

PATENTABILITY OF GENETIC INVENTIONS; CHALLENGES AND DILEMMAS

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Abstract

Genes forms the basic element of human life including the basis for his emotional and intellectual constitution. Scientific advancement in gene based technologies is advancing rapidly and patenting of such inventions becomes a major issue in the legal scenario as it has immense advantages and major embroilments. In this article we are examining gene (isolation of DNA) patenting in Indian legal scenario for that we examined the general ethical challenges in patenting and whether our patent law consider ethics in our patent law, lastly, we discuss whether genes can be an invention according to patenting standards of our law.

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Introduction

Genetic engineering has made manifold advancements in the field of life, health and health services.¹ Also it is a major area of embroilment in patent system especially matters with regard to genes and patenting of genes.² It has been raised in several judicial dicta's that patenting of genes restricts research and development and forestalls innovation in the field of genetic engineering.³ Also it poses immense ethical challenges including access to medical services.⁴

In this article we examine the scope of gene patenting in the India legal scenario, especially the patent eligibility of isolated genes. The first phase of this article discusses the basics of patent and patenting of biotechnology followed by basic understanding about DNA and isolated DNA. The Indian legal scenario and patenting of genes is discussed in the next session.

Genes and DNA- General Introduction

Genes form the basis of human inheritance, human genome consist of approximately 20,000-22000 genes in 23 pairs of

chromosomes.⁵ The prime matters of heredity in all living organisms are genes.⁶ Gene is made up of DNA; this controls physiology of living organisms.⁷ Modern technology can applied to extract, isolate, edit⁸ DNA from its natural environment and is generally called isolated DNA and it is a useful diagnostic and therapeutic tool and for e.g. isolation of mutated BRCA genes help in managing health issues related to breast and ovarian cancer.⁹

There is a term called cDNA which is a manmade complementary DNA by modifying an isolated DNA, this modification process generally involve splicing and removing the non-coding introns that are usually interspersed with exon sequence in a given genetic sequence.¹⁰ In this article we pertinently concerned with issue of patenting isolation of human genes and its implication in the Indian patent law scenario.

Role of patenting in Genetics

Generally patenting of genes contains number of claim for sequence of human DNA and isolation of DNA, piece of DNA removed from human cell. The patenting of

¹ Wing Yin Chan, Should Isolated Human Genes Be Patentable Subject Mater, 5 *Manchester Rev. L. Crime & Ethics* (2016) 64, 64-91 (2016)

² *Id* at 67.

³ *Association of Molecular Pathology v. Myriad Genetics* 133 S.Ct 2107 (2013), *Diamond v. Chakraborty* 44 U.S. 303, (1980), *Funk Brothers Seeds v. Kalo Inoculant Co.* 333 U.S. 127, (1948)

⁴ *Ibid.*

⁵<https://www2.le.ac.uk/projects/vgce/highereducation/topics/dna-genes-chromosomes> Last Visited on Dec 1, 2017.

⁶ *id.*

⁷ *Supra* note 10 at 7.

⁸ CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats)

⁹ *id* at 10.

¹⁰<https://nopr.niscair.res.in> Last Visited on December 2, 2017.

isolated DNA is always a disputed area. Patents typically play an economic role in the society. It provides incentives to activities which promote scientific progress to the society.¹¹ So it covers the investors risk and thereby induce research and development by offering high return on their investment.

Research associated with genes and isolation of genes requires huge investment and expensive technologies. Isolating of genes are done by the use of different sophisticated technology including recombinant DNA technology¹² and this is high expensive process and the supporters of gene patent refers that this sophistication and high investments in this area should be acknowledged through patent law systems¹³. There were many issue raised in granting patent to gene isolation and associated matters. Granting of monopoly in DNA and isolation of DNA to the patent holder for a particular has manifold ethical, economic and legal repercussions.

For instance, Mr. X cannot give his gene sequence to his doctor and ask him to see for any mutations without permission of the

patent holder, take the case of 10-year-old Abigail, who was suffering with long QT syndrome, a complicated heart related disease. There is a genetic test that can detect the disease, but it was patented, the only lab which was equipped to conduct the test was not testing because of threat of suing the lab from the company which patented the test and by the time Abigail died¹⁴.

The role of patent in genes provide rewards and fairness for the inventors and investors thereby give social returns, also it has many ethical and legal issues, In the next session we discuss what are the ethical issues in gene patenting and analyse whether ethical concerns restrict patenting of genes in the Indian legal scenario further session examines whether gene can be a subject matter of patent and would it pass the technical standards of patents according to Indian patent law.

Ethical Concerns and Patent of Genes

When examining the aspect whether genes can be patented, the question has to be analysed from two aspects of ethics as Barbara Looney pointed out;

1. Whether it is ethically permissible to patent segments of human genome

¹¹ Elizabeth Siew-Kuan, Patenting Human Genes: Wherein Lies the Balance between Private Rights and Public Access in India and the United States, 11 Indian J.L. & Tech. (2015)2-51,2(2015).

¹²<https://www.ncbi.nlm.nih.gov/books/NBK26837/> (Last visited Dec 1 ,2017,10.45 P.M)

¹³ Barbara Looney, Should Genes be Patented? The Gene Patenting Controversy: Legal, Ethical and Policy Foundations of an International Agreement, 26 Law & Pol'y Int'l Bus. (1994) 236, 231-272 (1994).

¹⁴<http://ideas.time.com/2013/04/15/do-human-genes-belong-to-people-or-corporations/>(Last visited,19 Dec 2017 11.00 A.M)

when these segments represent part of human kinds natural or universal heritage;

2. The aspect whether it is unethical to deny patenting of the human gene as it needs immense economic resource and sophisticated human effort in identifying it?¹⁵

The Human Genome Organization has opined that “the human genome is our common is our common heritage and collective property; genetic information is...in the public domain.....human DNA is not patentable, but belongs to human kind “and it has been referred by Barbara Looney¹⁶ also human genes are basic element of human life , which are the basis of his intellectual and emotional constitution ,as far as genes considered part of human body or a matter lying in the public domain, interference with gene sequence is intrusion of privacy because privacy is stated by ethicists as limited access to a person.¹⁷

Next ethical issue on contrast is whether denying patent will disregard reward for human effort thereby restricts scientific progress, research and development and disregarding the effort would require researchers and investors to spend their resources without guarantee of potential

return on their efforts would be fundamentally unfair¹⁸.

Ethics and Indian Patent Act 1970

Patent and related matters is governed in India under Indian Patent Act 1970. When analysing genes can be a subject matter of patent under our law it should be initially analysed whether any ethical component has been embedded in our patent law. Under section 2(j) of Indian Patent act ¹⁹ states that to be an invention, it should qualify the standard of industrial application and according to WIPO industrial application means the invention should have some practical applicability or susceptible of industrial application or it can be used in agricultural, public health or other sectors of the economy²⁰.

As it is a subjective standard it reflects morals. According to section 3 (b) refers that inventions should not be against general moral norms of the society and section 3(c) refers that invention should not be discovery because according to patent law jurisprudence ideas located in public domain cannot be patented because patenting such ideas involves tremendous reallocations of wealth toward the property holders of these

¹⁵ Supra note 7,237.

¹⁶ Supra note 7,239.

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ Patent Act 1970, sec 2(j)

²⁰ www.wipo.int/scp/en/meetings/session_5/doc/scp5_inf.doc(Last visited, Dec 2 ,2017,12. 00P.M)

ideas²¹ and further it restricts society of something regarding which it already has ownership and access.

By examining this provision of our patent law, it can be understood that ethical consideration has been embedded in our patent law implicitly, but it is not clear whether it have strong influence on the decisional process of patent as far as there is no settled case pertinent to this matter.

Patenting of Genes in Indian Legal Scenario

In India, matters relating to patent are regulated under Patent Act 1970.²² Earlier, biotechnological and microbiological processes or product were not granted patent under the act.²³ After the decision in *Diminiaco AG v Controller of Patents & Designs*²⁴ and by subsequent amendments in 2002²⁵ and in 2005,²⁶ permitted product and process patent also in the field of biotechnological.²⁷

But whether genes are subject matter of patent in Indian patent system has not yet been settled.²⁸ The remainder of this article examines patent eligibility of genes under the Indian patent system. In order to

analyse this question we have to look into the scope and implications of section 3 of the Patent Act, which enumerates a list of subject matter that are not patentable, particularly section 3(c) and 3(j) of the act.²⁹

Under section 3(c) mere discovery of a scientific principle or the formulation of an abstract theory, principle or the formulation of an abstract theory, discovery of any living substance occurring in nature is not patentable,³⁰ under section 3(j) plants and animals in whole or any part thereof, other than micro-organisms but including seeds varieties and species and essentially biological processes for production or propagation of plants and animals would not be patented.³¹

Naturally occurring genes with in a chromosome is not patentable under section 3 (c) as a discovery of a naturally occurring living thing is not patentable.³² While it is true, it must be noted that in case of isolated gene and cDNA the question whether it would fall within the scope of section 3(c)³³ is not clear.³⁴ Elizabeth Siew Kuan suggests that isolated genes are not a subject matter under section 3 (c) as nucleic acid sequences, proteins enzymes, compounds etc which are directly isolated from nature is

²¹ Justin Hughes Philosophy of Intellectual Property, 77Geo.L.J.287,366,320(1988).

²² Patents Act, 1970.

²³ id at Section 3.

²⁴ AID No. 1 of 2001 (High Court of Calcutta).

²⁵ The Patents (Amendment) Act 2002.

²⁶ Supra note 6.

²⁷ id at Sec 3.

²⁸ Supra note 11,at 23.

²⁹ Supra note 6.

³⁰ id at Sec 3 (c).

³¹ Id at Sec 3 (j).

³² Supra note 10 at 23.

³³ Supra note 30.

³⁴ Supra note 28, at 24.

treated as a discovery under 2013 Biotechnology Guidelines.³⁵

In the case of complimentary DNA the above author states that on a general reading of the section it can be argued that cDNA is not more than a discovery and thus not patentable but on precise analysis the term cDNA and a narrower interpretation of the word ‘discovery’ in the section pose that cDNA can be a subject matter of patent.³⁶ As far as section 3(j) is concerned it excludes any animal or plant “in whole or any part there of” from patentability.³⁷

So it has to be analysed whether the term “animal” in the section includes humans and also whether gene constitutes a part of humans. The Manual of Patent Practice and Procedure provides drafted manual in 2005³⁸ stated that any living entity of artificial origin such as transgenic animals and plants and any part thereof are not patentable but stated that recombinant DNA and plasmids are patentable if there is substantial human intervention, the 2008 manual also restated that genetically modified gene sequence /amino acids can be a subject matter of patent under section 3(j).³⁹

³⁵http://www.ipindia.nic.in/writereaddata/Portal/IPGuidelinesManuals/1_38_1_4-biotech-guidelines.pdf Last Visited on December 3, 2017.

³⁶*Id.*, at 28.

³⁷ *Supra* note 31.

³⁸<http://www.ipindia.nic.in/manual-patents.htm> Last Visited on December 4, 2017.

³⁹ *id.*

But 2011 manual does not provide any further elaboration on patentability of genes.⁴⁰ Also the scope and implications of above subsections have not been much discussed judicially. Elizabeth Siew discussed two cases which have some implications on this area in her work.⁴¹ In *Emergent genetics India v Shailandra Shivam*⁴² learned Justice Bhatt opined that the genetic sequence was not an original expression of idea but mere reproduction of something found in nature, although these pronouncement were made in the context of copy right law, extending these to patent law author infer that human genes are not a patentable subject matter.⁴³

In this context it is also relevant to discuss some aspects of the famous case *AMP v Mryiad Genetics*⁴⁴ judgement the court reversed all liberal approach granting patent towards isolated DNA in USA. In that case Myriad Genetics’ researchers identified the precise location of BRCA gene saga on chromosome 17 and 13 this was a major breakthrough in medical tests for identifying breast and ovarian cancer at an early stage. Myriad filed patent application for this isolated DNA cDNA.

While deciding this justice Bryson opined that “Extracting a gene is akin to snapping a

⁴⁰ *id.*

⁴¹ *Supra* note 36.

⁴² 2011 (47) PTC 494 (Del).

⁴³ *Supra* note 42 at 36.

⁴⁴ *Supra* note 3.

leaf from a tree. Like a gene, a leaf has a natural starting and stopping point. It buds during spring from the place that it breaks off and falls during autumn. Yet prematurely plucking the leaf would not turn it into human made invention...That would remain true if there were minor differences between plucked leaf and the fallen autumn leaf, unless those differences imparted “markedly different characteristics to the plucked leaf.”⁴⁵

Based on the points above it can be understood that human genome and isolated DNA are not patentable in India under section 3 of the Indian Patent Act. In the USA until 2009 the trend was different, with the decision in *Diamond v Chakraborty*⁴⁶ in 1980 it was held that all things under the sun can be a matter of patent, which allowed immense number of isolated DNA patents. In 2009 with *APM v Myriad Genetics* all the liberal approach with regard to patent of isolated DNA were reversed and held DNA is product of nature occurring naturally thus it cannot be matter of patent.⁴⁷

Conclusion

Biotechnological advancements contributed manifold advantages to public health and medical field. One of the vastly developing such field include gene and genetic based inventions. Patentability of genes has been

controversial since its inception. The article discussed basics of genetic technology, role of patenting in gene technology and also Indian patent scenario and genetic based invention. The reflection of the discourse points that patenting of genetic inventions has not been explicitly dealt under the patent act also there were no settled judicial position or discussion in this regard. In our opinion it would be better to interpret the provisions of our act precisely for preventing carrying of objects placed under public domain.

It is deemed that U.S. position in *Myriad genetics* i.e. isolated genes is naturally occurring matter and should not qualified for patenting is based on the economic policy, i.e. federal government is the largest funder of genetic research⁴⁸. In India Government cannot be such large funder as it is dearth of resource and we consider taking a stand blindly based on U.S position for Indian scenario is adversely affect research and development in the field of gene based inventions.

⁴⁵ Supra note 3.

⁴⁶ Supra note 3.

⁴⁷ Supra note 3.

⁴⁸ Supra note 1 at 73.