDS pandemic and other diseases such as malaria and tuberculosis.[6] IPRs, for example patents, play a significant role in the pricing of pharmaceutical products, which, in many cases, become too expensive and, therefore, inaccessible to developing countries and LDCs.[7]

TRIPS Flexibilities

The TRIPS Agreement contains flexibilities that may be used to ensure the balance between protection offered under the Agreement and other social, economic and public interests. For patents, they include 'transition periods, compulsory licensing, parallel importation, the Bolar Provision and exceptions from patentability'[8]. It is not possible to give a full account of flexibilities due to space constraints so only a few will be highlighted. For instance, LDCs are not required to apply the provisions of the TRIPS Agreement, save for Articles 3, 4 and 5 until 1 July 2034 or when they cease to be an LDC (whichever occurs first). This extension is the third granted to the LDCs, with the first granted in 2005 and the second, which expired on 1 July 2021, granted in 2013.[9] In addition, there is a pharmaceutical transition period until 1 January 2033 or when an LDC ceases to be an LDC, whichever occurs first.[10] Under this transition period, an LDC does not have to issue pharmaceutical patents.[11] However, many LDCs have chosen to forego this flexibility and have been granting pharmaceutical patents for a considerable period of time.[12] African countries have not taken advantage of flexibilities at their own peril[13,14], and only six countries exclude pharmaceutical patents in their national legislation, namely Angola, Burundi, Liberia, Madagascar, Rwanda and Uganda[15,16]. In addition, Rwanda's IP Policy of 2018 recommended the adoption of an international exhaustion regime to facilitate parallel importation of generic medicines. Rwanda is unique in its approach and consistency.

Article 30 allows WTO Members the power to provide limited exceptions to the exclusive rights granted under patents. These exceptions are subject to the three-step test, specifically that they (1) should not unreasonably conflict with the normal exploitation of the patent; (2) should not unreasonably prejudice the interests of the legitimate patent holder; and (3) should consider the legitimate interests of the third parties.[17] Article 31 provides for compulsory licensing subject to several conditions, including that the authorised use shall be limited to the domestic market and subject to payment of adequate remuneration to the patent holder. This flexibility is of little or no use to developing countries and LDCs with limited or no manufacturing capacity for pharmaceutical products and which would not be in a position to pay for the remuneration to the patent holder where a compulsory licence is issued pursuant to Article 31 (h). This issue is addressed further below.

Exclusion of the patentability of pharmaceuticals does not per se lead to access to medicines, because patent information may not be immediately available to be replicated and may be guarded as undisclosed information. Further, if countries do not have adequate manufacturing capacity to produce the medicines, the availability of information and technology will not solve the problem. Currently, only a few African states have manufacturing capacity that can be dedicated to COVID-19 vaccines production, such as: Egypt, Morocco, Senegal, South Africa and Tunisia.[18] Under the Partnerships for African Vaccine Manufacturing (PAVM) launched in April 2021 by the AU, several new partnerships were developed which will enable other countries, including Rwanda, Congo and Senegal, to produce vaccines using the mRNA technology.[19] However, these solutions target specific and limited actions that do not address a systemic lack of manufacturing capacity in Africa. A cooperative approach is necessary to ensure adequate manufacture and distribution of pharmaceuticals and medical devices across the continent, which includes enhanced procurement and import of pharmaceuticals and medical devices into the continent.[20] The adoption of a regional or international exhaustion of IP rights regime by African states would ensure that there is meaningful movement of these supplies across the continent. Therefore, it has been recommended that such an approach be advanced by the IP Protocol of the African Continental Free Trade Agreement that is being negotiated.[21]

Doha Declaration, TRIPS Waiver and Article 31bis of TRIPS Agreement

Prior to 2005, countries like India and Brazil had flourishing pharmaceutical industries dealing in generic medicines that they produced for their domestic market as well as for export because they did not have patent protection for the original pharmaceutical products.[22] As of 2005, when they became obliged to protect product patents, their production and export of generic pharmaceutical products was no longer possible where there was a patent on the originator pharmaceutical. Further, even where this was done under a compulsory licence, there were difficulties with the transit of generics.[23]

The HIV/AIDS crisis highlighted developing countries' and LDCs' difficulties in accessing medicines.[24] This difficulty was brought to the fore when a pharmaceutical industry association with its 39 affiliate companies filed an application against the South African government[25], alleging that the introduction of parallel importation provisions, among others, by the *Medicines and Related Substances Control Amendment Act* was inconsistent with the provisions of the TRIPs Agreement. A full account of this litigation is available elsewhere.[26-30] This matter was ultimately settled and the amendments were implemented, following the adoption of the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration).

The Doha Declaration was adopted on 14 November 2001 at the WTO Ministerial Conference[31] to address the complex issues that arose in relation to access to essential medicines[32]. The Declaration applied to access in relation to a broad spectrum of public health issues and is not limited to a set of certain limited circumstances as provided for under Article 31 (h) of the TRIPS Agreement.[32] Paragraph 6 of the Declaration enabled the use of compulsory licences to facilitate access to medicines for Members with insufficient or no manufacturing capacities in the pharmaceutical sector. Under the WTO General Council Decision on Implementation of Paragraph 6 of the Doha Declaration[33], Members agreed to waive Article 31 (f) of the TRIPS Agreement to allow importation of pharmaceutical products, under compulsory licence, by Members without manufacturing capacity, subject to specific conditions. It also permitted the issuance of a compulsory licence by any Member for the manufacture of essential pharmaceutical products. Eligible importing members are defined as LDCs and other states which notify their intention to use the system.[34] They are required to notify the Council for TRIPS of the pharmaceutical products they intend to import as well as the quantities.[33] Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and the United States of America indicated that they would not use the system as importing states. Other states indicated that they would have recourse to it in a limited way such as during national emergencies.[35] In 2005, the Protocol amending the TRIPS Agreement rendered the above mechanism permanent.[36] The amendment, (article 31*bis*) together with an Annex, came into force on 23 January 2017 after it was accepted by two thirds of WTO Members. The waiver provisions under the General Council Decision of 30 August 2003 on the implementation of Paragraph 6 of the Doha Declaration continue to apply to those Members which are yet to accept the protocol, and the amendment is currently open for acceptance until 31 December 2023.[37]

African implementation of the TRIPS Waiver and Article 31*bis*

Only 29 African states had accepted the TRIPS amendment by 30 April 2022[38], raising the following related questions: (1) Why have some African states not accepted the amendment? (2) Why have those that have accepted the amendment not filed notification of their intention to use the system as importing states? (3) Why have those which have not accepted the amendment not filed their notifications, because it is not dependent on acceptance of the amendment, as the waiver decision applies to those states which are yet to accept the amendment? Finally, one may ask, generally: Why has the system not been extensively used to date? There is no official statement from any state on why it has not accepted the amendment nor filed a notification to use the system as an importing state, so it is difficult to state the answers to the first three questions with any certainty. There has been some scholarly commentary on the minimal use of the system which will be discussed below, to advance potential answers to the fourth question.

Since its adoption in 2003, the system has been used only once by Canada (exporter) and Rwanda (importer). However, since the start of the COVID-19 pandemic, Antigua and Barbuda[39] as well as Bolivia[40] filed notices of their intention to use the system as importers. They await notification by other WTO member states of their availability to serve as exporters. Specifically, Bolivia has entered into an option agreement with Biolyse, in the hope that Canada will issue a compulsory licence that will enable the firm to export pharmaceuticals to Bolivia.[41]

The minimal use of the system has been attributed to several factors. The bureaucratic strictures of the notification process which is coupled with navigating the exporting state's national laws on compulsory licensing are unduly burdensome. Canada's Access to Medicines Regime (CAMR)[42] under which compulsory licences are issued for the manufacture of pharmaceuticals for export to eligible importing countries, has proven to be complicated and lengthy.[43-45] The Canadian company seeking a compulsory licence must first negotiate a voluntary licence (which usually takes a significant period), and upon the failure of such negotiations, must obtain a compulsory licence, which also takes some time. These licences are subject to challenge in court under a good faith clause to ensure that the generic manufacturer is not competing with the originator manufacturer. In the single use of the system, the delay was also because Rwanda had to file its notification[46] as an importing country before Apotex could seek a voluntary licence. It took at least 3 years to navigate the CAMR before the Canada–Rwanda export–import could be implemented.[45] This arduous process likely discouraged any further efforts to use the system, until the notifications filed in 2021 as noted above. As noted by Nkomo[43(p.289)] and others[11-16], there seems to be an engrained reluctance to use health-related TRIPS flexibilities by African states. However, if the export–import process takes up to 3 years, then it is not suitable for emergency situations as innumerable lives will be lost as the process unfolds.

Concerns about the profitability of such schemes or strong incentivisation of generic manufacturers have been raised.[43-45] The CAMR's 4-year maximum duration of the compulsory licence and the maximum quantity requirement also contribute to the unworkable nature of the system. Rwanda, a LDC, faced no significant internal hurdles as there were no relevant patents in relation to which compulsory licences had to be sought. In an importing country where relevant patents are in place, domestic licences must be obtained to enable the import of generics which would further complicate and delay the inbound process. Indeed, as Vincent[45(p.3)] has noted, 'in practice, the compulsory licensing system under Article 31*bis* does not meet the standards it aims to establish and represents little more than a patchwork to fix specific problems that arose from Article 31'. Therefore, it is understandable how it has not fulfilled the promise it initially held out and why the TRIPS Waiver proposal has been tabled, as set out below.

TRIPS Waiver for the prevention, containment and treatment of COVID-19

India and South Africa presented a proposal to waive the implementation, application or enforcement of the sections dealing with copyright, industrial designs, patents and protection of undisclosed information in the TRIPS Agreement in October 2020.[47] The proposal is not limited to patents because hindrance to access to COVID-19 related technologies extends beyond patents and includes other IPRs such as the protection of undisclosed information embedded in all processes of research and development.[48] Revised proposal text was presented on 25 May 2021, which refined the scope to include products and technologies, their materials or components, as well as their methods and means of manufacture, and focused only on COVID-19 prevention, treatment and containment.[49] Waivers to rules established by WTO legal instruments are provided for in Article IX.3, 4 and 5 of the Agreement Establishing the WTO. Article IX.3. (b) establishes that 'A request for a waiver concerning the Multilateral Trade Agreements in Annexes 1C and their annexes shall be submitted initially to the Council for TRIPS which is mandated to discuss it within 90 days and submit a Report to the Ministerial Conference.' The Ministerial Conference should make a decision within the 90 days and if consensus is not reached during the time period, any decision to grant a waiver shall be taken by three fourths of the Members. Article IX.4 requires that the following be contained in the Ministerial Conference decision: exceptional circumstances justifying the decision, the terms and conditions governing the application of the waiver, and the date on which the waiver shall terminate. This is to ensure compliance with the exceptional nature of the waivers and that the waiver is granted for a limited period. Further, if the waiver is granted for a period of more than one year, it shall be reviewed by the Ministerial Conference not later than one year after it is granted, and thereafter annually until the waiver terminates. Pursuant to the outcome of the annual review, the waiver may be extended, modified or terminated.

The TRIPS Waiver proposal articulates the exceptional circumstances that motivate it as the failure to make diagnostics, therapeutics and vaccines for COVID-19 available promptly, in sufficient quantities and at affordable prices to meet global demand. Further, developing countries and LDCs face challenges in relation to using TRIPS flexibilities, such as compulsory or government use licences, and navigating the cumbersome and lengthy process for the import and export of pharmaceutical products for countries with no manufacturing capacity.

The proponents highlighted the need for WTO Members to work together to ensure that IPRs do not hinder timely access to affordable medical products including vaccines and medicines or to scaling up of research, development, manufacturing and supply of medical products essential to combat COVID-19. They called for global solidarity. The proposed duration of the waiver is an initial period of 3 years, to continue until widespread vaccination is in place globally and the majority of the world's population has developed immunity. The proposal also urges WTO Members not to challenge any measures taken in conformity with the provision of the waivers nor to resort to WTO's Dispute Settlement Mechanism.

The proposal was promptly embraced by more than 100 countries, including all AU member states and other developing states, which included Bolivia, Fiji, Indonesia, the LDC Group, Maldives, Mongolia, Pakistan, Vanatu and Venezuela. By mid-2021, it was supported by developed states such as the USA (qualified support)[50], but it faced resistance from other developed states, particularly the EU, which argued that IP is not the major obstacle to access to health products and technologies related to COVID-19. Instead, they place the blame on infrastructure, supply chains and production capabilities and capacity in recipient countries as the major stumbling blocks in distributing medicines and vaccines.[51] They further warn of the risk that the IP Waiver may undermine R&D and innovation, as it may reduce the incentives that spark innovation.[52,53]

This argument overlooks the fact that the research that led to the existing vaccines was largely financed by public funds.[48,54] Hence, the argument of threats to the reward to the investors seems not to hold on this occasion.

It is also argued that there are many alternatives to the waiver, such as the voluntary and compulsory licences and even bilateral arrangements with suppliers which are already selling the vaccines at 'reasonable prices'. Finally, it is pointed out that the waiver will not address the main concerns of developing countries, such as lack of manufacturing capacity or the transfer of technology and goodwill, hence it is useless. Efforts to enhance manufacturing capacity on the continent have already been outlined above.

Those in support of the proposal view call for its urgent adoption as it will contribute to a fair distribution of vaccines and is in keeping with the human rights obligations of states.[55] The TRIPS Waiver could assure manufacturers that their activities will not attract litigation or seizure of their vaccines during the process of export with allegations of patent infringement. It is far more effective than compulsory licences due to the procedural intricacies that surround compulsory licences, as outlined above.[48] There are further disadvantages in using compulsory licences, including that they are applicable on a product-by-product, and country-by-country basis due to the territorial nature of IP rights, and some countries are reluctant to make use of them for fear of reprisals or sanctions. Further, regulatory obstacles – including protection of data and marketing exclusivities – pose serious hindrances. It is unclear what should constitute adequate remuneration required for the rights holders in times of a pandemic and the lack of information on the existing relevant patents to vaccines, their content, manufacturing and regulatory processes makes it difficult to be precise about which IP rights a compulsory licence should target.

Notwithstanding the shortcomings in the compulsory licensing system, the EU presented a communication on 'Urgent trade policy responses to the COVID-19 crisis' to the General Council and to the TRIPS Council on 4 June 2021.[56] The EU proposes a global trade initiative for equitable access to COVID-19 vaccines and therapeutics encompassing: (1) trade facilitation and disciplines on export restrictions; (2) expansion of production, including through pledges by vaccine producers and developers; and (3) clarification and facilitation of TRIPS Agreement flexibilities relating to compulsory licences. In essence, it hinges on the compulsory licence mechanism to meet the objectives of providing COVID-19 vaccines for all. It has been denounced as a diversion from the India–South Africa proposal.[57,58] Indeed, instead of maintaining the text-based negotiation of the previous proposal, it reopens the discussion and redirects the debates on the effectiveness of compulsory licences, which as illustrated above, are inadequate. However, at the TRIPS Council, Members agreed to continue the discussions based on both proposals, which they have done primarily through the quad negotiations, and the proposals will be considered at the 12th Ministerial Conference which has been postponed until June 2022.

IP and the International Treaty on Pandemics

WHO indicates that the proposed International Treaty on Pandemics aims at providing improvement in alert systems, data sharing, research, and local, regional and global production and distribution of vaccines, medicines, diagnostics and personal protective equipment.[59] The European Council proposal for the Convention highlights: risk monitoring, better financing and coordination of research, greater efficiency in alerts and information sharing, improved access to healthcare resilience by strengthening healthcare systems, and secure supply chains.[60] However, notwithstanding the rhetoric of a 'comprehensive and multisectoral instrument' the proposed solution is not a systemic and all-encompassing response. First, the WHO's starting premise is that access to vaccines is predominantly a health issue.[61] This needs to be extended by an appreciation of the crucial role of other areas – such as trade rules, IP, technology transfer and environment – in facilitating access to medicines and health technologies. Indeed, a holistic approach to access to health care must not overlook the research and development, innovation, ownership and exploitation of the intangible assets developed which will have a final bearing on access to medicines and health-related technologies. So, the ongoing WHO, World Intellectual Property Organization (WIPO) and WTO Trilateral Cooperation on Public Health, IP and Trade is welcomed. However, it remains to be seen whether WHO, as a sectoral agency, will be the most suitable site to implement and enforce a Treaty that is by its nature cross-cutting.

Second, the WHO seeks to make this Treaty binding, like the Framework Convention on Tobacco Control and the revised International Health Regulations which entered into force in 2007. The overwhelming ratification of the Framework attests to the fact that health issues prevailed over the tobacco lobbies. However, the Treaty may not have the same fate. The pharmaceutical industry lobby has shown more strength and may not be amenable to a binding instrument that may hurt its commercial interests. There are two examples that demonstrate that treaties with mandatory technology transfer provisions fail. After more than a decade of negotiations, the UNCTAD 'Draft International Code of Conduct for the Transfer of Technology' failed because of divergent positions regarding its binding character.[62] Developing countries wanted a binding instrument while developed countries preferred guidelines. The success of the Convention on the Law of the Sea only came after the removal of mandatory rules on technology transfer because, with such provisions in place, Western states, led by the USA, did not join the Convention.[63] The deadlock was only overcome in 1994 through UN Resolution 48/263 ('Agreement relating to the Implementation of Part XI of the United Nations Convention on the Law of the Sea of 10 December 1982') that repealed article 5(3) that had imposed the mandatory regime. Thereafter, ratifications started to flock in. Therefore, although the Pandemics Treaty seems to be consensual and was initiated in the political sphere, it may suffer deadlock if it includes obligations related to IP and transfer of technology related to medicines, vaccines and health technologies. However, a non-binding instrument may also be problematic: some have highlighted that the current pandemic could have been tackled efficiently if the existing International Health Regulations as revised in 2005 were binding and had been enforced.[64-66]

Third, what emerges clearly is that the proposed instrument is not an IP Treaty, but as access to vaccines and health technologies is entangled with IP, the proposed Treaty should consider IP matters with sufficient detail, which can only result from diplomatic negotiations. One can foresee probable minimum content such as: possible automatic waivers of IP during pandemics, compulsory licences, remuneration to rights holders, incentives to encourage transfer of technology, access to relevant information and data, technical assistance to LDCs, free flow of required medicines and health technologies, and empowerment of developing countries to gain manufacturing capacities.

Fourth, the proposed Treaty seems to focus on operational issues to tackle emergency situations such as risk monitoring, early alert to outbreaks, and mobilisation of financial resources to curb the pandemics. However, some pandemics are a result of excessive global consumption and trade patterns that are overstretching the capacities of the globe.[67,68] Therefore, the response must also encompass the transformation of human behaviours and encouragement of sustainable practices. The Treaty must therefore go beyond health and trade and include environment preservation and balanced exploitation of natural resources.

Fifth, the proposed framework seems to focus on the public sector response. It became clear during the current pandemic that health and technology endeavours are owned by private entities and governments struggle to force companies to share their knowledge and intangible assets. In the context of implementation of article 66.2 of the TRIPS Agreement, developed states have always expressed their inability to force transfer of technology to occur, claiming that they do not own most technologies subject to transfer and cannot force the private sector to transfer technologies.[69] And yet, the current debates on the Pandemic Treaty were sparked by political figures, driven by them and seem to rely on private sector commitment. A statement by the International Federation of Pharmaceutical Manufacturers & Associations issued on 30 March 2021 attests to the desire of the private sector to be included in the negotiation of the new Treaty.[70] Lack of private sector cooperation may derail operationalisation of government commitments. This situation may be evidenced by the recent case of the C-TAP mechanism which failed partially due to lack of endorsement and support by the pharmaceutical industry.

Conclusion: Necessary national and continental responses

The proliferation of multilateral IP rules has restrained the policy space available for developing countries, especially in Africa, to craft balanced patent laws that enable pursuit of public policies, including that of facilitating access to medicines. However, some policy space compatible with TRIPS is still available, and should be used, to undertake reforms, such as: reviewing patentability standards, use of pre- grant and post-grant opposition, facilitating legal challenges to the validity of patents, adopting stricter rules of examination of patents and involving other public authorities in examination or litigation, imposing legal sanctions for misconduct by patent applicants and holders leading to abuse of patent rights and remedies, limiting divisional applications, and increasing registration and maintenance fees to dissuade patent applicants from filing trivial applications.[71] Scholarship is also focused on the desirability of compulsory licensing for trade secrets, which, due to space constraints, we cannot address here. Suffice it to note that the COVID-19 pandemic has clearly emphasised the significance of trade secrets in the race to produce and supply the necessary products and therapeutics. For various reasons, discussed above, this policy space has not been fully used by African states to reform patent laws to ensure that they fully cater for the public interest. Specifically, in relation to LDCs, the general LDC transition period and the pharmaceutical exemption period outlined above, are very significant as they provide them with policy space to refrain from application of patent laws before the specified date. However, as also noted above, many LDCs surrendered these transitional periods and enacted legislation almost fully compliant with the TRIPS Agreement before they were required to do so. Similarly, African states have neglected the reform of other IP laws which may be beneficial to scientific endeavours to develop medical products and devices to prevent, treat and contain COVID-19. A full discussion of the national solutions required under the current TRIPS rules is precluded by space constraints. Suffice it to note that it has been the subject of scholarly commentary elsewhere and may inform follow-on publications in this journal by the authors.

Having said that, it is important to reiterate that the existing mechanisms are inadequate and have failed to meet COVID-19 challenges, and those of endemic diseases. A case in point is the WHO backed mRNA vaccine technology transfer hub in South Africa which has shown impressive capacity in developing its own copy of the Moderna vaccine but is not yet able to produce the amounts of vaccine required to meet the dire need. Momentum would be aided by a royalty-free voluntary licence for low-income and low-to-middle-income countries but this is unlikely. Therefore, it is evident that a private sector/market reliant response that hopes for charity is inadequate, and the IP legal framework needs to be revised as well, to ensure equity and the full use of existing and future manufacturing capacity. Hence the proposal for a TRIPS Waiver that would suspend copyright, industrial designs, patents and protection of undisclosed information. African states, collectively, have supported the TRIPS Waiver, which may provide a fix to the current COVID-19 pandemic but is not a sustainable solution for possible recurrent pandemics in the future. Hence, the calls for the adoption of an International Treaty on Pandemics; it behoves the continent to also support this Treaty as a possible complementary response, and its progress merits watching.

Finally, the TRIPS Waiver, if it were passed, would not be self-executing, so national legislative changes would have to be enacted to implement it domestically. Even if it were not passed, African states must take domestic action to enhance access. Indeed, it is odd that they would spearhead international norm-setting reforms, whilst neglecting to act domestically. For instance, there have been sustained calls for South Africa to reform patent laws spanning at least a decade, yet even in this period of crisis, the necessary reforms are not forthcoming. The introduction of substantive patent examination, in accordance with the National IP Policy, Phase 1, 2018, would have gone a long way in preparing the patent office to deal with COVID-19 related patent applications.

Acknowledgements

This work was carried out under the auspices of the DSI–NRF SARChI: Intellectual Property, Innovation and Development, University of Cape Town. It is based on research supported in part by the National Research Foundation (NRF) of South Africa (grant number: 115716). Any opinion, finding and conclusion or recommendation expressed in this material is that of the authors and the NRF does not accept any liability in this regard. We acknowledge Ghati Nyehita's research and editorial assistance and the anonymous peer reviewers for their comments.

Competing interests

We have no competing interests to declare.

Authors' contributions

Each author contributed to the conceptualisation, research, writing and finalisation of the manuscript. Authors are listed alphabetically. C.B.N. served as project manager and leader.

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