INTELLECTUAL PROPERTY RIGHTS

IP WAIVER FOR COVID-19 VACCINES, TRIPS AND ITS IMPLICATIONS

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Points and objectives of this blogs and article.

1. Letter to WTO by India and South Africa in October 2020 to propose certain IP and TRIPS Waiver for COVID-19 related drugs and products.

2. More than 100 countries, mostly developing countries have signed on, in support of waiver. A few developed countries signalling their opposition.

3. Geopolitical stand on innovation and IP.

4. TRIPS on innovation and IP vis-à-vis balancing of rights.

5. Ambiguity created with proposed TRIPS waiver.

Introduction

With pandemic taking the life of human being to a complete new paradigm since last one year effecting human being, countries, their economic lives, their social behaviour and new thinking.

1. In October 2020, India and South Africa addressed a letter to WTO requesting to suspend certain Intellectual Property ('***IP***') protections for COVID-19 vaccines and related products. Both the countries have asked WTO to consider the waiver of the part of the Agreement on trade related aspects of intellectual rights giving reasons that in the absence of the same, it has slowed down production of an excess to COVID-19 vaccine.

2. As of May 2021, more than 100 countries mostly developing countries have joined and supported India and South Africa's calling for the waiver of IP for COVID-19 vaccines and related products.

3. In USA the Joe Biden administration recently announced their support to the TRIPS waiver request. But was it pro-active? It is believed that it was decided after the pressure from certain progressive activists and democratic law maker in Congress. In contrast to this, the White House has released a statement that really manufacturing is the biggest problem. They believed it is not the IP but logistical distribution challenges and lack of sufficient frontline workers has contributed to slow down of production and access to COVID-19 vaccines and related products. In other words, it is believed that scaling of production instead of TRIPS waiver is something required at this stage.

TRIPS and its understanding:

1.The TRIPS agreement is an international trade agreement amongst 164 members nation countries of WTO with an objective to unified trade and smooth functioning of international economic relationship. The basic objectives of the TRIPS are following:

2. Providing minimum IP protection and standard for all WTO members.

3. Provisions for enforcement action that signatories to WTO can undertake to remedy violation of above standards.

4. A dispute settlement procedure to allow members nation countries to negotiate and end any present and future disagreements.

5. TRIPS also provided for compulsory licensing of IPs in situations like public health emergency to use and use IP related products without the permission of the original manufacturer, however, with the approval of WTO.

6. The present proposal submitted by India and South Africa supported by other 100 developing nations is meant for following four specific waivers:

(i) Patents

(ii) Copyrights

(iii) Trademark

(iv) Undisclosed Information Procedure

7.If the TRIPS requirements have been waived has to be approved by WTO, this will be the broadest waiver since its enactment in 1995.

Geopolitical stand on innovation and IP

1. Presently few developed nations like in European Union, Switzerland, Norway and other countries like Australia, Canada, Japan and United Kingdom have signalled their opposition to the waiver.

2. Regardless of where you stand on the issue of IP waiver any support to the IP waiver, the world as an whole will be risking the agonies, strong resistance and angering of the leading vaccine suppliers and those who advocate for big pharma IP monopolies. Though IP right remains critical weapon which can establish control positions for the medicines and pharmaceutical industries worldwide. One cannot ignore the capital risk and the reality of aligning incentives for the risking innovations carried on by all pharma giants worldwide since July 2020 investing more than 10 billion dollars for vaccine projects.

3.Waiving of IP rights may also adversely affect biotech industry and their investor, the COVID-19 vaccine has raised an view point to be considered that one needs to be more strategic in this innovation wars.

4. What you have to learn out of the debate on TRIPS waiver is that IP rights matter to every country sovereignty with respect to the health policy and the health infrastructure.

5.It is fundamental principle of any IP system that there has to be balancing of rights related to IP on one side and public health and human life protection on the other side. A good IP system would always strike a proper balance amongst the both.

Ambiguity created with proposed TRIPS Waiver

1.Under the present proposal of TRIPS waiver, if granted, would mean that any drugs that have used for patients with COVID-19 including that pleaded the pandemic could lose the patent production. Thus, a foreign company could produce the specific drug for COVID-19, but sell it for another diseases. Moreover, the foreign company would not have to provide any financial compensation to the company from whom they took the IP. However, the TRIPS waiver need not benefit the manufacturing of the COVID-19 vaccine because it is not possible to have reverse engineering for the companies who are manufacturing vaccines as of today and along with the patent there is also a technical know-how and other components of vaccines not covered by IP are also required for vaccine manufacturing.

2.It is also noteworthy that the vaccines developed by Pfizer, Mordena and Johnson & Johnson are not currently approved by the Indian Government for use in India due to regulatory obstacles related to localise clinical trials. At one end, India is seeking for TRIPS waiver and at the other end they have an obstacle for obtaining vaccines which they have not even approved for use in their own country.

3.It’s a global effort to ensure access to COVID-19 vaccines in all the countries. The WHO and GAVI i.e. (Global Alliance for Vaccine and Immunisation) have an initiative design specifically to distribute vaccines to developing world to the extent of 2 billion vaccines by end of 2021.

4.Secondly, it should also be noted that Mordena has already pledged not to enforce its COVID-19 vaccine patents during the pandemic.

5.The TRIPS agreement and its IP protection were created to increase unity and certainty in global economy. The economic certainty provided by IP protections preserve competitiveness and increase the value i.e. in other words IP protection provides incentives to create new and path breaking technologies. Waiving of TRIPS would weaken the market forces that encourage innovation. TRIPS waiver would lead to loss of innovation in many industries and sectors of global economy.

6.The primary justification for waiving TRIPS is that IP protection cause under-used manufacturing capacity. By granting TRIPS waiver, developing nations would copy patented drugs and use their own manufacturers to produce vaccines. This rationale has been negated by the fact that Mr. Adar Poonawalla, CEO of Serum Institute of India, currently the largest producer of the COVID-19 vaccines doses in the world has argued that access to IP is not limiting vaccine production, rather it is a time involved in scaling up manufacturing capacity.

7.So, to conclude, one may ask this if the TRIPS waiver is a misconception that the IP protection was a barrier to COVID-19 vaccine production or it is the difficulty of scaling of production of vaccine, a key challenge. TRIPS waiver will do nothing to increase the vaccine production rather it will prove as poor policy towards IP and would create a big trade policy challenges and restrict the innovations of path breaking technologies.

8.What is required today, is a re-thinking on new kinds of Alliances , for a global vaccine drive that will help Organisations, Countries and Manufacturers to secure supply chains and increase access to vaccines and end the pandemic.

Resources: Articles published by American journals, online magazines, and blogs.