Indian Patent Regime clash with the U.S. Norms

For Prelims: Special Report 301, IPR, Doha Declaration, Priority watch list, Indian Patent Act

For Mains: IPR related issues of India, Indian Patent Act

Why in News?

The U.S. Trade Representative highlighted IP challenges in India in its annual **Special 301 report.**

- The report highlighted a range of issues in domains ranging from **copyright and piracy to trademark counterfeiting and trade secrets**, saying that India remained one of the world's most challenging major economies with respect to protection and enforcement of IP.
- It has decided to retain India on its **Priority Watch List** along with six other countries- **Argentina, Chile, China, Indonesia, Russia and Venezuela.**
- U.S. trade law ("Special 301") requires an annual review of intellectual property protection and market access practices in foreign countries.
- Trading partners that currently present the most significant concerns regarding IP rights are placed either on the Priority Watch List or Watch List.

What is the Indian patent regime?

- A patent is **an exclusive set of rights granted for an invention**, which may be a product or process that provides a new way of doing something or offers a new technical solution to a problem.
- **Indian patents** are governed by the **Indian Patent Act of 1970**. Under the act, patents are granted if the invention fulfils the following criteria:
    - It should be novel
    - It should have inventive step/s or it must be non-obvious
    - It should be capable of Industrial application
    - It should not attract the provisions of sections 3 and 4 of the Patents Act 1970.
- India has gradually aligned itself with international regimes pertaining to intellectual property rights.
- It became a party to the **Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement** following its membership to the **World Trade Organization** on 1st January, 1995.
    - Following this, it amended its internal patent laws to comply with TRIPS, most notably in 2005, when it introduced **pharmaceutical product patents** into the legislation.
- **Other IPR related conventions**
    - India is also a signatory to several **Intellectual Property Rights (PR)** related conventions, including the **Berne Convention**, which governs copyright, the **Budapest Treaty, the Paris Convention for the Protection of Industrial Property, and the Patent Cooperation Treaty (PCT)**, all of which govern various patent-related matters.
- The **original Indian Patents Act did not grant patent protection to pharmaceutical products** to ensure that medicines were available to the masses at a low price.
    - This was based on the recommendations of a 1959 commission chaired by the jurist

Rajagopala Ayyangar.

- Patent protection of pharmaceuticals was re-introduced after the 2005 amendment to comply with TRIPS.

What are the Indian Issues Highlighted by USTR?

- Patent issues continued "to be of particular concern in India," highlighting the **threat of patent revocations, lack of presumption of patent validity and narrow patentability criteria as issues** which "impact companies across different sectors".
- The issue of narrow patentability criteria was again raised in relation to Section 3(d) of the Indian Patent Act, with the report saying that in the pharmaceutical sector, the United States "continued to monitor the restriction on patent-eligible subject matter in Section 3(d) of the Indian Patents Act and its impacts.

What do Section 3 and section 3 (d) of Indian Patent deal with?

- **Section 3** deals with **what does not qualify as an invention under the Act.**
- **Section 3(d)** in particular excludes "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance
    - or the mere discovery of any new property or new use for a known substance
    - or of the mere use of a known process, machine or apparatus unless such known process results in a new product
    - or employs at least one new reactant" from being eligible for protection under patent law.
    - Section 3(d) prevents what is known as **"evergreening"** of patents.
        - It is a corporate, legal, business, and technological strategy for extending/elongating the term of a granted patent in a jurisdiction that is about to expire, in order to retain royalties from them, by taking out new patents.
- According to the Committee's report, Section 3(d) allows for **generic competition by patenting only novel and genuine inventions.**
- The seminal judgment in the case ***Novartis vs. Union of India (2013)***, upheld the validity of section 3(d).

What is the Semi Judgement in Novartis vs. Union of India?

- In this case, pharmaceutical company Novartis filed a patent for the final form of cancer drug **Gleevec,** which was challenged in the Supreme Court.
- The Supreme Court held that **Gleevec was merely a beta crystalline form of a known drug, namely, i matinib mesylate,** and did not differ significantly in properties with regard to efficacy. **Hence, it could not be patented in India.**
- The judgment also says that the section 3 complies with the TRIPS agreement and the Doha Declaration.
    - The **Doha Declaration on the TRIPS Agreement and Public Health** was adopted on in November 2021, by the WTO member states.
        - This declaration recognises the **"gravity of public health problems affecting developing and least developed nations"** and stresses the need for TRIPS to be part of the wider national and international action to address these problems.
        - The declaration points out that the agreement "can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all."
        - These flexibilities include the right to grant **compulsory licenses** and the grounds for such licenses,
        - the right to determine what "constitutes a national emergency or other circumstances of extreme urgency, including public health crises"
        - and the right to establish its own regime for the exhaustion of intellectual property rights.
- **Compulsory licenses can be invoked by a state in public interest**, allowing companies apart from the patent owner to produce a patented product without consent.

Way Forward

- India must **not compromise on the patentability criteria under Section 3(d)** since as a sovereign country it has the flexibility to stipulate limitations on grants of patents in consistence with its prevailing socio-economic conditions.
    - This ensures the growth of generic drug makers and the public's access to affordable medicines.
- India should resolve its differences with the U.S. regarding the disqualification of incremental inventions through bilateral dialogue.
- The member countries of WTO make full use of the policy space available in the TRIPS agreement by adopting and applying rigorous definitions of invention and patentability that curtail 'evergreening' and ensure that patents are only awarded when genuine innovation has occurred.
- Through Section 3(d), India strives to balance the international patent obligations and its commitments to protect and promote socio-economic welfare and public health.

Source: TH