

WTO's vaccine patent waiver may have little impact on ground now: Industry

Serum Institute says while patent waivers for Covid-19 vaccines are 'encouraging', demand for vaccines today is declining

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Organisation (WTO)'s approval of a politically significant deal of a patent waiver for the manufacture of Covid-19 vaccines may have little immediate impact on boosting vaccine production or getting new technologies for vaccine production, industry and experts feel.

India's commerce and industries minister Piyush Goyal said that the Trade-Related Aspects of Intellectual Property Rights (TRIPS) decision will boost vaccine equity, accessibility and affordability. "It will enable ease of authorisation for production of patented vaccines and India can produce for domestic requirements and exports," he said.

The minister added that a country can authorise production of vaccines patented elsewhere and no consent would be required and there would be no limit on exports. "A decision on diagnostics and therapeutics would be taken in six months. Response to the pandemic would be faster in future and there would be fewer trade barriers in pandemics," Goyal said.

The world's largest vaccine manufacturer by volume, Pune-based Serum Institute of India (SII), said that while patent waivers for Covid-19 vaccines are an 'encouraging' step, the demand for vaccines today is declining.

An SII spokesperson said: "During the Covid-19 pandemic, innovators and vaccine developers partnered to develop a life-saving vaccine at the earliest. It led to licensing deals like SII-Novovax, SII-AstraZeneca, J&J, and Aspen among many others. Today, the demand for vaccines is declining. That said, the patent waivers for covid vaccines are an encouraging and progressive step towards safeguarding the accessibility & mass production of essential drugs and medicines, in the face of future pandemics."

Legal experts point out that it needs to be seen what exactly a 'partial' waiver is.

Aparna Gaur, leader, IP practice, Nishith Desai Associates told Business Standard, "News reports mention a 'partial waiver'. Maybe we need to wait and see what's 'partial' about the waiver. Either way, it may be too little, too late."

She added that vaccine demands are not at the same level where they were when the talks started. "And a patent waiver is only an initial step towards a potential vaccine launch. Several other hurdles like regulatory approvals, testing etc. will need to be cleared which can take several months," Gaur added.

Actually IP rights are no longer considered an obstacle to increasing access for Covid19 vaccines globally. India and South Africa have been pushing for lifting IP rights for Covid19 vaccine production for some time now.

In March, Mahima Datla, managing director, Biological E (BE), the makers of Corbevax, a protein subunit vaccine for Covid-19, had said that Baylor College of Medicine in Houston, Texas (with which BE collaborated to develop the vaccine) has already waived any IP restrictions because they wanted to make sure that this vaccine is as accessible as possible.

Datla had said that while IP is not the only obstacle, the more serious obstacle is having infrastructure to make the vaccine, trained manpower, etc.

Moreover, vaccine makers feel that unless the innovator company comes forward to handhold another manufacturer, the process of making a vaccine is not that simple even if the IP restrictions were to be waived.

"Even if the technology were available immediately, it would take nine months to a year to develop the processes and commercialise the same. Vaccines are biological products using viruses, and manufacturing it involves an extremely complex process. Any change in that process can result in failure to get the right vaccine candidate," said a senior executive of a vaccine firm.

Manufacturers may need the patentee's know-how to develop a marketable product. Regulatory approvals for manufacturing and marketing such vaccines will still be required. So even if the waiver applies to India, it may not have an immediate impact, added an industry insider.