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3D Bioprinting: Patent Eligibility and Statutory Roadblocks in India

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ABSTRACT

India is on a precipice of significant advancement in healthcare as 3D bioprinting could help overcome the limitations of the current tissue engineering methods. According to health care expert Tom Todorow, the introduction of 3D bio printed organs into the field of medicine is a relative certainty; not a question of if, but when. This new technology's potential applications are limitless. Hence, customization will drive the next generation, allowing doctors to replace limbs and customize drugs. However, the patent framework that exists in India is not flexible enough to keep up with the rapid development of 3D bioprinting. This Article assesses the limits of patentable subject matter necessitated by 3D bioprinting technology under the Indian patent law and investigates how the Indian patent system will need to adapt to the advent of 3D bioprinting.

I. INTRODUCTION

Three-dimensional (3D) bioprinting is a subset of three-dimensional printing that combines 3D printing concepts with synthetic biology to create biological materials². 3D bioprinting is an additive manufacturing process where tissue-like structures that imitate the actual micro and macro-environment of natural tissues are created using cells and other bio-compatible materials. This state-of-the-art technology uses various biological materials, including biochemicals and bio cells to create structures through layered deposition of material in a precisely controlled setting³.

Three-dimensional bioprinting has garnered immense interest as it facilitates the printing of cells, tissues, and organs on demand. This innovative bioprinting is highly promising as the availability of donors for tissue or organ will no longer be a bottleneck for transplantation surgeries. Every year, over 500,000 people die in India due to a paucity of a replacement organ. 3D printed organs may eliminate the need to obtain organs from both living and deceased

¹ Author is a student at SASTRA Deemed to be University, India.

² Jasper L. Tran, To Bioprint or Not To Bioprint, 17 N.C. J. L. & TECH. 123, 129 (2015).

³ Ali Bakshinejad & Roshan M. D'Souza, A Brief Comparison Between Available Bio-printing Methods, Great Lake Biomedical Conference (2015), <https://pdfs.semanticscholar.org/f9cb/1d43990f14eaf6f3a9ed632b432cd050a05c.pdf>

donors⁴. 3D bioprinting has been recognized for having the following advantages: significantly reducing the demand for donor organs; printing with autologous cells will prevent tissue and organ transplantation rejections; reducing illegal human organ trade; extension of lifespan; and credible, animal-free drug and vaccine testing⁵.

Researchers have produced 3D bio printed aortic valves, bones, cartilage, ears, eyes, heart tissue, kidneys, skin, windpipes, and vasculature in laboratories⁶. However, 3D bioprinting is still in its infancy, and its future growth and dispersion are hampered by a variety of factors. Despite several drawbacks, 3D bioprinting is seen as a promising technique with enormous potential in the fields of medical science and engineering. Three-dimensional bioprinting is a promising trend, and its rapid development has presented a number of challenges. The progress made in research and commercialization has not been matched by addressing ethical, regulatory, and policy issues surrounding this technology. However, some limitations and challenges must be addressed in order for this new technology to be widely adopted.

II. PATENT LANDSCAPE OF 3D BIOPRINTING IN INDIA

With the convergence of the biological and mechanical worlds, 3D bioprinting presents yet another biotechnological innovation that will require the Indian Patent Law to evolve to facilitate the creation of new products, healthcare solutions, and promote commerce. The advent of 3D bioprinting has magnified the ambiguous patentable subject matter boundaries and the legal standards that govern what can and cannot enter those boundaries. Regardless of whether one believes 3D bioprinting inventions should or should not be patentable, it is widely acknowledged that the concept of patent eligibility is particularly critical even in this incipient stage⁷. Patentability, infringement, and licensing strategy are all issues associated with patents on 3D bioprinting technologies, the latter of which has a direct impact on the extent to which the technologies can be transferred and disseminated to the general public.

The Patents Act, 1970 (“Patent Act”) forms the legislative framework that governs patent protection in India. For an invention to be patentable under the Patents Act, 1970, it must meet certain conditions. The invention must be new, inventive, and industrially applicable. While

⁴ Aastha Ahuja, Lack of Organ Donation In India: Here Is Why Half A Million People Die Annually In India Due To Unavailability Of Organs, NDTV (2017), <https://sites.ndtv.com/moretogive/lack-organ-donation-india-half-million-people-die-annually-india-due-unavailability-organs-2107>.

⁵ David Sher, now it is Time to Commercially De-Liver for Organovo: 3D Printing Industry, (2014).

⁶ Sean V. Murphy & Anthony Atala, 3D Bioprinting of Tissues & Organs, NATURE BIOTECH (2015), <https://www.nature.com/articles/nbt.2958>; Evan R. Youngstrom, 3D Printing and Healthcare: Will Laws, Lawyers, and Companies Stand in the Way of Patient Care?, 6 PACE. INTELL. PROP. SPORTS. & ENT.L.F. 91 (2016).

⁷ Margo A. Bagley, Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law, 45 WM. & MARY L.REV. 469 (2003).

bioprinting fulfills all the statutory requirements mentioned above, it is kept beyond the scope of patent-eligible subject matter as per Section 2 (1) (j) introduced by Patent Act (Amendments), 2000 read with Section 3 (j). This section reads: “*plants and animals in whole or any part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals*”. Pacemakers, hearing aids prosthetics, artificial limbs, and other medical devices, however, remain patentable.

The morality clause is incorporated into patent laws in order to achieve equilibrium and coherence between science and culture. The patentability of 3D printed organs is viewed differently as the process entails a great deal of complexity and novelty when it comes to manipulating human tissues, and it touches on the delicate ethical taboo of working with human cells. It is the most potentially disruptive issue surrounding 3D bioprinting as it uses viable biological material as bio ink which is derived from human/animal cells or human embryonic stem cells. It calls into question the existing legal and intellectual property framework, as well as long-held societal views and concepts of human dignity and human identity. Section 3(b) of the Patent Act expressly prohibits the granting of patents for 3D printed organs that are primarily intended to replace a damaged or non-functional part of the organ. Section 3(b) states that: “*an invention the primary or intended use or commercial exploitation of which could be contrary to **public order or morality** or which causes serious prejudice to human, animal or plant life or health or to the environment*”. A plain reading of Section 3(b) reveals that 3D printing of organs is not patentable as the naturally occurring organs or biomaterials are used in the process. Although the Indian patent law incorporates moral and public order grounds for understanding the role of non-economic variables in the commercial realm, the interpretation of such considerations has been rather limited.

At this stage, considering the ethical challenges posed by the transplantation of 3D-printed organs raises more questions than answers. The most fundamental question that remained unanswered is ‘would a modified replication suitable for substitution of damaged/ non-functional body part become patentable under Section 3(j) if it is a product of a non-essential biological process? While the explicit explanation of ‘*plants animals and part thereof*’ in the first part of Section 3(j) keeps such inventions beyond the scope of patent eligibility as such claim is directed to plants and animals or parts thereof *per se*, the second part of section 3(j) states that the process of production is patentable if it is not “*essentially biological processes for production or propagation of plants and animals*”. This allows for the granting of patents on processes that are not fundamentally biological, such as 3D printing with bio-inks to create

three-dimensional objects suitable for the replacement of damaged/ non-functional human body parts. Furthermore, the second part of Section 3(j) specifically deals with “*essentially biological processes for production or propagation of plants and animals*” while omitting “*part thereof*”. As a result, it is safe to conclude that the legislative intent of the Patent Act of 1970, as amended, clearly favors the patentability of bio-printed products created in the above-mentioned manner.

Aside from the conflicting interpretations of the provisions, the United States Supreme Court unanimously ruled in the case of *Association for Molecular Pathology v. Myriad Genetics*⁸ that patent protection can be granted to bio printed organs. The Supreme Court held that a naturally occurring DNA segment was a product of nature and therefore not patentable simply because it was isolated, however, cDNA was patentable because it was not naturally occurring. There have been numerous instances where Indian courts have relied on foreign court judgments as they are considered to have persuasive value. Hence, the emphasis should be on man-made characteristics, quality, and alterations to obtain a patent on a bio-printing-related invention. Bio-printed organs are created in-vitro in a human-controlled environment which is significantly different from the naturally occurring organs. The bio-printing process simply replicates the natural organ generation process and cannot be equated to the same.

III. CONCLUSION

Bioprinting has the potential to revolutionize medical practice by eradicating organ shortage and transplant rejection issues. As 3D-printed organs become available for human transplantation, a careful assessment of the ethical challenges they pose will be critical. Bioprinting patents would be possible in India if the claims are drafted to accentuate the man-made and non-essential biological processes as opposed to naturally occurring processes or product aspects. As nations such as China transition closer to human transplantation of 3D printed organs⁹, India's wealthiest cohorts will be able to travel for transplantation if these organs are not made available in India. As a result, it is necessary to devise methods for bringing this technology to Indian hospitals in an ethical manner. The world must brace itself to invest the requisite resources to tackle the challenges ahead as arriving at a point where no one dies for want of an organ transplant is unquestionably worth doing. The ultimate result is too important to choose any other course.

⁸ 569 U.S. 576, 133 S. Ct. 2107 (2013)

⁹ Serenitie Wang & Katie Hunt, Chinese Company Implants 3-D Printed Blood Vessels into Monkeys, CNN (Jan. 10, 2017), <http://www.cnn.com/2017/01/10/health/china-3d-printed-blood-vessel>