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Compulsory Licensing: A Viable Solution for India to Override the Covid Vaccine Patents Domestically

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During this worldwide health crisis, India is clearly facing a shortage of vaccines where Indian pharmaceutical companies are now struggling to fulfill their own supply commitments to the nation due to the limitations imposed by patented vaccines. Thus, like many countries, the viable solution for the Indian government to combat the insufficient supply of vaccines and control the spread of the virus is to grant "Compulsory licences" for these vaccines. This article discusses the concept and power to grant compulsory licences given under the Indian Patents Act, 1970. In spite of these statutory powers, it also points out the challenges that the Indian government is facing and the possible reasons behind the delay to invoke these provisions. Further, it highlights how the international authority which is responsible for the protection of patents is changing its dynamics responding in the aspect of the worldwide health crisis in pursuance of maintaining a balance between its responsibilities and protection of an individual's right. The author in pursuance of her own opinion on the current situation has suggested the alternatives which can be adopted to combat and control the spread of this novel deadly virus.

Keywords: *compulsory licensing, voluntary licensing, patent waiver, vaccines.*

INTRODUCTION

In the past two years, the world has witnessed the deaths of millions of people because of the deadly novel Coronavirus. In the absence of any drugs and vaccines, people saw their loved ones dying, some lost their children, some became orphans, and the most painful part was that they were not able to do anything to save them. And now when we have developed vaccines to combat this coronavirus, the situation in India is still a nightmare. The availability and access to these vaccines depend upon few factors like the cheap prices, production capacity, and standards required in producing effective vaccines.

In India, the industrial value of pharmaceutical firms is more than thirty billion dollars, comprising more than 3,000 pharmaceutical firms in India, together they run almost 10,500 manufacturing and production facilities which in total can accomplish the prerequisite of 1,878 million dosages of vaccines. But at present, only two domestic firms i.e, Serum Institute of India (SII) and Bharat Biotech, in their limited capacity of only 80-90 million dosages per month are producing COVID vaccines to control the pandemic. There is clearly a supply deficit in the nation that must be addressed on a conflict balance. Therefore, just like several other countries is invoking the legislative groundwork known as "Compulsory Licensing" to meet the accessibility and affordability of such patented vaccines, India also needed to lay this legislative groundwork permitted under the Indian Patents Act 1970 and Trade Related Intellectual Property Rights (TRIPS) agreement, same as it was done first time in 2012 when Hyderabad-based Natco Pharma was permitted to produce the *Nexavar* for the treatment of cancer.

INDIAN LEGAL PROVISIONS FOR COMPULSORY LICENSING

Before, moving further let us understand the concept of 'Patent' first. The World Intellectual Property Organization (WIPO) defines it as a right granted to an original inventor on a process or product by the government authorities that allows the original inventor to exclude others from manufacturing, selling, or using the invention for a certain period of time, generally 20

years from the filing date of the patent application.[1] This particular system is designed to encourage inventions that are unique in nature and useful to the public at large, and these granted rights[2] also promote innovation and at the same time encourages inventors too.

Compulsory licensing is a concept where authorizations are given to a third party by the government (Controller General) or regulators to make, use or sell a particular patented product or use a particular patented process, without seeking the patent owner's permission.[3] It is broadly discussed under Chapter XVI of the Indian Patents Act 1970.

The *Nexavar* case was the first instance in India that occurred in 2012, where Natco pharmaceutical company was granted the first ever compulsory license to manufacture Bayer Corporation's patented generic anti-cancer drug "*Nexavar*".[4] This case is now marked as a precedent which showed that patent rights are not absolute when it comes to the safety and protection of the public at large, and displayed that in the case of the patents also the patented generic drug can be manufactured by other pharma companies at a more reasonable price to attain the optimum goal of accessibility, while reasonable royalties are provided to the original patent holder.

Section 84 under Chapter XVI of the Indian Patents Act 1970 grants the compulsory licences under the conditions which are based on effectiveness, affordability, accessibility, and non-working of the patents. It provides an opportunity to an interested party to apply for a compulsory licence at any time, but only after three years from the date of grant of the patent.[5]These conditions are:

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[1] 'Patent' (*World Intellectual Property Organization*) <https://www.wipo.int/patents/en/> accessed 23 May 2021

[2] 'If the patent is for a process, then the patentee has the right to prevent others from using the process, using the product directly obtained by the process, offering for sale, selling or importing the product in India directly obtained by the process.If the grant of the patent is for a product, then the patentee has a right to prevent others from making, using, offering for sale, selling or importing the patented product in India' (*World Intellectual Property Organization*) <https://www.wipo.int/patents/en/faq_patents.html> accessed 25 May 2021

[3] 'Compulsory Licensing of Pharmaceuticals and TRIPS' (*World Trade Organization*) <https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.html> accessed 24 May 2021

[4] The Leaflet, 'Big Win For Affordable Medicine' (*Bloomberg Quint*, 30 April 2019) <https://www.bloombergquint.com/law-and-policy/natco-pharma-bayer-patented-drug-export-case-big-win-for-affordable-medicine> accessed 24 May 2021

[5] Indian Patents Act 1970, s 84

- Failure to meet reasonable requirements of public at large
- Inaccessibility of the patented invention at a reasonably affordable cost to the public
- Non-working of the patented invention in the Indian territory.

On the other hand, Sections 92 and 100 under Chapter XVI of the Indian Patents Act 1970 are the provisions that provide flexibility in the area of patent protection and grant the patent under certain circumstances. Section 92 of the Act is a special provision that provides that compulsory licences can be issued ***suo motu*** by the Patent Controller pursuant to a declaration notice issued by the Central Government under three essential circumstances.[6]These are as follows:

- National Emergency
- Public non-commercial use
- Extremely urgent requirement.

Section 100 enables the government, or any individual authorized by it, to use patented products, or inventions for the purposes of the government itself.[7]

Not to mention, the patent owner is paid a reasonable royalty or fee for the licenses been issued under the above provisions. This is done to justify and balance the conflicting interest between the original inventor and the other licensed manufacturers. It ensures the encouragement of innovations and provides the deserved incentives to the inventors for their research and development.

CAN INDIA OVERRIDE THE VACCINE PATENTS DOMESTICALLY?

The coronavirus wave has caused the world's biggest health crisis and the situation in India is likely to get worsen in the coming times. Several forecasts by the eminent institutes reflect the

[6] *Ibid* s 92
[7] Patents Act (n 5), s 100

urgent need for India to increase the mass vaccination programme at all levels to control the spread of the virus, but for its execution, we need more dosages of vaccines.[8]

It is the government's job to protect the patents, and sometimes during emergencies government themselves can override the patents for the greater good of the people, through the instruments like *Compulsory Licensing.* This is a global health crisis that is not just restricted to India only, and there is an urgent requirement to increase the manufacturing and production units of these vaccines to treat the infections caused by a coronavirus. Even the court has asked the government to consider the powers vested under the law to grant the licences of patented products to others or to use for its own purposes in case of emergencies, i.e. Section 92 and 100 of Indian Patents Act 1970.[9]

A deadly novel virus is killing almost 4,000 Indians a day and this scenario definitely qualifies to invoke Section 92 and 100 of Patents Act 1970 by the government authorities. The compulsory licensing is a viable option to manufacture the COVID vaccines by the rest of the unutilized Indian pharmaceutical firms to meet the demands of the population at large.

WHAT IS THE HURDLE TO IMPLEMENT COMPULSORY LICENSING IN THE NATION?

The Apex Court of India has asked the Central Government to consider and exercise its powers granted under Indian Patents Act 1970. But the only possible reason the government is not going ahead with this is that the Indian IPR law being subjected to limitation imposed on compulsory licensing under Article 31 of the TRIPS agreement. This Article imposes limitations on compulsory licences to domestic productions and usages.[10] Countries cannot

[8] Shruti Menon, 'India coronavirus: Vaccine makers are prioritising local needs' (*BBC News*, 20 May 2021) <https://www.bbc.com/news/world-asia-india-55571793> accessed 24 May 2021

[9] Livelaw News Network, 'Why Centre Not Considering Compulsory Licensing For COVID Drugs Like Remdesivir, Tocilizumab? Supreme Court Ask' (*Live Law*, 2021 April 30) <https://www.livelaw.in/top-stories/why-centre-compulsory-licensing-covid-remdesivir-tocilizumab-supreme-court-asks-173413> accessed 28 May 2021

[10] 'Part II — Standards concerning the availability, scope and use of Intellectual Property Rights' (*World Trade Organization*) <https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm> accessed 28 May 2021

issue compulsory licences to the organizations which are outside the territory, and also the organizations within their territories to manufacture products for exports.

Therefore, the Indian government can only provide compulsory licences to the 'Indian' IP vaccines. Bharat Biotech's Covaxin is the only homegrown vaccine, whereas the other vaccines like Covishield, Remdesivir, Tocilizumab are global vaccines. They are IP of other companies which have either issued voluntary licences to the Indian companies, or they are being imported and then distributed in the country. Additionally, one barrier is to manufacture the Covaxin which requires specific biosafety level-3 production facility which is only owned by two companies in India, i.e., Bharat Biotech along with Panacea Biotech.[11]

CAN THE WTO WAIVE PATENTS ON EXISTING COVID VACCINES?

In October 2020, India along with South Africa proposed to the World Trade Organization (WTO) for a waiver of specific provisions of trademarks, copyrights, protection of undisclosed information, industrial designs, and patents in the Trade Related Intellectual Property Rights (TRIPS) agreement for the prevention, treatment and control the spread of Wuhan virus across the globe. The proposal has gained the support of almost 120 countries including the US by now, but in opposition, there are some major developed countries like UK, European Union, Canada, and Australia.[12] They are of the opinion that the patent waiver would rob them out of incentives and will discourage the pharma innovators to innovate and produce more, especially when they are required to remain on their toes to combat this worldwide health crisis.[13] These countries are self-sufficient in their capacity to produce life-saving drugs and vaccines for their citizens, they have a surplus for themselves. Therefore, the possible reason for them to block this waiver is the lobbying of giant pharmaceutical companies. The waiver could have enabled to buy and produce these vaccines at a lot less expensive prices than the

[11] 'Bharat Biotech agrees to open Covaxin manufacturing to others' (*BusinessToday.in*, 13 May 2021) <https://www.businesstoday.in/sectors/pharma/bharat-biotech-agrees-to-open-covaxin-manufacturing-to-others/story/439004.html> accessed 29 May 2021

[12] Annalisa Merell, 'Big pharma wants you to think sharing vaccine patents overseas is very dangerous' (*Quartz, Scary Myths*, 28 May 2021) <https://qz.com/2013661/big-pharma-argues-poor-nations-cant-be-trusted-to-make-vaccines/> accessed 29 May 2021

[13] Ashutosh Pandey, 'Rich Countries Block India, South Africa's Bid to Ban COVID-19 Vaccine Patents' (*The Wire*, 15 February 2021)<https://thewire.in/health/covid-19-vaccine-patents-india-south-africa> accessed 27 May 2021

branded equivalent ones. Hence, the WTO should realize that the patent waiver is the need of the hour and there is an existing precedent to this as well.

In 2001, the World Trade Organization (WTO) had granted a waiver of drug patents to the least developing countries(LDC), and further on 6 November 2015, this waiver was extended for another 17 years i.e., till 2033.[14] This waiver provides an exemption to least developing countries (LDCs) from several obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in regard to patents or other intellectual property rights on pharma products and clinical data. This should enable the LDCs to buy and produce generic medicines that are a lot less expensive than the branded equivalent. This shows that patents are not absolute to just one individual's right when it comes to the life of the whole of humanity on earth.

CAN THE PATENT WAIVER EASE THE INDIA'S VACCINE SUPPLY-DEMAND CRUNCH?

Patent waiving is not the same as patent sharing. When a patent is waived, the other manufacturers have to go through reverse engineering to manufacture the vaccines which will include bridging clinical trials as well. This all is time taking and demands the manufacturers to go through several IP mechanisms. Seeing the current scenario, India can't spare even a single day. Thus, patent sharing can be a powerful solidarity tool brought into existence referred to as '*Voluntary Licensing*'. It is an expedient process than compulsory licensing where authorization given by the patent owner to other manufacturers to make, sell and use the patented products in specific regions in consideration of a royalty fee, and it also minimizes the regulatory risks imposed by patent wavering.[15] Taking the example set by Serum Institute

[14] 'WTO drugs patent waiver for LDCs extended until 2033' (*World Trade Organization*) <https://www.un.org/ldcportal/wto-drugs-patent-waiver-for-ldcs-extended-until-2033/> accessed 30 May 2021

[15] 'Voluntary licenses and non-assert declarations' (*International Federation of Pharmaceutical Manufacturers & Associations*, 28 July 2010) <https://www.ifpma.org/resource-centre/voluntary-licenses-and-non-assert-declarations/> accessed 30 May 2021

of India and AstraZeneca sharing technologies to produce Covishield, voluntary licensing seems to save time and money.[16]

Keeping in mind that compulsory licensing is only applied domestically i.e., to say that a country cannot issue compulsory licences to the organizations which are outside the territory, and also the organizations within its territory cannot manufacture products for export purposes, voluntary licensing can be another expeditious and effective tool which can fulfill the required supply of these patented covid vaccines to save millions of lives around us.

India is suffering through a supply deficit situation, even when it has the potential to fulfill the supply requirements to an extent. The unutilized pharma companies' production and manufacturing units can be brought into action to beat the immediate bottleneck are through issuing a voluntary licence to these unutilized domestic industries by the patent owned pharma companies.

CONCLUSION

In response to the demand for COVID vaccines across the nation, there is an urgent need to upscale the production which can only happen when several unutilized manufacturing units are brought into action through the instruments like compulsory licensing and voluntary licensing. Since compulsory licensing is a domestic legislative framework and has its own territorial boundaries, voluntary licensing still remains a great alternative option. Voluntary licensing is an effective step to save lives especially when they are being lost by minutes, and the big firms should be encouraged to provide those. On the other hand, Compulsory Licensing is an obligatory powerful tool to combat the supply crunch of the nation. This instrument is an exception that exists for a worldwide health crisis such as COVID-19, at the same time securing the place of innovations through a grant of reasonable rewards and

[16] Divya Rajagopal, 'AstraZeneca & Serum Institute of India sign licensing deal for 1 billion doses of Oxford vaccine' (*Economic Times*, 4 June 2020) <https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/astrazeneca-serum-institute-of-india-sign-licensing-deal-for-1-billion-doses-of-oxford-vaccine/articleshow/76202016.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst> accessed 30 May 2021

royalties for the patent owners. The Indian governments along with the International organizations can play a vital role to fight this public health crisis by loosening the reins on compulsory licensing. Even it cannot be denied that India may need some time to ramp up and set up the facility standards required for global vaccine's production, it still would be a great start for the Indian government to set an example by granting the compulsory licence for our 'Indian' vaccine i.e. Covaxin to other domestic pharma manufacturers. Now is the time when each and every hand should be on deck to save the lives of our peoples.

SUGGESTIONS

Compulsory licensing is the need of the hour because due to the shortage of vaccines people are getting infected at a rapid pace and every day hundreds of people are losing their lives. India should take the lessons from its peers as well as from the past when it itself had adopted this mechanism way back in 2012 and should realize that now is the time when the government needs to invoke compulsory license more than ever.

While the Indian pharma companies need to reach out for licences to combat coronavirus and help to put the next gear to mass vaccination measures, the big pharma vaccine producers also need to have global solidarity through issuing more voluntary licenses against reasonable royalty fee. This giant pharma should put an end to the access-profit debate and realize that together all of us can make the limited time and resources available worthwhile for all of humanity. The licence fee should be reasonable, keeping in mind the affordability criteria of the nation as the countries lacking behind are most of the developing countries. Therefore, the primary focus should be on the affordability, accessibility, and effectiveness of these vaccines.

The technologies required to manufacture these COVID vaccines are complex and contains multiple technology patents, know-how, trade secrets, industrial designs, etc. Therefore, such a compulsory licensing system is required which should address not just patents but all the IP as well.

Apart from this, the government and Indian pharma companies also need to focus on the technology and establish the facility standards required to produce the global vaccines to ramp

up and eliminate the supply crunch, because without the proper technology the patent waiver, voluntary licensing, and compulsory licensing will mean nothing.