

The Geopoliticization of TRIPS Rules on Access to Medicine

Nuraidil Nabilah binti Arabi - Faculty of Law, Universiti Kebangsaan Malaysia, Malaysia.

Siti Nursyafiqah binti Hamdan - Faculty of Law, Universiti Kebangsaan Malaysia, Malaysia.

Dhanika Tan Kaleesvaran - Faculty of Law, Universiti Kebangsaan Malaysia, Malaysia.

Nur Aisyah binti Anuar - Faculty of Law, Universiti Kebangsaan Malaysia, Malaysia.

Rizal Rahman* - Faculty of Law, Universiti Kebangsaan Malaysia, Malaysia.

Thamer Ramadhan Ameen Al-Dulaimi - Al-Mustaqbal University, Iraq.

Received: 19/09/2024

Accepted: 02/12/2024

Abstract

This article explores the concept of critical geopolitics to understand how international trade laws influence access to medicines within the framework of the TRIPS agreement. Classical geopolitics traditionally emphasizes how geographical features shape state strategy and global power dynamics, whereas critical geopolitics interprets geographical arrangements as constructs shaped by political, economic, and technological forces. By adopting a critical geopolitics approach, this article investigates how developed and developing nations use their ideas, actions, and interpretations of international trade laws to influence the implementation of TRIPS provisions in their favor. The TRIPS agreement, a multilateral treaty aimed at standardizing global intellectual property laws, often benefits developed nations by strengthening patent protections, which in turn restricts access to affordable generic medicines in developing and least developed countries. Despite the inclusion of safeguards and flexibilities designed to promote broader access to medicines, significant inequalities in access persist. This article examines the differential application of TRIPS across diverse national contexts, focusing on how developed and developing nations collaborate—or conflict—in balancing the need for strong patent protection with the imperative of public health access. By analyzing these geopolitical dynamics, the study illuminates the strategic actions employed by nations to navigate the intricate relationship between international trade law and access to pharmaceuticals. The findings offer important insights into the power imbalances that shape global health outcomes under the TRIPS regime.

Keywords: Geopolitics, TRIPS Agreement, Intellectual Property Law, Pharmaceuticals.

* E-mail: noryn@ukm.edu.my

1. Introduction

Geopolitics, the intersection of geography and politics, involves the exercise of power through actions that shape global and regional dynamics (Flint, 2022). Traditionally, classical geopolitics emphasizes how physical geographic features—such as terrain, climate, and natural resources—directly shape state strategies, national security, and economic dominance. This perspective prioritizes control over strategic locations, trade routes, and natural resources, framing geography as a critical factor in state behavior and global power dynamics.

However, critical geopolitics offers a more nuanced understanding, viewing geographical arrangements as socially constructed by human agency and political, economic, and technological forces. It asserts that geography is not a static determinant of power, but is shaped by human actions, ideas, and policies. This perspective explores how geopolitical narratives and representations are created to legitimize particular policies or actions, revealing the influence of power relations on global governance (Vaculchuk and et al., 2020).

This study adopts a critical geopolitics framework to investigate the intersection of international trade laws and access to medicines under the TRIPS agreement. The TRIPS agreement, designed to standardize global intellectual property (IP) laws, often strengthens patent protections for developed countries, thereby limiting access to affordable generic medicines in developing and least developed countries. Although safeguards and flexibilities have been introduced to address these inequities, access disparities persist (WHO, 2017).

By examining the operation of TRIPS across diverse country contexts, this article addresses a critical research gap: how developed nations leverage strong IP protection while developing nations attempt to utilize TRIPS flexibilities to enhance pharmaceutical access. Understanding these dynamics is crucial for achieving a balance between global health needs and intellectual property rights.

1-1. Overview: What are TRIPS Rules?

TRIPS came into force in 1995, as part of the agreement that established the World Trade Organisation (WTO). TRIPS establishes minimum standards for the availability, scope, and use of seven forms of intellectual property namely, trademarks, copyrights, geographical indications, patents, industrial designs, layout designs for integrated circuits, and undisclosed information or trade secrets. Its key aspects are:

1. Minimum Standards: TRIPS sets out minimum standards for the regulation of various forms of intellectual property (IP) as applied to nationals of other WTO Members.
2. Scope of IP Rights: it covers several types of intellectual property, including copyright and related rights, trademarks, geographical Indications, industrial designs, patents and layout-designs of integrated circuits and undisclosed information
3. Enforcement: TRIPS requires that IP rights be enforceable under national laws, with appropriate procedures and remedies available.
4. Dispute Settlement: The agreement includes provisions for resolving disputes between WTO members over IP issues.
5. Flexibilities: TRIPS allows for certain flexibilities, especially for developing countries, to balance IP protection with public interests, such as access to medicines.
6. Technology Transfer: Encourages technology transfer and the spread of knowledge and innovation.
7. Transition Periods: Provides different transition periods for developing and least-developed countries to comply with TRIPS standards (TRIPS agreement).

1-2. which developing countries used, TRIPS Rules?

Malaysia used Compulsory Licensing (CL – which is one of the safeguards offered under the TRIPS rule of flexibility) in September 2017 for sofosbuvir tablets to treat hepatitis C. After a failure to negotiate prices with the patent holder, the Malaysian government introduced the Rights of Government under Patent Act 1983 to exploit the patented invention of sofosbuvir tablets due to the hepatitis C being a public health concern. The tablets were only distributed at government hospitals and facilities.

In April 2003, Zimbabwe issued a CL for the creation of all HIV and AIDS-related medications after a declaration of emergency for HIV and AIDS was made for a period of time. Varichem Pharmaceuticals produced and supplied three quarters of the medication to State-owned health institutions and medication supplied under the CL was subject to price-control.

In 2007, Brazil used its ability to produce generic HIV drugs to negotiate price discounts for patented ones. After failed negotiations in 2006, Brazil issued a CL for the drug efavirenz in 2007, allowing generic imports from India at much lower prices. This resulted in significant cost savings, with the government saving nearly 58.47% by 2012. The CL was renewed for another five years in 2012.

Ecuador, in 2009, had issued a decree to allow CL for essential medicines, prioritising public health. The Ecuadorian Institute of Intellectual Property (IEPI) and the Ministry of Public Health coordinated to grant these licences. Detailed procedures were established in 2010, leading to CL for ritonavir in 2010 and abacavir/lamivudine in 2012. This resulted in significant cost reductions. By 2014, additional CL was issued for cancer, arthritis, and other diseases, achieving substantial savings for the Ministry of Health (WHO,2017).

2 .Methodology

Doctrinal methodology is used to provide a conceptual analysis of relevant legislations and case laws (Althabhwai and et al,2023). It not only organises and describes the law but also identifies and describes the underlying theme or statement the law is trying to make (Hutchinson,2015). Doctrinal methodology is done through the collection of bibliographic materials (Rohaida and et al,2021) such as by referring to the UKM Law Library and the Tun Sri Lanang Library (PTSL) as well as through online databases such as HeinOnline, JSTOR, ScienceDirect, Scopus and Google Scholar (Trihastuti and et al,2024; Noor Azlina and et al,2022). It also uses the qualitative approach (Muhamad Sayuti and Rohaida,2023; Ifa Sirrhu and et al,2022). The primary sources for this article are statutes such as the TRIPS Agreement and relevant domestic legislations of a State. Secondary sources used are books and journal articles .

3 .Geo-Politicization of TRIPS Rules in Pharmaceuticals

The focus on the pharmaceutical industry in this study is justified due to its unique characteristics and profound global impact on both public health and economies. Pharmaceuticals are distinct from other chemical industries because each compound has a unique structure, properties, and biological effects, requiring specialized research methodologies. Unlike other chemical categories, pharmaceuticals cannot be uniformly classified, necessitating tailored regulatory and evaluation frameworks for each compound. Furthermore, the pharmaceutical industry plays a critical role in public health, particularly in low- and middle-income countries, where medicines often constitute a large proportion of healthcare expenditures. Given the industry's importance in these regions, its operations warrant close examination. Additionally, the sector faces specific regulatory and intellectual property challenges, especially under frameworks like the TRIPS Agreement, which significantly influence the availability, accessibility, and affordability of essential medicines in developing nations.

Therefore, focusing on this industry provides valuable insights into the broader implications of international trade laws on global health outcomes.

Molecular biology, genomics, and bioinformatics are three areas in which the pharmaceutical industry is at the forefront of technological advancement. In addition, the pharmaceutical industry is at the forefront of technological progress. In the process of discovering and developing new drugs, these advancements have brought about a significant transformation that has brought about major changes. The transition of the industry from traditional herbal remedies to contemporary pharmacology provides a comprehensive framework for understanding the practices that are currently in use as well as the trends that are expected to emerge in the future.

The discovery of antibiotics is a significant historical event that exemplifies the significant impact that pharmaceuticals have on the outcomes of health care. An additional justification for conducting a targeted study is provided by the intricate nature of pharmaceutical systems, which involve a multitude of stakeholders and complex decision-making processes. This research is solely concerned with the pharmaceutical industry, with the objective of conducting an in-depth analysis of the various challenges, advancements, and contributions that the industry has made. The purpose of this article is to discuss the growing geopolitical influence of developing nations, to examine the repercussions it will have on future IP regimes and identify the approaches that are beneficial to nations and IP law.

3-1 .Innovation of the Pharmaceutical Industry

3-1-1 .What is Pharmaceutical

The pharmaceutical industry, often referred to as the Pharma industry, has unique characteristics that distinguish it from other sectors (Azlinda and Abdul Samad,2023). These include its diverse range of chemical compounds, stringent regulatory frameworks, high R&D costs, and significant impact on public health and global economics. In dealing with the pharmaceutical industry, we must beforehand acknowledge the importance and the usage of pharmaceuticals in the pharmaceutical industry. Pharmaceuticals represent a broad and varied group of chemical compounds that do not share a common set of characteristics. Unlike phthalates or PCBs, which can be grouped together because they have similar chemical, physical, structural, or biological properties, pharmaceuticals do not fit into such a unified category. Phthalates and PCBs have similarities in their chemical structures and properties, allowing scientists to study and regulate them as a cohesive group. Pharmaceuticals, on the other hand, vary widely

in their chemical makeup, physical form, structural complexity, and biological effects. This diversity means that there is no scientific reason to treat all pharmaceuticals as a single category (Taylor,2015).

Pharmaceuticals can range from complex chemical structures to remarkably simple ones. For instance, propofol, a common anaesthetic, is a simple aromatic molecule (2,6-diisopropylphenol), characterised by a stable ring structure. Nitroglycerine, used as a vasodilator, is an example of a simple aliphatic molecule (1,2,3-trinitroxypropane), composed of linear or branched chains of carbon atoms. Atorvastatin, a statin used to lower cholesterol, is more complex but still has a relatively low molecular weight compared to large biomolecules like proteins (Taylor,2015). Given this wide range of structures and properties, pharmaceuticals cannot be scientifically or logically grouped into a single category. Each pharmaceutical compound must be studied and regulated based on its unique characteristics, ensuring that each drug is evaluated on its own merits and risks.

The concept of a pharmaceutical system can be defined in different ways, each with its own focus and limitations. Roberts and Reich (2011) use the terms "system" and "sector" interchangeably, emphasising the sequence of stages that pharmaceutical products go through from development to use. Their definition outlines a linear process involving several key functions: research and development, clinical trials, registration, manufacturing and packaging, procurement and importing, supply chain, dispensing, and sales/use. This approach focuses on the product lifecycle from the producer or supplier's viewpoint.

In contrast, the World Health Organization (WHO) offers a different perspective in its transparency assessment tool. WHO makes a clear distinction between the pharmaceutical system and sector, defining the system as the network of interactions and relationships among various actors within the pharmaceutical sector and the decision-making processes, particularly within the government (WHO,2019). This definition emphasises the dynamic and relational aspects of the pharmaceutical system, highlighting how different stakeholders interact and how decisions are made within the sector.

The absence of standardised definitions and reliable metrics for pharmaceutical systems strengthening (PSS) poses significant challenges. Countries need clear guidelines to make informed decisions about where to invest their resources in PSS. They also require dependable measures to evaluate whether these investments are yielding the desired outcomes. Without these tools, it is difficult to assess the effectiveness of PSS

interventions. This issue is particularly critical in low- and middle-income countries. In these regions, medicines represent a substantial portion of the total health expenditure. On average, about 25% of the health budget is spent on medicines, and in some cases, this figure can be as high as 67%. This high expenditure on medicines underscores the importance of having effective pharmaceutical systems. However, without clear definitions and measures, countries may struggle to ensure that their investments in PSS are addressing the most critical needs and are having a positive impact on health outcomes.

3-1-2 .History of Pharmaceutical

The pharmaceutical industry and chemists produce products that are labelled in an assortment of ways, with the definitions of these labels evolving gradually. Pharmaceutical, medicinal, medicinal product, therapeutic, and drug are all frequent usage terms. While these terms are frequently employed in comparable contexts, they do not completely interchange. Clarification is required in order to comprehend the unique intricacies and proper application of each term (Anderson,2005). As an illustration, the term 'pharmaceutical' includes all products developed by the pharmaceutical industry, whereas 'medicine' generally denotes substances employed for the purposes of disease prevention, diagnosis, or treatment. While the term 'therapeutic drug' refers exclusively to drugs used for treatment,'medical product' can also encompass devices. A comprehension of these differentiations facilitates precise correspondence and comprehension within the domains of healthcare and pharmaceuticals.

The term 'pharmaceutical' encompasses active ingredients and vaccines in addition to medicines'. Although 'pharmaceutical' and 'medicine' are frequently used interchangeably in colloquial speech, the term 'pharmaceutical' is employed to refer to the pharmaceutical industry. In addition to pharmaceuticals and vaccines, this sector also manufactures a wide variety of secondary products and unfinished biological substances (Anderson,2005). Moreover, it encompasses a wide range of medical devices, over-the-counter (OTC) medications that are accessible without a prescription, veterinary medications, and diagnostic products utilised for the purpose of identifying health conditions. The extensive nature of the pharmaceutical industry and its effects on the health of both humans and animals are underscored by this broad scope.

The origins of pharmaceuticals can be traced back to ancient civilizations, where individuals relied on herbal and natural remedies to treat a wide range

of health ailments. As knowledge progressed, this resulted in the emergence of pharmacology, a scientific field dedicated to the examination of drugs and their interactions with the human body. Remarkable advancements were achieved during the 19th and 20th centuries, particularly with the breakthrough of antibiotics. Dichtel (2023) asserts that this significant development represents a crucial turning point in the field of medicine, as it has had a profound effect on the treatment of infectious diseases. The introduction of antibiotics brought about a significant transformation in medical care, significantly enhancing the capacity to fight against infections that were previously challenging or unmanageable to treat.

3-1-3 .The Technology

The pharmaceutical industry has made significant advancements in the identification and creation of novel medications. The significant progress can be attributed primarily to the advancements made in the fields of molecular biology, genomics, and bioinformatics. Molecular biology investigates the intricate mechanisms occurring at the molecular level in cells. Genomics, on the other hand, is concerned with the comprehensive study of genomes, encompassing their structure, function, evolution, and mapping. Bioinformatics, a multidisciplinary field, integrates biology, computer science, and information technology to analyse and make sense of biological data (Dichtel,2023). These fields have collectively improved our capacity to identify potential drug targets, which are specific molecules in the body that drugs can interact with to produce a therapeutic effect.

Modern methodologies, such as high-throughput screening and computational modelling, are essential in this process. High-throughput screening enables researchers to rapidly perform millions of chemical, genetic, or pharmacological assays. By conducting these tests, scientists can detect active compounds, antibodies, or genes that regulate a specific biomolecular pathway. Computational modelling employs computer algorithms to simulate and analyse the dynamics of intricate biological systems and the interactions between drugs (Dichtel,2023). These techniques, when used in combination, allow for the quick and effective identification of lead compounds, which are chemical substances that have the potential to be developed into new drugs, from a large number of options.

3-2 .The usage of TRIPS Rules in Pharmaceuticals Industry

3-2-1 .Pharmaceutical IP Definition

Intellectual property (IP) refers to a wide array of original works that result

from human creativity and intellect, including fields such as art, literature, technology, and science. These creations are safeguarded by intellectual property rights (IPR), which are legal provisions intended to grant creators exclusive authority over their inventions or works for a specific duration (Singh,2004). This guarantees that the creators can reap the rewards of their hard work and original ideas, thereby preventing unauthorised use or reproduction of their work. The pharmaceutical industry faces scrutiny for excessively reinforcing and abusing intellectual property rights (IPR), which adversely affects competition and consumer welfare. This exploitation creates a market environment where competition is suppressed, leading to higher medication prices and reduced access for consumers (Kartal,2007). Furthermore, the industry's reluctance to engage in risky innovations exacerbates the issue. This lack of innovation results in fewer new drugs being developed, ultimately harming public health. Legislative reforms alone are insufficient to address these problems. To effectively tackle the issue, antitrust law must step in to ensure fair competition and safeguard consumer interests. Antitrust laws are designed to prevent monopolistic practices and encourage healthy competition, which can help mitigate the misuse of IPR and promote innovation within the pharmaceutical industry.

3-2-2 .The Implementation of TRIPS Rules in Pharmaceutical

The TRIPS Agreement, which establishes international standards for intellectual property rights, has sparked debates about its effects on the availability of medicines in developing and least developed countries. Supporters of intellectual property protections (IPP) argue that these protections are essential for pharmaceutical companies because they help recoup the significant costs associated with research and development (R&D). By granting companies exclusive rights to sell their innovations for a certain period, IPP ensures that companies can recover their investments, thus providing a financial incentive for ongoing investment in biopharmaceutical research and innovation (Grabowski and et al,2015).

This is crucial for the creation of new and effective medicines. However, there is a concern that strong IP protections can lead to higher drug prices, making essential medicines less affordable for poorer populations. Critics argue that this can negatively impact drug accessibility in developing regions. Despite these concerns, supporters maintain that the long-term benefits of continuous pharmaceutical innovation, made possible by IP protections, ultimately lead to the development of new treatments that benefit global health (Kesselheim,2007). Thus, while the TRIPS

Agreement's intellectual property protections are critical for encouraging investment in drug research and innovation, they also raise important questions about affordability and accessibility in less affluent areas.

3-2-3 .How to Patent it under TRIPS Rules

The TRIPS Agreement requires countries to ensure patent protection for inventions across all fields of technology, including both processes and products. This requirement significantly impacts the pharmaceutical industry, making it impossible for countries to exempt pharmaceuticals from patent protection or to limit pharmaceutical patents solely to processes, as some countries, like India, did before TRIPS. Understanding the difference between product and process patents is crucial. A product patent grants the holder exclusive rights to make, use, sell, or import the patented product, while a process patent restricts others from using the patented process to produce, use, or sell the resulting product. This exclusivity can lead to higher prices for patented healthcare products, which can be a barrier to affordability, particularly for poorer populations. Without additional measures to lower prices or increase funding, the monopolistic nature of patents can restrict access to essential healthcare products. Therefore, the impact of intellectual property regimes on access to medicines is highly dependent on the specific context and circumstances within each country (WHO,2017).

3-2-4 .How to Protect the Patent

Pharmaceutical companies use various strategies to extend the patent protection of their important compounds, thereby prolonging their commercial lifespan and maximizing profitability. Initially, during the research and development phase, companies typically secure patents for the general chemical compound and its methods of use in treating specific diseases. This initial patent provides exclusive rights to the company for usually 20 years. Once granted, this patent becomes prior art, meaning any new patents related to the same compound must consider what has already been disclosed (Gupta and et al,2010). As a result, new patents often cover narrow improvements or new uses of the drug not mentioned in the original patent.

To secure patent protection, a technologist must demonstrate that their invention meets three key criteria: novelty, industrial applicability, and non-obviousness. Novelty requires that the invention is new and has not been previously disclosed or made available to the public. Industrial applicability means that the invention can be used in some kind of industry, ensuring it

has practical utility. Non-obviousness involves proving that the invention is not an obvious development or improvement to someone with ordinary skill in the relevant field. These stringent criteria ensure that only genuinely innovative and useful inventions are granted patent protection (Nor Ashikin, 2009). To extend the patent life further, companies employ several strategies. One approach is patent layering, where multiple patents are filed for various aspects of the drug, such as its formulation, manufacturing methods, and usage. This creates overlapping patents that extend the exclusivity period. Legal mechanisms also allow for patent extensions; for example, in the U.S., a patent term extension compensates for time lost during the FDA approval process, and in Europe, Supplementary Protection Certificates (SPCs) can extend patent life. Another strategy is obtaining orphan drug designation for drugs developed for rare diseases, providing additional market exclusivity, typically seven years in the U.S. and ten years in the EU (Gupta and et al,2010).

Additionally, evergreening involves making minor modifications to a drug, such as changes in dosage form or delivery method, which can be separately patented, extending overall exclusivity. Companies also seek new use patents if an existing drug is found to treat a different condition, providing further protection beyond the original patent's expiration (Gupta and et al, 2010). These strategies enable pharmaceutical companies to delay the entry of generic competitors, maintain higher drug prices, and maximise revenue and return on investment, although they raise ethical and economic concerns about drug affordability and patient access.

3-3 .The Current Climate of the Pharmaceutical Industry in Relation to TRIPS

The main producers of pharmaceutical products are namely the United States and China (Statista,2022). Prior to the formation of WTO's Trade-Related Aspects of Intellectual Property Rights agreement or TRIPS, industries that rely on big investments in the research and development of their products, such as the pharmaceutical industry, faced pirating problems (Subhan,2006). The formation of TRIPS allowed patent rights on pharmaceutical innovation to be protected for 20 years; however TRIPS was also found to be ineffective in that it limits developing and least-developed countries from being able to have control over their nation's health priorities (Moerman and Van Der Laan,2006). Due to this, these countries have less say in the importation, the production and the marketing of mostly generic . There are however safeguards or flexibilities provided by TRIPS for the

issue above namely Article 31 which provides for compulsory licensing. Compulsory licensing allows patent holders to give a licence to another country, usually less developed ones, to produce a pharmaceutical drug, which allows the production of a drug to continue before the original patent expires. This allowed less developed countries to be able to have access to essential medicines not only during public health crises but in general as well (Kaltenboeck and Bach,2022). As an example, compulsory licensing was commonly used for the treatment and management of HIV and AIDS to which countries have used compulsory licensing to increase access and provide for cheaper prices through negotiations (Moir and et al,2022). Compulsory licensing however comes at a price where countries that are granted with a licence should pay remuneration according to the current circumstances. While compulsory licensing promotes competition and decreases the possibility of a monopolistic trade, it does pose risks as to a country's bilateral and multilateral commercial sanctions which is caused by the power imbalance between countries involved in the trade of pharmaceutical products (Lopez and et al,2023; Oliveira and et al,2006). Proponents of economic rationalism typically support liberal economic policies such as market deregulation, the promotion of free market systems, privatizing state-owned enterprises, shifting from direct to indirect taxation, and reducing the scope of the welfare state.

This can be seen in 2020 during the COVID-19 pandemic that we saw the weakness of compulsory licensing in the face of vaccine nationalism where major producers of the COVID-19 vaccine were reluctant to allow the provision of the vaccine for other countries (Menezes,2021). South Africa and India thus proposed to the TRIPS council for a waiver of intellectual property rights for the prevention of COVID-19 only until vaccination has been done widespread. Naturally, the United States and members of the European Union were reluctant to allow the relaxation of TRIPS rules but South Africa and India argued that if they were to do compulsory licensing, it would be too technical to be coordinated in such a dire health emergency like the COVID-19 pandemic (Menezes,2021). Furthermore, in 2024, the US imposed sanctions on a Chinese biotech company on the grounds that the company has links to China's Communist Party and military to which the US finds that it threatens their national security as the Chinese government might have access to the genetic data of Americans (Reuters, 2024). While the sanction is not regarding the access of pharmaceutical products, this shows how politics and government policies permeate into the pharmaceutical industry. As to how far the power of TRIPS in a geopolitical

perspective is carried will be discussed below.

3-4 .The Power of TRIPS Rules in Geopolitical Perspectives

3-4-1 .Access to Medicine

Several impacts on TRIPS rules on developing nation can be seen clearly and the existence of TRIPS rules regarding patents on pharmaceuticals may limit the ability of developing countries to produce or import generic versions of essential drugs or even a crisis of public health that could lead to a strain relation between developing countries and pharmaceutical-producing nations (Urias,2020). In other ways this would lead to disputes over access to medicine and public health policies since without the incentive of patents, the private sector especially would invest so much in the discovery of medicines so more people would be able to afford the treatment they require when they need it. This would cause an imbalance as the production cost hit the cap but the profit earned would not be able to cover the loss they obtain to produce such medicine (Zinatul Ashiqin,2011). As intellectual property rights are amended to be enforced globally, the cost of medicines itself in developing countries would likely increase unless reasonable steps have been taken to facilitate the availability at lower cost in developing countries.

Though it causes limitations in producing medicines, TRIPS still allows considerable flexibility in countries to design their patent system since most developing countries do not have a significant research capability as they have little to gain by providing extensive patent protection to encourage research. Nonetheless, they would still fall behind from the impact of patents on prices so most countries should amend a provision in their law to facilitate the entry of generic competitors as soon as the patent has expired on a particular drug or medicine product (Wujie,2023). This is what the society refers to as the 'Bolar exception' which allows generic companies to create their own version of patented drug in the making of the patent without infringing it.

According to France-based Medicines Sans Frontieres, they concluded that 'people who rely on low cost medicine will have to wait three years before a generic company could produce the drug whereas people in wealthy companies have the freedom to access new medicines immediately when they are proven safe and effective (Medecins Sans Frontieres Access Campaign,2020). The regulation of TRIP causes a flock of patent applications which are pending in the mailbox and this would only complicate the situation of generic companies helping in producing more

medicines for a cheaper price. Though the TRIPS rule helps classify drugs and medicines more efficiently and ensures that those drugs are safe even in the long term, developing countries would suffer more as they needed to pay a higher price for a patent. One way in obtaining medicines at a lower price is to discuss policy drug for countries to use mechanism called 'compulsory licensing'

3-4-2 .Trade Negotiation

International relations with any official diplomatic attributes is considered the basis and guarantee of international tourism with nongovernmental diplomatic attributes (Ritcher,1983) as a good relation would open space for developing countries to access global markets which soon invite foreign investment upon their country. In other ways it also promotes international tourism interaction which the impact would influence tourism politics. Foreign direct investment (FDI) had be shown to be resilient during financial crises and taking East Asian countries as example, such investment was extraordinarily stable during the global financial crisis in 1997 up to 1998 and the resilient was also evident during the Mexican crisis as well as Latin American debt in 1980s (Lipsey,2001).

A larger market size would come from TRIPs rules as the policy itself was laid out by WTO in which larger economies leverage vast consumer markets, as example, the European United's market sizes that had given them a significant influence in trade negotiations (Annual Activity Report 2022, European United). It is also very important to ensure that the competition among countries are kept at a harmonious level to avoid any conflict (Mokhtari,2020).

Thus, debate arises on the basis of the discussion why the TRIPS rule is still relevant and being used? First off is due to the global standard since TRIPS establishes minimum standards for intellectual property protection for World Trade Organization (WTO) member countries to adhere to (Goes and Bekkers,2022). The centralization simplifies international trade relations by ensuring consistency and predictability in the treatment of intellectual property rights across different jurisdictions. As every countries have their own sovereignty, hence it is vital to ensure a harmonised approach (Sajanee and et al,2023). The jurisprudential aspect also needs not be ignored (Muhammad Amirul and et al,2023). WTO Membership Obligation also exists in which all parties of WTO membership must comply with TRIPS agreement as failure to do so may result in dispute and potential sanction. However, TRIPS plays a crucial part in ensuring a peaceful operation since

without its existence, there would be a lack of consistency in state operations. If each country uses their own rule for international property, trading would be more complicated as it would lead to more dispute and certainty without the existence of a common legal framework. In other ways, the WTO would receive less cooperation from each of its members in working on important global issues.

4 .Approaching Towards Better Future IP

Nevertheless, since the Trade-Related Aspects of Intellectual Property Rights (TRIPS) rule had come into action, it had influenced the intellectual properties policies where those are supposedly governed by the Agreement on TRIPS. Some of the tactics in improving the existence framework consist of strengthening global cooperation through adversarial perspective, addressing the criticism gained on the current framework and reforming it to prioritize a broader public interest to provide social justice and sustainable development (UN Press,2023). The inclusivity in negotiations must be evoked to encourage transparent negotiations that involve World Trade Organization (WTO) members including the least-developed countries and at the same time help ensure a diverse perspective for reformation_Still, the criticism of the current IP framework must be allowed to encourage a constructive reformation of intellectual property laws as well as regulation that could better align with border societal goals, extending from just the state (Faster Capital,2024). Support for developing countries would need to be provided as well, especially in the technical assistance to help developing countries strengthen their IP rights and implications of it for economic development. In moving towards a better future IP, it requires multifaceted strategies that must balance the interest of various stakeholders as well as promoting equity and sustainability so; the obvious benefit of geopoliticization of TRIPS rules to the nation that can be point out is the enhanced bargaining power. The foreign policy should also be structured accordingly to back this coordination (Rasooli,2022).

A collective negotiation power formed by regional alliances and coalitions helps in presenting a unified stance in international forums like WTO for less developed countries and equitable rules that are promoted through reformation reflects the need and interest of countries to promote fairness in balancing interest of diverse stakeholders (McAlevy,2021). Afterward, an increase in leverage of technology and innovation could be achieved as countries with robust IP frameworks could negotiate better terms for

technology transfer as well as promising the gain access to latest innovations for their own benefit. Thus, this proves that a global standardization could promote harmonies of intellectual property law and regulation across different regulations especially in addressing public health concerns. During health crises, countries could leverage international support within TRIPS to negotiate better terms for accessing essential medicines and technologies as mentioned before.

5 .Conclusion

Essentially, the TRIPS Agreement establishes the framework for ongoing discussions between rich and poor countries, particularly in the area of pharmaceuticals. Although historically the industrialized countries have benefited from the power dynamics, there is a discernible shift towards poorer countries having more influence. This shift emphasizes how urgent it is to go from taking opposing positions to working together to shape the future of intellectual property laws. In order to create a more just and long-lasting international intellectual property regime that benefits the various stakeholders involved, this talk emphasizes the necessity of striking a balance between IP safeguards and public health imperatives.

The strategic paths of TRIPS rules have a significant influence on global health outcomes, national policy formation, and complex international diplomacy. This complex interaction highlights how important TRIPS laws are to maintaining a steady supply of necessary pharmaceuticals around the world. Governments, international organizations, and advocacy groups must work together to address the underlying issues and create an environment that is favorable to innovation and accessibility.

Fundamentally, the TRIPS Agreement provides the framework for continuing discussions between developed and developing countries, especially those pertaining to pharmaceuticals. While wealthy countries have historically had a significant impact on these dynamics, there is a clear trend towards less economically advantaged countries being empowered. This shift emphasizes how urgent it is to go from taking opposing positions to working together in order to create a more just course for intellectual property laws. Maintaining public health requirements while protecting intellectual property rights requires a careful balance in the reconfiguration of international intellectual property frameworks to ensure justice and sustainability.

6. Acknowledgment

The authors wish to thank Al-Mustaqbal University, Iraq for funding this

article.

References

1. Althabhwai, N. M; Chao, W. Z; Nadia Sofea Zainal Abidin; Imari, M. H. O. (2023). Personal media restrictions on freedom of speech: A social contract theory behind it. *Geopolitics Quarterly*, 19(Special Issue), 119-144.
2. Anderson, S. (2005). *Making medicines: A brief history of pharmacy and pharmaceuticals*. Pharmaceutical Press.
3. Arza, V; López, A; Montes-Rojas, G; Pascuini, P. (2023). In the name of TRIPS: The impact of IPR harmonisation on patent activity in Latin America. *Research Policy*, 52(6), 104759. <https://doi.org/10.1016/j.respol.2023.104759>.
4. Azlinda Abdul Samad; Abdul Samad Abdul Ghani. (2023). corporate crime in the pharmaceutical industry: Why we must be concerned. *JUUM*, 32, 3–12. <https://doi.org/10.17576/juum-2023-32-01>.
5. Calboli, I. (2022). Intellectual property exhaustion and parallel imports of pharmaceuticals: A comparative and critical review. In C. M. Correa & R. M. Hilty (Eds), *Access to Medicines and Vaccines*. Springer. https://doi.org/10.1007/978-3-030-83114-1_2
6. Colin, F (2021). *Introduction to geopolitics* (4th ed.). Routledge, Taylor and Francis Group.
7. Correa, C. (2020). Trade related aspects of intellectual property rights: A commentary on the TRIPS agreement. Oxford University Press.
8. De Menezes, H. Z. (2021). The TRIPS waiver proposal: An urgent measure to expand access to the COVID-19 vaccines. Research Paper, No. 129, South Centre, Geneva.
9. Dichtel, H. (2023). The evolution of pharmaceuticals: advancements, challenges, and the future of healthcare. *Perspective - Pharmaceutical Bio processing*, 11(6), 122-123. [https://doi.org/10.37532/2048-9145.2023.11\(6\)](https://doi.org/10.37532/2048-9145.2023.11(6)).
10. Geng, Q; Lo, K. (2024). Geopolitical strategies and transnational environmental governance: A comparative study of international NGOs in Cambodia. *Geoforum*, 154, 104063. <https://doi.org/10.1016/j.geoforum.2024.104063>.
11. Goes, C; Bekkers, E. (2022). The impact of geopolitical conflict on trade, growth, and innovation. Economic Research and Statistic Division. https://www.wto.org/english/res_e/reser_e/ersd202209_e.pdf.
12. Grabowski, H. G; DiMasi, J. A; Long, G. (2015). The roles of patents and research and development incentives in biopharmaceutical innovation. *Health Affairs*, 34(2), 302–310. <https://doi.org/10.1377/hlthaff.2014.1047>.
13. Gupta, H; Kumar, S; Roy, S; Gaud, R. (2010). Patent protection strategies. *Journal of Pharmacy and Bioallied Sciences*, 2(1), 2.

- <https://doi.org/10.4103/0975-7406.62694>.
14. Hutchinson, T. (2015). The doctrinal method: Incorporating interdisciplinary methods in reforming the law. *Erasmus Law Review*, 8(3), 130. <https://doi.org/10.5553/ELR.000055>.
15. Ifa Sirru Samsudin; Ramalingam Rajamanickam; Rohaida Nordin. (2022). Roles of human rights bodies on chain remand complaints in Malaysia. *Cogent Social Sciences*, 8(1), 2095079. <https://doi.org/10.1080/23311886.2022.2095079>
16. Japan Patent Office. Asia-Pacific Industrial Property Centre, JIII. Introduction to TRIPS Agreement. <https://www.jpo.go.jp/e/news/kokusai/developing/training/textbook/document/index/TRIPsAgreement.pdf>.
17. Kartal M. (2007). Intellectual property protection in the natural product drug discovery, traditional herbal medicine and herbal medicinal products. *Phytother Res*, 21(2), 113-9. <https://doi.org/10.1002/ptr.2036>.
18. Kesselheim, A. S. (2007). Intellectual property policy in pharmaceutical sciences: The effect of inappropriate patents and market exclusivity extensions on the health care system. *The AAPS Journal*, 9(3), 306-11, <https://doi.org/10.1208/aapsj0903033>.
19. Lu, Y; Hernandez, P; Abegunde, D. (2011). Medicine expenditures. In WHO. *The World Medicines Situation 2011*. 3rd edition. World Health Organization. <http://apps.who.int/medicinedocs/documents/s18767en/s18767en.pdf>.
20. Martina, M. (2024). US lawmakers call for sanctions on China's WuXi AppTec biotech firm. Reuters. <https://www.reuters.com/business/healthcare-pharmaceuticals/us-lawmakers-call-sanctions-chinas-wuxi-apptec-biotech-firm-2024-02-12/>.
21. McAlevy, J; Lawlor, A. (2021). Turning the tables: Participation & power in negotiation. UC Berkeley Labor Center.
22. Moerman, L; Van Der Laan, S. (2006). TRIPS and the pharmaceutical industry: Prescription for profit? *Critical Perspectives on Accounting*, 17(8), 1089-1106. <https://doi.org/10.1016/j.cpa.2005.09.001>.
23. Mokhtari Hashi, H. (2020). Interstate rivalries within regional organizations case study: Economic Cooperation Organization (ECO). *Geopolitics Quarterly*, 16(60), 334-350.
24. Muhamad Sayuti, H; Rohaida Nordin. (2023). Pengiktirafan hak orang asal di sisi undang-undang: Analisis perbandingan antara Malaysia dengan Filipina dan New Zealand. *JUUM*, 33, 3-20. <https://doi.org/10.17576/juum-2023-33-01>.
25. Muhammad Amirul Hakimie Bin Romainoor, Ahmad Muhammad Amirul Fawwaz Bin Mohamad Khairi, Muhamad Sayuti Hassan, & Zainab Kadhim Motlag Al Marzog. (2023). Jurisprudence and its relation to Malaysia political scene. *Geopolitics Quarterly*, 19(Special Issue), 22-36.

26. Noor Azlina Che Hasan; Muhamad Helmi Md. Said; Fatimah Yusro Hashim. (2022). Penjagaan bersama melalui konsep perkongsian keibubapaan: Satu tinjauan kepada undang-undang keluarga Australia dan Sweden. *JUUM*, 31, 31-45. <https://doi.org/10.17576/juum-2022-31-03>.
27. Nor Ashikin Mohd Yusof. (2009). Biotechnology Law policy for developing countries: The third patentability requirement is still a constraint. *JUUM*, 13, 170-190. <https://ejournal.ukm.my/juum/article/view/7565/3084>.
28. Oliveira, M. A; Bermudez, J. A. Z; Chaves, G. C; Velásquez, G. (2004). Has the implementation of the TRIPS Agreement in Latin America and the Caribbean produced intellectual property legislation that favours public health? *Bulletin of the World Health Organization*, 82(11), 815-821.
29. Piscitello, A. S. (n.d.). Twenty-five years since TRIPS: Patent policy and international business. *Journal of International Business Policy*, 3(4). <https://www.doi.org/10.1057/s42214-020-00079-1>.
30. Qunaj, L; Kaltenboeck, A; Bach, P.B. (2022). Compulsory licensing of pharmaceuticals in high-income countries: A comparative analysis. *The Milbank Quarterly*, 100(1), 284-313. <https://doi.org/10.1111%2F1468-0009.12557>.
31. Rasooli Saniabadi, E. (2022). China's reaction to external threats from the perspective of foreign policy and international politics theories. *Geopolitics Quarterly*, 18(68), 202-225.
32. Roberts, M. J; Reich, M.R. (2011). *Pharmaceutical reform. A guide to improving performance and equity*. The World Bank.
33. Rohaida Nordin; Norainina Shariful Anuar; Nur Syafiqah Izzati Zahari; Norizan Abdul Samad Uthayasoorian. (2021). Hak orang asal berkaitan dengan pengambilalihan tanah: Kajian perbandingan antara Malaysia dengan Filipina. *KANUN: Jurnal Undang-Undang Malaysia*, 33(1), 1-28.
34. Sajanee Sukumaran, Yuh, H. C., Rizal Rahman, & Kadhim, A. A. (2023). Jurisprudence concerning 'fake news' and related concepts in Malaysia. *Geopolitics Quarterly*, 19(Special Issue), 79-99.
35. Singh, R. (2004). *Law relating to intellectual property: A complete comprehensive material on intellectual property covering acts, rules, conventions, treaties, agreements, case Law and much more*. Universal Law Publishing.
36. Statista.(2022). Market share of leading 10 national pharmaceutical markets worldwide in 2022.
37. Subhan, J. (2006). Scrutinized: The TRIPS agreement and public health. *McGill Journal of Medicine: MJM*, 9(2), 152-159.
38. Taylor, D. (2015). The pharmaceutical industry and the future of drug development. In R. E. Hester & R. M. Harrison. *Pharmaceuticals in the Environment* (pp. 1-33). The Royal Society of Chemistry.

39. Trihastuti, N; Hananto, P. W. H; Prabandari, A. P; Salawati Mat Basir, Pratama, A. A; Puteri, E. A.P. (2024). The impact of environmental terrorism on land degradation: legal comparative studies between Indonesia and Malaysia. *Journal of Property, Planning and Environmental Law*, 16(2), 105-116. <https://doi.org/10.1108/JPEL-05-2023-0023>.
40. TRIPS agreement. Pp 319 – 351.
41. UHC Technical Brief. Country Experiences in using TRIPS safeguards: Part I. World Health Organization Publication. [https://iris.who.int/bitstream/handle/10665/272977/Country-experiences-TRIPS Part1.pdf? Sequence=1](https://iris.who.int/bitstream/handle/10665/272977/Country-experiences-TRIPS%20Part1.pdf?Sequence=1).
42. Urias, E; Ramani, S.V. (2020). Access to medicines after TRIPS: Is compulsory licensing an effective mechanism to lower drug prices? A review of the existing evidence. *Journal of International Business Policy*, 3(4), 367-384. <https://doi.org/10.1057%2Fs42214-020-00068-4>.
43. Vaculchuk, R; Overland, I; Scholten, D. (2020). Renewable energy and geopolitics: A review. *Renewable and Sustainable Energy Reviews*, 122. <https://doi.org/10.1016/j.rser.2019.109547>.
44. WHO, World Bank, Global Alliance on Vaccines Initiative (GAVI), Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM). (2009). *Monitoring and Evaluation of Health Systems Strengthening. An Operational Framework*. Geneva: WHO.
45. World Health Organization. (2017). TRIPS, intellectual property rights and access to medicines. [https://iris.who.int/bitstream/handle/10665/258915/TRIPS .pdf?sequence=1](https://iris.who.int/bitstream/handle/10665/258915/TRIPS.pdf?sequence=1).
46. Wujie, X. (2023). The impact of geopolitical risks and international relations on inbound tourism—evidence from China and key source countries. *Cogent Social Sciences*, 9(2), 1-30. <https://www.doi.org/10.1080/23311886.2023.2285244>.
47. Zinatul Ashiqin Zainol. (2011). Pharmaceutical patents and access to essential medicines in sub-Saharan Africa. *African Journal of Biotechnology*, 10. <https://www.doi.org/10.5897/AJB11.1052>.

COPYRIGHTS

©2023 by the authors. Published by the Iranian Association of Geopolitics. This article is an open-access article distributed under the terms and conditions of the Creative Commons Attribution 4.0 International (CC BY 4.0) <https://creativecommons.org/licenses/by/4.0>

