PATENTABILITY OF HUMAN GENES: SCALING AN INDIAN PERSPECTIVE

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PIONEERING THE BASIC CONCEPTS

These days many projects across the globe are being carried out by universities, research institutions, hospitals with research institutions etc. contributing to the excellent development in the field of medicine vis-à-vis mankind. These medicines and such life-saving techniques are not only driven by the emotion to accelerate general good but also by greed of money which the inventor gets by the way of patents. In the past few decades patents have indeed been life savior in the form of medicines (life-saving drugs), biotechnology (for research and analysis of the body, genes etc.), medical instruments (heart stents) etc.

Patent is a monopoly right conferred by Patent Office on an inventor to exploit his invention subject to the provisions of the relevant Patent Act of a country for a limited period of time. During this period, the inventor is entitled to exclude anyone else from commercially exploiting his invention[1]. Although there are few differences between countries, there are a couple of broad principles that are common to all patent systems. A patent is a limited-term monopoly in most cases lasting 20 years, to prohibit others from making, using, selling or importing an invention. According to The Patents Act, 1970 (Indian law on Patents), patent means a patent for any invention granted under this act[2]. As per Halsbury's Law of England, the word patent is used for denoting a monopoly right in respect of an invention[3]. Thus there are three basic essentials of a patent which are Invention, Novel and Industrial application.

Invention mean a new product or process involving an inventive step and capable of industrial application[4]. A bare perusal of the definition of invention clearly shows that even a process involving an inventive step is an invention within the meaning of the act. It is, therefore, not necessary that the product developed should be totally new. Even if a product is substantially improved by an

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[1] VK Ahuja, Law Relating to Intellectual Property Rights, LexisNexis, at p. 479 (2nd Ed, 2013).
[2] The Patents Act, Section 2 (1) (m) (1970).
[3] *Bajaj Auto Ltd*. v *TVS Motor Company Ltd*, 2008 (36) PTC 417 (Mad) at p. 439.
[4] The Patents Act, Section 2 (1) (j) (1970).

inventive step, it would be termed as an invention[5]. "New Invention" means any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application with complete specification, i.e., the subject matter has not fallen in public domain or that it does not form part of the state of the art[6].

The next requirement of Patent Act, 1970 requires an invention to be new in the sense that on the date of filing a patent application, it should not form part of the state art. The state of art comprises all matter made available to the public before the priority date of the invention by written or oral description, by use or in any other way[7]. The Apex Court in a recent landmark case[8] held that in case of pharmaceuticals additional requirements of clauses (j) which says "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art; and clause (ja) of section 2(1) and the test of efficacy as provided explanation to section 3 (d)[9] have to be satisfied.

Capable of industrial application means that the invention is capable of being made or used in an industry[10]. Mere usefulness is not sufficient to support a patent but must have industrial application[11].

A gene is the basic physical and functional unit of heredity. Genes, which are made up of DNA, act as instructions to make molecules called proteins. Every person has two copies of each gene, one inherited from each parent. Most genes are the same in all people, but a small number of genes (less than 1 percent of the total) are slightly different between people. Alleles are forms of the same gene with small differences in their sequence of DNA bases. These small differences contribute to each person's unique physical features[12]. Due to these differences in the genes various medical treatments from cancer has been discovered in USA.

The medicines or other treatments which are made or use genes clearly indicate that the above criteria is satisfied but due to section 3 (i)[13] of the Patent Act, 1970 human genes cannot be patented

[5] *Dhanpat Seth & Ors* v. *Nil Kamal Plastic Crates Ltd*, 2008 (36) PTC 123 (HP)(DB) at p. 127.
[6] The Patents Act, Section 2 (1) (l) (1970).
[7] A similar provision may also be found in Article 54 of the European Patent Convention 1973.
[8] *Novartis AG & Ors* v. *Union of India*, 2013 (54) PTC 1 (SC) at p. 80.
[9] For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.
[10] Patents Act, 1970, Section 2(1) (ac) (1970).
[11] *Indian Vacuum Brake Co. Ltd.* v. *ES Luard*, 1926 AIR (Cal) at p. 152.
[12] What is a gene, Genetics Home Reference, National Institute of Health, USA, (http://ghr.nlm.nih.gov/handbook/basics/gene, retrieved on February 15, 2016).
[13] States that what are not inventions for the purposes of Patents in India.

in India. In USA such patents are allowed leading to a flourishing American economy and India is behind in the research and development of medicines as, patents cannot be claimed over human genes in India. No patents over a subject matter (referring to human genes) means that there is very little source of motivation for the inventor that is good to mankind.

TURNING BACK THE PAGES OF HUMAN GENES PATENT

In 1953, the foundation for modern genetics was laid when the scientific journal, Nature, published Watson and Crick's hypothesis about the double helix structure of DNA[14]. Their article suggested a mechanism by which genetic material could be stored, transferred and copied. The first gene patent (US 4,447,538) did not appear until 1982. It claimed a recombinant DNA transfer vector containing the *Chorionic Somatomammotropin gene*[15]. Commercialisation of genetic technology followed soon after when, in 1976, Boyer and Swanson established the first known biotechnology company, Genentech Inc, in Berkeley, California. In 1977, Genentech reported the production of the first human protein manufactured in a bacterium. The technology demonstrated that molecules could be produced in large quantities in bacterial vectors and then administered to patients, raising hopes that recombinant technology could aid the treatment of human disease. A second crucial breakthrough in genetic science occurred in 1977 when Sanger identified a method for reading DNA sequences. A third major innovation in genetics was the development of PCR (P*olymerase chain reaction)*. Developed in the 1980s by Mullis and others at Cetus Corporation, PCR provided a quick and easy method for selective amplification of DNA fragments, removing the need for cloning in micro-organisms. The process has become the foundation for almost all genetic laboratory work, making access to the patented technology crucial[16].

Across the world Human Gene Patent was highlighted in the year of 1980 after the decision of US Supreme Court in the case of *Diamond v Chakrabarty*[17] held that manmade, living organisms could be patented. In its decision, the Supreme Court urged a broad interpretation of patent eligibility, holding that "anything under the sun that is made by man," including living organisms can be patented, which in turn clearly highlights that genes if modified by some technology juxtapose their natural form, genes can

[14] Watson J.D. and Crick F.H.C. , A Structure for Deoxyribose Nucleic Acid, Nature at p.737-38 (1953).
[15] Goodman, Howard M., Shine, John, Seeburg, Peter H. Microorganism containing gene for human chorionic somatomammotropin. U.S. Patent 4,447,538 (1984).
[16] A brief History of Gene Patents, Australiam Government, Australiam Law Reform Commission; *available at* http://www.alrc.gov.au/publications/3-gene-patents/brief-history-gene-patents#_ftnref21.
[17] *Diamond* v. *Chakrabarty,* 447 US 303 (1980).

be patented. This decision is considered as the founding case of the patentability of Human Genes. Therefore, the triumph of Human Genes Patent started from the USA and slowly and gradually affected the entire global world, leading to generation of endless debates on the issue of patentability of genes and human cloning.

Following this US Supreme Court decision, the 1982 Canadian case of *Re Application of Abitibi*[18] compelled the Canadian Intellectual Property Office to allow patenting of biological organisms and genes. The permissive nature of USA patent policy led to changes in international instruments like NAFTA, TRIPS, and GATT[19], thereby provisions were also made in such international instruments for patentability of human genes.

There were various other judicial precedents in the Unites States which shaped their law of patents relating to genes like *Mayo v Prometheus*[20] where the Apex Court of US laid the principle that an application of a law of nature to a known structure or process may deserve patent protection. However, in order to transform a law of nature into something worthy of a patent, the applicant must do more than simply state the law of nature while adding the words 'apply it'. Following the case several diagnostics tests were rendered non-patentable. In the recent case of *Association for Molecular Pathology, et al. v U.S. Patent and Trademark Office*[21], the case was for getting specific genes patented which helped in analysis of breast cancer, Supreme Court of US didn't allow the patent and held that naturally occurring gene sequences, and their natural derivative products, are not patent eligible. However, the Court observed that the creation of a new product in a lab exempts that product from being a product of nature. Therefore, gene sequences refined by synthetic processes to create molecules that do not occur naturally are patent eligible.

In India, law is still silent on genetic inventions and their protection in the form of patents. In 2002, the Calcutta High Court, in its decision in *Dimminaco AG* v. *Controller of Patents and Designs*[22], opened the doors for the grant of patents to inventions where the final product of the claimed process contained living microorganisms. The court concluded that a new and useful art or process is an invention, and where the end product (even if it contains living organism) is a new article, the process leading to its

[18] Re Application of Abitibi, 62 Patent Board and Commissioner of Patents CPR (2d) 81 (1982).
[19] B.M. Knoppers, Biotechnology: Sovereignty and Sharing, Springer Science and Business Media, In: Caulfield T, Williams-Jones B, eds., The Commercialisation of genetic research, ethical, legal and policy issues. New York, Kluwer Academic/ Plenum Publishers, at p. 1-11 (1999).
[20] *Mayo* v *Prometheus* 566 U.S. (2012).
[21] *Association for Molecular Pathology*, v. *U.S. Patent and Trademark Office* 569 U.S. 2013.
[22] *Dimminaco AG* v. *Controller of Patents and Designs* 255 IPLR (Cal) 2002.

manufacture is an invention. The Dimminaco case was related to a process for the preparation of a live vaccine for protecting poultry against Bursitis infection. The Controller of Patents had refused the application for grant of patent on the ground that the vaccine involved processing of certain microbial substances and contained gene sequence. The Controller had decided that the said claim was not patentable because the claimed process was only a natural process devoid of any manufacturing activity and the end-product contained living material. The subsequent major step, which amended the patent policy in the field of biotechnology, was in the year 2002 when the Patents Act, 1970 was amended by the Patents (Amendment) Act, 2002 where biochemical, biotechnological and microbiological processes were included within the scope of chemical processes for the grant of patent. The definition of "invention" was also changed to "any new product or process involving an inventive step and capable of industrial application" thereby deleting the word "manner of manufacture" as mentioned in the earlier Act. The debate in India for genetic inventions is still on and not yet settled.

A GLIMPSE OF SCIENTIFIC BACKGROUND AND PATENT REGIME

In the early 1970s, scientists developed techniques to remove a section of one organism and insert into genetic sequence of another[23]. The cell uses the sequence of bases in genes to build proteins[24]. The simplicity of DNA of which genes is a part, is what allows genetic engineering to work. The basic composition of DNA, that is, sugar, phosphate etc. is the same whether the DNA is in an insect, plant, animal or a human being[25]. This compatibility in chemistry makes it possible to recombine genes from different organisms and different species. Such hybrid of genes has served as solution to many contagious diseases including detection of certain diseases. In USA patents can be claimed over such modified genes by way of biotechnology and hence serves as motivation for the patent owners to develop such genes. United Kingdom is in race with USA when it comes to the patenting of genes[26].In India Human Genes or even gene patenting regime does not exist due to which the scientists do not even think in the backdrop of gene development, which has majorly created a setback for the country not only in terms of economy by way of importing technology from the developed world for such patent regime (gene) exits but also in domain of public health by way of expensive medicines and treatment.

[23] E.S. Grace, Biotechnology Unzipped: Promises & Realities Washington, Joseph Henry Press DC at pp 41-12 (1997).
[24] S.R. Barnum, Biotechnology: An Introduction, Cole Publishing Company, Chicago at page 34 (1998).
[25] L.Burlingame, 'Lamarck, Jean Baptiste Pierre Antoine de Monet de' in C.C. Gillispie, Dictionary of Secientific Biography, Volume 7, New York: Charles Scribner's son at p 584,589-90 (1973).
[26] GeneWatch UK, *available at* http://www.genewatch.org/sub-531144.

PATENTING HUMAN GENES: GATE TO BRIGHT FUTURE OR UNETHICAL CATCH

Though India does not have a human genes patent regime or as intensive research as the advanced countries like USA. The world's first Human Genome Sequence was a result of the International Human Genome Project comprising scientists from the US, UK, France, Germany, Japan and China. The Project began in 1990, and the sequencing was completed in 2003. India has research on human genome, that is to say, in layman language studying the sequence of DNA. Using as little as 10 milliliters of blood from a "healthy 52-year-old-man", scientists at the Institute of Genomics and Integrative Biology (IGIB) in Delhi successfully mapped the Human Genome Sequence for the first time in India. The breakthrough paves the way for predictive healthcare and the possibility of identifying why certain people (with particular gene sequences) do not respond to certain medications, and what diseases a particular gene carrier, or a population, is likely to develop. India can further excel once the patent in the domain of genes are allowed as India spent much less on human genome project juxtapose other countries[27].

India can benefit from the project mainly in the field of health and good trim. This can be seen from the case of *Asahi Kasei Kogyo's Application*[28] , the patent was claimed for the protein known as Human Tissue Necrosis Factor produced by recombinant DNA technology. Its use was in reducing brain tumours in humans, patent was granted and thereby enabling to improve human life. Research findings from the human genome project and the cancer genome projects in India are starting to make personalised medicine a reality. However, given that such applications are in its infancy (due no patent system regarding genes), it will be sometime before all the information is fully applied in mainstream practice of medicine[29]. This has an economic facet also, research scientists who work in public institutions often are troubled by the concept of intellectual property because their norms tell them that science will advance more rapidly if researchers enjoy free access to knowledge. By contrast, the law of intellectual property rests on an assumption that, without exclusive rights, no one will be willing to invest in research and development. When genes are patented by responsible scientists who have discovered their existence, it is easier to check on their use and misuse, as it is the owners of these genes that are responsible for the

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27 Express News Service, India Maps First Human Genome Sequence, The Indian Express (Dec 09, 2009, 08:49 a.m.) *available at* http://archive.indianexpress.com/news/india-maps-first-human-genome-sequence/551844/1.

[28](1991) R.P.C 485,(HL).

29 Sreekanth Ravindran, 'Genome Man' Of India (10-March-April-2013), available at <http://www.futuremedicine online.com/detail_news.php?Id=78>.

effects of these where-ever they are used. Just as a company is liable when there are toxic spills, the owner of a gene is liable if the gene does not act as promised[30].

Now it is imperative to comprehensively see the ethical or unethical basis of patentability of human genes, Vitalists believe that there is some sort of vital force running through living beings and that life is due to force. The force is immaterial and cannot be explained by science. Materialists on the other hand, believe everything can be explained by science. The first argument by materialists in favour of patentability of human genes because human being can control life and manipulate its genetic composition in a straightforward and predictable manner, on the contrary Vitalists state that the human beings are unpredictable, Vitalists argue the complexity and autonomy of life defy true control because the force is larger than the humans. Therefore Vitalists considered it unethical to patent any kind of genes as the lives of all creatures are beyond the control of human beings.

The next ethical basis is based on 'Uniqueness and Fungibility'. Fungible means that the life forms are no longer unique, rather they are 'freely exchangeable or replaceable for one another of like nature or kind'. Patenting genes would consider an animate thing as in inanimate and thus patent of living organisms or any part thereof should not be allowed. Such organisms are the outcome of the same complexity that led to existence of the humans. Forcing living organisms patentable ignores these ethical concerns.

The third set of ethical basis is indeed derived from the second, that is, sanctity and violability. It premise rests on the question of whether the limits of what is ethical and right are equal to what is legal and can be legally enforced. Some scholars suggest that there are ethical restrictions above law. Sacred covers in its scope two fundamental values, vis-à-vis, profound respect for life and protection of human spirit[31]. Violability is a product of control and fungibility. If these two principles (sanctity and violability) are undermined then it is unethical to patent lives of any kind including human genes[32]. These were a few theoretical ethical concerns for patentability of human genes.

Ethical concerns with the patenting of genes, however, are not limited to worries that people may be unable to buy, lease or sell services that they ought to be able to buy, lease or sell. On the contrary, many people object to the patenting of genes because they deny that genes should be thought of

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30 The Human Genome Should Be Patented, *available at* http://debatewise.org/debates/3693-The-Human-Genome-Should-Be-Patented/.

31 M. Somerville, *'Making Health, Not War- Musings on Global Disparities in Health and Human Rights: A Critical Commentary by Solomon R. Benatar'*, American Journal of Public Health, at p 295 (1998).

32 Johanna Gibson, *'Patenting Lives: Life Patents, Culture and Development (Intellectual Property, Theory, Culture)*, Routledge, at p. 34-37(September 28, 2008).

as property at all. Some of these objections reflect explicitly religious premises and others appear to have an implicitly religious character, albeit with no definite theological content which is similar to Vitalists point of view[33]. Hence doing business on natural phenomenon which is genes according to such people is unethical

There is another view which states that patent of human genes is ethical or unethical depending on the purpose of research which is related to the genes, if the patent research of human genes is against the public policy and morality then it must not be permitted, but it is difficult to interpret what amount to public policy and morality as these are dynamic concepts and keeps on changing with the passage of time and society[34].

The people who consider patenting human genes ethical believe that the critics of human gene patents are often accused of being ungrateful, or of being unwilling to reward those who have advanced scientific and medical knowledge, or they are thought to have overlooked the fact that patented inventions are not spontaneous natural occurrences, but require human effort and skill to produce[35].

India, like other major countries have immensely involved in various biotech and medical research area, being one of the topmost competitor in commercial market in biological therapeutic and diagnostic domains globally. Gene patent cannot be granted in the light of section 3(c) of the Patent Act, 1970[36]. More or less in India the ethical concerns remain the same as in any other country as stated above. But the call of the hour is that human gene regiment should be structured in the country with a formalized procedure. These days the burning ethical issue related to the practice of human cloning and is prohibited across the globe. The debate is still on ablaze and the flame is not conceived to doze off any sooner.

EXTENT OF GENE PATENTING: HUMAN CLONING ANALYSIS

Cloning generally means the isolation and duplication of genes or cells. Researchers have been cloning animal, plant and other organism cells and genes for over twenty years. Cells can be cloned by isolating them from the body through a biopsy and culturing them. The cells will grow and divide,

[33] S. R. Munzer (2002) J. Burley and J. Harris (eds.), A Companion to Genetics: Philosophy and the Genetic Revolution, Oxford: Blackwells, at pp. 438-454 (1st Edition).
[34] Thambisetty S. "*Understanding Morality as a Ground for Exclusion from Patentability Under European Law"*, EU Bio Science Journal, Asian Int. Bioethics at pp. 46–52 (2002); also see Article 27 (2) of the TRIPS.
[35] P. Ossorio (2002) 'Legal and Ethical Issues in Patenting Human DNA' in J. Burley and J. Harris (eds.) A Companion to Genethics: Philosophy and the Genetic Revolution (Oxford: Blackwells) pp. 418.
[36] a*ny process for the medicinal, surgical, curative, prophylactic, diagnostic therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products*' are not patentable.

producing new cells identical to the original cells. The resulting cells, called a 'cell line', have an identical genetic makeup[37].

On July 5, 1996 Dolly (sheep) was cloned using a technique known as 'somatic cell nuclear transfer technology'. A somatic cell is any cell of the embryo, fetus, child or adult which contains a full complement of two sets of chromosomes. Germ cells, i.e., an egg or a sperm, contain only one set of chromosomes. In this technology, a cell nucleus containing complete DNA from any somatic cell is transferred into an egg from which the nucleus has been removed and grown into an embryo. In Dolly's case the nucleus from an udder cell of one lamb was introduced into an egg from another lamb. The announcement of the birth of Dolly the transgenic sheep, and the announcement by Richard Seed that he plans to start a human cloning business; the world's attention has focused on the biotechnology of cloning. The U.S. Patent and Trademark Office turned down that application, however, citing a federal law that restricts the subject matter of a patent to exclude "laws of nature, natural phenomena, and abstract ideas." So did the US Federal court said on this case[38].

Taking in terms of human cloning, the patent covers a way of turning unfertilized eggs into embryos, and the production of cloned mammals using that technique. But unlike some other patents on animal cloning, this one does not specifically exclude human from the definition of mammals; indeed, it specifically mentions the use of human eggs[39]. But the patenting of modified genes can be said to exist as in *Parke-Davis and Co. v. H. K. Mulford and Co*.[40], a lower Court held that purified human adrenaline was patentable because, through purification, it became "for every practical purpose a new thing commercially and therapeutically". Thus even patenting such a process is prohibited in India but for micro-organisms the case is not the same. Critics claim, the difficulty with the main moral objections to human gene patents is not simply that they confuse legally patentable genes with naturally occurring genes. In addition, they confuse patenting with owning. Thus, they fail to see that whatever the complexity involved in legal ownership, a patent simply does not confer legal ownership of anything. One can have a legal patent on a bicycle without owning any bicycles. Indeed, one can have a legal patent on an invention, but lack any legal rights to use that invention, let alone to license others to use or manufacture it. This is

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[37] William S Feiler, Patent aspects of human cloning in the US, Grain (28 September 1998),*available at* https://www.grain.org/article/entries/2125-patent-aspects-of-human-cloning-in-the-us.

[38] Kelly Servick, No Patent for Dolly the Cloned Sheep, Court Rules, Adding To Industry Jitters, (may. 14, 2014 , 7:30 am) *available at* <http://www.sciencemag.org/news/2014/05/no-patent-dolly-cloned-sheep-court-rules-adding-industry-jitters>.

[39] Andrew Pollack, Debate on Human Cloning Turns to Patents, The New York Times (May 17, 2002), http://www.nytimes.com/2002/05/17/us/debate-on-human-cloning-turns-to-patents.html.

[40] 189 F. 95 (SDNY 1911), affd 196 F. 496 (Second Cir. 1912). P.102. Quoted In Ossorio, p. 413.

because the only legal right conferred by a patent is the right to prevent others from using or possessing one's invention: "…patents do not grant rights of use or possession, only rights to exclude". Hence, Ossorio (a leading scientist in USA) concludes, a human gene patent cannot be identified with legal ownership of human bodies, not simply because human gene patents confer no rights over naturally occurring genes, but because patent rights confer none of the positive rights to possess and use in which ownership typically consists[41].

At various instances such human clones can prove to be real assets to humanity. The main aim of China's one child norm policy was to control the population of the country but to introduce such a policy proved to be fatal in the long-run, indicated by a rise in the old-age population which is indeed as a matter of fact inappropriate to work. To counter this problem China shifted to two child norm policy whereby in China a couple can have two children. This was done to boost up the young population[42]. Though there is no guarantee that such akin situation would not arise in China once again and also China was late in adopting such a policy. But this can be countered by human cloning, producing human being with desirable qualities and cloning the desirable number of humans. Such a measure may be needed in India because by 2022 India is expected to overtake China in terms of population[43]. Therefore, India may allow such practice though may be unethical but should be made legal considering its developmental needs and International commitments. India has started its human genome project even though genes are not a subject-matter of patent as afore stated (in pioneering the basic concepts). The country should give serious thoughts about expanding the project to human cloning project due to its benefits as mentioned above[44].

LEGAL BASIS OF LIFE PATENTS IN EUROPE AND USA

The Agreement on Trade Related Aspects of Intellectual Property (hereinafter referred to as TRIPS) mandates that patent protection must be extended to all fields of technology which by necessary implication includes biotechnology[45]. Such inventions might include inventions based on genes or whole organisms; known as life patents (here, life patents refer to patents of human genes). Life patents can be understood by laws relating to it in Europe and USA.

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[41] P. Ossorio (2002) 'Legal and Ethical Issues in Patenting Human DNA' in J. Burley and J. Harris (eds.) A Companion to Genethics: Philosophy and the Genetic Revolution (Oxford: Blackwells) pp. 408-19.

[42] The great graying of China: Why the new two-child policy is too little, too late (December 24, 2015), http://qz.com/580784/the-great-graying-of-china-why-the-new-two-child-policy-is-too-little-too-late/.

[43] 'India to Overtake China's Population By 2022' – UN, BBC NEWS (30 JULY 2015), *available at* http://www.bbc.com/news/world-asia-33720723.

[44] See Supra: Patenting Human Genes: Way Ahead or Unethical Catch.

[45] Article 27.1 of TRIPS.

The European patent system displays a disciplined yet inclusive regime of according patent rights to biotechnology and its numerous progenies. The guideline prescriptions for the European nations regarding municipal patent laws are incorporated in two primary documents–the European Patent Convention (EPC) and the Biotechnology Directive of 1998[46] (the Directive). Four criteria are highlighted in the EPC for determining patentability of any subject matter. The EPC directs that for successful patent protection, the matter concerned should be patentable; should display novelty and include an inventive step; and must prove industrial usage. These four criteria were reaffirmed in the Directive of 1998. In fact, for the purposes of ensuring compatibility between the EPC and bio-patents, the Directive categorically under Article 3.2 specifies that biological material, after considerable human processing and intervention, cannot be precluded from the ambit of patent protection simply because its initial existence was inherent in nature. The decision in Harvard/Onco mouse represents adoption of these attributes by the European Patent Office (EPO). In this case, inventor successfully patented the Onco mouse, a transgenic organism, which was mutated and altered by sufficient human and technical intervention to improvise it into a novel organism. The Onco mouse was receptive to breast cancer and therefore, could successfully facilitate an early diagnosis. The EPO deliberated over Harvard's application for securing a patent for the 'Onco mouse'. However, this was dismissed by the EPO as it considered the subject matter 'a variety of animals' and thus barred from patent protection under Section 53(a) of the EPC. On appeal, numerous parties enjoined briefs to the motion before the appellate body which did not uphold EPO's decision of declaring Onco mouse as an animal variety. It did however, recommend the patent office to consider the briefs of the enjoined parties and determine if the invention in question was in violation of public order or morality. The EPO ultimately, in 1994, ruled in favour of applicants granting them the disputed patent. Du Pont, the main sponsor of the research and creation of the organism, was also granted the patent rights. The Harvard mouse case vividly shows willingness and urge in Europe to grant patents to adequately humanly engineered biological products. Again in 1995, the Court granted a patent for a DNA sequence encoding a human protein, produced by pregnant women, which assisted with the pregnancy[47]. It was held that the subject matter in question was more than a mere discovery as it 'had to be isolated from its surroundings and a process had to be developed to obtain it.' This case restricted the applicability of the 'products of nature' doctrine. The European position, as far as life patents are concerned, has been lax and derives a lot from the TRIPS Agreement. However practically, a stricter practice is followed in Europe.

[46] Directive 1998/44/EC on the legal protection of biotechnology inventions.
[47] Harvard/Onco mouse, 1992 O.J. E.P.O. 588 (Examining Div.), reprinted in 1991 Eur. Pat. Off. Rep. 525, 525-27.

The American law on patentability of life is liberal as against the European law on it, The Constitution of the United States empowers Congress to 'secure for limited times to authors and inventors exclusive rights to their writings and inventions' for the promotion of innovation[48]. Under US law[49], there are four requirements for granting a patent vis-à-vis the invention must be novel, must not statutorily be barred from acquiring patent rights, must have utility, and must be non-obviousness. There is no imposition of any statutory bar on the patentability of the subject matter, other than these aforementioned four prerequisites. The American law regarding patentability of life patents is 'all inclusive'. With the inclusion of biological material to patentable subject matter disputes over their 'inventive' status and private ownership or monopoly over life, on the face of it emerged. There exists a debate over whether new advances in technology mandate a new patent regime. The US Supreme Court however, seem to favour patentability on human genes as it says that if an invention is of novel nature that it cannot be regarded as 'product of nature and hence patented'[50].

The Supreme Court, while expanding the functional framework of § 101, held that if a product were novel and portrayed characteristics which were hitherto unknown to mankind, it would suffice the clause's requirement[51]. As a result of US patent regime it has 3,000–5,000 patents on human genes and 47,000 on inventions involving genetic material[52].

INDIA AND INTERNATIONAL COMMITMENTS: A STEP TOWARDS HARMONISING HUMAN GENES PATENT SYSTEM

The international inconsistencies in gene patentability pose an abstruse problem. Inconsistent patent regimes can result in uncertainty among biotechnology firms, as well as unequal access to genetic testing and health care for patients. Due to the global nature of biotechnology, a solution will likely need to come from international organizations. Some nations have argued for amending TRIPS to ban patents on life forms[53]. But previous attempts at this have failed, and it seems unlikely, given the

[48] U.S. Constitution. Art. I, § 8, Cl. 8.
[49]U.S. Patent Act (35 U.S.C.) August 16, 2008 (The US Patent Act is found in Title 35 of the US Code and contains the federal statutes governing patent law in the United States), http://www.bitlaw.com/source/35usc/index.html.
[50] *Diamond* v *Chakrabarty*, 447 US 303 (1980).
[51] Funk Bros Seed Co v Kalo Inoculant Co, 333 U.S. 127 (1948) .
[52] Robert Cook-Deegan, Gene Patents , The Hastings Center, *available at* http://www.thehastingscenter.org/Publications/BriefingBook/Detail.aspx?id=2174, also see Robert Cook-Deegan, "Gene Patents, in*From Birth to Death and Bench to Clinic: The Hastings Center Bioethics Briefing Book for Journalists, Policymakers, and Campaigns,* at pp 69-72, Mary Crowley edition (Garrison, NY: The Hastings Center, 2008).
[53] Cydney A. Fowler, Comment, Ending Genetic Monopolies: How the 1IRIPS Agreement's Failure to Exclude Gene Patents Thwarts Innovation and Hurts Consumers Worldwide, 25 Aus. U. INT'L L. Rev. 1073 (2010).

WTO's (World Trade Organisation) "law-making deficit" that any substantive response will occur in the future. Article 27 of the TRIPS require patent for all inventions in all fields of technology including biotechnology.

TRIPS principally regulates domestic laws of signatory countries. It requires that countries should have an effective patent system for virtually all areas of technology which is subject to two exceptions provided in second and third clauses of the provision. First, Article 27(2) provides that members may exclude inventions from patentability where preventing the commercial exploitation of the invention is 'necessary to protect order public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment'[54]. Secondly, Article 27(3) provides that members may exclude diagnostic, therapeutic and surgical methods for the treatment of humans or animals and plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. It would be pertinent to mention that Article 30 of TRIPS ensures that enforcement of such exceptions does not interfere with normal exploitation of patent and legitimate interest of the patent holder.

The WTO has remained relatively silent on the patentability of genes, although more recent conferences have noted some countries' growing concerns regarding access to diagnostic testing[55] which is to say, the human genes which help in detecting a disease, patent should be allowed on them.

International patent cooperation has been extensive and largely successful in coordinating procedural patent protections. Under the Paris Convention, signatory countries committed to offer "the same opportunity to receive and enforce patent rights to other signatories as they offer to their own nationals." "Subsequent treaties have led to the standardization of the form of patent applications, the procedure for applying, and the terms of protection. However, the term "international patent harmonization" was originally understood to mean "uniform patent laws throughout the world," which would require more uniform substantive, as well as procedural, standards.

WIPO has issued many of its own guidelines regarding genetic patents and resources. In the past decade, it made an attempt to streamline and clarify policies as they apply to gene patents, during

[54] Adelman and Baldia, Prospects and limits of the patent provision in the TRIPS Agreement: The case of India, Vanderbilt Journal of Transnational Law, George Washington University , at pp 507-533 (1996).

[55] See, for example, World Trade Organization, Trade Policy Review, at 76, WT/TPR/S/177 (2005) (pointing out that, as of 2005, the Commission "has not taken a position on Member States' interpretations on the preferable type of protection for gene sequence"); see also World Health Organization, World Trade Organization, and World Intellectual Property Organization Technical Symposium, Access to Medicines, Patent Information and Freedom to Operate (Feb. 18, 2011), *available at* http://www.wto.org/english/news e/news11 e/trip_ 18feb11 summary e.pdf (briefly noting the role of gene patents in vaccines for influenza and the human papillomavirus).

negotiations for the Substantive Patent Law Treaty, it sought to clarify patent requirements and exceptions, including those on "life forms and public health patents."[56] An increasing number of voices in the debate over gene patents, WIPO members have struggled to reach agreement regarding the scope of patentable material. The Director General of WIPO, Dr. Francis Gurry, has identified a shift in patent law from a "unimodular" to "interactive" system where a broad range of actors influence patent policy[57].

India is member of TRIPS, WIPO, Paris Convention etc[58], which provide for patentability of human genes and USA has already availed benefit of it. Even the European system is on its shift by allowing genetic patenting of small organisms and debate of the genetic patents of large organisms. India should also avail benefit of it as is permissible by the TRIPS Article 27 and prohibiting it is violating Article 30 of TRIPS indirectly as it restricts creativity and gives no protection to a person who has made wonders in the field of human genetics. Therefore India should align its patent protection policy in the line of the developed world patent policies.

CRITERIA FOR PATENTABILITY OF HUMAN GENES IN INDIA

Though patentability of human genes is barred in India per se from the very letters of section 3 of Indian Patent Act, but criteria for patentability is almost the same in India as in USA[59]. Therefore such life patents should be allowed in India. This would further be in compliance with the International commitments that India has made (already stated in the immediate afore discussed topic) and would foster the economy and innovation in the field of science and medicine which would be in turn beneficial to public at large. *Salus Populi Suprema Lex* which means the welfare of public is the supreme law[60]. Granting life patents in India justifies the maxim.

In India the patent criteria is the item should be new (novelty); involve an inventive step (non-obviousness of the invention); and should be capable of industrial application[61]. The first condition, that is, of novelty with regard to genes and gene products is fugaciously complied with, since they are considered chemical entities, and these can be patented in most patent offices if they are purified and

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[56] WIPO Standing Committee on the Law of Patents, Experts' Study on Exclusions from Patentable Subject Matter and Limitations to the Rights, SCP/15/3 Annex 1 (Feb. 3, 2011), *available at* http://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15-3-annexl.pdf. See also World Intellectual Property Organization, Comments Made by Members and Observers of the SCP on Document SCP/15/3 (October 11-15, 2010), available at http://www.wipo.int/edocs/mdocs/scp/en/ scp-j 5/scp 15_3-comments.pdf.

[57] Francis Gurry, Intellectual Property, Knowledge, Policy and Globalization, Going Global 2006 (Helsinki, Finland, Sep. 21, 2006), available at http://www.6cp.net/downloads/ 06helsinkigurry.pdf.

[58] India, WIPO, available at http://www.wipo.int/wipolex/en/profile.jsp?code=IN.

[59] *Ibid* pg. 12.

[60] *Lala Ram (D) by LRS & Ors*. v *Union of India*, Civil Appeal Nos. 243-247 of 2003

[61] *Ibid* pg. 1 & 2.

isolated from the form in which they occur in nature. In most countries, a claimed gene is considered novel if the claim covers the isolated and purified gene. The applicant must be able to prove that the existence of the gene was not known and that he was the first to isolate it, characterize it and define its utility.

An invention in biotechnology is obvious if the prior art provides motivation for the invention and enables one of skill in the art to invent with a 'reasonable expectation of success'[62]. In 1996, the US Supreme Court in *Graham v John Deere Co*[63] articulated four factors to determine non-obviousness. The four factors include: (1) the scope and content of the prior art, (2) the difference between the prior art and the claimed invention, (3) the level of ordinary skill in the art; and (4) other secondary considerations. Secondary considerations may include commercial success; long felt but unsolved need; unexpected result; other's failure to solve the same problem.

The Court of Appeals for the Federal Circuit in, *In re Deuel*[64], held that 'general motivation to search for some gene that exists does not necessarily make obvious a specifically defined gene that is subsequently obtained as a result of that search'. Hence, it was possible to obtain a gene patent using an obvious method[65]. Furthermore, even if the prior art provides the motivation for success and a 'reasonable expectation of success,' the exhibition of 'unexpected properties' will render an invention non-obvious[66]. Examples of unexpected properties are superior purity, specific activity, and unexpected yield[67]. Therefore the criterion of inventive step (invention) is fulfilled.

DNA sequences, such as Genes, ESTs (Expressed Sequence Tag) or SNPs (*Single Nucleotide Polymorphism)*, have a wide variety of applications. In many cases, there are known uses of DNA, like for producing proteins or diagnostics or in forensic sciences (DNA fingerprinting). However, there are also increasingly innovative uses for DNA, like the sensor developed by the University of Illinois at Urbana-Champaign that can detect lead using specially designed DNA[68]. The use of DNA sequences for (pre and post symptomatic) diagnostic testing requires, identification of the disease-causing gene(s), sequencing the gene and identifying the ESTs or SNPs that characterize the disease-causing nature of the gene and production of said DNA fragments. Once this knowledge is available, testing a patient's genome

[62] In re O'Farrell, 853 F 2d 894, 903-04, 7 USPQ 2d (BNA) 1673, 1681 (Fed Cir 1988).
[63] 383 US 1 (1996).
[64]51 F3d 1552 (Fed Cir 1995).
[65]Morrison I E Anna, The USPTO's New Utility Guidelines: Will They be Enough to Secure Gene Patent Rights? , The Hohn Marshall Law School http://www.jmls.edu/ripl/vol1/issue1/ morrison-middle.html.
[66] *In re Vaeck*, 947 F 2d at 494, 20 USPQ 2d (BNA) at pp 1443-44.
[67] Hill Laurie L, The race to patent the genome: free riders, hold ups, and the future of Medical breakthroghs, Texas Intellectual Property Law Journal, 11(2) at p 221 (2003).
[68]Illinois News Bureau, *available at http*://www.news.uiuc.edu/scitips/00/11lead.html.

for the gene is made simple. However, since not all diseases are Mendelian (single gene) diseases, and since these identified genes may only predispose a person to the disease and not actually cause it, diagnostic testing of DNA must also be accompanied with pre and post-test counselling. Patented diagnostic tests are available for Diabetes (Harvard, University of Chicago), Canavan disease (Miami Children's Hospital) etc[69]. The examination guidelines for patent applications relating to inventions in the field of chemicals, pharmaceuticals and biotechnology (Annexure 1, Manual of Patent Practice and Procedure, Patent Office, 2005, India) states that gene sequences and DNA sequences are not patentable if functions (utility for the genetic inventions) are not disclosed. However, a lack of case laws in India requires looking at utility or industrial applicability requirements in other countries. Therefore, the third and last criterion of patentability of human genes is yet again satisfied. But the only step required is from the Government of India, to implement this system of Human Gene Patent System.

The Trilateral Project (US Patent and Trademark Office, Europe Patent Office, and Japan Patent Office) has studied in detail the patentability of ESTs and DNA fragments (including genes) which are worth of studying while shifting towards the life patent system in India. The conclusions that were drawn are:

1. A mere DNA fragment without indication of a function or specific asserted utility is not a patentable invention.
2. A DNA fragment, of which specific utility, e.g. use as a probe to diagnose a specific disease, is disclosed, is a patentable invention as long as there are no other reasons for rejection.
3. A DNA fragment showing no unexpected effect, obtained by conventional method, which is assumed to be part of a certain structural gene based on its high homology with a known DNA encoding protein with a known function, is not a patentable invention (EPO, JPO). The above-mentioned DNA fragment is unpatentable if the specification fails to indicate an asserted utility (USPTO).
4. The mere fact that DNA fragments are derived from the same source is not sufficient to meet the requirement for unity of invention[70].

Another aspect, which has to be considered for patentability of gene/DNA sequences, is

[69] Malathi Lakshmikumaran, Patenting of Genetic Inventions, Journal of Intellectual Property Rights, Vol 12 at pp 44-56, January 2007.

[70] Trilateral project B3b. Comparative Study on Biotechnology Patent Practices Theme: Patentability of DNA Fragments *available at* http://www.trilateral.net/projects/biotechnology/patentability.pdf.

the sufficiency of the specification of such inventions. In many cases the disclosures are unable to describe the inventions sufficiently well so as to achieve the results as claimed by it. The effect of making a broad claim has frequently led to invalidating the patent for lack of subject matter. However, in the case of biotechnological inventions a new scenario arises where a given result may be obtained by different means and the various means have nothing in them, which can relate to the subject matter disclosed in a specification. This is a type of insufficiency, which is called the *Biogen* insufficiency. The term was coined in the House of Lords decision in *Biogen v* Medeva[71]. The patent claimed a recombinant DNA molecule characterized by the sequence of the antigens, namely core and surface antigens. The patent was held invalid by the House of Lords which consented that even though the patent enabled the production of both antigens by the single method described, the claims were for every way of achieving the stated result, namely the production of antigens (was not there).

SUGGESTIONS: ROAD AHEAD WITH THE HUMAN GENE PATENTS IN INDIA

As seen from the above discussions it can be sufficiently gauged that Indian patent system needs a fresh look because all the essentials of patent are fulfilled and the criteria of patentability in India is that akin to USA, yet in USA genetic patents are allowed but not in India. Even Europe is moving in the same direction as USA. Hence, India should not lag behind and take advantage of genetic patent regime and not rely on the developed nations for successes by way of biotechnology (including genetic transformations and uses).

India being a signatory to the international conventions of which America is also part allows the Life Patent regime. Though the truth that natural phenomenon or genes per se are not patentable per se pervades all the patent system across the world and for only modified genes patents are granted (in the USA) provided essential patent criteria as reiterated above[72]. To implement such a patent protection system conspicuously amendments in the Indian Patent Act, 1970 are required allowing patentability of genes by appending an explanation to section 3(j) which provides patentability of genetically modified genes satisfying the three-pronged stated criterion for patent protection. Additionally criteria of sufficient disclosure of patent should also be introduced[73]. This would help India to give competitive edge in terms of economic advantage and welfare measures. Global inequity is not a new problem, but it is of central importance. Because of the importance of international protection of IPRs for technological and cultural

[71](1997) RPC 1 (HL).
[72]*Ibid* pg. 1&2 read with pg. 15 & 16.
[73]*Ibid* pg. 17.

exchanges and promotion of free trade, there is an international system for Intellectual Property Rights. In 1883 the Paris Convention for the Protection of Intellectual Property was established. India not granting genetic patents is leading to inconsistencies in the Global Patent Regime. This enables other countries where such patents are allowed lead to exploitation of the Indian market, which could be avoided by bringing the Indian Patent System in alignment with the patent system of such other countries where patentability of Human Genes is allowed.

Although being intended to promote the facilitation of genetic diagnosis using patented genes, as well as Research and Development activities using patented research tools, several policy measures are required like compulsory license, voluntary relinquishment of patent etc. Where there is issue of public and private ownership of patented inventions by having patent holders issue a non-exclusive license under reasonable terms and conditions, instead of an exclusive license to a single licensee. Furthermore, the degree of public ownership can be increased by having patent holders issue a non-exclusive license to any applicant in a non-discriminatory manner, because such non-discriminatory issuance would effectively provide prospective users with inexpensive access to patented invention. In other words provide a license under reasonable and non-discriminatory conditions.

Genetic research will make further advances and eventually almost all human genes, which form the foundations of research, will come to be known. When this happens, a patent will be obtained each time a disease-causing mutation of a specific gene is identified, which would easily bring about a situation where a multiple number of entities held patents for a multiple number of mutations of a single gene. In order to facilitate the provision of genetic diagnosis under such a situation, it is desirable to have a mechanism in which all such patents for mutations are gathered at and provided by a single organization. In the Life Science Research, respondents were asked under what situation they would be willing to offer their parents to the consortium (association of companies) if they were patent holders. It was found that 46 percent of the respondents were in favour of a system based on principle of reciprocity; in other words, they would offer their patented inventions for free use id they were entitled to the free use of patented inventions owned by others. They exceeded the 27 percent of the respondents who replied they would provide their patents if they received sufficient financial compensation. There were very few people who did not want to offer patented inventions under any conditions. Moreover, such a mechanism could be severely convenient and expedient tool for genetic diagnosis providers, if the mechanism is designed in such a way those users, by accessing the organizations, can easily search databases for gene patents held

by the organisation and conclude the necessary license agreement[74].

This calls for appropriate policy measures to provide for establishment of consortiums which supports development of human resources, make it a rule to have all the results derived from governmental funded research projects placed under a consortium. However such policy actions should also be binding for research activities not financed by the government. It is correctly stated that "Drastic Times calls for Drastic Measures".

[74]Stephen A. Bent, Intellectual Property Rights in Biotechnology, Macmillan, at pp 85 to 92 (1987).