INTERNATIONAL JOURNAL FOR LEGAL RESEARCH AND ANALYSIS

Open Access, Refereed Journal Multi Disciplinary
Peer Reviewed

www.ijlra.com

ISSN: 2582-6433

DISCLAIMER

No part of this publication may be reproduced or copied in any form by any means without prior written permission of Managing Editor of IJLRA. The views expressed in this publication are purely personal opinions of the authors and do not reflect the views of the Editorial Team of IJLRA.

Though every effort has been made to ensure that the information in Volume II Issue 7 is accurate and appropriately cited/referenced, neither the Editorial Board nor IJLRA shall be held liable or responsible in any manner what sever for any consequences for any action taken by anyone on the basis of information in the Journal.

ISSN: 2582-6433

EDITORIALTEAM

EDITORS

Dr. Samrat Datta

Dr. Samrat Datta Seedling School of Law and Governance, Jaipur National University, Jaipur. Dr. Samrat Datta is currently associated with Seedling School of Law and Governance, Jaipur National University, Jaipur. Dr. Datta has completed his graduation i.e., B.A.LL.B. from Law College Dehradun, Hemvati Nandan Bahuguna Garhwal University, Srinagar, Uttarakhand. He is an alumnus of KIIT University, Bhubaneswar where he pursued his post-graduation (LL.M.) in Criminal Law and subsequently completed his Ph.D. in Police Law and Information Technology from the Pacific Academy of Higher Education and Research University, Udaipur in 2020. His area of interest and research is Criminal and Police Law. Dr. Datta has a teaching experience of 7 years in various law schools across North India and has held administrative positions like Academic Coordinator, Centre Superintendent for Examinations, Deputy Controller of Examinations, Member of the Proctorial Board

Dr. Namita Jain

Head & Associate Professor
School of Law, JECRC University, Jaipur Ph.D. (Commercial Law) LL.M., UGC-NET Post Graduation Diploma in Taxation law and Practice, Bachelor of Commerce.

Teaching Experience: 12 years, AWARDS AND RECOGNITION of Dr. Namita Jain are - ICF Global Excellence Award 2020 in the category of educationalist by I Can Foundation, India. India Women Empowerment Award in the category of "Emerging Excellence in Academics by Prime Time & Utkrisht Bharat Foundation, New Delhi. (2020). Conferred in FL Book of Top 21 Record Holders in the category of education by Fashion Lifestyle Magazine, New Delhi. (2020).Certificate of Appreciation for organizing and managing the Professional Development Training Program on IPR in Collaboration with Trade Innovations Services, Jaipur on March 14th, 2019

ISSN: 2582-6433

Mrs.S.Kalpana

Assistant professor of Law

Mrs.S.Kalpana, presently Assistant professor of Law, VelTech Rangarajan Dr.Sagunthala R & D Institute of Science and Technology, Avadi. Formerly Assistant professor of Law,Vels University in the year 2019 to 2020, Worked as Guest Faculty, Chennai Dr.Ambedkar Law College, Pudupakkam. Published one book. Published 8Articles in various reputed Law Journals. Conducted 1Moot court competition and participated in nearly 80 National and International seminars and webinars conducted on various subjects of Law. Did ML in Criminal Law and Criminal Justice Administration.10 paper presentations in various National and International seminars. Attended more than 10 FDP programs. Ph.D. in Law pursuing.

Avinash Kumar

Avinash Kumar has completed his Ph.D. in International Investment Law from the Dept. of Law & Governance, Central University of South Bihar. His research work is on "International Investment Agreement and State's right to regulate Foreign Investment." He qualified UGC-NET and has been selected for the prestigious ICSSR Doctoral Fellowship. He is an alumnus of the Faculty of Law, University of Delhi. Formerly he has been elected as Students Union President of Law Centre-1, University of Delhi. Moreover, he completed his LL.M. from the University of Delhi (2014-16), dissertation on "Cross-border Merger & Acquisition"; LL.B. from the University of Delhi (2011-14), and B.A. (Hons.) from Maharaja Agrasen College, University of Delhi. He has also obtained P.G. Diploma in IPR from the Indian Society of International Law, New Delhi. He has qualified UGC – NET examination and has been awarded ICSSR – Doctoral Fellowship. He has published six-plus articles and presented 9 plus papers in national and international seminars/conferences. He participated in several workshops on research methodology and teaching and learning.

ISSN: 2582-6433

ABOUT US

INTERNATIONAL JOURNAL FOR LEGAL RESEARCH & ANLAYSIS ISSN- 2582-6433 is an Online Journal is Monthly, Peer Review, Academic Journal, Published online, that seeks to provide an interactive platform for the publication of Short Articles, Long Articles, Book Review, Case Comments, Research Papers, Essay in the field of Law & Multidisciplinary issue. Our aim is to upgrade the level of interaction and discourse about contemporary issues of law. We are eager to become a highly cited academic publication, through quality contributions from students, academics, professionals from the industry, the bar and the bench. INTERNATIONAL JOURNAL FOR LEGAL RESEARCH & ANALYSIS ISSN 2582-6433 welcomes contributions from all legal branches, as long as the work is original, unpublished and is in consonance with the submission guidelines.

ISSN: 2582-6433

"THE ROLE OF PATENTS IN THE PHARMACEUTICAL INDUSTRY: INCENTIVES VS. ACCESSIBILITY"

AUTHORED BY - PRITI KUMARI
Student
Amity law school
Amity university Patna

ABSTRACT

Patents are the cornerstone of pharmaceutical innovation, granting temporary Market exclusivity to recover the $2.8 billion average cost of bringing a new drug To market. Yet, this monopoly often delays generic entry, inflates prices, and restricts Access particularly in low- and middle-income countries (LMICs). This article examines the dual role of drug patents: as drivers of R&D and barriers to public health. Using case Studies from the U.S., India, and global health crises (e.g., HIV, COVID-19), it evaluates Patent extensions, evergreening, compulsory licensing, and patent pools. Policy Reforms-limiting secondary patents, expanding delinkage models, and enforcing International reference pricing-are proposed to balance innovation with Equitable access.

The analysis highlights how secondary patents and "pay-for-delay" tactics extend monopolies by 5-15 years, while generic entry post-expiry reduces prices by 80-90%.

Police recommendations include capping total exclusivity at 12-15 years, raising thresholds for secondary patents and expanding TRIPS flexibilities and patent pools.

A balanced patent framework-preserving R&D incentive while enforcing as essential For sustainable global health progress.

KEYWORDS

Drug patent, evergreening, generic medicines, compulsory licensing, public health, R&D incentives

ISSN: 2582-6433

1. INTRODUCTION

In the intricate ecosystem of the pharmaceutical industry, patents stand as a Double-edged sword-serving as powerful catalysts for innovation while simultaneously Posing formidable barriers to equitable access to life-saving medicines. At their core, Drug patents grant inventors exclusive rights to manufacture, market, and profit from novel therapeutics for a limited period, typically 20 years from filing. This monopoly Incentivizes pharmaceutical companies to invest billions in research and development (R&D), navigating the high-risk gauntlet of clinical trials, regulatory approvals, and Market uncertainties. Yet, this very exclusivity often inflates drug prices to prohibitive levels, exacerbating global health disparities, particularly in low-and middle-income countries where affordability determines survival.

The tension between incentives and accessibility is further amplified by mechanisms Like patent extensions-such as supplementary protected certificates (SPCs) in Europe or patent term adjustments for regulatory delays-and the delayed entry Of generic medicines, which can slash costs by up to 90% upon market Authorization.

This article delves into the mechanics of drug patents, explores the rationale and Controversies surrounding extensions, and controversies surrounding extensions, and analyses the transformative impact of generics on healthcare equity.

By examining case studies, policy debates, and emerging alternatives like compulsory Licensing and patent pools, we aim to illuminate pathways towards a more balanced System-one that fosters innovation without compromising the fundamental right To health.

1.1.BACKGROUND

“THE ROLE OF PATENTS IN THE PHARMACEUTICAL INDUSTRY: INCENTIVES VS. ACCESSIBILITY”

This article explores the **core tension** in the pharmaceutical sector between **rewarding innovation** through patent protection and **ensuring affordable access,** To life-saving medicines. Below is a structured background that sets the stage For the article’s analysis of **drug patent, patent extensions, and generic medicines** in the context of **public health**.

ISSN: 2582-6433

1. **What Are Drug Patents and Why Do They Matter?**

   Definition: A patent grants a pharmaceutical company **exclusive right** To manufacture and sell a new drug for a limited period (typically **20 years from Filing).**

   - **Purpose:**
   - Protects the **massive R&D investment** (often $**1-2.6 billion per drug**, including failed candidates).
   - Enables companies to charge premium prices during exclusivity to recoup costs and fund future research.
   - **Trade-off:** high prices during patent life improve incentives for innovation but limit access, especially in low-income regions.

2. **The Innovation Incentive Argument**

   - **R&D is risky and expensive:**
   - Only 1in 5,000-10,000 compounds reach the market.
   - Clinical trials (Phase I-III) cost hundreds of millions and take 10-15years.
   - **Patent Monopoly =profit Motive:**
   - Allows companies to earn **high margins** (e.g., Gilead's Sovaldi for hepatitis

   C launched at **$84,000 per course** in 2013).

   - **Evidence:**
   - Countries with **stronger patent regimes** (e.g., U.S., EU) attract **~80% of global pharma R&D spending.**
   - Weak IP protection correlative with **less investment in neglected diseases** (e.g., pre- TRIPS era in India).

3. **The Accessibility Challenge**

   - **High Prices Exclude Patients:**
     - In the U.S., 25% OF adults skip does due to cost (KFF, 2023).
     - In low-income countries, essential medicines are unaffordable for
     - >50% of the population (WHO).
   - **Patent Extensions Amplify the Problem:**

ISSN: 2582-6433

- **Evergreening**: Minor modifications (e.g., new formulations) secure additional patents, delaying generics.

  Example: AstraZeneca extended Nexium patents via **pediatric Exclusivity** and **new salts,** blocking generics until 2014.

  - **Pay-for-delay deals:** Originator firms pay generic makers to delay Makers to delay market entry (illegal inEU post-2010; fined heavily).

4. **Generic Medicines: The Counterbalance**
   - **Post-Patent Entry:** generics enter at 20-80% lower prices after Exclusivity ends.
   - **Compulsory Licensing**: Allows government to override patents in Public health crises.
   - **TRIPS Flexibility** (WTO, 1995): Permit parallel imports and early Generic production for export to countries without manufacturing Capacity.

5. **Public Health in the Balance**
   - **Success stories:**

HIV\AIDS; Generic antiretrovirals (post-200 Doha Declaration) reduced Treatment cost from $10,000\year to <$100, saving >20 million lives.

- **Ongoing failures:**

Neglected Tropical Diseases: <1%of new drugs (1975-2020) targeted Diseases like chagas or sleeping sickness (DNDi).

Cancer Drugs: Median price>$100,000/year; survival gains often <4 Months (ICER reports).

- **COVID-19 case study:**

mRNA patent enabled repid vaccine development.

But horading by rich nation and delayed tech transfer left LMICs with <25% vaccination by mid-2022.

Incentive for Innovation: The Pro-Patent Argument

Patents mitigate the high-risk, high-cost nature of drug development, Where only~12% of candidates reach approval. Without exclusivity, firms Argue, investment in novel therapies-

ISSN: 2582-6433

especially for rare or neglected diseases Would plummet. The TRIPS Agreement (1994) mandates minimum patent Standards to harmonize global incentives, while flexibilities like compulsory Licensing allow access in crises.

Data from 2020-2025:

R&D Surge: global pharma R&D spending rose 8-10% annually, reaching 147 billion USD in 2023, driven by patented biologics and oncology drugs.

Patent Extensions' Role: under hatch-waxman, 49% of top-selling drugs (2000-2018data, extended into 2020s) received extension averaging 2.75 years, yielding 13.75 years of effective exclusivity.

Blockbuster impact: patented drugs like Keytruda (pembrolizumab, Merck) earned 25 billion USD in 2023, funding further innovation.

These incentives align with public health by accelerating therapies for pandemics and chronic diseases, but critics note they skew toward profitable markets (e.g., oncology over tropical diseases).

Accessibility Challenges: High Prices and Barriers to Generics

Monopolies allow pricing at "what the market will bear," often 10–100 times production costs, straining healthcare systems. In the U.S., out-of-pocket costs averaged 1,200 USD annually per patient in 2022, up 15% from 2020. Globally, 2 billion people lack affordable essential medicines, per WHO 2024 estimates. Patent extensions delay generics, which supply 90% of U.S. prescriptions but only 20% of spending due to branded dominance.

Data from 2020–2025:

Price Inflation: U.S. drug prices rose 5–7% annually; a 2021 Commonwealth Fund analysis of top-10 drugs showed 71% increases (2014–2019 baseline, continuing to 2023), linked to 69 average patents per drug (37.5 years total protection).

Generic Delays: Evergreening added 52.6 billion USD in U.S. consumer costs (2018–2023 estimate, UCLA 2024). In low-income countries, TRIPS-plus rules in trade deals extended monopolies, reducing generic penetration by 30–50% for antiretrovirals (2020–2024).

Public Health Toll: A 2022 PMC study estimated evergreening restricted access for 3–5

ISSN: 2582-6433

million hepatitis C patients globally (2020–2025), with prices 5–10x higher than generics. In the Netherlands, Roche's subcutaneous trastuzumab (Herceptin) evergreening near 2017 expiry limited biosimilar uptake to <20% by 2020, costing 50 million EUR extra annually.

Recent Developments (2020–2025): The Patent Cliff and Policy Responses

The 2020–2025 period saw heightened scrutiny amid COVID-19, which exposed access inequities (e.g., vaccine patents waived under TRIPS in 2022 for low-income countries, though implementation lagged). U.S. Inflation Reduction Act (2022) capped Medicare prices for select drugs, indirectly pressuring patents. India's 2025 Delhi High Court ruling on Roche's Risdiplam prioritized public interest, denying injunctions to enable NATCO generics for spinal muscular atrophy, reducing costs 80%.

Patent Cliff Data:

- 46 drugs face U.S. expiry 2025–2026, including Eliquis (apixaban, 12 billion USD sales) and Jardiance (empagliflozin, 8 billion USD). Generics could save 100 billion USD by 2030.
- 25 high-value expiries in 2025 (e.g., Farxiga for diabetes) project 20–40% price drops, boosting access for 50 million patients.

Analysis: Balancing Incentives and Public Health

Patents undeniably drive innovation—evidenced by 300+ new therapies (2020–2024)—but data shows diminishing returns: 80% of extensions yield marginal gains, prioritizing profits (pharma profits: 100 billion USD in 2023) over access. Evergreening inflates prices 25–70%, per JAMA 2024, disproportionately harming vulnerable groups (e.g., 30% of U.S. patients skip doses due to cost). In public health terms, this violates ICESCR rights to essential medicines, as noted in 2020 PMC reviews.

Trade-Offs Quantified:

- **Incentives**: Extensions correlate with 15–20% R&D growth but skew to high-margin areas (e.g., 70% of approvals for lifestyle diseases vs. neglected ones).
- **Accessibility Losses**: Delays cost 200–300 billion USD globally (2020–2025), per Oxfam, with generics post-expiry increasing utilization 50–100% while cutting prices 80%.

ISSN: 2582-6433

Conclusion

The pharmaceutical patent system remain a double-edged sword. Between 2020 And 2025, it fuelled $1.2 trillion in global R&D, delivered 300+ novel therapies, and enabled rapid COVID-19 vaccine deployment- proof that exclusivity drivers innovation.

Yet, the same mechanisms—evergreening, patent thickets, and stacked exclusivities—added over $200 billion in excess costs, delayed generics by 3–6 years, and left 2 billion people without access to essential medicines.

The 2025–2030 patent cliff, with $300 billion in sales at risk, offers a pivotal chance to restore balance. If generics enter on time, $100–150 billion in savings could fund equitable access. But without reform—stricter secondary patent scrutiny, mandatory licensing in crises, and delinking R&D rewards from pricing—evergreening will erode these gains.

Ultimately, patents must serve public health, not just profits. The system needs recalibration: temporary incentives, not perpetual monopolies—ensuring innovation benefits humanity, not just shareholders.