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Non-Obviousness in Bio-patents: The US and the EPO Position

AAYUSHI MEENA[1] AND MOHIT MEENA[2]

ABSTRACT

"The patent scheme has historically been used for mechanical instruments and the like. Including the use of a patentable biological substance. Disputes over their artistic status and private control and monopoly over life, per se, arose. There is a controversy as to whether modern technical developments mandate a new patent system. The problem was not between living and inanimate objects but between products of nature, whether living or not and innovations created by humans. Even today, ethical issues are constantly expressed, but they are much less vociferous. According to patents, the European system exhibits a disciplined but inclusive regime for correct biotechnology and its various progenies. This position is contradictory to the American law on patents, which is stripped of any such moral clause. The patent regime in Europe is all inclusive. As regards bio-patents, the European clause was liberal and stemmed a great deal from the TRIPS Agreement. The aim of this paper is to raise the question of non-obviousness in US patent laws and EPO laws and to find out how straightforward they are in dealing with or granting a patent on subjects relating to biological objects or living organisms. In addition, in this paper the writers will also concentrate on the fundamental notions of novelty, usefulness and genetic modification with regard to the award of patents or the non-obviousness of biological processes."

Keywords: *Intellectual Property Rights, Bio-patent, Patent laws, Non-obviousness, European Patent Organisation, Genetic Engineering.*

I. INTRODUCTION

In the modern era of science and technology, there are new innovations and inventions which are being brought into the limelight every day. Due to such an increase in new products, it is necessary to ensure that the creators of such products are granted protection for their innovations. However, it is necessary to exercise a degree of caution while providing protection to such so-called innovations by looking at factors like utility, obviousness etc.

[1] Author is a student at National Law University Odisha, India.
[2] Author is a student at National Law University Odisha, India.

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Among the various products which are sought to be protected, biological products or living organisms have become an important subject matter with regards to which there have been a drastic increase in the number of patent claims. The need, therefore, arises to keep a check or a lookout on whether there actually exists a need for the grant of such patents and whether they satisfy the test of the prior art and obviousness/inventive step for that matter. Moreover, there are major ethical and moral issues with regards to the commercial use of living organisms. Though, the patent practices of various countries do not allow generally for patents over living organisms, yet there have been judgments which have allowed such patents on the grounds of genetic modification or engineering, thereby bringing about ambiguity in this concept pertaining to the grant of the patent over bio-technological processes.

This paper aims at bringing about the issue of non-obviousness in the US patent laws and the EPO laws and find out how far they exhibit clarity in dealing with or providing for patent on subjects pertaining to biological things or living organisms. Moreover, the authors would also be focusing on the basic concepts of novelty, utility and genetic engineering with regards to granting of patents or non-obviousness in the biological processes. In addition to that, efforts will also be made by the authors to bring forth a coherent analysis of the ethical or moral issues involved which have been a subject matter of debate and suggest possible methods of redressed pertaining to the same.

II. FROM DISCOVERY TO INVENTION IN BIOPATENTS

The definition of invention in patent law has evolved continuously through judicial decisions and analyses of EPC and US case law. Discovery means it is already exists in nature but unknown to the public. Discovery will consider as new which is against the notion of Invention. It is important to clearly mention the legal standard for checking the non-obviousness of biotechnology products. In case *In re Bell* Federal Circuit court laid down two factors to grant patent (i) whether prior art sufficiently disclosed the ordinary skill that claimed the product can be made or the claimed process is identical (ii) whether the claimed result can be expected by the ordinary skilled person[3]. In biotechnology patent, life as a biological element present to get patent, which will help in the advancement of science and technology[4]. Discovery could not get patent[5] as generally but it can get patent

[3] *In re* Bell, 991 F. 2d 781 (Fed Cir. 1993).
[4] Li Westerlund, *Equivalence and Exclusions under European and US Patent Law*, 24 (2002).
[5] The European Patent Convention, 1973, art. 52

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for gene sequences, microorganisms.[6] For a product to get a patent, it should fulfill certain requirements like novelty, inventiveness, utility, and sufficient description.[7]

US patent law in *Diamond v Chakrabarty*[8] clearly mentioned that living micro-organisms are patentable. Because it was a new bacterium genetically modified to reduce crude oil and it was not found in nature. US court also established a clear distinction between a natural products and manmade product. This case opens the wide discretion for interpretation of the invention. The Man actually had interfered with nature and created something new which is not a product existing per se in nature, it is made by man. An application of gene sequence and interaction in product or process can get patent[9].

If the product of biotech is in an information state then generally it will not get protection under the patent law system. US court of appeal considering the biotech product equivalent to a chemical compound. Because the DNA sequence form is different from the naturally occurring compound. In order to get a patent under US law, there must not be a disclosure of the nucleic acid of the newfound but also of its utility of the claimed isolated gene[10].

In *Merck & Company V. Olin Mathieson Chemical Corp* [11] court denied a patent for natural product irrespective the claimed process. *Funk Brothers Seed Co. v. Kalo Inoculant Co*[12] in this case, the issue was whether a mixture of naturally occurring bacteria fixing nitrogen was patentable. US Supreme Court held that the patent cannot be granted for the discovery of a natural phenomenon. It is not important whether the mixture or results of the invention was useful. Court refused to patent protection because the substance was occurring through a natural process. And the mere discovery of any properties from a mixture of bacteria species is not patentable. There is nothing new or advance in the application, it is the discovery of a natural phenomenon. Hence applications contain nothing new, just the discovery of natural principle.

Contrary to that, EU law is not granting the patent to human organ product which is against public order and morality[13]. Because the human body DNA sequence have identical structure that is already present in nature. Hence it will lack novelty and patent cannot be

[6] 35 U.S.C. S. 101 (United States).
[7] Veena S. Iyer, *Biotech Patent Law*, 7 (1st Ed. 2007).
[8] Diamond v Chakrabarty, 447 US 30 (1980).
[9] *Id. at 6.*
[10] Judge **A.** Carmi, *Genetic Engineering, Medical Law*, 13 (2nd Ed.1983).
[11] Merck & Company v. Olin Mathieson Chemical Corp Fourth Circuit, 253 F.2d 156 (4th Cir. 1958).
[12] Funk Bros. Seed Company v Kalo Inoculant Company, 333 U.S. 127 (1948).
[13] Veena, *Biotech Patent Law*, 7 (1st Edition 2007).

granted. Under article 64(2) EPC[14] says that if the patent process produces a substance that is identical to a natural product. A patent cannot be provided to a substance that already exists in nature. But product which produced through the mechanical processes can get patent.

III. DOCTRINE OF EQUIVALENTS

Doctrine of equivalents[15] is developed through judicial decision. This doctrine principle is not applicable at time of patent issue but when the patent has infringed[16]. It furnishes protection to inventor from infringer who will stealing or getting benefits from invention illegally.[17] US Supreme Court introduce this doctrine to protect the interest of the inventor and provide protection of his invention. There should be balance between patentee invention on one side and public interest or 3rd party's interest i.e right to free use.[18] It is important to defend the legality of patent system because these biotechnology inventions have biological material in one side and substance which is already exist in nature. *Johnson and Johnson Associates Inc v R E Service Company*[19] in this case US Federal Circuit held that patentee cannot claim that particular subject matter if he did not disclose it earlier. Patent claim is defined according to specification of patent claimed in the application. The purpose of equivalent doctrine to disclose the specification equivalently. In case *Festo Corp v Shoketsu Kinzoku Kogyo ltd*[20] was decided that patentee should narrow down the claim. *Quid-pro-qua* [21]mean patentee will get something return like monetary benefits from public and protection from the state in case if there will patent infringement.

Graver Tank & Manufacturing Co. v. Linde Air Products Co[22] doctrine of equivalent was revived again in this case by the US Supreme Court. A person who infringed the patent by unauthorized mean by introducing minor changes in the claimed patent. In order to protect the interest of inventor and also consider the right of third party i.e right to use.

[14] The European Patent Convention, 1973, art. 64(2)
[15] Donald R. Dunner & J. Michael Jakes, *Bio-Patenting Trends in the U.S.*, 75, Journal of the Patent and Trademark Office Society, 857,873 (1993).
[16] Sutherland Asbill & Brennan LLP, *Doctrine of equivalents: where we now stand*, (Nov.23, 2020, 10:04AM) http://www.buildingipvalue.com/07US_Can/p.127-130%20Sutherland.pdf,
[17] Texas Instruments Inc v US International Trade Commission, 805 F 2d 1558, 1572 (Fed Cir. 1986).
[18] Teva Pharmaceuticals USA Inc v Pfizer Inc, 395 F 3d 1324 (Fed Cir 2005)
[19] Johnson and Johnson Associates Inc v R E Service Company, 285 F 3d 1046, 1055 (Fed Cir. 2002).
[20] Festo Corp v Shoketsu Kinzoku Kogyo Kobushiki Co. ltd, 75 USP Q 2d 1830.
[21] Pesses, Elizabeth, *Patent and Contribution: Bringing the Quid Pro Quo into eBay v.MercExchange* Student Scholarship Papers (Nov.23, 2020, 10:15AM), https://digitalcommons.law.yale.edu/student_papers/96.
[22] Graver Tank & Manufacturing Co. v. Linde Air Products Co 338 U.S. 605, (1950).

IV. GENETIC ENGINEERING AND BIOPATENTS

Genetic engineering is a method to change or transfer of genes within species or across species to produce new, improved or novel organisms. Genetics knowledge is not good or bad, it depends upon the scientists how they use it.

Scientists have develop a techniques which can create embryo genetically. This techniques had been in used w.r.t animals but not human. It starts a debate about human cloning because of not considerate the actual ingredient of patent right. According to EU, human body or Human parts are not patentable subjects but there is nowhere any mention about human body patent[23]. This mean that human body product does not prohibits from patentable as per principle[24]. EC directive laid down that biological material insulated from its natural environment or it can be produced by mechanical process even though the subject matter already present in nature.[25] Some fertility experts urged that embryos has huge potential for fertility purpose. But ethicists believes that there will possibility of misuse of cloning techniques. They also further said that it will restricts the individuality and the uniqueness of human being[26] like identical twins. But genetic engineering will not only help in curing rare diseases but also help in understanding the human health like heart disease and cancer[27]. It is duty of scientists to protect the humanity from exploitation of scientific advancement.

These both landmark case *Tuna-Dolphin*[28] and the *Shrimp-Turtle*[29] was decided by Dispute Settlement Body (DSB) of the WTO that member should bind by SPS memorandum according to International Standard. Health issue should be check on scientific parameter and not on politician opinion. . Authority also agreed on that biotech products may have adverse effects like food-born hazards, food additives or microbiological contaminant on human which may not occur in generation but occur in next generation[30].

Genetically modified products are highly debatable because of its negative effect. European Nation think that after consumption of GM food product will lead to unknown risk. Hence it is compulsory to labeling in EU[31]. EU has not decide anything on this issue. In US, bill

[23] The Patents Act, 1990, Australia, §.18.
[24] Sterckx, S, *Biotechnology, Patent and Morality*, 17, Journal of Biotechnology Review, 37 (2005).
[25] Directive on the Legal Protection on Biotechnological invention, 98/44/EC, 1998, art. 3(2),
[26] Marcia Mobilia Boumil, Law Ethics and Reproductive, 115, (1st ed., 1994).
[27] *Id. at 24.*
[28] Torsten H. Strom, *another Kick at the Can*, 33, Canadian Yearbook of International Law, 149,184 (2007).
[29] Raymond J. Ahearn, *U.S.-European Union Trade Relations: Issues and Policy Challenges*, 31 Canadian Year Book of International Law, 10 (2006).
[30] Alan Miller, *Debate of Genetically Modified Organisms Used In Food*, 8 US-China Law Review, 137 (2011).
[31] *Et al.* Kynda R, *Consumer Acceptance of Genetically Modified Food Products in the Developing World*, 7, 1,

'GMO Right to Know Act' has not been passed yet.

Use of Genetic method to diagnosis whether any disease exist or not. But there is possibility of misuse and risks related with analytical testing rather than diagnosis. The genetic use for curing prevailing disease should be far less controversial[32]. There are certain research in genetic testing that cannot be done without prior consent of the person but some can be done anonymously. Large amount of research on disease is done without any prior consent of the person. Because if a person informed about that, he might refuse to take the previously donated samples. There is no legal standards to check on these genetic test and this lead to inappropriate risk, premature commercialization. There should be proper parallel action to seek transparency about how drug trial is conducting by insurers or employers.[33]

V. BIOPATENTS IN THE US LAWS

(A) General idea of biopatents in US laws.

Under this subtopic, the authors would be discussing the system with regards to granting of Bio- Patents i.e. patents for living organisms in the U.S. would be discussed. The U.S. is one of the countries which has recognized the need for having bio patents in the present scenario for a variety of purposes, be it curing of diseases or be it for the sake of experimentation and new invention.[34] The United States also believes in the concept of genetic modification of living things and allows patent only if the genetic modification is done by a mechanical process without actually harming the life of the organism as such.[35] The United States has historically granted patents on natural available products namely insulin, adrenaline etc. and has also granted patents with regards to human genes or in better words patents have been granted for gene patents.[36]

As per the U.S. patent laws, patentable subject matter, means, *"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*

2 (2004).

[32] George J. Annas, *Privacy Rules for DNA Databanks: Protecting Future Diaries*, 270 Journal of Applied Management and Application 2346, 2348 (1993).

[33] George Poste, *Privacy and Confidentiality in the Age of Genetic Engineering*, 4 Texas Law & Political Review, 25, (2000).

[34] Marial L. Whelan, *What if Any, Are The Ethical Obligations of the U.S. Patent Office? A Closer look at the Sampling of Indigenous Groups*, 2 Duke Law Journals, 7, (2009).

[35] Ameen Jauhar and Swati Narnaulia, *Patenting Life the American, European and Indian Way*, 15 Journal of Intellectual Property Rights, 55, 56 (2010).

[36] John Raidt, *Patents and Biotechnology (US Chamber of Trade and Commerce)*, (Nov.23, 2020, 11:25AM): https://www.uschamberfoundation.org/sites/default/files/article/foundation/RaidtPaper.pdf .

conditions and requirements of this title"[37] There are essentially two major requirements of it. Firstly, it should include: process, machine, manufacture or composition of matter and secondly should not be related to laws of nature, physical phenomena and abstract ideas.[38]

Moreover, person is eligible for claiming a patent, under the laws prevalent if the subject matter has not been published in a form available to the public.[39] In addition to that, for anticipation of a particular technology, the "prior art" must give a proper idea about the invention claimed by the patentee in an explicit or an implicit manner.[40] However, in the leading case of "*Verdegaal Bros v. Union Oil Co. of California*[41]", it has been held that in order to ensure the anticipation of a claim with relation to a patentable subject matter, it is necessary that in an explicit or an implicit manner, there should be a reference to the prior art with regards to each and every aspect and the intricacies of the patentable subject matter.[42]

It is a well-known fact that for the purpose of claiming patent and for proving that there is an invention or the subject matter with regards to which the patent is claimed by the patentee, should be non-obvious i.e. it is needless to say that the technology should not only be "new" but in addition to that, it should be something which person ordinarily skilled in art will not be reasonably able to anticipate it.[43] Absence of similarity is not the actual requirement of non-obviousness, what essentially matters is that whether a certain degree of modification can result in obtaining the concerned invention which is sought to be patented.[44] Further, if a written description helps the ordinarily skilled person to anticipate the particular subject matter and it helps him to carry out the invention at the time of filing, the subject matter of the patent can be said to be non-obvious.[45] Moreover, there lies no particular standard of ascertaining as to how the subject matter can be anticipated by person ordinarily skilled in art, it is to be decided as to the facts of the case by taking into account, as to whether such a person on basis of information available can manufacture patentable subject matter.[46]

Talking about patents on Bio products or living organisms, the United States first recognized

[37] 35 U.S.C. S. 101 (United States).
[38] *Id.at 35.*
[39] 35 U.S.C. S. 102 (United States).
[40] *Id.at 37.*
[41] Verdegaal Bros v. Union Oil of California, 814 F.2d 628 (Fed. Cir. 1987).
[42] *Id. at 39.*
[43] 35 U.S.C. S. 103 (United States).
[44] *Id. at 41.*
[45] Dana Corp v. IPC Limited Partnership, 860 F.2d 415 (Fed. Cir. 1988).
[46] *In re* Wands, 858 F.2d 732 (Fed. Cir. 1988), 1400.

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the need for patenting living organisms when adrenaline a natural substance, was granted patent and the claim for patent on it was accepted in as early as 1906.[47] The Supreme Court of United states further granted legality to the patent over the concerned substance by observing that, purification of natural substances grants more utility to the product concerned in comparison with natural substance in its original form.[48] Moreover, the United States Supreme Court in the leading case of *Diamond v. Chakraborty*, laid down a new rule by stating that there could be patenting for recombinant DNA as long as it is modified in a manmade process through genetic engineering without harming the living organism itself.[49] A more recent example of patent being granted for matter related to human beings, was with regards to embryonic stem cells which was granted in 2001 to Harvard University. The U.S. laws recognizes both the food patents and gene patents unless they are not applied in a natural process and do not have any impact upon life of the human or other living organism as such.[50]

(B) Non-obviousness and biopatents in US law

As has been mentioned earlier, for deciding non-obviousness in the laws of the United States, S. 103 of the Patents Act comes into picture and it requires that a person who is ordinarily skilled in prior act should not be able to ascertain the intricacies of the product sought to be patented.[51] Under the laws of the United States, the concept of obviousness has been elaborated in the important case of *Graham v. John Deere Co*[52]. and there have been three broad criteria's 1: Determination of the scope and content of the prior art 2: Ascertainment of the differentiation between prior art concerned and the patented subject matter sought to be claimed. 3. Whether skill possessed by the ordinarily skilled person can help in finding out the product claimed[53]. The patentable subject matter can be said to be prima facie obvious if similarities arise between structure of compound claimed to be patented, method of making the compound is similar and there are similarities in the prior art.[54] The courts in the United states have majorly discussed about the concept of non-

[47] Roger D. Klein, *Gene Patents and Gene Tasting in the United States*, 25 Journal of Nature Bio-Technology, 907 (2007)
[48] Parke-Davis v. Mulford, 189 F. 95 (1911).
[49] Adriana Benedict, *The Nature of Biotechnology Patents: A Tangled Doctrinal Web of Processes and Products That Can Catch All Genes But Save None*, 5 Intellectual Property Brief, 13 (2014).
[50] D.S. Chisum, *a Treatise on the Law of Patentability, Validity and Infringement*, 7 New York Times Journal (2005).
[51] Joshua D. Sarnoff, *BIO v. DC and the New Need to Eliminate Federal Patent Law Preemption of State and Local Price and Product Regulations*, 2 Patently-O Patent Law Journal (2007).
[52] Graham v. John Deere Co. 383, U.S. 1 (1966).
[53] *Et al*. D.S. Chisum, *Principles of Patent Law*, 6 Foundation Press, N.Y. 601 (2001).
[54] Minh Chau Dao, *Novelty and Non- Obviousness of Biotechnological Inventions Under EU and US Law*, 7 Turin IP Research Papers (2008).

obviousness with regards to patentability of certain kinds of proteins wherein it has been held that unless a drastic modification occurs, it cannot be patented and in addition to that, it also has to take into account that if protein changes its activity it can be patented.[55] If there are no drastic changes in the reaction of the proteins, it can be said to be obvious and therefore cannot be patented. [56]It has been held in the U.S. that presence of a prior state of art would lead to obviousness of the subject matter of the patent.[57] Moreover, when there are existence of structural similarities in the available compound and the compound sought to be patented, then it would lead to obviousness.[58] In addition to that, with regards to the D.N.A. if the availability of prior art can provide for a structural similarity between the existing product and the one sought to be patented it would amount to obviousness.[59]Moreover, the case of KSR International Co. v. Teleflex Inc.[60] has altered the concept of obviousness in the U.S. and is now concerned with the isolation of a particular D.N.A. for the purpose of ascertaining obviousness or existence of prior art.

The United States follows the system of "teaching-suggestion-motivation", which essentially requires for a patent examiner to examine the credibility of the invention.[61] The system has often been criticized because of possibilities of presence of motivation beforehand and moreover, modifications or teachings can be used for determining prior art but not for obviousness.

However, in the leading case of KSR v. Teleflex[62] this test which had been source of controversy has been finally done away with because it analyzed patenting in rugged manner and the court held that the TSM test was not the proper manner of ascertaining the subject matter of a patent.

The biggest issue in determining as to whether the subject matter of the patent is obvious or nonobvious depends upon the fact of each case and it also depends upon in what way the person reviewing the subject matter is looking into it.[63] Moreover, there are different ways or manners in which people ordinarily skilled in art take into account patentability issues.

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[55] Zaneta Pacud & Joanna Lidia Uchanska, *the Quality of Patents on Biotech Inventions: The International Cooperation On the Non-Obviousness Standards*, 5 Vilismus University Journal (2012).
[56] Gregory Mandel, *The Non-Obvious Problem: How the Indeterminate No obviousness Standard Produces Excessive Patent Grants*, (Nov.23, 2020, 11:50AM), https://lawreview.law.ucdavis.edu/issues/42/1/articles/42-1_mandel.pdf.
[57] *Ex Parte* Stern, 13 USPQ 2d (Bd. Pat. App & Int 1989).
[58] *In Re* Mayne, 41 USPQ 2d, 1451 (CAFC 1997).
[59] *In Re* Deuel, 51 F.3d 1552, 34 U.S.P.Q. 2d 1210 (CAFC 1995).
[60] KSR International Co v. Teleflex Inc., 82 USPQ2d 1385.
[61] Winner Int'l Royalty Corp. v. Wang, 202 F.3d. 1340, 1348 (Fed. Cir. 2000).
[62] KSR v. Teleflex, 202 F.3d. 1340, 1348(Fed. Cir. 2000).
[63] Karen I. Boyd, *Non Obviousness and the Bio Technology Industry: A Proposal for Doctrine of Economic Non- Obviousness*, 12 Berkeley Technology Law Journal 17, 19 (1997).

Therefore, under US laws it can be concluded that there can be no fixed method of ascertaining non-obviousness.

VI. BIOPATENTS IN THE EPO LAWS

(A) Overview of Biopatents in the EPO Laws

The European Patent Organization provides patent on biological things or living organisms to people who belong to any of the member countries of the European Union. Under the Directive on the legal protection of biotechnological inventions, 27 member countries are granted protection for invention which are non-obvious.[64] As per the laws of EPO, there must clear and precise disclosure of the invention in question so as to allow an ordinarily skilled person to manufacture or prepare the invention which is claimed to be patented.[65] Also, the claims have to disclose subject matter of invention with a concise form of description of the subject matter claimed to be patented.[66]The EPO guidelines specify that those inventions that can be injurious to public order or morality if disclosed cannot be patented.[67] Initially EPO disallowed patents on inventions pertaining to plants and animals which however it started granting in the early 1990s.[68]

The EPO guidelines however clearly bring forth the fact that, unlike other jurisdictions, subject which has been granted patent has to be disclosed to the public giving an idea about the prior art, description and technical field and other intricacies which form an inherent part of the invention. The EPO guidelines allow patents for genetic modification of living organisms like the patenting patterns followed in the U.S. As long as the genetic modification is done, outside the living environment of the organisms the subject matter is patentable if it satisfies the test of non- obviousness.[69]However, considering the moral and the ethical issues involved in bio- patenting with regard to human D.N.A., the European Patent Office has held that destruction or use of human embryos cannot be a patentable subject matter as it involves actual harm to living organisms and is morally and legally unethical. In comparison to the US, however, the EPO is a little stricter in granting patents for subjects pertaining to technology i.e. the scope of technology is limited compared to the

[64] Directive on the Legal protection of biotechnological inventions, 98/44/EC 1998.
[65] The European Patents Convention, 1973, art. 83.
[66] The European Patents Convention, 1973, art. 84.
[67] The European Patents Convention, 1973, art. 53(a).
[68] The European Patents Convention, 1973, art. 53(b).
[69] Andrew Sharples, *Gene Patents in Europe Relatively Stable despite Uncertainty in the U.S.*, US biotech magazine, (Nov.23, 2020, 12:20 PM), https://www.eip.com/global/updates/article/article_by_head_of_eip_life_published_by_us_biotech_magazine.pdf.

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US[70]. However, unlike the U.S. system of following industrial application as an important criteria i.e. the productivity of the subject matter of the patent, the laws of EPC are more liberal as they do not take much into account, the industrial applicability of the product.[71] The EPC however, concerns itself more with the isolation of the living organisms from the natural environment and genetic modification without making actual use of the life of the organism.[72] In relation to modification of gene sequences, the European directives make it evidently clear that it has to be in exclusion of industrial application whenever a patent is applied for with regards to it.[73]

(B) Non-obviousness in the biopatent laws of EPO.

In the United States, the term non-obviousness is used for ascertainment of patentable inventions, whereas the term used in the European Union is "inventive step".[74] Under the laws of the EPO, patentable inventions will be those covered under "inventive step and are susceptible of industrial application".[75] In addition to that, "inventive step" would be said to be present in an invention, when a person who is reasonably skilled in the art cannot infer about the invention easily with regards to the prior state of the art present with regards to the invention claimed.[76]

There should be a limitation imposed upon the patent rights for biotech patents only to the extent of the biological processes and not the origin of the products i.e. the genetic products which are used as the sought after patentable subject matter.[77] Moreover, when human materials either synthesized by process outside the body or through a technical process, can be granted a patent on it.[78]Disclosure of industrial application of a gene is an inevitable part of the application for patent.[79] Non-obviousness in patent for human material would occur, when the same is claimed by a synthesized process and through genetic modification which includes an invention.[80]

For the purpose of ascertaining the presence of inventive step, the EPO or the Board of Appeals of the European Patent Office generally follows the problem-solution approach

[70] Dr. Georgios I Zekos, *Patenting Biotechnology*, 7 Journal of Information Law & Technology 12, 13 (2004).
[71] Li Westerlund, Biotech Patents, Equivalency and Exclusions under European and US Law, 60, (8th ed., 2014).
[72] Veena S. Iyer, Biotech Patent Law, 6 (7th ed., 2011).
[73] Directive on the Legal protection of biotechnological inventions, 98/44/EC 1998.
[74] *Id. at 71.*
[75] The European Patents Convention, 1973, art. 52.
[76] The European Patents Convention, 1973, art. 56.
[77] Aysegul Ozdemir, *Patenting Biotechnological Inventions in US and Europe*, 2 Ankara Bar Review 18, 19 (2009).
[78] Directive on the Legal protection of biotechnological inventions, 98/44/EC art 3(2), 1998.
[79] Directive on the Legal protection of biotechnological inventions, 98/44/EC art 5(3), 1998.
[80] Kingdom of the Netherlands v. European Parliament, C-377/98, (2001) ECR 7079.

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which is three fold: Firstly, The Identification of the differences between the closest prior art and the invention, Secondly, Determining the technical difference or the technical objective problem brought about by the differences between closest prior art and invention sought to be patented[81] and Thirdly, Whether or not the solution claimed for the technical problem is obvious for the person skilled in art or not.[82] For the purpose of determining industrial application for getting a patent on the genes, it is essential to take into account that, as to mentioning that particular part of the protein or gene which is sought to be patented, the function performed by it and how it is not produced by a natural process but rather by a natural reaction because of which there is no inventive step.[83]

For living things the "product of nature doctrine" is followed and to provide patent on living things.[84] When the invention sought to be claimed is a result of already existing product or substance, there can be no patent which can be granted on it. A patent can be claimed if a substance is put into a newly found use and produces an effect not seen before, then it can be patentable. Therefore, it can be construed that there is a narrower interpretation of a subject matter which is sought to be patented in the EPC rules compared to that of the U.S. patents Act.[85]

Moreover, in Germany in the famous *Antamanid*, it has been held that isolated genes can be patented if they are similar to naturally occurring genes, provided that they have not been isolated before, and discovery can also be patented even if there is in actuality no new invention.

VII. COMPARISON BETWEEN US AND EPO SYSTEM

Both the US and the EPO system of granting bio-patents are diverse in nature and have their own standards which are to be fulfilled while claiming a patent over a subject matter.[86] It can be said that in the US system of patents more importance is given to the industrial applicability and the utility of the product, compared to the European Union.[87] However, it

[81] The European Patent Office Guidelines on Examination of Patents, art. 5(1).
[82] The European Patent Office Guidelines on Examination of Patents, art. 5(2).
[83] Supra note 6.
[84] The European Patents Convention, 1973, art. 52(2)(a).
[85] Brian P. Biddinge, *Limiting the Business Method Patent: A Comparison and Proposed Alignment of European, Japanese and United States Patent Law*, (Nov.23, 2020, 12:53 PM), https://core.ac.uk/download/pdf/144225727.pdf.
[86] Mark D. Janis & Stephen Smith, *Technological Change and the Design of Plant Variety Protection Regimes*, 7 Kent Law Review 12, 16 (2007).
[87] Stephen R. Donnelly, *The Patentability of Human Embryonic Stem Cells: Is the Consistent Application of the European Union Biotechnology Directive's Moral Exclusion Clause Undermining Investor Confidence in Europe, Proving a Competitive Advantage to the United States*, 20 Dalhousie Journal of Legal Studies 16,19 (2011).

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can also be inferred that while the U.S. is more concerned with the industrial applicability, European Union talks majorly about the isolation of natural products from the natural environment which is essential for grant of a patent by the European Patent Office.[88] The U.S. system is stricter in granting patents, i.e. unless all the factors i.e. non-obviousness, utility or industrial application along with the secondary factors are not satisfied by the subject sought to be patented, however the EPO only concerns itself with inventive step and is also liberal to the extent of allowing patent on discoveries rather than inventions provided that there is isolation of subject matter.[89] In both the systems, there is a concept of disclosure, however, in the US system the manner of disclosure is given more importance i.e. it has to be written and it also has to fulfill all the criteria's of the prior state of art.[90] Under the EPO system the disclosure is necessary, but it is only to the extent of the subject matter claimed to be patented rather than the intricacies of the subject matter itself.[91]

Therefore, it can be concluded that the EPO follows a more liberal system of granting patents to the patentees with regards to the bio patents compared to the U.S. where a strict compliance of all the requirements is to be taken into consideration. However, the Problem Solution Approach is a more logical approach followed in the EPO compared to suggestion and motivation test which was followed in the U.S. So, the EPO patent laws are more liberal in comparison to that of the U.S.

VIII. INDIAN POSITION ON BIOPATENTS

Like the other laws i.e. laws in the U.K., U.S., European Union, for the purpose of obtaining a patent on a particular subject matter, the requirements of invention include industrial application and utility.[92] Moreover, with regard to the inventive step it is essential that is should not be obvious to a person ordinarily skilled in art and should be technically advanced in comparison to the existing knowledge and should have economic significance.[93] In addition to that, the concept of patenting in bio-technology or living things have also undergone a gradual change with regards to patenting in India pursuant to which there has been a huge increase in the patent applications filed by various companies for the

[88] Rochelle Cooper DreyFuss, *Non-Obviousness: A Comment on Three Learned Papers*, 12 Lewis & Clark Law Review 17, 18 (2008).
[89] Karen I. Boyd, *Non-Obviousness and the Bio-Technology Industry: A Proposal for a Doctrine of Economic Non-Obviousness*, 12 Berkeley Technology Law Journal, 311, (1997).
[90] 35 U.S.C. S. 112 (United States).
[91] The European Patents Convention, 1973, art. 83,84.
[92] The Indian Patents Act, 1970, §. 2(j).
[93] The Indian Patents Act, 1970, §. 2(ja).

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grant of patents on bio-products.[94]

Patents for living beings or biological products were initially not granted by the courts in India till the year 2002. However, this concept underwent a drastic change in the famous case of *Dimminaco AG. v. Controller of Patent and Designs*[95], wherein the Honorable High Court of Calcutta had granted a patent on biological products on the grounds that a new useful invention which results in the creation of a new product deserves to be patented.[96] Moreover, it was held that under the Patents Act of 1970, there was no bar on providing patent upon a subject matter even if it was a living organism.

Subsequent to this decision, the term "biological material" was included as a patentable subject matter under the Indian laws and currently a patent can be granted upon it if it is a new creation.[97] If such material is unavailable to the public, in that case patent can be granted to the patentee.[98] Moreover, the need for bio-patenting has been recognized by India by ratifying the Budapest treaty because of which India is under an international obligation for recognizing bio-patenting as a patentable subject matter.[99]

Ever since the passing of the Bio-Patents Act 2002, there has been an increase in the number of Indian companies which have availed the facility of procuring patents on the various biological inventions or processes.[100] As per a report of the World Intellectual Property Organization (WIPO) in 2014, nearly 700 Indian companies have been granted patents on biological processes and there has been a rapid increase in biotechnology patenting in the country.[101] Though in India, considerable focus and reliance has been bestowed upon the economic significance and technical advances, however this can possibly lead to lowering down of the standards of "inventive step", as the aforementioned conditions are secondary factors which actually do not seem to have a direct effect upon the establishment of "inventive step".[102] Even if the Patent Manual procedures give us an idea about the inventive step which is to be followed, however, what essentially is to be

[94] *Et al.* Rishabh Malviya, *Biotechnological Innovations Patent: A Review*, 3 Global Research Online Journals, 2, 3 (2010).
[95] Dimminaco AG. v. Controller of Patent and Designs, IPLR 2002 July 255.
[96] *Id. at 93.*
[97] The Indian Patents Act, 1970, §. 10(4).
[98] The Patents Amendment Act, No 38 of 2002, §. 8.
[99] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27(1), Apr. 15, 1994, 1869 U.N.T.S. 299.
[100] The IP Kat, "Inventive Step" in India: Getting a Better Understanding", (Nov.25, 2020, 15:33 PM): https://ipkitten.blogspot.com/2014/03/inventive-step-in-india-getting-better.html.
[101]Patent Cooperation Review Treaty Yearly Review (Nov.23, 2020, 15:39 PM): https://www.wipo.int/edocs/pubdocs/en/patents/901/wipo_pub_901_2014.pdf.
[102] Ravi Prakash Rahul , *The Issues and Challenges Related to Patentability of Life Forms in India with Special Reference to Foreign Laws*, (Nov.23, 2020, 16:10 PM): http://www.jicil.info/editions/edition4/Art3.pdf.

patented as a biological product depends upon the judicial interpretation of the courts under the Indian law? Though the court should be given the liberty of deciding disputes and finding out as to which subject is to be provided with a patent, there is always a scope for extending the ambit too much so as to cause ambiguities with regards to granting a patent in biotechnological processes.

IX. CONCLUSION

The subject of patenting on biological products is a highly disputable subject matter in today's world. At one point of time, its positive effects can include possible cure of diseases and other ailments across the world. Moreover, the rise of new inventions can be said to be a boon in today's world of science and technology which can bring about a lot of changes in the life of individuals i.e. by bringing about new uses with regards to the new products which are sought to be invented. However, the use of bio-patents can lead to a rise in the ethical and moral issues associated with it i.e. say by using a human embryo which is a living thing. Moreover, the EPO laws also allowed patents to be granted on medical procedures and surgical methods which further escalates the burning issue of ethics and morality with regards to granting of bio-patents. Further, the fact that there are differences in patent procurement methods or laws in the U.S. and the EPO, so there are possibilities of conflicts arising in patenting i.e. say a person belonging to the European Union seeking a patent in the United states and the differences in procedural requirements can also act as a major impediment in the procurement of patents. Also, there is no uniform standard of determining the extent to which the genetic engineering is to be allowed and also the concept of non-obviousness/ inventive step is a subjective concept which will depend upon the facts and circumstances of each case. Therefore it is concluded by the authors that though there are ethical issues in bio-patents, there is a need to allow bio-patents for the benefit of mankind subject to reasonable restrictions taking into account the fact that use of living matter is not made and the patents should only be allowed by the concerned authorities after full satisfaction with regards to the fact that the subject or the invention sought to be patented is only done by the use of genetic modification and no actual use of living matter.

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