PATENTABILITY CRITERIA OF BIOTECHNOLOGY-RELATED INVENTIONS: AN ANALYSIS OF U.S. PATENT LAW

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ABSTRACT

Although adoption and ratification of Trade Related aspects of Intellectual Property Rights has enabled the member countries to allow patenting of inventions belonging to all fields of technology, including biotechnology, but the advancement in the field of modern biotechnology including genes and life forms have posed new challenges before the existing Patent Laws of the countries. The scope and coverage of the Traditional Patent Laws of the country were confined to chemical and mechanical inventions only, however, advancement of technology forced the Countries to grant patent to biological inventions relating to life. The Countries have adopted different approaches towards patenting life. Some are restricted by the ethical and moral concerns surrounding these inventions, while others have overlooked all such restraints, and moved towards adjusting their Patent Laws to give due space to the biotechnology-related inventions.

This paper shall exclusively deal with the approach adopted by U.S., which is regarded as the pioneer in the field of patenting biotechnological inventions, and shall take into account the interpretation of the patentability criteria adopted by U.S. while allowing the life forms to be patented.

Key Words: Patentability, Biotechnology, United States, Novelty, Utility, Non-obviousness, Written Description.

1. INTRODUCTION

In 1944, Oswald Theodore Avery, a Canadian-American physician, medical researcher and molecular biologist, discovered that DNA is the actual elementary unit of a living being. Based on Avery's ground breaking discovery, Cohen-Boyer in 1974, introduced the world to their new platform technology, known as 'The Recombinant DNA technology' which changed the way the people perceived the field of biotechnology so far.

The field of biotechnology was known merely for the process of fermenting beer, wine and ale, or for the process of making cheese and bread, until Cohen-Boyer technology took over. However, Cohen-Boyer did not limit their success to publishing their discovery, rather they realised the worth of their hard work put into by them towards giving a new direction to this industry, and decided to commercialise their ingenuity through patenting their r-DNA technique.

The biotechnology-IPR relation further strengthened in 1980, when U.S. Supreme Court allowed patenting of genetically-modified micro-organisms in the case of *Diamond v. Chakrabarty,*[3] and later in 1988, this

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[3] 447 U.S. 303, 309 (1980).

relationship took an intensified approach when U.S. Patent-Office granted patent to Harvard College for a transgenic onco-mouse carrying *Myc* genes.[4]

However, society was very critical of such pro-patent[5]developments, which paved way towards several on-going debates between the researchers and the public-at large. On one hand, the society demanded a defined limit to accord patent rights, while on the other hand, the researchers supported the approach of judiciary towards allowing patenting of broad claims not only for the purpose of reimbursing the high cost incurred by them in carrying out research and development in the rich field of biotechnology, but also because such approach encourages them to invest their minds into bringing something new to the world.

2. U.S. PATENT SYSTEM AND BIOTECHNOLOGY

In United States, the patent law is authorised by the U.S. Constitution, and is codified in the ***'Title 35 of The United States Code, 1952'***, which underwent significant changes in 1994, after the then U.S. President signed ***"The General Agreement on Trade and Tariffs (GATT)"*** on December 8, 1994.

Prior to becoming a member of GATT, a 'Patent' in U.S. gave the patentee an exclusive right for a specified period of time to prevent others from making, using or selling his invention, without his consent, within the United States, its territories and possessions. However, after ratifying and adopting GATT, the ambit of the definition of 'U.S. Patent' expanded and gave additional patent rights to the patent owner. The updated definition of patent allowed the patent owner to exclude others from making, using, selling, offering for sale, or importing his invention, without his consent, within the United States, its territories and possessions.

U.S. has always adopted a liberal approach while granting patent to an invention, and is a pioneer in patenting Biotechnology-Related inventions.

Biotechnology-related inventions are a combination of human ingenuity and natural processes involving biological systems, living organisms like micro-organisms, plants, animals, or their derivatives, for the purpose of making or modifying products or processes for specific use.[6] These inventions are the product of extensive research and intellect of human mind. Patenting of biotech inventions allow the inventor to freely disclose their innovation to the public without any fear of his innovation being misappropriated by others. Moreover, the research in the field of biotechnology involves massive investments with uncertain returns, as such researchers and scientists in this industry exclusively rely on intellectual property protection, especially patent protection, to prosper and earn high profits. Researchers and investors, in fact, believe that enforcement of strong patents is the only way for biotechnology sector to remain viable, or to succeed, and to prevent the imitators from copying the research and generating high profits from the hard-work of others.

For an invention to be patented, it has to fulfil the universal three-pronged test of novelty, non-obviousness, and usefulness. The similar criteria is applicable to Biotechnology-related inventions too. However, since biotechnology related inventions involve *'life'* and *'living organisms'*, determining their patentability becomes too complex and demands special attention.

2.1.1. PATENTABILITY OF BIOTECHNOLOGICAL INVENTIONS IN UNITED STATES

In United States, patent is granted only if the proposed invention satisfies the following five-elemental requirements:

a. Patentable Subject-Matter

[4]Harvard Oncomouse got patent in U.S. on 12th April, 1988.
[5]Sandra Schmieder, "Scope of Biotechnology Inventions in the United States and in Europe- Compulsory Licensing, Experimental Use and Arbitration: A Study of Patentability of DNA-Related Inventions with Special Emphasis on the Establishment of an Arbitration Based Compulsory Licensing System", (Santa Clara High Technology Law Journal) Vol. 21, (2004), https://digitalcommons.law.scu.edu/cgi/viewcontent.cgi?article=1373&context=chtlj, accessed March 8, 2019.
[6] Article 2 of UN Convention on Biological Diversity, 1992.

b. Novelty
c. Non-obviousness
d. Utility
e. Written description/Specification

2.1.1.1. PATENTABLE SUBJECT-MATTER

In United States, for an invention to be patentable, the foremost requirement is that it must fall in the domain of the *'Patentable Subject-Matter'* illustrated in *Section 101 of Title 35 of United States Code, 1952.*

The United States Patent Law does not, however, expressly provides what constitutes patentable subject matter. It only skeletonises the broad scope of the patentable subject matter to include any new and useful method of manufacture, machine, composition of matter or process.[7]As regards biotechnological inventions including life, the U.S. Patent Law is silent, and it is for this reason that the patentability of an invention belonging to the prolific sphere of biotechnology is determined by U.S. Judiciary on case-to-case basis. One of the most important judgments pronounced by U.S. Judiciary that till date holds relevancy and gets appreciation for turning the face of biotechnology patent industry is that of *Diamond v. Chakrabarty*,[8] where the Court faced the dilemma of granting patent to a genetically-altered micro-organism capable of breaking down crude oil without itself being affected by the environmental conditions. Although, the U.S. Patent-office, at that time, did not regarded a living being to fall into the sphere of patentable subject-matter, the U.S. Supreme Court held different perspective. While granting patent to a living micro-organism, the Supreme Court of United States explicitly intended the patentable subject-matter to *"include anything under the sun that is made by man",* and broadened the scope of section 101 of title 35 U.S.C. In a 5:4 ruling, the holding of the SC was that *'the living bacterium made by Chakrabarty involves re-composition of physical and chemical properties, and hence constitutes a "composition of matter" within the patentable subject-matter. Further, SC held that the Congress' grant of patent under section 101 should be broadly construed.'*

After this magnanimous decision, the Patent-offices throughout the world started granting patents to living micro-organisms altered through biotechnology.

Subsequently, U.S. Supreme Court and U.S. Patent office covered plants,[9] animals,[10] human genetic material[11] (DNA)[12], as well as methods of human cloning[13] within the ambit of the term "composition of

[7] *Section 101 of 35 U.S.C.:* "Whoever 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 therefor, subject to the conditions and requirements of this title."
[8] Supra note 3.
[9] *Ex Parte Hibberd*, 227 U.S.P.Q. (BNA) 443: In this case, for the first time, a mutant maize plant was claimed for the patent. However, the patent examiner rejected the claim on the ground that the claim was for a living thing. He regarded the claim as non-patentable for it was claiming patent on a 'product of nature'. The United States Patent Board of Appeals, relying on the principle laid down in Chakrabarty case, held that when human ingenuity is added to a product of nature, it becomes a product of man, hence, the mutant maize plant was accorded patent protection.
[10] Harvard Oncomouse decision in 1988: For the first time, the U.S. patent office granted patent to a transgenic non-human mammal carrying *myc* genes, which are susceptible to cancer. The patent was granted to the mouse on the basis of the observation of the Board of Patent and Appeals in the case of *Ex Parte Allen*, where the claim was made for a genetically-modified oyster. The Board of Appeals, although rejected the patent for the oyster on the ground of lack of non-obviousness, but clarified that the genetically modified oyster was a non-naturally occurring living matter. Relying on the principle laid down in *Allen case,* U.S. Patent office regarded the onco-mouse to be a non-naturally occurring human-made living being, and opened the floodgates for animal patenting by bringing the proposed living animal within the sphere of patentable subject-matter.
[11] *Amgen Inc. v. Chugai Pharmaceuticals Co. Ltd.* 18 USPQ 2d 1016 (Fed. Cir. 1991): For the first time, patent was claimed for an isolated and purified DNA that coded for a protein called erythropoietin that boosts red blood cells production. The patent was granted, although it faced opposition on the ground of actual isolation, possession and conception of invention. The court in this case defined the term 'conception' to mean actual knowledge of the invention with its properties (physical or chemical) and reducing it to successful practice.
[12] In *re Bell,* patent was claimed for DNA and RNA coding for human insulin growth factors that play a major role in mediation of somatic cell growth on administration of growth hormones. It was opposed on the basis of prior art suggestive of general method for isolation of genes and DNA. However, the Federal Court of U.S. while granting patent to it established a principle that the general matter suggestive of isolating a gene, or DNA, or any other genetic material would not deprive the inventor, who establishes a specific method for isolating a DNA coding for human insulin growth factor, from patent.
[13] *Pioneer Hi-bred International v. Holden Foundation seeds Inc.* 31 USPQ 2d. 1385

matter", and were given patent in United States. However, human beings are still out of the domain of the patentable subject-matter under U.S. Patent Law.[14]

2.1.1.2. NOVELTY

Once an invention falls within the domain of patentable subject-matter enumerated under Section 101 of Title 35 of United States Code, the next step is to test its novelty. The term 'Novel' means new or original.

In United States, an invention is regarded as novel if it is not known or used or described in any printed publication, or previously patented in U.S.A. or any other foreign country. [15] However, when biotechnological inventions come into picture, their novelty is difficult to determine since such inventions involve pre-existing biological material in nature, and in United States, a 'product of nature' being manifestation of nature does not satisfy the criteria of novelty and is not eligible for patenting. A biotechnological invention gets patent only when the inventor is able to sufficiently prove an improvement over the product of nature. In other words, a biotechnological invention consisting of product of nature is granted patent only when through some human intervention or ingenuity such invention is sufficiently modified that it becomes product of man. The *doctrine of 'product of nature'* was used by patent offices and courts in U.S. to reject patents on product of nature or naturally occurring living beings. For instance, the court refused to grant patent in case of *American Fruit Growers v. Brogdex*[16] for oranges coated with preservatives, on the ground of *doctrine of 'product of nature'*, and held that the coated oranges did not show sufficient human intervention that distinguished them from the naturally existing ones.

Similarly, in the case of *Funk Brothers Seed Co. v. Kalo Innoculant Co.,*[17]the applicant observed that different strains of root-nodule bacteria are used to innoculate different species of leguminous plants. This is when the applicant tried to create a mixed culture using different species of bacteria to innoculate multiple species of leguminous plants in a single mixed culture. However, the court refused to grant patent to the applicant because the different strains of bacteria when combined together inhibited each other's effectiveness, which made the applicant's invention a mere discovery, unable to illustrate adequate human ingenuity.

In another case,[18] arguments in favour of biotechnology inventions not being product of nature but new living beings were put forth. The Applicant claimed patent for producing valuable vitamin products through fermentation. The invention, in particular, relates to the isolation and purification of Vitamin B12 active concentrates from the selected strains of micro-organisms belonging to sub-phylum fungi. The claim was also for the method of producing vitamin B12 active concentrates that contained *animal protein factor (APF),* and which, in turn, promotes the growth of micro-organism *Lactobacillus Lactis Dorner (LLD).* Opposition was faced since vitamin B12 is produced naturally in minute quantities in the liver of cattle and in some micro-organisms. However, the Court granted patent and held that although the claimed vitamin is a 'product of nature' but since it is not produced naturally in purified form, as such patent can be granted to any 'product of nature' if it is a new and useful composition of matter.[19]

Subsequently, the fear of inventors regarding claiming patent on life forms of biotechnological inventions was set aside. It was understood that although all biotechnological inventions are 'product of nature', so

[14] Cloning of Humans is punishable under The Human Cloning Prohibition Act, 2003.
[15] *Section 102 of Title 35 of U.S.C.: Novelty; Prior Art:* A person shall be entitled to a patent unless-
(1) the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or
(2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.
[16]283, U.S. 1.8, USPQ, 131 (1930).
[17] 33 U.S. 127 (1948).
[18] *Merck & Co. v. Olin Mathieson Chemical Corp.* 253 F. 2d. 156 (4th Cir. 1958).
[19] *ibid.*

applying the doctrine of 'product of nature' in strict sense would restrict the patenting of such inventions, but once improvement is made on that product of nature by adding human ingenuity or through human efforts, then such 'product of nature' becomes 'a novel product of man', and is eligible for patenting.

2.1.1.3. NON-OBVIOUSNESS

Once an invention falls within the sphere of patentable subject-matter and satisfies the novelty criteria, the next requirement is that the invention must show enough advancement over previously discovered information that it would not be obvious for a person skilled in the art.[20] The invention must be non-obvious not from the eyes of the inventor, but from the eyes of the person ordinarily skilled in the art. The quest for non-obviousness is the most difficult and complex aspect of a biotechnological invention because it is well-known that all biotechnological inventions in the beginning involve biological materials pre-existing in nature. Patent is granted only if it is proved that such pre-existing natural material witnesses sufficient advancement that the subject-matter witnessing such advancement is different and non-obvious beyond reasonable doubt from the substance that previously existed in nature.

For instance, most of the biotechnological inventions such as DNA, DNA sequences, genes, and the like involve biological materials existing in nature. Identification of such DNA or gene sequence is a mere discovery, and not patentable. However, isolation and purification of that DNA or gene sequence is eligible for patent because it is known that their isolation and purification is not an easy task. Once the applicant satisfies that through the efforts of ingenuity, such isolation and purification became possible, and that such efforts of ingenuity in isolating and purifying DNA or gene sequence signifies a leap forward from the prior art consisting of naturally existing un-isolated and un-purified DNA or gene sequence, the applicant shall be successfully granted patent.[21]

In United States, obviousness is a question of law. The burden of proving obviousness lies on the patent-examiner, who when establishes it, then the burden to rebut shifts on the applicant claiming patent. The test of non-obviousness was laid down by the U.S. Federal Court in *Graham v. John Deer Co.*,[22]where the court first and foremost simplified the meaning of the term 'non-obviousness' provided under Title 35 of the United States Code, 1952. The Court said that 'non-obviousness' involves a leap forward by the invention over and above the existing knowledge in the prior art.[23] Further, the Court has proposed a test for determining the non-obviousness of invention. The test established following three requirements that needs to be satisfied for an invention to accord patent:

1. The Courts must survey the scope and content of the prior art.[24]

2. It must examine the differences between the prior art and the claimed invention.

3. There shall be a determination as to the level of ordinary skill in the art.[25]

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[20] *Section 103 of Title 35 of U.S.C.:* Conditions for Patentability; Non-Obvious subject-matter: Patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

[21] Patentability of Biotechnology Inventions, http://shodhganga.inflibnet.ac.in/bitstream/10603/73596/6/chapter%203.pdf, accessed March 8, 2019.

[22] 383 U.S. 1142.

[23] *Richard Stin,* "Intellectual Property, Patents, Trademarks and Copyrights",(West Thomson Learning, West Legal Studies, United States) ed. 2nd, (2001) p. 442.

[24]Prior art means the knowledge existing in the public domain before the claimed invention. Such knowledge may related to an already existing technology or an already existing subject-matter claimed in the patent application. See, Manu Luv Shahalia, "perspectives in Intellectual Property Law: many sides to a coin," (Universal Law Publishing Company Pvt. Ltd., Delhi) (2003) p. 174.

[25]Becca Alley, "The Biotechnology Process Patent Act of 1995: Providing Unresolved and Unrecognised dilemmas in U.S. Patent Law", Journal of Intellectual Property Law Association, Becca, Fall, 2004.

The Federal Court also laid down a fourth requirement to test the obviousness of an invention which involved using secondary considerations such as commercial success, long felt but unsolved needs, or the failures of others to shed light on the circumstances surrounding the origin of the inventive subject-matter.[26]

In *Hybertech Inc. v. Monoclonal Antibodies Inc.,*[27] U.S. judiciary , for the first time, attempted to test and analyse the question of non-obviousness in a biotechnology invention. The claimed invention was an immunoassay[28] that used monoclonal antibodies[29] for measuring the concentration of certain antigens. The invention was granted patent as it was first of its kind in evolving a method of administering antibodies against antigens. However, the patent was later challenged in appeal and was declared invalid on the ground of anticipation of prior art and obviousness. Relying on the Graham factors, the Court of Federal Circuit deciphered the non-obviousness of the claimed invention in following three steps:

1. The Court examined the series of four articles that anticipated using of monoclonal antibodies as immunoassays.

2. The Court assessed the original monoclonal antibody, an article explaining the antibody assays, and an existing patent for a polyclonal antibody sandwich assay.

3. The Court compared the monoclonal antibodies explained in an article with the monoclonal antibodies in the present invention.

After contemplating the three factors, the Court held that existence of anticipation in prior art is not suggestive of how the result might be achieved since the articles in the prior art merely explained immunoassay invention, but in no way exhibited any scientific methods to design the invention. The Court believed that due to the anticipations in the prior art, the theory of immunoassay invention might have become an obvious invitation to try the same in practical, but in no way, the actual invention is obvious without employing successful techniques. The Court, in fact, did not consider any references given by the opposition as capable of making the claimed invention successful. Eventually, the Court concluded that since the prior art was insufficient to have reasonably disclosed the expectation of success of the invention, the court cannot hold the present immunoassay obvious or does not involve an inventive step in the light of the prior art.

2.1.1.4. UTILITY/USEFULNESS/INDUSTRIAL APPLICATION

Once an invention satisfies the above three criterion of patentability, it can be granted patent if such invention demonstrates some immediate practical utility for the public at large, or if it demonstrates its capability of being used in an industry.

The utility of an invention must be sufficiently disclosed in the written specification at the time of filing for patent. The same rule applies to biotechnological inventions also. But, except few biotechnological inventions, utility of most of these inventions is not known until the function of that invention is characterised or the product of such invention is determined. As such, the criteria of Utility possess serious threats while patenting of biotechnological inventions.

In United States Patent Law, the criteria of utility as a condition for patentability is not defined separately. The Courts imposed the requirement of utility by interpreting the words of Section 101 "any new and useful invention". For the first time, U.S. Supreme Court emphasised on the presence of element of utility in the case of Brenner v. Manson,[30] and rejected the patent on the ground of lack of utility. The Court held patent

[26] Patentability of Biotechnology Inventions, Supra Note 1.
[27] 802 F. 2d. 1367 (Fed. Cir. 1986).
[28] Immunoassay means a method for detecting or measuring antigens using antibodies. Antibodies are proteins produced by immune system inside the body of living beings against the antigens. Antigens are disease-causing insecticides.
[29] Monoclonal Antibodies are antibodies raised from a single cell inside the body to fight against the targeted antigens.
[30] 35 U.S. 519 (1966).

shall be granted to an invention only when the invention us useful and brings certain benefit to the society. The Court also laid down the following guidelines[31] for identifying the utility of an invention:

1. The term 'useful' is not so broad to include any invention not harmful.

2. Utility shall be established before the grant of patent. Mere fact that the invention is an object of scientific enquiry did not establish utility.

3. The function of the invention shall be made known. Patent shall not be granted to an invention whose function is not known.

With regard to patenting of biotechnological inventions, the patent office demanded submission of clinical data and result of clinical trials conducted on the invention in support of utility of the invention, failing which the many applicants were not accorded patent for lack of establishing the utility of their inventions. The applicants claiming patent for biotechnological inventions, in particular, were agitated by the approach of the patent examiners. Seeing this, the U.S. patent office felt the need of establishing a framework to determine the utility of biotechnological inventions involving DNA, genes, nucleotides and the like, and finally issued the "Utility Examination Guidelines"[32] in 2001, reflecting the same.

The Guidelines provide following four-pronged test for evaluating the utility of the invention, satisfying which the invention is said to have fulfilled the utility requirement:

1. Does an invention has a well-established utility?[33]

2. Does an invention has specific utility?[34]

3. Does an invention has substantial utility?[35]

4. Does an invention has credible utility?[36]

Further, as per the Guidelines,[37] the examiner must adhere to the following procedure for establishing utility:

a. There shall be determination of specific claim as the invention.
b. There shall be determined whether the specifications and claims made in the application disclose any credible utility of the invention.
c. If no credibility is disclosed or asserted, and if such utility would not have been readily apparent to one of normal skill in the art, the application should be rejected for lack of utility.
d. If the utility would be credible to a person of ordinary skill in the art in view of the evidence submitted on record, the application should not be rejected.

[31] Brian C. Cannon, "Toward a clear standard of obviousness for biotechnology patents", Cornell Law Review, Cornell University, March 1994, accessed March 9, 2019.
[32] USPTO new "Utility Examination Guidelines, 2001", https://www.uspto.gov/web/offices/com/sol/og/2001/week05/patutil.htm, accessed March 9, 2019.
[33] Well-established utility means that the utility must be specific, substantial and credible. It is utility supported by enough evidence disclosed in the specification.
[34] Specific Utility means the utility that is applicable to a particular subject matter.
[35] Substantial utility means when the invention does not require any further research to prove its utility, or to confirm its use. Such invention must be capable of fulfilling the needs of the society practically, and must be complete in itself.
[36] Credible utility points towards the reliability of invention. If the utility is reliable then such utility is credible. Reliability of utility depends upon the evidence asserting the utility, which may include, report of clinical trials, expert statements, laboratory records, and the like.
[37] USPTO new "Utility Examination Guidelines" 1995, revised in 2001. See, Brian C. Cannon, "Toward a clear standard of obviousness for biotechnology patents", Cornell Law Review, Cornell University, March 1994, accessed March 9, 2019.

The burden lies on the examiner to prove lack of utility beyond reasonable doubt with sound reasoning and evidence. Once the examiner succeeds in proving that the invention lacks utility, the burden shifts on the applicant who will then have to rebut that his invention possesses sufficient utility to get the patent.

2.1.1.5. WRITTEN DESCRIPTION/SPECIFICATION

An invention must be sufficiently disclosed in the written form in order to get patent.[38] The written description must provide complete and clear details of the invention in concise manner as well as the best mode of processing, making and using the invention. The sole purpose of written specification is to enable the person ordinary skilled in the art to make and use the invention once the patent for the same expires and the invention falls in the public domain.

With the advancement of technology, particularly biotechnology, the Patent offices and the Courts impose the requirement of written description stringently to determine the scope of biotechnological inventions, and to confine or limit the scope of the inventions only to the extent of what is described by the patentee in the written description.

In United States, the requirement of written description is enumerated under *Section 112 of Title 35 of United States Code.*[39] With regard to biotechnological inventions, the U.S. Patent office is said to have interpreted Section 112 to consist of three dimensions:

i. ***Written Description:*** There is as such no difference between the written description of any other invention and that of biotechnological inventions. However, The Federal Courts of U.S. stresses on the strict fulfilment of the requirement of written description of biotechnological inventions.

ii. ***Enablement:*** The specification relating to an invention must be enabling, i.e., it must provide enough details of the invention to enable the person ordinary skilled in the art to practice the invention even if the best mode of carrying out the invention is not disclosed.

iii. ***Best mode and deposit of the invention:*** Although any mode of practicing the invention can enable the person skilled in the art to practice the invention. However, U.S. Patent Law requires the inventor to disclose the best mode of practicing his invention, in order to claim patent. Without disclosing the best mode of invention to the public, the patentee is not entitle to claim the monopoly rights over his invention. If the inventor uses multiple number of methods for carrying out his invention, then the best mode preferred by him must be disclosed. If he does not discloses such preferred mode of invention, but discloses any other mode practiced by him, he shall be deemed to be violating the written description requirement. Further, if an inventor does not believes any method of practicing the invention to be the best mode of practice, even though the opposing party believes a certain method to be the best mode, then the inventor not disclosing the best method but the method used by him shall not be regarded as violation of the requirement of written description. As long as the inventor knows the better method of carrying out the invention than that disclosed by him in written description, he shall be liable for violating the written description requirement.

Owing to the complexity of biotechnological inventionslike DNA, gene sequences, and the like, it is difficult for the inventor to describe the invention in detail elaborating all its chemical and physical properties, structure, sequencing, etc. In such a case, depositing of the biotechnology-

[38] Article 29 of TRIPS Agreement: Members shall require that an application for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

[39] *Section 112 of Title 35 of Unites States Code, 1952: Specification:* The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is mostly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

related invention in recognised depositories[40] is regarded as the best mode of practicing the invention.

In the case of *Hybertech Inc. v. Monoclonal Antibodies Inc.*,[41] the Court of Federal Circuit for the first time attempted to throw light on all the dimensions of written description, to discuss in detail and to apply the requirement of written description to the claimed biotechnology invention which was challenged in appeal for the written description was unable to disclose the method of making and screening the monoclonal antibodies and the method of measuring the monoclonal antibodies affinity. Also, the written description was non-enabling and insufficient to prescribe the best mode of making and using the claimed invention.

With reference to all the claims alleged against the inventor, the Court held that "the claims read in the light of specification reasonably appraise those skilled in the art both at the utilization and scope of the invention. Moreover, the language is precise. The Courts cannot demand more."[42] Further, with regard to disclosing the best mode of carrying out the invention, the Court observed that "not complying with the best mode requirement amounts to concealing the preferred mode contemplated by the applicant. There was a testimony by Hybertech employees alleging the concealment of best mode by the inventor. The testimony states that screening process disclosed by the inventor is intensive and time consuming. But the Court does not relies on this testimony to say that the inventor concealed the best mode."[43] The Court held that "if the process is intensive and time consuming, it does not mean that it is not a best mode. The inventor satisfies the written disclosure, enablement and best mode requirements of his invention, as such the patent is valid."[44]

In *Amgen Inc. v. Chugai Pharmaceuticals Co. Ltd.*[45], the claims were for DNA sequences encoding erythropoietin and host cells transformed with a DNA sequence. The inventor disclosed the mode of practicing the invention. However, since he did not know the best mode of practicing the invention, the defendants alleged that in order to fulfil the written description requirement, it is essential for the inventor to deposit his invention. The Court observed that deposit of the invention is necessary only when the material in the claimed invention is not readily available to the public. But in the present case, since the invention involves biological material which can be easily made in the laboratory using the description or the method disclosed in the patent application, the deposit of invention is not required. Moreover, the written description guidelines nowhere suggest that the deposit of invention is necessary when the biological material could be readily produced in the laboratory. The Court pointed out that here the issue is about disclosure of the best mode of carrying out the invention, and not deposit of the invention. Further, with regard to enabling the person skilled in the art to carry out the invention, the Court held that "merely because the respondent is unable to practice the invention as per the method provided by the inventor, does not mean that the invention must be deposited. No scientist could ever duplicate the best mode described in any patent application. The requirement is to sufficiently disclose the best mode contemplated by the inventor to practice the invention, and not to give guarantee to be able to duplicate the invention exactly."[46] Eventually the Court concluded that "when the application describes the best mode to practice the invention without undue experimentation, it is not necessary to deposit the invention."[47]

[40] The Budapest Treaty provides for the establishment of depositories all over the world to acknowledge and accept the deposit of microorganisms and living material for the purpose of patent protection.
[41] Supra note 27.
[42] *ibid.*
[43] *ibid.*
[44] *ibid.*
[45] 927 F.2d 1200 (Fed. Cir. 1991).
[46] *Amgen Inc. v. Chugai Pharmaceuticals Co. Ltd.* 927 F.2d 1200 (Fed. Cir. 1991).
[47] *ibid.*

3. CONCLUSION

U.S. is a pioneer in patenting of biotechnology inventions. With respect to patenting of biotechnological inventions, U.S. Judiciary has played an important role which could be seen in plethora of cases discussed above. The focus point is that U.S. Patent Law has recognised the requirement of TRIPS Agreement as well as the need of modifying the traditional patent law with the advancement of technology, particularly biotechnology inventions including life forms. The Patentability Criteria in U.S. is in line with the TRIPS Agreement yet the interpretation of the criteria done by U.S. Courts and Patent Office is the reason for advancement of this rich industry. Although U.S. Bill of Rights guarantees inherent dignity and equal treatment to all, and also talks about intrinsic value attached to life, yet all the ethical and moral concerns raised while deciding the question of patenting life were overlooked by the U.S. Courts. The Courts in U.S. seem to believe the famous quote of Geoffrey Carr, *"Biotechnology can transform humanity provided humanity wishes to be transformed"*[48], and therefore, have adjusted and interpreted their Patent Laws in such a manner as to provide a broader patentability criteria in order to advance maximum benefit to the society at large through the significant inventions of the rich field of biotechnology.

[48] Geoffrey Carr, Science Editor and Economist.