



ISSN 2582 - 211X

# LEX RESEARCH HUB JOURNAL

On Law & Multidisciplinary Issues

Email - [journal@lexresearchhub.com](mailto:journal@lexresearchhub.com)

**VOLUME II, ISSUE III**  
**APR - JUNE, 2021**

<https://journal.lexresearchhub.com>

**Lex Research Hub  
Publications**

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**COMPULSORY LICENSING  
IS A REMEDY FOR STATUTORY CURE FOR  
COVID 19 VACCINE**

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## **ABSTRACT**

*“Who owns the patent on this vaccine?*

*Well , the people, I would say, there is no patent*

*Could you patent the sun? “ - Jonas salk*

India faces major shortage of covid 19 vaccine. This indeed has brought the researcher to conduct at the research work to identify the major factor that affecting the supply of covid 19 vaccine. This study has identified compulsory licensing of covid 19 vaccines will be the remedy to statutory cure in the shortage of covid 19 vaccines. Considering the fact that the world is short of vaccine, India cannot expect to import huge quantities of foreign vaccines. This makes a crying need for the compulsory licensing of vaccines. Even if the government subsidies the price to make the vaccine cheap or ideally free of cost. At present there are not enough vaccine to administer the critical mass of the population in poor & middle- income country while at present around 30% of Americans are fully vaccinated less than 3% of Indians have received vaccination. There cannot be a more important occasion than the current circumstances for issuing compulsory license for producing vaccine. One of the most effective ways in which global trade rules can contribute to better access of vaccine and medicine is by enabling compulsory licensing. Equally important is that speed of vaccination as a delay Risk further mutations.<sup>1</sup>

## **INTRODUCTIONS**

The Covid-19 Pandemic is an ongoing global pandemic of coronavirus disease 2019. It is one of the most dangerous challenges that the world has been facing now. On 11<sup>th</sup> march 2020, the WHO carried out a virtual press conference and confirmed it as a deadly virus and declared a pandemic<sup>2</sup>, with such a wide reach and explosive magnitude the world itself for the impact, even lockdown were imposed in each and every country and international travelling were also forced to stop, people were starting to locked up themselves only because to control the spread of the pandemic.

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<sup>1</sup> Sakshi pawar, Using compulsory license to address the vaccine shortage, VIDHI centre for legal policy, (June 22, 2021, 11:30 AM) <https://vidhilegalpolicy.in/blog/using-compulsory-licensing-to-address-the-vaccine-shortage/>

<sup>2</sup> Helen Branswell and Andrew Joseph, WHO declares the Coronavirus outbreak a pandemic, STAT NEWS, (June 22, 2021, 6:30 PM), <https://www.statnews.com/2020/03/11/who-declares-the-coronavirus-outbreak-a-pandemic/>

Each country faced their own issues relating to this pandemic among those the most common issue faced by the whole world is public health and economic crisis. So far the country has reported a total of 2,98,79,477 cases and 3,86,694 deaths. Recently survey says that on June 19, 2021 India recorded 56,687 new Covid cases<sup>3</sup>. To stop these losses the great scientists have come up with some effective drugs and vaccines to treat this virus and protect public from getting affected. It is impossible for vaccines and drugs alone to make this pandemic to end but it is also in the hands of public to follow all the effective measures imposed by their respective countries and state to fight against Covid-19.

### **STATEMENT OF PROBLEM**

Even though In India we have Covid-19 vaccines and drugs to treat and protect public from getting infected then also their arises a problem with shortage of vaccine. Moreover in this Pandemic situation compulsory licensing is the only solution to sort out the vaccine shortage. But in India it is not given any importance even in this situation. This research paper will be dealing with compulsory licensing which is the only hope to the mankind to eradicate the covid pandemic.

India’s drug regulator, the central drug standard control organization, at mainly approved two corona virus vaccines candidates- Covidshield and covaxin both are for “restricted” use in “emergency” situations<sup>4</sup>. Several states in India are hardly struggling to supply enough vaccines to vaccinate everyone who are above 18 years of age. Though Astrazeneca has committed not to make a profit “During the pandemic” but then also that alone willnot increase the delivery of vaccines because since the Astra Zeneca in turns has entered into a licensing agreement to share technology with Serum Institute of India (SII) which made it difficult to meet its both national and international obligations at the same time In addition, Serum Institute set up to supply vaccines to low and middle income countries by the end of 2021 and has committed 100 million doses to this yearend followed by 900 million more. Though such production capacity is promising but also

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<sup>3</sup>Special Correspondent, Coronavirus- 3.6% of India’s Population fully Vaccinated till June 19, 2021, (June 23, 2021,10:30AM),<https://www.thehindu.com/news/national/coronavirus-nearly-4-per-cent-of-indias-population-fully-vaccinated-till-june-19-2021/article34861349.ece>

<sup>4</sup>Shambhavi Sinha, Should India Grant Compulsory Licences to Increase the supply of Vaccines, THE WIRE, (Jun 24, 2021, 11:30 AM), <https://thewire.in/health/india-patent-law-compulsory-licenses-covid-19-vaccines>



timing is an important factor here. As the faster people are vaccinated, the closer we get to exit this pandemic<sup>5</sup>.

### **RESEARCH METHODOLOGY:**

This study has used mixed methodology. In this research doctrinal and secondary sources of information are relied upon, newspapers, articles by various writers are referred to.

### **OBJECTIVE OF THE STUDY:**

- To identify the factor affecting the shortage of vaccine.
- To analyze the correlation between the Compulsory Licensing and Covid-19 Vaccine.
- To analyze the socio-economic justification of compulsory licensing

## **VACCINES AND THEIR PRODUCTION CAPACITY**

India's other big hope is the Sputnik V vaccines, which Indian pharmaceutical companies like Panacea Biotech are producing in partnership with the Russian direct investment fund and its local partner Dr. Reddy's laboratories. The production of the Sputnik V vaccine has only just got begun at Panacea's plant in the northern state of Himachal Pradesh, and at present it is unclear whether they will be able to manufacture 156 million doses in India till December and about the production of Covaxin until the month April the Bharat Biotech had claimed that they are having capacity to make over 700 million doses annually. Which can also be roughly calculated as 58 million doses per month? But as far now Bharat Biotech had only delivered around 9 million vaccines to the Indian government in the first week of May. The company explains that this lag is because each production cycle takes up to four months from initiation to delivery. The Indian government claims that it will vaccinate over 1 billion Indians with 2 billion vaccine doses by December month but by having a view over the production capacity it tells some different story. So far India has

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<sup>5</sup> Vikas Kathuria & Arul Scaria, Compulsory License Under Patent law to Ensure Vaccine Equity, ORFONLINE.ORG,(Jun 24, 2021,1:00 PM),<https://www.orphonline.org/expert-speak/compulsory-license-under-patent-and-competition-law-to-ensure-vaccine-equity/>

administered shots to over 28.8 crore people out of which 5.2 crore people have been fully vaccinated according to Health Ministry survey on 22 June. India's adult population is roughly 94 crore, which means that we need 188 crore doses to fully vaccinate all those people who are 18 and above. So as per the doses we have manufactured earlier, we need more 159.2 crore of doses to be manufactured quickly by the end of this year. At the beginning of June, the centre placed order for 450 million fresh doses of vaccines, including 250 million doses of Covidshield and 190 millions of Covaxin. Since India plans to achieve 100% adults to be get vaccinated in 2021 itself<sup>6</sup>.

### **COMPULSORY LICENSING:**

Compulsory license are authorizations given to a third party by the controller general of patents to use or sell a product. There are various conditions which need to be fulfilled for a compulsory license to be grant. Section 84 of the patents act revolves with compulsory licenses. It defines three grounds on which a compulsory license can be granted by the controller general of patents

- When reasonable requirement of citizens has not been satisfied with respect to the patented invention.
- When the patented invention is generally unavailable at an affordable cost.
- When the patented invention not manufactured in India<sup>7</sup>.

Importantly under section 92 of the act, in cases of a national emergency the central government can grant a compulsory license in respect of any patent in force to any person interested. Under sec 100 government can permit the use of the technology behind the vaccine. In this sec registration of patent is not mandatory. No such notification has been issued by the central government yet. This disjunctive nature of these provisions provides considerable liberty to the controller.

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<sup>6</sup> Arman Bhatnagar, Record 88 lakh doses in a day: Enough to vaccinate all Indians by December?, TIMES OF INDIA, (Jun 25, 2021, 8:30 AM), [https://m.timesofindia.com/india/indias-vaccine-math-what-will-it-take-to-vaccinate-all-adults-by-year-end/amp\\_articleshow/83750533.cms](https://m.timesofindia.com/india/indias-vaccine-math-what-will-it-take-to-vaccinate-all-adults-by-year-end/amp_articleshow/83750533.cms)

<sup>7</sup> [Praharsh gour, Compulsion for Compulsory license, SPICYIP, ( Jun 25, 2021 , 9.00 AM), <https://spicyip.com/2021/05/compulsion-for-compulsory-licenses-for-covid-vaccines-climbs-but-are-they-the-cure.html>

## **BAYER CORPORATION VS UNION OF INDIA& OTHERS**

India's first Compulsory license under the amended Patent Act(1970) was issued in 2012 when Natco was allowed to manufacture Bayer's advanced kidney cancer drug named Nexavar, with a royalty payment to the latter.<sup>8</sup>

The Bombay high court expressed compulsory licensing under Indian Patent Act. The court upheld the decision of the controller to grant compulsory license to another company to manufacture life-saving drug as all three requirements under **section 84** of this act is fulfilled.

## **CORRELATION BETWEEN THE COMPULSORY LICENSE AND COVID-19 VACCINES:**

The compulsory licensing is often used as a medium of ensuring access to medical utilities in pandemic situations and has been used by many countries to fight covid-19. The Doha Declaration on the TRIPS Agreement and Public health in 2001 highlighted a provision of the TRIPS Agreement i.e. **Article 31**, emphasizing a signatory's right to grant compulsory licenses. This provision has been used by various countries to tackle these public health situations and almost twenty nations have either issued or publicly entertained compulsory licenses for pharmaceutical production since 1995. Similarly, many nations have adopted the distribution patents approach for fighting the Covid-19 pandemic. The license was issued to increase the supply of the vaccines in the country since the usual vaccines producers were unable to cope with the increasing demand. The country's shortage of vaccine doses would continue throughout July, when production is expected to increase from about 60 to 70 million doses a month, to 100 million ordering more vaccines to meet demand.<sup>9</sup>

By analysis it is noted that given the supply restrictions, many wealthy countries are still standing in queue for vaccine doses despite their purchasing power. At the same time. The limited supply

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<sup>8</sup> Khaitan & co, compulsory licensing amidst the covid 19 pandemic, LEXOLOGY, (June 25, 2021, 5:00 PM) <https://www.lexology.com/library/detail.aspx?g=253ff273-55fb-46cf-9331-04d632ac055e>

<sup>9</sup> Srihari, covid 19 & the shortage of drugs, THE LEAFLET, ( June 26, 2021, 11: 00 AM), <https://www.theleaflet.in/covid-19-and-the-shortage-of-drugs-a-case-for-compulsory-licensing/>

of vaccines is extremely unfairly distributed, with 90% of all the vaccines produced by the top four global vaccine manufacturers in the United States (US) and Europe having been administered on population within North America and Europe in the first quarter of 2021 while India's vaccination plans grapple in the face of a deadly second wave, the regular global comparisons and coverage is significant. However, more than 1.91 billion doses administered globally, the vaccination coverage is still inequitable and slow, and covering 12.5% of the global population China is leading the world with 639 million doses, followed by the United States with 295 million doses administered as of 31<sup>st</sup> May 2021. The average rate of inoculations stands at 33.5 million doses a day, a rate at which it will take a year to cover 75% of the population resulting in a good level of global immunity against the deadly virus Covid-19.

**SHARE OF THE POPULATION FULLY VACCINATED AGAINST  
COVID-19, JUNE 25, 2021<sup>10</sup>**

| <b>COUNTRIES</b> | <b>VACCINATED PERCENTAGE</b> |
|------------------|------------------------------|
| Israel           | 63.2%                        |
| United Kingdom   | 47.3%                        |
| United States    | 45.3%                        |
| Germany          | 34.5%                        |
| <b>India</b>     | <b>3.9%</b>                  |

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<sup>10</sup> Coronavirus( COVID-19) Vaccinations, Our World in Data, ( June 26, 2021, 6:30 PM), <https://ourworldindata.org/covid-vaccinations>

**VACCINE PRODUCTION LEVEL IN INDIA<sup>11</sup>:**

| <b>COVID-19VACCINE</b>                     | <b>COVISHIELD</b>  | <b>COVAXIN</b>     |
|--|--------------------|--------------------|
| India’s desired doses till December        | 750 million        | 550 million        |
| Current monthly capacity                   | 65 million         | 10 to 58 million   |
| Vaccines possible to produce till December | 630 million        | 406 million        |
| <b>CAPACITYGAP</b>                         | <b>120 MILLION</b> | <b>144 MILLION</b> |

**FINDINGS:**

Considering the fact that the world is short of vaccine, India cannot expect to import huge quantities of foreign vaccines. This makes a crying need for the compulsory licensing of vaccines. Granting compulsory license to India Pharma companies for manufacture of foreign vaccines, though permissible under Doha Declaration in the TRIPS Agreement and Public Health issued in November 2001 clarifies a key flexibility afforded to countries under Article 31 of the TRIPS Agreement<sup>12</sup>.The right to grant compulsory licenses clause 5(c) provided that “Public Health crises and epidemics can constitute a **National emergency** or other circumstances of extreme urgency”. There can be no bigger crisis than the present covid second wave sweeping India that qualifies as a “NATIONAL EMERGENCY”.

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<sup>11</sup> Manavi Kapur, India’s lofty vaccination goal rests on supplies that may or may not turn up, QUARTZ INDIA, (June 27, 2021, 10:30 AM), <https://qz.com/india/2013630/will-india-have-enough-covaxin-and-covishield-doses-by-december/>

<sup>12</sup> [https://www.wto.org/english/tratop\\_e/trips\\_e/public\\_health\\_faq\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm)

### **RECOMMENDATION:**

- 1) Introduction and Establishment of a permanent International law with respect to compulsory licensing, which applies equally to all the member nations to develop and safe guard the intentions of patent law.
- 2) The grant of compulsory licensing should be given at most level of authority which can supersede the patent law and such granting should not raise any conflict between compulsory license and patent law.
- 3) Independent department should be constituted in respect to regulate compulsory licensing and other patent laws.
- 4) The ground for issuing compulsory licensing should be particularly defined and elaborated.
- 5) The number of private entities involving in manufacturing of vaccines should be increase. Such way of giving opportunity for some Micro, Small and Medium Enterprises (MSME) will not only reduces the demand and increase the production of vaccines but also increases the employment rate.

### **CONCLUSION:**

This study has identified compulsory licensing of Covid 19 vaccines can address the shortage of vaccine. The requirement of the production must be 3 times more than the current production rate of 65 million doses per month. one of the most important reason for the supply shortfall is limitation manufacturing to only two companies in India (Serum institute of India & Bharat Biotech) so by granting rights using Compulsory licensing to some Middle, Micro Small Industries can increase the production rate of Covid-19 Vaccines. There cannot be a more important occasion than the current circumstances for issuing compulsory license for producing vaccine. One of the most effective ways in which global trade rules can contribute to better access of vaccine and medicine is by enabling compulsory licensing. By efficiently vaccinating can prevent “a new infection”, “a new admission to hospital” or “to intensive care unit” and can make difference **Between Life and Death.**