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BIOTECHNOLOGY PATENTS & AMBIGUITIES IN LAW

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ABSTRACT

With the emergence of biotechnology inventions, there is a demand for a specific legal mechanism for its safeguard and protection around the globe, under the aegis of Patent laws, this led to the argument that unduly broad protection, would, however undermine the patent system itself, as it would turn into an impediment and ‘unfair’ to the people at large. On the other hand, with the rapid change and scientific development in the society, coupled with unfit and insufficient legal policy and framework there is incursion of both excitement and fear among the common populace. At this situation one could find that with the introduction of biotechnology inventions, there is lot speculations and rumours instead of an explicit and certain law. However, there had been many international conventions and treaties but that had still not produced a concrete practice or custom, which could be uniform around the world unlike IPRs which as a whole have systematic and organised laws, biotechnology patents as being part of it does not have any credible and definite framework. Biotechnology Patents being a complex issue, which affects vast number of aspects of human life needs to have certain and unambiguous laws, so that the technology could be used for human benefit and welfare. Therefore, this article seeks to analyse present legal frameworks around the globe and present the interplay between the biotechnology inventions and patent laws around the world. Further, this article tries to bring out the problems and ambiguities in the laws of different countries dealing with biotechnology patents, thereby it also throws light on the impact of the same on

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the developing countries and the protective measures adopted by them, in the spheres like agriculture, so as to minimise the effect of biotechnology on the public.

Keywords: Biotechnology Patents, Biotechnology & TRIPS, Plant & Animal Patent, Agriculture Patent, Impact on third world countries, PVRs, Farmer's Rights, Indian Patent Act, 1970.

INTRODUCTION

The classic view that patent law does not, to a great extent concerns itself with the living material no longer accords with reality, the first patent in life forms was issued in Finland in 1843, and in the US in 1873 a patent was granted for isolated yeast.² Under US law the Plant Patent Act, limited to the protection of asexually propagated varieties, was passed in 1930 followed by the Plant Variety Protection Act, also encompassing sexually propagated plants.³

Due to the belief that living organisms and cells were non-patentable products of nature, patent protection for biological material was for many years restricted.⁴ Under the rationale that naturally occurring organisms were not new, the assumption was that patents could not be granted. In such a case the grant of a patent would remove from the public domain something 'which nature has produced and which nature has intended to be equally use for the use of all men'. Thus, although micro -organism-related inventions were patentable, the micro-organisms were per se held non-patentable.⁵

The application of modern biotechnology to industry and agriculture is quite recent in its origin, as being less than thirty years old. This new revolution of biotechnology has just started to enter the lives of the people living in developing world. As been highlighted, this discipline has the immense potential to change the lives of the people of developing countries like, India, by utilizing the biotechnology to its advantage to solve some of its intractable problems of

² United States Patent No. 141,072 (claiming pure yeast culture).

³ Li Westerlund, *Biotech Patents : Equivalence and Exclusions under European and U.S Patent Law*, (1st edn, Kulwer Law International, 2002).

⁴ See *In re Mancy*, 499 F.2d 1289, 1291 (CCPA 1974).

⁵ See *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, (1948).

productivity, health and environment⁶. Biotechnology has played an important part in the large number of patents granted to biotech firms.

The biotechnology revolution is based on massive scientific advances that have been made over the last sixty years. These advances have given scientists an extremely detailed understanding of life processes, have allowed life forms to be deliberately manipulated at the genetic level and enabled the creation of novel organisms containing genes from other species. To understand the history of the biotechnology revolution, it is useful to look at the development of the science that has helped to create it. There was a significant merging of chemistry and biology (still seen by many as two distinct strands of science) in the early 1950s as connections were made between the molecular structure of deoxyribonucleic acid (DNA) and its role in inheritance. The revolutionary techniques of genetic engineering and genome sequencing stem from this convergence.⁷

Humans have been using the living organisms and biological processes for thousands of years; the earliest applications were probably in the production of food and drink products such as beer, bread and cheese. Early applications made use of entirely natural processes and did not require any understanding of what these processes were. Some applications of modern biotechnology still use naturally occurring processes, which are now far better understood. Genetic engineering has been used to improve understanding of biological processes and to improve them, and it has also been used to create new sources of particular products and completely novel products that have never before occurred in nature. Biotechnology is now applied across a huge range of industries and there has been great expansion in the scope of its applications since the development of rDNA techniques. The present range of industrial sectors using biotechnology includes health care, food, mining, plastics, chemical, textiles and waste treatment. It is also widely used in agriculture and animal husbandry. There are far too many applications for them all to be discussed here, but some of their uses within these sectors are briefly outlined.

In *Systemix Inc.*, a patent was granted on human tissue. The patentee was granted patent covering a method of isolating very pure stem cells. Not only did this patent cover the method of isolation, but it also gave *Systemix Inc.* the rights to stem cells themselves, as a product. This

⁶ Jayashree Watal, 'Indian Patent Law on Biotechnological Inventions' (2000) 4(4) APBN < <https://pdfs.semanticscholar.org/3e2a/882936f58afef5015f32ccfc4cc19b657db9.pdf> > accessed on 20 January 2019

⁷ Catherine Rhodes, *International Governance of Biotechnology*, (Blommsbury Academy 2010).

was the first time that a normal, non-engineered human cells or tissue was being patented. Although court battles continue over this, the stage has been set for significant corporate ownership of various parts of the human body. Learned commentators express the view that the originators of the patent process could never have foreseen such difficulties, and, as usual, our ability to deal with the effects of new technology itself.⁸

Plant Variety Protection laws have been developed in almost all countries providing *sui generis* protection for agricultural and horticultural innovations⁹. Patent Protection was not originally considered to be a particularly effective system for the protection of the plant varieties. Prior to the development of modern biotechnology, the breeding of a new variety could not be said to involve an inventive step.¹⁰ Even the US Supreme Court failed to see plants as manufactures in the sense of the general patent law, but considered plants to be products of nature and hence not patentable. The general argument was that the patent protection for plant life would be the granting of the patents for the use of natural powers and would undoubtedly be of little or no help in promoting progress. Plant Varieties were originally excluded from patentable subject-matter because, as “products of nature”, they did not meet the requirement of new, non-obvious subject-matter, and because they could not be described with enough specificity to meet the patent statute written description requirement.

In India the patents act expressly excludes some areas of technology¹¹, this has resulted in the rise of interpretation and the question as to whether the biotechnology can be patented or not? To bring rest to the controversy the government appointed Mashelkar Committee, which concluded that the micro-organisms per se should not be excluded from the patent protection as that would violate TRIPS Agreement.

BIOTECHNOLOGY & TRIPS

The Punta del Este declaration of September 1986 launched the Uruguay Round of multilateral trade negotiations under the auspices of GATT. The so-called Trade-Related Aspects of Intellectual Property Rights (TRIPs) were part of the negotiating mandate. Between 1987 and 1989, developing countries were successful in stalling discussion on norms and standards of

⁸ D. Bourgaize, T.R Jewel & R. Buiser, *Biotechnology: Demystifying the Concepts*, (1st edn, Benjamin Cummings 2000)

⁹ § 3(j), Patent Act, 1970(IND) & Article 27, TRIPS.

¹⁰ Elizabeth Verkey, *Law of Patents*, (2nd edn, EBC 2012).

¹¹ § 3, Patent Act, 1970 (IND)

Intellectual Property Rights (IPRs). But in April 1989, developing countries agreed to discuss norms and standards of IPRs. The Uruguay Round concluded with the adoption of the final act in April 1994 at the Marakkesh ministerial meeting.

The most contentious of the issues in the TRIPs Agreement was that relating to patents. Within this, Article 27 attracted the most attention because it stipulates the technology fields to be covered and exceptions to patentability. A close look at Article 27 (3) (b), which deals with bio- technology patents, is necessary. This article has given rise to many apprehensions for developing countries¹².

In this particular part we will analyse the Article 27 (3) (b) of the TRIPS Agreement for that one could see Article 1(3) of the Paris Convention mentions that “Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers, and flour”.

Though the Paris Convention does not require the participating countries to provide the patent protection to biotechnology. At the same point of time it does not prohibit the same, thereby leaving it to the member countries to decide whether or not to extend the protection to the biotechnology.

It could be said that for various reasons, including ethical reasons, living organisms were generally regarded as being outside the patent system. A committee of experts on biotechnological inventions and industrial property was setup by the WIPO to start the works on the patentability of biotechnology inventions. Between 1984 to 1988 the said committee met four times, with the participation of the developing countries, the committee did lot of important work and addressed various ambiguities and problems, but it was not able to reach to a consensus.

It may be added that on the question whether life forms can be patented, many think it is morally repugnant to patent life in nature. On the other hand, many national laws allow the patent of such life forms on condition that if life form is isolated from its eco-system, or produced by means of technology and as the other criteria for grant of patent are fulfilled. This

¹² C Niranjana Rao, 'Patents for Biotechnology Inventions in TRIPS' (2002) 37 E&P Weekly 2126

is also in line with the broad concept in TRIPS provisions, as TRIPS lays emphasis on non-obviousness and utility aspect.

The words used in the TRIPS Agreement are 'ordre public'. It is to be understood not merely to issues of public order (security issues), but may extend to protection of life of humans, animal and plants lives as well as environment. Article 27 (3) (b) of the TRIPS Agreement provides for the protection of plant biotechnology inventions. This provision could be regarded as being quite ambiguous as it states:

Members may also exclude from patentability: (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes...The provisions of this sub-paragraph shall be re- viewed four years after the entry into force of the agreement establishing the WTO.

This particular provision can be viewed as : (1) Plants need not be patentable (means that product patents need not be granted but process patents can be granted); (2) Animals need not be patentable (means that product patents need not be granted but process patents can be granted); (3) Micro-organisms are patentable; (4) Essentially biological processes for the production of plants are not patentable; (5) Essentially biological processes for the production of animals are not patentable; (6) Non-biological processes for the production of plants are patentable; (7) Non-biological processes for the production of animals are patentable; (8) Microbiological process for the production of plants are patentable; and (9) Microbiological process for the production of animals are patentable.¹³

Article 27 (3) (b) its roots in the Strasbourg Convention on the 'unification of certain points of substantive law on patents for inventions' of 1963 of the Council of Europe. Article 2 (b) of the Convention states:

The contracting states shall not be bound to provide the grant of patents in respect of...for plant or animal varieties or for essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.

¹³ See *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, (1948).

This provision tried to make a distinction between biology and micro-biology, was applicable to the scientific knowledge of that time. But later scientific developments have blurred the distinction between these two.

The convention on the grant of European patents European Patent Convention (EPC), of 1973, chose to follow Article 2 (b) of the Strasbourg convention closely. Its Article 53: exceptions to patentability, says:

European patents shall not be granted in respect of...(b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof.

On the other hand, it could be said that there is a wide interpretation given by the European Patent Office and laws and court decisions in the European Courts bound by EPC. The plant genera and species not covered by the plant breeder's legislation are covered under the patent laws and although breeder's right cover under plant varieties, plants come under the protection of patent protection. Further wider interpretation is given to determine the essentially biological and essentially non-biological.

This question of determination of the essentially non-biological process, for which patent could be granted came before the court in the *Novartis case*¹⁴ in this case no clear indication was given, it could be deduced that a process without human intervention would constitute an essentially biological process and hence non-patentable. In contrast where (human) technical intervention plays a significant role in determining or controlling the result it is desired to achieve, the process would not be excluded.

The buttress for the patent of the biotechnology was formulated by the patent which was awarded to Anand Chakraborty, than a microbiologist working for General Electrics in the US. His patent application involved a genetically altered bacterium developed by him, it was the oil eating bacteria. US Patent office (USPTO) turned down the application as according to them the living and inanimate things, i.e., microbes, were not eligible for patent. But later after long

¹⁴ 2000 OJ EPO III.

legal battle the US Supreme Court¹⁵ held in the favour of granting the patent to him for his oil consuming bacterium. Thereby the court's judgment opened the path for the grant of patent of the self-created micro-organism.

PLANTS & ANIMALS PATENT: AN OVERVIEW OF THE LAWS AROUND THE WORLD

Plant variety is another band of exceptions, which were originally excluded from patentable subject matter, as product of nature. They also not fulfil the long-held conditions for patentability as they are not new, non-obvious. The US Supreme Court also viewed that plants are not manufacturers for the purpose of patent law. Industrial applicability and utility is also said to be lacking among the plant breeders products. In the US, the Plant Variety Protection Act (PVRA) and 35 USC (United States Code) seek to protect new plant varieties. Both of these two statutes govern patentability of plants and only differs in terms of rights and obligations imposed in each of them. Therefore, protection of seed-grown plants under the PVRA, does not exclude them from the patentable subject matter under 35 USC¹⁶. At the same point of time the US Supreme Court laid to rest the question whether the sexually reproduced plants were statutory subject-matter under § 101. The Court made it clear that if inventors of new varieties of plants are able to meet the stringent patentability standards, they will be entitled to utility patent protection.¹⁷

In the US, there are now three main ways in which an inventor or breeder may obtain formal Intellectual Property Rights (IPRs) on plant materials:

- Patent rights under the Plant Patent Act (PPA)
- Plant Breeder's Rights through the Plant Variety Protection Act (PVRA), and
- Patent rights (for inventions) as a utility patent, the Utility Patent Act (UPA), under 35 USC Section 101.

On the other hand, the exclusion of plant varieties from patent protection in Europe¹⁸ was framed by the case laws of EPO. The story of the patentability in the Europe started when in the 1960s Europe faced the issue of patentability in modern biotechnology when a German pigeon breeder sought a patent on a method of breeding a dove with "a considerably larger"

¹⁵ *Diamond Commissioner of Patents and Trademarks v. Chakrabarty*, 67 L.Ed. 2d 155 (1981)

¹⁶ 35 U.S.C § 101 (2012)

¹⁷ *JEM Ag Supply v. Pioneer Hi-Bred International*, 151 L Ed 2d 508

¹⁸ European Patent Convention[2007], Article 53(b) (1977)

red plumage.¹⁹ In refusing to grant a patent, the Bundesgerichtshof (German Federal Supreme Court) explained that breeding was biological, rather than technical because there was no guarantee of "reproductibility".²⁰ Patentability required the "technical nature" of the invention to control natural forces and achieve predictable results.

Finally, the first consideration of the distinction between plant and plant variety by the Technical Board of Appeal of the EPO occurred in the year 1984²¹. Article 53(b), EPC prohibits only the patenting of plants or their propagating materials in the genetically fixed form of the plant variety. At the same point of time in the *Plant Genetic System* case²² claims on plants per se were not considered patentable. But claims to individual non-biological transformed plant cells were allowed, as were claims to processes for producing plant. The claims in this case related to plants, plant cells, and seeds that possessed foreign gene which made them resistant to herbicide. Greenpeace objected to it on the ground that the material claimed was a plant variety and thus excluded by Article 53(b). The board of Appeals rejected the contention as according to them the plant cells as such cannot be allowed to fall under the definition of plant varieties.

At the same point of time Article 53(b) of EPC led to different interpretation in various countries. Hence 'the directive on the legal protection of biotechnological inventions' was issued by the European Commission in October 1988, to standardise the practice of patenting biotechnology inventions in the European Community countries. It suggested that all biotechnology inventions could be patented except human beings. The European Parliament rejected this directive in March 1995, the revised version was passed in May 1998.

In *Plant Genetic Systems*²³, claims on plants per se were not considered patentable. A claim to genetically engineered plant was refused on the ground that it met the requirement of plant variety. Claims to individual non-biological transformed plant cells were allowed, as were claims to processes for producing the plants. This particular view was reiterated in the *Novartis*

¹⁹ Rote Taube HC 01/1970 at 136, 137. (Judgment of March 27, 1967, Bundesgerichtshof, 52 Bundesgerichtshof in Zivilsachen [BGHZ] 74 (Rote Taube)). A single patent claim sought protection for crossing an Altdeutscher Kröpfer with a Rote Römertaube. The doves resulting from the selection were crossed with a Roter Hessenkröpfer, and then with an Altdeutscher Kröpfer

²⁰ Rote Taube, at 141. The court explained that the German Patent Act § 2(2) explicitly denied patent protection for plant or animal varieties, or essentially biological processes for the production of plants or animals. Arguably, the court's ruling implied that replicable biotechnological inventions can be patented. See A. Schrell et al., *Biotechnology Patenting Policy in the European Union - as Exemplified by the Development in Germany*, 107 Adv. Biochem Engin/Biotechnol. 13 (2007), available at <http://www.ncbi.nlm.nih.gov/pubmed/1752>

²¹ *Ciba-Geigy's Propagating Material Application*, Bergy, re, 596 F 2d 952

²² *Plant Genetic Systems N.V., Et Al v. Greenpeace ltd.*, 1995 OJ EPO 545

²³ *Plant Genetic Systems N.V., Et Al v. Greenpeace ltd.*, 1995 OJ EPO 545

case²⁴, by the enlarged board of appeal when the Technical Board of Appeal referred the patentability of processes for the protection of plants and of plant varieties to the Enlarged Board, according to it the patentability could be granted to plant varieties provided that plant varieties were not individually claimed. Article 64(2), EPC does not preclude protection for plant varieties. Plant variety containing a gene introduced into an ancestral plant by recombinant gene technology are excluded from patentability.²⁵

The question on the patent on biotechnology can further be analysed by seeing the practices in other countries, as this question was dealt by the Israeli Supreme Court²⁶, as according to the Israeli law, an invention by which a known substance, or a known device is used for therapeutic treatment of the body or an invention relating to a process for the treatment of human beings, is patentable. It was held there would be no injustice done, if one adopts the recent developments in the patent happening around the world. Thereby in this case the Court upheld the patent right on the process of treatment of human beings. At the same point of time in an Australian High Court Case²⁷ where the claim included a container having written instructions of the suitability of contents for the treatment of anaplasmosis in cattle was refused, as the contents were a known range of chemicals. The same type of question in this context was considered by the New Zealand Court²⁸ where the claim included a drug previously used for treating malaria, was used for treating leukemia, on that part the court held that a process of treatment of human illness or disease is not a manufacture and thereby excluded from patent. On the same context it could be said that exclusion of patent on inventions for the method of medical or veterinary treatment only applies to methods of treatment that are practiced on or in the human or animal body, instead it does not include the methods used or substances that are removed from the body.²⁹ Thus, the blood for the storage in a blood bank or a diagnostic testing of blood samples are patentable. However, blood during dialysis, with the blood being reunited to the same body would not be patentable.³⁰

After the *Chakrobarty* judgment by the Supreme Court of US, countries like Canada, took the cognisance from this judgment but created its own statutory interpretations to suit national

²⁴ 2000 OJ EPO III

²⁵ D. Bourgaize, T.R Jewel & R. Buiser, *Biotechnology: Demystifying the Concepts*, (1st edn, Benjamin Cummings 2000)

²⁶ *Wellcome Foundation Ltd. V. Plantex Ltd.*, (1974) RPC 514

²⁷ *Wellcome Foundation Ltd Australian. Appln*, (1981) FSR 72

²⁸ *Commr of Patents v. Wellcome Foundation*, (1983) 2 IPR 156

²⁹ EPO Guidelines c-iv, 4.3.

³⁰ *Baxter v. Blood Extraction Method*, T.329/94 (1998) EPOR 363,366-7

requirements. In one case the claim was related to a genetically engineered mouse (Harvard OncoMouse) containing an additional gene that makes the mice more susceptible to cancer.³¹ The Harvard OncoMouse had already been granted patent protection in the United States.³² Thereby in the instant case the Appeal Court granted the patent protection to the mouse, so as to succumb to the economic pressure mounted on them, but unlike the appeal courts decision the Supreme Court of Canada³³ posited public interest considerations ahead of economic issues. "Parliament" declared the Supreme Court of Canada, "did not intend higher life forms to be patentable" under the Canadian Patent Act. Hence, the Court declared that the OncoMouse was an unpatentable subject matter.

BIOTECHNOLOGY PATENTS AND ITS IMPACT ON AGRICULTURE AND THIRD WORLD COUNTRIES

More than one million children die each year because of a chronic lack of vitamin A. Millions more suffer disease. Many of these children live in developing nations where rice is the main staple. To help solve this problem, scientists have genetically engineered a variety of rice that is rich in beta carotene, an important source of vitamin A. Dubbed golden rice because of its yellow color, it could help improve millions of lives in developing countries, as well as improve the nutrition of legions of people in developed countries. But a careful study shows that anyone wanting to produce golden rice might have to secure licenses for more than 30 groups of patents issued to separate entities.³⁴ With the expected 50% rise in the population in the over next half century the problem is daunting, the green revolution is the solution that could be found in sight, and the modified crops can only lead this revolution to its genuine goal as these crops could be drought and salt resistant and thereby could also be made disease proof, The first Green Revolution grew from an international public research system that began in the 1940s with support from the Rockefeller Foundation and expanded to include 16 research centers, including the International Rice Research Institute (IRRI) in the Philippines and the Centro Internacional de Mejoramiento de Maiz y Trigo (CIMMYT), the corn and wheat research center in Mexico. These centers collaborate through the Consultative Group on International Agricultural Research (CGIAR), a consortium of donors including foundations, national governments, United Nations Institutions, and the World Bank.

³¹ M. Kamber, *Coming out of the Maze : Canada Grants the Harvard Mouse Patent*, 35 Geo. Wash. Int'l L. Rev. 761 (2003)

³² U.S. Patent No. 4,736,866 (1988).

³³ *Harvard College v. Canada (Commissioner of Patents)*, (2002) 4 S.C.R 45 (Can.)

³⁴ John H. Barton, Peter Berger, 'Patenting Agriculture' (2001) 17 (4) UTD 43

A threshold consideration in the food security debate is whether agriculture is a proper subject for IP protection. In one of the case the Australian High Court³⁵ discussed the said issue in detail, in this particular case the constitutional validity of Plant Variety Rights Act 1987 and its, successor the Plant Breeder's Rights Act 1994 was challenged. To this the court tendered to respond positively to creation of new categories of IPR to the protection for the products of intellectual efforts, as according to them the Australian Constitution of 1900 empowered Parliament to legislate on the subjects of 'Copyrights, patents of inventions and designs and trademarks'³⁶, at the same point of time these terms are treated as general categories of legislative subject.

On the context of food security and agriculture, it is worth bearing in mind the US Supreme Court's qualification in *Graham case*³⁷ that Congress may not 'enlarge the patent monopoly without regard to the innovation, advancement or social benefit gained thereby'. Until about 1980s, the only intellectual protection available for crop protection was Plant Breeders Right (PBRs), a relatively weak form of legal protection that prevailed in most developed countries. A country's department or ministry of agriculture issued a PBR certificate to seed owner that prevented competitors from selling seeds or breeding material from the owner's specific seed variety. Under PBR the competitors were allowed to use the protected varieties as source of subsequent seed variation in their own breeding program. On the other hand, the United States started to permit the patent on micro-organism, plants and seeds, as well as on genes and other biological components, which was more restrictive than PBRs. These practices contributed to the creation of biotechnology industry and thereby infused the much-needed force in the research and development of modified plant varieties.

PVRs

Scheme of Protection

Plant varieties are protected in most countries by specialist (*sui generis*) legislation modelled on the UPOV. The 'breeder' or persons claiming through the breeder is afforded the protection under this legislation.³⁸ Defines the breeder as the person who 'bred, or discovered a variety',

³⁵ *The Grain Pool of WA v. The Commonwealth*, [2000] HCA 14

³⁶ Australian Const. § 51 (xviii).

³⁷ *Graham v. John Deere Co.*, 383 US 1 at 5-6 (1966).

³⁸ UPOV Convention Art. 1 (iv) (1961).

breeding is defined as including the discovery of a plant together with the use in selective propagation so as to achieve a result.

The UPOV Convention defines ‘plant varieties’ in terms of a plant grouping within a single biological taxon of the lowest known rank, the grouping of which can be:

- Defined by the expression of characteristics (such as shape, height, colour and habit) resulting from a given genotype or combination of genotypes;
- Distinguished from any other plant grouping by the expression of at least one of the said characteristics; and
- Considered a unit with regard to its suitability from being propagated unchanged.

In 1984, a case³⁹ was heard by the Technical Board of Appeal of the European Patent Office (EPO) in which the distinction was considered between a plant which for reasons of public policy cannot be the subject of private property rights or PVR laws. This determination concerned a plant that had been treated with a chemical compound to confer on the plant a degree of protection from the toxic side-effects of certain herbicides.⁴⁰ This particular approach was applied by the Technical Board of Appeal in the *Lubrizol (Hybrid Plant)* case⁴¹, where the board held that the term “plant varieties” means a multiplicity of plants, which are largely the same in their characteristics (i.e. homogeneity) and remain the same within specific tolerance after every propagation (i.e. Stability). Thereby it was held that the European Biotechnology Directive permits the patentability of inventions concerning plants where ‘the technical feasibility is not confined to a particular plant variety’.⁴²

On the same instance one could find that the broadest sense of patent on agriculture variety is given by the United States, regular patents are issued to entire plant lines, such as specific lines of herbicide resistant rice. However, in some countries only PBR protection is available on such plant lines, the U.S. patentability of plant varieties was granted early in 2000 in an appellate case⁴³, which was also upheld by the Supreme Court. The claims of these patents typically extend to the progeny of the plant and its seeds. The claims clearly are designed to

³⁹ *Ciba/Geigy*, [1984] O.J EPO 112.

⁴⁰ See also *Ciba/Geigy*, [1984] O.J EPO 112 at 114-115, It stated that ‘plant varieties...are all cultivated varieties, clones, lines, strains and hybrids’.

⁴¹ [1990] O.J EPO 71.

⁴² Directive on the Legal Protection of Biotechnology Inventions, Art. 4(1) para. 2, [1998] O.J L 213/130

⁴³ *Pioneer Hi-Bred International Inc. v. J.E.M Ag. Supply Inc.*, 148 L.Ed.2d 954 (2001)

keep other breeders from using the protected seed for breeding material, which will restrict its use in U.S. research for developing-world applications

The general duration of plant breeder's rights (PBR) under legislation based on the UPOV Convention is 25 years in the case of trees and vines and 20 years for any other variety. Plant Variety Protection (PVP) is established after a registration process. A plant variety is considered able to be registered if it has a breeder, and if it is distinct, uniform, stable and has not been exploited. PVR following from the 1991 version of UPOV, also extends to varieties that are 'essentially derived' from protected varieties, although in practice there is a fair degree of confusion as to the criteria to be applied in ascertaining whether a variety is essentially derived.⁴⁴

Farmer's Rights

There is a problem with the legislations for the Farmer's Rights is that there is no accepted definition of this term, or agreement as to how these rights can be realized. For this particular issue the Fridtjof Nansen Institute in Norway started the Farmer's Rights Project in order to facilitate a common understanding on how the Farmer's Rights can be realized under the ITPGRFA and to develop a basis for proposals to the Governing body of the ITPGRFA on specific measures to be taken to realize these rights.⁴⁵ After analysis two approaches were devised to understand farmer's rights:⁴⁶

- The ownership approach, which refers to the rights of farmers to be rewarded for genetic material obtained from their fields which is used in commercial varieties and/or protected with IPR.
- The stewardship approach, which refers to the rights that farmers must be granted in order to enable them to continue as stewards of agro-biodiversity. The idea is that the farmers involved in the maintenance of agro-biodiversity should be rewarded and supported for their contributions.

Usually excepted from PVRs is a seed saved by a farmer from harvested material and treated for the purpose of sowing a crop on that farmer's own land. For example, Art. 14 of European Community Plant Variety Rights Regulation sets out the terms for the so-called agricultural

⁴⁴ Michael Blakeney, *Intellectual Property Rights and Food Security*, 25 (2009).

⁴⁵ <http://www.farmersrights.org/fr-project/index.html>, (Jan. 20 2019, 3:11 PM)

⁴⁶ R. Anderson, *Realising Farmers Rights Under the International Treaty on Plant Genetic Resources for Food and Agriculture. Summary of the Findings from the Farmers Rights Project, Phase 1*, The Fridtjof Nansen Institute, Lysaker (2006).

exemption (Farmer's Privilege). This exemption gives farmers the right to use farm-saved seed without the consent of the owner (right holder) of the variety in question. At the same point of time sensible equitable remuneration, which should be lower than the amount charged for the licensed product should be paid by the farmer.⁴⁷ However, if the parties cannot agree upon the level of the remuneration, such remuneration should be 50% of the amounts charged for the licensed production of propagation material.⁴⁸

Article 14(2) of the European Regulation limits the agricultural exemptions only to the agricultural plant species listed there. Those species are divided into four categories, namely fodder plant, cereals, potatoes, and oil and fibre plants. To assist the policing of this provision Article 14(3) imposes on farmers an obligation to provide certain information such as (i) the name of the farmer, the place of his domicile and the address of his holding, (ii) the fact whether the farmer has made use of the product of the harvest belonging to one or more varieties of the holder for planting in the field or fields of his holding, (iii) the amount of the product of the harvest belonging to the variety or varieties concerned, which has been used by the farmers in accordance with Article 14(1).⁴⁹ The information to be provided must refer to the current marketing year, and to one or more year of the three preceding marketing years for which the farmer had not previously provided relevant information on request made by the holder in accordance with the provision. This obligation to provide information was explored by the European Court of Justice (ECJ) in *Schulin(Agriculture)*.⁵⁰

INDIAN PATENTS ACT,1970 & BIOTECHNOLOGY PATENTS

Unlike the patent laws of most developed countries, the current patent law in India, viz, the Patent Act, 1970 does not explicitly exclude or include any biological matter. For instance, the European Patent Convention explicitly excludes the patenting of plant and biological varieties and essentially biological processes for their production, on the other hand the microorganisms and microbiological processes are included. Although there is no such provision in the Indian law, instead there are number of provisions which guide the Indian patent office in deciding the patent application of biotechnology inventions.

⁴⁷ Council Regulation (EC) No. 2100/94 on Community plant variety rights, OJ No L 173/14, 25.7.95 CPVR, Article 14(3).

⁴⁸ Council Regulation (EC) No 1768/95 of 24 July 1995 implementing rules on the agricultural exemption provided for in Article 14(3) of CPVR.

⁴⁹ "Supra at 39".

⁵⁰ [2005] 1 CMLR 17.

The Indian Patent Act⁵¹ defines patent as 'patent for any invention granted' under the Act, at the same point of time invention⁵² can be defined as 'a new product or process involving an inventive step and capable of industrial application'. On the other hand, the terms "process" or "manufacture" or "substance" have not been defined and therefore could be presumed to include biotechnological processes. However, the practice built up so far is that the manner of manufacture must result in a non-living substance. Thereby one could find that unlike its US and European counterparts the Indian Act excludes the process of preparing the microorganism from patent, which is extremely narrow and restricted view.

On the same instance one could see that whether the Indian Patents Act provides protection for other plant biotechnology inventions is a controversial issue. As seen earlier Indian Act explicitly excludes some areas of technology, on the other hand the absence of biotechnology inventions from such excludes has given rise to speculations about their patentability, by reading the Act it can be found that the most relevant provision for exclusion biotechnology are given in § 3 which states that:

(h) a method of agriculture or horticulture;

(i) any process for the medicinal, surgical, curative, prophylactic or other treatment of human beings or any process for a similar treatment of animals or plants to render them free of disease or to increase their economic value or that of their products.

Clause (b) of Section 3 of the Indian Patent Act excludes inventions which could be contrary to public order or morality or which cause serious prejudice to human, animal or plant life or health or to the environment. This particular clause covers not only public order and morality but also covers prejudice to human, animal, plant life and to environment as well, thereby it could be considered to be wide in interpretation.

On the context of plants and animals it could be observed that Indian Patent Act excludes plants and animals in whole from patent protection.⁵³ The Indian Act while dealing with plants, animals, other than microorganisms includes seeds, varieties and essentially biological process for production of plants and animals.⁵⁴ At the same point of time unlike its US and European

⁵¹ Indian Patent Act, § 2(m) (1970).

⁵² Indian Patent Act, §2(j) (1970).

⁵³ Indian Patent Act, § 3(j) (1970).

⁵⁴ Indian Patent Act, § 3(j) (1970).

counterparts which provides patent even to the living subject-matter, as seen in the co-mouse case where the patent of the living mouse was awarded to Harvard⁵⁵, in India, the Act is silent with regard to patenting of living subject-matter. On the same context in other developed countries the patent is awarded on the production of the micro-organism in isolation⁵⁶, however the same is doubtful in India.

On the same context, contradictory views could be seen in the Bombay High Court Judgment⁵⁷, according to which the honourable court had reversed an order of rejection of patent by Controller- General of Patents. In this case the petitioner had applied for grant of patent for providing an image on an organic product, being flowers. The respondent rejected the petitioners' application on many grounds, one of which was being non-patentable under the Act.⁵⁸ The legal framework of patenting of microorganisms in most countries was that though they are not specifically excluded from patentability, micro-organisms were not granted patent protection on the ground that it was contrary to natural law, but with the evolution of law the same practice has been changed both in US and Europe, for example in Chakrobarty case⁵⁹, the patent was granted on an oil-eating bacterium. In India, on the other hand the Patents Act is silent with regard to patenting of living subject-matter, but the Calcutta High Court⁶⁰ has different views, accordingly it has held differently, in this case application was for a patent on a process that resulted in the manufacture of a live vaccine that was useful as a cure for infectious bursitis in poultry. This claim was rejected by Patent Office, on the ground that the definition of manufacture did not include a process that resulted in a living organism, and in the instant case a living vaccine was involved. Thereafter the Calcutta High Court overturned the decision of the Patent Office and directed the same to reconsider the application, which resulted in the grant of patent protection to the vaccine.

Moreover, the recent Supreme Court Judgment on Monsanto GM cotton seeds⁶¹ could be taken into consideration, in this particular case the issue was that Monsanto entered into an agreement with the defendant for an initial period of ten years, but thereafter around 2003 the defendant (Nuziveedu), had to face the de-facto biosafety regulatory regime under the Ministry of

⁵⁵M. Kamber, Coming out of the Maze : Canada Grants the Harvard Mouse Patent, 35 Geo. Wash. Int'l L. Rev. 761 (2003).

⁵⁶ *American Cyanamid v. Berk*, (1976) RPC 231

⁵⁷ *Speaking Rose International Inc. v. Controller General of Patents*, 2007 109 Bom LR 630.

⁵⁸ Indian Patent Act, § 3(j) (1970) (IND)

⁵⁹ *Diamond v. Chakrobarty*, 447 US 303 (1980).

⁶⁰ *Dimminaco AG v. Controller of Patents*, (2002) IPLR 255.

⁶¹ *Monsanto Technology LLC v. Nuziveedu Seeds LTD.*, Civil Appeal Nos. 4616-4617 of 2018.

Environment & Forest, which resulted into a sub-license agreement between both the parties, thereby making it mandatory to have the consent of Mosanto so as to use the Bt technology in its cotton hybrids, this was for Bollgard I technology which was not patented in India. The case was first heard by the single judge bench of the Delhi High Court which didn't deliberate on the validity of patent which was with the Mosanto, instead directed both the parties to be bound with the agreement, thereafter the division bench of the High Court invalidated the Patent of Mosanto on the ground of § 3(j) of the Indian Patents Act. This particular Judgment is recently been overturned by the Supreme Court, but still there is no clarity about the validity of these type of patents in India, as the Apex Court didn't talk about it, instead directed the parties to file fresh petition in front of the single bench of Delhi High Court.

At last one could observe that the Indian Patent Act, does not exclude the living organisms per se, though not explicitly excluded, the spirit of act is against the patenting of biotechnology inventions, the reasons for such exclusions are not clear. Many a times the international convention (for example Strasbourg Convention) and patent laws have taken into consideration the matter of patenting the biotechnology inventions. The Patent Office rejected the claims of biotechnology inventions till 1980s, but now the things have changed. Hence, we can say that there was a change in the way the Patent Office interprets the act. Some biotechnology process inventions seem to be patentable under the Indian patent law, including micro-organisms.

CONCLUSION

Genetical research, as talked earlier promises many, changes in many different fields of laws. As explained in this work, the field of genetics is built upon the technical application of new discoveries, or new implementations of earlier works. This particular force of genetics or biotechnology has raised cringles and goose bumps in the minds of the people as the possibility of making change at molecular/genetic level has forced the mankind the world through new perspectives. The blurring of line between the life and technology has raised tension in the society and resulted in the panic among the individuals.

The system of patents has come into notice among the multitudes with the changing nature of society and technology, and is been opposed on the ground of the 'feelings' that patenting biological material in different respects is not at all proper and is against the laws of nature which have allowed every living organism to use natural products for their needs, and thereby giving someone the monopoly over it is the total violation and breach of natural law. On that particular context instead of criticising the biotechnology inventions many issues could be considered and specially addressed by specific regulations for instance, by prohibiting human cloning, making provisions for environmental considerations, etc.

As talked in this paper it could be said that the laws concerning biotechnology are complex, they not only comprise of different field but also relies upon a variety of mechanisms. With the rapid development in genetic research and biotechnology inventions, there should be growth of governmental regulatory rules and policies so that they can reflect change in social policy in the light of scientific development. However, these concerns have been mirrored in the international level, but the patent system is itself been challenged with respect to biotechnology inventions because of the impediments in the path to free and secure research without any insecurities. On that particular part with the ambiguous and unclear laws there had been uncertainty with respect to biotechnology inventions, which needs to be eradicated so as to promote investment and research in the field of biotechnology for the benefits of mankind.

At the end it could be said that there are ambiguities even with respect to the perspectives related to the biotechnology patents as under the TRIPS agreement innovators not being awarded for a novel (genetically modified) crop would be a negative impact, although, in other agreement, the International Treaty on Plant Genetic Resources, the restriction of access to a plant genetic resource within its multilateral system that might result from a patent is viewed as a negative impact There is no guidance as yet, as to how such issues ought to be balanced.

So therefore, it could be concluded that there is dire need of the specific and well-defined law on the biotechnology patents, and till then it is the duty of the Courts to take appropriate and informed decision with respect to these types of inventions so as to bridge a gap between the vagueness and certainty in the laws.