The Indian Patent Regime and its Clash with the U.S. Norms

What is the issue?

The U.S. Trade Representative (USTR) said in a recent report that India was one of the most challenging major economies as far as IP protection and enforcement is concerned.

How is India's 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 steps 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 became a party to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement following its membership to the World Trade Organization in 1995.
- The original Indian Patents Act did not grant patent protection to pharmaceutical products and was re-introduced after the 2005 amendment to comply with TRIPS.
- India is also a signatory to several IPR related conventions including
    - The Berne Convention (governs copyright)
    - The Budapest Treaty
    - The Paris Convention for the Protection of Industrial Property
    - The Patent Cooperation Treaty (PCT)

What were the challenges raised by USTR?

- **Special 301 Report**- The USTR releases Special 301 Report on intellectual property (IP) annually.
- It identifies trading partners that do not adequately/ effectively protect and enforce IP rights or deny market access to U.S. innovators and creators that rely on protection of their IP rights and place them in the Priority Watch List or Watch List.
- India continues to be on the '**Priority Watch List'** of the USTR for lack of adequate IP rights protection and enforcement.
- **Issues-** Concerns raised include what can be patented, waiting times for obtaining patents, reporting requirements, and data safety.
- The USTR also highlighted the threat of patent revocations, lack of presumption of patent validity and narrow patentability criteria as issues.
- The USTR report too highlighted issues relating to judicial delays despite constituting the

2015 Commercial Courts Act.
- It has also expressed the concerns against the abolition of IPAB under Tribunals Reforms (Rationalisation and Conditions of Service) Ordinance, 2021.

What is India's stance on the issue?

- The issues regarding IPR were tackled by the Parliamentary Standing Committee which undertook a 'Review of the Intellectual Property Rights Regime in India'.
- **Article 3(d) of the Indian Patent Act**- Section 3 and Section 3(d) deals with what does not qualify as an invention under the Act.
- The Parliamentary Standing Committee pointed out that the section acts as a safeguard against frivolous inventions thus preventing "evergreening" of patents.
- Section 3(d) allows for generic competition by patenting only novel and genuine inventions.
- It said that this ensures the growth of generic drug makers and the public's access to affordable medicines.
- The Committee refers to the judgement in the *Novartis vs. Union of India* which upheld the validity of section 3(d) and held that it complies with the TRIPS agreement and the Doha Declaration.
- It concluded that India must not compromise on the patentability criteria under Section 3(d) as a sovereign country.

What is Doha Declaration?

- The Doha Declaration on the TRIPS Agreement and Public Health was adopted in 2021 by the WTO member states.
- It 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.
- 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
    - 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.

What positive steps were taken by India regarding IPR?

- **Accession to treaties**- The positive steps taken by India in the recent past include accession to the
    - World Intellectual Property Organization (WIPO) Performances and Phonograms Treaty
    - WIPO Copyright Treaty (collectively known as the WIPO Internet Treaties) in 2018
    - Nice Agreement in 2019
- **Revised manual**- India issued a revised Manual of Patent Office Practice and Procedure in 2019 and revised Form 27 on patent working in 2020 to reduce redundancy of information filing by patent applicants in India.
- **IP division**- After IPAB was abolished, the Delhi High Court created an IP division in 2021, for which the draft rules have been released for comment.

- **CIPAM**- The Cell for Intellectual Property Rights Promotion and Management (CIPAM) has been promoting IP awareness across India.
- **MoU**- The United States Patent and Trademark Office (USPTO) and Department for the Promotion of Industry and Internal Trade (DPIIT) are working to further a MOU signed in 2020 relating to IP technical cooperation mechanisms.

References

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