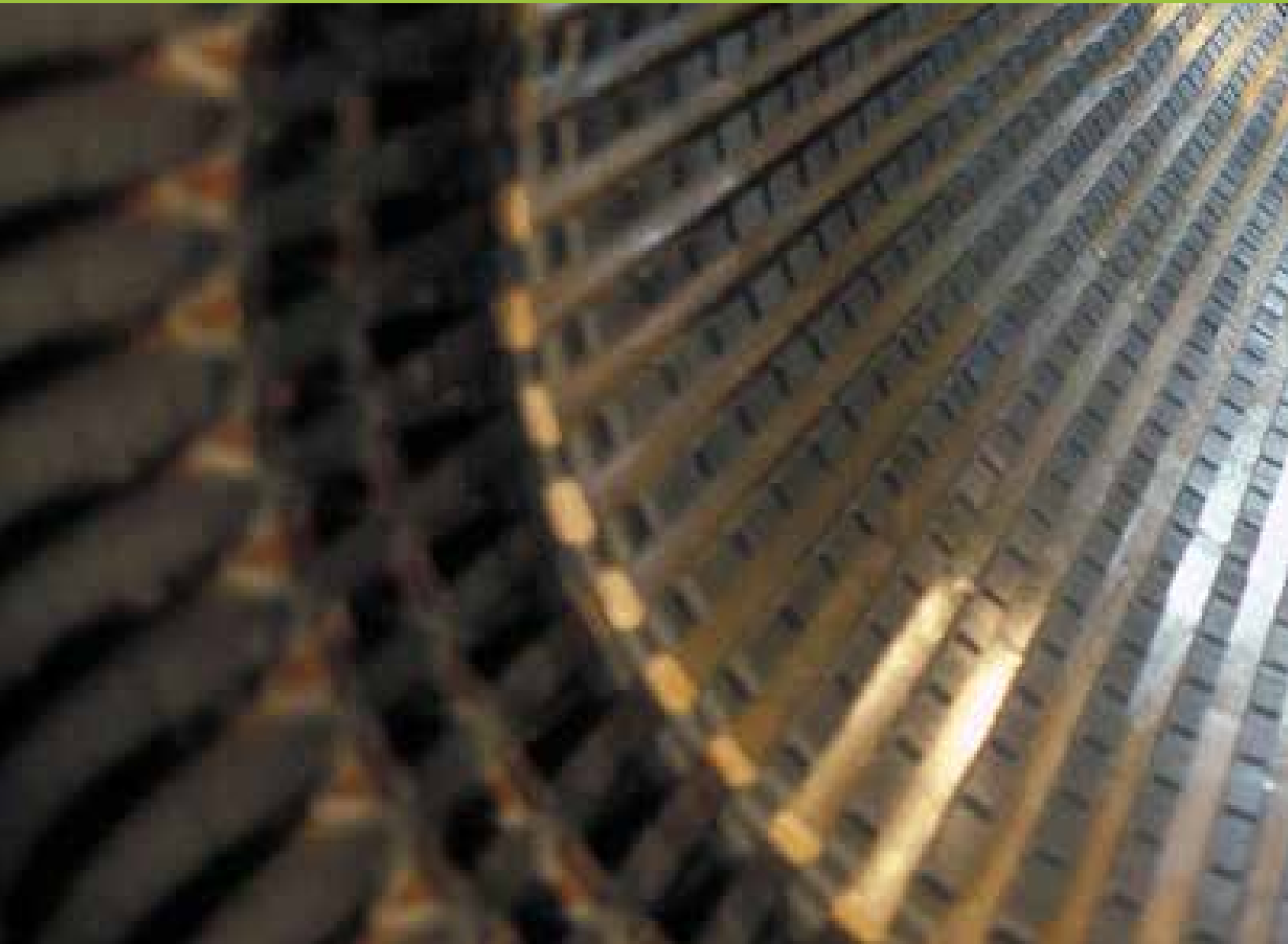


Patentability, Global Development and Ethical Considerations of Bioprinting

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Introduction

This article seeks to inform the potential of bioprinting (3D printing of human organs), the legal aspects of the technology, its patentability, regulation, and ethical considerations. The U.S. Patent and Trademark Office (Patent Office) has already granted some bioprinting patents and many more patent applications are pending.² Although these patents are presumed valid, the validity of some of these might be litigated in due course, as the technology advances and the market expands.

Before bioprinting can be used routinely for the regeneration of complex human tissues and complex organs with intricate 3D microarchitecture, several technological limitations must be addressed. However, if history teaches us anything with respect to the interplay between biotechnology advances and the corresponding legal/regulatory/ethical milieu, we should safely assume that bioprinting facilities with the ability to print human organs and tissue will advance far faster than general understanding and acceptance of the ramifications of this technology. We should be prepared.

Background

“Bioprinting” officially became a word in 2015, making its entrance into Oxford dictionaries.³ In the broadest sense, bioprinting is the use of additive manufacturing, i.e., 3D printing technology, with materials that incorporate viable living cells. Cell function and viability are preserved within the printed construct. Bioprinting can be defined as a subcategory of 3D printing.

Since its initial use as pre-surgical visualization models and tooling molds, bioprinting has evolved to create unique compositions, implants, and scaffolds for tissue engineering. This technology has the tremendous potential of producing *in vitro* desired tissues and organs, using a layer-by-layer bioprinting with a 3D printer. Bioprinted tissues and organs can have numerous applications that range from research, drug development and testing, to tissue engineering and the generation of organ transplants for use in regenerative medicine. For example, one can only imagine the potential of combining stem cells with custom 3D scaffolds for personalized regenerative medicine.

Additive manufacturing, also known as three-dimensional (3D) printing technology, promises to revolutionize manufacturing. It is a disruptive technology and a major driving force in many areas including bioengineering and medicine.⁴ The main economic advantages of 3D printing are that it substantially reduces the cost of manufacturing, and virtually eliminates cost of distribution. Medical applications for 3D printing are expanding rapidly and are expected to

² See *infra* for exemplary patents.

³ Brian Krassenstein, 'Bioprinting' Officially Becomes a Word, Enters Oxford Dictionaries, 3DPrint.com, February 27, 2015, available at <https://3dprint.com/47533/bioprinting-definition/>; see also <https://en.oxforddictionaries.com/definition/bioprinting>.

⁴ Phoebe H. Li, *3D Bioprinting Technologies: Patents, Innovation and Access*, 6 LAW, INNOV. AND TECH. 282-304 (2014).

revolutionize health care.⁵ The technology of bioprinting, which synergistically combines synthetic biology's building blocks with the 3D printer's mechanics to form functional living tissues and organs, provides much more than mere economic implications – it promises medical breakthroughs on an unprecedented scale. It is likely that this technology will gain prominence in the coming years and have a far-reaching impact on our daily lives⁶. For example, more than 119,000 men, women and children are currently on the national transplant waiting list.⁷ Many of them would benefit from the development of 3D printed, functional human tissues and organs⁸. Not surprisingly, the race is on to be the first to 3D print a transplantable human organ.⁹

In simplistic terms, the process of 3D printing stacks multiple layers of two-dimensional printing on top of one another. These technological advances have enabled 3D printing of biocompatible materials, cells and supporting components into complex 3D functional living tissues. Unlike the printing of non-biologicals, bioprinting is a complex process that involves different technical challenges such as choice of materials, cell types, growth and differentiation factors, living cells' sensitivities, and tissue construction. Addressing these complexities requires integration of different technologies from the fields of engineering, biomaterials science, cell biology, physics and medicine.¹⁰

The bioprinting aspect of the industry that is discussed in this Article is focused on the digitization of human body parts and, potentially, entire human beings. The 3D printing technology is rapidly developing. The capability to use human (stem) cells as a biological ink fed into a 3-D printer to commercially bioprint transplant size and compatible organs should be developed in the coming years. Indeed, bioprinting has already been used for the generation and transplantation of several tissues, including multilayered skin, bone, vascular grafts, tracheal splints, heart tissue and cartilaginous structures¹¹; brain tissue 3D printing is at our doorstep¹². The emergence of *in vivo* bioprinting offers a pathway to bridge bioprinting and robotic surgery, with *in situ* fabrication of biomaterials (human cells, tissues, and organs).¹³ Other applications include developing high-throughput bioprinted tissue models for research, drug discovery and toxicology.¹⁴

Bioprinting is gradually emerging as an area which is garnering attention from a lot of academicians. Numerous start-ups have recently sprung up to develop products based on

⁵ C. Lee Ventola, *Medical Applications for 3D Printing: Current and Projected Uses*, 39 P&T 704-711 (2014).

⁶ See Roots Analysis, *3D Bioprinting Market, 2014-2030* (2014), available at http://www.rootsanalysis.com/reports/view_document/3d-bioprinting-market-2014-2030/55.html

⁷ See U.S. Department of Health & Human Services, U.S. Government Information on Organ Donation and Transplantation, at <https://www.organdonor.gov/statistics-stories/statistics.html>, accessed January 23, 2017.

⁸ For purposes of this Article, the term "3D bioprinted organs" encompasses 3D bioprinted medical implants, cells, tissues, and organs.

⁹ Clare Scott, *Wake Forest Researchers Successfully Implant Living, Functional 3D Printed Human Tissue Into Animals*, 3DPrint.com, February 16, 2016, available at <https://3dprint.com/119885/wake-forest-3d-printed-tissue/>.

¹⁰ Helena N. Chia and Benjamin M. Wu, *Recent Advances in 3D Printing of Biomaterials*, 9 J. BIOL. ENG. 1-14 (2015).

¹¹ Sean V. Murphy and Anthony Atala, *3D Bioprinting of Tissues and Organs*, 32 NAT. BIOTECH. 773-785 (2014).

¹² Rodrigo Lozano, Leo Stevens, Brianna C. Thompson, Kerry J. Gilmore, Robert Gorkin III, Elise M. Stewart, Marc in het Panhuis, Mario Romero-Ortega, Gordon G. Wallace, *3D Printing of Layered Brain-Like Structures Using Peptide Modified Gellan Gum Substrates*, 67 BIOMATERIALS 264-273 (2015).

¹³ William L. Warren et al., *Architecture tool and methods of use*, U.S. Patent No. 7857756 B2 (issued Dec. 28, 2010).

¹⁴ Sean V. Murphy and Anthony Atala, *supra* note 12.

bioprinting; some of these are spin outs from university research. It is widely anticipated that the bioprinting market has tremendous potential: it requires hardware (bioprinters), software (CAD), biocompatible materials (bio-ink and bio-paper), each of which has the capability to grow into separate niche industries. For example, the market has at least 14 industry sponsored bioprinters, focused on a variety of commercial applications.¹⁵ The widening supply-demand gap for organ transplants presents a huge unmet need. As the development progresses, it is expected that the next generation of bioprinters will offer additional features (e.g. multiple arms), which will also likely be relatively more affordable, driving wider adoption. By 2030, bioprinting is predicted to be a multi-billion dollar industry.¹⁶

Applications of Bioprinting

The greatest potential of bioprinting is in relation to regenerative medicine, to ultimately address the need for tissues and organs suitable for transplantation in humans. Possible applications include the use of bioprinting for biomedical/biopharmaceutical research and development, the potential for the production of custom-made/individually-tailored prosthetics and implants, and pre-surgical planning.¹⁷

Various bioprinting technologies have been developed and utilized for applications in life sciences, ranging from studying cellular mechanisms to constructing tissues and organs for implantation, including heart valve, myocardial tissue, trachea and blood vessels.¹⁸ The power of bioprinting is additionally derived from the computer-aided design and manufacturing (CAD/CAM) process, which enables this technology to fabricate biomimetic-shaped tissue or organ(s). However, many technological challenges remain that presently hamper the transition of this technology from lab-based environment to harnessing its potential for clinical use.¹⁹

Patentability of Bioprints, Legal and Regulatory Considerations: US Law Perspective

Bioprinting Patent Landscape

Arguably the first issued bioprinting patent (for “[i]nk-jet printing of viable cells”) was awarded to Thomas Boland and co-inventors from Clemson University in 2006.²⁰ The field has advanced and expanded significantly in the last decade. Some patentability trends are noticeable in terms of the push to design the first clinical bioprinting apparatus, *in vivo* bioprinting robots, and

¹⁵ PR Newswire, *3D Bioprinting Market, 2014-2030*, March 17, 2014, available at <http://www.prnewswire.com/news-releases/3d-bioprinting-market-2014-2030-250645071.html>.

¹⁶ *Id.*

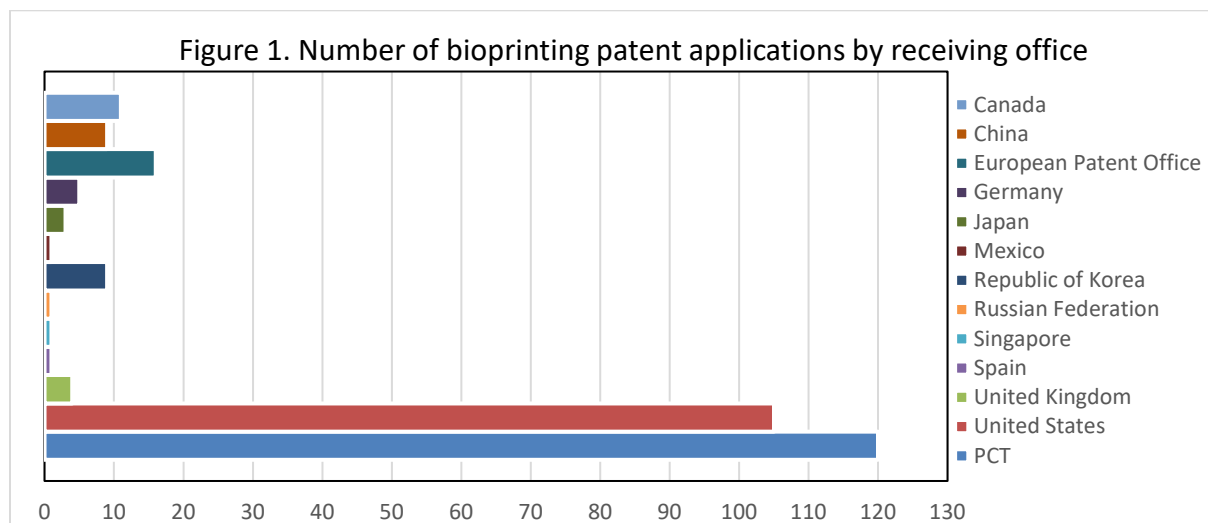
¹⁷ Matthew Varkey and Anthony Atala, *Organ Bioprinting: A Closer Look at Ethics and Policies*, 5 WAKE FOREST J. L. & POL'Y 275 (2015).

¹⁸ Young-Joon Seol, Hyun-Wook Kang Sang Jin Lee Anthony Atala James J. Yo, *Bioprinting Technology and Its Applications*, 46 EUR J CARDIOTHORAC SURG 342-348 (2014).

¹⁹ *Id.*

²⁰ U.S. Pat. No. 7,051,654 (issued May 30, 2006); see also Rudolph Bell, *Greenville Company Explores 'Bioprinting' Tech*, Greenville Online, December 9, 2014, available at <http://www.greenvilleonline.com/story/money/business/2014/12/09/greenville-company-izumi-explores-emerging-market-bioprinting/20136147>.

methods to fabricate vascularized tissue.²¹ Figure 1 below shows the number of received bioprinting-related patent applications by receiving office, based on WIPO Patent Scope data from December 2016.²² The largest number of patent applications has been received in the U.S.A.²³



Patentability

In addition to the intellectual property problems common to all 3-D printing, 3-D printed organs medical implants and bioprinted tissues and organs raise additional issues for protecting intellectual property.

The patentability of bioprinting inventions in some instances touches on the issue of subject matter eligibility. Ingrained in the U.S. Constitution, the U.S. patent system exists to promote innovation and to incentivize inventors to recoup their investments.²⁴ Patent-eligible subject matter includes (i) process, (ii) machine, (iii) manufacture, and (iv) composition of matter.²⁵ Courts have consistently construed 35 U.S.C. § 101 very broadly. Ever since the pronouncement of the Chakrabarty mantra,²⁶ patentable subject matter expressly includes “anything under the sun that is made by man”. However, the prohibition against patent claims directed to or

²¹ Timothy Sheehan, Vladimir Mironov, Vladimir Kasyanov, Roger R. Markwald, *Recent Patents and Trends in Bioprinting*, 4 REC. PAT. BIOMED. ENG. 26-32 (2011).

²² See WIPO PatentScope, available at <https://patentscope.wipo.int/search/en/search.jsf>.

²³ As of February 8, 2017, there were 25 U.S. patent applications or patents comprising the term bioprint/bioprinted/ bioprinting in their title; there were 65 U.S. patent applications or patents comprising the term bioprint/bioprinted/ bioprinting in their abstract; 160 U.S. patent applications or patents comprising the term bioprint/bioprinted/ bioprinting in their disclosure; and 10 U.S. patent applications or patents comprising the term bioprint/bioprinted/bioprinting in their claims.

²⁴ Analysis is given with respect to the U.S. patent system. Other jurisdiction may differ.

²⁵ 35 U.S.C. § 101.

²⁶ *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

encompassing a human organism remains.²⁷ Of course, the core of the patentability issue is in determining what is considered a “human organism”.²⁸

Bioprinting patent applications and patents can be broadly classified into four groups that encompass both product claims and process claims: 1) materials used for the production of bioprinted organs (e.g., bio-inks, tissue scaffold materials)²⁹; 2) bioprinted compositions (groups of cells, tissues, organs)³⁰; 3) bioprinting devices³¹, and 4) methods of bioprinting³². Patents have so far issued in all of these categories; some patents include both product and method claims.

Regarding patent-eligible subject matter, current bioprinted human living tissues are functionally similar but structurally different than real human living tissues. Although a bioprinted organ may contain cells that are genetically identical to a naturally occurring counterpart, the bioprinted organ itself should be patent-eligible subject matter because of its novel functional and structural properties,³³ which should amount to “significantly more” vis-à-vis “product of nature”, as required under the current interpretation of 35 U.S.C. § 101.³⁴ Of course, if a bioprinted organ is an exact replica of a naturally occurring tissue, then that bioprinted organ would not be patent-eligible subject matter.

Bioprinted organs are also subject to scrutiny under AIA § 33(a), which forbids issuance of patents directed to or encompassing a human organism.³⁵ Applying the broadest reasonable interpretation standard, the United States Patent and Trademark Office can reject any bioprinting claim “directed to” or “encompassing” human. However, a possible way of claim drafting is to couch bioprinted human living tissues/organs as implants or medical devices to use in a human body. For example, U.S. Patent No. 8,394,141 claims an implant formed from “fibers of defatted, shredded, allogeneic human tissue” including a “tendon, fascia, ligament, or dermis” and a “growth factor” (to induce cell growth).³⁶

²⁷ Leahy-Smith America Invents Act (AIA), Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified as amended in scattered section of 35 U.S.C.), at § 33(a), 125 Stat. at 340.

²⁸ In the absence of an AIA-given definition of what constitutes a “human organism,” the courts may be left to decide how the law should be interpreted.

²⁹ See, e.g., U.S. Pat. No. 8,691,974 B2, directed to three-dimensional bioprinting of biosynthetic cellulose implants and scaffolds for tissue engineering.

³⁰ See, e.g., U.S. Pat. No. 9,481,868 B2, directed to engineered renal tissues and arrays thereof; see U.S. Pat. No. 9,222,932 B2, directed to engineered liver tissues and arrays thereof; see U.S. Pat. No. 8,747,880, directed to engineered biological nerve graft.

³¹ See, e.g., U.S. Pat. No. 9,039,998 B2, directed to a bioprinting station. These may include U.S. design patents, e.g., as ornamental designs for a bioprinter; see U.S. Pat. No. D760,825 S.

³² See, e.g., U.S. Pat. No. 8,241,905, directed to methods of making engineered tissue using self-assembling cell aggregates; see U.S. Pat. No. 6,942,830, directed to a device and method for the production of three-dimensional objects; see U.S. Pat. No. 8,691,274, directed to inkjet printing of tissues and cells.

³³ Judith L. Toffenetti and Atabak R. Royaei, *Patentability of 3D-Printed Organs*, GENETIC ENGINEERING & BIOTECHNOLOGY NEWS, May 15, 2014.

³⁴ *Ass'n. for Molecular Pathology v. Myriad Genetics* (formerly *v. USPTO*), 653 F.3d 1329, 99 USPQ2d 1398 (Fed. Cir. 2011), cert. granted, judgment vacated and remanded to the Court of Appeals for the Federal Circuit, No. 11-725, 80 U.S.L.W. 3380, 2012 BL 72224 (U.S. Mar. 26, 2012), reversed, ---- S.Ct. ----, 106 USPQ2d 1972, 1974-75 (2013).

³⁵ Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified as amended in scattered section of 35 U.S.C.), at § 33(a), 125 Stat. at 340.

³⁶ Jasper L. Tran, *To Bioprint or Not to Bioprint*, 17 N.C. JOURN. LAW & TECH 1: 123-178 (2015).

Methods of bioprinting various compositions have been patented. These include patents on methods for forming an array of viable cells³⁷, methods of producing 3-D nano-cellulose based structures³⁸, and methods of producing a three-dimensional biological structure using self-assembling multicellular bodies³⁹. The bioprinting-related methods are not *per se* deemed a law of nature or a natural principle, thus they avoid the *Mayo*⁴⁰ prohibition on patentability. Patent claims to methods practiced using bioprinted implants must also overcome immunity from 35 U.S.C. § 287(c).⁴¹

Ample opportunity remains for further patentability of inventions directed to bioprinting-related compositions and methods. As the goal of the patent system is to promote innovation and incentivize invention, granting bioprinting patents should allow more bioprinting advances and thus makes bioprinting available sooner.

Some degree of skepticism and critique should be expected. Tinkering with human genetic materials typically attracts fierce public policy scrutiny. An oft-used and overplayed criticism is “Playing God”, which has surfaced in such diverse topics as anesthesia, contraception, transplantation, brain death diagnosis, recombinant DNA technology, stem cell research, genetic engineering of organisms, and synthetic biology.⁴² If humans play God, they risk offending many people, including those who belong to established religions. But if humans do not play God, they would not discover, progress, and innovate.⁴³ On balance, it seems better to play God while keeping this ethical consideration in mind; thus, much as patentability of (embryonic) stem cells, bioprinting of human organs should be patentable.⁴⁴

Potential Regulatory Concerns

Even though most regulatory concerns are not unique to bioprinting, regulating bioprinting will likely differ from regulating 3D printing. In the United States, the Food and Drug Administration (“FDA”) will evaluate all bioprinted tissues and organs for safety and effectiveness and assess the benefits and risks involved. Numerous regulatory and legislative hurdles will need to be cleared before the first printed kidney, liver, or heart implant becomes commercially available.⁴⁵ Technological advancements in terms of software, the development of more sophisticated bioprinters, and advances in tissue engineering and regenerative medicine technology are needed before the widespread application of bioprinting occurs.⁴⁶ It does not

³⁷ U.S. Pat. No. 7,051,654.

³⁸ U.S. Pat. No. 8,691,974.

³⁹ U.S. Pat. No. 8,143,055

⁴⁰ *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. ___, 132 S.Ct. 1289,101 USPQ2d 1961 (2012).

⁴¹ The purpose of 35 U.S.C. § 287(c) was to protect individual physicians who treat patients and their sponsors from being sued for patent infringement in the context of “biotechnology patent(s)” that permits enforcement. Yet the scope of the phrase “biotechnology patent” will probably have to be determined in court. See David S. Forman, *Patent Difficulties For 3-D Printed Medical Implants*, LAW360, available at <https://www.law360.com/articles/797305/patent-difficulties-for-3-d-printed-medical-implants> (June 1, 2016).

⁴² Peter Dabrock, *Playing God? Synthetic Biology as a Theological and Ethical Challenge*, 3 SYST. SYNTH. BIOL. 47-54 (2009).

⁴³ Jasper L. Tran, *Patenting Bioprinting*, HARV. J. L. & TECH. DIG. (2015).

⁴⁴ Bratislav Stankovic and Mirjana Stankovic, *The Selfish Patent*, 3 CASE W. RES. J.L. TECH. & INTERNET 207 (2011); see also Bratislav Stanković, *Patenting the Minotaur*, 12 RICH. J.L. & TECH. (2005).

⁴⁵ Varkey and Atala, *supra* note 16.

⁴⁶ *Id.*

take much human imagination to understand that a lung printed on a (home?) bioprinter should be regulated differently from a common household item, for example, a 3D-printed fork⁴⁷. Current regulations on synthetic biology are not fitted well to the field of bioprinting because bioprinting moves synthetic biology's production out of the laboratory and into the home. Currently there is no *lex specialis* which regulates the area of bioprinting. Its regulation could fall under human stem cell research regulation for bioprinting ink, organ transplantation regulation for bioprinted organs, or both.

The United States Congress needs to regulate bioprinting at a federal level for consistency. The principle of regulatory parsimony should encourage fostering an achievable balance of intellectual freedom and responsibility. Regulatory parsimony calls for "only as much oversight as is truly necessary to ensure justice, fairness, security, and safety while pursuing the public good." Policy makers should avoid restrictive rules that offer few benefits and hinder progress in science, medicine, and health care.

Global Development and Ethical Conundrum

Bioprinting of human organs is a technology that can widen the division between the rich and the poor. While the state-of-the-art of 3D printing (including 3D printing of human organs) in developing countries is still at an early stage, the technology application promises vast solutions to existing societal problems. On one hand, bioprinting's ability to build customized human anatomical parts has pervasive appeal in medical device markets, especially in economically weak and war-torn regions where it might address the high demand for prosthetic and other medical devices. On the other hand, densely populated regions with inadequate access to emerging healthcare technology could face inequality issues. Bioprinting can also contribute to inequality between different countries because it could advance unabated in countries with less-restrictive government oversight, whereas clinical trials and testing of organs for transplantation in some countries could take up to a decade (e.g., given the FDA's stringent reviews in the United States). Additionally, some bioprinted products could become cheaper and more accessible but other products which could be extremely complex to bioprint (e.g., functioning hearts), would likely be only accessible to those willing to pay for personalized treatments.⁴⁸ If bioprinted human tissues and organs are more expensive than the existing medical treatments, healthcare would likely not cover such cost, and thus, only the rich would be able to afford them.⁴⁹ Thus the majority of the population in the developing countries could be deprived of the benefits of this new technology.

Challenges posed by bioprinting to developing and least developed countries include: (i) the lack of experts in the field; (ii) inadequate and/or poorly enforced intellectual property rights;

⁴⁷ Tran, *supra* note 37.

⁴⁸ Richard Adhikari, *Bioprinting, Part 2 - The Ethical Conundrum*, TECHNEWSWORLD (Mar. 27, 2014 6:30 AM PT), available at <http://www.technewsworld.com/story/80205.html>.

⁴⁹ Tran, *supra* note 37.

(iii) possible decrease in manufacturing jobs; (iv) the availability of limited and fixed materials, as opposed to the required complex biomaterials; and (v) access to financing.⁵⁰

Opportunities that bioprinting of human organs presents to developing and least developed countries include: (i) health improvement; (ii) economic empowerment; (iii) emergence response; and (iv) improving science education.⁵¹

The prospects of bioprinting applications hold the promise of better medical treatment while raising a host of ethical issues and challenges. For instance, using bioprinted products inside a human body may cause biosafety and liability concerns. As well, using bioprinted products inside a human body might be interpreted as violation of human dignity and integrity by the human rights activists. Other ethical concerns include the questionable sources of the biomaterials, environmental pollution, as well as how to eliminate the created “waste.”⁵² For example, if embryonic stem cells are utilized in the bioprinting process, for those who view human embryos as human beings, killing embryos would be wrong, even if the end goal is to save human life.⁵³ If brain transplantation is made possible, there is a concern that this might lead to losing one’s identity and personality (e.g., by memory loss, character, psychological development, and brain-body history).

It is no secret that patients undergoing novel or experimental medical treatments often serve as guinea pigs. Although most people would have a choice whether they would use a bioprinted product, some people, especially those on the organ transplantation waitlist, might be distressed. This form of experimentation can be viewed as coercion—desperate terminal patients have no choice but to accept an experimental and unverified bioprinted organ.

Some of the ethical considerations are country- and society-specific. A comparative analysis of the ethics landscape in different countries with respect to bioprinting should provide insight into these. The following ethical principles could serve as guidance to focus on pursuing public benefit while minimizing both personal and public risk in the context of bioprinting:

Respect for Persons and Human Enhancement

The respect for persons provides a strong basis for protecting individual privacy in the pursuit of public benefit. At the heart of these ethical debates is a question about the ownership of our body parts (cells, tissues, organs), including the ownership of one’s genetic profile.⁵⁴

⁵⁰ Fredrick R. Ishengoma and Adam B. Mtaho, *3D Printing: Developing Countries Perspectives*, 104 INT. J. COMP. APPL. 30-34 (2014).

⁵¹ *Id.*

⁵² Tran, *supra* note 37, at 131.

⁵³ Bonnie Steinbock, *The Morality of Killing Human Embryos*, J. LAW, MED. & ETHICS (2006).

⁵⁴ The question is whether your genetic profile belong solely to you, or whether family members who share parts of your DNA have some claim to it. In a recent survey, 60% of people said that genetic information belongs not just to an individual, but also to all his or her blood relatives. See Barbara A. Koenig, Carmen Radecki Breitkopf, Susan M. Wolf, Marguerite E. Robinson, Kari Rabe, Noralane M. Lindor, and Gloria M. Petersen, *Returning Incidental Findings to Family Members of Deceased Research Participants: Perspectives from a Cancer Biobank*, American Society of Human Genetics Annual Meeting, San Diego, California (2014).

If the technology can be used to develop replacement organs and bones, couldn't it also be used to develop human capacities beyond what is normal for human beings?

Public Beneficence and Responsible Stewardship

The principle of public beneficence asks us to pursue and secure public benefits and minimize personal and public harm. It encompasses society's duty to promote activities that have great potential to improve the public's well-being; bioprinting has precisely the potential to accomplish that. Public beneficence also supports scientific enterprises that benefit society by increasing economic opportunities; we should be alert to the needs of the bioprinting technology as it develops, and should respond adequately to nourish its potential.

Responsible stewardship in bioprinting calls upon governments and societies to proceed prudently in promoting scientific advancement by taking into account and respecting the interests and needs of those who are not in a position to represent themselves (e.g., children, the mentally ill, future generations, or individuals that may be unaware of risks). In this context, democratic deliberation embraces respectful debate of opposing views and active participation by citizens. As any emerging technology, bioprinting presents particularly profound challenges to responsible stewardship because the societal understanding of the potential benefits and risks is incomplete and uncertain. This makes it all the more important that we take great care not to make choices that have a substantial chance of causing irreversible harm to current or future generations.

Intellectual Freedom and Responsibility versus Social Solidarity

Intellectual freedom grants scientists, acting responsibly, the right to use their creative abilities to advance the bioprinting science for purposes of the public good. Sustained and dedicated creative intellectual exploration produces much of the scientific and technological progress. Intellectual responsibility calls upon scientists to adhere to the ideals of research; to avoid harm to others; and to abide by all applicable policies, rules, and regulations. Institutions, policies, and practices of a free society—along with the many citizens who support them—collectively provide the means for scientists to do their work, and the culture that recognizes and upholds intellectual freedom. Scientists bear profound collective responsibility to society. Bioprinting should be offered to all people following principles of distributive justice.

Justice and Fairness

The just and fair distribution of benefits and burdens across society calls for ensuring that the unavoidable burdens of the bioprinting technological advances do not fall disproportionately on any particular individual or group, and that the benefits are widely and equitably distributed. The advances stemming from societal investments in the bioprinting of organs should be made accessible to the broadest possible number of persons, consistent with the ability to advance science and medicine for the true benefit of the public.

Circumstances arise in which the values of autonomy, privacy, confidentiality, and equity might give way to prevent serious harm to others. Determining the exceptions to the general ethical principles is no easy matter, however. There may be instances in which harm can be prevented by violating one of these principles, but in which the value of upholding the principles will nonetheless outweigh the chance of averting harm. In weighing the gravitas of such decisions, we should strive to establish a forum for discussion of these challenging questions: How serious is the harm to be averted? Is violating one of the principles the best way to avert the harm? What will be the medical, psychological, and other risks of violating the principle? What will be the socio-economic costs of violating the principle? This ethical matrix of principles should inform the public policy recommendations.

Conclusion

The prospects of bioprinting are staggering, as they can offer great benefits in medicine. The emerging field of bioprinting of human organs is very exciting for our society; it rises novel scientific, regulatory, legal, and ethical challenges. Multidisciplinary approach will be needed to meet these challenges and to realize the potential of bioprinting to transform the medical field. At the same time, the bioprinting also holds the potential of metastasizing a countless number of decentralized, non-commercial infringements of intellectual property rights.⁵⁵

It does not take much human imagination to comprehend that someday in the not too distant future some of us will eventually have 3D-printed body parts. As the technology develops and expecting patients begin receiving bioprinted tissues and organs, “bioprinting” will become a commonly used word within the English vocabulary. Unfortunately, it is going to be a little too late for Van Gogh and his ear.

⁵⁵ Ben Depoorter, *Intellectual Property Infringements & 3D Printing: Decentralized Piracy*. 65 HASTINGS L. J. 1483 (2013-2014).

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