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PATENTING OF BIOTECHNOLOGICAL INNOVATION: ITS CHALLENGES TO ACCORD PATENTABILITY

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Abstract

Innovation, when induced with human labour, skill, knowledge, and judgement, forms a fragment of Manmade Invention, which gives him exclusive right to reap the benefits either by claiming reward by its very nature on the product or the manufacturing process. The reward for innovation is granted using Intellectual Property Rights, which gives the inventor a monopoly in the market for a limited period. One such Intellectual Property Right includes a Patent granted if the invention is novel, non-obvious and has an Industrial application. Patents are generally granted to non-living beings, so there is no conflict with the laws of nature. Involvement of the product of nature-focused the study to analyses the scope and evolution of patency on Manmade invention to protect and safeguard the invention from beings exploited by human beings and living organisms from being exploited by the innovators. The disparity arose when patentability rights were offered to biotechnological innovation involving living organisms without considering the Ethical, Legal, Moral, Social and Political grounds which form the basis of this research. It is a multidisciplinary field highlighting the transformation from traditional methods to modern biotechnology techniques. This article highlights the concept of Biotechnology and patents, its evolution, challenges faced by the inventor and reasonable suggestions to accord patentability.

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Introduction

Before delving into the concept of patent, it is necessary to understand the meaning of the terms *'Property'* and *'Intellectual Property Law'*. Property means having exclusive control over the right of ownership and disposing of the object whenever needed or demanded. In ***JilubhaiNanbhai Khachar* v. *State of Gujrat***[2], the Supreme Court has stated that subject to limitation and qualifications, a property consumes *"Everything which has an exchangeable value, state of ownership whether real or fictional, tangible or intangible, corporeal or incorporeal and which is quantifiable in the form of Wealth, Estate or Status".* In ***R.C. Cooper* v. *Union of India***[3], the Supreme Court has stated that Property includes Intellectual Property like trademarks, copyrights, and patents. In the Constitution before the 44th Amendment, the Right to Property was considered a Fundamental Righted guaranteed under Articles 19(1)(g) and 31, which later shifted it to being a legal right under Article 300A, which states that a person should not be destitute of his rights except in violation of public purpose or inadequate payment of compensation. This article does not limit intangible property like Intellectual Property Rights. The patent, trademark, copyright, and industrial designs are illustrated under Entry 49 List I (Union List) of the Seventh Schedule, which empowers parliament to implement laws concerning these subjects. Whereas under the same list with residuary power under Entry 97 (1), the parliament can implement laws for other Intellectual Property Rights like geographical indications, plant varieties and layout designs.

Supporting this concept, various jurists have propounded theories to augment in favour of considering Intellectual Property within the realm of Property. According to Utilitarian Theory by Jeremy Bentham, Intellectual Property provides incentives to the inventor by encouraging them to create work which benefits a larger population based on his principle of providing "maximum benefit to a *maximum number of people"*. According to John Locke, if a product is created by applying his Labour, then he has natural rights over the fruits cultivated by his labour,

[2]JilubhaiNanbhai Khachar v. State of Gujrat, AIR 1995 SC 142: (1995) Supp (1) SCC 596 (58)
[3] R.C. Cooper v. Union of India, AIR 1970 SC 564

and this principle is used in the case of Intellectual Property where the *"Knowledgeable goods"* invented by his intellect will belong to the inventor. According to Hegel and Kant in Personality Theory, they have stated that for an invention to be formulated, the creator must apply his will, or there must be a psychological connection between him and his invention. This Theory forms the basis for understanding the concept of Intellectual Property in depth. Intellectual Property is creating a work by applying the phenomenal mind of a human being. The main aim of providing statutory protection for intellectual property is to award the inventor for his invention and provide access rights to the general public. There are nine types of Intellectual Property Rights: i) Patent, ii) Trademark, iii) Copyright, iv) Industrial Design, v) Geographical Indication, vi) Semiconductor and Layout Design of Integrated Circuits, vii) Plant Varieties, viii) Trade Secrets, ix) Technical know-how. This paper deals with the patenting of biotechnological inventions, so the concept of patents will be discussed in detail.

Concept of Patent and Biotechnology

Patent has not been defined under the Indian Patent Act of 1970 (The Act). According to Section 2(1)(m), it means any invention for which a patent is granted. It allows the inventor to enjoy monopoly rights in the market for a limited period. In other words, as pronounced by the Division Bench of Delhi High Court in the Telemecanique case,[4] *"A Monopoly of the patent is the reward of the inventor".* It is a negating right as it excludes others except authorised users from manufacturing, selling, importing, and utilising the goods for 20 years. It is a right granted to the inventor to obtain a reward for making the invention available to the public by reasonable means. To geta patent, the inventor must apply for the patent and fulfil the necessary conditions as stated in the Act, which is in accord with the International Convention. The patent can be classified as a product patent or process patent. The Patents Amendment Act of 2005 introduced product patents for food, drugs, and pharmaceuticals in India, before which only process patent was granted. In ***Thomson Brandt* v. *Controller***[5], it was held that there is a distinct link between product and process patents; both patents are independent. The right to be registered as a patentee is limited to a person for the time being in force. The firm, corporation or body of

[4]Telemecanique& Controls (I) Limited v. Schneider Electric Industries SA, 2002 (24) PTC 632 (Del) (DB)
[5] Thomson Brandt v. Controller of Patents, AIR 1989 Del 249

corporation cannot be acclaimed as a sole patent proprietor unless by assignment or joint ownership with the proper and first inventor i.e, patentee[6].

In the book *"Biotechnology of Meat, Fat and Milk Production in an Agriculture Large Scale Farm"* the Hungarian Scientist Karl Ereky coined the term *"Biotechnology"*, which means utilising the technology to modify the original structure of plants and animals and develop a favourable product for the society. The term involves a combination of words "Bio" and "Technology", where the former refers to an ecological system or its cultivation procedure, and the latterrelates to technique, structure, and tools to generate resourceful products from these environmental systems. The early onset of biotechnology dates back 10,000 years, when the cultivation of crops like wheat and barley was prominent. The prospective employment of methods of hunting and fire to domesticate sheep, goats, and cattle were conventional in the Sahara region of Africa. The current practice of *'Selective Breeding'* was manmade, assembled, cultured, and domesticated the seeds and wild species of plants and animals. The most prominent part of this was the process of fermentation, which was used to manufacture bread, cheese, wine, and beer. The concoction of scientific and traditional knowledge efficiently implements Biotechnology. Especially in India, if we consider the fermentation procedure of idli and curd, it's an age-old practice amalgamating traditional knowledge and scientific training. Under the Modern age of Biotechnology, Recombinant DNA (rDNA), genetic engineering and various other forms of technology are used to manipulate the original structure and develop a new and valuable product.

Evolution of Biotechnological Patents in India

The *Indian Patents Act* of *1970* did not state anything about the inclusion or exclusion of Biotechnological Inventions, as it was an unexplored field of technology. Only after its expansion in the United States of America and the European Union did there feel a need for the Indian Economy to review and consider the inventions relating to the Biotech Industry. *Trade-related aspects of Intellectual Property Law (TRIPS) brought about a revolutionary impact on the* Biotechnological Industry under the Patent regime. This international agreement was ratified

[6] V K Ahuja, *Law Relating to Intellectual Property Rights*p.no. 3 – 6, 479 – 482, 488 & 489 (LexisNexis, Haryana, Third Edition 2017)

by India and administered by the World Trade Organization. It requires member states to adhere to the minimum standard of international regulations empowered by Intellectual Property Rights. The TRIPS agreement mandates the member country not discriminate against another member country regarding the place of invention and field of technology if they fulfil the essential criteria of patentability. *Article 27* of the TRIPS Agreement states about the patenting of living organisms, and since India has ratified this agreement, it has become mandatory for it to accept the patenting of biotechnological inventions. The significant changes regarding the 2002 amendment relate to biotechnological, microbiology and biochemical industry patenting. The Budapest Treaty further mandated the deposit of biotechnological inventions in the repository of the country where the invention has taken place or the application has been accepted. The amendment of 2005 has brought a drastic change by allowing the flow of applications to process patents and product patent applications[7].

India accepted the TRIPS agreement in January 1995 and between 1995 to 2005 for a period of ten years the system of Mailbox applications and Exclusive Marketing Rights was followed in India after passing of an ordinance. Even after the lapse of the ordinance within five years, the mailbox system followed by accepting product patent applications in the pharmaceutical industry until 2005, after which the process of examination and scrutiny was initiated. In ***Auguron Pharmaceuticals Inc*** **v.** ***Controller of Patents***[8], the claim was to set aside the order of the controller general, which stated that the patent application which was in the Mailbox system should not considered patentable which was reverted by the High Court of Kolkata under which the controller withdrew his order and as per the directions of court patent claims between January 1995 to December 2004 were examined with relevance to the Patents Act of 2005. F Hoffmann Roche was the first Swiss Pharmaceutical company to acquire a pharmaceutical patent on Hepatitis Drugs for a limited period of 20 years from 1997. After this, the patent applications were accepted both on the process of manufacture of the product and the product itself.

Criteria of Patenting Biotechnological Inventions

[7] Jahnavi Deshpande, An Analysis on Patentability of Biotechnological Invention in India, *available at:*An-Analysis-on-Patentability-of-Biotechnological-Invention-in-India.pdf (ijilr.org) (Last Visited April 19, 2024)
[8]Auguron Pharmaceuticals Inc vs. Controller of Patents MIPR 2009 (2) 345.

The three essential criteria of patentability that, are Novelty, Inventive Step and capability of Industrial application are applied to inventions relating to Biotechnological Inventions. Apart from these criteria, certain other issues must also be addressed while granting patents, as it includes inventions relating to life forms which have a higher velocity than other forms of patents on non-living beings. The pertinent issues include:

- The most important one is granting patent protection to inventions which have a life or deal with living organisms.
- Another aspect is narrating the main elements of the inventions.
- Finally, to distinguish between invention and discovery and under which category the particular product fits.

Patentable Subject Matter:

Before delving into the criteria, it is necessary to understand if the invention falls within the realm of patentable subject matter and discuss their uniformity regarding biotechnological inventions, which was not prevalent before the enactment of the *Trade-Related aspect of the Intellectual Property Rights (TRIPS)* agreement. This agreement provides flexibility that biotechnological inventions relating to products and processes may be granted patent protection if they fulfil the essential criteria of patentability without discrimination against the place of invention and manner of production (i.e. locally manufactured or imported from any foreign country). It can exclude patent protection if they hamper living organisms, obstruct public order and morality, or cause environmental prejudice. Furthermore, tools or methods used for diagnosing, conducting surgeries, or performing any therapy to treat living beings, mammals, plants, and their related essential biological processes may also be excluded from the realm of patent protection under the TRIPS Agreement. However, it does not exclude microbiological or non-biological processes. To understand under which criteria an invention will fall, it is pertinent to distinguish between Invention and Discovery.

Invention versus Discovery:

It is a fact that only inventions are subject matter of patents, and discoveries are already available, and the person searching for it is only finding it now so that it might be new for him or many like him but not for others. On the other hand, the invention is a new or novel concept for him and everyone as he is creating a new product that is nonexistent. Therefore, it is necessary to differentiate where the discovery ends and the invention begins. The term invention is not defined under any international convention or directive except the United States statute, which states that invention includes innovation or discovery. So, it can be construed that the US statute does not differentiate between Invention and Discovery. Biotechnological invention, deals with manipulating the living organisms, which a product of nature, as opposed to discovery, which does not result in the creation of any new things and merely finding things available in nature, so it is necessary to bifurcate between product of nature and innovation of new material with the help of product of nature to claim patent protection. It is pertinent to note that products of nature or already existing materials amount to discovery. The main element for creation from the discovered product to biotechnological invention is the human intervention in altering the form of the biological product, which yields non-natural and artificial products. Therefore, until a new inclusion is made to a new, it is merely a discovery and upon its insertion, it shifts from discovery to innovation. The pertinent issue is to what extent the traditional concept of patent can be applied to manmade inventions on human beings, which can be determined by the judicial precedents and practice of courts rather than a sharply defined set of laws. The four primary criteria of inventions include,

a) Novelty
b) Inventive Step
c) Capable of Industrial Applications and
d) Written Description

Novelty:

According to the various enactments, any person who brings something new to the table will be termed the inventor and shall be granted limited monopoly rights for that particular invention for a limited period.

*In the **United States of America:***

As discussed, earlier patents in the United States were granted for novel inventions if they were not in utility or published within their national or international states. However, the main element that the invention should not have in prior existence cannot be witnessed about biotechnological invention as it is related to living organisms, which are products of nature. In the case of ***American Fruits Growers Case***[9] and ***Funk Brothers Seeds Co. Case***[10]The patent was rejected on the grounds of the product of nature. Being a natural product impedes granting patent protection as they do not qualify for the novelty step. However, there was criticism against this contention that biotechnological inventions are not inherently found in nature and new things are cultivated from the products available, which does not result in the new product being a product of nature. This contention was supported in ***Merck & Co.*** **v.** ***Olin Mathieson Chemical Corp.***[11]Where vitamin cultivated in cattle through natural processes in minute qualities were isolated and purified to be cultivated by fermentation process which is different from the natural process, and patent were claimed for such inventions for which it was rejected on the grounds of product of nature. But the court reversed their contention and earlier judgements and held that if the product is new, useful and composition of matter then doctrine of product of nature does not hold validity and patent should not be henceforth rejected for such inventions. This doctrine created a fear in the minds of scientific field because every product is a part of nature and unless any human ingenuity is introduced it will remain a product of nature and if this principle is applied then patent can never be granted for any biotechnological inventions. This shift was drastically witnessed in the ***Diamond Case***[12] where for the foremost time patent was granted on a man-made, non-existing and genetically manipulated bacteria which is a microorganism. This case has altered the structure of Doctrine of Product of nature and has given a new meaning for the term Novel. Now in the context of biotechnological invention the term novel means that any product which possess the qualities of a enhanced variety of the original, adheres to a developed form or structure or a combination of few or all of them will be considered as biotechnological innovation and patent can be claimed for such innovation.

In ***European Union:***

[9] American Fruit Growers Inc v. Brogdex Co. 283 US 1.11.51 S.ct, 328, 330, 75 L.Ed.801 (1931).
[10] Funk Brothers Seed Co. v. Kalo Inoculant Co 33 US 127 (1948).
[11] Merck & Co. v. Olin Mathieson Chemical Corp. 253 F. 2d 156 (4th Cir. 1958)
[12] Diamond v. R Chakraborty (1980) US SC 447 at 303.

The issue with regard to Novelty was never the contention in European Union as patent was granted for invention before the landmark judgement of Chakraborty. The essential ingredient is that the claimed invention must not be prior published or part of any state of art before the filing of patent application anywhere in the world. In 1969 when patent was claimed on a creative method to breed red dove it was rejected due to lack of consistency, but novelty was never a question raised for biotechnological invention. This was later accepted in an official way by including the biotechnological invention under the realm of *European Patent Convention*. United States form the main reason for the strong acceptance of patent protection in European Union as before the enactment there was a major dilemma, and various debates were being conducted on whether to accept patent protection in European Union or not which was clarified later by laying down the precedent in genetically modified microorganism case in the United States. It is noteworthy to mention that just because there is a general idea for an invention already in existence it does not make the actual expressed invention non patentable and likewise if the invention is already in existence like a DNA fragment it does not exclude the isolated and purified version of it from claiming it as a biotechnological innovation. Following the moral and ethical code of conduct, if any invention is likelihood to cause prejudice to living organisms, then such innovation is excluded from the ambit of patent protection even in European Union.

In ***India:***

The term novelty is nowhere defined under the patents act, so it is at the discretion of the judiciary and patent office to interpret this term with the help of various judicial pronouncements. It does provide a list of certain matters which do not fall under the ambit of patentable subject matter which in other words say that they are not novel inventions under the act. Microorganisms and human genetic material are subject matter of patent not in their original form but their genetically modified versions. In ***Dimminaco AG* v. *Controller of Patents and Designs*[13],** the claim was to produce a vaccine to prevent the poultry infection using a live virus. It was held by the patent office that the invention is not new and useful which was later reversed by the Calcutta high court that the claimed invention though being a living organism is eligible for patent protection as it fulfills the novelty and other criteria of patentability. So, this

[13]Dimminaco AG v. Controller of Patents and Designs 2002 LP.R.L. 255 [Calcutta High Court].

judgement was pronounced before the amendment act, and it raises the bar on patenting living organisms if it fulfills all the essential conditions of patentability. After the enactment and ratification of TRIPS agreements in India it has become a settled notion that both product and process patent are granted patent protection in India and there was not much debate and discussion unlike United States and European Union as it became a settled law in India.

Inventive Step:

Ultimate Condition of Patentability:

It is noteworthy to state that it is not necessary that all the inventions, if new will be subject to patent eligibility instead it must also involve inventive step. The term inventive step is equivalent to that of Non obviousness and the non-fulfillment of this condition can act as a major impediment to the grant of patent. What is obvious relates to the technical aspects and for an invention to be innovative it must be questioned from the perspective of skilled person in art and must be beyond the reach of public knowledge.

In ***United States of America:***

The process with regards to test of obviousness is a question of law according to the United States patent system. The primary burden falls on the patent examiner to provide a prima facie case of obviousness and then it becomes the duty of the applicant to prove otherwise. The test has been laid down in ***Graham* v. *John Deer Co.*** [14]**,**where the court has laid down perspicuity with regard to the term *'non-obviousness'* as it means that the innovation should not be present in the prior art, and it should be an enhanced improvement over the already existing one. Other condition laid down by the court include:

- The court must study and analyze the context and extent of prior art.
- The distinction between the already available knowledge and the claimed invention must be understood carefully.

[14] Graham v. John Deer Co. 383 U.S 1142. See, No. 69

- The person skilled in the art must be able to deduce and ascertain the level of the claimed invention.
- If these basic conditions are not fulfilled it must consider other secondary elements like commercialization of the invention and the yield it will produce, unresolved demand which is pending for a longer period of time, or the lack of other inventors to test the obviousness over the subject matter.

These conditions are not exclusive or discouraging but are highly cogent in determining the nature of obviousness.

In order to determine the state of prior art the time frame during the date of filing of patent application should be considered and not the date of examination or grant of patent. In ***Hybertech Inc Case***[15]**,** patent was granted initially for immunoassay method that used monoclonal antibodies to detect the antigens in a particular solution. Later it was rejected on prior anticipation and the court considered the test of Graham in arriving at a conclusion. Reading the articles which highlighted the method of immunoassay and comparing the existing invention with that of the article which stated about similar method employed in polyclonal antibody assay method. While doing so the court held that mere prediction without suggesting a complete scientific method will not make the existing invention prone to prior art. Mere prediction might make the invention obvious to try but it will not provide guaranteed result without conducting experiments which was lacking in the article mentioned in the prior art. It further observed that obvious to try does not create an assumption that it is known to the person skilled in the art and patent cannot be rejected on the basis of assumption unless there is corroborative evidence to support the fact. Based on this analyzation patent was granted for this invention. It is challenging to establish prior art as it relates to information which is well-documented knowledge, and its search can be horrendous. With regards to prior printed publication there is no restriction or limit on the number of copies so it means that even a single copy indexed or publicly available will amount to printed publication under United States patent law. The ***Person Having Ordinary Skilled in the Art (PHOSITA)*** is an imaginary person who is presumed to have known all the knowledge available in that particular field and the invention is

[15]Hybertech Inc. v. Monoclonal Antibodies. Inc. 802 F. 2d 1367(Fed. Cir. 1986)

not determined from the perspective of Inventor but from the eyes of the imaginary person. In ***Re o Farrell***[16]**,** the claim was to produce a foreign bacterium using the process of isolation and coding of the DNA. The test laid down by court include:

- That success must not be predicted well in advance.
- The difference between the prior art and the claimed invention should not be indicated in desired result.
- The prior art must provide only routine guidance which is not specific.

In this particular case the prior art suggested prior anticipation by way of publication of an article which indicated the procedure and method to conduct with a reasonable determination of success. On the basis of this analysis, it was found that the innovation has failed the test of non-obviousness. In ***Amgen Inc. Case***[17]**,** the term obvious to try was interpreted in the light of reasonable expectation of success. In other words, it can be questioned as to whether every obvious to try procedure will provide a reasonable expectation of success. In this case, the probing strategy was already conceived by the plaintiff but it was the defendant who conceived it and here conception refers to shifting the idea in to practice with the object of getting a desired result and the court contended that the person who conceived the innovation and implemented it in to practice will be the one who will be deemed as the true inventor of the innovation. Another contention is that at times known or similar processes are used to produce innovative product with different raw materials. This can become an issue for patentability which is discussed in the case of ***Re Durden***[18]**,** where a new product was created using a old process which indirectly means that the primary and end products are new while the process used for manufacturing is old and known. The court held that prior art predicted such an invention making it obvious to the person skilled in the art and rejected the claimed invention. It further held that just because the starting and the ending point is nonobvious it does not make the intermediary portion of using old process unobvious too. This decision created chaos in the scientific community and was held that the same standpoint should not be held in future cases and every case should be determined

[16] Re o Farrell 853 F.2d 894 (Fed.Cir. 1988).
[17] Amgen v. Chugai Pharmaceuticals 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991).
[18] In Re Durden 763 F.2d 1406 (Fed. Cir. 1985).

upon their factual circumstances. In ***Re Huch***[19]**,** the decision of the examiner overruled the earlier decision of the Court which was eventually supported by the Federal Court as well. In this case the claim was for manufacturing a compound using a new and non-obvious which is not found in the prior art, and it is different from procedure or manufacturing of utilizing a compound. This created a wave and relaxed the restriction in biotechnological invention as the scientist used similar isolating technique to create a new product which is nonobvious to the person skilled in the art.

In ***European Union:***

The similar principle of United States with regards to state of art is followed in European Union as well with few variations. The development of the inventive step as a category of patent in European Union can be illustrated with a test in the case of ***Windsurfing International Inc.*** **v.*Tabur Manne Ltd.***[20]

- Firstly, identify the inventive step in the claimed invention.
- Secondly, to analyze and evaluate the prior art from the perspective of an ordinary person who has knowledge but as an unimaginative addressee.
- Thirdly, to differentiate between the prior art and the claimed invention.
- Finally, assessing from the perspective of ordinary person having skill in the art.

In ***Genentech Inc. Case***[21]**,** the claimed innovation was rejected for an application relating to recombinant technology in bacteria which is a known technique and there was reasonable expectation of success and prior art suggested and could foresee such an invention. This discouraging decision was overruled in ***Chiron Corporation*** **case**[22]where the particular invention relating to immunoassay kit used for detecting antibodies was held as enhanced improved over the already existing prior art. Therefore, there was no suggestion in the prior art stating this

[19]In Re Huch 475 F.2d, 658, 177 USPQ 250 (CCPA 1973).
[20] Windsurfing International Inc. v. Tabur Manne (Great Britain) Ltd., (1985) RPC 59.
[21]Genentech Inc v. The Welcome Foundation (1989) R.P.C 147
[22] Chiron Corporation v. Murex Diagnostics Ltd and Organon Teknika Ltd. (1996) R.P.C 535, CA

particular method on the date of filing of the patent application. Meanwhile in few cases there was conflict between the House of Lords and Board whereas in most of the member countries the decision of the Board was considered as enforceable, but it is pertinent to consider even the decision of House of Lords in matters relating to inventive step in biotech industry.

In ***India:***

The similar concept of United States and European Union is being applied in India as well with regards to Inventive step. There has not been any major changes or development in India with regards to inventive step in biotechnological invention and even if there are few cases the same principle of *Indian Patents Act* is being applied for inventions relating to biotech industry.

Utility or Industrial Application:

Demonstrating utility or special benefit is an important aspect under industrial application as it provides peculiar benefit to the society. This requirement needs to be fulfilled at the time of grant of patent and not during the date of filing of the patent application. Utility alone is not sufficient if it is not corroborated with written description of the invention. Illustrating the utility with respect to genetically modified animal and plants is convenient as the animal yield wool, milk and various other products and plants provide high yield resistance, drought tolerance and various other attributes but it is difficult to prove in case of gene or DNA as their functionality is unknown until they are specified and ventured into the product.

In ***United States:***

Earlier utility was not an aspect of patentability under the United States Patent System until the enactment of Section 100 of the United States Patent Law which highlights about the industrial application of the inventions. In ***Brenner* v. *Manson*[23],** the application was rejected as they did not fulfill the criteria of utility, and the invention did not reap any benefit to the society. The following are the guidelines laid down by the court regarding this:

- If any invention is harmful or hampers the right of the society then such an invention will not fall under the criteria of Utility.

[23] Brenner v. Manson 383 U.S. 519

- Scientific enquiry is not the sufficient requirement to fulfill the criteria of utility even though it is established before the grant of patent. Apart from this if any innovation is filed for patentability, utility should not be proved after the grant of patent.
- If the functionality of the patent is hidden or not made available through written form, then criteria of utility cannot be fulfilled.

All these categories are applied for innovation relating to biotechnological inventions as well. A few of the ways by which the utility can be claimed include submitting clinical data and results of the clinical trials default of which may result in rejection of patent application. In order to have a workable framework the United States patent office has issued a guideline in 2001 especially regarding inventions relating to gene and DNA as their utility is difficult to specify. The test includes questions relating to fulfillment of four criteria that is whether the invention is well established, has a specific utility, substantial utility, or credible utility. While doing so the examiner must also adhere to certain sets of guidelines before rejecting the patent with proper reasoning. There must be a parameter to ascertain a certain claim, and such a specification must have a credible utility, the credibility will be judged from the perspective of ordinary person having knowledge in art and if there is corroborative evidenced adduced in its favor then patent will not be rejected. The primary proof of burden falls on the examiner to prove beyond doubt that there is no credible utility if it's proved then the burden shifts on the inventor to rebut it to derive a best outcome.

*In **European Union:***

The term utility has been replaced as Industrial Application in the European Patent Office. It includes all kinds of industries especially agricultural. The principle, guiding rules and regulation are not different from United States Patent system on Industrial application regarding the utility or industrial application of biotechnological inventions. There is only one exception under the European Union that it prohibits biotechnological invention on therapies which is ascertained even by TRIPS agreements. Whereas the United States Patent system considers everything available on the planet earth is not rejected from claiming a patent.

In India:

The term ***'Capable of Industrial Application'*** means and includes inventions being manufactured and employed within the territorial boundaries of the country. The procedure and governing laws dealing with Industrial application are similar to that of the United States and European Union Patent system. In ***Dimminaco AG case***[24]**,** the concern was with the other aspects of patentability like novelty and inventive step, but it was a settled notion with regards to Industrial application. Even in appeal the claim on utility was not questioned as it appeared that the patent office has accepted and assumed utility on inventions relating to genetically modified plants, animals and human materials.

Written Description:

Apart from fulfilling all the three basic criteria of patent it is important to fulfill another essential condition of written description in order to claim patentability. The Trade Related Aspect of Intellectual Property Rights mandates that the written description must be absolute and with adequate clarity so that the person skilled in the art may be able to understand it and describe the best mode of performing the invention. The main objective of this requirement is to highlight the procedure for making and carrying out the invention. It acts as a public notice, useful in evaluating the claimed invention and acts as a guarantee that the innovation is the ingenious work of the inventor, and he has complete and exclusive authority over it. In the ancient era written description was not an essential criterion but with the evolution of biotechnological patent this condition has become a mandatory requirement without which patenting of living organisms is impossible. Few of its objectives includes having ownership of the invention at the time of filing of application, bring it to the attention of the society by publishing, confine the application to certain restrictions, make it available for the person skilled in the art to have recourse of the invention after expiry of the time period and provide the best mode of manufacturing the product for the person skilled in the art to utilize the knowledge in creating the same product after the expiry of the exclusive right of the patentee.

In United States:

[24]Dimminaco AG v. Controller of Patents and Designs 2002 LP.R.L. 255 [Calcutta High Court]

According *to* ***Section 112*** of the ***United States Patent and Trademark Office*** the three essential requirements should be fulfilled in order to satisfy the criteria of written description:

1) Written Specification which was later replaced as Written description by the ***Patent Act of 1793*** to provide complete, unambiguous, and lucid information to the public about the invention.
2) Allowing the innovation to perform the way it has been desired or demanded to do so.
3) Provide the best mode of manufacturing and facilitating the deposit of invention.

In ***Hybertech Inc. Case***[25], the requirement for written description has been strictly construed and was discussed for the first time even though there is no difference between written description under the patent act and written description under the biotech industry. The major concern in this case was the default of the inventor to specify the written description. The district court held that there was inadequacy in defining the best mode assessment and they did not specify the method of creating the invention. It further held that enablement means assessing it from the legal point of view to make the person skilled in the art under such an invention and see to it that the invention is not excessively costly which was not proven with corroborative evidence in this case and patent was upheld as valid. With regard to best mode assessment the employees of the firm provided a testimony that the method was time consuming and exhaustive, and it is not the best mode available and there is concealment of fact from the opposite party which was denied by the court as unfair and wrong statement. The question regarding reasonable and undue experimentation has been discussed in ***Re Wands case***[26]**,** depositing the invention will aid as a successful tool in written description and this step is necessary only when there is undue or excessive experimentation which is not necessary in this particular case. The court further held that if any invention requires excessive experimentation, then it will not be prudent for the person skilled in the art to exercise such an invention to practice. On the other hand, the reasonable experimentation which is conducted to pin down the invention to practice would not constitute the written description as insufficient. Another essential requirement is that the best mode of practice should be disclosed by the inventor. The person skilled in the art can even practice on the other mode, which is not up to the mark, but the United States Patent Office has

[25] Ibid F.No. 14
[26] In Re Wands 858 F.2d 731 (Fed. Cir. 1988).

mandated to practice only the best mode so as to abstain the inventor from enjoying the monopoly right after the expiry of his term and concealment of the best mode amounts of contravention of rights entrusted upon the inventor. The third party or the person skilled in the art cannot judge the best mode, if the description states the best mode, then it is sufficient enough to prove that the inventor has recommended the best mode in his written description. In ***Mycogen*v. *Monsanto*[27],** it was held that intention of the inventor is immaterial, and his state of mind plays in major role in determining if he has concealed the best mode or not. Violation of this right has certain consequences like patent invalidation, breach of antitrust laws, abridgement of his defense and hampering his trade secrets which affects the patentability of the inventor irrespective of his intention. Another concern which is foreseen by many is that since biotechnological inventions related to living organisms it is difficult to describe them with their chemical, physical and structural properties. To get accustomed to such a situation it is requested to deposit the invention in a recognized depository either in its place of origin or international depositories established for this purpose. The Budapest treaty has taken the initiation to accept depositories relating to micro-organisms and living organisms all over the world. It provides the following benefits:

- The mandatory requirement of delineating the innovation when it is laborious to explain in detail the specification in the written description.
- Indemnifies against the factual errors made at the time of filing the application.
- Aids the inventor in negating the complaints relating to fallacious or invalid claims of the patents.
- Act as a supporting tool for improper and vague descriptions.
- In case the inventor fails to explain his invention through written description the depositories will act as corroborative evidence and rectify his failure of non-fulfillment of this requirement.

In ***Amgen Inc. Case*[28],** it was held that deposit of materials is not necessary in all cases and if the written description provides the details in a clear and concise manner also the materials utilized was known and preexisting to public in such cases there is no need for undue experimentation. In

[27]Mycogen v. Monsanto 164 F.R.D. 623 (E.D. Pa. 1996)
[28]HiBred International v. JEM AG Supply Inc 2d 794 (D.lowa 1999) No.99-1035

***Evans Medical* v. *American Cyramid*[29],** it was held that in the initial stage if the inventor has defaulted in complying with the written description and deposit of material then before the grant of patent, he must fulfill such requirement. This time frame was extended from date of filing of patent to grant of patent to have a better understanding of the state of mind of the inventor.

In ***European Union:***

The position of the European Union regarding the written description is not different from that United States. The developments of law with regards to sufficiency of disclosure was witnessed for the foremost time in the case of ***Genentech Case*[30],** it was held that it is necessary to apply for one method even though that method is general and is been applied to other plasmids and bacteria but that general method should function throughout the complete scope of the claim and convenient for the ordinary person having a knowledge in that field to perform just be referring to the disclosure. Further it held that if the inventor has formulated a general method, it itself is enough and he need not describe the method with each member of class to claim monopoly as the general method is of a higher contribution to the state of art. In ***Onco Mouse Case*[31],** this issue of insufficiency in disclosure was reiterated when a general method was formulated to be applied for all classes of species or bacteria. It was opposed on the ground that the claim sought was too broad and just be applying this method on a mouse without any clinical trial or practical experimentation on any other mammals he propounded a general method which also lacked sufficient disclosure. This contention was rejected by the Board of Appeals by comparing it with the precedents and held that there was reasonable and requisite description available for practicing this invention. Regarding claiming the priority dates for an invention, the claims should be specific and there must be complete disclosure. Undisclosed information or claims cannot be disputed on a later date to be considered for claiming priority rights. With regards to disclosure of invention Lord Hoffman in the ***Biogen Case*[32]** has issued certain guidelines. He states that:

[29] Evans Medical v. American Cyramid US patent No. 5,4,77,841 (841 patent).
[30] Genentech Inc v. The Welcome Foundation (1989) R.P.C 147
[31] Harvard College v. Commissioner of Patents Canada T 19/90 (1990) OJEPO 476, Tech. Bd App; (1991) E.P.O, R.525, Ex. D.

[32] Biogen v. Medeva (1997) R.P.C 1, HL

- The disclosure should be cognizant with the claim of the invention.
- It must satisfy the foremost requirement of the patent to indubitably validate the claims and content of the patent application.
- Prudent for the normal person having a knowledge in that particular field to have understanding to put the patent into practice otherwise the patent application stands rejected.

It further held that regarding the dates for complete disclosure the time frame should be construed from the date of filing of the application and not the date of publication or grant.

In India:

The patent application regarding the written description is insofar not different from that of the position in United States and European Union. According to the Indian Patent Act there is a mandatory requirement of filing the provisional and complete specification before the grant of patent. During the date of filing of application, it is not necessary that complete specification must be filed but it must be filed on the latter date so that application in the initial stage will be upheld if there is provisional specification with the essential disclosure of the specification attached with the drawing or models if any. The time frame between the filing of provisional specification and complete specification is twelve months. It must also disclose the best mode of carrying out or performing the innovation. In case of claiming the earlier priority date on an application the earlier application must disclose the complete specification of the invention to allow the person skilled in the art to carry out the invention in his best interest. It must also state the scope of the invention by addressing the claim or claims of the innovation. The amendment act of 2005 incorporated the requirement of depositing the biotechnological invention according to the *Budapest Treaty*. It stated that the biotech invention must be deposited in a government authorized and recognized depository which has been notified by the official gazette. The application must also specify the name, address and date of deposit upon which an access number will be issued by the depository which will be used for future references. There have not been any cases dealing with written description of the biotechnological invention as it is in its preliminary stages of development. Further the patent system of United System of America and European Union did not have the contradictory requirement of disclosing the source of origin

and geographical indication, but it was mandated in India. This necessity was stated in the *Biological Diversity Act* where the source of the biological resource was claimed to be disclosed so that the people residing in a particular geographical area can reap the benefits and conserve their reserve which has been used as a raw material for manufacturing the innovation. This was in contrast and let to a debate with the *Trade Related Aspect of Intellectual Property* as it did not mandate the indication of source of origin. Since India has ratified both these agreements it becomes pertinent for it to follow the procedures laid down in both the agreements uniformly. Written description forms an important part of patent laws. In a clarity and comprehensive manner, it exhibits its chemical and somatic characteristics in every structure and sequence presented before it even though it is a challenging and concerning task to describe the attributes of a living organism. To reduce this confusion the procedure of depositing the materials was later accepted in conscience with the international conventions and agreements. [33]

Suggestive Measures:

- The criteria of Novelty should not be strictly construed as in the case of biotechnology the invention revolves around the product of nature making it difficult to fit into the criteria of novelty and patent for many biotechnological inventions are rejected because strict application of novelty is applied on such cases. For this purpose, a separate act has to be introduced like *Plant Varieties Act* or amendments should be made in the already existing act which deals exclusively with the provision relating to patenting of biotechnological invention or which negates the strict construction of novelty only for invention relating to biotechnological inventions.
- The human being or an individual should not be patent eligible, but the invention derived from human being using his parts are subject to be patented and the person who has invented will be enlisted as an inventor. The human being from whom the parts are derived will be given a share in the benefit and will be acknowledged for the same.

Conclusion

[33] Dr. Sreenivasulu and N.S. Dr. Raju C.B., *Biotechnology and Patent Law Patenting Living Beings* 4,5 & 16, (Manupatra Information Solution Pvt. Ltd., Noida, 2008)

When drawing an inference both sides of the coins should be considered. Biotechnology has positive as well as negative effects and both of them cannot be negated or eliminated. Growth and development should be established keeping in view the benefits that could be derived with biotechnology innovation without causing any hindrance or detriment to the living organisms or product of nature. The country is already working on the national and international level by introducing and ratifying various conventions and agreements to encourage the development of biotechnology without any negative effects on society. Now it is upon the inventor and society to adhere to all the guidelines set forth and work in a coordinated manner so that technology can be used in an ecofriendly manner and not otherwise.