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# Current Issues in TRIPS in the Aspect of World Trade Organisation

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## ABSTRACT

*The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is essential for promoting trade in knowledge and innovation, resolving intellectual property trade disputes and ensuring the freedom of World Trade Organization (WTO) members to pursue their domestic objectives. The current issues in the TRIPS agreement range from access to medicines and concerns relating to public health from the time frame of COVID 19 to issues relating to geographical indications, digital trade, E- commerce, traditional knowledge and genetic resources. This paper focuses mainly on the current issue of biotechnology and traditional knowledge in the TRIPS agreement and how it is addressed by the World Trade Organization.*

***Keywords:*** *Biotechnology, Traditional knowledge, TRIPS Agreement, World Trade Organisation (WTO).*

## I. INTRODUCTION

The global arena of trade and intellectual property rights has undergone a profound transformation over the past few decades, making it increasingly complex and multifaceted. In this ever-evolving environment, the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), created under the auspices of the World Trade Organization (WTO), plays a key role in shaping the norms and regulations governing the global intellectual property regime. Within TRIPS, two critical areas stand out as foci of contention and development: traditional knowledge and biotechnology. These areas exemplify the dynamic interplay between traditional and cutting-edge, timeless and innovative, as well as between global and local.

Signed in 1994, the TRIPS Agreement marked a major milestone in international trade by harmonizing and strengthening the protection of intellectual property rights, including patents, copyrights, trademarks, and trade secrets. It has paved the way for a new era of global trade in which the protection and enforcement of intellectual property have become paramount. However, the implications of this landmark agreement have been the subject of considerable debate and scrutiny, particularly in relation to traditional knowledge and biotechnology.

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Traditional knowledge[2], often passed down through generations within indigenous and local communities, embodies the collective wisdom of cultures and societies around the world. The challenge is to balance the recognition and protection of these invaluable resources while respecting the rights of those who have historically owned and shared them. The fair treatment of traditional knowledge under TRIPS remains an ongoing debate that requires a different approach to the prevention of misappropriation and the preservation of cultural heritage.

On the other hand, the field of biotechnology represents the cutting edge of scientific progress, promising innovations with transformative implications for health, agriculture, and environmental sustainability. In the context of TRIPS, it presents a unique set of issues related to patenting, access to essential medicines, and the impact of intellectual property rights on research and development. Finding the balance between fostering innovation and ensuring availability and affordability remains a challenge of paramount importance in the ever-evolving field of biotechnology.

In this examination of current issues in TRIPS, we delve into the complex interplay of traditional knowledge and biotechnology, their impact on international trade, and ongoing WTO negotiations to address these challenges.

## II. TRADITIONAL KNOWLEDGE

Traditional knowledge refers to the knowledge, innovations, and practices of indigenous peoples. Traditional knowledge, which has been developed based on experience gained over centuries and adapted to the local culture and environment, is often passed down orally from generation to generation. It is commonly owned and can be expressed in stories, songs, folklore, proverbs, cultural values, beliefs, rituals, etc. It is also a source for the traditional use and management of land, territory, and resources with indigenous agricultural practices that care for the Earth without resources having been exhausted. Indigenous peoples follow oral traditions with dances, paintings, carvings, and other artistic expressions that have been practiced and passed down for millennia.

Traditional knowledge[3] is at the core of indigenous identities, cultural heritage, and livelihoods. Intergenerational transmission of traditional knowledge is essential for the protection and promotion of indigenous cultures and identities, as well as for livelihood sustainability, resilience to man-made and natural disasters, and sustaining culturally appropriate economic development.

[2] *Wto*, Gateway https://www.wto.org/english/tratop_e/trips_e/trips_issues_e.htm.
[3] *Traditional Knowledge*, https://www.wipo.int/tk/en/tk/.

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## III. TRADITIONAL KNOWLEDGE AND DIGITAL LIBRARIES

Traditional knowledge and digital libraries are issues that have been discussed within the World Trade Organization (WTO). The areas in which traditional knowledge and digital libraries are connected are:

- Preservation and Documentation: Digital libraries provide a platform for the systematic preservation and documentation of traditional knowledge. Traditional knowledge often exists in oral or non-digital form. By digitizing this knowledge and storing it in digital libraries, it can be preserved for future generations.
- Accessibility: Digital libraries make traditional knowledge available to a wider audience. This is particularly important for indigenous and local communities, whose knowledge might otherwise remain inaccessible to the wider world. Digital libraries can bridge the gap between traditional knowledge holders and researchers or other stakeholders.
- Sharing and collaboration: Traditional knowledge can be shared and collaborated on through digital libraries. This can facilitate partnerships and collaboration between traditional knowledge holders, researchers, and other stakeholders interested in using or preserving this knowledge.
- Protection of intellectual property: Digital libraries can establish mechanisms to protect intellectual property rights associated with traditional knowledge. This helps ensure that knowledge is used and shared in a way that respects the rights and wishes of the communities that own it.
- Education and Research: Researchers, scholars, and students can access traditional knowledge stored in digital libraries for academic and research purposes. This can lead to a better understanding of traditional practices and innovations.
- Cultural preservation: Digital libraries can play a role in preserving and celebrating cultural heritage associated with traditional knowledge. This is important for preserving cultural identity and diversity.
- Legal frameworks and regulations: Many countries and international organizations are creating legal frameworks and regulations to protect traditional knowledge. Digital libraries can help comply with these regulations by ensuring proper documentation,

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access control, and usage tracking.[4]

## IV. PROBLEMS RELATING TO TRADITIONAL KNOWLEDGE

The concerns relating to traditional knowledge in the context of the World Trade Organization (WTO) primarily revolve around how these issues intersect with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and global trade.

1. **Protection of Traditional Knowledge**: Many indigenous and local communities possess valuable traditional knowledge related to agriculture, medicine, and other fields. There are concerns that this knowledge can be misappropriated or exploited by corporations or individuals without proper recognition or compensation. Some countries have sought ways to protect traditional knowledge within the TRIPS framework.
2. **Biopiracy**: Biopiracy refers to the unauthorized use of traditional knowledge or genetic resources from indigenous or local communities for commercial purposes. It's often tied to concerns about intellectual property rights. Some countries argue that TRIPS should provide stronger protection against biopiracy and ensure that traditional knowledge holders have a say in how their knowledge is used.
3. **Access to Genetic Resources**: As with biotechnology, traditional knowledge can be closely linked to access to genetic resources. Indigenous and local communities often have traditional practices for using these resources. There are concerns about the fair and equitable sharing of benefits arising from the commercial use of these resources, as well as informed consent.
4. **Benefit-Sharing Mechanisms**: Discussions within the WTO have touched upon creating mechanisms to ensure that benefits from the commercialization of traditional knowledge and genetic resources are fairly shared with the communities that hold this knowledge. This can include discussions about prior informed consent (PIC) and mutually agreed terms (MAT) in access and benefit-sharing agreements.

## V. BIOTECHNOLOGY

Biotechnology is a multidisciplinary field of wisdom and technology that uses natural systems, living organisms, or their derivations to develop or produce new products and processes for colorful operations. It covers a wide range of operations in colorful sectors, including drugs, husbandry, food products, environmental operations, and assiduity. Biotechnology uses the

[4] *About the Traditional Knowledge Digital Library*, https://www.wipo.int/meetings/en/2011/wipo_tkdl_del_11/about_tkdl.html.

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knowledge of biology, genetics, and molecular biology to manipulate and use living organisms and their factors for practical purposes. Some crucial areas and operations of biotechnology include

Medical Biotechnology

- Pharmaceuticals: development of medicines and curatives, including the products of biopharmaceuticals such as insulin and monoclonal antibodies.
- Inheritable engineering: gene remedy and inheritable revision to treat or help inheritable conditions
- Individual tools: development of advanced individual tools similar to PCR and DNA sequencing

Agrarian biotechnology

- Genetically Modified Organisms( GMOs): revision of shops and crops to ameliorate yield, pest resistance, and nutritive content
- Crop and Beast: Enhancement of parentage shops and creatures to ameliorate desirable traits
- Precision Agriculture: Harnessing Biotechnology for Further Effective and Sustainable Agricultural Practices

Artificial biotechnology

- Enzyme product: the use of enzymes for colorful artificial processes, similar to the products of biofuels and cleansers.
- Bioremediation: The use of microorganisms to clean up adulterants in the terrain
- Biofuels: development of biofuels similar to biodiesel and bioethanol
- Environmental biotechnology
- Wastewater treatment: using microorganisms to break down and remove adulterants from water
- Biodegradable Plastics: The Development of Environmentally Friendly Plastics
- natural control: using natural bloodsuckers or pathogens to control pests

Biotechnology in food products

- Turmoil is a product of food products similar to rubbish, yogurt, and beer.
- Genetically modified foods: creating crops with specific characteristics, such as

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resistance to pests or better nutritive content.

- Food Safety: Developing Styles for the Discovery and Prevention of Foodborne Ails

Biotechnology in research:

- Genomic research: the study and sequencing of genomes to understand genetics and disease
- Proteomics is the study of proteins to understand their function and role in disease.
- Cloning and stem cell research: techniques used in regenerative medicine and scientific research

## VI. PROBLEMS RELATING TO BIOTECHNOLOGY

Biotechnology concerns in relation to TRIPS and the WTO are

1. Patentability of life forms[5]: One of the key issues within the WTO is the patentability of life forms, including genetically modified organisms (GMOs) and biotechnological inventions. The TRIPS Agreement allows the patenting of "microorganisms" and "non-biological and microbiological processes", but does not expressly address the patenting of higher life forms such as plants and animals. This has led to debates about whether and under what conditions such patents should be allowed.
2. Access to genetic resources: Biotechnology often relies on access to genetic resources from countries rich in biological diversity. There are concerns that some developed countries and corporations may exploit these resources without fair and equitable benefit-sharing agreements with their countries of origin. The Nagoya Protocol, a separate international agreement within the Convention on Biological Diversity, addresses some aspects of the issue but intersects with trade discussions within the WTO.
3. Biosafety and trade: Trade in GMOs and biotech products raises biosafety concerns. Some countries have strict regulations and labeling requirements for genetically modified organisms and products containing GMOs, which can affect trade. Disputes arose when countries with different regulatory approaches clashed over the import and export of biotech products.

[5] *Untitled-1*, (Oct. 14, 2006), https://www.cuts-citee.org/pdf/RREPORT97-03.pdf.

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## VII. DISCUSSIONS BY THE WTO

### (A) Traditional Knowledge

1. Special Session of the TRIPS Council: The TRIPS Council has established a special session to specifically address intellectual property issues related to traditional knowledge, genetic resources, and folklore. During these special meetings, member countries discussed various proposals and potential amendments to the TRIPS Agreement to address traditional knowledge-related concerns.
2. Disclosure requirements: One of the proposals discussed was the idea of mandatory disclosure requirements for patent applicants. This would require patent applicants to disclose the origin of the genetic resources or traditional knowledge used in their inventions, as well as provide evidence of prior informed consent (PIC) and mutually agreed terms (MAT) with the communities or countries that are the source of the genetic resource or knowledge. The aim is to ensure transparency and compliance with access and benefit-sharing agreements.
3. Protection and recognition: Some discussions have focused on how to protect traditional knowledge under TRIPS. This includes recognizing the importance of traditional knowledge, promoting its documentation and protection, and ensuring that the rights of indigenous and local communities are respected.
4. Prevention of biopiracy: WTO discussions have also focused on the prevention of biopiracy, which involves the unauthorized commercial exploitation of traditional knowledge or genetic resources. There have been debates on how to strengthen TRIPS to provide more effective protection against biopiracy and to ensure that the benefits from the commercial exploitation of this knowledge and resources are fairly shared with the communities that own them.
5. Sui generis systems: Some countries have advocated the creation of sui generis systems (unique and specific legal systems) to protect traditional knowledge, similar to the systems established for Geographical Indications (GI) under TRIPS. These systems would provide specialized protection for traditional knowledge and potentially allow communities to have greater control over its use and commercialization.
6. Capacity building and technical assistance: WTO discussions have also highlighted the importance of capacity building and technical assistance to help developing countries establish legal frameworks and mechanisms to protect traditional knowledge.

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**(B) Biotechnology**

1. Patentability of biotechnological inventions: TRIPS stipulates that patents must be available for all inventions, whether products or processes, in all fields of technology. However, the patentability of biotechnological inventions, especially those involving life forms such as genetically modified organisms (GMOs), is still debated. Some countries have sought to clarify the conditions under which biotechnological inventions can be patented, considering issues of ethics, morality, and the balance between innovation and the public interest.
2. Disclosure and Access to Genetic Resources: The TRIPS Agreement does not directly address access and benefit sharing of genetic resources, which is a central issue in biotechnology. The Nagoya Protocol, a separate international agreement within the Convention on Biological Diversity, deals with this issue more comprehensively. Nevertheless, discussions within the WTO often intersect with these topics, as access to genetic resources is essential for many biotechnological innovations.
3. Biosafety and harmonization of regulations: WTO discussions also touched on the harmonization of regulations and biosafety measures. Disputes can arise when countries with different regulatory approaches to biotechnology clash over the import and export of biotechnology products. Discussions often focus on how to ensure that trade is not impeded by divergent national regulations while allowing countries to protect human health and the environment.
4. Geographical Indications (GI) for Agricultural Biotechnology Products: The protection of geographical indications is a debated topic in the context of biotechnology and agriculture. Some countries argue that geographical indications should be extended to include agricultural biotechnology products. This intersects with the wider debate on geographical indications, an issue also addressed by TRIPS.
5. Data exclusivity and regulatory data protection: Data exclusivity and regulatory data protection are key issues in the pharmaceutical and biotech industries. These concerns relate to the protection of data submitted to regulatory agencies to obtain approval to sell biotech products. Discussions often center on how to balance the need to protect data to stimulate innovation with the need to access that data to support generic competition.
6. Traditional knowledge and biodiversity: Biotechnology often relies on access to genetic resources from countries rich in biodiversity. Issues of access and benefit-sharing,

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including prior informed consent (PIC) and mutually agreed terms (MAT), are addressed in the context of biotechnological innovation, particularly with regard to traditional knowledge.

7. Technical assistance and capacity building: Developing countries often require technical assistance and capacity building to manage the complexities of biotechnology, intellectual property, and trade regulation. The WTO, in cooperation with other international organizations, provides support to help countries build the necessary expertise to effectively address these issues.

## VIII. CASE LAWS

### (A) Neem and Turmeric Case

The case of neem and turmeric[6] refers to a remarkable example of biopiracy and misappropriation of traditional knowledge by multinational corporations, mainly involving neem (Azadirachta indica) and turmeric (Curcuma longa). Neem and turmeric are plants with extensive historical use in traditional medicine and cultural practices in India and other countries.

In the late 20th century, several Western entities attempted to patent various applications of neem and turmeric without acknowledging the traditional knowledge of indigenous communities. For example, patents have been filed for neem-based pesticides, turmeric-based skin care products, and other applications.

The case attracted international attention and caused controversy as it exemplified issues related to intellectual property rights and the protection of traditional knowledge. India in particular has played a significant role in opposing these patents, emphasizing the importance of preserving indigenous knowledge and preventing biopiracy.

The Neem and Turmeric case ultimately led to a review of international patent laws and regulations to better protect traditional knowledge and ensure that communities with long histories of natural resource use are recognized and compensated when their knowledge is exploited for commercial purposes. She also highlighted the need for ethical practices in bioprospecting and a more comprehensive approach to intellectual property rights, especially regarding traditional knowledge and biological resources.

[6] Saipriya Balasubramanian, *Traditional Knowledge And Patent Issues: An Overview Of Turmeric, Basmati, Neem Cases.*, Germany (Apr. 18, 2017), https://www.mondaq.com/india/patent/586384/traditional-knowledge-and-patent-issues-an-overview-of-turmeric-basmati-neem-cases.

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### (B) Access to Medicines in Developing Countries

"Access to Medicines in Developing Countries"[7] is a critical global issue centered on ensuring that essential and life-saving medications are readily available and affordable in economically underprivileged regions. Developing countries frequently face challenges such as high medicine prices, insufficient healthcare structures, and non-supervisory barriers that impede their capability to give essential specifics to their populations.

Efforts to address this issue include measures like mandatory licensing, differential pricing, and technology transfer to make drugs more affordable and accessible. Also, transnational associations, governments, and non-governmental associations work to ameliorate healthcare structures and strengthen healthcare systems in developing countries.

Access to medicines in developing countries is a complex problem that demands a multi-faceted approach, with the goal of guaranteeing that individuals in these regions can access the drugs they need to treat and help with conditions effectively. This issue remains a critical global health and human rights challenge.

### (C) Novartis v. Union of India

Novartis has applied for an Indian patent on Glivec, a drug used to treat chronic myeloid leukemia. The Indian patent law has undergone changes as a result of commitments under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO).Under the amended Indian Patent Act, only inventions that represented a significant advance or new development were eligible for patents, a departure from the previous regime that allowed patenting of drugs.

In a landmark case, the Supreme Court of India upheld the rejection of Novartis' patent application. The court ruled that Glivec did not represent a significant therapeutic advance and as such could not be granted a patent under Indian law. The decision highlighted the need to balance the interests of pharmaceutical companies and public health and access to affordable medicines.

The Novartis case was seen as a major victory for public health advocates as it confirmed the Indian government's commitment to making essential medicines, especially for life-threatening diseases, available and affordable. It also set a precedent for interpreting India's patent law in a way that promoted public health and access to medicines over the protection of pharmaceutical companies' intellectual property rights. The case had wider implications for the global debate

[7] P Rojo, *[Access to essential drugs in developing countries]*, PubMed (Dec. 12, 2001), https://pubmed.ncbi.nlm.nih.gov/11858791/.

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on intellectual property, patents and access to medicines, particularly in the context of developing countries.[8]

### (D) Tobacco plain packaging case

In 2012, Australia introduced the Tobacco Packaging Act, which required all tobacco products to be sold in standardized plain packaging with large graphic health warnings.

The plain packaging legislation aimed to reduce the appeal of tobacco products, discourage smoking and improve public health.

In 2012, Ukraine, Honduras, the Dominican Republic and several other countries filed complaints with the WTO, arguing that Australia's plain packaging measures violated international trade agreements, including the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

The WTO Dispute Settlement Committee was established to assess these complaints. In 2017, a WTO panel ruled in Australia's favour and found that the plain packaging measures were consistent with its WTO obligations. Legal battles over plain tobacco packaging have had a significant impact on public health measures around the world, particularly in relation to tobacco control. Australia's introduction of plain packaging has been a model for other countries trying to reduce tobacco consumption. The WTO ruling in Australia's favour was seen as a victory for public health over commercial interests in the tobacco industry. The case contributed to discussions about the balance between public health policy and trade and intellectual property rights in international agreements.[9]

## IX. CONCLUSION

In conclusion, the current challenges to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) framework, as observed in the World Trade Organization (WTO), highlight the need for a delicate balancing act in the areas of traditional knowledge and biotechnology. These multifaceted issues underscore the complex nature of intellectual property rights and their far-reaching implications, affecting the protection of culture, innovation, global trade, and the public good.

The treatment of traditional knowledge under TRIPS reflects the complex interplay between

[8] Mohammad Suleman Palwala, *A Study On: Novartis AG v. Union Of*, United States (July 17, 2019), https://www.mondaq.com/india/patent/826478/a-study-on-novartis-ag-v-union-of-india.

[9] *WTO | dispute settlement - DS467: Australia — Certain Measures Concerning Trademarks, Geographical Indications and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging*, The Disputes https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds467_e.htm.

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preserving cultural heritage and ensuring equitable protection. Achieving consensus on the protection of traditional knowledge while respecting the rights of indigenous communities is a dynamic challenge that requires innovative solutions and global collaboration.

On the other hand, biotechnology raises concerns related to patenting, access to essential medicines, and environmental sustainability. In the modern age of biotechnological advancement, it is essential to strike a balance that encourages innovation while ensuring the affordability and availability of life-saving treatments.

As a global platform for trade negotiations and rule-making, the WTO plays a key role in addressing these issues. Ongoing negotiations, regional and bilateral agreements, as well as landmark cases such as the Neem and Turmeric dispute, provide crucial insight into the direction and potential solutions under TRIPS. This continuous dialogue is essential to ensuring that TRIPS remains a relevant and adaptable tool in a rapidly evolving global environment.

In this context, it is essential that TRIPS evolve to reflect the diverse needs and interests of all stakeholders, from indigenous communities and local innovators to global corporations and public health advocates. The pursuit of equitable and sustainable solutions in areas of traditional knowledge and biotechnology requires creativity and collaboration. Strengthening the link between intellectual property and societal well-being is a paramount effort.

In navigating the complexities of TRIPS within the WTO, the ultimate goal must be to foster an environment where innovation is nurtured, cultural heritage is preserved, and essential technologies and medicines are accessible to all. Only through comprehensive and forward-looking measures can we ensure that intellectual property rights continue to serve the greater good and contribute to the development of our global society.

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