

Why has human genetic patenting proved to be a deeply contentious matter?

Any invention whose claims are directed to modification of existing laws of nature, or are contradictory to the existing laws of nature, or are related to substances naturally occurring in nature, are excluded from patentability.

One such subject matter involves genetic modification of naturally occurring species. In the term of 2013, the U.S. Supreme Court ruled out an appeal against a patent which claimed a process of creating synthetic complementary DNA (cDNA) by isolating natural deoxyribonucleic acid (DNA) strands. This is illustrated in detail by the following case law:

Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576

The facts of the case are as follows:

- Myriad Genetics Inc. (hereinafter referred to as Myriad) discovered of precise location and sequence of BRCA1 and BRCA2 genes, the mutations of which results in alterations of genes, and results in development of cancer.
- Based on the detections of BRCA1 and BRCA2 genes, Myriad developed medical tests to detect mutation of these genes. Presence of the mutations indicate a high risk of cancer.
- The test involved two processes:
 - The first process involved isolation of DNA strands containing the sequences of nucleotides, found in BRCA1 and BRCA2 genes.
 - The second process involved creating a copy of original DNA sequence consisting only of exons (nucleotides that code for amino acids, the building blocks of proteins), and thus forming cDNA.
- Based on the above research, Myriad obtained multiple patents on the process of isolation and creation of cDNA.
- But other medical institutions started BRCA testing after discovery of the said genes by Myriad. Knowing this practice, Myriad ordered them to stop the testing, believing that the method of testing performed by the other institutions infringed one of Myriad's patents.
- In response to the order, one of the scientists of the other institutions, Dr. Harry Ostrer, along with other doctors, patients, and advocacy groups, sued Myriad and challenged the validity of their patents under 35 U.S.C. § 101.

The matter when reached the court, the following issue was analyzed by the court:

- Does sequencing of certain human genes, in isolated form as well as purified form, falls within the subject matter for which a patent may be allowed, or eligible under 35 U.S.C. § 101?

As a result the Federal Summary Court granted summary judgement to Dr. Ostrer, and other plaintiffs, that the subject matter protected by Myriad's patents were invalid as it covered the products of nature.

However, Myriad appealed the decision of the Federal Summary Court, which then reached the Court of Appeals who then observed the following:

- On Appeal, the Court of Appeals for the Federal circuit reversed the judgement, stating that except for isolated DNA, cDNA is patentable. The Supreme court considered the claims of patent granted to Myriad under 35 U.S.C.S. § 101, whether or not they were directed to laws of nature, natural phenomena, and abstract ideas which are not patentable.
- The Court stated that though Myriad found an important and useful gene, isolating the gene from the genetic environment does not constitute an invention, as the process of isolating the gene does not yield a patentable product, i.e., not a specific molecule with a certain chemical composition.
- Further, the Court stated that cDNA is not naturally occurring. In cDNA, the non-coding regions have been removed, to form a new creation. However, this statement was also challenged by petitioners, explaining that the sequence of nucleotides is dictated by nature, which was simply copied into an exons-only cDNA.
- The Supreme court disagreed with the arguments of the petitioners, clearly stated that though cDNA follows nucleotide sequence of the natural isolated DNA, but cDNA is a new creation, which is patentable.

Summarizing the case of Molecular Pathology v. Myriad Genetics, it can be illustrated by an example – If DNA is metaphorically understood as coal, and isolating the DNA may be understood as mining coal from a coal mine, the process of extracting coal from the coal mine can be subjected to patentability, but the coal cannot. However, processing the coal to form various products or substances which does not occur naturally, the products or substances can be subjected to patentability.

Analysis of Molecular Pathology v. Myriad Genetics, Inc, in view of Indian Patents Act 2007:

Further, Article 27.3 (b) of Trips Agreement, which states “*Members may also exclude from patentability... plants and animals other than micro-organisms, and essentially biological*

processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either “by patents or by an effective sui generis system or by any combination thereof.”

India, being a member of Trips Agreement, exercises the sub-sections (c), (i) of Section 3 of the Patents Act, 2007, which specifies that naturally occurring micro-organisms are non patentable.

- **Section 3(c) of the Patent Act, 1970**, states “*the mere discovery of a scientific principle or the formulation of an abstract theory [or discovery of any living thing or non-living substances occurring in nature]*” is deemed unpatentable.
- **Section 3(i) of the Patent Act, 1970**, states “*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 or that of their products*” is deemed unpatentable.

With reference to the subject matter for which Myriad already obtained a patent, the same would have attracted objection under Section 3(c) of the Indian Patents Act, 2007. The process of isolation of the DNA from the genetic environment of the human body which is already occurring in nature, and well-governed under the laws of nature, does not form a new gene. Therefore, such isolation does not produce any new molecule comprising any new chemical composition.

Also, the process devised by Myriad involved isolation of a naturally occurring DNA and a copying the isolated DNA to detect genetic mutation which results in cancer, therefore, such process may also be subjected to Section 3(i) of the Indian Patents Act, 2007. Detection of the mutation would also diagnose high risks for cancer is a detection process. Such diagnosis even if realized as an *in vitro* medical diagnosis process, is non-patentable under Section 3(c).

Therefore, based on the discussion above, the controversy of patenting of Human-genetics is still unclear, as Patent Offices worldwide are under the impression that the genetics are naturally occurring in nature, and no such matter is patentable unless a new gene or a new creation is exhibited.