



DAILY EDITORIAL ANALYSIS

TOPIC

**PATENT RIGHTS & PUBLIC HEALTH:
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Context

- India stands at a critical intersection between the enforcement of **Intellectual Property Rights (IPRs)** and the fulfillment of its **public health obligations**.

Public Health and Patent Rights in India

- Public health obligations** demand **equitable access** to affordable medicines and technologies, while **patents** are designed **to promote innovation and encourage investment in research**.
- It is essential for ensuring that Intellectual Property (IP) laws serve both innovation and humanity, as **India (Bharat)** serves as the '**pharmacy of the Global South**'.

Constitutional and Institutional Framework

- Article 21 of the Constitution:** It guarantees the **right to life**, a right that the Supreme Court has consistently interpreted to **include the right to health**.
- World Trade Organization (WTO):** India is a **member of the WTO** and bound by the **Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement**.
 - It mandates the protection of intellectual property and allows **flexibilities** like member states have the right to protect public health and promote access to medicines for all (**Doha Declaration on TRIPS and Public Health, 2001**).
- The Patents Act, 1970** and its **amendment in 2005** provides the legal backbone for India's patent system.
 - It embeds **safeguards** to prevent abuse of monopoly rights while it protects genuine inventions.

TRIPS Flexibilities and India's Strategic Use

- India's patent regime utilizes TRIPS-compliant flexibilities to promote health equity. These include:
 - Parallel imports:** Allowing importation of patented products marketed abroad at lower prices.
 - Compulsory licenses for export (Section 92A):** Permitting production of patented drugs for export to countries with insufficient manufacturing capacity.
 - Price control mechanisms:** Ensuring affordability through the **National Pharmaceutical Pricing Authority (NPPA)**.
- Such measures have earned India recognition as a **model for developing nations**, balancing TRIPS obligations with social justice.

Concerns & Issues Surrounding Public Health and Patent Rights in India

- Evergreening Challenge:** Evergreening in the pharmaceutical and agricultural sectors **undermines equitable access to essential goods**.
 - Pharmaceutical companies from the Global North often attempt to '**evergreen**' patents by making minor modifications such as new salts, formulations, or dosage forms without significant therapeutic advancement.
 - It restricts competition, delays generic entry, and inflates drug prices.
- Conflict Between Innovation and Access:**
 - For innovators**, patents represent recognition of intellectual effort and a means to recover R&D investments.
 - For society**, excessive monopoly protection risks **making essential medicines unaffordable**, particularly for low-income populations.
- High Cost of Patented Drugs:** Patented medicines in India often cost **ten to thirty times more** than generic alternatives.
 - Patent monopolies directly affect affordability and access**, especially for chronic and life-threatening diseases like cancer and hepatitis.

- ◆ As a result, millions of Indians are pushed into **catastrophic health expenditure** every year due to high drug costs.
- **Limited Use of TRIPS Flexibilities:** Though TRIPS allows nations to adopt **flexibilities** like **compulsory licensing, government use provisions, and parallel imports**, India's use of these tools has been **sporadic and cautious**.
 - ◆ Since 2012, only one compulsory license has been granted largely due to **political pressure** and **fear of trade retaliation** from developed countries.
- **Pressure from Global Trade Partners:** India faces **significant diplomatic and trade pressure** from developed nations, especially the United States and the European Union **to strengthen IP enforcement** and dilute domestic safeguards and compulsory licensing.
 - ◆ Inclusion of India on the **US Trade Representative's 'Priority Watch List'** reflects ongoing scrutiny of its patent practices.
 - ◆ Such external pressures threaten India's sovereign right to design IP policies suited to its **public health and socio-economic realities**.
- **Weaknesses in Healthcare Infrastructure:** It includes inadequate distribution of essential drugs in rural areas, dependence on private healthcare, where drug prices are unregulated, and limited public procurement of patented or life-saving medicines.
- **R&D and Indigenous Innovation Gaps:** Domestic innovation remains underfunded, as India spends less than **1% of its GDP on R&D**, compared to over **2.5% in developed countries**.
- **Abuse of Dominant Position:** Some patentees engage in **anti-competitive behavior**, such as imposing excessive licensing fees; restricting supply chains; and engaging in 'patent clustering' to deter generic entry.
 - ◆ Such practices may violate the **Competition Act, 2002**, but enforcement remains limited.

Balancing Public Health and Patent Rights in India

- **Safeguards Against Evergreening:** The **Section 3(d) of the Patents Act** prohibits patents on new forms of known substances unless they result in **enhanced therapeutic efficacy**.
 - ◆ It prevents pharmaceutical companies from '**evergreening**' patents prolonging monopolies through trivial modifications to existing drugs.
- **Compulsory Licensing:** The **government or any interested party** can seek a **compulsory license** (under **Sections 84 and 92A** of the Patents Act) to produce a patented drug without the patentee's consent if:
 - ◆ The drug is not available at a reasonable price,
 - ◆ The patentee has failed to meet domestic demand, or
 - ◆ It is required for public health or export to countries lacking manufacturing capacity.
- **Protecting Public Health:** India's Patents Act gives the **central and state governments** several powers to safeguard public health:
 - ◆ **Section 47(4):** Allows the government to use or import patented inventions for public institutions without patentee consent.
 - ◆ **Section 66:** Permits revocation of a patent if it is 'mischievous to the state' or 'prejudicial to the public'.
 - ◆ **Section 102:** Authorizes the government to acquire a patent in the public interest, compensating the patentee fairly.
- **Balancing Through Competition Law:** The **Competition Act, 2002** acts as a complementary mechanism to the Patents Act.
 - ◆ It prohibits **abuse of dominant position** and **anti-competitive practices** by patent holders.
 - ◆ India promotes both **innovation and affordability** by integrating **competition principles** with patent law.

Policy Recommendations for a Sustainable Balance

- **Formulate a National Patent Policy** integrating public health objectives.
- **Encourage indigenous innovation** through state-funded R&D and academic partnerships.
- **Enhance the use of TRIPS flexibilities**, including compulsory licensing in public interest.
- **Strengthen collaboration** between the Patent Office, Drug Controller, and Competition Commission.
- **Improve drug distribution systems**, ensuring rural access to essential patented and generic medicines.
 - ◆ These measures can ensure that intellectual property rights coexist with India's constitutional commitment to health and welfare.

Daily Mains Practice Question

[Q] Balancing patent protection with the right to public health remains a persistent challenge in India. Examine it in balancing intellectual property rights with the need to safeguard public health.

Source: IE

