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A STUDY ON PATENTABILITY OF 3D BIOPRINTED ORGANS

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ABSTRACT:

The 3D bioprinting field is undergoing rapid development and has been employed in numerous biomedical contexts. This technology differs from conventional 3D printing methods in that it employs bioinks made from cells and other biomaterials to facilitate the creation of intricate functional tissues. The bioprinting process involves a combination of computational modeling, bioink preparation, deposition, and the subsequent maturation of the printed materials; this complex process requires careful consideration of bioink composition, the chosen bioprinting method, and the type of bioprinter used during the development of organs. The primary motivation for recent developments in 3D bioprinting has been its practical applications in human medicine, cosmetic treatment, and pharmaceutical testing. The inventors were granted patent protection for the method of manufacturing a 3D bioprinted organ, but not for the organ itself. The reason for this exclusion from patentability is the stringent patentability criteria that are widely applied across the international community. The author of this paper aims to examine the existing patentability standards that impede patent protection for 3D bioprinted organs and tissues, particularly in jurisdictions such as the USA, the EU, and India. A broader interpretation of invention should be considered, rather than prioritizing exceptional levels of innovation. This would avoid duplication between the issue of patentable subject matters and the patentability criteria of novelty, inventiveness, and industrial applicability. The boundary of exclusions must be redefined, distinguishing between natural environments and living organisms. The reason for this is that nature is no longer the sole creator of living organisms. The authors forecast that biomaterials will be the primary catalysts driving future industries, necessitating robust patent protection.

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Keywords: *3D Bioprinting, Patentability standards, Bioink, Bioprinted organ, Industrial applicability.*

1.0 INTRODUCTION:

The field of 3D bioprinting is rapidly advancing, with the capability to revolutionize regenerative medicine. 3D bioprinters employ bioinks consisting of living cells and biomaterials to produce three-dimensional printed tissues. Three-dimensional printing is founded on additive manufacturing technology. This process involves layering materials according to a bottom-up methodology. The initial stage of 3D bioprinting involves the development of a digital model of the intended item, which is essentially a three-dimensional image of the actual object. When the actual object is unavailable or incapable of scanning, computer-aided design software (CAD) is employed to create a model of it. The second step involves converting the blueprint into a navigable path for the printer to follow. This translation is performed by computer-aided manufacturing software, also known as CAM. The final stage is the layer-by-layer printing of the desired object using bioprinters.

Numerous technological, ethical, and regulatory obstacles must be addressed before 3D bioprinting can be effectively integrated into clinical settings. Three-dimensional bioprinted organs should be eligible for patent protection. The lines separating man-made innovations and naturally occurring phenomena need to be redefined.

2.0 PATENTABILITY OF A 3D BIOPRINTED ORGAN:

The 3D bioprinting essentially involves many technologically advanced features that requires and demands patent protection. The innovators seek patent protection because of its uncompromised nature. On close perusal of patents already granted on 3D Bioprinting and associated technologies, one could infer that there still exists a reluctance for the patent granting authorities to completely recognize this aspect of technology to be eligible for patent protection. No such product patent is granted for the 3D bioprinted organ or the tissues. The patent offices rest their decisions on different statutory barriers such as “The Product of the Nature Doctrine” and several other exclusionary principles. Apart from this ethical and moral concern also plays a vital role in prohibiting the patent conferrment on these products.

 ISSN:2582-6433

2.1 THE TRIPS STANDARD:

The TRIPS agreement which prescribes the minimum standard protection that is to be awarded to different kinds of Intellectual Properties, also defines the eligible subject matter tht could be conferred protection. Article 27 to Article 34 deals with patents. The TRIPS agreement confers patents on any invention, that could be process or product, in all fields of technology. The requirements for being awarded patent is that the concerned invention must be novel, it must involve an inventive step and it must have utility.[2]

The TRIPS agreement along with defining the eligible conditions for patentability, also lays down few categories of inventions that could be excluded from patentability, such as

1. Inventions and their commercial exploitation, if affects public order or morality.
2. Inventions that could be harmful to the plant, human or animal life and helath by way of its commercial exploitation
3. Inventions if exploited results in unreparrable harm to the environment.
4. Inventions that are mere methods (surgical, diagnostic, therapeutic, prophylatic) of treatment to animals or humans
5. Inventions that seek for patenting plants, animals or essential biological process for production and propogation of them.[3]

2.2 PATENTABILITY STANDARDS IN USA:

Any new and a useful process, product, composition of matter or a manufacture and also the new and useful improvements on the above mentioned categories can be conferred patent protetion.[4] The judiciary has for a long time emphasised on an exclusionary principle to limit the scope of patentable subject matter. It lays down that "Laws of nature, Natural phenomenon and abstract ideas are exclued from patentability". Thus, any person cannot claim ownership over anything which is naturally found or nature made. For eg. No one could claim patent for a discovery of a new mineral from earth. Similarly, well established natural laws such as law of gravity, law of buyoncy etc., can't be patented. This exclusion is laid because all these natural laws and phenomenon are handicrafts of nature, they are free to all men. No one could claim monopoly over it. Conferring monopoly over these concepts would exclude the possibility of others to further research on it and the the use of it would be pre-empted.

[2] THE TRIPS AGREEMENT, Art 27
[3] Ibid
[4] The Patent Act, 35 U.S.C §101 (1952).

 ISSN:2582-6433

It is essential to understand that every invention or development is in one way or the other connected to the nature. There can be no invention withoout the input from natural law/phenomenon. Therefore, a balnket ban on usage of nature is not justifiable. On this line, the judiciary has spelled a wide array of verdicts on The Product of Nature doctrine, which can be helpful in understanding the patentability of the 3D bioprinted organs and tissues, since it is a combination of living and non-living material for the creation of an exact replica of a naturally found organ.

THE PRODUCT OF NATURE DOCTRINE:

The doctrine was first laid in the case of American Wood Paper Co. v. Fiber Disintegrating Co,[5] which introduced the concept of nature related invention. Thereafter, in Latimer case[6], the fiber obtained from the needle of *Pinus Australius* was also excluded from patentability. The court had a strict interpretation of this doctrine which made them to exclude not just the product obtained but also the process for extracting the fiber was excluded from patentability. The judiciary then, felt that conferring patent on plants and other life forms will result in conferrment of monopoly over the entire nature, thereby precluding it from public usage and enjoyment.

This doctrine was expanded further with the introduction of "The Therapeutic Value test" and the concept of purification in the case of Kuehmsted v. Farbenfabriken of Elberfeld Co,[7] where importance was given to the medical utility of the product found. Thus, any product which doesn't actually exist in the nature in its discovered purified form was construed to be eligible for patent protection. Several inventions were recognised after this landmark coinage. Recognition and patent protection was awarded to substances that were isolated and purified from its natural form, if it had therapeutic utility. The ultimate objective of patentability was construed to be on the aspect of "utility to mankind". Further, the isolated and purified materials were required to have a different use and an useful property when compared to its natural form. The doctrine of "The Product Of Nature" was further expanded when living organisms were protected by patent.

In 1977, while deciding the patentability of the Bergy's Application, the judiciary firmly laid

[5] American Wood Paper Co. v. Fiber Disintegrating Co, 90 U.S. 566 (1874)
[6] Ex parte Latimer, (1889)
[7] Kuehmsted v. Farbenfabriken of Elberfeld Co, 179 F.701 (1910).

 ISSN:2582-6433

down that there is no ground in excluding patentability of a manufacture or a composition of matter just because it included something which is alive. This view further strenghtened when a living organism as such was conferres patentability in the case of Diamond v. Chakrabarthy.[8] In this case, a microbiologist named Anand Chakrabarthy, would have manufactured a bacterium from the genus *Pseudomonas* containing four different plasmids, capable of degrading four different components of crude oil. All these plasmids were identified in different bacterium, they were transferred and maintained stably into a single *Pseudomonas* bacterium manufactured by Chakrabarthy. The existing patentability standard was construed to be very wide encompassing "Any manufacture or composition of matter to be patentable if they are new and useful". Thus, the term "manufacture" includes production of useful articles from raw materials, thereby giving them new form, quality or property and the term "composition of matter" would refer to composition of two or more substances that result from a chemical union or a mechanical mixture. The court probed into the intention of the congress and highlighted that "Anything under the sun made by man is patentable". Thus, any invention will be awarded patentability if it is

1. Human made
2. Non naturally occuring
3. With markedly distinct characteristic, function and use[9].

Post Diamond v. Chakrabarthy, the branch of genetic engineering witnessed an immense growth. Huge number of patents were filed on different life forms, including transgenic animals and others. It was only around 2012, the verdict rendered in the case of Mayo Collaborative Services v. Prometheus Laboratories Ltd[10], that made a huge breakthrough in refining The Product of Nature Doctrine. This case refined the two step test that were laid down in previous cases. Thus, after Mayo if a claim recites any natural phenomenon, law of nature or an abstract idea, outrightly it will not be excluded patent. Further, there must an application of such natural phenomenon, law of nature or an abstract idea and that application must result in creation of something new. Along with this, the cliam must also recite some additional elements which are significantly more than the judicial exception[11]. Thus, in order to transform a mere application of law of nature to patent eligible subject matter, an inventive step is required.

[8] Diamond, Commissioner of Patents and Trademarks v. Chakrabarthy, (1980)
[9] Ibid
[10] Mayo Collaborative Services v. Prometheus Laboratories Inc, 566 U.S. 66 (2012)
[11] Ibid

 ISSN:2582-6433

The patentability of isolated materials which was considered as an unsettled loophole in the Product of Nature doctrine became a settled matter of law after the judgment in the case of Association for Molecular Pathology v. Myriad Genetics Inc.[12] In this case, Myriad Genetics Inc were successful in discovering the existence of BRCA1 and BRCA2 on human chromosomes. They were also able to identify the connectivity between these gene mutations and the breast cancer. Along with this findings, they were also capable of synthesizing a BRCA cDNA (complementary DNA). When Myriad filed patent application for these two discoveries. Only cDNA was rendered patent eligible. The act of mere isolation of human genes was found not eligible for patenting, since it was just an isolation of a naturally occuring DNA segment which have no markedly distinct characteristics, function or use. Thus, the ideology after Myriad was that even a groud breaking discovery would be not awarded patent and will be construed to be a mere discovery if it doesn't possess a markedly distinct characteristics, function or use when compared with the naturally existing product.

At this juncture, it is essential to discuss about Section 33 of The Leahy Smith America Invents Act (AIA) 2011, which prohibits issuance of patent on any claim directed to or encompassing human organism. The term "human organism" is not defined in the Act. Thus, by following the practice of the broadest reasonable interpretation, any claim with reference to human organism can be brought under this limitation.

The Interim Guidance for the determination of the patent eligibility of nature- derived inventions, issued by USPTO on 2014 is based on these decisions that stresses for the requirement of the markedly distinct characteristics, function or use. This practice became further established in the case of Re Roslin Institute,[13] where patentability of a cloned sheep was the question. In this case, the argument was straight between the human ingenuity involved in the creation of clones (copies) of a sheep and that the end result was just a copy of a naturally occurring sheep with no markedly distinct characteristics, function or use. The end result claimed was genetically identical to the naturally found animal. The court also would have given weightage to the socio-ethical concern and finally didn't confer patent protection to the clone.

Now, when considering the non-patentability of the 3D bioprinted organ, the arguments

[12] Association for Molecular Pathology v. Myriad Genetics Inc, 569 US 12-398 (2013).
[13] Re Roslin Institute, 750 F.3d 1333 (Fed.Cir 2014)

 ISSN:2582-6433

mooted would be:

1. Firstly, It is also an exact replica of the natural organ and it is structurally as well as functionally similar with no markedly different characteristics, function or use.
2. Secondly, It doesn't claim something which is significantly more than the judicial exception and it lacks an inventive step.

But, when we consider the intriacies involved in the 3D bioprinting technology, few researchers also probe on the possibility of getting all these bioprinted organs patentable by including those as medical devices or implants, but that would yet again be suject to the product of nature doctrine. It is essential to understand the materials involved in preperation of bio-ink is essentially a mixture of natural and artificial materials. The composition of bio-ink itself is a novel one having significant utility as it ensures printability and bio-compatibility. The resulting bioprinted organ, even being structurally and functionally similar and being the exact replica of the naturally occurring one, can be patented because the composition, material involved and the manner of production and maturation is also quite different. Apart from all these differences, the end product has an increased commercial utility and an indisputable involvement o human ingenuity is present which could obviously render them patentable.

2.3 PATENTABILITY STANDARDS IN EUROPEAN UNION:

The European Patent convention confers patent protection for any invention, in all the fields of technology. The statue in line with The TRIPS agreement requires that the invention must be novel, with an inventive step and must be capable of having an industrial appliaction or utility[14]. With special reference to the concept of 3D Bioprinting, one could confine the exclusion that relates to discoveries and scientific theories.[15]

The statue also provides a list of inventions that ought to be excluded from patentablity which is in accordance with THE TRIPS permitted exclusions, such as

1. The inventions which would affect the public order or morality, if commercially exploited.
2. Invention relating to plant or animal varieties or that claims the essentialaly biological process for production of such palnts and animal varieties. But, patent is granted if the invention claims a microbiological process.

[14] THE EUROPEAN PATENT CONVENTION, Art 52(1).
[15] THE EUROPEAN PATENT CONVENTION, Art 52(2)

 ISSN:2582-6433

3. Methods (surgical, diagnostic, therapeutic, prophylatic) for treating human or animal body. Provided, patent protection can be confeerred to specific substances or products or compositions used in any of the above mentioned methods[16].

Patent was sought for the 'Method of producing Transgenic Animals'and 'The Oncomouse' was a transgenic mouse which was first granted patent protection in Europe in 1992. After which, this evolved to be a serious ethical concern globally, and later in 2001, The European Patent Office decided to limit this patent protection only with respect to "Transgenic Rodents" and excluded the patent protection to mammals. It was essentially a patent protection that opened the gateways for "Transgenic non-human mammalian animals". Thereafter, this patent was reaffirmed in Canada.[17]

Relaxin is a hormone that relaxes the uterus in female during the childbirth. Therefore, considerable research was undertaken to extend its medical application even to caesarean and complicated deliveries. In 1926, the researchers found the Relaxin hormone in pigs. Only in 1975, The Howard Florey Institute isolated and ound the chemical structure of the hormone found in human beings. In order to explore its therapaeutic use, it was necessary for them to manufacture its synthetic form. Therefore, they cloned the gene to produce a synthetic Relaxin. This case, popularly known a Relaxin case was decided in 1991 where the European Patent Office granted patent for the genetically engineered form of the human H2 Relaxin harmone[18].

This attempt was vehemently criticised as it was an attempt to patent life. The act of isolation of a gene from a pregnant women was considered to be a violation on human dignity. Patenting human genes or indusrtial and commercial purpose was considered to be non-acceptable. The product as such was criticized to be a mere discovery, that lacked inventive step and novelty.

The European Patent Office was able to solve all these criticisms. They stated that only a discovery of a substance that is freely found in nature, lacks patentability. But here, the substance was isolated and it also contended that the coded orm of relaxin was not known until it was isolated. Further on, it reiterated that even every gene in a human body is cloned, it would be impossible to again reconstitute a living human. Thus, a broader view was adopted on the notion of "patenting of human life". Thus, in Europe considerable importance was attached to

[16] THE EUROPEAN PATENT CONVENTION, Art 53.
[17] Harvard College v. Canada (Commissioner of Patents), 2002 SCC 76.
[18] Relaxin/Howard Florey Institute, T 0272/95 of 23.10.2002

 ISSN:2582-6433

the technical effect involved. On the other hand, the European Patent Convention prohibis patenting if Human embryo is involved in such a way if it is used for an industrial or commercial purpose.[19]

In the case which decided the Wisconsin Alumini Research Foundation/ James Thomsan Stem Cell Application[20] , the patentability request for the process of obtaining stem cells from human embryos was not accepted. This process involve destruction of human embryos which has the potential of devoloping into adults, for the purpose of stem cell production. Therefore it was found to violative of human dignity.

The European model, does not confer protection for a mere discovery of any element or a genome sequence. On the other hand, if a technical process is involved for the purpose of isolating an element from a human body or in producing it. It constitutes a patentable invention even if the structure of the element such isolated or produced is similar or idntical to that of the naturally occurring one. Such gene sequence can also be used for industrial or commercial purposes.[21]

However, in addition to exceptions laid down in Article 53 of The European Patent Convention, following are also not construed to be eligible for patentability:

1. Cloning of human beings
2. Act of modifying the germ line of the human beings as that would affect the genetic identity
3. Using human embryos for commercial or industrial purposes.[22]

2.4 PATENTABILITY STANDARDS IN INDIA:

A living organism could be a single entity or being that is present in the natural world. This could encompass anything from a plant or animal to a virus, or even a human being. Over the years, the Indian Patent Office has implemented various initiatives to tackle the complexities associated with patenting living organisms. Although the initiatives have contributed to clarifying the misunderstandings to some degree, further efforts are necessary to achieve a

[19] THE EUROPEAN PATENT CONVENTION, Rule 28(c).
[20] Wisconsin Alumini Research Foundation/ James Thomsan Stem Cell Application, T1374/04 of 7.4.2006
[21] Directive 98/44/EC of The European Parliament and of the council on the legal protection of biotechnological inventions, Art 5, (adopted on Jul. 6, 1998).
[22] Directive 98/44/EC of The European Parliament and of the council on the legal protection of biotechnological inventions, Art 6, (adopted on Jul. 6, 1998).

 ISSN:2582-6433

clearer understanding for the stakeholders.

The position of the Indian government regarding the patenting of living organisms has evolved gradually over time. In the couple of decades prior, India had opposed the issuing of patents for life forms. It's clear from India's call for a review of Article 27.3 of the TRIPS agreement and its backing of the African group's 1999 proposal to review Article 27.3, which advocated for a ban on patents covering life forms and microbiological processes. TRIPS required member countries to permit patents for all technologies and microorganisms as well. Amendments to the Indian Patents Act of 1970 were implemented between the years 1999 and 2005 to meet India's international obligations under the TRIPS agreement. A key amendment was made in 2002, enabling patents for microorganisms. The amendment revealed new avenues for securing patent rights for newly developed microorganisms, as well as other areas related to microorganisms.

To obtain patent protection for a living form in India, the invention must comply with the conditions specified under the Act. The prerequisites encompass comprehensive revelation of the invention, the invention must be novel, unobvious, and utilitarian, it has to pass the vendibility test, and the invention benefits the public. The Patents Act does not award patents for naturally occurring living or non-living substances, so the product or process to be patented must be isolated from nature through human intervention.

The Calcutta High Court delivered a judgment in the Dimminaco AG case. The Controller of Patents and Designs made a pivotal change in January 2001, significantly altering the landscape of patenting life forms in India. Diminaco A G, a Swiss company, petitioned the Hon'ble High Court of Calcutta after being denied a process patent for its live vaccine preparation intended for Bursitis treatment. The company's application was rejected on the basis that a patent for an invention incorporating a living organism could not be granted under section 2(1)(j). The Controller of Patents concluded that the process did not qualify as an invention, given that the resulting product yielded a living organism, thereby rendering it ineligible for patent protection. In contrast, the High Court applied the vendibility test to the invention and concluded that the process yields a new and useful vendible item. A patent was granted for the process since it yielded a salable item, and the fact that the product contained living material was not considered in reaching this decision. From this case, it can be inferred that patent protection is afforded to a process, if the resulting product is something that can be sold.

 ISSN:2582-6433

In 2002, the Act was modified to incorporate Section 3(j), which prohibits patenting biological processes for producing plants and animals, including those in whole or in part, except for microorganisms. This amendment enabled the patenting of living organisms, including microorganisms, in addition to the processes involved in their creation. The extent to which Section 3(j) would facilitate the patenting of microorganisms is still unclear due to a lack of clarity regarding the definition of a microorganism. Having a well-defined concept of "microorganism" is crucial to be incorporated into legislative amendments in India.

Patenting Genetically Modified Organisms (GMOs) is a distinct issue. As living entities, GMOs are classified under life forms, yet they do not emerge naturally in the environment. Substantial human involvement is required for the creation of genetically modified organisms. As a result, the Act offers greater flexibility in the patenting of GMOs.

The patentability of 3D bioprinted organs continues to be a million dollar question that remains unresolved. It is worth noting that biotech companies make significant investments in research and development to create new, advanced technologies that can potentially replicate human organs with high accuracy. Given the substantial financial investments and significant risks undertaken by these companies, it is only fair that they receive compensation for their efforts. Denying patents for this highly sought-after technology, which is a product of extensive research and significant investment, is greatly demoralizing for the companies. Genetic engineering and biotechnology should also be taken into account as a significant contributor to a country's development. Nations with developed economies, including the US, Japan, and European countries, have established laws that simplify the patenting process for living organisms. Over time, the Indian government has implemented necessary changes to address patenting concerns regarding living organisms. While improvements have been made, more work is needed to achieve full satisfaction. In light of the foregoing points, the Indian government must enact legislation to resolve the uncertainties surrounding the patenting of life forms and 3D bioprinted organs.

3.0 CONCLUSIONS AND RECOMMENDATIONS:

The patent eligibility of 3D bioprinting products will be one of the key factors that will enhance research and development in this field. There is an increasing number of arguments to sustain the applicability of the patent system to 3D bioprinting inventions. The fact that 3D bioprinting inventions incorporate a “biologically active organism” does not negate their patentability

 ISSN:2582-6433

when the other patentability requirements are met. In addition, the notion of "markedly different characteristics" needs to be revisited and properly defined in the context of 3D bioprinting and more comprehensive reforms are needed.

The contemporary patent system requires a reevaluation of what is and is not patentable subject matter. Every man's creation should be considered a patentable subject matter. The worry that ordinary and uninspired tasks might be patented will not be alleviated by the exclusions. In addition to being pre-empted by prior art, a nature-based invention is also excluded from patent protection if it fails to demonstrate an inventive step or industrial applicability, which are two of the three other key patentability requirements. The mere disclosure of natural facts does not make them eligible for patent protection. In order to be patentable, a subject matter must have been the product of human ingenuity.

The current boundaries of what can be discovered or created from nature should be redefined. Nature and life are no longer synonymous. Natural materials can also be parts of inventions eligible for patent protection. The patentability of claimed inventions should not be hindered by the nature of their components; rather, it should primarily be based on the innovative manner in which those components have been combined.

The author proposes shifting emphasis from a high level of inventiveness to a broader understanding of the concept of invention. This would avoid a duplication of the issues surrounding patentable subject matters and the patentability criteria of novelty, inventiveness, and industrial applicability. Redrawing the boundaries of exclusions requires a distinction between the natural world and living organisms. The reason for this is that nature is no longer the sole creator of living organisms. The author's forecast indicates that biomaterials will play a crucial role in the development of future industries, necessitating stringent patent protection.

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