The ruling, besides paving the way for easing the accessibility and availability of drugs in India, affirms and upholds the patent regime in India, thereby protecting genuine innovators in India. The impact of the judgment on other Global Pharmaceutical Companies is yet to be seen, needless to say that they would be considerably more cautious in their approach, keeping in mind the depth of the judgment in the present case. Needless to say, the repercussions of the judgment, if any, shall not be too damaging to the Indian economy, as one with the backing of a population exceeding Two Billion, shall always remain a beguiling market, which will almost impossible for Pharmaceutical corporations to overlook.

PATENTABLE SUBJECT MATTER IN THE US AFTER *MAYO V. PROMETHEUS*, 566 U. S. ____ (2012)

- **Avani Verma**[332]

Abstract

Patentable subject matter has always been a matter of debate in intellectual property laws of various countries. Especially, in the United States, this topic has become a subject of much importance due to a catena of incoherent judgments. A recent judgment in MAYO V. PROMETHEUS, 566 U. S. ____ (2012) ("Mayo"), involving a challenge to a patent dealing with a method of optimizing therapeutic efficacy for the treatment of gastrointestinal disorder, has joined the series of previous judgments. The judgment, inter alia, discussed the patentability of claims involving laws of nature, physical phenomena, abstract ideas and the applicability of the Machine or Transformation test. This judgment has been criticized as being overly broad as the effect of the judgment entails that it would invalidate almost all method claims. On the other hand, it is applauded as incentivizing research in the pharmaceutical industries. This comment discusses the position in relation to "patentable subject matter" before Mayo and the effects on the position of the U.S. courts on "patentable subject

[332] Student, 5th Year, B.A LL.B (Hons.) National Law Institute University, Bhopal

matter" after the judgment in Mayo. In the subsequent parts, it evaluates the merits and adverse effects of the Mayo judgment. In the conclusion, it is argued that the judgment has firstly read the Patent Statute erroneously, and secondly failed to clarify the patent- eligibility requirements of process claims in the USA.

1. INTRODUCTION

'Anything under the Sun that is made by man' is patentable. This much discussed phrase was a part of the testimony on the Patent Act of 1952 of the USA, the provisions of which, remain mostly effective to this

day, as they were during the time of their enactment. However, the American judiciary has created certain exceptions and qualifiers to this statement. To enumerate one of the qualifiers –namely in relation to laws of nature, physical phenomena and abstract ideas, has recently been reiterated in the case of *Mayo Collaborative Services, Dba Mayo Medical Laboratories, Et Al* v. *Prometheus Laboratories, Inc.*[333]

Since, the Patent Statute(s)in the United States[334] does not provide for a list of patentable subject matter, it was expected that the decision in *Mayo* would distinguish between patentable and non-patentable subject matter. However, it was disappointing when the US Supreme Court failed in making fundamental clarifications on the subject of patentability.

This article analyses the *Mayo* case in order to show that the judgment was at best a step backward in defining the patent eligibility of an invention. An attempt would be made to prove that the Mayo case merely reiterated the previously laid down equivocal criteria for determining the patent eligibility of an invention. The US judiciary has lost the much awaited opportunity of drawing a boundary line between patentable and non-patentable subject matter, leaving the inventors and researchers in the state of perplexity as before.

2. POSITION BEFORE MAYO

Before the *Mayo* case was decided, the issue of patentable subject matter was discussed in a series of cases. In *Gottschalk v. Benson*[335], the US Supreme Court recognized that if a process claim is as abstract and sweeping as to cover both known and unknown uses of the natural law, abstract idea, or physical phenomenon, then it could not be patented. Further, the 'transformation and reduction of an article "to a different thing" is the clue to the patentability of a process claim that

[333]*Mayo Collaborative Services, Dba Mayo Medical Laboratories, Et Al. v. Prometheus Laboratories, Inc.,* 566 U. S. ____ (2012) [hereinafter Mayo]
[334]U.S. Patent Law, 35 U.S.C. §§ 1 etseq (2006) [hereinafter, US Patent Law].
[335]*Gottschalk v. Benson*, 409 U.S. 63 (1972).

does not include particular machines.'[336]Here, the Court interpreted the Machine or Transformation (MoT) test, which states that for an invention to become eligible for a grant of a patent, must be either (i) tied to a particular machine or apparatus, or (ii) transform a particular article into a different state or thing.[337] Thereafter, in *Parker v. Flook,* [338] the US Supreme Court further observed that if a concept limits an abstract idea to one field of use or adds token post-solution components, it is not patentable. However, in a subsequent decision of, *Diamond v. Diehr*[339], the Supreme Court clarified that even if the claims contain mathematical formulae/abstract ideas/natural laws, but as a whole the claim presents a valid application of a natural phenomenon or abstract idea, then the invention may be patentable. At the same time it has to be checked that the 'inventive concept cannot derive solely from the fundamental principle'[340]. In simpler words, an inquiry is to be made to make sure that the application does not seek protection on the natural phenomenon or abstract idea.

The MoT test was used by the Federal Circuit in *In Re Bilski*[341] as 'a definitive test' for patentability. In this case, the Federal Circuit denied protection to an algorithm as it was not a 'process' but an abstract idea, and therefore non-patentable. The Court held that granting a patent 'would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself'[342]. When the same matter went to the Supreme Court,[343] it reaffirmed the Federal Circuit's decision and reiterated that Natural Law, physical phenomena and abstract ideas have categorically been excluded from the purview of being patentable subject matter. They have to be treated as a part of prior art, which is already known. Until this point, the question as to

[336]*Ibid,* at 71-72.
[337] *Ibid.*
[338] *Parker v. Flook*, 437 U.S. 584 (1978) [hereinafter, Parker].
[339]*Diamond v. Diehr*, 450 U.S. 175 (1981) [hereinafter, Diamond].
[340]*Ibid.*
[341]*In Re Bilski*, 545 F.3d 943.
[342]*Ibid.* slip op., at 10.
[343]*Bilski Et Al. v. Kappos, Under Secretary of Commerce for Intellectual Property and Director, Patent and Trademark Office*, 561 U. S. ____ (2010) [hereinafter, Bilski].

whether diagnostic methods appropriately constitute patentable subject matter remained uncertain. At one point the Court's decision in Bilski suggests that 'advanced diagnostic medicine techniques' might be patented. On the other hand, the Court confirmed that 'laws of nature' could not be patented and explained that broadly preemptive claims were likely non-patentable.

3. MAYO CASE: FACTS, ISSUES AND JUDGMENT

In *Mayo*, Prometheus Laboratories Inc. obtained a patent on steps of testing the proper dosages of drug treatments used to treat gastrointestinal diseases like Crohn's disease, and later sued Mayo Clinic for attempting to use similar test.[344] A federal judge invalidated the patents, holding that the patent couldn't cover the body's reaction to drugs. [345] The Federal Circuit observed that in addition to these natural correlations, the claimed processes also contain the steps of administering and determining. 'The patents satisfied the Circuit's "Machine or Transformation Test", which the court thought sufficient to "confine the patent monopoly within rather definite bounds", thereby bringing the claims into compliance with Section 101.[346] Therefore, the Federal Circuit overturned the District Court's decision, which was in favour of Mayo. On appeal, the Supreme Court remanded back the case to Federal Court to reconsider it in the light of *Bilski*. [347] The Federal Circuit reaffirmed its previous decision saying that the machine or transformation is an important clue to decide patentability. [348] An appeal was then again made to the Supreme Court.[349]

[344] *Mayo*, Supra note 333, op., at 5-6.
[345] *Ibid,*
[346] *Ibid*, at 7.
[347] *Ibid.*
[348] *Ibid.*
[349] *Ibid,* at 8.

In this landmark judgment delivered on 20th March 2012, by Justice Breyer for the unanimous opinion, the US Supreme Court held that the Prometheus invention identifying 'relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove [either] ineffective or cause harm' is not patentable. [350]

Claim 1 of the Prometheus, U.S. Patent No. 6,355,623, read as 'A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder'[351], was comprised of three steps. The first step involved 'administering' a drug to a subject having said disorder. The second step involved 'determination' of the level of the drug in that subject, and thereafter, the third 'wherein' step involved describing the metabolite concentrations at which there is a likelihood of harmful side-effects or ineffectiveness, and informing the doctor of that metabolite concentrations. [352]

The claim certainly had steps in addition to the law of nature; 'administering' the thiopurine drug, 'determining' the level of the relevant metabolites, and 'wherein' the drug dosage should be adjusted. The issue before the court was whether the claimed processes have transformed the non-patentable natural laws into patent-eligible applications of those laws. [353]

The reasoning given by the court can be broadly put under two segments. Firstly, that the additional three steps were not sufficient or enough to bring the claimed invention under patentability. [354] However, the Court never explained what 'enough' is, and, therefore, has left the question open again. 'The threshold of "enough" will likely include adding therapeutic (such as method of treating) steps based on the diagnostic information, rather than simply detecting or considering

[350] *Ibid*, at 24.
[351] *Ibid*, at 5.
[352] *Mayo*, *Supra* note 333, slip op., at 1.
[353] *Mayo*, Supra note 333 , op., at 3.
[354] *Mayo*, *Supra* note 333, slip op., at 2.

natural phenomena'[355]. According to Justice Breyer, the three steps simply 'tell the relevant audience (the Doctors) about the laws while trusting them to use those laws appropriately where they are relevant to their decision making[356].'The process comprised 'understood, routine, conventional activity previously engaged in by researchers in the field'.[357] In simpler words, the claim merely advises the audience, being the doctors who are familiar to the treatment, to use the law.

Secondly, the court was concerned with the policy impact of allowing such process to be patented. [358] The Court pointed at the potential inhibition of further discovery by allowing patents that might preempt future and unpredicted directions in technology.[359] A patent on inventions merely describing application of the law of nature will 'threaten to inhibit the development of more refined treatment recommendations (like that embodied in Mayo's test), that combine Prometheus' correlations with later discovered features of metabolites, human physiology or individual patient characteristics.'[360]

The Court made a distinction between the claims at hand and 'a typical patent on a new drug or new way of using an existing drug,'[361] mentioning that the latter were particular applications of natural laws.[362] Hence, this can be inferred that the Court did not totally rule out the possibility of patent on a new drug or new way of using an existing drug being a patentable subject matter.

On the point of application of the MoT Test, the Court was clear that it hardly has much relevance to §101 inquiry of the Patent Act of the

[355]GauriDhavan, Irene Hudson & J. Peter Fasse, "Patent Eligibility Of Method Claims: What Is The Impact Of The Supreme Court's Prometheus Decision?",*Industrial Biotechnology* Vol. 8, No. 3, (2012) 107-109 [hereinafter Dhawan*et. al.*].
[356]*Mayo*, *Supra* note 333, slip op., at 9.
[357]*Ibid*, at 4.
[358] *Mayo*, *Supra* note 333, op., at 23.
[359] *Ibid*, at 23 et. al.
[360]*Ibid,* at 18.
[361]*Ibid,* at 18.
[362] *Ibid*, at 18.

USA[363] in as much as the biological process claims are concerned.[364] It stated that transforming the human body by administering a drug or transforming blood is irrelevant and insufficient to conclude as to their patentability. [365] This also indicates that the Court wanted that the future technology and inventions must be considered while deciding patent eligibility.

The US Government through an *amicus curae* argued 'virtually any step beyond a statement of a law of nature itself should transform an non-patentable law of nature into a potentially patentable application sufficient to satisfy §101's demands.'[366] It further stated that this doesn't mean that any leap ahead of natural law is patentable, but if the application satisfies the novelty (§102), non-obviousness (§103) and enablement/description (§112) requirements of the Statute, it shall be held patentable. [367] The Court rejected this presentation by saying that this approach will make the natural law exception created by Court previously [368] a 'dead letter.' Holding the inquiry for additional steps under §101 better than that given under §§102, 103, 112, the Court said that the Government's intended approach would make the three titles do what they are not equipped to do. [369] Further, the Government's proposal of ignoring the novelty and non obviousness requirements of natural law will make every invention ineligible for patent as 'all inventions can be reduced to underlying principles of nature which, once known, make their implementation obvious.'[370]

The patent is granted if the invention is novel, or differs from the subject matter disclosed by an earlier patent, publication, or other state-of-the-art knowledge[371] and non-obvious to a person having

[363] US Patent Law, *Supra* note 334.
[364] *Ibid*, at 21.
[365] *Ibid*, at 9.
[366] *Ibid*, at 20.
[367] *Ibid.*
[368] See, for instance in Bilski, *Supra* note 343; Diamond, *Supra* note 339; Parker, *Supra* note 338, *Gottschalk v.Benson, supra* note 3.
[369] *Mayo*, *Supra* note 333, op., at 21.
[370] *Ibid*, at 22.
[371] U.S. Patent Law, *Supra* note 334, §102.

ordinary skill in the art to which said subject matter pertains.[372] An invention will not be patentable even if these attributes are present but the invention is not a patentable subject matter. §101 provides that a person who 'invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore…'. [373] The US law, thus, provides for four categories of inventions which can be patented, without defining them; process, machine, manufacture, or composition of matter. However, Supreme Court precedent 'provides three specific exceptions to § 101 's broad patent-eligibility principles: laws of nature, physical phenomena, and abstract ideas'. [374]

A 'process', meaning 'process, art, or method.'[375],is patentable under the US law. Process patents claim a series of steps that may be performed to achieve a specific result. The USPTO and Courts have restricted the meaning of the term process. [376][Patent applications involving abstract ideas, mathematical equations, or mental processes have been rejected in past. However, the patent application which seeks protection for discrete applications of such equations, abstractions, etc. can be entertained under § 101.

4. POST MAYO DECISION

4.1. ACTIONS

Right after the decision in *Mayo* was pronounced, the Deputy Commissioner for Patent Examination Policy issued a memorandum to all patent examiners, implementing a new procedure for determining whether a process claim is a patent-eligible, practical application of the law of nature or whether the claim is effectively drawn to the law of

[372] *Ibid,* §103.
[373] *Ibid*, §101.
[374] Bilski, *Supra* note 10.
[375] U.S. Patent Law, *Supra* note 334, §100(b).
[376] See, for instance Cochrane v. Deener, 94 U.S. 780, 788 (1877); *Parkar*, Supra note 338; *Diamond*, Supra note 339

nature itself, in view of *Mayo*.[377] It recommends using the machine-or-transformation test as an investigative tool, but not as the only and conclusive test for deciding patent-eligibility.[378] Hence, the decision was implemented in the form of this policy, making MoT a helping but not the determinative tool for deciding patentability. Also, these guidelines take within their fold both product and process claims, even though *Mayo* dealt only with the process claims.

4.2. EFFECT OF MAYO

In one scholar's'[379] views on the case, which pertained to the patentability of an invention involving a discovery, it was stated:

"The invention-discovery distinction, however, confronts an unusual feature of U.S. patent law. The patent clause in the U.S. Constitution says "Discoveries," and Congress deliberately blurred this very distinction in its 1952 rewrite of the patent statute: "The term 'invention' means invention or discovery." It does not follow, however, that the invention-discovery distinction has disappeared."[380]

This has been reaffirmed by Justice Breyer in the Mayo case. He further adds that 'The larger legal significance of this case, which does carry great precedential importance, is if the Supreme Court decides to revitalize the distinction between invention and discovery long dormant in Court of Appeals for Federal Circuit jurisprudence.'[381]

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[377] USPTO Commissioner, 'New Examining Procedure Related to Mayo v. Prometheus'(2012), Director's Forum: A Blog from USPTO's Leadership,at http://www.uspto.gov/blog/director/entry/new_examing_procedure_related_to (last accessed 02 April 2014).

[378] *Mayo*, Supra note 333 Slip op., at 18.

[379] Robert Cook-Deegan, "Law and Science Collide Over Human Gene Patents", *SCIENCE*, Vol. 338, (2012) 745-747.

[380] *Ibid*, at 747.

[381] *Ibid*, at

A narrow interpretation of the judgment puts thousands of existing patents at peril and prevents many upcoming inventions from receiving the benefits of patent protection. For instance, a new method of applying a medicine derived from Turmeric, which is known for its anti- infectious properties, may not anymore be patentable. 'For example, the patent eligibility of classic method of treatment claims—a method of treating disease X by administering drug Y—may be vulnerable post-Prometheus. Even when drug Y has been known in the art, a new, nonobvious, and useful method of using it has long been patentable as a method of treatment. However, under the reasoning in Prometheus, the administration of a known drug to a patient would be considered "well understood, routine, and conventional."

The judgment is going to have an adverse impact even on the winning party in the *Mayo* dispute, let alone the world. For example, even though genetic mutation is a naturally occurring phenomenon, Mayo itself has licensed a test for a genetic mutation that predicts side-effects for a certain colon-cancer drug.[382] The judgment may jeopardise the validity of this, and similar patents held by Mayo as well.

On a wider interpretation, *Mayo*'s effects may stretch to even scientific, mechanical inventions, and all other inventions. For instance, 'in a future case, it may be argued, as some computer scientists hold, that software is nothing more or less than mathematical algorithms'[383]. The decision 'creates a framework for patent eligibility in which almost any method claim can be invalidated.'[384]

[382]"Prometheus unsound", *The Economist*, March 24, 2012.

[383] Rob Tiller, 'Initial thoughts on Mayo v. Prometheus and Software Patents' (2012), International Free and Open Source Law Review, Vol. 4, Issue 1, 63-66, 64, *at* http://www.ifosslr.org/ifosslr/article/view/68 (last accessed 30 March 2014).

[384] Robert R. Sachs, 'Punishing Prometheus: The Supreme Court's Blunders in Mayo v. Prometheus'(2012), PATENTLY-O , *at* http://www.patentlyo.com/patent/2012/03/punishingprometheus-the-supreme-courts-blunders-in-mayo-v-prometheus.html (last accessed 30 March, 2014). (Page not found)

Natural law is ever transformative for they reiterate the physical events. In as much as the inventions involving laws of nature are concerned courts are required to look into the transformation part of MoT test, i.e, which approach has been taken in past with patent applications involving abstractions. Once the application comes out successfully out of the transformation test, the second step is to see if it is novel and not an attempt to patent a natural law on the name of the process. However, it has been also argued after this decision, that this case asserts the redundancy of the MoT test itself.[385]

Additionally, some commentators state that the case follows defined legal principles and helps maintaining crucial medical and scientific data within the public domain.[386]However, the critics believe that the decision will negatively impact medical research in the areas of biotechnology and personalized medicine.[387] Also, the outcome of this case may affect the financial incentives for medical research and development in the patent industry, and may also impact the cost and

[385] Lynn C. Tyler, 'Section III of Mayo v. Prometheus: Better Left Unwritten?',*BNA's Trademark & Copyright Journal*, 83 PTCJ 839, (2012) at p. 2, *at* http://www.btlaw.com/files/Uploads/Documents/Publications/BNA's%20Patent%20Trademark%20and%20Copyright%20Journal-L%20Tyler-April%202012.pdf (last accessed 29 March 2014) [hereinafter Tyler].

[386] See, American Medical Association, Statement, 'AMA Welcomes Supreme Court Decision to Invalidate Prometheus Patents' (2012), American Medical Association, *at* http://www.ama-assn.org/ama/pub/news/news/2012-03-20-supreme-courtdecision-prometheus-patents.page, (last accessed March 29 2014). (Page doesn't exist)

[387] John R. Thomas, 'Mayo v. Prometheus: Implications for Patents, Biotechnology, and Personalized Medicine', *Congressional Research Service*, *at* http://www.fas.org/sgp/crs/misc/R42815.pdf, (last accessed March 30 2014).

quality of patient health care.[388] Further, it is argued that Section III of the judgment is redundant as it:

'(1) calls into question the status of the MoT Test as a "useful and important clue" to determining subject matter eligibility; (2) appears to reveal an inherent inconsistency in the Court's analysis; (3) seemingly overvalues §101 compared to §§102, 103, and 112; and (4) appears inconsistent with the court's prior opinion in *Parker v. Flook*.[389]

The Court seems to have been confused between the patent eligibility and patentability of an invention. In order to be patentable, an invention must be first patent-eligible. The threshold for patent eligibility has been provided under § 101, whereas §§ 102, 103, and 112 provide the requirements of patentability. The Court observed that even though the claim of Mayo did not tantamount to natural law or phenomenon, but the additional steps were not sufficient for it to be patentable. It is to be noted here that a combined study of the statute and case law suggests that as long as the claim is not on the laws of nature or physical phenomena or abstract ideas itself, the invention is patent-eligible. Its patentability is to be tested under §§ 102, 103 and 112. The Court, in the *Mayo* case, tested the patentability only on the basis of § 101, while undermining the other Sections, which certainly is not the mandate of the statute.

Further, the Court stated that the claimed process was well known among the players in the concerned field. This negates the requirement of novelty and non- obviousness, which are enquiries under §§ 112 and 113. The Court erred in reading this under § 101, which merely provides guidance as to inventions on which patent may be sought.

[388]Cheryl Blake & Jennifer Uren, 'Mayo Collaborative Services v. Prometheus Laboratories, Inc. (10-1150)' (2011) EdanShertzer ed., Cornell University Law School Legal Information institute, *at* http://www.law.cornell.edu/supct/cert/10-1150 (last accessed 04 April 2014).

[389]Tyler, *Supra* note 385, at p. 3.

Furthermore, one scholar[390] has identified that after the *Mayo* case there will be a split in the Federal Circuit. On one side will be 'Coarse Eligibility Filter' proponents and on the other will be 'Abstracted Claim' concept proponents. In the coarse eligibility approach, "the court does not presume to define "abstract" beyond a recognition that this disqualifying characteristic should exhibit itself so manifestly as to override the broad statutory categories of eligible subject matter and the statutory context that directs primary attention on the patentability criteria of the rest of the Patent Act." [391] This approach was taken in cases such as *CLS Bank* v. *Alice Corp.*[392] and *Research Corp.* v. *Microsoft.*[393] Whereas, the abstract claim concept approach firstly takes off the non-essential language in order to extract the basic concepts. Then the exception of natural law patentability is tested only on those underlying concepts An example of this approach could be seen in *Bancorp v. Sun Life*[394]. This case was related to a system for administering and tracking the value of life insurance policies in separate accounts. The Court while explaining how the coarse filter approach used in *CLS Bank* case and *Research Corp* case does not apply, held the invention non-patentable.

Post-*Mayo*, the transformation involving natural laws should be looked into even more carefully to determine if they are merely incidental to the claims. If it is so, the claim, on being read in entirety, will be disqualified from patentability, since the essence is the natural law only. However, if the transformation, which took place by virtue of natural law was just an element of the invention, the transformation is novel and non-obvious, and therefore patent eligible.

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[390]Stephen C. Durant, Warren D. Woessner, Robin A. Chadwick & William E. Kalweit, 'Patentable Subject Matter Eligibility in the Aftermath of Bilski and Prometheus' (2013), Patents4software, *at:* http://www.patents4software.com/wp-content/uploads/2013/01/Patentable-Subject-Matter-101.pdf (last accessed April 03 2014).

[391] *Research Corp.* v. *Microsoft,* 627 F.3d 859, at 868 [hereinafter Research Corp]

[392]*CLS Bank* v. *Alice Corp*., 685 F.3d 1341 [hereinafter CLS Bank].

[393] *Research Corp*, Supra note **Error! Bookmark not defined.**.

[394]*Bancorp* v. *Sun Life*, 687 F.3d 1266.

In a recent Federal Circuit *CLS Bank* judgment,[395] Judge Lourie, writing for the majority, firstly cleared the cloud of confusion between the Supreme Court's 'inventive concept' requirement for §101 patent eligibility and the requirements for patentability directive envisaged under §§102, 103, 112. He cleared 'inventive concept' must refer to a 'genuine human contribution to the claimed subject matter.'[396] However, one of the dissenting judges, Judge Pauline Newman, argued that the requirement of §101 has been interpreted improperly so as to make it a test of patentability. According to her, 'when the subject matter is within the statutory classes in §101, eligibility is established.'[397]

4.3. SUBSEQUENT JUDGMENTS

One of the immediate impacts of the holding in *Mayo* was expected to be on a well-publicized litigation, *Association for Molecular Pathology* v. *U.S. Patent & Trademark Office*[398], popularly known as *Myriad*. The outcome of this litigation determined the patent eligibility of genes/ DNA.

The facts of the case are as follows:

The respondent Myriad Genetics, Inc. (Myriad), obtained several patents after discovering the precise location and sequence of the BRCA1 and BRCA2 genes, mutations of which can dramatically increase the risk of breast and ovarian cancer… If valid, Myriad's patents would give it the exclusive right to isolate an individual's BRCA1 and BRCA2 genes, and would give Myriad the exclusive right

[395] *CLS Bank International* v. *Alice Corporation,* Fed. Cir. May 10,*2013 en banc.*
[396] *Ibid*, slip op., at 20.
[397] *Ibid*, slip op., at11.
[398] *Association for Molecular Pathology* v. *U.S. Patent & Trademark Office*, 569 U. S. ____ (2013) [hereinafter Myriad].

to synthetically create BRCA cDNA. Petitioners filed suit, seeking a declaration that Myriad's patents are invalid under 35 U. S. C. § 101.[399]

The District Court granted summary judgment to petitioners as Myriad's claims were covered under products of nature. However, the Federal Circuit, by the decision given on July 29, 2011, *inter alia*, held that isolated deoxyribonucleic acid (DNA) sequences are patent-eligible subject matter under §101. [400] While rejecting the claims on 'comparing' and 'analyzing' such sequences, the Federal Circuit granted protection on claims with respect to a method of screening of isolated DNA that may cause cancer. [401] On Myriad's petition for certiorari, the Supreme Court remanded the case to the Federal Circuit for reconsideration in view of Mayo. [402] This time the Federal Circuit found both isolated DNA and cDNA patent- eligible. [403]

However, following *Mayo*, the Supreme Court held that naturally occurring DNA segment being a product of nature is not patent eligible merely because it has been isolated. [404] However, DNA is patent eligible because it is not naturally occurring. It observed that '*Myriad* did not create anything. To be sure, it found an important and useful gene,'[405] the Court added, 'but separating that gene from its surrounding genetic material is not an act of invention… Groundbreaking, innovative, or even brilliant discovery does not by

[399] *Ibid,* Slip op., at 6.
[400] *The Association for Molecular Pathology And Ors. v. United States Patent And Trademark Office And Myriad Genetics, Inc.,v. Directors Of The University Of Utah Research Foundation,* In Appeal From The United States District Court For The Southern District Of New York In Case No. 09-Cv-4515.
[401] *Ibid,* Slip op., at 54.
[402] *Ibid*, at 7.
[403] *Ibid*, at 8.
[404] Ibid, at 18.
[405] *Ibid*, , at 12.

itself satisfy the §101 inquiry.'[406] The judgment makes a very well distinction between 'invention' and 'mere discovery'.

This outcome was expected after *Mayo*. This is so because even though there is a difference between the two claims, which is that the subject matter claimed by Prometheus is a process while Myriad claims a DNA, i.e., composition of matter, in a number of recent decisions the Federal Circuit has hardly seen process and composition claims as distinctive. Further, the claimed DNA uses the well known process of isolating human DNA, which made the distinction even smaller. Further, the decision was also in conformity with the initial 'human ingenuity' threshold used by the US Courts to decide patent eligibility.

Therefore, the blurred picture of patent eligibility created by the Supreme Court in *Mayo* remained so even after *Myriad*. Therefore, until patent eligibility is defined, the patent applicants should try to include, if not all, at least one claim which can't be tagged as conventional or well known.

5. CONCLUSION

A factual analysis of the *Mayo* case shows a grim picture, in which the Court merely used the MoT Test, which may prove to be obsolete in light of the advanced technology of the present days. It is said that every patent is an invention, but every invention is not patentable. What can not patentable, is not defined by any statute in the US. The judiciary failed to fill in the legislative gap. The judgment has hit the research industry, specifically pharmaceutical, by reducing the probability of patent protection on process claims. Hence, the judgment is a deserving recipient of widespread criticism.

Another blunder that the Court made was overemphasizing on § 101, while devaluating §§102, 103, 112. The Courts supplanted § 101 for performing enquiries, which the statute drafters had equipped §§ 102,

[406] *Ibid.*

103, and 112 to perform. This has resulted into an obscurity between patentability and patent-eligibility.

It can also be concluded that the judgment may dissuade research by not providing incentives to development or increment over known drugs. However, howsoever divided the opinions on Mayo may be, it's undisputed that it stands as the current view on the §101 patent-eligibility requirements.