Patent Waiver Plan for Vaccines

For Prelims: World Trade Organisation (WTO) , Trade-Related Aspects of Intellectual Property Rights (TRIPS), Doha Declaration.

For Mains: Patent Waiver, Covid-19, Intellectual Property Rights.

Why in News?

Recently, the Geneva Health Files, a Switzerland-based newsletter portal, revealed that a small group of **World Trade Organisation (WTO)** members were discussing to exclude drug manufacturers in India and China from prospective waivers to **Intellectual Property Rights** obligations under **Trade-Related Aspects of Intellectual Property Rights (TRIPS).**

- In 2020, India and South Africa had proposed a waiver from the implementation and application of certain provisions of the TRIPS Agreement (waiving IP rights like patents, copyright, and trademarks) for prevention, containment or treatment of Covid-19.

What is the TRIPS Agreement & its Relationship with Indian Patent Law?

- The TRIPS agreement was negotiated in **1995** at the WTO, it requires all its signatory countries to enact domestic law.
    - It guarantees minimum standards of IP protection.
    - Such legal consistency enables innovators to monetise their intellectual property in multiple countries.
- In 2001, the WTO signed the **Doha Declaration**, which clarified that in a public health emergency, governments could compel companies to license their patents to manufacturers, even if they did not think the offered price was acceptable.
- This provision, commonly referred to as **“compulsory licensing”**, was already built into the TRIPS Agreement and the Doha declaration only clarified its usage.
- Under **Section 92 of the 1970 Indian Patents Act**, the central government has the power to allow compulsory licenses to be issued at any time in case of a national emergency or circumstances of extreme urgency.

What is the Need for Invoking Compulsory Licensing?

- **Plugging Shortage of Vaccine:** The richest countries have cornered about 80% of vaccine supplies so far.
    - While India needs to supplement its output to ensure that a population of over 900 million which is above 18 years of age gets about 1.8 billion doses at the earliest.
    - Thus, compulsory licensing can be used to augment the supply of drugs and other therapeutics.
- **Nudging Voluntary Licensing:** An assertive posture on compulsory licences would also have the advantage of forcing several pharmaceutical companies to offer licences voluntarily.
- **Leading By Example**: Licensing Covaxin widely would enable India to live up to its reputation of

being the ‘pharmacy of the world’ and also put pressure on developed countries to transfer their vaccine technology to developing countries.
    - Thus, the government should not only transfer Covaxin’s technology to domestic pharmaceutical companies, to boost national supplies, but also offer it to foreign corporations.
    - By unlocking its vaccine technical know-how to the world, India would demonstrate its resolve to walk the talk on the TRIPS waiver.
- **Favourable Regulatory Environment:** A commitment to supply vaccines to India requires trust in the country’s regulatory and institutional environment, which the government must strive to instil through dependable commitments.
    - Such confidence, combined with the expedited process for vaccine approval, can help India quickly overcome its supply shortage.

Why are the Issues With TRIPS Waiver?

- **Complex Intellectual Property Mechanism:** The process of vaccine development and manufacturing has several steps, and involves a complex intellectual property mechanism.
    - Different types of IP rights apply to different steps and there is no one kind of IP that could unlock the secret to manufacturing a vaccine.
    - The expertise to manufacture it may be protected as a trade secret, and the data from clinical trials to test vaccine safety and efficacy may be protected by copyright.
- **Complex Manufacturing Mechanism:** Manufacturers will need to design the process for manufacturing the vaccines, source necessary raw materials, build production facilities, and conduct clinical trials to get regulatory approvals.
    - The manufacturing process itself has different steps, some of which may be subcontracted to other parties.
    - Thus, a patent waiver alone does not empower manufacturers to start vaccine production immediately.

Source: TH