Page 1573 - 1587 **DOI:** *https://doij.org/10.10000/IJLMH.112446*

INTERNATIONAL JOURNAL OF LAW MANAGEMENT & HUMANITIES

[ISSN 2581-5369]

Volume 4 | Issue 6

2021

© 2021 *International Journal of Law Management & Humanities*

Follow this and additional works at: https://www.ijlmh.com/
Under the aegis of VidhiAagaz – Inking Your Brain (https://www.vidhiaagaz.com/)

This Article is brought to you for "free" and "open access" by the International Journal of Law Management & Humanities at VidhiAagaz. It has been accepted for inclusion in International Journal of Law Management & Humanities after due review.

In case of **any suggestion or complaint**, please contact **Gyan@vidhiaagaz.com**.

To submit your Manuscript for Publication at **International Journal of Law Management & Humanities**, kindly email your Manuscript at **submission@ijlmh.com.**

Human Gene as a Non-patentability Subject Matter

LATIKA CHOUDHARY[1]

ABSTRACT

All living things have genes that act as their foundation. Characteristics such as the colour of the hair and eyes, the likelihood to contract cancer, etc. are all controlled by genes. Their omnipotence is, therefore, a given. Gene patents are highly sought after owing to the ability of companies to make the best use of this omnipotence. Keeping other requirements of being patentable aside, various cases have tested the eligibility of human genes to be treated as 'inventions' that are valuable enough to be protected by patents under 35 U.S.C. § 101. The Federal Circuit held Human genes to be patentable in the landmark case of Association for Molecular Pathology v. U.S. Patent and Trademark Office (the Myriad decision).

An approach based purely on structure has been chosen by the majority over the biological importance of the informational contents of the deoxyribonucleic acid (DNA) molecule. By holding that a DNA molecule, in isolation, is "markedly different from a natice DNA molecule, owing to slight differences in structure, the court has made an error in judgement. By doing so, the court has accidentally failed to acknowledge that both an isolated DNA molecule and the relevant portion of native DNA contain identical biological information due to their same sequence of nucleotides. The Federal Circuit 's approach reeks of bigotry. However, there exists an alternative, more comprehensive approach that perceives the structure of a DNA molecule by considering the two significant properties of DNA together.

By taking a totality-of-the-circumstances approach, this paper aims to analyse biological molecules under § 101 for both aspects, the structure and the information underlying in it. Germane precedents of patent law have been discussed and critically analysed in Part A. Part B digs deeper into the Federal Circuit's decision in the landmark Myriad Case. Part C explores the after effects of the recent Supreme Court judgement in Mayo Collaborative Services v. Prometheus Laboratories. Part D, lastly, solves the conundrum revolving around the eligibility of the human gene. Eyeing the issue through the lens of a totality-of-the-circumstances approach, this paper ultimately concludes that human genes are, in fact, not patentable.

[1] Author is an Assistant Professor at University of Petroleum and Energy Studies, Dehradun, India

© 2021. International Journal of Law Management & Humanities [ISSN 2581-5369]

I. PRECEDENTS ON PATENTABILITY OF GENES

Only when an invention fulfils the Title 35 requirements can it be said to be patentable.[2] § 101 envisages the eligibility criteria the subject matter must meet to be able to get patent protection. An invention ought to be a "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[3] The intent of the Congress behind bringing this statute in force was to allow broad interpretations of provisions so that "anything under the sun made by man" may fall within its ambit[4]. The court has enumerated that such a proposition is marred by three significant limitations. As per the court's observation, the inventor cannot accord patent protection to physical phenomena, abstract ideas or the laws of nature, etc.[5] "The concepts covered by these exceptions are 'part of the storehouse of knowledge of all men … free to all men and reserved exclusively to none.'"[6]

The Court, while interpreting such an exception in *Diamond v. Chakrabarty* was tasked with achieving the resolution of the issue of patentability of a man-made, genetically engineered bacterium.[7] Ultimately the Court held that these limitations must be extended to the bounties of nature.[8] A marked difference from what is found in nature due to the application of human imagination and creativity is a must to make the invention patentable. It must also have a distinctive name, character and usage.[9] By adding two plasmids with an oil degrading nature, the court thus concluded that Chakrabarty had ended up creating a new bacterium, which differed sufficiently different from the naturally occurring ones.[10]

A "markedly different" standard, as propounded by the Court in Diamond v Chakrabarty, owes its existence to the case of *Hartranft v. Wiegmann* where it was deliberated whether the ambit of an article of manufacture extends to a polished seashell.[11] After harvesting raw seashells, they were acid etched and then ground so that the interior, polished layer could be exposed.[12] The Court observed that even after undergoing changes, the seashells still had the same character, name and usage, akin to a shell picked up from the ground.[13] The polished shells had

[2] 35 U.S.C. § 101 (2006).
[3] *Id.*
[4] 9 S. Rep. No. 82-1979 5 (1952).
[5] Diamond v. Chakrabarty, (1980) 447 U.S. 303, 309.
[6] Bilski v. Kappos, (2010) 130 S. Ct. 3218, 3225; see Funk Bros. Seed Co. v. Kalo Inoculant Co., (1948) 333 U.S. 127, 130.
[7] 447 U.S. 305.
[8] H. R. Rep. No. 1129 7 (1930); S. Rep. No. 315 6 (1930).
[9] Diamond, *supra* note 10, at 309-10 (quoting Hartranft v. Wiegmann, 121 U.S. 609, 615 (1887)).
[10] *Id.*, at 310.
[11] Hartranft, 121 U.S. 613.
[12] *Id.*, at 611.
[13] *Id.*, at 615.

© 2021. International Journal of Law Management & Humanities [ISSN 2581-5369]

not, therefore, become a distinct article of manufacture.[14]

The inoculant created in *Funk Brothers Seed Co. v. Kalo Inoculant* is corresponding to the seashells in Hartranft,[15] The Court, in Funk Brothers, was tasked with determining whether a patent for an inoculant which contained varying species of bacteria that were not mutually inhibiting in nature would be valid.[16] The bacteria housed in the inoculant were exactly similar to the naturally occurring ones and therefore, the patent claimed these properties, relying on the fact that the desirable properties of each other are not inhibited upon combination.[17] Thus, the Court found that the invention in question could not be patented as it seeks to claim the laws of nature.[18] With this precedent as the backdrop, the Federal Circuit set out to determine whether human genes can be said to be patentable subject matter.

II. THE PATENTABLE SUBJECT-MATTER IN MYRAID CASE

In 2009, the controversy was birthed when the Association for Molecular Pathology[19] instituted a declaratory judgment action against Myriad Genetics, the University of Utah Research Foundation, and the U.S. Patent and Trademark Office (collectively "Myriad"). They alleged that fifteen claims, comprising of seven patents, were for non-patentable subject matter and therefore, invalid;[20] challenging the validity of claims 1, 2, 5, 7, and 20 of U.S. Patent 5,747,282, claims 1, 6, and 7 of U.S. Patent 5,837,492, claim 1 of U.S. Patent 5,693,472, claim 1 of U.S. Patent 5,709,999, claim 1 of U.S. Patent 5,710,001, claim 1 of U.S. Patent 5,753,441, and claims 1 and 2 of U.S. Patent 6,033,857. The impugned patents spanned over segments of isolated DNA and cDNA[21] from the BRCA1 and BRCA2 genes along with the methods employed for analysing or comparing different segments of isolated DNA with the presence of mutations.[22] The BRCA1 and BRCA2 enable the repair of DNA breaks by virtue of encoding gene proteins.[23]

Certain mutations in these genes correspond to the susceptibility to breast and ovarian cancer, as per studies.[24] The district court understood the significance of the case and therefore stated

[14] *Id.*
[15] Funk Bros. Seed Co., *supra* note 11.
[16] *Id.*, at 128.
[17] *Id.*, at 131.
[18] *Id.*, at 132.
[19] *Id.*
[20] *Id.*, at 184.
[21] Isolated DNA is a nucleotide segment removed from the chromosome and separated from the extraneous cellular components.
[22] Myriad II, *supra* note 3.
[23] Kiyotsugu Yoshida and Yoshio Miki, 'Role of BRCA1 and BRCA2 as Regulators of DNA Repair, Transcription, and Cell Cycle in response to DNA Damage', (2004) 95 Cancer Sci. 866, 866-68.
[24] Myriad II, *supra* note 3, 1339.

the issue in a concise manner: "[a]re isolated human genes . . . patentable?"[25] The district ultimately concluded that human genes cannot be patented under § 101 as DNA enumerates the physical manifestation of biological information and therefore falls within the bounds of the law of nature exception to § 101.[26] Aggrieved by this holding, Myriad preferred an appeal to the Federal Circuit.[27]

III. JUDGEMENT

Majority Opinion

The court meticulously examined the patentability of all these types of DNA and decided upon the fates of genomic DNA and cDNA which is a synthetic DNA, manufactured by humans in a laboratory). The court found the naturally occurring nature of native DNA to be the factor that distinguishes it from genomic and cDNA. The court opined that native DNA is not a product of human ingenuity or modification and is therefore not a subject matter that is eligible to be patented under § 101[28] while cDNA was held to be patentable.[29] The granting of patent to cDNA was substantiated by stressing that its creation arises from an extensive array of human intervention and modification and is therefore, quintessentially made by man[30] and must be accorded patent protection under § 101.[31]

Conversely, the determination of the patent eligibility of isolated genomic DNA sequences needs intricate analysis. The court examined isolated DNA from a chemical perspective, rather than a biological one and compared it to its native counterpart.[32] By way of the chemical perspective, the variation in DNA structure was compared while the differences in the information content characteristic from a biological perspective were overlooked.[33] Judge Lourie, during an observation of the structural nature of chromosomal DNA, noted that the chromosomes which contained the BRCA1 and BRCA2 genes are almost eighty million and one hundred fourteen million nucleotides in length, respectively.[34] Actual genes exist as fragments inside astronomically large strands of DNA which comprise each chromosome.[35] In

[25] Myriad I, 702 F. Supp. 2d 185.
[26] *Id.*
[27] Myriad II, *supra* note 3, 1333.
[28] *Id.*, at 1351.
[29] *Id.*, at 1350.
[30] *Id.*, at 1338-39.
[31] *Id.*, at 1350.
[32] *Id.*, at 1351-53.
[33] *Id.*
[34] *Id.*, at 1351-52.
[35] BRCA2 is one of 720 genes composing the 115M BP of Chromosome 13, and BRCA1 is just one of the 1773 genes on the 81M BP Chromosome 17. NCBI Map Viewer, Chromosome 13, Nat'l Centre for Biotechnology Info., http://www.ncbi.nlm.nih.gov/mapview/maps.cgi?ORG=humandMAPS=ideogr,est,locandLI NKS=ONand

the creation of isolated DNAs when the BRCA1 and BRCA2 genes are removed, they are approximately 7,000 and 11,000 base pairs in length, respectively.[36]

It was found by the court that the extensive modification that the chemical structure of the genomic DNA undergoes makes the structure of the isolated DNA substantially varied from that of native DNA.[37] For gauging the differences from the native form, the change in physical structure of the molecule and not the information that is conveyed is the correct metric, the court opined.[38] Judge Lourie thereby came to the conclusion that the breakage of chemical bonds during the creation of isolated DNA is structural change that is sufficient to justify the eligibility of patent.[39]

Minority Opinion

The minority Judge opined that isolated DNA cannot be said to be patentable subject matter because it does not have any material difference native genes.[40] While addressing the changes that take place during the creation of isolated DNA, the judge observed that the majority had placed undue emphasis on the breakage of the chemical change.[41] Chemical bonds undergo regular breakage through a vast myriad of processes, for instance, during the cutting and cleaning of diamonds or while the element is being isolated.[42] Similarly, regular breaking and reforming of the chemical bonds that hold the DNA molecule together is a common phenomenon in genetics.[43] The sheer routineness of the breaking of such bonds therefore makes it too arbitrary a method to determine the patentability of DNA, especially keeping in mind that the method has encountered express rejections in the past.[44]

Isolated DNA also warrants consideration in the same manner. Genomic DNA is a product of nature. Breaking off a small segment may lead to the developing of some new utility, it however, cannot be said to change the fact that the particular segment was created by nature. Judge Bryson, therefore, held DNA sequences which have been isolated from genomic DNA to be non-patentable.[45]

VEOSE=ONandCHR=13
[36] Myriad II, *supra* note 3, 1351-52.
[37] *Id.*, at 1352.
[38] *Id.*, at 1353.
[39] *Id.*, at 1352-53.
[40] *Id.*, at 1373-75 (Bryson, J., dissenting).
[41] *Id.*, at 1376.
[42] *Id.*, at 1375-77.
[43] Robert F. Weaver, Molecular Biology 658 (4th edn. 2008).
[44] Myriad II, *supra* note 3, 1376 (Bryson, J., dissenting).
[45] *Id.*, at 1377.

© 2021. International Journal of Law Management & Humanities [ISSN 2581-5369]

IV. THE EFFECT OF CASE OF MAYO V. PROMETHEUS LABORATORIES

In the case of Mayo Collaborative Services v. Prometheus Laboratories, Inc., the Federal Circuit court assumed the responsibility of reconsidering its earlier stance that isolated human DNA can be eligible to receive patent protection.[46] While the Mayo decision was centred around processes that claim the laws of nature, even the, the Court's reasoning provides noteworthy insights in the realm of patentability of claimed inventions that mimic the laws of nature and § 101.[47] The Court, while rejecting the unimportant or fruitless measures behind the direct application of a law of nature, fortified the notion that in order to be patentable, a substantial human innovation must have taken place.[48] Prometheus' patents claimed subject matter that was ineligible to be patented.[49] The patents under consideration claim methods for improving the therapeutic efficacy of the treatment of certain diseases of an autoimmune nature.[50]

The claimed methods aimed at recreating the natural process of dispensing a drug and the physiological effects that follow.[51] The Court held that since such processes result from a direct application of the laws of nature, they cannot be patentable.[52] The claimed processes had been drafted in a way to include a transformative step beyond the law of nature in order to preclude a § 101 rejection,.[53] While such redundant measures would have been successful in obviating a § 101 rejection in accordance with Bilski's machine or transformation test, the Court propounded that it was not making any new additions that were not already a part of the laws of nature.[54] Hence, the Court held patentability cannot be imparted upon the laws of nature, even when the addition of these well-understood, routine, conventional measures are undertaken.[55]

While establishing this opinion, the Court revisited one of the basic patent principles i.e. patents should be such that they promote scientific innovation.[56] Thus, while examining patent claims involving laws of nature, courts must be mindful that the scope of such claims is not so broad

[46] Ass'n for Molecular Pathology v. Myriad Genetics, No. (2012) 11-725 WL 1 (vacating the judgment and remanding to the Federal Circuit for reconsideration).
[47] Mayo Collaborative Services v. Prometheus Labs, Inc., (2012) 132 S. Ct. 1289, 1294.
[48] *Id.*, at 1297.
[49] *Id.*, at 1305.
[50] *Id.*, at 1295.
[51] *Id.*, at 1296.
[52] *Id.*, at 1294.
[53] *Id.*
[54] *Id.*, at 1298.
[55] *Id.*
[56] U.S. Const., Art.1, § 8, cl. 8 ("To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.").

that it ties up with prospective use of the laws of nature in an improper way.[57] Restricting future research on the law of nature would put embarkments upon one of the basic tools of scientific and technological work and would thereby, directly contradict a fundamental goal of patent law.[58]

The striking similarities between the Prometheus and Myriad patents, involving a law of nature and then a redundant step, must be appreciated by the Federal Court when it revisits the patent eligibility of Myriad's isolated DNA claims. Akin to the relationship between the quantity of a drug and its effect, human gene is also bound by the laws of nature.[59] Therefore, the step of isolating the gene from the chromosomal DNA is an additional step that must be analysed like the "administering," "wherein," and "determining" measures of the Prometheus patents.

The step of DNA isolation is in no way a new procedure, it is corresponding to the laws of nature and therefore, there lies no merit in patenting it. For a law of nature to become patentable subject matter, there need to be subsequent steps that go above and beyond the conventional, obvious, routine, or insignificant.[60] The isolation from genomic DNA does not lead to a deviation or variation from the laws of nature which the isolated gene embody, just like the Prometheus patent.[61] Conversely, it is one of molecular biology's many universally known rules: identical to the kind of routine, conventional, well understood activity which has already been in use in the scientific community which was found to be insufficient to change the eligibility of a patent in Prometheus. [62] The claims aimed at the isolation of BRCA1 and BRCA2 genes is simply an attempt at monopolizing the market in laws of nature embodied in the genes. Hence, it can be concluded that claims towards isolated DNA must not be held to be patentable subject matter.

V. PATENTABILITY OF HUMAN GENES

The eligibility of patent protection does not extend to human genes which are found as isolated DNA. The Federal Circuit's *Myriad* holding was vacated by the Supreme Court after the majority had erroneously placed sole reliance upon a chemical perspective pertaining to variations in the structure of DNA while the differences between native and isolated DNA were being examined. The Federal Circuit, on the other hand, should have delved into an

[57] Mayo Collaborative Services, *supra* note 52, 1301.
[58] Mayo Collaborative Services, *supra* note 52.
[59] *Id.*, at 1296.
[60] *Id.*, at 1298.
[61] *Id.*
[62] Dennis Crouch, 'Mayo v. Prometheus: Natural Process + Known Elements = Normally No Patent', Patent L.Y.O., http://www.patentlyo.com/patent/2012/03/mayo-v-prometheus-natural-process-known-elements-normally-no-patent.html.

examination of not only the structure, but also the information, while examining the eligibility of DNA to receive patent protection. The biggest fallacy of the chemical perspective is that it overlook the importance of the information contained inside the DNA and a gene, in particular. When viewed from a biological perspective, it is clear that a fragment of isolated DNA resembles native DNA and therefore, does not meet the markedly different standard promulgated by the court. The Federal Circuit should, when rehearing the issue on remand and examining the patentability of biological molecules, touch upon both structure and information of the DNA.

Significance of information content of DNA:

The archetype of life is formed by DNA.[63] By virtue of the information contained within, it enables the entire formation of a human being. A DNA molecule is made up of a series of nucleotides which are enjoined in a chain by way of a phosphate group and is therefore, not variegated in itself.[64] A deoxyribose sugar and one of four nitrogenous bases: adenine ("A"), thymine ("T"), cytosine ("C"), or guanine ("G") is contained in each nucleoside.[65] The structure of a DNA molecule is that of a right-handed helix simply comprised of repetitive nucleotide segments made of a nitrogenous base, the deoxyribose sugar, and the phosphate group.[66] DNA molecules are found in the form of a double stranded nucleus, or a hydrogen which is bonded to a complementing fragment of DNA, and is wounded around histone proteins in the chromatin.[67] The main function of the histone is that it contains a huge volume of DNA to enable it to fit within the nucleus.[68] It merely holds the exterior of the DNA molecule together and in no way does it alter the DNA or its structure.

Even though the structure of the DNA is of utmost importance to its function, the information housed within the nucleotide sequence-the order of the A, T, C, and Gs is what renders DNA indispensable to the organism. A protein is produced during translation using a copied sequence after the organism activates a gene by reading and copying the nucleotide sequence when the transcription process is on. A copy of the activated gene out of the RNA is made by the cell's machinery, during transcription. Subsequently, the RNA structure undergoes modification, along with the removal of introns, which leads to the creation mRNA. Three base segments of the mRNA, also called codons, are 'read' in such a way during translation that a particular

[63] Robert Aronson and Jacqueline McMurtie, 'The Use and Misuse of High-Tech Evidence by Prosecutors: Ethical and Evidentiary Issues', (2007) 76 Fordham L. Rev. 1453, 1469.
[64] J. D. Watson and F. H. C. Crick, 'Molecular Structure of Nucleic Acids', (1953) 171 Nature 737, 737-38.
[65] *Id.*
[66] *Id.*
[67] Tony Kouzarides, 'Chromatin Modifications and their Function', (2007) 128 Cell 693.
[68] *Id.*

© 2021. International Journal of Law Management & Humanities [ISSN 2581-5369]

amino acid gets subsumed within the nascent protein, due to the sequence of the nucleotides in the specific codon. Later, the protein gets assimilated into the performance of one of the many human processes. Therefore, as the DNA provides a blueprint for the formation of proteins in the cells, the information found within a DNA molecule is a notable facet that cannot be neglected.

Unlike around histones, transcription does not take place when the gene exists in the double stranded form. The histone proteins move away and bifurcate with the assistance of the cell machinery, to motivate the gene for transcription and the strands of DNA separate into the transcription bubble. It can therefore be concluded that during the time when the information within a DNA molecule is actually accessible, the gene exists in a strikingly similar condition to an isolated, single stranded DNA that is not bound to a protein.

a) CHEMICAL AGAINST BIOLOGICAL PERSPECTIVE: A chemical or biological perspective are two lenses through which the subject matter can be scrutinised vis-à-vis the eligibility to receive patent protection. The chemical perspective revolves around taking a stringent view at the structure of the molecules that construct DNA.[69] It singles out the structural characteristics of a DNA molecule, the set up of the backbone and nucleotides and other alterations made by humans. While incorporating this perspective, Judge Lourie, on behalf of the majority, had held that the mere breakage of the backbone of DNA and its double stranded structure becoming unzipped adds up to a change in the genomic DNA that is markedly different.[70] The examination of just the skeletal structure, while completely overlooking the information it contains is an error that ignores one of the most fundamental properties of DNA.

On the other hand, the biological perspective gives due importance to the information held by the gene. It looks at both the structure and the information content by putting them on an equal footing. Due to this information that has the capability of creating entire living organism, DNA is touted to be the blueprint of life. The role of the structure, even though significant, comes second to the importance of the biological content that inherently determines the informational content of the biological perspective. Greater significance is accorded to the sequence of genes, or the order in which nucleotides are arranged in each gene. No alteration in the chromosomal structure can be said to amount to a change in the information held by each gene. The genetic sequence and information in the isolated DNA, even though unchanged, fails the test of a

[69] Myriad II, *supra* note 3, 1356.
[70] 'Biography of Alan D. Lourie', http://www.cafc.uscourts.gov/judges/alan-d-lourie-circuit-judge.html.

markedly different standard upon being compared to the genomic DNA's information and sequence.

To understand the importance of the biological perspective that supersedes the chemical one, a book can be taken to be a fitting analogy. The portrayal of information by an author, contained in a book makes it copyrightable.[71] This can be attributed to two factors; the structure i.e. the cover, method of binding or even the number of pages does not affix the book's societal value. It is the representation of the information contained in the book, through the imaginativeness of the author that makes it worthy enough to be used and copyrighted.[72] Henceforth, a person would be held to be an infringer if they decide to copy the contents of the book.[73] The infringer did not engage in the alteration of contents in any chapters but merely took a part already found in the book and tried to pass it off as her own creation. The chapter may then have a markedly different structure, but its informational content is identical to what previously existed in the book. The infringer's want of gaining a new copyright on that content would get defeated due to the prior existence of content, even though the infringer's rendition may be entirely structurally different, proving the fact that the books value lies in its contents and not in the way it is structured.[74]

Let us now apply this analogy to the law of patents and considering genomic DNA to be the book from which isolated DNA, i.e. the chapter has been copied. Much like a book which is a collection of different chapters, native DNA can be said to be a repository of multiple genes contained in one DNA strand. Similarly, the largest portion of isolated DNA may at maximum hold a single gene and it is therefore like a chapter.[75] What makes the DNA noteworthy for both the human body and for commercial purposes is the information it contains and not the structure that shapes it. If an attempt is made to decide upon the eligibility of DNA to be patented only based on what its structure is like, it would amount to according copyrights to books basis their physical appearance and structure. The information contained in the isolated DNA in this case is in no way markedly different from the informational content of a similar fragment of the genomic DNA, akin to how information contained in the chapter taken by the infringer is not markedly different from the original text from the pen of the author. They are, in contrast, absolutely identical. Therefore, it can be concluded that just like simply removing a chapter from a book and publishing it would not render it worthy of a copyright, similarly,

[71] Feist Publications, Inc. v. Rural Telephone Services Co., (1991) 499 U.S. 340, 348.
[72] *Id.*
[73] 17 U.S.C., § 501(a) (2006).
[74] *Id.*
[75] Myriad II, *supra* note 3, 1338.

the mere isolation of a specific portion of DNA does not make it patentable.

b) **NON- PATENTABILITY OF ISOLATED DNA:** A totality-of-the-circumstances approach should be preferred by courts while examining the patentability of DNA, considering both, its structural as well as informational content. Such approaches have been held to be mutually exclusive from each other by the District Court for the Southern District of New York and the Federal Circuit. In a historic move, the Supreme Court however disapproved of this water tight application of a unitary test.[76]

The Court, in the case of *KSR International v. Teleflex Inc.*, Court disallowed the exclusive incorporation of the "teaching, suggestion, or motivation test" when hearing issues of obviousness under § 103.[77] In the case of *Bilski v. Kappos* the Supreme Court utilised a similar approach during a hearing to determine the eligibility of patent protection to be granted to processes under § 101, and observed that the "machine-or transformation test" cannot be the only criteria employed to test patentability.[78] The aforesaid cases are a befitting example that demonstrate the Court's penchant for disallowing application of such narrow rules in the law of patents. The lower courts were acting based on such constriction while the district court was solely focused on information and the Federal Circuit restricted itself to the structure.[79] The only way to fittingly acknowledge the significance of a nucleotide sequence is to appreciate not just the structure, but the information contained within as well.

By applying the "markedly different" standard, it becomes explicit that no vast difference lies between isolated genomic data and genomic data to make it eligible for patent protection. Analysis based on both the biological and chemical perspectives makes it clear that there is extreme likeness between the structure and information contained in the isolated DNA and the genomic DNA. The breaking away of four covalent bonds leads to the reproduction of DNA, however, this change is extremely minor to be able to cover come the identical nature of both molecules and to consider them to be markedly different.

i) Duplication of Information Content: Upon examination, it becomes clear that the information found within isolated DNA is not markedly different from the information found within genomic DNA. In its nucleotide sequence, DNA consolidates all its information and it is the sequence that controls the production of a particular protein. Therefore, in order for the information contained within the DNA to be markedly different, it is imperative that the

[76] KSR International Co. v. Teleflex, Inc., (2007) 550 U.S. 398; Bilski v. Kappos, *supra* note 11.
[77] 550 U.S. 407, 415.
[78] Bilski, *supra* note 11, at 3231.
[79] Myriad I, *supra* note 30; Myriad II, *supra* note 3, 1351-52.

isolated DNA sequence contains a code for a protein which significantly varies from the one present in nature.

The protein formed from the transcription of the gene in isloated genomic DNA resembles the protein synthesised during the transcription of native DNA, owing to the characteristics of isolated genomic DNA. Removing an entire gene, or a specific sequence of genomic DNA from the components of its cells, gives rise to isolated DNA.[80] This isolated fragment of DNA was as much a creation of nature as native DNA, with an identical sequence, introns and promoters.[81] Therefore, by way of containing the identity of the sequence of native DNA, the information contained in the isolated DNA is the same.

Under 282 Patent where Claim 1 covers all isolated DNAs that encode for the BRCA1 protein, such an exposition can be found[82] The sequence reveals the nucleotide, but has left the specificities of the sequence ambiguous. The informational content stored inside the isolated DNA owes its existence to millions of years of evolutionary changes and not to the ingenuity of mankind. Therefore, it becomes clear that the informational content contained in an isolated BRCA1 DNA is not in any case markedly different from its genomic counterpart, and is not patent eligible subject matter by virtue of the reasoning employed in *Chakrabarty.*

ii) Where Structure is Different: Noteworthy structural changes in the DNA whose information content is being judged can enable it to qualify as a subject matter eligible to be patented. The formation of synthetic DNA such as cDNA, for example, is made up of a structure which is notably different from what occurs naturally and it is, therefore, patentable. The isolation technique employed in genomic DNA, however, does not create a "new … composition of matter" which has been mandated to be a necessary condition under § 101. The isolated DNA, in fact, is comprised of exactly identical nucleotides, placed exactly in the same sequence as found *in vivo* in the genomic DNA. Isolation is done via a technique which is referred to as the "removal from its naturally occurring environment."[83] Thus, by way of isolation, removal of an already existing part of the cell takes place, rather than any sequence undergoing alteration.

In the claims of the '282 patent, such facet is clearly depicted. Isolated DNA coding for the BRCA1 protein is enumerated under Claim I.[84]A reading of the claims of the patent, subject to specifications, makes it clear that the isolated DNA being claimed consists of a fragment of

[80] U.S. Patent No. 5,747,282 Col. 19.
[81] *Id.*, at Col. 19.
[82] *Id.*, at Col. 153.
[83] *Id.*, at Col. 19.
[84] *Id.*, at Col. 153.

© 2021. International Journal of Law Management & Humanities [ISSN 2581-5369]

the genomic DNA which was isolated from the coding of cellular proteins for BRCA1. The total length of an isolated genomic DNA piece, inclusive of the promoter and introns is revealed as being 24,026 base pairs long. The sequence that is disclosed is even inclusive of several unknown sequence regions, which is denoted by repetitive 'v's in the patent. This is what leads to the identical structures of both the claimed isolated DNA and the genomic DNA.

One minor difference stands out, even though the structures are similar. The segment becomes isolated due to the sundering of four covalent bonds into the DNA backbone.[85] As per Judge Laurie, it is this bifurcation of the four bonds that leads to the creation of a "markedly different" molecule.[86] Such a conclusion can be termed to be erroneous when viewed in tandem with the roots of the markedly different standard. The Supreme Court's judgements in *Chakrabarty* and *Hartranft* birthed the markedly different test used by the Federal Circuit.[87] This standard was created in *Hartranft* and used to determine whether physical changes undergone by a seashell are sufficient enough to render it to be a manufactured object, rather than a natural one.[88] The Court ultimately held that the acid etching which leads to breaking away of layers of shell is not substantial enough to fulfil the markedly different criteria as inherently, it is still a shell.[89] Similarly, the breakage of four covalent bonds in an isolated DNA is insignificant since it amounts to the breaking of only four bonds out of the many thousand that are present within the molecule. The extent to which it gets modified is lesser than the removal of layers of shell by acid etching in *Hartranft*. Therefore, the breakage of these covalent bonds cannot be said to formulate a "markedly different" DNA molecule.

a) WHETHER cDNA IS A PATENTABLE SUBJECT-MATTER: The informational identity of the DNA molecule that is complementary in nature gets eclipsed by the major structural changes to the molecule, justifying its patenting under § 101. This complementary DNA is, in fact, a type of fake DNA that gets manufactured in accordance with the messenger RNA transcript of a gene which has become mature. Following transcription, the mature messenger RNA undergoes considerable alterations, the most notable of which is the excision of introns, which is capable of deleting thousands of nucleotides.[90] The BRCA1 gene, for example, due to it splicing, becomes shorter, from 80,000 nucleotides in genomic form to just 7,000 nucleotides

[85] Myriad II, *supra* note 3, 1351.
[86] *Id.*, at 1352.
[87] Diamond v. Chakrabarty, *supra* note 10; Hartranft v. Wiegmann, (1887) 121 U.S. 609.
[88] *Id.*
[89] *Id.*, at 615.
[90] Excision of the introns shortens the BRCA1 gene from 81,188 nucleotides in length to 7,224 nucleotides. See e.g. Homo Sapiens Breach Cancer 1, Early Onset (BRCA1), Transcript Variant 1, mRNA, NIH NCBI Genbank, http://www.ncbi.nlm.nih.gov/nuccore/NM_007294.3.

© 2021. International Journal of Law Management & Humanities [ISSN 2581-5369]

found in the messenger RNA .[91] Subsequently, scientists employ the reverse transcript on this messenger RNA and formulate an artificial, man-made DNA molecule, which is made up of coding exons that otherwise do not occur naturally.[92]

Complementary DNA becomes subject matter that is patentable, when viewed using the totality of the circumstances approach. Even though complementary DNA codes consist of identical protein as is found in humans, its artificial nature and the significant changes in structure it undergoes make it markedly different, varying from any other thing that may be found in humans. As enumerated above, the importance in the information content found inside a DNA needs notable alterations in structure that a native DNA must undergo, to make its patenting permissible. While isolated DNA is one which is found in and taken from naturally occurring genomic DNA, complementary DNA is artificially manufactured by humans in a laboratory. It necessitates the isolation of the target messenger RNA to be reproduced, as well as the hybridization of a polythiamine primer to the polyadenine tail to aid the synthesis enzyme's binding. The resultant is therefore a DNA molecule that is found existing with no introns, which makes it different from the DNA sequence which is corresponding in a human body[93] The coupling of its artificial nature and an altered sequence leads to substantial modifications which show their effect in the structure of the complementary DNA to conquer the information identity and make it subject matter that is eligible to be patented.

VI. CONCLUSION

The relevance of the question of whether human genes are patentable is readily lost in the results of eukaryotic genetics.. Each legal mind considering the question has come to a different conclusion due to the relevance of each element of DNA. The dissenting opinions in the district court and Federal Circuit has upheld and celebrated the superior nature of the information content found inside a DNA. The significance of the structural changes is stressed upon by the majority and concurrence in the Federal Circuit. However, disregarding either the structure or the information diminishes the significance of these basic qualities .The totality-of-the-circumstances approach compares both information and structure so as to establish the "markedly different" properties of the whole molecule and not just whether one property varies from the other. Keeping such analysis in mind, it can be concluded that an isolated genomic DNA is not eligible to become patent subject matter owing to the minor nature of structural changes undergone when considered against the exactly same information content because of

[91] *Id.*
[92] Sam Brook and Russell, Molecular Cloning: A Laboratory Manual §§ 11.1-11.19 (3rd edn. 2001).
[93] Myriad II, *supra* note 3, 1339.

the drastic man-made changes of the molecule's structure, complementary DNA is patentable subject matter in light of the molecules identical information content.

*****

© 2021. International Journal of Law Management & Humanities [ISSN 2581-5369]