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INFLUENCE OF THE WTO-TRIPS FRAMEWORK ON INDIAN PATENT LAW: LEGAL CHALLENGES IN PROTECTING HYBRID PLANT VARIETIES

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Abstract

This research article rigorously analyzes the impact of the WTO-TRIPS Agreement on Indian patent law, concentrating on the problems and possibilities associated with the protection of hybrid plant types. The research examines the convergence of international requirements and national legislative responses, particularly via the Protection of Plant Varieties and Farmers' Rights (PPVFR) Act. This study examines case studies, including Sakata Seed Corporation v. Deputy Controller of Patents and Designs, Monsanto v. Nuziveedu Seeds, and Novartis v. Union of India, to illustrate the evolution of Indian law in accommodating human engagement in biotechnology processes. The study used a content analysis technique to assess legislative provisions, judicial interpretations, and policy changes that affect the patentability of hybrid plants. It underscores the need for a sophisticated legal framework that promotes innovation, safeguards traditional agricultural rights, and aligns with food security objectives. The results indicate India's progressive compliance with international intellectual property norms, while maintaining a pro-farmer and pro-public interest stance in its patent system.

Keywords: WTO (World Trade Organization), Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, Indian Patent Law, Hybrid Plant Varieties, Biotechnology.

1 Introduction

As business travels globally and technology continues to evolve, it is more crucial than ever to have consistent laws protecting intellectual property rights. Intellectual property rules dictate how ideas are developed, employed, and distributed, ensuring that creators receive the recognition and compensation they deserve. However, national variations in IP legislation have historically hindered international trade, commerce, and innovation. Two of the most significant steps toward harmonizing global intellectual property laws were the establishment of the WTO and the adoption of the TRIPS agreement in 1995 [1]. TRIPS introduced minimum standards for IP protection, aligning national laws with multilateral frameworks and bringing more predictability to international trade. Despite its intended benefits, TRIPS has generated considerable debate, particularly concerning its impact on developing nations. While developed countries argue that stringent IP enforcement drives innovation and economic growth, developing nations raise

[1] Abdul Rehman Dar, *The Role of WTO and TRIPS in Shaping Global Intellectual Property Laws*, 2 280 (2025).

concerns over access to essential medicines, rising technology costs, and limitations on local innovation.

A specific area of contention under TRIPS is the protection of new plant varieties. The agreement mandates WTO members to adopt legal frameworks for such protection, allowing countries to choose between patents, an effective sui generis system, or a combination of both. This flexibility recognizes the diverse economic and agricultural conditions across nations. Developed countries typically favor strong patent protections that incentivize biotechnological advancements, whereas developing countries prioritize preserving traditional farming methods and farmers' access to seeds. The core challenge lies in striking a balance between encouraging innovation through IP rights and safeguarding public interests like food security, sustainable development, and equitable access to genetic resources [2]. Yet, current legal discourse often prioritizes breeders' rights and commercial biotech advancements over broader societal needs.

Intellectual property rights (IPR) are crucial in international trade law, as they protect inventions, creations, and technologies created by both people and legal entities [3]. The WTO governs the defence of IPR through the TRIPS Agreement, which aims to standardize IPR protection standards among member nations. The goals of international trade law are to achieve stability in global trade, increase the value of global trade, and improve the standard of living for people worldwide. Trade liberalization is the primary objective of international commerce, promoting long-term expansion and wealth for the whole world community. Each nation engages in international commerce, and its regulatory policies are formed using international rules to establish the content, structure, and course of its international commerce [4]. The defence of intellectual property rights is essential in protecting domestic industry and national economic interests, and policies that support the creation of IP-based goods can promote the export of creativity and innovation. However, government action can affect the flow of international commerce, particularly when it comes to the import and export of products and services protected by intellectual property rights.

A hybrid plant is a result of a controlled cross-pollination between two genetically distinct parent plants. This process aims to combine desirable traits from both parents into a single offspring. The process involves transferring pollen grains from one parent plant's flower to the other's pistil. Successful fertilization initiates the development of a hybrid seed, which carries a unique genetic blueprint inherited from both parents. The hybrid plant resulting from this seed will have a distinct genetic makeup, exhibiting a new array of characteristics derived from both parents. A patent is a legal entitlement granted by a government to an inventor of a new, useful, and non-obvious invention. It prevents others from using, selling, or distributing the invention without the inventor's

[2] Chenwen Wu, *Balancing Protection of Plant Varieties and Other Public Interests*, 16 SUSTAIN. (2024).

[3] Ram Narain Meena & Kapil Meena, *Intellectual Property Rights in Trade: Implications for Indian Agriculture* (2018).

[4] ANTONY TAUBMAN, HANNU WAGER & JAYASHREE WATAL, A HANDBOOK ON THE WTO TRIPS AGREEMENT (2020).

permission for 20 years. Patents stimulate innovation and technology development by protecting inventors' ability to sell their work and making them part of the public domain once the patent expires. There are three categories of patents: Utility Patents, Design Patents, and Plant Patents [5]. The patent system operates on the principle of disclosure for exclusivity, requiring inventors to disclose fully how their invention works in a patent application, creating knowledge-sharing and further innovation.

The WTO mandates member states to provide patent protection for new inventions in all technology fields, except for plant and animal processes. Article 27(3)b of the TRIPS agreement mandates member states to protect plant varieties either by patents or an effective sui generis system. There are four policy options for member states: sui generis system for protection of plants and plant varieties, patenting of plant varieties, a combination of the first two, or a sui generis system for plant varieties only [6]. The deadline for developing countries to provide protection was 1 January 2000, while least developed countries have until 1 January 2005. Many developing countries are currently examining options or formulating legislation to implement a sui generis system to comply with the TRIPS agreement. The most relevant policy questions are on the options available for members under a sui generis system.

The TRIPS agreement mandated member countries to protect plant varieties through patents, an effective sui generis system, or any combination thereof. India's response was the Protection of Plant Varieties and Farmers' Rights Act (PPV&FR Act), which sought to balance innovation in plant breeding with the protection of farmers' and traditional communities' rights [7]. The Act provided a sui generis regime, allowing farmers to save, use, sow, resow, exchange, share, or sell farm produce of a protected variety subject to specified conditions. The act also acknowledges the role of farmers and traditional communities in conserving and developing plant genetic resources. The influence of the WTO and the TRIPS agreement on Indian patent law, specifically on hybrid plants, is complex and debatable. Significant areas of concern include achieving a balance between innovation and access, farmers' rights and traditional knowledge, the effect on the seed industry, essentially derived varieties (EDVs), patentability of life forms, and challenges in implementation [8]. The changing legal and policy environment around plant variety protection in India demonstrates continuous attempts to balance innovation, farmers' rights, and maintenance of traditional farming systems in the context of global trade commitments. More research and analysis are required to evaluate the long-term effect of the WTO and the TRIPS agreement on Indian agriculture and ensure that the IPR regime supports sustainable and equitable growth.

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[5] Trevor Cook, *A User's Guide to Patents* (2019).

[6] D. J.F EATON, TRIPS AND PLANT VARIETAL PROTECTION: ECONOMIC ANALYSIS AND POLICY CHOICES (2002).

[7] Zainab Hussain Akram A. Khan, *TRIPs in Agriculture of India: An Overview* (2019).

[8] Aditya Satpute Aggarwal, Vani, *Role of Trips in Indian Agriculture Sector: Balancing Traditional Knowledge and Biotechnology*, AGECON SEARCH 1 (2024).

Plant Variety Protection (PVP) is a specific intellectual property rights system that provides plant breeders with exclusive rights over new varieties based on certain conditions. Regulated by the International Union for the Protection of New Varieties of Plants (UPOV), the system is recognized in 75 member states and provides rights like the Plant Breeder's Right (PBR) and Plant Variety Right (PVR), usually for at least 20 years. To be eligible for protection, a new plant variety should be novel, distinct, uniform, and stable (DUS) [9]. Most countries, such as the USA, Japan, and Australia, supplement PVP with plant patents and utility patents, protecting innovations like genetic characteristics or breeding techniques. The DUS test is the key to confirming these requirements. Recent developments involve the incorporation of molecular marker-based DUS tests, which provide higher precision, reproducibility, and consistency with respect to environmental conditions [10]. SNP and SSR markers are being used more for varietal identification, enhancing efficiency in variety registration and protection. Application of techniques like next-generation sequencing (NGS) and genome editing (e.g., CRISPR-Cas9) represents the emergence of more accurate, DNA-based plant breeding methods. Nevertheless, legal interpretation of EDVs remains contentious and questions regarding the harmony among innovation, breeders' rights, and social welfare especially as developments like the Open-Source Seed Initiative (OSSI) undermine traditional IP paradigms need to be addressed.

This study is useful since it examines how the global rules, i.e., the WTO-TRIPS Agreement, have influenced the Indian patent laws and the plant variety protection laws. In a country like India, where agriculture is a major contributor to the economy and people's livelihood, the protection of new crop varieties, especially hybrid crops, is important. These hybrids increase the yield of a crop, are resistant to disease, and help farmers cultivate quality crops. However, legally safeguarding them is tricky because one has to balance the rights of breeders who create these hybrids with the traditional rights of farmers. This research helps us understand how well India's current laws, like the PPVFR Act, are faring in this regard. It also analyzes whether such legislations need to be improved so that innovation is promoted but the interest of farmers and the agricultural industry remains safeguarded.

The main aim of this research is to study the influence of the TRIPS Agreement on the Indian legal system in protecting plant varieties, especially hybrids. It discusses India's response to international regulations by creating its own law, the Protection of Plant Varieties and Farmers' Rights (PPVFR) Act. The study will look into the effectiveness of this law in protecting new hybrid varieties and whether it's meeting the needs of farmers along with breeders. It will also study any legal or pragmatic issues faced while enforcing these laws. The scope of the study includes understanding the legal system, analyzing the issue of protecting hybrid plant varieties, and

[9] Ju Kyung Yu & Yong Suk Chung, *Plant Variety Protection: Current Practices and Insights*, 12 GENES (BASEL). (2021).

[10] Rolf Jördens, *Progress of Plant Variety Protection Based on the International Convention for the Protection of New Varieties of Plants (UPOV Convention)*, 27 WORLD PAT. INF. 232 (2005).

suggesting how the current system can be improved. This study is of special relevance to lawyers, and agri-innovators who are interested in building a balanced and fair intellectual property system for Indian agriculture.

This research notably contributes by combining statutory analysis, court rulings, and policy discussions to evaluate the safeguarding of hybrid plant types under Indian law. This study integrates international frameworks with India's sui generis legal response via the PPV&FR Act, in contrast to prior material that typically examines TRIPS responsibilities or plant variety protection separately. It underscores the changing function of Indian courts in reconciling innovation with farmers' rights, therefore providing a unique viewpoint on the alignment of global intellectual property standards with local socio-economic conditions.

2 Literature review

The TRIPS Agreement, introduced by the WTO has had a direct effect on the national patent regimes, like in India. One such significant field that has been affected is the protection of plant varieties, particularly hybrid plants that have been developed through scientific research. The following is a literature review that addresses the effect of TRIPS on Indian patent law specifically in relation to challenges and opportunities for the protection of hybrid plant varieties. It addresses the evolution of India's legal framework, specifically the passage of the Protection of Plant Varieties and Farmers' Rights (PPVFR) Act, and its interfacing with patent law. The discussion also refers to scholarly debates regarding balancing innovation, farmers' rights, and national interests in the context of international commitments under TRIPS. [11] Since the TRIPS Agreement in 1994, intellectual property policy making has become more complex and sophisticated. IP governance is now viewed as a broader policy aimed at increasing commercially relevant creativity and innovation. This, if done correctly, can lead to increased welfare and economic development. Recent analyses highlight the importance of innovation clusters, which combine public and private funding, higher education resources, and structures to attract and retain innovators and new companies. However, governance does not necessarily fit all, and one size does not fit all.

[12] explored the impact of the digital economy on intellectual property law, highlighting that despite numerous laws, no implementation has been made. The digital world has significantly impacted intellectual property law, with cyber squatter legislation and significant legal and economic developments. They emphasized the importance of technology-independent policy formulation and adapting copyright laws to ensure free access to information in the digital economy. Stakeholder participation is crucial for designing such adaptations.

[11] Daniel Gervais, *Trips and Innovation : How Recent Developments Might Inform Canada ' S Foreign Technology Policy* *, 141 (2021).

[12] Ximei Wu, *Impact of Digital Economy on Intellectual Property Law*, 13 117 (2020).

[13] The TRIPs agreement, set to be reviewed at the end of 1999, aims to set minimum standards for IP rights worldwide. Successful implementation requires legal, administrative, and institutional reforms, appropriate research investments, and first-rate science and technology capability. The agreement can promote innovations, technology transfer, foreign direct investment, use of genetic resources, and environmental protection. The success of Indian agriculture may be determined more by effective marketing and product innovation than yield improvement.

[14] analyzed international legal regimes for intellectual property rights in protecting life forms and plant varieties. It provided regulatory options for national governments to protect plant varieties while achieving public policy objectives related to plant genetic resources. They included tables to convey complex information and identifies international institutions and intergovernmental organizations that regulate intellectual property rights in plant varieties and plant genetic resources. It also discussed the core obligations outlined in international intellectual property agreements. [15] Patent Law and Competition Law are crucial for innovation and consumer welfare, but achieving a balance between them is challenging. Countries can adopt different approaches to achieve this balance, leading to varying interfaces between Competition Policy and IPRs. They examined the interface between IPRs and competition from two perspectives: pro-competition provisions in patent law and IP-related provisions in competition law, focusing on India's case. The IP-Competition interface is traced at the time of patent law-making and law enforcement.

[16] explored the motivations behind preferential trade agreements (PTAs) and their influence on international regime complexity. It suggested that states strategically reference their preferred norms and institutions in adjacent forums to make regime complexes more compatible with their preferences. The success of these connections depends on the power and preferences of the negotiating countries. They analyzed data on intellectual property rights provisions in over 500 PTAs between 1992 and 2018, identifying connections preferred by developed countries to reinforce the WTO and WIPO, and those preferred by developing countries to advance alternative norms and institutions. [17] Patents are legal rights granted to inventors after publishing an invention disclosure document. They are private and require a patent holder to enforce them. The process of obtaining patents varies between countries, with US requirements including novelty, utility, and no obviousness. Under the WTO's TRIPS Agreement, patents are available for new, innovative,

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[13] Surinder Kumar & Aditya Mishra, *Impact To Trips Agreement on Indian Agriculture*, 234 (2016).

[14] Sayed Arsalan & Sadat Nasseri, *An Overview of Protection the Life Forms and Plant Varieties Under Intellectual Property Laws; a Comparative Study Between India and Afghanistan*, 1.

[15] Base Fish, *Interface between Competition Policy and Intellectual Property Rights: Select Case Studies from India*, 2507 1 (2020).

[16] Manfred Elsig et al., *Connecting Regimes: Preferential Trade Agreements and the Management of the Intellectual Property Rights Regime.*, PEIO.ME 0 (2024).

[17] PRAMIT CHANDRA ROUT, Subhankar Behera & Ananya Swain, *Patentability Criteria in India: A Critical Analysis of Case Laws*, SSRN ELECTRON. J. 1 (2024).

and industrially applicable inventions in WTO member states. Subject matter varies, and a minimum twenty-year protection period is required. A patent application must disclose technical details about the innovation. The Indian Patents Act, 1970, provides a study on patentability criteria.

[18] The special issue explored the impact of the TRIPS agreement on international business in the late 20th and early 21st century. It provides a background on TRIPS, examines national patent policies, and reviews literature on historical variation. The issue of domestic politics of implementation as new rules migrate from international to national levels is also discussed. The special issue also examines the implications of TRIPS for the governance of innovations in ICT-based industries, where IPR becomes less effective and more necessary due to the speed and distributed nature of innovation. [19] The patent protection for genetically modified plants in India is uncertain due to economic and ethical considerations. Consistent public policy and regulatory control are crucial for introducing genetically engineered crops in India, which aims to foster an innovation-based economy. Research questions include how traits like insect resistance are inserted in plants through transformation methods, whether genetic modification can be considered an essentially biological process, and how to classify this process for the purpose of Section 3(j) of the Indian Patents Act, 1970.

[20] explored the legal regimes governing intellectual property rights in the protection of life forms, patents on life forms, and plant varieties. It provided regulatory options for national governments to protect plant varieties while achieving public policy objectives related to plant genetic resources. A patent is an exclusive right granted by the government to a patentee in exchange for full disclosure of their invention and excluding others from using, using, selling, or importing the patented product. Identified international institutions and intergovernmental organizations that regulate intellectual property rights in plant varieties and genetic resources.

[21] discussed the legal control mechanism of the Protection of Plant Varieties and Farmers' Rights Act, passed by the Indian Government in 2001. India became a signatory to the TRIPs in 1994, requiring legislation for plant variety protection. India practiced this alternative, implementing the Indian Patent Act, 1970, which excluded agriculture and plant strategies from patentability. A sui

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[18] Suma Athreye, Lucia Piscitello & Kenneth C Shadlen, *Twenty-Five Years since TRIPS: Patent Policy and International Business*, 3 J. INT. BUS. POLICY 315 (2020).

[19] WENJUAN ZHANG, CONSTITUTIONAL GOVERNANCE IN INDIA AND CHINA AND ITS IMPACT ON NATIONAL INNOVATION (2019).

[20] Mohammad Rasikh Wasiq, *INTELLECTUAL PROPERTY RIGHTS FOR LIFE FORMS:A LEGAL DISCOURSE TO INDIAN LEGAL FRAMEWORK*, IV (2023).

[21] Upendra Grewal, *THE FUNDAMENTAL ISSUES RELATED TO THE LEGAL CONTROL MECHANISM OF PROTECTION OF PLANT VARIETIES AND FARMERS ' RIGHTS IN INDIA* (2021).

generis framework was developed, integrating the privileges of breeders, farmers, and village communities, while ensuring impartial sharing of advantages.

[22] India has developed IPR laws to regulate GM technologies, including GM crops, seed production, benefit sharing, preventing biopiracy, and foreign exploitation of natural resources. This paper aims to collect and discuss these laws, focusing on India's intellectual property laws related to GM crops and other laws and institutional frameworks available to regulate the impact of transgenic or GM crops on the environment, human health, and biosafety. The aim is to assess their effectiveness in light of the global scenario, as biotechnology, like all new technologies, has some apprehensions and risks.

[23] explored the current framework of Intellectual Property Rights in agriculture, focusing on farmer's rights and equal importance given to innovation and development. It compared the International Framework for Intellectual Property Rights (UPOV) convention and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). They aimed to balance farmer's privilege with plant breeder's rights, highlighting the conflict between the need for farmers to conserve and sustainably use diverse varieties and the need for breeders to commercialize protected varieties. They suggested that international instruments like TRIPS provide a solid foundation for "sui generis IP" and allow member countries to model their own legislation based on either UPOV or CBD & ITPGRFA.

2.1 Research Gap

Despite extensive amounts of literature on the impact of the TRIPS Agreement has changed Indian copyright law, but there is still a big hole in the study about how plant variety protection, especially for hybrid plants, and the changing legal situation under the TRIPS rules interact. Many research papers have been written about how TRIPS would impact intellectual property rights around the world. These papers have looked at agricultural innovation as well as plant genetic resources. However, there aren't many that talk about the specific problems and chances that exist in India when it comes to hybrid plant varieties. The Protection of Plant Varieties and Farmers' Rights (PPVFR) Act has also been looked into, but there hasn't been a lot of study that looks at how well it works when property laws are in disagreement. Also, the moral and financial effects of patenting genetically modified plants, as well as the legal uncertainty of the patents, have not been fully studied yet. This means that there is a lack of knowledge about how these issues affect Indian agriculture and innovation.

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[22] V O L Vi & Arun Maurya, *CURRENT LEGAL STATUS OF GM CROPS IN INDIA WITH SPECIAL REFERENCE TO INTELLECTUAL PROPERTY*, VI 51 (2021).

[23] Divya Sampath, *Bridging the Gap between the Developing and Developed Worlds: An Analysis of International IP Instruments in Agriculture Policy*, 23529 GROU 1 (2018).

3 Research Methodology

This research adopts content analysis as a method for investigating the association between international patent law and protecting hybrid plant varieties in India with the WTO-TRIPS Agreement. The paper examines major legal cases, judgments by courts, legislative documents, and academic papers to determine the role of principles of intellectual property, international standard-setting, and domestic legal contexts in determining protection of plant varieties. The research is centered on the interaction between the WTO-TRIPS Agreement and India's Protection of Plant Varieties and Farmers' Rights (PPVFR) Act, impacting the legal protection and recognition of hybrid plant varieties. Secondary data collected from research articles, law journals, policy reports, and global treaties are examined using content analysis to determine prevalent themes and lessons learned about the economic, legal, and social implications of hybrid plant protection in the context of India's compliance with TRIPS.

4 Case Studies

4.1 Influence of WTO-TRIPS Agreement on Indian Patent Law

The Agreement on TRIPS was part of the WTO agreements established during the Uruguay Round (UR) negotiations, designed to provide a robust framework for WTO member countries to enforce the Intellectual Property Rights (IPR) of domestic firms beyond territorial boundaries. The Agreement on TRIPS is the most crucial component of GATT concerning knowledge and invention-based economic sectors [24]. It was previously shown during trade talks that many nations differ significantly in their economic and developmental state, as well as in their capacity to produce or use contemporary technology [25]. Member nations were obligated to initiate legislative reforms to establish rules and regulations that meet international standards, as outlined in the TRIPS Agreement. If the inventing businesses from member countries are dissatisfied with the IPR protection granted for their discoveries, disputes between the innovating firm's host nation and the offending country are managed via the WTO's Dispute Settlement Understanding (DSU). The DSU allows for cross-agreement retaliation, meaning that a country found in violation of its TRIPS Agreement obligations may face retaliatory trade sanctions under a different WTO agreement, typically the General Agreement on Tariffs and Trade (GATT) [26].

The incorporation of the TRIPS Agreement into the WTO marked a significant distinction for multilateral trade accords, as it emphasized a key non-trade concern for the first time. The TRIPS Agreement delineates the obligations of member countries regarding the protection of intellectual property rights within their domestic jurisdictions, whereas other WTO agreements aim to

[24] Akram A. Khan, *supra* note 7.

[25] M D Nair, *GATT, TRIPS, WTO and CBD–Relevance to Agriculture* (2011).

[26] Ryan Cardwell & Pascal L Ghazalian, *The Effects of the TRIPS Agreement on International Protection of Intellectual Property Rights*, 26 INT. TRADE J. 19 (2012).

establish a conducive regulatory framework for international trade and to mitigate barriers and deceptive trade practices among member nations. Member countries of the WTO, under pressure from developed nations, consented to the inclusion of the TRIPS Agreement in exchange for guaranteed access to the markets of developed countries for industrial and agricultural goods. The adoption of the TRIPS agreement has prompted inquiries about the potential benefits of extending intellectual property rights protection to agriculture for both manufacturers and consumers, as well as its probable effects on food security. [27]. Considering the discrepancies, it is essential to apply uniform standards across all members, regardless of their evolving needs. A critical concern is the influence of TRIPs on food security due to the elimination of restrictions placed by TRIPs on patented agricultural items, including germplasm, plant varieties, seeds, and processed foods. This topic was not addressed in Doha because agricultural matters fall under the Agreement on Agriculture and constitute a significant aspect of discussions under the Doha Development Agenda. A comprehensive elucidation of several pertinent sections in TRIPs and corresponding national rules might greatly aid developing nations in addressing the challenges posed by the intellectual property system in agriculture and food security.

The rationale behind the TRIPs Agreement and Patent Protection

The Uruguay Round concluded with the negotiation of the TRIPS Agreement. For the first time, the agreement mandates that member patent biotech innovations, including products, processes, and plant varieties. Additionally, it establishes a legal procedure for safeguarding intellectual property rights. Organizations are granted comprehensive control over the entire food chain, as well as research and development, through patent protection in this field. Consequently, Monsanto, DuPont, and Syngenta have gained global control over the sale of seeds [28]. Monsanto owned or authorized transgenic traits on over 80% of the land in the United States that was planted with primary field crops [29]. In order to utilize this patented seed, farmers must submit a licensing fee and execute an agreement with the biotech corporation. The authorizations prohibit the conventional practice of seed storage, in favor of farmers adhering to specific farmer practices and selling in a specific market. The company can fraudulently increase the price of seedlings in this way [30]. Furthermore, the patent provided safeguards the rights of the companies in terms of extant GM production; the company's objective is to safeguard impending production. An additional issue that patenting has enabled is the threat to natural species and varieties, in addition to the business

[27] Jane Payumo, Howard Grimes & Philip Wandschneider, *Status of National Intellectual Property Rights (IPRs) Systems and Its Impact to Agricultural Development: A Time Series Cross Section Data Analysis of TRIPS Member-Countries*, 5 INT. J. INTELLECT. PROP. MANAG. 82 (2012).

[28] Philip H Howard, *Visualizing Consolidation in the Global Seed Industry: 1996–2008*, 1 SUSTAINABILITY 1266 (2009).

[29] J Fernandez-Cornejo, *Monsanto Transgenic Trait Dominance in US Market 1996–2007*, ORGAN. COMPET. MARK. LINCOLN, NE, USA (2008).

[30] Tatjana Papić Brankov & Koviljko Lovre, *WTO Law and Genetically Modified Products* (2013).

monopoly. Developing nations accuse developed nations of appropriating their traditional knowledge and varieties. The TRIPS Agreement was established six months following the Convention on Biological Diversity (CBD). The CBD convention establishes the conservation of biological diversity as "a common concern of humankind" for the first time in global law. It also specifies the equitable allocation of resources and access to technology, the safety approach, and the evaluation of traditional knowledge. The substantial differences between the two agreements, TRIPS and CBD, have resulted in a conflict. The provisions that pertain to agriculture suggest that nations are not obligated to grant patents for vegetation and animals. They should provide protection for plant varieties through patents, an effective sui generis system, or both.

Article 27.1 of the TRIPs Agreement mandates that members grant patents for "all inventions, whether products or processes, in all fields of technology." Plants and animals are exempt from patentability under Article 27.3(b), but microorganisms are not. Additionally, it requires member nations to permit the protection of new plant varieties through patents, an effective sui generis system, or a combination of both. One potential sui generis system that is likely to be recognized as effective is the Plant Breeders Rights (PBR) by the Convention of the UPOV. The International Convention for the Protection of New Varieties of Plants (UPOV Convention) was undoubtedly in the minds of the drafters of the TRIPS Agreement, a system that is currently being implemented by numerous countries. Nevertheless, certain developing countries are establishing their own sui generis systems, citing aspects of UPOV that they wish to enhance [31].

4.2 The Case in Brief: Biotech Innovation Meets Patent Law

Sakata Seed Corporation, a well-established entity in the global agricultural sector, pursued a patent for a novel approach to the production of cytoplasmic male sterile (CMS) Eustoma plants. This method, which entailed the application of genetic techniques to introduce male sterility into plants for the purpose of hybrid seed production, was crucial for the advancement of agricultural productivity. Nevertheless, the Indian Patent Office denied the application, citing Section 3(j) of the Patents Act, which forbids patents on "essentially biological processes" for plant propagation. Sakata refuted this decision, contending that their approach necessitated substantial human intervention and was not solely a biological process, but rather a technical innovation. They filed an appeal with the Madras High Court, which conducted a review of the case and established the groundwork for a significant legal change in the perception of biotechnology patents [32].

The Role of Section 3(j) in India's Patent Law

The Indian Patents Act's Section 3(j) explicitly excludes biological processes for plant production from patentability. The objective of this section is to safeguard the public domain from monopolistic control over naturally occurring processes and materials by preventing the patenting

[31] Kshitij K Singh, *Intellectual Property Rights in Agricultural Biotechnology and Access to Technology: A Critical Appraisal*, 18 ASIAN BIOTECHNOL. DEV. REV. (2016).

[32] Aumirah, *The Sakata Seed Case: A Landmark Decision Shaping India's Biotech Patent Landscape*, (2024).

of naturally occurring biological phenomena. Nevertheless, the distinction between a biological process and a technical, human-influenced process is not always evident. This ambiguity has resulted in substantial legal challenges, necessitating that the courts establish the boundaries of patentable biotechnological inventions in India.

Internationally, biotechnological patents are treated in a comparable manner, with frameworks such as the European Patent Convention (EPC) distinguishing between biological processes and those that necessitate technological intervention. This distinction is the foundation of the Sakata case, in which the Court was tasked with determining whether the human-engineered components of the process were sufficient to transcend the definition of "biological processes."

Key Arguments from Sakata Seed Corporation

Sakata Seed Corporation put forth several critical points during the appeal:

- **Significant Human Intervention:** Sakata underscored the innovative aspect of the genetic engineering used in their methodology, stressing that the procedure required considerable technological assistance.
- **Deviation from Natural Processes:** The corporation said that the approach constituted not only a traditional breeding technique but a sophisticated biotechnology intervention.
- **Global Precedents:** Sakata cited international patent legislation, particularly the European Patent Convention, which differentiates between biological processes and those including human innovation and technological methodologies.
- **Previous Indian Legal Rulings:** The corporation cited prior Indian legal rulings, notably the IPAB opinion in O.A./02/2012/PT/DEL (2013), which determined that human participation in biotechnological methods suffices to render the methodology patentable.

The Madras High Court's Judgment

The Madras High Court ruled in favor of Sakata Seed Corporation and sent the matter back to the Patent Office for further review. The Court identified five significant considerations in its ruling:

- **The Distinction of Human Intervention:** The Court recognized that the approach in issue had significant human involvement, which distinctly separated it from a purely biological process.
- **Global Consistency:** The Court's judgement conformed to international legal norms, indicating that the method's technical and human-engineered components rendered it patentable under Indian law.
- **Reevaluation of Patent Examination:** The ruling emphasized the need for uniform use of patent examination standards in India, particularly concerning biotechnological advancements.

Global Context: A Comparative Perspective

The rationale of the Sakata case largely adheres to international legal norms. In Europe, the Tomato II and Broccoli II cases demonstrated that methods requiring technological procedures, such as genetic modification, may be eligible for patent protection, even when they pertain to biological material. In the United States, judicial precedents like Mayo Collaborative Services v. Prometheus Laboratories underscore the need for an innovative application of natural laws, which is essential for patent eligibility.

Impact on Biotechnology in India

The judgment in the Sakata case has far-reaching implications for the Indian biotechnology sector:

1. **Encouraging Technological Innovation:** The case reinforces the importance of human-driven innovation in biotechnology, encouraging further developments in genetic engineering, hybrid seed production, and other technical innovations.
2. **Fostering Agricultural Advancements:** The patented process could have a significant impact on India's agricultural productivity, improving crop resilience, pest resistance, and overall yield, which is essential for food security.
3. **International Collaboration:** The alignment of Indian patent law with international standards fosters global collaboration and encourages foreign investment in India's growing biotechnology industry.

The ruling establishes a definitive precedent for the biotech and agricultural industries: substantial human participation and technological measures may elevate a process above the "biological process" restriction, rendering it eligible for patent protection.

"At Aumirah, we focus on navigating the dynamic realm of biotechnology patent law." Our staff is proficient in navigating the intricacies of Section 3(j) and offers strategic counsel to inventors pursuing patent protection for human-operated processes. We collaborate intimately with customers to safeguard their ideas, both in India and internationally, while accommodating the evolving landscape of biotechnological innovation.*"*

Conclusion:

The Sakata Seed Corporation case signifies a crucial development in India's biotechnology patent legislation. The ruling clarifies the meaning of Section 3(j) and recognizes the significance of human interaction in biotechnological processes, hence facilitating more innovation in India's biotech industry. This case enhances India's legal structure and establishes the nation as a significant participant in the global biotechnology arena.

4.3 Case Law on Protection of Hybrid Plant Varieties

Monsanto Technology LLC v. Nuziveedu Seeds Ltd. (2018)

Monsanto had a patent (IN214436) for Bt cotton technology, which included the incorporation of a gene (Cry2Ab) into cotton plants to provide resistance against bollworms. Monsanto granted a license for this technology to Nuziveedu Seeds and its affiliates [33] .

Legal Issue: Nuziveedu contested the legitimacy of Monsanto's patent, asserting that the subject matter was included by the exclusion in Section 3(j) of the Indian Patent Act, since it related to plants and fundamentally biological processes.

Court's Decision: The Delhi High Court determined that the incorporation of the Bt gene into cotton plants constitutes an "essentially biological process" and is thus not patentable under Section 3(j). The court underscored that while the gene may be patentable in isolation, its incorporation into the plant becomes it part of a biological process, which is not eligible for patent protection [34].

Implication: This case highlights the difficulties in securing patents for biotechnology innovations in India, particularly in relation to agriculture. It underscores the need for a distinct separation between patentable biotechnological discoveries and non-patentable biological processes.

4.4 Case of Novartis AG v. Union of India, (2013) 6 SCC 1

Novartis submitted a patent application for the beta crystalline variant of Imatinib Mesylate, used in leukemia treatment. The Indian application Office rejected the application according to Section 3(d) of the Indian Patents Act, which prohibits patents on changes of existing chemicals unless they demonstrate improved medicinal effectiveness.

Issue: Determining whether the modified version of Imatinib Mesylate represents a novel innovation or is just an effort to extend the duration of an existing patent.

The Supreme Court determined that the alteration did not improve medicinal effectiveness and rejected the patent. It determined that "efficacy" under Section 3(d) pertains to therapeutic effectiveness, and simple enhancements in bioavailability do not meet the criteria.

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[33] Ghayur Alam∗, *6 . MONSANTO ' S BT COTTON PATENT , INDIAN COURTS AND PUBLIC POLICY Ghayur Alam ∗ ABSTRACT This Paper Primarily Deals with an Unanswered Substantial Question of Patent Law That Has Arisen in India . The Question Is Whether an Invented Nucleic Acid Sequenc*, 71 (2019).

[34] Pratistha Sinha, *India: Monsanto Technology LLC And Ors Vs. Nuziveedu Seeds Ltd. And Ors*, KHURANA KHURANA ADVOCATES IP ATTY. 1 (2018).

This decision demonstrated that incremental discoveries without medicinal benefit are not patentable in India. It emphatically bolstered India's position on public health and equitable access over patent monopolies.

4.5 Case of Sakata Seed Corporation v. Deputy Controller of Patents and Designs, Madras High Court, 2023

Sakata Seed Corporation submitted a patent for a method to cultivate Eustoma plants exhibiting CMS by backcrossing processes. The Patent Office denied the application according to Section 3(j) of the Patents Act, asserting it constituted an "essentially biological process" and was thus non-patentable [35].

Issue: The determination of whether the asserted technique, including human involvement, is subject to exclusion from the limitation on biological processes for plant production as delineated in Section 3(j).

The Madras High Court determined that the innovation included considerable human participation, including hybrid seed screening and trait selection, so transcending a purely natural biological process. The Court determined that the technique was not prohibited by Section 3(j) and remitted the issue to the Patent Office for reevaluation.

This decision broadens the parameters for patent protection in biotechnology and agriculture by confirming that human-engineered technologies, especially those associated with plant production, may be patented. It harmonizes Indian interpretation with international norms (e.g., EPC Rule 26(5)) and facilitates prospects for patenting hybrid seeds and GMOs under Indian legislation.

Ambiguity Regarding Sale and Propagation of Hybrid Seeds Case

In Maharashtra Hybrid Seed Co and Anr v. Union of India and Anr [(2015) 217 DLT 175], the petitioners challenged the ruling of the Registrar, PPVFR Authority, which determined that parent lines of established hybrid varieties are ineligible for registration as 'new' plant varieties under the PPVFRA. If the hybrid is classified as a 'extant variety' with general awareness, its parental lines cannot be considered new [36].

The Delhi High Court resolved many difficulties concerning specific sections in the Act, notably that a hybrid seed does not constitute 'propagating material' as it cannot regenerate any of the parent line kinds. The Act does not define "harvested material"; nevertheless, "propagating material" is defined under Section 2(r) as a plant or seed capable of regeneration. Invalid input. Please provide text for rewriting. The court determined that the selling of hybrid varieties contravenes Section 15(3)[ii] of the Act for those varieties that may germinate into either parent

[35] Kan & Krishme, *Sowing the Seeds of Change: Patent Law, Biotechnology, and the Sakata Case* (2024).

[36] Pranavnayar, *Analysis of Protection of Plant Varieties and Farmers Rights Act, 2001 in Light of Judicial Decisions Laid Down by the Indian Courts* (2020).

plants, constituting exploitation of such plants. According to the petitioner's interpretation of the Act, they would acquire exclusive rights over the hybrid and parent seeds for a maximum of 45/54 years, which considerably exceeds the 15/18-year duration stipulated in the Act.

The High Court used the mischief rule to rule against the petitioners, notwithstanding the ambiguity in the text of Section 15(3). The court acted accordingly, since it is firmly established that in cases of statutory ambiguity, a purposive interpretation that advances the Legislature's aim must be used. The legislative purpose of the PPVFRA is to protect the interests of farmers and plant breeders. Furthermore, the Administrative and Legal Committee of UPOV, according to Article 6(1) of the 1991 Act of the UPOV Convention, determined in a similar issue that the originality of the parent lines is lost via the commercial exploitation of its hybrid, rendering such interpretations untenable. India was mandated to safeguard the intellectual property rights of certain plant types due to its ratification of the TRIPS agreement.

4.6 Findings

The examination of the impact of the WTO-TRIPS Agreement on Indian patent law, particularly concerning hybrid plant types, uncovers a multifaceted and dynamic legal framework. India's strategy has been to reconcile its international commitments under TRIPS with its local interests, especially in ensuring food security, fostering innovation, and guaranteeing farmers' rights. The integration of Article 27.3(b) of the TRIPS Agreement into Indian patent law via Section 3(j) of the Patents Act has resulted in a constrictive interpretation that precludes the patentability of plants, seeds, and fundamentally biological processes. Recent legal rulings, like the Sakata Seed Corporation case, have expanded this approach by acknowledging the importance of human engagement in developments connected to plants. The judiciary has delineated the parameters of patentable subject matter in biotechnology through pivotal case laws, including Monsanto v. Nuziveedu, Novartis AG v. Union of India, and Dimminaco AG, differentiating between naturally occurring processes and those requiring significant human and technological intervention. The ruling in Maharashtra Hybrid Seed Co. v. Union of India underscores the regulatory difficulties in delineating and safeguarding hybrid seeds and their parental lines within the sui generis framework of the PPVFR Act, 2001, illustrating the necessity for clarity and uniformity in policy and legal interpretation. The results underscore that India has achieved TRIPS compliance while prioritizing national interest and public welfare.

5 Conclusion

In conclusion, the WTO-TRIPS Agreement has profoundly impacted Indian patent law by necessitating the adoption of international norms for intellectual property protection, particularly in biotechnology. India has customized its implementation to align with its socio-economic interests, especially in agriculture. The progression of judicial interpretation, particularly in cases concerning hybrid plant varieties, illustrates an increasing recognition of the necessity to foster technological innovation via patent protection when warranted, especially when human intervention distinguishes an invention from a naturally occurring process. The Sakata case

signifies a pivotal moment, indicating a transition towards a more sophisticated and internationally harmonized understanding of patentability in plant biotechnology. Nonetheless, uncertainty persists about the regulation of hybrid seeds under the PPVFR framework, indicating a need for more legislative and judicial elucidation. As India advances its agricultural and biotech industries, the equilibrium between fostering innovation, adhering to TRIPS requirements, and guaranteeing fair access for farmers and the public will persist as a critical issue in the formulation of its intellectual property system.

6 Bibliography

Abdul Rehman Dar, The Role of WTO and TRIPS in Shaping Global Intellectual Property Laws, 2 280 (2025).

Chenwen Wu, Balancing Protection of Plant Varieties and Other Public Interests, 16 Sustain. (2024).

Ram Narain Meena & Kapil Meena, Intellectual Property Rights in Trade: Implications for Indian Agriculture (2018).

Antony Taubman, Hannu Wager & Jayashree Watal, A Handbook on the WTO TRIPS Agreement (2020).

Trevor Cook, A Userâ€™s Guide to Patents (2019).

D. J.F Eaton, TRIPS and Plant Varietal Protection: Economic Analysis and Policy Choices (2002).

Zainab Hussain Akram A. Khan, TRIPs in Agriculture of India: An Overview (2019).

Aditya Satpute Aggarwal, Vani, Role of Trips in Indian Agriculture Sector: Balancing Traditional Knowledge and Biotechnology, AgEcon Search 1 (2024).

Ju Kyung Yu & Yong Suk Chung, Plant Variety Protection: Current Practices and Insights, 12 Genes (Basel). (2021).

Rolf JÃ¶rdens, Progress of Plant Variety Protection Based on the International Convention for the Protection of New Varieties of Plants (UPOV Convention), 27 World Pat. Inf. 232 (2005).

Daniel Gervais, Trips and Innovationâ€¯: How Recent Developments Might Inform Canada â€™ S Foreign Technology Policy *, 141 (2021).

Ximei Wu, Impact of Digital Economy on Intellectual Property Law, 13 117 (2020).

Surinder Kumar & Aditya Mishra, Impact To Trips Agreement on Indian Agriculture, 234 (2016).

Sayed Arsalan & Sadat Nasseri, An Overview of Protection the Life Forms and Plant Varieties Under Intellectual Property Laws; a Comparative Study Between India and Afghanistan, 1.

Base Fish, Interface between Competition Policy and Intellectual Property Rights: Select Case Studies from India, 2507 1 (2020).

Manfred Elsig et al., Connecting Regimes: Preferential Trade Agreements and the Management of the Intellectual Property Rights Regime., Peio.Me 0 (2024).

PRAMIT CHANDRA ROUT, Subhankar Behera & Ananya Swain, Patentability Criteria in India: A Critical Analysis of Case Laws, SSRN Electron. J. 1 (2024).

Suma Athreye, Lucia Piscitello & Kenneth C Shadlen, Twenty-Five Years since TRIPS: Patent Policy and International Business, 3 J. Int. Bus. Policy 315 (2020).

Wenjuan Zhang, Constitutional Governance in India and China and Its Impact on National Innovation (2019).

Mohammad Rasikh Wasiq, INTELLECTUAL PROPERTY RIGHTS FOR LIFE FORMS:A LEGAL DISCOURSE TO INDIAN LEGAL FRAMEWORK, IV (2023).

Upendra Grewal, THE FUNDAMENTAL ISSUES RELATED TO THE LEGAL CONTROL MECHANISM OF PROTECTION OF PLANT VARIETIES AND FARMERS â€™ RIGHTS IN INDIA (2021).

V O L Vi & Arun Maurya, CURRENT LEGAL STATUS OF GM CROPS IN INDIA WITH SPECIAL REFERENCE TO INTELLECTUAL PROPERTY, VI 51 (2021).

Divya Sampath, Bridging the Gap between the Developing and Developed Worlds: An Analysis of International IP Instruments in Agriculture Policy, 23529 Grou 1 (2018).

Akram A. Khan, supra note 7.

M D Nair, GATT, TRIPS, WTO and CBDâ€“Relevance to Agriculture (2011).

Ryan Cardwell & Pascal L Ghazalian, The Effects of the TRIPS Agreement on International Protection of Intellectual Property Rights, 26 Int. Trade J. 19 (2012).

Jane Payumo, Howard Grimes & Philip Wandschneider, Status of National Intellectual Property Rights (IPRs) Systems and Its Impact to Agricultural Development: A Time Series Cross Section Data Analysis of TRIPS Member-Countries, 5 Int. J. Intellect. Prop. Manag. 82 (2012).

Philip H Howard, Visualizing Consolidation in the Global Seed Industry: 1996â€“2008, 1 Sustainability 1266 (2009).

J Fernandez-Cornejo, Monsanto Transgenic Trait Dominance in US Market 1996â€“2007, Organ. Compet. Mark. Lincoln, NE, USA (2008).

Tatjana PapiÄ‡ Brankov & Koviljko Lovre, WTO Law and Genetically Modified Products (2013).

Kshitij K Singh, Intellectual Property Rights in Agricultural Biotechnology and Access to Technology: A Critical Appraisal, 18 Asian Biotechnol. Dev. Rev. (2016).

Aumirah, The Sakata Seed Case: A Landmark Decision Shaping Indiaâ€™s Biotech Patent Landscape, (2024).

Ghayur Alamâˆ—, 6 . MONSANTO â€™ S BT COTTON PATENT , INDIAN COURTS AND PUBLIC POLICY Ghayur Alam âˆ— ABSTRACT This Paper Primarily Deals with an Unanswered Substantial Question of Patent Law That Has Arisen in India . The Question Is Whether an Invented Nucleic Acid Sequenc, 71 (2019).

Pratistha Sinha, India: Monsanto Technology LLC And Ors Vs. Nuziveedu Seeds Ltd. And Ors, Khurana Khurana Advocates IP Atty. 1 (2018).

Kan & Krishme, Sowing the Seeds of Change: Patent Law, Biotechnology, and the Sakata Case (2024).

Pranavnayar, Analysis of Protection of Plant Varieties and Farmers Rights Act, 2001 in Light of Judicial Decisions Laid Down by the Indian Courts (2020).