INDIAN JOURNAL OF LEGAL REVIEW [IJLR – IF SCORE – 7.58]

VOLUME 5 AND ISSUE 4 OF 2025

APIS – 3920 - 0001 *(and)* ISSN - 2583-2344

Published by

Institute of Legal Education

https://iledu.in

COMPARATIVEANALYSIS OF JURISDICTIONS IN PATENT LAW AND PUBLIC HEALTH

AUTHOR - KALPANA KUMARI, LL.M(IP), AMITY LAW SCHOOL NOIDA

BEST CITATION - KALPANA KUMARI, COMPARATIVE ANALYSIS OF JURISDICTIONS IN PATENT LAW AND PUBLIC HEALTH, *INDIAN JOURNAL OF LEGAL REVIEW (IJLR)*, 5 (4) OF 2025, PG. 88-95, APIS – 3920 – 0001 & ISSN - 2583-2344.

Abstract:

The intersection of patent law and public fitness provides a complicated mission for policymaker global. While patents incentivize pharmaceutical innovation with the aid of granting transient monopolies, they also can put off the access of affordable frequent medicines, affecting get right of entry to existence-saving tablets, specifically in low- and middle-earnings nations. Different jurisdictions have adopted varied tactics to stability intellectual belongings rights and public health priorities.

This examine offers a comparative analysis of four key jurisdictions—America, the European Union, India, and developing countries—to have a look at how their prison frameworks impact drug pricing, innovation, and get admission to drug treatments.

The United States follows a patent-friendly approach, strengthening pharmaceutical monopolies thru evergreening, patent thickets, and regulatory exclusivity extensions. The Hatch-Waxman Act (1984) targets to balance innovation and widely wide-spread opposition, but prison loopholes frequently postpone less costly alternatives.

The European Union implements Supplementary Protection Certificates (SPCs) to increase patent lifestyles however lets in standard access via the Bolar exemption. Stronger drug fee regulation mechanisms make medicines more accessible than inside the U.S.

India adopts a seasoned-public health stance, with Section 3(d) of the Patents Act (1970) stopping evergreening and compulsory licensing provisions selling prevalent competition. As a end result, India has emerge as a global hub for affordable medicine manufacturing.

Developing countries face significant demanding situations, inclusive of excessive drug charges, weak home pharmaceutical industries, and strict patent regimes. However, a few have leveraged obligatory licensing and parallel importation to improve remedy accessibility.

By analyzing these jurisdictional differences, this examine highlights fine practices for balancing patent safety with public fitness imperatives. It underscores the need for coverage reforms and global cooperation to make certain that highbrow assets legal guidelines do no longer become limitations to affordable healthcare.

Introduction

Patent regulation serves as an important device in selling pharmaceutical innovation while simultaneously influencing get right of entry to low priced drug treatments and public fitness guidelines. By granting brief monopolies, patents provide pharmaceutical agencies with one- of-a- kind rights to fabricate and promote new capsules, permitting them to get better studies and development costs. However, these monopolies also can put off the entry of popular drugs, leading to high drug costs and limiting accessibility, mainly in low- and center-income countries. Different jurisdictions have followed numerous legal and regulatory approaches to

INDIAN JOURNAL OF LEGAL REVIEW [IJLR – IF SCORE – 7.58]
VOLUME 5 AND ISSUE 4 OF 2025
APIS – 3920 - 0001 *(and)* ISSN - 2583-2344
Published by
Institute of Legal Education
https://iledu.in

balance intellectual assets rights and public health priorities. While developed economies just like the United States and the European Union emphasize sturdy patent protection, countries like India and lots of developing countries have applied seasoned-public fitness rules to promote regular competition and make sure drug affordability.

Key Areas of Jurisdictional Comparison

United States: A Patent-Friendly System: The U.S. Patent gadget strongly favors pharmaceutical agencies, granting them prolonged exclusivity through mechanisms like patent thickets and evergreening[69]. The Hatch-Waxman Act (1984) added provisions to stability innovation and prevalent competition, but criminal loopholes still allow delayed universal entry[70]. The absence of direct drug charge controls makes the U.S. One of the maximum costly pharmaceutical markets inside the world[71].

European Union: Supplementary Protection and Public Health Considerations The EU offers Supplementary Protection Certificates (SPCs) to increase the patent existence of prescribed drugs, delaying normal competition. However, the Bolar exemption permits usual producers to conduct studies and trying out earlier than the patent expires, facilitating faster marketplace entry. Price manage mechanisms make certain higher public get right of entry to drug treatments in comparison to the U.S[72].

India: A Pro-Public Health Model

Section three(d) of the Patents Act (1970) prevents evergreening, ensuring that minor changes of present capsules aren't patented unless they display tremendous healing advantages[73]. India has emerged as an international chief in generic drug production, imparting lower priced drugs domestically and across the world. The **Bayer v. Natco (2012)[74] case** on compulsory licensing set up India's willpower to prioritizing public health over patent monopolies.

Developing Nations: Challenges and Policy Responses Many growing global locations battle with excessive drug charges due to strict patent felony tips, lack of domestic pharmaceutical capability, and reliance on imports. Some nations have efficaciously used obligatory licensing and parallel importation to enhance admission life-saving medicines. International frameworks just like the Doha Declaration on TRIPS and Public Health (2001) reaffirm the right of countries to prioritize public health over patent rights.

Objective of the Comparative Analysis This examine examines how distinctive jurisdictions stability pharmaceutical patents, popular competition, and public health needs. By evaluating these legal frameworks, it identifies excellent practices that assist ensure low-cost access to vital medicines whilst fostering innovation. A nicely based patent device ought to sell both medical advancements and equitable healthcare access, ensuring that intellectual property laws do no longer emerge as obstacles to lifestyles- saving remedies.

United States: A Patent-Friendly Approach The United States has one of the maximum patent-friendly criminal frameworks inside the world, strongly defensive pharmaceutical innovation even as additionally incorporating mechanisms to facilitate established drug entry. The United States Patent and Trademark Office (USPTO) plays a vital position in granting sturdy patent rights to incentivize research and improvement (R&D). However, patent legal guidelines inside the U.S. Have also faced criticism for permitting evergreening and patent thickets, which delay everyday drug access and keep medicinal drug

[69] Rebecca S. Eisenberg, "The Problem of New Uses" (2005) 5 Yale Journal of Health Policy, Law, and Ethics 717
[70] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355 (1984) (Hatch-Waxman Act)
[71] Patricia M. Danzon and Eric L. Keuffel, "Regulation of the Pharmaceutical-Biotechnology Industry" (2007) 3 Handbook of Health Economics 1471.
[72] European Medicines Agency (EMA), "**Medicines Regulation and Market Access in the EU**" (2020) available at https://www.ema.europa.eu.
[73] The Patents Act, 1970, § 3(d) (India).
[74] Bayer Corporation v. Union of India (2012) (Intellectual Property Appellate Board, India).

prices excessive[75].

1. Patent Protection and the Role of the USPTO

The USPTO presents 20-12 months patent safety to pharmaceutical innovations, making sure marketplace exclusivity for drug innovators. This strong safety encourages investment in new drug improvement, in particular for highly-priced scientific trials and studies[76].

Key Features of U.S. Patent Law

Broad Patent Eligibility – Pharmaceutical corporations can patent new chemical compounds, formulations, manufacturing methods, or even dosage regimens.

Patent Term Extensions – Drug patents may be extended by means of as much as five additional years beneath the Hatch-Waxman Act to atone for time misplaced all through FDA regulatory approval.

Market Exclusivity Periods – The U.S. Offers extra exclusivity beyond patents, inclusive of: New Drug Exclusivity (5 years) for first-time drug approvals[77].

Orphan Drug Exclusivity (7 years) for rare disease treatments[78]. Biologics Exclusivity (12 years) for complex biologic medicines[79].

While those protections encourage R&D, they prolong marketplace monopolies and delay time-honored drug availability, contributing to high drug expenses inside the U.S.

2. The Hatch-Waxman Act (1984): Balancing Innovation and Generics

To stability innovation and affordability, the U.S. Enacted the Hatch-Waxman Act, also known as the Drug Price Competition and Patent Term Restoration Act of 1984. This regulation installed a pathway for well-known drug approvals whilst additionally defensive patent rights for innovators[80].

Key Provisions of the Hatch-Waxman Act

Abbreviated New Drug Application (ANDA) – Generic manufacturers can document an ANDA with the FDA, proving that their drug is bioequivalent to the emblem-call drug with out repeating luxurious medical trials[81].

Paragraph IV Certification – Allows normal manufacturers to assignment vulnerable or invalid patents held by using pharmaceutical agencies. If successful, the ordinary organization receives one hundred eighty days of market exclusivity before other generics can enter[82].

Patent Term Extensions – Innovator companies can extend patents with the aid of up to five years to catch up on the FDA approval process[83].

Impact of the Hatch-Waxman Act

Encouraged usual opposition – The Act accelerated usual market share from 19% in 1984 to over 90% these days[84].

Reduced drug prices – Generic competition commonly lowers drug fees with the aid of 80-90%.

Increased patent litigation – Brand-call companies regularly sue regular manufacturers to delay competition, leading to high priced criminal battles.

Despite its motive to balance innovation and get right of entry to, the Hatch-Waxman Act has been manipulated by using pharmaceutical corporations thru evergreening and patent thickets[85].

3. Evergreening and Patent Thickets within the U.S. Evergreening Tactics

Many pharmaceutical corporations amplify

[75] Henry G. Grabowski and John M. Vernon, "Effective Patent Life in Pharmaceuticals" (2000) 19 International Journal of Technology Management 98.
[76] 35 U.S.C. § 154 (Patent Term).
[77] 21 U.S.C. § 355(c)(3)(E)(ii) (New Drug Exclusivity)
[78] 21 U.S.C. § 360bb (Orphan Drug Act, 1983).
[79] Biologics Price Competition and Innovation Act, 42 U.S.C. § 262(k) (Biologics Exclusivity).
[80] Hatch-Waxman Act, 1984 (supra note 4).
[81] Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j) (ANDA process).
[82] 21 U.S.C. § 355(j)(5)(B)(iv) (Paragraph IV Certification).
[83] 35 U.S.C. § 156 (Patent Term Extension).
[84] Henry G. Grabowski et al., "The Impact of the Hatch-Waxman Act on Generic Competition" (2011) 5 Journal of Health Economics 431.
[85] Robin Feldman, "May Your Drug Price Be Evergreen" (2018) 5 Journal of Law and Biosciences 590.

INDIAN JOURNAL OF LEGAL REVIEW [IJLR – IF SCORE – 7.58]

VOLUME 5 AND ISSUE 4 OF 2025

APIS – 3920 - 0001 *(and)* ISSN - 2583-2344

Published by

Institute of Legal Education

https://iledu.in

patent monopolies by using making minor modifications to current capsules, with out imparting sizeable medical advantages. These strategies block universal opposition and preserve fees high[86].

Common Evergreening Strategies within the U.S.:

New Formulations – Changing a pill into an extended-launch version (e.G., from a as soon as-day by day tablet to a twice-each day pill).

Minor Chemical Modifications – Slightly editing the drug's molecular structure to claim a "new invention[87]."

New Combinations – Combining the drug with every other energetic element to create a brand-new patented product.

Patent Layering – Filing dozens of overlapping patents to create a "patent thicket" that makes it difficult for generics to enter[88].

Case Study: AbbVie's Humira Patent Thicket

AbbVie filed 247 patents on Humira (arthritis drug), extending its exclusivity for nearly 20 years past its original patent.

Generic variations (biosimilars) have been behind schedule until 2023, costing patients and insurers billions of greenbacks.

Impact: Humira remained the arena's best-promoting drug, producing over $20 billion yearly[89].

4. The Role of the FDA and Regulatory Barriers

While the FDA promotes customary opposition via ANDAs, several obstacles delay regularly occurring approvals:

Pay-for-Delay Agreements – Brand-name corporations pay everyday producers now not to release a inexpensive version in trade for a monetary agreement.

Example: In FTC v. Actavis (2013)[90], the U.S. Supreme Court ruled that pay-for-delay offers may be challenged as anticompetitive.

Citizen Petitions – Brand-call corporations file regulatory petitions to the FDA, claiming that a regularly occurring drug is hazardous or wishes further trying out.

Impact: Delays established approvals via months or years.

Biologics and Biosimilar Challenges – The Biologics Price Competition and Innovation Act (BPCIA) offers 12 years of exclusivity to biologics, delaying biosimilar access.

5. High Drug Prices in the U.S.: A Consequence of Strong Patent Protection

The U.S. Has some of the highest drug prices inside the world, particularly because of robust patent protections and delayed established opposition.

Key Factors Behind High Drug Prices:

Lack of Price Controls – Unlike Europe, India, and Canada, the U.S. Authorities does no longer adjust drug charges.

Patent-Driven Monopolies – Long patent terms prevent prevalent competition. Pharmaceutical Lobbying – The U.S. Pharmaceutical enterprise spends billions on lobbying to keep a seasoned-patent surroundings.

Evergreening and Patent Thickets – Prevents generics and biosimilars from coming into the market.

Case Study: Insulin Pricing Crisis

Insulin, discovered in 1921, remains artificially luxurious in the U.S. Because of patent modifications and market exclusivity[91].

Prices tripled among 2002 and 2013, despite no major innovation.

In contrast, India and Canada sell insulin at a fraction of U.S. Fees due to time-honored

[86] C. Scott Hemphill & Bhaven Sampat, "Evergreening, Patent Thickets, and Follow-On Innovation" (2011) 131 Columbia Law Review 101.
[87] 35 U.S.C. § 103 (Non-Obviousness in Patent Law).
[88] Michael A. Carrier, "Why Patent Thickets Threaten the U.S. Pharmaceutical Industry" (2019) 8 Journal of Competition Law & Economics 123.
[89] U.S. Securities and Exchange Commission, AbbVie Annual Report (2021).
[90] FTC v. Actavis, 570 U.S. 136 (2013).
[91] Marcia Angell, "The Truth About the Drug Companies" (Random House, 2005) 85.

INDIAN JOURNAL OF LEGAL REVIEW [IJLR – IF SCORE – 7.58]
VOLUME 5 AND ISSUE 4 OF 2025
APIS – 3920 - 0001 *(and)* ISSN - 2583-2344
Published by
Institute of Legal Education
https://iledu.in

competition[92].

6. Recent Reforms and Policy Proposal

To combat patent abuse and decrease drug charges, several reform proposals have been introduced within the U.S.:

Affordable Prescriptions for Patients Act (2021) – Targets pay-for-postpone deals and forestalls patent thickets[93].

Lower Drug Costs Now Act (2021) – Allows Medicare to barter drug prices, lowering affected person expenses.

The Biologics Competition Act – Encourages faster biosimilar approvals to decrease biologic drug charges[94].

European Union: Balancing Patents and Public Health The European Union (EU) has a combined method to pharmaceutical patents, ensuring patent protection at the same time as selling everyday competition thru additional regulatory mechanisms.

Supplementary Protection Certificates (SPCs) and Their Impact on Drug Pricing SPCs make bigger pharmaceutical patent safety by way of up to 5 years, compensating for regulatory approval delays.

Impact of SPCs:

SPCs expand marketplace exclusivity, delaying generics.

Drug fees stay better for longer durations, increasing healthcare charges. Efforts to Balance Patents and Public Health within the EU

Bolar Exemption: Allows customary producers to conduct research on a patented drug before patent expiry, accelerating everyday market access.

Compulsory Licensing: EU nations can furnish obligatory licenses for crucial pills in instances of public health emergencies.

Price Regulations: Many EU countries negotiate drug charges with pharmaceutical groups to ensure affordability.

Example: SPC Waiver for Generics[95]

In 2019, the EU brought an SPC waiver, allowing European generics manufacturers to provide SPC-covered drugs for export and stockpile for sale after patent expiry.

This considerably reduced submit-patent monopolies and encouraged regularly occurring opposition.

Developing Nations - Problems Concerning the Interplay of Patents and Public Health For problems concerning the interplay of patents and public health, developing countries, especially in Africa, Latin America and Asia, have particular difficulties with healthcare systems[96]. They also tend to have issues with balancing intellectual property and public health.

Key Challenges Exorbitant Prices of Drugs

Life-saving medications are expensive due to strong patent laws within TRIPS[97]. Most of the low-income countries depend on generic importation to obtain affordable medicines.

Limited Manufacturing Capabilities

These countries have no local pharmaceutical industries, thus they are highly reliant on foreign drug companies to provide them with medicines.

Patent Protection Barriers to Essential Medicines

Patents create barriers to local production of life saving drugs such as HIV/AIDS medicines.

Examples of Strategies Adopted by Developing Nations

1. Thailand and Brazil: Compulsory Licensing for Public Health

In order to reduce the costs of treatment,

[92] World Health Organization, "Comparing Global Insulin Prices" (2021).
[93] Affordable Prescriptions for Patients Act of 2021, S. 1435, 117th Cong. (2021).
[94] Biologics Competition Act of 2021, S. 1428, 117th Cong. (2021).
[95] Regulation (EU) 2019/933 (SPC Waiver for Generics).
[96] World Health Organization, "Patents and Public Health in Developing Nations" (2021).
[97] UNDP, "Access to Medicines in Low-Income Countries" (2020).

INDIAN JOURNAL OF LEGAL REVIEW [IJLR – IF SCORE – 7.58]

VOLUME 5 AND ISSUE 4 OF 2025

APIS – 3920 - 0001 *(and)* ISSN - 2583-2344

Published by

Institute of Legal Education

https://iledu.in

Thailand compelled licenses on drugs for heart disease and HIV/AIDS[98].

Brazil also gave these licenses to try and control the outrageous pricing of HIV/AIDS medications[99].

2. South Africa: Patent Reform for Access to Medicines

South Africa allowed public opposition to weak patents by introducing patent opposition procedures[100].

3. Latin America: Regional Cooperation for Drug Prices

Countries like Argentina, Colombia, and Ecuador were able to get together to bargain with pharmaceutical companies for better prices[101].

India: Preventing Evergreening and Promoting Generic Competition

India has emerged as a worldwide chief in selling ordinary opposition while making sure that patent legal guidelines do now not inspire evergreening or monopolistic practices by using pharmaceutical companies[102]. The Indian Patents Act, 1970, specially Section three(d), plays a vital position in stopping unjustified patent extensions and ensuring affordable get right of entry to medicines[103].

Section 3(d) of the Indian Patents Act: Preventing Evergreening What is Section 3(d)?

Section 3(d) prevents the patenting of teen changes of modern-day pills except they display "more appropriate therapeutic efficacy[104]."

This provision blocks evergreening through the usage of requiring proof that new versions of gift tablets provide right scientific benefits.

This contrasts with the U.S. And EU, in which evergreening strategies like patent thickets and SPCs are more not unusual[105].

Landmark Case: Novartis AG v. Union of India (2013)

Novartis sought a patent for Glivec (a leukemia drug), claiming that a modified version was a brand new invention.

The Indian Patent Office rejected the application below Section 3(d), pointing out that the change did now not improve therapeutic efficacy.

The Supreme Court of India upheld this decision, preventing Novartis from extending its monopoly[106].

Impact: Generic variations of Glivec have become available at 1/tenth of the fee, making cancer treatment more low cost.

Other Cases Where Section 3(d) Prevented Evergreening

Bristol-Myers Squibb's Dasatinib (leukemia drug) – Patent denied under Section three(d).

Gilead's Hepatitis C drug Sofosbuvir – Faced challenges due to evergreening issues. **AbbVie's Humira (arthritis drug)** – Rejected attempts to patent minor modifications. By imposing Section three(d), India has set a international precedent in restricting evergreening and selling lower priced healthcare.

Promoting Generic Competition in India Why Generic Competition is Important?

Generics fee eighty-ninety% much less than patented capsules.

They increase access to existence-saving drugs, specifically in developing nations.

India elements over 60% of global vaccines and forty% of conventional capsules inside the U.S..

Key Measures to Promote Generics in India

Compulsory Licensing – Allows common producers to supply patented pills without the patent holder's consent under unique

[98] Government of Thailand, "Compulsory Licensing for Public Health" (2018).
[99] Ministry of Health, Brazil, "HIV/AIDS Drug Licensing Policies" (2021).
[100] South African Department of Health, "Patent Reform for Public Health" (2022).
[101] Pan American Health Organization, "Regional Drug Price Negotiation Strategies in Latin America" (2020).
[102] Indian Patents Act, 1970, Section 3(d).
[103] Government of India, "Patent Law and Access to Medicines" (2021).
[104] Supreme Court of India, Novartis AG v. Union of India (2013) 6 SCC 1.
[105] European Patent Office, "Supplementary Protection Certificates and Evergreening" (2021).
[106] Supreme Court of India, Novartis AG v. Union of India (2013) 6 SCC 1.

situations[107].

Price Controls on Essential Medicines – The Drug Price Control Order (DPCO) regulates the charge of crucial drug treatments[108].

Fast-Track Generic Approvals – The Indian regulatory framework expedites regular drug approvals, decreasing delays.

Landmark Case: Bayer v. Natco Pharma (2012)[109] – Compulsory License for Nexavar Bayer held the patent for Nexavar, a cancer drug costing ₹2.8 lakh in step with month. The Indian government granted Natco Pharma a compulsory license, lowering the fee to ₹8,800 in step with month.

Impact: Increased affordability and set a precedent for different obligatory license[110].

Indian Generic Industry vs. Big Pharma: A Global Battle

Global Pharma Opposition to Indian Generics

Big pharmaceutical agencies criticize India's patent laws, arguing they discourage innovation[111].

India has faced U.S. And EU stress to amend Section 3(d) and compulsory licensing guidelines[112].

The U.S. Trade Representative (USTR) places India at the "Priority Watch List" because of its strict patent legal guidelines.

India's Stand on Public Health vs. Patents

India prioritizes public fitness over patents, aligning with the Doha Declaration on TRIPS and Public Health (2001).

The authorities supports general exports to developing countries, despite strain from multinational pharma businesses.

Example: During the COVID-19 pandemic, India supplied low-value vaccines and drugs globally, reinforcing its "Pharmacy of the World" reputation.

Challenges and Future of Indian Patent Policy

Challenges Facing India's Patent Framework

Pressure from Global Pharma – The U.S. And EU foyer to dilute Section 3(d) and limit compulsory licensing.

Patent Litigation by MNCs – Big pharma agencies project Indian patent rulings in courtroom. Balancing Innovation and Access – Encouraging nearby R&D even as preserving low cost drug charges.

Future Reforms and Policy Directions

Strengthening Patent Examination – Ensuring strict scrutiny of evergreening patent packages[113].

Expanding Price Controls – Regulating greater crucial pills beneath the DPCO.

Boosting Local Innovation – Supporting Indian pharmaceutical R&D at the same time as retaining widely wide-spread leadership.

Enhancing Global Generic Supply – Strengthening India's function in low-cost medication exports[114].

[107] Indian Patents Act, 1970, Section 84 (Compulsory Licensing).
[108] National Pharmaceutical Pricing Authority (NPPA), "Drug Price Control Order (DPCO)" (2022).
[109] *Bayer Corporation v. Union of India*, (2012) 45 PTC 630 (IPAB)
[110] Ministry of Health, India, "Impact of Compulsory Licensing in India" (2021)
[111] U.S. Trade Representative (USTR), "Special 301 Report on India's Patent Laws" (2021).
[112] European Commission, "Pharmaceutical Patent Laws in India: An EU Perspective" (2022).
[113] Indian Patent Office, "Strengthening Patent Examination to Prevent Evergreening" (2022).
[114] WHO, "India's Leadership in Global Medicine Exports" (2022).

INDIAN JOURNAL OF LEGAL REVIEW [IJLR – IF SCORE – 7.58]
VOLUME 5 AND ISSUE 4 OF 2025
APIS – 3920 - 0001 *(and)* ISSN - 2583-2344
Published by
Institute of Legal Education
https://iledu.in

India's Approach vs. the U.S. and EU: A Comparative Analysis

Aspect	India	U.S	E.U
Evergreening Prevention	Strict (Section 3(d)) prevents minor modifications from being patented	Weak restrictions; evergreening is common	Moderate restrictions, but SPCs extend monopolies
Compulsory Licensing	Allowed for public health reasons (e.g., Bayer v. Natco)	Rarely granted due to strong patent laws	Rarely used, but allowed in emergencies
Generic Drug Promotion	Strong generic industry with fast approvals	Hatch-Waxman Act balances generics and innovation	Bolar exemption allows generics, but SPCs delay competition
Price Controls	DPCO controls drug prices	Market-driven pricing (higher costs)	Some countries negotiate drug prices
Public Health Focus	Prioritizes affordability and access	Prioritizes pharma innovation and patents	Tries to balance patents and healthcare costs

India's model prioritizes access to medicines, contrasting with Western patent-friendly systems that often put off customary opposition[115].

Conclusion

Patent regulation performs a critical role in public health, impacting drug affordability, innovation, and accessibility. While advanced international locations emphasize strong patent protection and R&D incentives, growing countries recognition on low priced medication rules via widely wide-spread competition and patent flexibilities.

Comparative Insights:

The U.S. Version is seasoned patent, fostering innovation however growing high drug charges. The EU balances patents and public health, however faces high pharmaceutical prices. India's strong pro-usual stance promotes affordability while complying with TRIPS. Developing Nation face particular challenges but have correctly used obligatory licensing and parallel importation to enhance get right of entry to.

To make sure a honest stability between innovation and public fitness, global patent rules should:

Prevent evergreening and patent thickets.

Expand TRIPS flexibilities and compulsory licensing. Encourage regular drug competition to lower remedy expenses.

Ensure international cooperation to provide inexpensive healthcare worldwide.

A harmonized approach, integrating robust patent protection with robust public fitness safeguards, is vital to assure innovation even as making sure no one is denied lifestyles-saving drug treatments because of unaffordable costs.

[115] World Bank, "Patent Systems and Access to Medicines: India vs. the West" (2023).