
PATENT LINKAGE SYSTEMS AND THEIR IMPACT ON ASIAN PHARMACEUTICAL MARKETS: A CRITICAL ANALYSIS WITH SPECIAL FOCUS ON INDIA

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ABSTRACT

Patent linkage systems, which tie pharmaceutical regulatory approval to patent status, have emerged as contentious mechanisms in global pharmaceutical governance. This paper examines divergent approaches to patent linkage across three major Asian pharmaceutical markets India, China, and South Korea analyzing implications for drug access, pricing, and innovation. India has consistently rejected patent linkage through judicial decisions, maintaining separation between patent enforcement and regulatory approval. South Korea implemented linkage in 2015 under Korea-United States Free Trade Agreement (KORUS FTA) pressure, while China adopted a modified system in July 2021. Drawing on legal precedents, empirical data on patent activity, and price comparisons, this paper argues that India's resistance to patent linkage has preserved affordable medicine access while maintaining innovation incentives. As India faces renewed pressure through trade negotiations, this analysis provides critical assessment of public health and economic implications of potential policy shifts.

Keywords: Patent Linkage; TRIPS-Plus Provisions; Access to Medicines; Intellectual Property Rights; Trade Agreements; India; China; South Korea; Doha Declaration; Section 3(d) of the Patents Act.

Introduction

The intersection of intellectual property rights and pharmaceutical regulation has become one of the most contested domains in global health governance. At the center lies patent linkage a regulatory mechanism connecting generic drug approval to originator patent status.¹ While the United States pioneered this system through the Hatch-Waxman Act of 1984, its global diffusion has been uneven and contested, particularly in developing countries where affordable medicine access remains critical.² Asian pharmaceutical markets present instructive case studies in patent linkage political economy. The region encompasses major generic drug producers, notably India, which supplies approximately 20% of global generic medicines by volume, serving as the pharmacy of the developing world.³ Simultaneously, Asian markets represent diverse regulatory philosophies, from India's steadfast linkage rejection to South Korea's trade-agreement-driven adoption and China's recent modified implementation. This paper examines patent linkage systems across India, China, and South Korea, emphasizing India's experience and pressures to alter its approach.⁴ The analysis grounds itself in legal precedents, empirical patent activity data, and comparative price evidence.⁵ The central argument: patent linkage, particularly when imposed through trade agreements as TRIPS-plus provisions, creates generic competition barriers that disproportionately harm medicine access without generating commensurate innovation benefits. The timing proves particularly salient. India currently engages in trade negotiations with the European Union and recently concluded agreements with the European Free Trade Association (EFTA), raising concerns about potential TRIPS-plus intellectual property provisions, including patent linkage requirements. Understanding neighbouring countries' linkage experiences and India's current non-linkage regime consequences is essential for informed policy-making.⁶

¹ Kato Lelisa, *The Intersection of Intellectual Property and Public Health*, 4(2) *J. Mod. L. & Pol'y* 15 (Aug. 2024), https://www.researchgate.net/publication/382836071_The_Intersection_of_Intellectual_Property_and_Public_Health.

² Garth Boehm et al., *Development of the Generic Drug Industry in the US After the Hatch-Waxman Act of 1984*, 3 *Acta Pharmaceutica Sinica B* 297 (2013), <https://doi.org/10.1016/j.apsb.2013.07.004>.

³ Sonam Lavtepatil & Soumitra Ghosh, *Improving Access to Medicines by Popularising Generics: A Study of 'India's People's Medicine' Scheme in Two Districts of Maharashtra*, 22 *BMC Health Servs. Res.* 643 (2022), <https://doi.org/10.1186/s12913-022-08022-1>.

⁴ Peter K. Yu, *A Half-Century of Scholarship on the Chinese Intellectual Property System*, 67 *Am. U. L. Rev.* 1251 (2018), <http://digitalcommons.wcl.american.edu/aclr/vol67/iss4/3>.

⁵ Susan K. Sell, *TRIPS Was Never Enough: Vertical Forum Shifting, FTAs, ACTA, and TPP*, 18 *J. Intell. Prop. L.* 447 (2011), available at https://www.researchgate.net/publication/265304950_TRIPS_Was_Never_Enough_Vertical_Forum_Shifting_FTAs_ACTA_and_TPP.

⁶ Ministry of Commerce & Industry, *Factsheet: India and European Union Trade Agreement "Mother of All Deals" Unlocking Opportunities, Empowering India@2047*, PRESS INFORMATION BUREAU,

Theoretical Foundations of Patent Linkage Systems

Patent linkage systems operate at the intersection of two distinct legal regimes: patent law and pharmaceutical regulation. In non-linkage systems, these domains remain separate. Patent holders enforce rights through civil litigation, while drug regulatory authorities evaluate marketing approval applications based solely on safety, efficacy, and quality criteria.⁷ Generic manufacturers can obtain regulatory approval even if originator drug patents remain in force, though they risk infringement litigation upon commercialization. Patent linkage systems integrate patent status into regulatory approval processes.⁸ The archetypal U.S. Hatch-Waxman model requires originator companies to list relevant patents in publicly accessible registers (the Orange Book). Generic applicants must certify their products do not infringe listed patents or challenge patent validity. When generic manufacturers file “Paragraph IV certifications” challenging patents, originators can trigger automatic 30-month approval stays by filing infringement lawsuits within 45 days.⁹ Proponents argue linkage provides legal certainty, reduces litigation costs, and creates early patent challenge incentives through provisions like 180-day exclusivity periods for first generic challengers. They contend linkage prevents “patent infringement by regulatory approval” and protects legitimate patent rights without requiring innovators to monitor markets for potential infringers.¹⁰

Critics emphasize several problematic features.

- linkage creates opportunities for strategic behaviour by originators, including listing weak or irrelevant patents to delay generic entry “evergreening.”¹¹
- The automatic approval stays can delay generic entry even when patents are ultimately found invalid or not infringed¹²

<https://www.pib.gov.in/PressReleasePage.aspx?PRID=2219146®=3&lang=2>.

⁷ K.D. Raju, *Patent Linkages and Its Impact on Access to Medicines: Challenges, Opportunities for Developing Countries*, in *Access to Medicines and Vaccines* 213 (Carlos M. Correa & Reto M. Hilty eds., Springer 2022), https://doi.org/10.1007/978-3-030-83114-1_12.

⁸ Hu H. & Hou G., *The Localization of Drug Patent Linkage System in China: Where Should It Go?*, 43 *Biotechnology L. Rep.* 211 (2024), <https://doi.org/10.1089/blr.2024.57239.hh>.

⁹ John (Jay) R. Thomas, *The Hatch-Waxman Act: A Primer* (Sept. 28, 2016), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=5147984

¹⁰ Bryan Mercurio, *Patent Linkage*, in *Drugs, Patents and Policy: A Contextual Study of Hong Kong* 183 (Cambridge Univ. Press 2018), <https://doi.org/10.1017/9781108615235.008>.

¹¹ Olga Gurgula, *Strategic Patenting by Pharmaceutical Companies- Should Competition Law Intervene?*, 51 *Int'l Rev. Intell. Prop. & Competition L.* 1 (Oct. 2020), <https://www.researchgate.net/publication/345840607>.

¹² S. Kannappan et al., *The Timing of 30-Month Stay Expirations and Generic Entry: A Cohort Study of First*

- linkage systems impose administrative burdens on regulatory authorities, diverting resources from core safety and efficacy evaluations, and
- fundamentally, linkage can delay generic competition, maintaining high drug prices and limiting essential medicine access.

From public health perspectives, the critical question is whether patent linkage systems appropriately balance pharmaceutical innovation incentives with timely affordable medicine access.¹³ The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) does not require patent linkage; it is a TRIPS-plus provision exceeding minimum international obligations. The Doha Declaration on TRIPS and Public Health (2001) explicitly affirmed that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health” and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.¹⁴

3. Comparative Analysis of Patent Linkage Regimes in Asia

3.1 India’s Rejection of Patent Linkage

India’s patent linkage approach has been characterized by consistent judicial rejection of attempts to integrate patent enforcement into pharmaceutical regulation. The legal foundation was established through cases, most notably *Bayer Corporation v. Union of India* and related Delhi High Court proceedings.¹⁵ In these cases, Bayer attempted to compel India’s drug regulatory authority to refuse generic manufacturer marketing approvals on grounds their products would infringe Bayer’s patents. The Delhi High Court unequivocally rejected this argument, holding that patent linkage cannot be read into existing Indian statutory provisions. The court emphasized that India’s patent law (Patents Act, 1970, as amended) and drug regulatory law (Drugs and Cosmetics Act, 1940, and rules) operate in separate spheres. Patent disputes must be resolved through civil court litigation, not through drug regulator

Generics, 2013–2020, 14 *Clinical & Translational Sci.* 1917 (2021), <https://doi.org/10.1111/cts.13046>.

¹³ Thomas Pogge, Matthew Rimmer & Kim Rubenstein, *Incentives for Global Public Health: Patent Law and Access to Essential Medicines* (Cambridge Univ. Press 2010), <https://doi.org/10.1017/CBO9780511750786>.

¹⁴ Vanessa B. Kerry & Kelley Lee, *TRIPS, the Doha Declaration and Paragraph 6 Decision: What Are the Remaining Steps for Protecting Access to Medicines?*, 3 *Globalization & Health* 3 (Feb. 2007), <https://www.researchgate.net/publication/6309011>.

¹⁵ *Bayer Corp. v. Union of India*, 2019 AIR ONLINE Del 1712 (Del. H.C.) (India).

administrative action. This judicial stance reflects several policy considerations deeply embedded in India's pharmaceutical regulatory philosophy.

- It maintains institutional separation between patent adjudication complex legal determinations requiring specialized expertise and drug safety evaluation, regulatory authorities' core competency.
- It preserves the principle that regulatory approval should be based solely on whether drugs are safe, efficacious, and of acceptable quality, not on private commercial disputes between patent holders and generic manufacturers.
- It ensures generic manufacturers can obtain regulatory approval and prepare for market entry, even if they must await patent expiry or infringement litigation resolution before commercialization.

India's non-linkage regime's practical effect has been facilitating robust generic competition. Generic manufacturers can complete regulatory approval processes during patent terms, enabling immediate market entry upon patent expiry or successful challenge. This "at-risk" launch capability has been particularly important for ensuring rapid price reductions following exclusivity loss.¹⁶ India's position is also consistent with its broader pharmaceutical policy framework, emphasizing medicine access as a constitutional right to health component under Article 21 of the Indian Constitution.¹⁷ The Supreme Court has repeatedly affirmed that the right to life includes health rights and essential medicine access. This constitutional foundation provides strong normative support for regulatory policies prioritizing access over extended market exclusivity. However, India's non-linkage regime faces increasing external pressure. Trade negotiations with the European Union, United Kingdom, and other partners have raised concerns about potential TRIPS-plus intellectual property provisions. While specific negotiation texts are not fully public, civil society organizations and public health advocates have warned that patent linkage requirements could be included in broader intellectual property chapters.¹⁸

¹⁶ Chittaranjan Andrade et al., *The New Patent Regime: Implications for Patients in India*, 49 Indian J. Psychiatry 56 (2007), <https://doi.org/10.4103/0019-5545.31520>.

¹⁷ Ibid.

¹⁸ Muhammad Abbas, *India's Distinct but Opposing Patent Model Is Under Pressure: Prospects and Challenges in the Global Arena*, 80 India Q. 1 (2024), <https://www.researchgate.net/publication/377971280>.

3.2 South Korea's Implementation Experience

South Korea presents a contrasting case, having implemented patent linkage in March 2015 as part of KORUS FTA obligations. The Korean system requires originator companies to list patents in national registers and provides mechanisms for generic manufacturers to challenge listed patents or certify non-infringement.¹⁹ Empirical analysis of South Korea's 2012-2019 experience reveals important patterns. During this period, 659 brand-name drugs listed patents in the national register, indicating substantial originator company participation. However, patent challenges were initiated against only 95 brand-name drugs approximately 14.4% of listed products.²⁰ This relatively low challenge rate suggests generic manufacturers have been cautious in contesting patents, possibly due to litigation costs, risk aversion, or strategic market entry timing calculations. Notably, there was a brief patent challenge surge immediately following 2015 linkage implementation, but challenge activity declined in subsequent years. This pattern suggests the initial challenge wave may have targeted the most vulnerable patents, while subsequent generic entrants adopted more conservative strategies, potentially waiting for patent expiry rather than engaging in costly and uncertain litigation.

The South Korean experience illustrates a key patent linkage system limitation: while they create formal patent challenge mechanisms, they do not guarantee robust challenge activity. Generic manufacturers face significant patent challenge barriers, including litigation costs, damage risks if challenges fail, and possibilities that originators will settle with early challengers on terms delaying subsequent generic entry. Moreover, 180-day exclusivity periods awarded to first challengers in some linkage systems can paradoxically reduce competition by creating incentives for originators to settle with first challengers in exchange for delayed entry, thereby blocking subsequent generic competition. The South Korean case also demonstrates trade agreements' role in diffusing patent linkage systems.²¹ The KORUS FTA, entering force in 2012, included explicit patent linkage requirements as part of its intellectual property chapter. South Korea's linkage adoption was thus not a voluntary domestic policy choice but rather a concession made to secure broader trade benefits.

¹⁹ Kyung-Bok Son, *Patenting and Patent Challenges in South Korea After Introducing a Patent Linkage System*, 18 *Globalization & Health* 1 (2022), <https://www.researchgate.net/publication/365349020>.

²⁰ C. Scott Hemphill & Bhaven N. Sampat, *When Do Generics Challenge Drug Patents?*, 8 *J. Empirical Legal Stud.* 613 (Dec. 2011), <https://www.researchgate.net/publication/227693633>.

²¹ David E. Korn et al., *A New History and Discussion of 180-Day Exclusivity*, 64 *Food & Drug L.J.* 335 (2009), <https://pubmed.ncbi.nlm.nih.gov/19999288/>.

3.3 China's Hybrid Approach

China implemented drug patent linkage on July 4, 2021, representing a significant pharmaceutical regulatory framework shift. China's system incorporates U.S. model elements but includes country specific modifications designed to balance innovation incentives with access considerations.²² Under China's linkage system, originator companies can list patents in national registers maintained by the China National Intellectual Property Administration (CNIPA) and National Medical Products Administration (NMPA). Generic applicants must address listed patents through several pathways: certifying no patents are listed, certifying listed patents have expired, certifying non-infringement, or challenging patent validity. If generic applicants challenge patents, originators can file infringement lawsuits, triggering approval stays for up to nine months significantly shorter than U.S. 30-month stays. China's system also includes features designed to mitigate potential generic entry delays. First, the nine-month stay is shorter than other linkage jurisdictions, limiting regulatory approval delay periods. Second, China has implemented strict patent listing criteria, limiting registrable patent types to those covering active pharmaceutical ingredients and approved uses, thereby reducing strategic peripheral patent listing opportunities. Third, Chinese authorities have emphasized that linkage systems should not improperly delay generic entry, and regulatory guidance has stressed balancing patent protection with public health needs. China's linkage system early outcomes remain subject to ongoing evaluation. Initial reports suggest moderate patent listing activity levels, but comprehensive data on challenge rates, litigation outcomes, and generic entry timing impacts are not yet available. China's experience will be particularly instructive given its dual role as both major generic drug producer and increasingly important innovator market.

4. Impact on Pharmaceutical Markets and Access to Medicines

4.1 Price Differentials and Generic Competition

Patent linkage systems' most direct pharmaceutical market impact operates through their effect on generic competition and drug pricing. Generic entry typically produces substantial price reductions, with empirical studies documenting 50-90% or greater price declines following

²² Xiaowen Yuan et al., *Impact of China's Drug Innovation Policy on Patent Quantity and Quality: Evidence from a Representative Chemical Pharmaceutical Enterprise*, *Pharmacol. Res. Persp.* (2025), <https://doi.org/10.1016/j.pharp.2025.11.001>.

exclusivity loss in competitive generic markets. Any mechanism delaying generic entry therefore has significant drug affordability and access implications. India's non-linkage regime has facilitated particularly robust generic competition, with dramatic price reductions following patent expiry or successful challenges. A particularly instructive example is sorafenib, a cancer drug treating liver and kidney cancers. When Bayer's sorafenib patent was in force, the branded version (Nexavar) was priced at approximately ₹280,000 (roughly \$3,400) per month of treatment. Following the 2012 compulsory license grant and subsequent generic entry, generic versions became available at approximately ₹8,000-10,000 (\$100-120) per month a price reduction exceeding 90%. While the compulsory license was later revoked on procedural grounds, multiple generic manufacturers had by then obtained marketing approval and entered the market, sustaining competitive pricing.

This rapid price decline pattern following generic entry is not unique to sorafenib. Across therapeutic categories, India's generic market has consistently delivered substantial price reductions, making essential medicines accessible to populations otherwise unable to afford patented products. The non-linkage regime has been instrumental in enabling this outcome by allowing generic manufacturers to obtain regulatory approval and prepare for market entry without patent linkage procedure delays. In contrast, patent linkage systems can delay generic entry through multiple mechanisms. Automatic approval stays, even if time-limited, postpone generic competition onset. Strategic patent listing by originators can force generic manufacturers to either challenge multiple patents or wait for their expiry. Settlement agreements between originators and generic challengers can result in delayed entry in exchange for payments or other considerations. Each mechanism extends monopoly pricing periods, with corresponding drug expenditure and access impacts.

4.2 Patent Listing and Challenge Activity

Patent linkage system effectiveness in promoting or hindering generic competition depends critically on both originator and generic company behaviour within linkage frameworks. Patent listing practices by originators and challenge activity by generics are key indicators of how linkage systems function in practice. As noted, South Korea's 2012-2019 experience revealed that while 659 brand-name drugs listed patents, challenges were initiated against only 95 products. This 14.4% challenge rate suggests the majority of listed patents go unchallenged, with generic manufacturers either accepting patent validity or choosing to wait for expiry rather

than engage in litigation. Listed patent quality is also a critical concern. In the United States, studies have documented instances of originators listing patents of questionable validity or relevance, including patents on minor formulation changes, packaging, or use methods that do not meaningfully contribute to therapeutic value. India's patent law includes provisions designed to prevent such "evergreening" practices, most notably Section 3(d) of the Patents Act, which excludes from patentability new forms of known substances unless they demonstrate enhanced efficacy.²³ This provision was upheld by the Indian Supreme Court in *Novartis AG v. Union of India*, where the court rejected a patent application for a beta-crystalline form of imatinib mesylate (Gleevec) on grounds it did not demonstrate enhanced efficacy over the known compound. The interaction between patent quality standards and linkage systems is crucial. A linkage system allowing listing of weak or peripheral patents can create significant generic entry barriers, even if those patents would ultimately be found invalid or not infringed in litigation. Conversely, strict patent quality standards, such as those embodied in Section 3(d), can limit strategic patent listing scope and reduce linkage system potential to delay generic entry.

5. Trade Agreements and TRIPS-Plus Provisions

Global patent linkage system diffusion has been driven primarily through bilateral and regional trade agreements rather than through multilateral intellectual property treaties. The TRIPS Agreement, establishing minimum intellectual property protection standards among World Trade Organization members, does not require patent linkage. Linkage is thus a TRIPS-plus provision a requirement exceeding TRIPS minimum standards and typically imposed through trade negotiations. The United States has been the primary patent linkage advocate in trade agreements, having included linkage requirements in numerous bilateral and regional agreements, including the KORUS FTA, Dominican Republic-Central America Free Trade Agreement (DR-CAFTA), and original Trans-Pacific Partnership (TPP). These agreements typically require parties to establish mechanisms preventing regulatory approval of generic drugs that would infringe patents, effectively mandating patent linkage systems. Patent linkage and other TRIPS-plus provision inclusion in trade agreements has been controversial. Proponents argue that stronger intellectual property protection promotes innovation and technology transfer, benefiting both developed and developing countries. Critics contend that

²³ Kayla Siletti Brown, Incremental Improvement of the Patentability Standard of Nonobviousness, 92 Fordham Law Review 1741 (2024), <https://ir.lawnet.fordham.edu/flr/vol92/iss4/15>.

TRIPS-plus provisions disproportionately benefit pharmaceutical companies in developed countries while imposing costs on developing countries in the form of delayed generic entry, higher drug prices, and reduced medicine access.

India has historically resisted TRIPS-plus provisions in trade negotiations, maintaining that its intellectual property framework is fully TRIPS-compliant and that additional obligations would undermine public health objectives. However, India faces increasing pressure to accept TRIPS-plus provisions as part of trade agreements with major partners. The European Union, in particular, has sought stronger intellectual property protections in its negotiations with India, though specific provisions under discussion are not fully public. Recent trade negotiations have raised particular concerns about potential patent linkage requirements.²⁴ Civil society organizations, including Médecins Sans Frontières (MSF) and Third World Network, have warned that patent linkage provisions in trade agreements with India could undermine the country's generic pharmaceutical industry and its role as an affordable medicine supplier to developing countries. These organizations have called for public health safeguards in trade agreements, including explicit carve-outs for measures necessary to protect public health and promote medicine access. The Doha Declaration on TRIPS and Public Health provides important normative guidance for evaluating TRIPS-plus provisions in trade agreements.²⁵ The Declaration affirms that “the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health “and that intellectual property protection “should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations. “India’s negotiating position in ongoing trade talks will have significant implications not only for its domestic pharmaceutical market but also for global medicine access. As the world’s leading generic medicine supplier to developing countries, India’s regulatory policies have spillover effects far beyond its borders. If India were to adopt patent linkage as part of a trade agreement, resulting generic entry delays could affect medicine availability and pricing in low- and middle-income countries depending on Indian generics.²⁶

²⁴ Thupten Tshering & Dorji Tshering, *Aligning Intellectual Property Protection with Public Health to Ensure Access to Medicines in Bhutan* (2026), <https://doi.org/10.21203/rs.3.rs-8597770/v1>.

²⁵ Vanessa B. Kerry & Kelley Lee, *TRIPS, the Doha Declaration and Paragraph 6 Decision: What Are the Remaining Steps for Protecting Access to Medicines?*, 3 *Globalization & Health* 3 (2007), <https://doi.org/10.1186/1744-8603-3-3>.

²⁶ Anshul Mittal, *Patent Linkage in India: Current Scenario and Need for Deliberation*, 15 *J. Intell. Prop. Rts.*

6. Policy Implications and Recommendations

The comparative analysis of patent linkage systems in India, China, and South Korea yields several important policy implications for countries considering whether to adopt linkage mechanisms and for such system design if adoption is deemed necessary.

- **patent linkage is not required by international law.** The TRIPS Agreement does not mandate linkage, and countries are free to maintain separate patent and regulatory approval systems. The Doha Declaration explicitly affirms countries' right to adopt measures to protect public health, including measures facilitating generic competition. Countries facing pressure to adopt linkage through trade agreements should carefully evaluate whether such provisions serve their public health and economic interests.
- **if patent linkage is adopted, system design matters enormously.** Specific linkage system features including approval stay duration, patent listing criteria, patent challenge mechanisms, and abuse remedies significantly affect their impact on generic entry and drug pricing. China's nine-month stay period represents a more balanced approach than the U.S. 30-month stay. Strict patent listing criteria, limiting eligible patents to those covering active ingredients and approved uses, can reduce strategic peripheral patent listing opportunities.
- **patent quality standards are essential complements to any linkage system.** India's Section 3(d), which prevents patenting of minor modifications that do not demonstrate enhanced efficacy, serves as an important evergreening safeguard. Countries adopting linkage systems should ensure their patent laws include robust patentability standards and that patent offices have resources and expertise to apply these standards rigorously.
- **Fourth, transparency and monitoring are crucial.** Patent linkage systems should include public registers of listed patents, publicly available data on patent challenges and their outcomes, and regular evaluation of system impact on generic entry timing and drug pricing. Such transparency enables informed policy debate and allows for evidence-based linkage system refinement over time.

187 (2010),
https://www.researchgate.net/publication/292636068_Patent_Linkage_in_India_Current_Scenario_and_Need_for_Deliberation.

- **trade agreements should include robust public health safeguards.** If countries agree to patent linkage or other TRIPS-plus provisions in trade agreements, those agreements should include explicit provisions affirming parties' right to adopt measures necessary to protect public health and promote medicine access.

For India specifically:

1. **Maintain the current non-linkage regime.** India's judicial rejection of patent linkage has served the country well, facilitating robust generic competition and affordable medicine prices.
2. **Resist TRIPS-plus provisions in trade negotiations.** India should continue to assert that its intellectual property framework is fully TRIPS-compliant and that additional obligations would undermine public health objectives.
3. **Strengthen domestic patent quality standards.** India should continue to rigorously apply Section 3(d) and other patentability standards to prevent evergreening.
4. **Build coalitions with like-minded countries.** India should work with other developing countries to resist TRIPS-plus provisions in trade agreements.
5. **Enhance transparency in trade negotiations.** India should ensure that civil society organizations, public health experts, and other stakeholders have opportunities to provide input on intellectual property provisions in trade agreements before finalization.

7. Conclusion

Patent linkage systems represent a significant departure from traditional separation of patent enforcement and pharmaceutical regulation. While proponents argue that linkage provides legal certainty and protects legitimate patent rights, evidence from Asian markets suggests that linkage systems can delay generic entry, maintain high drug prices, and limit essential medicine access without generating commensurate innovation benefits. India's consistent rejection of patent linkage, grounded in judicial decisions maintaining institutional separation between patent adjudication and drug safety regulation, has facilitated robust generic competition and dramatic price reductions following exclusivity loss. The sorafenib case exemplifies India's

approach's public health benefits, with generic entry producing price reductions exceeding 90% and making life-saving cancer treatment accessible to patients who could not afford branded products. South Korea's experience with patent linkage, adopted under KORUS FTA pressure, reveals limited patent challenge activity and suggests that linkage systems do not necessarily promote robust generic competition. China's recent adoption of a modified linkage system, with a shorter approval stay period and stricter patent listing criteria, represents an attempt to balance innovation and access objectives, though comprehensive impact evaluation remains premature.

As India faces renewed pressure to adopt patent linkage through ongoing trade negotiations, the stakes extend far beyond its domestic market. India's role as the world's leading generic medicine supplier means that changes to its regulatory framework have global implications for affordable medicine access, particularly in low- and middle-income countries. Patent linkage adoption could delay generic entry, increase drug prices, and undermine India's capacity to serve as the "pharmacy of the developing world." The fundamental question is not whether patent rights should be protected they should, and India's patent law provides robust civil litigation enforcement mechanisms. Rather, the question is whether patent enforcement should be integrated into pharmaceutical regulation in ways that can delay generic entry and limit medicine access. The evidence examined in this paper suggests the answer is no. Patent linkage is not required by international law, does not serve compelling public health objectives, and risks imposing significant costs on patients and health systems.

India should maintain its current non-linkage regime, resist TRIPS-plus provisions in trade agreements, and continue to apply rigorous patent quality standards that prevent evergreening. In doing so, India will not only serve its own public health interests but also preserve its critical role in ensuring global affordable medicine access. The choice between patent linkage and non-linkage is ultimately a choice between prioritizing extended market exclusivity for pharmaceutical companies and ensuring timely access to life-saving medicines for patients. India has made the right choice, and it should not be pressured to reverse course.