PATENT ELIGIBILITY OF 3D BIOPRINTED ORGANS IN TAIWAN

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ABSTRACT

3D printing, or the digitization in production, has radically transformed the traditional model of manufacturing. 3D printing has also extended its application to biology by means of regenerative medicine. 3D Bioprinting provides the missing path by transforming digital information into biological models that mimic actual organs. It also provides unprecedented access for both physicians and patients waiting for organ donation. However, despite these promises, 3D Bioprinted human organs bring new challenges to the existing patent policies and practices. This paper examines the impacts and implications arising from 3D Bioprinted organs, looking specifically at their patent eligibility under patent laws and jurisprudence of Taiwan and the United States. This paper argues that under current patent jurisprudence, the patenting of 3D Bioprinted organs *per se*, is difficult, but it is still possible depending on the location and size of the organ.

Keywords: 3D Bioprinting, 3D Bioprinted Organs, Patent, United States and Taiwan

INTRODUCTION

3D printing is believed to bring the third industrial revolution.[1] According to one report, the 3D printing market is expected to grow to $7 billion by 2025, of which at least $3 billion will be attributed to bioprinting.[2] 3D bioprinting, or the technology to synthetically create human organs, is especially important in regenerative medicine to address the need for tissues and organs suitable for transplantation without having to wait for a suitable donor.[3] In addition, by using a patient's own cells in creating the organs, this also eliminates the possibility of the organ being rejected by the patient's immune system.[4] As of 2017, over 116,000 Americans were on the waiting list for donated organs, but fewer than 34,000 received an organ transplant in 2016.[5] Furthermore, the average time on the transplant waiting list for an organ such as a kidney is between three and five years.[6] By increasing the

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[1] *See A Third Industrial Revolution*, THE ECONOMIST (Apr. 21, 2012), http://www.economist.com/node/21552901 (discussing manufacturing in the digital age).

[2] Brittney Stevenson, *3D Printing Market Worth $7 Billion by 2025? Is a New Report Underestimating the Market?* 3D PRINT (June 1, 2014), https://3dprint.com/4946/3d-printing-market-value/.

[3] Brandon Griggs, *The Next Frontier in 3-D Printing: Human Organs*, CNN (Apr. 5, 2014), https://www.cnn.com/2014/04/03/tech/innovation/3-d-printing-human-organs/index.html.

[4] Sean V. Murphy & Anthony Atala, *3D Bioprinting of Tissues and Organs*, 32(8) NAT. BIOTECHNOL. 773, 781 (2014).

[5] *Organ Donation Statistics*, U.S. DEP'T OF HEALTH & HUM. SERV., http://www.organdonor.gov/about/data.html.

[6] *The Kidney Transplant Waitlist – What You Need to Know*, NAT'L KIDNEY FOUND. (Feb. 10, 2017), https://www.kidney.org/atoz/content/transplant-waitlist.

number of available organs, this demand could be met.[7] In China, scientists working for Sichuan Revotek have successfully 3D-printed blood vessels and implanted them in monkeys, a feat that could aid nearly 1.8 billion patients who suffer from cardiovascular diseases.[8] Additionally, by successfully bioprinting blood vessels, scientists are well on their way towards bioprinting organs on a large scale, which will aid in typical human organ transplant procedures.

In 2011, in his "We Can't Wait" initiative, President Obama launched the National Additive Manufacturing Innovation Institute to foster the U.S.' growth capabilities and strength in 3D printing.[9] In 2016, the Executive Yuan of Taiwan (Taiwan's supreme administrative agency) also announced a 10-year plan to promote the biotech industry, with an annual growth rate from 6% to 9% and aiming to reach one trillion yuan output value by 2025.[10] To foster industry development, patent has always been used as an incentive;[11] however, in light of the special characteristics of 3D Bioprinted organs, their patent eligibility raises new questions. For example, whether the current patent system provides adequate protections and, more specifically, whether a synthetically created version of an organ using natural materials (e.g., cells) and having the similar structure and function of the natural organ is patent-eligible. Since the patent jurisprudence of the U.S. often have profound impact on Taiwan's patent policy, this paper examines the possibility of patent eligibility of 3D Bioprinted organs in the U.S. in comparison with Taiwan. This paper concludes by providing policy recommendations for Taiwan.

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[7] *See China Developed its First 3D Bio-Printer*, 3DERS (Aug. 7, 2013), https://www.3ders.org/articles/20130807-china-developed-its-first-3d-bio-printer.html (discussing the capabilities of 3D printing technology in this area).

[8] Serenitie Wang & Katie Hunt, *Chinese Company Implants 3-D Printed Vessels into Monkeys*, CNN (Jan. 10, 2017), http://edition.cnn.com/2017/01/10/health/china-3d-printed-blood-vessels/index.html.

[9] Office of Press Sec'y, *We Can't Wait: Obama Administration Announces New Public-Private Partnership to Support*, THE WHITE HOUSE (Aug. 16, 2012), https://obamawhitehouse.archives.gov/the-press-office/2012/08/16/we-can-t-wait-obama-administration-announces-new-public-private-partners.

[10] *Taiwan's 3D Bioprinting Material Enters the World*, TECHNEWS (Sept. 20, 2016), http://technews.tw/2016/09/20/3d-printing-taiwan-technology/ (text in Mandarin only)

[11] Neil S. Tyler, *Patent Nonuse and Technology Suppression: The Use of Compulsory Licensing to Promote Progress*, 162 U. PA. L. REV. 451, 453 (2014).

I. WHAT IS 3D BIOPRINTING

3D Bioprinting, in general, involves depositing consecutive layers of cells as "bio-ink" in a desired pattern and controlling cell aggregations, fusions, and differentiations until a living three-dimensional structure with specialized compartments or specialized cell types is produced.[12]

The current state of the art in the field of regenerative medicine is directed to: (1) the 3D printing of biocompatible cell-free solid scaffolds (e.g., cellulose) in the shape of an organ (e.g., an ear) that can act as a support for human cells (e.g., cartilage or skin cells) to then adhere to and naturally grow on them; (2) the 3D printing of cellularized scaffolds[13] that allows for fabrication of structures with two or more cell types located at precise locations (e.g. a joint structure with bone and cartilage portions); (3) the 3D Bioprinting of tissue and organs without the need for solid supports.[14] Constructs for heart values fingers, nerves, muscles, and other lower-level biological entities are currently under development and could become available within three to five years.[15] For entire organs, some estimates that 3D Bioprinted kidneys and livers could be available within six years, while 3D Bioprinted hearts, with their complex internal geometrics, will take a bit longer.[16]

a) The Process of 3D Bioprinting

3D Bioprinting is a computer-aided manufacturing process that deposits living cells together with hydrogel-based scaffolds and allows for patterning of individual components of the tissue or organ therefor facilitating formation of complex tissue architecture.[17] "3D printing blends the low-cost scalability of mass-

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[12] Robert W. Esmond & Deborah Sterling, *Bioprinting: The Intellectual Property Landscape*, *in* 3D PRINTING AND BIOFABRICATION 2 (Aleksandr Ovsianikov et al. eds., 2019).

[13] Scaffold means a structure providing support to 3D Bioprinted cells to multiply.

[14] Judith L. Toffenetti & Atabak R. Royaee, *Patentability of 3D-Printed Organs*, GEN (May 15, 2014), http://www.genengnews.com/gen-exclusives/patentability-of-3d-printed-organs/77900129.

[15] Eric Lindenfeld, *3D Printing of Medical Devices: CAD Designers as the Most Realistic Target for Strict, Product Liability Lawsuits*, 85 UMKC L. REV. 79, 84 (2016).

[16] *Printed Human Body Parts Could Soon Be Available for Transplant*, THE ECONOMIST (Oct. 31, 2017), https://www.economist.com/news/science-and-technology/21715638-how-build-organs-scratch.

[17] Murphy & Atala, *supra* note 4, at 773.

produced products with the personalized properties of a tailor-made product."[18] These goals are accomplished through dispersion and additive manufacturing. Dispersion recognizes that complicated designs can be reduced into abstraction of simpler subsystems and components.[19] Addictive manufacturing recognizes that a manufacturer can deposit simple materials in a specific arrangement to arrive at the original design.[20]

The process of 3D bioprinting begins with a digital blueprint of the object, usually created from a three-dimensional scan of a real object or modeled with the assistance of computer-aided design (CAD) software.[21] Computer aided manufacturing (CAM) software then translates this digital blueprint into a path that a machine will follow to assemble a real object from a variety of materials.[22] The selection of appropriate biomaterials is also essential[23] to ensure printability and biocompatibility. Biomaterials are materials that can be successfully transplanted in a patient without rejection.[24] In the process of 3D Bioprinting, hydrogels and sugar are used for scaffolding, while a culture of cells is also needed.[25] To generate cells used with these techniques, researchers develop techniques for growing cell cultures that can differentiate into the specialized cells of an organ.[26] Currently, researchers use induced pluripotent stem cells (iPSCs) for the same result because they can divide for a long time *in vitro*, recruited as specialized cells, which perform the individual functions required by organs and using methods unobtrusive to

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[18] Jeremy T. Harbaugh, *Do You Own Your 3D Bioprinted Body? Analyzing Property Issues at the Intersection of Digital Information and Biology,* 41 AM. J. L. & MED. 167, 170 (2015).

[19] Yan Yongnian et al., *Rapid Prototyping and Manufacturing Technology: Principle, Representative Technics, Applications, and Development Trends*, 14 (S1) TSINGHUA SCI. TECHNOL. 1, 2 (2009).

[20] *Id.* at 2–3.

[21] MICHAEL WEINBERG, IT WILL BE AWESOME IF THEY DON'T SCREW IT UP: 3D PRINTING, INTELLECTUAL PROPERTY, AND THE FIGHT OVER THE NEXT GREAT DISRUPTIVE TECHNOLOGY 2 (2010).

[22] *See id*. at 6 (for further discussion of how 3D printers work).

[23] *See, e.g.*, TED, *Printing a Human Kidney | Anthony Atala*, YOUTUBE (Mar. 8, 2011), https://www.youtube.com/watch?v=9RMx31GnNXY (discussing 3D printers outputting organs) [hereinafter TED].

[24] *Id.*

[25] Rhiannon Williams, *The Next Step: 3D Printing the Human Body*, THE TELEGRAPH (Feb. 11, 2014), https://www.telegraph.co.uk/technology/news/10629531/The-next-step-3D-printing-the-human-body.html.

[26] *See, e.g.*, TED, *supra* note 23 (for further discussion of methods).

patients.[27] Essentially, in order to reproduce a functioning organ using 3-D bioprinting technology, there must be "a digital blueprint of the organ's structure, the hydrogel or scaffolding biomaterial, and a culture of cells."[28]

b) Challenges to 3D Bioprinting

Despite the promises, in comparison with nonbiological printing, 3D Bioprinting involves additional complexities such as the choice of materials, cell types, growth and differentiation factors, and technical challenges related to sensitivities of living cells and the construction of issues; to address these complexities requires the integration of technologies from the fields of engineering, biomaterials, cell biology, physics, and medicine.[29] The most important criterion is maintenance of cell viability in the bioprinting organs, since they will be exposed to different conditions such as temperatures or microenvironments during various printing steps.[30]

Another aspect would be to recapitulation of the exact 3D microstructure of these organs, which will facilitate interaction between the different types of cells in these organs and allow for complete functionality of the respective organ.[31] Currently vascularity, or establishment of a stale blood supply in the bioprinted organ, is the most challenging hurdle in 3D Bioprinting.[32] Lastly, the ability to recapitulate the native tissue in the bioprinted organ remains an issue. Although it is relatively easy to generate digital models for simple tissues or organs such as cartilage, bladders, or skin,[33] the structure complexity of organs such as the heart, brain, and kidney requires a vast variety of growth factors and signaling factors to help them integrate into a functional network after printing.[34]

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[27] Osagie K. Obasogie & Helen Theung, *Moore Is Less: Why the Development of Induced Pluripotent Stem Cells Might Radically Upend Property Law Concerning Human Tissues as We Know It*, 16(1) STANF. TECHNOL. LAW REV. 51, 66–67 (2012).

[28] Harbaugh, *supra* note 18, at 181.

[29] Esmond & Sterling, *supra* note 12, at 3.

[30] Murphy & Atala, *supra* note 4, at 778.

[31] Ibrahim T. Ozbolat & Yin Yu, *Bioprinting Toward Organ Fabrication: Challenges and Future Trend*s, 60(3) IEEE TRANS BIOMED ENG 691, 694 (2013).

[32] *Id.*

[33] Shannon Fischer, *The Body Printed: How 3-D Printing Could Change the Face of Modern Medicine—and Why that Future is Still So Far Away*, 4 IEEE PULSE 27, 28, 31 (2013).

[34] Bethany C. Gross et al., *Evaluation of 3D Printing and Its Potential Impact*

c) 3D Bioprinted Organs

An ideal 3D Bioprinted organ would be an exact copy of the natural healthy organ.[35] However, a 3D Bioprinted organ might possess different characteristics than the natural organ. For example, a 3D Bioprinted liver may include blood vessels that are naturally occurring, but the vessel network created may be connected in a way different from the natural liver.[36] Sometimes, a 3D Bioprinted organ might develop non-naturally occurring characteristics during the printing process.[37] To date, just a few successful printing attempts have been reported, and the organs have all been miniature in size.[38] A significant technical challenge is to achieve biologically realistic tissue thickness,[39] because once the thickness of an engineered tissue exceeds 150-200 micrometers, oxygen can no longer diffuse between host and transplanted tissue.[40]

Aside from the potential for human organ transplant, 3D Bioprinted organs could also serve other important purposes—among them, preclinical testing and serving as tissue source for repairing or replacing defective organs. For example, using 3D Bioprinting technology, researchers can print very small human organ-like structures to create a realistic ground for testing how the human body might react to given chemical and biological entities, including therapeutic compounds.[41] This is based on the idea of linking a number of very small 3D Bioprinted organ-like structures together to enable more accurate testing of how a chemical or biological entity might affect the human body as a

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on Biotechnology and the Chemical Sciences, 86 ANAL. CHEM. 3240, 3246–47 (2014).

[35] Murphy & Atala, *supra* note 4, at 775.

[36] *See* Tanya Lewis, *3D-Printed Blood Vessels Could Be Used for Transplants*, LIVE SCIENCE (June 3, 2014), http://www.livescience.com/46067-3d-printed-blood-vessels.html. "Scientists have developed artificial tissue from the heart, liver and lungs, but creating a synthetic network of blood vessels to support these organs has been a challenge."

[37] Murphy & Atala, *supra* note 4, at 776.

[38] Jim Banks, Adding *Value in Additive Manufacturing: Researchers in the United Kingdom and Europe Look to 3-D Printing for Customization*, 4(6) IEEE PULSE 22, 25 (2013).

[39] Xiaofeng Cui et al., *Thermal Inkjet Printing in Tissue Engineering and Regenerative Medicine*, 6(2) RECENT PAT DRUG DELIV FORMUL 149 (2012).

[40] *Id.*

[41] *Military Applications: Body on a Chip,* WAKE FOREST SCHOOL OF MED. (Apr. 12, 2016), http://www.wakehealth.edu/Research/WFIRM/Projects/Body-on-a-Chip.htm.

whole, or at least a number of organs,[42] providing more economical and accurate testing results. The short-term application for 3D Bioprinted organs is to create an alternative to animal testing;[43] the mid-term application "relates to the creation of tissue components such as human heart valves," for specific vulnerable populations, such as pediatric patients, "who suffer specific problems with current bioprosthetic or mechanical heart valve (MHV) options;"[44] and the long-term application will be organ regeneration without immunological issues and waiting for donors.[45]

II. PATENT ELIGIBILITY ISSUES FOR 3D BIOPRINTED ORGANS

To give incentives to further develop the nascent field of 3D Bioprinting, patents are always the most direct incentive for the industry. Bestowing patents on 3D Bioprinting processes and products means the patent holder is able to receive a property right over the inventions for a limited period of time.[46] The patent landscape of 3D printing suggests the following areas attract most interest in the field of biotechnology nowadays: 3D printing processes, 3D printing plastic powder formulations, 3D medical modelling, bone implants, dental implant manufacture, stereo lithograph, and software/interfaces for 3D printing.[47] Currently, most 3D Bioprinting-related patent applications center around the invention of bioink, such as US 14/126,681 by Cyfuse Biomedical KK and Organovo's Chinese patent application CN103946374A.[48] "Since 3D Bioprinted organ is unlikely to be sold in the mass market, the patentability of the 3D Bioprocesses and bioink is more significant than the patentability of the end product itself."[49]

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[42] *Id.*

[43] Niki Vermeulen et al., *3D Bioprint Me: A Socioethical View of Bioprinting Human Organs and Tissues*, 43(9) J MED ETHICS 618, 620 (2017).

[44] *Id* at 618.

[45] *Id.* at 620–21.

[46] *Id.* at 621–22.

[47] *See generally* U.K. INTELL. PROP. OFFICE, 3D PRINTING: A PATENT OVERVIEW (2013) (for the state of 3D printing).

[48] The basic invention of Organovo is to prepare the bio ink, hydrogel, and the model of organ intended to print, then (1) print the bio ink and let the cell be on top of each other, (2) print the hydrogel and paste the hydrogel on the cell, and (3) repeat steps no. 1 and 2 until the organ is ready. *Bioprinting Process*, ORGANOVO, http://organovo.com/science-technology/bioprinting-process/.

[49] Jamil Ammar, *The "Medical Mile" Gearing Toward 3D-Bespoke Healthcare: A Comparison of United States and European Patent Regimes*, 52 GONZ. L. REV. 279, 305 (2017).

Despite being an exciting development, there is a question of whether bioprinted organs are patent eligible as the elements of a bioprinted organ are naturally occurring and made from human tissue.[50] Patent eligibility has been a critical issue in cases concerning patentability and patent validity, hence, before assessing the patentability of 3D Bioprinted organs, the issue of patent eligibility should be dealt with by looking into three preliminary areas: 1) Are these organs patentable subject matter or inventions; 2) Are they product of nature; and 3) Are they against *Public Ordre* or Morality?

a) Are they Patentable Subject Matter/ Invention?

United States

According to 35 U.S.C. § 100, invention means invention or discovery.[51] 35 U.S.C. § 101 provides that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter . . . may obtain a patent."[52] 35 U.S.C. § 101 is also known as the utility requirement, which an invention has to be credible,[53] specific, and substantial.[54] In *Diamond v Chakrabarty*,[55] Chakrabarty claimed a man-made bacterium, genetically engineered and not existing in nature, capable of breaking down multiple components of crude oil.[56] The Court ruled that the claim was a manufacture[57] or composition of matter,[58] and the bacterium was deemed a product of human ingenuity that had "a distinctive name, character [and] use."[59] The Court also carved out a few exceptions for patentable subject matter: laws of nature, products of nature, physical or natural phenomenon, and abstract

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[50] Toffenetti & Royaee, *supra* note 14.

[51] 35 U.S.C.A. § 100 (West, Westlaw through P.L. 115-140 approved 03/20/18).

[52] 35 U.S.C. § 101 (2006).

[53] *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1358 (Fed. Cir. 1999). *See also Newman v. Quigg*, 877 F.2d 1575, 1582 (Fed. Cir. 1989) (concluding that the claimed invention was unpatentable because it failed to comply with 35 U.S.C § 101 for lack of utility).

[54] *Brenner v. Manson*, 383 U.S. 519, 534–35 (1966).

[55] 447 U.S. 303 (1980).

[56] *Id.* at 305.

[57] *Id.* at 308 (defining "manufacture" as "the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery").

[58] *Id.* (defining "composition of matter" as "all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids").

[59] *Id.* at 309–10

ideas.[60]

In 1988, U.S. patent no.4,736,866 was granted on the Harvard Oncomouse, which claimed "[a] transgenic non-human eukaryotic animal whose germ cells and somatic cells contain an activated oncogene sequence introduced into the animal."[61] These engineered mice with cancer-prone genes are therefore useful as a dependable animal cancer model for scientists to employ as a test subject in experimental cancer treatments. Organs can be artificially produced by man through methods such as cloning and 3D Bioprinting. As long as the organ does not fall within the judicial exceptions, it does not matter whether the organ is living; there is no express provision against the patenting of man-made organs in the U.S.[62]

Taiwan

In relation to patentable subject matter, Taiwan does not have the same classifications for product inventions as the U.S., but rather simply a patent is categorized into either products or process.[63] This is unlike the U.S., which uses § 101 as a powerful gatehouse that allows the Patent Office and courts to subjectively decide when or if something can be patented.[64] Whether a product is a patentable subject matter in Taiwan depends first on whether it is an invention, defined as a technical creation that utilizes the rule of nature;[65] and second, whether they are statutory unpatentable subject matter.[66]

Industrial applicability—Taiwan's counterpart to the utility requirement—requires that an invention not be "easily made by a person ordinarily skilled in the art based on prior art."[67] It is also a prerequisite before assessing inventive step or novelty.[68] According to the Taiwan Intellectual Property Office's (TIPO) Title

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[60] *Id*. at 309.

[61] U.S. Patent No. 4,736,866 (issued Apr. 12, 1988).

[62] *See Diamond*, 447 U.S. at 309 ("Congress intended statutory subject matter to 'include anything under the sun that is made by man.'").

[63] Charles Chen et al., *Taiwan Patents,* GETTING THE DEAL THROUGH (Apr. 2018), https://gettingthedealthrough.com/area/25/jurisdiction/45/patents-taiwan.

[64] Rebecca S. Eisenberg, *Analyze This: A Law and Economics Agenda for the Patent System*, 53(6) VAND. L. REV. 2081, 2083–84 (2000).

[65] Taiwan Patent Act art. 21 (2017).

[66] *Id.* at art. 24. Unpatentable subject matters include: animals, plants, and essential biological processes for their production, except for processes for producing microorganisms; diagnostic, therapeutic, and surgical methods for hu mans or animals; and inventions contrary to public order or morality.

[67] *Id.* at art. 22.

[68] *Id.* at art. 22–23.

2, Chapter 2 of the Examination Guidelines Explaining What's an Invention of 2013 (the Invention Guidelines), an invention should involve technical character; simple discovery, scientific principles, simple information disclosure, and simple artistic creation do not constitute patentable subject matter.[69]

According to TIPO Title 2, Chapter 14 of the Examination Guidelines on Biotechnology Inventions of 2013 (the Biotech Guidelines), it has provided an exhaustive list of 13 categories of biotech inventions, but 3D Bioprinted organ is not on the list.[70] The Biotech Guidelines state that natural tissues and organs are formed through complicated steps, and the elements are not composed by using man-made substances and do not require human technical intervention; hence, tissues and organs are not considered an invention because they are mere discovery.[71] However, with technicality[72] and human intervention to produce structures that is akin to tissue and organ, then it will be considered as an invention.[73] Thus, the keywords for been considered as a biotech-based invention in Taiwan is to have a solution to a technical problem using rules of nature. Therefore, it could be argued that 3D Bioprinted organs are a patentable invention in Taiwan.

b) 3D Bioprinted Organs- Are They Product of Nature?

United States

According to *Chakrabarty*, the court set a two-prong test to avoid the "product of nature" claim: a manufacture[74] or composition of matter must be: 1) a product of human ingenuity and 2) non-naturally occurring ("with markedly different characteristics from any found in nature").[75] In light of the Supreme Court decisions, the United States Patent and Trademark Office (USPTO) issued

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[69] Examination Guidelines Explaining What's an Invention, § 2-2-1 (2013) [hereinafter Invention Guidelines].

[70] Examination Guidelines on Biotechnology Inventions, §§ 2-14-1, -2 (2013) [hereinafter Biotech Guidelines].

[71] *Id.* at § 2-14-3.

[72] *See* 104 Min Chuan Su 91 (Taiwan Intellectual Property Ct. 2015). An inven tor must present a question/conception s/he wants to solve in his or her invention and propose a technical solution to that problem.

[73] *Id.*

[74] *See Diamond*, 447 U.S. at 308 (defining the term "manufacture" as "the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or machinery").

[75] *Id.* at 309–10.

an interim guidance providing patent eligibility test for nature-based products.[76] The guidance provides a two-step approach to determine patent eligibility;[77] in step 2B, when determining whether a claim is directed to a product of nature, the examiner should compare the claimed product to its naturally occurring counterpart to identify "markedly different characteristics."[78] In this step, changes in structure, functional, and other non-functional characteristics can evidence "markedly different characteristics."[79] "To show a marked difference, a characteristic must be changed as compared to nature, and cannot be an inherent or innate characteristic of the naturally occurring counterpart."[80]

It could be argued that 3D Bioprinting is a result of human ingenuity, but the more difficult prong is proving that 3D Bioprinted products are non-naturally occurring.[81] Ideally, a 3D Bioprinted organ would be an exact copy of a natural, healthy organ.[82] However, an exact copy will render the organ patentable as stated in *Roslin*,[83] the Federal Circuit held that a cloned sheep patent was ineligible because she was genetically identical to her natural counterpart, and did not possess any "markedly different characteristics from any [farm animals] found in nature."[84] If a 3D Bioprinted organ is indistinguishable from its natural counterpart, then that 3D Bioprinted organ is not patent-eligible because it would not have any "markedly different characteristics."[85]

Taiwan

Unlike the United States, here the excluded subject matter is provided by the legislature, not by the courts.[86] The concept of product of nature is not from the legislation nor the courts, but

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[76] 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74618, 74619 (Dec. 16, 2014) (to be codified at 37 C.F.R. pt. 1) [hereinafter Interim Guidance].

[77] *Id.* at 74621–22.

[78] *Id.* at 74622–23.

[79] *Id.* at 74623.

[80] U.S. PAT. & TRADEMARK OFF., 2106 PATENT SUBJECT MATTER ELIGIBILITY, MPEP (9th ed., Rev. 8, Jan. 2018).

[81] Jasper L. Tran, *Patenting Bioprinting*, JOLT DIGEST (Sept. 23, 2015), https://jolt.law.harvard.edu/digest/patenting-bioprinting.

[82] Murphy & Atala, *supra* note 4, at 775.

[83] *In re Roslin Institute (Edinburgh)*, 750 F.3d 1333 (Fed. Cir. 2014).

[84] *Id*. at 1337.

[85] Xiaoban Xin, *Patent Eligibility of 3D-Printed Organs* 44 AIPLA Q.J. 143, 164.

[86] *See* Taiwan Patent Act art. 24 (for what cannot be patented by law in Taiwan).

through administrative guidelines.[87] According to the Biotech Guideline, product of nature is merely discovery of what is already existing in the nature, such as wild plants or animals, microorganisms, proteins, or a DNA sequence, which have not been isolated or purified, hence they are not considered as inventions.[88] However, through human intervention such as isolation and purification from the nature, it will become patent-eligible.[89] According to the Invention Guidelines, an invention should be the fruit of human intellectual and technical creation; a mere discovery of a product of nature or characteristics of the product of nature lacks technicality, and is not patent-eligible.[90] However, if one can utilize the discovered characteristics and put it into practical use, then it will be considered a patent-eligible.[91]

Furthermore, if one is able to isolate a product of nature and derive different structural, physical, or chemical characteristics from the known art, then it will also be patent-eligible.[92] Although Taiwan emphasizes largely the isolation method, the requirements to not be considered as a product of nature is similar to the U.S. Hence, if a 3D Bioprinted organ or its living tissue is a complete redesign of another naturally occurring organism or its living tissue,[93] or develops non-naturally occurring characteristics during the printing process,[94] these inventions may be patent-eligible. Ironically, since the current state of art of 3D Bioprinted products are functionally similar but structurally different than real human tissues, they will be patentable until scientists can 3D Bioprint structurally similar living tissues.[95]

c) 3D Bioprinted Organs: Are they against Public Order or Morality?

United States

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[87] *See* Biotech Guidelines, *supra* note 70, at § 2-14-3 (for discussion of the requirements of a patentable invention).

[88] *Id.*

[89] *Id.*

[90] Invention Guidelines, *supra* note 69, at § 2-2-2.

[91] *Id.*

[92] *Id.*

[93] *See* Tran, *supra* note 81 ("Until scientists can bioprint structurally similar living tissues, bioprinted products are in the clear to be patent-eligible subject matter.").

[94] *See* Murphy & Atala, *supra* note 4, at 775–76 (explaining potential impacts of the printing process).

[95] Tran, *supra* note 81.

The patent eligibility for 3D Bioprinted organs usually does not involve the issue of morality.[96] The judicially created moral utility requirement asserted utility should not be "injurious to the morals, the health, or the good order of society"[97] was replaced in *Juicy Whip, Inc v. Orange Bang, Inc.*,[98] in which the Court stated that imposing a moral component to § 101 should be left to Congress.[99] However, with the development of the biotechnology industry and the issuance of biotechnology patents, the ethical controversy raises new concerns.[100] Congress responded to some of these concerns with § 33 of the Leahy-Smith America Invents Act (AIA),[101] which states that "[n]otwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism."[102]

'Human organism' is not a term of art in patent law, was not used anywhere else in the AIA, and appears nowhere in the Patent Act.[103] Further, this phrase is undefined in most dictionaries.[104] The vagueness of these phrases may allow them to be construed in ways that could disrupt the patenting of controversial biotechnology inventions.[105] In this situation, the court will certainly look to the common definitions of each term separately.[106]

However, in the Congressional Records, "Human organism" is defined as "human embryos, human fetuses, human-animal

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96 *See* Cynthia M. Ho, *Splicing Morality and Patent Law: Issues Arising from Mixing Mice and Men*, 2 WASH. U. J.L. & POL'Y. 247, 283 (2000) ("[M]orality is not within the technical capacity of present patent examiners. . . . [E]xperience with issues of morality is not typically expected.").

97 *Bedford v. Hunt*, 3 F. Cas. 37, 37 (D. Mass. 1817).

98 185 F.3d 1364 (Fed. Cir. 1999).

99 *Id.* at 1368.

100 *See generally* M. Mameli, *Reproductive Cloning, Genetic Engineering and the Autonomy of the Child: The Moral Agent and the Open Future*, 33 J MED ETHICS 87, 87–93 (2007) (discussing objections to genetic engineering and reproductive cloning); Françoise Baylis & Jason S. Robert, *Part-Human Chimeras: Worrying the Facts, Probing the Ethics*, 7(5) AM. J. BIOETHICS 41, 41–45 (2007) (discussing ethical concerns over the creation of chimeras); H-W Denker, *Potentiality of Embryonic Stem Cells: An Ethical Problem Even with Alternative Stem Cell Sources*, 32 J MED ETHICS 665, 665–71 (2006) (discussing ethical concerns surrounding stem cell research).

101 Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 33, 125 Stat. 284, 340 (2011).

102 *Id.* at § 33(a).

103 Ava Caffarini, *Directed to or Encompassing a Human Organism: How Section 33 of the America Invents Act May Threaten the Future of Biotechnology,* 12 J. MARSHALL REV. INTELL. PROP. L. 768, 780–81 (2013).

104 *Id.* at 781.

105 *Id.* at 778.

106 *Id*. at 781.

chimeras, 'she-male' human embryos, or human embryos created with genetic material from more than one embryo."[107] The Record also defined "human organism" as "human embryo, fetus, infant, child, adolescent, or adult."[108]

This definition has left out the pre-embryos, which corresponds to a court's definition in *Davis v Davis*[109] "We conclude that preembryos are not, strictly speaking, either 'persons' or 'property' . . . "[110] However, the Court offers preembryo some "special respect" because of their potential for human life.[111] In addition to the ambiguity in the definition for human organism, AIA has also failed to consider inventions having the potential for human life as raised in *International Stem Cell Corporation v. Comptroller General of Patents, Designs and Trademarks*[112] rendered by a court of the European Court of Justice (ECJ).[113] As stated earlier, iPSC stem cells have been used as a source for organ bioprinting.

Research has shown that iPSCs can create the ability to genetically reprogram somatic cells into a pluripotent state that may allow them to differentiate into other types of cells, including eggs and sperms that can be used to create new organisms, meaning soon iPSCs may soon be able to give ordinary somatic body cells the same potential for human life as naturally embryos and gametes.[114]

Taiwan

The ambiguity of the definition for human is also lacking in Taiwan. According to Article 6 of the Taiwan Civil Code, the right of a person begins at birth and ends at death.[115] Article 7 of the Civil Code states that the right of unborn is protected as if already born, contingent upon being alive after birth.[116] Although there are

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[107] 157 CONG. REC. E1184 (2011).
[108] *Id.* at E1180.
[109] 842 S.W.2d 588 (Tenn. 1992).
[110] *Id.* at 597.
[111] *Id.*
[112] Case C-364/13, *Int'l Stem Cell Corp. v. Comptroller Gen. of Patens, Designs and Trade Marks*, ECLI:EU:C:2014:2451 [hereinafter Case C-364/13].
[113] The Court interpreted the patent exclusion of human embryos for commercial or industrial purposes as in Art. 6(2)(c) of the Biotech Directive to find that a "non-fertilised human ovum must necessarily have the inherent capacity of developing into a human being" to be classified as a "human embryo" and thus be patent-ineligible. Council Directive 98/44, art. 6, 1998 O.J. (L 213) 18 (EC); Case C-364/13, at para. 27–28.
[114] Obasogie & Theung, *supra* note 27, at 52.
[115] CIVIL CODE art. 6 (2015) (China).
[116] *Id.* at art. 7.

numerous academic theories debating when the time for birth or death is, the center point is on when the rights of a person begin and end rather than asking what a human is.[117] The law is also silent on at what stage a life could be considered as human.[118] Patent law is also unclear in what kind of inventions are against public interest or morality, according to Article 24(3) of the Taiwan Patent Law.[119]

The Biotech Guidelines illustrate a list of unpatentable inventions, such as human cloning, changing the inheritance traits of humans and the following products, chimeras produced using animal/human germ cells or animal/human totipotent cells and their methods, and product or process involving any stages of human body development (germ cells, zygote, morula, blastocysts embryo, fetus, and baby).[120] In this definition, Taiwan is more aligned with the European Biotech Directive.[121] As for stem cells, if there is a possibility of developing into a human, such as human embryonic totipotent stem cells, it will not be patentable; however, if it does not have the potential of developing into a human, then it will be patentable, such as human embryonic pluripotent stem cells.[122] Although Taiwan did not define what constitutes a human organism, TIPO has provided examples of unpatentable subject matter; it seems that if the invention has no possibility for human life, constitutes any stage for human life, or changing the hereditary trait of a human being, then it shall be patentable. In light of this definition, although the Biotech Guidelines have not mentioned the patent eligibility for 3D Bioprinted organs or iPSC, the potential for 3D Bioprinted organs could bar its own patent eligibility.[123]

d) Summary

The preliminary inquiries of the three issues suggest that, in the

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[117] *See* J M Harris, *Before Birth – After Death*, 30 J MED ETHICS 425, 425 (2004) (discussing how different events have shaped the conversation regarding what point in time humans acquire rights).

[118] *See* CIVIL CODE art. 6–7 (not defining "human").

[119] Taiwan Patent Act art. 24(3).

[120] *See* Biotech Guidelines, *supra* note 70, at §§ 2-14-3, -4 (for unpatentable inventions).

[121] *See* Council Directive 98/44, 1998 O.J. (L 213) 14, 16 (demonstrating the limits on patents for human embryos).

[122] *See id.*

[123] *See* Vermeulen et al., *supra* note 43, at 621 (hypothesizing as to young people's suitability for replacement organs).

U.S., 3D Bioprinted organs may be patentable subject matter and might not be considered as products of nature if the organ possesses different characteristics from the natural organ. Taiwan, on the other hand, has a higher threshold than the U.S. Although man-made organs are patentable and not a product of nature, there is an additional moral layer regarding whether the invention has the possibility for human life or involves in the development stage of a human. However, the scope to these moral bars is unclear, and the patent eligibility of 3D Bioprinted organ is likely to be more difficult than in the U.S.

III. AMBIGUITIES IN TAIWAN PATENT LAW AND REGULATIONS

According to the Biotech Guideline, an artificial organ using man-made elements is patent-eligible.[124] However, Article 24(3) of the Taiwan Patent Law prohibits the patenting of immoral inventions, and the Biotech Guidelines further explains immoral means inventions involving: 1) any stage of human development and 2) having the potential of becoming a human.[125] The ambiguity here is what constitutes "human" under the Biotech Guideline—a human organism, a full sequence of human DNA, or parts/elements of the human body? As mentioned earlier, with reprogramming, iPSC is able to turn into a pluripotent state without having to destroy an embryo. If an organ is made using iPSC as the bioink, will it be patentable because of its potential for human life? Furthermore, once the 3D Bioprinted organ is implanted into the patient, will this constitute involving stages of human life? Not only are the Biotech Guidelines silent in these issues, but it also contradicts itself.

a) Stages of Human Development

In both the U.S. and Taiwan, a product of nature is patentable by integrating the ineligible subject matter with subject matter that is patent-eligible.[126] This rule, however, is not applicable when the invention involves the patenting of a human.[127]

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[124] Biotech Guidelines, *supra* note 70, at § 2-14-3.

[125] Taiwan Patent Act art. 24(3); Biotech Guidelines, *supra* note 70, at § 2-14-4.

[126] U.S. PAT. & TRADEMARK OFF., 2106.05 ELIGIBILITY STEP 2B: WHETHER A CLAIM AMOUNTS TO SIGNIFICANTLY MORE, MPEP (9th ed., Rev. 8, Jan. 2018).

[127] *Id.* (explaining that if the broadest reasonable interpretation of the claimed invention encompasses a human organism, then it will be rejected under 35 U.S.C. § 101 and/or AIA § 33(a)); U.S. PAT. & TRADEMARK OFF., 706.03(A) REJE

"Generally speaking, a patent claim cannot encompass a human organism and likewise, a claim encompassing an otherwise unpatentable human organism will not become patentable by integrating elements that are subject matter patentable."[128] Although under AIA, "human organism" is left undefined by the Congress, we can still construct the meaning through the practice of USPTO.

USPTO Manual of Patent Examining Procedure § 2105, Eighth Ed., Rev 9 (August 2012) states that "[i]f the broadest reasonable interpretation of the claimed invention as a whole encompasses a human organism, then a rejection under 35 U.S.C. 101 and AIA sec. 33(a) must be made indicating that the claimed invention is directed to a human organism and is therefore nonstatutory subject matter."[129] In *Ex parte Kamrava*,[130] the Patent Trials and Appeals Board (PTAB) concluded that the patent with claims directed toward a uterine catheter that can be used to deposit a fertilized embryo with some of the claims include the embryo as an element of the claim to be unpatentable.[131] The reasoning of the PTAB was that the embryo constitutes part of the human body because it is a product of nature and has no "markedly different characteristics" from its natural counterparts.[132] Under this reasoning, a structurally similar 3D Bioprinted organ will be unpatentable because it is an exact copy of what occurs in nature as *In re Roslin*.[133]

Like the USPTO, TIPO has expressly banned the patenting of human *per se*.[134] However, components of human, such as man-made organs, are patentable.[135] This corresponds to USPTO's practice of altering the nature of an organism. As mentioned *supra*, both the Invention Guidelines and Biotech Guidelines mention that an invention is patentable if it can provide different structural, physical, or chemical characteristics from known arts. If the manmade organ is altered, manipulated, or different from

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CTIONS UNDER 35 U.S.C. 101, MPEP (9th ed., Rev. 8, Jan. 2018).

128 Dennis Crouch, *Patents Encompassing a Human Organism*, PATENTLY-O (Dec. 2, 2012), http://patentlyo.com/patent/2012/12/ex-parte-kamrava.html.

129 U.S. PAT. & TRADEMARK OFF., 2105 PATENTABLE SUBJECT MATTER—LIVING S UBJECT MATTER, MPEP (8th ed., Rev. 9, Oct. 2012).

130 APN 10/080,177 (P.T.A.B. Nov. 26, 2012).

131 *Id.* at 5–6.

132 U.S. PAT. & TRADEMARK OFF., 2106.04(B) LAWS OF NATURE, NATURAL PHENO MENA & PRODUCTS OF NATURE, MPEP (9th ed., Rev. 8, Jan. 2018).

133 *In re Roslin*, 750 F.3d at 1335.

134 Biotech Guidelines, *supra* note 70, at § 2-14-3.

135 *Id.*

its natural counterpart, then it may be patent-eligible. This is a common practice within the pharmaceutical and biotech-patenting jurisprudence. However, in light of creating a 3D Bioprinted organ having the similar structure and function as the natural organ, the practice bars this type of invention. In addition to product of nature, even if the structure and function is different, the patient's body will grow together with the implanted 3D Bioprinted organ, and the Biotech Guidelines might consider this as involving in the development of human organism and therefore still patent-ineligible.

b) Potential for Human Life

According to the Biotech Guidelines, potential for human life is one of the criteria to ban patent eligibility.[136] The United States, however, did not consider the issue of potential for human life in its patent laws and practices.[137] This requirement is also not available in the EU Biotech Directive, which has the closest requirements to Taiwan's Biotech Guidelines.[138] However, a similar concept was raised in *Brüstle v Greenpeace*,[139] where the European Court of Justice (ECJ) said the meaning of human embryo should be limited to cells that have the capacity to develop into a human being, hence any non-fertilized human ovum "whose division and further development have been stimulated by parthenogenesis are also included in the concept of a human embryo."[140]

Later, in *Int'l Stem Cell Corp.*, the ECJ made clear that within the meaning of Article 6(2)(c) of the Biotech Directive, a non-fertilized human ovum must necessarily have the inherent capacity of developing into a human being to be classified as a "human embryo."[141] This seems to suggest that any organism unable to develop beyond a certain stage due to a disability or impairment, whether incidental or engineered, may not be considered as an embryo and thus, at least in principle, constitutes patentable subject matter.[142] The ECJ's ruling made clear that the

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136 Biotech Guidelines, *supra* note 70, at § 2-14-4.

137 *See* Biological Material, 37 C.F.R. § 1.801 (2015) (providing examples of "biological matter," excluding explicit mention of human life).

138 *See* Council Directive 98/44, 1998 O.J. (L 213) 14 (for the EU guidelines).

139 Case C-34/10, *Oliver Brüstle v. Greenpeace eV*, ECLI:EU:C:2011:138 [hereinafter Case C-34/10].

140 *Id.* at para. 7.

141 Case C-364/13 at para. 27.

142 Ana Nordberg & Timo Minssen, *A "Ray of Hope" for European Stem Cell*

phrase "capable of commencing the process of development of a human being" is considered to have to complete the process of cell division and produce a viable human being rather than simply to start the development process under the current stage of scientific knowledge.[143]

The Biotech Guidelines has not delineated the meaning of potential as the ECJ.[144] The issue could become more acute since iPSC has the potential to be differentiate into reproductive cells with the potential to become autonomous human beings. If Taiwan adopts the more restrictive interpretation of invention able to commence the process of developing human life, then the industry development might be stalled due to lack of patent incentive. However, it might be argued that the Biotech Guidelines only forbid the patenting of inventions involving totipotent stem cells, hence the use of iPSC will not be considered as having the potential for human life.

IV. POLICY RECOMMENDATIONS FOR TAIWAN

a) Patentable Organs

The advent of 3D Bioprinting brings both hype and doubt for the industry and certainly presents new challenges for the patent community. To foster development in this nascent field, it is necessary for Taiwan to have a clear set of laws and regulations for industry to follow. Under current patent law, 3D Bioprinted organs will be considered as an invention, but it is both a product of nature and immoral under both the Biotech Guidelines and Invention Guidelines. To make patent eligibility for 3D Bioprinted organs more predictable, there are two ways to achieve this: 1) to create a *sui generis* examination guideline for 3D Bioprinting inventions or 2) to clarify using the currently available rules. This paper opts for the second option, using currently existing rules as foundations by distinguishing whether the organ is *in vivo* (within the human body) or *in vitro* (outside the human body) and whether the organ is a full scale capable of transplantation or miniature incapable of transplantation.

Patents or "Out of the Smog into the Fog"? An Analysis of Recent European Case Law and How It Compares to the U.S., 47(2) INT. REV. INTELLECT. PROP. COMPET. LAW 138, 153 (2016).

143 Case C-34/10 at para. 7, 36.

144 *See* Biotech Guidelines, *supra* note 70, at § 2-14-4 (for the extent of the disc ussion of potential for human life in the Guidelines).

i) In vivo or in vitro

As stated before, the printing of a 3D organ serves different purposes, including an alternative to animal testing or repreogramming an individuals own cells to generate 3D bioprinted organs that test "the potency and efficacy of pharmaceutical drugs."[145] Since the 3D Bioprinted organ is *in vitro* without the chance of potential for human life or involving in the stages of human life, this should eliminate the morality concerns, and such organs should be patentable.

ii) Actual Organ Size or Miniature

The ability to produce this type of research tool is invaluable in the development of personalized medicine. As it currently stands, about 60% of drugs fail before they reach the clinic stage, and even more fail before they are approved for human use.[146] While this may seem shockingly low, in arriving at this number, one must consider that many drugs affect humans and animals differently.[147] This requires some drugs, although safely tested on animals, to be withdrawn from the market as they produce toxic results in humans.[148] The capability of manufacturing micro-tissue with the a complimentary physiological relation as its full-size counterpart would provide "a faster and potentially more reliable drug testing platform, and hopefully an end to animal testing."[149] In this regard, since these mini organs are *in vitro*, despite having the similar functions, they do have different structures from the actual organ. In this way, they are product of man and no longer are product of nature, hence these mini organs should also be patentable.

b) Unpatentable Organs

Taiwan's current law and examination guidelines, ironically, bar the ultimate goal for 3D Bioprinting: organs printed on demand. Although the benefits of 3D Bioprinted organs are great,

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145 Vermeulen et al., *supra* 43 at 620.

146 Steven M. Paul et al., *How to Improve R&D Productivity: The Pharmaceuti cal Industry's Grand Challenge* 9 NATURE REV. DRUG DISCOVERY 203, 206 (2010).

147 Alan Faulkner-Jones et al., *Bioprinting of Human Pluripotent Stem Cells and Their Directed Differentiation into Hepatocytelike Cells for the Generation of Mini-Livers in 3D*, 7 BIOFABRICATION 1, 1 (2015).

148 *Id.*

149 *Id.*

including avoiding immune rejection from organ transplants[150] and lower costs associated with transplantation,[151] the ideal 3D Bioprinted organ is a natural one, with similar structure and function. If the manufactured organ is incapable of performing the function as if it were a natural one, then its production is meaningless, and if the manufactured organ is capable of performing superior functions, then it falls into the ethical dilemma of enhancement.[152] Furthermore, once these newly printed organs are transplanted *in vivo*, they may be regarded as immoral, due to the intersection with development of human life. Under these moral grounds, these organs will not be patent-eligible, and Taiwan, among other nations, will never see bioprinted organs mass produced without the possibility of patent-eligibility.

V. CONCLUSION

To foster innovation in this nascent field, it is urgent for Taiwan to resolve the issue on patent eligibility for 3D Bioprinted organs. Although the manufacturing process is patentable as a process, the end product may not be due to bioethical concerns. This paper looks into the issues regarding patent eligibility by questioning whether 3D Bioprinted organs are on the list of unpatentable inventions because they are a product of nature or an invention against morality. Since the current technology has not yet matured enough to print an organ for implantation, issues discussed in this paper will arise once the technology matures in the future. As a policy matter, whether to grant a product patent to 3D Bioprinted organs should depend on whether they are *in vivo* or *in vitro* and whether they are actual organs or miniature in size.

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150 Vermeulen et al., *supra* note 43 at 621.

151 Yahya E. Choonara et al., *3D-Printing and The Effect on Medical Costs: A New Era*? 16 EXPERT REV. PHARMACOECONOMICS & OUTCOMES RES. 23–32 (2016). *See* Vermeulen et al., *supra* note 43 at 621.

152 *See* John C. Fletcher and W. French Anderson, *Germ-line Gene Therapy: A New Stage of Debate*, 20 J. L. MED. & ETHICS 26 (1992).