CHAPTER 4

PATENTABLE SUBJECT MATTER

3. Regeneration of damaged tissues

4. Eradication of genetic diseases

5. Understanding of diseases like cancer[98]

Subject matter filter is the gatekeeper or the entry requirement that defines the subjects that are eligible for patent protection[99]. An invention is eligible for patent protection only if it falls within one of the categories enumerated under subject matter and outside the list of exclusions from subject matter.

The size of patent and public domains is determined by the list of categories within the inclusions and exclusions of subject matter filter. The primary debate and controversy over patenting of genes and proteins revolves around this filter[100]. The patentable subject matter inquiry is the locus for much of the vigorous opposition to DNA gene patents because the determination of patent eligibility governs the entry of genes into the patent system[101]. Sharp criticism from professional medical organizations, Nobel Prize winners, government officials, religious leaders, and bioethics councils has surrounded the issuance of DNA gene patents[102]. One of their primary concerns was about allowing genes into the patent domain, as that would block basic research by granting patents to naturally occurring materials. In addition to that concern, certain interest groups raised moral and ethical issues relating to patentability of genes and proteins.

[98] http://www.cs.virginia.edu/~jones/tmp352/projects98/group1/how.html visited on 30th January 2006.

[99] Splitting The Gene: DNA Patents And The Genetic Code, Eileen M. Kane, 71 Tenn. L. Rev. 707 (Summer, 2004).

[100] Id. at 727

[101] Id. at 727

[102] Id. at 728

This chapter explores the law relating to eligibility of genes, genetically modified organisms and gene therapies as subject matter in USA, EU and India and analyzes the impact of subject matter on patent and public domains.

USA

In United States, biotech inventions are considered to be eligible for patentable subject matter under section 101 as Compositions of matter or manufactures. Unlike in Europe and India, there are only three exclusions on the scope of subject matter in USA. The exclusion most relevant for biotech inventions is 'Laws of nature'. As per this exclusion anything that naturally exists or a 'product of nature' is not patentable.

Genetically Modified Organisms

Unicellular Organisms

The question relating to patentability of unicellular organisms first came before the US Supreme Court in Funk Bros. Seed Co. v. Kalo Inoculant Co[103]. The case involved an invention relating to a mixed culture of Rhizobium bacteria capable of simultaneously inoculating the seeds of plants belonging to several cross-inoculation groups. The court in this case held that the mere aggregation of species falls short of invention within the meaning of the patent statute because the combination of species produces no new bacteria and no change in the six species of bacteria. As there is no change in the species, the court stated that qualities of the non-inhibitive strains are the work of nature and therefore not patentable subject matter as products of nature.

After the Funk Bros. case, the patentability of unicellular organisms was questioned and clarified by the US Supreme Court in Chakrabarty's case. In

[103] 333 US 127 (1978)

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After the Funk Bros. case, the patentability of unicellular organisms was questioned and clarified by the US Supreme Court in Chakrabarty's case. In Diamond v. Chakrabarty, which is considered to be the most important biotech case relating to patentable subject matter, the United States Supreme Court by holding that everything under the sun made by man is patentable, cleared all doubts and opened the gates for patentability of biotech inventions. The case involved Chakrabartys invention of a genetically modified pseudomonas bacterium capable of degrading oil spills and a process by which four different plasmids, capable of degrading four different oil components, could be transferred to and maintained stably in a single Pseudomonas bacterium, which by itself has no capacity for degrading oil. Chakrabarty's patent claims were of

[103] 333 US 127 (1978)

three types: first, process claims for the method of producing the bacteria; second, claims for an inoculum comprising of a carrier material floating on water, such as straw, and the new bacteria; and third, claims to the bacteria themselves. The patent examiner accepted the claims falling into the first two categories, but rejected claims for the bacteria. The decision rested on two grounds: (1) that microorganisms are "products of nature," and (2) that as living things the pseudomonas bacteria are not patentable subject matter under section 101. The US Supreme Court rejected both the arguments. It rejected the product of nature argument by stating that Chakrabarty has produced a new bacterium with markedly different characteristics from any found in nature. The court went on to say that the test for determining whether an invention falls within the scope of 'Product of nature' is whether the invention in question involves a hand of man. If yes, the invention is not product of nature or naturally existing. If No, it is naturally existing and therefore not patentable. As the pseudomonas bacterium in question involved the hand of man in inserting four different plasmids into it, the court held that it is not naturally existing and therefore patentable. The court rejected the second argument by holding that microorganisms are patentable as manufactures or compositions of matter and that the Congress did not intend to keep them out of the scope of subject matter.

The Chakrabarty decision opened the gates for patentability of genetically engineered unicellular organisms and processes involved in genetic engineering. After the decision non-naturally existing unicellular organisms became patentable in USA. After this decision, The USPTO has granted patents to many microorganisms since 1980. Microorganisms are considered by USPTO as manufactures or compositions of matter.

Multicellular Organisms

In the year 1987, the USPTO announced that non-naturally occurring, non-human multicellular organisms are patentable. The notice, signed by Donald J. Quigg, Commissioner of Patents and Trademarks, stated that as a result of the Board's decision in Ex parte Allen[104], the PTO now considers non-naturally occurring, non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of section 101 [105]. The case involved a patent application over polyploid oysters and a process of inducing polyploidy in them. The examiner allowed claims relating to the process but rejected claims over the oysters stating that they are living organisms, which are not patentable subject matter under section 101. The Board of Patent Appeals and Interferences reversed the examiner's rejection by holding that the polyploid oysters are subject matter, as they do not naturally exist due to involvement of the hand of man in creating them. Relying on Chakrabarty's decision the Board stated that the relevant enquiry for subject matter is not the difference between living and inanimate things, but between products of nature and human-made inventions.

After the oyster decision USPTO granted a patent to an invention relating to a transgenic mouse into which an oncogene sequence was introduced[106]. The mouse was created for study of breast cancer and was called oncomouse. The USPTO granted a patent over the mouse in the year 1988 one year after Exparte Allen. The Harvard mouse patent can be said to be the first patent that expanded the scope of patent protection to multicellular organisms. After Oncomouse, a number of patents were granted to transgenic animals including mice, rabbit, etc[107].

[104] 2 U.S.P.Q.2d (BNA) 1425 (Bd. Pat. App. & Interferences Apr. 3, 1987).
[105] 35 U.S.C. § 101.
[106] Patent No. 4,736,866.
[107] U.S.Patent No. 5,175,383, . U.S.Patent No. 5,175,384, U.S.Patent No. 5,175,385 and U.S. Patent No. 5,183,949.

In Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.[108], the US Supreme Court held that newly developed plant breeds could be protected under the utility patent statute and concluded that neither the Plant Protection Act nor the Plant Variety Protection Act bars obtaining utility patents for plants. The court in this case held a genetically modified corn plant to be patentable subject matter as it involves human intervention. The decision elucidates the fact that genetically modified plants are patentable in USA.

Genes

Gene Sequences, ESTs and Gene probes are patentable in USA. As there has not been any judicial scrutiny of patentable subject matter relating to gene or DNA sequences, the interpretation of USPTO stands good. The USPTO has extended patent protection to isolated DNA, RNA and proteins under section 101 stating that gene and protein sequences are new compositions of matter resulting from human intervention as opposed to naturally occurring products, which are not patentable. The product of nature exclusion is not a hurdle to patenting of gene or DNA sequences because isolated and purified sequences are not naturally existing and contain only the regions of naturally existing DNA that code for proteins. A large number of patents have been granted to DNA sequences based on the aforementioned analysis. The number of patents over gene sequences skyrocketed after NIH filed patent applications over cDNA sequences and ESTs in the early 1990s[109]. Organizations like Human Genome Sciences, Millennium Pharmaceuticals, Incyte Pharmaceuticals, Celera Genomics; etc filed and acquired hundreds of patents over DNA sequences[110].

[108] 534 U.S. 124 (2001).
[109] Shanshan Zhang, Proposing Resolutions To The Insufficient Gene Patent System, 20 Scchitlj 1139, 1154 (May, 2004)
[110] Giles Stokes, Patent Applications of Genetic Sequences on the Up (Apr. 2000), at http://thomsonderwent.com/ipmatters/patlife/8205003 (last visited Jan. 14, 2004).

The USPTO awarded over 8,000 patents on genes and genetic material, including at least 1,500 claiming sequences of human genetic material[111].

The US Supreme Court has recently granted a writ of certiorari to decide the validity of a process patent relating to an amino acid. Patent experts believe that this case will have a profound impact on gene patents. The patent at issue relates to methods for detecting Cobalamine (Vitamin B12) and Follate (Folic Acid) deficiency by determining the levels of homocysteine in the body[112]. Claim 13 of the patent claims a method for detecting a deficiency of cobalamin or folate in warm-blooded animals comprising the steps of: assaying a body fluid for an elevated level of total homocysteine and correlating an elevated level of total homocysteine in said body fluid with a deficiency of cobalamin or folate.[113]

Metabolite, the licensee of the patent sued LabCorp the sub-licensee, for patent infringement in the District Court of Colarodo.[114] The district court held that LabCorp by supplying the results relating to levels of homocysteine in human body to doctors was liable for contributory infringement and granted damages to a tune of seven million dollars.[115] The court said that the doctors by co-relating levels of homocysteine to Vitamin B deficiency directly infringed claim 13 of the patent. As Lab Corp. supplied the data to make such an analysis, it said that Lab Corp. was liable for contributory infringement. On appeal the Federal Circuit upheld the decision of the District Court. [116]

[111] Jordan Paradise, European Opposition to Exclusive Control Over Predictive Breast Cancer Testing and the Inherent Implications for U.S. Patent Law and Public Policy: A Case Study Of the Myriad Genetics' Brca Patent, 59 Fooddlj 133 (2004).
[112] U.S. Patent No. 4,940,658.
[113] See Supra at Claim 13 of the Patent.
[114] Metabolite Laboratories, Inc. v. Laboratory Corp. of America Holdings, 370 F.3d 1354, 1362 ((C.A.Fed. (Colo.),2004).
[115] Id.
[116] Id. at 1374.

Therefore, Lab Corp. filed a writ of certiorari before the US Supreme Court claiming patent invalidity. [117] The US Supreme Court accepted the writ of certiorari filed by Lab Corp., challenging the decision of the Federal Circuit on validity of claim 13 of the patent. The question to be decided by the court was "Whether a vaguely worded patent claim "directing a party simply to correlate test results can validly claim a monopoly over a basic scientific relationship used in medical treatment such that any doctor necessarily infringes the patent merely by thinking about the relationship after looking at a test result." [118] Professor Jon Barton of Stanford Law School and Affymetrix filed an amicus brief before the US Supreme Court submitting that upholding claim 13 of the patent valid would expand the scope of patentable subject matter to such an extent that one may effectively own a natural biochemical relationship by excluding others from any and all testing of that relationship. [119]They believe that such a broad scope of patentable subject matter would nullify the law of nature doctrine and would impact genetic research adversely. [120]Under such broad patentable subject matter, patents would be available for relationship of a gene to a disease/amino acid or relationship between genes of different individuals and so on. They also submitted that grant of such broad patents over biological relationships would block genetic research and chill gene testing. [121]

The US Supreme Court dismissed the writ of certiorari as improvidently granted[122]. By dismissing the writ, the Supreme Court upheld the decision of the Federal Circuit, which means that Claim 13 of the patent is valid and that Laboratory Corp. is liable for patent infringement. As a result the Supreme Court has broadened the scope of subject matter by narrowing the product of

[117] Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc., 2005 WL 3543099 (2006).
[118] Petitioner's Brief, Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc., 2005 WL 3543099 (2006).
[119] Amicus breif of Affymetrix and Jon Barton, Laboratory Corporation of America Holdings v. Metabolite Laboratories, Inc., 2005 WL 3597814.
[120] Id. at 16.
[121] Id.
[122] Laboratory Corporation of America Holdings, Dba Labcorp, Petitioner V. Metabolite Laboratories, Inc., Et Al., No. 04-607 (June 22, 2006).

nature doctrine. According to this decision, discovery of a relationship between a gene and a disease can get a patent.

Gene Therapy

Genetic therapy is used to correct genetic disorders and can be considered to be a method of medical treatment. The expansive scope of subject matter under section 101 allows the right to patent a method of medical treatment as a process[123]. However, the patent statute under section 287(c)(1)[124] abrogates the remedy available for its infringement, thus nullifying the right to patent. Section 287(c)(1) states that infringement provisions shall not apply to a medical activity performed by a medical practitioner or a related health care entity[125]. The term medical activity has been defined in the same section to include performance of any medical or surgical procedure[126]. These provisions were added to the statute in the year 1996 through an Omnibus Consolidated Appropriations Act. They deny the patentee a remedy for infringement of a medical or surgical procedure. Therefore, though a gene therapy, which is a medical method, is patentable subject matter, a patent over it is ineffective as it is not enforceable.

Human beings

Human beings are not patentable in USA. The Patent and Trademark Office has stated in a notice that human multicellular living organisms are not patentable

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[123] 35 USC Sec. 101

[124] 35 USC Sec. 287 (2002).

[125] Section 287(c)(1) reads, "With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b) of this title, the provisions of section 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.

[126] The term 'Medical activities' are defined in 35 USC 287(c)(2)(A) as "the performance of a medical or surgical procedure on a body, but shall not include (i) the use of a patented machine, manufacture, or composition of matter in violation of such patent, (ii) the practice of a patented use of a composition of matter in violation of such patent, or (iii) the practice of a process in violation of a biotechnology patent"

subject matter within the scope of 35 U.S.C. 101[127]. A patent claim including or covering a human being at any stage of development is considered by the USPTO, as non-statutory subject matter under Section 101[128].Though MPEP does not expressly address claims directed to a human embryo. In practice, examiners would treat such claims as non-statutory[129].

The U.S. Patent and Trademark Office recently rejected a 1997 patent application, filed by Dr. Stuart Newman of New York Medical College covering fusion of embryonic human and animal cells to create chimeras for medical research[130].The patent application related to a mammalian embryo developed from a mixture of embryo cells, embryo cells and embryonic stem cells, or embryonic stem cells exclusively, in which at least one of the cells is derived from a human embryo, a human embryonic stem cell line, or any other type of human cell, and any cell line, developed embryo, or animal derived from such an embryo[131]. The applicant's objective was to prevent grant of patents over human based living organisms either by obtaining a patent on technology he would not use or by getting the USPTO to declare such inventions contrary to law. The USPTO's rejection was based on the ground that the patent would violate the 13th Amendment's ban on slavery and would be inconsistent with the constitutional right to privacy[132].

EUROPE

The EU Council promulgated the Biotechnology Directive[133], in the year 1998. The Administrative Council of the European Patent Organization amended Rule

[127] U.S. Patent and Trademark Office, "Notice: Animals--Patentability," 1077 Official Gazette U.S. Pat. and Trademark Off. 8 (April 21, 1987).
[128] U.S. Patent and Trademark Office, Manual of Patent Examining Procedure (Revised February 2003), Sec. 2105: "Patentable Subject Matter--Living Subject Matter".
[129] Testimony of Karen Hauda on behalf of USPTO to the President's Council on Bioethics, June 20, 2002,
[130] No Patent On Embryonic Human-Animal Chimera, 24 Biotechlr 290 (June, 2005).
[131] US Patent Published Application Number - 20030079240.
[132] No Patent On Embryonic Human-Animal Chimera, 24 Biotechlr 290 (June, 2005).
[133] 98/44/EC.

23 of the Implementing Regulations of the European Patent Convention on June 16, 1999, and brought it in line with the Biotechnology Directive[134]. Rule 23(b) provides that for European patent applications and patents concerning biotechnological inventions, relevant provisions of the Convention will be applied and interpreted in accordance with the provisions of chapter VI of the implementing regulations[135]. It further provides that the European Biotechnology Directive on the legal protection of biotechnological inventions will be used as a supplementary means of interpretation[136].

Genetically Modified Organisms

Unicellular Organisms

Article 53 (b) of European Patent Convention (EPC) excludes plant and animal varieties and essentially biological processes for the production of plants and animals from the scope of patent protection but provides and exemption for patenting microbiological products or processes[137]. Rule 23b(6) of the Implementing Regulations provides that a "Microbiological process" means any process involving or performed upon or resulting in microbiological material and Rule 23c(c) provides that a microbiological or other technical process, or a product obtained by means of such a process other than a plant or animal variety is patentable subject matter[138]. It was held In T356/93 that microorganisms are patentable as products of microbiological processes, and were defined as generally unicellular organisms with dimensions beneath the

[134] Rule 23 of the IMPLEMENTING REGULATIONS TO THE CONVENTION ON THE GRANTOF EUROPEAN PATENTS of 5 October 1973 as last amended by Decision of the Administrative Council of the European Patent Organisation of 9 December, 2004.
[135] Id.
[136] Id.
[137] Article 53(b), European Patent Convention.
[138] Rule 23b(60 and Rule 23c(c) of the Implementing Regulations To The Convention On The Grantof European Patents of 5 October 1973 as last amended by Decision of the Administrative Council of the European Patent Organisation of 9 December, 2004.

limits of vision, which can be propagated and manipulated in a laboratory[139]. As per the aforementioned provisions a process of genetic engineering when applied on a microorganism and the resultant microorganism are patentable subject matter as they come within the ambit of microbiological process and product.

Multicellular Organisms

Article 53(b) of EPC provides that European patents are not available for plant or animal varieties and essentially biological processes for the production of plants or animals[140]. Rule 23c of the regulations provides that plants or animals are patentable if the technical feasibility of the invention is not confined to a particular plant or animal variety[141]. Genetically modified animals and plants have been held to be patentable as they fall outside the scope of animal or plant variety.

"Plant variety" has been defined in the regulations as any plant grouping within a single botanical taxon of the lowest known rank, which grouping, irrespective of whether the conditions for the grant of a plant variety right are fully met, can be:

(a) Defined by the expression of the characteristics that results from a given genotype or combination of genotypes,
(b) Distinguished from any other plant grouping by the expression of at least one of the said characteristics, and

[139] Denis Schertenleib, the Patentability And Protection Of Living Organisms In The European Union, 203-213 E.I.P.R. 2004, 26(5).
[140] Article 53(b), European Patent Convention
[141] Rule 23c of the Implementing Regulations to the Convention on the Grantof European Patents of 5 October 1973 as last amended by Decision of the Administrative Council of the European Patent Organisation of 9 December, 2004.

(c) Considered as a unit with regard to its suitability for being propagated unchanged[142].

A plant variety is considered patentable if it falls outside the meaning of the term plant variety defined in the implementing regulations. The biotechnology directive provides that a plant grouping which is characterised by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is therefore not excluded from patentability even if it comprises new varieties of plants[143]. As per the directive transgenic plants fall outside the scope of the definition of plant variety and are therefore, patentable subject matter. In Decision G1/98 it was held that transgenic plant was a patentable embodiment of an invention.

In another case involving Novartis, relating to patentability of transgenic plants into which DNA has been inserted using recombinant technology, the Technical Board of Appeals held that genetically modified plants are patentable subject matter. [144]The Technical Board observed that as genetically modified plants were not conceived at the time of drafting, it can be concluded that they do not fall within the scope of exclusion (plant variety) to patentable subject matter. [145]It further stated that if a genetic modification can be applied to more than one variety then the invention is patentable subject matter as it falls outside the scope of exclusion that is plant variety. [146]

As the term 'animal variety' has not been defined in the Convention or Regulations, patentability of genetically modified animals depends on the interpretation of EPO. Patentability of genetically modified animals has been

[142] Rule 23b(4) of the Implementing Regulations To The Convention On The Grantof European Patents of 5 October 1973 as last amended by Decision of the Administrative Council of the European Patent Organisation of 9 December, 2004.
[143] Recital 30 of Biotechnology Directive.
[144] NOVARTIS/Transgenic Plant, Technical Board of Appeal 3.3.4, [1999] E.P.O.R. 123.
[145] Id. at para 91, Reasons for the decision.
[146] Id. at para 96, Reasons for the Decision.

tested and approved through the decision of the Technical Board of Appeals in Oncomouse case[147]. The case related to a genetically altered mouse, which involved inserting an activated oncogene to develop cancer in the mouse. The patent application was initially rejected by the examining division based on the reasoning that the Oncomouse falls within the scope of Article 53(b), which excludes animal varieties from the scope of patentable subject matter. The examination division interpreted the term 'Animal variety' to include all animals. On appeal, the Technical Board held that the wording of Article 53(b) indicates that all animals are not excluded from patentable subject matter because the usage of both the terms "animal varieties" and "animals" in the same provision illustrates that the legislature did not intend to exclude all animals from patentability. As rodents and mammals form a taxonomical unit higher than any animal variety, they are considered to be patentable. On remand the examining division granted a patent on the mouse based on the aforementioned interpretation. So, genetically modified multicellular organisms including rhodents and mammals are patentable subject matter in Europe.

Article 53(b) of EPC provides that essentially biological processes are not patentable[148]. The meaning of an essentially biological process has been defined under Rule 23b(5) of the Implementing regulations as a process for the production of plants or animals consisting entirely of natural phenomena such as crossing or selection[149]. As a process of genetically engineering plants or animals falls outside the scope of crossing or selection, the process is not essentially biological and is patentable. In T320/87, it was decided that existence of human intervention determines whether a process is essentially biological or not. If there is human intervention, the process is not essentially biological and therefore patentable subject matter. As a method of genetically

[147] Decision T 19/90.
[148] Article 53(b), European Patent Convention.
[149] Rule 23b(5of the IMPLEMENTING REGULATIONS TO THE CONVENTION ON THE GRANTOF EUROPEAN PATENTS of 5 October 1973 as last amended by Decision of the Administrative Council of the European Patent Organisation of 9 December, 2004.

engineering animals or plants involves human intervention, it falls outside the scope of essentially biological processes and is therefore patentable.

Genes

The EPC is silent about patentability of genes but the implementing regulations that adopted the EU Biotechnology Directive has specific provisions dealing with patentability of genes. The implementing regulations provide that biological material, which is isolated from its natural environment or produced by means of a technical process even if it previously occurred in nature, is patentable[150]. Biological material has been defined as any material containing genetic information and capable of reproducing itself or being reproduced in a biological system[151]. A gene is considered a biological material because it can be reproduced in a biological system such as a cell or bacteria and is patentable if isolated from its natural state. Rule 23e specifically mentions that gene sequences are patentable[152]. It provides that though the sequence or partial sequence of a gene, cannot constitute patentable inventions, an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element. Based on the Implementing regulations, partial and complete gene sequences are patentable under the EPC.

In a case relating to patentability a DNA sequence coding for Human H2 Relaxin, the Opposition Division of EPO held that the DNA sequence is patentable subject matter.[153] While holding so, the Opposition Division observed that if a substance found in nature has first to be isolated from its

[150] IMPLEMENTING REGULATIONS TO THE CONVENTION ON THE GRANTOF EUROPEAN PATENTS of 5 October 1973 as last amended by Decision of the Administrative Council of the European Patent Organisation of 9 December, 2004.
[151] Id.
[152] Id.
[153] Howard Florey/Relaxin(Oppositions by Fraktion der Grunen Im, Europaischen Parlament; Lannoye), Opposition Division, [1995] E.P.O.R. 541.

surroundings and a process for obtaining it is developed, that process is patentable.[154]Moreover, it also observed that if this substance can be properly characterised by its structure and it is new in the absolute sense of having no previously recognised existence, then the substance per se may be patentable. [155]Based on the aforementioned principle, the Opposition Division reasoned that as Human H2- relaxin had no previously recognised existence and as the patent holder developed a process for obtaining H2-relaxin and the DNA encoding it, has characterised these products by their chemical structure and has found a use for the protein, the DNA sequence of Relaxin was patentable subject matter. [156]The Opposition Division went on to state that it was justified to grant patent protection in this case as H2 Relaxin was made available to the public for the first time. [157] EPO has granted number of patents over different types of genes till date.

Gene Therapy

Article 52, Clause (4) excludes methods of treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on humans from the scope of patentable subject matter[158].The law relating to patentability of medical methods has been elaborated by decisions of the EPO board of appeals and other national boards. These decisions have laid down certain guidelines to be followed while deciding upon the patentability of surgical, therapeutic and diagnostic methods.

Surgical methods: There is no conflict in the decisions of various boards with regard to patentability of surgical methods. The term "surgery" has been held

[154] Id. at 4.1
[155] Id.
[156] Id. at 4.2.
[157] Id.at 4.3.
[158] Article 52(4), European Patent Convention.

to include not only invasive operations, but also non-invasive procedures such as repositioning[159].

Therapeutic methods: Therapeutic methods are not patentable if they involve a therapy on human or animal body. The term "therapy" has been defined to include anything that relates very broadly to the treatment of a disease in general or to a curative treatment as well as to the alleviation of the symptoms of pain and suffering[160]. The patentability of a 'therapy' depends upon the nature of the treatment[161]. Generally cosmetic methods are patentable in EPO[162].

Diagnostic methods: Diagnostic methods are of two types: *In vivo* and *In vitro*[163]. In vivo methods are barred from patentability but In vitro methods are patentable[164].

So, surgical and therapeutic methods using genes are not patentable prima facie. However, diagnostic methods using genes are patentable provided they are In vitro. There is no ban on patentability of implements and kits used for genetic therapies.

Human Beings

Article 53(a) of the European Patent Convention provides that inventions the publication or exploitation of which would be contrary to ``order public" or morality are not patentable[165]. Rule 23d of the regulations provides that Under

[159] T182/90 (OJ 9/94, 641)
[160] T144/83 (OJ 1986/301).
[161] T144/83 (OJ 1986/301)
[162] Patenting Inventions in the Field of Medical Technology by Dr. Axel von Hellfeld WUESTHOFF & WUESTHOFF.
[163] *In vivo* methods are methods performed on a human or animal body and *in vitro* methods are methods that don't involve human or animal body.
[164] Patenting Inventions in the Field of Medical Technology by Dr. Axel von Hellfeld WUESTHOFF & WUESTHOFF.
[165] Article 53(a), European Patent Convention.

Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern processes for cloning human beings, processes for modifying the germ line genetic identity of human beings, uses of human embryos for industrial or commercial purposes and processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes[166]. Rule 23e provides that the human body, at the various stages of its formation and development, and the simple discovery of one of its elements is not patentable[167]. However, elements isolated from the human body or otherwise produced by means of a technical process are patentable even if the structure of that element is identical to that of a natural element[168]. So, human beings or parts/elements of human body and processes of cloning or altering them are not patentable but elements isolated from human body through a technical process are patentable in Europe.

In a recent case, the Examining Division of EPO rejected a patent relating to human embryos stating that it is in violation of Article 53(a) of EPC.

WARF Case

The case related to a patent application titled, primate embryonic stem cells filed by Wisconsin Alumni Research Foundation (WARF)[169]. The examination division rejected the application as it did not comply with Article 53(a) EPC in conjunction with rule 23d(c) of EPC. Rule 23d(c) of EPC precludes the grant of

[166] IMPLEMENTING REGULATIONS TO THE CONVENTION ON THE GRANTOF EUROPEAN PATENTS of 5 October 1973 as last amended by Decision of the Administrative Council of the European Patent Organisation of 9 December, 2004.
[167] Id.
[168] Id.
[169] WARF/Stem cells, Technical Board of Appeal 3.3.8, [2006] E.P.O.R. 31.

a European patent for the use of human embryos for industrial of commercial purposes.

The Examining Division considered that the application related to the generation of human embryonic stem cell cultures where human embryos were described in the application as filed as indispensable starting materials, which meant a use thereof for industrial purposes within the meaning of rule 23d(c) of EPC. As the description of the application in suit provided only one source of starting cells, namely pre-implantation embryos, the Examining Division thus regarded it as irrelevant that the claimed subject matter related to cell cultures and not a method of their production. WARF appealed to the Technical Board, which referred the case to the Enlarged Board for clarifying the scope of exclusion of patentability of human embryos.

INDIA

Living Organisms, Genes and Gene Therapies

The Indian Patent Act prohibits patents on discovery of any living thing occurring in nature[170]. It provides that plant and animals in whole or any part thereof including seeds; varieties, species and essentially biological processes for production or propagation of plants and animals are not patentable subject matter[171]. However, the Patent Act allows patents for microorganisms and microbiological processes[172]. In a case, the Controller of Patents rejected a patent application over a vaccine for infectious bursitis virus on the ground that it is a living organism[173]. The Calcutta High Court reversed the decision of the controller holding that a living microorganism constitutes patentable

[170] Section 3(c), Indian Patent Act, 1970 as amended in 1999, 2002 and 2005.
[171] Section 3(j), Indian Patent Act, 1970 as amended in 1999, 2002 and 2005.
[172] Id.
[173] Dimminaco A.G. v. Controller General of Patents, Designs and Trademarks, 2002 at http://www.tifac.org.in/do/pfc/case/microbio.htm visited on Novermber 21st, 2005.

subject matter as a manufacture[174]. Based on this decision, it can be said that in India, genetically modified microorganisms are patentable.

Genetically modified multicellular organisms including plants, animals, human beings and their parts are not patentable in India as per Section 3. The Manual of Patent Practice and Procedure provides that biological materials such as recombinant DNA, Plasmids and processes of manufacturing thereof are patentable if they are produced by substantive human intervention[175].

Gene sequences and DNA sequences having disclosed functions are considered patentable in India[176]. The processes for cloning human beings or animals, processes for modifying the germ line, genetic identity of human beings or animals, uses of human or animal embryos for any purpose are not patentable as they are against public order and morality[177].The list of non patentable inventions in India also includes any 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[178]. As genetic therapies are therapeutic and are meant for rendering an animal or human being free of disease, they are not patentable in India.

Patentability of gene related subject matter in USA, India and Europe

Country ⇒ / Subject Matter ⇓	USA	EPC	India

[174] Id.
[175] ANNEXURE - I, Examination Guidelines for Patent Applications relating to Inventions in the field of Chemicals, Pharmaceuticals and Biotechnology, Manual Patent Practice and Procedure, 2005.
[176] Id.
[177] Id. citing Section 3(c), Indian Patent Act, 1970 as amended in 1999, 2002 and 2005.
[178] Section 3(i), Indian Patent Act, 1970 as amended in 1999, 2002 and 2005.

Genes	Patentable	Patentable	Patentable
Genetically modified Unicellular Organism	Patentable	Patentable	Patentable
Genetically modified Multicellular Organism	Patentable	Patentable	Not Patentable
Genetically modified Animals (Excluding Humans)	Patentable	Not Patentable (Except mammals)	Not Patentable
Genetically modified Plants	Patentable	Patentable	Not Patentable
Genetically modified Humans	Not Patentable	Not Patentable	Not Patentable
Gene Therapy	Patentable but not enforceable	Not Patentable	Not Patentable

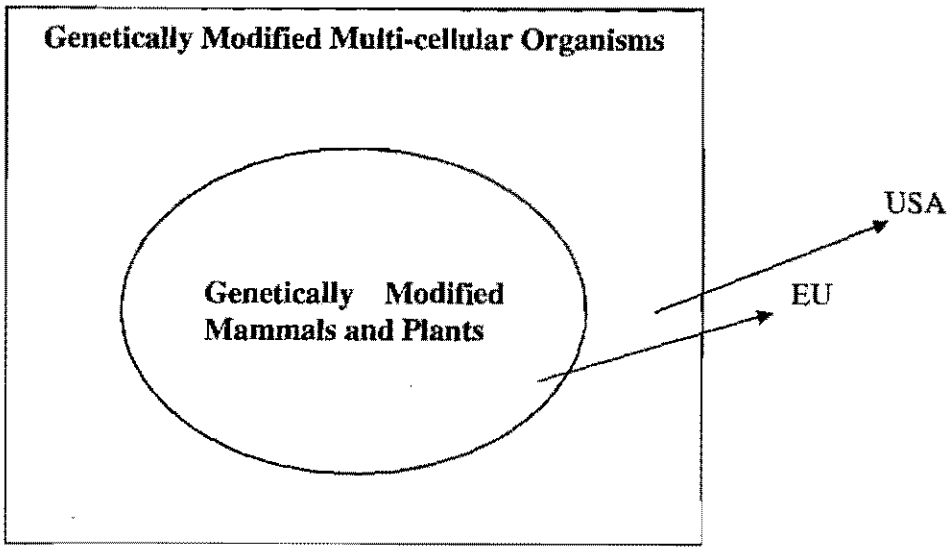
Patentable Subject matter and Patent/Public domain

As a gatekeeper requirement, patentable subject matter gives governments the power to define the size of public and patent domains in their respective countries. By defining the list of subjects eligible for subject matter and list of subjects excluded from subject matter, a government lays down straightforward entries or exclusions from the scope of patent system. If a subject is listed within the scope of subject matter, it means that it is eligible

to enter the patent domain and if a subject is excluded, it means that the subject is not eligible for patent domain and would enter into the public domain. Though analysis under this requirement seems preliminary and straightforward, ambiguities in interpretation of the meaning of subjects listed under the requirement have given rise to some uncertainty when it comes to gene based inventions. Differences in the scope of subject matter in USA, Europe and India relating to gene based inventions and the complications arising there from have already been elucidated in this Chapter.

The differences in the patentable subject matter of gene based inventions in USA, EU and India gives rise to variances in sizes of patent and public domains among them. The table above elucidates the patentability of genetically modified organisms, genes, gene therapies and human beings in these countries based on the scope of patentable subject matter. There is no variation of the subjects eligible for patent domain when it comes to genetically modified unicellular organisms, genes and genetically modified human beings. While genes and genetically modified unicellular organisms are patentable in all three countries, genetically modified human beings are not patentable in all three countries. However, there is a variation in the scope of subject matter when it comes to Genetically Modified Multicellular Organisms and Gene therapies. While all genetically modified multicellular organisms are patentable in USA, only genetically modified mammals and genetically modified plants are patentable subject matter in Europe and genetically modified multicellular organisms are not patentable subject matter in India. As a result all genetically modified multi-cellular organisms are eligible for patent domain in USA and only genetically modified mammals and plants are eligible for patent domain in Europe, which means that non mammalians and plants not genetically modified are public domain in Europe and all genetically modified multicellular organisms fall into the public domain in India. The figure below illustrates the variance in patent/public domain when it comes to genetically modified multicellular organisms.

Figure 4.1 - GM Multi-cellular Organisms - Patent domain variance.



In case of gene therapies, they are patentable in USA but not patentable in Europe and India. So, gene therapies fall within the scope of eligible patent domain in USA and into the public domain in Europe and India.

Wide public domain in India and narrow public domain in USA means that companies and research institutes in India can legally utilize GM Multicellular Organisms or Gene therapies for their own commercial or research purposes, while the same Organism or therapy cannot be used for such purposes in USA or Europe (if it is a mammalian multicellular organism or Genetically Modified Plant). So, India has an advantage as free access and availability of the organism enables Indian companies and researchers to utilize the multicellular organism, while companies and researchers in USA are blocked due to existence of a patent. As a result, the progress of technology relating to and dependant on such a multicellular organism can be faster in India due to free access. However, in most cases, one road block that most companies or research institutes face is access to the biological material i.e. organism itself. Though they are allowed to freely use the organism for any purpose, the acquisition of the organism might be blocked or conditioned on agreements limiting the use

of the organism. Assuming that such an organism is accessible easily, India would be in a better position than USA and Europe and Europe would be in a better position than USA to promote research in the area of or relating to Multicellular Organisms.

Such a situation provides opportunities for Indian organizations to research and use patented multicellular organisms in US and Europe and to earn commercial benefits by acquiring a patent in USA. So, the incentive is not lost due to the patent domain in USA, which grants handsome returns and public domain in India, which allows Indian organisations to freely access and utilize patented multicellular organisms. Such a situation puts India in an advantageous position as India can reap benefits of patent law without granting national patent protection. Having said that such an advantage is limited to organizations in India, which have transnational reach or capability.

Though the differences in the size of patent and public domain with regard to gene based inventions based on variations in patentable subject matter in different countries seems to provide certain strategic advantages to certain organisations in India that has the potential of stunting the development of indigenous institutes based on problems pertinent to India. An Indian organisation would invest on acquiring a patent in USA only if it foresees a market for its patent in USA. Therefore, the incentives offered by the patent domain in USA will encourage progress of science and technology relating to living conditions in that country because there is market only for such inventions. As a result Indian organisations might focus their research on US markets. So, Indian organizations might not have the incentives offered by patent regime for subjects such as genetically modified multicellular organisms or gene therapies that are directed to living conditions in India.