

# Waiving Intellectual Property (IP) Protection for Covid-19 Vaccines

June 2, 2021

The Biden administration announced it would support a “TRIPS waiver” of intellectual property protections related to COVID vaccines. Sharing the know-how behind making COVID-19 vaccines is key to not only scaling up production, but also bringing forward the second generation of vaccines we will need to address emerging variants.

**In news:** Taking ‘extraordinary measures,’ Joe Biden backs suspending patents on Covid-19 vaccines

**Placing it in syllabus:** Economy

**Dimensions:**

- What is TRIPS?
- USA stance on Waiver
- India and South Africa stance
- What is Text based negotiation at WTO?
- Advantages of IPR waiver
- Potential challenges of waiver

## Content:

### What is TRIPS?

- In 1995, when the **World Trade Organization** came into existence, those signing up as members agreed that in exchange for the lowering of barriers to trade, they would abide by the Agreement on **Trade-Related Aspects of Intellectual Property Rights, or TRIPS**.
- This Agreement, pushed by knowledge-based economies like the United States and the multinational, research-

intensive pharmaceutical industry, imposed a base of protections for intellectual property rights, from patents to copyrights.

- Before this was negotiated, more than 50 countries did not recognize patent protection on pharmaceutical products.
- The TRIPS Agreement changed that, and after a transition period of 10 years, ratcheted up these requirements on all but the least developed countries.
- Middle-income countries like India came into compliance by 2005.

### **TRIPS waiver for COVID vaccines:**

- The TRIPS waiver refers to a proposal to the World Trade Organization to **waive intellectual property rights protection for technologies needed to prevent, contain, or treat COVID-19** “until widespread vaccination is in place globally, and the majority of the world’s population has developed immunity.”

The TRIPS waiver just seeks to **temporarily suspend these protections** until the pandemic has ended, so the world can better access the knowledge needed to combat the worst pandemic in a century.

### **USA stance on Waiver:**

- The United States had been a major holdout at the World Trade Organization over a proposal to suspend some of the world economic body’s intellectual property protections related to Covid Vaccines.
- But President Joe Biden had come under increasing pressure to throw his support behind the proposal
- In May 2021, the United States reversed its earlier stance and announced support for waiving intellectual property protection for Covid-19 vaccines, saying extraordinary circumstances call for extraordinary

measures.

- United States Trade Representative Katherine Tai said the US will pursue **“text-based negotiations”** on the waiver at the World Trade Organization (WTO).

## **India and South Africa stance:**

- In October 2020, India and South Africa had asked the WTO to waive certain conditions of the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement that could impede timely access to affordable medical products to combat Covid-19.
- The countries had asked the TRIPS Council to recommend, “as early as possible”, a waiver on the implementation, application and enforcement of four sections in the second part of the agreement.
- These sections – 1, 4, 5, and 7 – pertain to copyright and related rights, industrial designs, patents, and the protection of undisclosed information.
- The proposal had said that developing countries “especially”, may face institutional and legal difficulties when using flexibilities available in the TRIPS Agreement.

## **What are patents?**

- A patent represents a powerful intellectual property right, and is an exclusive monopoly granted by a government to an inventor for a limited, pre-specified time.
- It provides an **enforceable legal right** to prevent others from copying the invention.
- Patents can be either process patents or product patents.
- A **product patent** ensures that the rights to the final product is protected, and anyone other than the patent holder can be restrained from manufacturing it during a specified period, even if they were to use a different

process.

- A **process patent** enables any person other than the patent holder to manufacture the patented product by modifying certain processes in the manufacturing exercise.
- India moved from product patenting to process patenting in the 1970s, which enabled India to become a significant producer of generic drugs at global scale, and allowed companies like Cipla to provide Africa with anti-HIV drugs in the 1990s.

But due to obligations arising out of the TRIPS Agreement, India had to amend the **Patents Act in 2005**, and switch to a product patents regime across the pharma, chemicals, and biotech sectors.

## **What are Text Based Negotiations at WTO?**

- Text-based negotiations involve negotiators exchanging texts with their preferred wording and then thrashing out a consensus on the working
- Negotiations are expected in a mix of virtual and in-person meetings. They will take time given the consensus-based nature of the institution and the complexity of the issues involved.
- All 164 WTO members must agree on the draft, and any one member can veto it.

## **Advantages of IPR waiver :**

### ***Boosting production:***

- Sharing the know-how behind making COVID-19 vaccines is key to scale up production.
- It also allows for bringing forward the second generation of vaccines we will need to address emerging variants.

### ***Bringing vaccine equity:***

- No single vaccine manufacturer can produce enough vaccines to cover the globe, and demand has far outstripped supply, with high-income countries taking the lion's share of reserved doses.

### ***Diversification of Production:***

- The IP waiver might open up space for production of Covid vaccines with emergency use authorisations (EUA) – such as those developed by Pfizer, Moderna, AstraZeneca, Novavax, Johnson & Johnson and Bharat Biotech – on a larger scale in middle-income countries.
- Most production is currently concentrated in high-income countries; production by middle-income countries has been happening through licensing or technology transfer agreements

### **Potential challenges of waiver:**

Multinational pharmaceutical companies have vocally opposed the waiver, and disclosure forms from the first quarter of 2021 reveal that over 100 lobbyists had been enlisted to oppose the TRIPS waiver.

### ***Disincentive for future innovation***

- companies will be reluctant to invest in new technology if they feel that they cannot reap full financial benefit from their successes.
- Pharma companies including Pfizer and AstraZeneca have opposed the proposed waiver – saying eliminating IP protections would undermine the global response to the pandemic, including the ongoing R&D efforts to tackle new variants

### ***Safety and Quality Concerns***

- Pharma Companies also argue that waiving IPR & opening production facilities in developing countries could also undermine public confidence in vaccine safety and create

a barrier to information sharing.

### **Other challenges to increasing Vaccine Production:**

- **Trade barriers:** Countries like the US had blocked exports of critical raw materials used in the production of some Covid-19 vaccines using regulations like the American Defence Production Act.
- Bottlenecks in supply chains
- Unwillingness of rich countries to share doses with poorer nations.

For years to come, we will need COVID-19 vaccines. A sustainable and affordable pipeline—one that will deliver in a timely way to all in need, not just to those in wealthy countries—must be put in place.

In the best-case scenario, a TRIPS waiver for sharing COVID-19-related knowledge and technology can lay an important foundation to an innovation ecosystem that ensures a fairer path out of the pandemic than we took going into the pandemic.

**Mould your thought:** Discuss the issues involved in TRIPS waiver for Covid Vaccines. Will such a waiver really solve the vaccine crisis of the world?

### **Approach to the answer:**

- Introduction
- Discuss the TRIPS mechanism in brief
- Discuss the stance of USA, India and South Africa related to TRIPS Waiver
- Discuss the potential advantages of the waiver
- Discuss the challenges of the waiver
- Conclusion