

## COMPULSORY LICENSING –RARE DISEASE: SCIENCE & TECHNOLOGY

**NEWS:** Rare disease patients demand compulsory licensing for life-saving drugs: Here's why it's significant

### WHAT'S IN THE NEWS?

Rare disease patients have approached the Karnataka High Court seeking compulsory licensing of costly patented drugs under India's Patents Act, 1970, to improve access to life-saving treatments. The move highlights urgent gaps in affordability, policy support, and timely availability of rare disease therapies.

### Context

- Recently, **rare disease patients** approached the **Karnataka High Court**, urging the government to invoke **compulsory licensing** provisions under the **Indian Patents Act, 1970** to access life-saving medicines.

### About Compulsory Licensing (CL)

#### Definition

- A **Compulsory License (CL)** is a government authorization allowing a **third party** to produce a **patented product or process** without the consent of the patent owner.
- It is typically used in cases of **public health emergencies**, **non-availability**, or **high costs** of essential medicines.
- CL can be issued **even when the patent is still valid**.

#### International Legal Basis

- **WTO's TRIPS Agreement (Article 31):** Allows member states to issue CL under specific conditions.
- **Doha Declaration on TRIPS and Public Health (2001):** Reaffirms WTO members' rights to protect **public health** and promote **access to medicines for all**.

### Compulsory Licensing in India

#### Legal Provision

- Governed by **Section 84** of the **Indian Patents Act, 1970**.

#### Eligibility

- Can be invoked after **3 years** from the **grant of the patent**.

#### Grounds for CL

- **Public Interest:** Reasonable requirements of the public are not being met.
- **Affordability:** Patented invention is not available at a **reasonably affordable price**.

- **Availability:** Patented invention is not being **worked** (manufactured or made available) sufficiently in India.

## Process

- A **third party** (not necessarily the government) can apply to the **Controller General of Patents** for a CL.
- The **Controller** has discretion to grant or reject a CL based on:
  - **Nature of the invention.**
  - **Capacity of the applicant** to manufacture/use effectively.
  - **Potential benefit to the public.**

## Ownership Retention

- The **patent holder retains ownership** of the patent.
- The licensee receives only **limited rights** to manufacture/use the invention.
- The patent holder is entitled to **reasonable compensation/royalties**.

## Example

- CL has been used only **once** in India:
  - In **2012**, **Natco Pharma** received a CL to manufacture **Nexavar**, a cancer drug patented by **Bayer**.

## About Rare Diseases

### Definition

- Rare diseases are **low-prevalence conditions** affecting a small population.

### WHO Criteria

- A disease is considered rare if it affects **1 or fewer per 1,000 individuals**.

### Types

- **Genetic disorders** (e.g., Spinal Muscular Atrophy, Duchenne Muscular Dystrophy).
- **Rare cancers.**
- **Neglected tropical diseases.**
- **Degenerative and autoimmune disorders.**

## National Policy for Rare Diseases, 2021

## Classification of Rare Diseases

- **Group 1:** One-time **curative treatment** available.
- **Group 2:** **Lifelong/long-term treatment** needed, at lower cost.
- **Group 3:** **High-cost, lifelong treatment**, with patient selection challenges.

## Financial Support

- Up to **₹50 lakh per patient** at notified **Centres of Excellence (CoEs)**.
- Separate from **Rashtriya Arogya Nidhi (RAN)** scheme (₹20 lakh limit).

## Centres of Excellence (CoEs)

- **12 CoEs** identified, primarily in **government hospitals**.

## National Registry

- A **hospital-based national registry** is being developed to collect data and support research.

## Treatment

- Begins **immediately after registration**.

## Diagnostic Support

- **Nidan Kendras** provide **genetic testing** and **counselling**.

## Tax Exemptions

- **GST and customs duty waived** on imported drugs for rare diseases.

## Research and Drug Development

- **National Consortium (NCRDTRD)** promotes R&D and local **affordable drug manufacturing**.

## Reasons for Demand of Compulsory Licensing by Rare Disease Patients

### Drug Prices

- Imported medicines such as:
  - **Risdiplam** (for Spinal Muscular Atrophy).
  - **Trikafta** (for Cystic Fibrosis).
- These can cost up to **₹70 lakh** for a **3-month course**.
- Even generics are unaffordable for most Indian families.

## Limitation of Government Fund

- Under Rare Diseases Policy 2021, **₹50 lakh per patient** is provided.
- However, the **limited corpus** is quickly exhausted, leaving many patients **without access** to life-saving therapies.

## Import Dependence

- Families rely on **social media** to contact Indians abroad to bring medicines.
- This ad-hoc method is **risky, unreliable**, and **not scalable**.

## Delayed Market Entry

- Some pharma companies obtain **patents in India** but do not **register or sell the drug**.
- This **restricts access** while maintaining monopoly rights.

## Issues Related to Compulsory Licensing

### Trade and Diplomatic Pressure

- Countries issuing CL may face backlash from:
  - **Developed nations.**
  - **Pharmaceutical lobbies.**
- Example: After **Nexavar CL**, USTR placed India on the **Priority Watch List**.

### Discouragement of Innovation

- Patent holders argue that CL **undermines R&D incentives** and **weakens the global IP regime**.
- Over-reliance on CL may deter:
  - **Voluntary licensing.**
  - **Foreign investment.**

### Complex Legal Procedures

- Applying for and granting CL involves a **lengthy, bureaucratic process**.
- This delays **timely access** to critical drugs.

### Limited Use in India

- India has issued only **one CL** in two decades due to:
  - **Political caution.**

- **Institutional inertia.**

### **Limited Manufacturing Capacity**

- Not all local firms have the **technical or infrastructural capability** to produce patented drugs after CL.

### **Royalty and Compensation Disputes**

- Determining "**reasonable remuneration**" often leads to **legal disputes**.
- This affects the **timely rollout** of affordable alternatives.

### **Way Forward: Ensuring Access to Life-Saving Drugs for Rare Disease Patients**

#### **Price Regulation & Generic Substitution**

- Enforce **price caps** on patented drugs via **National Pharmaceutical Pricing Authority (NPPA)**.
- Encourage **import and licensing** of low-cost generics until **local production** scales up.

#### **Proactive Use of CL**

- Government and courts should actively invoke:
  - **Section 84** (normal CL).
  - **Section 92** (emergency CL) of the Patents Act.
- Especially important for **Group 3 rare diseases**.

#### **Increasing Financial Support**

- Expand financial assistance under the **National Policy for Rare Diseases**:
  - Increase cap **above ₹50 lakh**, especially for Group 3 diseases.
  - Pool **CSR funds, crowdfunding, and state contributions**.

#### **Boosting Indigenous R&D and Drug Development**

- Scale up funding for **NCRDTRD**.
- Incentivize:
  - **Academic institutions**.
  - **Start-ups** to develop **orphan drugs** with:
    - **Fast-track trials**.
    - **Regulatory support**.

## International Collaboration

- Leverage **South-South cooperation** to share affordable **therapeutic innovations**.
- Negotiate **patent pool agreements**.
- Participate in global initiatives like the **Medicines Patent Pool (MPP)**.

## Judicial Sensitivity and Policy Alignment

- Courts should adopt a **rights-based approach** to interpret IP law.
- **Right to health** should be prioritized over profits.
- Streamline legal processes:
  - Enable **fast-track CL approval** in rare disease cases.
- Align **IP, health, and pharmaceutical policy** under a coherent **national framework**.

## Conclusion

- A **robust and compassionate approach** is essential to ensure **access to life-saving drugs** for rare disease patients in India.
- This requires a combination of:
  - **Compulsory licensing tools**.
  - **Policy reforms**.
  - **Manufacturing capability**.
  - **Financial support**.
- **Government, judiciary, industry, and civil society** must work **together** to promote:
  - **Equity**.
  - **Affordability**.
  - **Access** for rare disease patients.

Source: <https://indianexpress.com/article/health-wellness/high-costs-life-saving-drugs-patients-rare-diseases-indian-variants-10055851/>