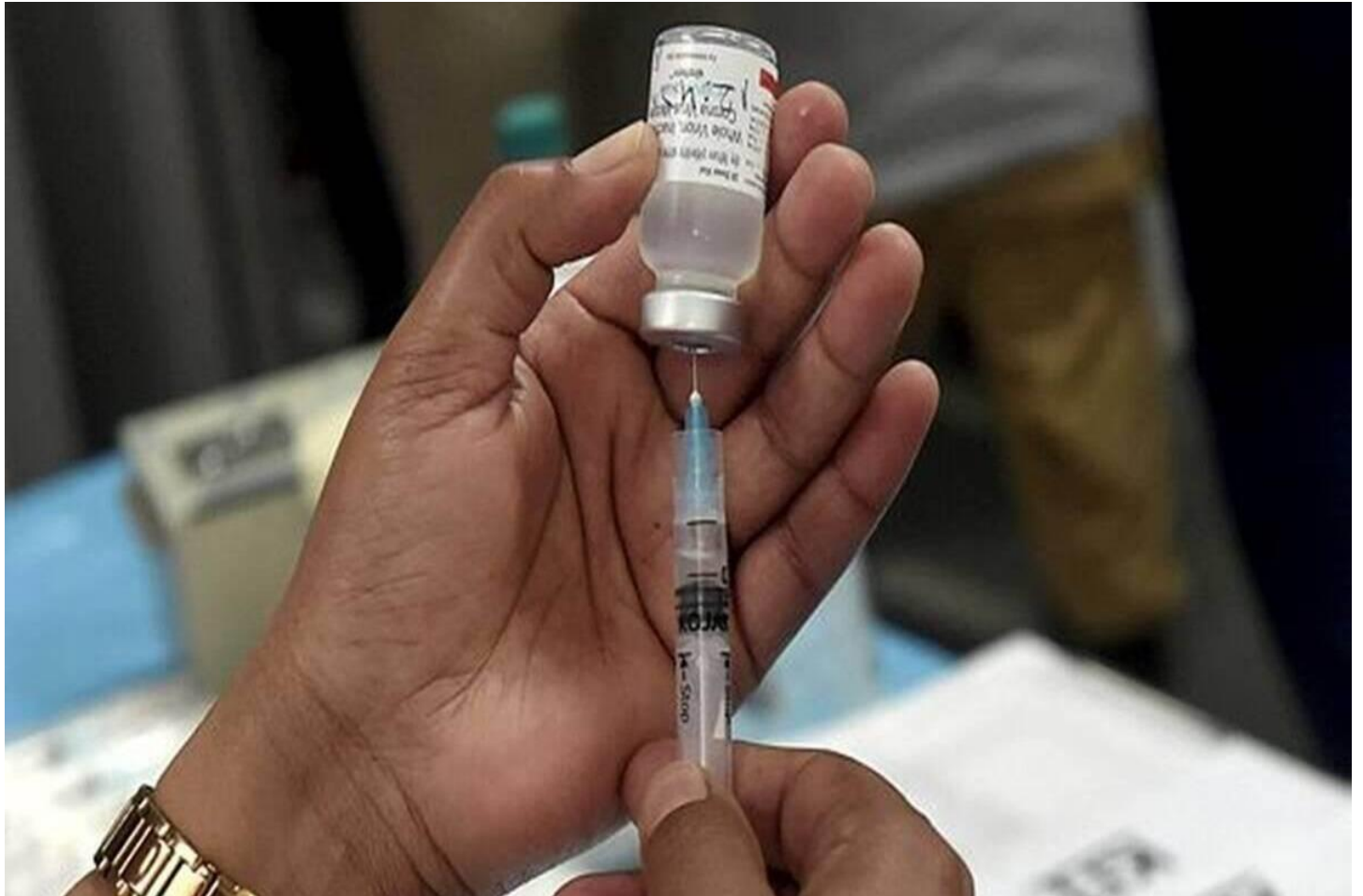


# The TRIPS Waiver Paradox: what does it mean for India's COVID-19 vaccine race

Updated: June 04, 2021

Nations have realised that building new healthcare systems and fortifying existing apparatus are the necessary armour needed to fight COVID-19.



The White House fact sheet on Monday did not provide exact figures for how many doses would be sent to each country. (Representational image:)

**By Professor (Dr.) Ashish Bharadwaj,**

*“(...) it’s the largest human management project in the world. It’s a very plural society, and we have to make sure nobody is left out.”*

Within one year of discovery of the coronavirus’s genome, countries began administering vaccines making this the fastest vaccine development initiative in human history. With 80 vaccines currently in clinical trials, coronavirus continues to test scientific efforts, healthcare planning and policymaking. Nations have realised that building new healthcare systems and fortifying existing apparatus are the necessary armour needed to fight COVID-19.

India is expected to deliver vaccines to more than 90 countries, and now we are finding ways to crank up the pace of our own immunization plans. It is now a moot question whether this expectation was

based on prior commitments to the COVID-19 Vaccines Global Access (COVAX), or as a part of India's vaccine diplomacy. It was reported that the G20 is now promoting voluntary licensing and technology transfer of COVID-19 vaccine patents, rather than supporting the waiver on intellectual property (IP) at the World Trade Organization (WTO). There are other important issues that need to be urgently addressed by India. The masterplan must involve ensuring timely access to biologics, negotiating voluntary license agreements with anyone who has proven medical solutions, and executing viable plans for technology transfer with the private sector.

### **'Standing on the Shoulders of Giants'**

We tend to forget that there is free entry into the innovation race to obtain IP rights including patents. To get the latest technological solutions in time to solve collective problems is a key benefit of the IP system. India's stand last week to expand the scope of TRIPS waiver beyond COVID-19 vaccine means that legal and procedural hurdles will take time to cross at the WTO. National patent systems and the WTO involve procedural complexity and sluggish internal processes. While a symbolic waiver is a step in the right direction, it is impractical for increasing vaccine production domestically, and providing therapeutics is unlikely in the short-term.

The manner in which other governments have supported medical innovation is remarkable. For example, to trigger an effective immune response, leading vaccine developers used a coronavirus spike protein (on mRNA platform) that was developed by the US National Institute of Health. Merck, which created life-saving MMR and chickenpox vaccines, suspended its COVID-19 vaccine candidates because of unsatisfactory results. These outcomes are not entirely unanticipated because in normal circumstances vaccines require more than 10 years in the preclinical phase and still have a market entry probability of only 6%. The commercial risks vis-à-vis performance against new variants and massive demand are mitigated with financial protection, government support, public subsidy, IP coverage, and regulatory certainty.

### **'Amateurs talk strategy, professionals talk logistics'**

The waiver will certainly address some challenges, but its sufficiency in mitigating the COVID19 outbreak is disputable. Vaccines involve patents, data from clinical trials, trademarks, and trade secrets at different stages of development and commercialisation. A waiver can provide legal clarity and protect generic manufacturers against retribution, but without the technical know-how, IP would be worthless to scale up production. In February 2021, Serum Institute's Poonawalla shared that patents are not an impediment to speedy vaccine rollout and that "it just takes time to scale up". Even if the Indian government (which holds patents on Covaxin) were to grant licence to others to manufacture Covaxin, getting them to produce a desired quantity will take considerable time.

Let's not forget that the initial phase of India's vaccination drive ran into a stone wall because of (1) failing to secure advance vaccine purchase agreements and voluntary licenses; (2) failing to expand

and repurpose existing plants in India, and (3) failing to deal with a guaranteed demand shock for biologics, therapeutics and equipment. We need extraordinary state support at this time with policy certainty on prices, regulatory approvals, and fast-track process for manufacturing and export permits. To spur production and dissemination, India's central and state governments must stockpile vaccines by pre-booking bulk order and making deferred payments, if needed. This is the only way to ensure that in India we vaccinate as many as possible and as fast as we possibly can.

### **'Huge risk of not taking any risk'**

In parallel to the WTO negotiations, we must expand manufacturing capability, scale up industrial infrastructure including biosafety containment facilities, procure essential COVID-19 supplies, encourage voluntary licenses, and facilitate technology transfer negotiations with the private sector. Voluntary licensing will not only ensure access to the most effective treatments and proven therapeutics, it will propel production capacities that already exist in the country. For instance, patent holders Eli Lilly and Merck/MSD recently signed non-exclusive, voluntary licenses with several generic Indian manufacturers for Baricitinib (royalty-free) and Molnupiravir, respectively, for COVID-19 treatment will provide immediate relief to people in India and importers who depend on India.

The quote at the beginning is not about COVID-19. It is from a former Election Commissioner describing India's 2019 national election that involved a billion people including voters, officers and security personnel in close to a million polling booths. India has carried out coordinated exercises of such mammoth proportions in the past, and we can do it again to end this pandemic. For that, we need to ensure that we have sufficient vaccines, medicines and equipment. It is a race against new pathogens with pandemic potential, a new wave or new strains of the coronavirus.

*(The author is Dean at O.P Jindal Global University (JGU). Views expressed are personal and do not reflect the official position or policy of the Financial Express Online.)*