



From Molecule to Monopoly: The Geopolitics of Patents and Medicinal Access

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Abstract. The article aims to examine and address the various concerns arising from patent politics around the globe and how these are contributing to despair, thereby hampering basic human rights. In this era of scientific advancement & innovation, patents are key to uplifting these advancements. The patent is a protective right that also incentivizes future development, but when patent system regulations are disregarded due to the political and economic hegemony of developed nations over developing nations, third-world countries are primarily concerned about access to medicine. The US retaliatory positioning over labelling it has IP protection by issuing US 301 special report, bilateral trade agreements between states like TTP (Trans-Pacific Partnership Agreement), CTPP (Comprehensive and Progressive Agreement for Trans-Pacific Partnership), CETA (Comprehensive Economic and Trade Agreement), USCA (US-Canada-Mexico Agreement), and their repercussions can be seen through enforcement of ISDS, Investor State Dispute Settlement and the repercussions is evidentiary in *Elli lily v. Canadian government* case and another example *Phillips Morris v. government of Australia* and the Big pharma role in pharmaceutical ethics and greedy pricing policies of the essential medicines.

Why are there no changes in the patent system for accessing essential medicines, following orthodox rules of the patent system, like compulsory licensing is only seen rather than any new methodology.

Ultimately, the findings would likely suggest that global power dynamics in patent politics constitute a form of modern economic warfare, posing ethical and humanitarian concerns. By providing recommendations, this paper aims to stimulate policy reforms that balance economic interests with the urgent need to safeguard public health and uphold human rights, envisioning a revised patent system that enables equitable access to medicines without overshadowing the protective and incentivizing role of patents.

Keywords: patent politics, human rights, medicine, geopolitics.

1 Introduction

The practice of patents and the patent system have evolved to promote advancements in society, essentially incentivizing and encouraging inventors for their novel creations, which in turn uplift society for further advancements. The beauty of the patent system is that it balances both

individual aspects and societal aspects equally. But Still, the major parties in the market have different plans to utilize the patent in the medicinal field in various ways; it is being dramatically manipulated by one wing of the world, which has strong Geopolitical and economic influence (Tenni et al., 2022). In contrast, the other wing of the world is being subjugated and being victimized as it is still evolving through its disparities and imbalances (*TRIPS@30: Thirty Years of Widening Inequities in Access to Medicines*, n.d.). Here, in the paper its categorization divides the world into two wings: one comprises developed countries, including pharmaceutical industries, and the other comprises developing countries and third-world countries. To uncover these, the study has been conducted. this research paper explores& analyses about the imbalance created in patent system at the cost of medicinal access. This imbalance also affects human right aspect as right to medicinal access is right to health, a fundamental human right also questioning the essential basic human right for a sustainable living (*General Comment No. 14: The Right to the Highest Attainable*, n.d.)

The primary research question for the following paper is:

- How do geopolitical power differences and the transnational political, economic pressure shape the pharmaceutical patent regime around the world for control and hegemony over the pharmaceutical industry for the profit maximization and the ways it deteriorating medicinal access to the low and middle-income countries?

To address this question the paper is been examined through three sub questions;

- How the pharmaceutical industries and developed states use trade instruments like; political trade dependence, Trips plus provision, lobbying networks to over compliance the intellectual property protection standards especially in pharmaceutical patents standards in developing countries?
- What legal mechanisms and institutions such as Investor State Dispute settlement, regulatory chill, Patent thickets, special US 301 power pressure are being used to weaken or neutralize the social and public health-oriented patent flexibilities provided for medicinal access?
- What are the systemic failures created from within the orthodox pharmaceutical patent system when the profit maximization is focused prior rather than human rights to medicinal access?

To proceed the paper has been divided into five chapters. The chapter 1 gives a brief introduction of the research topic and the chapters in it. Followingly the chapter 2; transnational political and political and economic power influence where it clearly explains of how the developed nations create a political trade dependence, lobbying and other unethical practices taken to promote Trips-plus agreements and critiques prioritizing commercial interest over public health and try to navigate the dependent countries to adopt the stringent IP norms. chapter 3 is about analyzing case studies which examines and about US 301 special report, regulatory chill created through Investor state dispute settlement body in the same chapter, the other section explains what causing the failure of the patent system. Chapter 4 continues to analyze imbalanced patent system and its paradoxical nature providing arguments & evidence against the manipulated patent system. Lastly chapter 5 concludes the research and provides suggestion and recommendations.

This paper adopts a doctrinal methodology, based on statutory texts, international instruments, case law, trade agreements and the scholarly literature to systematically analyze how patents are being used for benefitting pharmaceutical industries rather benefiting medicinal access also the

research takes along with the geopolitics influence in shaping pharmaceutical patenting regime which creates a favored system for pharmaceutical industries often creating ascending profit maximization and descending equitable medicinal access. While examining these issues it showcases how developed nations keep nexus with the patent system, pharmaceutical industries, bilateral treaties and trade agreements to control the patents for their transnational political control and lucrative gains over the developing and third world countries.

And also extending the research arm to law policy reforms, regarding the orthodox patent regimes where it gives out a very few mechanisms to promote medicinal access provided, the need for a crucial change in orthodox patent regime, a need at world level by creating patent mechanisms such to prevent hampering of medicinal access and also to collectively critique upon the developed nation's actions for deterring medicinal access in deliberate manner.

2 Transnational Political and Economic Power Influence - Interplay in Pharmaceutical Patents and Deterring Medicinal Access

One of the root causes of deterring access to medicine is evident in the analysis of the influence of transnational politics and economic power on pharmaceutical patents. The influence is mainly causing by the pharmaceutical industries having highest proportion of market share in the medicine drug development field, since these industries wants to maintain monopoly as they are lucrative, it's an common fact but what the unknown fact is how they strategically they are acting to make things turn their side, most of the pharmaceutical industries are placed in developed nations base, thus these dominating pharmaceutical industries pawn the state actors and lobby them to provide them the highest possible IP protection because they see patent in medicine is an most lucrative business the lobbied states pitch in to provide them IP protection greater than what actually TRIPS agreement, moreover the Doha Declaration 2001, has enumerated and also like bilateral trade agreements, TRIPS plus agreements, and also the developed nations indirectly mandate the low-middle income states (LMIC) to be obligated towards them. Below there are detailed explanations about the mechanisms used to derive for the above mentioned.

Geopolitics influence over PRO IP standard compliance; Trips to Trips Plus engagements

The US has the highest pharmaceutical market and industries (18 out of 30 big pharma are from the US), and being one of the economic leaders in the world, it needs to retain its leadership over all. Thus US, through its bilateral trade agreements, wants to maintain hegemony in the pharmaceutical industries, to provide the highest possible IP protection to its industries. Moreover, the U.S. has launched a global intellectual training academy for implementing IP protection (Shadlen, 2017). This technical assistance is provided to countries that are ready to implement their IP policy strategically, thereby earning credibility and showcasing themselves as an investment destination. This approach enables them to provide effective IP protection, which is

beneficial for capitalism not only in the EU through its bilateral trade agreements like EFTA (European Free Trade Association), but also for Cotonou agreement, which created base baseline for IP protection for their future economic bilateral agreement (European Commission 2002). ENP (European Neighborhood Policy) and also the EU partnership agreement with Jordan mandate to have patent protection for chemical and pharmaceutical products 2 years earlier than the TRIPS (European Commission 2002). (Gleeson et al., 2019) present an analytical framework that identifies categories of provision in recent trade and investment agreements such as the TPP, CPTTP, CETA, and USMCA, which profile TRIPS-PLUS provisions, investor-state dispute settlement mechanisms, procedural constraints on pricing, and regulatory requirements affecting the safety and efficacy hindering the medicinal access, in their study under table.1 and 2 provided detailed explanation of the repercussions of these trade agreements.

The graphs 1&2 below were generated from the study of (Islam et al., 2019) for better understanding, which represents the findings of the study made;

- Showcase the ex-ante and ex-post studies which report on how substantially. Findings indicate that both ex-ante and ex-post studies report.
- The ex-ante study predicts about 50%to 600% price increase after trips plus agreements where in ex-post study confirmed that from 3% to 50% the actual price hike has been incurred which is completely less as compared to ex-ante study but ultimately ex-post study show there is inflating of the price of the medicine which is max of 50% it's also a heavy hike for persons with low income thus hampering the medicinal access
- Also, there is a significant delay in generics after the trips-plus agreements

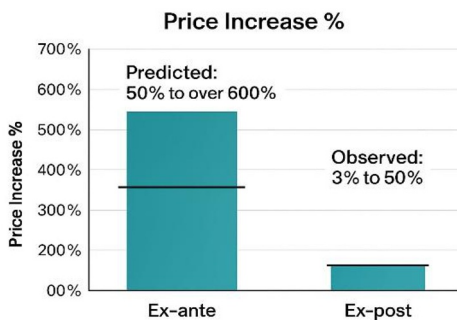


Table 1. [Graph 1.]

Graphic representation of the depiction of the ex-ante studies price increase of medicines before the trips plus agreements and the actual rise in medicines price after trips plus agreement

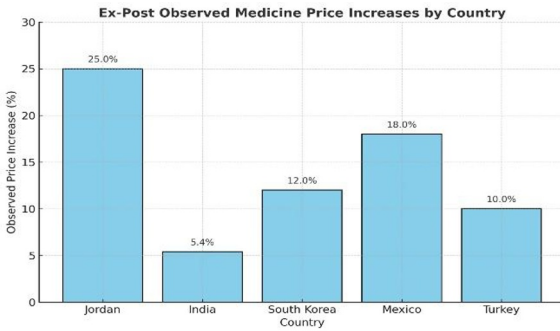


Table 2. [Graph 2.]

Graphic representation of how developing countries are affected by the triad-plus agreements, as well as how prices are inflated after the agreement (ex-ante to ex-post).

Political trade dependence mechanism & theory

By creating ‘POLITICAL TRADE DEPENDENCE’ (The concept of political trade dependence is developed and explored in Manger and Shadlen (2014) and Shadlen (2008). Political Trade Dependence is a geopolitical gear where the developing nations economies heavily depend upon the exports to the developed nations so the Low and middle income countries or developing nations are more susceptible to the external pressure and which leads to adopting to stringent IP norms, as (Shadlen, 2017) in his research states that “dependence on removable, discretionary trade preference” which stimulates the exporters in the domestic who were earlier indifferent about the IP policies now, in fear of losing market access compel the domestic nation to reform their policies in align with their foreign demands.

The higher the political dependence a nation has to be higher the compliance with their Pro-IP standards (Manger & Shadlen 2014). A study reveals the truth about Mexico's highly political dependence on the US through the NAFTA agreement, which led to Mexico adopting pro-IP standards in its patent system (Sell 2003). In contrast, countries with low political trade dependence have the power to retain their autonomy over IP policy in a manner that avoids over-compliance (Correa, C. M. (2000), for example, Argentina. Thus, political trade dependence influences legal harmonization for patent compliance, domestic coalition's, regulatory institutions. The processes and patterns the pharmaceutical industries advanced to adopt is same as what evolutionary economists refer to as “selection” and “structured feedback” (Malerba and Orsenigo 2015)

country	Political trade dependence	Compliance	Domestic coalition	Patent system outcome
Argentina	low	minimum	defensive and protective	Had its autonomy to shape
Brazil	moderate	Neo-developmentalism approach	Intermediary	Balanced Eg: regulatory control through ANVISA,
Mexico	high	Over compliance	Weakened domestic coalition	Trips -plus compliance

Table 3. typology representing the effects on patent system through PTD (political Trade dependence)

Here is a Table 1, which is extracted from Kenneth Shelden's (Shadlen, 2017) framework upon how the PTD and domestic coalitions catalyzing to adopt pro – IP standards through trade pressure, the author shalden had reported upon Argentina, Mexico, Brazil as a study upon the framework on Political Trade Dependence (PTD) and domestic coalitional reactions to global IP political pressures. This will showcase the transnational politics in pharmaceutical patents and the dependence on transnational politics for access to medicine, which, in turn, affects human rights by hampering medical access due to excessive IP protection.

The lobbying networks & its influence for PRO IP driven standards

The top pharmaceutical industries around the globe leveraging their economic and political influence, shape the United States' trade policy. The pharmaceutical industries like Pfizer, Merck, Eli Lilly, and PhrMA are being members of the USTR adding to that the United States is one of the nations to have a major stake in the pharmaceutical industries and has about \$846.7 billion in sales in 2022 (Business Market Insights 2023), which shows the United States stringent IP policies, especially regarding patents (Gleeson et al., 2019). Pharmaceutical industries can influence U.S. trade policy by lobbying, funding campaigns, and also being in key advisory positions in trade institutions like the USTR (Office of the United States Trade Representative), (Public Citizen 2020; DC Transparency 2025) resulting in Trips-plus agreements through FTAs, limiting generic drugs, restricting compulsory licensing, and affecting access to medicine in low-middle income countries (LMIC) (Islam et al., 2019).

Beyond the formal engagement with the state institutional bodies, the pharmaceutical industries also depend upon the indirect lobbying strategies to create an environment which shape the patent regulation into their needs. As pointed out in literature;

(i) American Bio Industry Alliance (ABIA) a Lobby networks were introduced to shape global IP policy in favor of brand-name pharma. (Drahos & Braithwaite, 2002; Sell,

2007) , and (ii) ,PhRMA lobbied third parties indirectly through funding, building a network for voicing them; Intellectual echo chamber of economists—a standing network of economists and thought leaders to speak against federal price control regulations through articles and testimony.” It has set aside \$550,000 “for placement of op-eds and articles by third parties” and at least \$2 million for outside research and policy groups “to build intellectual capital and generate a higher volume of messages from credible sources” backing industry positions. Overall, the group will devote \$12.3 million to “alliance development,” ... with ... economists, doctors, patients, and minority groups(*Intellectual Echo Chambers — Crooked Timber*, n.d.; “Opinion | Behind the Lobbying Curtain,” 2003; Sell, 2007) . These documented facts showcases that tens of millions of dollars are raised for campaign contributions and expenditure for the lobbying groups this stands as a strong evidentiary value to the statements “the pharmaceutical industries manipulate patent regulation and its policies” and it also substantiates for the argument ‘where big pharmaceutical industries drive these for their profit maximization with the help of state political advantage.

Moreover The state nexus with the pharmaceutical industries must be to enhance the R&D of the medicines and to increase medicinal access at times in future but the nexus staging here ; The Pro IP driven industry standards stances \$30 million was raised by pharma led lobby groups in 2002 campaigns of republican congress(Drahos & Braithwaite, 2002; Sell, 2007), depicts a clear political gain for state parties and this is being in exchange with economic gain for the pharmaceutical industries. Such reciprocal arrangements distort the patent system, as the core principle objective of patenting is to bring scientific advancement, incentivize the author and with that balancing the societal welfare but it being turned as an aid for the political and economic gains and more focused on investors or author’s interest by pharmaceutical industries and state institutional bodies rather focusing on medicinal access and scientific advancements. This disbalance in the patents in pharmaceuticals is leading to systemic failure.

3 CASE STUDIES

The case studies related to legal mechanisms in, Trade & bilateral agreements, Investor State Dispute Settlement Body (ISDS), U.S. special 301 report between countries.

ON US 301 SPECIAL REPORT

i. U.S. Special 301 Report — India's Experience

The US 301 special report, issued by the United States Office of Trade Representative, is for not maintaining the standard of IP protection by partner trading nations or treaty

countries. The report lists countries to be on the watchlist for not being in compliance with US-managed IP protection, as the US, being one of the developed countries, uses its power to impose trade sanctions upon those who aren't in compliance with its intellectual property policies. India was also once affected by suspending the \$60 to 80 million trade benefits under the generalized preference system, for India not following the US strict IP policy on pharmaceutical patents (Asok, 2019; "Interface Between Human Rights and Intellectual Property Rights with Special Reference to Patent Regime and Right to Health in India," 2020).

Thailand is also one of the countries that was hit by retaliation from the US Special Report 301 for issuing compulsory licenses for life-saving drugs, such as Plavix, Kaletra, and Efavirenz, which illustrates how developed nations will play their hand with a system to control LMICs. hence hampering medicinal access and infringing Trips flexibilities(Asok, 2019; Sell, 2007).

Deriving from these case studies of the U.S. special 301report it functions not just as an annual review of IP laws, but it's the tool of the US to pressure politically to adopt stringent IP norms which are above Trip and WTO prescribed limits, the nation's avoiding to change their norms face pressure as India and Thailand faced. this critiques of how the one developed nation showing its hegemony over the low and middle income countries.

ii. Philip Morris Asia Limited v. The Commonwealth of Australia (PCA Case No. 2012-12)

One of the exemplary cases where "regulatory chill" is being framed in the minds of countries and affecting their regulations for going against trade in the interest of public health. Where Australia introduced a law where it stated, to have plain packaging for tobacco products so it attracts less attention from youths. Even though the Australian government won the case but it cost a huge amount to engage in a lawsuit, which is why the majority of countries fear to involved in lawsuits for regulating trade practices(Gleeson et al., 2019) . This just an exemplary case for explaining the regulatory chill repercussions.

iii. Eli Lilly and Company v. The government of Canada (ICSID Case No. UNCT/14/2)

One of the landmark cases where it shows how regulatory chill is created, which would lead to repercussions in access to medicine, policy making (here contention related to "patent policy's doctrine of promise utility" meaning if any promise of usefulness is stated in patent application, then it must require to be demonstrated, if not patent can be invalidated), also affecting public health at large. Despite this, Canada won the case against the pharmaceutical company. Eli Lilly's case has held that invalidation of patents for the two drugs, based on the doctrine of promise utility, is legitimate and valid. An interesting fact is that, later, after this case, Canada abandoned the promise utility doctrine in its patent system. Thus, it's evident how

these pharmaceutical networks influence and create pressure and demand situations to get the easiest way possible to pave their way for patenting medicine, which would enable them to be profitable (Gleeson et al., 2019).

4 Systemic Failure of Pharmaceutical Patent System:

The pharmaceutical patents, rather than promoting advancements in drug research and the innovation of new drugs, are being misused and manipulated by the pharmaceutical industry to manipulate the patenting formula for leveraging the highest possible return on their one drug, instead of being involved in research to bring new drugs. In this altruistic mindset, the pharmaceuticals have forgotten the ethical value of the patent for which it's being created, and it's evident in the research made, Journal of Law and Biosciences paper has shown that 78% of patents filed in the FDA's record are not for new drugs, but for existing ones, adding to the patent and exclusivity protection cliff, particularly for the 100 top-selling drugs (Feldman, 2018).

Patent thickets

The pharma industry's abuse of the patent system through “**patent thickets**.”

A “patent thicket” is a dense web of overlapping patents which is used to retain the patent upon the component already existing as patented product but in order to increase the patent lifetime, for commercial exploitation, reversely which hurts the innovation and increases the cost of the product. Big Pharma uses the technique to extend their monopoly pricing power and delay low-cost competition from generics and biosimilars, according to the Drug Patent Book. The Senate Health, Education, Labor and Pensions (HELP) committee has as reviewed some of the drugs which were of big pharmaceutical industries, showing how strategic these industries are to exploit the patenting exclusivity for their commercial gains. These extended patent protections allow companies to maintain high pricing and limit generic competition, reinforcing concerns about drug affordability.

Table.4 patent data for selected drugs where showing the No. of patent have been created for single same drug. Provides an explanation to how the pharmaceutical patents being misused and manipulated and the data here clearly gives out the picture of how pharmaceutical industries are behind the patent protection for profit maximization.

The fact that the patents filed after the FDA approval is more than fifty percentage on average of patents filed for total of 3 drugs which gives out the statement evidently where pharma industries are strategically finding loophole in the patent system and filing patent application where they can shoot up their drug prices, as FDA approval gives an privilege of being safe, effective and tested drug certification thus boosting trust in public. Adding to the fact the named drug in the table is from the bi

pharmaceutical industries, where Keytruda drug is from Merck's, Stelara drug is from Johnson and Johnson's and Eliquis drug if from Bristol Myers Squibb. these facts strongly validate the fact that how the big pharma industries indulge to manipulate the patent protection instead of pushing their innovation and research capacity to reward more to the society.

The table.4 herein gives an explanation to how the pharmaceutical patents being misused and manipulated for evergreening of patents and the data here clearly gives out the picture of how pharmaceutical industries are behind the patent protection for profit maximization.

Drug	Patents filed	% of patents filed after FDA approval	Active patents	Pending patents	Expired patents
Keytruda	168	64% (107)	64	51	53
Stelara	57	79% (45)	15	21	21
Eliquis	37	30% (11)	18	2	17

Table 4.

Table 4. table representing data of patents filed as patent thickets for the following three drugs.

The Paradox of Patent and its systems: Between Incentive, Inequity, and Structural Loopholes

The investment in research and development (R&D) has increased exponentially in the pharmaceutical field to develop new drugs; however, an interesting fact is that the pharmaceutical industry has not witnessed a proportionate growth in novel therapeutics or drug formulations. From the recent study of (Wouters et al., 2020) has estimated that the median capitalized cost to bring a new medicine to market between 2009 and 2018 was approximately \$985 million, with a mean cost of \$1.34 billion, accounting for failed trials and opportunity costs. Showcasing the disparity between rising cost and stagnant innovation and yet inflated drug prices these inefficiency implication from the intellectual property policies against the health equity in particularly the low-income person's in the developed nations and the low-middle income countries are being victim for ensuring right access to medicine, thus it brings the clear picture how functional & innovation upbrining the orthodox patent regime's under pharmaceutical are rather being an element to step up the advancement in innovation building and scientific advancements its being an barrier for competitive advancements and hindering medicinal access.

Additionally, the dispute settlement understanding body was used in order to implement their Pro-IP standard policies, especially the U.S. used it to discipline IP standards rather than to solve genuine disputes, leading to misuse of legal tools and fostering over-compliance in Pharma IP policy (Benkimoun, 2006; Sell, 2007) which reflects the poor access to medicine.

5 Conclusion

The geopolitics in the pharmaceutical sector, particularly regarding patents, reveal a complex interplay between innovation, human rights, and economic and political power. The system, which evolved to reward the inventor for their novel creation and also to encourage future innovations and advancements as a society, is now being misused through the exploitation of its loopholes and is being exploited as a means to maximize profits. As developed nations and large pharmaceutical companies capture the inequalities and needs of the people, it creates an opportunity to institutionalize these structural inequalities and establish geopolitical dominance through them.

The research highlights how geopolitical dominance and structural inequalities have shaped IP Patent protection into a gamble for monetization. Developed nations are pressuring trade-dependent Low- and Middle-Income Countries to adopt their triad-plus standard. The pharmaceutical industry uses a lobbying network to establish its over-compliance IP protection through highly influential state actors, creating a regulatory chill by instilling fear among the states, which is evident. Whereas investor-state dispute cases directly question states and make them answerable for foreign corporations, even for domestic states regulating IP policy for public health. They have also been targeted, as seen in the cases of *Philip Morris v. Australia* and *Eli Lilly v. Canada*, by exploiting legal loopholes, such as creating patent thickets. Overall, these developments reflect a weakening of the patent system and its original spirit.

It's very evident that the current patent regime is only successful in incentivizing research and innovation to a limited extent in the pharmaceutical industry, and more recently, it has lost its balance, unable to maintain humanitarian imperatives alongside balanced economic interests. The intellectual property governance in the field of medicines needs more ethical governance. This radical change is going to lift the humanitarian grounds. Thus, creating and advocating for a thorough overhaul of the orthodox patent system, incorporating human rights aspects and ethical considerations into the IP system, would foster a balanced patent system ecosystem, safeguard public health, and promote the intended scientific progress in the original spirit of the patent system.

In light of the findings, several reforms are essential to ensure a balanced, human rights-based, and sustainable patent system that prioritizes accessibility and innovation:

- While considering patent protection, the developing countries should focus on exploiting the TRIPS flexibilities, i.e., maximizing the TRIPS flexibilities

- Encouraging to building of the initiative of human rights aspect into intellectual property rights and human rights on access to medicine by establishing treaty pacts and regional and intergovernmental organizations especially among the developing nations or LMICs, building the balance to tackle the geopolitical dominance by developed nations at international forums
- Developing nations in fact should become self-independent for staging this disparity caused by the developed nations instead serving the repercussions in fearing of trade sanctions by the developed states and should find a way so that it's maintained through international cooperation and also WHO and UNDP should resist the undue pressure caused to maintain the over compliance IP- trade policy creating checks and balances in the system.
- Lastly, developing and third world countries should cope with making in-country initiative's so that growth countries help to tackle overall imbalance in accessibility
- The dominance of developed nations in patent ownership, as reported by the WIPO 2020 report, is a key reason why they shape intellectual property policies to serve their own interests. Consequently, developing countries should focus on strengthening their self-reliance and innovation capabilities. By doing so, they can reduce vulnerability to sanctions and limited technology transfer imposed by developed nations.
- Morality-based and law treatment at the international level, indexation should be introduced for maintaining accountability of the nations, also the Sustainable Development Goals. This system has to be introduced so whoever violates these should serve a penalty at the international level, and penalties should be utilized to improve accessibility to medicine by improving the
- The orthodox length of patent term for essential medicines should be reduced, and priority should be established for these medicines internationally.
- IP policy framing in the context of products essential for human needs, such as medications, should be outside the orthodox patent system. A new regulatory patent mechanism should be introduced, allowing pharmaceuticals to maintain a margin of profit, thereby preventing them from losing interest in innovation. The pharmaceutical industry should not be left out to be fully privatized; the government in the locals must have a hand in pharmaceutical ownership, then regulating patents for essential medicines would be a lot easier.

References

1. Addressing global health inequities: An open licensing approach for university innovations. (n.d.).
2. Asok, A. (2019). *Compulsory licensing for public health and USA's Special 301 pressure: An Indian experience*.
3. Benkimoun, P. (2006). How Lee Jong-wook changed WHO. *The Lancet*, 367(9525), 1806–1808. [https://doi.org/10.1016/S0140-6736\(06\)68787-4](https://doi.org/10.1016/S0140-6736(06)68787-4)
4. Borrell-Fontelles, J. (2022). *Done at Brussels*, 2 June 2022.
5. Correa, C. M. (n.d.). *Intellectual property rights, the WTO and developing countries*.
6. Deere, C. (n.d.). *The TRIPS Agreement and the global politics of intellectual property reform in developing countries*.
7. Deere-Birkbeck, C. (2009). *The implementation game: The TRIPS agreement and the global politics of intellectual property reform in developing countries*. Oxford University Press. <https://doi.org/10.1093/acprof:oso/9780199550616.001.0001>
8. Drahos, P., & Braithwaite, J. (2002). *Information feudalism: Who owns the knowledge economy* (1st ed.). Taylor & Francis.
9. Feldman, R. (2018). May your drug price be evergreen. *Journal of Law and the Biosciences*, 5(3), 590–647. <https://doi.org/10.1093/jlb/lsy022>
10. Gleeson, D., Lexchin, J., Labonté, R., Townsend, B., Gagnon, M.-A., Kohler, J., Forman, L., & Shadlen, K. C. (2019). Analyzing the impact of trade and investment agreements on pharmaceutical policy: Provisions, pathways and potential impacts. *Globalization and Health*, 15(S1), Article 78. <https://doi.org/10.1186/s12992-019-0518-2>
11. Hill, A. M., Barber, M. J., & Gotham, D. (2018). Estimated costs of production and potential prices for the WHO Essential Medicines List. *BMJ Global Health*, 3(1), e000571. <https://doi.org/10.1136/bmjgh-2017-000571>
12. Intellectual echo chambers—Crooked Timber. (n.d.). <https://crookedtimber.org/2004/10/12/intellectual-echo-chambers/>
13. Interface between human rights and intellectual property rights with special reference to patent regime and right to health in India. (2020). *Journal of Intellectual Property Rights*, 25(6). <https://doi.org/10.56042/jipr.v25i6.31669>
14. Islam, M. D., Kaplan, W. A., Trachtenberg, D., Thrasher, R., Gallagher, K. P., & Wirtz, V. J. (2019). Impacts of intellectual property provisions in trade treaties on access to medicine in low- and middle-income countries: A systematic review. *Globalization and Health*, 15(1), Article 88. <https://doi.org/10.1186/s12992-019-0528-0>
15. Joseph, S. (2003). Pharmaceutical corporations and access to drugs: The “fourth wave” of corporate human rights scrutiny. *Human Rights Quarterly*, 25(2), 425–452. <https://doi.org/10.1353/hrq.2003.0018>
16. Khachigian, L. M. (2020). Pharmaceutical patents: Reconciling the human right to health with the incentive to invent. *Drug Discovery Today*, 25(7), 1135–1141. <https://doi.org/10.1016/j.drudis.2020.04.009>
17. Malerba, F., & Orsenigo, L. (2015). The evolution of the pharmaceutical industry. *Business History*, 57(5), 664–687. <https://doi.org/10.1080/00076791.2014.975119>
18. Manger, M. S., & Shadlen, K. C. (2014). Political trade dependence and North–South trade agreements. *International Studies Quarterly*, 58(1), 79–91. <https://doi.org/10.1111/isqu.12048>
19. Oke, E. K. (2013). Incorporating a right to health perspective into the resolution of patent law disputes. *Health and Human Rights*.

20. Opinion | Behind the lobbying curtain. (2003, June 9). *The Washington Post*. <https://www.washingtonpost.com/archive/opinions/2003/06/09/behind-the-lobbying-curtain/d96b5f19-2f82-4ea1-814c-1b6468f40974/>
21. Pharmaceutical lobbying in 2025 and US policy influence. (2025, November 16). <https://dctransparency.com/hidden-power-of-drug-lobbyists-political-influence-and-regulatory-pushback-in-us/>
22. Pingali, S., & Chatterjee, C. (2025). *Balancing affordability and availability in a drug patent regime*.
23. Says, B. (2024, April 24). Big pharma, big lies: Patent stacking. *Wickersham's Conscience*. <https://wickershamsconscience.wordpress.com/2024/04/24/big-pharma-big-lies-patent-stacking/>
24. Sell, S. K. (2003). *Private power, public law: The globalization of intellectual property rights*. Cambridge University Press. <https://doi.org/10.1017/CBO9780511491665>
25. Sell, S. K. (2007). TRIPS-plus free trade agreements and access to medicines. *Liverpool Law Review*, 28(1), 41–75. <https://doi.org/10.1007/s10991-007-9011-8>
26. Shadlen, K. C. (2017). *Coalitions and compliance*. Oxford University Press. <https://doi.org/10.1093/oso/9780199593903.001.0001>
27. Shadlen, K. C., Sampat, B. N., & Kapczynski, A. (2020). Patents, trade and medicines: Past, present and future. *Review of International Political Economy*, 27(1), 75–97. <https://doi.org/10.1080/09692290.2019.1624295>
28. *TRIPS@30: Thirty years of widening inequities in access to medicines*. (n.d.). Retrieved January 7, 2026, from <https://www.twm.my/title2/resurgence/2025/363/cover01.htm>
29. The Drug Patent Book | I-MAK. (n.d.). <https://i-mak.org/drug-patent-book>
30. Tenni, B., Moir, H. V. J., Townsend, B., Kilic, B., Farrell, A.-M., Keegel, T., & GleesonD.(2022). What is the impact of intellectual property rules on access to medicines? A systematic review. *Globalization and Health*, 18(1), 40. <https://doi.org/10.1186/s12992-022-00826-4>
31. Wouters, O., McKee, M., & Luyten, J. (2020). Estimated research and development investment needed to bring a new medicine to market, 2009–2018. *JAMA*, 323, 844. <https://doi.org/10.1001/jama.2020.1166>
32. United Nations Committee on Economic, Social and Cultural Rights. (2000). *General comment No. 14: The right to the highest attainable standard of health*.

Generative AI Use Disclosure

Generative AI tools were used to assist with manuscript structuring and limited drafting support for references also in section 2.1 & 2.2 under table 1,2 for generating graphs for visual representation, data provided by the author for generating graphs and used Zotero for references to improve clarity and readability. No confidential, sensitive, or identifiable personal data were entered into these systems. All AI-assisted outputs were critically reviewed, edited, and independently verified by the authors, who retain full responsibility for the integrity and accuracy of the work.

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