GENE PATENTS AND RIGHT TO HEALTH

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Genes hold the blueprint of the human body. Since genetic code contains all the necessary information for the continued physiological functions of the organism, patent over a gene can potentially determine all the downstream inventions. In light of genes modified with significant human intervention being considered a valid patentable subject matter under the Patents Act, 1970, this article explores the conflicts between gene patents and the right to health at four different levels, viz., availability, accessibility, quality & acceptability of better healthcare. The propensity to infringe right to health calls for a prudent and vigilant approach. The relevant provisions of Patents Act, 1970 and Competition Act, 2002 may help in this endeavour. The best solution, however, is to expressly exclude genes from patentable subject matter under the Patents Act invoking the rationale in the recent Myriad judgment.

I. INTRODUCTION

Biotechnology is a rapidly growing field in which new products and services are developed from an increasingly complex and cumulative set of underlying technologies. The sequencing of genes,[1] identifying their functions and mutations, creating systems to selectively express, regulating or silencing genes, predicting protein structures and expressions, mapping the influence of genetic make-up on metabolism and analysing the vast amounts of genetic data has been dubbed as the 'genomics revolution'. These technologies have contributed to the rapid pace of advancement in life sciences. They offer tremendous promise for improving human health. Genetic tests are slowly but steadily emerging as an important component of health care services as they provide means to establish difficult diagnoses and detect persons at risk before expressing the disease. Such tests are of immense benefit to the public. Unfortunately, patenting of genes has raised genuine concerns pertaining to the future of the genomics revolution and its potential benefits for public health.

The legality of gene patents is a contentious debate. On one hand, it may be argued that the isolation of a gene amounts to 'discovery' and not 'invention' and hence not patentable. On the other hand, it may be argued that the subject matter is not the isolated gene *per se* but the purified gene which comes under the realm of "invention" and not "discovery" and hence patentable. Further,

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[1] *Infra* note 26.

it is debatable whether a purified gene is a "part thereof" of human body. This debate has intensified in the light of recent judgment by District Court of Southern District of New York which invalidated seven of twenty-three patents on BRCA1 and BRCA 2 genes. The judgment, in effect, undermined the very idea that a DNA sequence can be patented.[2] If the decision is upheld, it will have far-reaching implications in the realm of biotechnology.

Part II of the article shall deal with the nature of gene patents. Part III and Part IV shall discuss the concept of 'right to health' & validity of patenting of genes under the Patents Act, 1970 respectively. Part V shall argue that gene patents, for their very nature, can infringe 'right to health'. The article concludes by advocating for a prudent and vigilant approach towards gene patents.

II. NATURE OF GENE PATENTS

Every organism on the planet has a genome that contains the biological information necessary to maintain itself and to reproduce. Most of the genomes are made of DNA, deoxyribonucleic acid-the molecular basis of heredity. The DNA molecule has a double helix structure which looks like a ladder twisted on itself. The long sides consist of sugars and phosphate groups, while the crosspieces consist of a pair of nitrogenous organic bases or nucleotides-adenine (A) coupled with thymine (T), or cytosine (C) coupled with guanine (G). A always couples with T and C always couples with G. This coupling characteristic serves as an instruction manual for replication and protein synthesis. There are approximately 3.2 billion nucleotides in the human nuclear genome. However, not all of them carry instructional information for protein synthesis. Only a small fraction of the nucleotides carry protein synthesis instruction. These stretches of the DNA are called genes. They hold the blueprint of the human body. Any change in the genetic code affects the production of proteins and thereby the ultimate function of the cell.[3]

Genetic disorders, in fact, comprise changes at the nucleotide code level. This can result in abnormality in production of proteins. Many genetic diseases, including certain cancers, can be attributed to this change in protein

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[2] Myriad Genetics along with the University of Utah Research Foundation holds several patents on two breast cancer genes, BRCA1 and BRCA2. It is the sole provider of the full sequencing of these genes in the US on a commercial basis. Judge Robert Sweet invalidated the gene patents on the ground that DNA's existence in an isolated form alters neither its fundamental quality nor the information it encodes. Further, denying the patentability of the method claim, he held that the comparisons of DNA sequences are abstract mental processes and therefore cannot be patented. [Mita Sheikh, *Are Genes Patents Possible?, Managing Intellectual Property*, September 1, 2010, available at http://www.managingip.com/Article/2665095/Supplements/Are-gene-patents-possible.html?supplementListId=77403 (Last visited, September 19, 2010)].

[3] Lorelei Perez Westin, *Genetic Patents: Gatekeeper to the Promised Cures*, 25 T. JEFFERSON L. REV. 271 (2002).

expression. Since the genetic code contains all the necessary information for the continued physiological functions of the organism, all the therapies geared towards the treatment of genetic disorders must also utilize the genetic code of the organism in some form. Thus, genes are essential for the practice of all downstream inventions pertaining to gene therapy. In other words, a patent over a gene can potentially determine all the downstream inventions and thereby "guard" entry into a field.[4] Hence they are known as gatekeeper patents. Even if one disputes the absolute terms of this argument, it cannot be denied that, unlike other patented inventions, it is difficult to "invent around" patented genes or find substitutes for them.[5]

III. RIGHT TO HEALTH

Article 12 of the International Covenant on Economic, Social and Cultural Rights[6] (*hereinafter* ICESCR) requires parties to the Covenant to *"recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health"*. It enumerates a list of non-exhaustive obligations of states parties' which includes the creation of conditions which would assure medical services and medical attention to all. Article 12 of the ICESCR along with Article 25 of the Universal Declaration of Human Rights[7] (*hereinafter*, UDHR) has explicated the content of 'right to health'.

Article 51(c) of the Constitution which is one of the Directive Principles of State Policy enshrined in Part IV provides that the State shall endeavour to foster respect for international law and treaty obligations. It has to be read in the light of Article 37 which states that the principles laid down in Part IV are fundamental to the governance of the country. In other words, it shall be the duty of the State to apply these principles in making laws. It is thus settled that the raison d' etre of Article 51(c), when read with Article 37, is to introduce and implement various international instruments which are consistent with the fundamental rights and in harmony with its spirit.[8] Since India is a signatory, she is bound to fulfil its obligations enumerated in ICESCR & UDHR and facilitate the enjoyment of 'right to health' by its citizens.

Further, Article 21 of the Constitution has been held to include 'right to health'.[9] Article 21 of the Constitution guarantees protection for life and personal liberty by providing that no person shall be deprived of his life or personal liberty

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4 Lorelei Perez Westin, supra *note 3*

5 Shamnad Basheer, *Block Me Not: How "Essential" Are Patented Genes?,* 1 University of Illinois Journal of Law, Technology & Policy, 81, (2005).

6 G.A. Res. 2200A (XXI), 21 U.N.GAOR Supp (No. 16) 49, U.N. Doc. A/6316 (1966), 993 U.N.T.S. 3 (January 3, 1976).

7 G.A. Res. 217A (III), U.N. Doc A/810 (December 10, 1948).

8 Vishaka v. State of Rajasthan, AIR 1997 SC 3011; People's Union for Democratic Rights v. Union of India, AIR 1982 SC 1473.

9 M.K. Sharma v. Bharat Electronics Ltd, AIR 1987 SC 1792.

except according to the procedure established by law. The Supreme Court has expanded the repertoire of Article 21 so as to make life meaningful and not a mere vegetative existence. The Court held that the right to health and medical care is a fundamental right under Art. 21 read with Arts. 39(e), 41 and 43.[10] Deliberating on this issue, the Court further held that in a welfare state it is the obligation of the state to ensure the creation and the sustenance of conditions congenial to good health.[11] Moreover, improvement of public health is one of the primary duties of the State.[12] The 'right to health' has four interrelated and essential dimensions[13] - availability[14], accessibility[15], quality[16] and acceptability[17].

IV. GENE PATENTS UNDER PATENTS ACT, 1970

§3(c) of Patents Act, 1970 precludes patenting of discovery of any living thing or non-living substance occurring in nature. As per §3(j), plants and animals in "whole" or "any part thereof" is not patentable. Thus, a merely isolated natural gene is not patentable. However, a genetically modified sequence which is new, inventive and has industrial application is patentable.[18] In essence, naturally occurring genes, under the present patent regime, cannot be *per se* patented but when modified with significant human intervention resulting in revealing its distinct functions, coupled with its industrial viability, they form patentable subject matter.[19]

Further, §3(i) proscribes patenting of diagnostic methods. Accordingly, Draft Manual of Patent Practice and Procedure, 2008[20] (*hereinafter*, DMPPP) excludes methods of diagnosis practised on the human or animal body. However, it does not exclude methods of diagnosis performed on tissues or fluids, which have been permanently removed from the body.[21] Thus diagnostic methods employing DNA are patentable to the above extent.

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[10] Consumer Education and Research Centre v. Union of India, (1995) 3 SCC 42, ¶ 24.

[11] Vincent v. Union of India, (1987) 2 SCC 165.

[12] Art.47, Constitution of India.

[13] CESCR, General Comment No. 14 (2000), The Right to the Highest Attainable Standard of Health (Article 12 of the International Covenant on Economic, Social and Cultural Rights, 22nd Session) E/C. 12/2000/4, August 11, 2000, ¶ 12.

[14] "Availability" requires adequate facilities in healthcare so as to meet the needs of the population.

[15] The component "accessibility" requires facilities in healthcare to be physically and economically accessible to all the sections of the population without discrimination.

[16] "Quality" refers to the scientific and medical appropriateness. This includes access to medicines which is within reasonable reach and at an affordable price.

[17] "Acceptability" relates to the degree to which healthcare is ethically and culturally appropriate.

[18] ¶5.8.11 f (iv), The Draft Manual of Patent Practice and Procedure, 2008.

[19] Sheikh, *supra* note 2.

[20] Available at www.patentoffice.nic.in/ipr/patent/DraftPatent_Manual_2008.pdf (Last visited, September 19, 2010).

[21] ¶4.9.14, The Draft Manual of Patent Practice and Procedure, 2008.

In the light of genes being a valid patentable subject matter under the Patents Act, 1970, this article explores the conflict between gene patents and right to health. The article intends to analyse the various concerns pertaining to right to health at four different levels, viz., availability, accessibility, quality & acceptability of better healthcare. Part III shall analyse the implications of gene patents on each of these four facets.

V. GENE PATENTS AND RIGHT TO HEALTH

A. GENE PATENT CAN IMPEDE "AVAILABILITY" AND "ACCESSIBILITY" TO BETTER HEALTHCARE

The component "availability" requires the presence of adequate healthcare facilities so as to meet the needs of the population. Such facilities must be "accessible" to all the sections of the population without any discrimination. They should be both physically and economically "accessible". Gene patents can infringe upon both these facets of 'right to health'.

Gene patents claim underlying fundamental information about genetic behaviour which is pertinent for both upstream and downstream research[22]. The very nature of gatekeeper patents allow them to entail that all the uses of the gene including gene therapy and pharmacological modulation of the gene must go through original gene patent before practising an invention using that gene.[23] Thus the patentee ultimately *controls* all the activities / research pertaining to the gene. In other words, such patents can easily attain the character of 'blocking patents' which can have an 'anti-commons effect' on the society.

The term 'blocking patent' can be used in myriad ways. In its widest sense, any patent is by definition a blocking patent as a patent confers upon its proprietor the right to stop others from making, using, offering for sale, selling or importing the patented invention. The notion 'blocking patent' is a tautology in this sense. In a more narrow sense, a blocking patent is a patent covering essential features of the invention which cannot be invented around. Such patents give scope for restrictive licensing.[24] In the area of genetic diagnostics[25], a patent

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[22] Upstream research refers to a position within the production stream closer to manufacturing processes. Downstream research points toward the latter stages of a usual industrial process or to the stages after manufacture. Upstream research may include products which are required by downstream researchers in the course of their future R&D.

[23] John H. Barton, *Patents and Antitrust: A Rethinking in Light of Patent Breadth and Sequential Innovation*, 65 ANTITRUST L.J. 449, 454 (1997).

[24] Geertrui Van Overwalle, *Of Thickets, Blocks and Gaps – Designing Tools to Resolve Obstacles in the Gene Patents Landscape* in GENE PATENTS AND COLLABORATIVE LICENSING MODELS – PATENT POOLS, CLEARING HOUSES, OPEN SOURCE MODELS AND LIABILITY REGIMES 389 (Geertrui Van Overwalle ed., 2009).

[25] A genetic diagnostic test is a test aiming at detecting pathogenic mutations in genes responsible for inherited and acquired genetic disorders. Conversely, a genetic diagnostic method encompasses any method or technology to detect a link or association between a disease and a specific defect in a gene.

encompassing claims on the entire (or relevant part of the) gene sequence[26], on a common pathogenic mutation or on the fundamental method to determine the association between a mutated gene and an inherited disease can be considered as 'blocking' for carrying out the genetic test based on nucleotide analysis for that disease.[27] It is impossible to develop an alternative diagnostic test that would not require the gene sequence or gene product.[28] Hence, it is misleading to discuss about alternative tests as they can operate only by interrogating the same genetic sequence. Thus, the owner of a gene patent may effectively have a "blocking patent" as he holds a patent covering all or part of the features of a gene which are essential for diagnosis. For instance, United States Patent and Trademark Office (USPTO) granted patent to Human Genome Sciences (*hereinafter*, HGS) which claimed rights to a gene, the precise function of which was initially unknown and the utility of which was asserted to be a research reagent or material for diagnostics. When other researchers subsequently discovered that the DNA sequence actually coded for CCR5 receptor[29], the "docking receptor" used by the HIV virus to infect a cell, it was widely feared that this patent would have a "blocking" effect on AIDS research. Since HGS had issued several licences for research into new drugs and did not prevent academicians from undertaking unlicensed research on CCR5, this fear became unfounded.[30] But if HGS had decided otherwise, it would have had a devastating effect on AIDS research.

Even products that do not have prima facie relation to the gene in question and are researched independently of the gene may require licensing from the patentee before using that product.[31] For example, an inventor could create a drug which itself will not infringe any other product patent but will infringe the gene patent if that drug modulates the patented gene – as working 'on' the patented gene without authority constitutes infringement.[32] The proliferation of gene patents, including multiple patents on various research tools, can necessitate negotiating multiple licences when developing a single product or process. Such patent thickets[33] have the potential to raise the transaction costs of R&D and possibly the ultimate cost of products owing to stacking of royalties. The

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[26] Gene sequencing is a process by which the individual base nucleotides in an organism's DNA is identified. It helps in identifying genetic abnormalities in an individual.

[27] Overwalle, *supra* note 24, 389-390.

[28] *Id*., 390.

[29] CCR5 (chemokine (C-C motif) receptor 5) is a protein which in humans is encoded by the CCR5 gene. They are predominantly expressed in T-cells and hence play a vital role in inflammatory responses to infection.

[30] *Genetic Inventions, Intellectual Property Rights and Licensing Practices – Evidence and Policies, Organisation for Economic Corporation and Development (OECD)*, available at http://www.oecd.org/dataoecd/42/21/2491084.pdf (Last visited, September 20, 2009), 13.

[31] *Id*.

[32] *Id*.

[33] The term '*patent thicket*' has been coined to characterize a technological field where multiple rights owned by multiple actors may impede R&D owing to the difficulty or cost of assembling the necessary rights. It can be used to refer to a multitude of essential, blocking patents which are held by a multitude of patent owners.

diagnostic sector is vulnerable to patent thickets.[34]

Research tool patents (e.g. patents on markers, assays, receptors, transgenic animals) claim products "identified by" the patented tool or method. If such a claim is granted, patent owners can demand royalties on the sale of a product found with the help of their research tool. Since many different patented research tools must be used in the development of a drug, such reach-through claims increase royalty stacking. The DuPont - Cre-lox controversy is the archetypal example of the above concerns. Cre-lox is a gene-splicing tool patented by Harvard University. It was exclusively licensed to DuPont Pharmaceutical Co. But it asked researchers to sign an agreement which would limit their ability to use and share the Cre-lox technique and subject their articles to pre-publication review by the company. DuPont wanted commercial rights over future inventions that might arise from experiments using transgenic animals which involved the use of Cre-lox splicing tool (*i.e.* reach-through rights). Some prominent institutions, including the National Institutes of Health (*hereinafter*, NIH), refused, claiming that they created obstacles to biomedical research. Finally a memorandum of understanding was signed between NIH and DuPont (and separate agreements with academic laboratories), which simplified access conditions for the US public sector to this patented research tool.[35]

Thus the following points may be concluded from this discussion:

- Gene patents claim underlying fundamental information about genetic behaviour pertinent for future, downstream research. They can acquire the character of 'blocking patents'.
- The diagnostic sector is vulnerable to patent thickets.
- Even products that do not have prima facie relation to the gene in question and are researched independently of the gene may require licensing from the patentee. This shall raise the cost of R&D.
- Patenting of research tools help a patentee to claim products "identified by" the patented tool or method. This increases royalty stacking and thus scuttles R&D on the product identified by the patented tool or method. This impedes the development of a better healthcare.
- The rapid proliferation of gene patents will increase commercial uncertainty owing to possible dependency between granted patents.

It is thus evident that the patenting of genes can impede R&D in healthcare which can be of immense benefit to the public. It can scuttle the progress of a better and effective healthcare. Further, it can spiral the cost of healthcare and streamline the access to the elite sections of Indian population. Thereby it can violate "availability" & "accessibility" to better healthcare.

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[34] Overwalle, *supra* note 24, 387-389.
[35] *Supra* note 30, 14.

B. GENE PATENT CAN IMPEDE THE DEVELOPMENT OF "QUALITY" HEALTHCARE

The human genome sequencing project has brought about many potential applications for therapeutic uses. Gene therapy was recently reported to correct sickle cell anaemia, an inherited disorder caused by a mutation in the beta globin gene that causes individuals to manufacture abnormal haemoglobin. There are at least five thousand genetic diseases which do not have any treatment. Genetic sequences can determine the propensity of an individual to contract a disease and cure the disease through gene therapy or targeted pharmacological modulation of the gene itself or the protein that the gene codes for.[36] For example, research revealed that mutations in the genetic sequences of two genes (BRCA-1 and BRCA-2) can be linked to hereditary forms of breast cancer.[37] Detection of the mutations alerts physicians to the propensity of the individual for breast, ovarian and other cancers.[38] Patients with these mutations may be referred for genetic counselling to evaluate the risk of surgical intervention or explore the scope of gene therapy. Gene patents can deprive a large section of the Indian population of the immense benefits that such improved healthcare can provide. Thus gene patents can infringe 'right to quality healthcare' which mandates access to quality healthcare within reasonable reach and at an affordable price. The infringement of this important facet of 'right to health' shall be discussed in the subsequent paragraphs.

Gene therapy, that is, correction of genetic defects within the cell genome has varying levels of successes dependent upon the model system being studied. Gene therapy is carried out either *ex vivo*[39] or *in situ*[40] through the delivery of genetic vectors[41]. Such therapy requires genetic sequence information so as to explore the scope of mutation and correct the defect in case the genetic sequence is mutated. Therefore all therapy products used in the gene therapy must flow from the original genetic information source. If the original genetic information source is patented, all practitioners must obtain licence to use that original information before they can use the therapy products derived from it.

Patent law grants patent holder the right to prevent any other individual or institution from making, using, offering to sell or selling the invention for twenty years. In the arena of gene patents, the exclusive rights of the patent holder can raise the costs of genetic services, diminish the quality of genetic tests

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[36] Michael J. Malinowski & Maureen A. O' Rourke, *A False Start? The Impact of Federal Policy on the Genotechnology Industry*, 13 YALE J. ON REG. 163, 165-167 (1996).

[37] See M.O. Nicoletto et al., *BRCA-1 and BRCA-2 Mutations as Prognostic Factors in Clinical Practice and Genetic Counseling*, 27 CANCER TREAT. REV. 295 (2001).

[38] *Id.*

[39] *Ex vivo* is defined as the substitution or insertion of the genetic sequence occurring outside the body, after which the cells are transplanted to the host organism.

[40] *In situ* is defined as the substitution or insertion of the genetic sequence within the host organism, usually through directed target binding.

and treatments and interfere with access to health care. Usually, gene patent holders let only their laboratories to use the patented gene. Exclusive licensing of a gene patent can itself interfere with the development of diagnostics. Various mutations in the same gene can cause a particular disease. But companies that do not let anyone else test *"their"* gene make it more difficult for the discovery of other significant mutations in that gene. In countries where the Alzheimer's gene and hemochromatosis gene were not patented, researchers were able to discover previously unknown mutations.[42] These additional mutations are often critical tools for diagnosing individuals who would not otherwise be diagnosed by the patented gene or diagnostic test. Thus gene patents run the risk of directly harming a patient by failing to make available a medical diagnostic procedure that can detect a disease in her genetic make-up. The controversy in Myriad patent over BRCA1 & BRCA2 genes can be cited in this regard.

Five to ten percent of the breast cancer cases diagnosed have been found to have involved mutated BRCA1 & BRCA2 genes. Women with BRCA1/ BRCA2 mutations are seven times more likely to develop breast cancer than the general female population. Myriad Genetics obtained exclusive rights to conduct diagnostic tests for BRCA1 and BRCA2 in many of the OECD member countries. However, Myriad's licensing strategy met with strong opposition. For instance, the company insisted that all testing worldwide be performed by Myriad's own laboratories. Since it enjoyed monopoly, it charged over USD 2,500 per test which was almost thrice the cost of such tests in other laboratories. It is reported that several companies which developed technologies for mutation analysis, stayed away from BRCA1 and BRCA2 for these patents. Hence, regrettably, more than ten years have been lost for the development of novel technologies that could have been applied to BRCA genes.[43] Further, the French government decided to challenge the Myriad patent owing to the possibility of inappropriate diagnostics method used by Myriad laboratories. The French government, in its opposition, pointed out that the sequencing technique used by Myriad failed to detect ten to twenty percent of expected mutations in BRCA1.[44]

A patent holder can forbid others from using the genetic sequence that he has patented for developing a diagnostic test even if he himself does not offer one using that sequence. Most drugs work only on a certain percentage of patients who use them.[45] Genetic testing can help distinguish those patients for

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[41] Gene therapy vectors are host organisms, usually a virus, which carry the DNA to be inserted or substituted directly to the host organisms target cells.

[42] Lori B. Mathews & Jordan Paradise, *Gene Patents: The Need for Bioethics Scrutiny and Legal Change*, 5 Yale J. Health Pol'y, L & Ethics 403 (2005).

[43] Gert Matthijs and Gert-Jan B. Van Ommen, *Gene Patents, From Discovery to Invention: A Geneticist's View* in Gene Patents and Collaborative Licensing Models– Patent Pools, Clearing Houses, Open Source Models and Liability Regimes 321(Geertrui Van Overwalle ed. , 2009).

[44] Sophie Gad et al., *Identification of a Large Rearrangement of the BRCA1 Gene Using Colour Bar Code on Combed DNA in an American Breast/Ovarian Cancer Family Previously Studied by Direct Sequencing*, 38 J. Med. Genetics 388, 388 (2001).

[45] Allen D. Roses, *Pharmacogenomics and the Practice of Medicine*, 405 Nature 857 (2000).

whom a drug will work from those for whom it will not. But such tests will also limit the market for drugs. For example, it is possible for a pharmaceutical company to file a patent on a genetic test to determine the effectiveness of a particular drug and at the same time does not develop the test or let anyone else develop it as such a genetic test can affect the market value of that drug. However, patent law in India, unlike in the United States, provides certain protection against such actions by requiring the inventor to actually "work" (i.e., use or develop) the invention. If the inventor does not "work" the invention, the inventor may be compelled to license the invention to another entity.[46] It can also be a ground for revoking the patent.[47]

It can thus be concluded that the exclusive rights of the patent holder can raise the costs of genetic services and diminish the quality of genetic tests and treatments. It is practically impossible for a single entity to enlist all the possible mutations of a gene. It has already been shown that gene patents can impede "availability" and "accessibility" to a better healthcare. This can hinder the development of a better healthcare and thus violate 'right to quality healthcare'.

C. GENE PATENTS MAY NOT BE "ACCEPTABLE"

The 'right to acceptable healthcare' encompasses right to a healthcare which is ethically and culturally appropriate. This facet of 'right to health' shall be discussed from the perspectives of bioethics and utilitarian justification for granting of patents.

Bioethics is defined as the *"systematic study of the moral dimensions—including moral vision, decisions, conduct and policies of the life sciences and health care, employing a variety of ethical methodologies in an interdisciplinary setting.*[48] Patents covering human genetic material raise myriad issues related to legal appropriateness, scientific and medical research, health care, access to appropriate health care and violation of individual rights. All the above mentioned issues, in one way or another, come under the realm of bioethics. However, the discussion in this essay is limited to the issue of gene patents impeding access to better health care.

It has already been pointed out that there are about five thousand genetic diseases which are incurable. There are many other diseases which can be traced to malfunctioning of genes. Though medicines exist for such diseases, gene therapy is much more effective as this therapy addresses the root cause of such diseases. Hence gene therapy can play a significant role in ensuring access

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[46] §84 (4),The Patents Act, 1970.

[47] §84 (5),The Patents Act, 1970.

[48] Protection of the Human Genome by the Council of Europe, Council of Eur., Comm. on Legal Affairs & Human Rights Doc. 9002 (Mar. 19, 2001); Universal Declaration on the Human Genome and Human Rights, UNESCO Gen. Conference (Nov. 11, 1997), adopted by G.A. Res. 152, U.N. GAOR, 53d Sess., U.N. Doc. A/RES/53/152 (1999).

to appropriate healthcare. But as argued before, gene patents can impede the very progress of such healthcare. Further, they can spiral the costs of such healthcare. It has already been discussed how gene patents can impede "availability", "accessibility" and development of a "quality" healthcare. Thus a large section of the Indian society may not benefit from such developments in the medical field.

Respect towards fellow beings is a significant factor for maintaining the social fabric of mankind. It ensures co-existence with fellow beings. The granting of patent rights in genetic material is tantamount to granting property rights in life which could lead to the exploitation of human beings as commodities.[49] This can be detrimental to the basic ethos of human society as such patents indirectly patent a vital element of life. This can set in slow commercialization of human life and human relationships. This can denigrate basic human ethos and prejudice moral standards of the society. Thus gene patents can become unethical.

Further, there have been instances where genes have been discovered and patented with the help of vast quantities of public funds. Myriad, the U.S. genetics company that first patented BRCA1, used over five million dollars from a government agency when researching the patent [50] and utilized sequence data from public databases. Thus, public may end up paying twice - first for the research and second for the high royalty costs that many patent holders require for subsequent use of their patented gene in a product.

Further, utilitarian justification[51] which is the most prominent justification for patents can never vindicate gene patents when it violates right to health. This justification is based on two assumptions. First, it assumes that such a right provides an incentive for inventors to invent. Second, it presupposes that the greater the quantity of inventions and creative works eventually released into the public domain, the more the public benefits through economic or cultural enrichment, or enhanced quality of life. They conceptualize the award of IPRs as a kind of contract between the holder and the government on behalf of the citizenry. Both the assumptions are closely interlinked. The first assumption logically leads to the second assumption. Let us consider the applicability of these assumptions in the instant case. Gene patents are not like any other kind of patents. They can impede R&D. The creativity, ingenuity and invention which an efficient patent system should nurture and encourage can be undermined by gene patents as they can add costs to medical and scientific research and, in some instances,

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[49] Mark A. Chavez, *Gene Patenting: Do the Ends Justify the Means ?*, 7 Comp. L. Rev. & Tech. J. 255, 260-67 (2003).

[50] Bryan Williams—Jones, *History of a Gene Patent: Tracing the Development and Application of Commercial BRCA Testing*, 10 Health L.J. 123, 131 (2002).

[51] Patent is a monopoly right conferred by the state on an inventor to exploit his invention for a limited period of time. Patents give inventors the right to exclude others from making, using or selling the patented technology for a limited period of time. In return, it is *conceived* that the society will benefit from the added knowledge through innovations and its eventual lapse into the public domain at the end of its patent term.

hindering it altogether. Thus the first assumption cannot apply in such cases. Hence logically the second assumption does not also apply. Even otherwise, the argument of 'public benefit' will not stand when gene patents infringe all the four facets of 'right to health'.

VI. CONCLUSION

It can thus be concluded that gene patents, for their very nature, have a high propensity to violate all the four facets of 'right to health'. Further, utilitarian justification cannot vindicate gene patents when they result in violation of right to health. However, this does not mean that all gene patents will result in violation of right to health. On the other hand, it means that the violation will be contingent on other factors such as the approach of the patent holder. For instance, consider the patent over Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene. This gene is mutated in patients with cystic fibrosis.[52] It was patented by Hospital for Sick Children of Toronto and the University of Michigan. The patent holders of this gene granted free access to the gene sequence for diagnostic testing. This allowed diagnostic laboratories to offer tests for cystic fibrosis using commonly available technologies for mutation analysis. The patent holders also offered licences to several companies that developed kits for the simplified identification of the most frequent mutation. These steps have greatly promoted the availability of the CFTR tests at a reasonable cost.[53] However, the patent holder may not be always as munificent as in this case. The character of a gene patent cannot be allowed to be completely determined by the patent holder. It will be naïve to always expect a philanthropic approach from patent holders. There could be instances where the patent holder might abuse his dominant position and infringe right to health. A pertinent instance is the dispute over the patenting of the gene which causes Canavan disease. Canavan disease is an inherited disorder which affects children of about 3 months; they cannot crawl or walk, they suffer seizures and eventually become paralyzed and die by adolescence. Formerly, there were no tests to predict this disease. Some of the affected families engaged a researcher to identify the gene. Canavan families around the world donated tissue and money for this cause. When the gene was identified in 1993, the families secured the commitment of a New York hospital to offer a free test to anyone who wanted it. However, Miami Children's Hospital Research Institute, the employer of the researcher, patented the gene and refused to allow any health care provider to offer the test without paying any royalty. Since, the parents voluntarily did not provide their names for the patent, they had no control over the outcome.[54]

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[52] Kerem B., Rommens J. M., Buchanan J.A., Markiewicz D., et al, *Identification of the Cystic Fibrosis Gene: Genetic Analysis,* SCIENCE 1073-80, 1989, 245.

[53] Matthijs & Ommen, *supra* note 43.

[54] Michael Crichton, *Patenting Life*, NEW YORK TIMES (New York) February 13, 2007.

India is bound to fulfil its obligations enumerated in ICESCR & UDHR and facilitate the enjoyment of 'right to health' by its citizens. Further, 'right to health' being part of Article 21 is a guaranteed fundamental right. Moreover, the Constitution mandates the State to accord justice to all members of the society in all facets of human activity.[55]

The character of gene patents and its implications on right to health calls for a prudent and vigilant approach. The relevant provisions of The Patents Act, 1970 and The Competition Act, 2002 may help in this endeavour. The Patents Act allows compulsory licence to be granted when the reasonable requirements of the public with respect to the patented invention have not been satisfied[56] or when the patented invention is not available to the public at a reasonably affordable price.[57] §4 of the Competition Act, 2002 can be invoked when an enterprise abuses its dominant position in the market. The abuse of dominant position which results in denial of market access in any manner can trigger essential facilities[58] doctrine.[59] This doctrine can be used in case of those patent owners whose permission is required for the development or production of downstream products of the gene. For instance, the doctrine can be used for mandatory issue of licence on commercially reasonable terms. The prudential use of these laws may help in precluding the violation of 'right to health'. However, this may not be a panacea for addressing the conflicts between gene patents and right to health. The best solution is to expressly exclude genes from patentable subject matter under the Patents Act invoking the rationale in Myriad judgment. If the judgment of District Court of Southern District of New York is upheld at later stages, it will further fortify the rationale. This suggestion should be appreciated in the light of practical difficulties in excluding genes from patentable subject matter *per se* on its *propensity* to infringe right to health. Moreover, cue may be taken from the express exclusion of business methods from patentable subject matter considering policy repercussions and exclusion in various jurisdictions.[60]

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[55] Air India Statutory Corporation, etc. v. United Labour Union and others, AIR 1997 SC 645.

[56] Reasonable requirement of public can *inter alia* include creating apposite circumstances for the growth of R&D.

[57] §84, The Patents Act, 1970.

[58] The outcome of a competitive process is expected to result in lower prices, higher output, better quality and innovation. The competitive process faces obstacles when a market player does not have access to certain facilities without which it cannot compete effectively. These are known as essential facilities.

[59] The report of the Working Group on Competition Policy, constituted by the Planning Commission, recommended the recognition of essential facilities doctrine in no uncertain terms. *See* Amitabh Kumar, *The Essential Facilities Doctrine*, Financial Express, March 23, 2007, available at http://www.cci.gov.in/images/media/articles/facilities_doctrine_23_3_2007_FE_20080409111745.pdf (Last visited, November 13, 2009).

[60] §3(k), The Patents Act, 1970.