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PATENT LAWS IN INDIA: A COMPREHENSIVE OVERVIEW

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Introduction

Patent laws are a cornerstone of intellectual property regimes worldwide, designed to encourage innovation by granting inventors exclusive rights to their creations for a limited time. India's patent system has undergone a significant transformation since independence, balancing the need to protect inventors with public interest concerns such as affordable access to medicines. The Indian Patents Act, 1970, and its subsequent amendments have shaped a unique legal framework that aligns with international obligations under the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This article explores the historical context, key provisions, landmark judicial decisions, and ongoing challenges of patent laws in India, supported by Bluebook citations.

Historical Background

India's patent regime has its roots in the colonial era, with the first substantive legislation being the **Indian Patents and Designs Act, 1911**, modeled on the British Patents Act. After independence, the Act remained largely unchanged until the need arose to foster domestic industrial growth and self-reliance.

The **Patents Act, 1970** was enacted to overhaul the patent regime, shifting India's focus toward process patents rather than product patents, especially in pharmaceuticals and agro-chemicals,

allowing local industries to reverse-engineer products without infringing patents, thus making affordable products available to the masses. The Act was designed to spur innovation and prevent monopolies detrimental to public health and development.

The Patents Act, 1970: Framework and Philosophy

The 1970 Act remains the primary legislation governing patents in India. It was influenced by socio-economic policies favoring accessibility and industrial growth over protectionism favoring patent holders.

1. Patentability Criteria

Under **Section 2(1)(j)**, “invention” is defined as any new product or process involving an inventive step and capable of industrial application. Section 3 outlines exclusions from patentability:

- Mere discoveries of scientific principles or formulations of abstract theories (Section 3(c))
- Methods of agriculture or horticulture (Section 3(h))
- Substances intended for mere treatment of diseases without new efficacy (Section 3(i))
- Inventions frivolous or contrary to public order or morality (Section 3(b))

These exclusions reflect India's emphasis on promoting genuine innovation while safeguarding public interest.

2. Process Patents for Pharmaceuticals and Agro-Chemicals

Section 5 of the Act restricted patents in pharmaceutical and agrochemical sectors to **process patents only**, explicitly forbidding product patents. This enabled Indian companies to legally manufacture patented drugs using different processes, enhancing affordable drug availability domestically.

3. Term of Patent

Initially, patents were granted for **14 years** from the date of filing, shorter than international norms, reflecting the government's intent to avoid long monopolies.

4. Compulsory Licensing

Section 84 introduced **compulsory licensing**, empowering the government to authorize third parties to produce patented inventions without consent under conditions like non-working of the patent or public interest, which has been a critical tool in India's public health policy.

TRIPS and the Need for Amendments

India's accession to the WTO in 1995 required compliance with the TRIPS Agreement, which mandates minimum standards for intellectual property protection, including product patents in pharmaceuticals and agricultural chemicals.

The TRIPS Agreement compelled India to amend its patent laws significantly, especially regarding product patent protection and patent term extensions.

Patents (Amendment) Act, 2005: Major Changes

The **Patents (Amendment) Act, 2005** marked a watershed moment, aligning Indian law with TRIPS:

- **Product patents** were introduced for all fields of technology, including pharmaceuticals and agriculture.
- Patent term extended to **20 years** from the date of filing (35 U.S.C. § 154; TRIPS Agreement Art. 33).
- Introduction of **mailbox provisions** to handle applications for product patents filed between 1995 and 2005.
- Establishment of **exclusive marketing rights** (EMRs) for patent applicants awaiting patent grant.

- Strengthened compulsory licensing provisions under Sections 84 and 92A.

These amendments balanced international obligations with India's policy goals, including access to medicines and public health safeguards.

Patent Application Process in India

1. Filing and Publication

Patent applications are filed with the **Office of the Controller General of Patents, Designs and Trade Marks (CGPDTM)**. Applicants may file:

- **Provisional Application:** To secure an early filing date.
- **Complete Application:** Filed within 12 months of provisional filing.

Applications are published after 18 months from the filing or priority date, or earlier upon request.

2. Examination

Applicants must file a **request for examination** within 48 months of filing. The Patent Office examines the application against patentability criteria, issuing a **First Examination Report (FER)** citing objections or reasons for acceptance.

3. Opposition Proceedings

India allows **pre-grant and post-grant opposition**. Third parties may challenge patents to ensure only deserving inventions receive protection (Patents Act §§ 25(1), 25(2)).

4. Grant or Refusal

If objections are satisfactorily addressed, the patent is granted and published in the patent journal.

Key Provisions in Indian Patent Law

Section 3(d): Anti-Evergreening Provision

One of India's most controversial and unique provisions, **Section 3(d)** prevents patenting new forms of known substances unless they demonstrate **enhanced therapeutic efficacy**. The Supreme Court upheld this in the landmark **Novartis AG v. Union of India**, denying patent protection for an improved cancer drug, Glivec, to prevent evergreening of patents that extend monopolies without significant innovation.

Novartis AG v. Union of India, (2013) 6 S.C.R. 226 (India).

This provision strikes a balance between rewarding genuine innovation and preventing unjustified patent extensions that restrict access to medicines.

Compulsory Licensing

Compulsory licensing enables the government to authorize production of patented inventions without the patent holder's consent under specified conditions.

The first compulsory license was granted in 2012 to **Natco Pharma Ltd.** for the cancer drug Nexavar, on grounds that Bayer did not make the drug reasonably affordable or available.

Natco Pharma Ltd. v. Bayer Corp., Indian Patent Office Order No. 01/2012.

Section 84 allows compulsory licensing after **three years** from grant if reasonable requirements are unmet or the patented invention is not sufficiently worked in India.

Bolar Exception (Section 107A)

The Act permits generic manufacturers to use patented inventions for research and regulatory approval purposes before patent expiry, facilitating timely market entry post-patent life.

Judicial Interpretations and Landmark Cases

1. Novartis v. Union of India (2013)

The Supreme Court applied Section 3(d) to deny a patent for the β -crystalline form of imatinib mesylate (Glivec), emphasizing the need for increased efficacy to warrant patent protection. The judgment reinforced India's commitment to balancing patent protection with public health.

2. Roche v. Cipla (2015)

This case involved patent infringement claims by Roche over Erlotinib, an anti-cancer drug. The Delhi High Court examined patent validity and injunctions, highlighting issues around patent enforcement and access to affordable medicines.

3. Bayer v. Natco (2012)

Natco's successful application for compulsory licensing against Bayer's Nexavar marked a landmark in public health jurisprudence, recognizing affordability and availability as vital criteria.

Challenges in the Indian Patent Regime

1. Patent Office Backlogs and Quality

India's patent office faces a backlog of applications, delaying grant and impacting innovation incentives. Quality concerns have been raised regarding examination rigor, though recent digital reforms aim to address these.

2. Tensions Between Access and Innovation

India's pro-public health stance, especially on pharmaceuticals, has attracted criticism from multinational corporations and developed countries arguing it undermines innovation incentives.

3. International Pressure and Bilateral Agreements

India faces pressure in trade negotiations to dilute safeguards like Section 3(d) and compulsory licensing, often framed as barriers to market access.

Recent Trends and Future Directions

Digitization and E-Governance

The Indian Patent Office has embraced digitization, enabling e-filing, e-examination, and public access to records to improve efficiency.

Focus on Biotech and Software Patents

India continues to refine its position on patentability of biotechnological inventions and computer-related inventions, balancing innovation with ethical and economic concerns.

Enforcement and Litigation

Efforts are ongoing to strengthen patent enforcement mechanisms to reduce infringement and piracy while protecting legitimate public interests.

Conclusion

India's patent laws represent a nuanced legal framework reflecting the country's dual goals of promoting innovation and ensuring public access to essential technologies. From the pioneering Patents Act of 1970 to TRIPS-compliant amendments, India has crafted a patent regime that is robust yet sensitive to socio-economic realities. Judicial decisions, notably *Novartis*, reinforce India's distinctive approach to intellectual property rights, making the Indian patent system a model of balancing global standards with domestic priorities.

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