Page 737 - 744 **DOI:** *https://doij.org/10.10000/IJLMH.112543*

INTERNATIONAL JOURNAL OF LAW MANAGEMENT & HUMANITIES

[ISSN 2581-5369]

Volume 5 | Issue 1

2022

Compulsory Licensing: A Remedy for COVID Vaccines?

AYUSHI SRIVASTAVA[1] AND SANCHITA JAIN[2]

ABSTRACT

"Out of the mountain of despair, a stone of hope."

Martin Luther King

Since the recent World Health Assembly didn't declare future Covid-19 vaccines a world' public good', they're confirmed as private (intellectual) property and can be subject to patent rights protection as a pharmaceutical product. In expectation of the wants of their most at-risk populations, governments of developing countries are obliged to prepare to issue compulsory licenses of any effective COVID-19 treatments. Compulsory licensing, a provision within the Agreement on Trade-Related Aspects of intellectual property rights ("TRIPS Agreement"), enables governments to provide their citizens with generic versions of patented treatments either through domestic production or foreign imports. The compulsory licensing of trade secrets present some unique obstacles, and consideration is given to some practical solutions that might balance the interests of technology owners and the public interest in increased access to vaccines. These covid vaccines are new, and their internal capabilities and efficacy ensure the potential futility of compulsory licensing. This paper studies the compulsory licensing and with respect to the covid drugs and vaccines, the Doha Declaration on the TRIPS Agreement and the Public Health. The paper further discusses the situation of providing compulsory licensing to covid vaccines in India and how much of a viable alternative can compulsory licensing, in this case, can be?

Keywords- *Covid vaccine, Covid-19, TRIPS agreement, Doha Declaration, Compulsory licensing, Intellectual Property Rights.*

I. INTRODUCTION

The worldwide race to develop breakthrough Covid-19[3] pharmaceutical products (or medicines), including vaccines, access may become an issue for both developing countries and richer countries, which can have insufficient and no capacity to manufacture certain pharmaceutical products. The issues around the manufacturing, export and import of generic

[1] Author is a student at The ICFAI University, Dehradun, India.
[2] Author is a student at The ICFAI University, Dehradun, India.
[3] Coronavirus disease (COVID-19) is an infectious disease caused by the SARS-CoV-2 virus.

 [ISSN 2581-5369]

versions of patented pharmaceutical products could emerge, especially because the 73rd World Health Assembly[4] didn't declare future Covid-19 vaccines a worldwide public good. As private (intellectual) property, they're going to be subject to patent protection. After a protracted and difficult battle with COVID-19, people got a ray of hope with the emergence of vaccines across the world. However, it's safe to mention that things haven't quite gone in line with the plan. In practice, it seems extremely unlikely that patent holders will attempt to block the utilization of a patented product or process needed for the fight against COVID-19. By the end of 2019, humanity was confronted by a new communicable disease caused by a new coronavirus, the covid-19, that led, on March 11th, 2020, the globe Health Organization (WHO)[5] to declare the state of a world pandemic. The fight against this new virus has demanded several technical innovations, but the vaccine, many are the inventions that required the protection by patent: retroviral medicines, diagnostic tests or medical devices, like ventilators, are a number of these examples. Nevertheless, the foremost visible face of this combat has been the vaccine, which put the pharmaceutical companies in a very race for its development. Compulsory licensing, a provision within the Agreement on Trade-Related Aspects of intellectual property rights ("TRIPS Agreement")[6], enables governments to provide their citizens with generic versions of patented treatments either through domestic production or foreign imports.

II. WHAT IS COMPULSORY LICENSING?

A patent provides a monopoly to the owner and to provide and distribute a patented product as they see fit and to keep other parties from doing the same. A compulsory licensing provision empowers the govt. To grant such rights to parties apart from the patentee without the consent of the patentee. Alternatively, the govt may use the patent itself. The nations that are party to the TRIPS Agreement are mandated to provide for compulsory licensing. The origin of the concept of compulsory license at a global level is traced through the Paris convention of 1967. Article 5(A) of the Paris Convention first recognized the concept of Compulsory License. Article 5(A) (4), in specific, provides that "A compulsory license might not be applied for, on the ground of failure to figure or insufficient working, before the expiration of the period of 4 years from the date of filing of the application or three years from the date of the grant of a patent, whichever period expire last; it shall be reduced if the patentee justifies his inaction by

[4] It is attended by delegations from all WHO Member States and focuses on a specific health agenda prepared by the Executive Board.
[5] The World Health Organization is a specialized agency of the United Nations responsible for international public health.
[6] The Agreement on Trade-Related Aspects of Intellectual Property Rights is an international legal agreement between all the member nations of the World Trade Organization.

 [ISSN 2581-5369]

legitimate reasons. Doha Declaration binds its members to act for public welfare to enhance the social and, therefore, the financial condition of a state.[7] The doctrine which aids the rationale mentioned above is compulsory licensing. In Indian jurisdiction, it's stated under the Act. Chapter sixteen of the Indian Patent Act, 1970, deals with the concept of compulsory licensing in India. Section 84 (1)3 of the Indian Patent Act provides that an application will be made to the Controller for the grant of compulsory license, only after the expiration of three years from the date of grant of patent to the patent holder, in any of the subsequent conditions–

1. When the reasonable requirement of the general public with relevance the patented invention have not been satisfied, or

2. When the patented invention isn't ready to the general public at a reasonably affordable price, or

3. When the patented invention isn't worked within the territory of India. [8]

Section 92 of the Indian Patent Act gives us that the Controller may also issue the compulsory license suo moto pursuant to the notification made by the Central Government just in case of a national emergency or extreme urgency or public non-commercial use.

The Section 92A of the Indian Patent Act states that the Compulsory License will be available for the manufacture and for the export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity within the pharmaceutical sector for the concerned product to deal with public health problems, provided compulsory license has been granted by such country or such country has allowed the importation of the patented pharmaceutical products from India. When the receipt of an application within the prescribed manner is provided, the Controller shall grant a compulsory license solely for the manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as could also be specified and published by him.

There are certain judicial pronouncements, such as in the case of Natco Pharma Ltd. vs Bayer Corporation, India's first-ever compulsory license was issued. The facts were that Bayer Corp. had the patent right for the assembly of the drug "Nexavar" – used to cure liver and kidney cancer. It had been established during this case that only 2% of the population had access to the drug because it absolutely was sold at the worth of Rs. 2.8 lacs for the dosage of a month which was quietly very high. Section 84(1) were completely satisfied during this particular

[7] Doha Declaration 2021, THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH.
[8] Indian Patent Act 1970, s 84(1).

 [ISSN 2581-5369]

case, and also the Indian patent office issued a compulsory license to Natco Pharma which promised them to make available the drug at the worth of Rs. 8,800 just for the dosage of the month. Also, in the case of BDR Pharma vs Bristol Myers Squibb, the Controller rejected the application for compulsory license made by BDR Pharma. The reason behind the rejection of the application was that the BDR Pharma did not make a clear case for the making of an order under Sections 87 of the Act.

Under the IPA, the provisions on compulsory licensing have two objectives to fulfil, and therefore the Controller, when issuing these licences, must make sure that these objectives are well satisfied:

a) "The patented inventions are worked on a commercial scale in the territory of India without any delay and to the fullest extent that's reasonably practicable.
b) That the interests of a person for the time being for working or developing an invention in the territory of India under the protection of a patent aren't unfairly prejudiced."

In India, as per section 92 of the Act, the central government has the ability to categorize the Covid-19 pandemic under "national emergency" or "extreme urgency". Furthermore, under the Epidemic Diseases (Amendment), Ordinance 2020, a commutable virus is recognized as a deadly infectious The observations which were made by the Controller are as under –

a) BDR Pharmaceuticals hasn't made any such try to acquire a voluntary license from the Patent holder.
b) The application has also not acquired the power to figure the invention to the general public advantage.

III. WHY HAS INDIA ASKED FOR A WAIVER OF THE TRIPS AGREEMENT?

In the month of October 2020, India and South Africa had submitted a joint communication titled "Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19" to the TRIPS Council at the WTO. This waiver of the TRIPS Agreement requested halting of enforcement of patent rights which might allow companies to domestically produce supplies for COVID-19. While it's not been specified whether the waiver will provide compensation to the patent owners, it's a temporary measure that may not end in anybody losing their patent and has been requested within the face of a raging pandemic.

Despite receiving considerable support from many developing and under-developed countries, the United States, EU and other developed countries had initially opposed the waiver. Many pharmaceutical and technological giants hail from these countries, and their patents form part

of their country's investment and resources. The waiver thus extended a deadlock at the WTO.

Countries that opposed the waiver also stated their intention to help the distribution of vaccines to developing and under-developed countries through the COVID-19 Vaccines Global Access facility (COVAX) or through voluntary licensing agreements at a non-profit basis to the other companies. They asserted that curbing the pandemic wouldn't need a waiver of the TRIPS Agreement in light of those alternatives. However, this position did not consider that India had requested a waiver of patent rights on treatment methods and equipment for COVID-19 and not just vaccines. There are certain drugs, such as Remdesivir[9] and Tocilizumab[10] , that are patented or in the process of being patented in many of the countries, and their production is therefore limited to the owner of the patent or select licensed companies. While around seven companies in India have the licence to manufacture Remdesivir, their production isn't able to meet the present demand at a reasonable cost.

Presently, many countries that have opposed the waiver have stepped in to help India by sending emergency medical supplies. However, these shipments cannot provide all the things required and can only temporarily ameliorate the situation. The current health crisis or a future one is wholly addressed only by ensuring that companies within India can manufacture all materials and diagnostic equipment needed.

IV. THE TRIPS AGREEMENT AND COMPULSORY LICENSING

The TRIPS Agreement, which was the fallout of the Uruguay Round of Negotiations (1986-94), was pushed by developed countries for the protection of IP rights. It had been significantly pushed by the United States – who were backed, at the time, by their pharmaceutical corporations.[11] Strong cross-border IP protection meant greater revenue for pharma, and other IP protected corporations. Since these discussions, proponents for IP protection and also the 'right to health' have held extensive debates and discussions. While the previous states that IP protection incentivizes invention and progress, the latter contends that IP protection, especially patents within the pharma sector, ends up in inaccessible and unaffordable vaccines and drugs within the developing south. The vaccines are clearly subjected to the TRIPS Agreement and eligible for patent protection. It's due to this that India and South Africa, two 'developing' countries, have raised demand patent waivers to the WTO.1 In fact, under paragraph 4 of the

[9] Remdesivir, sold under the brand name Veklury, is a broad-spectrum antiviral medication developed by the biopharmaceutical company Gilead Sciences.
[10] Tocilizumab, sold under the brand name Actemra among others, is an immunosuppressive drug, used for the treatment of rheumatoid arthritis and systemic juvenile idiopathic arthritis, a severe form of arthritis in children.
[11] World Trade Organization. Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 Apr. 1994. Available: https://www.wto.org/english/docs_e/legal_e/27-trips.pdf. Accessed: 02 September 2021.

 [ISSN 2581-5369]

Declaration on the TRIPS Agreement and Public Health (2001), member countries recognized that TRIPS doesn't and will not prevent hindrances in matters of public health. It acknowledges the requirement for increased accessibility for medicines and drugs for tired a public healthcare crisis. The Doha Declaration on the TRIPS Agreement and Public Health was held in November 2001 and highlighted and clarified key flexibility afforded to countries in Article 31 of the TRIPS agreement: the proper way to grant compulsory licenses.[12] Compulsory licensing refers to the utilization of a patent without the authorization of the patent holder. Furthermore, issuing a compulsory license for a pharmaceutical treatment allows the government to locally manufacture or import generic versions of the treatment without the patent holder's consent. Clause 5 of the Doha Declaration mentioned that "each [WTO] member has the specific right to grant compulsory licenses and also have the freedom to work out the grounds upon which such licenses are granted". Additionally, in situations of "national emergencies" and "other circumstances of maximum urgency," governments can issue compulsory licenses without normal requirements, like negotiating with the patent holder. Clause 5(c) further make clear that: "public health crises, including those of regarding HIV/AIDS, tuberculosis, malaria and other epidemics" can constitute "a national emergency or other circumstances of maximum urgency." There is no doubt regarding the present COVID-19 pandemic is a public health crisis within the meaning of clause 5(c) that justifies the utilization of compulsory licenses. India and Brazil, for instance, had previously only allowed for process patents and not product patents. These things permitted domestic generic pharmaceutical companies to reverse-engineer and produced bioequivalent drugs.

V. Compulsory License for Covid-19 Vaccine in India

There are two coronavirus vaccines, COVAXIN and COVISHIELD, which are approved by Central Drug Standards Control Organizations for "emergency use" in India. COVAXIN is an indigenous vaccine developed by Bharat Biotech together with the Indian Council of Medical Research (ICRM) – National Institute of Virology (NIV), while COVISHIELD is Serum Institute of India's version of AZD1222, which was developed by British Swedish drugmaker AstraZeneca.

The compulsory license could be a powerful public health tool for overcoming public health emergencies and situations of either expensive pricing or lack of supply. Presently pricing of both these vaccines are kept on the lower side, and thus the sole concern left is of the production

[12] World Trade Organization. Declaration on the TRIPS Agreement and Public Health, 20 Nov. 2001. Available: http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm. Accessed: 02 September 2021.

 [ISSN 2581-5369]

capacity. India has a much bigger role to play in helping the globe overcome the present pandemic because it has one of the entire world's biggest vaccine manufacturing capacities. India has been supplying lakhs of vaccines to several countries around the world. Further, it's a population of over 1.3 billion of its own. Therefore there lies an unlimited task prior to us since vaccines are required in large numbers.

Although Serum institute has the world's largest vaccine manufacture unit, it's also a part of WHO's COVAX alliance, and so it's to balance its supplies to both local and international markets. Further, India is seeing what's being called the second wave of Coronavirus as positive cases are increasing at daunting rates. What's required here is to quickly vaccinate as many folks as possible to keep the number of positive cases and, more importantly, the death rate as low as possible. Therefore during this particular time of dire need where time is of the importance of government might imagine granting Compulsory License for Covid vaccines by making a declaration under section 92 of Indian Patent Act, 1972 of this situation as a "National emergency" or situation of "Extreme urgency" or to facilitate "Public non-commercial use."

Presently, India is enough and secured supply of both COVAXIN and COVISHIELD, but the present coronavirus pandemic does qualify as a "National emergency" under section 92 of the Indian Patent Act, 1972, and if the requirement arises, the government should be prepared to tackle a situation of shortage of vaccines by preparing a swift mechanism of granting Compulsory licenses to other pharmaceutical companies to make sure availability of a sufficient number of vaccines to comply by both its national and international obligations.

VI. COMPULSORY LICENSING IS A VIABLE ALTERNATIVE?

There are several arguments against compulsory licensing, and those arguments don't stand the scrutiny of experience and ground reality.

Investment is required to make sure high production and scale of vaccines: the traditional case against price capping or compulsory licensing is that such measures chill investment in innovation. In these extraordinary times, this argument takes offstage because the short-run welfare supersedes the long-run welfare.

In the particular context of COVID vaccines, the investment protection argument also fails for the reason that almost all vaccines benefit from direct or indirect public money. Johnson & Johnson, Moderna, AstraZeneca, and Bharat Biotech have evidently benefitted from public money, while many others might need to be received support indirectly. To be clear, CLs aren't royalty-free licenses. Developers are paid reasonable royalty determined by an appropriate adjudicating authority. Moreover, the original manufacturer also stays within the business.

 [ISSN 2581-5369]

The vaccines are difficult to copy, even with the patents shared. This has been one of all the first defences against compulsory licensing. The identical argument was advanced at the peak of HIV. By that time, the developing countries had successfully started manufacturing HIV drugs.

A related argument widely seen within the context of COVID vaccines is that getting the know-how related to the manufacturing process can be the largest challenge in facilitating the mass manufacture of vaccines. But history has shown us multiple times that several firms have successfully reversed engineered diverse types of pharmaceutical products even within the absence of voluntary sharing of know-how from big pharma. Moreover, history can even tell us that there are instances wherein agencies like the Federal Trade Commission within the US have ordered know-how transfer.

VII. CONCLUSION

The pandemic has turned the world upside down, challenging the health and medical infrastructures in every corner. In order to defeat this pandemic, covid vaccines and their distribution worldwide is urgently needed, and compulsory licensing can be an additional aid in it. Compulsory licensing is a powerful public health tool – it will be instrumental for alleviating insufficient supplies of necessary pharmaceuticals also as mitigating prohibitively expensive drug prices. The arguments from the legal standpoint oscillate between the jurisprudence of patent laws and spirits of fundamental rights within the course of a worldwide pandemic. The previous has originated from the requirement for the protection of innovation to market healthy competition within the market and increase the accessibility for the masses. While the rewards of patent protection are necessary to support continual innovation, the compulsory licensing exception exists for public health emergencies like the present COVID-19 crisis. When future Covid-19 vaccines are under patent rights protection, the policy choice of compulsory licensing might be engaged to enrich voluntary licensing, to facilitate affordable access to future Covid-19 pharmaceutical products and to deliver on the commitment to public health.

"*Imagine the action of a vaccine not just in terms of how it affects a single body, but also in terms of how it affects the collective body of a community.*"

~ *Eula Biss*

*****

 [ISSN 2581-5369]