4. Data Exclusivity in India – Science & Technology

The Indian government is considering implementing "data exclusivity" in the pharmaceutical drugs sector. The government's approach appears to be driven by the expectation that the provision could help bring in additional investment in the country

Patent System in the Pharmaceutical Industry- Conceptual Overview

A patent is a statutory right granted to an inventor, giving exclusive rights to make, use, sell, or license an invention for a limited period. In pharmaceuticals, patents are critical because

1. Drug development is capital-intensive, risky, and time-consuming (10–15 years).
2. Only a small fraction of molecules succeeds in clinical trials.

Pharma patents protect both products and processes, unlike many other sectors

Pharmaceutical Patents Protect

Pharma patents can cover multiple dimensions of innovation-

Drug Molecules (Product patents)- New chemical entities (NCEs), biologics, vaccines.
Manufacturing Processes (Process patents)- Novel or cost-efficient methods of synthesis.
Formulations- Modified dosage forms (e.g., sustained release tablets).
New Uses of Known Substances- Second medical use (subject to restrictions under Indian law).
Drug Delivery Systems- Transdermal patches, inhalers, nano-carriers.
This broad coverage makes pharmaceuticals one of the most patent-intensive industries globally.

Types of Pharmaceutical Patents in India

Under the Patents Act, 1970 (as amended), India recognises the following-

Product Patents

1. Protect the final drug molecule.
2. Introduced in 2005 to comply with TRIPS.

Process Patents

1. Protect the method of manufacturing a drug.
2. Earlier focus of India's generic industry.

Improvement (Incremental) Patents

1. Minor modifications such as polymorphs, salts, dosage changes.
2. Restricted under Section 3(d) to prevent evergreening.

Biotechnology Patents

1. Cover biologics, recombinant DNA products, vaccines, monoclonal antibodies.
2. Subject to higher scrutiny due to ethical and public health concerns. An invention must satisfy all three statutory conditions

1. Novelty- The invention must be new globally, not disclosed anywhere in the world. Prior publication or prior use destroys novelty.
2. Inventive Step- The invention must not be Obvious to a person skilled in the art. A simple modification or combination of known substances. India applies a strict inventive step standard, especially for pharmaceuticals.
3. Industrial Applicability- The invention must be Capable of being manufactured or used in industry. Practically workable, not merely theoretical.
Term of Patent Protection- Patent term in India 20 years from the date of filing. Uniform across technologies. Fully compliant with TRIPS Agreement obligations.

Compulsory Licensing (CL)- Public Health Safeguard

Concept- Compulsory Licensing allows the government to permit third parties to manufacture a patented product without the consent of the patent holder.
Legal Basis- Provided under Section 84 of the Patents Act, 1970. Reflects India's use of TRIPS flexibilities. Grounds for Grant of CL. Reasonable public requirements not satisfied. Unaffordable prices of essential medicines. Non-working of patent in India (not manufactured or adequately supplied domestically).

Significance- Balances monopoly rights with Right to Health. Instrumental in ensuring access to life-saving drugs (e.g., cancer, HIV).

Patent Cooperation Treaty (PCT) System

The Patent Cooperation Treaty provides a single-window international patent filing mechanism.

Benefits

1. One application gives priority rights in all PCT member countries.
2. Delays high-cost national filings.

India joined PCT in 1998. All PCT activities are administered by the World Intellectual Property Organization, headquartered in Geneva.

TRIPS Agreement and India

Key Features of TRIPS- A binding WTO agreement in force since 1995. Sets minimum standards for

1. Patent protection
2. Enforcement mechanisms

Applies to all WTO members, including India.

India's Strategy under TRIPS- Adopted product patents but

1. Retained **Section 3(d)** to curb evergreening.
2. Actively uses compulsory licensing and pre-grant oppositions.

Reflects a public-health-centric interpretation of TRIPS.

World Intellectual Property Organization (WIPO)

World Intellectual Property Organization is a self-financing UN agency. Established in 1967 by the WIPO Convention. Membership- 194 countries, including India. India joined WIPO in 1975.

Role

1. Administers PCT and other IP treaties.
2. Promotes global IP cooperation and innovation.

Data Exclusivity- Concept and Indian Position

Data Exclusivity- A regulatory protection mechanism that Prevents drug regulators from relying on originator's clinical trial data to approve generics. Operates independently of patent protection.

Indian Scenario- India does NOT provide data exclusivity. Regulators can rely on existing clinical data for approving generics after patent expiry. This policy choice

1. Prioritises affordable medicines.
2. Has enabled India to become the largest global supplier of generics.

Significance of Data Exclusivity (Pro-Arguments)

Incentive for Innovation- Protects costly clinical trial investments.

Attracts Foreign Direct Investment- Signals predictable IP environment.

Encourages Original Drug Discovery- Shifts firms from reverse engineering to R&D.

Alignment with Global Practices- USA, EU, Japan provides data exclusivity.

Concerns with Data Exclusivity (Against Indian Adoption)

Economic and Industrial Concerns- Delays generic entry, creating de facto monopolies beyond patent term. Weakens India's generics-based pharmaceutical industry (≈90% firms).

Public Health Concerns- Increases medicine prices. Delays access to affordable drugs for-

1. Domestic population.
2. Developing countries dependent on Indian generics.

Ethical and Systemic Issues- Encourages duplicative or unethical clinical trials. Raises burden on public healthcare systems. Undermines India's role as "pharmacy of the world" supplying Africa, Asia, and Latin America.

Way Forward- India's Balanced IP Model

India follows a calibrated IP regime, combining

1. TRIPS compliance.

2. Strong public health safeguards.

Policy stance reflects

1. Constitutional commitment to health.
2. Pragmatic use of TRIPS flexibilities.

Future strategy

1. Promote innovation through **public-funded R&D and incentives**.
2. Protect access through **strong competition and regulatory oversight**.

Conclusion

India's rejection of data exclusivity and its nuanced patent framework reflect a deliberate developmental choice—to balance innovation incentives with equitable access to medicines. This model has global relevance, especially for the Global South, and exemplifies how intellectual property law can be aligned with public welfare and ethical governance.

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