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PATENT RIGHT CHALLENGES IN ARTIFICIAL ORGAN TRANSPLANTATION: PATENTING BIOMEDICAL DEVICES AND ORGAN PRINTING IN INDIA

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STUDENTS AT SASTRA DEEMED TO BE UNIVERSITY

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Abstract:

Through a doctrinal research methodology, the paper analyzes statutory provisions, leading judicial pronouncements, and international standards such as the TRIPS Agreement and WIPO guidelines. Comparative insights are drawn from jurisdictions like the United States and the European Union, where patent laws provide a broader scope for biotechnology and medical device innovations. The paper explores fundamental issues of novelty, inventive step, and industrial applicability in relation to artificial organs, while also addressing the challenges posed by hybrid inventions combining biological and mechanical elements.

Furthermore, the research evaluates the balance between patent protection and public health imperatives, particularly in the light of compulsory licensing provisions under Sections 84 and 92 of the Patents Act. It highlights how excessive patent monopolies could lead to affordability concerns and limited accessibility of life-saving technologies, thereby necessitating a policy framework that incentivizes innovation without compromising public health objectives.

The findings suggest that while Indian patent law offers a structured mechanism for protecting biomedical inventions, the existing exclusions under Section 3 and ambiguous interpretations create uncertainty for innovators in the field of artificial organ technology. The paper concludes by recommending reforms that align Indian patent law with global best practices, ensuring clarity on patent eligibility criteria for biomedical devices and fostering an ecosystem conducive to innovation and ethical compliance.

Introduction

Artificial organ transplantation represents a groundbreaking advancement in medical science, offering a lifeline to patients with organ failure. With the increasing demand for organs and the limited availability of donors, artificial organs and bioprinting technologies have emerged as viable alternatives. These technologies involve the creation of functional human tissues and organs through biocompatible materials, stem cells, and 3D printing techniques.
The significance of intellectual property rights (IPR) in this domain cannot be overstated. Patents serve as an incentive for innovation, ensuring that inventors and corporations receive legal protection for their inventions. However, when it comes to life-saving technologies like artificial organs, the issue becomes complex. Balancing the encouragement of innovation with ethical considerations and public health needs remains a significant challenge.
This paper aims to examine the challenges associated with patenting artificial organs and biomedical devices in India. It explores the legal framework under the Patents Act, 1970, the ethical dilemmas involved, and compares India's approach with global practices.

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Understanding Artificial Organ Technology

Artificial organs refer to devices or engineered tissues designed to replace the function of a natural organ. These can include artificial hearts, kidneys, lungs, and more sophisticated innovations like 3D-bioprinted organs. Organ printing uses bio-inks, comprising living cells, and biocompatible scaffolds to recreate functional tissues. Biomedical devices, on the other hand, include implants, prosthetics, and support systems essential for transplantation procedures.

Recent developments in 3D bioprinting have accelerated the possibility of creating patient-specific organs, reducing dependency on donors. Start-ups and research institutes globally, including in India, are investing heavily in bioprinting technologies. However, these advancements raise critical questions regarding the scope and limits of patent protection.

Patentability Issues under Indian Patent Law

The Indian Patents Act, 1970, governs the patentability of inventions in India. Section 2(1)(j) defines an invention as a new product or process involving an inventive step and capable of industrial application. However, there are significant restrictions under Section 3, which lists non-patentable subject matter. Relevant provisions include:

- Section 3(b): Inventions contrary to public order or morality. This provision Says that Inventions contrary to public order or morality, or harmful to life/health/environment, are not patentable.and the Application here is that Patenting human-like organs may raise ethical objections or Are we "commercializing" the human body?For Example: A company trying to patent a 3D-bioprinted human heart may face rejection if considered morally unacceptable.

- Section 3(c): Discovery of a living thing or non-living substance occurring in nature.This section says that The discovery of a living thing or natural substance is not patentable and Application here is that If an organ is merely a copy of a naturally existing human organ, it could be considered a "discovery," not an invention.But if it involves technical human intervention (bioprinting process, artificial scaffolds), then there is an argument for patentability.

- Section 3(i): Processes for any medicinal, surgical, curative, or therapeutic treatment of humans or animals.This provision says that Processes for treatment of humans or animals (surgical, medical, curative, therapeutic) are not patentable. And also Application here is that a method of transplanting an artificial kidney into a patient cannot be patented. However, the device itself (artificial kidney design, bioprinter technology) may still be patentable.

These provisions pose challenges for patenting bioprinted organs, as they involve living cells and therapeutic applications. The ambiguity in distinguishing between a "product of nature" and a "human-made invention" creates legal uncertainty. Furthermore, Section 3(b) raises ethical questions regarding the commodification of human organs. Case law such as Dimminaco AG v. Controller of Patents and Designs (2002) a Swiss company, applied for a patent in India for a process to prepare a live vaccine for protecting poultry from contagious bursitis disease. The Indian Patent Office rejected the application.The Controller said the process involved living organisms (the vaccine contained live virus) → therefore not an "invention" under Section 2(1)(j) of the Patents Act.and the issue arised Can a process that results in a product containing living organisms be considered patentable under Indian Patent Law?

The Court overturned the Controller's rejection. And held that, A process that results in a useful, tangible, and vendible product (like a vaccine) is patentable, even if it contains living organisms.There is no bar in the Patents Act against patenting an invention involving living matter, as long as it is new, involves an inventive step, and has industrial application.

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Established that a product containing living organisms could be patentable if it is a result of human intervention. However, the principle's application to complex organs remains debated.

Ethical and Legal Challenges

Ethical considerations form the core of the debate surrounding artificial organ patents. The commodification of human-like organs raises questions about human dignity and public morality. Patents grant exclusivity, which may lead to monopolies in life-saving technologies, impacting affordability and accessibility, especially in a developing country like India. Another challenge lies in ensuring equitable access. India faces socio-economic disparities, and granting broad patent rights without a regulatory framework could restrict access to essential medical technologies. Furthermore, the absence of explicit legal provisions for bioprinting in the current Patents Act creates uncertainty for innovators.

Comparative Analysis

Globally, the approach to patenting artificial organs varies. In the United States, the landmark case Diamond v. Chakrabarty (1980) Ananda Mohan Chakrabarty, a microbiologist, developed a genetically engineered bacterium (a modified strain of *Pseudomonas*).This bacterium could break down crude oil, useful in cleaning oil spills.He applied for a patent in the U.S. The Patent Office initially rejected it, arguing that living organisms are products of nature and thus not patentable and the issues arised Can a human-made, genetically modified living organism be patented? The Court allowed Chakrabarty's patent and court held that A human-made microorganism is patentable subject matter under Section 101 of the U.S. Patent Act.The bacterium was not merely "discovered" in nature — it was created by human ingenuity.The key phrase: *"Anything under the sun that is made by man"* can be patented. And allowed patents on genetically modified organisms, signaling openness toward biotechnological innovations. The U.S. Patent and Trademark Office permits patents on artificially created tissues, provided they meet the criteria of novelty, non-obviousness, and utility.

In contrast, the European Patent Convention (EPC) includes stricter morality provisions under Article 53(a), which excludes inventions contrary to public order or morality. The EU Biotechnology Directive (98/44/EC) allows patenting of biological material produced by technical processes but prohibits patents on human body parts as such. India adopts a more conservative approach, guided by Sections 3(b), 3(c), and 3(i) of the Patents Act. While biomedical devices may qualify for patents, bioprinted organs involving living cells may face rejection on ethical grounds.

Moore v. Regents of the University of California case the facts held that,John Moore, a patient undergoing treatment for leukemia at UCLA Medical Center, had his spleen removed as part of therapy. Without Moore's knowledge, doctors used his cells to develop a valuable **cell line** that showed unique biological properties. This cell line, later patented, became extremely profitable, generating millions of dollars through commercial licensing.

Moore sued, arguing that **he retained ownership rights over his cells**, and therefore the university had used his biological material without consent and profited unfairly.

No property rights in removed tissues

Moore **did not retain property rights** over his tissues once removed. Thus, he **could not claim ownership** over the patented cell line or profits generated from it.

2. However, doctors violated informed consent

The Court agreed that doctors failed to properly inform Moore of their **financial and research interests**, which **breached the duty of informed consent**.

3. Patenting of human-derived cell lines is legal

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The Court upheld that human-derived **cell lines can be patented**, as they are considered **human-made inventions**, not natural substances — because they undergo extensive human manipulation. And this case gave the some clarifications to the patents in biology that is,

1. **It clarifies whether biological materials can be patented**

The Court held that biological materials **modified through human intervention** can be patented.
This supports patent claims over **3D bioprinted tissues, engineered scaffolds, or bio-printed organs**, provided they involve human technical manipulation.

2. It highlights ethical issues in commercialization of body parts

The case raises fundamental questions about:

- ownership of human tissues,
- consent in biomedical research, and
- fairness in profit-sharing.

These issues directly overlap with debates on **artificial organs**, which often incorporate human cells.

It supports the argument for clearer guidelines in India

India's Section 3(b) and 3(c) restrict patenting biological materials.
Moore shows that courts elsewhere allow patents if:

- the invention is man-made,
- substantially modified,
- and serves medical advancement.

This comparative insight strengthens your recommendation to **modernize Indian patent law** to accommodate bioprinted organ technologies.

Judicial Pronouncements and Case Laws

Indian case law on biotechnological patents remains limited. However, cases like Dimminaco AG and Monsanto Technology LLC v. Nuziveedu Seeds Ltd.(2018) *Dimminaco AG*, a Swiss company, applied for a patent in India for a process of preparing a vaccine for Bursitis (disease in poultry). The Controller of Patents rejected the application, saying that, The process involved a living organism (the vaccine contained live virus).Hence, it was not an "invention" under the Patents Act. The Calcutta High Court reversed the rejection.And held that a process does not cease to be an invention just because it involves living microorganisms.What matters is the technical advance and industrial applicability and allowed the patent for the vaccine-preparation process.

provide guidance on interpreting biotechnological inventions. Internationally, Association for Molecular Pathology v. Myriad Genetics (2013) *Myriad Genetics* discovered the precise location and sequence of the BRCA1 and BRCA2 genes (mutations linked to higher risk of breast and ovarian cancer).Myriad obtained patents on these isolated genes and the Association for Molecular Pathology (AMP) and others challenged the patents, arguing that genes are products of nature and shouldn't be patentable. clarified that naturally occurring genes are not patentable, but cDNA (synthetically created DNA) can be. The U.S. Supreme Court held that Naturally occurring DNA sequences cannot be patented, even if isolated from the human body. cDNA (complementary DNA), which is synthetically created in labs and not naturally occurring, can be patented because it is man-made.These cases underline the global trend of distinguishing between natural discoveries and human-made inventions, a principle crucial for organ printing patents.

Current Scenario in India

India has witnessed growing interest in bioprinting and artificial organs, with several research institutions and start-ups exploring the field. However, patent filings in this area remain low due to legal uncertainty. According to WIPO

data, most patent applications for bioprinting originate from the U.S., China, and Europe, with India lagging behind. The Indian Patent Office lacks specific guidelines on bioprinting technologies, creating ambiguity for applicants. Without clear legal provisions, innovators risk rejection or prolonged examination of patent applications. The Patentables are Bioprinting machines, biomedical devices, artificial scaffolds.Processes for creating artificial/synthetic tissues or organs (if not naturally occurring).Genetically modified microorganisms. And not Patentables are Naturally occurring organs, tissues, cells.Surgical/therapeutic methods of transplant itself.Seeds, plants, and animal varieties (post *Monsanto*).

Legal Reforms

To Clarify Section 3 of the Patents Act with respect to artificial organs and this Allow patents for man-made, engineered, or bioprinted organs, while keeping natural human organs excluded.Issue specific guidelines from the Indian Patent Office (like biotech guidelines of 2013) for artificial organ technologies.

Ethical & Public Health Safeguards

To Ensure a morality clause so that patents do not lead to commercialization of *natural human body parts*.Introduce a compulsory licensing mechanism (like in pharma) for artificial organs to ensure affordability in public hospitals.Encourage open-source biomedical research alongside patents, to balance innovation with accessibility.

Institutional Support

To Create a specialized "Biotech & Medical Devices Cell" in the Indian Patent Office with experts in life sciences, to examine complex biotech applications.Develop public-private partnerships to fund R&D in artificial organ transplantation.

International Harmonization

Align Indian law with TRIPS flexibilities while learning from the US (Myriad case) and EU directives.Promote collaborative patents and cross-licensing to reduce monopoly control.

Promotion of Innovation

Provide tax incentives and grants for startups and universities working on 3D bioprinting, stem-cell scaffolds, and artificial organs.Establish fast-track patent examination for life-saving biomedical devices.Encourage patent pooling so multiple innovators can share technology without litigation battles. Balancing IPR protection with ethical, social, and public health concerns is the key. India must encourage patents in artificial organ technology to promote innovation, but also ensure affordability and accessibility so that the right to health is not compromised.

Stronger Regulatory Framework

Draft specific legislation or rules under the Patents Act for biomedical patents (like the U.S. Bayh–Dole Act model for biotech).Set up an ethics committee within the Indian Patent Office to review sensitive biotech inventions (artificial wombs, organs, genetic modifications)

Transparency & Public Awareness

Patent applications in artificial organ transplantation should have mandatory disclosures of risks, potential public use, and cost implications.Conduct public consultations before granting broad patents in sensitive medical fields to maintain trust.

Encouraging Collaborative Research

Develop a national artificial organ research hub linking IITs, AIIMS, NIPER, and private biotech firms.Promote open-licensing frameworks where innovators share technology for public good while still earning royalties.

Affordability & Accessibility

Make patents subject to price control mechanisms in lifesaving technologies (similar to essential medicines).Introduce compulsory

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licensing when artificial organs are priced beyond reach.Encourage government-funded procurement of patented organs/devices for distribution in public hospitals.

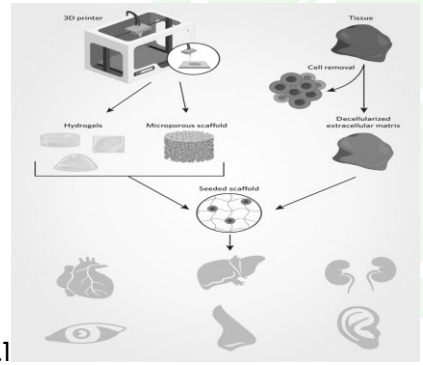
International Cooperation

Negotiate bilateral/multilateral agreements with countries leading in 3D bioprinting (US, Japan, EU) for tech transfer.Push for a WIPO framework on artificial organ patents to harmonize global rules and prevent misuse.

To address these challenges, India must adopt a balanced approach. Recommendations include:

- Issuing detailed patent examination guidelines for bioprinting and artificial organs.
- Amending the Patents Act to clarify the status of bioengineered products.
- Introducing compulsory licensing mechanisms for life-saving technologies to ensure access.
- Establishing ethical oversight committees to monitor patent grants in sensitive domains.

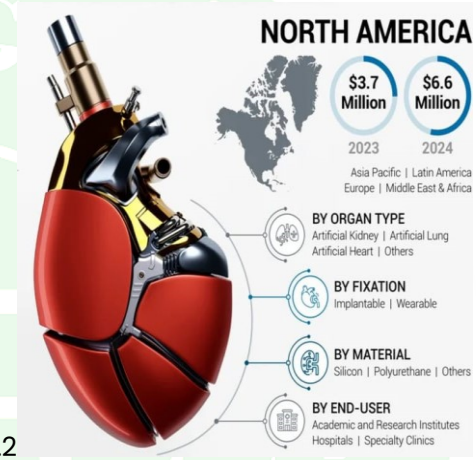
Pictorial Representation:



f.g.1

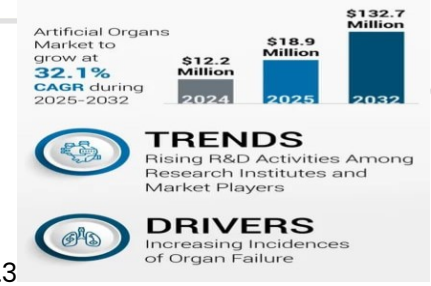
Scientists use 3D printing to make scaffolds that mimic the extracellular matrix, such as hydrogels, or rely on pre-existing organ architectures in decellularized tissues. Stem cells and other cell types are seeded onto the scaffold, which can be incubated in a bioreactor for cell proliferation and maturation of different artificial organs.

This process has been used to create prototype organs such as artificial tracheas, bladders, mini-livers, kidney tissues, and heart patches.While fully functional complex organs (like hearts and kidneys) are still under development, lab-grown tissues are already being used for drug testing, disease modeling, and regenerative therapies.scaffold design (hydrogels, polymers, bioprinting methods) can be patented.The process of seeding cells and bioreactor incubation may also be patentable as a novel industrial application.However, the organ itself, once formed and mimicking a natural organ, is less likely to be patentable under Indian law due to Section 3 restrictions.



f.g.2

The trends shown in the image—such as increased R&D activities—also highlight the **competition among biotech companies** to secure patents, not just for whole artificial organs, but also for smaller innovations like materials, tissue scaffolds, or proprietary bioreactors. This raises ethical and legal questions: should life-saving technologies be monopolized under patent rights, or should governments ensure broader accessibility through licensing frameworks? The balance between encouraging innovation through IP protection and safeguarding public health becomes critical in this context.



f.g.3

This image provides empirical evidence of the anticipated growth of the artificial organ

market, projecting a compound annual growth rate (CAGR) of 32.1% between 2025 and 2032. The data indicates a sharp increase from $12.2 million in 2024 to $132.7 million by 2032. Such exponential growth highlights both the demand for artificial organs and the commercial potential of biomedical innovations. For patent law analysis, this data serves as a justification for why stakeholders are increasingly attempting to secure exclusive rights over organ-related technologies and devices**.**

The section on trends emphasizes the growing role of research and development (R&D) activities among market players and research institutes. This rise in innovation directly correlates with the surge in patent applications for biomedical devices, artificial tissues, and organ-supporting technologies. However, this also creates challenges under Indian patent law, where determining the scope of patentability in medical biotechnology remains contested.

conclusion :

while patent protection is vital for encouraging innovation in artificial organ technology, it must not compromise ethical standards and public health objectives. A comprehensive legal framework tailored to emerging biotechnologies is essential for India to strike a balance between innovation, morality, and accessibility.

Researchers omit the predesign stage of manufacturing and utilize pre-existing organ architectures that they treat to remove cells while maintaining the extracellular matrix Artificial organ transplantation represents one of the most promising frontiers of modern medicine, combining biotechnology, biomedical engineering, and intellectual property law. While the technology offers life-saving potential for patients suffering from organ failure, its regulation under patent law remains complex. The Indian patent regime, rooted in the Patents Act, 1970, takes a cautious approach by excluding natural substances, methods of treatment, and essentially biological processes from patentability. Judicial precedents such as *Dimminaco AG* signaled a willingness to recognize biotechnological processes as patentable, whereas cases like *Monsanto v. Nuziveedu* reaffirm India's restrictive stance on life-related inventions. Globally, the *Myriad Genetics* decision further highlights the fine line between what is naturally occurring and what constitutes a human-made invention.

In this context, India's challenge lies in balancing the encouragement of innovation with safeguarding ethical values and public health. Artificial organs created through bioprinting, synthetic scaffolds, and biomedical devices clearly fall into the category of man-made inventions and thus deserve patent protection. However, the commercialization of natural human body parts or medical treatments must remain excluded. Strengthening institutional expertise, issuing clear guidelines, and harmonizing with international standards will ensure greater certainty for innovators. At the same time, mechanisms such as compulsory licensing and open innovation frameworks can guarantee accessibility and affordability, preventing monopolies in life-saving technologies. Ultimately, patent law in India must evolve to reflect the realities of emerging biomedical technologies. By striking a balance between intellectual property rights and the right to health, India can foster an environment that promotes innovation while upholding ethical, social, and constitutional commitments. Artificial organ transplantation, therefore, provides not only a test case for India's IPR regime but also an opportunity to demonstrate how law, science, and ethics can co-exist for the larger good of humanity.

Recommendations :

1.The Indian Patent Office should issue specific examination guidelines for artificial organs, 3D bioprinting, stem-cell based scaffolds, and biomedical devices and Introduce a clear statutory distinction between the *natural biological materials* (non-patentable), and

human-engineered artificial organs (eligible for patents) and also need a clear Amendment in the Section 3(b), 3(c), and 3(i) to explicitly address biotechnological inventions, reducing examiner discretion and ambiguity.

2.To create a Biotech & Medical Device Wing within the Patent Office to examine complex applications involving tissue engineering and cellular manipulation. And to Appoint examiners with life sciences, biomedical engineering, and patent law expertise to improve consistency and accuracy in patent decisions.

3. Form an independent **Ethics & Bio-Safety Review Committee** to evaluate inventions involving human cells, tissues, and organ models and also to ensure patents involving human biological material comply with dignity, safety, informed consent, and public health standards. Promote transparency in research to prevent exploitation, as highlighted in *Moore v. Regents of the University of California*.

4. To Provide **tax incentives, grants, and incubation support** for start-ups and R&D institutions working on artificial organ technology and to Facilitate public–private partnerships (PPP) to accelerate innovation and reduce financial burden on universities and hospitals.

5. To use **compulsory licensing** and **government-use provisions** for essential artificial organ technologies to ensure affordability and encourage reasonable royalty frameworks to allow technology access while protecting inventors' rights.

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