Trends in Biomaterials and Artificial Organs
www.biomaterials.org.in/tibao
ISSN 0971-1198
https://doi.org/10.5281/zenodo.17234000

Legal Perspective

Emerging Ethical and Legal Dimensions of Patenting 3D Bioprinting Biomaterial Based Technologies for Equitable Access to Medicines

P.G. Prajitha*, B. Venugopal*

School of Law, Vel Tech Dr. Rangarajan Dr. Sakunthala R&D Institute of Science and Technology, (Veltech Dr. RR and Dr. SR.Technical University), Avadi, Chennai 600062, Tamil Nadu, India

Received: *28 May 2025*
Accepted: *22 July 2025*
Published online: *30 September 2025*

Keywords: *bioink, 3D bioprinting, patent ethics, biomedical law, translational medicine, accessibility*

The emergence of advanced biomaterials and bioink-based 3D bioprinting is revolutionizing drug discovery and drug delivery by enabling the fabrication of complex biological structures. However, the patentability of such technologies introduces ethical and legal challenges, particularly concerning access, affordability, and innovation. This study examines the evolving patent landscape of biopolymer-based bioinks and highlights how ethical and legal considerations influence the trajectory of 3D bioprinting technologies. A patent portfolio analysis was conducted to assess the inventiveness, translational potential, and commercial viability of bioink applications in biomedical research. The findings provide critical insights into how intellectual property frameworks can either facilitate or hinder the development of affordable and accessible medicines, an essential component of the universal right to health. The study further argues for tailored regulatory and R&D strategies that account for the multifaceted legal complexities associated with 3D bioprinting and bioink based innovation.

Introduction

Advancing biomaterials for developing advanced medical technologies is an area of immense interest. Three-dimensional (3D) bioprinting has emerged as a transformative technology at the intersection of engineering, materials science, and regenerative medicine. It involves the layer-by-layer deposition of bioinks comprising living cells, biomaterials, and bioactive molecules to fabricate tissue-like structures and organ analogs with high spatial resolution and functional complexity [1-3]. This innovation is paving the way for a paradigm shift in how we model diseases, screen drugs, and design personalized therapeutic strategies [4,5]. The 3D tissue models are being developed for drug discovery. Accelerating the drug discovery process is one way to reduce the cost of therapy [6] that can ensure affordable and accessible medicines.

For that, biomaterials are advanced being explored to develop *in vitro* disease models [7]. These 3D models help to screen the molecules before preclinical studies. The 3D disease models are superior to 2D models, showing tissue-specific organ-specific responses that mimic tissue/organ-specific pathological signatures such as increased resistance to drug treatment [8]. Bioinks are being used to develop 3D models for various chronic disease models. Beyond this application, they are being used for cellular guidance processes in, tissue engineering, and regenerative medicine[9,10]. Bioink-based innovations related to drug discovery help in reducing the time required for screening and are advantageous over otherwise tedious multi-stage screening involved in drug discovery and development [11]. The screening of molecules in preclinical animals is expected to replace these studies both from ethical and economic perspectives. From a socio-economic point of view, it can lead to a reduction in cost, and thus the medicines can be made affordable and accessible.

In addition, bioinks are being used for prototype delivery devices that need to be developed for complex targeted drug delivery applications of chronic diseases [12]. Subsequently, there is a convergence of advanced biomaterials, bio-inks, and 3D bioprinting [13] that helps in developing biomimetic complex

* *Coresponding authors*
E-mail address: *bangaruvenu@gmail.com* (*B. Venugopal, Dean, School of Law, Vel Tech Dr. Rangarajan Dr. Sakunthala R&D Institute of Science and Technology, Avadi, Chennai 600062, Tamil Nadu, India*)
prajithapg194@gmail.com (*Prajitha P.G., Research Scholar, School of Law, Vel Tech Dr. Rangarajan Dr. Sakunthala R&D Institute of Science and Technology, Avadi, Chennai 600062, Tamil Nadu, India*)

synthetic structures. They can be used for advanced drug delivery applications [14]. This is advantageous to develop affordable and accessible medicines as it reduces the cost of advanced drug discovery models and delivery devices [15, 16].

Another strategy is combining the bioink with cells and tissue fluids [17]. That helps in modifying the cellular phenotypes and that has therapeutic potential [18]. They are being used for *in vitro* tissue-to-organ development. However, it raises ethical concerns and thus faces regulatory constraints upon its approval.

Overall bio-ink is turning out as a sustainable product [19] pipeline based on biomaterials in the affordable and accessible medicine sector, which has the potential to reduce the treatment cost substantially[20, 21]. This creates a new set of intellectual property portfolios that are patentable [22]. On the contrary, the socio-ethical concerns oppose its patentability in some cases [23]. The emerging scenario of knowledge dissemination alternative to patents leads to localized business models wherein procedure-based technologies and constructs are being developed [24]. The advantage of rapid screening and changes in the international approval process creates a demand for increased use of such technologies and bioinks. It is essential to analyse the strategic advantage of exploring the field of 3D bioprinting for developing affordable and accessible medicines and surfing in the translational medicine landscape which is a step towards personalized medicine.

The translational impact of bioinks extends beyond lab-scale innovations. With increasing efforts to adapt these materials for clinical and industrial applications, issues related to patentability, ethical constraints, and regulatory approval have come to the forefront [25]. While the development of patent portfolios around biopolymer-based bioinks reflects a robust innovation landscape, ethical considerations particularly regarding the bioprinting of human tissues and organs continue to shape regulatory pathways and public perception

This paper addresses three critical questions, (1) What is the current patent landscape of biopolymer-based bioinks? (2) How are these innovations progressing within the translational and clinical development pipeline? (3) What strategic insights can be drawn from this innovation ecosystem in relation to affordable and accessible medicines, especially in the context of emerging ethical and legal challenges?

By analyzing the transition from material composition to function and clinical application, this study offers patent intelligence that reflects the evolving role of bioinks as sustainable, impactful tools in translational medicine and personalized healthcare. Given these developments, it is essential to reflect on the ethical implications that accompany the innovation and patenting of bioink technologies.

Ethical dimensions of bioink patentability and access

The ethical implications of 3D bioprinting and bioink patentability raise fundamental questions about equity, justice, and the right to health [23]. While bioinks promise more affordable and personalized approaches to drug discovery and delivery, the commodification of these innovations through intellectual property regimes may restrict access, especially in low- and middle-income countries [14] [13]. This creates a moral tension between incentivizing innovation and ensuring fair distribution of life-saving biomedical technologies. The potential for organ printing and regenerative constructs to become commercial products also evokes bioethical concerns about the human body, enhancement, and the boundaries of commodification. If bioinks incorporate human-derived materials such as cells or extracellular matrices, issues related to donor consent, tissue ownership, and benefit-sharing emerge. Furthermore, the trend toward personalized, just-in-time bioprinting at the clinical level complicates existing ethical frameworks that were developed for mass-manufactured medical products.

From a normative ethics perspective, patent strategies that limit widespread use of bioinks especially in public health settings, may violate principles of distributive justice. A Rawlsian framework, for example, would argue that access to essential medical innovations should benefit the least advantaged first. Conversely, utilitarian ethics might justify patents only if they promote the greatest good without disproportionate harm to vulnerable populations. Yet, current patent practices often prioritize market value over public health outcomes. Therefore, any strategy for advancing 3D bioprinting technologies must engage with these ethical dimensions. Ethical oversight should be embedded into R&D processes, technology transfer agreements, and regulatory pathways to ensure that the benefits of bioinks are equitably shared and do not widen existing health disparities.

Method

To analyze the current innovation landscape of biopolymer-based bioinks, a structured patent search was conducted using the ESPACENET database. The search utilized the keyword phrase "biopolymer-based bioinks", yielding a total of 127 patent documents relevant to the topic. Each patent was reviewed and manually categorized based on content and context, using both the title and, when necessary, additional metadata. In cases where the title lacked clarity, expert judgment was applied to infer the patent's relevance and intent. Titles were simplified to their core descriptive elements, typically reduced to a minimum of three essential words for classification purposes.

This was categorized into four groups (1) polymers, (2) bioink formulations, (3) disease-mimicking bioinks, and (4) reconstructive/regenerative constructs. Among these, the Bioink Formulations category accounted for the highest number of patents, reflecting intense research and commercialization activity. This was followed by patents related to Reconstructive/Regenerative Constructs, Disease-Mimicking Formulations, and finally, patents focusing solely on Polymers. This classification provides insights into how intellectual property in the biopolymer-based bioink domain is distributed across the value chain—from materials development to clinical and translational applications.

Results

Patent portfolio of bioinks: Bioink is sufficiently diversified

The bioink is a product available in various forms to serve different clinical and research needs in biomedical sector. There is a novelty associated with each application. The figure-1 shows the translational potential based patent portfolio analysis and classification.

The patent portfolio of bioinks is classified as follows. They are based on Polymers can be calssified into, (1) natural bioinks, (2) semisynthetic polymer based bioinks, (3) Synthetic bioinks, (4) Functional bioinks and (5) Bioink formulations.

Natural bioinks are bioinks made of natural polymers. They include, protein enriched bioinks, acholetin polysaccharide bioinks, chitosan based bioinks, equine type I collagen based bioinks, gelatin- alginate bioinks, sterile concentrated proteins for bioinks, hydrogel forming protiens, elastin based 3D printing bioinks, sustainable source

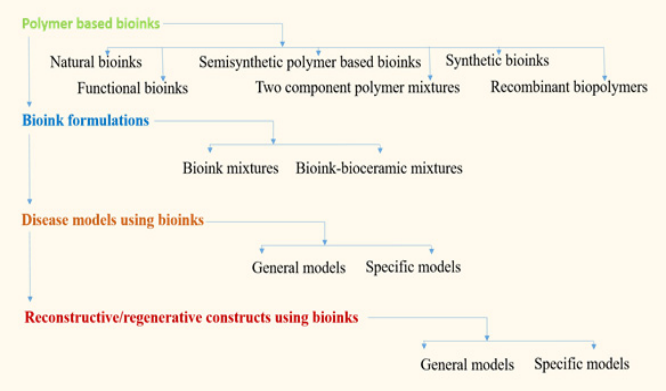

Figure 1: Translational potential based patent portfolio analysis and classification of bioinks

based biomaterials for bioinks, marine polysaccharide bioinks, polysaccharide cross linked structures as bioinks.

Semisynthetic polymer based bioinks are chemically modified natural polymers based bioinks. They include, chemically cross-linked alginic acid based bioinks bio-block bioinks, peptide containing hybrid bioinks, interlocking porous hydrogel blocks as bioinks, modified lignin based bioinks, amino cellulose based biopolymer bioinks, amino acid enriched tunable bioinks, modified pendant biopolymer based bioinks. Synthetic bioinks are bioinks made of synthetic polymers. They are mainly of PEG crosslinking to biomaterials.

Functional bioinks are bioinks with a specific function, and is made of more than one components. They includes, interlocking porous hydrogel blocks, photo cross-linkable bioinks, phase changing hydrogels as bioinks, guest-host polymer based bioinks, electro-stimulatable bioinks, interlocking porous hydrogel blocks based bioinks, phage based bioinks, enzyme immobilised bioinks, drug loaded microparticle containing bioinks, vanishing hydrogel growth factor enrichment bioinks, gradient printing bioinks, 3D printed freeze dried hydrogels for bioinks, microscaffold bioinks, non-planar free form fused deposition bioinks , hydrogel bioinks, bioinks for 3D cell manufacturing, shape morphing hydrogel constructs as bioinks, bioinks with tissue sealing properties**,** porous collagen microparticles based bioinks, transparent bioinks, bioink sets, acoustically responsive bioinks, temperature responsive bioinks, support medium for 3D printing, mediums for portable 3D printing, particle based 3D printing, particle based 3D printing, double networked 3D printed biomaterials, bioinks for electrospinning, antioxidant gelatin hydrogel bioink, fiber based bioinks, thermogelling bioinks, bioink to print over cell layers, bioink and cross-linkable support,

There are recombinant biopolymers based bioinks such as, human tissue specific ECM based bioinks**,** granular hydrogel bioinks, recombinant fibrinogen based proteins for bioinks.

In addition, two component polymer mixtures are there such as biopolymer composites, synthetic degradable/ natural biopolymer combination bioinks, two independently crosslinkable bioinks.

Bioink formulations are bioinks for a specific application. They include, Prefabricated bioink structures, bioink mixtures such as Cured 3D printing compositions, and bioink-bioceramic mixtures like Coral –polymer boinks, Cellulose –calcium particle based bioinks, Gelatin/hydroxyapatite composite bioinks. Bioinks are mainly being used for disease modelling in *in vitro* systems for drug screening and discovery. The disease models using bioinks are classified into (1) General models and specific models. The general models include, prefabricated 3D beds for cells, bioink based spheroid forming kits, microfluidic assisted 3D printing of bioinks, Biopolymer based 3D tumor tissue scaffolds, Bioinks for spheroids, Bioink arrays. The specific models include liver tissue models, bioink formulations for cornea, Bioink for autologous fat graft, Heart tissue models. Bioinks for priniting skin on wound surface and antimicrobial bioinks.

Further, reconstructive/regenerative constructs are developed using bioinks. They are classified into (1) general constructs and specific constructs. The general constructs are, wound conformal guidance giving 3D printed constructs, injectable and *in situe* gelling hydrogels as 3D printing bioinks, bioinks for stem cells, porous 3D implants using bioinks, cell laden bioink scaffolds, drug delivery patches using bioinks, bioinks for tissue and organ repair and drug eluting bioinks for conduit. The specific constructs using bioinks include, bioinks for stem cells to reduce immune attack, collagen stimulating bioinks, hard tissue bioinks for skull repair and bioinks for minimally invasive deep tissue applications. Given the patent portfolio of bioinks the translational landscape is set to analyse.

Translational Landscape Assessment of Bioinks: Personalised medicine is the new trend

The complete product line emerging for bioink based research is (1) bioinks, (2) 3D printed tissue constructs and (3) 3D printed drug delivery systems. The bioink as such don't enter regulatory landscape. While the 3D printed tissue constructs and 3D printed drug delivery systems will enter regulatory landscape. Thus, the bioink as such is having the highest translatability. The other two routes probably enter in clinical research and then followed by the translational phase. However, personalised therapy is an emerging area where the customisation of therapy is to be done with respect to specific unmet needs. There all these three areas can go to translation. That is the trending research area leading to translation related to bioink. However, it faces several ethical and legal dilemmas and that can lead to legal exercise in future.

Patent intelligence: Bioink and 3D printing is going to lead affordable and accessible medicines

3D printing is emerging as a holy grail in drug discovery process. There are difference in cell response from 2D to 3D state, such that 3D cultured cells are more resistant. In cancer drug screening assays there are significant difference in cell response between the 2D and 3D states. The figure-2 shows how the 3D printing could contribute towards affordable and accessible medicines.

It is observed that, drug response to 3D cultured cells are much lesser than compared to 2D responses. This is particularly true in the case of anti-cancer drugs. Bioinks are widely being explored for 3D printing. While, cells are explored for cell screening and 3D printing with bioinks and drugs are used for controlled delivery purposes. 3D printed cell constructs are explored for drug screening purposes. That avoids animal preclinical studies to a greater extend. Which, helps to save the time and money for drug discovery process. Similarly, the drug can be specifically delivered to the targeted tissue in a controlled manner by 3D printing technologies. That helps in customised precision delivery. Also helps in saving the time and expenditure in the optimisation process of drug delivery. Overall this helps in the faster translation of the drug to the clinics ensuring affordable and accessible medicines.

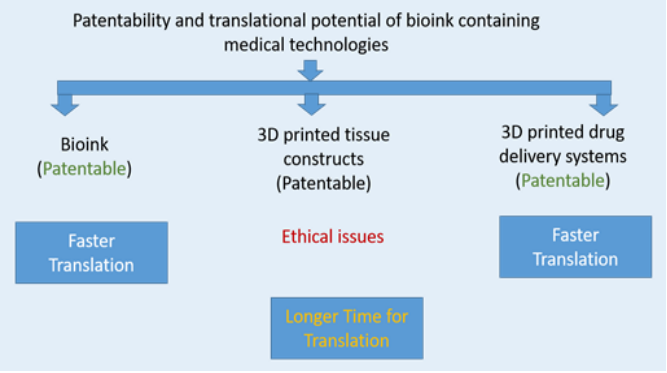

Figure 2: Shows the translational landscape assessment of bioinks

Legal aspects of 3D printing

The 3D printing of organs combines engineering using synthetic and biological components towards clinical unmet needs, this raises several ethical and legal dilemmas. That includes questions like, (1) whether 3D printed constructs are patentable, since biological components are involved? (2) Who will be responsible for defective prints, and (3) What is the applications of existing medical regulations?

When biological components such as natural genes, cells and proteins are used they are not patentable. Thus 3D bioprinting using any of these components can become non-patentable. In the Myriad case (Molecular Pathology v. Myriad case) court ruled that "isolation of a naturally occurring gene alone is not patentable, as it is a product of nature" [26]. Which is significant for 3D printing. As a general Laws often exclude natural components or processes. Thus, novelty and non-obviousness is apparent for patentability of 3D printed constructs its assemblies and methods. Very interestingly the process for 3D printing are readily patentable. Modified natural components based on bioinks are readily patentable. On the other hand, Scaffolds made based on bioinks are generally complex and in that case beyond discovery the novelty need to be established by providing details of innovation. Court need to clearly understand that the patentable entity, scaffold is distinctly different from the naturally occurring one. The patentablity of bioinks and scaffolds vary between various countries. For example, in India, the scaffold patentability may be challenged by exploring section 3(d) and section 3(j) of patent act. Section 3(d) deals with claims related to biological processes. On the other hand the section 3(j) is concerning tissues and organs [27]. Stem cells are widely being explored for 3D printing and that raises a lot of ethical and legal concerns. This is to be noted that developing countries have unique patent management strategy that contribute towards affordable and accessible medicines. Once these technologies are not patentable its availability will be wide spread for drug discovery research. On the other hand, patentable entities that are significantly novel are patentable. So most of the advanced bioinks are patentable. This helps in two ways; kindle the drug discovery and innovation at the same time advance the bioink and scaffold for advanced research [28]. Very importantly, one need to clearly understand what is patentable in the case of boinks and scaffolds, whether it is process, material or design of construct and its novelty and nonobviousness need to be established for effective patenting.

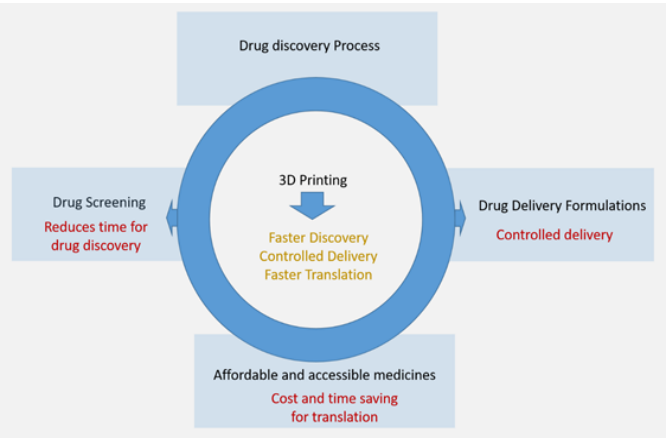

Figure 2: 3D printing for affordable and accessible medicines

It is to be noted that recently coming up with new customised ideas is a trend. Next important question emerging is whether customised ideas are patentable? The answer is yes. In the Star Athletica LLC vs Varsity Brands is an example for how abstract designs of products by creators are having IP value. Here the copyright of abstract designs is protected legally and the court ruled against Star Athletica as they are not the original creators of these designs. Varsity Brands designed these models[29]. This case has significance for 3D printing, as conceptualisation of the abstract idea and creating designs using 3D printing has IP value through copyright law.

Defective prints are a possibility in 3D printing. When 3D printing is explored for personalised medicine it can create accountability issues and legal pursuit. The Consumer Protection Act 1986 (CPA) of the developing countries such as the India is regulating the liability issues of defective goods with manufacturers and service providers [30]. It also covers retailers if the warranty is breached. The whole responsibility of the buyer is to provide evidence for it. In the case of 3D bioprinting defective prints need to be traceable. Generally, the patient is a customer and has no access to the whereabouts of the 3D bioprinted implants. So the harm due to which element is to be traceable; whether it is due to material, machine, drawing or process. It may be due to manufacturing error or due to transport error or due to wrong administration error. The product liability laws treat 3D printed goods as a commodity liable to transparency is important here; the design, manufacturing, performance of 3D bioprinted implants all are to be documented and informed to the service provider and user and informed consent need to be taken.

While this is applicable generally; healthcare related organ printing using bioinks require special attention. Wherein, the bioink may remain with the transplant and start influencing the biological response. This creates shadow on the boundaries of law and needs much attention. In this scenario, the direct service provider, is likely to be sued. Customising the organ with respect to patient needs is coming under the realm of personalised medicine. There the direct service provider is doctor.

Same in drug discovery labs, the service provider is a bioink manufacturer. The 3D printing machine, software is provided by companies with exclusive expertise in their domains. When these

components are at faulty it is to be traceable to the extend who is responsible for the harm. There should be systems to check and control faults and harm. That need to be connected through proper quality control systems to ensure that faults are minimum and liability is minimum. So establishing quality system will come into picture, that can affect the affordability and accessibility of these services. From a larger population perspective, the company providing the customised constructs can be sued for product liability. Breach of warranty scenario emerge upon the failure of the device if it fails in its stability or performance.

Existing regulatory frame work of medical regulations that of medical devices and drugs don't suite that for 3D printed constructs creating uncertinities about their approval and use. This is because existing regulatory framework is developed for mass manufactured therapies. The 3D organ printing add another level of complexity to this issue that natural agents such as gene, cells and tissue components are added to manufacturing [31]. This generally Law don't appreciate as anything natural is not patentable and there can be additional harm due to biological reactions. So the burden goes to regulatory agencies to ensure safety and efficacy need to be well established. Regulatory agencies face the challenge that personalising therapies at a hospital level cannot be regulated. Now the entire liability burden goes to the doctor. Overall this complexity hinders the massive global expansion of 3d printed organs.

Since the 3D printing involves the natural agents incorporated in these constructs, the failure/enhancement of the constructs inside the body can cause legal and ethical dilemmas. Their ownership and consent issues will raise and lead to legal pursuits as per NIH [32]. The first bioethical question raise is human enhancement and immortality. The human enhancement concepts lead to rejuvenation technologies that creates further technology driven healthcare disparity and several questions are raised based on that lead to why we need to print an organ after all. Those discussions are now stabilised around focusing on "repair" the organs than "replace" it.

Another dimension of bioethical discussions is that the 3D organ printing explores viable cells for printing that creates typical ethical and regulatory problems. The type of cells used have a direct influence on the performance of the bioprinted construct. Allogenic cell transplantation face classical ethical issues related to cell donation, donor confidentiality, invasive procedures and donor cell ownership. In Europe organ printing comes under the category of advanced therapy medicinal products (ATMPs). The regulatory frame work for ATMPs are now available and is to be applied at every stage of its manufacturing[33]. Risk regulation and responsibility for product quality is key aspect of bioprinting management[34]. One of the basic rules of medical ethics is *Primum non nocere* (Do not harm). However, there is sofar no verdict among clinicians and researchers regarding the basic rule. Subsequently there are chances of medical malpractice and misuse. That need to be analysed and verified based on the moral nature of the event, intention, adverse effects, proportionality of good and bad effects. Its intensity become manyfold when organ printing is tend to "Commercialize". It can be wrongly presented as commercialisation of human body or body parts. So organ printing need to be distinguished clearly that its synthetically manufacturing the constructs which is equivalent to human body parts [35].

The emerging use of AI also is causing a major problem in the legal domain related to bioprinting. The major question about the legal validity of patentability of AI generated designs are that about the inventorship. Traditionally all patent laws define the inventor is a natural person. Now in the case of AI-generated designs there is no natural person. That causes serious challenge to inventorship. This is further damaged when open AI is used for developing new designs. In the case of Thaler Vs. Vldai court rejected the notion of AI being recognised as an inventor [36].

In summary specific court cases are missing in the case of bioink and organ printing as this field is now emerging as an advanced medical product. However, the technology's emerging ethical and legal implications are sufficiently large and that need developing new regulatory framework with a focus for improving its affordability and accessibility. Wherein, questions of patentability, liability and harm need to be assessed and proper regulations need to be put forth for developing adequate intellectual property rights to drive the economy positively exploring bioinks and organ printing.

Discussion

The patentability of bioinks must be carefully assessed to protect the intellectual property rights of new innovations, especially since bioinks do not form part of the final product. This distinction presents legal and ethical challenges. In this study, we have attempted to develop a patent intelligence strategy for bioinks that accounts for these complexities, with a focus on their potential to foster the development of advanced, affordable, and accessible medicines. The analysis of bioink patents is framed with a broader perspective, considering organ printing as an eventual application.

Our assumptions while formulating this strategy were as follows: for an already existing polymer, the product can be dissected into three components: the primary constituent (chemistry/composition), the novelty component (modification/activation/responsiveness), and the third component, its application (e.g, printability, transparency, cellular or molecular responsiveness, and degradability). The keyword selection was made to facilitate academic research, given that the bioink industry is still in its developmental stage. The first stage of translation occurs when a material fulfills a set of critical attributes that allow its application in fields such as 3D bioprinting. The term "biopolymer" was chosen because it encompasses naturally occurring materials that closely mimic biological properties.

This strategy enabled us to efficiently identify and categorize the patent landscape, which was segmented into four key areas: (1) Polymers, (2) Bioink formulations, (3) Bioink formulations designed to mimic disease, and (4) Reconstructive/regenerative constructs using bioinks. Our findings show that the "Bioink formulations" category contains the highest number of patents, followed by "Reconstructive/regenerative constructs using bioinks," then "Bioink formulations to mimic disease," with "Polymers for bioinks" being the least populated category. Subsequently, we assessed the translational landscape. However, the preliminary work carried out before bioinks became a recognized keyword is less relevant for this study, as those patents do not directly contribute to advancing bioink technology. Furthermore, many of the groundbreaking bioink inventions are not necessarily conducive to the development of affordable and accessible medicines.

The regulatory and non-regulatory landscapes were also evaluated to understand the ease of invention. If a chemical composition is inert and does not require regulatory approval, its modification such as crosslinking, swelling, or release properties—does not necessitate further regulatory scrutiny. However, when bioinks are modified to become bioactive, requiring biological assessment, regulatory approval becomes necessary. For instance, if a material is

only active upon interacting with a biological environment, evidence of its biological activity must be provided to secure regulatory approval. In the case of regenerative materials, it is essential to demonstrate that the degradation products are inert and provide evidence of their elimination route. As the bioactivity and exposure of materials increase, the regulatory process becomes more stringent. Moreover, nanoscaling of chemical building blocks must be assessed for both biological and environmental impacts.

Beyond technical and regulatory challenges, the development and patenting of bioink technologies present fundamental ethical dilemmas. The drive to secure intellectual property rights often prioritizes commercial competitiveness over equitable access. In contexts where bioprinting may one day contribute to regenerative therapies or organ replacement, questions emerge about distributive justice: who benefits from these innovations, and at what cost? Patent strategies that restrict access to bioink formulations—particularly in low- and middle-income countries, risk exacerbating global health disparities and undermining the principle of the right to health. From a Rawlsian perspective, ethical innovation should serve the least advantaged. However, patent regimes rooted in commercial exclusivity often conflict with such justice-oriented frameworks. Furthermore, bioinks that incorporate human-derived materials such as stem cells or extracellular matrices raise questions around consent, ownership, and benefit-sharing. The ethical acceptability of bioprinted tissues and constructs must also consider societal perceptions of bodily integrity, identity, and commodification. As bioprinting technologies move closer to clinical applications, embedding ethical analysis into both patent strategy and R&D governance becomes crucial. Policies that support open innovation, flexible licensing, and tiered pricing may offer more ethically sustainable paths to innovation, ensuring that life-saving biofabrication technologies align with public health goals rather than being monopolized by private interests.

Based on these findings, we conclude that advancing biopolymer based biomaterials is capable of crosslinking to form 3D structures that are activatable and resorbable at the microscopic level are in high demand for 3D printing applications. These materials have high translational potential in the near future. However, the involvement of cellular or tissue harvesting presents ethical concerns that hinder the translational process. When considering 3D organ printing, the patented bioinks will be explored further to develop tissue constructs, which will bring additional ethical and legal challenges. Therefore, advancing the regulatory framework is crucial to accommodate these emerging technologies.

Conclusion

This study investigates the patentability and translational potential of advanced biomaterial based bioinks, with a focus on their role in enabling the development of affordable and accessible medicines. Data collected from the ESPACENET database using the keyword "biopolymer-based 3D bioink" led to the identification and classification of several relevant patents. Our findings suggest that the highest levels of innovation are occurring in the "Bioink formulations" category. Among these, inert bioinks show the greatest clinical translation potential and are poised for market introduction as the industry develops. Clinical protocols that use commercially available bioinks represent a promising strategy for accelerating drug screening, targeted delivery systems, and 3D construct development. However, beyond technical innovation, the ethical and legal challenges, particularly concerning tissue or cell harvesting, consent, ownership, and global access, must be centrally addressed. The commodification of bioinks, especially when derived from human materials, raises serious concerns about equitable access, benefit-sharing, and the right to health. To ensure that the benefits of 3D bioprinting technologies are not monopolized or limited to privileged contexts, regulatory frameworks must be reimagined in tandem with ethical oversight. Incorporating principles of distributive justice, open innovation, and socially responsive licensing mechanisms will be essential in steering this emerging field toward a more inclusive and ethically sound trajectory.

Acknowledgement

Prajitha PG wanted to thank her colleagues and friends for kind discussions, various stake holders she met during the study period.

References

1. Irvine, S.A., Venkatraman, S.S.: Bioprinting and Differentiation of Stem Cells. Mol. Basel Switz. 21, 1188 (2016).
2. Murphy, S.V., Atala, A.: 3D bioprinting of tissues and organs. Nat. Biotechnol. 32, 773–785 (2014).
3. Stanton, M.M., Samitier, J., Sánchez, S.: Bioprinting of 3D hydrogels. Lab. Chip. 15, 3111–3115 (2015).
4. Mota, C., Camarero-Espinosa, S., Baker, M.B., Wieringa, P., Moroni, L.: Bioprinting: From Tissue and Organ Development to in Vitro Models. Chem. Rev. 120, 10547–10607 (2020).
5. Peng, W., Datta, P., Ayan, B., Ozbolat, V., Sosnoski, D., Ozbolat, I.T.: 3D bioprinting for drug discovery and development in pharmaceutics. Acta Biomater. 57, 26–46 (2017).
6. Waring, M.J., Arrowsmith, J., Leach, A.R., Leeson, P.D., Mandrell, S., Owen, R.M., Pairaudeau, G., Pennie, W.D., Pickett, S.D., Wang, J., Wallace, O., Weir, A.: An analysis of the attrition of drug candidates from four major pharmaceutical companies. Nat. Rev. Drug Discov. 14, 475–486 (2015).
7. Barrs, R.W., Jia, J., Silver, S.E., Yost, M., Mei, Y.: Biomaterials for Bioprinting Microvasculature. Chem. Rev. 120, 10887–10949 (2020).
8. Bertassoni, L.E.: Bioprinting of Complex Multicellular Organs with Advanced Functionality-Recent Progress and Challenges Ahead. Adv. Mater. Deerfield Beach Fla. 34, e2101321 (2022).
9. Tripathi, S., Mandal, S.S., Bauri, S., Maiti, P.: 3D bioprinting and its innovative approach for biomedical applications. MedComm. 4, e194 (2023).
10. de Melo, B.A.G., Jodat, Y.A., Mehrotra, S., Calabrese, M.A., Kamperman, T., Mandal, B.B., Santana, M.H.A., Alsberg, E., Leijten, J., Shin, S.R.: 3D Printed Cartilage-Like Tissue Constructs with Spatially Controlled Mechanical Properties. Adv. Funct. Mater. 29, 1906330 (2019).
11. Neufeld, L., Yeini, E., Reisman, N., Shtilerman, Y., Ben-Shushan, D., Pozzi, S., Madi, A., Tiram, G., Eldar-Boock, A., Ferber, S., Grossman, R., Ram, Z., Satchi-Fainaro, R.: Microengineered perfusable 3D-bioprinted glioblastoma model for in vivo mimicry of tumor microenvironment. Sci. Adv. 7, eabi9119 (2021).
12. Clegg, J.R., Wagner, A.M., Shin, S.R., Hassan, S., Khademhosseini, A., Peppas, N.A.: Modular Fabrication of Intelligent Material-Tissue Interfaces for Bioinspired and Biomimetic Devices. Prog. Mater. Sci. 106, 100589 (2019).
13. Liu, S., Cheng, L., Liu, Y., Zhang, H., Song, Y., Park, J.-H., Dashnyam, K., Lee, J.-H., Khalak, F.A.-H., Riester, O., Shi, Z., Ostrovidov, S., Kaji, H., Deigner, H.-P., Pedraz, J.L., Knowles, J.C., Hu, Q., Kim, H.-W., Ramalingam, M.: 3D Bioprinting tissue analogs: Current development and translational implications. J. Tissue Eng. 14, 20417314231187113 (2023).
14. Kaladhar, K., Abhi, C., Gokul, T., Anusree, S., Baby, A., Sreejith, T.: Design of a Combination Model of an Abdominal Tourniquet, a 3D Printed Drug Delivering Endotracheal Tube and a Transdermal Patch for Improving CPR Efficiency at Inhospital Conditions. Trends Biomater. Artif. Organs. 35, 283-286 (2021).
15. Kamalasanan, K.: Affordable medicines exploring organ printing using" make in India" campaign. Trends Biomater. Artif. Organs. 30, 161–163 (2016).
16. Thrivikraman Nair, S., VR, V., Kamalasanan, K., Thankappan Presanna, A.: Quantum Insights into Partially Molecular Imprinted Microspheres for Anticancer Therapeutics: Experimental and Theoretical Studies. ACS Biomater. Sci. Eng. 10, 7005–7017 (2024).
17. Gungor-Ozkerim, P.S., Inci, I., Zhang, Y.S., Khademhosseini, A., Dokmeci, M.R.: Bioinks for 3D bioprinting: an overview. Biomater. Sci. 6, 915–946 (2018).
18. Rutz, A.L., Gargus, E.S., Hyland, K.E., Lewis, P.L., Setty, A., Burghardt, W.R., Shah, R.N.: Employing PEG crosslinkers to optimize cell viability in gel phase bioinks and tailor post printing mechanical properties.

Acta Biomater. 99, 121–132 (2019).
19. Cui, X., Li, J., Hartanto, Y., Durham, M., Tang, J., Zhang, H., Hooper, G., Lim, K., Woodfield, T.: Advances in Extrusion 3D Bioprinting: A Focus on Multicomponent Hydrogel-Based Bioinks. Adv. Healthc. Mater. 9, e1901648 (2020).
20. Matai, I., Kaur, G., Seyedsalehi, A., McClinton, A., Laurencin, C.T.: Progress in 3D bioprinting technology for tissue/organ regenerative engineering. Biomaterials. 226, 119536 (2020).
21. Murphy, S.V., De Coppi, P., Atala, A.: Opportunities and challenges of translational 3D bioprinting. Nat. Biomed. Eng. 4, 370–380 (2020).
22. Fatimi, A.: Exploring the Patent Landscape and Innovation of Hydrogel-based Bioinks Used for 3D Bioprinting. Recent Adv. Drug Deliv. Formul. 16, 145–163 (2022).
23. Du, L., Lin, S., Kamenova, K.: Framing Ethical Concerns and Attitudes towards Human Gene Patents in the Chinese Press. Asian Bioeth. Rev. 12, 307–323 (2020).
24. Vijayavenkataraman, S., Lu, W.F., Fuh, J.Y.H.: 3D bioprinting – An Ethical, Legal and Social Aspects (ELSA) framework. Bioprinting. 1(2), 11–21 (2016).
25. Gilbert, F., O'Connell, C.D., Mladenovska, T., Dodds, S.: Print Me an Organ? Ethical and Regulatory Issues Emerging from 3D Bioprinting in Medicine. Sci. Eng. Ethics. 24, 73–91 (2018).
26. Assoc. for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013), *https://supreme.justia.com/cases/federal/us/569/576/*
27. Patenting 3d Bioprinting In India - Obhan & Associates, *https://www.obhanandassociates.com/blog/patenting-3d-bioprinting-in-india/*
28. Patentability of 3D-Printed Organs, *https://www.genengnews.com/insights/patentability-of-3d-printed-organs/*
29. Liability For Defective 3D Printed Products | Adam S. Kutner, *https://www.askadamskutner.com/product-defects/defective-3d-printed-products/*
30. Punnen, D., Chatterjee, P.: The changing face of product liability regime in India and its impact on the med-tech sector, *https://nishithdesai.com/content/document/pdf/Articles/200813 (last acc-essed on 26/08/2025).*
31. Mladenovska, T., Choong, P.F., Wallace, G.G., O'Connell, C.D.: The regulatory challenge of 3D bioprinting. Regen. Med. 18, 659–674 (2023).
32. Kirillova, A., Bushev, S., Abubakirov, A., Sukikh, G.: Bioethical and Legal Issues in 3D Bioprinting. Int. J. Bioprinting. 6, 272 (2020).
33. Advanced therapy medicinal products: Overview | European Medicines Agency (EMA), *https://www.ema.europa.eu/en/human-regulatory-overview/advanced-therapy-medicinal-products-overview*
34. Sekar, M.P., Budharaju, H., Zennifer, A., Sethuraman, S., Vermeulen, N., Sundaramurthi, D., Kalaskar, D.M.: Current standards and ethical landscape of engineered tissues—3D bioprinting perspective. J. Tissue Eng. 12, 20417314211027677 (2021).
35. Bioprinting Technology as a Legal Challenge: Determining the Model of Legal Regulation | Bogdanov | Lex Russica, *https://lexrussica.msal.ru/jour/article/view/807?locale=en_US*
36. AI-Generated Inventions and Patentability: Navigating Legal Implications. - Lexology, *https://www.lexology.com/library/detail.aspx?g =3b4d450b-c83a-476e-a79f-4215c9ae86d1*