

Proposed TRIPS Waiver hangs in the balance: urgent call for national advocacy

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Many developing countries have expressed serious concerns over the barriers imposed by the TRIPS Agreement on affordable access to diagnostics, vaccines and therapeutics that are being currently developed for combating the COVID-19 pandemic, as well as the so-called “vaccine nationalism” already occurring even before clinical trials have concluded. Seven months into the pandemic, these growing concerns culminated in a proposal by India and South Africa for a waiver for a range of intellectual property rights provided for in the TRIPS Agreement for COVID-19 products until a vaccine is widely available.

South Africa, in particular, had raised concerns about the TRIPS Agreement as early as June. Officials from South Africa repeatedly highlighted^{1,2,3} the importance of TRIPS flexibilities in facilitating access to medical products which might otherwise be not available or affordable. At an informal meeting of the TRIPS Ministerial Council in June^{4,5} South Africa pointed to the barriers that many developing countries face in using TRIPS flexibilities. South Africa also highlighted the inadequacies of the provisions in the TRIPS Agreement for compulsory licensing for export (so that countries without local manufacturing can access the benefits of compulsory licensing in the COVID-19 response). At a meeting in July, sponsored by the Africa Union, African health ministers also underlined their concern that patents and other technology barriers could negatively impact the ability of developing countries to access future COVID-19 vaccines⁶.

Ideas for strategies to overcome the barriers created by TRIPS had already been circulating in civil society forums. In a webinar in May, organised by the South Centre⁷, Dr Carlos Correa discussed how IP can create barriers to affordable access and discussed the various instruments that governments can use legitimately to overcome these, including through the non-grant of secondary medical use patents and application of rigorous standards in the examination of patent applications. Other instruments cited included compulsory licensing and the use of the security exception under Article 73(b) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Dr. Correa also discussed proposals for a moratorium on TRIPS obligations and the pooling of IP-protected technologies, know-how and data. He pointed out that these instruments are not mutually exclusive and all options should be on the table.

On 2 October India and South Africa communicated to the WTO TRIPS Council a proposal for a waiver of certain provisions of the TRIPS Agreement⁸. India and South Africa referred to reports about IPRs hindering or potentially hindering timely provisioning of affordable medical products to patients. In particular, they cited the cumbersome and lengthy process for

the import and export of pharmaceutical products under the requirements of Article 31bis. They requested that the TRIPS Council endorse a waiver of sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement, in relation to COVID-19; to remain in place until widespread vaccination is in place globally, and the majority of the world's population has developed immunity. Section 1 of part II of the TRIPS Agreement pertains to copyright and related rights; section 4 deals with industrial designs. Section 5 of part II of the TRIPS Agreement pertains to patents; section 7 deals with the protection of undisclosed information.

There was widespread civil society support for the waiver proposal. A sign on letter sponsored by the Third World Network attracted over 400 signatories from around the world⁹. The letter assembles comprehensively the case for the waiver, referring to the refusal of the pharmaceutical companies to participate in WHO's C-TAP, the use of secretive and restrictive licensing agreements, commercial disputes regarding alleged IP infringements in relation to COVID-19 products and global shortages. The letter acknowledged the possibility of deploying TRIPS flexibilities but pointed out that, "compulsory license offers a "product by product", and "country by country" approach with variations in national laws, whereas the pandemic requires collective global action to tackle IP barriers and facilitate technology transfer". It also noted the clumsy requirements of Article 31bis in issuing compulsory licenses for export/import.

MSF circulated a detailed briefing paper¹⁰ which included an overview of the impact of IP barriers on access to therapeutics, vaccines and diagnostics; three case studies examining IP barriers in the context of COVID-19 and examples of Article IX waivers that have been granted with respect to provisions under the Trade-Related Aspects of Intellectual Property Rights Agreement (TRIPS) Agreement in the past.

The proposed waiver was also supported by UNAIDS¹¹, UNITAID¹² and WHO's Director General Dr Tedros¹³.

Soon after the India and South Africa proposal was tabled, the WTO Secretariat pulled together an 'information note' on the TRIPS Agreement and COVID-19¹⁴, apparently designed to cut across the waiver proposal and to provide arguments for countries opposing.

When the proposal was opened at the TRIPS Council meeting on 16 October it was supported by a number of developing countries including China^{15,16} but opposed by several wealthy countries (plus Brazil). The proposal was suspended with the expectation of it being reviewed in a further meeting later this year^{17,18}.

Three main arguments were brought forward in opposition to the waiver: that IP protection is not a barrier to wider access to COVID-19 health products; that the flexibilities provided for in the TRIPS Agreement are adequate; and that IP is necessary to fund innovation¹⁹. See for example the UK statement²⁰.

It is true that there are a range of barriers to be overcome in the development of diagnostics, treatments and vaccines, not all of which are related to IP. However, there are several

examples that demonstrate that exclusive IP rights can be a barrier. It is also true that IP disputes have created barriers to scaling up vaccine production in the US²¹ and that the voluntary licenses imposed by AstraZeneca on the Serum Institute of India include arbitrary restrictions on countries to whom vaccines can be sold²².

The argument that IPRs are necessary to fund innovation is not consistent with the dependence of current R&D on donor funding and advance purchase agreements.

The proposition put forward by opponents of the waiver that the flexibilities provided for in the TRIPS Agreement are adequate is extremely cynical in view of the big power bullying of L&MICs by the EU and the US regarding legislating for and using such flexibilities²³. As was pointed out in the CSOs letter, organized by TWN, existing TRIPS flexibilities are not sufficient for the present pandemic situation. Compulsory licensing provides a “product by product”, and “country by country” approach whereas the pandemic requires collective global action to facilitate technology transfer and scale up manufacturing more broadly.

It is important to be clear about the differences between the proposed waiver, the existing TRIPS flexibilities (where they have been domestically legislated), WHO’s C-TAP initiative, MSF's campaign to not give patents to COVID-19 diagnostics, treatments or vaccines²⁴, or the Open COVID-19 Pledge²⁵, which would allow voluntary use (open licensing) of all patents and other intellectual property rights.

The waiver would suspend the protections provided under TRIPS for copyright, industrial designs, patents and technical knowledge. One of these protections is the requirement for countries to legislate to enable national judiciaries to issue permanent and preliminary injunctions under Articles 44 and 50 of the TRIPS Agreement^{26,27}. In the present circumstances if countries do not injunct domestic manufacturers who breach IPRs deriving from sections 1,4 ,5 & 7 they are exposed to the risk of country to country disputes and sanctions. However, if the waiver proposal were adopted the enforcement provisions of Section 2 would not apply. Countries would not be obligated to enforce.

The IP protections provided for under TRIPS ultimately depend on state to state dispute settlement. Deployment of protected vaccine technologies might still be illegal under domestic law but under a waiver, government would not be obligated to issue injunctions. Where TRIPS flexibilities have been incorporated into domestic law, access to such technologies could still be facilitated through compulsory licensing, parallel importing or other mechanisms. However, the waiver would also be useful here having regard to the difficulties of using Article 31bis and the ‘product by product’ character of compulsory licensing.

There is a certain logic in collective action by L&MICs through a TRIPS waiver, given the aggressiveness of US and European sanctions on individual countries who seek to legislate for the full use of TRIPS flexibilities and to actually use them. A group of South African academics wrote to President Ramaphosa in the lead up to the TRIPS Council meeting

congratulating him on the Indian and South African initiative²⁸ but urging him to act to reform the SA patent laws as well as acting globally and regionally. However, he may have judged that he would be less exposed to sanctions if the waiver proposal was adopted than if South Africa were to act unilaterally.

The opposition to the waiver in the TRIPS Council was predictable but the proponents could still find the 75% of members required to agree to the waiver²⁹. There is an immediate and urgent need for civil society organisations to explain and advocate to governments of all persuasions why they should support the waiver.

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2. <https://www.keionline.org/wp-content/uploads/W666.pdf> (996, 17 July)
3. <http://msfaccess.org/msf-applauds-south-africa-championing-health-safeguards-meeting-wto-members> (1116, 3 Aug)
4. <https://twn.my/title2/health.info/2020/hi200610.htm> (642, 24 June)
5. <https://www.keionline.org/33388> (587, 19 June)
6. <https://msfaccess.org/african-union-says-urgent-need-address-patents-and-technology-barriers-access-future-COVID-19> (678, 2 July)
7. <https://us5.campaign-archive.com/?u=fa9cf38799136b5660f367ba6&id=c865cdddb9> (1193, 8 May)
8. <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W669.pdf&Open=True> (1550, 2 October)
9. https://twn.my/announcement/signonletter/CSOLetter_SupportingWaiverFinal.pdf (1746, 15 Oct)
10. <https://msfaccess.org/india-and-south-africa-proposal-wto-waiver-ip-protections-COVID-19-related-medical-technologies> (1610, 9 Oct)
11. https://www.unaids.org/en/resources/presscentre/pressreleaseandstatementarchive/2020/october/20201015_waiver-obligations-trips-agreement-COVID-1919 (1643, 15 Oct)
12. <https://unitaid.org/news-blog/unitaid-supports-call-for-intellectual-property-waivers-and-action-for-access-to-COVID-19-products/> (1632, 13 Oct)
13. <https://www.thehindubusinessline.com/economy/who-lends-support-to-ip-waiver-proposal-from-south-africa-india/article32885984.ece> (1670, 18 Oct)
14. https://www.wto.org/english/tratop_e/COVID-19_e/trips_report_e.pdf (1663, 15 Oct)
15. <https://mailchi.mp/southcentre/southnews-wto-trips-council-discusses-major-proposals-for-waiving-certain-trips-obligations-and-extension-of-transition-period-for-ldcs?e=59a8962a20> (1721, 23 Oct)
16. <https://genevahealthfiles.substack.com/p/a-peek-into-covax-machine-the-curious?token=eyJ1c2VyX2lkjoxNTUwNzIxOCwiczG9zdF9pZCI6MTM1NTc2NjcsIl8iOiJyYk4dClslmlhdCI6MTYwMzQwNzg5NiwZlXhwjoxNjAzNDExNDk2LzJpc3MiOiJwdWltNzgzOTYlClJzdWl0iJwb3N0LXJlYWN0aW9uIn0.RAYImQ60jH0DxrVcj4Op0yWkrNt9-XkOeMKE8xvZiPA> (1712, 22 Oct)
17. https://www.wto.org/english/news_e/news20_e/trip_20oct20_e.htm (1683, 20 Oct)
18. <https://www.keionline.org/34275> (1685, 20 Oct)
19. <https://twn.my/title2/health.info/2020/hi201011.htm> (1681, 20 October)
20. <https://www.gov.uk/government/news/uk-statement-to-the-trips-council-item-15> (1679, 16 Oct)
21. <https://www.twn.my/title2/health.info/2020/hi200606.htm> (544, 19 June)
22. <https://www.astrazeneca.com/media-centre/articles/2020/astrazeneca-takes-next-steps-towards-broad-and-equitable-access-to-oxford-universitys-potential-COVID-19-vaccine.html> (827, 4 June)
23. <https://twn.my/title2/health.info/2020/hi201012.htm> (1682, 20 Oct)
24. <https://msf.org.au/article/statements-opinion/COVID-19-msf-calls-no-patents-or-profiteering-drugs-tests-and-vaccines> (1 April)
25. <https://openCOVID-19pledge.org/2020/04/07/patent-holders-urged-to-take-open-COVID-19-pledge-for-quicker-end-to-pandemic-2/> (7 April)
26. https://www.wto.org/english/docs_e/legal_e/27-trips_05_e.htm#1
27. https://www.southcentre.int/wp-content/uploads/2020/10/RP-119_reduced.pdf
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29. https://www.wto.org/english/docs_e/legal_e/04-wto_e.htm#articleIX (see Article IX, Clause 3)