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Patentability of Bioprinting Technology: Where Invention Meets Requirement

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With the ability to print human organs on demand, 3D bioprinting has the potential to be a "game-changer," eliminating the need for human or animal transplantation or living or deceased donor organ donation. The market of organ transplantation is mammoth, driving several companies to opt for patent protection of their bioprinting technology over other means of intellectual property. By resorting to a doctrinal study powered with deductive reasoning, the study highlights that even though clinical organ transplantation present ethical challenges, bioprinting has its own set of practical, ethical, and regulatory issues that need to be resolved. These have to do with controlling public expectations and the morality of biomedicine's continued reliance on pricey technological fixes. The legitimacy of patent monopoly by providing essential health products and services as luxury goods has come under scrutiny, particularly in Low and Middle Income Countries (LMICs), where such technologies relentlessly widen the gaps in healthcare. Put simply, usage of living cells, brings in the thought of patentability issue in relation to bioprinting technology. The purpose of this study has been to envisage a road map towards developing a viable, equitable and sustainable industry will need to strike an optimal balance between rights and responsibilities among different stakeholders, including governments, 3D bioprinting companies and patients (and the public).

Keywords: 3D Bioprinting, Patent, Living Cells, Biotechnology, Bio-Ink, Therapeutic Efficiency

Bioprinting technology signifies the creation of a living three-dimensional structure with specialized compartments (such as cavities and vasculature) and specialized cell types (such as smooth muscle cells, endothelial cells, connective tissue cells, lung cells, or liver cells) by depositing successive layers of adult or embryonic stem cells as "bio-ink" in a desired pattern.[1] Introduced with an aim to revolutionize the healthcare sector by providing customized solutions to the medicine industry, bioprinting technology stands as an one-time solution for restoring the balance between demand and supply of organs for transplantation among patients.

3D printing or bioprinting is the brainchild of emerging technologies in the field of biotechnology, driven with the purpose of synthetically producing tissues alongside biological constructs, by means of using 3D bioprinters. The technology is welcomed as a sustainable replacement of the prevalent custom of sale and trafficking of human organs with a profit motive for the purpose of organ transplantation during shortage of such organs, as have been dealt with in this study. This brings us to the first research question of this study which is to enquire as to whether the bioprinting technology can be a promising catalyst in the see-saw of necessity and ethical consideration.

The market of organ transplantation is mammoth, driving several companies to opt for patent protection of their bioprinting technology over other means of intellectual property, to have an upper edge over growing competitors. It is ideal to note that when a patent claim has been made for bio-printed lungs, the same excludes all other from making, using, offering to sell, selling or importing into the country granting patent any other bio-printed lungs, irrespective of the process used for developing it. But, when viewed from the lenses of patent law, bioprinting technology poses a prime question as to whether human organs and tissues that are being made with technology interference, from naturally occurring human cells, be a patent-eligible subject matter or not.Left with ambiguity majorly, bioprinting as a patentable subject-matter remain a grey area for several patent regimes across the world. Ethical issues can always be seen through the lenses of luxury issue, that is to say a secondary consideration in the environment of urgent need. But, in the context of bioprinting technology, such concerns are a forefront player which will

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continue to bother inventors and stakeholders of such technology. This brings us to the question as to whether patenting of bioprinting technology is justified in the wake of perpetual requirement of organs for transplantation.

As the future rests on bioprinting, the patent regime of the United States powered with judicial decisions have been in consistent support of the progressive technology thereby being the leg of this literature as well. Consistently as well, there has been insights of the European Patent Office for its active involvement in the discussion as have been highlighted by literatures and India, a nation which is still juvenile to the relationship of 3D bioprinting with existing praxis. The study has adopted doctrinal research methodology to delve into the available literature thereby answering the existing gaps. Further, deductive research method has also been adopted to answer the proposed research questions in a specific manner, while discussing the current study in general.

A Global View on Patentability of Bioprinting Technology

After 2013, 3D bioprinting technology entered a phase of rapid development. The primary hotspots are 3D bioprinting tools, techniques, and materials, as well as biomedical and polymer materials. The main technologies in this subject include medical model construction, medical implants, drug delivery, printing materials, 3D printing techniques, craftsmanship and procedures, and medical devices and equipment. China, the United States, and Korea are the three nations with the highest rates of production.In terms of fundamental technologies and goods, the United States seems to take a lead.[2] China has a lot of patents in the related field, but few of them are for fundamental technologies, and both the quality and impact of patents need to be increased.

For instance, Hyun-WookKangsee and his co-authors presented an integrated tissue-organ printer (ITOP) that can create stable, human-scale tissue constructs of any shape in their paper titled *"A 3D bioprinting system to produce human-scale tissue constructs with structural integrity"*[3] in Nature Biotech in 2016.[4] Hyun-WookKangsee and his colleagues[5] were successful in incorporating micro-channels into tissue-constructs, which enhances the diffusion of nutrients to printed cells. However, producing three-dimensional, vascularized cellular constructs of clinically relevant size, shape, and structural integrity unquestionably remains a major challenge for tissue engineering. By achieving this feat, they not only increased the likelihood of cell survival in designed tissues but also showed off the 3D bioprinter's capacity to create "mandible and calvarial bone, cartilage and skeletal muscle." They also stated that "the production of tissues for human applications and the building of more complex tissues and solid organs" will be the focus of their future bioprinting research.

A 3D printer that can manufacture human tissues has been developed by a start-up that a graduate of IIT Madras helped co-found and with the help of the same,the Indian Institute of Science had the first Mito Plus prototype installed.[6] In addition to applications in cancer biology and cosmetology, the bioprinter could print a variety of biomaterial for use in pharmaceutical drug discovery and drug testing. The bioprinter would lay down a layer of biomaterial, which might include living cells, to produce complex structures like skin or liver tissue, adding that there are still many obstacles to overcome before an organ can be made that is completely functioning and viable for human transplant.

Modern 3D bioprinting businesses, like Organovo, are based on these exciting research findings and aspire to design, produce, and ultimately market living human tissues that more accurately reflect human biology and function, like native tissues and organs. Their goal is to bridge the gap between pre-clinical research and clinical trials by using 3D bioprinting technologies to create novel medicines.

The vast ramifications of bioprinting and its enormous potential present a number of critical legal questions. These could include issues with regulating research, its consequences on society and broader ethical ramifications, as well as concerns with commercialization, innovation policy, and technological governance. Such have been affirmatively discussed in the following parts of the study.

Patent Actors, Activities and Stakeholders in regards to Bioprinting

The bioprinting sector and researchers are depending more and more on patent protectionas a result of the significant and risky investments made in this sophisticated new technology, and it is anticipated that the number of patent applications will continue to climb. This is emphasized in a research[7] by Hornick and Rajan, who searched patent databases throughout the world for bioprinting-related inventions.

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It is ideal to note that a bulk of patent applications are being filed in the United States, according to Robert W. Esmond's analysis of recent patent activity.[8] The results of this search combined the patents issued in three key areas of pertinent technologies that have especially active patent markets. The most pertinent technological areas and typical patent claims can be divided into three categories based on the distinct stages of development in bioprinting:

(i) A preprocessing or design phase;
(ii) A production phase; and
(iii) A post-production maturation phase.

Patent claims are frequently focused on devices, processes, and procedures utilized in bioimaging and computer-aided design (CAD)during the preprocessing or design phases. The US Patent No. 8579620, entitled "Single-action Three-Dimensional Model Printing Methods," issued to Andy WU on May 30, 2031,[9] is one illustration that fits within this category. For simplified 3D physical model printing applications, the patented method leverages printing templates to encapsulate complex geometric representations and difficult data conversion processes from users.

Some of the most significant patents issued during the manufacturing phase are focused on bioinks, particularly hydrogels, biopaper, and bioprinting equipment as a whole. One illustration is "Self-assembling multicellular bodies and methods of producing a three-dimensional biological structure using the same", as described in US Patent No. 8143055.[10] The patterned discrete filler bodies in the patent claims appear to prevent the migration and ingrowth of patterned multicellular bodies comprising living cells in bioprinted tissues and organs.

Additional patenting opportunities in advanced organ production may materialise throughout the maturation and post-production phases. These include "maturongens," which are biochemical and physical elements that hasten tissue maturation, or "bioreactors," which are novel tools, materials, and devices that feed cells during the "post-print" stage.

Viewing Bioprinting as an Experimental Phase

The UK Intellectual Property Office (IPO) has acknowledged[11] that the biomedical use of 3D printing, particularly in the field of regenerative medicine, is an important area for patent applications. Regenerative medicine refers to the use of the body's natural healing abilities to improve treatment options through tissue engineering. Tissue engineering is the process of creating artificial tissues and organs (bio-artificial tissues) by using a patient's own cells (a technique known as "self-to-self" therapy).

In 3D bioprinting, bioactive structures are created using robotic, computer-controlled machines referred to as "bioprinters," with the potential to be used in medicine. The concept of experimental space has helped us to understand the diverse relationships and processes that bioprinting has sparked. The experimental space allegedly contains numerous dimensions. Generally, there are three prime dimensions that can be associated with the concept of hioprinting, namely, the legal dimension, the social dimension and the geographical dimension.

The proliferation of patent documents, referencing one another and creating a discursive network, first creates a legal dimension. The experimental environment is occupied by cutting-edge businesses and academic institutes, engaged in bioprinting, thereby adding to a social component as well. Last but not least, the spatial operations and global geography of bioprinting has been responsible for giving rise to the geographical dimension.[12]

While 3D printing uses inorganic materials, bioprinting aims to construct structures that resemble body parts using organic materials, including living cells.Specialized bioprinters use biological inks (bioinks), such as differentiated human embryos or induced pluripotent stem cells (iPSCs), to print three-dimensional constructs consisting of living organic components. It is claimed that these new printing technologies will revolutionize and democratize the fields of regenerative medicine and manufacturing, just like book printing did.The evolution of the printing press in the fifteenth century and the development of 3D bioprinting in the twenty-first century bear striking similarities in terms of process, as well as the influence of resources and accessibility for both printing technologies.[13]

As human organs could be printed on demand, long-term 3D bioprinting has the potential to be a "game-changer" by offering a different source of organs and eliminating the need for live or deceased human organ donation. Thus, the experimental phase can prove out to be an absolute essential in the coming times. The technique is not yet advanced enough to allow for the bioprinting of an entire organ. The development of alternatives to animal testing using 3D bioprinting is a feasible and short-term objective that the technology aims to achieve.Drug testing, for instance, can be carried out using bioprinted structures integrated into lab-on-a-chip devices, and is even made better by the dramatically higher throughput the technology provides.However, a mid-term benefit that has yet to be realized relates to the development of tissue components like human heart valves, particularly for younger people (like paediatric patients) who have specific issues with the available bioprosthetic or mechanical heart valve (MHV) options.The essential tissue components can be modified in terms of geometry (size and shape) to properly fit the patient's needs because they are made from the patient's own cells, which lowers the risk of rejection. Such tailored tissue components that are 3D bioprinted, have the capacity to grow with the patient, unlike mechanical implants, removing the need for additional operations to replace components that are no longer appropriate.

While clinical organ transplantation raises ethical questions, bioprinting poses its own set of problems that need to be worked out on the practical, moral, and legal fronts. These concern regulating public expectations and the ethics of biomedicine's persistent reliance on costly technology solutions.For example, the expense of creating a customized organ could result in waiting lists that are similar to those for transplants of humans or allografts. Put simply, usage of living cells, brings in the thought of patentability issue in relation to bioprinting technology.[14]

Ownership in Bioprinting Technologies: A Commodification Issue

Significant legal and moral issues surround 3D printing in the biomedical field. The matter of ownership is intimately related to patients' data and materials and includes concerns about individual ownership of identity and health information (which are necessary to develop new devices and may, therefore, encourage innovation). It also addresses the use of information to spur non-therapeutic applications. In regards to data security, IP, and privacy, three-dimensional printing also presents legal difficulties.

There is a pool of dangers connected with keeping and using particularly private physical or medical information. In the context of 3D bio-printing, designing a personalized medical device would entail giving access to very detailed information and perhaps even photographs about the patient's anatomy, problems, and preferences to many players in a decentralized supply chain. IP protection may also be threatened by illegal file sharing within specific communities, where designs for physical products are sold illegally in the same way that MP3 or video files are.

Primary (or "direct") liability occurs in the context of 3D printing when one party is held legally liable for another party's injury. People who post unlawful designs for sale on 3D printing design websites, download and print unlawful materials from such websites for public use, or deal in unlawful items are to be held accountable. Although there are many different players (the owner of the printer, the manufacturer or supplier of the printer, and the person who actually created and/or used an untested product), the close involvement of patients in the context of 3D manufacturing and the fact that the customer is the actual manufacturer, mean that there may be overlaps in liability obligations and the corresponding regulatory challenges. The collection and transfer of personal data, as well as the accountability of designers and software programmers, are additional dangers associated with 3D printed objects.

It is challenging to include many new bio-AM applications in the pillars or classifications of the law as it stands now. Recognizing how differently biological and non-biological components are regulated is another important difficulty in controlling AM. However, applications for additive manufacturing are frequently seen as combination goods that contain both biological and non-biological components.[15] These biological elements tend to raise more ethical questions and the need for public policy attention when they come from humans. Due to the combination of materials and methods used in AM, the current established pillars of European Union regulation (pharmaceuticals, medical devices, advanced therapies, tissues and cells, and organs) may not be adequate for bio-AM regulation in medicine, requiring reevaluation. For example, it is not always clear whether applications including bioprinting are biological goods (because their interaction with the body is more "natural" when in use) or non-biological components, such as advanced medical equipment or treatments.

Understanding Bioprinting in Light to the *Case of Diamond* V *Chakrabarty*

When it comes to the patent system of the United States, Sections 101, 102, 103, and 112 of the Title 35 of the United States Code ('the Patent Act') lays down pre-requisites of patent protection in form of utility, novelty, obviousness, written description and enablement requirements. The landmark case of *Diamond* v *Chakrabarty* (1980)[16] that knocked the doors of the Supreme Court of the United States, interpreted Section 101 of Title 35 of the United States Code (the Patent Act) to state that anything made by a man under the sun will be patentable subject to certain exceptions. The exceptions relate to nature's manifestation that are available for free without any exclusive reservation.

Analysis of the Chakrabarty Tests

The case of *Diamond* v *Chakrabarty* (1980) had laid down two guiding tests that if satisfied would answer the addressed issue of patenting printing of naturally occurring human cells, in affirmative. The inter-related tests are:

(i) Whether bio-printed organs can be considered to be a naturally occurring manufacture?

(ii) Whether bio-printed organs can be categorized as a humanized invention being subject to similar considerations like the previous tests?

The first asked question can be answered taking into account the meaning of the terms 'bioprinting' and 'manufacture'. While the former is already known, the latter in light to the discussed case draws attention. Bioprinting is a manufacture as the Apex Court defines the term as the process of creating products out of raw or prepared materials by giving them new set of traits, whether through man-made effort or machineries. It is essential to note that the bio-printed organs are creation in-vitro in a human-controlled environment, which greatly differs from naturally occurring organs.

The concept of patentability in relation to bioprintingmakes it obligatory for the bio-printed product to be inclusive of human ingenuity thereby not being naturally occurring. Put simply, a bio-printed organism or its live tissue is not patent-eligible subject matter if it is a precise reproduction of an existing organism or its living tissue. On the contrary, a complete redesign of a naturally occurring organism or its living tissue in a bio-printed organism qualifies it as a patentable subject matter. In the *Chakrabarty case*, the Court was convinced with the contentious engineered bacteria featured with the ability to break down multiple components of crude oil that differentiated it from naturally occurring bacteria, to be a product of human ingenuity.

Dilemma in Indian Patents Act, 1970 Surrounding Bioprinting

When it comes to India, the Indian Patents Act, 1970 is the guiding statute for patentability of inventions. Novel, non-obviousness, inventive step, industrial application and written description are the eligibility criteria for an invention to be patentable under the legislation. It is interesting to draw attention towards Section 3(b) which obstructs invention whose usage appears to be contrary to public order or morality or which causes serious prejudice to human, animal, plant life, health or to the environment.The purpose behind3D printed organs is to replace a damaged or non-functional part of the naturally existing organ. The technology involves using human/animal cells or human embryonic stem cells, which *ipso facto* involves concepts of human dignity and human identity. With morality as the legislative intent behind Section 3(b) and lack of legislative flexibility, patenting of bioprinting technology appears difficult in Indian context.

Sections 3(d) and (e) are two additional clauses that present negligible obstacles to the patentability of bioprinting technology. While Clause (e) prohibits substances obtained by a mere admixture that results only in the aggregation of the properties of the components thereof or a process for producing such substance,Section 3(d) prohibits the patenting of the mere discovery of a new form of a known substance that does not enhance the known efficacy of that substance or of a new use for a known substance or process.

The exclusion to Section 3(j) of the Patents Act, 1970 as provided in the provision itself, stating, *"but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals"*, does impliedly include bioprinting in its scope. Granting of patent on procedures that are not biological, like the use of bio-inks in 3D printing to produce three-dimensional objects appropriate for replacing damaged or dysfunctional human body parts, is therefore allowed under Section 3(j).

Consequences of Patentability of Bioprinting Technology

The rationale behind making bioprinting patentable is comparable to the rationale behind creating a patent system and granting patents in the first place: both serve to promote innovation and give inventors financial incentives to recoup their expenses.The patent system exists to encourage innovation. Quid pro quo agreements require inventors to reveal their inventions to the public in return for a 20-year monopolyon those inventions. Throughout this exclusive period, they can recoup their R&D expenditures. Without this time restriction, inventors are less inclined to produce new inventions. As a result, the patent system was established to promote innovation. Bioprinting patents come with benefits and drawbacks. Granting more bioprinting patents results in a quicker time to market for bioprinting.[17]

If bioprinting patents were awarded, however, the cost of bioprinting would likely rise as some of the proceeds would go towards covering the inventors' patent fees. One the one hand, at least some people could afford to bioprint, even though everyone would have to wait longer for the technology to become available.It goes without saying that one of these options is better than the other; each day that bioprinting is not employed, people's lives,in general, deteriorate or even result in death, therefore there is no time to lose in introducing the technology to the market. Since time is a more important component than cost when comparing the two factors, bioprinting ought to be patented.

Not only is 3D printing being used to copyand fix replacement components for different items, but it is also being used to replicate and mend human tissues, organs, and body parts. According to a recent biotechnology discovery, it is now possible to reproduce human tissues and organs both in situ and on demand. This appears to be the realisation of a formerly unthinkable concept.[18] The transformative aspects of mass digitization and the widespread use of 3D scanning and printing technologies present both opportunities and challenges for the current legal framework governing product liability, health and safety regulations, environmental protection, risk management, patient and consumer protection, bioethics, and intellectual property.There are many different materials that can be used for bioprinting. Since stem cells can quickly adapt to host tissues, they are a preferred substitute for cells and collagen when used as bio-ink to print different organs and tissues.

The most often used applications in the biotechnology industry, as per the 3D printing patent landscape, are 3D printing methods; 3D printing plastic powder formulations; 3D medical modelling; dental implant manufacturing; bone implants; stereolithography; and 3D printing software and interfaces.Patents pertaining to 3D bioprinting technology raise issues of patentability, infringement, and licencing strategy (new business and governance model). The final issue has a direct bearing on how broadly the public can access these technologies.

The Product-Process Conflict of Bioprinting Technology

Recently,[19] patents for products and methods involving 3D-engineered tissues or organs have been obtained. Organovo was granted patents on 3D printed tissues that can be used for toxicological testing, drug discovery, and the study of human disease. This discovery relates to tissue engineering and regenerative medicine, more specifically to the creation of multilayered vascular tubes. The 'Multilayered Vascular tubes' patent offers[20] protection for the development of designed multilayer vascular tubes, methods for making such tubes, and applications for such tubes in therapeutic, diagnostic, and research settings.

A 3D bioprinting patent claim of this kind would bar anyone from creating, utilizing, proposing to sell, selling, or importing any goods that satisfy the claim. Access to these technologies will therefore be significantly impacted by the scope of patentability. The next stage in determining whether 3D bioprinted tissues or organs are patentable inventions is to determine if the subject matter is exempt from patentability.

Whether a bioprinted product is a creation of human intellect and not something that naturally occurs, determines the scope of patentability of bioprinting technologies. The procedures and products used in bioprinting are both created by humans, thus technically everything associated to it is a product of their inventiveness. Proving that a bioprinted product is artificially occurring is difficult.Abioprinted creature or its living tissue is not a patent-eligible subject matter if it is a precise reproduction of an existing organism or its living tissue. On the other hand, a bioprinted creature or its living tissue may be patented if it completely redesigns another naturally occurring organism or its living tissue. The latter describes the goods that now represent the state of the art in bioprinting.Human living tissues used today are architecturally distinct from actual human live tissues yet functionally similar. Bioprinted goods are sufficiently distinct from their naturally occurring analogues to qualify as patent-eligible subject matter unless researchers are able to bioprint biological tissues that are structurally similar.

Bioprinting may still be patentable as process claims rather than product claims even if it failed to pass the above discussed gatekeeper.Abioprinting method claim can be focused on the printing operations rather than the prohibited goods. A bioprinting process claim is patentable as long as it does not refer to items that are prohibited, such as those that are bioprinted. Examples include U.S. Patent No. 7,051,654 which claims a technique of "forming an array of viable cells" and U.S. Patent No. 8,691,974 which claims a method of "producing 3-D nano-cellulose based structures."[21] Simply said, the 3D printing method itself does not inherently breach the concept of no patent for human organisms, even though 3D-printed cells could theoretically eventually be employed in unpatentable items.

We have already talked about liability previously when it comes to bioprinting technology. In regards to considering the technology to be a product, the visuals of product liability appear to be striking. According to the Product Liability Directive,[22] when a producer's product is faulty and results in personal injury, strict liability must be applied. This "strict liability" only applies to goods that have been mass-produced, reviving the debate over whether 3D printed objects should be considered custom-made or modifiable standards. The problem may actually affect how the liability system is implemented. Given that the Medical Device Regulation's liability obligation (Article 10 (16)) contains no exceptions for manufacturers of custom-made equipment, the Product Liability regime on customized devices also applies to medical devices. When a product has a flaw, the manufacturer is responsible for the resulting harm. All actors in the supply chain and producers participating in the production process may be held accountable. The actor who is posing as the producer can also be the manufacturer or supplier of the 3D printer, its components, or the input material. Liability claims necessitate the injured party's demonstration of damage, a product flaw, and cause. If a product does not deliver the safety that a person has a right to anticipate, it is to be considered defective.

Exclusion of Patentability of Bioprinting Technology on Morality Grounds

One of the most controversial (and disruptive) aspects of 3D bioprinting is the use of living biological material as bio-ink made from human/animal cells or human embryonic stem cells (HESC).[23] When it comes to working with human tissues, the procedure is quite innovative and sophisticated, touching on the sensitive social and religious taboo of working with human cells, particularly HESC. The ethical question of using (and destroying) HESC thus raises doubts about long-held notions of human dignity and identity as well as the existing legal and intellectual property system.

The patent system encompasses more than just a technical check list. Given that the system is predicated on the concepts of justice and merit in the form of monopolies, the evaluation of patentability will involve value judgements. For the purpose of promoting harmony and coherence between science and culture,the morality clause is ingrained in patent laws. If such actions are thought to violate moral norms in society, they should not be encouraged as a business endeavour. Patents do not, in fact, exist in a vacuum. They ought to be a natural reflection of the culture and tastes of the populace, upon which deliberative democracy is based. Without a connection to cultures and social values, the patent system would isolate itself from society, especially in contentious matters involving the dangers and uncertainty of emerging technology, where public opinion is crucial in determining the appropriate risk regulation.

The European Directive on the Legal Protection of Biotechnological Inventions, also known as the "Biotech Directive,"[24] explicitly prohibits the commercialization of certain technologies due to their immorality. These technologies include human cloning, genetic identity modification, the use of human embryos for industrial or commercial purposes, and the modification of animal genetic traits when the suffering of the animal outweighs the significant medical benefit to humans or other animals. It is uncertain whether the directive, which prohibits the patentability of human embryos, also covers cells or cell lines developed from embryos. Furthermore, it is unclear whether the prohibition of human cloning from patentability applies solely to technology used in reproduction or also to cloning done in order to generate stem cells for medicinal purposes.

The Harvard/Transgenic Animals case[25] validated the balance test created in the earlier Onco-mouse case.In Wisconsin Alumni Research Foundation (WARF)/Stem Cells, a broad reading of Rule 23d(c) of the EPC led to the invalidation of patent claims for stem cell products and methods of producing stem cell cultures. This case concerned innovation utilizing HESC. This implies that, even if the method of production is not sought after for patent protection, any act involving the killing of embryos, in the study leading to an invention, establishes grounds for refusing patentability. The morals clause was interpreted by the court to mean that patentability would be forbidden if human body instrumentation was used in the creation of the invention.It is also noteworthy that no procedure is eligible for patent protection if it "offends against human dignity." In accordance with this comparison, a patent claim for 3D printed tissues or organs will be immediately denied if it can be demonstrated that doing so "offends against human dignity" by exposing human components to instrumentation and commercialization.

It is ideal to note that the hospital and the manufacturer are required to engage into a processing agreement in accordance with the GDPR,[26] which must include specific clauses pertaining to the duties of each party. The right to informed consent is recognized by EU legislation, but there is no clear direction on how to put this right into practice when it comes to cutting-edge tools or methods like 3D printing medical devices. A living person's transplantable tissue may only be removed by a licensed individual. Such removal would have to be for charitable purposes. It is anticipated that a fully informed consent process will reduce the possibility of injury and potential ethical violations. The donor must expressly consent before having his or her tissues removed, stored, or used.

The patient has a right to specific information about how their data is processed. The GDPR provides protection for the subsequent processing of patient data for reasons other than 3D printing medical equipment, particularly for scientific, marketing, and insurance purposes.This indicates that 3D printing does not present an additional risk to privacy in the event that patient data obtained for 3D printing purposes is processed further.The data processing for 3D printing must be under the control of a national public supervisory authority. In most cases, a third nation outside the EU must provide a sufficient degree of data protection before patient data can be transferred there (for example, to foreign 3D printing facilities).

The TRIPS Agreement also specifies exclusions and exceptions to patent protection under certain conditions in order to minimise the unjustified effect of blanket patent protection. Particularly, moral considerations such the preservation of the environment, human, animal, or plant life, or health, are considered principled arguments to patentability. TRIPS additionally states that WTO members have the authority to bar medical treatment technologies—such as therapeutic, surgical, and diagnostic procedures for people or animals—from patent protection. In *Brüstle*v *Greenpeace*[27], the word ‘embryo’ was defined as something which was ‘capable of commencing the process of developing into a human being’. The stance adopted was that a human embryo is defined as a structure (blastocyst) made up of the first few cells (totipotent cells) to develop from conception and that this structure fits under the definition of a human body under Article 5(1) of the Biotech Directive. Nonetheless, because pluripotent cells, which are seen in blastocysts, are unable to evolve into human bodies in the future, they are regarded as patentable. According to this, an invention that includes the destruction of embryos during the process will not be eligible for patent protection; but, if the invention's manufacturing could be accomplished without the destruction of embryos, it might still be eligible for protection.

In line with Brüstle, patent claims pertaining to 3D printing, which entail the death of stem cells during the process, will be invalidated. The Brüstle court limited its ruling to the meaning that was relevant to the patent because it understood that the definition of "human embryo" was a delicate social matter. Only creations that adhere to the rulings in Brüstle will be eligiblefor patent protection when using stem cells for 3D printing. Thus, applications would not be eligible for patentability if the novel goods and techniques claimed arose from the destruction of human embryos, even if the claims do not involve the use of human embryos.

Limitation of Patentability of Bioprinting Technology on Grounds of Medical Treatment

Article 53(c) of the European Patent Convention states that, at the European level, patents cannot be awarded for inventions pertaining to techniquesfor treating the human or animal body through surgery, therapy, or diagnostic procedures performed on the human or animal body. However, products such as substances or compositions intended for use in these techniques are exempt from this provision. Article 53(c) of the European Patent Convention, which specifies a unique restriction to patentability for medical treatments, is included into Section 4A of the UK Patents Act (UKPA). It specifies that techniques for diagnosing conditions involving the human or animal body, as well as procedures for treating the human or animal body through surgery or therapy, are not eligible for patents. It was held in *Bristol-Myers Squibb*[28] that the limited purpose of the provision is to ensure that 'actual use, by practitioners, ofmethods for medical treatment when treating patients should not be subject to restriction or restraint by patent monopolies'.

The US has had more freedom to patent methods for medical treatment than the UKPA, notwithstanding some significant changes to the extent of protection. The UKPA's approach excludes patents for methods for treating the human or animal body through surgery or therapy. The awarding of such patents was constrained before the 1980s.The Physicians' Immunity Statute was introduced to give doctors some protection from being sued for infringing on a medical treatment method patent as it became popular for medical treatment methods to be copyrighted.

The US court has become stricter in recent years when considering the parameters of patentability. The court decided in *Mayo* v *Prometheus*[29] that diagnostic procedures involving "laws of nature" are not patentable. The techniques covered by the patent claims help doctors determine the right dosage for patients with autoimmune diseases receiving thiopurine therapy. It was determined that the claimed procedures did not transform natural inventions that were not suitable for patenting into uses that were worthy of patent protection. The court questioned whether or not the claims significantly enhanced the explanation of the association between the medicine and human reaction in order to support the methods that the right holders claimed were patentable.

Surgery is defined as procedures that involve the professional competence of a surgeon or other medical professional. However, procedures that do not necessitate a surgeon may still be considered surgical, such as the method of implanting a marker into the body to facilitate CT scans.The implantation of a 3D-printed organ is therefore considered to be surgical, but the creation and printing of the organ will not be viewed as surgery. To summarize, it would be necessary to distinguish between "using a 3D bioprinter for reproducing cells/organs" and "using a 3D bioprinter in the treatment of the human or animal body by implantation" while drafting successful claims. The former is probably covered by the medical exemption; while the latter, offers technical effects of duplicating materials for additional implantation and is unlikely to be covered by "methods for medical treatment."

Patent protection is granted to inventions in this sector only when they satisfy three basic requirements, anmely, novelty, inventive step or non-obviousness, and industrial application or utility. Additionally, the patentability of 3D bioprinting technology must be determined. A minimum of 20 years of market exclusivity are granted to the holder of a 3D bioprinting patent, enabling them to stop anyone from making, utilising, offering to sell, selling, or importing any goods that meet the patent's requirements. Long-term market exclusivity will help patent holders compete more successfully in the marketplace. But it might also negatively affect information freedom, which would stifle creativity, and negatively affect the human right to health, particularly in light of the health regime.

Safety and Security Concerns of Patenting Bioprinting Technology

A significant regulatory concern in the area of 3D printing is safety. Safety in the context of bioprinting largely refers to the dangers of doing medical treatments away from formal medical settings. Rarely have the negative implications of bio-printing been discussed, including issues with tissue integration, biocompatibility, and continual tissue creation while materials degrade.In the context of 3D bioprinting, the DIY body modification community conducts interventions in non-medical contexts that are both medical and non-medical. The deliberate implantation of processed living cells into the human body carries a number of dangers to the health of the patients. The management of rules is complicated by the emergence of new participants, such as DIY communities, and new producers, such as hospitals in a decentralized medical sector.

Given the prevalence of do-it-yourself techniques in this field, safety and health are among the first issues that come to mind when thinking about 3D bioprinting. In any case, it is important to think about how standards can be upheld if cutting-edge 3D bioprinting technologies are increasingly widely used outside of established professional settings.Biomaterial sources, unhealthy donors, implant effectiveness, and post-transplant infections are all safety concerns. The utilization of living cells put into a human body in 3D bioprinting is still an unproven clinical paradigm; hazards include cancer, dislodgment, and migration of implanted material.

The EU Tissues and Cells Directive (EUTCD) 2004/23[30] regulates the early stages of donation, procurement, and testing of tissue and cells to assure the quality and safety of cell and tissue material used in bio-printing. How much testing is necessary when items are created in 'batches of one' (patient-matched, or 'batches of one'),and maybe on demand, is a critical question for product validation and release. It is doubtful that the final product will be tested, especially if it is created in vivo and then implanted into the patient. In addition to the use of patient (stem) cells, the use of cells originating from other humans carries special safety hazards,such as the accidental transmission of disease through the implantation of tissues or organs printed using such cells. It is not yet apparent whether bio-AM applications can be evaluated similarly to currently available goods and services or if a new validation and testing methodology is necessary.

It is ideal to note that scenarios in India in regards to safety concerns of bioprinting technologies has not developed it. This is because India has not been a part of the innovation race in regards to healthcare in the past times. The first 3D bioprinting Centre of Excellence (CoE) in the Indian subcontinent has opened its doors, thanks to a partnership between the Indian Institute of Science (IISc), Bengaluru and Sweden-based CELLINK, the world leader in producing 3D bioprinters. The CoE, which is based at the IISc Bengaluru campus and is housed at the Centre for BioSystems Science and Engineering (BSSE),will give researchers access to 3D bioprinting equipment, allowing them to move more quickly through important applications with the ultimate goal of enhancing health outcomes. With this introduction, the road to a brighter and a concerned future remains undiscovered.

Potential security concerns are also brought up by 3D bioprinting, both on an individual and a societal level. One of the main worries is that the technology might be misused to improve organs by adding functionality or breeding human and animal cells to give the patient an advantage over other people. Such performance improvements might draw those who are active in the military and professional sports, among others. The potential dual use of 3D printing technology, such as the printing of potentially harmful viruses, may result in dubious methods and results.

Since practically every civil technology development can be converted to military technology development, security and dual-use considerations must also be taken into account. For instance, a small uproar developed when online instructions for 3D printing guns at home were made available for free.The availability of 3D bio-printing facilities has expanded, allowing enabling the manufacturing of biohazards or even bioweapons due to the equipment's lower cost, more availability, and easier use.

While 3D bioprinting has the ability to boost human performance on an individual basis, it also brings up questions about how to distinguish between therapy and other forms of body alteration or human enhancement. The potential for distributed and local manufacturing of various bio-AM applications suggests increased user responsibility, both in terms of user behaviour and production safety and quality requirements. Furthermore, the same technology that allows for the duplication of any component of the human body may also be used to print the entire body. By producing small quantities of physiologically functional tissues that can be used in place of animals for toxicological and medical research, bioprinting has the potential to lessen the usage of animals in trials. This is a result of the progressive phase-out and eventual prohibition of cosmetic testing.

The hazards and difficulties associated with organ transplantation, cell therapy, stem cell therapy, and implanted medical devices are all presented by 3D bioprinting. However, the current legal frameworks do not take into consideration, for instance, customization-related issues or distinctions between goods produced utilizing 3D printing technology and traditional tissue engineering techniques. When it comes to applying current regulatory frameworks for stem cell and cell therapy research to bioprinting regulation, there is a lack of clarity. The numerous entities involved in the supply and production chain add to the legal ambiguities surrounding bio-printing. In the case of high-risk 3D printed medical equipment, a new definition of "custom-made device" is required,as well as clarification of the certification requirements.Low-risk devices that are not intended to be hosted beneath the skin, such as glass eyes and prescription lenses, can be approved in the same way as high-risk specialized devices like 3D printed implants. EU authorities don't make a clear statement about how to classify related 3D prints.

Suggestion and Recommendation

There has been discussion regarding the patentability of 3D bioprinting items because they are made from natural resources, whether they are pre-printing materials, printed tissues, or printed organs. The uniqueness of bioprinting products, such as bioprinted tissues and organs, as well as the pre-printing materials required in the printing process, would present a hurdle in comparison to "natural" biomaterials. Their patentability is based on how inventive they are and how different they are from naturally occurring analogues. The USPTO released interim advicein 2014 for determining whether inventions derived from nature qualify for patent protection. According to the guidelines, the claim of an invention must first be related to a process, production, machine, or composition of matter in order to be considered patentable. The "judicially recognized exceptions" test, which has two facets, is the next section of the advice. It must be decided in the first prong (2A) whether the claim refers to a "product of nature" or a natural phenomenon. If so, it is necessary to conduct the second prong (2B)in order to find any potential additional features that give the claim "markedly different characteristics."

The advent of America Invents Act, 2011 with the intent to harmonize the States patent laws with other nations does not only stand fundamental in times of bioprinting technology revolution but is also the key to rooms for new technologies development that initiates growth and job creation.Affirmative implementation of Section 30 of the Act will not only open new opportunities for 3D bioprinting to gain wings to fly but will also make its own efforts to fly with all others so as to promote harmonious growth and inclusivity.

On similar ground as the USPTO, the Indian Patents Act of 1970 can introduce additional changes in provisions such as Sections 3(b) and 3(j) that remains ambiguous while talking about bioprinting technologies, which can help the jurisprudence of such technology develop in India. The path towards maintaining the balance between monopoly rights over bioprinting technologies on one hand and public interest on the other, turns out to be smoother if clarity in regards to patenting provisions stands transparent.

Another concern which has been raised in this paper is surrounding privacy and security issues that is entangled with organ transplantation. If seen from the Indian perspective, Article 21 of the Indian Constitution that guarantees right to life and personal liberty, is inclusive of right to privacy as well. Any legislation that stands in abeyance of this right will ipso facto be declared ultra vires. Keeping the same in mind, whatever amendments are made in the Patents Act of 1970, have to be in abidance of such pre-existing regulation.

Conclusion

It is interesting to note that tissue engineering and regenerative medicine are now possible because of 3D bioprinting.By illustrating a doable fantasy of printing human tissues and organs on demand, it gives sufferers a ray of hope. However, building on the ideas above, the existing patent system for encouraging a vibrant 3D bioprinting market could lead to commercial exclusivity, putting unnecessary barriers to health. Global free trade, where large pharmaceutical corporations actively consolidate their global market exclusivity by erecting barriers to health products and services, seems to be aggravating the conflict between patents and the right to health. Particularly in developing and underdeveloped countries, where such technologies continually deepen healthcare gaps, the validity of patent monopoly by offering necessary health products and services as luxury items has come under threat. Given these factors, a new governance mechanism for the development of these technologies is preferred to prevent inequities in the aforementioned situation.This raises the issue of whether 3D bioprinting should be considered a necessary technology or a luxury good in the market. The promise of an accessible and affordable healthcare remains an unrealistic dream if the technology is kept at the top of the pyramid, where it is inaccessible and unreachable. Consideration should be given to a new governance model that balances ownership and access in order to reduce socio-economic and health inequities. States must actively participate in creating the roadmap for 3D bioprinting innovation by adopting a portfolio strategy that includes different means of stimulating innovation, taking into account the requirement to fulfil the benefit-sharing obligations of these technologies. To mitigate the drawbacks of patents, the prize system and government support should be implemented. Patent pools, a new form of communal licencing, will improve access to healthcare immensely. The best possible balance between the rights and obligations of various stakeholders, including governments, 3D bioprinting businesses, and patients (and the general public), need to be established in the development of a road map for a viable, equitable, and sustainable sector.

Refrences

1 Devarapalli P & Dar A, The impact of 3D bioprinting innovation on IP ecosystem and patent law: An Indian

and US perspective, *SSRN*, https://papers.ssrn.com/sol3/papers.cfm?abstract_id=4431417 (accessed on 13 April 2025).

2 Kang H W, Lee S, Ko I, *et al.,* A 3D bioprinting system to produce human-scale tissue constructs with structural integrity,*Nature Biotechnology*, 34 (2016) 312, https://doi.org/10.1038/nbt.3413. National Library of Medicine, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5979294/ (accessed on 7 April 2025).

3 Zeming Gu, Jianzhong Fu, *et al*., Development of 3D bioprinting: From printing methods to biomedical applications,*Asian Journal of Pharmaceutical Sciences*, 15529 (2020) 540, https://www.sciencedirect.com/science/article/pii/S1818087619311869.

4 The Better India, https://www.thebetterindia.com/303783/chennai-startup-avay-biosciences-builds-bio-3d-printer-to-print-human-tissues/ (accessed on 7 April 2025).

5 Kang H W, Lee S, Ko I, *et al.,* A 3D bioprinting system to produce human-scale tissue constructs with structural integrity, *Nature Biotechnology*, 34 (2016) 312, https://doi.org/10.1038/nbt.3413.

6 The Hindu, https://www.thehindu.com/news/national/tamil-nadu/startup-develops-indigenous-3d-bioprinter/article66165434.ece (accessed on 15th April 2025).

7 Hornick J F & Rajan K, *The 3D Bioprinting Patent Landscape Takes Shape as IP Leaders Emerge*, Finnegen, https://www.finnegan.com/en/insights/articles/the-3d-bioprinting-patent-landscape-takes-shape-as-ip-leaders.html (accessed on 15 April 2025).

8 Kessler S, https://www.sternekessler.com/app/uploads/2022/10/USPTO_Cancer_Drug_Pilot_Program_Not_Likely_To_Be_Used_Much.pdf (accessed on 20 April 2025).

9 Bournemouth University, https://eprints.bournemouth.ac.uk/29809/3/2%20cg%2031%20mar_Ch%207_Bioprint_Minssen_Mimler%20review%20MMTM%2029032017%20review%20MDM%2031032017.pdf (accessed on 20April 2025).

10 Google Patents, https://patents.google.com/patent/US8143055B2/en (accessed on 20 April 2025).

11 GOV.UK, https://assets.publishing.service.gov.uk/media/5bf41d76e5274a2af47c464f/3D-printing.pdf (accessed on 20 April, 2025).

12 Gress D R, Geographies of production in 3D: Theoretical and research implications stemming from additive manufacturing, *Science Direct*, https://www.sciencedirect.com/science/article/abs/pii/S0016718515000044 (accessed on 20 April 2025).

13 Asia IP-Informed analysis, https://asiaiplaw.com/section/in-depth/3-d-bioprinting-patentability-challenges-in-india (accessed on 27 April 2025).

14 Badwaik R, 3D printed organs: The future of regenerative medicine, *Research Gate*, https://www.researchgate.net/publication/337166178_3D_Printed_Organs_The_Future_of_Regenerative_Medicine (accessed on 27 April 2025).

15 A Harding, Application of additive manufacturing in the biomedical field- A review, *ScienceDirec*t, https://www.sciencedirect.com/science/article/pii/S2666964123000115 (accessed on 27 April 2025).

16 *Diamond* v*Chakrabarty* 447 U.S. 303 (1980)

17 Root Analysis, https://www.rootsanalysis.com/reports/3d-bioprinting-intellectual-property-landscape.html (accessed on 24 April 2025).

18 National Institutes of Health, https://pmc.ncbi.nlm.nih.gov/articles/PMC7336133/ (accessed on 24 April 2025).

19 National Institutes of Health, https://pmc.ncbi.nlm.nih.gov/articles/PMC8773692/ (accessed on 24 April 2025).

20 Google Patents, https://patents.google.com/patent/GB2478801A/en (accessed on 24 April 2025).

21 *Harvard Journal of Law and Technology*, https://jolt.law.harvard.edu/digest/patenting-bioprinting (accessed on 24 April 2025).

22 Europa.eu, https://single-market-economy.ec.europa.eu/single-market/goods/free-movement-sectors/liability-defective-products_en (accessed on 24April 2025).

23 National Institutes of Health, https://pmc.ncbi.nlm.nih.gov/articles/PMC8102287/ (accessed on 25 April 2025).

24 Europa.eu, https://single-market-economy.ec.europa.eu/industry/strategy/intellectual-property/patent-protection-eu/protection-biotechnological-inventions_en (accessed on 25April 2025).

25 Harvard/Transgenic Animals [2005] EPor 31.

26 General Data Protection Regulation, https://gdpr-info.eu/ (accessed on 25 April 2025).

27 *Oliver Brüstle* v *Greenpeace* [2012] 1 cMLr 41

28 *Bristol Myers Squibb Co* v *Baker Norton Pharmaceuticals Inc,* [2001] rPc 1.

29 *Mayo Collaborative Services* v *Prometheus Laboratories, Inc*, 566 uS 10-1150 (2012).

30 EUR-Lex, https://eur-lex.europa.eu/eli/dir/2004/23/oj/eng (accessed on 25th April 2025).