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RIGHT TO LIFE SAVING DRUGS - A STUDY IN CONTEXT TO INDIAN PATENT LAW AND DRUGS AND COSMETICS ACT

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INTRODUCTION

The Right to access life saving drugs in India occupies a vital juncture where Constitutional Rights, Public Health Programs and Intellectual Property Law intersects. In a nation of over 1.4 billion people, ensuring equitable access to essential medicines is not only a moral imperative but a Constitutional mandate flowing from Article 21 of the Indian Constitution. This right[339], however, must coexist with the legitimate rights of pharmaceutical innovators protected under the Indian Patent Act, 1970[340] and The Drugs and Cosmetics Act, 1940[341], which regulates drug quality, safety and efficacy.

This article attempts a comprehensive analysis of how Indian Laws attempt to balance the Right to Life with Patent Rights and Drug Regulations ensuring that medicines remain affordable, available and effective. It delves into statutory frameworks, landmark cases, policy innovations and current challenges to provide a holistic picture of India's efforts to uphold the Right to Life Saving Drugs.

[339] Right to Life - Article 21 Constitution of India.
[340] The Patents Act, 1970.
[341] Drugs and Cosmetics Act, 1940.

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THE RIGHT TO LIFE AND ACCESS TO MEDICINES: A CONSTITUTIONAL IMPERATIVE

Article 21 - Right to Life

Article 21 of the Constitution reads:

"No person shall be deprived of his Rights or personal liability except according to procedure established by Law."

This Article has evolved through judicial interpretation to include the Right to Health[342] and, by extension, access to Life Saving Drugs.

1. **Bandhua Mukti Morcha v. Union Of India (1984)[343]:** The Supreme Court held that The Right to Live with Human Dignity includes Protection of Health.
2. **Paschim Banga Khet Majdoor Samity v. State of West Bengal (1996)[344]:** The Court mandated that the failure of a Government Hospital to provide timely medical treatment amounts to violation of Article 21.

Directive Principles of State Policies

While the Directive Principles under Indian Constitution are non-justiciable, they act as guiding principles for the State. Article 47 obligates the State to raise the level of nutrition and improve public health[345]. Combined with Article 21, these principles strengthen the case for a justiciable Right to access essential medicines.

INDIAN PATENT LAW AND PUBLIC HEALTH

The Indian Patent Act, 1970: Historical Perspective

Before 2005, India only allowed process patents for pharmaceuticals and not product patents. This allowed Indian companies to reverse engineer drugs using different processes and sell them at lower prices. However, India's compliance with the TRIPS Agreement[346] necessitated product patent protection for drugs.

The 2005 amendment introduced such protection but included safeguards aimed at ensuring that patent rights do not override public health needs.

Key Provisions that Safeguard Public Health

1. **Section 3d - Preventing Evergreening**

   Prevents Evergreening of Patents by disallowing Patents on new forms of known substances unless they show enhanced efficacy[347]. This ensures that pharmaceutical companies cannot extend monopolies by making minor modifications.

   Novartis AG v. Union of India[348]

   The Supreme Court denied a patent on Glivec, an anti-cancer drug due to lack of enhanced therapeutic efficacy. This upheld India's commitment to make essential medicines affordable.

2. **Section 84 - Compulsory Licensing**

   Allows the government to grant a compulsory license to a third party to manufacture a patented drug if[349]:

   The reasonable requirements are not being met.

   The drug is not available at an affordable price.

   The patented invention is not being worked on in India.

   Nacto Pharma v. Bayer Corporation 2012[350]

   The first compulsory license was issued in India to Nacto Pharma to manufacture the patented cancer drug Naxavar by Bayer. Bayer priced the drug at Rs. 2.8 lakhs per month, while Nacto offered it at Rs. 8800 per month. The Controller

[342] Francis Coralie Mullin v. Administrator, Delhi (1981) AIR 746.
[343] Bandhua Mukti Morcha v. Union of India, AIR 1984 SC 802.
[344] Paschim Banga Khet Mazdoor Samity v. State of West Bengal, AIR 1996 SC 2426.
[345] Constitution of India, Article 47.
[346] TRIPS Agreement, WTO, 1995.
[347] Indian Patents Act, Section 3(d).
[348] Novartis AG v. Union of India, (2013) 6 SCC 1.
[349] Indian Patents Act, Section 84.
[350] Bayer Corporation v. Natco Pharma, Compulsory License Order, 2012.

General of Patents ruled in favour of Nacto, stating that Bayer had failed to make the drug accessible to Indian patients. The ruling became a global precedent for affordable healthcare.

3. **Section 92 and 92A - National Emergency and Export**[351]

   Section 92: Government can issue compulsory license during Health emergencies.

   Section 92 A: Allows Indian companies to manufacture and export drugs to countries with no manufacturing capabilities.

4. **Section 83 - Working Requirements**[352]

   Encourages Patents to be worked in India, that is, Locally Manufactured rather than being imported, ensuring accessibility.

THE DRUGS AND COSMETICS ACT, 1940: REGULATORY FRAMEWORK FOR QUALITY AND ACCESS

Scope and Objective

The Drugs and Cosmetics Act, 1940 is India's Central Legislation for regulating import, manufacture, distribution, and sale of drugs and cosmetics. It ensures that drugs available in India meet standards of safety, efficacy and quality[353].

Key Features of the Act

1. **Section 3**[354]

   Provides for the constitution of technical bodies like the Central Drugs Standard Control Organisation (CDSCO) and Drug Technical Advisory Board (DTAB).

2. **Section 16 and 17**[355]

   Define standards for quality and label requirements to prevent adulteration and misbranding.

3. **Section 26A**[356]

   Empowers the Government to prohibit the manufacture and sale of drugs that pose a risk to human beings.

4. **Section 122A and 122B**[357]

   Regulates new drug approvals, clinical trails and licensing.

Licensing and Regulation

- The drugs must be approved by the Drugs Controller General of India.
- Clinical trials must demonstrate safety and therapeutic efficacy.
- Special procedures exist for emergency approvals

Rules and Standards[358]

- Schedule Y - Regulates clinical trials
- Schedule M - Good manufacturing practices
- Schedule H and H1 - Regulates prescription drugs, many of which are life saving

Ensuring Affordability and Availability

Through price control measures, generic promotion and quality control, the Act supports the constitutional mandate under Article 21. Drugs in the National List of Essential Medicines are subject to Price Caps under the Drugs Price Control Order issued under the Essential Commodities Act.

Role of Drugs Control General Of India (DCGI)

- Approved new drugs and vaccines
- Monitors adverse drug reactions
- Grants permission for emergency use

[351] Patents Act, Sections 92 and 92A.
[352] Patents Act, Section 83.
[353] Drugs and Cosmetics Act, 1940.
[354] Drugs and Cosmetics Act, 1940 Section 3
[355] Drugs and Cosmetics Act, 1940- Sections 16 and 17.
[356] Drugs and Cosmetics Act, 1940- Section 26A.
[357] Drugs and Cosmetics Act, 1940- 122A and 122B.
[358] Drugs and Cosmetics Rules, 1945.

- Coordinates with State Drug Controllers for enforcement

Role of Central Drugs Standard Control Organisation (CDSCO)

- Organisation headed by DCGI which is responsible for drug approvals, clinical trial oversight and import export regulation.

Fast - Track Approvals

In crisis like COVID - 19, regulatory frameworks allowed emergency approvals for vaccines and antivirals like Remdesivir and Favipiravir.

NATIONAL LIST OF ESSENTIAL MEDICINES (NLEM) AND DRUG PRICE CONTROL

Purpose and Importance

- Prepare under the guidance of WHO's essential medicines model.
- Inclusion is based on disease burden, efficacy, safety and affordability.

Links with Drug Pricing

- Drugs listed under NLEM[359] (National List of Essential Medicines) are automatically brought under Drug Price Control Order (DPCO)[360].
- The National Pharmaceutical Pricing Authority (NPPA) fixes ceiling prices.
- The best example is that, Price of Cancer Drug Imatinib was reduced by over 75% after NLEM listing[361].

GOVERNMENT POLICIES AND PUBLIC HEALTH WELFARE SCHEMES

Jan Aushadhi Scheme (PMBJP)[362]

- Over 10,000 Jan Aushadhi Kendras provides generic medicines at 50 - 90% reduced prices.
- Includes essential life saving medicines like anti-hypertensives, antidiabetics and anti-cancer drugs.

Ayushman Bharat (PMJAY)[363]

- This flagship scheme provides health insurance upto Rs. 5 lakhs per family per year for secondary and tertiary care hospitalization.
- It includes coverage for expensive and life saving treatments like dialysis, cancer therapies and cardiac surgeries.

Health Ministry Free Drugs Schemes

- Several states for example, Tamil Nadu and Rajasthan have State level free medicine schemes[364].
- It contributes in improving last mile delivery of essential medicines.

National Pharmaceutical Pricing Authority (NPPA)

- It was established in 1997[365] and regulates the drug prices under the DPCO and enforces price compliance.
- It has capped prices of stents, knee implants and cancer drugs in public interest.

Indian Council of Medical Research (ICMR)

- It plays a vital role in research and emergency approvals for public health emergencies.
- For example, during COVID-19 crisis, ICMR worked with DCGI and Pharma companies to fast-track vaccines and drug approvals[366].

THE CONFLICTS AND CRITICISM: THE PATENT MONOPOLY Vs. PUBLIC HEALTH

While the patent system aims to incentivise innovations, there are many side effects too.

TRIPS-plus Provisions and FTA's

Free trade agreements often include TRIPS-plus Provisions that:

- Extend patent durations

[359] National List of Essential Medicines, Ministry of Health.
[360] Drug Price Control Order (DPCO), 2013.
[361] NPPA Circular, Price Regulation of Imatinib (2014).
[362] Jan Aushadhi (PMBJP) Portal.
[363] Ayushman Bharat PMJAY Website.
[364] State Health Departments of Tamil Nadu and Rajasthan.
[365] NPPA Official Website.
[366] Indian Council of Medical Research Annual Reports, 2020–2022.

- Restrict compulsory Licensing[367]
- Introduce data exclusivity

These provisions may undermine India's public health flexibilities.

Global Pressure

- The U.S. and EU pharmaceutical lobbies pressure India to amend Section 3(d) and Section 84.
- India has resisted much pressures to maintain its global role as the "Pharmacy of the Global South."

High Cost of Patented Drug

- Patents grant 20 years monopolies, during which companies can charge exorbitant prices[368].
- Most life saving patented drugs are out of reach for average Indians without insurance.

Judicial Balancing

Courts have tried to balance this through:

- Denying patents on frivolous modifications[369].
- Supporting compulsory Licensing when justified.
- Recognizing the state's role in public health as a positive obligation under Article 21.

Case Study: HIV / AIDS Crisis

In the early 2000, Patented Antiretroviral (ARV) drugs cost over $10000 per patient per year. Indian companies like Cipla began producing generics at $300 per year. Activists argued that access to ARV's is a Right to Life issue and Indian Law responded with legal innovations to facilitate generic entry.

The Supreme Court and the Indian Patent Authorities have consistently recognised that access to Life saving medicines must trump commercial interests when public health is at stake.

INDIA'S GLOBAL ROLE: A MODEL OF PUBLIC HEALTH INNOVATION

India is often called the "Pharmacy of the Global South" because of its ability to supply affordable generic medicines to developing countries. Indian Patent Law, particularly the compulsory Licensing regime, has been a model for many other countries facing similar public health challenges.

Generic Manufacturing Power

- India supplies over 60% of Global vaccines[370].
- Largest provider of Antiretrovirals to Africa under Global Health Programs.

Role in COVID-19

- Developed and distributed Covaxin and Covishield under emergency use authorization.
- Exported vaccines under Vaccine Maitri initiative[371].

CHALLENGES FACED BY INDIA

While India has a robust legal framework for ensuring access to Life saving drugs, certain challenges remain:

- **Delay in granting license**

  Delay in granting compulsory licenses due to bureaucratic hurdles.

- **Resistance from multinational companies**

  This includes lawsuits and lobbying by multinational companies.

- **Judicial Delays**

  Patent challenges and compulsory license petitions can take years.

[367] UNDP Policy Brief on TRIPS-plus Provisions (2016).
[368] WHO Report on Access to Medicines (2020).
[369] Novartis and Bayer cases (Supreme Court & Patent Controller).
[370] WHO Vaccine Supply Data (2021).
[371] Ministry of External Affairs, "Vaccine Maitri" Reports.

- **Global trade pressure**

  India faces pressure from the US and EU to amend its patent regime and weaken pro health provisions.

- **Limited Manufacturing**

  Even with the licenses, Indian manufactures may lack capacity for complex biologies or new drugs.

- **Poor awareness**

  Many doctors and patients remain unaware of the affordable generics[372].

- **Pharma Lobbying**

  Aggressive patenting and marketing strategies hinder fair competition.

RECOMMENDATIONS

- Codify Right to Health as the Fundamental Right for stronger legal enforceability.
- Expand NLEM coverage and include more biologics and cancer drugs.
- Simplify and streamline compulsory Licensing procedures.
- Boost public investment in R&D for the neglected diseases.
- Encourage public - private partnerships for rare and orphan diseases.
- Strengthen the CDSCO with more resources and autonomy.
- Guard against TRIPS-plus obligation in trade agreements.
- Expand public health infrastructure to ensure last mile delivery of medicines.
- Promote generic use, NLEM drugs, other government schemes and programs widely[373].
- Enhancing transparency in drug pricing and availability.

CONCLUSION

India's legal and policy architecture reflects a deliberate and conscious attempt to balance the competing interests of intellectual property rights and public health obligations. The synergy between the Indian Patent Act and the Drugs and Cosmetics Act, along with the Constitutional Protection under Article 21, has enabled India to chart a unique path in Global Health Policy.

However, this balance is fragile and under continuous threat from International pressure and internal inefficiencies. A robust defence of India's pro-health legal framework is essential, not only for Indian citizens but for millions across the world for rely on Indian generics for survival. In a Nation where the Right to Life is sacrosanct, access to Life saving drugs must never be a privilege but it must be a legal and moral entitlement.

[372] MSF India Report on Access Barriers (2022).
[373] NITI Aayog Health Sector Report (2023).