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Patentability of Bio-Printed Organs and Tissues: Ethical Boundaries and IP Rights

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Emerging three-dimensional (3D) bioprinting technologies, which enable layer-by-layer deposition of living cells and biomaterials to mimic complex tissue architectures as well as organ constructs, have emerged as powerful tools for regenerative medicine. However, they bring up difficult questions about intellectual property (IP) and ethics. The Patents Act, 1970 (as amended) is the law governing patentability, which requires novelty, non-obviousness and industrial applicability and including no inventions against morality (Section 3(b)), and medical/surgical treatment methods (Section 3(i)). This paper considers how bioprinted organs and tissues would be treated under India's patent law. In this context, we address the relevant patent considerations – novelty and inventive step (for biomimetic products), and statutory exclusions in sections 3(b), 3(c), 3(i) and 3(j) – in India. Comparative reference is made to the US (USPTO) and European (EPO) systems and WIPO practices. Here in US, SCOTUS and post-AIA (§101, §33) control eligibility and recommend only patent bioprinting methods, not organs. The EU/EPO bases the Biotech Directive, accepts (but technically produced) isolated human material but makes exceptions to inventions contrary to "public order or morality" (hence no human cloning). The core ethical issues—respect for human dignity, the commodification of the body, patient autonomy—are present across the board. For instance, the application of embryonic stem cells in designs evokes respect for unborn life. While we highlight global trends (such as Organovo securing a U.S patent for tissue printing), we also want to emphasize that India's domestic IP jurisprudence is still in its nascent stage. Therefore, India should define the middle path between innovation and bioethics of not allowing patents on technical methods and not allowing it on non-embryonic composition of matter while still upholding human dignity and ensuring equitable access. This might include the steps such as: ethical sourcing of cells; patient consent/ rights in bioprinting innovations and, perhaps even making patent grants contingent upon benefit sharing.

Keywords: 3D Bioprinting, Patentability, Patents Act 1970, Section 3(B), Section 3(I), Novelty, Inventive Step, Ethical Considerations, Human Dignity, India

Bioprinting is the use of 3D printing–like techniques with the cellular biology to create tissues.[1] With 3D bioprinting, you could print with cells using bio-polymer gels and other materials and biomaterials and produce anything in the biological world. For instance, researchers have used bioprinting to create bone, cartilage, skin, liver tissue and corneal implants for drug testing.[2] The technology has the potential to mitigate organ scarcity with regenerative implants, but it raises fundamental questions on patent systems and bioethical standards. In India inventions are regulated under the Patents Act, 1970[3]. The Act provides that new, nonobvious, and useful subject matter may be patented. However, several exceptions apply: in particular, Section 3(b) excludes patents for inventions which are "contrary to public order or morality" or "prejudicial to health"; Section 3(i) excludes methods of medical and/or surgical treatment of humans/animals; and Section 3(j) excludes plants and animals in whole or in part. These enumerated provisions raise questions, e.g.: *Does a printed tissue count as a part of an animal (3(j))? Are they wrong by moral standards (3(b))?*

In constructing this question, we also use international comparison. IP in the U.S. allows patents on man-made like forms (*Diamond* v *Chakrabarty, 1980*)[4] but recent cases contract "products of nature". The U.S. America Invents Act (2011)[5] prohibits patents on "human organisms". The European Patent Convention[6] also bans patents which are contrary to public order or morality and exclude methods of treatment, but the EU Biotech Directive specifies that human-derived products can be patented.[7] Worldwide, TRIPS Article 27 allows ethical, including whether such patenting is permitted for human genes.[8]

Yet beyond that, profound bioethical questions hang in the balance. But Print-a-Body — the idea of

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bioprinted organs — raises questions around human dignity, bodily integrity and the "commodification" of human tissue.[9] *Do patients have rights to tissues that have been printed from their cells?* In the first place, *should life-saving innovations be patentable, especially in a world of organ scarcity?* Bioprinting is unregulated, and Indian law has no specific principles regulating this field. That would leave patent examiners to classify bioprints as products of nature, or parts of animals, and steered bioprinters into the type of controversy that has attended stem-cell patents.

This paper will, therefore, evaluate Indian patent law on bioprinting within the context of global IP and ethics. Having set forth the most relevant requirements, we apply the most significant Sections 3(b), (c), (i), (j) to bioprints. We look at USPTO/EPO practice and global discussion. Lastly, we consider ethical aspects—human dignity, consent, equity—and provide recommendations for India's policy.

Indian Patent Law and Bioprinting

Patentability Criteria in India

Under the Patents Act, an invention that is alleged to be a patentable product or process should satisfy the test of novelty, non-obviousness and industrial applicability (Section 3(1)(ja),(jb)). An object such as a 3D-bioprinted organ may be considered a product of manufacture of matter, a product and method of the bioprinting being considered a method.[10] Bioprinting with technology is patentable in principle in India. For instance, patents can protect essence of bioprinting material (bio-ink), method of printing, bioprinters (hardware) and software also.[11] Accordingly, it is not that the 'form' of subject matter itself (i.e, living tissue) cannot fall within the definition of patentable subject matter but, rather, the Act determines eligibility and exclusions.

The regular tests of novelty and inventive step for an Indian applicant is mandatory. For an organ printed by 3D printing to be taught as novel and unobvious, it must be biologically and functionally distinct from the prior art. But there's a conflict: If a bioprinted organ is nearly identical to the natural organ, it may confront novelty or eligibility issues. Ifbioprinted tissues model existing structures well, then they may not be novel under patent law. On the other hand, a bioprinting process tends to use engineered scaffolds, artificial growth factors, cell designs, which, in of themselves, can be innovative step.[12] So, it is certain that there could be patents granted for the bioprinting processes or formulations (e.g. particular bio-inks or devices), and product claims to the organ itself will come under intense scrutiny.

Patent Exclusions under Section 3

The primary legal hurdles for bioprints in India are Sections 3(b), 3(c), 3(i), and 3(j) of the Patents Act.

(i) Section 3(b)[13] (Morality/public order): No patent shall be granted if the invention is intended primarily or mainly to use plants, animals, mineral, micro-organisms, and that to use it would be contrary to public order or morality, or the use of the invention will cause serious prejudice to human, animal or plant life or health or to the environment. It is broad but context-specific (e.g e-cigarette patents denied for 3(b) on health grounds). In the context of bioprinting, the ethical front centers around human life and respect. In practice, that would invalidate inventions that use the destruction of embryos or that raise serious ethical concerns. For example, when we bioprint with embryonic stem cells (ESCs), the embryo is killed in the process, and Indian examiners consider that as unethical.[14] It would most likely not even be patentable if a bioprinted construct is drawn up from a basis of [ESCs], some have the opinion, unless an applicant can show that the [ESCs] were not derived by processes that result in the destruction of an embryo.[15] In contrast, induced pluripotent stem cells (iPSCs), which bypass embryos, encounter fewer moral objections. More generally, any bio-printing process that is perceived as tantamount to "human cloning" or life creation could spur 3(b). Useful is the analogy to EU law: there, the EPO will refuse patents for processes that are considered identical to cloning a human being (Art. 6(1)(i) Biotech Directive). Indian law also values human dignity. For instance, the Act's exclusion (such as of animals in (3(j)) represent a legislative directive to ensure harmony between moral, cultural and scientific values.

(ii) In other words, Section 3(b) signals to examiners that they need to look for ethical red flags in any invention related to bioprinting. Embryonic cells could potentially be used, or it could be implied commodification of human tissues that may render a claim contrary to morality. But new technical processes that circumvent those

problems (for example, using adult stem cells or patient-derived cells) are also more likely to clear.[16] Indian experience till date has not seen any 3(b)-rejection reported on bioprinting yet, though 3(b) jurisprudence in other life-science are as (such as the rejection of patent applications on sex-toys or genetically modified insects on 'morality' grounds) do suggest one ought to tread carefully where this subject matter was concerned.

(iii) Section 3(c)[17] (Discovery of natural substances): This section does not include naturally occurring organisms and non-living natural substances in the scope of patent-eligible subject matter. Organisms' 3D printed with cells are made of live biomaterials. If a patent stakes its claim on merely the "discovery" or isolation of something natural (such as a human cell or protein) without any changes to it, that would not be allowed[7]. Yet, bioprints are generally artificial constructs – assemblies of cells, scaffolds, bioactive molecules but they do not exist as fully integrated in nature. So, carefully stating the claims to say this is a "technical" process (3(c) step) rather than just isolation of the natural material should avoid 3(c). The EU biotech directive tackled a near-analogous problem by only allowing isolated elements (genes and cells) to be patented if manufactured by a technical process.[18] By analogy, one could say in India that the printed organ is not a "discovery of a living thing existing in nature" but a product created by humans.

(iv) Section 3(d)[19] (New form of known substance): This prevents evergreening, i.e., the practice of pharmaceutical companies finding new forms of known substances to prevent other companies from entering the market with a generic product. This is often used in pharma for polymorphs and may be less appropriate for large tissue constructs. Unless a bio printed claim is directed simply to a recitation of a known tissue with an insignificant change, 3(d) should not apply. More crucially, bioprinting novelty will be around composition and process. Indian examiners would have determined whether a claimed organ differs in terms of one or more functional characteristics or structure from a known tissue or a scaffold.

(v) Section 3(i)[20] (Medical treatment methods): This excludes patents on any process for the medicinal, surgical, curative, prophylactic, diagnostic treatment of human beings. This is similar to Europe's rejection of therapy techniques. An independent claim to a surgical method of implanting a bioprinted organ into a patient would be objected as a claim with human body as categories of claims are not open to judicial construction. (India also bans general surgical techniques.) However, Section 3(i) does not exclude products and devices (e.g., organs, printers). So, one could obtain a patent on a bioprinted graft, or on the machine printing a so-called graft, but not a claim such as: "surgical process for the replacement of a heart by a bioprinted heart." This is similar to the law in the U.S. that medical treatments are not patentable (statute 35 USC 287(c)), but apparatus and products can be patented.

(vi) Section 3(j)[21] (Plants & animals): This prohibits patents for animals or animal's parts. The Indian Patent Office (IPO) has treated bioprinted constructs as "parts of an animal," especially if human cells are involved. For instance, a three-dimensional printed (3D) liver made up of human cells is probably a "part of an animal" (the animal being a human)[22]. It is also pointed out that 3D bioprinted tissue constructs or organs are treated as part of an animal by the IPO. Applicants should point out differences in their claimed bioprinting structure/template and a natural organ (e.g. synthetic matrix, printed geometry) to overcome this. If the transplanted organ is viewed as a "fundamentally biological" process, this could also exclude it under3(j). It is a major obstacle until examiners will be trained in the specificities of each bioprinting process. (The EU excuses "essentially biological processes" plants/animals – product claims are not prohibited.) In short, any patent claim on the biological product of bioprinting (cells or tissues) has to contend with 3(j). Claims may instead emphasize the technology (bio-ink formulations, scaffolding, printer apparatus) to prevent being construed as "an animal part.

Technically, Indian law doesn't have a blanket ban on bioprints, yet there are many things around this technology that are highly scrutinized. Novel methods, software, and substances (bio-inks) can be patented most reliably. Claims about the organs themselves run the risk in sections 3(b) and 3(j). Early guidance from the Indian Patent Office focuses on demonstrating how the claim is distinct from nature. That reflects international guidance that bioprintedproducts have to

show "markedly different characteristics" from natural organs in order to be patented.

Comparative Perspectives

United States (USPTO)

In the U.S., patent eligibility is represented by 35 U.S.C. §101 (the statutory categories) and case law along with statute. In the U.S., the concept of patent eligible subject matter is defined by 35 U.S.C. §101 which encompasses "any new and useful process, machine, manufacture, or composition of matter". Bioprinted organs may be considered "manufactured" or "compositions". But under U.S. law, laws of nature, natural phenomena, and abstract ideas are not patentable. The Supreme Court's *Diamond* v *Chakrabarty (1980)*[23] decision said that a man-made micro-organism was, in fact, patentable because of its "markedly different characteristics" from the natural bacteria that it was based on. By contrast, *AMP* v *Myriad* (2013)[24] held that an isolated DNA segment, as long as it was identical to a native gene, is not subject to patent (not "markedly different").

According to bioprinters, the essential question is *whether an organ printed in a factory is a natural product?* One viewpoint holds that a bioprinted organ is fundamentally a reproduction of a natural organ: hence not patentable. Yet others argue that printing is a product of human invention and is often missing part of a natural complexity (e.g., not being vascular), and is therefore patent eligible.[25] Examiners at the USPTO have allowed patents on bioprinting methods. For instance, United States Patentto Organovo describes a process of 3D tissue development utilizing a cellular "bio-ink" and manipulation of thermal cycling. The patent is focused on the individual process steps (bio-ink preparation, extrusion, hypothermic hold, incubation) rather than the organ. These process patents seem invulnerable because they encompass "man-made inventions" (bio-inks, scaffolds) and transformative procedures.

A complicating factor, as authored in the United States, is America Invents Act §33(a)[26], that "no patent may issue on a claim directed to or encompassing a human organism". "Human organism" is not defined or is indecipherable; USPTO guidance, 2011[27] reads this as not having changed the law (which already bans issuance of patents per se on human beings). How this would apply to a bioprinted organ (which does not make up an entire human) is unclear. It is generally believed among patent experts that 3D organs don't meet the definition of "human organisms" within the meaning of §33(a), so §33(a) probably doesn't apply to bioprint claims. The U.S. Patent Office itself even recognized that §33(a) should not preclude the patenting of organs, since it "does not change existing law that a claim directed to or encompassing a human being is not patentable".

The recent U.S. Supreme Court decisions have also further constrained §101.[28] Such cases call for a two-step inquiry (i.e., whether claim is directed to a judicial exception, and when so, whether it provides an inventive concept). There is some fear that as bioprints become more and more lifelike, they may be classified as "products of nature" under Myriad. It seems that the real is not so real and organ parts that mimic functioning are not so new with the experts observing an inverse relationship, "3D organs may well turn out to be patent-eligible but only insofar as they have `markedly different characteristics' than products of nature, oddly, the more 3D organs are developed to mimic real organs, the less likely they may be to be considered eligible".

To sum up, the U.S. position is that bioprinting methods and mixtures are patentable, as long as they survive the eligibility test. However, multiple experts recommend taking a cautious approach charging for these services, but not necessarily the end organ that was printed. The vast majority of experts don't advocate for allowing patent claims that only cover a process as a way to reconcile innovation with morality. In fact, companies file method patents (as Organovo did), not product claims on the organ. Overall, the U.S. is said to be very positive in outlook toward bioprinting patents today: "there does not appear to be anything in Section 33(a) of the AIA or Section 101 that would prevent claims directed to 3D organs or bioprinting." That said, the law is developing; and any product claim(s) (eg "A bioprinted heart") may still give rise to accusations of infringement under the §101 exceptions.

European Union (EPO)

Novelty, inventive step and industrial applicability the requirements of the EPC for validity of a claim to a European patent may be compared to U.S. law in this regard (EPC Art. 52-57). However, it specifically excludes innovations against "public order or morality" (EPC Art. 53 a) and does not apply to processes of human/animal treatment (Art. 53(c)). Additionally, in Europe, the EU Biotechnology Directive[29] provides special rules for bioinventions.

Importantly, under EU law it is legal to patent isolated or technical biological material. According to

the Biotech Directive, i.e., Article 5(2) of that directive, an element may be patented when it is "isolated from the human body or otherwise produced by means of a technical process", even if it is identical to a natural element.[30] It does not in practice; It granted patents on human cell lines, on genes, etc. if they are described as technical processes of production. By analogy, a machine-made bioprinted organ could be regarded as a technical product. The EPO has stressed that isolated living material (such as an isolated gene) may be patentable and that it is the "technical invention" – which also includes the production process – that counts.[31]

But, in stark contrast, morality and human dignity don't seem to be important at all. Directive 98/44 Art. 6.1(a)[32] reflects EPC Art. 53(a)[33], which makes unpatentable an invention if its use would be "contrary to morality". The EPO Boards in previous cases (e.g. *Relaxin/Howard Florey Institute*)[34] have construed the expression "public order" and "morality" as issues of public safety, personal integrity, the environment and of course, on basic moral principles. Most pertinent are provisions that ban "uses of human embryos" and "human cloning". For example, Art. 6(2)(c) of the Directive states that patents on the "use of human embryos for industrial or commercial purposes" are excluded "from patentability" under the Directive. Cases at the EPO and EU courts have invalidated patents that require human embryo destruction (e.g. *Brüstle* v *Greenpeace* (2011)[35]).

Is bioprinting any different? Not exactly. Typically, with bioprinting the "ink" used to print a given structure comprises cells (which might or might not be stem cells), but not the production or implantation of a human embryo. It has been shown that "bioprinting is not human cloning. Researchers at Tel Aviv University even bioprinted a "heart" made from a patient's cells and an extracellular matrix, but this was considered regenerative medicine, not reproductive cloning.[36] In this regard, the EPO would presumably consider a bioprinted organ similar to a medical device or tissue-engineered product. And indeed, the Tilburg study insists that not only is the "human cloning" ban, (Art. 6(1)(a)) did not apply to bioprints as they were not "exact genetic replicas".[37]

In reality, the EPO has awarded patents over bioprinting machines and methods (involving "technical" steps such as printing cells). It would decline only if something violated moral clauses. For instance, bioprinting procedures that use human embryonic stem cells derived from human embryos could be rejected (as a ban on working with embryos unless, as in the case of parthenotes, or similarly ethically sourced human embryonic stem cells, the procedure is allowed).[38] EU law precludes also patents on surgical procedures (like India's Sec 3(i)) but allows patents on therapeutic products.

As the EU's stance is that bioprinting patents to be allowed as long as they uphold human dignity. Devices, bio-inks and methods that do not employ forbidden embryos or cloning are eligible for patent. An application to patent a bioprinted organ by itself that may be considered under morality will probably be a hurdle, but method claims (e.g. "a method of manufacturing a tissue implant by depositing cells") are likely to be fine.

WIPO/International

There is no treaty as yet for bioprinting at the international level. Yet in TRIPS (enforceable by WIPO overseeing), members can exclude inventions "for the protection of public order or morality". TRIPS Art. 27(2) Modelled on India's 3(b) highlights: India's morality exclusions are TRIPS-compliant (morality clauses are explicitly allowable, not required).[39] WIPO forums are starting to observe new issues in biofabrication: patent authority's promote convergence, and expect eventual guidelines. For example, by WIPO in the PatentScope database or by the industry in Patent Technology Trends on 3D printing. Although the WIPO has not promulgated formal rules, it adopts (through TRIPS) the position that moral issues fall within the discretion of the nation.

Practically, international protection seeking applicants file under the PCT or US/EU patents first because those offices have been around for a longer period of time. India's Patent Officehas also granted acceptance of bioprint inventions, but the rulings will be closely based on sections 3(b/i/j). No WIPO working group has yet issued specific opinion on bioprinted organs; it's early days for the sector. India could potentially engage in WIPO conversations on health innovation in creating global standards for tissue printing.

Ethical and Societal Considerations

Bioprinting patents cannot be divorced from ethics. Core concerns include human dignity, bodily commodification, and equitable access.

Human Dignity and Consent:[40] The concept of printing human organs begs the question of what are the limits of human existence? Some ethicists assert that it is contrary to the intrinsic dignity of the human person to manufacture body parts for commerce. Indian constitutional values (right to life, personal liberty), ethical norms in medicine emphasize that bodies cannot be treated like property. Section 3(b) embodies this philosophy in law. Patent awards might give the impression of "commodifying" body parts. The EU, by way of example, identifies "human dignity and integrity" as reasons to ban cloning and embryo uses. There is less jurisprudence on this front in India, but at least such jurisprudence as there is in the public domain interprets human cells and tissues to have a special status (see The Transplantation of Human Organs Act, 1994,[41] which has made illegal the trade in organs). One possibility is that if a bioprinted organ is made using the patient's own cells, ethical fairness would imply that the patient could have rights in the invention that the organ comprises.Patents on the other hand right now simply give rights of ownership to the inventor (company or researcher). But as a matter of ethic it could feel wrong if the raw material comes from the patient. India's law is not explicit on this point, but we believe that any patent regime should include informed consent and possibly benefit-sharing. A patient donating stem cells for a bioprint should not be compelled and should be informed if the outcome will be patented. In a legal sense it might be possible to imagine the patent office will demand that an applicant would have to divulge the origin of the cells or/and consent from individual donor.

Commodification of Life:[42] Closely related is the concern that patents may legitimate human body parts as tradable goods. And because it involves the use of human tissues in marketable products, one review of biomedical ethics cautions that it "is at odds with human dignity and the ban on commodification of human body parts" and could exploit donors who are in need of money. For example, disadvantaged members of society may economically incentivized to contribute biological materials, should there be profitable patents that stem from them. India has very strict laws on organ sale but since the bioprinted organs would clearly be "artificial" it may open up a loophole (technically I didn't trade an actual kidney!).

Equity and Access:[43] Patenting may also determine who benefits from bioprinting. If a life-saving organ is patented and licensed with fat fees, perhaps only the wealthy could afford it. Low-Cost Bioprinting: Can the Developing World Benefit? Gender-related and diversity issues are important aspects of scholarly social issues, and to this extent, I suspect that most authors think about diversity and equality at various points in the writing process. In the Indian scenario, with paucity of public health resources, it is essential to bring the bioprinting technologies to be low cost so that they can easily be afforded. Legal tools could include compulsory licenses (if an organ is patented and still too costly, India could authorize others to use it) or conditional patents (on the grounds of "reasonable pricing").

Regulatory Vacuum: India doesn't have any explicit legislatures yet for bioprinting apart from drugs / therapeutics. The new Drugs and Clinical Trials rules (2023)[44], which was recently amended, permits 3D-printed tissues to be used for the preclinical drug tests, thus indicating regulatory backing for the research. But there is no law that specifically addresses the use of a bioprinted organ in a patient. Bioprinting does not provide examiners with specific guidance. This vacuum requires that the ethical oversight (institutional review boards, stem cell guidelines) step in. For instance, India's ICMR Guidelines for Stem Cell Research forbid therapeutic cloning or cloning of embryos for research.[45] Bio-printing centers might have to comply with these; otherwise, patents for forbidden processes should be declined.

If India wants to make sure that there are ethical constraints to patenting in the field of bioprinting, there is a principled way to go about it: the requirement of morality impact statements in bioprinting patent applications, as required for clinical trials to get over the ethical bar of approval. Globally, organisations such as UNESCO have considered bans on organ trade; India's IP regime must reflect such trends.

Case Studies and Patent Developments

Real life patent bioprint activity is now taking form internationally. About a decade later, US Patent was issued to Organovo Holdings—a revolutionary company in the field (Oct, 2023)—for "Methods of producing three-dimensional engineered biological tissues using bio-ink". This includes methods to

prepare a living-cell bio-ink, extruding the bio-ink, and employing a controlled hypothermic hold to enhance tissue viability.[46] The patent makes clear that no artificial cross-linkers are employed in tissue formation. Importantly, it is a method of printing tissue structures, not claims an organ. This technique, says Organovo, "lowers apoptosis in bioprinted tissue compared to other methods", showing a truly innovative biological effect. This is an example of the fact that US product patents for the bioprinted organs themselves have not issued, but patents on processes using mimetic bioprinted inks and printed organs have.

In Europe, patent applications reflect the same trend. For example, Israel's Tel Aviv University (TAU), discovered a way to bioprint human tissues using patient-derived stem cells. This wasn't the first time TAU researcher's 3D printed a beating human heart with cells, vessels and chambers – in 2019.[47] This was then followed by a patent application (exploited by the startupMatricelf) for the underlying technology. Submitted in 2024 in the United States and in Europe, the application covers the printing process that stabilizes the construct with nanoparticles and then removes the support.[48] Unlike Organovo's patent, one of TAU's concentrates on the process and materials (stem-cell bio-ink, nanocellulose matrix), not on a product claim for "a 3D-printed heart." This approach presumably sidesteps patent bars directed to organ-as-animal.

In India, patent filling in the area of self-assembly is sparse. We're not aware of any patent issued on a 3D-printed organ or tissue as of yet. According to patent agents, India's applications are in line with worldwide trends: bio-ink compositions and printer apparatus are what they say. One patent application (still pending) filed in India, for example, referred to a "bioprinted skin graft" but was written in process-and-material language rather than terms of organs. News stories indicate that Indian companies and labs (e.g., Pandorum, 4D Life) are involved in R&D[49], but there is little publicly available data on their IP. However, patent searches in 2023 indicated over 50 patents had been approved worldwide (predominantly in the US and the EU) with many more regarded as pending in this area. India, where a biotech industry is developing, is also likely to face more filings in the near future.[50]

Significantly, no jurisprudence on Section 3(b)/ (i) in relation to bioprints has appeared in India. But lessons may be found in cases across the world. High levels of moral review are also seen in cases such as Brüstle (CJEU) and ICS (EPO) in Europe which deal with the patenting of embryonic stem cells. In the US, there was a brief period where federal funding for therapeutic cloning was held to be against the law - *Sherley* v *Sebelius* (eventually settled). These indicate that all Indian applications in the area of cloning or embryo would be subject to a patent refusal and also that such applications would statutory be not allowable. On the inventive-step/natural-product side, the U.S. Porcine-BMD judgment is referred, which rejected a patent for a naturally preserved bone on the grounds that it was fundamentally natural. Similarly, a claim to a non-stimulated biological tissue could be invalid by analogy.

These evolving trends add up to a cautious, but innovation-welcoming path: patents on bioprinting techniques are being won across the world, with ethical red lines (embryos, cloned humans) out of bounds. India may look towards these developments while considering its examination system.

Conclusion

Bio-printed organs and tissues stand at the intersection of cutting-edge technology and profound ethical questions. There are no outright prohibitions against bioprintable inventions under India's Patents Act, but substantial barriers remain. Section 3(b) requires that patents not violate human dignity or health; 3(i) prohibits pure medical methods; 3(j) prohibits animal parts. To circumvent this, Indian innovators and examiners are required to look at patentability of technology (bio-inks, devices, processes) and not the organ product. Claims should be directed to technical characterising features (such as artificial scaffolds, novel cell configurations) which set the invention apart from no more than natural tissue. Just the way in the USA the interchangeable use of "process of making an organ" and "organ per se" is bearable, so are applicants free to claim only the process of making an organ and, hence, not the organ "as such".

From a legal-ethical perspective, India's IP system needs to counterpoise incentives with human values. We recommend the following:

(i) Guideline Clarification: Exam guidelines should be issued speaking about bioprinting on how 3(b)/(j) applies. Such guidance might say, for example, that patient-specific prints (autologous implants) would be acceptable even if there was no human cloning.

(ii) Ethical Protections: Build ethics algorithms into the patent process. Applicants should indicate their sources of biological material (eg stem cells)

and whether they have obtained or intend to obtain ethical approval (consent, regulatory approvals). Approaches using human embryo-derived cells should clearly not even be considered under 3(b) and established Stem Cell Guidelines.

(iii) Promote Process Patents: Emphasize patenting of novel apparatuses (bioprinters), bio-ink compositions and printing processes. This will create new investments in the body, without exactly privatizing the human body itself. India's statute may specifically note bioprinting methods as patent eligible subject matter to help foster this push.

(iv) Halt the Monopoly on Life-saving Organs: If the law sees printed organs the same as medical devices, institutions won't violate morality. Possibly include mandatory licensing provisions: for instance, if a lifesavingbioprinted organ (eg. printed cornea) is patented at outrageous cost, the government can require its production for public health.

(v) International Cooperation: India should cooperate with WIPO and global patent bodies to align itself with standards. Contribution to TRIPS discussions may help to prevent global disparities (e.g. the definition of "human organisms" in patents).

(vi) Public engagement and knowledge sharing: Build awareness of the ethical application of bioprinting Value. Choreography of Patents should not override Patients' Privacy.

(vii) Bioprinting is too impactful to set aside, too delicate to lump with mere invention. In India, technology is evolving and the legal framework, being the Patents Act and supporting laws (like organ transplant law, bioethics guidelines), must also evolve. Through developing patent eligibility criteria and inserting ethical guidelines, India can drive bioprinting innovation and promote human values and societal well-being.

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