

Compulsory Licensing to Save Lives and End COVID-19

Neeraj Bidhuri, Galgotias University.

ABSTRACT

Over the past few months, the second wave of covid-19 has fizzled out the country's healthcare sector. Many states in the country are giving SOS calls to the center for the shortage of medical supplies. There are notices at the entry gate of many hospitals displaying "no beds available". The situation in the country has turned precarious with an insufficient supply of medical oxygen and essential drugs. so far three vaccines have been approved by the government of India for the treatment of covid-19 — Covaxin, Covishield, and Sputnik V for restricted use. However, with the second-highest population in the world, ensuring treatment to be accessible and affordable to everyone is also a challenging part for the government. In anticipation of the needs, the government should find the best ways to ramp up the vaccination. On the grounds of public policy, the Government can use compulsory license as a tool to increase the production of patented vaccines. This article talks about the provisions under the Patents Act, 1970, and their application in the current emergency-like situation.

I. Introduction

As the second wave of Coronavirus has traumatized the nation's health care system, people are running here and there helplessly to provide medical help to their loved ones. India with the second largest population in the world is facing an acute shortage of medical oxygen, vaccines, and even beds in hospitals. The Central Drug Standard Control Organization which is a national regulatory body for medical devices and pharmaceuticals has approved three Vaccines in India such as Covaxin, Covishield, and sputnik V for "restricted use" in "emergency" situations. Covaxin is developed by Bharat Biotech in association with the Indian Council of Medical Research - National Institute of Virology (NIV). The vaccine is manufactured in Bharat Biotech's BSL-3 (Bio-Safety Level 3).¹ The second Vaccine Covishield has been extracted from British-Swedish drug-maker AstraZeneca. AstraZeneca has a deal with Pune-based drug-maker Serum Institute of India to manufacture Covishield in India. Serum Institute is also part of the Covax alliance backed by WHO set up to provide vaccine supply to low and middle countries.

The third vaccine approved in India is sputnik V, it is developed by Russia's Gamaleya National Center. The Russian Direct Investment Fund, which is a bank launching the vaccine developed by Gamaleya National Center has tied up with six firms to manufacture around 850 million doses of sputnik V in India likely to hit the Indian market in July. The Indian government is also engaging with other foreign manufacturers such as Johnson & Johnson, Pfizer, and Moderna. so that these vaccines can be easily imported for emergency Use authorization in India.

India's population is 1.38 billion. India ranks second among the countries with the most active coronavirus cases in the world. At this stage, India must consider its vaccine requirements, how many vaccine doses it can produce and what major steps it can take to boost vaccine production. Timely vaccination is a necessary and important factor, the faster people get vaccinated, the faster we can get rid of this pandemic.

¹ Bharat Biotech, available at: <https://www.bharatbiotech.com/covaxin.html> (last visited May 14, 2021).

At this phase, the government must take measures not only to ensure the availability of vaccines for the virus but also to ensure treatment of Covid-19 affordable to everyone. government should consider compulsory licensing under its patent law for covid vaccines.

II. Indian Patent Act and Covid-19

A patent is an exclusive right that is granted for an invention of a product or a process that provides a new technical solution to a problem or a new way of doing something. The technical information about the invented product must be disclosed to the public in an application for a patent². A Patent is a legal title government grant to an inventor for a limited period for his technical invention and it excludes others from making or selling the same. Once the patent is granted the inventor got the governance role on that invention for the period of 20 years, this allows them to put terms and conditions on which the third party can use that invention. Patent protection facilitates a monopolistic position to the inventors that generally cause higher prices as compared to competitive market prices. Consequently, it becomes unaffordable to many customers. For example, the University of Oxford has already patented the technology ‘Covishield’. Serum Institute and AstraZeneca entered into an agreement to share technology. Such agreement is known as ‘voluntary licensing’, one way of commercializing intellectual property rights.

On October 2, 2020, India and South Africa together moved a joint proposal in the World Trade Organization for temporary waving off certain provisions of the TRIPS Agreement concerning the prevention and treatment of Covid-19. However, this proposal has met opposition from developed

² World Intellectual Property Organization, available at: <https://www.wipo.int/patents/en/> (last visited May 15, 2021)

countries, and discussions are still ongoing on it. It is still unclear whether this proposal for a temporary waiver of certain provisions of intellectual property rights will be accepted or not.

In case of “public health crises or “extreme urgency”, the government can use compulsory licensing as an alternative tool to provide generic versions of patented drugs to its citizens.

III. Compulsory licensing

A compulsory license is a permit by the government to the third party to produce, use or sell a patented product without the consent of its inventor. A Compulsory license prevents the monopolization of a patent. It is generally considered in pharmaceuticals in cases of national emergency to protect public health. The statutory provisions regarding compulsory license are laid down under Chapter XVI of the Indian Patent Act, 1970. The grounds for granting the compulsory license and the factors to be considered by the controller are laid down under sections 84 and 92 of the Act.

As per section 84 of the Act, a compulsory license can be granted on an application by any interested person, after the expiry of three years from the date of grant of the patent, on the following grounds³namely:

1. The reasonable requirements of the public have not been satisfied with respect to patented invention; or
2. The patented invention is not available at a reasonably affordable price to the public; or
3. The patented invention is not operational in the territory of India.

³ The Patents Act, 1970 (Act 39 of 1970), s. 84(1).

An application for the grant of a compulsory license can be made to the Controller by any person interested despite he is already the holder of a license under the patent when the given conditions are satisfied. The application must describe the nature of the applicant's interest and the facts which form the basis of the application⁴. If the Controller is satisfied that any of the above-mentioned grounds subsists, he may grant a license upon such terms as he deems fit.⁵

While considering the application, the Controller shall take into account the following aspects:⁶

- A. the nature of the invention;
- B. the time which has elapsed forasmuch as the sealing of the patent;
- C. the measures which are taken by the patentee or licensee to make full use of the invention;
- D. the ability of the applicant to work the invention for the advantage of the public;
- E. the capacity of the applicant, if the application is granted, to undertake the risk in providing capital and working the invention;
- F. Whether the efforts made by the applicant to get a license from the patentee have been made on reasonable terms and conditions and have been made within a reasonable time, as the controller may deem fit.

However, these aforementioned details shall not be taken into account in case of national emergency or under circumstances of extreme urgency.

Under section 92⁷ of the Act, the central government, after the sealing of the patent, may, at any time grant a compulsory license to any interested person in:

- A. a circumstance of national emergency; or
- B. a circumstance of extreme urgency; or
- C. a case of public non-commercial use.

⁴ The Patents Act, 1970 (Act 39 of 1970), s. 84 (3).

⁵ The Patents Act, 1970 (Act 39 of 1970), s. 84 (4).

⁶ The Patents Act, 1970 (Act 39 of 1970), s. 84 (6).

⁷ The Patents Act, 1970 (Act 39 of 1970), s. 92.

Taking into account that Covid-19 has been announced as a pandemic by World Health Organization, the present situation qualifies as a national emergency under section 92 of the Patent Act. While Patent protection is necessary to support continual innovation, an exception exists for public health emergencies.

IV. Judicial view on compulsory licensing

In India, the first compulsory license was granted to a company called Natco pharma, in a case named Bayer Corporation v. Union of India.⁸ The case arose on a compound called “Sorafenib Tosylate”, which was used for the treatment of liver cancer. Bayer corporation was the inventor of “sorafenib tosylate” and marketed it under the name “Nexavar”. Natco pharma contacted Bayer for a grant of voluntary license for manufacturing the patented drug and selling it under its brand name in India. However, the talks for the voluntary license failed. Thereafter, Natco filed an application to the controller for a grant of a compulsory license. The controller after considering the various provisions of the Act granted the license to Natco. The said order was also upheld by Intellectual property Appellate Boards.

Bayer disgruntled by the order approached the Hon’ble High Court of Bombay. The Hon’ble High court dismissed the appeal and also held that the grant of the compulsory license is based on the purpose that the patented product is made accessible to the society in sufficient numbers and at a reasonable price.

There cannot be a more important moment than the current covid-19 crises to use compulsory license as a weapon against coronavirus. Thus, a Compulsory license can be a useful tool over an insufficient supply of pharmaceutical products. If the government grants compulsory licenses it would help in bulk manufacturing and fast delivery of patented vaccination at reasonable prices.

⁸ Bayer Corporation v. Union of India, AIR 2014 Bom 178.

V. CONCLUSION

The entire basis of the compulsory license is to maintain a balance between the rights of the inventor and the public interest. In the present situation, where many hospitals reporting a shortage of treatment drugs, medical oxygen, and even beds for infected persons, if the pace of vaccination against coronavirus doesn't shoot up, India could take many years to inoculate its population. A compulsory license could be a support mechanism for the government to rapidly upscale the production of the vaccination and enhance the process so that we can make our way out of the pandemic faster. The covid-19 crisis underpins the importance of compulsory license that can be the best way for the quick access to covid medicines and the government should not hesitate to use it as a support mechanism and also should take appropriate legislative steps for future aspects.