


Making the TRIPS Agreement Work Effectively for the Public Health Challenges

ISID organised a Working Session on “Reforming the TRIPS Agreement to respond effectively to the public health challenges” on October 1, 2021. The distinguished panel moderated by Prof Nagesh Kumar, Director, ISID, comprised Dr Carlos Correa, Executive Director, South Centre, Geneva; Prof Kevin Gallagher, Director, Global Development Policy Centre, Boston University; Ambassador Faizel Ismail, Director, Nelson Mandela School of Public Governance, University of Cape Town and former PR of South Africa to WTO; and Prof Srividhya Ragavan, Professor of Law, Texas A&M University. The YouTube link of the session is available at <https://www.youtube.com/watch?v=xl3Virzw4TU> 

Key Messages

A concern was expressed about the inequities in the distribution of covid-19 vaccines with very poor rates of vaccination in the least developed countries. Vaccines need to be treated as global public goods because it would not be possible to contain the pandemic without quick vaccination of the entire global population. The Doha Declaration on TRIPS Agreement and Public Health has been of limited relevance in addressing the challenges of pandemic. Hence, India and South Africa sought a temporary waiver of certain TRIPS provisions for facilitating access to vaccines and other covid treatments. Some major constraints in exercising the TRIPS flexibilities include the fear of economic sanctions by advanced countries, especially the US; intense lobbying against the use of flexibilities by the pharma industry globally, including in developing countries; interpretation of TRIPS provisions by WTO panels based on trade jurisprudence, without regarding the policy objectives of IPRs; and TRIPS-Plus provisions in the

FTAs. Even though the proposal has been supported by over 100 countries, it has not yet been approved by the TRIPS Council.

The TRIPS Waiver proposal is very specific and pragmatic. It is only making a demand for a waiver from the current rights of IPR holders so that vaccines become more accessible and affordable to most of the world's population. The amended proposal makes it clear that all health products and technologies for the prevention and treatment of COVID-19 should be subjected to this waiver. As this proposal is very specific and for a limited period to address the pandemic, it should be supported.

On the issue of equitable distribution of COVID-19 vaccines, a three pillars approach is needed for global vaccine equity *viz.* TRIPS Waiver, technology transfer and robust financing. TRIPS Waiver will remove all the legal barriers in scaling up vaccine production. Technology needs to be transferred to those who have production capabilities. It is estimated that

\$23 billion is needed to upgrade facilities to take advantage of TRIPS Waiver.

The COVID-19 pandemic has led to the realisation that there will be no trade if peoples' health is not protected. Health trumps trade. TRIPS Waiver is essential for many reasons. It waives all IPRs as opposed to patents. The waiver will make the rule uniformly to all relevant IPRs. The waiver can minimise the cumbersome procedure involved in issuing compulsory license (CL) and can result in scaling up local production. A public health treaty, starting with this pandemic and ready to address all future public health challenges without compromising on innovation that can lead to sustainable development, is the need of the hour.

Summary of the Proceedings

Prof Nagesh Kumar

The world is passing through one of the greatest challenges that humanity has ever faced namely, the COVID-19 pandemic. This pandemic has affected more than 240 million people and more than 5 million people have lost their lives. The only option available for us to address this pandemic is to vaccinate everyone. Although vaccines have been developed through the involvement of public sector institutions and private enterprises, the accessibility of vaccines remains a major concern, especially in developing countries. A large number of people in developing countries are still unvaccinated which is a threat to everyone else as no one is safe until everyone is safe. As mutants are emerging, the only solution is to vaccinate the global population. In that perspective, the vaccines should be considered as global public good rather than proprietary products of the innovator. It is about two decades since the Doha Declaration on

TRIPS Agreement and Public Health was adopted and still, it has been of limited relevance to WTO members in addressing the pandemic. It was in this context, a TRIPS Waiver proposal was initiated in the WTO by India and South Africa.

Dr Carlos Correa

It has been two decades since the adoption of the Doha Declaration on TRIPS Agreement and Public Health. But it has been of limited relevance to countries for handling the COVID-19 pandemic. What are your reflections on the constraints that countries face in exercising public health exemptions in the TRIPS Agreement?

There are a few constraints that countries face in using the public health exemptions for addressing public health challenges. One, design of the IP laws. Complying with the TRIPS agreement required major changes in the national IP laws of developing countries. There was pressure from advanced countries, especially the United States (US), to incorporate provisions in the IP laws that are similar to those existing in advanced countries. Major threats came from the Section 301 of the Trade Act 1974 of US, which allows the US government to impose trade sanctions against those countries whose IP laws harm its interests. Argentina did not fully use the transition period for the implementation of product patents in pharmaceuticals due to the threat. Ironically, the US law related to Section 301 of the Trade Act provides that compliance with TRIPS Agreement is not sufficient to prevent the threat of sanctions under that section. Two, lobbying by the Pharma industry. A recent report shows that in the last 22 years pharma industry has spent \$4.4 bn for lobbying in advanced countries as well as in developing countries. The lobbying in

developing countries is for not exercising TRIPS flexibilities. Three, interpretation of TRIPS provisions. The WTO panels have interpreted TRIPS provisions based on trade jurisprudence, without regarding the policy objectives of IPRs. Four, TRIPS Plus provisions in FTAs is undermining the TRIPS flexibilities. Five, Configuration of TRIPS Flexibilities – CL applies only to patents and not know-how and other IPRs.

Use of Article 31 bis is a cumbersome process. It is possible to manufacture and export under Article 30 of the TRIPS Agreement. However, countries do not exercise this option due to the threat of sanctions. Recently, the EU has waived off the protection given under supplementary protection certificates, which provide for an extension of patent rights, for the manufacture and export of pharma to non-EU Members. The theory behind this measure is perfectly applicable to Article 30 for exports.

There are some issues in using CL as a mechanism for addressing the covid pandemic. Patent rights are territorial in nature and there are difficulties in knowing the details of patents like whether a patent is for chemical or biological molecule or compound. And the process is long. We already have lost time. Now, it is time to act fast and TRIPS Waiver is the desirable solution.

Amb Faizel Ismail

India and South Africa have made a proposal in the WTO for a waiver from TRIPS obligations of vaccines and other treatments for COVID-19 pandemic. Despite the support this proposal has received from other members of WTO, a final decision has not been arrived at. How significant is the proposal in your view and will MC-12 endorse the proposal?

COVID-19 has exposed asymmetries and imbalances in society as well as in the patent system. The first democratic government of South Africa, led by Nelson Mandela, had to face this asymmetry and imbalance in the context of AIDS epidemic. The Government's decision to parallel import cheaper medicines for HIV/AIDS was challenged in the court by 39 pharma MNCs on grounds of violation of the TRIPS Agreement. It was in this background that the Doha Declaration on the TRIPS Agreement and Public Health was announced. There has been a tension between the rights of patent holders and their obligations to society. There were commissions that looked into this issue and highlighted the imbalances and asymmetries in the rights and obligations of patent holders. The WHO Commission of 2000 and the report of the UN Secretary-General in 2016 brings out the tension between patent rights and the rights of people for treatment. It is found that R&D in the pharmaceuticals sector is focused on selected diseases that are prevalent globally. Those diseases which affect mostly the developing countries do not receive any priority in the R&D strategy leading pharma firms.

The manufacturing capacity is controlled by big pharma firms in rich countries. The rollout of COVID-19 vaccine brings out the asymmetry in the distribution of vaccines. Only two percent of the people in Africa has been vaccinated.

The proposal on TRIPS waiver is very specific and pragmatic. It is not asking for overhauling of the patent system. It is only making a demand for a waiver from the current rights of patent holders so that vaccines become more accessible and affordable to the majority of the world's population. The amended proposal makes it clear that all health products

and technologies for the prevention and treatment of COVID-19 should be subjected to this waiver. And this waiver is proposed for a period of three years, which could be reviewed after that. This proposal is very specific and for a limited period to address the pandemic and therefore this proposal should be supported. The US has expressed its willingness to negotiate on this. However, the EU is not engaging on a text-based negotiation. The EU needs to engage before MC-12 for a meaningful outcome from MC-12.

Prof Kevin Gallagher

The Global Development Policy Centre at Boston, recently published a policy brief on three pillars of vaccine equity. Can you elaborate on the three pillars?

The failure to vaccinate the world is a historic tragedy of multilateralism that people will talk about for centuries. While the US has vaccinated 70 percent of its population, only two percent of the population has been vaccinated in poor countries. This raises not just moral outrage but is resulting in economic calamity. The International Chamber of Commerce has estimated that the economic cost of not vaccinating is more than \$9 trillion. There are major issues not only in vaccine distribution but also in vaccine production.

The policy brief is proposing three pillars for ensuring vaccine equity. They are - TRIPS Waiver, technology transfer and robust financing. TRIPS Waiver will remove all the legal barriers in scaling up vaccine production. Technology needs to be transferred to those who have production capabilities. Many of the firms who were asked to share the technology voluntarily did not do so. They need to be compelled to share the technology with

WHO Technology Access Pool and few other mechanisms. The US, for example, can use its rights under Biomedical Advanced Research and Development Authority to compel the firms to share the technology. It is estimated that \$23 billion is needed to upgrade facilities to take advantage of TRIPS Waiver.

CL is not a solution for addressing this pandemic. It requires issuing licenses for every patent and it is a time-consuming process. And the process involved in exporting vaccines under CL is very long. The TRIPS waiver will remove all these barriers. Oxfam estimates that it is five times costlier (as compared to \$23 billion) to vaccinate due to monopoly rights.

Prof Srividya Raghavan

You have written about the strengths and weaknesses of the TRIPS Waiver proposal. What are your views about the proposal? How do you see the counterproposal of the EU that the existing provisions of the TRIPS Agreement is sufficient to address the COVID pandemic?

COVID-19 pandemic has led to the realisation that there will be no trade if peoples' health is not protected, health trumps trade. The TRIPS Waiver is essential for many reasons. First of all, it waives all IPRs as opposed to patents. Waiving off trademarks, copyrights and trade secrets along with patents is essential for facilitating access to covid products. With a waiver, Article 39.3 of TRIPS can be used for sharing of trade secrets. Some AI technologies are protected under copyrights. CL can be issued for copyrights also. But the waiver will make the rule uniformly to all relevant IPRs. Secondly, the waiver can minimise the cumbersome procedure involved in issuing CL. Every state will have to meet the legal requirements for issuing CL

and there are additional cumbersome requirements for exporting or importing under CL. Thirdly, the waiver can result in scaling up local production and thus meet the objectives of Articles 7 and 8 of the TRIPS Agreements in meeting the sustainable development agenda. Countries like Bangladesh and Botswana are ready to scale up local production. The waiver will enable countries to move to the next level of development.

WTO should have robust involvement with WHO to address public health issues rather than spinning on its own axis. A public health treaty, starting with this pandemic and ready to address all future public health challenges without compromising on innovation and that can

lead to sustainable development, is a need of the time.

TRIPS waiver is more useful in promoting access to covid products. Using CL for pushing down prices will take a long time and thus making vaccine available quickly a redundant exercise. Humira, a non-covid medicine, has 150 live patents. Issuing CL for all 150 patents for bringing the price down will be a long cumbersome process. Although this is a non-covid drug, it shows the complexities involved in relying on CL mechanism for addressing COVID-19 challenges.

The EU counter proposal will end up in delaying the final decision. Many Members of the European Parliament are aware of this and hopefully EU will stay away from that proposition soon.

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