



WTO and the Legal Challenge of Patent Protection in the Anti-globalization Environment: A Case Study of the Patent Protection Dispute between the United States and India in Pharmaceuticals and Agrochemicals

Yanan Zheng

Beijing Institute of Technology, Zhuhai, Zhuhai 519000, China

202120138@uibe.edu.cn

Abstract. The globalized framework of patent protection, under the World Trade Organization (WTO) and its Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, is increasingly challenged by anti-globalization trends. This paper analyzes the patent protection dispute between the United States and India, particularly in the pharmaceutical and agrochemical sectors, to explore the legal challenges WTO faces in an era of deglobalization. It discusses the tension between intellectual property protection and public welfare, highlighting the impact of compulsory licensing and the limitations of the WTO's dispute resolution mechanisms. Furthermore, the paper addresses the growing conflict between the global application of patent laws and the sovereignty of developing countries, emphasizing the need for flexible reforms in the TRIPS agreement to accommodate national developmental goals. The study suggests that balancing intellectual property rights with public health, as well as expanding the legal and operational flexibility within the WTO framework, are essential for achieving fairer global patent protection amidst rising nationalism and protectionism.

Keywords: WTO, Intellectual property protection, TRIPS Agreement, Public health, Patent protection.

1 Introduction

1.1 Background

On July 2, 1996, the US consultation on India's patent protection in pharmaceuticals and agrochemicals aroused the world's attention to the international protection of intellectual property rights. With the development of globalization, the strengthening of international trade, investment and transnational cooperation has made intellectual property the key to global competition [1]. The WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) encourages countries to develop uniform

international standards on patents, Copyrights and other intellectual property rights, with the aim of guaranteeing global protection of innovative achievements.

International protection of intellectual property rights is a key component of the development of globalization, and it provides an important support for globalization. At the same time, globalization has also effectively promoted the international protection of intellectual property, so the advent of anti-globalization is bound to have a certain impact on the international protection of intellectual property [2].

In recent years, with the frequent occurrence of international events such as Brexit, the rise of populism in Europe, the election of Donald Trump, who opposes free trade, and the slow growth of world trade, anti-globalization is manifested in the form of major political events, thus attracting the attention and concern of the international community.

1.2 Background

In this paper, the legal challenges of WTO patent protection under the background of anti-globalization will be discussed in detail from the balance between patent protection and public interest, the limitations of WTO dispute settlement mechanism, and the weakening of multilateral cooperation [3].

1.3 Questions and Structure

The core issue of this paper is the legal challenge of WTO to patent protection under the trend of anti-globalization. This paper mainly consists of four parts: The first part mainly introduces the situations and contents related to the TRIPS Agreement and intellectual property protection; the second part takes the patent protection disputes between the United States and India on drugs and agricultural chemicals as an example, and studies the legal disputes based on the positions of both sides; the third part mainly analyzes the legal challenges to patent protection and anti-globalization under the WTO framework. Mainly from the perspective of legal limitations and conflicts of laws, the fourth part is about the legal reform and future prospects of WTO patent protection under the background of anti-globalization.

2 The Framework of Patent Protection in WTO and TRIPS

2.1 Overview of TRIPS Agreement

The TRIPS Agreement, integral to the WTO framework, establishes baseline standards for the protection of intellectual property (IP), harmonizing it within the multilateral trade system [1]. By ensuring non-discriminatory treatment of patents across all technological sectors, including pharmaceuticals and agrochemicals, it seeks to balance private IP rights with public policy objectives.

Scope and Conditions of Patent Protection. Under Article 27, TRIPS mandates patent protection for inventions in all fields of technology, including pharmaceuticals

and agrochemicals [4]. Inventions must satisfy three fundamental criteria: novelty, inventive step, and industrial applicability. These requirements ensure a level playing field, providing equitable legal protection for technological advancements in research and development.

Term of Patent Protection. Pursuant to Article 33, the minimum patent term is set at 20 years from the filing date, granting sufficient market exclusivity for recouping R&D investments. Additionally, some jurisdictions provide supplementary protection mechanisms, such as Supplementary Protection Certificates (SPCs), to mitigate the impact of extended regulatory approval periods, particularly in the pharmaceutical sector [5].

Protection of Undisclosed Data. Article 39 mandates the protection of undisclosed test data submitted for regulatory approval, preventing unfair commercial use. This provision safeguards the proprietary interests of R&D entities and discourages unauthorized reliance on confidential data for regulatory approval processes.

2.2 The Flexibility Clause of the TRIPS Agreement

While TRIPS sets out robust standards for patent protection, it incorporates several flexibility mechanisms to address the diverse economic and public policy contexts of member states.

Compulsory Licensing: The Restricted Use of Patent Rights. Article 31 allows for the issuance of compulsory licenses, enabling third parties to exploit patented technologies without the patent holder's consent, under specific conditions [6]. This provision is a vital tool for balancing private IP rights with public health or safety needs, as demonstrated during public health emergencies like the HIV/AIDS crisis and in securing access to essential agrochemicals for food security.

Limited Exceptions: Special Considerations of Necessity. Article 30 permits member states to enact limited exceptions to patent rights, primarily for research, experimental use, and drug development. The "Bolar Exception" exemplifies this, allowing generic manufacturers to conduct necessary trials prior to patent expiration, facilitating timely market entry [7]. Such exceptions must adhere to the principles of necessity and proportionality to avoid unreasonable harm to the patent holder's economic interests, with disputes subject to WTO review.

Least-Developed Country Immunity. Article 66 provides preferential treatment for Least Developed Countries (LDCs), allowing them to defer patent-related obligations for a specified period. This exemption facilitates the production or importation of affordable medicines and supports the development of domestic agriculture and food security, reflecting TRIPS' flexibility towards the needs of economically disadvantaged members [8]. The exemption period is extendable based on the specific needs of LDCs, with the Doha Declaration further extending the timeline for drug patent implementation until 2033.

Public Policy Alignment and the Doha Declaration. TRIPS recognizes the primacy of certain public policy objectives, such as public health, food safety, and technology transfer [9]. The 2001 Doha Declaration clarified that TRIPS provisions may be applied flexibly in the context of public health, empowering countries to override

patent rights to address public health crises by producing and exporting generic medicines, even in the absence of domestic production capacity. This provision underscores the adaptability of TRIPS in responding to global health challenges.

In conclusion, the TRIPS Agreement, through mechanisms such as compulsory licensing, limited exceptions, LDC exemptions, and the alignment of public policy priorities, provides a nuanced approach to patent protection that balances the rights of patent holders with broader societal needs. These provisions ensure that TRIPS remains a dynamic and inclusive framework for international intellectual property governance.

3 The Challenge of Anti-globalization

In recent years, the rise of the anti-globalization trend has brought new challenges to the application and effectiveness of the TRIPS Agreement. Anti-globalization is not only reflected in the slowdown of global trade integration, but also reflected in the rise of protectionism and the decline of transnational cooperation. This puts the TRIPS agreement under legal, economic and policy pressures.

3.1 The Impact of Rising Protectionism

Against the background of anti-globalization, countries pay more attention to the localization of intellectual property rights, which weakens the principle of "national treatment" and "non-discrimination" in the TRIPS Agreement [8]. In addition, developed countries promote higher standards of intellectual property protection (TRIPS+ rules) through bilateral and regional agreements, which further makes it more difficult for developing countries to acquire technology, deviating from the original intention of TRIPS to promote the balance between technology transfer and innovation.

3.2 Institutional Implications of Technological Fragmentation

Geopolitical tensions have led to technological decoupling and fragmentation, weakening international patent cooperation and technology transfer mechanisms. Article 7 and Article 8 of TRIPS Agreement emphasize that intellectual property protection should promote technological innovation and transfer, but under the trend of anti-globalization, technology blockade and export control are becoming increasingly strict [5]. For example, restrictions on patent transfer of advanced technologies such as artificial intelligence and green energy are key technologies that are more difficult for developing countries [5]. Colleagues, different geopolitical blocs may adopt incompatible IP rule systems, further increasing the complexity of international patent protection and the risk of cross-border IP disputes.

3.3 The Divergence of National Interests between the North and the South Has Intensified

Anti-globalization intensifies the conflict of interest between developing and developed countries in IPR protection. Especially in the field of pharmaceuticals, developing countries have long advocated lowering the threshold of patent protection to ensure the accessibility of basic medical services, while developed countries are more inclined to protect the interests of their own pharmaceutical companies. This has led to resistance from developed countries to flexible provisions in TRIPS, such as compulsory licensing. For example, despite the recognition of public health priorities in the Doha Declaration, the practical use of compulsory licensing in developing countries still faces obstacles such as complex procedures and political pressures.

3.4 Patent Protection Disputes between the United States and India

The intellectual property dispute between the US and India has highlighted the legal divergence between developed and developing countries over patent protection. The United States advocates strict protection of intellectual property rights, which it believes can help spur innovation and safeguard the interests of multinational enterprises. India, in turn, has called for more flexibility by emphasizing public health and access to technology. For example, in the case of pharmaceutical patents, the US once challenged the "significant innovation" standard of Section 3 (d) of the Indian Patent Act as being too restrictive. But India argues that the provision is aimed at preventing "patent evergreens" and ensuring the affordability of drugs [3].

3.5 Challenges of Patent Protection under the WTO Framework

The TRIPS agreement faces many legal restrictions in coordinating the interests of developed and developing countries. Its design is biased towards the interests of developed countries, such as 20 years of uniform patent term is not practical for developing countries [1]. Although TRIPS provides some flexibility (such as compulsory licensing), complex application procedures and political pressures limit its practical use.

3.6 Limitations of the Dispute Settlement Mechanism

Although the WTO Dispute Settlement Mechanism (DSM) is authoritative, it has obvious deficiencies in practice. Firstly, developing countries are at a disadvantage in dispute settlement and lack sufficient legal and technical resources to deal with complex disputes. Secondly, the dispute resolution procedure takes too long, which is not conducive to a quick response to patent disputes. In addition, developed countries often use their economic and technological advantages to pressure developing countries to limit the use of flexibility clauses.

3.7 Rise of Regional and Unilateral Measures

With the deepening of anti-globalization, countries have gradually turned to regional and unilateral measures to replace the global framework of TRIPS [10]. At the same time, some countries, such as the United States, implement unilateral technology protection measures to further restrict international technology flows and affect global intellectual property governance.

With the intensification of globalization and anti-globalization, countries gradually turn to regional and unilateral measures to replace the TRIPS agreement, which faces great challenges [8]. True balance and equity will require reforms that enhance technological capacity building in developing countries, make flexibility provisions more operational, and reform the WTO dispute settlement system [9]. Future international intellectual property rules should seek a more inclusive and pluralistic balance between protecting innovation and promoting the public interest.

4 Legal Reform and Future Prospect of WTO Patent Protection under the Background of Anti-globalization

4.1 The TRIPS Agreement Makes Legal Reform Possible

In response to the anti-globalization trend, the TRIPS Agreement must evolve to accommodate the divergent needs of member states while adapting to shifts in global economic and technological landscapes. Key reforms should enhance the flexibility mechanisms within TRIPS to address transnational challenges, including global public health crises and climate change.

Enhancement of Compulsory Licensing. Compulsory licensing remains a critical flex clause under TRIPS, permitting member states to override patent rights for public interest under specific conditions. However, the current system faces impediments such as bureaucratic complexity and international pressure. Reforms should streamline procedural requirements, expand the scope of application, and introduce automatic triggers for compulsory licensing in emergencies, such as pandemics, to ensure equitable access to essential technologies and medicines.

Strengthening Technology Transfer Provisions. Although Article 66 stipulates obligations for technology transfer to least-developed countries (LDCs), the lack of binding implementation mechanisms has constrained its effectiveness. Reform should establish concrete institutional frameworks, with binding obligations for developed countries to periodically transfer technologies, particularly in sectors like clean energy and public health, to foster sustainable development in the global South [8].

Introduction of Crisis Response Exceptions. The persistence of global challenges such as climate change and pandemics necessitates a coordinated international response [7]. TRIPS could incorporate a global patent pool or establish temporary exceptions for critical sectors—such as renewable energy technologies or pharmaceuticals during health crises. Such measures would address patent concentration and facilitate cross-border technology transfer in the face of urgent global needs.

Promotion of Fairness and Predictability in Flexibility Application. While TRIPS affords flexibility, developing countries often face retaliation or diplomatic pressure when invoking these provisions [4]. Legal reforms should include stronger safeguards against abuse of power, enhancing legitimacy protections for developing nations exercising flexibility clauses. A multilateral body could be established to provide technical and legal support, reducing the risks of unjustifiable trade retaliation.

Strengthening Multilateral Cooperation and Institutional Innovation. The success of TRIPS reforms hinges on robust multilateral negotiation processes. The WTO should establish a dedicated working group for TRIPS reform, regularly reviewing member states' needs and integrating recommendations from international bodies such as WIPO and WHO to create a more cohesive global intellectual property (IP) governance system.

In conclusion, strengthening TRIPS' flexibility will not only improve its adaptability but also facilitate a more inclusive global framework that better addresses the needs of both developing and developed nations.

4.2 The Role of Multilateral and Bilateral Legal Agreement

Regional and bilateral agreements have increasingly supplemented WTO frameworks, often advancing beyond TRIPS in establishing higher IP protection standards ("TRIPS+"). While these agreements address gaps in global governance, they also introduce complexity and fragmentation in international IP law [10].

Harmonization of IP Rules and Enhanced Protection. Bilateral and regional agreements, such as the EU's unified patent system, streamline cross-border patent enforcement and dispute resolution [5]. However, the expansion of TRIPS+ provisions—such as extended patent terms, stricter data exclusivity, and limited compulsory licensing—enhances IP protection for multinational corporations but may hinder technology access for developing countries.

Enhanced IP Enforcement Mechanisms. Regional agreements often include stricter enforcement provisions, such as the Trans-Pacific Partnership's (TPP) mandates for stronger customs enforcement and penalties for online IP infringements. These mechanisms increase the effectiveness of IP protection across borders but contribute to the fragmentation of global IP standards [4].

Facilitating Technology Transfer and Innovation Cooperation. Agreements like the Regional Comprehensive Economic Partnership (RCEP) place a stronger emphasis on fostering scientific and technological cooperation. This approach seeks to balance patent protection with the developmental needs of member states, particularly those in the developing world.

Addressing Emerging Technological Challenges. Regional agreements such as the USMCA have demonstrated greater agility than the WTO in addressing emerging technologies, offering specialized provisions for biopharmaceuticals and digital technologies. This flexibility provides clear legal frameworks for nascent sectors but may exacerbate inequalities in IP access [4].

Limitations and Fragmentation. The proliferation of regional agreements has resulted in a fragmented global IP landscape. Divergences in IP provisions between

agreements raise compliance costs for multinational corporations and create uncertainty in global trade.

Path Forward. To mitigate fragmentation, the WTO must enhance coordination between regional agreements and TRIPS, establishing technical intermediaries or cross-agreement dialogue platforms to ensure compatibility while safeguarding the interests of developing countries. The integration of successful regional reforms, particularly in technology transfer and enforcement, into the multilateral framework should be prioritized.

4.3 Global Patent Protection Law Framework and Prospects

For global IP governance to remain stable and effective, the WTO must foster flexibility and inclusivity in the TRIPS framework while respecting the autonomy of member states.

Enhancement of Flexibility and Equity in TRIPS. The core objective of TRIPS is to balance IP protection with the public interest. Reforms should strengthen provisions for compulsory licensing and public health exceptions, ensuring that member states can swiftly respond to crises. Moreover, the WTO should establish a global technology transfer fund, supported by developed countries, to mitigate the disparities in access to innovation [1].

Integration of Regional Outcomes with Multilateral Rules. The WTO must incorporate best practices from regional agreements, such as the digital IP protections in the CPTPP and the technology exchange mechanisms in RCEP, into its multilateral framework [4]. By doing so, the WTO can ensure that global rules remain dynamic and responsive to technological advancements and public policy needs.

Addressing Legal Challenges in Emerging Technologies. The rapid evolution of technologies like AI, biotechnology, and digital innovations demands that the WTO formulate updated IP protection frameworks. These frameworks should ensure that emerging technologies are accessible to developing countries while promoting innovation. The WTO could negotiate balanced provisions for AI-generated content and biotechnology, including patenting rules that prevent monopolistic practices [8].

Inclusive Dispute Settlement Mechanisms. As anti-globalization sentiments rise, the WTO should enhance its dispute settlement process to ensure transparency and inclusivity [10]. Introducing specialized mediation mechanisms could help developing countries resolve IP disputes, particularly in public health or critical technology sectors, without the fear of unjust legal or economic retaliation.

Restoring Legitimacy and Attractiveness of Multilateral Cooperation. To rebuild trust in multilateralism, the WTO must engage in proactive efforts to encourage innovation cooperation among member states. Establishing incentives for collaborative IP research and development, alongside providing developing countries with greater influence in rule-making processes, will reinforce the legitimacy and stability of the global trading system.

In conclusion, the future of global patent protection lies in a flexible, integrated approach that combines the strengths of regional agreements with the multilateral framework of the WTO. This will ensure that IP law remains responsive to technological progress, public welfare, and equitable development [6].

5 Conclusion

5.1 Core Point

The patent dispute between the US and India, particularly in pharmaceuticals and agrochemicals, underscores significant challenges to WTO patent protection amid anti-globalization.

National Sovereignty vs. International Norms. While TRIPS mandates uniform patent standards, India's measures like compulsory licensing prioritize public health, conflicting with US advocacy for stronger IP protections. This highlights tensions between sovereignty and global trade norms [10].

Public Health vs. Patent Protection. India's flexible patent laws safeguard medicine access, contrasting with US corporations' demand for stringent enforcement to foster innovation. Balancing IP rights and public health remains a global challenge [10].

Flexibility of TRIPS. Developing nations argue TRIPS should reflect socio-economic needs, especially for pharmaceuticals. However, developed nations favor stricter enforcement, revealing a legal impasse.

Multilateralism vs. Unilateral Action. The US often resorts to unilateral trade measures, whereas India relies on WTO mechanisms. This divide exposes governance flaws in international IP protection [6].

Developing vs. Developed Countries. Developed countries advocate stronger IP standards, while developing nations push for flexibility to address socio-economic needs, intensifying global disparities.

Enforcement of WTO Rulings. WTO rulings face enforcement challenges, with unilateral actions like US retaliations undermining multilateral systems and fueling governance concerns.

These disputes highlight systemic inadequacies in WTO patent protection, emphasizing the need for reforms to ensure fairness and global cooperation [5].

5.2 Suggestions for Future Research

Future research should address WTO patent reforms to balance innovation, public welfare, and development needs.

Reinterpretation of TRIPS. Explore enhancing TRIPS flexibilities, like compulsory licensing, to align IP laws with socio-economic needs, ensuring fairer policy space for developing countries.

Balancing IP Rights. Investigate frameworks to reconcile IP standards between developed and developing nations, emphasizing equitable global IP governance [8].

Public Health and IP. Examine mechanisms to balance patent protection with medicine access during global health crises, addressing affordability and availability.

Dispute Settlement. Focus on making WTO dispute resolution more accessible to developing countries, potentially through specialized IP tribunals.

Regional Cooperation Models. Analyze how regional IP systems can empower developing nations to negotiate fairer terms in global trade [11].

Global Governance Reform. Research how WTO can integrate successful regional mechanisms, align with organizations like WHO, and adapt to evolving global challenges [9].

Under the trend of anti-globalization, the legal demands of developing countries in the WTO patent protection framework mainly focus on how to find a balance between protecting innovation and satisfying the public interest, and how to resolve the contradiction between intellectual property rights and development needs through legal and policy adjustments. Future research directions should focus on the flexibility of international patent law, coordination of multilateral and regional cooperation mechanisms, and innovation of global governance structures to promote a more equitable IP protection system.

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