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GENE PATENTING: A COMPARATIVE STUDY BETWEEN INDIA AND USA

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Abstract

Biotechnology involving DNA genetic engineering has made it possible to build upon potential health solutions. Initially, patent law advocated patenting of only products and processes which were related to industrial inventions and technology and excluded life forms patenting. However, with the evolving biotechnology and pharmaceutical industry, several countries modified their patent law to include gene patenting. Gene patenting refers to granting exclusive rights to the holder for extracting a specific sequence of gene or the process for obtaining them, which results in monopolistic ownership of commercial usage and research of patented genes by the holder. Though gene patenting incentivises future innovation, it also hides essential information required for future research and development. The paper discusses the concept of gene patenting, its consequences and international regime over its regulation by critically analysing the legislative and judicial stance of India and the USA. In addition, the paper throws light on the ongoing tussle between biotech directives, who are spending their labour to research and extract a gene sequence and enthusiasts who display concerns regarding unhealthy consequences of gene patenting. The scope of the study is broad enough to include study of laws related to gene patenting, specifically dealing with isolated genomic DNA, in India and the USA. The study examines several judicial pronouncements to understand the legal validity of gene patenting. Additionally, the paper contains recommendations and awareness for policymakers, bio-medical persons and the public about the concerns and net social benefit of gene patenting.

KEYWORDS: *Gene patenting, biotechnology, DNA Theft and TRIPS agreement.*

I. INTRODUCTION

In June 2013, the Supreme Court of US addressed the issue of whether a biotechnology company can get a patent for their two genes and opined that *"Genes cannot be patented as it being a product of nature must require some man-made intrusion and not just separating that gene from its surrounding genetic material"*.[1] This gave a new dimension to gene patenting. Countries around the world are reforming their patent laws to accommodate the increasing scope of gene patenting. Gene patenting refers to granting exclusive rights to the holder for extracting a specific sequence of gene or the process for obtaining them, which results in monopolistic ownership of commercial usage and research of patented genes by the holder. Gene is patented for three inventions, namely; diagnostics, compositions of matter, and functional uses. Section 101- 103 of Title 35 of the US Code, 2018 and Section 3 of the Patents Act, 1970, lays the conditions of granting patents and exempts 'law of nature' from patent eligibility. However, ambiguity regarding the meaning of 'product of nature' continues as certain inventions in biotechnology resemble such products. The problem with the currently recognised concept is the absence of considering the effect of gene patenting on the initial legislative setup which was enacted to protect mechanical inventions. Apart from this, not all countries have reformed their patent law according to new developments in the international law. However, India has tracked the development of gene patenting to follow international practice and support its health biotechnology sector.[2]

Gene patenting is often considered as "DNA Theft".[3] This is because of the legal and ethical consequences attached to it. It is often argued that genetics research is quite commercial and something which cannot have monopolistic ownership as it directly encroaches on the privacy rights of the individual. In the Myriad case, one of the SC judges opined that "*DNA is just nature sitting there, it is reserved exclusively to none to claim ownership*".[4] However, it must be considered that gene patenting cannot be rejected because of the argument of privacy as gene/ DNA is not owned by any person. Therefore, to bring clarity on this, a country needs to enact a separate law on gene patenting.

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[1] *Association for Molecular Pathology v. Myriad Genetics Inc.*, 569 U.S. 576 (2013).
[2] Adam Chilton, "India's Evolving Patent Laws and WTO Obligations: The Rejection of Abbott Laboratories Application for a new Kaletra Patent", 39 J. L. Med. & Ethics 296-297 (2011).
[3] P. John, "Inventing DNA or Stealing It?, The Role of Metaphor in Gene Patenting Debates" (2012).
[4] E. Richard Gold & Julia Carbone, "Myriad Genetics: In the Eye of the Policy Storm", 12 Genetics in Med. 39-45 (2010).

In this paper, the author has discussed several ethical and legal consequences of gene patenting, apart from answering questions such as, what modifications must be introduced in the gene sequence to make a natural product patent eligible[5] and granting of patent will incentivize others or will create unhealthy monopolistic ownership. The paper throws light on the jurisprudence of India and the U.S. on gene patenting amid the ongoing tussle between biotech directives, who are spending their labour to research and extract a gene sequence and enthusiasts who display concerns regarding unhealthy consequences of gene patenting. Additionally, the paper contains recommendations and awareness for policymakers, bio-medical persons and the public about the concerns and net social benefit of gene patenting.

II. CONCEPT OF GENE PATENTING

Biotechnology is considered as a powerful tool for developing countries. DNA genetic engineering has made it possible to build upon potential health solutions. This helps to fight genetic disorders and diseases like cancer, AIDS etc. Currently, the ongoing situation of COVID- 19 is getting controlled because of the development of vaccines which involves genetic research on the virus and the manufacturer companies are rewarded by patent protection under certain restrictions by the government. Now the question is that what is the role of the patent in Biotechnology sector. Patent comprises exclusive rights granted by the state to the inventor upon fulfilment of certain conditions.[6] In case the patent is granted for any biotechnological development, the holder does not have the right to possess the gene but he can exclude others from commercial exploitation, further research on patented genes etc. In the case of *Brenner v. Manson*[7], the court opined that *"a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."* Though gene patenting incentivises future innovation, it also hides essential information required for future research and development.

Initially, patent law advocated patenting of only products and processes which were related to industrial inventions and technology and excluded life forms patenting. However, with the evolving biotechnology and pharmaceutical industry, several countries modified their patent

[5] *Vanda Pharms. Inc. v. west-ward Pharms. Int'l Ltd.*, 887 (Fed. Cir. 2018).
[6] Elizabeth Ng, "Immoral Inventions: Interaction between ethics and biotechnology patent law", 22 Singapore Academy of L. J. 931-947 (2010).
[7] 383 U.S. 534, 536 (1966).

law to include gene patenting. Gene patenting refers to granting exclusive rights to the holder for extracting a specific sequence of gene which results in monopolistic ownership of commercial usage and research of patented genes by the holder. Gene is patented for three inventions, namely; diagnostics, compositions of matter, and functional uses. Laws state the rules while courts interpret them to devise a solution for a case. The same model is utilised to decide what constitutes a patentable subject matter.[8] In the case of *Kirin- Angen, Inc. v. Board of Regents of University of Washington*[9], the court held that *"an isolated gene can be eligible for patent protection, as it does not have to be considered a mere discovery, but can constitute an artificially created state of affairs."*[10]

III. IMPACT OF GENE PATENTING

There are various consequences of gene patenting. It encourages research and innovation in the biotechnology sector, which requires a great amount of hard work and funds; it supports small industries to develop their research without facing any competition hurdles, and it benefits public at large by providing a cure for deadly diseases.

However, gene patenting revolves around issues of public health, low-cost access to healthcare, restrain on further and advanced research on the gene and its mutations and monopolisation over a vital part of the human body. It attracts ethical, moral and environmental issues like surging experiments on God created creatures and causing danger to their lives by indulging in creation of Genetically Modified Organisms (GMOs). In the case of *Harvard (Onco-Mouse)*[11], the court rejected the patent application and observed that under Article 53(b) of EPC, the intent of legislation was to exclude animals from patentability. Further, the court pointed out certain observations of US courts regarding consequences of gene patenting, including, *"Animals are regarded as objects and descendants of the transgenic animals might escape into the environment and spread malignant foreign genes through mating".*

Since the time gene is getting patented, the courts have viewed the challenge of infringement it can cause from every possible angle. In the case of *Madey v. Duke University*[12], the US court observed that *"regardless of whether a particular institution or entity is engaged in an*

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[8] I. Mgboeji & B. Allen, "Patent First, Litigate Later! The Scramble for Speculative and Overly Broad Genetic Patents: Implications for Access to Healthcare and Biomedical Research", 2 CAN. J.L. & TECH. 83-85 (2003).
[9] (1995) 33 IPR 557.
[10] *Id.*, ¶ 33.
[11] OJEPO (1990) 476.
[12] 307 F 3d 1351 (Fed Cir 2002).

endeavour for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, the act does not qualify for the very narrow and strictly limited experimental use defense." Gene patenting attracts certain privacy issues including infringement of bodily, genetic and behavioural privacy,[13] as it allows the holder to extract and use a person's DNA without authorisation.[14]

Moreover, Critics argue that gene patenting does not align with the conditions of granting patent and therefore must not be patented. They opine that gene is a natural product and as for getting patent, chemical compounds are recognised as composition of matter and therefore, they are mere discoveries and not an invention.[15] Apart from this gene patenting can be a hurdle for small research activities which are done to study basic elements of nature. There is a need to revisit the dilemma that whether gene should be an eligible subject matter of patent or must remain "free to all men and reserved exclusively to none"[16]. Hence, this research open ups the scope of further discussion on the same.

IV. REGULATION OF GENE PATENTING: A COMPARATIVE ANALYSIS

1. LEGAL FRAMEWORK OF GENE PATENTING

a. INDIAN PATENT LAW

India is a developing country unlike the US and therefore it requires to cater the needs of its people along with focusing on the country's development as a whole. Gene patenting pops up two major questions for India; first, whether shall India ban gene patenting providing that lifesaving genetic drugs comes with huge cost, thereby, cannot be afforded easily by many citizens and second, whether India is obliged under international obligations like TRIPS to regulate gene patenting. Article 27(3) of the TRIPS agreement excludes member states to consider patentable subject matters, namely; *"(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (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."* According to Article 8(1) of TRIPS agreement,

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[13] J. Adhikary, *DNA Technology in Administration of Justice*, 267 (LexisNexis, New Delhi, 1st ed., 2007).
[14] *Id.*
[15] W.H. Schacht, "Gene Patents: A brief overview of Intellectual Property Issues", Cong. Research Serv., 1-3 (2008).
[16] *Funk Brothers Seeds v. Kalo Inoculant Co.*, 333 U.S. 127 (1948).

member states are required to amend their domestic IP legislation *"to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement."* Therefore, by interpreting the above two provisions together, it is concluded that a country for its benefit can disallow gene patenting. Moreover, TRIPS agreement does not define the term "microorganism", which lays ambiguity in its application. Some countries consider it to include DNA within its meaning whereas, few conveniently exclude it. Thus, if India disallows gene patenting it does not violate its TRIPS obligation.

India has witnessed changes in its Patent Act, initially from concentrating on its pharmaceutical industry to now fulfilling its international obligation. The first post-independence patent legislation was Patents Act, 1970. The Act gave protection to the product and process of industrial and mechanical application and excluded sectors like pharma, food and biotechnology from patentable subject matters.[17] Further, as per Section 3(c) of the Act, *"the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substance occurring in nature is not patentable"* and therefore, microorganisms were excluded from getting patent protection as it is existing in nature and thus would constitute merely a discovery and not an invention in its true sense. However, in 1995, India became a signatory to TRIPS agreement by joining WTO and as a result, India was expected to modify its laws based on TRIPS agreement. Between 1995 to 2002, India brought three amendments to its Patent Act to comport with India's TRIPS obligation. This was done by expanding the patentable subject matter to microorganisms, introducing provisions for compulsory licensing of patent, and strengthen the application of international corporation principle. In 1999, an amendment was brought to expand marketing rights. Then, the 2002 amendment increased the period of protection to 20 years and include microorganisms in the list of patentable subjects. This major change was brought when India became a member of "the Budapest Treaty on the International recognition of the deposit of microorganisms patent procedure." And as a result, two of the gene banks of India, namely, "Institute of Microbial Technology (IMTECH) in Chandigarh and Microbial Type Culture Collection (MTCC)", became International Depository Authority. Lastly, in 2005 the amendment brought change in the grant of product patents on pharmaceutical industry, which was ignored initially by the

[17] J.M. Mueller, "The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the rise of Indian Pharmaceutical Innovation", 68 U. PITT. L. Rev., 491-518 (2007).

government of India to protect its public health and focus on manufacturing and distributing drugs at low cost. Patent Act, 2005, allows gene patenting with fulfilment of conditions of Industrial applicability[18], novelty, invention[19], utility and non-obviousness. In *Bishwanath Radhey v. Hindustan Metal Industries*[20], the court rejected the claim of granting patent on the ground that the invention lacked usefulness. Therefore, for an invention to get patented it must be new and useful to public at large. Further, the Manual of Patent Office Practice and Procedures[21], states that *"when a genetically modified gene sequence or amino acid sequence is novel, involves an inventive step, and has an industrial application, patents on the following can be claimed: (1) A gene sequence or amino acid sequence, (2) A method of expressing the above sequence, (3) An antibody against the protein or sequence, (4) A kit made from the antibody or sequence"*. Moreover, Section 3(c) of the Patent Act, 1970, states that any invention is eligible for patent if it involves substantial human intervention. It is clear from this point that isolating a gene from human body requires human intervention and is therefore capable of getting patented.

b. US PATENT LAW

US Patent Act was enacted early in 1952. Section 101 of Title 35 of the US Code provides for patentable subject matter; machine, new and useful process, manufacturer, composition of matter and any other improvement. This signifies that US Patent law from its inception supported the biotechnological inventions or discoveries by patent to the inventor upon satisfaction of certain conditions. US Constitution under Article I, Section 8, provide for constitutional mandate to grant IPR to inventions to promote scientific development. In 1990, the US launched its "Human Genome Project" to identify all the genes in a human. This led to development of new technology and capitalisation of gene patenting. Under the Genetic Information Non-discrimination Act (GINA), ownership is provided to the person whose DNA sample is extracted to sufficiently deal with the privacy issue.[22] In 2016, Bill rider's bill was

[18] The Patents Act, § 2(1) (ac) (1970).
[19] The Patents Act, 1970, § 2(1)(j) (2005).
[20] AIR 1982 SC 1444.
[21] WIPO IP Portal, WIPO Lex, pg. 98. (Visited on June 7, 2021, 12:32 PM).
[22] Mark A. Rothstein, "Genetic Secrets?: Protecting Privacy and Confidentiality in the Genetic Era", 33 Yale University Press, New Haven and London (1997).

drafted and is still pending. It was enacted to amend the "Consolidates Appropriations Act" and control the gene research.[23]

Interestingly, US Patent and Trademark Office (USPTO) granted patent to a wide range of application for protection of DNA engineering, ignoring the conditions of patent eligibility. This has been pointed out by US courts in its several judgements, one such being the case of *AMP v. Myriad*[24]. Further, USPTO started to grant patent for cDNA and isolated DNA in huge chunks, rejecting the judicial precedent of *Amgen v. Chugai*[25], where the court explicitly mentioned the distinction between patent-eligible matters and patent ineligible. This liberal practise of USPTO was halted by US SC's landmark decision in Myriad case on patenting of isolated gene.[26]

2. GENE PATENTING AND JUDICIAL TREND

Judiciary puts forth its decision on a case-to-case basis. This can be construed from the judgment of *Cancer Voices Australia v. Myriad Genetics, Inc.*[27], where the Australian Federal Court heard the gene patent challenge similar to that raised in *Myriad Case*[28] before US Supreme Court. Though both the cases involved the issue of BRCA1 and BRCA2 gene patentability, the judgment rendered was in total contrast of each other. The court noted the reasons for such contrast, which are; first, laws and constitution differ in both the countries and second, evidence given and conclusion drawn from such evidence differed significantly in both the cases.

a. INDIAN JUDICIARY

The Patents (Amendment) Act, 2005, changed the outlook of judiciary in recognising microorganisms as a subject matter of patent protection. In *Dimminaco A.G. v. Controller of Patents*[29], the Calcutta HC observed that *"the contentions of the Controller were not justified because the law did not bar the processes ending in the creation of a living thing."* Here the petitioner filed the case against orders of the Controller of Patents for rejecting the petitioner's

[23] The Consolidated Appropriations Act, Pub. L. No. 114-113, § 749 (2015).
[24] *Supra*, note 1.
[25] 927 F.2d 1200 (1991).
[26] M. Mendicino, "Genetically Customized Generations- A Need for Increased Regulatory Control over Gene Editing Technology in the United States", 73 SMU L. REV. 585 (2020).
[27] (2013) FCA 65.
[28] *Supra*, note 1.
[29] 2001 AIR 1 (Cal.).

application of patenting vaccine manufactured by them to fight bursitis. This judgment came up before the 2005 amendment in Indian Patent Act, which shows that courts were inclined to follow the international principle and rules on patentable subject matters. In *J. Mitra v. Kesar Medicaments*[30], the court granted a temporary injunction after satisfying itself that the patent granted for diagnostic kit for detecting HCV in humans, lacked novelty, inventive step and other eligibility criterion. In *Emergent Genetics India v. Shailendra Shivam*[31], the court rejected the granting of the patent on the ground that it lacked originality and observed that *"The microbiologist or scientist involved in gene sequencing discovers facts…So long as a researcher constructs a DNA sequence based on a sequence discovered in nature, there is no independent creation, no minimum creativity and thus no originality."* These judgements show that gene patenting can be granted only after the inventor satisfies all the essentials.

b. US JUDICIARY

The first case related to patenting biotechnology was presented before SC in the case of *American Wood Paper Co. v. Fibre Disintegrating Co.*[32], where the SC rejected the claim observing that "*extracted substances from nature are not patentable because they cannot be called a new manufacture; however, the process itself may be patent eligible."* In *Parker v. Flook*[33], the US SC opined that *"laws and products of nature, natural phenomena, and abstract ideas and are not patentable subject-matter*[34]*."* Further, in *Funk Brothers Seed Co. v. Kalo Inoculant Co.*[35], the court held that *"Gene were manifestations of…nature, free to all men and reserved exclusively to none."* In the historic judgment of *Diamond v. Chakrabarty*[36], the US SC held that *"patents were available for anything under the sun that is made by man."* In this case, the question before the SC was whether human-made living matter is patentable subject matter or it being a natural product cannot be viewed under the ambit of Patent Act, 1952. The court affirmed the grant of patent and observed that *"…Relevant distinction was not between*

[30] (2008), CS(OS) No. 2020/2006.
[31] (2011) (47) PTC 494 (Del).
[32] 90 U.S. 566 (1874).
[33] 437 U.S. 584 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972).
[34] *JEM v. Pioneer HI-Bred*, 534 US 124 (2001).
[35] *Supra*, note 15.
[36] 447 US 303 (1980).

living and inanimate things but between products of nature, whether living or not, and human-made inventions."

However, the long-standing practice of granting patents for isolated DNA sequences was overturned by the US SC in the case of *AMP v. Myriad Genetics*[37]. The case is related to the question of patenting two isolated gene from a human body namely; BRCA1 and BRCA2 gene, presence of which in a woman's body marked the risk of suffering from breast and ovarian cancer and its mutation if found could increase the risk of the same to a considerable amount. This invention was indeed instrumental to diagnose the chances and provide pre-hand medical treatment to the patient and therefore, the grant of patent to Myriad as the sole proprietor over conducting genetic testing and research on the gene's mutation and other aspects was challenged before the US District Court, then USCAFC and later before the Hon'ble SC. The SC held that isolated genomic DNA are not patentable subject matter whereas cDNA sequence is man-made and thus patentable, forming an exception to Section 101 of the US Patent Act, 1952. The court further observed that "*Without this exception, there would be considerable danger that the grant of patents would tie up the use of such tools and thereby inhibit future innovation premised upon them…which would be at odds with the very point of patents, which exist to promote creation*." This judgment marked a focal point in US patent jurisprudence by settling the ongoing battle of patent-eligible subject matter. In the case of *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*[38], the court resolved the issue of patenting method and laid distinction between the patentable method which is applied natural law and non-patentable method which elaborates on the existing law of nature. The court held that *"the claims regarding the processes used to find the correlation between human metabolites and efficacy of the drugs only described natural relations between naturally occurring substances, and nothing more.*

V. COMPARITIVE ANALYSIS

India and US projects contrasting difference on gene patenting pertaining to difference in their laws and constitution. The US Constitution under Article I, Section 8, provides for constitutional mandate to grant IPR to inventions to promote scientific development. However, the Indian Constitution does not mandate for IPR protection rather it contains a provision

[37] *Supra*, note 1.
[38] 566 U.S. 66 (2012).

regarding it in the Union List[39] which gives power to the Central Government to frame laws on it. The US Patent law from its inception supported the biotechnological inventions or discoveries by patent to the inventor upon satisfaction of certain conditions, whereas in India, the 2002 amendment to Patents Act, 1970, included microorganisms in the list of patentable subjects and the 2005 amendment allowed gene patenting after fulfilment of conditions of Industrial applicability, novelty, invention, utility and non-obviousness. Further, it is a settled judicial practice in both the countries that a gene has been rightly patented when it fulfils the conditions of Industrial applicability, novelty, invention, utility and non-obviousness and when the invention involves sufficient amount of human intervention. However, courts in US witness large number of cases on gene patenting as compared to Indian courts. The SC of US has curved out an exception to Section 101 of the US Patent Act, 1952 which is of cDNA sequence i.e., man-made and thus patentable. Thus, the judicial perspective in both the jurisprudence has witnessed dynamic evolution in their precedents at par with the biotechnological development. However, like the US, the Indian patent office must showcase a lenient approach in granting patents while adhering to the pre-requisite conditions and the judiciary is entailed to exercise judicial activism and carve the exception of gene patenting from the existing provision.

VI. CONCLUSION AND SUGGESTIONS

Gene patenting is a highly debatable topic as till now both India and the US are trying to reach equilibrium in its application. Consequences of gene patenting are dark as has been observed by the judiciary. It is evident from the above-mentioned research that both the countries have a contrasting approach towards the concept of gene patenting as they differ significantly in terms of economic, technological and ethical principles. Both nations have tried to balance the right of patent and public interest at large. However, it is recommended that they should follow European Patent law for regulating gene patenting in the country as, in Europe, under Chapter V, Rule 26(3) of the Convention on the Grant of European Patents (EPO), the term microorganism has been substituted with "biological material" and defined as "any material containing genetic information and capable of reproducing itself or being reproduced in a biological system" to clear the ambiguity regarding patentable subject matter. Also, both the countries can develop something on the lines of "Biotechnology Directive", developed by Europe to respond to the calls concerning gene patenting and in addition, the GDPR regulates

[39] The Constitution of India, List I (49) (1950).

the privacy concerns. There is a balance between the law which makes it easier to implement the concept efficiently.

As it is unclear whether gene patenting has beneficial or detrimental effect overall, the stakeholders of this field must work to minimise the detrimental effect by adopting licensing methods like advocating for the grant of compulsory licensing in public interest[40], inventing new outcomes from the publicly known information on the patented gene and have bonafide intention to research. There must be parity between the need to grant gene patents to incentivise future innovations and maximising public good by providing open scope for better access to medical help. This balance could be achieved by inserting provisions relating to non- infringement of patent and public order under TRIPS agreement. It must be acknowledged that isolated genomic DNA must be *"free for all men and reserved exclusively to none".* Further, to avoid false patent applications, a special step in the examination process related to gene examination must be included to ensure novelty, substantial human intervention and utility of the product or process applied for relating to human gene or DNA. Doing this will in turn help the executive body to maintain the status quo of examination process even after accommodating the application of gene patenting.

[40] D. Jain & J. Darrow, "An Exploration of Compulsory Licensing as an Effective Policy Tool for AntiretroviralDrugs in India", 23 Health Matrix (2013).