Why we need your support

Why we need your support for India and South Africa's proposal for Waiver of Intellectual Property Protections in TRIPS for COVID-19 related technologies

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Why do we need your support?

On 02 October, 2020, India and South Africa made a joint submission to the WTO TRIPS Council (hereinafter, the "Proposal") seeking a temporary waiver on certain provision of the Agreement on the Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement). The waiver is sought to ensure prevention, containment and treatment of COVID-19.

This waiver to be further discussed by the TRIPS Council within 90 days of its submission, that is by December 31, 2020 and submit its report to the WTO Ministerial Council.

At its introduction most Low- and Middle-Income countries (LMICs) either supported the Proposal or were undecided, while a few developed nations opposed it. We need your intervention to ensure that the general consensus or at least an overwhelming majority support the Proposal in the upcoming meetings of the TRIPS Council.

It would also help for this Proposal to be announced and endorsed by the United Nations Special Meeting on COVID-19 being convened in early December.

What is the waiver that is being asked for?

The Proposal seeks waiver of implementation, application and enforcement of provisions related to copyright (Section 1 of Part II), industrial design (Section 4 of Part II), patents (Section 5 of Part II) and protection of undisclosed information under the TRIPS Agreement (Section 7 of Part II).

The Proposal is made under Article IX of the Marrakesh Agreement Establishing the WTO that allows waiver from certain obligations of the member countries under WTO treaties in exceptional circumstances.

Why we need your support for India and South Africa's proposal for

How long will it last?

This temporary waiver is sought for a period till vaccination of a comprehensive population worldwide is achieved and the immunity is developed in majority of the world's population.

What happens if the waiver is granted?

- It will remove many of the barriers that exist today for better access to essential COVID-19 related medical products by making it easier for innovation, rapid ramping up manufacture of these and further development/improvement reducing costs and enabling imports of the most affordable options.

- Many of the barriers to access relate to transfer of technology and restriction to reproduce. If the waiver is granted, the countries will have the freedom to **suspend grant or enforcement** of copyright, industrial design, patents and protection of undisclosed information in their country on all COVID-19 related drugs, diagnostics, vaccines, treatments, medical supplies, bio-similars and test data, all of which are barriers to transfer of technology and production by reverse engineering.

- Some barriers to access relate to trade aspects and the waiver will ensure ability of all countries to import and export COVID-19 related products according to their needs without fear of sanctions under the international trade regime. The public health mechanism available under TRIPS allowing compulsory license for import of pharmaceutical products is saddled with bureaucratic pre-requisites. The waiver when enforced in the exporting and importing country, will allow bypassing the long time-consuming process, to ensure speedy access to COVID-19 tools across all countries.

- The waiver will ensure greater sharing of information that would stimulate innovation, and also allow countries to **respond better to the needs of its population** with no accessibility or affordability barriers. This means there will be no monopoly over varied COVID-19 tools across the supply-chain (value-chain) such as testing kit components, ventilator valves, medicines, and other essential equipment.

- The waiver will help overcome cost and regulatory barriers, helping avert many deaths due to lack of timely and affordable access to health tools.

- The waiver will be applicable to all WTO members, including least-developed, developed and developing countries but not mandatory to invoke. Member countries can choose to not invoke the waiver, if they need to.

What reasons are advanced by some developed nations against this waiver and why do we oppose these:

Contention 1: Intellectual Property (IP) is not a barrier to innovation and production.

Our response: Simply NOT true.

Only when countries with production capacity do not have IP barriers, will they be able to immediately provide support to countries lacking manufacturing capacity. To export the products, the countries will have to ensure that there is no intellectual property restriction in *both*, the

countries, one that is exporting and the country that is importing. Further, in case of vaccines, intellectual property protection runs across entire process of vaccine development, production and use, making it all the more necessary to overcome intellectual property barriers in a holistic manner. Yet another example is how Netherlands could not scale up its testing because Roche refused to share the know-how related to a buffer in testing reagent. Many other such examples exist:

Contention 2: Pharma companies are providing voluntary licensing for manufacture in LMICs.

Our Response: Experience shows otherwise- even in COVID-19 itself. For instance, despite calls for non-enforcement of its patents on Remdesivir, Gilead went on to negotiate voluntary licenses in secrecy that completely exclude Latin American countries and despite the voluntary licenses the prices are unaffordable. This also means that competition is limited and costs and markets are decided by the IP owner- so there is higher cost and restricted market even where (limited) manufacture is allowed. Also, no transfer of technology is permitted, restricting scaling up.

Contention 3: Existing TRIPS flexibilities will suffice in responding to the COVID-19 pandemic.

Our Response: The TRIPS flexibilities are helpful, but in such a pandemic they are not enough. Use of flexibilities like applying a compulsory license, have to be done on a country-to-country

- In 2002, the LDC members under paragraph 9 of Article 70 of the TRIPS Agreement were waived with respect to pharmaceutical products until 1 January 2016.
- In 2003, the under Article 31(f) of the TRIPS Agreement was waived with certain conditions for exporting countries compulsory license for export of pharmaceutical product(s) and its export.
- In 2015, the waiver to LDCs to not implement, or enforce obligations under Article 70.8 and 70.9 of the TRIPS Agreement with respect to exclusive market rights and mailbox obligations, was extended

Examples of Article IX waivers granted for provisions under the TRIPS Agreement

and product-to-product basis. This is very tedious, time- consuming process needing state intervention at frequent times, for each product of the supply chain (value-chain), and will slow down the collaborative action against COVID-19, which requires rapid response. With the evolving nature of treatment, it would be difficult for countries to target specific products to use a case by-case approach. With the waiver the know-how can be shared in public domain.
Further, countries that have used TRIPS flexibilities like compulsory license come under intense pressure from the USA and few other developed countries in international trade and diplomacy.

Contention 4: IP is essential for innovation of new drugs and vaccines. Without IP protection pharmaceutical companies cannot recover what they spend on innovation.

Our Response: Most of the innovation is developed with assistance of public financing, and therefore there is a public right to the scientific advancement so achieved. Further, there is no evidence indicating that IP is helpful for innovation where public health needs are concerned, rather the evidence suggests to the contrary. A better approach would be for pharmaceutical companies to be transparent about costs of innovation and production.

Is the waiver adequate to solve the problem of access to COVID-19 medical products?

The waiver is essential, but not sufficient. A waiver will give countries the confidence to mutually co-operate and encourage local producers to contribute to development of COVID-19 related tools without fear of infringement proceedings.

Questions over equitable distribution of COVID-19 tools continue to loom. Countries with the financial resources are entering into advance purchase agreements to secure doses of (future) COVID-19 vaccines for their populations. The LMICs and LDCs lacking such financial resources may not be able to afford so many vaccine doses. Such countries may have to wait for over a year to procure these drugs albeit only to the extent the country's financial ability permits.

Which countries and institutions are supporting the Proposal?

The Proposal has been submitted by India and South Africa and is co-sponsored by Kenya and Eswatini. It is being supported by the group of LDCs, ACP and Africa group of countries, and Nicaragua, Pakistan, Sri Lanka, Tunisia, Venezuela, Holy See, Nigeria and Senegal. WHO and UNAIDS have also extended their support to the Proposal.

What would it mean for *insert country name* to support the Proposal for waiver?

* Acceptance of the Proposal for waiver will allow *insert country name* to bring in emergency policies to respond to many challenges that our country is facing without without fear of trade sanctions or tedious paper work. Examples of such challenges are:

cartridges for essential machines could not be 3-D printed, COVID-19 medicines are being sold in black market at high costs, there is stock out of N95 masks etc.*