

Why no compulsory licensing measures were taken by government to provide vaccines to public in the current pandemic

Compulsory Licensing is allowed for patented inventions after the expiry of 3 years as per section 84 of the Patent Act, 1970. However, the Patent Act, 1970 outlines certain pre-requisites or grounds based on which a Controller may grant compulsory license of a patent. The ground being:

- a) the reasonable requirements of the public with respect to the patented invention have not been satisfied
- b) the patented invention is not available to the public at a reasonably affordable price
- c) the patented invention is not worked in the territory of India.

Although, patent protection is granted for 20 years from time of filing, much of this time is spent in product development and regulatory review in case of pharmaceutical drugs. After the regulatory review, a short patent term of 7-10 years remains. Further, most vaccine makers have secured the technology by way of Tradesecrets which cannot be licensed. Therefore, the vaccines developed after the pandemic were still in their research phase and some were not entirely patented or partially patented.

Also, it should be considered that the Govt. of India ensured that the manufacturing capacity of the vaccines were sufficient to cater to the public requirements. The Govt. of India granted “Restricted Use in Emergency Situation” (also referred to as “Emergency Use Authorisation-EUA) to two indigenously manufactured vaccines: Covishield, which was manufactured by a collaboration of Oxford University and Serum Institute of India, and Covaxin was indigenously prepared by Bharat Biotech is developed in collaboration with the Indian Council of Medical Research (ICMR) - National Institute of Virology (NIV).

EUA of Covaxin was initially challenged as it was approved for restricted use as a preventive vaccine. The restricted use was considered as part of a clinical trial. However, the vaccine was approved based on results from phase 1 and 2 clinical trials through an accelerated process. In contrast, as per rules and guidelines any vaccine may be given emergency use authorization after clearing phase 3 clinical trial. But in exceptional circumstances, if ongoing trials show promising results and are safe then an express approval may be given.¹

The Union Health Minister, Dr. Harsh Vardhan also declared that the people who would receive the shots of Covaxin would be monitored as volunteers in clinical trials.

Further, Revised Guidelines for implementation of National COVID Vaccination Program was formulated based on scientific and epidemiological evidence, WHO guidelines and global best practices.

The Govt. of India ensured that vaccines were available to the public for free in phased manner. The front line workers and population above age of 60 were administered free vaccines in a first

¹ Rachit Garg, ‘Legal procedure for the approval of Bharat Biotech’s Covaxin (without phase 3 data)’ (14 September 2021) <<https://blog.ipleaders.in/legal-procedure-approval-bharat-biotechs-covaxin-without-phase-3-data/>>

phase. The second phase of vaccine administration included administration of free vaccines to people above 18 years. Thus, prices of the vaccines were regulated by the Govt. of India to ensure that the public at large could be vaccinated. Therefore, the Govt. of India ensured that the public received the vaccines and at appropriate pricing, without the requirement for a compulsory license.