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Gene Patenting: Implications on Crop Variety Protection in India

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The role of IPR's ability in the progress of society is undisputable. Such protections are be instrumental in making sure that adequate investment in terms of money and time are made for food security and sustainable agriculture ecosystem. Revolutionary technologies of genetic transformation leading to the products like genetically modified crops (GM) have glamorized an otherwise rustic industry. There is a general consensus in relation to the complexity of the issue and granting gene patents which in themselves (isolation) are worthless. Only in conjugation with complex biological system of a plant can they show their effect. Super crops are now possible through various plant biotechnological interventions to obtain the desired traits by changing the genome of plants. Such techniques are research intensive and demand high investment, hence legal protection through intellectual property rights is imperative. But it is complicated to grant a patent or similar monopoly on plant genetic resources as it has direct implications on food affordability and security especially in developing countries. Additionally, giant seed companies of developed countries have gained many patents on genes of plants, misappropriating the plant genetic resources of poor or undeveloped countries which are rich in biodiversity giving rise to biopiracy. The purpose of the article is to examine the legal framework for gene patenting in reference to plant variety protection (PVP) in India.

Keywords: GM crops, Gene Patent, Monopoly, Plant Genetic Resources, PPVFRA

In agriculture, crop varieties have served as a fundamental tool to increase food production and ensure nutrient security of the ever-increasing population. Crop varieties can be understood as plant populations with a specific set of traits which in turn are essential to its identification. The process of development of crop varieties are rooted in the science of plant breeding which derives its origin from the subject of genetics. The crop varieties as a technological product reaches the farmer in the form of seeds which is a major agricultural input. Their development is an everlasting endeavor to meet the ever-evolving challenges in the form of various biotic and abiotic stresses. In recent years, the nature of innovation in crop improvement has rapidly evolved.[1]The whole process of variety development has been revolutionized by advanced tools of agricultural biotechnology especially transgenic crop varieties e.g.*Bt* cotton. But the advent of these transgenic or GM crops have raised multiple issues with regard to patent protection of the technology involved. After the DNA molecule's structure was finally discovered, technology advanced significantly. Since then, crop scientists have developed various techniques to determine the sequence of nucleic acids or genes, their functions in the plant biology, and how to manipulate them to produce a desirable plant type.[1] Biotechnology patents frequently raise questions about patentability due to their intimate ties to nature and utilization of it to get desired effects. In addition to legislation protecting or patenting biological resources, such as plant cultivars, genes, and various enabling technologies, change has been sped up by advances in biology and information technology.[2] Particularly, patents based on genes and nucleic acids have generated controversy in recent years.[3] The majority of countries acknowledge the recognition of new plant varieties as a form of intellectual property right (IPR) as established by the International Union for the Protection of New Varieties of Plants (UPOV) Article 27.3(b) of the WTO Agreement on Nations. According to the Trade Related Aspects of Intellectual Property Rights (TRIPS), WTO members are obligated to "establish protection for plant varieties through patents or an effective sui generis system or a combination of both."[4] Their protection as a product on the principles of intellectual property rights is an absolute requirement to provide financial impetus for research and development in this field.

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Conceptions to Jurisdiction

The issue of gene patenting has raised significant concerns, and due to the lack of a universally recognized criteria, determining its patentability is challenging. Today, each nation has its own criteria for determining patentability, with some countries granting patents while others do not. A gene patent is a general word that covers both the act of manipulating DNA and the chemical compounds associated with it not only genes but also gene sequences, gene fragments like express sequence tags, and even sequences from non-coding regions of the genome might be the subject of patent claims.[5] It may also refer to a vector or plasmid that contains a sequence and an organism (such as a plant variety) that has undergone transformation using a similar vector. Natural DNA products are not patentable. They will be patented only when they are isolated, purified, modified and new form which is not found in nature and such gene-based inventions must also be useful in the actual world.

In United States (US)the idea involving product of nature is widely accepted. This states that every man-made structure iseligible for patent but if it is natural occurring, it is not patent eligible. Figure 1 depicts the rise in plant gene patents in the country, the steady increase shows the emphatic nature of growth of seed industry in US which dominates on a global level. Delving into the history of gene patent in the US, the case of *Diamond*v*Chakrabarty*, 447 U.S. 303 (1980), was a significant ruling by the United States Supreme Court that dealt with the question of whether living organisms can be patented. Ananda Chakrabarty, the complainant, applied for a patent on a genetically modified microbe designed to degrade crude oil. The Court's ruling established that genetically modified organisms (GMOs), which are live organisms altered by human intervention, are eligible for patent protection, therefore expanding the scope of patent law. This decision ignited discussions regarding the

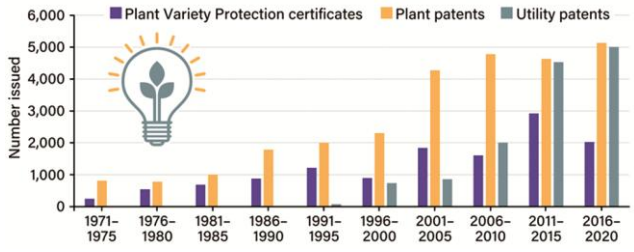

Fig. 1 — Intellectual property rights for new crop varieties during 1971-2020

patenting of living organisms, which had significant implications for the biotechnology and pharmaceutical sectors. It established the ability to patent genetically modified organisms, thereby establishing a precedent for patenting living organisms that have been manipulated for industrial use. Furthermore, it had a profound impact on the legal framework surrounding biotechnological innovation.[6]

In the Supreme Court case of *The Association for Molecular Pathology* v *Myriad Genetics, Inc.* in 2013, it was determined that DNA sequences that occur naturally cannot be patented. Although this ruling facilitated the availability of genetic information to the public, it also generated apprehensions regarding its potential ramifications on biotechnological advancement. The differentiation between naturally occurring DNA and manufactured cDNA was a critical factor, enabling some patent safeguards. The case represented a delicate equilibrium between promoting scientific research and preserving incentives for biotechnology progress. This choice is equally applicable to genes found in plants.[7]

In Association for *J.E.M Ag Supply, Inc.* v *Pioneer Hi-Bred International, Inc.* (2001) the court ruled it is permissible to grant utility patents for sexually reproduced plants. The Court recognized that plants are naturally occurring, but emphasized the human inventiveness required to develop new and unique plant varieties. This ruling effectively reconciled the protection of intellectual property rights with the crucial objective of promoting innovation in the field of agriculture. It was made clear that, given specific circumstances, plants could qualify for utility patents, which would safeguard biotechnological advancements. The verdict therefore had an impact on the developing field of patent law, namely in relation to GMOs in agriculture.[8]

Within the continent of Europe, the clarity about the patentability of isolated genes is uncertain due to the requirement of clearance from each state. According to the European Patent Convention, a finding cannot be classified as an invention.In order to determine the nature of a gene, it must first be classified as either a "discovery" or an "invention".[7] The European Union's regulation on the legal protection of biotechnology inventions stipulates that the mere detection of an element in humans is not eligible for patenting unless it can be isolated. Therefore, it is conceivable to get a patent for isolated

genes, but not when they are integrated with a complex molecular entity.[8] As per Article 52(2)(a)discoveries are not patentable inventions and substance which is freely occurring in nature are not patent eligible, but discovery of any human technical invention is also patent eligible.[9]

Gene Patenting in India

Section 3(c) of the Indian Patents Act, 1970 states that the simple identification of a scientific concept or the creation of an abstract theory, as well as the discovery of any living or non-living substance found naturally, cannot be granted a patent. Furthermore, according to Section 3 (i), it is explicitly stated that plants and animals, excluding microorganisms but including seeds, varieties, species, and fundamental biological processes for the production or propagation of plants and animals, are not eligible for patent protection.[10]

According to the 2005 Draft Manual of Patent Practice And Procedure released by the IPO, any living item that is artificially created, such as transgenic animals and plants, as well as their components, plant varieties, seeds, species, and genes, are not eligible for patents.[11] It is stated that recombinant DNA and plasmids can be patented if there is a significant level of human intervention.[12,13]

The *Monsanto* v *Nuziveedu* Seeds case, a significant legal dispute in India, revolved around the issues of patent rights, genetically modified (GM) technology, and seed royalties. Monsanto, a multinational agricultural firm, created and obtained patents on genetically modified *Bt* cotton seeds that exhibited resistance to pests. Nuziveedu Seeds, an Indian seed company, acquired licenses from Monsanto to utilize its patented technologies. Nevertheless, a disagreement emerged concerning the remuneration and contractual conditions for the use of intellectual property.

The central focus of the lawsuit centered on India's Patents Act and the Protection of Plant Varieties and Farmers' Rights Act. Monsanto contended that it possessed patent rights for its Bt cotton technology and aimed to compel Nuziveedu to make royalty payments for the ongoing utilization of its patented seeds. Conversely, Nuziveedu argued that according to Indian legislation, Monsanto's patent for seeds was invalid and that the royalties requested were exorbitant and contravened Indian norms.[14]

Nuziveedu intensified the legal dispute by questioning the legitimacy of Monsanto's patents, contending that Indian laws do not grant copyright protection to plant kinds and seeds. The case has sparked issues regarding the farmers' rights to reuse seeds that contain patented technology, as well as the delicate balance between innovation and accessibility in the field of agriculture.

In 2017, the Delhi High Court issued a verdict in favor of Monsanto, affirming the legitimacy of its patents and endorsing its entitlement to receive royalties. Nevertheless, this verdict was subjected to appeals and further challenges, resulting in the emergence of an intricate legal terrain.[15]

The case garnered substantial international interest due to its ramifications for intellectual property rights in the field of agriculture, particularly with relation to genetically modified (GM) technologies and seeds. The situation highlighted the necessity for precise and unambiguous legal structures regarding patents, the rights of farmers, and the availability of cutting-edge agricultural technology. The case also underscored the clash between the exclusive rights of multinational businesses and the concerns of farmers and agricultural sustainability.

The *Monsanto* v *Nuziveedu Seeds* case is a significant moment in the ongoing discussion about intellectual property rights, agricultural advancement, and the delicate balance between commercial interests and farmers' rights in developing nations like India.

Protection of Plant Varieties and Farmer's Rights Act (PPV & FRA)

At the time of independence in 1947, agriculture development was keyed in with other national goals like rural development, which can be mainly divided in 3 phases. The first being removal of Zamindari system (1956-60); second being self-sufficiency in food grains (1961-65) and third Green Revolution (1969-73). Currently India is self-sufficient and Agriculture has started to lean towards more of a private innovation, rather than a public affair. During 1980s, India moved towards promoting agricultural trade owing to two major factors: Entry of foreign seed corporations (which also gave rise to demands for IP protection) and membership of WTO and consequently its obligations.[16]

The inclusion of Article 27.3(b)74 in the TRIPS Agreement allows for the possibility of excluding plants from patentability. This provision acknowledges both the concerns of Members regarding the patentability of plants and the fact that WTO

Members have diverse socioeconomic and political circumstances, making it clear that a uniform approach may not be suitable for all.

In India, there is a widespread apprehension about patents in general, and specifically towards the patenting of plants and seeds. The approaches of other WTO Members differ from that of India.Article 27.3(b) of the TRIPS Agreement provides Members with the opportunity to choose not to grant patents for plants and instead safeguard them through a sui generis regime.An impartial analysis of the TRIPS Agreement suggests that its efficiency relies on how each member countries incorporates the international trade system according to its own national needs.[17]

To promote the growth of plant varieties in accordance with national welfare objectives, an efficient system was sort giving priority to objectives such as, ensuring food security, conservation of biodiversity and promoting the long-term and environmentally responsible growth of indigenous communities.

PPVFRA has a primary focus on achieving a balance between the rights of farmers and breeders (seed firms). This highlighted the importance of safeguarding plant varieties through intellectual property rights (IPR) to encourage investment in research and development. This applies to both the public and private sectors, aiming to promote the creation of new plant varieties.[18] However, it also recognized the rights of farmers, who play a crucial role in conserving, improving, and granting access to plant genetic resources for the development of innovative plant cultivars. In India, the farmer possesses the legal entitlement to keep, utilize, cultivate, replant, trade, distribute, or vend his agricultural produce, which include seeds. It is crucial to emphasize that seeds that are meant for sale must not be branded. This is basically consistent with the Farmers' exception as specified in UPOV 78.

The objective of the act is to establish a robust system for safeguarding plant varieties, ensuring the rights of farmers and breeders, and fostering the advancement of new plant varieties in line with the TRIPS Agreement.[19] A new variety can be registered under the Act if it meets the requirements and applicant has to provide information on whether any genetic material utilized in the process of breeding, evolving, or creating the variety was obtained in a lawful manner. The objective is to solicit assertions regarding the sharing of benefits, if applicable, in relation to the pertinent registered plant variety. Benefit sharing claims can be submitted by either an individual Indian citizen or a group of Indian citizens, an Indian enterprise, or an Indian governmental or non-governmental organization. The National Gene Fund will receive the benefit sharing sum deposited by the variety breeder.[20]

The Biological Diversity Act of 2002 was established to guarantee the safeguarding of biological diversity, the sustainable usage and an equal distribution of profits derived from the utilization of biological resources. The establishment of a National Biodiversity Authority and State Biodiversity authority serves as central authority responsible for overseeing the conservation, utilization, and equitable sharing of benefits derived from the usage of "biological resources" for this objective. [21]

The stipulations impose rigorous criteria for any non-citizens seeking to get genetic resources and associated information. Companies must obtain prior authorization from the National Biodiversity Authority in order to collect any biological resource found in India or associated information for study, commercial use, or bio-survey and bio-utilization purposes.

Section 6 plays a vital role in safeguarding intellectual property rights related to biological resources. The provision stipulates that individuals are prohibited from seeking intellectual property rights, either within or outside of India, for any invention derived from a biological resource received from India, without obtaining prior authorization from the National Biodiversity Authority. Nevertheless, in the event that a patent application has been filed, the National Biodiversity Authority (NBA) might grant approval subsequent to the patent's approval but before to the patent authority's official issuance of the patent. The approving body has the authority to impose "benefit sharing fees, royalties, or both, or to enforce constraints, such as requiring the sharing of financial benefits derived from the commercial use of certain rights. Clause 18 requires the NBA to establish criteria for benefit sharing that are just and impartial, and that enable the use of genetic resources. [21]

PPVFR Act is excluded from the aforementioned rule. The Act's omission of plant variety laws from its scope generates apprehension that plant varieties could be developed from biological resources without obtaining approval from the NBA. The clarification has been provided under Section 18 of the PPVFR Act, 2001.[20]

Impact on Stakeholders

The present circumstances require innovative approaches to feed a big population, incorporating modern technologies such as plant genetic engineering which would only be encouraged by strict gene patenting regulations. A comprehensive survey was undertaken to assess perception of the various stakeholders of the seed industry analyzing the role of various IPR regimes. It reported a support for the hypothesis that IP regimen in the form of plant variety protection has positive impact in both public and private sector seed industry especially with regard to the plant breeders. Though the study did not involve the attitude of the companies with regard to gene patent. It also highlighted the apprehensions of the company about the lengthy litigations, associated costs due to absence of a complete database of existing varieties which leads to false claims of variety ownership and hence conflicts in seed industries.[22]Another study highlighted that increasing acquisition in agriculture business and innovations by a few corporate entities poses the problem of monopoly, this in turn acts against interest of farmers and indigenous breeders/small companies especially in agro based economies like India. The powerful companies are obviously seeking effective forms of protection in order to avoid uncertainty which stems from contradictory overlaps between the provisions of Patent Act and PPVFRA. But developing countries like India economy is mostly based on agriculture, and most of them are farmers. Given that the significance of agriculture biotechnology innovations cannot be undermined in view of a larger picture of impact on economy and development of products for general public good which is inadvertently the whole idea of IPR protection. In this complex and convoluted conundrum of the given problem at hand the author states a proactive role of the judiciary as a responsible vanguard by defining a clear-cut pathway to bolster agriculture innovation in the country. The judiciary may have to play the role on a case-to-case basis to solve stalemates of this complex but important problem.

Conclusion

When the agriculture industry was reorganized in the 1980s and 1990s, several large-scale global agri-biotech companies used their patent rights strategically to prevent others from adopting important research tools and materials. The legal and anticipated practice of impeding competitive products or subsequent inventions, has enabled a small number of corporations to exert significant influence or control over worldwide agricultural advancements and hence monopoly over food supply. This circumstance, which many find unsettling, may be the underlying cause of the ongoing opposition to emerging agricultural technologies, especially development of GM crops. But India being a developing economy with majority of the population directly finding employment in traditional ways of agriculture must simultaneously develop plant biotechnology and safeguard the interests of its farmers. Also, due to its abundance in biodiversity, it is concerned about the problem of bio-piracy on its own terms. In order to maximize the benefits of technological and scientific advances in agricultural research we need substantial improvements in transparency. This includes improving the clarity of patent meaning, disclosing patent ownership, providing information about license status, and ensuring that patent rights are placed within the framework of innovation knowledge. These measures will enable a wide range of ideas, participants, and public support to contribute to agricultural innovation.

The Guidelines in relation to plant biotechnology issued by the Indian Patent Office continue to govern gene patenting operations in India which are merely recommendations and not rules. They may be interpreted by a court of law, subject to statutory changes, and benefit from helpful feedback from stakeholders. The requirements of the Patent Act, 1970 and the Patent Rules, 2003, shall govern in the event of a dispute between these recommendations and those laws. To control the issue of plant gene patenting, the Patent Act of 1970 itself should establish clear guidelines.

There is a serious need to bring clarity to the jurisdiction involving plant gene patent. The whole point of a seed not patentable defeats the purpose of a gene patent in plants. Therefore, the subject matter of patentability should be focused on in plants and their propagating material to be patentable which under PPVFRA and Patent Act is prohibited. So, the discussion about gene patent loses power as proved by various court hearings such Monsanto v *Nuziveedu* case.

A fundamental change will be required with respect to PPV and FRA before any debate on

gene patents. Scientists, policy makers and farmers bodies need to get on a common ground regarding this.

A starting point can be to permit plant patents in a particular crop only which has less bearing to the food security of the country. As in case of boll guard, the GM cotton variety are allowed to be cultivated but still not covered under a patent.

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