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RIGHTS OF PATENT HOLDERS AND ITS IMPLICATIONS IN AGRICULTURE AND MEDICAL FIELDWORK

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ABSTRACT

Intellectual property rights have arisen as a result of the creation, innovation, and commercial worth. Patents are a kind of intellectual property that bestows rights onto an individual for their creation of a product or technique that has commercial worth. The notion of a patent is not novel. Inventions have been numerous throughout history. They are highly valuable intellectual property assets for their owners, granting them exclusive rights to prohibit others from using, selling, or distributing the inventions once they obtain patent protection. This protection typically lasts for a minimum of 20 years from the date of filing the patent application.

For millennia, farmers worldwide have been actively choosing and preserving various agricultural plant kinds, therefore making substantial contributions to the conservation and advancement of new crops. They have a key role in several domains, notably in food production, preservation of traditional knowledge, and conservation of a country's ecological variety. While intellectual property rights safeguard the motivations of plant breeders in creating novel plant varieties derived from farmers' varieties, the custodians of plant genetic diversity for food and agriculture do not receive adequate protection for their motivations within the current framework of intellectual property protection.

India has the third position worldwide in terms of pharmaceutical manufacture based on volume and ranks 14th in terms of value. The domestic pharmaceutical industry consists of 3,000 pharmaceutical enterprises and 10,500 manufacturing facilities. These findings resulted in the creation of novel life-saving drugs, which need protection via Intellectual Property

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Rights (IPRs). Patents provide pharmaceutical businesses with exclusive privileges to commercialize medicines and prohibit others from producing, vending, or manufacturing these medications for a duration of 20 years. Intellectual property rights (IPR) are essential for pharmaceutical enterprises to discover, strategize, market, and safeguard their innovations. Additionally, it serves as a vital instrument for protecting investments, time, and effort, while also fostering fair competition, which in turn drives industrial advancement and economic well-being. Intellectual property rights (IPRs) also incentivize pharmaceutical enterprises to allocate funds towards research and development.

This paper work focuses upon rights of patent holders and its implications in agriculture and medical fieldwork. The researcher details about what are IP rights and what are the different IPR. The focus is upon patents and patent in agriculture and pharmaceutical industry.

INTRODUCTION

Patents are a prominent manifestation of intellectual property rights used across several businesses. A patent is a legal entitlement that restricts the unauthorised use of a novel, innovative, and beneficial product or procedure by individuals or entities other than the patent holder. The patent grants the patent holder exclusive control over the production, use, commercialization, and importation of the patented innovation inside the nation for a finite duration of 20 years[3]. The patenting system plays a crucial role in fostering innovation and driving technological advancements throughout businesses, including the pharmaceutical sector. The expenses associated with the development of novel pharmaceutical goods are significantly elevated. Consequently, in order to recoup these substantial costs, it is crucial for pharmaceutical businesses to safeguard their new medicines from unauthorised commercial utilisation in the market by means of patent protection. In addition to medicines, patents also have significant importance in the field of agriculture. It is essential to bolster and augment our nation's capacity in cutting-edge domains of science and technology in order to capitalise on the unique prospects presented by both home and international markets[4]. Patent laws play a significant role in this context. Patents serve as a protective barrier for

[3] A. KockMichall, S. Porzing and E. Willinegger, "The Legal Protection of Plant Biotechnological Inventions and Plant Varieties in Light of the EC Biopatent Directives" (2006) 37(2) International Review of Intellectual Property and Composition Law pp.135-156

[4] A.B. Endres and Carly E. Giffin, "Necessity is the Mother, but Protection may not be the Father of Invention: the Limited Effect of Intellectual Property Regimes on Agricultural Innovation" (2012) XIV The Columbia Science and Technology Law Review pp.203-253

innovations, trademarks create and distinguish companies, copyrights provide safeguarding for supporting content, and designs registrations include unique shapes, forms, and ornamentation that visually influence buyers. The Plant types and Farmers' Rights (PPV and FR) Act 2001[5] will provide safeguarding measures for plant types. These intellectual property rights instruments are essential elements of strategy development. The government is implementing several legal and institutional changes to enhance Intellectual Property (IP) protection in order to effectively address the problems posed by globalization.

PERCEPTION OF PATENT

A patent encompasses a collection of rights, such as the right to sell, produce, import, etc., and its interpretation varies depending on how it is understood. From a certain perspective, a patent might be seen as a legally awarded and safeguarded exclusive privilege. Patent, as a consequence of the exclusive right, is also considered a monopoly, but it has difficulties in conforming to the traditional definition of monopoly. The process of granting a patent may be seen as a contractual agreement between the inventor and the state, which raises intriguing inquiries about the potential payment that might be provided in exchange for the award[6]. A patent grants a legal entitlement that may be safeguarded. A patent does not provide the owner an explicit entitlement to use the innovation, but rather grants the authority to prohibit others from utilising the invention for a certain duration. A patent grants a negative exclusionary right, which prevents others from using the patented subject matter. A patent grants an exclusive privilege to produce, use, market, distribute, or import the innovation. The ownership of a patent is distinct from the ownership of the tangible assets that the patent represents. Patents are legally conferred with the status of property. According to the Indian Patents Act of 1970[7], patents are classified as moveable property and are subject to the legal principles governing ownership and transfer of movable property. The primary objective is to guarantee that the exclusive rights provided by the patents are limited to the specific innovation created by the patent applicant. The second objective is to guarantee that, in exchange for the granting of the monopoly, the general public is granted complete control over the means to implement the innovation. This ensures that, after the patent has lapsed, the public may fully profit from the invention.

[5] The Protection of Plant Varieties and Farmers' Rights Act, 2001
[6] Anitha Ramanna, "India's Policy on IPRs and Agriculture Relevance of FAO's New International Treaty" 2001 Economic and Political Weekly pp.4689-4692
[7] The Patents, Act, 1970

RIGHTS OF PATENT HOLDERS AND THEIR IMPLICATIONS IN AGRICULTURE

Agricultural production has long been associated with three main functions: feeding the world, providing jobs in rural areas, and supplying raw materials to factories. The public has a lot of faith in India's agricultural potential and farmers' capacity to embrace new technology because of the tremendous strides made in agriculture over the last three decades. Further economic progress and poverty reduction in India can only be achieved via the agriculture sector. It would seem that Indian agriculture is now at a crossroads, confronted with fierce competition in the global agricultural trade and consumption market. In order to take advantage of the rare chances in both local and international markets, our nation's capacity in cutting-edge scientific and technological fields has to be fortified and improved[8]. Improving agricultural production and expanding agri-based companies are often prerequisites for making this change. It has recently come to light that having a lot of grain on hand isn't enough to compete; we also need to make sure our goods are diverse and of high quality, and we can get them to national and international markets quickly. Developed nations were able to do this by refocusing their research missions on developing agricultural technologies that were both efficient and relevant to the needs of the moment; these innovations were crucial in bringing about the industrial revolution.[9]

In reality, it was during the Uruguay Round (1986–1994) that agriculture was first included in the intergovernmental discussions for the General Agreement on Tariffs and Trade (GATT), making its status as a rule-bound sector of investment and profit making very clear. By the end of this session, in January 1995, the WTO had been officially established. Currently, there are six intergovernmental agreements pertaining to agriculture that are part of the World Trade Organization. These include the following: AoA, SPS, TBT, Anti-dumping, Subsidies and Countervailing Measures, Safeguards, and TRIPS, which deal with trade-related aspects of intellectual property rights.[10]

[8] Daniel Robinson, "Sui Generis Plant Variety Protection Systems: Liability Rules and Non-UPOV Systems of Protection" (2008) 3(10) Journal of Intellectual Property Law & Practice pp.659-665

[9] A. Krattigerand and R.T. Mahoney (eds.), *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practice* (MIHR: Oxford, United Kingdom, 2007).

[10] Lionel Bently and Brad Sherman, *Intellectual Property Law* (Oxford University Press, New York, 1st edn., 2003).

The result is a cutthroat international race to be the first to market with innovative research goods for home use, international commerce, and industrial applications. An efficient way to safeguard and compensate inventors is via recognition of intellectual property, which stimulates economic and technical growth[11]. The emergence of international institutional mechanisms like the CBD and the WTO, as well as the signing of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)[12], have brought to light the increasing significance and worldwide reach of intellectual property rights (IPR) in the agricultural sector.

The value of intellectual property rights (IPR) as a tool for monetizing agricultural R&D has recently come to light. At each and every step of agricultural technology development, from initial concept to final product, it is crucial to comprehend the TRIPS agreement and its consequences.

INTELLECTUAL PROPERTY RIGHTS AND FARMERS

The agricultural industry may make use of a number of the intellectual property rights (IPRs) listed above to safeguard agricultural products and services. Trade secrets, geographical indications, patents, trademarks, and plant breeders' rights are the most common examples. It is conceivable to combine agriculturally-oriented chip layout designs into industrial machinery, however this is predicated on the assumption that such designs will be used in such equipment. Similarly, it is not believed that this industry is directly responsible for producing scientific publications or television programs that discuss agricultural concepts.

Because they provide the most robust [13]protection for patentable plants and animals and biotechnological procedures used to produce them, patents are perhaps the most essential intellectual property rights (IPR) for agricultural commodities and services today, wherever they are accessible. A patent always grants the patent holder the exclusive right to manufacture, use, and sell the patented invention. But patents must be made public via the patent papers. Researchers may then utilize this information to create even more valuable

[11] Daniela Guitart, Catherine Pickering, Jason Byrne and Charles Lawson, "Farmers' Rights in Australia: Community Gardens may be a Way in Which a Developed Country Complies with Its International Obligations" (2013) 1(2) Griffith Journal of Law and Human Dignity pp.216-239

[12] The FAO International Treaty on Plant Genetic Resources for Food and Agriculture, 2001

[13] Mohan Dewan, XVI *IPR Protection in Agriculture: An Overview* 131-138 (Journal of Intellectual Property Rights, India, 2011).

goods and services. To be eligible for patent protection, a product must satisfy three requirements:

(1) be innovative (not known in the previous art),
(2) be non-obvious (requiring an inventive step), and
(3) be useful (within the context of an industrial setting).

These requirements are followed by patent laws worldwide, with some subtle variations. But patenting microbes, biotechnological techniques, or even plants and animals is illegal in several nations.

When it comes to agricultural innovations that can boost production, biotechnology is where the future lies. Major multinational corporations based in the United States, Europe, and Japan control the vast majority of biotechnology research and development funding. The importance of exclusive rights over information is growing, especially in this particular area of technology[14]. Even ideas involving animals and human DNA sequences may be given patents in the US today, provided they meet the criteria. The patenting of bacteria that "ate" oil spills in the early 1980s sped up the development of case law in the US. This led to the practice of patenting naturally occurring microorganisms whenever human technological involvement was novel, innovative, and practically applicable. The 'Harvard oncomouse,' a tool for cancer research, was also the subject of a seminal patent lawsuit. Because of pushback from eco-warriors in the EU's parliament, the bloc has been hesitant to follow suit with plant and animal patenting. With the new Biotechnology Directive, which will soon be finalized by the European Parliament, allowing for the patenting of plants and animals with few restrictions, this is now mostly resolved. Therefore, in certain industrialized nations, research into animal cloning, which is progressing at a fast pace, might be eligible for patent protection.[15]

Plant breeders' rights have been established in several nations as a means of compensating traditional plant breeding initiatives. The right holders can only stop other parties from

[14] David Lange and J.H. Reichman, "Bargaining around the TRIPS Agreement: The Case for Ongoing Public-Private Initiatives to Facilitate Worldwide Intellectual Property Transactions" (1998) 9(91) Duke Journal of Comparative & International Law pp.11-68
[15] Elizabeth Verkey, XII *Shielding Farmers' Rights* 131-138 (Journal of Intellectual Property Law and Practice, New York, 2nd edn., 2007).

making money off of the protected content, which is a lesser kind of sui generis protection compared to patent protection. Such protection is based on less stringent criteria than patentability, which are that a plant must be "distinguishable" from previously known varieties, "uniform" in that all plants must exhibit the same essential traits, and "stabilized" in that the essential traits must be retained during reproduction. The private sector is encouraged to embark on breeding activities by such protection. Such initiatives in underdeveloped nations have often come from government agencies or foreign research organizations[16]. The implementation of such safeguards by poor nations is a relatively new phenomenon.

Products and services from both the agricultural and industrial sectors may be protected by trademarks. Trademarks are used in the marketing of seeds and spraying services, for example. To avoid customer confusion, a trademark must clearly identify the products and services of one business as distinct from those of another. This safeguard against the unauthorised use of business trademarks is permanent, albeit registration may need renewal at regular intervals. Trademarks are protected by law in almost every nation on Earth.[17]

The agriculture business might use trade secret protection as a means to safeguard hybrid plant types, among other examples. Therefore, even in nations that do not acknowledge the rights of plant breeders, the use of hybrids provides a certain level of appropriability, provided that it can be maintained in confidentiality. The protection of trade secrets against third-party theft may be achieved by legal measures pertaining to unfair competition, restrictive trade practices, and contract law. Trade secret laws in the United States are distinct and applicable at the state level[18]. The duration of trade secret protection is not restricted, but, unlike patents, the drawback of this kind of protection is that it is forfeited if it is independently uncovered by a third party. One benefit, particularly for the owner, is that, unlike patents, there is no need to reveal the innovative or imaginative concepts to the public.

PATENT PROTECTION: AN AGRICULTURAL ASPECT

Patent legislation was implemented in several countries throughout the 19th century. These statutes specified the patent setting and similar provisions. These regulations specify that

[16] David R. Downes, "How Intellectual Property Could be a Tool to Protect TK" (2000) 25 Columbia Journal of Environmental Law pp.253-279

[17] Jonathan Curci, *The Protection of Biodiversity and Traditional Knowledge in International Law of Intellectual Property* (Cambridge: Cambridge University Press 2010)

[18] Douglas Sanders, "Collective Rights" (1991) 13(3) Human Rights Quarterly pp.368-386

patents should only be granted to certain categories of inventions[19]. In the majority of domestic patent laws, the basic step of patentability requirements remained consistent, requiring inventions to possess both novelty and industrial usefulness. The need for non-obviousness or creative step was subsequently established by legal precedents in the mid-1900s and formally documented.

Patents pertaining to agricultural instruments and equipment, as well as the design process of agricultural chemicals, may be principally enforced in line with the Indian Patent Act of 1970 and later amendments. However, the practices in agriculture and horticulture encompass various microorganisms, including plant varieties, animal strains or breeds, fish or birds, as well as chemical and biochemical products. These practices also include the procedures employed to ensure the safety of livestock or crops from diseases, enhance their economic value, and utilize them for medical or curative purposes. The patentability of materials intended for medicinal and food purposes, with the exception of process improvements related to chemicals such as alloys, optical glass, semi-conductive compounds, and intermetallic compounds, was not established until early 2005. The patenting of improvements pertaining to agrochemicals as goods was made possible by the Patent Act (Amendments) 2005, effective from 2005.[20]

India does not have any existing regulation pertaining to the safeguarding of plant types. Nevertheless, it was believed that enacting such legislation was necessary after turning into a participant to the TRIPS Agreement. This is because Article 27.3(b) of the TRIPS Agreement mandates the protection of plant varieties through patents, an effective unique scheme, or a combination of both. In India, a unique initiative was established that brings together breeders, peasants, and other organizations to ensure the protection of plant types[21]. Sui generis permits the creation and modifications of a patent system to safeguard unique plant types. The enactment of the Protection of Plant Varieties and Farmers' Rights Act (PPVFR) of 2001[22] in India resulted in the establishment of intellectual property rights (IPR) protection for fresh plant species. The aforementioned advancements have created advantageous legal conditions for international biotechnology research and development organizations.

[19] Edwin C. Hettinger, "Justifying Intellectual Property" (1989) 18(1) Philosophy and Public Affairs pp.31-51
[20] Geertrui Van Overwalle, "Patent Protection for Plants: A Comparison of American and European Approaches" 39 *The Journal of Law and Technology* 144 (1999).
[21] Elizabeth Verkey, "Shielding of Farmers Rights" (2007) Journal of Intellectual Property Law & Practice pp.825-833
[22] The Protection of Plant Varieties and Farmers' Rights Act, 2001

The Act of 2001 on the Protection of Plant Varieties and Farmers' Rights

The primary catalyst for the implementation of the Plant Variety Protection (PVP)[23] system in India is the mandate imposed by the World Trade Organization (WTO) that all member countries must adopt intellectual property (IP) safeguards for plant varieties, as stipulated in Article 27.3(b) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). In 2000, PVP was considered essential for promoting food security, especially from the perspective of business breeders, farmers, and agro-biodiversity conservation. To ensure the protection and preservation of producers' freedoms while simultaneously granting benefits to plant breeders, the implementation of a unique Plant Variety Protection (PVP) policy in India became imperative. Patents pertaining to agricultural instruments and equipment, as well as the design process of agricultural chemicals, may be principally enforced in line with the Indian Patent Act of 1970 and its later amendments. Agricultural and horticultural practices encompass the utilization of various microorganisms, including plant varieties, animal strains/breeds, fish, birds, as well as chemical and biochemical products. These practices aim to ensure the safety of livestock or crops from diseases and enhance their economic value.[24]Additionally, they are employed for medical or curative purposes. The patentability of materials intended for medicinal and food purposes, with the exception of process improvements related to chemicals such as alloys, optical glass, semi-conductive compounds, and inter-metallic compounds, was not established until early 2005. The patenting of improvements pertaining to agrochemicals as goods was made possible by the Patent Act (Amendments) 2005, effective from 2005[25]. India lacked regulations pertaining to the safeguarding of plant types in the past. Nevertheless, it was believed that enacting such legislation was necessary after becoming a signatory to the TRIPS Agreement. The aforementioned advancements have created advantageous legal conditions for international biotechnology research and development organizations.[26]

Farmers' Rights

An obstacle to intellectual property rights (IPR) was the significant role played by traditional breeders in enhancing plant genetic resources, particularly in developing

[23] The Protection of Plant Variety and Farmers' Rights Act, 2001 Preamble
[24] Mrinalini Kochupillai, "The Indian PPV&FR Act, 2001: Historical and Implementation Perspectives" 16 *Journal of Intellectual Property Rights* 89 (2011)
[25] Enrico Bonadio, "Crop Breeding and Intellectual Property in the Global Village" (2007) 29(5) European Intellectual Property Review pp.167-171
[26]Idbi.

nations. The concept of farmer's rights refers to the entitlements that arise from the efforts made by farmers to preserve, enhance, and ensure the availability of plant genetic resources, particularly those found in areas of origin or variety. This definition is outlined in Council decision 5/89 of the Food and Agriculture Organization (FAO) Council. An approach was to endeavor to modify existing intellectual property rights (IPR) laws in order to provide manufacturers the ability to obtain exclusive privileges. [27]

India has been among the pioneering countries to implement legislation that simultaneously grants rights to both peasants and breeders inside a unified Act. The existing legislation in this particular domain establishes official rights for farmers in a way that upholds their self-sufficiency, while also recognizing the efforts of crop breeders in the advancement of novel plant kinds. The Act recognizes that producers serve as both cultivators and custodians of the farm type by safeguarding the rights[28]. The objectives of the Act are to create an effective system for safeguarding crop varieties, preserving the freedoms of producers and crop breeders, promoting investment in research and development in the seed industry, and guaranteeing that farmers and other landowners, including horticulturalists, have access to high-value plants and growing materials for improved species[29]. The Plant Variety Protection (PVP) system in India provides advantages to licensed breeders in several aspects, including the preservation, utilization, seeding, reseeding, sharing, and sale of their fresh range. Additionally, breeders who are registered with a fresh variation have the authority to prohibit individuals from marketing, exporting, importing, or manufacturing such a range without their approval. It may also be misleadingly similar to the use, sale, export, import, or production of any kind.

INTERNATIONAL CONVENTIONS AND FARMER'S RIGHTS

The involvement of many stakeholders and specific States in addressing the legal protection of plant varieties is facilitated by international conventions and accords on intellectual property, which provide a versatile framework. The potential reduction or weakening of plant

[27] Anitha Ramanna, "Farmers' Rights in India: A Case Study" 4 *The Farmers' Rights Project, Background Study* 136 (2006)
[28] F.K. Beier and J. Straus, "Genetic Engineering and Industrial Property" (1987) 11 Industrial Property
[29] G. Wurtenberger, "The Cornerstones of Plant Variety Protection in India" (2008) 3(5) Journal of Intellectual Property Law & Practice pp.343-344

variety protection will adversely affect private firms operating within this area. Genetic resources of plants have a crucial role in the domains of food and agriculture[30]. Plant genetic resources are essential for enhancing crop genetics. Gene enhancement may be attained via several methods, including farmers' selection, traditional plant breeding, or contemporary biotechnologies. Hence, it is essential to ensure the protection of both farmers and plant breeders in order to facilitate genetic advancements.

THE TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS AGREEMENT (TRIPS) 1994

The TRIPS agreement was developed as a component of the GATT, which stands for the General Agreement on Tariffs and Trade. The TRIPS Agreement has significant prominence as a fundamental business treaty in contemporary times. It will fundamentally transform the handling of intellectual property in the nations that have signed the agreement[31]. The Agreement was negotiated with the aim of mitigating distortions and obstacles to global commerce. Section I of the Agreement delineates overarching requirements and fundamental principles, including a commitment to national treatment[32]. This commitment mandates that individuals from other parties must get treatment that is no less advantageous than that granted to a party's own national in terms of safeguarding intellectual property. The agreement also includes a most-favored-nation clause, which is a unique feature in international intellectual property agreements. This clause mandates that any benefit provided by one party to the citizens of another country must be promptly and unconditionally extended to the citizens of all other parties, regardless of whether such treatment is more advantageous than that provided to its own citizens.

The TRIPS agreement brought about a significant transformation in the function of international trade law in advancing and ensuring the safeguarding of intellectual property worldwide. According to the TRIPS Agreement, it is mandatory for all member nations to align their national intellectual property rights (IPR) legislation with specific stipulations included in the new Agreement. TRIPS is a global agreement that mandates member nations

[30] Gail E. Evans, "Unsettled International Intellectual Property Issues" (2010) 16(1) International Trade Law and Regulation (Publication Review) pp.33-36
[31] The Agreement on Trade Related Aspects of Intellectual Property Rights, 1994
[32] Geertrui Van Overwalle, "Patent Protection for Plants: A Comparison of American and European Approaches" (1999) 39 The Journal of Law and Technology pp.143-194

to provide robust intellectual property safeguards under their national legislation[33]. The advancements in biotechnology and plant breeding have resulted in the widespread unauthorized acquisition of resources from underdeveloped nations. The level of intellectual property protection offered by different countries exhibited significant variation, hence creating an opportunity for emerging nations to engage in the unauthorized appropriation of technical advancements from industrialized nations. The industrialized nations, led by the United States, sought to establish a robust framework for safeguarding emerging technology. The TRIPS Agreement encompasses all aspects of intellectual property and furthermore sets out a set of baseline protection criteria. Member nations are obligated under the Agreement to offer protection for patents in every field of technology[34]. The Agreement also specifies the innovations that Member-states have the authority to exclude from being eligible for patent protection.

The TRIPS Agreement of 1994 allows members to exclude biological processes that are fundamental for the production of plants or animals, except for nonbiological and microbiological activities.190 Nevertheless, the Agreement stipulates that members must ensure the safeguarding of plant varieties via either patents, a robust sui generis system, or a combination of both. The parties of the Agreement have significant autonomy to choose the protection system that best suits their needs. Upon the implementation of the TRIPS Agreement, the majority of industrialized nations had established mechanisms to safeguard plant varieties, and a significant number of them had already ratified the UPOV Convention.

Members are obligated by the Agreement to ensure the preservation of a certain plant type. The phrases "plant" and "plant variety" are clearly differentiated. A plant variety may be defined as a genetically modified version of a naturally occurring plant that falls within the botanical kingdom. In addition, the Agreement explicitly excludes innovations that are deemed essential for safeguarding "order public or morality," including the protection of human or plant life or health, as well as the prevention of significant harm to the

[33] Gurdial Singh Nijar, "Sui Generis Law for Plant Varieties: Preserving the Knowledge and Creativity of Traditional Breeders: A Third World View" (1999) Third World Network

[34] Harbir Singh, "Plant Variety Protection and Food Security: Lessons for Developing Countries" (2007) 12 Journal of Intellectual Property Rights pp.391-399

environment[35]. The phrase "order public," derived from French law, refers to the safeguarding of public security and the physical well-being of the general public as an integral element of society. While including environmental concerns, this term is more limited in scope compared to the notion of public order.

The UPOV Acts, which have offered intellectual property rights (IPR) protection for plant varieties for over four decades, have experienced a decline in importance due to the adoption of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in 1994. The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is the first and only intellectual property rights (IPR) pact that aims to create universally applicable, baseline levels of safeguarding across key domains of intellectual property, including patents, copyrights, trademarks, industrial designs, integrated circuits, and trade secrets[36]. Despite the limited focus on plant breeders' rights and plant variety protection in the TRIPS accord, and its omission of the UPOV Acts, its implementation has significantly promoted the legal safeguarding of plant varieties more than any other global accord.

INTELLECTUAL PROPERTY RIGHTS OF FARMERS IN INDIA

An agricultural economy is the backbone of India's economy. Because its farmers come from such a wide range of socioeconomic backgrounds, it's unlikely that they would get any financial rewards from their labor. The agricultural community in India may be roughly categorized into three groups: marginal, small and medium, and big farmers, according to their land holdings and income. The agro-forestry industry is vital to the livelihood of India's vast tribal population. Due to their great poverty and lack of resources, tribal and marginal farmers hardly use modern farming techniques. These farmers are unlikely to gain from advancements in plant breeding since, save in rare instances, they have been discovered to adopt superior kinds[37]. Unauthorized usage of their land races and other germplasm might cost them if they don't learn about farmer rights.8 High input farming poses a significant threat to small and medium farmers since they often do not have the capital or education to use contemporary agricultural practices. This group of farmers stands to gain a great deal if

[35] Ikechi Mgbeoji, "Patents and Traditional Knowledge of the Uses of Plants: Is a Communal Patent Regime Part of the Solution to the Scourge of Bio-Piracy" (2001) 9(1) Indiana Journal of Global Legal Studies pp.163-186

[36] J. Staffler, "Overview on Article 27.3(b)" (2003) Turin University/WIPO

[37] K. Kariyawasam, "Terminator Technology as a Technological Means of Forcing Intellectual Property Rights in Plant Germplasm: Its Implications for World Agriculture" (2009) 31(1) European Intellectual Property Review pp.37-44

they are educated about the benefits and drawbacks of modern farming, as well as strategies to mitigate the latter[38]. The wealthy big farmers know about the new technology and are prepared to pay for it. The economic preservation of plant types is obviously beneficial for these farmers.

The Indian Council of Agricultural Research (ICAR) performs the bulk of India's plant breeding. In order to maintain food security in an environmentally friendly way, it is necessary to investigate the prudent use of contemporary biotechnological technologies in plant breeding. The private seed firms are progressively benefiting from patents and licenses that cover this technology's procedures and goods, which is a major concern. A small number of powerful transnational corporations (TNCs) based in the developed world control the vast majority of intellectual property rights (IPRs) in agricultural biotechnology. This power concentration is a direct result of the patenting of ever-increasing layers of IPR on germplasm.

The Indian farmers should be protected due to the significant role they play in preserving biodiversity. When farmers help preserve land races and generate new plant kinds, they get protection that is proportionate to their efforts. The private sector plant breeders will focus on the highly lucrative hybrid seed sector, but the public sector and farmers will have to shoulder the burden of developing pure line varieties for marginal and high input areas because of farmers' rights. This limits the profit from developing and selling these varieties.

The UPOV Convention of 1961 does not include India as a member. But as India was one of the original members of the World Trade Organization, it is a signatory to the Trade Related Intellectual Property Rights (TRIPS) Agreement, the principal pact intended to bring member nations' IP laws into line with one another. All members of the World Trade Organization are required to adhere to its bare minimum standards[39]. In addition to its responsibilities, the TRIPs Agreement offers some leeway and flexibility with regard to the conservation of plant varieties. The member states are obligated to provide the protection of plant varieties via patents, sui generis systems, or a hybrid of the two, according to Article 27(3)(b). Developing nations have enough leeway to craft a system that works for them and achieves their aims and

[38] K. Mahamuni, "TRIPs and Developing Countries: The Impact on Plant Varieties and Traditional Knowledge" (2006) 12(6) International Trade Law and Regulation pp. 134-141

[39] K. Mechlem, "Agricultural Biotechnologies Transgenic Crops and the Poor: Opportunities and Challenges" (2010) 10(4) Human Rights Law Review pp.749-764

objectives, which is why the sui generis system was proposed as a substitute for the patent system for plant species. The interests of the agricultural community must be considered by emerging nations when they establish their own unique protection system.

India is one of the first countries to have passed a legislation granting rights to both breeders and farmers under the Protection of Plant Varieties and Farmers' Rights Act, 2001 (PPV&FR Act). It recognizes the phenomenal contribution of farming communities in conserving biodiversity and developing new plant varieties[40]. India's PPV&FR Act is said to be a unique legislation in that it simultaneously aims to protect both breeders and farmers.

Given India's leadership in drafting a legal framework protecting farmers' rights, its international role in negotiating these rights, its status as a biodiversity hotspot, and the complexity of its agricultural sector, the country's efforts to implement these rights are of paramount importance. The Indian gene center is well-known for its abundant plant genetic resources, making India's example particularly noteworthy[41]. The Act's efforts to establish a system of multiple rights could create a number of problems for farmers when it comes to sharing and using plant genetic resources.

The Indian legal system developed out of an effort to balance the competing interests of breeders in the private sector, government agencies, NGOs, and farmers all within the context of property rights. The Act's goals are to promote the creation of novel plant varieties, safeguard the rights of plant breeders and farmers, and set up a mechanism to effectively preserve plant varieties.

The Act also aims to increase funding for plant breeding research, which would speed up the process of creating new plant varieties, expand the seed business, and ensure that farmers have access to high-quality seed and planting materials. It upholds the rights of farmers and acknowledges the need of intellectual property protection for plant types. In the context of protecting farmers' rights, there are a number of statutes that are important, including the PPV&FR Act.

[40] K. Venkataraman and S. Swarna Latha, "Intellectual Property Rights, Traditional Knowledge and Biodiversity of India" (2008) 13 Journal of Intellectual Property Rights pp.326-335

[41] K.P. Ramesha, "Intellectual Property Rights Regime for Livestock Agriculture in India: Present Status and Future Prospects" (2011) 16 Journal of Intellectual Property Rights pp.154-162

"The following part discusses the provisions of the Seeds Act, 1966; the Patent Act, 1970; the PPV&FR Act, 2001; the Biological Diversity Act, 2002; and the Seed Bill, 2010 having bearing on the issue of farmer's rights"

The Seed Act, 1996

Seeds serve as the foundation for a sustainable food system. Hence, it is of utmost significance to keep the purity and quality of seeds throughout the many phases of their development. In 1966, the Seeds Act[42] was enacted to provide regulations for the quality of certain seeds available for purchase. The term "seeds" encompasses various categories of seeds utilized for the purpose of sowing or planting. These categories include seeds of food crops, such as edible oil seeds and seeds of fruits and vegetables, as well as cotton seeds and seeds of cattle fodder. Additionally, seeds of food crops or cattle fodder include seedlings, tubers, bulbs, rhizomes, roots, cuttings, grafts, and other vegetatively propagated materials. According to the Act[43], the Central Government has the authority to designate a certain kind or variation of seed as a notified kind or variety if it deems it essential or advantageous to control the quality of seeds intended for agricultural purposes. The minimum limits of germination and purity for any seed of a recognized type or variety may be specified by the Central Government. Additionally, the mark or label used to indicate that the seed meets these minimum limitations of germination and purity, as well as the specific details included in the mark or label, may be specified.[44]

Farmers' Rights Protection under Seed Bill, 2010

The Seed Bill of 2010 aims to revoke the current Seeds Act of 1966 in order to enhance the provision of high-quality seeds to farmers and establish regulations for the seed trade. In contrast to the Seeds Act of 1966, the 2010 Bill stipulates that the trading of any seed, with the exception of farmers' seeds, is prohibited in India unless it is registered.[45] The Seeds Bill encompasses a comprehensive range of seeds, including as well as live embryos and vegetative planting material, such as seedlings, tubers, bulbs, rhizomes, roots, cuttings, grafts, tissue culture plantlets, and synthetic seeds. All individuals involved in the production of these seeds, with the exception of farmers, processing units, distributors, and traders, are

[42] The Seeds Act, 1966
[43] The Seeds Act, 1966
[44] The Indian Seed Act And Patent Act: Sowing the Seeds of Dictatorship, *available at*: http://www.countercurrents.org/gl-shiva150205.htm
[45] The Seed Bill, 2010 Section 13(1).

required to undergo compulsory registration at the state level. The Seeds Act stipulates that a variety released by the central or state government can be marketed for a maximum of 15 years. However, the Seeds Bill changes this period to 10 years for annual or biennial plant varieties and 12 years for perennial plant varieties. The Seeds Bill also allows for the possibility of renewing the marketing period for an equal term if the agronomic performance of the varieties is revalidated.[46]

The proposed legislation requires that all traded seeds be clearly identifiable based on the variety they belong to, ensuring that they fulfill the minimum defined requirements for germination, genetic and physical purity, maximum standard for seed health, and an acceptable degree of agronomic performance. Seed standards certification is obligatory and conducted by certified Central and State Seed Testing Laboratories[47]. The proposed legislation aims to implement a system for evaluating the agronomic performance of many locations in order to ascertain the suitability of a particular variety for registration. The National Register of Seeds is responsible for documenting the specifics of all registered cultivars. The Bill establishes new criteria for labeling and includes a statement on the anticipated performance of the seed and the necessary circumstances to achieve such performance.[48]

Compensation is available to farmers who are unable to achieve the desired performance from the seed under the specified growing conditions. The responsibility for enforcing the majority of the regulatory provisions outlined in the Bill lies with the state administrative structure, which includes the involvement of seed inspectors at the field level. The Bill grants these authorities the authority to enter and search any location where there is suspicion of an offense, seize counterfeit seeds with a signed order from the district magistrate, and commence legal proceedings against the perpetrators. Nevertheless, the historical track record of implementing the Seeds Act in several states is remarkable, since farmers bear a significant burden due to the lack of action, incompetence, and corruption within the enforcement system, as well as the lenient penalties imposed on violators. This measure safeguards the farmer seeds system from regulation. The Seeds Bill, 2010 has included many

[46] V. Santhy, P.R. Vijaya Kumari, Anshu Vishwanathan, R.K. Deshmukh, "*Legislations for Seed Quality Regulation in India*" 1(2009) CICR Technical Bulletin No. 38
[47] Kamalesh Adhikari, "Farmers Rights over Plant Varieties in South-East Asian Countries" (2008) Southeast Asian Council for Food Security & Fair Trade
[48] Sections 13(1) and (2)

significant suggestions from the PSCA[49]. The following recommendations present a revised definition of the term 'farmer' that encompasses his multifaceted roles as a cultivator, conserver, and breeder. They aim to provide effective protection for farmers' rights to engage in activities such as growing, saving, re-sowing, exchanging, sharing, or selling seeds and planting material. However, it is important to note that such sales should not be conducted under a brand name. Additionally, the recommendations propose excluding farmers from the category of seed producers and granting exemptions for farmers' varieties to be registered in the National Register of Seeds (NRSs).

RIGHTS OF PATENT HOLDERS AND THEIR IMPLICATIONS IN MEDICAL INDUSTRY

The Indian pharmaceutical industry is a lucrative sector that relies on advanced technology and has had consistent growth over the last thirty years. As a result of advantageous governmental regulations and little international competition, the current landscape of the sector comprises several privately-owned Indian businesses that have successfully captured a substantial portion of the local pharmaceutical markets. Nevertheless, the emergence of Indian enterprises from local markets and their preparation for international competition is being facilitated by the liberalization of the Indian economy. With the increasing integration

[49] Kamalesh Adhikari, "Protection of Farmers' Rights over Plant Varieties in Southeast Asian Countries" (2008) Southeast Asian Council for Food Security & Fair Trade

of India's markets into global commerce, the pharmaceutical sector in India is facing the need to reassess its long-term strategy and business strategies. The significance of intellectual property protection is increasing due to the growing need to safeguard expensive expenditures in research and development (R&D)[50]. India is now undertaking measures to tackle concerns over the enforcement of its current intellectual property legislation. The government is actively engaged in the development of a patent system that fosters technological progress and aligns with its international obligations.

PATENTS IN THE PHARMA INDUSTRY

Section 3 of the Patents Act, 1970, outlines the specific innovations that are not eligible for patent protection, even if they meet the conditions for patentability. In the realm of pharmaceutical innovations, particular emphasis is placed on Section 3(d) of the Patents Act, 1970, since it explicitly stipulates: Section 3 of the Patents Act of 1970 delineates the categories of innovations that are deemed ineligible for patent protection, although satisfying the criteria for patentability. In the realm of pharmaceutical innovations, Section 3(d) of the Patents Act of 1970 necessitates particular consideration due to its provision that states: "The mere identification of a novel manifestation of a recognized substance that does not lead to an augmentation of the established effectiveness of said substance, or the mere identification of any novel characteristic or application for a recognized substance, or the mere utilization of a recognized process, apparatus, or machinery, unless said established process yields a fresh product or involves at least one novel reactant.[51]" In this clause, it is determined that salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations, and other derivatives of a known substance are regarded as identical substances, unless they exhibit substantial differences in terms of efficacy.

The primary objective of Section 3(d) of the Patents Act of 1970 is to prohibit the practice of ever-greening pharmaceutical patents and to extend the scope of patent protection to innovations, namely those pertaining to pharmaceuticals or chemical compounds[52]. According to this section, an invention that presents a new version of a well-known substance

[50] M.S. Swaminathan, "The Protection of Plant Varieties and Farmers' Rights Act: From Legislation to Implementation" (2002) 7 Journal of Intellectual Property Rights, pp.324-329

[51] Max Stul Oppenheimer, "The 'Reasonable Plant' Test: When Progress Outruns the Constitution" (2008) Minnesota Journal of Law, Science & Technology pp.417-452 at 417

[52] Margaret Llewelyn, "The Legal Protection of Biotechnological Inventions: An Alternative Approach" (1997)19(3) European Intellectual Property Review at 115

or a second and subsequent use of a well-known substance with set medicinal properties is considered the same substance and cannot be patented unless the invention greatly enhances the effectiveness of the known compound in terms of treatment.

The Supreme Court of India, in the case of **Novartis AG v. Union of India &Ors.**[53]**,**underscored the genuine legislative purpose of Section 3(d) of the Patents Act, 1970. The court underlined that Section 3(d) is specifically designed to address chemical substances, with a particular focus on pharmaceutical items. The revised section 3(d) explicitly outlines the additional criteria for chemical substances or pharmaceutical items, aiming to allow for legitimate and genuine discoveries while also prohibiting the occurrence of "repetitive patenting or patent term extensions based on false justifications." Furthermore, while examining the concept of "efficacy," the Court articulated that within the realm of pharmaceutical patenting, "efficacy" pertains to the capacity to effectively enable the functionality of a product[54]. Furthermore, the Court asserted that the term "efficacy" within the realm of pharmacological patenting pertains to the capacity to produce a target or intended outcome. Consequently, the term "improved therapeutic efficacy" does not refer to a modification in the structure of an already acknowledged structure that has intrinsic characteristics of that structure. In order for a novel form to be eligible for patent protection, it must explicitly establish its therapeutic effectiveness[55]. It is essential to acknowledge that the Indian Patent Office gives applicants the opportunity to provide additional evidence or experimental testing during the evaluation of applications in order to substantiate the "therapeutic efficacy" of the invention, a factor that was not explicitly stated in the specifications during the first filing.

Section 3(e) of the Patents Act, 1970, is about patenting of combination inventions, in the field of chemical as well as biotechnological sciences and states –

In the realm of Indian patent law, it is well recognized that the simple amalgamation of many components, which does not need the application of creative faculties and serves its intended function autonomously, is not eligible for patent protection. The patentability of the subject

[53]**Novartis Ag Vs. Union Of India (Uoi) And Ors.** [2013] 13 S.C.R. 148
[54] Mrinalini Kochupillai, "The Indian PPV&FR Act, 2001: Historical and Implementation Perspectives" (2011) 16 Journal of Intellectual Property Rights pp.88-101
[55] Mohammad Reza Parvin, "Patentability of Plants: Technical and Legal Aspects" (2009) 14 Journal of Intellectual Property Rights pp.203-213

matter is contingent upon the establishment of functioning interrelationships resulting from the collocation of various components, which are interconnected to provide innovative or enhanced outcomes. Claims pertaining to pharmaceutical compositions under Section 3(e) of the Patents Act, 1970 are often rejected by the Indian Patent Office[56]. This is because such claims include a known composition or a straightforward combination of known components that does not result in any synergistic effects. One of the primary reasons for objections to patent applications is the challenge in understanding terminology such as "mere mixing" and "aggregate of the qualities" as outlined in Section 3(e) of the Patents Act, 1970.

The term "mere admixture" was defined by the Hon'ble Bombay High Court in the case of **LallubhaiChakubhaiJarivala v. ShamaldasSankalchand Shah[57].**According to the court, "mere admixture" refers to the act of combining known materials with the intention of achieving an additive effect of both substances. When an individual encounters a greater than anticipated cumulative impact, the combination is often known as a synergistc composition. Preparing a blend of an unknown material is unattainable when both its composition and properties are unknown. Consequently, the chemical structures of the new medication or molecule cannot be referred to as a "mere admixture" due to the absence of prior knowledge of the compounds used in such compositions or any associated characteristics.

The Bhabha Atomic Research Centre v. Union Of India case established that the act of combining pre-existing features, which were already known prior to the priority date and were arbitrarily selected from various combinations, does not qualify as a patentable invention. Instead, it constitutes the aggregation of properties.

Section 3(i) of the Patents Act, 1970, states – “any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products” is not a patentable invention.

Within the realm of pharmaceuticals, assertions on the efficacy of treatment methods are often presented as composition claims. It is crucial to bear in mind that in India, any assertion

[56] S. Bucher, “The Protection of Genetic Resources and Indigenous Knowledge: Disclosure of Origin of the International and Latin American Agenda” (2008) 39(1) International Review of Intellectual Property and Competition Law pp.35-50

[57]**LallubhaiChakubhaiJarivala v. ShamaldasSankalchand Shah,** AIR 1934 BOMBAY 407

related to therapy is not eligible for patent protection. In contrast, patents may be awarded for surgical, pharmaceutical, or diagnostic equipment or apparatus.

TRIPS AGREEMENT AND INDIA'S PHARMACEUTICAL PATENT SYSTEM

India demonstrated its commitment to the General Agreement on Tariffs and Trade (GATT) by being an early signatory. Nevertheless, it is apparent that GATT shown a more favorable inclination towards industrialized nations rather than emerging ones. During the Uruguay Round negotiations, certain developing nations, notably Brazil and India, have put forth the proposition that the General Agreement on Tariffs and Trade (GATT) lacks jurisdiction over matters pertaining to the safeguarding of intellectual property.

The TRIPS Agreement became effective on January 1, 1995, necessitating India, as a member of the World Trade Organization (WTO), to relinquish some longstanding positions in the intellectual property domain in order to adhere to the stipulations outlined in the TRIPS Agreement[58]. India, being classified as a developing nation, has been granted a 5-year transition time and an extra 5-year term to revise its patent legislation pertaining to the safeguarding of pharmaceutical patents. This research examines the effects of the TRIPS Agreement on India's pharmaceutical patent system, using the revisions made to the Indian Patent Law in 1999, 2002, and 2005.

THE IMPACT OF INDIAN PATENT LAW ON THE LOCAL PHARMACEUTICAL INDUSTRY

Rejection of Product Patent

In 1959, the Patent Law Amendment Commission, led by Shri Justice N. RajagopalaAyyangar, submitted the Report on the Revision of the Patent Law. The report highlighted that during that period, foreigners possessed 80% to 90% of India's patents, with 90% of these patented products not being produced within Indian borders. Foreign corporations have the potential to impede the manufacturing of their patented medications in India, resulting in the stagnation of the local pharmaceutical sector in India. Therefore, the Commission held the belief that multinational firms had used the patent system to establish a

[58] The Report of Commission on Genetic Modification on New Techniques in Plant Biotechnology (2002) CGM/061024-2002

monopoly in the market, particularly within the food, pharmaceutical, and chemical sectors[59]. The presence of market monopolies resulted in elevated product pricing. Hence, the Commission advised that patentability should be limited to methods or processes in the aforementioned domains, in contrast to the Indian Patents and Designs Act of 1911, which allowed patents for both product and process discoveries in the pharmaceutical industry.

The Patents Act of 1970 embraced this proposal, establishing the groundwork for the rapid growth of India's generic pharmaceuticals sector. As per the provisions outlined in the Patents Act of 1970, it is stipulated that patents shall not be awarded for claims pertaining to substances that are intended for use or have the potential to be employed as medicine or drugs, or those that are associated with substances that are made or generated by chemical processes. The Patents Act of 1970 only provides method patents in the medicines and chemicals sectors due to the obstructive impact of product patents on other relevant research. These patents might impede others from acquiring the same items using other techniques. Upon the granting of product patents to pharmaceuticals, patent holders get the ability to regulate the manufacturing of patented products, resulting in an unjustifiable increase in the pricing of vital medications[60]. Consequently, the denial of drug product patents ensured that Indian generic businesses could manufacture pharmaceuticals with same or comparable compositions by reverse engineering, so evading allegations of infringement. Until the conclusion of the transition period of the TRIPS Agreement on January 1, 2005, India refrained from granting product patents within the pharmaceutical industry[61]. The prolonged denial of product patents within the pharmaceutical business for a period beyond three decades has presented a favourable circumstance for the development of the generic medicine sector in India.

Compulsory Licensing System

The Patents Act of 1970 included a dedicated section for compulsory licences, and the Patents (Amendment) Act of 2002 and 2005 made further enhancements to the system. The implementation of the obligatory licencing system increases the likelihood of successful

[59] Jonathan Curci, The Protection of Biodiversity and Traditional Knowledge in International Law of Intellectual Property (Cambridge: Cambridge University Press 2010)
[60] L. Bently, and B. Sherman, Intellectual Property Law (New York: Oxford University Press 2001)
[61] Michael Blakeney, Trade Related Aspects of Intellectual Property Rights. A Concise Guide to the TRIPs Agreement (London: Sweet & Maxwell 1996)

bargaining for voluntary licencing between indigenous Indian pharmaceutical businesses and international multinationals.

As per the provisions of Indian Patent Law, it is stipulated that with the expiry of a period of three years subsequent to the sealing of a patent, any anyone with a vested interest is entitled to submit an application to the Controller. Prior to filing for a compulsory licence, the applicant must first make an effort to obtain a voluntary licence from the patent holder[62]. In the event that this endeavour fails to provide results within a period of six months from the original solicitation, the applicant has the right to submit a compulsory licence application.

The obligatory licence for Nexavar (Sorafenib Tosylate), a kidney cancer medication patented by Bayer Corporation (Bayer), was issued by the Controller in 2012, after the application of Natco Pharma Ltd. (Natco). This is the first and only mandatory licence in India[63]. The Controller's judgement was based on the fact that the medicine Nexavar was not produced in India, but rather imported and sold in the Indian market. The word "(not) work(ed)" specifically refers to production and does not include its importation or sale.

The Controller highlighted that the TRIPS Agreement does not explicitly specify the criteria for awarding compulsory licenses, so giving WTO members significant latitude in determining the application of these criteria within their respective national legislations. In 2014, the Supreme Court validated the judgement made by the Controller, which was first reviewed by the Intellectual Property Appellate Board (IPAB) and courts. However, concerns were raised about the potential negative impact of the compulsory license on foreign direct investment in India.

Undoubtedly, the Nexavar case will ultimately raise patent holders' awareness of the potential for compulsory licensing and increase their willingness to engage in voluntary licensing. Consequently, this will provide more opportunities for talks related to voluntary licensing, ultimately leading to a reduction in medicine costs.

Subsequently, the Controller has shown a rigorous approach in the issuance of obligatory licenses. In March 2013, BDR Pharmaceuticals Intl. Pvt. Ltd. (BDR) submitted a formal request for a compulsory license pertaining to Dasatinib, a cancer medication developed by

[62] T. Ramappa, Intellectual Property Rights under WTO: Task before India, (New Delhi: Wheeler Publishing 2000)

[63] V.K. Ahuja, Law Relating to Intellectual Property Rights (Nagpur: Lexis Nexis Butterworth Wadhawa 2007)

Bristol-Myers Squibb. Dasatinib is specifically prescribed for individuals diagnosed with chronic myeloid leukemia. BDR also argued that the patentee's tablet cost was INR 2761 per tablet, resulting in a total of INR 1,65,680 for 60 tablets per month per patient. Upon acquiring the license, BDR made a commitment to make the medicine accessible to the general public at a cost of INR 135 per pill, resulting in a monthly expenditure of INR 8100[64]. Additionally, BDR pledged to provide the drug free of charge to a certain proportion of patients. In October 2013, the Controller rejected BDR's application, citing insufficient efforts made by BRD to get a voluntary license for the medicine. By means of its refusal, the Controller has shown that any decision about compulsory licensing would be conducted with meticulous consideration, ensuring the proper safeguarding of intellectual rights. The proposed strategy successfully achieves a harmonious equilibrium between the concerns of international corporate patent holders and local generic firms.

Compulsory Licensing Of COVID-19 Drugs & Vaccine in India

Since the onset of the COVID-19 pandemic in 2019, India has seen a pressing need for pharmaceuticals and immunisations. The number of COVID-19 cases has seen a significant and rapid increase. However, the imbalance between the demand and availability of COVID medications and vaccinations has been a cause for worry for the last two years.

India's crude mortality rate in the previous year was at around 7.3 per 1000 people, with approximately 5.07 lakhs succumbing to COVID-19. The implementation of mandatory licencing for COVID-19 drugs and vaccines has emerged as a proactive measure to address the insufficient supply of vaccines. This approach involves the government compelling vaccine manufacturers to share their intellectual property with other pharmaceutical companies, thereby facilitating expedited vaccine production.

The legitimacy of forced licensing in the context of pharmaceutical pharmaceuticals in India is supported by a substantial body of precedents. In 2012, the Indian patent office issued a compulsory license to Natco, a pharmaceutical headquartered in Hyderabad, to produce and market a comparable version of Bayer's Nexavar, an advanced medication for kidney cancer. In 2000, the nation saw Cipla, a prominent pharmaceutical company, challenging the

[64] Walter V. Reid (eds.) Biodiversity Prospecting: Using Genetic Resources for Sustainable Development (Washington, D.C.: World Resources Institute 1993)

Government's decision to enforce compulsory licensing for the Anti-Aids medicine, despite the fact that the law allows for it.

Currently, the private sector exhibits a certain degree of hesitancy in adopting compulsory licenses, even when they are issued by the government. This hesitancy stems from concerns regarding potential prolonged litigation by multinational corporations or the possibility of being denied partnerships, even for contracted manufacturing. The public health sector, which has traditionally served as the primary means for implementing government-issued obligatory licenses, has seen significant decline due to prolonged neglect[65]. The majority of public health sectors are either closed or on the verge of collapse, indicating that our failure to effectively use obligatory licenses has resulted in negative consequences.

In a press statement released on May 27, 2021, the NITI Ayog expressed that India has no intentions of implementing compulsory licenses for COVID-19 vaccines. Additionally, the NITI Ayog emphasized the need of active collaboration from the original vaccine manufacturers.

Consequences of Compulsory licensing of Pharmaceutical Drugs

- Pharmaceutical reproductions derived under a required license may not adhere to equivalent quality criteria. The presence of an obligatory license does not necessarily indicate that the firm have the background knowledge to manufacture medications with equivalent efficiency to the original drug.
- Compulsory licensing has the potential to hinder the progress of developing novel therapies. Pharmaceutical manufacturers heavily depend on existing patents to generate economic benefits by producing replicas of established drugs, hence impeding their ability to prioritize the development of novel pharmaceuticals.
- The imposition of compulsory licensing serves as a deterrent for firms to conduct clinical trials in nations that do not uphold patent rights. This is a detriment for patients who forego an opportunity to undergo medical intervention[66]. Additionally, it

[65] Anitha Ramanna, India's Plant Variety and Farmers' Rights Legislation: Potential Impact on Stakeholder Access to Genetic Resources (2003) Environment and Production Technology Division, International Food Policy Research Institute, Washington D.C. 2003, EPTD Discussion Paper 96

[66] Carlos M. Correa, Access to Plant Genetic Resources and Intellectual Property Rights (1999) Commission on Plant Genetic for Food and Agriculture, Background Study Paper No.8

is detrimental to local businesses that might otherwise benefit from the presence of clinical trials in a particular place.

IMPORTANT CASE LAWS

Eli Lilly Vs. Sun Pharma and Others[67]

The Federal Circuit clarified that pharmaceutical manufacturers and prescribing physicians have distinct roles, and as a result, pharmaceutical companies cannot directly violate claims related to the method of treatment. The defendants' request for partial summary judgement, which states that there is no direct infringement, was approved[68]. Lily was unsuccessful in the struggle due to the lack of proof, and she also lost the request for reconsideration of the verdict for the same reasons.

Pfizer Inc V/S SRS Pharmaceutical INC

The Presiding Judge, Cesar O. Unialan, of the Makati Regional Trial Court, on 31st March 2009, declared that, "this Court hereby denies the issuance of a preliminary injunction for plaintiffs (meaning Pfizer) since they miserably failed to prove their right over the subject molecular ingredient/element or sulbactam sodium or sodium sulbactam for the simple reason that the same ingredient had been subject of a prior art.[69]" The case was thereby dismissed by the Court for a simple reason that there was nothing more to be done in the case considering the relief prayed for the plaintiffs under their Amended Complaint.

Millennium Pharmaceuticals Inc Usa Vs Natco Pharma Ltd. India

In the aforementioned case, it was determined that the challenged invention does not possess inventive step, thereby rendering it ineligible for patent protection under section 2(1)(j). Upon careful examination of the submissions put forth by both parties, including their evidence, arguments, and all the documents submitted, as well as the overall circumstances of this case, it has been determined that the claims made in the present application are not permissible. This determination is based on the fact that the claims were readily apparent to a person with expertise in the relevant field and lacked an innovative element. Hence, the assertions made

[67] *Sun Pharmaceutical Industries, Ltd. v. Eli Lilly & Co.*, 611 F.3d 1381 (Fed. Cir. 2010)

[68] Maria Scurrah, Regine Andersen and Tone Winge, Farmers' Rights in Peru: Farmers' Perspectives (2008) Farmers' Rights Project, The Fridtjof Nansen Institute, Background Study 8

[69] Regine Andersen, Realising Farmers' Rights Under the International Treaty on Plant Genetic Resources for Food and Agriculture (2006) Summary of Findings from the Farmers' Rights Project, The Fridtjof Nansen Institute

did not meet the criteria for being considered an invention under section 2(1)(j) of the Patents (Amended) Act, 2005.

Bilcare Ltd V/S Amartara Pvt. Limited

The Court decided to vacate the injunction due to the balance of convenience after reviewing all of the reasons and taking into account the patent's recent grant and the ongoing post grant challenge. In addition, the court ruled that the plaintiff's best interests may be safeguarded if the defendant was ordered to maintain records of the disputed product throughout the litigation and provide them quarterly.

CONCLUSION AND SUGGESTIONS

IN RESPECT OF RIGHTS OF PATENT HOLDERS IN THE AGRICULTURE SECTOR

Conclusion

The laws that primarily regulates intellectual property rights pertaining to farmers in India are the Protection of Plant Varieties and Farmers' Rights Act, 2001, and the Biological Diversity Act, 2002. The Protection of Plant Varieties and Farmers' Rights Act, 2001 especially deals with the rights of farmers. The aforementioned legislation confers onto farmers a range of entitlements, including the sharing of benefits, the capacity to register their crop variety, compensation for default seeds obtained from breeders, and acknowledgment of their customary rights. The Biological Diversity Act of 2002 is linked to farmers' rights since it regulates Access and Benefit Sharing (ABS). This legislation sets out mutually acceptable conditions and criteria for obtaining prior informed consent (PIC) for the use of biological resources in India. These guidelines are crucial for safeguarding the rights of farmers and ensuring the equitable and unbiased allocation of benefits derived from the use of plant genetic resources.

The need for society to endorse and regulate the continuously expanding proficiency and ingenuity of the human mind is shown by the establishment of legal structures to safeguard the rights of farmers. The framework of farmers' rights encapsulates the international community's approach to addressing the apparent incongruities arising from technological improvements inside the intellectual property law. These technological breakthroughs

enhance our comprehension of the agricultural community's engagement in the preservation of biological variety. The aforementioned system, which seeks to achieve a harmonious equilibrium between the welfare of the general public and the private sector, serves as an exemplification of the ongoing struggle within global societies to ensure that human innovation yields advantages for both the collective and the individual.

Throughout history, farmers have played a key role in the conservation and advancement of plant genetic resources. The issue of reaching an agreement about their rights, however, is now under deliberation. Indeed, the absence of agreement becomes evident subsequent to the emergence and use of plant biotechnology, which entails the exploitation of resources as primary inputs for the advancement of multinational corporations, sometimes disregarding the significance of agricultural communities. Presently, several deliberations have occurred advocating for the safeguarding of farmers' rights, with a diverse range of justifications put up in behalf of the agricultural sector. Although the existing intellectual property framework seems inadequate in ensuring the rights of farmers, it is imperative to establish a system that safeguards intellectual property for individual farmers or agricultural communities in order to provide fairness and justice for them. It is essential to promptly establish a complete definition of these rights in order to ascertain their specific substance. This is a pressing request. To prevent this inadequacy at the national level, one may use the unique option provided by the TRIPs Agreement.

International efforts pertaining to the protection of intellectual property rights for farmers are now in their early stages of development. The inclination towards safeguarding intellectual property rights pertaining to plant genetic resources, as a substitute for patents, might be attributed to the economic aspect associated with intellectual property. However, initially, this request did not primarily help farmers, but rather favoured commercial plant breeders. The need for safeguarding intellectual property rights among farmers arose as a result of the need to preserve plant genetic resources associated with intellectual property. The UPOV Convention was seen as a potential substitute for the prevailing patent system; nonetheless, it proved ineffective in safeguarding the interests of farmers. As per the 1978 version of the Convention, farmers were provided with many exclusions. The expansion of breeders' rights to let farmers to employ harvested goods on their land, as outlined in the 1991 version of the Convention, is praiseworthy on a worldwide level.

The current investigation reaches the conclusion that the UPOV, FAO, and CBD do not acknowledge the ownership rights of farmers, both at an individual level and as a component of the community. Additionally, the TRIPs Agreement, which is the sole binding rule-based multilateral document, does not offer specific information regarding the potential unique model. It is seen by many as an opportunity and by others as a loophole. The majority of nations have recognised the significant contribution of farmers in the preservation of plant variations and the development of novel plant kinds. However, the legal safeguards for farmers' rights seem to be either insufficient or inadequate. The absence of sufficient safeguards for novel plant cultivars will lead to a failure in offering a crucial motivation for prospective investment and endeavours to advance agriculture. As a result, there would be a missed chance for them to cultivate their domestic agricultural sector and bolster their total economic progress in the domains of agriculture, horticulture, and forestry.

The study's findings suggest that the implementation of effective intellectual property protection measures for farmers has the potential to improve their social standing. The promotion of farmers' rights as intellectual property rights is facilitated by the effectiveness of the institutional structure developed under Indian sui generis law. The sui generis law in India is widely regarded as a distinctive legislative framework. However, its execution remains a challenge due to the absence of a definitive agreement among the many stakeholders over the means to effectively safeguard these rights. This should function as a global indication that the mere establishment of laws is inadequate in successfully advancing the rights of farmers. It is essential for nations to actively strive towards establishing intellectual property rights (IPR) frameworks that do not impede stakeholders' ability to access genetic resources. Simultaneously, these regimes should not diminish the significance of gene conservators and gene contributors. There is an urgent need for an international system to facilitate the establishment of a consensus over the definition and implementation of these crucial rights. If the international community fails to confront the task of clearly expressing the rights of farmers, the progress made so far in the struggle to create these rights may be lost. The magnitude of this loss would have significant implications for farmers in India and other developing nations, since they rely on farmers to safeguard their livelihoods, ensure their access to resources, safeguard their rights to seeds, and, most importantly, alleviate their impoverished circumstances.

The analysis of the effectiveness of legislation in India indicates that the current institutional framework does not have any significant shortcomings; the issue lies in the correct execution of future-oriented aspects of the PPV&FR Act, 2001. Initially, the registration of farmers' variety and extent variety showed concerning patterns. However, it is encouraging to note that Indian farmers are now showing a growing inclination towards registering their varieties.

Suggestions

International perspective

- Ongoing research is needed to ascertain if the existing system adequately safeguards landrace innovations in the context of informal farmland innovation, which may not meet the stringent requirements of homogeneity and stability, and if the legislation adequately supports such innovations when implemented by individual farmers without access to contemporary scientific research and development tools.
- In the context of protecting plant varieties, it is crucial that the TRIPs Agreement acknowledge the communal ownership of farmers' variety and traditional knowledge.
- It is not advisable to create a unique technique for protecting plant varieties in a vacuum. There should be a unified rule that incorporates CBD and TRIPs requirements; plant varieties are only one part of biological resources. All WTO and CBD member nations should work towards this goal.
- Both official and non-official groups should work to raise public understanding of the farmers' rights legislation. Since there have been almost no requests for the registration of farmers' varieties submitted so far, it is clear that farmers do not trust or care about the legislation.

National Perspective

- It is possible to merge the Seed Act of 1966, the Protection of Plant Varieties and Farmers' Rights Act of 2001, and the Biological Diversity Act of 2002, all of which deal with biodiversity protection and access, in order to make their implementation go more smoothly. Though the Seed Act and the PPV&FR Act are now in concord after several overlapping concerns were resolved. Additional coordination between the PPV&FR Act and the Biological Diversity Act's implementation is possible.

- In order to prevent the denial of registration based on immaturity and to provide farmers an opportunity to rectify and enhance their variety before the final application, the PPV&FR Act may permit provisional applications for farmers' varieties. The provision for provisional filings is analogous to that in section 9 of the Patent Act, 1970.
- The PPV&FR Act and Rules do not include any language or recommendations about the need to inform the general public when a plant variety is registered. Unintentional violation may occur in the lack of such notice. Hence, it would be beneficial to have a sign or indicator of registration.
- By taking whatever action it deems appropriate, the PPV&FR Authority is obligated by the Act to safeguard the interests of the farmers. The Authority should investigate why farmers were uninterested in exercising their rights under the special PVP statute and provide conclusions based on those findings.
- The PPV&FR Authority/Registry has failed to provide a resolution to the PVP problem involving the varieties of those crops or species that have not been informed by the Central Government. It will be necessary to find a reasonable solution to the problem of existing variety protection at some point; it cannot be continued forever. Breeders of eligible extant varieties of non-notified crops and their owners alike may be understandably anxious about any holdups in the issuance of licenses and cross-licenses that may prevent them from quickly expanding their valid extant variety portfolios. As with the 1999 patent amendment clause, one potential answer might be to include a provision in the PPV&FR Act for the receipt and recording of PVP applications in the mail box. The PVP registry is required to accept applications for all eligible existing varieties for a postponed examination in accordance with this provision/notification, regardless of whether their genera/crops have been notified or not. Meanwhile, in order to expedite commercial transactions for all existing varieties, applicants whose varieties are now waiting in the mail box may be awarded exclusive marketing rights. Traditional varieties of self-and open-pollinating staple crops, such rice, wheat, and lentils, continue to get little investment from the commercial sector in research and development, in contrast to hybrids. It would seem that the PPV&FR Act does not provide the private sector with any further incentive in this regard. The success of India's present policy in fostering the expansion of the private seed

business and research and development initiatives is, hence, questionable. Finding common ground between competing policies that encourage seed replacement and those that allow the storing and resowing of all seeds, including hybrid seeds, might be a good idea.

- The process of reviewing applications requires the hiring of permanent personnel. There is no provision for the regular employment of PVP examiners, hence the examination of PVP applications under the PPV&FR Act is done by temporary workers engaged on a tenure basis.
- If breeders are unable to fulfil farmers' demand, it will lead to planting material shortages, higher market prices, and monopolies; as a result, breeders should lose their rights. In section 47, which deals with forced licensing, it would be preferable to replace the terms "reasonable price" with "reasonable affordable price."

Fundamentally altering the configuration of the innovation, the Plant Patents Regime recognizes the importance of nature in the development of new plant kinds. Specifically, breeders were innovators after the fact, in contrast to mechanical inventors who were innovators initially. Meanwhile, the responsibilities typically performed by those engaged in the invention's production were turned upside down by plant patent law. Nature conducted the innovating for plant patents, and the breeder's job was to find and replicate nature's innovations. An effect of this is that instead of developing a novel genetic concept, breeders inferentially hijacked an existing natural phenomenon. As a result, creation is now based on inductive reasoning rather than an initial deed.

Efforts to secure intellectual property rights (IPR) with calls for fair benefit distribution would undoubtedly aid in the preservation of genetic heritage and traditional knowledge. Ultimately, the most pressing issue is making sure that the far-sighted provisions of the PPV&FR Act, 2001 are properly put into practice, and this is dependent on how well-informed different stakeholders and beneficiaries are about the legislation. It is widely believed that India's preponderance in agriculture and robust research and development infrastructure in conventional plant breeding explain why the country is less likely to embrace patent protection regimes for its plant varieties and more likely to embrace non-patent sui generis laws.

IN RESPECT OF RIGHTS OF PATENT HOLDERS IN THE PHARMACEUTICAL SECTOR

Conclusion

Fundamentally altering the configuration of the innovation, the Plant Patents Regime recognises the importance of nature in the development of new plant kinds. Specifically, breeders were innovators after the fact, in contrast to mechanical inventors who were innovators initially. Meanwhile, the responsibilities typically performed by those engaged in the invention's production were turned upside down by plant patent law. Nature conducted the innovating for plant patents, and the breeder's job was to find and replicate nature's innovations. An effect of this is that instead of developing a novel genetic concept, breeders inferentially hijacked an existing natural phenomenon. As a result, creation is now based on inductive reasoning rather than an initial deed.

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Suggestions

1. The notion of patents is still unfamiliar to many people. Both the agents and the inventor are woefully uninformed when it comes to inventions and the Patent Act, which governs them. Programs to raise public understanding of patents and their administration are now in the works. In order for the Patent Management to run smoothly and quickly, it is important that both the inventor and the agents be up-to-date on the latest scientific developments in the pharmaceutical business.
2. The pharmaceutical sector is infamous for its chronic patent infringement. The onus for keeping tabs on infringements does not rest with the Controller of Patents; rather, it falls squarely on the inventor. The creator is obligated to promptly notify the relevant

authorities of any infringement that they may detect. There has been a lot of alleged infringement in the pharmaceutical sector, therefore the creator has to be vigilant about protecting his idea.

3. Litigation including invention, pre and post opposition, and infringement is prevalent in the pharmaceutical sector. The patents, inventors, and pharmaceutical businesses are all negatively impacted when these cases go on for too long or get bogged down by bureaucracy in various court bodies. The parties impacted by infringement should make every attempt to resolve their disputes amicably, rather than resorting to litigation. If you need a quick resolution to a legal dispute, you should look into alternatives to going to court, such as arbitration.
4. In order for all parties engaged in the pharmaceutical patent to be able to contribute effectively and on time, the rules governing intellectual property rights and related legislation pertaining to the pharmaceutical industry need to be simplified.
5. It typically takes six years for a patent application to be approved in India, according to a study done by the India Spend95 team. A staggering 98% of all patents issued in 2015 were on ideas that were at least five years old. Even applications submitted before the 19-year mark were awarded patents in 2015. The United States and the United Kingdom have an average patent clearance time of three years. Because of this holdup, the Indian government's "Make In India" initiative is suffering. It is worth mentioning that the pharmaceutical and drug business has the longest delays in patent issuance.
6. The Brain Drain problem is about to happen. The United States, the United Kingdom, and Canada are receiving patent applications from a large number of Indian innovators. This problem is being caused by a combination of factors, including a lag in patent issuing in India, less litigation in other countries, and more appealing policies in India. India has to rein in this trend if it wants to catch up to other industrialised nations in the pharmaceutical business and make strides forward.
7. The costs for the online application and the physical application are different. Additionally, the charged costs are quite substantial. With the advancement of technology, it is now necessary to submit the application online. The applicant may feel compelled to seek patents for all of his ideas if the costs are reduced. This allows the innovator to safeguard his creation.

This research has shown that India's pharmaceutical sector has the potential to become the world's leading supplier of affordable, high-quality pharmaceuticals in the near future. Both efficient marketing and a solid regulatory framework, which must include measures to safeguard inventions (a function that patent administration plays an essential part in), are necessary to accomplish this. A "Governance Model" for the pharmaceutical sector, which effectively addresses regulatory challenges in India and overseas, should serve as the primary metric for this goal. To ensure a smooth and transparent procedure, it is essential to adhere strictly to the laws of both the home and foreign nations. As stated before, India is meeting the pharmaceutical needs of over 200 countries.