Draft Letter to WTO Members Urging Support for the Proposed Covid TRIPS Waiver

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WTO Ambassador
Your Excellency,

Scores of countries and thousands of civil society organisations around the world are hoping that you will support the proposed Covid TRIPS waiver at the TRIPS Council this week.

Many developing countries are facing the prospect of long delays and significant cost barriers in accessing vaccines, medicines and diagnostics to control the pandemic (see below '1. Delays and Barriers). Such delays and cost barriers are likely to be the cause of avoidable deaths and will perpetuate a heightened risk of international transmission.

In the face of the prospect of delays and cost barriers, the rapid scaling up of local production could make a big difference to pandemic control in developing countries. Scaling up local production calls for collaborative capacity building including organised technology transfer partnerships. Scaling up of local production would be greatly facilitated by waiving compliance with Sections 1, 4, 5, and 7 of Part II of the TRIPS Agreement (dealing with copyright, industrial designs, patents, and the protection of undisclosed information) in relation to Covid and for the duration of the pandemic.

Three main arguments were brought forward by countries opposing the waiver when it was first considered by the TRIPS Council: (i) that intellectual property protection is not a barrier to wider access to COVID-19 health products; (ii) that the flexibilities already provided for in the TRIPS Agreement are adequate; and (iii) that IP is necessary to fund innovation.

In fact, the protection of intellectual property is a very real barrier to scaling up local production, albeit not the only challenge (see below '2. IP is a real barrier to local production and availability').

In fact, the flexibilities already provided for in the TRIPS Agreement are not well suited to the task of scaling up across a range of health products and involving collaborating groups of countries (see below '3. Existing TRIPS flexibilities are not the answer').

In fact, the proposed waiver would only apply to Covid-19 products; would only apply for the duration of the pandemic; and would only apply to those countries who chose to make use of it. In view of the very significant funding mobilised internationally to support research and development for Covid-19 health products, it is most unlikely that allowing the limited waiver proposed would materially affect commercial incentives to invest in innovation for Covid-19 products during the pandemic.

The proposed waiver would only apply to countries who choose to make use of it. Intellectual property rights would remain untouched in countries who chose not to make use of the waiver (see below, '4. Adopting the waiver would be voluntary'). However, countries whose access to Covid products is secure should not stand in the way of those countries who need the policy space to scale up local production in the face of the very real threat of delays and cost barriers and the consequential morbidity and mortality.

It would be an act of international solidarity if countries who have secured vaccine supplies were willing to actively participate in an organised approach to capacity building and technology transfer. Such technology transfer could be greatly facilitated by the suspension of IP protections under the proposed waiver.

In late November, Australia, Canada, Chile and Mexico, circulated eight questions to Trips Council members regarding the proposed waiver. The questions variously deal with procurement, local production, use of Article 31, use of Article 31bis, copyright, industrial design, undisclosed information, and giving effect to the waiver. This communication is a rhetorical intervention against the waiver, notwithstanding the innocent tone of inquiry. These questions are intended to embarrass, frustrate, and obfuscate. Countries should not attempt to answer them because their answers will be used to legitimise opposition to the waiver. See Annex 2 below for a more detaied analysis of the Eight Questions.

Your Excellency, for reasons of solidarity, public health and our collective interest in ending the pandemic, please support the proposed waiver in the TRIPS Council.

Annex 1. Further details

1. Delays and barriers

The ACT Accelerator looks set to be underfunded and likely to face supply limitations consequent upon large scale advanced purchase agreements by countries and regional blocs.

The Covax facility excludes upper middle income countries and only provides vaccine doses for the priority population fraction, at maximum 20% of the population.

Widespread and large scale advance purchasing will greatly limit supplies for direct purchasing by developing countries and push up prices because of the competition.

Monoclonal antibodies (mAbs) look set to be one of the more promising therapeutics. However, the production of mAbs is slow and complex and the end products are notoriously expensive.

There are several promising rapid diagnostic tests (RDTs) in the pipeline and as they become available they will be critical for the control of pandemic surges (such as currently taking place in Europe and the US). The advantage of RDTs in an epidemic surge is the scope for widespread and frequent testing. For these reasons the RDTs are likely to be in short supply for quite a while and probably quite expensive (in the face of Northern demand).

Delays and barriers in accessing vaccines, medicines and tests carry a real threat of avoidable morbidity and mortality.

2. Intellectual property protection is a real barrier to scaling up local production and availability

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 significant barrier.

It is also true that IP disputes have created barriers to scaling up vaccine production in the US and that the voluntary licenses imposed by AstraZeneca on the Serum Institute of India include arbitrary restrictions on countries to whom vaccines can be sold.

3. Existing TRIPS flexibilities are not the answer

While the TRIPS Agreement contains flexibilities that can promote access, many WTO Members may face challenges in using them promptly and effectively. For instance, 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 associated with various platform technologies as well as specific products.

Where the IP barrier lies beyond patents – design, copyright or trade secrets - national laws may not provide for sufficient flexibilities. Further, Article 31bis, a mechanism to enable compulsory licenses for export to without manufacturing capacity, does not provide an expedited solution and many countries have also opted out of using the mechanism.

4. Adopting the waiver would be voluntary

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. In the present circumstances if countries do not injunct domestic manufacturers who breach IPRs deriving from sections 1,4 ,5 & 7 they would be exposed to the risk of country to country disputes and consequent sanctions. However, if the waiver proposal were adopted and a country chose to take advantage of it the 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 by useful here having regard to the difficulties of using Article 31bis and the 'product by product' character of compulsory licensing.

Annex 2. The Eight Questions Communication

In late November, Australia, Canada, Chile and Mexico, circulated eight questions to Trips Council members regarding the proposed waiver. The 'Communication' can be retrieved from: https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W671.pdf&Open=True.

The questions variously deal with procurement, local production, use of Article 31, use of Article 31bis, copyright, industrial design, undisclosed information, and giving effect to the waiver.

This communication is a rhetorical intervention against the waiver, notwithstanding the innocent tone of inquiry. These questions are intended to embarrass, frustrate, and obfuscate.

Many developing countries, if they take the questions at face value, would have to reply in the negative and thus give support the case for rejecting the waiver. The fact that some developing nations have not tested the limits of the TRIPS regime in responding to Covid-19 may reflect a lack of capacity and/or political will. However, it is essential to recognize the threats and arm twisting in trade negotiation through which the EU and the US and their friends in Pharma, supported by Trojan horse technical assistance from WIPO and rich country patent offices, have sought to force countries to adopt IP laws which preclude the use of TRIPS flexibilities.

Where countries have adopted laws operationalizing the TRIPS flexibilities, the bullying has been around the application of such laws. The Super 301 provisions of the US Trade Act have been used repeatedly to prevent countries from using TRIPS flexibilities and heavy pressure in trade negotiations have been used to prevent countries from domesticating the flexibilities of the TRIPS Agreement. Pharma and the USTR work hand in glove in deciding which countries to target through Super 301.

IP rights deter generic companies and competitive producers from even exploring the possibilities of market entry because of the threat of crushing legal liabilities.

The questions as loaded and countries should not attempt to answer them because their answers will be used to legitimise opposition to the waiver. This is not a debating session where the best team wins. These questions are directed to justifying opposition to the waiver while assuming a mantle of rationalism in policy; more effective diplomatically than taking a more explicit position defending the interests of transnational pharma.

These four countries are all progressive social-democratic polities with publicly funded universal health coverage systems. They are all IP importers and it would be in their interest to have cheaper drugs through more relaxed IP regimes. So, why are they looking after the interests of transnational Pharma?

Some more specific comments on the specific questions:

While we criticize the eight questions as a rhetorical intervention, there are legitimate answers to all of them.

1. Procurement. This question asks about diagnostics, equipment, therapeutics and vaccines. As noted above there are as yet no products under the latter two items (only just in the case of vaccines). However, it would be interesting to know if there have been any cases involving diagnostics and equipment (PPE, oximeters, oxygen concentrators, etc). Question 1 asks about "IP challenges" impeding procurement. Price gouging owing to supply shortages ought to be raised here in any commentary. Vietnam's decision not to proceed with vaccine procurement because of the cost is relevant here.

2. Local production. Again, the listing of therapeutics and vaccines is quite theoretical but it would be interesting to know about diagnostics and equipment. The rising importance of 'platforms' in therapeutics and vaccines points to a range of second order IPRs which are necessary for platforms but not tied to particular products. The paper on Examples of IP issues and barriers in COVID-19 pandemic presented by co-sponsors of the waiver doesn't answer the eight questions but certainly demonstrates the 'thicket' of patent barriers to local production. Patent rights on COVID 19 technologies, many of which have already been granted and 1000s of which are pending, lie unpublished in patent offices around the world, and deter alternative producers from investing in generic product development since they could so easily be sued for infringement by deep pocket technology right holders.
3. Use of Article 31. The formulation of this question clearly seeks to exclude from consideration pressures to not domesticate the provisions of Article 31 or big power bullying around the deployment thereof. Again, the question is quite theoretical in relation to drugs and vaccines. The pressures which rich countries have used to prevent countries from domesticating TRIPS flexibilities and from using them is undeniable. While compulsory licenses could theoretically be used, to be effective in responding to the pandemic they would often have to be coordinated in order to source components from other countries with patent barriers and to create sizeable markets attractive for generic entry.
4. Use of Article 31bis. This is not an honest question. Following the 2001 Doha decision to legislate from compulsory licensing for export, the rich countries, first, sought to defer action, and then sought to construct the most impractical provisions to (theoretically) give effect to that decision. Article 31bis is impossibly difficult to use.
5. Copyright. copyright can be used to protect medical device software programs, industrial blueprints, and the like.
6. Industrial design. Industrial designs can also protect medical devices, especially closed systems that frustrate interoperability and use of alternative cartridges.Likewise.
7. Undisclosed information. Trade secrets present enormous barriers to production of vaccine and biologic medicines because of exclusive rights over complex manufacturing know-how and key biological inputs including cell lines This is a seriously smarmy question.
8. Giving effect to the waiver. The legal mechanisms required at the national level to give effect to the waiver would be country specific, depending on the broad legal environment and the specifics of their IP laws and provisions regarding prosecution and litigation.