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The Veiled Demon or Constructive Advancement Analyzing the Scope and Legal Provisions of Gene Patenting in India & China in light of Moral Dilemma as a Potential Hindrance

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ABSTRACT

The implications of Diamond v. Chakrabarty decision are reflected in different sectors where application of biotechnology has only lent a helping hand to the process of advancement. Life forms have been the object of the 'Midas touch' of science, which has indeed facilitated transformations as precious as gold. Protection of such unique and new inventions becomes inevitable and the same is ensured by granting of Patents. Biotechnological inventions utilizing life forms as subject matter have changed the global patent scenario with the continuous dilemma of boon or bane. Gene patenting is one such relatively new phenomena which has shown potential in various forms and sectors. Scientists world over have confirmed their faith in gene related inventions & therapies, which makes the critics resort only to moral & ethical objections against the same. Adhering to Bentham's theory of Utilitarianism which seeks to give precedence to the needs and positive effects on the society, the game should end in boon over bane. In light of the growing importance and dependence on gene based inventions, this paper seeks to analyze the concept, legality and the moral dilemma with regard to gene patenting in India, a developing country having tremendous scope for the application of gene based technologies, China, a developed country having a stringent and well defined legislation for regulating patents and draw a comparison of the above stated Asian countries with the U.S., which not only has a well-defined patent legislation but also a clearly laid down law for gene patenting.

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I. INTRODUCTION

The implications of *Diamond v. Chakrabarty*² decision are reflected in different sectors where application of biotechnology has only lent a helping hand to the process of advancement. Life forms have been the object of the 'Midas touch' of science, which has indeed facilitated transformations as precious as gold. Protection of such unique and new inventions becomes inevitable and the same is ensured by granting of Patents. Biotechnological inventions utilizing life forms as subject matter have changed the global patent scenario with the continuous dilemma of boon or bane. Gene patenting is one such relatively new phenomena which has shown potential in various forms and sectors. Scientists world over have confirmed their faith in gene related inventions & therapies, which makes the critics resort only to moral & ethical objections against the same. Adhering to Bentham's theory of Utilitarianism which seeks to give precedence to the needs and positive effects on the society, the game should end in boon over bane. In light of the growing importance and dependence on gene based inventions, this paper seeks to analyze the concept, legality and the moral dilemma with regard to gene patenting in India, a developing country having tremendous scope for the application of gene based technologies, China, a developed country having a stringent and well defined legislation for regulating patents and draw a comparison of the above stated Asian countries with the U.S., which not only has a well-defined patent legislation but also a clearly laid down law for gene patenting.³

II. WHAT ARE PATENTS AND HOW ARE THEY USEFUL

A right is basically an advantage to every other person to utilize or stop the misuse by an unauthorized person. A right is a privilege to one which disallows every other person from performing or not playing out specific activities with respect to the invention protected. The proprietor of a land hence has the right against the entire world to bar anybody from utilizing that specific land. Protected innovation Rights are a lot of intangible rights conceded over the results of insight. These right changes relying upon the type of protected innovation. For example, patent rights are allowed over licenses, copyright over imaginative articulation of thoughts, plan rights over plans, geological signs for items and administrations addressing interesting attribute of a particular topographical area and so forth. Intellectual Property rights satisfy double motivation for the in the form of incentive and award. These rights fill in as a prize for the inventor or creator who has placed in labor to change a thought into a substantial articulation. It likewise fills in as an impetus to additionally create/make, which will bring

² 447 U.S. 303.

³ *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013).

about conceding of imposing business model right to the inventor. The cycle of advancement and improvement ought to be never-ending as change is the lone consistent.

Patent eligibility criteria consists of three major aspects-

1. Novelty
2. Inventive step/non-obviousness
3. Industrial application/utility

These aspects may vary with regard to how stringently they are applied while judging an invention. In addition to these basic criteria, certain jurisdictions also pose the requirement of the subject matter of invention to not be against 'public order and morality'. For instance India in compliance with the TRIPs agreement has the requirement that "an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment"⁴. The European patent Convention also expressly prohibits patent over inventions, "... the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment"⁵. This implies that inventions which are either based on or make use of subject matter which is opposed to public policy & morality will not be granted patent. Gene Patents are one such controversial subject matter of patents which even though resented by many jurisdictions, have been granted protection by others.

III. INTRODUCTION TO GENE PATENTING

We are the inhabitants of the 21st century which has witnessed developments in the form of skyscrapers, 4G internet, fast sports cars, high yielding varieties of plants and life-saving medicines. Science has progressed so far that many facets of the human life today are dependent on technology for more than just convenience. It wouldn't be entirely erroneous to state that the horizon of science & technology has expanded so much so as to include everything under the sun and modify it with its 'midas touch'. Whether or not this modification is a boon is open for the humans to test and conclude. They say that the world is divided into black and white, but science falls in between various shades of black and white making it difficult for us to decipher its true nature. So far, the advancements have definitely proven beyond doubt that science and technology has indeed enhanced the quality of human life but the same has been defied by critics who oppose advancement on pretext of its

⁴ Article 27.2 TRIPs; Section 3(b), Indian Patent Act, 1970.

⁵ Article 53(a) European Patent Convention, 16th edition, (2016).

evilness. Morality and ethics are resorted to where the evility of a scientific phenomenon cannot be established or proven. The same has been witnessed in the case of gene patenting, which is a relatively new technology phenomena.

The Concept

The concept of Intellectual Property Rights emerged not only to provide reward to the inventor for his labor but also to act as an incentive for innovation.⁶ Patent is one such form of an intellectual property which is granted as an exclusive right to the inventor. Biotechnology has been a subject matter of patentability ever since the horizons of the same were opened for reach after the landmark judgement in *Diamond v. Chakraborty* wherein the United States Supreme Court held patentability of living organisms as valid.⁷ Various researches have since not only taken the standards of technology up a notch but have also drastically improved fields biotechnology has been implemented in. Application of biotechnology involves utilizing of living organisms, which has raised many an eyebrows by the flag bearers of morality who believe that the utmost divine creation of God cannot be destroyed for purposes, however noble they may be. The scientific community opposing such inventions have based their arguments on the missing novelty, which is one of the essential eligibility criteria for the grant of patent in every jurisdiction.

Inventions which use living organisms or parts for manufacturing various products may be known as biotechnological inventions. The United Nations Convention of Biological Diversity has provided a concise definition of biotechnology as “*any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use*”.⁸ Biotechnology combines different sciences to industry and is thus not confined to mere application of biology to different arenas. Modern biotechnological inventions have provided the world with breakthrough products that have drastically improved the quality of life in different ways. From combating deadly diseases to world hunger, efficient and environmentally safer technologies to proficient industrial manufacturing processes, lives have transformed in a never before way.

We no longer live in the era where biologists accidentally come across a new specie as often as every day. By now, most of the species have been uncovered and most genomes discovered thereby creating a need to develop a uniform definition of a gene. Biologically, a gene can be understood as the basic structural and functional unit of heredity that produces phenotypes.

⁶ Mikhalien Du Bois, *Justificatory Theories for Intellectual Property Viewed through the Constitutional Prism*, 21 PER / PELJ, 2-38 (2018).

⁷ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

⁸ Convention on Biological Diversity, Article 2, 1993.

Living organisms have specific physical characteristics which is due to the presence of genes. These characteristics are collectively referred to as phenotype. A phenotype is responsible for physical characteristics of an organism and thus a gene carries instructions for the existence or absence of a particular characteristic in a living being. The term was coined by Johanssen and was used in an abstract sense since he consciously abstained from speculating the physical attributes of a gene.⁹ The definition has emerged with advancing technology and research. Scientists believe there is no objective definition of gene which could encompass all the components and objects that could be defined as genes. These genes are composed of Deoxyribose nucleic acid or DNA.¹⁰ The DNA is a molecule which carries instructions which vital for the development, reproduction and life of an organism. These instructions are heritable from parents to offspring. This double helical structure entwined as a double helix is generally found in the nucleus of the cell.¹¹ DNA is transcribed into Ribonucleic acid or RNA and then through the process of translation into proteins. Transcription and translation are two essential phenomena that are involved in the process of protein synthesis. Transcription involves copying of the genetic information which is stored in the DNA double strands into a single strand RNA molecule like the messenger RNA or mRNA, tRNA.¹² Thus, a gene serves as the medium for transmission of genetic information from parents to offspring in living organisms, and it is this property that has attracted interest of researchers to exploit genes as a subject-matter of patentability.

IV. THE SCIENCE

DNA is the store house of information which is composed of exons and introns. There exist sequences of DNA in the body which do not participate for making of protein. The exons are the coding region and the introns are the junk DNA or the non-coding region which do not carry any information relevant for synthesis of protein. These introns are removed from the messenger RNA during the process of transcription leaving the DNA with the coding region only i.e. the exons.¹³ Messenger RNA, also called the “transcript” differs from DNA as it is single stranded sequence which transmits genetic information from the DNA in the form of codons.¹⁴ The process of transcription involves copying of genetic information which is

⁹ Petter Portin & Adam Wilkins, *The Evolving Definition of the term “Gene”*, 205 GENETICS, 1353-1364 (2017).

¹⁰ Karen Hopkin, *The Evolving Definition of a Gene*, 59 BIO SCI. 928-931 (2009).

¹¹ Andrew Travers & Georgi Mushkhelishvili, *DNA structure and function*, 282 FEBS (2015).

¹² PELIN PELIT ARAYICI ET ALL, APPLICATIONS OF MOLECULAR GENETICS IN PERSONALIZED MEDICINE (OMICS INTERNATIONAL EBOOKS) (2014).

¹³ Enrico Carlon et al, *Exons, Introns and DNA Thermodynamics*, 94 PHYS. REV. LETT., 178101-4 (2005).

¹⁴ A. Mishra, *Messenger RNA*, ENCYCLOPEDIA OF ANIMAL COGNITION AND BEHAVIOR (2018), <https://doi.org/10.1007/978-3-319-47829-6>

stored in DNA to single stranded RNA molecule like mRNA.¹⁵

A gene is essentially a product of nature i.e. it is created by nature without any human intervention, thereby deeming then to be unworthy of patents.¹⁶ When a DNA is created comprising exclusively of the exon or the coding region, it becomes a novel invention which is different from the gene as available in the natural form. The same is ensured by the process of isolation and purification. The process of segregating a specific sequence or region of DNA is known as isolation which allows study of a particular sequence for a better understanding of the genome structure.¹⁷ For diagnostic purposes, isolation serves as an excellent method to detect problems which are contained to a specific DNA sequence. Purification of a gene on the other hand essentially entails the removal of unwanted or non-coding region from the isolated sequence of DNA, the residual DNA comprising only of the coding region or exon. The process of isolation and purification is undertaken to ensure that the patent sought over such an isolated or purified gene reflects some amount of human intervention and is not a mere “product of nature”, an argument advanced while objecting to gene patents.¹⁸ Complementary DNA is one such invention which is patent eligible in many jurisdictions. The messenger RNA is often reverse transcribed to achieve complementary DNA, utilizing the enzyme Reverse Transcriptase. This cDNA, by the virtue of being synthetically created is devoid of introns and is thus not a product of nature.¹⁹

V. INDIA AND GENE PATENTING

The Indian Patent scenario is regulated by Indian patents Act 1970. Indian patent regime has journeys through different phases of evolution beginning in the colonized era to post independence and finally the era of globalization which demanded a well-established framework for patents. It was the efforts of Government of India appointed committee, in the year 1957 under the chairmanship of Justice N. Rajgopala Ayyanger which bore the responsibility of reviewing the then existing Patents Act. The recommendations of the committee led to changes in the Indian patent law to evolve and become what exists today.²⁰ The changes more so, were necessitated as India acceded to the World Trade Organization in

¹⁵PELIN PELIT ARAYICI et al, APPLICATIONS OF MOLECULAR GENETICS IN PERSONALIZED MEDICINE (OMICS International eBooks) (2014).

¹⁶ Daniel J. Kevles, *Inventions, yes; Nature, No: the Products of Nature Doctrine from the American Colonies to the U.S.Courts*, 23 PERSPECT. SCI 14, (2015).

¹⁷ STEFAN SURZYCKI, BASIC TECHNIQUES IN MOLECULAR BIOLOGY 1-32 (Springer Lab Manuals) (2007).

¹⁸ John M. Conley, *Gene Patents and the Product of Nature Doctrine*, 84 CHI.-KENT. L. REV, (2009).

¹⁹Y.Kohara, *Complimentary DNA*, ENCYCLOPEDIA OF GENETICS (Nov. 29, 2019, 11:20 A.M), <https://doi.org/10.1006/rwgn.2001.1412>.

²⁰ UDAY S. RACHERLA, HISTORICAL EVOLUTION OF INDIA’S PATENT REGIME AND ITS IMPACT ON INNOVATION IN THE INDIAN PHARMACEUTICAL INDUSTRY 271-298 (2019).

1995²¹. Subsequently, India became a member state of the Trade Related aspects of Intellectual Property Agreement.²² This agreement laid down mandatory minimum obligations to protect Intellectual Property, for each member nation. For implementing these obligations member states resorted to either amending their existing legislations or making of new ones altogether.²³ Radical modifications in the economic policies coupled with obligations laid down in TRIPS led to reforms in the Indian Patent laws.²⁴

The TRIPS agreement makes provision for excluding certain inventions from the ambit of patentability.²⁵ Article 27(3) of the agreements 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.....”

As per this provision, inventions pertaining to plants, animals and essentially biological processes have to be excluded from the purview of patentability. Micro-organisms, processes for production of non-biological and microbiological processes however have been excluded from the exclusion itself thereby allowing scope for their patenting. Thus, technically genes, as products of nature cannot be granted patents as per the TRIPS obligation but isolated and purified genes or even cDNA, which are a product of human intervention distinct from their natural form can be granted patent.²⁶ Interpretation of the provision has often caused doubts and the same was faced by India while deciding the fate of biotechnology inventions. Towards resolving this issue and ensuring smooth compliance to the TRIPS agreement Mashelkar Committee was set up in 2005. The committee was entrusted with the task to review exclusion of microorganism from the patentability subject matter and whether the same was consistent with TRIPS agreement. The report submitted in 2009 stated that micro-organisms cannot be excluded from patentability as the same would amount to violation of the obligations imposed by TRIPS. Further the committee observed that as long as prescribed criteria for patentability are fulfilled, “*microorganisms involving human intervention and*

²¹Member Information: India and the WTO, WORLD TRADE ORG., http://www.wto.org/english/thewto_e/countries_e/india_e.htm.

²²Amy Kapczynski, *Harmonization and Its Discontents: A Case Study of TRIPS Implementation in India's Pharmaceutical Sector*, 97 CAL. L. REV. 1571, 1579 (2009).

²³Manjula Podila et al, *TRIPS and its Impact in Indian Pharmaceutical Industry*, 3 EJPMR, 259-263 (2016).

²⁴V.K. Unni, *Indian Patent Law and TRIPS: Redrawing the Flexibility Framework in the Context of Public Policy and Health*, 25 PAC. McGEORGE GLOBAL Bus. & DEV. L.J. 323, 330-31 (2012).

²⁵The Agreement on Trade-Related Aspects of Intellectual Property Rights, Art. 27(3) (1995).

²⁶Abhijeet Kumar & Adrija Mishra, *Gene patenting vis-à-vis Notion of Patentability*, 20 JIPR 352, 349-362 (2015).

utility are patentable subject matter under the said Agreement". These observations were criticized on pretext of being reflective of the intended prospects of Foreign Direct Investments via foreign collaborations.²⁷

Section 3 of The Indian Patents Act 1970 lays down an exhaustive list of inventions which are not patentable. Genes being product of nature are barred from patentability by the virtue of Section 3(c) which states that "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 unpatentable subject matter. Simultaneously Section 3(j) excludes "*plants and animals in whole or any part thereof other than micro-organisms*" from patentability. Thus, a gene, as occurring in nature, cannot be patented for being a mere discovery. Also, the subject matter of the invention itself being either part of plant or animal is excluded. In such a scenario the only scope left for an invention utilizing gene to be patent worthy is for it to be in the form of isolated gene or a synthetically created complementary DNA. The Patent Office of India has provided a Manual of Patent Practice and Procedure²⁸ which contains provisions directed specifically towards biotech and pharma inventions. This manual excludes from patentability living entities as well as transgenic plants and animals. Even so, considering the advantages of such inventions in medical field some scope has been provided to recombinant DNA and plasmids provided the invention reflects substantial human intervention.²⁹ The manual also provides opportunity of patenting inventions in the following form, which fulfil the basic eligibility criteria of novelty, inventive step and industrial application-

- “(a). *Gene sequence / Amino Acid sequence* ·
- (b) *A method of expressing above sequence* ·
- (c) *An antibody against that protein / sequence* ·
- (d) *A kit made from the antibody / sequence*”³⁰

These provisions do create an impression of the possibility of patenting genes which are not in their natural form. The Manual released in 2011 did not provide any elaboration regarding the above mentioned aspects.

²⁷ Ameen Jauhar & Swati Narnaulia, *Patenting Life the American, European and Indian Way*, 15 JIPR 62, 55-65 (2010).

²⁸ Manual of Patent Practice and Procedure, Third edition, 2008 available at http://www.ipindia.nic.in/writereaddata/Portal/IPOGuidelinesManuals/1_28_1_manual-of-patent-office-practice_and-procedure.pdf

²⁹ *Id.* at 70

³⁰ *Id.* at 133

Another set of guidelines available for reference regarding biotech inventions were released in the year 2013 namely the ‘Guidelines for examination of biotechnology applications for patents’. These guidelines have also clarified the stand with regard to patentability of genes as it states “Products such as microorganisms, nucleic acid sequences, proteins, enzymes, compounds, etc., which are directly isolated from nature, are not patentable subject-matter”. Further, with regard to Section 3(j) the guidelines state that “*Although, microorganisms are excluded from non-patentability list, a conjoined reading with Section 3 (c) of the Act implies that only modified microorganisms, which do not constitute discovery of living thing occurring in nature, are patentable subject matter under the Act*”, thereby establishing that genes as products of nature are absolutely not patentable. However the same, synthetically created, can be patented. These provisions being a part of mere guidelines do not have enforceability and thus in case of any conflict the Indian Patents act and the relevant provisions therein will be resorted to. In spite of this, the Indian Patent Office has time and again aberrated and granted patents on the basis of the Manual and guidelines in existence. For instance in the invention related to ‘genetically stable JEV cDNA based on Japanese Encephalitis Virus’³¹, patent was granted on “ A genomic RNA of Korean isolate consisting of...” thereby creating the possibility of patenting cDNA sequences. It can thus safely be stated that naturally occurring genes are not patentable but non-naturally occurring genes having a delineated function or utility remain under the ambit of patentable subject matter. There thus remains a dire need for uniformity with regard to patentability criteria for biotech inventions involving genes.³²

VI. CHINA AND GENE PATENTING

The Intellectual Property system of China is relatively young as there was no patent law until 1984. It was in the late 1970s that China introduced certain political and economic reforms, bringing about radical changes to its legal system. Introduction of protection to Intellectual property was a move intended to attract foreign investment.

The history of IP protection in China commenced with the legacy of “the four modernizations” policy, launched in the year 1978 by Deng Xiaoping³³ With China’s economic development and advent of foreign investors, the government begun working on the implementation of a comprehensive system of IP protection. Towards this goal, China

³¹ Lee Y, Lee s & Yun S, Genetically stable Jev cDNA based on Japanese Encephalitis Virus (JEV), Indian Patent No. 243799 (8 November 2010).

³² Ravi Bhavishyavani, *Gene Patents in India: Gauging Policy by an Analysis of the Grants made by the Indian Patent Office*, 18 JIPR, 323-329 (2013)

³³ The Commission on the Theft of American Intellectual Property, 2013

also established multiple institutions for the development & monitoring of the IPR compliances.³⁴

China has been a World Trade Organization (WTO) member since 2001. An important agreement on IPR of the World Trade Organization is Trade Related Aspects of Intellectual property Rights (TRIPs) which establishes minimum obligations to be undertaken by member states towards protection of IPR. China is a signatory to the Berne Convention on Copyright and is also a member of World Intellectual Property Organization (WIPO) since 1980. China joined the Paris Convention on patents in the year 1985.

After the death of Mao Zedong, the world leaders pressurized China to have a working patent system for protection of inventions which would help attract foreign investments. Internally many ministries, specifically the State Science Commission and the Ministry of Foreign Trade were vehemently supporting a patent system and were working towards enactment of a patent law. In 1978 the successor of Mao Zedong, Hua, who was the chairman of the Communist Party, decided to bestow the mandate for patent related matters on the State Science Commission. In 1979 the Commission submitted a feasibility study to the State Council recommending the establishment of a patent system in China. This was strongly opposed specially by the industrial sector for concerns such as China being technically behind the industrialized nations would imply fewer patents to domestic companies, restriction on free copying of technology, paying of heavy royalty to foreign licensors etc.

With regard to the general policy of the state, the State Council permitted the report in 1980 which led to the approval of commencement of drafting of a patent law and establishment of State Patent offices. This decision ended the debate over concerns with respect to the appropriateness of a patent system for China. After a yearlong study, the Commission proposed the first draft of Patent Act in the year 1981. With modification to find the best suited model, the Patent Act was submitted to the Standing Committee of the People's Congress for approval, only to meet severe objection by influential politicians till 1984, when it was finally passed and came into force in 1985.

China and United States entered into trade negotiation in the year 1989, as a result of which China was forced into making amendments to the existing Patent Act. The amendments were passed in 1992 by the Standing Committee of the People's congress and came into force in 1993.

³⁴ WILLIAM P. ALFOLD, *TO STEAL A BOOK IS AN ELEGANT OFFENSE: INTELLECTUAL PROPERTY LAW IN CHINESE CIVILIZATION* 214 (Stanford University Press) (1998).

Another revision in the patent Act was brought forth due to China's entry in the World Trade Organization, as a part of obliging the provision of the TRIPs Agreement. Thus the Standing Committee passed the second amendment bill in the year 2000 and the same was made effective in the year 2001.

Patentable Subject Matter

The Chinese patent Act provides protection to inventions, utility models and designs.³⁵ The Act also makes use of the term invention –creation to imply all the three categories.³⁶ The term invention means a “new technical solution proposed for a product, process or improvement thereof.”³⁷ Thus the principle legal standard of eligibility of an invention's subject matter is a “three technical elements approach”, as per which the invention has to utilize technical means to provide solution to a technical problem, thereby producing technical effects. The invention to be protected is examined as a whole and both the technical as well as non-technical contents are considered for patent. The standard is usually met when there is a distinct roadmap for the identification of the three technical elements in the description which are related to the technical effect as disclosed.³⁸

While assessing the eligibility of an invention, the entire invention must be analyzed to ensure whether or not it uses technical means to solve a technical problem and produces technical effects. The mere presence of some technical parameter does not suffice in proving technical means to achieve the same. The epicenter of evaluation should be the features used in the invention as a whole, and is not limited to only the problem to be solved by the invention as is described in the specifications of the invention.

Exclusion From Patentability

Some subject matter have been excluded from the purview of patentability and falling under the same guarantees non-grant of patent in China. Article 5 and Article 25 of the patent legislation of China lays down certain subject matter which fall outside the purview of patentability. Article 5 states that “*Patent rights shall not be granted for invention-creations that violate the law or social ethics, or harm public interests. Patent rights shall not be granted for inventions that are accomplished by relying on genetic resources which are*

³⁵ Art 2, Patent Law of the People's Republic of China, 2008.

³⁶ Art 3, Patent Law of the People's Republic of China, 2008.

³⁷ Art 2, Patent Law of the People's Republic of China, 2008.

³⁸ Jordan B. Delano et al, *A Global Perspective on Patent Subject Matter Eligibility and Software-Related Inventions Court cases, legislation and regulations are described along with practice hints for navigating patent eligibility in Australia, Canada, China, Europe, Japan, Korea and the United States*, INTELLECTUAL PROPERTY OWNERS ASSOCIATION (2019) https://ipo.org/wpcontent/uploads/2019/12/IPO_eligibility_whitepaper11-20-19.pdf.

obtained or used in violation of the provisions of laws and administrative regulations.”³⁹

This provision stipulates that patent protection shall not be given over inventions-creations which violate the law or social ethics, or harm public interest. To understand this provision, one has to understand the society the law pertains to as the criteria is judged from the perspective of this society itself. Thus gambling facilities, drug administration equipment, tools for counterfeiting currency etc. will be excluded from the ambit of patentability. Such inventions are treated as contrary to social morality and thus to avoid hurting the sentiments of the people of the country, have been removed from the patentable subject matter. Inventions which may cause detriment to public interest have also been excluded on the same pretext.

Article 25 lays down the following as expressly excluded from patentability-

“(1) scientific discoveries;

(2) rules and methods for intellectual activities;

(3) methods for the diagnosis or treatment of diseases;

(4) animal or plant varieties;

(5) substances obtained by means of nuclear transformation; and

(6) designs that are mainly used for marking the pattern, color or the combination of the two of prints.”⁴⁰

Scientific discoveries imply revelations of phenomena or substances which have already been in existence and in public domain. Due to this they are not considered as inventions as per the patent law and thus are not eligible for patent right.⁴¹ Similarly rules and methods for mental activities which govern how people think or analyze is a mere expression of judgement and it does not utilize any technical means to solve any technical problem, thereby does not constitute a technical solution.⁴² Diagnostic methods refer to the processes for identification, study, and determination of a cause of disease.⁴³ Methods of treatment of diseases refer to the processes of treating a particular disease by way of interception, relief or elimination of the cause of the disease.⁴⁴ Animal or plant variety can be protected by means of other laws but have been excluded from patentability under the patent law. Even so, patent rights may be

³⁹ Article 5, Patent Law of the People's Republic of China, 2008

⁴⁰ Art 25, Patent Law of the People's Republic of China, 2008.

⁴¹ State *Intellectual Property* Office, *Guideline for Patent Examination* (Beijing: Intellectual Property Publishing House, 2010), II. 4.1.

⁴² *Ibid.*, II. 4.2.

⁴³ *Ibid.*, II. 4.3.1.

⁴⁴ *Ibid.*, II. 4.3.2.

granted for the process of production of plant or animal variety.⁴⁵ A substance which is found in nature in natural state is a mere product of nature and an object of discovery and cannot be granted patent.⁴⁶

Gene Patentability in China

The Chinese Patents act specifically bars patenting of animal or plant varieties⁴⁷ thus removing the same from serving as a subject matter of an invention for patent. Further, inventions which are considered detrimental to public interest are also excluded from patentability ambit. The human body, at different stages of development, which includes germ cells and embryo cells is also a part of this exception to patentability as per the provisions of Art 5.1 of the Patents Cat.⁴⁸ Usually a gene technical process is eligible for a process patent in China but there are some exceptions to the same. For instance, the technology facilitating cloning of humans cannot be patented if it modifies the genetic composition of the human body. Same applies to an animal or plant. Biological methods will not be patented if they violate any ethical or moral norm or are contrary to public interest, such as human embryos. The propagation of plants and animals for commercial use is subject to the invention-creation provision under Art 5 of the Patent law of China.⁴⁹

Genetic screening diagnostic methods towards “the diagnosis or for the treatment of diseases” as laid down in Art 25 of the Patent law of China, are unpatentable subject matter. Transgenic animal or plants which are obtained through gene editing also do not fall within the purview of patentable subject matter.⁵⁰ With regard to transgenic microorganisms, which do not fall under the category of animals or plants, are patentable under the law. Genes are considered as products of nature and thus are mere discoveries and are unpatentable.⁵¹ However, whenever a gene or a DNA fragment, the base sequence of which is not recorded in the available technology and the precise characteristics of which can be determined, is separated or isolated from its natural form and is worthy to the industry, such a gene or DNA fragment and the process for manufacturing such a gene or DNA is patentable.⁵²

⁴⁵ Ibid., II.C10.9.1.2.4

⁴⁶ Ibid., II.C10.2.1

⁴⁷ Art 25, Patent Law of the People's Republic of China, 2008.

⁴⁸ State Intellectual Property Office, Guideline for Patent Examination (Beijing: Intellectual Property Publishing House, 2010), 3 Ibid., II.C10.9.1.1.1

⁴⁹ Li Wei, *Patenting Genes in China, the U.S., and the EU: How Does It Differ? Could It Get Out of Control?*, 35 BIOTECH. LAW REP.165, 165-168 (2016)

⁵⁰ Art 25, Patent Law of the People's Republic of China, 2008.

⁵¹ Ibid

⁵² Guidelines for Patent Examination, part II, ch. 10, x 9 (2010).

VII. RIGHT OR WRONG: THE ISSUE OF MORLITY

It cannot be argued that patents are purely economic in nature. The protected invention contributes to the wholesome progress and welfare of the society in exchange for the monopoly right which is allowed over the patented invention. However, it is not simply economics which Intellectual property pertains to. Patents are surrounded by many moral and ethical objections with regard to the subject matter of the invention and the same is a vital factor for deciding the fate of the invention.⁵³ Morals and ethics in any society play an enormously significant role with regard to determining how a specific act will be regarded. It comprises of the entirety of the recognized and established norms which are profoundly entrenched in a society and this morality may vary from nation to nation and even culture to culture.⁵⁴ Numerous jurisdictions including India have the requirement of an invention not being against public ordre and morality within their patent legislative framework.⁵⁵ This infers that the use or commercial exploitation of the subject matter of inventions should not be such which runs contrary to the public ordre or morality.

Morality is a subjective concept with many interpretations. Even so, it is established by the prevailant norms of a society and followed by the members of that particular society, who view actions as per this set standard of morals. It is the responsibility of these morals to ensure the welfare and interest of the people of the society.⁵⁶ It is the morality which guides man to decide his actions. It is thus the purpose of moral laws to perfect personal character.⁵⁷ Any act not in conformity with the morality is viewed as “wrong” and discouraged. For instance, it is considered immoral to lie but the same is not legally punishable offence. The significance and subject of morality in patent could be comprehended from the very purpose for which patents are granted.

Patents are granted to promote innovation which will be useful for the society at large. Inventions the use of which will be against the moral standards will not serve any purpose to the society and thus the exclusive rights granted to the inventor will be of no use since the invention itself is not going to serve any purpose or may even not be utilized or exploited. Justice Story of the United States has often quoted that “*a useful invention is one which may*

⁵³ 6 Philip W. Grubb Et Al., *Patents For Chemicals, Pharmaceuticals, And Biotechnology*, (Oxford University Press, 6th edn., pp 301-320).

⁵⁴ *Patents: Ordre Public and Morality*, IPRSONLINE (Nov., 2004), https://www.iprsonline.org/unctadietdsd/ocs/RB2.5_Patents_2.5.3_update.pdf

⁵⁵ Indian Patent Act, 1970, Act No. 39, Acts of Parliament, 1970 (India).

⁵⁶ Terrance Mcconnel, *Review: On The Nature and Scope of Morality*, 54 PPR, 421-425 1994.

⁵⁷ 3 T.J. GARDNER, *CRIMINAL LAW: PRINCIPLES AND CASES 7* (3rd ed. West Publishing Company) (1985).

be applied to a beneficial use in society, in contradistinction to an invention injurious to the morals, health, or good order of society, or frivolous or insignificant.”⁵⁸ A study conducted by WIPO has identified six justifications based on public policy for the exclusions from patentability.⁵⁹ The very first and the soundest justification is with regard to the purpose of patent laws in reflecting undesirable subject matter which has to be avoided by the inventor.⁶⁰ The public order & morality clause intends to safeguard the public trust in the patent system of their country and the same can be achieved by ensuring that inventions which may hurt or are objected by the society are discouraged. This ground can also be understood from an economic perspective. Neoclassical economy recommends that inventions which have been or may be granted patent, serve as an incentive for investors to invest in the same prospecting returns in the future from the exploitation of the same. If patents are discouraged in a particular field, there will be no investments in that field, but in the area where patents are encouraged. Thus, there will be direct flow of investments towards R&D in areas of current & more profitable research. Thus, the morality clause helps in promoting desirable inventions and indirectly influences the inventive activities. Thus morality finds a place in patent legislation and based on this justification there are many issues that arise with regard to patenting of genes.

VIII. MORALITY AND THE LAW: FRIENDS OR FOES

The phenomena of morality is often associated with behavioral patterns and activities of individuals in a society. For ensuring compliance with a set standard behavior the society has divided every act in the shades of right or wrong which determine the morality of a person. These values are instilled for better and proper functioning of the society.⁶¹ It is believed that such an approach educates every member of that society by shaping his perceptions and institutions.⁶² The society deciphers the nature of an act based on the established moral values which deem that act to be right or wrong. Even so, what is the place and importance of moral values in law and how far can moral aberration be justified on pretext of law or vice-versa.

⁵⁸ Viola Prifti, *The Limits Of “Ordre Public” And “Morality” For The Patentability Of Human Embryonic Stem Cell Inventions*, 22 J WORLD INTELLECT PROPERTY, 2-15 (2019).

⁵⁹ Lionel Bently et al., *Exclusions From Patentability And Exceptions And Limitations To Patentees’ Rights*, WIPO (2010), https://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex1.pdf.

⁶⁰ I. SCHNEIDER, CAN PATENT LEGISLATION MAKE A DIFFERENCE? BRINGING PARLIAMENTS AND CIVIL SOCIETY INTO PATENT GOVERNANCE, THE POLITICS OF INTELLECTUAL PROPERTY: CONTESTATION OVER THE OWNERSHIP, USE, AND CONTROL OF KNOWLEDGE AND INFORMATION, 129-157 (2009.)

⁶¹ Samuel Packer, *Embryonic Stem Cells, Intellectual Property, and Patents: Ethical Concerns* 37 HOFSTRA L. REV. 487-490 (2008).

⁶² Jonathan Haidt & Selin Kesebir, et al, *Morality*, HANDBOOK OF SOCIAL PSYCHOLOGY, 797-832 (2010).

Patenting genes have been criticized on various grounds and moral opposition has held a stronger position than legal or technical arguments against the same. It is believed that the living body is God's greatest creation and the divinity of the body cannot be deteriorated by commodifying the same and being treated as slaves for commercial exploitation.⁶³ Granting patent rights over God's creation is equivalent to owning the body which is a moral deviance and thereby the same should not be allowed, however beneficial it may be for the society at large. When law becomes the sanctioning force behind morals, the possibility of aberration becomes dim. The TRIPS Agreement provides that certain subject matter may be excluded from patentability by member states so as to protect ordre public or morality.⁶⁴ Complying with this standard, the Indian Patent Act has an exhaustive list of subject matter which falls outside the purview of patentability and due consideration has been given to 'public order' or 'morality'⁶⁵ to ensure that the established moral values of the Indian society are not violated by an invention seeking patent. This provision is not a mere legal requirement which can be bent as per the whims of the Indian Patent Office and is actually taken seriously while considering grant of patent. The Patent office has time and again rejected inventions which did not comply with this criteria and had the potential of disturbing the moral values of the society. For instance, the invention of a "U shaped sexual stimulating device"⁶⁶ of a Canadian entity, Standard Innovation Corporation was rejected on the pretext that "*The subject matter claimed in the instant application relates to "sexual stimulating vibrator"and falls under section 3(b) of the Patents Act and is not allowable.... Mostly these are considered to be morally degrading by the law*". Thus, patenting genes has time and again been vehemently opposed as being opposed to the morality of our society. Additionally it has also been stated that owning exclusive rights over this subject matter would imply restriction of further research which would lead to no competition and a monopolistic situation leading to exploitation of consumers.

The Patent Act of China also explicitly prohibits patenting of inventions which "violate the law or social ethics, or harm public interests."⁶⁷ Further, under Art 7 of the MPEG, inventions pertaining to biotechnology which are in contradiction to social morality or detrimental to public interest, such as cloning, modifying human biological protection system etc, are unpatentable. Thus it can be understood that importance has been given to the social ethics or

⁶³T. A. Caufield, *From human genes to stem cells: New challenges for patent law*, 21 TRENDS BIOTECH, 101 (2008).

⁶⁴The Agreement on Trade-Related Aspects of Intellectual Property Rights, Article 27(2) (1995).

⁶⁵Indian Patent Act, 1970, Act No. 39, Acts of Parliament, 1970 (India).

⁶⁶Application Number 4668/DELNP/2007.

⁶⁷Art 5, Patent Law of the People's Republic of China, 2008.

public interest, the contravention of which will not let any inventor avail patent protection over his invention.

The U.S. Patent Law on the other hand, despite the need to comply with the obligation of TRIPS, does not have any restriction on patent grant based on morality. In fact the practices followed by the USPTO have been very lenient when it comes to granting patents, to aid and facilitate technology and development. Whether that reflects a lower moral standard of the society or higher for technology is for their society to interpret, understand and if need be, object.

IX. CONCLUSION

There are far reaching medical benefits of providing patents on genes and the same have been established by researchers around the world. Considering these benefits appropriate laws have been formulated so as to reward inventions which are envisioned to aid mankind. Morals and laws may appear to be in contradiction to each other but the combination of the two can have effects, the achievement of which alone isn't smoothly possible for either. In the arena of patents, morality ensures drawing a line which separates and eliminates exploitation in the wake of development. Where morality does hold an important place in a society, it shouldn't be intended to dominate over laws. Thus, there can never be a straight-jacket formula to choose between law and morality. The deciding factor in such a scenario is not the intensity of the action itself in the form of good or bad, but the effect it will have on the society at large.
