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The Evolving Landscape of Plant Patents in Developing Nations

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The expansion of plant patents has surged over recent decades, notably in the Global South's developing nations and emerging economies. This article provides a comprehensive overview of plant patenting in these regions, analysing legal statutes, criteria for patentability, and court rulings. The study reveals that 60% of 126 surveyed countries permit patents on plants or their parts despite the TRIPS Agreement's[1] flexibilities. Plant-related patents encompass a wide range of genetic and biological elements. Significant U.S. rulings have influenced global interest in plant patenting, paving the way for broader patent eligibility. However, plant patents raise critical issues, including barriers to research and access to propagating materials, compounded by TRIPS Article 28.1(b).[2] This article focuses on the Global South, exploring legal and regulatory frameworks, socio-economic impacts, biodiversity conservation, and sustainable agriculture. The dynamic interplay between international agreements and national legislation is examined, highlighting ongoing efforts to balance innovation incentives with equitable access to agricultural technologies. The study underscores the diverse approaches to plant patentability across the Global South, reflecting varying national priorities in agricultural innovation and intellectual property law.

Keywords: *plant patents, trips agreements[3], biotechnology patents, and agricultural innovation.*

[1] Trade related Aspects of Intellectual Property Rights 1995
[2] TRIPS Agreement 1995, art 28.1(b)
[3] Trade related Aspects of Intellectual Property Rights 1995

INTRODUCTION

The expansion of patents on plants and plant parts has seen significant growth over the past few decades, particularly in developing nations and emerging economies of the Global South. This article aims to bridge the knowledge gap by providing a comprehensive overview of the state of plant patenting in these regions. This study is based on a thorough examination of legal statutes, criteria for patentability, and court rulings. By analysing these aspects, the article offers an in-depth understanding of how plant patenting has evolved and how it is currently practised in different countries within the Global South.

Studies indicate that in nearly half of the 126 Global South countries surveyed, national laws permit the patenting of plants or their parts, highlighting a significant trend toward the adoption of intellectual property protections in these regions. This occurs despite the flexibilities provided by the World Trade Organization's Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which permits countries to exclude plants from patentability. Numerous plant-related patents have been identified in these countries, with phenotypic and genotypic characteristics serving as the basis for patent grants in many jurisdictions. Additionally, in some nations, entire plant varieties may also be eligible for patents.

Plant-related patents encompass a wide range of elements, including nucleic acid probes, amino acid sequences (proteins), transit peptides, promoters, enhancers, individual exons, plasmids, cloning vectors, expression vectors, isolated host cells transformed with expression vectors, plant cells, parent lines and hybrids, seeds, and methods for genetically modifying plants and producing hybrids.

In the United States, three significant rulings have heightened academic interest in plant patenting. It was established that a live, artificially created microorganism is subject matter eligible for patent protection.[4] Following this, the U.S. Patent and Trademark Office (USPTO) Appeal Board concluded that plants are eligible for patent despite existing coverage under the

[4] *Diamond v Chakrabarty* [1980] 447 US 303

Plant Patent Act 1930[5] or the Plant Variety Protection Act 1970[6].[7] Finally, the U.S. Supreme Court affirmed that crops, as well as other sexually reproducing plants, could be subject to utility patents. These rulings collectively paved the way for the potential patenting of plants.[8] However, the grant of patent protection to plant and plant materials gives rise to many issues. Any patented component in a plant can create barriers to breeding and further research, significantly impacting access to and use of seeds and other propagating materials. Article 28.1(b) of the TRIPS Agreement[9] adds complexity by mandating that the protection extended to a process must also apply to the product directly produced from that process. This can potentially include plant-derived products such as food and feed.

These concerns are particularly relevant to developing nations. While plant variety protection (PVP) and its effects on these countries have been highlighted, the focus on plant patenting has predominantly centred on the United States and the European Union. In this context, understanding the dynamics of plant patenting in the Global South becomes paramount. It requires examining the legal and regulatory frameworks and socio-economic impacts on local communities, biodiversity conservation efforts, and sustainable agricultural practices. By broadening scholarly discourse and deepening empirical research, this article aims to illuminate the complexities of plant patenting in diverse global contexts and contribute to informed policy discussions on balancing innovation incentives with equitable access to agricultural technologies.

EVOLUTION OF PLANT PATENT PROTECTION: FROM PARIS CONVENTION TO TRIPS AGREEMENT AND FREE TRADE AGREEMENTS

The 1883 Paris Convention for the Protection of Industrial Property[10] marked an important point in the international protection of intellectual property. Through Article 1(3), the Convention broadly defined industrial property encompassing agriculture and natural products, including

[5] The Plant Patent Act 1930
[6] Plant Variety Protection Act 1970
[7] *Ex parte Hibberd* [1985] 227 USPQ 443
[8] *J.E.M. Ag Supply, Inc. v Pioneer Hi-Bred International, Inc.* [2001] 534 US 124
[9] Trade related Aspects of Intellectual Property Rights 1995, art 28.1(b)
[10] Paris Convention for the Protection of Industrial Property 1883

plants. This inclusive definition acknowledged the importance of plant-related innovations. However, the Convention did not mandate that all technological fields, including plant protection, be covered by patents. This omission allowed countries the freedom to choose whether to grant patent protection for plants, enabling them to customise their intellectual property laws according to their specific needs and circumstances.[11]

A significant transformation in the international intellectual property framework took place with the implementation of the TRIPS Agreement in 1994, a detailed multilateral agreement under the World Trade Organization (WTO). Article 27.3(b) of the TRIPS Agreement[12] was instrumental in shaping the scope of patentability for plants. Although the Agreement did not mandate member countries to offer patent protection for plants, it expressly permitted them to exclude plants from being patentable. This provision applied to both naturally bred and genetically modified plants, granting countries considerable flexibility in determining the extent of patent protection for plant-related inventions. This flexibility was particularly important for developing nations that needed to balance the interests of local farmers and agricultural industries with those of international patent holders.[13]

In response to the flexibility afforded by the TRIPS Agreement, many developing nations have enacted national legislation incorporating the exclusion of plants from patentability. The approaches taken by these countries vary significantly. Some nations have chosen to broadly exclude all plants from patent protection, thereby simplifying their legal frameworks and reducing potential conflicts with local agricultural practices. Others, influenced by European patent law, have opted to limit the exclusion to plant varieties. This approach allows for the possibility of patenting genetically modified plants, which can be seen as distinct from traditional plant varieties due to their engineered characteristics. This differentiation enables countries to support biotechnological advancements while protecting traditional agricultural practices.

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[11] *Ibid*

[12] Trade related Aspects of Intellectual Property Rights 1995, art 27.3(b)

[13] Mamta Ranga and Deepti Sharma, 'WTO and Indian Agriculture' (2011) 4(6) Indian Journal of Applied Research

Despite the TRIPS Agreement's provision allowing for excluding patent protection to plants, several Free Trade Agreements (FTAs), especially those involving the United States, impose obligations on developing nations to grant patents for plants or facilitate such patents.

These FTAs typically employ one of three strategies to achieve their objectives:

Mandated Plant Patents: Some FTAs explicitly require the member nations to provide for granting plant patents upon request, thereby standardising patent protection across the participating countries.

Best Effort Obligations: Other Free Trade Agreements (FTAs) incorporate 'best effort' or 'reasonable endeavour' obligations, suggesting that parties should strive diligently to implement patent protection for plants. This approach promotes compliance by encouraging parties to make sincere efforts without mandating strict, absolute requirements.

Silence on Plant Patentability: Some FTAs do not explicitly address plant patentability or exclusion, leaving room for interpretation and allowing countries to maintain their existing policies.[14]

The advent of the Trans-Pacific Partnership Agreement (TPP), now known as the Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), introduced new requirements concerning patents granted to plants. However, the necessity of including 'plant varieties' within the scope of protection remains ambiguous. Article 27.3(b) of the TRIPS Agreement distinctly treats plants and plant varieties as separate categories, which allows WTO member countries to prevent patenting of plants broadly. Nonetheless, the TRIPS-plus provisions in many FTAs, particularly those involving the US, restrict this flexibility by imposing more stringent requirements than those stipulated under TRIPS. These provisions often push developing countries towards adopting patent policies that align more closely with those of developed nations, potentially at the expense of their local agricultural sectors.

[14] Carlos Maria Correa, 'Implications of Bilateral Free Trade Agreements on Access to Medicines' (2006) 84(5) Bulletin of the World Health Organization 399-404 <https://pubmed.ncbi.nlm.nih.gov/16710551/> accessed 18 June 2024

As of now, at least 51 countries fully utilise the TRIPS Agreement's flexibility by excluding plant patents.[15] Most countries in the Global South follow the European model, excluding plant varieties and biological processes from patentability rather than all plants. This approach allows these nations to protect their agricultural biodiversity and support local farming practices. However, under FTAs with the US, some Global South nations have committed to allowing plant patents. The practical effects of these obligations are largely influenced by how patent offices and courts interpret and enforce the rules and exclusions related to patentability when an FTA is implemented. This variation implies that the real impact of FTAs on national patent systems can vary widely from one country to another.[16]

In practice, FTA obligations may minimally alter the situation regarding genetically engineered plants. This is because numerous countries already allow patents on modified plant parts and components (such as cells), even if they exclude entire plants or plant varieties from being patentable. The nuanced implementation of these international agreements illustrates the complex interplay between global trade policies, intellectual property laws, and national sovereignty in the context of agricultural biotechnology.[17] Countries must navigate these complexities to balance the interests of multinational corporations, local farmers, and national agricultural policies.

PATENTABILITY OF PLANTS AND PLANT MATERIALS

The distinction between 'invention' and 'discovery' is crucial in determining patent eligibility. An 'invention' results from human ingenuity applied to natural forces, implying human contribution. A 'discovery' refers to finding or identifying something that already exists in nature.[18] Most national legal frameworks do not grant patents for discoveries, meaning naturally

[15] Carlos Maria Correa, 'Interpreting the Flexibilities Under the TRIPS Agreement' (Access to Medicines and Vaccines, 2021)
[16] *Ibid*
[17] Carlos Maria Correa, 'TRIPS-Related Patent Flexibilities and Food Security: Options for Developing Countries (*International Centre for Trade and Sustainable Development*, 2012) <https://quno.org/sites/default/files/resources/ENGLISH_TRIPS-Related%20Patent%20Flexibilities%20and%20Food%20Security_CORREA.pdf> accessed 18 June 2024
[18] 'Difference between Discovery and Invention With Detailed Comparison' (*Byjus*, 30 July 2018) <https://byjus.com/physics/difference-between-discovery-and-invention/> accessed 18 June 2024

occurring entities, such as wild plants, are typically not patentable.[19] Even if a natural gene found in a plant is proven useful, it might not meet patent standards set by courts and patent offices. Similarly, discovering a novel property, like a plant's medicinal use, does not automatically make the plant patentable, as it lacks the inventiveness required for patents.[20] Patents on discoveries may not be granted due to their lack of inventiveness (because they already exist) or due to the intellectual work involved in finding rather than creating something new.

In biotechnology, the line between invention and discovery is becoming increasingly unclear. Biotechnology leverages biological systems and living organisms to develop or modify products or processes for particular applications.[21] According to European law, a natural substance can be patentable if it is defined by its structure, the process by which it is obtained, or other specific criteria, as long as it was not previously known to the public. Article 52(2)(a) of the European Patent Convention (EPC)[22] explicitly excludes discoveries from being eligible for patents. For instance, Brazil's Industrial Property Law excludes discoveries from being considered inventions.[23] Similarly, China's Patent Law excludes scientific discoveries from patent protection.[24] India's Patent law also excludes discoveries from being considered inventions.[25] In Peru, discoveries are considered inventions.[26] Vietnam's Law excludes scientific discoveries from protection as inventions.[27] Uganda's law excludes discoveries from being regarded as inventions.[28]

[19] Paris Convention for the Protection of Industrial Property 1883
[20] 'Patenting Criteria: Novel, Non-Obvious, and Useful' (*Thoughts to Paper*) <https://www.thoughtstopaper.com/knowledge/patenting-criteria-novel-non-obvious-useful.php> accessed 18 June 2024
[21] Einfolge, 'Patent of Biotechnological Innovations in India: A Legal Overview' *LinkedIn* (April 11, 2024) <https://www.linkedin.com/pulse/patent-biotechnological-innovations-india-legal-overview-einfolge-wc3jc/> accessed 18 June 2024
[22] European Patent Convention 1973, art 52(2)(a)
[23] Law on Industrial Property, art 10
[24] Patent Law of the People's Republic of China, art 25
[25] Patent Act 1970, s 3
[26] Patent Regulation, art 15
[27] Law on Intellectual Property, art 59
[28] Industrial Property Act 2014, art 33(2)

Many nations view genes as naturally occurring and classify them as discoveries rather than inventions. However, some countries allow the patenting of isolated genes and nucleotide sequences to prevent the appropriation of natural products. The EU permits patents on isolated genes if they meet specific criteria.[29] For instance, in Brazil's patent legislation, it is clearly stated that patents cannot be awarded for entirely or partially natural living organisms and biological materials found in nature, even if isolated from their natural environment, including the genome or germplasm of any natural living organism.[30] This implies that even if a gene is alleged to be 'isolated,' it would not be patentable in Brazil. Similarly, a natural plant genetic feature in Vietnam is considered a discovery and cannot be patented.[31] In Peru, an isolated gene is not regarded as an innovation even if it hasn't been previously characterised.[32]

In China, if a specific gene or DNA fragment can be accurately identified and has industrial applications, and if the method used to obtain it is not already known as prior art, both the gene or DNA fragment itself and the method of obtaining it may qualify for patent protection.[33] On the other hand, Indian legislation suggests that isolated genes would not be eligible for patent protection.[34] Here, the High Court of New Delhi ruled that hybridised transgenic plants with the integrated Bt trait[35] are not patentable,[36] as the gene integration process is considered 'essentially biological'.[37]

Countries like Argentina, India, and Uganda explicitly bar patents on plants, aligning with Article 27.3(b) of the TRIPS Agreement.[38] This prohibition extends to plant cells and seeds capable of regenerating into whole plants. For instance, Argentina excludes plants and their production processes from patentability.[39] Brazil establishes guidelines for reviewing

[29] Council Directive (EC) 98/44 Legal protection of biotechnological inventions
[30] Law on Industrial Property, art 10
[31] Law on Intellectual Property, art 59
[32] Common Provisions on Industrial Property, art 15
[33] Patent Law of the People's Republic of China, art 25
[34] *Nuziveedu Seeds Ltd & Ors v Monsanto Technology Llc* AIR 2019 SC 559
[35] The **Bt trait** refers to a specific type of genetic modification where genes from the bacterium *Bacillus thuringiensis* (Bt) are inserted into the plant's genome. Bt produces proteins that are toxic to certain insect pests but are safe for humans and other animals.
[36] Patent Act 1970, s 3
[37] *Ibid*
[38] Trade related Aspects of Intellectual Property Rights 1995, art 27.3(b)
[39] Patents and Utility Models and its Regulation, art 6

biotechnology-related patent applications, stating that biological processes are not considered 'natural' and are therefore patentable when human intervention is significant and affects a plant's genetic makeup. India excludes patents for essentially biological processes, as outlined in the Guidelines for Examination of Biotechnology Applications for Patent.[40]

Nearly all countries in the Global South follow a similar stance, prohibiting patents on plant development methods, materials, or cultivars.[41] The rationale is to prevent indirect control over entire plants or plant varieties through patents on their components. For example, an Argentine appeal court upheld the patent office's denial of a patent application, reasoning that genetically modified cells could produce a complete plant, thus violating the prohibition on plant patents.[42] This approach ensures that biological parts and components, whether altered or not, that allow for the regeneration of an entire plant are not patentable, maintaining the prohibition on controlling whole plants or plant varieties through patents.

Many nations in the Global South have adopted legal frameworks similar to the EPC[43], which excludes different varieties of plants from patentability. Instead, plant varieties are protected through Plant Variety Protection (PVP) laws. Cumulative protection under both PVP and patents is prohibited in countries like Brazil and Argentina, which are signatories to the 1978 amendment to the UPOV (International Union for the Protection of New Varieties of Plants) Convention.[44] This convention forbids cumulative protection to avoid overlapping IP rights. In Brazil, the PVP law provides protection exclusively through Plant Variety Protection Certificates, which safeguard the intellectual property rights of plant varieties. India has also implemented a sui generis system under the Protection of Plant Varieties and Farmers Rights Act, 2001, in compliance with Article 27(3)(b) of the TRIPS Agreement.[45] This legislation seeks to stimulate agricultural progress by fostering the creation of novel plant varieties and acknowledging farmers' roles in preserving and enhancing plant genetic resources.[46] The Act

[40] Patent Act 1970, s 3(j)
[41] *The Status of Patenting Plants in The Global South* (Oxfam International 2018)
[42] *Monsanto Technology LLC v Instituto Nacional de la Propiedad Industrial s/denegatoria de patente* (2015)
[43] European Patent Convention 1973
[44] International Convention for the Protection of New Varieties of Plants 1978 art 2(1)
[45] Trade related Aspects of Intellectual Property Rights 1995, art 27(3)(b)
[46] Virendra Kumar Ahuja, *Law Relating to Intellectual Property Rights* (2007)

outlines that a new variety must satisfy the requirements of novelty, distinctiveness, uniformity, and stability to qualify for registration.[47]

Most laws that provide patent protection in the Global South exclude biological methods for plant production from patent protection. These exclusions apply to 'essentially' or 'principally' biological processes used in plant cultivation, such as conventional breeding methods. However, these exclusions do not cover non-natural biological processes involving significant human intervention and may be patentable. For example, Brazil considers biological processes that involve permanent human intervention affecting a plant's genetic makeup as patentable. India's Patents Act excludes patents for conventional breeding methods but allows for patents on genetically modified plants or processes that do not primarily involve biological methods.[48] The Guidelines for Examination of Biotechnology Applications for Patent clarify that processes involving significant human intervention, such as genetic modification, may be considered for patent protection.

In many Global South countries, patents for methods, materials, or cultivars related to plant development are not granted to avoid inadvertently protecting plant varieties through process patents. Article 28.1(b) of the TRIPS Agreement[49] extends protection to the product directly obtained from a patented process. Thus, permitting patents on plant production methods could potentially result in the indirect patenting of the plants produced.

Patents are granted based on three main criteria: novelty, inventive step (non-obviousness), and industrial applicability (utility). In biotechnological inventions, determining novelty and inventive steps can be challenging, particularly when the invention involves known techniques or sequences. For example, in the Monsanto case, the Argentinean appeal court ruled that DNA molecules, a method for producing transgenic plants, and modified cell plants were not patentable due to a lack of inventive steps. The court found that there was very little difference between the sequences known before the application date and those claimed in the patent

[47] Protection of Plant Varieties and Farmers Rights Act 2001, s 15(1)
[48] *Ibid*
[49] Trade related Aspects of Intellectual Property Rights 1995, art 28.1(b)

application.[50] Similarly, in Brazil, the Regional Federal Tribunal upheld the patent office's decision to reject a patent related to polynucleotide sequences optimized for expressing pesticide toxins in plants, citing a lack of inventive activity. The court reasoned that the claimed gene sequences and optimization methods were known at the time of the application.[51]

Apart from the requirement of an inventive step, the laws in the selected countries also typically mandate industrial applicability or a technical effect for patentability. Applications for patents involving transgenic plants often emphasize DNA sequences as integral components of the plant genome, particularly where foreign DNA has been introduced. Although these DNA constructs might create unique sequences in the plant genome, they must demonstrate industrial applicability to be patentable.[52] The Indian Patents Act of 1970 sets forth the criteria for patentability, stipulating that an invention must be novel, possess an inventive step, and be suitable for industrial application.[53] The Act defines an inventive step as one that entails a technical advance over existing knowledge or has economic importance, rendering the invention non-obvious to someone skilled in the field.[54]

PATENTS VS PLANT VARIETY RIGHTS IN PLANT BREEDING

The interplay between patents and plant variety rights protection involves intricate implications, especially regarding potential infringements by plant breeders developing novel varieties.[55] Under the EU Directive on the Protection of Biotechnological Inventions, Article 12 addresses these scenarios by allowing for compulsory cross-licensing. This provision allows a breeder who is unable to obtain or use a plant variety right without violating an existing patent to request a compulsory license. Conversely, patent holders facing infringement of their rights by plant breeders may also apply for such licenses, contingent upon payment of appropriate

[50] Trade related Aspects of Intellectual Property Rights 1995
[51] *Mycogen Corporation e Outros v INPI-Instituto Nacional de Propriedade Industrial* (2016)
[52] Dr Mohan Dewan, 'Patentability of Transgenic & Genetically Modified Plants in India' *Lexology* (21 September 2022) <https://www.lexology.com/library/detail.aspx?g=2aecaf10-9631-4758-a83c-a04eadcce49f> accessed 19 June 2024
[53] Patent Act 1970, s 2(1)(j)
[54] Patent Act 1970, s 2(ja)
[55] Sankalp Jain, 'International Convention for the Protection of New Varieties of Plants - An Evaluation' (2020) SSRN <https://dx.doi.org/10.2139/ssrn.3902641> accessed 19 June 2024

royalties. This mechanism seeks to balance the interests of both parties in innovation and commercial exploitation within the biotechnological sphere.[56]

Plantum NL, the Dutch association representing breeding and seed trade, has articulated a definitive position regarding the intersection of patents and plant breeders' rights. They support the unrestricted availability of patented biological material to develop new varieties by the 'breeders' exemption' outlined in the UPOV Convention. This exemption ensures that once breeders have legally obtained a protected variety, they can freely use and exploit it without patent-related restrictions. Plantum NL highlights concerns over the increasing number of patents in plant breeding, noting that some companies with extensive patent portfolios seek to limit competitors' breeding programs that may involve patented traits. This stance threatens the established open innovation system in plant breeding, potentially stifling sector-wide innovation and diversity.

European legislation clearly states that 'essentially biological processes for the production of plants or animals' are not considered eligible for patent protection, particularly those methods that rely on natural phenomena like crossing or selection. Recent rulings by the Enlarged Board of Appeal of the European Patent Office (EPO), such as those concerning broccoli and tomatoes, have offered further guidance on how this exclusion is applied in practice.[57] The Board's decision clarified that processes involving sexual crossing and plant selection are typically not eligible for patent protection under Article 53(b) of the European Patent Convention (EPC).[58] Even if these processes incorporate technical steps aimed at aiding breeding, they remain excluded unless the technical step introduces or alters a trait independently of natural genetic processes. This nuanced interpretation aims to balance incentivizing biotechnological innovation and preserving traditional breeding practices.

Comparatively, the US patent law adopts a broader approach, allowing for patenting genetically engineered organisms and other biotechnological innovations, emphasizing human

[56] Michael Leslie Blakeney, 'Patenting of Plant Varieties and Plant Breeding Methods' 2012 63(3) Journal of Experimental Botany 1069–1074 <https://doi.org/10.1093/jxb/err368> accessed 19 June 2024
[57] Trade related Aspects of Intellectual Property Rights 1995
[58] European Patent Convention 1973, art 53

intervention as a critical criterion for patentability. In contrast, the EPO requires inventions to demonstrate a 'technical' character, ensuring that they involve isolated biological material, technical processes, or products obtained through such processes.[59]

CRITERIA, TESTING, AND LEGAL IMPLICATIONS

Plant Variety Protection (PVP), also known as Plant Breeders' Rights, is a framework created to encourage innovation in plant breeding, promote equitable competition, and conserve biodiversity. This system provides breeders with rights over new plant varieties that fulfill certain requirements: novelty, distinctness, uniformity, and stability (DUS).[60] In contrast to utility patents, which mandate complete disclosure, PVP permits breeders to maintain confidentiality regarding the parent lines of hybrid varieties while still receiving protection. This approach strives to strike a balance among the interests of breeders, farmers, and consumers by fostering the creation of novel varieties while safeguarding genetic diversity.

Under the UPOV 1991 Convention, novelty requirements for a plant variety stipulate that it must not have been commercially traded within the country of application for more than one year or for four to six years outside that country before the application. In contrast, the UPOV 1978 Convention permits a grace period as an option but mandates that the application must be submitted before the variety is traded or offered for sale.[61]

For a variety to qualify for Plant Variety Protection (PVP), it must demonstrate distinctiveness, which means it must exhibit clear phenotypic differences from existing varieties that are widely known in trade or still under evaluation. This assessment relates to specific locations, testing periods, and reference varieties. Despite advancements in molecular fingerprinting techniques to address environmental influences on DUS testing, their high cost limits their widespread application to major crops.[62]

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[59] Kevin W.O'Connor, 'Patents for Genetically Modified Animals' (1993) 71(3) Journal of Animal Science 34-40 <https://doi.org/10.2527/1993.71suppl_334x> accessed 19 June 2024
[60] 'International Plant Variety Protection' (*Intellectual Property Office of New Zealand*) <https://www.iponz.govt.nz/about-ip/pvr/international/> accessed 19 June 2024
[61] 'Plant Variety Protection - Which Way?' (*Association for Plant Breeding for the Benefit of Society*) <https://www.apbrebes.org/content/plant-variety-protection-which-way> accessed 19 June 2024
[62] *Ibid*

Official grow-out tests in European UPOV-member countries are pivotal for verifying the DUS characteristics of seed crops, leading to the establishment of extensive reference collections. These collections are essential for comparing and identifying unique traits among new and existing varieties annually.[63] This rigorous testing ensures the integrity of varieties strengthens technical knowledge, and serves as a robust defence against infringement, particularly in seed crops.

Defining essential derivation under UPOV involves intricate considerations, including genetic conformity thresholds between varieties. These determinations significantly influence the scope of protection, potentially extending it over varieties initially claimed as new but later found to be derived from existing ones. Litigation in PVP cases is infrequent due to the technical and legal discussions within UPOV bodies, where breeder organizations play a vital role in shaping policies and guidelines. The complexity of genetic conformity thresholds and the high costs associated with litigation often deter challenges in civil court cases, leaving disputes primarily within the realm of regulatory and industry-driven discussions.

This structured approach ensures that PVP not only incentivizes innovation in plant breeding but also safeguards biodiversity by encouraging the development of distinct and stable varieties while balancing the interests of breeders, farmers, and consumers.

SCOPE OF UTILITY PATENTS

The extent to which utility patents provide protection hinges significantly on how their claims are formulated, as these define precisely what falls under the patent's coverage. Unlike plant patents, which typically focus on specific plant varieties or their distinct parts, utility patents aim to secure broader protection, often encompassing various aspects of plant biotechnology and innovation.[64]

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[63] 'Plant Breeders' Rights and Listing' (*Raad voor Plantenrassen*) <https://www.raadvoorplantenrassen.nl/en/plant-breeders-rights-and-listing/> accessed 19 June 2024

[64] 'Using United States Utility Patents to Protect Innovation' (*Government of Canada*, 24 March 2022) <https://www.tradecommissioner.gc.ca/united-states-of-america-etats-unis-amerique/patents-protect-brevets-proteger.aspx?lang=eng> accessed 19 June 2024

In the process of patent examination, patent offices rigorously evaluate these claims to ensure they meet stringent criteria. This examination entails reviewing potential overlaps with existing prior art, prior inventions, or knowledge and evaluating whether the claimed invention constitutes a substantial improvement over what is already established in the field. Patent examiners have the authority to revoke claims that are deemed to either cover already existing technologies or extend far beyond the scope of the invention as originally described by the applicant.[65]

In the United States, where there is no formal opposition process for patents, applicants can appeal unfavourable decisions made by examiners. This contrasts with the European patent system, where third parties can file oppositions against patents they believe should not have been granted. This system allows for greater scrutiny and ensures that patents are granted only when they meet the rigorous standards set by the European Patent Office (EPO).

The European Patent Office (EPO) adopts a unique stance on patents related to plant varieties compared to the United States. According to Article 53(b) of the European Patent Convention, the EPO explicitly prohibits the patenting of plant varieties, irrespective of the technique employed to develop them. This prohibition was reinforced in the Novartis decision by the enlarged Board of Appeal, which emphasized that patent claims, including those involving genetic alterations like gene insertion, cannot encompass specific plant varieties.[66] In contrast, plant varieties are safeguarded by distinct legal frameworks like the International Union for the Protection of New Varieties of Plants (UPOV), which offers specialized protection designed specifically for plant breeders.

The divergence in patent policies between the US and Europe regarding plant varieties underscores differing approaches to IP protection in agriculture and biotechnology.[67] While the US allows for broad utility patents that may cover entire plant species or their components,

[65] Steven Shape, 'Utility Patent vs. Design Patent: What Protections Do They Offer? (*Dennemeyer*, 27 May 2022) <https://www.dennemeyer.com/ip-blog/news/utility-patent-vs-design-patent-what-protections-do-they-offer/> accessed 19 June 2024

[66] *Novartis Ag v Union of India & Ors* AIR 2013 SCR 1311

[67] 'Patent Policies in Flux: The Debate Surrounding Europe's Proposed Ban on New Genomic Techniques (NGT) Plant Patents' (*MC- IP Research & Analytics*, 10 April 2024) <https://iptechinsider.com/ngt-plant-patents/> accessed 19 June 2024

Europe maintains strict boundaries to ensure that plant varieties remain accessible for breeding and innovation under specialized protection regimes like UPOV.[68]

Despite the wide scope of protection afforded by utility patents in the US, challenges to the enforceability and validity of these patents can arise in court. However, litigation processes are often costly and complex, posing significant challenges for small-scale plant breeders and agricultural innovators who may seek to navigate around existing patents rather than risk infringement claims.

CONCLUSION

The evolution of plant patent protection, spanning from the Paris Convention to the TRIPS Agreement and various Free Trade Agreements (FTAs), illustrates a dynamic and evolving legal landscape. The TRIPS Agreement offers substantial flexibility for countries to exclude plant patents, enabling them to align intellectual property laws with their specific needs. However, FTAs, particularly those involving the US, often impose more stringent requirements, significantly influencing how countries regulate biotechnological innovations in agriculture. This interaction underscores the ongoing challenge of balancing innovation incentives with the preservation of local agricultural practices and biodiversity on the international stage.

The evolving terrain of patent law and plant variety rights reflects continuous efforts to harmonize technological advancement with the conservation of traditional breeding practices and biodiversity. Decisions made by international bodies and national patent offices play a pivotal role and how it will impact innovation within the global plant breeding sector.

The determinations in landmark cases such as those involving Broccoli and Tomato highlight that human intervention is a critical criterion in assessing the patentability of plant breeding methods. Processes involving technical steps that independently modify the plant genome are typically eligible for patent protection, while those facilitating natural breeding processes are

[68] 'Norms For IP Protection of Plants in US, India & Europe' (*Sagacious IP*, 29 April 2014) <https://sagaciousresearch.com/blog/norms-ip-protection-plants-us-india-europe/> accessed 19 June 2024

generally excluded. This nuanced approach aligns with legislative intents to distinguish between conventional breeding methods and biotechnological innovations in plant breeding.

When focusing on individual countries in the Global South, the policies regarding plant patentability vary significantly. Argentina, for instance, does not permit patents on plants or plant varieties in general, nor on essentially biological processes used in plant creation. However, the country does allow patents for genomic constructions and their constituent components. Brazil has enacted laws restricting the patentability of biological materials in unique ways, with plant varieties not covered concurrently by breeders' rights and patents. China restricts patent protection to plant types rather than actual plants but permits patents for genetically engineered plants, altered cells, and products derived from them, like food and feed.

Conversely, India broadly excludes plants, seeds, plant varieties, and essentially biological processes used in their development from patentability. Nevertheless, certain patents have shown some flexibility in the application of these regulations. In contrast, South Africa permits patents on plants and their components without rigorous review, theoretically aligning with the European patent law approach. Peru adheres to the Andean Community's policy that excludes biological elements from patentability, including parts or the entirety of living beings. Uganda follows a European model where patents are generally not granted for anything other than plant types and the essentially biological methods used in their production. Vietnam takes a similar stance to the European perspective, granting patents for DNA, modified cells, plants, and methods for detecting genetic events.

The varying legal positions across the Global South underscore a spectrum of approaches to plant patentability. Many developing countries and emerging economies have embraced plant patents, particularly following the European approach, which excludes only plant varieties. Alternatively, some nations permit the patenting of plant parts and components, such as nucleic sequences, thereby indirectly granting patent holders exclusive rights over the production and commercialization of plant varieties that incorporate these components, as well as the resulting products like food and feed.

These legal frameworks reflect diverse national priorities, balancing agricultural innovation with broader societal and environmental considerations. As global challenges like food security and climate change persist, these frameworks will continue to evolve to meet new challenges and opportunities in plant breeding and biotechnology, shaping the future of agricultural innovation and intellectual property law worldwide.