

21. Is The Global Pharma Industry Unhappy With India's Policies?

By Gopal Krishna Agarwal,

The Drugs Controller General of India. T on January 3, granted restricted emergency use authorization (EUA) for two Covid-19 vaccines -Bharat Biotech's Covaxin and Serum Institute of India's Covishield. Covaxin, developed by the Indian Council of Medical Research and National Institute of Virology in collaboration with Bharat Biotech, is India's first indigenous vaccine against Covid-19. Covaxin has now received EUA from a range of countries and is in the process of obtaining it in 60 other countries.

But the real battle on vaccines had begun earlier, when the original proposal submitted by India and South Africa to the TRIPS Council on October 2 emphasised the need for World Trade Organization (WTO) members to work together to ensure that intellectual property rights (IPR) "such as patents, industrial designs, copyright and protection of undisclosed information" do not create barriers to timely access to affordable medical products. A patent waiver would allow any company with the required capacity to start manufacturing the shot, even without an agreement with the original developer.

However, international developers of Covid-19 vaccines such as AstraZeneca, Pfizer and Johnson & Johnson opposed any waiver for their doses, claiming they were capable of producing adequate jabs to meet global demand. Pharmaceutical companies have reported sharp profit gains during the crisis. The industry's biggest lobby group warned that this unprecedented step would undermine the response of companies and compromise safety. India then revised its proposal, to state that patent protections for vaccines be waived for a limited timeframe to address the concerns of the United States, European Union and others that opposed the original proposal.

The Narendra Modi government made this proposal even before India had developed its indigenous vaccine, which it could manufacture and supply globally at a low cost. With India developing its indigenous vaccine, having the largest vaccine manufacturing capacity in the world, along with its stated intention to waive IPR, the threat to the global pharma industry. Particularly to the limited number of companies with vaccine patents, became real this was aggravated with India's Vaccine Maitri initiative.

India has been one of the pioneers for supply of cheap life-saving drugs under the compulsory licensing (CL) and process patent regime. Under CL, for the purpose of combat- ing a health emergency, a WTO member is allowed to override a patent and "license" a domestic manufacturer to produce a global vaccine. But many experts pointed out that since Covid-19 is a global pandemic, the Indian government may not want to exercise its power under Section 92 and 100 of the Patent Act for manufacturing through CL.

The government, in its affidavit to the Supreme Court, said, "It is earnestly urged that any discussion or a mention of exercise of drugs or vaccines having patent issues would have serious, and unintended adverse consequences in the countries efforts on global platform." Currently, the Centre is involved in finding a diplomatic solution, but it had not ruled out invoking the law at a future date.

The best option is domestic manufacturing using an open licensing policy. The government has given permission to several domestic vaccine manufacturers to manufacture Covaxin.

With an indigenously researched and produced vaccine catering to domestic and global demand, our pharma industry will come of age. This will also end the pharma industry's dependence on manufacture and export of generic medicines alone.

The world-class Indian vaccine, with several vaccine manufacturers and an open licence, is attractive for several countries, particularly in the developing world. The Indian pharma industry will gain immensely. But dominant global pharma companies stand to lose billions of dollars in profits due to the policies followed and stand taken by the Modi government and this is a strong enough reason for them to be unhappy.