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Don't Go Breakin' My (3D Bioprinted) Heart: Dissecting Patentability and Regulation of 3D Bioprinted Organs

Anna Marie Whitacre
University of Georgia School of Law

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Cover Page Footnote

J.D. Candidate, 2021, University of Georgia School of Law. I would like to thank Professor Joseph S. Miller and the Editorial Board of the Journal of Intellectual Property Law for their help, as well as Professor Stephen Wolfson for inspiring this Note's Repo Men theme. I would also like to dedicate this Note in loving memory to Ms. Suzanne Coleman, my eighth-grade science teacher. She was instrumental in developing my academic foundation. Ms. Coleman, thank you for giving me the spirit and confidence to push myself and for helping me to discover my love for science.

DON'T GO BREAKIN' MY (3D BIOPRINTED) HEART: DISSECTING PATENTABILITY AND REGULATION OF 3D BIOPRINTED ORGANS

*Anna Marie Whitacre**

*J.D. Candidate, 2021, University of Georgia School of Law. I would like to thank Professor Joseph S. Miller and the Editorial Board of the *Journal of Intellectual Property Law* for their help, as well as Professor Stephen Wolfson for inspiring this Note's *Repo Men* theme. I would also like to dedicate this Note in loving memory to Ms. Suzanne Coleman, my eighth-grade science teacher. She was instrumental in developing my academic foundation. Ms. Coleman, thank you for giving me the spirit and confidence to push myself and for helping me to discover my love for science.

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I. INTRODUCTION

Jude Law fashions a smirk.[1] Maintaining a cool demeanor, he says,

> "Mr. Smythe, . . . I'm from the Credit Union."
>
> Smythe stammer[s]. "Wait, I can pay."
>
> "Sorry," [Jude says] "That's not my department." [Jude] raise[s] the taser and [takes] steady aim. "I'm legally bound to ask you if you'd like an ambulance on standby, though you will be unable to secure another artiforg[2] from the Credit Union in replacement."
>
> "Wait," [Smythe says] again, "don't—"
>
> That's as far as [Smythe] got before [Jude's] taser darts slammed into [Smythe's] chest and released their electricity. He went down twitching . . .[3]

The ever-handsome Jude Law ties a white apron around himself.[4] He reaches into his duffel bag and withdraws a scalpel.[5] He pushes the sharp tip into Smythe's belly.[6]

Now, I am sure we can all use our imaginations to envision what happens next. If not, go see *Repo Men*.[7] Nonetheless, I will let a spoiler slip. Jude Law proceeds to thrust his hand into Smythe's open wound and dig out Smythe's artificial liver.[8] Why? Because Smythe defaulted on his "artiforg" payment.[9]

When *Repo Men* was released in 2010, those of us who saw it probably thought this type of scenario could *never* happen; in fact, the absurdity of the plot is likely what attracted us to the theater in the first place. Although the idea of creating

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[1] *See* REPO MEN (Relativity Media 2010) (adapted from ERIC GARCIA, THE REPOSSESSION MAMBO (2009)).

[2] Slang for "artificial organ."

[3] ERIC GARCIA, *supra* note 1, at 5.

[4] *See* REPO MEN, *supra* note 1.

[5] *Id.*

[6] *Id.*

[7] *Id. Repo Men* is a 2010 American science fiction action film—starring Jude Law, Forest Whitaker, and Liev Schreiber. *See* Plot Summary of *Repo Men*, IMDB, https://www.imdb.com/title/tt1053424/ (last visited Oct. 9, 2019) ("Set in the near future when artificial organs can be bought on credit, [*Repo Men*] revolves around a man who struggles to make the payments on a heart he has purchased.").

[8] *Id.*

[9] *Id.*

functioning artificial human organs is astonishing, it is frankly more frightening to think that a third party could legally retrieve one of our body parts without our consent. This fear is partly because artificial organs are not just outlandish ideas from a work of science fiction—they are scientific reality.[10] These artificial organs are not made from huge chunks of metal, as in *Repo Men*, or from other synthetic or nonliving materials.[11] 3D bioprinted organs actually comprise of living cells.[12]

I present this scene from *Repo Men* because it generates several important questions. First, was Smythe's organ really *his*? Well, it was his in the sense that the artificial organ was inside of him and functioned as a natural liver would (at least, we can hope it did). Yet, at the end of the day, we learn that Smythe did not have complete control and dominion over his liver because the "Credit Union" claimed superior title. The issue of title and ownership seems problematic in light of existing federal laws and regulatory schemes. Should 3D bioprinted organs be regulated as natural organs or as medical devices? What happens if 3D bioprinted organs are patentable? Is there ever a possibility that a recipient of a 3D bioprinted organ could face a *Repo Men* fate? In light of the growing reality of 3D bioprinted organs, legal issues arising from these concerns can easily bleed into our society. This bleeding therefore demands exploration.

The beginning of this Note dissects the scientific underpinnings of 3D bioprinted organs. Part II explores statutory authority and controlling, or otherwise persuasive, case law that pertains to subject matter patentability. Current rights associated with medical devices and one's own natural organs are also identified. Part III analyzes how 3D bioprinted organs should be regulated and how the patentability of 3D bioprinted organs squares with potential regulatory frameworks. Ultimately, this Note reaches the conclusion that 3D bioprinted organs are patentable subject matter and that, in general, 3D bioprinted organs should be regulated as medical devices. In the patentability wrinkle, this Note also observes how the anti-commodification of patented 3D bioprinted organs would be a legal contradiction under current federal law.

II. BACKGROUND

A. WHAT ARE 3D BIOPRINTED ORGANS?

3D bioprinting is a "manufacturing technique used to fabricate artificial implants or complex tissue constructs through a layer-by-layer building process for

[10] *See* sources cited and accompanying text *infra* note 29 (noting recent innovations in 3D bioprinted organs).

[11] *See* Haitao Cui et al., *3D Bioprinting for Organ Regeneration,* 6 ADVANCED HEALTHCARE MATERIALS 1, 2 (2017), https://doi.org/10.1002/adhm.201601118 ("3D bioprinting for organ []generation involves . . . printing multiple living cells.").

[12] *Id.*

patient-specific therapy."[13] Unlike traditional 2D printing, 3D bioprinting is "a comprehensive process requiring various design considerations, including imaging, modeling, printer choice, bioink selection, [cell] culture condition, and 3D construct development."[14]

There are two forms of 3D bioprinting that may be implemented to create a 3D bioprinted organ: cellular bioprinting and acellular bioprinting.[15] *Cellular* bioprinting involves "directly deposit[ing] bioinks with viable cells to form a 3D living structure."[16] Conversely, *acellular* bioprinting uses nonliving materials such as "ceramics, metals, polymers and their composites" to form a 3D *non*living structure.[17] This 3D nonliving structure is then integrated with cells, outside of the printing process, to form a 3D bioprinted organ.[18] Acellular, compared to cellular, 3D bioprinting "provides more extensive choices for material selection and manufacturing method."[19] Nevertheless, both cellular and acellular printing techniques may be employed to create a 3D bioprinted organ.[20]

B. THE PROMISE OF "ARTIFORGS"

Repo Men got one thing right: artificial organs would herald an era where recipients could extend or improve their quality of life.[21] 3D bioprinted organs can potentially revolutionize the medical world by "offer[ing] a pathway for scalable and reproducible mass production of engineered living organs" that "mimic their natural counterparts."[22] Given the high demand for donor organs, the United States' organ transplant system is notorious for its lengthy waiting list and

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[13] *Id.* at 3.

[14] *Id.* at 4.

[15] *See id.* (explaining how 3D bioprinting can be "divided into [cellular and acellular techniques]" to produce artificial organs).

[16] *Id.*

[17] *Id.* at 12 (citing C. Y. Yap et al., *Review of Selective Laser Melting: Materials and Applications*, 2 APPLIED PHYSICS REVIEWS (2015), https://doi.org/10.1063/1.4935926).

[18] *See* Chi-Chun Pan et al., *Bioprinting for Tissue Engineering and Regenerative Medicine*, MATERIAL MATTERS 49, 49 (2016), https://www.sigmaaldrich.com/content/dam/sigma-aldrich/docs/Aldrich/Brochure/1/material-matters-v11-n2.pdf ("Acellular bioprinting is used to manufacture the scaffold and biomaterial itself in the absence of cells during the printing process.").

[19] Cui, *supra* note 11, at 7.

[20] *Id.* at 4.

[21] *See* Xiaohong Wang, *Bioartificial Organ Manufacturing Technologies*, 28(1) CELL TRANSPLANTATION 5 (2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6322143/pdf/10.1177_0963689718809918.pdf (describing how 3D bioprinted organs "hold the promise to greatly improve the quality of health and average lifespan of human beings in the near future").

[22] Cui, *supra* note 11, at 15 (referencing Y. S. Zhang et al., *3D Bioprinting for Tissue and Organ Fabrication*, 45 ANNALS OF BIOMEDICAL ENGINEERING 148-63 (2016), https://link.springer.com/article/10.1007%2Fs10439-016-1612-8.

sluggish waiting time.[23] As of July 2019, over 113,000 men, women, and children were on the national transplant waiting list.[24] This number grows each day, and in fact, another person is added to the waiting list every 10 minutes.[25] To make matters worse, each day, 20 people die waiting for a transplant.[26] These numbers illustrate how 3D bioprinted organs may help to relieve the organ supply shortage by providing an additional supply source.[27]

While organ bioprinting has "shown great promise in current research," the challenge remains in formulating bioprinted organs that are suitable for implantation.[28] So, while we are not quite in a *Repo Men*-type world just yet, an implantable 3D bioprinted human organ future is in sight.[29] Conceivably, in just a few years, "industrial, scalable, biofabrication of patient-specific functional 3D living human organs suitable for clinical implantation" will occupy the marketplace.[30]

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[23] Health Resources & Services Administration, *Organ Donation Statistics*, ORGANDONOR.GOV (July 22, 2019), https://www.organdonor.gov/statistics-stories/statistics.html.

[24] *Id.*

[25] *Id.*

[26] *Id.*

[27] Cui, *supra* note 11, at 2 (recognizing that 3D bioprinted organs "show great promise for . . . ultimately mitigating organ shortage and saving lives").

[28] *Id.* at 15. *See also* Tim Lewis, *Could 3D Printing Solve the Organ Transplant Shortage?*, GUARDIAN (Jul. 30, 2017), https://www.theguardian.com/technology/2017/jul/30/will-3d-printing-solve-the-organ-transplant-shortage (explaining how the "one problem with creating whole organs that has to be overcome" is "creating capillaries, which can be smaller in diameter than the smallest cell, has been nearly impossible").

[29] *See* Cui, *supra* note 11, at 26 (explaining how 3D bioprinted organs suitable for human implantation has "remarkable potential" of being fully realized); *see also* Vanessa Listek, *Organovo: Bioprinting Could Be the New Solution to Organ Transplantation*, 3DPRINT.COM (May 6, 2019), https://3dprint.com/243160/organovo-bioprinting-could-be-the-new-solution-to-organ-transplantation/ (stating how Organovo, a San Diego-based tissue engineering company, is set to test its 3D bioprinted liver "patches" in human trials in 2020); David Freeman, *Israeli Scientists Create World's First 3D-Printed Heart Using Human Cells*, NBC NEWS (Apr. 19, 2019), https://www.nbcnews.com/mach/science/israeli-scientists-create-world-s-first-3d-printed-heart-using-ncna996031 (noting how Israeli researchers, in April 2019, were the first in the world to 3D bioprint a heart made of human cells, albeit the size of a rabbit's heart); Press Release, Rice University, Organ Bioprinting Gets a Breath of Fresh Air (May 2, 2019), https://news.rice.edu/2019/05/02/organ-bioprinting-gets-a-breath-of-fresh-air-2/ (announcing, in May 2019, how Rice University bioengineers were the first to ever develop bioprinting technology that "addresses the challenge of multivascularization in a direct and comprehensive way" and 3D-printed a "lung-mimicking structure"); Jesse Damiani, *BIOLIFE4D Just 3D Printed A Human 'Mini-Heart'*, FORBES (Sep. 9, 2019, 10:42am), https://www.forbes.com/sites/jessedamiani/2019/09/09/biolife4d-just-3d-printed-a-human-mini-heart/#26c60efd7eee (announcing how BIOLIFE4D, a Chicago biotech company used 3D bioprinting to produce a miniature human heart that "features the same cellular structure as a full-sized human heart").

[30] Cui, *supra* note 11, at 15.

C. PATENTABLE SUBJECT MATTER

The intent behind limiting patentable subject matter is rooted in the underlying sentiment that patents are tools for promoting progress.[31] In exchange for disclosing useful, novel, and nonobvious inventions to the public, inventors' "sweat of brow" is rewarded with patent protection of their invention.[32] The legal reward of a patent arms owners with "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States."[33]

1. Statutory Backbone

Title 35 of the United States Code is the backbone of the United States' patent framework.[34] Novelty, usefulness, and nonobviousness are necessary predicates for patenting an invention.[35] However, prior to pursuing the novelty, usefulness, and nonobviousness inquiries, one needs to ensure that the *subject matter* of her invention is patentable.[36] Section 101 dictates what is patentable and what is not:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.[37]

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[31] *See* U.S. CONST. art. I, § 8, cl. 8 (granting Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited times to Authors and Inventors the exclusive right to their respective Writings and Discoveries").

[32] *See* J. Phillips, *Patents and Incentives to Invent*, 8 ENDEAVOUR 90 (1984), https://doi.org/10.1016/0160-9327(84)90044-9 (explaining how a patent give its owners certain legal rights, "contingent upon . . . public disclosure").

[33] 35 U.S.C. § 154 (2018); *see also* Phillips, *supra* note 32, at 90 (stating that patents confer "a legal right to prevent anyone else from making or using the invention which is its subject").

[34] 35 U.S.C. §§ 1-390 (2018).

[35] *See* 35 U.S.C. § 101 (limiting grant of patents to inventions that are "new and useful"); *see also* § 102 (stipulating the novelty condition for patentability); § 103 (stipulating the "nonobviousness" condition for patentability).

[36] *See* Diamond v. Diehr, 450 U.S. 175, 188–89, 101 (1981) (emphasizing how novelty and nonobviousness are "of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter"); *see also* Mayo Collaborative Servs. v. Prometheus Laboratories, Inc., 566 U.S. 66, 90, 132 (2012) ("[T]o shift the patent-eligibility inquiry entirely to these later sections risks creating significantly greater legal uncertainty, while assuming that those sections can do work that they are not equipped to do.").

[37] 35 U.S.C. § 101.

In essence, § 101 effectively identifies four categories of patentable subject matter: (1) processes; (2) machines; (3) products of manufacture; and (4) compositions of matter.[38]

In 2011, § 101 underwent a significant transformation. The Leahy-Smith America Invents Act (AIA), enacted under President Obama, transformed the patent system. Not only did the AIA replace the "first-to-invent" system with a "first-to-file" system, the AIA also took statutory note in § 101 that human organisms are *not* patent-eligible subject matter:[39] "[N]o patent may issue on a claim directed to or encompassing a human organism."[40] Even though this § 101 amendment (albeit, in the form of a note) undoubtedly provided clarification to the already broad language, Congress did not specify what exactly it meant by "human organism."[41] Uncertainty lingers, especially when considering some forms of biotechnology, like 3D bioprinted organs, teeter the fine line between patentable and unpatentable subject matter.

2. Controlling and Relevant Case Law

Despite § 101's relatively broad wording, the Supreme Court has recognized non-statutory exceptions to subject matter eligibility.[42] Natural laws, natural phenomena, and abstract ideas are all subject matter that *cannot* be patented.[43] Because 3D bioprinted organs' usefulness comes from their potential to substitute natural organs,[44] 3D bioprinted organs experience the most tension with the "law of nature" exception.[45]

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[38] *Id.*

[39] Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 33, 125 Stat. 284 (codified as amended at 35 U.S.C. § 101).

[40] *Id.* § 33(a), 125 Stat. at 340.

[41] *See id.* (lacking an unambiguous definition of "human organism"); *see also* 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, 778 (2013) (explaining how the lack of a clear definition for the term "human organism" in section 33 of AIA is practically problematic and ambiguous).

[42] *See* Bilski v. Kappos*,* 561 U.S. 593, 601 (2010) ("This Court's precedents provide three specific exceptions to § 101's broad principles: 'laws of nature, physical phenomena, and abstract ideas.'") (quoting Diamond v. Chakrabarty*,* 447 U.S. 303, 309 (1980)).

[43] *See id.*

[44] Wang, *supra* note 21, at 5 (noting that bioprinted organs seek to be "exclusive organ substitutes for defective/failed human organs").

[45] *See* Jordana R. Goodman*, Patenting Frankenstein's Monster: Exploring the Patentability of Artificial Organ Systems and Methodologies,* 15 Nw. J. TECH. & INTELL. PROP. 35, 65 (2017)("If the object of creating an artificial organ is to replicate one already found in nature, then, as science gets closer and closer to the ultimate object, the products become less and less likely to be patentable subject matter.") (citing Ass'n for Molecular Pathology v. USPTO, 689 F.3d 1303, 1351 (2012)).

a. Application of the "Law of Nature" Exception

In *Association for Molecular Pathology v. Myriad Genetics, Inc.*, the Court considered the law of nature exception as it applied to patent claims. The Court noted that it had "'long held that [Section 101] contains an important implicit exception[:] Laws of nature, natural phenomena, and abstract ideas are not patentable.'"[46] In applying the law of nature exception, the Court in *Myriad* held that a genetic sequence that was neither created nor altered was not patentable.[47] While scientists from Myriad found "an important and useful gene," the Court explained that "separating [a] gene from its surrounding genetic material is not an act of invention."[48]

The Court distinguished its decision in *Myriad* from its earlier decision in *Diamond v. Chakrabarty*, which held that scientists could patent a modified bacterium.[49] In *Chakrabarty*, the Court ruled on the patentability of a genetically-modified organism.[50] Scientists added plasmids to a bacterium which enabled the bacterium to break down various components of crude oil.[51] The Court justified the patentability of the bacterium on the basis that it was modified.[52] The modified bacteria "plainly qualifie[d] as patentable subject matter" because the modified bacteria was "a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character [and] use.'"[53] Unlike the modified bacteria in *Chakrabarty*, the genetic sequence Myriad researchers sought to patent "fell squarely within the law of nature exception."[54] Myriad "did not create anything."[55] Rather, Myriad merely isolated the genetic sequence.[56] But, the isolation of the genetic sequence did not change the fact that the *sequence* was what Myriad claimed and that such sequence existed in nature

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[46] 569 U.S. 576, 589 (2013) (quoting Mayo Collaborative Servs. v. Prometheus Laboratories, Inc., 566 U.S. 66, 70 (2012)).

[47] *See generally id.*

[48] *Id.* at 591.

[49] *See id.* at 590-91 (explaining why the Court's holding in *Chakrabarty* is distinguishable from *Myriad*). *Cf. id.* at 591 (explaining how the Court's reasoning in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), that a naturally-occurring nitrogen-fixing bacterium could not be patented because the patent holder did not alter the bacteria in any way, is applicable to the issue in *Myriad*).

[50] *See generally* Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[51] *See id.* at 305 (describing Chakrabarty's invention as "a bacterium . . . containing . . . plasmids . . . capable of breaking down multiple components of crude oil").

[52] *See id.* (noting that the modified bacterium's oil degradation property was "possessed by no naturally occurring bacteria"); *id.* at 310 ("[P]atentee has produced a new bacterium with markedly different characteristics from any found in nature . . . . His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101.").

[53] *Id.* at 309-10 (quoting Hartranft v. Wiegmann, 121 U.S. 609, 615 (1887)).

[54] *Myriad*, 569 U.S. at 591.

[55] *Id.*

[56] *Id.*

before Myriad found it.[57] Myriad neither "create[d] or alter[ed] the genetic structure of DNA."[58] Neither were Myriad's claims "expressed in terms of chemical composition" or focused "in any way on . . . chemical changes that result[ed] from the isolation."[59] Moreover, the Court found that the genes Myriad isolated were not patentable subject matter.[60] The Court further explained that these genes were not like cDNA, which the Court believed could be patentable.[61] In contrast to regular DNA, cDNA is not naturally occurring.[62] Thus, a "lab technician unquestionably creates something new when cDNA is made."[63] Although cDNA "retains the naturally occurring exons of DNA, . . . it is distinct from the DNA in which it comes from."[64] Therefore, cDNA is not subject to the "law of nature" exception and "is patent eligible under [Section] 101."[65]

Process claims, like product claims, are similarly restrained by the law of nature exception.[66] While both *Chakrabarty* and *Myriad* resolved whether a product was patentable subject matter, *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* tackled whether a process that involved a law of nature was also patentable.[67] The Court held that Prometheus' claimed processes[68] were not patentable because "simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable."[69] The Court, however, recognized that the mere recitation of a law of nature in a patent claim will not render the subject matter unpatentable.[70] As long as the claimed process that invokes a law of nature "has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself," the claimed process containing the law of nature could be patentable subject

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[57] *See id.* at 590 ("It is undisputed that Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes. The location and order of the nucleotides existed in nature before Myriad found them.").

[58] *Id.* at 590.

[59] *Id.* at 593.

[60] *See id.* (holding that Myriad's claims are "insufficient to satisfy the demands of § 101").

[61] *See id.* at 595 (stating that cDNA is patent-eligible subject matter).

[62] *See id.* at 594 ("[C]reation of a cDNA sequence from mRNA results in an exons-only molecule that is not naturally occurring.").

[63] *Id.* at 595.

[64] *Id.*

[65] *Id.*

[66] *See generally* 566 U.S. 66 (2012)(applying "law of nature" exception in finding a process unpatentable).

[67] *See generally id.*; *Chakrabarty*, 447 U.S. 303 (holding a claimed bacterium patentable); *Myriad*, 569 U.S. 576 (holding a genetic sequence unpatentable).

[68] Prometheus' patent claims "tell a treating doctor to measure metabolite levels and to consider the resulting measurements in light of the statistical relationships they describe." *Mayo,* 566 U.S. at 86.

[69] *Id.* at 66.

[70] *Id.* at 77-78.

matter.[71] Thus, while the additional steps[72] within Prometheus's claims were not themselves natural laws, "neither [were] they sufficient to transform the nature of the claim."[73]

In light of biotechnological advancements not anticipated by Section 101 drafters, courts have been tasked with contouring Section 101's precise limitations.[74] This is best and most recently demonstrated by the Federal Circuit Court of Appeals' resolution of whether a cloned organism is patentable subject matter in *In re Roslin Institute (Edinburgh)*.[75] The Federal Circuit Court of Appeals held that Dolly, the cloned sheep, was not patentable subject matter.[76] Roslin conceded that the donor sheep's genetic material used to conceive Dolly could not be patented.[77] However, Roslin argued that Dolly herself could be patented as she was "the product of human ingenuity" and "not nature's handiwork, but [Roslin's] own."[78] The court rationalized that "Dolly's genetic identity to her donor parent," claimed to be identical to a natural sheep's, "render[ed] her unpatentable."[79] Given that animal clones do not possess "markedly different characteristics from any [animals] found in nature," clones are not patentable subject matter under § 101.[80] Thus, Dolly the Sheep could not be patented.[81] In response to critique that the court skimmed over the nuances of biology in reaching its

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[71] *Id.* at 77. *See* Parker v. Flook, 437 U.S. 584, 594 (1978) ("Even though a phenomenon of nature or mathematical formula may be well known, an inventive application of the principle may be patented. Conversely, the discovery of such a phenomenon cannot support a patent unless there is some other inventive concept in its application."); *see also* Diamond v. Diehr, 450 U.S. 175 (1981) (holding that the claimed process was patentable subject matter because the additional steps "implement[] or appl[y] that formula in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect"). *Cf. Parker*, 437 U.S. at 594 ("Respondent's process is unpatentable under § 101, not because it contains a mathematical algorithm as one component, but because once that algorithm is assumed to be within the prior art, the application, considered as a whole, contains no patentable invention.").

[72] Additional steps of Prometheus claims included an "administering" step, a "determining" step, and a "wherein" step. *Mayo*, 566 U.S. at 78.

[73] *Id.*

[74] *See generally, e.g.*, In re Roslin Institute (Edinburgh), 750 F.3d 1333 (Fed. Cir. 2014) (determining whether a sheep clone was patentable subject matter under § 101).

[75] *Id.*

[76] *Id.* Note, Roslin was already assigned a patent for the cloning process, which was not at issue. *Id.* at 1334.

[77] *See id.* at 1337 *("*Roslin does not dispute that the donor sheep whose genetic material was used to create Dolly could not be patented . . ."); *see also* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 593 (2013) (finding a naturally-existing gene unpatentable under § 101).

[78] *Roslin,* 750 F.3d at 1337.

[79] *Id.*

[80] *Id.* (quoting *Chakrabarty,* 447 U.S. at 310).

[81] *Id.*

decision,[82] the court (in dicta) conveyed that where claims explicitly identified such "markedly different" biological nuances, a cloned organism may be patentable under § 101:[83]

> There is nothing in the claims, or even in the specification, that suggests that the clones are distinct in any relevant way from the donor animals of which they are copies. The clones are defined in terms of the identity of their nuclear DNA to that of the donor mammals. To be clear, having the same nuclear DNA as the donor mammal may not necessarily result in patent ineligibility in every case. Here, however, the claims do not describe clones that have markedly different characteristics from the donor animals of which they are copies.[84]

Given this emphasis on claim construction, it could be said that the court in *Roslin* did not turn a blind-eye to science.[85] Arguably, *Roslin* affects claim construction more so than the patentable science.[86]

D. CURRENT REGULATION OF HUMAN ORGANS

1. The Right to (Not) Sell Your Organs

Section 274e of the Public Health Service Act, otherwise referred to as the National Organ Transplant Act or "NOTA,"[87] makes it illegal for "any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce."[88] The prohibition on the sale or purchase of human organs does not apply to human organ paired donations.[89] Congress' intent behind NOTA was "[t]o provide for the establishment of the Task Force on Organ Transplantation and the Organ Procurement and Transplantation Network, to authorize financial assistance for organ procurement organizations, and for other

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[82] *See, e.g.*, Gene Quinn, *Dolly the Cloned Sheep Not Patentable in the U.S.*, IPWATCHDOG (May 8, 2014), https://www.ipwatchdog.com/2014/05/08/dolly-the-cloned-sheep-not-patentable-in-the-u-s/id=49471/.

[83] *See Roslin*, 750 F.3d at 1339 (emphasizing claim construction contributed to the court's "unpatentable" holding).

[84] *Id.*

[85] *See id.* (reasoning that clever claim construction may be used to patent an organism with identical nuclear DNA).

[86] *See id.*

[87] National Organ Transplant Act of 1984 ("NOTA"), Pub. L. No. 98-507., 98 Stat. 2339 (codified as amended §§ 42 U.S.C. 273-74 (1984)).

[88] 42 U.S.C.A. § 274e(a) (West 2019).

[89] *See id.* ("The [prohibition] does not apply with respect to human organ paired donation"); *see also* § 274e(c)(4)(defining "human organ paired donation").

purposes."[90] The prohibition itself was meant to ban the commodification of human organs.[91] Congress' desire to anti-commodify human organs was primarily influenced by three factors: "the religious belief that one's soul is inextricably tied to their body, the lack of an altruistic system raises concerns about the quality of the organ supply, and because the free-market sale of organs will entrench social inequality by benefiting the wealthy at the expense of the poor."[92]

Importantly, NOTA goes on to define a "human organ" as:

> the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ (or any subpart thereof, including that derived from a fetus) specified by the Secretary of Health and Human Services by regulation.[93]

It is interesting to note, however, that the definition of "human organ" did not originally explicitly encompass fetal organs. In 1988, Congress amended the definition of "human organ" to include fetal organs (and organ tissue parts). Congressional desire to broaden such definition arose from:

> the fear of incentivizing abortions; (2) a lack of consent (it is immoral to allow a mother to consent to abortion on behalf of the fetus and the fetus obviously is unable to give consent to be aborted); (3) the conflation of the fetus as both the donor and the donation; and (4) the commercialization of fetal tissue.[94]

The Secretary of Health and Human Services further expands NOTA's "human organ" definition via its regulatory power by including "any vascularized composite allograft."[95] A "vascularized composite allograft" is defined as a body part with the following characteristics:

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[90] National Organ Transplant Act of 1984 (NOTA), Pub. L. No. 98-507., 98 Stat. 2339. *See also* Robert Jacobson, *3-D Bioprinting: Not Allowed or NOTA Allowed?*, 91 CHI.-KENT L. REV. 1117, 1122 (2016) (explaining how a principle purpose behind NOTA was to promote "equitable access" and "effective use" of organs (citing to S.REP. NO. 98-382, at 15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 3975, 3981)).

[91] *See* Jacobson, *supra* note 90, at 1122 (identifying the Senate's view that "human body parts should not be viewed as commodities.") (citing S.REP. NO. 98-382, at 15 (1984), *reprinted* in 1984 U.S.C.C.A.N. 3975, 3981).

[92] *Id.*

[93] 42 U.S.C.A. § 274e(c)(1) (West 2019).

[94] Jacobson, *supra* note 90, at 1132.

[95] 42 C.F.R. § 121.13 (2019)(emphasis added).

> (1) . . . vascularized and requires blood flow by surgical connection of blood vessels to function after transplantation;
>
> (2) Containing multiple tissue types;
>
> (3) Recovered from a human donor as an anatomical/structural unit;
>
> (4) Transplanted into a human recipient as an anatomical/structural unit;
>
> (5) Minimally manipulated (i.e., processing that does not alter the original relevant characteristics of the organ relating to the organ's utility for reconstruction, repair, or replacement);
>
> (6) For homologous use (the replacement or supplementation of a recipient's organ with an organ that performs the same basic function or functions in the recipient as in the donor);
>
> (7) Not combined with another article such as a device;
>
> (8) Susceptible to ischemia and, therefore, only stored temporarily and not cryopreserved; *and*
>
> (9) Susceptible to allograft rejection, generally requiring immunosuppression that may increase infectious disease risk to the recipient.[96]

Noticeably, the nine-part definition of a "vascularized allograft composite" is conjunctive, rather than disjunctive.[97] The conjunctive, rather than disjunctive, nature of the definition significantly affects NOTA's prohibition on organ sales and purchases in practice.[98] The Secretary's inclusion of "vascularized allograft composite" indeed broadens NOTA's prohibitory umbrella over the sale and purchase of human organs. But, the conjunctive, relative to the disjunctive, nature of the definition broadens the definition to a lesser an extent. To qualify as

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[96] 42 C.F.R. § 121.2 (2019).

[97] The "and" in "not cryptopreserved; and . . . [s]uscpetible to," 42 C.F.R. § 121.2., makes the definition of "vascularized allograft composite" conjunctive. *See A Guide to Reading, Interpreting and Applying Statutes*, GEORGETOWN UNIVERSITY LAW CENTER 1, 4 (2017), https://www.law.georgetown.edu/wp-content/uploads/2018/12/A-Guide-to-Reading-Interpreting-and-Applying-Statutes-1.pdf ("'And' typically signifies a conjunctive list, meaning each condition in the list must be satisfied, while 'or' typically signifies a disjunctive list, meaning satisfying any one condition in the list is sufficient.").

[98] *See A Guide to Reading, Interpreting and Applying Statutes*, *supra* note 97, at 4.

a "vascularized allograft composite," all nine parts must be met, rather than just one of the nine.[99] Thus, the U.S. Department of Health and Human Services effectively expanded the regulatory reach of NOTA's prohibition on organ sales/purchases by broadening the scope of what constitutes a "human organ" under the law.[100] Congress' expansion of the definition, however, is not as drastic in application as one may think.[101]

E. CURRENT REGULATION OF MEDICAL DEVICES

Most, if not all, ownership and possessory rights with respect to medical device implants are ascertained through contract law.[102] As a result, property rights can vary widely between of medical device recipients based on the flexibility and fluidity of the contractual processes that are available to them.[103] Recipients theoretically bear the right to freely negotiate contractual terms with the opposing party (most of the time, a hospital/physician)[104] and consent before being bound to such terms.[105] While knowledge of this variance is important, this Note will only focus on ownership rights inherent to medical device recipients, contract law principles aside.

The Federal Food, Drug, and Cosmetic Act ("FDCA") regulates medical devices to ensure their safety and effectiveness.[106] This regulation extends from pre-market devices to implanted devices.[107] FDCA recognizes that a recipient of

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[99] *See* 42 C.F.R. § 121.2.

[100] *See, e.g.*, Mariam Aslam et al., *Challenges and Best Practices for Health Systems to Consider When Implementing Risk-Share Contracts for Medical Devices*, MASSACHUSETTS MEDICAL SOCIETY (May 8, 2019), https://catalyst.nejm.org/doi/full/10.1056/CAT.19.0665 (highlighting the widespread contractual practices amongst device distributors, hospitals, and device recipients).

[101] At least not as significant as if a disjunctive "vascularized allograft composite" definition was adopted. *See A Guide to Reading, Interpreting and Applying Statutes*, *supra* note 97.

[102] *See* Aslam, *supra* note 100.

[103] *See* Aditi Bagchi, *Parallel Contract*, 75 U. PITT. L. REV. 139, 145 (2013) ("In the classical account of contract, parties . . . negotiate their agreements. Those agreements impose a specified set of performance obligations on each party, and the obligations of each are carefully tailored such that the bargain could not be improved to their mutual satisfaction.").

[104] While, in theory, recipients (technically "pre-recipients" as prior to actual receipt of the medical device) have the right to freely negotiate, this right is often diluted by the inherently unequal share of power in the patient-physician/hospital relationship and a possible discrepancy in bargaining power. EC Hui, *Doctors as Fiduciaries: A Legal Construct of the Patient-Physician Relationship*, 11 HONG KONG MED. J. 527, 527 (2005)("The acquisition of powers by one party implies an inequality of influence, knowledge, and bargaining ability in [a fiduciary relationship], and this provides the fiduciary 'a special opportunity to exercise the power or discretion to the detriment of that other person. . .'" (quoting Hosp. Prods. Ltd v U.S. Surgical Corp. (1984) 156 CLR 42 (Austl.)).

[105] *See* Bagchi, *supra* note 103, at 140.

[106] Medical Device Regulation Act (Medical Device Amendments of 1976), Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified at 21 U.S.C. ch. 9, subch. V (2018)).

[107] *Id.*

a medical device has an important ownership interest that must be protected.[108] However, the FDCA acknowledges that the recipient's right is not the only ownership interest in the medical device.[109] The device vendor, the hospital/physician that implanted the device, and the patent owner (if there is one) also possess ownership interests in the medical device.[110]

Under Medicare, an explanted medical device (i.e. an implanted device that is later removed) "must be pursued by the provider as for free replacement or reduced charges under warranty."[111] This provision captures the desire to hold vendors accountable for any faulty medical device implants that could jeopardize recipients' personal health.[112] Fairness dictates that the vendor should bear the cost of these defects, not the recipient.[113] Tort law, namely product liability, reinforces this rationale.[114]

1. 'Til Death Do Us Part?

Whether, in the event of death, medical implants are removed or left intact largely depends on how the body is disposed of at death.[115] In the case of burial, the general consensus is that there is no compelling reason to remove implants.[116] If the body is cremated, however, electronic and battery-containing medical implants, like pacemakers and ICDS, are "almost always" removed before

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[108] *Id.*

[109] *See id.*

[110] *See id.*; *see also* sources cited *infra* note 111.

[111] Kayla Bryant, *Hospital Compliance Programs Need to Integrate Explanted Device Policy*, WOLTERS KLUWER (Jul. 14, 2017), http://health.wolterskluwerlb.com/2017/07/hospital-compliance-programs-need-to-integrate-explanted-device-policy/; *see also* Brenda Mickow et al., *Medical Device* Replacements, MAYO CLINIC (2016), https://assets.hcca-info.org/Portals/0/PDFs/Resources/Conference_Handouts/Compliance_Institute/2018/W13_2.pdf ("All eligible explanted medical devices must be pursued for warranty credit and no-charge replacement. If the discounted replacement device cost is lower than half of the cost of the device, it must be reported on the claim." (citing 42 C.F.R. § 412.89 and § 419.45)).

[112] *See* 21 U.S.C. ch. 9, subch. V; Richard Kaye, *Federal Preemption of State Common-Law Products Liability Claims Pertaining to Medical Devices, Implants, and Other Health-Related Items*, 74 A.L.R. Fed 2d § 1, §§ 1-2 (2013).

[113] Kaye, *supra* note 112, at §§ 1-2.

[114] *Id.*

[115] Frank Swain, *What Happens to Prosthetics and Implants After You Die?*, BBC (Mar. 10, 2014), https://www.bbc.com/future/article/20140311-body-parts-that-live-after-death.

[116] *See id.* ("Inert devices such as breast implants and replacement hips tend not to be removed after death, largely because there's no compelling reason to do so, and they pose little threat to the environment.").

cremation.[117] Otherwise, the devices would inevitably explode during the creamation process.[118]

"Once removed, implants are typically discarded – both the European Union and the [United States], among others, have rules that forbid the reuse of implanted medical devices."[119] The ban on *reuse*, however, does not equate to a ban on *resale*. A decedent recipient's estate may elect to keep the recipient's implant and even choose to sell it (or a form of it) in the marketplace.[120] For example, a purchaser may be a collector of used devices or may be interested in scrapping the device's parts for money.[121] Nevertheless, this right to sell a patented implant, despite the ban on reuse, arises from the exhaustion doctrine.[122]

2. The Exhaustion Doctrine

The exhaustion doctrine, otherwise known as the first sale doctrine, is a "judicially created and judicially shaped doctrine" in patent law.[123] "A key to the exhaustion concept in the most common circumstances is that the patent owner has sold a product without restriction. The sale seems to bring along a promise that the patentee will not interfere with the customer's full enjoyment of that product."[124]

Absent contractual restrictions to control downstream use and re-sale of goods, "'[w]hen a patentee chooses to sell an item, that product is no longer within the limits of the monopoly' and 'instead becomes the private, individual property of the purchaser, with the rights and benefits that come along with ownership.'"[125] These doctrinal underpinnings establish the default rights purchasers of medical implants possess.[126] In this vein, purchasers of medical

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[117] *Id.*

[118] *Id.* (explaining that "because . . . batteries [and other electronics] can explode when heated" such devices are "often taken out of the body after death – and almost always before cremation").

[119] *Id.*; *see also* Draft Guidance from the Center for Devices and Radiological Health, FDA, on Reprocessing and Reuse
of Single-Use Devices (Feb. 8, 2000), https://www.fda.gov/media/71761/download (explaining that "if the device is an implant, . . . the [single-use device] is categorized as high risk" and the single-use implant cannot be reprocessed or reused).

[120] *Id.*

[121] *See, e.g.*, Clark Boyd, *Following Cremation, Recycling Surgical Implants*, PRI, (Jan. 30, 2012), https://www.pri.org/stories/2012-01-30/following-cremation-recycling-surgical-implants ((discussing a company that purchases old metal medical devices to smelt and sell).

[122] LYDIA PALLAS LOREN & JOSEPH SCOTT MILLER, INTELLECTUAL PROPERTY LAW: CASES & MATERIALS 701 (5th ed. 2017) ("[U]nlike copyright law, the patent exhaustion doctrine is not codified in the statute.")

[123] *Id.*

[124] *Id.*

[125] *Id.* (quoting Impression Products, Inc. v. Lexmark International, Inc., 137 S. Ct. 1523, 1531 (2017)).

[126] *Id.*

implants are able to use, sell, or import the implant as they wish, as long as such conduct does not transgress other legal constraints.[127] Recall, however, that the existing ban on reusing medical implants also restricts the market for used (explanted) medical devices.[128] Additionally, hospital regulations or other health regulations, may preempt—or, in the least, limit—an individual's ability to keep their explanted device.[129] Nonetheless, a slim market does not mean that recipients (or their estate) cannot and will not resell the device.[130] For example, a profit can be made by salvaging the metal from metal medical devices (like hip and knee implants) and selling that metal on the open market.[131]

The exhaustion doctrine allows purchasers and subsequent owners of explanted, patented medical devices to enjoy relatively unrestricted ownership rights over such devices once these devices are released to them.[132] The exhaustion doctrine, however, does not apply to the sale of human organs.[133] Human organs cannot be patented, so patent law and the judicially-created exhaustion doctrine under patent law is not implicated. In addition, NOTA prohibits the sale of human organs.[134]

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[127] *See id.* at 702 ("[T]he sale [of a patented object] transfers the right to use, sell, or import because those are the rights that come along with ownership, and the buyer is free and clear of an infringement lawsuit because there is no exclusionary right left to enforce.") (quoting *Lexmark*, 137 S. Ct. 1523 (2017)); *see generally Lexmark* (overturning the Federal Circuit's rejection of an exhaustion defense where the patentee had sold its products—toner cartridges for laser printers—with an explicit "single use, no resale" limitation).

[128] *See* Alec Klein, *Used Medical Devices Being Sold on Ebay*, Washington Post (Dec. 22, 2005), https://www.washingtonpost.com/archive/business/2005/12/22/used-medical-devices-being-sold-on-ebay/ded0a712-f4c4-4d81-ba0c-acdf37658303/(recognizing that a market, albeit marginal, exists for used medical implants).

[129] *See U-M Hospitals and Health Centers Policies and Procedures*, UNIVERSITY OF MICHIGAN HOSPITALS AND HEALTH CENTERS (2003), http://s3.amazonaws.com/rdcms-aami/files/production/public/FileDownloads/HTM/Idea_Exchange/EI_explants_UM.pdf(describing University of Michigan's hospital and health center's "explant policy" that explants are not to be returned to patients unless properly sterilized); *see also* ECRI Institute, *Ask HRC: Retaining Explanted Medical Devices*, HEALTHCARE RISK, QUALITY, & SAFETY GUIDANCE (2016), https://www.ecri.org/components/HRC/Pages/AskHRC122716.aspx (explaining how hospitals have a responsibility to manage certain risk when releasing explanted devices to patients); Nancy Chobin, *Advice on Explanted* Devices, INFECTION CONTROL TODAY (Oct. 13, 2015), https://www.infectioncontroltoday.com/sterile-processing/advice-explanted-implants ("While we would like to accommodate the patient's request, we must always comply with the standards and manufacturer's instructions.").

[130] *See, e.g.*, Clark Boyd, *supra* note 121 (discussing a company that purchases old metal medical devices to smelt and sell).

[131] *See id.*

[132] *See id.*

[133] *See* LOREN & MILLER, *supra* note 122, at 701.

[134] National Organ Transplant Act of 1984 (NOTA), Pub. L. No. 98-507., 98 Stat. 2339 (codified as amended §§ 42 U.S.C. 273-74 (1984)).

3. The Case of the Infringing Medical Implant

Another dilemma worth noting that invokes several ownership interests is the situation in which a recipient's implanted medical device may be subject to a patent infringement suit.[135] An individual is liable for patent infringement if he "without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent."[136] If the manufacturer of a recipient's medical implant is found liable for patent infringement, the manufacturer is most often required to pay damages to the plaintiff, the rightful patent owner.[137] Under current law, the individual is thankfully left alone and will not face Smythe's fate in *Repo Men*.[138]

III. ANALYSIS

A. PATENT SUBJECT MATTER ELIGIBILITY

The general consensus amongst legal scholars and scientists alike is that bioprinted organs are patentable subject matter, so long as the 3D bioprinted organ sought to be patented is properly claimed.[139] As patent applicants have learned from *Dolly*, claim construction largely dictates whether bioprinted organs can be patented.[140] Although these bioprinted organs are made from human cells, as long as an applicant can claim a "markedly different characteristic" in 3D bioprinted organs, then there is no reason such bioprinted organ claim will not pass the USPTO's patentability muster.[141] However, as scientists grow closer to producing a 3D bioprinted organ that is functionally fungible with a natural human organ, patentability grows more difficult.[142] This is because the closer

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135 *See generally, e.g.*, Howmedica Osteonics Corp. v. Zimmer, Inc., 822 F.3d 1312 (Fed. Cir. 2016) (patent infringement suit involving a component of a prosthetic hip implant).

136 35 U.S.C. § 271 (2018).

137 *See* Ted Sichelman, *Purging Patent Law of "Private Law" Remedies*, 92 Tex. L. Rev. 517, 536-42 (noting the commonality of damages as the form of relief in medical implant patent infringement cases).

138 *See id.*

139 *See generally* Tabrez Ebrahim, *3D Bioprinting Patentable Subject Matter Boundaries*, 41 SEATTLE U. L. REV. 1 (2017)(exploring how bioprinted organs, as long as properly claimed, can be patentable subject matter); Judith L. Toffenetti & Atabak R. Royaee, *Patentability of 3D-Printed Organs*, GENETIC ENGINEERING & BIOTECHNOLOGY NEWS (May 15, 2014), https://www.genengnews.com/insights/patentability-of-3d-printed-organs/77900129/ (advocating that bioprinted organs are patentable subject matter).

140 *See* In re Roslin Institute (Edinburgh), 750 F.3d 1333, 1339 (Fed. Cir. 2014) (indicating that a genetically equivalent or similar entity may be found patentable under § 101 depending on claim construction).

141 *See* Diamond v. Chakrabarty*,* 447 U.S. 303, 309-10 (1980) (holding a bacterium's "markedly different characteristics" rendered it patentable subject matter).

142 *See* Jordana R. Goodman*, Patenting Frankenstein's Monster: Exploring the Patentability of Artificial Organ Systems and Methodologies,* 15 Nw. J. TECH. & INTELL. PROP. 35, 63 (2017) ("The

scientists get, the closer scientists are to effectively replicating nature.[143] With this goal, scientists seeking to patent such bioprinted organs tip-toe § 101's implicit law of nature exception.[144]

In spite of bioprinted organs "tip-toeing" the law of nature exception, recent innovations demonstrate that 3D bioprinted organs nonetheless possess markedly different characteristics from natural organs that would render them patentworthy.[145] While a bioprinted organ may consist of human cells, which themselves are naturally occurring, this does not mandate the finding that a bioprinted organ is naturally occurring and, therefore, not patentable under § 101. Not only is a bioprinted organ significantly distinct from a natural organ, but it is also a product of human ingenuity. These two showings demonstrate that, under the *Chakrabarty*/*Myriad* framework, a 3D bioprinted organ is patentable subject matter.

A 3D bioprinted organ suitable for human implantation will ideally be functionally equivalent to a natural organ.[146] However, functional equivalence does not preclude patent subject matter eligibility as long as the 3D bioprinted organ possesses a markedly different characteristic from its natural counterpart.[147] Structurally, a 3D bioprinted organ may be markedly different from its natural counterpart.[148] Whereas a clone, like Dolly the Sheep, is necessarily genetically identical to its natural parent, a 3D bioprinted organ is not necessarily genetically identical to its natural analogue. Specifically, 3D bioprinted organs are typically built by scaffolding live stem cells on other biomaterials, like polymers, that are not present in a natural human organ heart.[149] Moreover, *Roslin* cannot be used to intuit that 3D bioprinted organs are unpatentable subject matter. A 3D bioprinted organ is distinguishable from a cloned organism.

In terms of human ingenuity, "stem cells cannot self-assemble into a uniform structure in vitro, let alone function as an organ."[150] The creation of a 3D

closer scientists get to replication of a natural product, the further scientists get to patent protection of their invention.").

143 See *id.* ("The problem lies in this progression: scientists are working to replicate a natural product."); *see also* background discussion *supra* Part II.B (explaining the origins of and practical effect of the law of nature exception).

144 *See* sources cited *supra* note 143.

145 *See* sources cited *supra* note 29.

146 *See generally* Wang, *supra* note 21.

147 *See Roslin*, 750 F.3d at 1339 (holding that genetic similarity does not necessarily preclude patentability under § 101).

148 *Id.*

149 *See* Wang, *supra* note 21, at 5 (describing how bioprinted organs built with human cells typically also consist of inanimate polymers, or other biological polymers, not inherent to a natural human organ).

150 Judith L. Toffenetti & Atabak R. Royaee, *Patentability of 3D-Printed Organs*, GENETIC ENGINEERING AND BIOTECHNOLOGY NEWS (GEN)(May 15, 2014), https://www.genengnews.com/insights/patentability-of-3d-printed-organs/. *See* Diamond v. Chakrabarty, 447 U.S. 303, 309-10 (1980) (holding a genetically-modified bacterium patentable because it was a

bioprinted organ requires human manipulation.[151] Natural forces, in isolation, are incapable of generating a 3D bioprinted organ.[152] A 3D bioprinted organ does not form in a mother's womb upon conception.[153] A 3D bioprinted organ is created by a scientist after numerous hours spent in the lab tinkering with cells, bio-solutions, and a 3D printer to create something unnatural.[154] Thus, a 3D bioprinted organ is a product of human ingenuity.[155]

Even if the organ itself cannot be patented as a product of manufacture, the process of synthesizing the organ–as long as drafted with proper specificity—may be eligible for a method patent.[156] In fact, this has already been done for a 3D bioprinted *tissue*.[157] There is no reason–holding all other variables constant-that a method for a bioprinted *organ*, which is a collection of tissues,[158] cannot be patented.

B. REGULATION OF PATENTED 3D BIOPRINTED ORGANS AS MEDICAL DEVICES

Assuming the patentability of 3D bioprinted organs, a patented 3D bioprinted organ would *not* qualify as a "human organism" because it is not subject to § 101's law of nature exception.[159] Moreover, a patented 3D bioprinted organ presents a sticky situation in terms of ownership rights. Human organs cannot be sold or purchased under NOTA.[160] Since a patented 3D bioprinted organ is

"product of human ingenuity" and possessed "markedly different characteristics from any found in nature"); *Cf. Myriad*, 569 U.S. at 590 (holding that the BRCA gene was not patentable subject matter because the genetic sequence was naturally occurring and Myriad neither "create[d] or alter[ed] the genetic structure of DNA").

151 *See* Wang, *supra* note 21, at 5 (describing the creation of 3D bioprinted organs as a "manufacturing process" by scientists).

152 In re Roslin Institute (Edinburgh), 750 F.3d 1333 (Fed. Cir. 2014).

153 *See id.* (emphasizing that 3D bioprinted organs are artificial and intended to serve as substitutes to natural organs).

154 *See* Wang *supra* note 21.

155 *See generally Chakrabarty*, 447 U.S. 303 (holding an altered bacterium to be patentable on the basis of human ingenuity).

156 *See* U.S. Patent No. 10390946 (granted Aug. 27, 2019) (claiming "[a] method of preparing biological tissue for use as a component of . . . a heart valve prosthesis" that contains biological tissue).

157 *See* U.S. Patent No. 20190093070 (granted Mar. 28, 2019) (claiming "[a] method of producing a three-dimensional tissue having a vascular system structure" where "the cell used for forming the three-dimensional tissue" includes-but is not limited to-"one derived from . . . a human").

158 *Organ*, MERRIAM-WEBSTER'S DICTIONARY, https://www.merriam-webster.com/dictionary/organ(last visited Nov. 19, 2019, 9:17 PM).

159 *See* Bilski v. Kappos, 561 U.S. 593 (2010) (case law explaining that for subject matter to be patentable the law of nature exception cannot apply).

160 National Organ Transplant Act of 1984 (NOTA), Pub. L. No. 98-507., 98 Stat. 2339 (codified as amended 42 U.S.C. §§ 273-74 (1984)).

neither a human organism nor a naturally-occurring composition of matter, a patented bioprinted organ is also not a natural human organ. In this vein, a patented 3D bioprinted organ would not be subject to NOTA's purchase/sell prohibition as it is not a "human organ." To say otherwise would be a legal contradiction and retroactively negate a finding of patentability. Additionally, the legislative intent behind NOTA makes the argument for creating a specialized "bioprinted organ" exception a tough argument to swallow.

A 3D bioprinted organ, patented or not, is more analogous to a medical device rather than a natural human organ for regulatory sake.[161] Thus, a 3D bioprinted organ should be regulated by the FDA as a medical device, specifically a Class III device.[162] Treating a 3D bioprinted organ as such, NOTA rightfully would not apply as NOTA stands now. Nor should Congress amend NOTA to extend the ban of the sale and purchase of organs to patented 3D bioprinted organs. Doing so would contradict the legislative intent behind NOTA, which, if you recall, was inspired by three considerations:

> (1) the religious belief that one's soul is inextricably tied to their body;
>
> (2) the lack of an altruistic system raises concerns about the quality of the organ supply; and
>
> (3) because the free-market sale of organs will entrench social inequality by benefiting the wealthy at the expense of the poor.[163]

1. Can You Print a Soul?

Beginning with the first factor, the religious belief that one's soul is inextricably tied to their body is not applicable to a 3D bioprinted organ. A 3D bioprinted organ is synthesized by a 3D printer controlled by a scientist.[164] A 3D bioprinted organ's origin is a 3D printer—not a human body.[165] An individual is not born

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[161] *See* Michael H. Park, *For A New Heart, Just Click Print: The Effect on Medical and Products Liability from 3-D Printed Organs*, U. ILL. J. L. TECH. & POL'Y 187, 199 (2015) ("[I]t is likely that with the combination of the FDA's oversight of biological tissues for transplantation, medical devices for transplantation, and the similarity between artificial hearts and 3-D printed organs that the FDA will have the duty to regulate the manufacture of 3-D printed organs.").

[162] *See id.* at 208. ("Since the artificial heart is already regulated as a Class III device, it would seem 3-D printed organs, hearts, livers, kidneys, etc., would be regulated as Class III devices [by the FDA]." (citing *Product Classification*, FDA www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/classification.cfm?ID=1021 (last updated Mar. 17, 2020) (classifying artificial heart))).

[163] Jacobson, *supra* note 90 at 1122-23; *see also* discussion *infra* Part II.C.

[164] *See generally* Wang, *supra* note 21.

[165] *Id.*

with a 3D bioprinted organ.[166] Therefore, one's soul cannot be inextricably[167] tied to a 3D bioprinted organ because the individual (and his soul) lived for a discrete period of time without a 3D bioprinted organ. As such, Congress' first consideration does not extend to 3D bioprinted organs.

2. There Cannot Be Altruism Without "You"

Congress' second consideration, that the lack of an altruistic system raises concerns about the quality of the organ supply, also does not extend to 3D bioprinted organs. This "altruistic" concern, in the natural human organ context, was buttressed by the belief that commodification would essentially destroy the voluntary organ donation system.[168] Namely, this belief sprung from the notion that "[c]ompensation to donors [would] degrade the quality of the organ supply, by inducing potential donors to lie about their medical histories in order to make their organs marketable."[169] Altruism can be "defined as acting with the absence of any personal benefit beyond the satisfaction of giving."[170] In the organ donation context, altruism is typically defined as "an absence of monetary exchange and commercialization."[171] Altruistic concerns are implicated by an individual's autonomy over their own organs — a function of bodily autonomy. Altruistic concerns are therefore relevant in the discussion of legalization of the sale/purchase of natural human organs. However, such concerns are irrelevant to determining whether 3D bioprinted organs should be commodified.

The primary purpose behind the FDA's medical device regulatory system is to ensure the overall quality of medical devices by certifying such devices' safety and functionality.[172] The quality of the supply of 3D bioprinted organs can therefore be ensured by regulating these organs as medical devices. There is not a lack

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166 *Id.*

167 Merriam-Webster defines "inextricable" as "incapable of being disentangled or untied." MERRIAM-WEBSTER'S DICTIONARY, https://www.merriam-webster.com/dictionary/inextricable (last visited Apr. 4, 2020, 8:01 PM).

168 *See* Flynn v. Holder, 684 F.3d 852, 860 n. 30 (9th Cir. 2012)(citing *National Organ Transplant Act: Hearing on H.R. 4080 Before the Subcomm. on Health of the H. Comm. on Ways & Means*, 98th Cong., 2d Sess. 26 (1984) (statement of Rep. Waxman) ("If [people are allowed to sell their kidneys], I believe our efforts to promote voluntary organ donations would collapse, and health risks to transplant patients would greatly increase. . . .").

169 *Id.*; *see also id.* n. 30 (citing to Maurice McGregor, *Pragmatic Altruism*, 160 CAN. MED. ASS'N J. 5, 91 (1999) ("The need for money is a disincentive to honest disclosure, a disincentive whose force will increase with the strength of the need.").

170 Akshara Meran, *Organ Donation: Altruism vs. Incentive*, AMA J. ETHICS (VIRTUAL MENTOR) (2002), https://journalofethics.ama-assn.org/article/organ-donation-altruism-vs-incentive/2002-08.

171 Marie-Chantal Fortin et al., *The Enigmatic Nature of Altruism in Organ Transplantation: A Cross-Cultural Study of Transplant Physicians' Views on Altruism*, 3 BMC RES. NOTES 1, 1 (2010), https://bmcresnotes.biomedcentral.com/track/pdf/10.1186/1756-0500-3-216.

172 *See Medical Device Overview*, FDA, https://www.fda.gov/industry/regulated-products/medical-device-overview (last updated Sep. 14, 2018) (stating that the FDA is responsible for "evaluat[ing] the safety and effectiveness of . . . medical devices").

of a system that guarantees quality. Granted, some regulations specifically tailored to 3D bioprinted organs may need to be added; however, the building blocks already exist.[173] The FDA already oversees biological tissues[174] for transplantation and 3D printed medical devices[175] for transplantation.[176] A 3D bioprinted organ, a 3D printed medical device for transplantation comprised of human cells,[177] is merely a hybrid of two entities the FDA already regulates. Moreover, the second consideration is inapplicable to 3D bioprinted organs as systems (or at least the building blocks of a system) assuring the supply quality of bioprinted organs currently exist under the FDA.

3. Social Inequality

As for Congress's third consideration in banning the purchase and sale of human organs, that the free-market sale of organs will entrench social inequality by benefitting the wealthy at the expense of the poor, key differences between 3D bioprinted organs and natural human organs render this consideration irrelevant. As such, a free-market sale of 3D bioprinted organs, unlike natural human organs, will resemble the free-market sale of medical devices. The free-market sale of bioprinted organs will cause no more inequality as medical devices sold on the market cause now.[178] This proposition draws from the similarities between medical devices already subject to regulation by the FDA, and the differences between 3D bioprinted organs and natural human organs. Like medical devices and unlike human organs, bioprinted organs are man-made.[179] Thus, the pressures of scarcity inherent to natural human organs are not inherent to 3D bioprinted organs or medical devices, like pacemakers.[180] Absent such scarcity of 3D bioprinted organs, bioprinted organs as free-market goods will most likely

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173 *See* Park, *supra* note 161, at 199 ("The FDA's regulations cover human cells and tissues that are intended for implantation, transplantation, infusion, or transfer into a [patient] . . . ." (citing *Tissue & Tissue Products*, FDA, http:// www.fda.gov/BiologicsBloodVaccines/TissueTissueProducts/default.htm (last updated Jul. 11, 2019))).

174 *Id.*

175 *See Medical Applications of 3D Printing*, FDA, https://www.fda.gov/medical-devices/3d-printing-medical-devices/medical-applications-3d-printing (last updated Dec. 4, 2017) ("The FDA regulates 3D printed medical devices through the same pathways as traditional medical devices[.]").

176 *See* Park, *supra* note 161, at 198 ("The FDA already regulates medical implants." (citing *Implants and Prosthetics*, FDA, http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/default.htm (last updated Sep. 30, 2019))).

177 *See supra* Part II.A (defining what a 3D bioprinted organ is).

178 Jacobson, *supra* note 90, at 1127 ("[3D bioprinted organ] expenses will probably be unaffordable to the poorer segments of society, in effect, establishing a two-tier organ replacement system: those with money can purchase a bioprinted replacement organ, while those without must wait on the lengthy organ donation list.").

179 *See id.*

180 *See id.*

not, as Congress envisioned and feared, drive a wedge between social classes in a way free-market natural human organs would.

An underlying catalyst behind this envisioned inequality is the anticipation that the majority of organ "sellers" would be low-income individuals.[181] Such a catalyst, however, is absent in a realm where 3D bioprinted organs exist. While inequality could arise with respect to wealthier individuals being able to better afford 3D bioprinted organs by similar logic, it would not similarly extend to incentivizing low-income individuals to physically deprive themselves of a body part—a situation that Congress imagined in a world where the sale and purchase of natural human organs was legalized. The concern of physical deprivation is not present in the transaction of a 3D bioprinted organ. One cannot be deprived of something he never owned or possessed.[182] The narrower scope of inequality associated with 3D bioprinted organs, relative to natural human organs, is largely due to a difference in these organs' origin. When talking about the sale of natural human organs, the theory is that low-income individuals would generally be directly subjected to inequality in two ways. As touched on earlier, the first mechanism captures donor-related inequality.[183] In a free-market of human organs, poorer people will face a greater incentive to donate their organs and will likely do so.[184] This decision, pressured by financial trouble, bears the risk of not being a well-informed one.[185] Moreover, the inequality surrounding the commodification of 3D bioprinted organs is more akin to, if not coterminous with, that of medical devices. Thus, 3D bioprinted organs should be regulated as medical devices.

C. THE FATE OF AN INFRINGING BIOPRINTED ORGAN

An individual who has a bioprinted organ subject to a successful patent infringement case will likely not be subject to a Smythe-like "seizure and extraction" for several reasons. First, seizure would certainly be contrary to longstanding public policy as the implant, albeit infringing, is nonetheless vital to that individual's health and wellbeing.[186] Additionally, as bioprinted organs should and will most likely be regulated as medical devices,[187] seizure of the infringing

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[181] *See id.*

[182] *See Deprivation*, BLACK'S LAW DICTIONARY (11th ed. 2019) ("An act of taking away."). In the event, however, that one gains a property right in a 3D bioprinted organ – if treated as a medical device regulation-wise – these rights would be established by contract (with the hospital/manufacturer) and hospital regulations. *See* discussion *supra* Part II.D; *See U-M Hospitals and Health Centers Policies and Procedures*, *supra* note 129 (example of internal hospital regulations for implants/explants).

[183] *See* discussion *supra* Part III.B.3.

[184] *See* Jacobson, *supra* note 90, at 1127.

[185] *See id.*

[186] *See, e.g.*, discussion about how pervading values of autonomy and bodily respect have influenced federal legislation *supra* Section II.D.1.

[187] *See* discussion *supra* Section III.B.

organ as the sole remedy for a patent infringement case would be counter to longstanding judicial practice.[188] Seizure would not serve a remedial purpose and would unduly burden the individual with the implant, rather than burden the primary infringer (the seller or manufacturer of the device). Judicial remedies, either compensatory or equitable, aim to make injured plaintiffs "whole again" or incentivize conformity with current law and disincentivize future aberrant behavior.[189] Seizing an individual's implant neither makes the patent owner "whole again" nor disincentivizes future infringement because the threat of seizure would be on the implant recipient, not the primary infringer. Thus, a remedy of "seizure and extraction" would be practically meaningless; it would merely be a remedy solely by name, not by function. Second, the seizure of infringing bioprinted organs would most likely be unconstitutional under the Fourth Amendment as an unreasonable search and seizure, and under the Fifth Amendment as a prohibited taking of private property.[190] Moreover given the myriad of policy and constitutional concerns, it is unlikely that individuals with infringing medical implants will end up like Smythe (at least not lawfully).[191]

IV. CONCLUSION

3D bioprinted organs will, more likely than not, be patent-eligible subject matter. It follows that a bioprinted organ, patented or not, should be regulated by the FDA as a medical device and should not be subject to NOTA's commodification ban on human organs. As NOTA stands now, 3D bioprinted organs do not fall within NOTA's regulatory framework. Neither should NOTA be amended to expressly cover 3D bioprinted organs as to preserve initial legislative intent.

With particular respect to *patented* 3D bioprinted organs, regulation of a patented 3D bioprinted organ as a "human organ" under NOTA would contradict a finding that a 3D bioprinted organ is patentable subject matter. Subjecting bioprinted organs to NOTA's anti-commodification provision would directly conflict with the patented organ's circumvention of § 101's law of nature exception. Thus, for the sake of remaining faithful to § 101's text and underlying intent, patented bioprinted organs should not be regulated as human organs.

As a final thought, the growing reality of bioprinted organs reflects the immense rate at which technology is growing and the astounding breadth of

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[188] *See, e.g.*, *Stryker Corp. v. Intermedics Orthopedics, Inc.*, 891 F. Supp. 751 (E.D.N.Y. 1995), *aff'd,* 96 F.3d 1409 (Fed. Cir. 1996) (rewarding $26,348,984 in lost profit damages to patentee's hip implant prosthesis).

[189] *See* Ted Sichelman, *supra* note 137 (explaining traditional remedies rewarded in patent infringement suits).

[190] U.S. CONST. amends. IV, V.

[191] As an additional consideration, family members who elect to sell a decedent's infringing implant would be protected from liability by the exhaustion doctrine. *See* discussion of the exhaustion doctrine *supra* Section II.E.2.

scientific innovation. We, the public, need to begin considering the brink on which we stand and ponder what possibly lies on the other side. A *Repo Men*-like world is grim, but knowledge serves as a vital component to preventing such an outcome. For the time being, it is unlikely that any of us will end up like Smythe. Remember though, "artiforgs" seemed like a distant reality in 2010 and now they are undergoing medical trials for implantation. Smythe's fate may similarly creep up on us if we turn a blind eye.