Do You Own Your 3D Bioprinted Body? 
Analyzing Property Issues at the Intersection of Digital Information and Biology

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I. INTRODUCTION

By the end of 2013, almost 122,000 organ transplant candidates in the United States remained active on the national waiting list. The current number of candidates exceeds 123,000. To address this overwhelming need, researchers have been exploring methods to supplement traditional organ donations. At the forefront of this research is regenerative medicine, the field of regenerating or replacing tissue and organ function by studying the body’s own healing mechanisms. Regenerative medicine is quickly fulfilling its promise of producing vascularized, functioning organs in vitro by combining two other areas of research: the replication of cell lines in vitro and the recent adaptation of three-dimensional printing for the health care industry. Today, physicians armed with the latest generation of bioprinters and imaging equipment are creating high-resolution airway splints and personalized bone replacements for human use. These techniques have even achieved success with more complicated structures, including human kidneys and livers.

1 See M. Celvin-Adams et al., OPTN/SRTR 2013 Annual Data Report: Heart, 15 AM. J. TRANSPLANTATION (SPECIAL ISSUE 2) 1, 9 fig.1.7, 20 fig.6.4 (2015) (3332 adult and 349 pediatric heart transplant candidates); R. Kandaswamy et al., OPTN/SRTR 2013 Annual Data Report: Pancreas, 15 AM. J. TRANSPLANTATION (SPECIAL ISSUE 2) 1, 7 fig.1.7 (2015) (2932 pancreas transplant candidates); W.R. Kim et al., OPTN/SRTR 2013 Annual Data Report: Liver, 15 AM. J. TRANSPLANTATION (SPECIAL ISSUE 2) 1, 6 fig.1.7, 20 fig.7.4 (2015) (15,001 adult and 577 pediatric liver transplant candidates); A.J. Matis et al., OPTN/SRTR 2013 Annual Data Report: Kidney, 15 AM. J. TRANSPLANTATION (SPECIAL ISSUE 2) 1, 9 fig.1.9, 25 fig.7.6 (2015) (96,533 adult and 1360 pediatric kidney transplant candidates); J.M. Smith et al., OPTN/SRTR 2013 Annual Data Report: Intestine, 15 AM. J. TRANSPLANTATION (SPECIAL ISSUE 2) 1, 6 fig.1.5 (2015) (257 intestine transplant candidates); M. Valapour et al., OPTN/SRTR 2013 Annual Data Report: Lung, 15 AM. J. TRANSPLANTATION 1, 9 fig.1.7, 19 fig.6.4 (2015) (1578 adult and 36 pediatric lung transplant candidates).

2 See HHS, Latest Data Report on National Waiting List Candidates, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, http://optn.transplant.hrsa.gov/latestData/viewDataReports.asp (follow “National Data” hyperlink; then select “Waiting List” for Step 1 category; then select “Candidates . . . .” for the counting method; then follow “Overall by Organ” hyperlink) (last visited Mar. 19, 2015). If patients require more than one type of organ transplant, then the calculated number of candidates may be greater than the total number of candidates.


4 See id. (describing the promise of regenerative medicine to stimulate “previously irreparable organs to heal themselves” and to empower “scientists to grow tissues and organs in the laboratory and safely implant them when the body cannot heal itself”).

5 Hannah Landecker, Between Beneficence and Chattel: The Human Biological in Law and Science, 12 SCI. CONTEXT 203, 211 & n.14 (1999) (observing that human tumor cell research in vitro started as early as 1913, but that the isolation and reproduction of the HeLa cell line in 1951 is attributed for the field’s historical success).

6 Natalja E. Fedorovich et al., Organ Printing: The Future of Bone Regeneration?, 29 TRENDS BIOTECH. 601, 601 (2011) (suggesting that three-dimensional printing can overcome the remaining challenges in regenerative medicine).

7 See, e.g., David A. Zopf et al., Biore sorbable Airway Splint Created with a Three-Dimensional Printer, 568 NEW ENG. J. MED. 2043 (2013).

8 See, e.g., Fedorovich et al., supra note 6, at 601.


Bioprinting is advancing at a dizzying pace, introducing questions to the legal profession that once sounded like science fiction. First and foremost, bioprinting challenges existing legal constructions of the human body that are tied to human biology. The rise of genomics in the 1990s has blurred the line between biology and digital information, but the relationship was primarily a one-way street from the biological to the digital. Bioprinting provides the missing path by transforming digital information into biological models that mimic actual organs. Second, bioprinting provides physicians with unprecedented access to models of a patient’s body, and the patient may be unaware of this access. This information asynchronicity will often carry the potential for abuse, especially when the interests of the physician and patient are misaligned. These issues should make us feel wary about the direction of bioprinting and our control over the digital self.

Structurally, this Note unfolds these issues in four parts. Part II provides the history of bioprinting, the implementation challenges, and insight into the future direction of the technology. Part III addresses the current legal landscape by examining the key cases that provide important policy considerations regarding bioprinting. Part IV analyzes the interests of the players in a hypothetical transplant of a bioprinted organ from an economic perspective. Part V offers a proposal on how to address the

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11 Throughout this Note, I use “bioprinting” to refer to techniques that produce functional human tissues and organs by three-dimensional printing technology in the field of regenerative medicine.

12 See MICHAEL CRICHTON, NEXT 251-52, 357-59, 372-77, 393-95 (2006) (discussing the fictional consequences of granting property rights over cell lines, such as the use of eminent domain to retrieve additional samples from the source or from descendants); Osagie K. Obasogie & Helen Thung, Moore Is Less: Why the Development of Induced Pluripotent Stem Cells Might Lead Us to Rethink Differential Property Interests in Excised Human Cells, 16 STAN. TECH. L. REV. 51, 69 (2012) (noting that advances in induced pluripotent stem cell research, a critical development for bioprinting, “raises important questions for property law that have not even been articulated yet alone addressed”).

13 See, e.g., Aaron T. Norton & Ozzie Zehner, Which Half Is Mommy? Tetragametic Chimerism and Trans-Subjectivity, 36 WOMEN’S STUD. Q. 106, 122 (2008) (“A challenge to professionals and lay individuals is (and will continue to be) to imagine alternative legal and medical frameworks that open more space to valuing lived experience over genetic codes, . . . . These legal precedents will not only directly challenge deterministic genetic assumptions but will also become reflexively involved with our evolving conceptualizations of bodies and their interrelations.”).

14 EUGENE THACKER, THE GLOBAL GENOME: BIOTECHNOLOGY, POLITICS, AND CULTURE 29 (2005) (“Genome databases, biological ‘libraries’ of cell lines, patient databases at hospitals and clinics, prescription databases, insurance databases, online medical services, and a host of other innovations are transforming the understanding of ‘life itself’ into an understanding of informatics.”)

15 The relationship was asymmetric in the sense that it was easier to translate biological data into digital information than the reverse — creating a biological form by means of a digital blueprint. See id. (“In rarer cases, cell therapies, in vitro fertilization, genetic screening, and tissue engineering are literal instances of this biopolitical condition, in which data is made flesh.” (emphasis added)); TED, Craig Venter Unveils “Synthetic Life,” YOUTUBE (May 21, 2010), https://www.youtube.com/watch?v=QHIocNOHd7A (unveiling “the first synthetic cell, a cell made by starting with the digital code in the computer” after fifteen years of effort).

16 See TED, supra note 9 (“So we go layer by layer through the organ, analyzing each layer as we go through the organ, and we then are able to send that information, as you see here, through the computer and actually design the organ for the patient.”).

17 See TED, Nina Tandon: Could Tissue Engineering Mean Personalized Medicine?, YOUTUBE (Dec. 6, 2012), https://www.youtube.com/watch?v=r6nSmSTKHGc (“[T]issue engineering is actually poised to help revolutionize drug screening at every single step of the path: disease models making for better drug formulations, massively parallel human tissue models helping to revolutionize lab testing, reduce animal testing and human testing in clinical trials, and individualized therapies that disrupt what we even consider to be a market at all.”).

18 See, e.g., Landecker, supra note 5, at 219 (suggesting that the attending physician manipulated Moore, the patient, into scheduling follow-up visits since it “was vital to Golde’s patent application that Moore’s blood not enter the public domain.”).
issues raised by bioprinting. The Note concludes with a discussion on the significance of bioprinting at the intersection of property and health law.

II. HISTORY OF BIOPRINTING

A. THE PROTOTYPING BREAKTHROUGH: THREE-DIMENSIONAL PRINTING

Rapid prototyping techniques, including three-dimensional printing, blend the low-cost scalability of mass-produced products with the personalized properties of a tailor-made product. In order to accomplish these goals, the techniques take advantage of two design principles. Dispersion, the first principle, recognizes that complicated designs can be reduced into an abstraction of simpler subsystems and components. In the case of a complicated three-dimensional structure, the structure can be reduced into a series of two-dimensional layers, which can be further reduced into lines and points. Additive manufacturing, the second principle, recognizes that a manufacturer can deposit simple materials in a specific arrangement to arrive at the original design. If a droplet can approximate a point, then a specific arrangement of droplets can form lines, which in turn can be used to form two-dimensional layers and eventually the desired structure.

Early rapid prototyping techniques existed in layered manufacturing patents as early as 1892. However, it was the significant technological advances during the 1980s that led to the development of three-dimensional printing, beginning with the rise of computer-aided design ("CAD") software and ultraviolet light-cured resin. While rapid prototyping principles can be practiced with traditional manufacturing techniques, digital environments supported by CAD software are ideally equipped to handle the complicated mathematical calculations used in dispersion. Furthermore, computer-aided manufacturing ("CAM") software can generate a path for reconstructing the desired object in a format that can be understood by automated manufacturing equipment, allowing a manufacturer to potentially realize savings in both man-hours and the overall production time. The development of ultraviolet light-cured resin allowed manufacturers to use known lithography techniques to print the dispersed layers of an object while bonding two adjacent layers together. A laser emitting ultraviolet radiation, guided by the path generated by the digital environment, would selectively scan the surface of a pool of resin in order to create a thin layer of...
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Cured resin. After many iterations of curing and incrementally shifting the cured layers away from the pool’s surface to expose more resin, the layers bond together and form a three-dimensional model.

The cost of three-dimensional printing has decreased through innovation and a shift from institutional to consumer-driven demand, but the fundamental process of developing a printed object has not changed significantly. The process 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 CAD software. This blueprint exists in a digital format that can be transferred anywhere over the Internet, giving rise to large online repositories of three-dimensional models that any Internet user can access. Then, CAM software translates this digital blueprint into a path that a machine will follow to assemble a real object from a variety of materials. The translation may vary by implementation, which primarily falls under two categories: techniques that rely on a laser or electron beam and techniques that rely on extrusion or droplets.

B. REGENERATIVE MEDICINE AND THREE-DIMENSIONAL PRINTING

Regenerative medicine has been studied since the early-to-mid twentieth century. Yet, the 1990s and early 2000s held the critical developments in biomaterials, cell growth, and vascular networks necessary for growing organs in vitro.

See Yongnian, supra note 20, at 4.
See "330 Patent col. 5 ll. 55-59 ("[A]s the fluid medium cures and solid material forms to define one lamina, that lamina is moved away from the working surface of the fluid medium and the next lamina is formed in the new liquid which replaces the previously formed lamina . . . ")."
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 3 (2010), http://publicknowledge.org/files/docs/3DPrintingPaperPublicKnowledge.pdf. The brevity of my description here does not imply that this step is simple. On the contrary, at least one leader in this field has suggested that the creation of a digital blueprint is an important barrier in the adoption of three-dimensional printing. TED, Lisa Harouni: A Primer on 3D Printing, YOUTUBE (Jan. 23, 2012), https://www.youtube.com/watch?v=OhYvDS7q V8 ("[W]hy don’t we all have one in our home? Because, simply, most of us here today don’t know how to create the data that a 3D printer reads . . . But there are more and more technologies, software and processes today that are breaking down those barriers.").
Weinberg, supra note 32, at 3.
Id. To simplify the technique employed by CAM software, assume that the software divides the digital rendering into stackable layers that can be printed one at a time. For example, if the intended object is an apple, the CAM software acts as a knife to thinly slice the apple. Then, the CAM software translates each layer into a set of instructions for the printer tool to follow, ensuring that the layers are filled properly. Three-dimensional printers today may employ a variety of techniques to hold the final object together, including a modified version of the ultraviolet light-cured resin process or a laser sintering process that fuses the deposited material. See Yongnian, supra note 20, at 4-6.
See Yongnian, supra note 20, at 4-6. For example, stereolithography, the technique involving a laser described in notes 28-30 and accompanying text, requires the formation of removable structures in order to support more complicated designs. See id. at 4. Another technique uses an ink-jet printing nozzle to deposit a small droplet of a liquid binding agent onto a powdered surface. See id. at 6. Once all of the droplets have been deposited for a single layer, a new thin layer of powder is spread over the previous surface. See id. Since the binder only causes adjacent material to solidify, the undisturbed powder provides support during formation but can be dusted off the final structure. See id. This process may use less material and follow a different tool path because no support structures are necessary. See id.
See TED, supra note 9.
Id.
Biomaterials are materials that can be successfully transplanted in a patient without rejection, including biodegradable polymers, ceramics, hydrogels, and combinations of the materials. Two common materials used in the three-dimensional printing industry—polymers and ceramics—are compatible with most printing techniques and have properties that offer a high degree of control, but the techniques are either too toxic or too extreme for live cells to be seeded during the printing process. These materials are best suited for "scaffolds," the base structures that are separately seeded with cells before a transplant.

Hydrogels, which are polymer chains that retain their three-dimensional shapes after absorbing water, have been successfully employed during the three-dimensional printing process to provide structure and deliver cells. The main interest in using hydrogels is that a cell can be suspended in a droplet of hydrogel, providing both a three-dimensional structure and an environment mimicking the properties of natural tissue. One challenge with hydrogels is creating a process that forms the droplets and links droplets of the hydrogel together without harming the suspended cells. The current solutions limit the available printing techniques available for hydrogels, significantly impacting resolution and speed. Another challenge is balancing the need for high-density hydrogel structures to increase strength and stability with the need for low-density hydrogel structures to promote cell migration and formation of vascular networks.

Sugar is also a promising material to use with hydrogels where intricate vascular networks require external assistance. Researchers are using sugar in a three-part sacrificial molding technique, rather than as a stand-alone biomaterial. In order to accomplish this, the vascular network is printed as a lattice of thin filaments in a type of sugar called carbohydrate glass, which is a mixture of sucrose and glucose developed for the food industry. Channels are then formed by casting the lattice network in a suspension of cells and hydrogel. Finally, the lattice network is dissolved, allowing the sugar to flow out of the structure through the formed channels. Like polymer and ceramic, sugar is compatible with some of the available high-resolution printing techniques; and, unlike polymer and ceramic, sugar has the

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38 See id.
39 See Melchels et al., supra note 19, at 1086.
40 Id. at 1087. Cell seeding is the spreading of viable cells onto a porous or mesh structure in a manner that encourages uniform cell distribution and penetration. See Gustavo A. Villalona et al., Cell-Seeding Techniques in Vascular Tissue Engineering, 16 TISSUE ENGINEERING: PART B 341, 342 (2010). A variety of cell seeding techniques have been developed, including gravity seeding, rotational seeding, and vacuum seeding. See id. at 342-43.
41 See Melchels et al., supra note 19, at 1086.
42 Id. at 1087.
43 See id.
44 Id.
45 Id.
47 Melchels et al., supra note 19, at 1088.
48 See Miller et al., supra note 45, at 768.
49 Id. Sacrificial molding refers to techniques where one material is cast into a bulk material with the intention of "sacrificing" the first material in order to reveal an intricate architecture within the bulk material. See id.
50 Id. (identifying carbohydrate glass as a material that had sufficient mechanical strength, dissolvability, and biocompatibility in the presence of living cells). In one embodiment, the carbohydrate glass was reinforced with dextrans, which also improved temperature stability. Id.
51 See id.
52 For a detailed explanation of the encapsulation method, see id. at 773.
53 Id. at 770 fig.2.
additional advantage of dissolving easily in the presence of living cells. The current disadvantage of using sugar is that the suspension of cells and hydrogel is not printed alongside the sugar; the suspension is cast around the sugar in a separate step.

In order to generate the cells used with these techniques, researchers have had to develop techniques for growing cell cultures that can differentiate into the specialized cells of an organ. In the past, embryonic stem cells showed promise for such a task, but the techniques used to extract these cells raised ethical objections. Current research efforts have yielded an exciting and less controversial method to achieve the same result: induced pluripotent stem cells (IPSCs).

IPSCs are the ideal solution for bioprinting in three regards: (1) they continue to divide for a long time in vitro; (2) they can be recruited as specialized cells, which perform the individual functions required by organs; and (3) a patient sample can be as unobtrusive as a skin scraping.

C. THE FUTURE OF BIOPRINTING

Do researchers need IPSCs in order to make bioprinting feasible? One day, computerized genome sequencing may allow doctors to create a bioprinted organ without a sample of the patient’s cells. The technology to make this a reality is lacking today, but the path has been charted with the development of the synthetic, self-replicating cell.

Researchers are also investigating the viability of organ fabrication as a commercial substitute for traditional organ donations. Three factors are critical for its success: automation, integration, and quality control. The development of three-dimensional printer technology holds the promise to address automation issues, especially as robotic control to deposit hydrogels and cellular spheroids continues to improve speed and resolution. By depositing the cells directly, the fabricator avoids

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52 Id. at 768 (noting that prior to using a type of sugar called carbohydrate glass, the organic solvents used were toxic to living cells and the process used to remove the lattice structure were harmful to living cells).
53 See id. at 770.
54 See TED, supra note 9 (remarking that the ability to grow different kinds of cells was a challenge to bioprinting).
55 See Obasogie & Theung, supra note 12, at 67 (noting the ethical controversy surrounding the destruction of human embryos that was necessary to further embryonic stem cell research).
56 Id. ("[T]he 2007 discovery of iPSCs was heralded as a new technology that might resolve this ethical and political problem.").
57 Id. at 66-67.
58 See id. at 68 (describing the success of inducing a pluripotent state in the skin cells of mice); TED, supra note 17 ("We induce cells, okay, say, skin cells, by adding a few genes to them, culturing them, and then harvesting them. So they’re skin cells that can be tricked, kind of like cellular amnesia, into an embryonic state. . . . [Y]ou can grow any type of tissue out of them: brain, heart, liver, you get the picture, but out of your cells.").
59 While computerized genome sequencing is not available today, it may be possible in the future. Cf. PRESIDENTIAL COMM’N FOR THE STUDY OF BIOETHICAL ISSUES, NEW DIRECTIONS: THE ETHICS OF SYNTHETIC BIOLOGY AND EMERGING TECHNOLOGIES 3 (2010), available at http://permanent.access.gpo.gov/gpo9019/PCSBI-Synthetic-Biology-Report-12.16.10.pdf ("The technical feat of synthesizing a genome from its chemical parts so that it becomes self-replicating, when inserted into a bacterial cell of another species, while a significant accomplishment, does not represent the creation of life from inorganic chemicals alone. . . . The feat therefore does not constitute the creation of life, the likelihood of which still remains remote for the foreseeable future.").
60 See TED, supra note 15.
61 See Mironov et al., supra note 31, at 667.
62 Id. at 668.
63 See id. at 668-69.
the manual steps involved in scaffolding and lattice networks.\textsuperscript{64} Integration is currently being explored by combining a bioreactor—an environment that promotes the growth of a vascular network in the bioprinted organ—and the bioprinter.\textsuperscript{65} Additionally, the fabrication stage for the cellular spheroids and hydrogel droplets is being developed for the bioprinter, but storage and premature fusion of the cells must be overcome to make integration feasible.\textsuperscript{66} Finally, quality control is important, as product failures may have great consequences in lifesaving organ transplants.\textsuperscript{67} In order to automate quality control, sensors will need to be developed to monitor progress at each stage and allow the system to respond in real-time.\textsuperscript{68} The planning phases ahead of the creation of an organ are equally important for reducing failures and obtaining regulatory approval.\textsuperscript{69}

II. LEGAL LANDSCAPE

If bioprinting is beginning to bridge the gap between human biology and data,\textsuperscript{70} then a two-pronged approach is appropriate for analyzing the policy arguments that relate to bioprinting. With respect to the biology side of the argument, the Moore case and its progeny provide the background for analyzing property interests in organs and tissue outside the human body.\textsuperscript{71} The second prong relates to the Myriad case, in which the Supreme Court addressed potential property interests in genetic information.\textsuperscript{72}

A. THE ROAD TO MOORE: HENRIETTA LACKS AND THE HE-La CELL LINE

In 1951, Dr. George Gey was attempting to grow cervical cancer cells in vitro.\textsuperscript{73} At the same time, a patient named Henrietta Lacks went to Johns Hopkins Medical School for a biopsy of a lesion on her cervix.\textsuperscript{74} Though Lacks died eight months later of cervical cancer, her legacy survived through the lesion tissue from her biopsy.\textsuperscript{75} Gey received a portion of the tissue, and his successful proliferation of the cells in vitro gave rise to the popular HeLa cell line.\textsuperscript{76} Rather than patent the HeLa cells, Gey distributed the cells without restriction.\textsuperscript{77} The HeLa cells were seen as “a great scientific success” and even played a role in the development and testing of Dr. Jonas Salk’s polio vaccine.\textsuperscript{78}

\textsuperscript{64} See id. at 667.
\textsuperscript{65} See id. at 670 (explaining that use of a bioreactor provides a critical step in bioprinting because it accelerates tissue maturation).
\textsuperscript{66} Id. at 669.
\textsuperscript{67} Id. at 671.
\textsuperscript{68} Id. at 671-72.
\textsuperscript{69} Id. at 677.
\textsuperscript{70} See supra text accompanying note 15.
\textsuperscript{71} Moore v. Regents of the Univ. of Cal., 793 P.2d 479 (Cal. 1990).
\textsuperscript{72} Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013).
\textsuperscript{73} Landecker, supra note 5, at 212.
\textsuperscript{74} Id.
\textsuperscript{75} Id.
\textsuperscript{76} Id. HeLa is the oldest human cell line that is widely used in scientific research. Id. While I do not discuss the issue in depth here, it is worth noting that the original HeLa cells were taken from Lacks without her knowledge or consent. For more information about the complicated ethical issues raised by Lacks’ own lack of property rights in her cells, see, generally, REBECCA SKLOOT, THE IMMORTAL LIFE OF HENRIETTA LACKS (2010).
\textsuperscript{77} Id.
\textsuperscript{78} Id.
Early on, the scientific community viewed the cell line as an extension of Lacks, such that the "immortalization" of the HeLa cells resulted in the perceived "immortalization" of Lacks herself after death. Beyond the metaphysical question of whether Lacks’s personhood survived her death, this notion of integrity between the cell line and person was necessary to further academic research. If the HeLa cells could exist apart from Lacks, their validity as a human analog and as a living organism would be questioned.

These continuity arguments lost ground in the 1980s. After recognizing the significant rewards that could be gained from working with valuable cell lines, researchers turned to patent law to obtain monopolies over their discoveries. However, to win such a potentially lucrative property right, the researchers had to form arguments appealing to a Lockean labor view of property. Unlike the prevailing personhood theory that recognized a property interest in things that were fundamentally bound up with one’s identity, the Lockean labor theory assumes that people own the fruits of their labor. Recognizing that such a departure may undermine the integrity of academic research with cell lines, the researchers also proposed to redefine the term “living” as the ability to “retain . . . biochemical integrity and . . . replicate.” These polarizing views on property rights in human cells paint the backdrop for the California Supreme Court case that followed.

1. Moore v. Regents of University of California

In Moore v. Regents of University of California, the Supreme Court of California considered an argument for an absolute property right in tissues and organs that have been abandoned by a patient. The plaintiff, John Moore, was treated for hairy-cell leukemia at the University of California at Los Angeles Medical Center. After a splenectomy, Moore’s attending physician and a researcher employed by the university made arrangements to study portions of Moore’s spleen at another research unit. By virtue of their access to the spleen, the attending physician and the researcher filed a patent that entitled them to a share of the university’s royalties and profits from the “potentially lucrative” cell line developed from the spleen. In order to ensure the validity of their patent, the attending physician carefully limited the information he

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79 B.J.C., HeLa (for Henrietta Lacks), 184 Sci. 1268, 1268 (1974). Early attributions were actually made to a pseudonym of Henrietta Lacks, Helen Lane, but the personhood argument for the immortality of Lacks still carried the same force. See id.
80 Landecker, supra note 5, at 214 (noting that “the information gleaned from cells is useless unless it eventually relates back to the biology and then the pathology of the patient”).
81 See id. (“The continuity between person and cell line was the rationale for using ‘cells in place of the whole patient.””).
82 Id. at 215.
83 Id.
84 See id. at 216 (noting that research institutions expended “real capital” in order to obtain potentially lucrative results, so the institution should gain the benefit of their expenditure).
85 See id. at 215 n.17 (characterizing the views as the “Lockean paradigm of radical individualism assuming a dualism between the body as commodity and the person as transactor and an older paradigm in which ownership of the self is understood in terms of the ability to defend one’s inalienable corporeal integrity against oppression and abuse”).
86 Id. at 215 (internal quotation marks omitted).
87 Moore, 793 P.2d 479.
88 Id. at 480.
89 Id. at 481.
90 Id. at 480, 482. While Moore signed a general consent form regarding his splenectomy, the court noted that “neither Golde nor Quan informed Moore of their plans to conduct this research or requested his permission.” See id. at 481.
told Moore about the research and limited Moore’s access to other facilities for drawing blood samples.\footnote{Landecker, supra note 5, at 219 (noting that “this anticipation also structured Golde’s manipulation of his human patient’ and that Moore’s blood could “not enter the public domain”).}

Among Moore’s claims was a claim for conversion, under the theory that Moore had ownership and possessory rights to the cell line and he did not extend authorization for the use of his spleen.\footnote{Id. at 488-89.} The court disagreed, first concluding that Moore could not have a possessory interest in the spleen after its removal.\footnote{Id. at 489 n.20.} Moore did not request possession of the actual cells in his complaint, and the court noted that such a request would have gone against California statutory law regarding the disposal of human tissue “by interment, incineration, or any other method determined by the state department of health services to protect the public health and safety.”\footnote{Id. at 489-91 (refusing to equate privacy rights with the property rights necessary for a conversion claim).} Then, the court systematically rejected Moore’s claim for ownership rights under (1) tort law concerning privacy rights,\footnote{Id. at 491-92 (concluding that the “practical effect” of the statutory scheme was the limitation of a property interest).} (2) the California statutory law regarding the destruction of excised cells,\footnote{Id. at 492-93 (concluding that the issued patent is an authoritative determination that the cell line and its derivative products were a product of invention, both “factually and legally distinct” from the cells taken from Moore).} and (3) patent law.\footnote{Id. at 497.} The court also refused to extend conversion theory to the facts of this case.\footnote{Id. at 497.} Although the court conceded that the legislature was better suited to balance the overriding policy considerations,\footnote{Id. at 492-93 (concluding that the issued patent is an authoritative determination that the cell line and its derivative products were a product of invention, both “factually and legally distinct” from the cells taken from Moore).} the court determined that the potential chilling effect on socially important medical research outweighed the patient’s “right to make autonomous medical decisions.”\footnote{Id. at 493-97 (noting that a patient still has the protection of tort liability when a physician violates a duty of disclosure).}

Moore provides key insight into the considerations for common law property rights in organs. The public has a strong interest in encouraging socially important medical research.\footnote{Id.} In light of the growing shortage of organs,\footnote{Id. at 496 (concluding that “[l]egislative interest is demonstrated by the extensive study recently commissioned by the United States Congress”). The study referenced by the Court, the “OTA Report,” expressed that “companies are unlikely to heavily invest in developing, manufacturing, or marketing a product when uncertainty about clear title exists.” Id. at 494 (citing OFFICE OF TECH. ASSESSMENT, U.S. CONGRESS, NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUES AND CELLS (Chris Elfring ed., 1987)).} research into alternative sources, such as bioprinted organs, is a strong public interest that may compel a court to create a common law right to sell organs. Yet, courts will likely defer to legislative intent and patent law to more appropriately balance the complex policy arguments that may arise,\footnote{Id. at 493-97 (noting that a patient still has the protection of tort liability when a physician violates a duty of disclosure).} especially in the face of ethical considerations against selling organs.\footnote{See supra text accompanying notes 1-2.} In the case of bioprinted organs, a court may find clear
legislative intent in the federal ban against the transfer of human organs “for valuable consideration.”

Oddly, the personhood argument that championed the right to personal liberty in the early life of the HeLa cell line was not sufficiently compelling for the Moore court. Still, the court identified the right as an overriding policy consideration and left open the possibility that the right could be used given another set of facts.

2. Cases Following Moore and the “Potential for Human Life”

At least one scholar has noted that a line of cases has branched from the Moore analysis with one critical factual difference: the cases concerned embryos and reproductive tissue. In 1992, the Supreme Court of Tennessee, in the case of Davis v. Davis, analyzed the interests of a divorced couple to dispose of frozen embryos in the absence of a state statute. Without concluding that the embryos were property or people, the court held that the embryos’ “potential for human life” entitled the genetic parents to “decision-making authority” over the embryos. Unlike Moore, the husband was able to prevail by invoking a personal autonomy argument, in particular the right to avoid procreation.

3. The Road to the Myriad: The Bayh-Dole Act

Before the 1980s, the federal government followed a general policy in which it retained title to inventions supported by government funding. As a result, only five percent of government-owned patents were used in the private sector, despite a total expenditure of $55.5 billion on research and development projects in 1980. Thus, the Bayh-Dole Act was a legislative initiative in 1980 “to cut down on bureaucracy and encourage private industry to utilize government financed inventions through the commitment of the risk capital necessary to develop such invention to the point of commercial application.”

Since government funds are typically expended for research in public goods, Congress made a policy trade-off; it determined that bringing the products of these research efforts to market and encouraging increased innovation was more important than recouping the government’s initial investment. Some critics warned that the public would not benefit sufficiently from the government’s investment in the biotechnology and pharmaceutical industries, where therapeutic costs were prohibitively high to seniors. The critics noted that the act’s flaw stems from its inability to distinguish “between inventions that lead directly to commercial products...
and fundamental advances that enable further scientific studies.” Gene research was influenced the most; approximately 33,000 patents related to DNA were granted by 2006. This tension set the background for the Supreme Court’s decision in Myriad.

4. The Myriad Decision

Myriad Genetics, Inc. ("Myriad") made a medical breakthrough in discovering the location of the BRCA1 and BRCA2 gene sequences. Mutations are changes in a genetic sequence, and Myriad’s discovery linked a mutation of BRCA1 and BRCA2 with a fifty to eighty percent risk of breast cancer and a twenty to fifty percent risk of ovarian cancer in women. Myriad used this knowledge to develop tests for the detection of BRCA1 and BRCA2 mutations that would signal an increased risk for breast and ovarian cancer. Myriad proceeded to obtain broad patents that claimed the DNA sequences for BRCA1 and BRCA2, the cDNA sequences that code for BRCA1 and BRCA2, and subsets of these sequences. Assuming that the patents

117 Id. at 22.
118 NAT’L RESEARCH COUNCIL, REAPING THE BENEFITS OF GENOMIC AND PROTEOMIC RESEARCH: INTELLECTUAL PROPERTY RIGHTS, INNOVATION, AND PUBLIC HEALTH 101 (2006) (noting that from 1971 to 2006, approximately 33,000 patents were issued). However, no more than 100 DNA-related patents were being issued per year until 1980. The annual rate peaked in 2001 at 4,500 issued DNA-related patents per year. Id. at 101-03.
120 Myriad, 133 S. Ct. at 2112; see also Ass’n for Molecular Pathology v. USPTO, 689 F.3d 1303, 1314 (Fed. Cir. 2012) (“Relying on a large set of DNA samples from families with inherited breast and ovarian cancers, the inventors correlated the occurrence of cancer in individual family members with the inheritance of certain marker DNA sequences.”).
121 Myriad, 133 S. Ct. at 2112 (observing that an average American woman has a twelve to thirteen percent risk of developing breast cancer).
122 Id. at 2112-13.
123 Id. at 2113. The Federal Circuit described the relevant technology, including cDNA, in the following manner:

Sequences of DNA nucleotides contain the information necessary to create strings of amino acids, which in turn are used in the body to build proteins. Only some DNA nucleotides, however, code for amino acids; these nucleotides are known as “exons.” Nucleotides that do not code for amino acids, in contrast, are known as “introns.”

Creation of proteins from DNA involves two principal steps, known as transcription and translation. In transcription, the bonds between DNA nucleotides separate, and the DNA helix unwinds into two single strands. A single strand is used as a template to create a complementary ribonucleic acid (RNA) strand . . . known as pre-RNA, whose nucleotides form an inverse image of the DNA strand from which it was created. Pre-RNA still contains nucleotides corresponding to both the exons and introns in the DNA molecule. The pre-RNA is then naturally “spliced” by the physical removal of the introns. The resulting product is a strand of RNA that contains nucleotides corresponding only to the exons from the original DNA strand. The exons-only strand is known as messenger RNA (mRNA), which creates amino acids through translation. In translation, cellular structures known as ribosomes read each set of three nucleotides, known as codons, in the mRNA. Each codon either tells the ribosomes which of the 20 possible amino acids to synthesize or provides a stop signal . . . .

DNA’s informational sequences and the processes that create mRNA, amino acids, and proteins occur naturally within cells . . . . It is . . . possible to create DNA synthetically through processes similarly well known in the field of genetics. One such method begins with an mRNA molecule and uses the natural bonding properties of nucleotides to create a new, synthetic DNA molecule. The result is the inverse of the mRNA’s inverse image of the original DNA, with one important distinction: Because the natural creation of mRNA involves splicing that removes introns, the synthetic DNA created from mRNA also
gave Myriad the exclusive right to isolate BRCA1 and BRCA2 sequences in DNA and to create BRCA1 and BRCA2 cDNA. Myriad sent letters insisting that entities stop genetic testing on BRCA1 and BRCA2. Patients, advocacy groups, and some of the targeted entities initiated a lawsuit to declare the Myriad patents invalid. Weighing in on the case, the Supreme Court held that the mere isolation of a naturally occurring DNA segment is not patent-eligible under 35 U.S.C. § 101, but a distinguishable cDNA segment is patent-eligible.

To reach this conclusion, the Court analyzed the claims in light of the framework it established in Chakrabarty over three decades earlier. In Chakrabarty, the subject matter at issue related to a genetically engineered bacterium that could break down crude oil. The Supreme Court held that the bacterium was patent-eligible under section 101. The Court explained that “a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity ‘having a distinctive name, character [and] use’” does not qualify as a product of nature and therefore is eligible under section 101. In Myriad, the Court simplified this framework into a two-step test. First, the Court analyzed whether the sequences had “markedly different characteristics from any found in nature.” In the case of the DNA segments, Myriad focused its claims on the encoded genetic information, not the chemical composition of the DNA segments. Because the DNA segment claims matched the genetic information encoded in naturally-occurring BRCA1 and BRCA2 gene sequences, the claimed DNA segments did not have “markedly different characteristics.” Second, the Court analyzed whether Myriad created or altered the genetic information. With respect to the DNA segments, the Court concluded that “Myriad did not create anything” and that merely “separating that gene from its surrounding genetic material is not an act of invention.”

Turning to the cDNA segments, the Court applied the same two factors with a different result. First, the Court recognized that the cDNA segments had a critical difference from their DNA counterparts. The process to create cDNA contains only the exon sequences. This synthetic DNA created in the laboratory from mRNA is known as complementary DNA (cDNA).
protein-coding regions of the DNA sequence while omitting the non-coding regions.\textsuperscript{138} Second, the Court concluded that Myriad created something new in the translation process from mRNA.\textsuperscript{139} Arguably, a distinction could be made here, since the cDNA was “dictated by nature, not by the lab technician” during mRNA translation.\textsuperscript{140} However, the Court rejected this argument.\textsuperscript{141} Therefore, the claims relating to cDNA segments were patent-eligible.

Applying this framework to bioprinting requires a walkthrough of the various components that may qualify for protection. First, a patient’s raw digital scans may serve as valuable information that warrants protection. Unless a physician modifies the scans, an exact copy is unlikely to be viewed as “markedly different” from the original organ.\textsuperscript{142} It is true that the scans are in an electronic, reproducible format and the original organs are tangible, but Myriad clarified the rule that merely claiming the same genetic information that occurs in nature\textsuperscript{143} or identifying the location of information in nature is not patent-eligible.\textsuperscript{144} Therefore, the raw digital blueprints from an organ scan will unlikely receive the benefit of patent protection.

Less clear is the patentability of a scanned organ that retains its form but has been transformed into a mesh structure with structural improvements in order to function as a scaffold.\textsuperscript{145} At least one author suggests that this is sufficient to satisfy the “markedly different” portion of the section 101 inquiry.\textsuperscript{146} Typically, the biomaterials used in bioprinting are proprietary chemical formulations, and therefore will likely satisfy section 101 requirements.\textsuperscript{147} While the section 101 inquiry is a good starting place to determine patent eligibility, it is not the only inquiry relevant in the prosecution of a patent.\textsuperscript{148} The overall patentability inquiry is fact dependent, and often the body of prior art,\textsuperscript{149} the

\begin{flushright}
138 \textit{Id.} at 2111.
139 \textit{Id.} at 2119 (“That may be so, but the lab technician unquestionably creates something new when cDNA is made.”).
140 \textit{Id.}
141 \textit{Id.}
142 \textit{Id.} at 2117.
143 \textit{Id.} at 2118.
144 \textit{Id.} at 2117 (“Myriad found the location of the BRCA1 and BRCA2 genes, but that discovery, by itself, does not render the BRCA genes ‘new . . . composition[s] of matter,’ that are patent eligible.” (internal citation omitted)).
145 See Melchels et al., \textit{supra} note 19, at 1090 (“Using this method, one can generate porous models that have the overall shape of the scanned tissue and/or organ, built up from fully connected straight struts to ensure manufacturability and optimal mechanical stability.”). While it is not a scanned and printed scaffold, patents have been granted for a scaffold created by decellularizing a donor organ. See, e.g., Culturing Different Cell Populations on a Decellularized Natural Biostructure for Organ Reconstruction, U.S. Patent No. 6,479,064 (filed Dec. 29, 1999).
147 See Melchels, \textit{supra} note 19, at 1086.
148 See Martin & Horton, \textit{supra} note 146 (“Patentability will likely rest on what the applicant seeks to patent . . . .”).
timeliness of application, and the disclosure to the Patent and Trademark Office will decide the ultimate question of patentability.

III. WHY IS A DIGITAL SCAN OR BIOPRINTED ORGAN VALUABLE?

A. DICHOTOMY OF GOODS ACCORDING TO RIVALRY AND COMPETITIVENESS

Since a patient, physician, university, and biotechnology company will experience different benefits from bioprinting and bioprinted organs, a brief discussion of rivalry and exclusivity is necessary in order to understand each party’s expected value. Some economists categorize property along axes of rivalry and exclusivity in order to simplify the relationship between private markets and state regulation of property. Rivalry is the degree that the use or consumption of a good reduces its availability for a subsequent user. Exclusivity is the ability to prevent others from enjoying the good.

As noted in Parts 0 and 0, three starting materials are necessary to reproduce a vascularized, functioning organ with three-dimensional printing technology: a digital blueprint of the organ’s structure, the hydrogel or scaffolding biomaterial, and a culture of cells. Like other forms of digital information, a blueprint of the organ’s structure has the potential to be copied without data loss or alerting the blueprint’s owner. Furthermore, experts warn that “once a networked machine has information, you lose all control over the disposition of the data.” In this sense, a digital blueprint lends itself to treatment as a public good due to its nonrivalrous, nonexclusive nature. Likewise, biomaterials can be reduced to chemical formulae and distributed as digital information. If patent law is excluded from this discussion, biomaterial also inherently fits the criteria for public goods.

Extending this rivalry and exclusivity analysis to cells is more complicated because the source of the cells becomes relevant. Normal human cell activity in vivo and in vitro suggests that cells generally will only sustain division for “a few dozen generations.” Yet, stem cells and cancer cells have the unusual potential for unlocking endless self-replication. This replication process is still subject to factors

\[\text{id.}\]

See id. $102(b)$.

See id. $112$.

See Landecker, supra note 5, at 205 ("Because patient, doctor, university, and biotechnology company each laid claim differently to the cell line, around it an intricate network of symbolic, material, legal, and monetary relations was rendered visible.").


See id.

See id.

See id. at 173 (asserting that the only reasonable protective measure is to isolate sensitive data from computers).

Kaul & Mendoza, supra note 153, at 87.

Id. at 84 (noting the specific example of a chemical formula as a nonrivalrous good due to its ease of being spread through email).

Id. ("In the form in which society often likes to see them, they fall into . . . the private domain, as nonrival but exclusive goods . . . . Judged on its natural properties, such knowledge is probably more of a nonrival, nonexclusive good . . . .").


See id. at 14, 16; Thomas A. Rando, Stem Cells, Ageing and the Quest for Immortality, 441 NATURE 1080 (2006) (discussing the possibility of stem cell use in regenerative medicine).
that reduce the cells’ genetic integrity, including an increased chance of mutations\textsuperscript{163} and sample contamination\textsuperscript{164} with each generation, but stem cells and cancer cells have unusually robust mechanisms to resist and repair damage.\textsuperscript{165} Since a cell line has the potential to self-replicate \textit{in vitro} independent from its source, the cell line can be viewed as a nonrivalrous good.\textsuperscript{166} A possessor of a cell line may lose control over the cells after the initial transfer of a culture, pushing the cell line towards the nonexclusive side of the axis and the category of a public good.\textsuperscript{167} In addition, a patient acts as a plant for the production of the parent cells for the cell line without regard to the consumption by other parties.\textsuperscript{168} Unlike the cell line, access to the parent cells is limited by physical proximity to the patient and the remaining shelf life of the cells.\textsuperscript{169} If a physician and a patient colluded to control access to the cells, the parent cells could be characterized as nonrivalrous, exclusive goods.\textsuperscript{170}

Therefore, the three main components of bioprinted organs—the blueprints, the biomaterials, and the cells—can generally be characterized as being nonrivalrous and noncompetitive. Thus, according to some economic definitions of property, one could rightfully assume that bioprinted organs should be regulated like other public goods.\textsuperscript{171} However, at least one author notes that “the properties of goods do not always correspond to this standard definition.”\textsuperscript{172} The patent system, for example, is one method that takes originally public goods and moves them to the private market for a limited time.\textsuperscript{173} Thus, arguments for broader property rights and increased regulation could be supported even if bioprinted organs are conclusively determined to be public or private goods by nature.\textsuperscript{174} Nevertheless, it is important to recognize that the value of bioprinted organs could change with broader property rights and increased regulation.

B. \textbf{The Patient’s Value}

The most direct beneficiary of bioprinting is arguably a patient who presents symptoms of a disease or is already on the organ donor waiting list.\textsuperscript{175} Consistent with

\textsuperscript{163} See Rando, supra note 162, at 1082 ("The accumulation of mutations in nuclear and mitochondrial DNA, despite the range of repair mechanisms for preventing such accumulation, sits at the pinnacle of the hierarchy, representing the most fundamental and irreversible changes from which many others follow.").

\textsuperscript{164} See Landecker, supra note 5, at 213 (suggesting that the HeLa cells were so active that they overtook other samples, and that the uncertainty of sample integrity cast "doubt . . . on past work").

\textsuperscript{165} See Rando, supra note 162, at 1082.

\textsuperscript{166} See Kaul & Mendoza, supra note 153, at 81.

\textsuperscript{167} See Landecker, supra note 5, at 212-13 (describing the early efforts to mass-produce the cells that eventually lead to a “threat to scientists’ sense of control over what had been heralded for years as a scientific success story").

\textsuperscript{168} See Kaul & Mendoza, supra note 153, at 92.

\textsuperscript{169} See Landecker, supra note 5, at 219 (suggesting that Moore had follow-up visits because the cultured cell line was not “fundamentally discontinuous and different from the cells in Moore’s body").

\textsuperscript{170} See id. (suggesting that the attending physician manipulated Moore, since it “was vital to Golde’s patent application that Moore’s blood not enter the public domain”). Parts 0 and 0 describe the incentives of the patient and doctor, suggesting that it is likely such collusion will take place in practice.

\textsuperscript{171} See Kaul & Mendoza, supra note 153, at 80 (“Public goods are defined as . . . being non-rival in consumption and having nonexcludable benefits. The market cannot price these goods efficiently.").

\textsuperscript{172} Id. at 84 ("Yet many knowledge elements are made exclusive and private through property rights. . . . An example is manufacturing procedures protected by process patents.").

\textsuperscript{173} Id. at 89 ("A more active, policy-driven approach to identifying public goods opens the door for an equivalent expansion of other aspects of public goods theory and research.").

\textsuperscript{174} The Moore case, discussed at length in Part 0, did not involve bioprinting or an organ transplant. However, the case may provide a useful illustration, as these actors are general to most cases involving
the sentiment that was present between the 1950s and the 1970s, a patient has an innate interest in a bioprinted organ because it is part of the patient’s personhood. A more developed version of the theory suggests that some non-fungible things can be bound up in the identity of an individual, and the person should have a stronger moral claim to those things than a third party. Aside from the moral argument this theory raises, it offers a persuasive explanation as to why a person feels loss for certain personal objects.

The personhood theory offers an initial measure of value, but this notion of loss is far too subjective to be satisfying. Furthermore, a measure of value based on loss by definition must be calculated ex post, since the loss is internalized only after the relationship to the patient has been severed.

Other forms of value are more satisfying. First, under contract law, the patient assigns value to the organ as a part of the bargain formed with the physician to perform an organ transplant. The value of this contractual relationship can be measured along another dimension. The bioprinted organ will likely be used in the treatment of the particular disease that the patient presented, so the value of the bioprinted organ is the actual improvement in the patient’s condition. Second, the patient may be in a position to bargain with a number of different physicians interested in using the resulting cell line for research, so the value would be the bargained cost of loyalty to the successful physician. Finally, the patient may receive value from having his or her information stored for a later use, including testing of a drug that may benefit the patient.

C. THE PHYSICIAN’S VALUE

The patient will enlist the skills of a physician, who will make a diagnosis and treat the patient. The most obvious interest of the physician is related to the initial goal of supplementing traditional organ donations; the physician will require at least a


176. See B.J.C., supra note 79, at 1268; Crichton, supra note 12, at 393 (“Even though [the cells] are removed from his body, he will rightly feel that they are still his. This is a natural and common human feeling.”).


178. Id. at 978.

179. Id. at 959.

180. See supra Part III.a.

181. Ward Farnsworth, The Legal Analyst: A Toolkit for Thinking about the Law 218 (2007) (“[T]he mind searches for a satisfying story to account for the ending. Once it is found, it makes the ending seem inevitable.”).

182. See id. at 111 (noting that one method of assigning value in a public goods problem is through contract law).

183. This is a distinct measure of value that courts recognize in the calculation of expectation damages. See, e.g., Hawkins v. McGee, 146 A. 641, 644 (N.H. 1929) (holding that the correct measure of damages for the breach of warranty was the difference between “the value of the hand which the defendant promised and the one which resulted from the operation.” (emphasis added)).

184. See Crichton, supra note 12, at 394 (“People will not donate their tissues for research. They will sell them to corporations instead. . . . Patients are not naive and neither are their attorneys”). Farnsworth, supra note 181, at 154 (noting that the competitive price to contract with a party should form a sense of loyalty in certain market conditions).

185. While Henrietta Lacks did not live long enough to benefit from Dr. Jonas Salk’s polio vaccine, another patient may receive the benefit of drug trials based on the sampled cell line or a medical device based on the digital blueprint. See Landecker, supra note 5, at 212.

186. See Moore, 793 P.2d at 480-82.
temporary possessory interest in the bioprinted organ in order to create and transplant
the organ into the patient.\textsuperscript{187}

Just as the patient can make an argument for a property interest under the
personhood theory, the physician can claim an interest under the Lockean labor theory
that characterized the 1980s and 1990s.\textsuperscript{188} Under this theory, the physician should have
a stronger property claim against others that have not expended effort, because the
physician obtains some of the materials and creates the final product—the bioprinted
organ.\textsuperscript{189}

Additionally, the physician has the benefit of the knowledge obtained from a
bioprinted organ or an artificial printed-organ model. For example, a physician
preparing heart surgery on a fourteen-year-old was able to forego many rounds of
exploratory surgery with the help of three-dimensional plastic models generated from
scans of the heart.\textsuperscript{190} Similarly, at least one manufacturer is printing more realistic
brain models with three-dimensional printers that teach the next generation of medical
students about a greater diversity of conditions.\textsuperscript{191}

If a patent is obtained, some doctors are under agreements to assign their rights in
exchange for a royalty that has the potential to be lucrative.\textsuperscript{192} In the \textit{Moore} case, the
attending physician had the additional bargaining power to obtain a position as a paid
consultant with the commercial developer of the cell line products, carrying additional
compensation and the promise of 75,000 shares of common stock.\textsuperscript{193}

\section*{D. The University’s Value}

The physician may have privileges at a teaching hospital or may be a party to a
research agreement that introduces the interests of a university into the transaction.\textsuperscript{194}
Either through general policy or formalized agreements, universities typically require
the physicians at their teaching hospitals to assign the rights to patents and other
intellectual property to the hospital.\textsuperscript{195} Similarly, the interests of research entities can
shift when institutions enter into further collaborative research agreements.\textsuperscript{196}

If physicians can claim a property interest under the Lockean labor theory,\textsuperscript{197} then
physicians should be able to assign their interest to the institutions that provide

\begin{itemize}
\item[\textsuperscript{187}] See, e.g., \textit{35 U.S.C. § 154(a)(1) (2012)} (“Every patent shall contain a short title of the invention and
a grant to the patentee, his heirs or assigns, of 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,
and, if the invention is a process, of the right to exclude others from using, offering for sale or selling
throughout the United States, or importing into the United States, products made by that process, referring to
the specification for the particulars thereof.” (emphasis added)).
\item[\textsuperscript{188}] See \textit{Landecker, supra} note 5, at 215.
\item[\textsuperscript{189}] See \textit{id.}
\item[\textsuperscript{190}] \textit{TJ McCue, About a Boy: 3D Printed Heart Model Saves Young Life, FORBES (Feb. 26, 2014, 9:33
\item[\textsuperscript{191}] \textit{Maanvi Singh, Novice Neurosurgeons Train on Brains Printed in 3-D, NPR (Dec. 16, 2013, 3:40
PM)}, \url{http://www.npr.org/blogs/health/2013/12/12/250577798/novice-neurosurgeons-train-on-brains-printedin-3-d}.
\item[\textsuperscript{192}] See, e.g., \textit{Moore}, 793 P.2d at 482.
\item[\textsuperscript{193}] Id.
\item[\textsuperscript{194}] Moore sought treatment at the University of California at Los Angeles Medical Center, and his
attending physician likely had obligations that resulted in the Regents of the University of California as the
assignee of the patent. See \textit{id.}
\item[\textsuperscript{195}] See, e.g., \textit{id.}
\item[\textsuperscript{196}] See Bd. of Trs. of the Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc., 131 S. Ct. 2188,
2192 (2011).
\item[\textsuperscript{197}] See \textit{Landecker, supra} note 5, at 215.
\end{itemize}
research opportunity and funding. Such a relationship has strengthened the patent portfolios of universities, which were awarded 3,088 patents in 2009 alone. Commercializing this research has been extremely lucrative for these universities; licensing opportunities contributed between $47 billion and $187 billion to the United States gross domestic product between 1996 and 2007. Furthermore, universities note that patent portfolios and the active licensing of patents "motivate[] firms to invest financial and human resources in technology development."

Universities may also choose to commercialize the products of academic research through startups. In a study covering fiscal year 2010, the creation of 651 companies was attributed to the commercialization of products from university research. This industry is a boon for local economic development, especially since most startups remain close to their founding universities. Like patents and licensing, entrepreneurial success is another metric that is used to calculate potential research funding. Equally important, entrepreneurs can be an important source of donations to the universities with which they have worked.

E. THE BIOTECHNOLOGY COMPANY’S VALUE

Finally, biotechnology companies are introduced when a doctor consults with a testing facility or if the companies decide to work with a university or research institution. As noted in Part 0, these relationships sometimes form because the university or research institutions creates a spin-off company in order to commercialize a product. Other times, the private company is a licensee of the research entity, agreeing to pay a royalty and possibly provide research funding for the research entity.

Depending on the particular facts, a private company may have a variety of interests at stake. If the private company is a licensee of a university, significant royalties and research funding are expended to secure access to the technology. Sometimes, an exclusive grant of access or an assignment of a complete interest in the technology can be negotiated. Other times, the private company may be a joint contributor to the technology and share in many of the benefits of the university.

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198 See Roche, 131 S. Ct. at 2199 (noting that “universities typically enter into agreements with their employees requiring the assignment to the university of rights in inventions,” doing “so without violence to the basic principle of patent law that inventors own their inventions”).
199 See SCHACHT, supra note 112, at 9.
200 Id. at 10. This estimate concerns university license agreements based on product sales, suggesting that other licensing opportunities may increase this number.
201 Id. at 9.
202 Id. at 10.
203 Id.
204 Id. at 12.
206 See id.
207 Id.
208 The Regents of the University of California and the attending physician negotiated agreements with Genetics Institute for cell line product development and commercial distribution. Moore, 793 P.2d at 482.
209 See SCHACHT, supra note 112, at 9-12; Kenney & Patton, supra note 205, at 1101.
210 See Moore, 793 P.2d at 482 (noting that the Regents of the University of California and Golde accepted at least $440,000 in funding and salary in addition to 75,000 shares of common stock).
211 See id.
212 See SCHACHT, supra note 112, at 9.
213 See Roche, 131 S. Ct. at 2198.
The primary difference between the interests of a private company and the research entity stems from the different goals of each party. Universities foster public goods in the form of publications and educational opportunities, and the universities prepare students to participate in the private sector. Thus, universities leverage patents and license agreements in order to fund further research and public goods. Private companies, on the other hand, are better suited to commercialize a set of products and services for investors. A private company can leverage access to a bank of bioprinted organs and scans in order to enter a market that may otherwise have a prohibitively high barrier to entry. If an exclusive arrangement is obtained, then the private company can exclude other potential competitors. This is particularly important in the biotech and pharmaceutical industries, where products can be reverse engineered or chemically analyzed by competitors to free ride on the research of others.

IV. PROPOSALS

In the Introduction, two overarching concerns were offered explaining why the general public may feel uneasy about bioprinting: (1) it challenges the traditional legal construction of the human body; and (2) it provides unprecedented access to the human body by physicians, research institutions, and biotechnology companies.

A. MORATORIUM ON BIOPRINTING RESEARCH?

In light of the concerns, one may be tempted to impose a moratorium on bioprinting research before it has the opportunity to reach commercialization. However, bioprinting is still in its infancy, and a moratorium would prevent the public from reaping the benefit from such a promising field. In particular, bioprinting has the potential to dramatically reduce the organ transplant wait list. Furthermore, private biotechnology companies may continue research despite the moratorium, and they may have more incentive to exploit the technology in order to subsidize research.

Instead, the Presidential Commission for the Study of Bioethical Issues has already committed to reviewing opportunities to encourage innovation in the area of synthetic biology and promote whole genome sequencing research that benefits the

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214 See SCHACHT, supra note 112, at 17.
215 See id. at 4.
216 See id. at 4, 19 (suggesting that universities generally do not look to patents and licenses as a profit mechanism, as “most university license offices barely break even”).
217 See id. at 4 (“Universities, however, generally do not have the means of production necessary to take the results of research and generate marketable products. Such activities are carried out by industry.”).
218 See id. at 3 (acknowledging that the use of licensing to exploit other markets encourages industry concentration).
219 See id.
220 Id.
221 See PRESIDENTIAL COMM’N FOR THE STUDY OF BIOETHICAL ISSUES, supra note 59, at 17 (noting the increased risks of synthetic biology when paired with commercial activity).
222 See TED, supra note 17 (“Wouldn’t you rather test to see if those cancer drugs you’re going to take are going to work on your cancer? This is an example from Karen Burg’s lab, where they’re using inkjet technologies to print breast cancer cells and study its progressions and treatments.”).
223 See supra text accompanying notes 1-2.
224 See supra note 18 and accompanying text.
225 PRESIDENTIAL COMM’N FOR THE STUDY OF BIOETHICAL ISSUES, supra note 59, at 7.
DO YOU OWN YOUR 3D BIOPRINTED BODY?

B. JUDICIAL RESPONSE

Courts should distinguish bioprinting cases from the analysis in Moore and Davis, as bioprinting introduces policy issues that have not yet been raised or addressed. Admittedly, some considerations will be similar. For example, providing universities and biotechnology companies with stronger property rights will benefit the drug screening process and personalized medicine, potentially resulting in a higher quality of care and greater access to care for patients. The lesson of Moore teaches that this social good should be rewarded, and sometimes the result will be a lucrative market for every party but the patient.

Nevertheless, other issues will reveal the complexity of trying to apply Moore and Davis to bioprinting. Can patients ever address their concerns through contracts that, for example, limit access to their bioprinted organs and scans? The majority opinion in Moore contemplated this question with regards to excised cells and addressed in dicta why a consent form would be unreasonable for assigning potential property rights in the cell line:

But consent forms do not come with guarantees of validity. As medical malpractice litigation shows, challenges to the validity and sufficiency of consent are not uncommon. Moreover, it is sheer fantasy to hope that waivers might be obtained for the thousands of cell lines and tissue samples presently in cell repositories and, for that reason, already in wide use among researchers.

A patient’s case involving a bioprinted organ may unfold differently. For example, the Davis court in dicta noted “that an agreement regarding disposition of any untransferred preembryos in the event of contingencies . . . should be presumed valid and should be enforced as between the progenitors.” Some authors argue that Moore can be reconciled—the Davis court may have distinguished itself from Moore by according special protection to embryos that had the “potential for human life.” This construction begs the question: can a bioprinted organ ever satisfy the “potential for human life”?

If IPSCs were used, one could argue that the IPSCs can be reprogrammed to function as a number of specialized cells and possibly have the potential for human life.

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227 For example, one related policy issue is the support of new research fields with great promise. President’s Comm’n for the Study of Bioethical Issues, supra note 59, at 7. Another related policy issue is the encouragement of research fields that could revolutionize vaccine and medicine development. See id. at 64 (“Improved production of drugs and vaccines, advanced mechanisms for personalized medicine, and novel, programmable drugs and devices for prevention and healing are among a few of the expected achievements.”); see also TED, supra note 17.

228 See Obasogie & Theung, supra note 12, at 69.

229 See supra notes 201, 218, 222 and accompanying text.

230 See Moore, 793 P.2d at 495-97.

231 Id. at 496 n.42.

232 See Davis, 842 S.W.2d at 597 (“We conclude that preembryos are not, strictly speaking, either ‘persons’ or ‘property,’ but occupy an interim category that entitles them to special respect because of their potential for human life.”); Obasogie & Theung, supra note 12, at 53.
life.233 One could make a similar argument for synthetic cells if the technology matures to the point where synthetic cells mimic specialized cells.234 Either way, the “potential for human life” standard becomes problematic when applied to bioprinting.235

Instead of strictly adhering to Moore and Davis, courts should issue a new framework that is tailored to the unique interests and concerns of bioprinting cases. Perhaps the courts should recognize a property interest in the bioprinted organs and scans.236 The property interest could be a reward for doctors, research institutions, and biotech companies for research and investments in bioprinting.237 Such an arrangement would even allow parties to transfer the property interest by contract.238

On the other hand, a patient should have an inherent right to control certain uses of the bioprinted organ and scans under a theory of personal autonomy.239 For example, if a transplant candidate authorizes the creation of a bioprinted organ for the purpose of a transplant, a property interest in the bioprinted organ cannot restrict the patient from receiving the transplant. This conclusion follows from the holding in Davis.240 It would be absurd to grant an absolute property interest in the bioprinted organ that could rob the patient of both the decision to have a transplant and control over further disposition of the bioprinted organ.241

Under this construction, the interests of the physician and patient become aligned, since the patient has the right to go to another physician and dilute the potential property interest if the patient’s expectations are unlikely to be met.242 Likewise, a physician does not have to fear a potential conversion or infringement suit from the patient based on a lucrative bioprinted organ, since the patient never receives an independent property right that can form the basis of a claim.243

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233 See Obasogie & Theung, supra note 12, at 54 (“[T]he proverbial spleen cells from John Moore and any other ordinary cells removed during medical procedures would potentially be just a few steps away from being turned into gametes that could then be used for reproductive purposes.”).

234 Contra PRESIDENTIAL COMM’N FOR THE STUDY OF BIOETHICAL ISSUES, supra note 59, at 3 (“The feat therefore does not constitute the creation of life, the likelihood of which still remains remote for the foreseeable future.”).

235 See Obasogie & Theung, supra note 12, at 54-55.

236 See id. at 76 (“We argue that courts should distinguish Moore to clearly identify a property interest in excised somatic cells that are reprogrammed and differentiated into reproductive cells through the processes of induced pluripotency.”). However, the property interest should be limited, not absolute, in order to address concerns about the unprecedented access afforded by bioprinted organs and scans. See infra notes 239-241 and accompanying text.

237 See Moore, 793 P.2d at 482 (noting that the Regents of the University of California acquired a patent).

238 See SCHACHT, supra note 112, at 9 (noting the benefits to universities of licensing and acquiring patents).

239 This limit is in addition to the traditional limitations of the property regime, such as federal patent law. U.S. CONST. art. I, § 8 (“To 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.”).

240 Such a construction may even reconcile Davis with Moore in a manner that avoids the “potential for human life” standard. The Moore court noted in dicta that personal autonomy may be an overriding policy concern. See Moore, 793 P.2d at 493-94. However, I am suggesting that personal autonomy should be recognized as an absolute right, not a factor to be balanced against the interests of other parties. Contra id. (“Liability based upon existing disclosure obligations, rather than an unprecedented extension of the conversion theory, protects patients’ rights of privacy and autonomy without unnecessarily hindering research.”).

241 In Davis, the court said that such a result “would rob [the husband] twice—his procreational autonomy would be defeated and his relationship with his offspring would be prohibited.” Davis, 842 S.W.2d at 604.

242 See, e.g., Stephen R. Munzer, Risk and Reward in Stem Cell Products: A New Model for Stem Cell Product Liability, 18 B.U. J. SCI. & TECH. L 102, 126 (2012) (“The transaction costs will exceed the increase in value from rearranging the legal outcome, which means that the transaction will not be entered into . . . ”).

243 Cf. Moore, 793 P.2d at 482 (unsuccessfully asserting a claim of conversion).
V. CONCLUSION

Bioprinting will continue to challenge our traditional understanding of property rights over the human body244 and the degree that a human can be reduced to a set of data.245 Although physicians may obtain unprecedented access and potential property rights over our bioprinted organs and scans,246 a judicial recognition of the patient’s personal autonomy can ensure access to the bioprinted organs without disrupting the existing incentives that encourage innovation.247 Bioprinting will continue to develop at its dizzying pace, and the law must be nimble enough to evolve with it.

244 See Landecker, supra note 5, at 204.
245 See id. at 215 (“Why does an artificial composition of matter that happens to replicate through biochemical activity still bear the adjective ‘human’ at all?”).
246 See supra notes 101-102 and accompanying text.
247 See supra text accompanying note Error! Bookmark not defined.