A PHM Policy Brief

for Waiver of Intellectual Property Protections in TRIPS for COVID-19-related technologies

November, 2020

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 provisions 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.

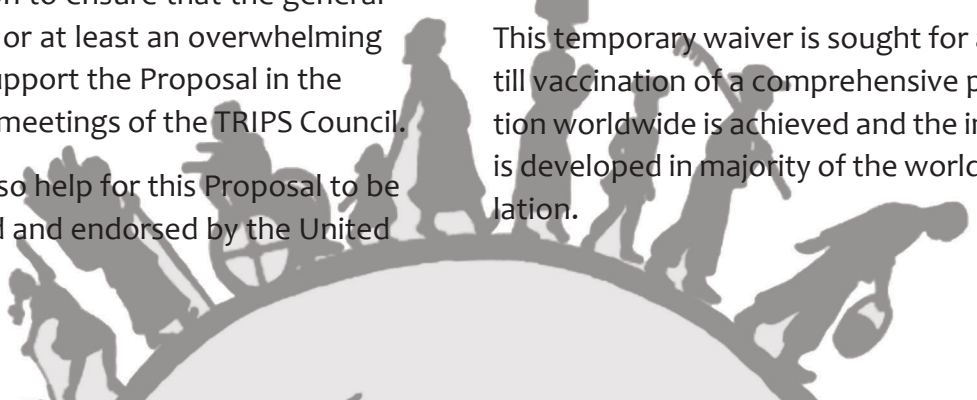
What is the waiver that is being asked for?

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 a legitimate one 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.

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. This would lead to:

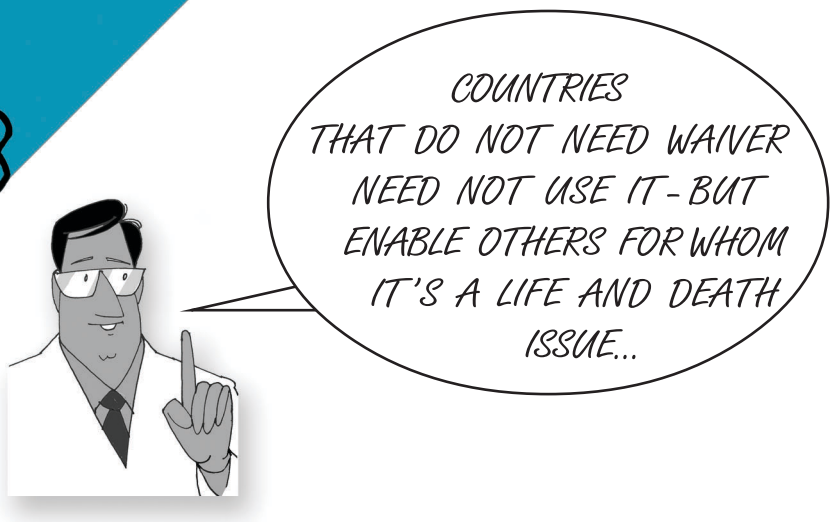
- *Rapid scaling up of manufacture worldwide:* The waiver enables technology transfer by enabling suspension of the grant or enforcement of copyright, industrial design, patents and protection of undisclosed information across the value-chain.
- *Stimulation of Innovation:* Greater sharing of information & removing monopoly would enable to develop more affordable products as well as newer, improved COVID 19 medicines, vaccines and essential equipments.
- *Enabling Imports of the most affordable product options* from the global market, without fear of sanctions under the international trade regime.
- *Lowering costs of the products and removal of regulatory barriers*

Why COVAX is not good enough?

COVAX is a facility created by a number of global health institutions to facilitate access to vaccine for developing countries. COVAX finances big pharma in return for supply of only limited doses for identified developing countries. This has been projected as the main answer for redressing inequity in access to vaccines.

However this approach has severe limitations:

- Limited supply: COVAX guarantees vaccines to only priority population around 20% of the population Rest will be at market rates.
- Will not enable transfer of technology and for rapid scale up of manufacture
- Strengthens existing intellectual property regime, undermines efforts at alternatives/improvements
- Inefficiencies and costlier as COVAX is paying more because of IPR costs when most of the funding is already from public money.
- No transparency in agreements with other countries: prices, delivery schedules, quantities unknown.
- Conflict of interests in governance structure: Role of WHO marginalized.



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

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 at *both ends*, the exporting countries and importing country. Further, in case of vaccines, intellectual property protection runs across entire value-chain (vaccine development, production and use) making it all the more necessary to overcome intellectual property barriers in a holistic manner. An 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.

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

- In 2002, the obligations of 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, obligation under Article 31(f) and 31(h) of the TRIPS Agreement on countries importing or exporting pharmaceutical products was waived.
- 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.

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 and product-to-product basis. This is very tedious, time- consuming and a lengthy litigation 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 of blocking innovation. 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.

Acceptance of the Proposal for waiver will allow developing countries to bring in emergency policies to respond to many challenges that tier country is facing without fear of trade sanctions or tedious paper work.

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, African, Caribbean and Pacific Group of States 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.

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