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Prudent Use of Compulsory Licensing, Voluntary Licensing and TRIPS waiver in the wake of Covid -19 pandemic: An Indian Perspective

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ABSTRACT

The Covid -19 pandemic has changed the lives of many because of its devastating effect. The unprecedented demand for life-saving drugs, equipment needed to save lives has put pressure on every country's ability to manufacture these essentials on a large scale. People have to be vaccinated to prevent people from being infected. Thus, the nations are exploring various methods to procure and manufacture these vaccines, medicines, and equipment to meet the needs of their citizens. In a vast country like India, the demand is immensely high. This article explores various options India have, such as Compulsory Licensing, Voluntary Licensing, and asking for a TRIPS waiver, in order to procure and manufacture vaccines and medicines.

I. INTRODUCTION

The pandemic is taking a toll on the life of human beings around the world. There is an unprecedented surge in the demand for vaccines, medicines, and equipment needed for the treatment of Covid -19. The concern regarding the availability of these life-saving essentials is a disturbing reality. The countries are looking at various methods in procuring and manufacturing these essentials. The developed countries that have vaccinated a major part of their population are willing to send vaccines, medicines, and other essentials needed for the treatment of the Covid-19. In a vast country like India with 130 million people, this help from foreign countries may not be sufficient. Thus, India has the option of adopting compulsory licensing according to the Patent Act,1970, or asking for a TRIPS Waiver or allow voluntary licensing to happen. In the backdrop of mutant variants and the consequent waves of infections every country must have certain ammunitions in store to fight the Covid-19 pandemic

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 [ISSN 2581-5369]

effectively. This article will be looking at the issues surrounding the TRIPS Waiver, Compulsory Licensing and voluntary Licensing

II. PATENT PROTECTION FOR AN INVENTION

According to WIPO, a patent is an exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem.[2] To get a patent, technical information about the invention must be disclosed to the public in a patent application. In principle, the patent owner has the exclusive right to prevent or stop others from commercially exploiting the patented invention[3]. In other words, patent protection means that the invention cannot be commercially made, used, distributed, imported, or sold by others without the patent owner's consent.[4]

A patent holder has the prerogative right over his invention for 20 years. The patent holder has the right to prevent others from commercially utilizing the patented product. But the patentee may allow utilization of the patented product by way of compulsory licenses in circumstances of national emergency or circumstances extreme urgency or in case of public non-commercial use. The patentee can also give voluntary license to eligible businesses to commercially exploit the patented product

III. COMPULSORY LICENSES UNDER THE PATENTS ACT,1970

Compulsory licenses are permissions given to a third party by the Controller General to make, use or sell a patented product or process in case of an emergency or urgent need. The notion of the compulsory license is accepted at the domestic and global level as it finds mention in the Patent Act,1970 and TRIPS Agreement. Certain preconditions are mentioned in sections 84-92 of The Patents Act,1970 to grant a compulsory license.

According to Section 84(1)of the Patent Act,1970, after the expiration of three years from the date of the grant of a patent, any person interested may make an application to the Controller for grant of compulsory license on patent on any of the following grounds, namely:-

(a) that the reasonable requirements of the public with respect to the patented invention have not been satisfied, or

[2] Wipo.int. 2021. *Patents*. [online] Available at: <https://www.wipo.int/patents/en/> [Accessed 25 September 2021].
[3] Ipmall.law.unh.edu. 2021. *Patent Law and Systems Globally*. [online] Available at: <https://ipmall.law.unh.edu/content/patent-law-and-systems-globally> [Accessed 25 September 2021].
[4] solutions, I., 2021. *IPR Solutions – Pharmademics Consulting Solutions*. [online] Pharmademics.com. Available at: <https://pharmademics.com/ipr-solutions/> [Accessed 25 September 2021].

 [ISSN 2581-5369]

(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.

In considering the application under section -84, the Controller shall take into account,-

(i) the nature of the invention, the time which has elapsed since the sealing of the patent, and the measures already taken by the patentee or any licensee to make full use of the invention;

(ii) the ability of the applicant to work the invention to the public advantage;

(iii) the capacity of the applicant to undertake the risk in providing capital and working the invention if the application were granted;

(iv) as to whether the applicant has made efforts to obtain a licence from the patentee on reasonable terms and conditions and such efforts have not been successful within a reasonable period as the Controller may deem fit

This clause shall not be applicable in case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use or on the establishment of a ground of anticompetitive practices adopted by the patentee, but shall not be required to take into account matters subsequent to the making of the application.[5]

Section 92 (1) (3) explains the special provision for compulsory licences on notifications by Central Government.

(1) If the Central Government is satisfied, in respect of any patent in force in circumstances of national emergency or in circumstances of extreme urgency or in case of public non-commercial use, that it is necessary that compulsory licenses should be granted at any time after the sealing thereof to work the invention, it may make a declaration to that effect, by notification in the Official Gazette, and thereupon the following provisions shall have effect, that is to say-

(i) the Controller shall on application made at any time after the notification by any person interested grant to the applicant a licence under the patent on such terms and conditions as he thinks fit;

(ii) in settling the terms and conditions of a licence granted under this section, the Controller shall endeavour to secure that the articles manufactured under the patent shall be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights.

[5] The Patents Act of 1970, Sec. 84

 [ISSN 2581-5369]

(3) Notwithstanding anything contained in sub-section (2), where the Controller is satisfied on consideration of the application referred to in clause (i) of sub-section

(1) that it is necessary in-

(i) a circumstance of national emergency; or

(ii) a circumstance of extreme urgency; or

(iii) a case of public non-commercial use,

which may arise or is required, as the case may be, including public health crises, relating to Acquired Immuno Deficiency Syndrome, Human Immuno Deficiency Virus, tuberculosis, malaria or other epidemics, he shall not apply any procedure specified in section 87 in relation to that application for grant of licence under this section: Provided that the Controller shall, as soon as may be practicable, inform, the patentee of the patent relating to the application for such non-application of section 87.[6]

India's first-ever compulsory license was granted by the Patent Office on March 9, 2012, to Natco Pharma for the generic production of Bayer Corporation's Nexavar, a life-saving medicine used for treating liver and kidney cancer.[7] Bayers sold this drug at exorbitant rates, with one month's worth of dosage costing around Rs 2.8 Lakh. Natco Pharma offered to sell it around for Rs 9000, making it affordable for people belonging to every stratum. All the 3 conditions of section 84 were fulfilled and the decision was taken for the benefit of the general public. 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 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.[8]

The Patent Controller failed to consider Bayer's R&D investment during the development of the drug and found Nexavar to be unaffordable and unreasonably priced for the Indian market. It established the standard that "reasonable affordable price" described in Section 84 should be seen from the point of view of the public and not from the point of view of the company. This case provides insight into the views of the Government on India on ensuring a steady and affordable price for the population, thereby promoting public health.

[6] Ipindia.gov.in. 2021. *Indian Patent Act 1970-Sections*. [online] Available at: <https://ipindia.gov.in/writereaddata/Portal/ev/sections/ps84.html> [Accessed 25 September 2021].
[7] Mondaq.com. 2021. *Compulsory Licensing In India - Intellectual Property - India*. [online] Available at: <https://www.mondaq.com/india/patent/772644/compulsory-licensing-in-india> [Accessed 25 September 2021].
[8] Goaltideias.com. 2021. *Goaltide IAS Academy | A Prelims IAS Academy | Online Quiz | UPSC Prelims*. [online] Available at: <https://www.goaltideias.com/dailycurrentaffair-detail/223> [Accessed 25 September 2021].

 [ISSN 2581-5369]

Section 92(A) of the Patent Act facilitates compulsory licenses that grant India-based companies to manufacture and export patented pharmaceuticals to another country which cannot manufacture the product on its own and where such country is addressing public health concerns. Thailand, Zimbabwe, and South Africa are some of the countries that use compulsory licenses to import generic pharmaceuticals from India.

This section safeguards access to medicines for countries suffering from a public health crisis and also safeguards India's generic industry by granting them the right to manufacture and export drugs that other nations urgently need. Thus, India's compulsory licensing model protects public health, both domestically and internationally, from the potential harm of patents.

The compulsory licensing provisions in the Patent Act have provided room for the presence of generic manufacturers, thereby achieving the twin objective of providing access to medicines and supporting local generic infrastructure. It can be argued that compulsory licensing provisions may undermine incentives for innovation, but India's pharmaceutical industry is a testament to the fact that promoting the development of a flourishing domestic pharmaceutical industry may stimulate innovation.[9]

IV. THE TOUGH DECISION INDIA NEED TO TAKE

In the wake of the Covid -19 pandemic, there is a need to have access to drugs and vaccines at a reasonable price. The demand for drugs and vaccines is enormous. The vaccine is considered the only weapon to control and prevent Covid-19 infections. Thus, the Government of India had to think of options like TRIPS waiver, compulsory licences, or voluntary licensing.

The country urgently needs Covid-19 vaccines and the current manufacturing capacity with the two companies, Serum Institute of India (Covishield) and Bharat Biotech (Covaxin), is not enough. One way out is that the homemade Covaxin can be got manufactured by other companies also. As these companies navigate through the red tape and get down to business, India stands opposite to a dilemma: whether to issue compulsory licences to Indian companies for the manufacture of foreign vaccines or cadge a waiver. The government seems to be taking the latter alternative. The US is seen relenting; Europe is disinclined.[10]

[9] Sethia, K., 2021. *Compulsory Licensing in The Post-Trips Era and Its Impact On Indian Pharmaceutical Industry*. [online] Legal Bites - Law And Beyond. Available at: <https://www.legalbites.in/compulsory-licensing-impact-india-pharmaceutical> [Accessed 25 September 2021].

[10] @businessline. 2021. *The dilemma of licensing in a pandemic*. [online] Available at: <https://www.thehindubusinessline.com/business-laws/the-dilemma-of-licensing-in-a-pandemic/article34573699.ece> [Accessed 25 September 2021].

 [ISSN 2581-5369]

TRIPS agreement

The TRIPS agreement which was negotiated in 1995 at the WTO, requires all its signatory countries to enact domestic law to adhere to the provisions. It guarantees minimum standards of IP protection which enables the innovators to monetize their intellectual property in multiple countries.

In 2001, the WTO signed the Doha Declaration, which clarified that in a public health emergency, governments could compel companies to license their patents to manufacturers, even if they did not think the offered price was acceptable. This provision, commonly referred to as "compulsory licensing", was already built into the TRIPS Agreement and the Doha declaration only clarified its usage.

In respect of each of the main areas of intellectual property covered by the TRIPS Agreement, the Agreement sets out the minimum standards of protection to be provided by each Member. Each of the main elements of protection is defined, namely the subject matter to be protected, the rights to be conferred and permissible exceptions to those rights, and the minimum duration of protection.

The TRIPS Agreement is a minimum standards agreement, which allows Members to provide more extensive protection of intellectual property if they so wish. Members are left free to determine the appropriate method of implementing the provisions of the Agreement within their legal system and practice. Article 8, entitled "Principles", recognizes the rights of Members to adopt measures for public health and other public interest reasons and to prevent the abuse of intellectual property rights, provided that such measures are consistent with the provisions of the TRIPS Agreement.

Compulsory licensing and government use without the authorization of the right holder are allowed but are made subject to conditions aimed at protecting the legitimate interests of the right holder. The conditions are mainly contained in Article 31. These include the obligation, as a general rule, to grant such licences only if an unsuccessful attempt has been made to acquire a voluntary licence on reasonable terms and conditions within a reasonable period of time; the requirement to pay adequate remuneration in the circumstances of each case, taking into account the economic value of the licence; and a requirement that decisions be subject to judicial or another independent review by a distinct higher authority. Certain of these conditions are relaxed where compulsory licences are employed to remedy practices that have been established as anticompetitive by a legal process. These conditions should be read together with the related provisions of Article 27.1, which require that patent rights shall be

 [ISSN 2581-5369]

enjoyable without discrimination as to the field of technology, and whether products are imported or locally produced.[11]

Legally, there are provisions under the TRIPS agreement that the government can invoke and force foreign vaccines to be produced by Indian companies here. Justice Chandrachud of the Supreme Court has noted in a recent order that "even as TRIPS obliges countries to ensure a minimum level of patent protection, it creates a permissive regime for the carving out of exceptions and limitations that further public health objectives."

An Indian company can apply for a compulsory licence under Section 84 of the TRIPs-compliant Indian Patents Act; the Controller of Patents can issue a compulsory licence under Section 92 of the Act.

Thus, clear pathways exist for the Indian government to force-manufacture of the much-needed, life-saving vaccines in India. However, it has taken the cautious and round-about route of asking for waivers.[12]

A decision to be taken by the Indian Government

If India decides to issue compulsory licenses under section 84 and 92 of Indian Patents Act,1970 there may be retaliation from foreign countries whose pharmaceutical companies own the patented vaccines and drugs. There could be sanctions from different countries.

The government's apprehensions on this count have been articulated in its recent affidavit to the Supreme Court – it noted that any exercise of statutory powers would have "serious, severe and unintended adverse consequences".[13]

The country would be forced to go for compulsory licencing if the TRIPS waiver as an option does not materialize. India has to issue compulsory licences and entrust the responsibilities to envoys to handle the repercussions or retaliation.

In a recent case, Rakesh Malhotra v Govt of National Capital Territory of India and Others. The court directed the government to step in and invoke its powers of compulsory licensing under the Patent Act. The court suggested encouraging the use of licensing to respect the commercial rights of patent holders by way of receiving licence fees while also addressing the

[11] Wto.org. 2021. *WTO | intellectual property - overview of TRIPS Agreement*. [online] Available at: <https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm> [Accessed 25 September 2021].
[12] @businessline. 2021. *The dilemma of licensing in a pandemic*. [online] Available at: <https://www.thehindubusinessline.com/business-laws/the-dilemma-of-licensing-in-pandemic/article34573699.ece> [Accessed 25 September 2021].
[13] @businessline. 2021. *The dilemma of licensing in a pandemic*. [online] Available at: <https://www.thehindubusinessline.com/business-laws/the-dilemma-of-licensing-in-pandemic/article34573699.ece> [Accessed 25 September 2021].

needs of the hour. The judges told the government to immediately "encourage" manufacturers, patent holders and licensees to increase the production of medicines used in the treatment of covid-19. The 11-page court order identified several drugs widely used in the treatment of the coronavirus which are said to be in short supply. In 2020, Gilead Sciences took the lead and entered into voluntary agreements with Indian pharmaceutical companies to manufacture Remdesivir. This pre-emptive strategy safeguarded the multinational pharma company from the advent of compulsory licensing, especially in the wake of state governments such as Uttar Pradesh providing Remdesivir free of charge to covid patients to combat the deadly virus.[14]

V. THE WAY FORWARD

The way forward is the practice of Voluntary. Voluntary license (VL) helps the license holder to make, produce and market the generic drug and provide that to patients at affordable prices through the process of Reverse Engineering. There is no legal provision given under Patent Act as this license access is done through a mutual contractual agreement. A patent holder may give license to the third party either with an exclusive or non-exclusive right, the right to manufacture, import, and distribute a pharmaceutical product, and much more. The licensee of the patent will act as an agent of the company. The terms in a voluntary license may set price ranges or could include other terms like the holder royalty from the distribution of the sales. Voluntary licensing arrangements, at the discretion of the holder, are usually made for strategic reasons rather than as price gestures and they may not entail any price reduction at all.

Exploring the option of Voluntary Licencing

The application for the Compulsory License requires the minimum waiting period of three years of time and after that, the applicant can file for Compulsory License to the Controller General and the decision will depend upon his discretion. This gap of three years can severely affect patient lives due to either high prices of medicines or due to the shortage of medicines. The very existence of statutory provisions on compulsory licenses may be adequate to encourage voluntary licenses. The voluntary licenses are based on the mutual contractual agreement between the patent holder and the third party who is a generic manufacturer. Voluntary License is more favourable as it can save litigation time and cost for both the companies and could save many patient lives. Voluntary License could speed up access to products. This could help the patent-holding company to get their product promoted and could reach the invented product to each corner of the world. It can speed up the manufacturing with

[14] 2021. *Court: Invoke compulsory licensing to combat covid*. [online] Available at: <https://law.asia/court-invoke-compulsory-licensing-combat-covid/> [Accessed 25 September 2021].

 [ISSN 2581-5369]

the help of generic manufacturers as the Patent holder being the single holder of the patent could not manufacture with regards to the demand of the whole world. It could also help to improve manufacturing in a better and more affordable way which would eventually lower down the prices for the drug consumer. It would increase competition (if the VL is not exclusive) in the market and curb monopolistic trade practices in pharma industry as one license could be issued to many generic companies.

However, there may be certain disadvantages to Voluntary License. The generic companies require enough technology to manufacture the generic medicines and most of the generic manufacturer's lack in the technology and only some of them are able to go forward with the release of the generic product but it doesn't create much difference with the prices. Licensor has all the authority to put any restriction during the agreement of the VL such as where to supply the medicines and where not to and many other restrictions to which the licensee is bound. Licensors' royalty rate eventually adds up in the product which is generally borne by the patient only.[15]

The need of the hour

Recently, India and South Africa have piloted the proposal to waive key provisions of the TRIPS agreement on Covid-19 vaccines, drugs, therapeutics, and related technologies. This proposal has been now backed by the U.S also.

The TRIPS waiver proposal would give immunity to member countries from a legal challenge at the WTO if their domestic Intellectual Property Regulation (IPR) laws suspend or do not enforce IP protection.

The core idea behind this TRIPS proposal is that the IPR should not become barrier in scaling up the production of medical products essential to combat Covid-19. However, the TRIPS waiver is unlikely to solve India's Covid-19 vaccine shortage.

Instead of trying to obtain an IP waiver, the Indian government must enable vaccine manufacturers to expand production (through compulsory licensing) & reduce inefficiencies in procurement & distribution.[16]

Whether TRIPS Waiver could solve India's Problem?

The TRIPS waiver may not solve India's shortage of vaccines because of the complex

[15] iPleaders. 2021. *Voluntary Licensing of Patents in India - An analysis.* [online] Available at: <https://blog.ipleaders.in/voluntary-licensing-patents/> [Accessed 25 September 2021].
[16] Drishti IAS. 2021. *TRIPS Waiver or Compulsory License.* [online] Available at: <https://www.drishtiias.com /daily-updates/daily-news-editorials/trips-waiver-or-compulsory-license> [Accessed 25 September 2021].

intellectual property mechanism. The process of development and manufacturing of vaccines may involve various complicated steps as the intellectual property rights involve in the product and process may vary. The skill, competence, and proficiency to manufacture vaccine may be protected as a trade secret and the data which is obtained from clinical trials of these vaccines to the public may be protected by copyright. For the manufacturing process to begin the companies may have to source the necessary raw materials needed and build or expand building production units. The clinical trials have to be done in different phases to get regulatory approval for administering the vaccine or drugs to the larger population.

Weighing on the options of compulsory licensing and Voluntary Licencing

The developed countries have accumulated 80 percent of vaccines so far. India prioritized vaccinating the elderly population and frontliners in the initial phases. But the need of the hour is to vaccinate the 900 million population of India who is above 18years of age and less than 60 years.

The recourse of compulsory licensing can be used to increase the supply of drugs and vaccines. An aggressive standpoint on compulsory licenses would force several pharmaceutical companies to offer licenses voluntarily. Licencing Covaxin widely would put pressure on developed countries to transfer their vaccine technology to developing countries.

The Government of India should consider the transfer of Covaxin's technology to domestic pharmaceutical companies to enhance present supply within the country. By unfastening its vaccine expertise to the world, India would demonstrate its resolve its stride on the TRIPS waiver. For the foreign corporations to supply vaccines to India, India need to instil trust in its regulations and institutions through reliable commitments.

Thus, the government should not only transfer Covaxin's technology to domestic pharmaceutical companies, to boost national supplies, but also offer it to foreign corporations. By unlocking its vaccine technical know-how to the world, India would demonstrate its resolve to walk the talk on the TRIPS waiver. A commitment to supply vaccines to India requires trust in the country's regulatory and institutional environment, which the government must strive to instil through dependable commitments.

Such confidence, combined with the expedited process for vaccine approval, can help India quickly overcome its supply shortage[17].

[17] Drishti IAS. 2021. *TRIPS Waiver or Compulsory License*. [online] Available at: <https://www.drishtiias.com/daily-updates/daily-news-editorials/trips-waiver-or-compulsory-license> [Accessed 25 September 2021].

 [ISSN 2581-5369]

VI. Conclusion

Prompt action is necessary as far as the supply of vaccines, drugs, and essentials to treat Covid-19 is concerned. There is an unprecedented demand and the Government must make sure that there is no hindrance in the supply of vaccines, drugs, and other essentials. There are also concerns regarding the mutant variant of the Covid-19 virus and there may be a continuous demand. The subsequent waves of infection among the public and mutant variants are adding to the burden of the Government of India to take effective action. The health infrastructure also have to be revamped so as to cater to the needs of the people from all stratas of the society. Considering the gravity of the circumstances and the increased demand, the Government of India may explore all the options such as TRIPS waiver, compulsory licensing, and voluntary licensing.

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 [ISSN 2581-5369]

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