WTO WAIVER OF IP RIGHTS IN CONSONANCE TO COMPULSORY LICENCES FOR COVID 19 VACCINES

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ABSTRACT

This paper identifies the proposal made by India along with South Africa for Waiver of IP rights over Vaccines at World Trade Organization in October , 2020 as equitable access to safe and effective vaccines being fundamental to saving lives and livelihoods. This paper further discusses the concept of Compulsory licence the provisions governing it and the case which introduced or established it in India. This paper further discusses the delay in negotiation for granting the WTO Waiver and the effects that commenced due to this delay to grant waiver on Covid 19 Vaccines.

Keywords: WTO Waiver, Covid Vaccines, Compulsory licence, Negotiation

INTRODUCTION

Since 2019, the world is facing serious consequences due to the pandemic caused due to COVID 19 virus which resulted in loss of livelihood of people at large, it also affected the economy of many countries and gradually hollowed the life of people in past three years. The initial and primary concern was to protect ourselves from this Virus by maintaining proper sanitization and then arose one of the most prominent concern i.e. to develop a vaccine to prevent this infection from spreading and affecting people. The research began by big Pharma Companies and later on trials took place and at last after a year or two vaccines across different countries were developed. Then countries who were rich or can afford the vaccines got vaccinated their population including first and second. But still there are many poor countries across globe where only 14% of the total population got vaccinated only with the first doze. Now question arose are profits for the companies and the nations supporting them are over lives of these poor people. Keeping this thought in mind India along with South Africa proposed Waiver of IP rights over Vaccines at World Trade Organization in October, 2020 as [1]equitable access to safe and effective vaccines being fundamental to saving lives and livelihoods.

WORLD TRADE ORGANIZATION

The World Trade Organization (WTO) is an intergovernmental organization that directs and works with international trade. Legislatures utilize the organization to lay out, reexamine, and uphold the guidelines that oversee international trade. It formally started procedure on 1 January 1995, compliant with the 1994 Marrakesh Agreement, in this way supplanting the General Agreement on Tariffs and Trade (GATT) that had been laid out in 1948. The WTO is the world's biggest international financial organization, with 164 part states addressing more than 98% of global trade and global GDP. The WTO works with trade in merchandise, administrations and licensed innovation among partaking nations by giving a structure to arranging trade agreements, which generally plan to lessen or dispose of tariffs, shares, and different limitations; these agreements are endorsed by delegates of part states and confirmed by their councils. The WTO likewise oversees free question goal for implementing members' adherence to trade agreements and settling trade-related debates. The organization denies

[1] Pope Francis

segregation between exchanging accomplices, yet gives exemptions for ecological insurance, public safety, and other significant objectives.

The WTO is settled in Geneva, Switzerland. Its top dynamic body is the Ministerial Conference, which is made out of all part states and normally gathers biennially; agreement is stressed in all choices. Everyday capabilities are dealt with by the General Council, comprised of agents from all individuals. A Secretariat of north of 600 faculty, drove by the Director-General and four deputies, gives regulatory, expert, and specialized administrations.

WORLD TRADE ORGANIZATION TRIPS WAIVER

The WTO TRIPS Agreement has consistently kept up with setting the base standard of protection of, and for, copyright, trademarks and Patents and so on. TRIPS likewise incorporates flexibilities to withdraw from the IPR protection requirements, including the instance of a health emergency. For instance, members can do compulsory licensing, which approves an individual to produce a patented product and then process it without the consent of the patent owner. As per it then, members can create generic copies for the

Domestic market (however not really for export), and implement fast-track procedures in health crises. Moreover, the Implementation Decision of the Doha Declaration on TRIPS and Public Health (2001) allows producing members to take on a compulsory license for the production of pharmaceuticals for export. [2]This provision enabled Canada to make and export a generic version of a patented AIDS medication to Rwanda, but lacked on manufacturing capacity, in 2007-2009. Therefore, TRIPS flexibilities have been criticized as in convenient and legally challenging.

The WTO Agreement enables members to waive an obligation in exceptional

Circumstances by agreement based decision-making; previously, members have effectively agreed to waive specific articles of the TRIPS Agreement concerning pharmaceutical products and least-developed countries (LDCs). In October 2020, India and South Africa made a landmark proposal to waive a few landmark proposal of the TRIPS Agreement, to address the counteraction, regulation and treatment of Covid-19. The waiver would enable members to not

[2] https: / / www. Europarl .europa . eu / RegData / etudes / ATAG /2021 / 690649 / EPRS_ATA (2021) 690649 _ EN . pdf

grant or enforce patents (section 5) or other IP obligations on copyright (section 1) , industrial designs (section 4) , and the protection of undisclosed information (section 7) connected with Covid-19 products and technologies. The revised Proposal was presented on 25 May 2021 and was supported by a number of members of WTO like Africa , Asia and Latin America etc , and it was proposed that the scope of it would apply to the health products and technologies. It basically includes diagnostics, therapeutics, vaccines, medical devices and personal protective equipment to treat or deal with Covid19. It was further proposed that the waiver would be in force for a Minimum of three years of time period , and it will be reviewed on annual basis. LDC members are excluded from applying most of the TRIPS Agreement till July 2034 or until their up liftment from the LDC category.

COMPULSORY LICENSING IN INDIA

In simple words, compulsory licenses are a kind of authorization that is given to a third party by the government to make, use or sell a particular product or a process which has been patented, without the need of permission of the patent owner. Compulsory licenses are only considered only in the case of health crises and national emergency. Also there are few pre-requisite conditions which need to be fulfilled to get a compulsory license for a patented invention.

Under Indian Patent Act, 1970 amended in 2005, chapter XVI covers the provisions that deal with the conditions for compulsory license grant.

a. [3]SECTION 84 OF INDIAN PATENT ACT, 1970

As per section 84, at any time after the expiration of 3years from the date of grant of patent any person interested may make an application to the controller for grant of compulsory license on any of the following grounds;

a. That the reasonable requirement of the public with respect to the patented invention have not been satisfied, or
b. That the patented invention is not available to the public at a reasonably affordable price, or
c. That the patented invention is not worked in the territory of India.

[3] Section 84 in The Patents Act, 1970

b. SECTION 92 OF INDIAN PATENT ACT,1970

As per [4]section 92A, compulsory licenses can also be granted when

a. For export , under exceptional circumstances
b. In case of national emergency, extreme urgency of public non commercial use, by the notification of central government.
c. To a country which has insufficient or rather no manufacturing power in Pharma sector to address public health.

INDIA'S FIRST CASE OF GRANTING COMPULSORY LICENSING

It was granted by IPO in 2012 to an Indian based company called Natco Pharmacy for the generic production of [5]Bayer Corporation's Nexavar, here all the three conditions of section 84 of the act, were fulfilled.

This medicine is used to treat liver & Kidney Cancer and one month's worth of dosage costs around 2.8 lakh rupees.

Natco offered to sell for 9000 rupees making this potentially life saver drug easily accessible to all parts of the society not only rich. The government took the decision for public welfare and benefit.

Compulsory licensing have vast impacts as it will decrease the innovation in under developed countries as these countries will prefer getting the drug or product compulsory licensed to a generic drug. Also it will increase the competition among the patentee and the licensed individual or company thus decreasing the costing of the patent and at last the patients will get the medicines at very cheap and reasonable rates.

Compulsory licensing has now become the hope for financially challenged patients in underdeveloped countries. India needs this provision owing to the economic condition of the

[4] 92A Compulsory licence for export of patented pharmaceutical products in certain exceptional circumstances , Patent Act,1970

[5] Bayer Corporation vs Union Of India ,2012

majority population. But the challenge is that on one hand, it has to comply with the international standards of patent protection and on the other, it has to safeguard public health.

DELAY IN NEGOTIATION

After a long wait of 2 years , the World Trade Organization finally approved a very prominent deal on June 17 , 2022 which drop down the Intellectual Property restrictions for the manufacture or development of COVID -19 vaccines , [6]The meet took place at Geneva , where many other agreements along with vaccine patent waiver were approved .

This waiver may not have a positive impact to vaccine manufacturers like Pfizer , Moderna ltd etc rather it created a blow as they had put in a loads of effort to prevent the waiver to happen.

This waiver was proposed by India but still the waiver is criticized as the waiver took too long to be addressed and enforced as per May , 2022 there were already 2.1 billion excess does of vaccine for COVID -19 as per the data of European Federation of Pharma Industries and associations , in this India said that it is due to the powerful nations who are members of World Trade Organization which dragged out the negotiation for so long as of now it [7]totally lost its relevance as Pharma manufacturer had already prepared an over supply of vaccines.

CONCLUSION

The World Trade organization took a lot of time , the proposal was proposed by India and South Africa in October 2020 , and World Trade Organization waived off the intellectual rights on COVID -19 vaccines after 2 years in June , 2022 . As per India this was due to the powerful nations which are members of World Trade Organization, as they dragged out the negotiation for so long as now in the present scenario this waiver has lost all its relevance as it could be prevalent when it was proposed, but for now Pharma manufacturer had already prepare an over supply of vaccine hence, in this current regime the needfulness of the waiver standstill.

[6] https:// www.bloomberg.com / news / articles / 2022 -06 -17 / wto –approves –vaccine –patent –waiver –to – help –combat –covid -pandemic

[7] Indian Trade Minister Piyush Goyal