HEARTLESS PATENTING: HOW THE ADVENT OF 3D PRINTED HUMAN ORGANS WILL RESHAPE OUR THINKING OF PATENT LAW

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I. Introduction

What once was purely imaginative, is now entirely possible, because within the next decade, humanity will have the ability to print replacement organs. 3D printed organs could someday be the solution for those anxiously waiting for an organ from the donor list – a lengthy process that does not guarantee a positive result. [1] With over 113,000

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[1] *See Can 3D Printing Help The Organ Shortage*, LIFECENTER (Oct. 19, 2018), *archived at* https://perma.cc/LD4E-7SJ9 (exploring the possibility of 3D printing as a solution to the transplant shortage); *see also* Matthew Shaer, *Soon, Your Doctor Could Print a Human Organ on Demand*, SMITHSONIAN MAG. (May 2015), *archived at* https://perma.cc/665F-K5AE (noting that after the creation of the National Organ Transplant Act, doctors had to let patients know that not every patient would be receiving a much needed organ transplant).

> According to the U.S. Department of Health & Human Services, 21 people die each day in this country alone waiting for an organ. 'For me, the demand wasn't an abstract thing,' [Doctor] Atala told me recently. 'It was very real, it was heartbreaking, and it drove me. It drove all of us to find new fixes.'

Shaer, *supra; see also* Anthony Atala, *Growing New Organs*, TED (Mar. 2009), *archived at* https://perma.cc/LF9Z-QJ4E (introducing the science behind printing human organs). *See also* Anthony Atala, *Printing a human kidney*, TED (Mar. 2011), *archived at* https://perma.cc/E5SK-T6GT (presenting on the possibility of 3D printing a human kidney and the recent healthcare developments in additive technology). The Wake Forest Institute for Regenerative Medicine is run by Dr. Atala and has been one of the leading researchers in the field of 3D bioprinting. *Id.*

women, men, and children on the national transplant waiting list there is a real need for organ transplants that can very well save the lives of thousands.[2] The story of a young girl named Alexa is a powerful reminder of this urgency—if she had a transplant she likely would have lived a long and happy life— unfortunately she never got the chance as she died waiting for a lung transplant that never came.[3] Fortunately, there is the potential to prevent what happened to Alexa as technology has evolved from simply printing a word document to potentially printing a life-saving human lung.[4]

This Note will discuss the need to keep 3D printed human organs patent ineligible to ensure that human life is not commercialized. However, should they be deemed patent eligible, there must be legislation that guarantees affordable generic alternatives for all of those who need lifesaving transplants. Part II of this Note explains the process of 3D printing and the methods being tested to eventually successfully print human tissue and organs. Also, Part II of this note details the abuses that have taken place as the pharmaceutical drug industry has used their patent monopolies to raise

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[2] *See Organ Donation Statistics*, ORGAN DONOR (July 22, 2019), *archived at* https://perma.cc/XTS9-V2QV (providing various statistics on human organ transplants). "20 people die each day waiting for an organ transplant." *Id. See Facts: Did You Know?,* AMERICAN TRANSPLANT FOUND. (Oct. 20, 2019), *archived at* https://perma.cc/J8ZG-XE6C (affirming statistics on organ transplant shortage and myths surrounding organ donation).

[3] *See Alexa Kersting*, LIFESOURCE (Mar. 30, 2020), *archived at* https://perma.cc/52MK-SFYK (detailing the heartbreaking story of Alexa, a 14-year-old with a fatal lung condition).

> Sadly, the call that would save her life never came and in July of 2004 Alexa died while waiting for her transplant. It's frustrating for Alexa's parents to know that the cure for their daughter existed, and all that it would have taken for her life to be saved is a generous grieving family, somewhere, who said 'yes' to donation.

Id.

[4] *See* Sam Lyon, *3D-printed hearts with 'beating' tissue could ease organ donor shortage*, NBC NEWS: MACH (Sept. 23, 2019), *archived at* https://perma.cc/C5B9-8CHP (describing current efforts to print a human heart and the process by which it may be achievable); *see also* Jonathan Shieber, *Implantable 3D-printed organs could be coming sooner than you think*, TECHCRUNCH (June 25, 2018), *archived at* https://perma.cc/6472-J39F (announcing the manufacturing of capillaries as a starting point for developing functioning capillary structured needed to create a fully functioning organ). Given the urgent need for organ transplants and human tissue, it is estimated that the global tissue engineering market will exceed $94 billion by 2024. Shieber, *supra*.

drug prices on life saving drugs. Additionally, Part II further details how patent law has gradually developed to consider the possibility of patenting nature, such as human organisms and naturally occurring material.

Furthermore, Part III sets forth current attempts by Congress to improve access to generic drugs, which could very well be applied to 3D-printed human organs. Ultimately, Part IV urges the reconsideration of the patenting of 3D-printed organs given the possibility that such patenting may be abused, much like how previous life-saving prescriptions were patented and then exploited. However, if bioprinted organs are granted patent eligibility, the legislative framework for generic drugs should serve as a blueprint for future legislation so that generic manufacturers can produce affordable organs that can save the life of a child who should not suffer the same fate as Alexa.

II. History

A. The 3D Printing of Human Organs

1. How Can 3D Printing Produce an Everyday Object?

The Xerox printer walked so that the 3D printer could soar.[5] To understand how the printer has grown from printing documents to printing a kidney, one has to first unpack how exactly a 3D printer works.[6] At its core, 3D printing is a means of manufacturing by

[5] *See* Clive Thompson, *How the Photocopier Changed the Way We Worked – and Played,* SMITHSONIAN MAG. (Mar. 2015), *archived at* https://perma.cc/K3S3-QUPN (describing the remarkable impact of the Xerox printer on everyday copying); *see, e.g.*, Jesse Roitenberg, *Students 3D Print a 2D Printer*, STRATASYS (Sept. 10, 2012), *archived at* https://perma.cc/8U5N-4GB9 (admiring the ability to use a 3D printer to print a 2D printer); *see also* Dana Goldberg, *History of 3D Printing: It's Older Than You Are (That Is, If You're Under 30)*, REDSHIFT (Apr. 13, 2018), *archived at* https://perma.cc/FZT2-M37N (laying out the long history of 3D printing that started in the 1980s and is still growing today as aircraft and jewelry are testaments of how far it has come). In terms of medical advancements, the 3D printer has allowed scientist to print, "a functional miniature kidney, built a prosthetic leg with complex component parts that were printed within the same structure, and bioprinted the first blood vessels using only human cells." Goldberg, *supra*.

[6] *See* Andrew Walker*, 3D printing for dummies: How do 3D printers work?*, INDEP. (June 21, 2013), *archived at* https://perma.cc/ES9W-WXBU (explaining how 3D

stacking layers of one or more materials to create a three-dimensional object.[7] While the sculptors of the classical times worked with a slab of marble to chisel their way towards a masterpiece, the 3D printer works in reverse as it adds thin layers on top of thin layers until it finally reaches the last layer of the finalized product.[8] Much like a 2D

printers are the new generation of printers that may very well print just about everything); *see also* Lauren Cahn, *20 of the Coolest Things Ever Made with a 3D Printer*, READERS DIGEST (Nov. 17, 2019), *archived at* https://perma.cc/58DK-HYNB (listing various items that have been printed via a 3D Printer). From a prosthetic foot for a dog to an entire bus, 3D printing has opened up the possibility of printing almost anything, possibly even a spaceship in the future. Cahn, *supra*. *See also* 3D Printing Industry, *The Free Beginner's Guide*, 3D PRINTING INDUS. (Oct. 20, 2019), *archived at* https://perma.cc/ZF3J-XX2R (asserting 3D printing has existed for several decades); Rebecca Matulka, *How 3D Printers Work*, DEP'T OF ENERGY (June 19, 2014) *archived at* https://perma.cc/WMY5-HKM5 (explaining 3D printing, or additive manufacturing, is "the process of making an object by depositing material, one tiny layer at a time."). *See also* Benjamin Roussey, *3D Printers Are Way Better Than 2D – Here's Why*, TECHGENIX (Dec. 11, 2017), *archived at* https://perma.cc/3LS5-HKGS (arguing 3D printing is advancing at a faster pace than 2D printing did when it was being developed). "While 3D printing might appear as 2D printing with another dimension, the technological lifecycle and evolution it's going through is entirely different from what we observed for 2D printers." *Id. See also* Bill Decker, *7 Ways 3D Printing Beats 2D Printing*, BIZTECH (Nov. 24, 2015), *archived at* https://perma.cc/ZM9Z-X5TE (speculating that 3D printing will develop at a rapid pace, ensuring businesses will not wait decades to reap the benefits); Amir H. Khoury, *The Makings of An 'Individualized-Industrial' Revolution: Three-Dimensional Printing and Its Implications on Intellectual Property Law*, 16 J. HIGH TECH. L. 1, 4 (2015) (suggesting that a paradigm shift will take place as 3D printing continues to grow).

[7] *See* Mark A. Lemley, *IP IN A WORLD WITHOUT SCARCITY*, 90 N.Y.U. L. REV. 460, 472 (2015) (demonstrating the potential of 3D printers to print a large range of objects from clothes to kayaks). One of the major benefits of 3D printing is that it allows manufacturers to print parts and pieces exactly as they should be, therefore complex devices, like jet turbines and engines, can be replicated exactly as needed to piece together an entire machine. *Id. See also* Louis Columbus, *The State of 3D Printing, 2019*, FORBES (May 27, 2019), *archived at* https://perma.cc/MS22-77LM (elaborating on a recent study that surveyed various industries on their potential uses for 3D printing). The study shows that 70% of enterprises have found new applications for 3D printing, indicating the majority of global industries are heavily adopting additive manufacturing. *Id.* "While budget and physical space are the two most significant barriers enterprises face in adopting 3D printing at scale, [companies'] optimistic outlook on the technology's future is driving greater adoption to the shop floor." *Id.*

[8] *See* Jasper Tran, *To Bioprint or Not to Bioprint*, 17 N.C. J. L. & TECH. 123, 133 (2015) (exhibiting how 3D printing adds another dimension). "Michelangelo carved statues 'by hewing away the rough walls that imprison the lovely apparition to reveal

printer, an inkjet nozzle releases the material but, unlike a 2D printer, rather than just releasing one layer, the 3D printer proceeds to add layer after layer to the base.[9]

The 3D printer receives its instructions from one of two sources.[10] The first option is to use a Computer Aided Design ("CAD"), which is a design file created using computer software, that is then downloaded into the 3D printer so that it can use the CAD design as a blueprint.[11] Alternatively, the 3D printer itself can scan an object to build a 3D model representation of it and then use this model to guide the printing process.[12] Think of the CAD file as the document

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it to other eyes as his see it.' 3D printing accomplishes the opposite – it transforms manufacturing." *Id.*

[9] *See* Chloe Kent, *The future of bioprinting: A new frontier in regenerative healthcare*, VERDICT MED. DEVICES (June 10, 2019), *archived at* https://perma.cc/Q429-L6NZ (differentiating between 2D printing and 3D printing).

[10] *See* Tran, *supra* note 8, at 134 (explaining users of 3D printers may provide the printer a blueprint by either creating a CAD file or scanning an object); *see also* American Institute of Physics, *Using Physics to print living tissue: Laws of physics replace trial and error in new approaches to bioprinting*, SCI. DAILY (June 4, 2019), *archived at* https://perma.cc/ER37-JC44 (introducing new methods of 3D bioprinting).

[11] *See* MecSoft Corporation, *What is 3D Printing & How Does 3D Printing Work?,* MECSOFT CORP. (Oct. 20, 2019), *archived at* https://perma.cc/7VCW-W394 (elaborating on the steps of 3D printing and its usage of CAD files). Once the CAD file or the scanned design has been uploaded, it is then converted into a digital file that slices the design into many thin layers that the 3D printer uses to print each layer until the final product is finished. *Id.* While this may sound simple, it is worth noting that creating a CAD file can be incredibly complex and requires a great deal of training in order to produce a design that can be 3D printed. *Id.* Unlike the average 2D printer that simply prints a document from any computer, 3D printers require "software systems that take input 3D data and convert it to 3D data that is amenable to be 3D printed." *Id.* Still, the pace of 3D printing technology is developing at a fast rate, thereby making its future very bright. *Id.*

[12] *See* Sarah Swanson, *3D Printing: A Lesson in History: How to Mold the World of Copyright*, 43 SW. L. REV. 483, 484 (2014) (demonstrating the possibility of scanning an object to then create a blueprint for 3D printing). Arguably, the most exciting aspect of 3D printing is the ability to re-print any item as many times as possible so long as the user has the digital blueprint available. *Id.* at 485. *See also How does 3D scanning work?,* SCULPTEO (Feb. 22, 2020), *archived at* https://perma.cc/RV7Y-RQK5 (explaining the 3D scanning process that serves as a base for 3D printing).

> 3D scanning is a process of analyzing an object from the real world, to collect all the data in order to recreate its shape and appearance, digitally. Thanks to this process, the object can become a 3D model, which could help you as a base for the 3D

or picture one sends to a 2D printer from one's computer whereas the 3D scanning process would be akin to how one uses a scanner to create a file and then print said file.

Once the preferred blueprint has been chosen and the printing process has begun, the printer takes the raw material, ranging from metal powders to chocolate, and heats the material, much like a glue gun melts glue, in order to begin adding each layer on top of the other.[13] The heating process, also known as material extrusion, happens simultaneously with the layering to produce a finalized product.[14] However, depending on the final product, the printed object may need to be cleaned off to remove excess material or processed further.[15] It is at this point that the 3D printer takes a bow and humanity flexes its innovative muscles.[16]

> project you are about to develop, but it can also be useful to reconstruct, analyze, or simulate ideas.

Id.

[13] *See Ultimate 3D Printing Materials Guide*, SIMPLIFY 3D (Nov. 17, 2019), *archived at* https://perma.cc/F8LH-7MAF (offering a list of materials currently being used in 3D printers). From polycarbonates to metal filled filaments, the materials that can be used in a 3D printer are varied, therefore many items can be printed so long as the proper materials are available to the printer. *Id*. *See also* Swanson, *supra* note 12, at 484 (articulating the ability of a 3D printer use various materials). "Think of an ink cartridge to a regular printer, only instead of ink a user starts with any substance at its liquidated state such as metal, plastic, or even chocolate." *Id.*

[14] *See* Additive Manufacturing Group, *About Additive Manufacturing*, LOUGHBOROUGH UNIV. (Oct. 20, 2019), *archived at* https://perma.cc/Y47M-L9HR (summarizing the step by step process of 3D printing). Material extrusion is the process by which material is "drawn through a nozzle, where it is heated and is then deposited layer by layer." *Id.* This particular process has been widely used and is an overall inexpensive process. *Id.*

[15] *See* Abhimanyu Chavan, *FDM 3D Printing Post Processing – An Overview for Beginners*, ALL3DP (Oct. 20, 2019), *archived at* https://perma.cc/6DFH-2VYF (outlining the various ways in which post processing can take place once the final product has been printed). Because 3D printed items may have a rough surface finish, there are certain steps that can be taken in order to produce a more desirable final product. *Id.* From simply removing any support material, such as any scaffolding, to sanding the product to remove any excess material, the post-processing step can vary depending on the final product. *Id.*

[16] *See* Khoury, *supra* note 6, at 6 (proclaiming that "printing is creating the miraculous, almost tele-transporting objects into being."). With the advent of 3D printing, humans can now replicate almost anything from aeronautics to simple home furniture. *Id.* at 5. The impact on commercial sales can understandably be great given that anyone with a 3D printer will be able to download and print an item in the

2. How Can a 3D Printer Create a Human Organ?

As if printing a fork or a cup from scratch were not impressive enough, 3D printing technology is developing to the point where it can print human tissue and, one day, maybe even vital human organs.[17] Although development has not reached the stage of printing vital organs such as a human heart, there is already an individual with a 3D bioprinted bladder walking among us.[18] Because the possibility of

comfort of their own home. *Id.* at 11–12. *See also* Shlomitt Yanisky-Ravid & Kenneth S. Kwan, *3D Printing the Road Ahead: The Digitization of Products When Public Safety Meets Intellectual Property Rights – A New Model*, 38 CARDOZO L. REV. 921, 921 (2017) (cautioning on the potential effects 3D printing may have on intellectual property rights, particularly in the medical field).

[17] *See* Tran, *supra* note 8, at 138 (proclaiming that 3D printing can convert the sci-fi myth of creating human body parts into reality). *See also* Haitao Cui et al., *3D bioprinting for cardiovascular regeneration and pharmacology*, NCBI (July 24, 2018), *archived at* https://perma.cc/V4T3-KDV9 (presenting on the advances of 3D bioprinting such as the ability to fabricate complex tissue architecture to better guide tissue regeneration). It is worth noting that "[a]lthough the bioprinting technique is still in its early stages, we believe it would be a feasible approach to produce a robust, and physiologically relevant, cardiac model by replicating *in vivo* tissue composition, geometry, and complexity." *Id. See also* Sean Murphy & Anthony Atala, *3D Bioprinting of Tissue and Organs*, 32 NATURE BIOTECHNOLOGY 773, 773 (2014) (noting that an important challenge in 3D bioprinting is the ability to evolve from printing plastics and metals to printing complex and sensitive living biological material).

> Many of the challenges facing the 3D bioprinting field relate to specific technical, material and cellular aspects of the bioprinting process. Although the field is at an early stage, it has already succeeded in creating several tissues at human scale that are approaching the functionality required for transplantation. Technological challenges include the need for increased resolution, speed and compatibility with biologically relevant materials.

Id. at 781.

[18] *See* Atala, *supra* note 1 (offering the real example of a young man who is the recipient of a 3D printed bladder). *See also* Brian Lord, *Bladder Grown From 3D Bioprinted Tissue Continues to Function After 14 Years*, 3D PRINTING INDUS. (Sept. 12, 2018), *archived at* https://perma.cc/5ASG-752G (elaborating on the 3D printed human bladder that used the patient's own cells to bioprint the bladder that is still in use today). Luke Masella received a 3D-printed bladder in 2004 that he continues to benefit from years after the initial implantation. *Id.*

> While this major achievement remains inspiring, it is worth noting that, according to Dr. Atala, flat structures like skin are easiest to print, whereas tubular structures like blood vessels and hollow

printing a complex human organ is such an incredible and rewarding feat, researchers have developed multiple methods to reach this final prize.[19]

The 3D printing of human organs, better known as bioprinting, will drastically differ from ordinary 3D printing as it will require the use of human material to build complex structures like a human heart. Instead of using raw materials like metal, powder, and plastic, the 3D printing of human organs uses living cells.[20] This new form of 3D printing follows a process similar to regular 3D printing but requires additional steps to ensure the final product is a living organ.[21] First, either a magnetic resonance imaging ("MRI") or computed tomography ("CT") neuroimage is uploaded to CAD software to build a digital 3D model known as a Bio-Computer Aided Design ("Bio-CAD").[22] A Bio-CAD file is then downloaded to the 3D printer for use as the blueprint to guide the printing process.[23] Next, using a

> non-tubular organs like bladders are more complex. Solid organs like hearts, lungs, and kidneys, are the most difficult to bioprint as they have more cells per centimeter, though some researchers have had small successes in this field.

Id.

[19] *See* Jamil Ammar, *The "Medical Mile" Gearing Towards 3-D Bespoke Healthcare*, 52 GONZ. L. REV. 279, 286 (2017) (providing the three bioprinting methods currently available).

[20] *See* Melissa Little & Gordon Wallace, *Printing the future: 3D bioprinters and their uses,* AUSTRALIAN ACAD. OF SCI. (Oct. 20, 2019), *archived at* https://perma.cc/2B98-XP83 (explaining that "[i]nstead of delivering materials such as plastic, ceramic, metal or food, they deposit layers of biomaterial, that may include living cells, to build complex structures like blood vessels or skin tissue.").

[21] *See* Tabarez Y. Ebrahim, *3D Bioprinting Patentable Subject Matter Boundaries,* 41 SEATTLE U. L. REV. 1, 9 (2017) (outlining the necessary steps used in the 3D bioprinting process in three steps which are the development of the blueprint of the organs, the actual organ printing, and the organ maturation process).

[22] *See id.* (describing the first step in bioprinting known as pre-processing). *See also* Jeff Mason et al., *An Overview of Clinical Applications of 3-D Printing and Bioprinting*, NCBI (Apr. 1, 2019), *archived at* https://perma.cc/PH7S-YAJF (expanding on the pre-processing phase of bioprinting as it requires converting images into files the printer can use as a base). Bioprinting may differ from regular 3D printing given that considerations as to what living cells to use and whether to collect samples are not considerations taken into account when printing other 3D-printed items. *Id.* at T2. Understandably, "[b]ioprinting follows a similar production path but with some notable differences throughout the process." *Id.*

[23] *See* Ebrahim, *supra* note 21, at 9 (explaining that "[t]he Bio-CAD file…creates or modifies a software representation of anatomic and geometric information of the 3D bioprinted tissue or organ"). *See also* Arianna Ferrari et al.,*Additive bio-*

downloaded Bio-CAD file, the 3D printer dispenses living cells and layers them on top of each other much like the regular 3D printing process.[24] Finally, the post-processing step takes place where the 3D printed tissue begins to fuse and assemble into a living organ.[25] Usually, this process requires the premature organ to be placed in an incubator where its growth and maturation can be monitored.[26]

Scientists have yet to perfect this process and currently are unable to create vital organs like human hearts or lungs.[27] Still, they

manufacturing: 3D printing for medical recovery and human enhancement, EUROPEAN PARLIAMENT (July 2018), *archived at* https://perma.cc/V2H5-9RBC (detailing the utility of bio-CAD files as they provide the appropriate resolution and contrast). "Image processing constitutes the largest hurdle for [additive manufacturing's] continuing introduction into the medical sector." *Id.* "The preparation of the data requires algorithms for the adjustment of the area contrast, for thresholding and segmentation as well as highlighting different areas of interest." *Id*. Because the image processing phase, which is no different than the creation of a Bio-CAD file, is so complex, medical professionals are needed to perfect the medical data needed to create an accurate 3D-printed file. *Id.*

[24] *See* Ebrahim, *supra* note 21, at 10 (elaborating on the processing step which deposits layer by layer onto hydrogels that aid in tissue formation and maturation). *See also* Little & Wallace, *supra* note 20, (focusing on the need of scaffolding). "Of course, you generally need more than just cells, so most bioprinters also deliver some sort of organic or synthetic 'glue'—a dissolvable gel, collagen scaffold or other type of support that the cells can attach to and grow on." *Id.*

[25] *See* Ebrahim, *supra* note 21, at 10 (concluding with the post-processing step of 3D bioprinting as it requires placing the bioprinted structure into an incubator for maturation and further observation). *See also* Mason et al., *supra* note 22, at T2 (providing a simplified table of the 3D bioprinting process, which details the focus on continued growth and development of the printed cells and biological structures). In 3D bioprinting, the post-processing phase may require further growth and development of the 3D printed cells, which includes the additional step of loading structures "into an incubator and provided with appropriate biological conditions to grow into mature tissue." *Id.* at T2.

[26] *See* Ebrahim, *supra* note 21, at 10 (providing additional steps such as incubation or further testing that may be needed to ensure the maturation process is completed). *See also* V.E. Passamai et al., *From 3D Bioprinters to a fully integrated Organ Biofabrication Line*, J. PHYSICS (2016), *archived at* https://perma.cc/GMB2-VPWJ (examining the post-processing phase of 3D bioprinting as the step that ensures the final product is fully functioning). "Post-processing is probably the most crucial step in organ printing procedures." *Id.* at 7. This is the most difficult step because the bioprinted organ still requires accelerated tissue maturation before it can fully function as a human organ. *Id.*

[27] *See* Jonathan Shieber, *3D-printing organs moves a few more steps closer to commercialization*, TECHCRUNCH (Aug. 11, 2019), *archived at* https://perma.cc/H2DG-98QL (highlighting that although enormous leaps have been made research has yet to bioprint complex organs).

have employed three distinct bio-printing methods that seek to explore the possibility of printing an organ.[28] The first method, inkjet bio-printing, consists of layering droplets of biomaterial on top of each other, much like ordinary 3D printing.[29] Although the aforementioned is the most commonly researched and used method, it is limited in its ability to achieve the proper biological cell density required to create live organs.[30] Still, this method has been used to bioprint functional skin and cartilage.[31]

In a temperature-controlled environment so that the beads of material blend with one another, the microextrusion method deposits beads of biomaterial onto a 2D surface as each layer is added on top of

[28] *See* Ammar, *supra* note 19, at 286–87 (reexamining the three methods of 3D bio-printing, which are inkjet-bioprinting, Microextrusion, and laser-assisted bioprinting). *See also* Theodore G. Papaioannou et al., *3D Bioprinting Methods and Techniques: Applications on Artificial Blood Vessel Fabrication*, 35 ACTA CARDIOL SIN. 284, 286–87 (2019) (elaborating the process by which inkjet printing primarily drops bioink onto the culture dish, material extrusion deposits each layer of biomaterial, whereas laser-assisted printing is based on the deposition of biomaterials using a laser as the energy source).

[29] *See* Ammar, *supra* note 19, at 286 (describing the Inkjet bioprinting process). *See also* Alane Lim*, What is Bioprinting?,* THOUGHT CO. (May 2, 2018), *archived at* https://perma.cc/F8U4-BMKH (focusing on the Inkjet bioprinting method and how it functions). Similar to regular 3D-printing, Inkjet bioprinting treats living cells like a printer treats ink, firing the biomaterial through tiny nozzles, which may also include a heating and vibration feature to print each layer of the material. *Id*.

[30] *See* Andrea Negro et al., *3D Inkjet Printing of Complex, Cell-Laden Hydrogel Structures*, SCI. REPORTS (Nov. 20, 2018), *archived at* https://perma.cc/D54L-5397 (focusing on the limitation of InkJet Bioprinting in failing to create greater cell density as this is the problem it has yet to overcome). Researchers have been trying to find ways to improve cell density to match the density that human organs require. *Id.* Methods such as overlapping several layers of cells have been studied in order to overcome problems of limited cell density in bioprinting. *Id. See also* Zelijka P. Kacarevic et al., *An Introduction to 3D Bioprinting: Possibilities, Challenges and Future Aspects*, 11 MATERIALS BASEL 1, 8 (2018) (noting that "the limitations of vertical printing and restricted viscosities may mean that inkjet bioprinting needs to be combined with other printing techniques for future developments.").

[31] *See* Bridget O'Neal, *Scientist 3D Printing In Situ for Tissue Regeneration*, 3DPRINT (Apr. 12, 2019), *archived at* https://perma.cc/UE6W-8AR6 (elaborating on the way *in situ* bioprinting may develop as research continues to make progress). *In Situ* bioprinting involves the printing of human tissue onto the patient in real time to treat burns and skin injuries. *Id*. Researchers have explored the possibility of printing human tissue on a live patient to help to treat wounds or skin defects by directly implanting cells onto the body for further growth. *Id. See also* Ammar, *supra* note 19, at 281–83 (pointing out the possibility of printing cartilage *in situ*).

the next.[32] While this process produces cells with higher densities than the Inkjet process, the cell viability of this process is lower than the other methods because the cells can die under high pressures.[33] Finally, Laster-Assisted bioprinting uses laser beams to guide the biomaterial, either living cells or stem cells, onto the printing surface.[34] Laser-Assisted bioprinting can deposit cells at incredibly accurate density levels due to the laser's heat, yet because of such high densities, it can be a long process that can also be expensive.[35] Ultimately, each method has its own way of moving humanity one step closer to reproducing the very organs that can save lives and revolutionize modern medicine.

[32] *See* Ammar, *supra* note 19, at 282 (explaining Microextrusion bioprinting as it is the most affordable process). *See also* Lim, *supra* note 29 (expanding on how Microextrusion "uses pressure to force material out of a nozzle to create fixed shapes. This method is relatively versatile: biomaterials with different viscosities can be printed by adjusting the pressure, though care should be taken as higher pressures are more likely to damage the cells.").

[33] *See* Dai V. Lee, *Three-dimensional bioprinting and tissue fabrication: prospects for drug discovery and regenerative medicine*, DOVE PRESS (Aug. 19, 2015), *archived at* https://perma.cc/PKN5-26RL (affirming that this method can accelerate tissue organization yet it can also create a high level of stress that can place too much pressure on the printed cells).

> The disadvantage of microextrusion bioprinting is that only materials with high viscosity can be extruded. This results in high shear stress, which tends to kill the cells during the printing process. Most reported studies showed that cell survival rates are generally lower than those seen with the inkjet printers, in the range of 40%–86%, with the survival rate decreasing with increasing extrusion pressure.

Id.

[34] *See* Ammar, *supra* note 19, at 286 (setting forth the final form of bioprinting that is Laser-Assisted Bioprinting that is increasingly used to engineer tissue and organs). *See also* Lee, *supra* note 33 (observing that Laser-Assisted Bioprinting is an expensive process to perform and suffers from low stability and scalability).

[35] *See* Ammar, *supra* note 19, at 283 (affirming the costly and time-consuming nature of Laser-Assisted Bioprinting). *See also* Christian Mandrycky et al., *3D Bioprinting for Engineering Complex Tissues*, BIOTECHNOL ADV. (Dec. 23, 2015), *archived at* https://perma.cc/87JL-24DR (reiterating that "[d]ue to the high cost, there are few laser-assisted bioprinters, which are usually cumbersome and complex compared to other types of printers.").

B. How Patent Law Has Evolved with Technological Advances

1. The U.S. Patent Act

Rooted in the Constitution, 35 U.S.C.S. § 101 ("Patent Act") sets forth the requirements necessary for an inventor to secure intellectual property rights.[36] The Patent Act states that, "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvements thereof, may obtain a patent, subject to the conditions and requirements of this title."[37] The invention must fit within one of these categories: process, machine, manufacture, or composition of matter in order to be recognized under the Patent Act.[38] Once an invention is deemed to fall within one of these categories, it may be granted subject matter eligibility, a requirement for patent protection.[39]

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[36] U.S. Const. art. I, § 8, cl. 8. (establishing the foundation of patent law in the United States as a means of promoting the arts and science). *See also* 35 U.S.C. § 101(1952) (codifying the constitution's authorization to patent inventions).

[37] *See* 35 U.S.C. § 101 (submitting the Patent Act). "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 therefore, subject to the conditions and requirements of this title." *Id.*

[38] *See* Sue A. Purvis, *Basics of Patent Protection*, USPTO (Oct. 20, 2019), *archived at* https://perma.cc/A6SL-C3MK (providing an overview of utility patents, which are the patents that fall under process, machine, or compositions of matter). *See also* Michael Henry, *What is Prior Art?,* HENRY (Sept. 7, 2017), *archived at* https://perma.cc/VQ3Y-YVBS (summarizing the element of new or novelty requirement under the Patent Act, which prohibits an invention from being already known or publicly available, also known as the prior art concept). Novelty can be understood as any instance where someone has already made public or known the idea that sought to be patented. *Id*. If an invention was previously known, then the invention has failed its patent application. *Id. See also General information concerning patents*, USPTO (Oct. 25, 2015), *archived at* https://perma.cc/H8Q2-CWA8 (defining what is considered useful under the Act). The USPTO defines useful as: "the condition that the subject matter has a useful purpose and also includes operativeness, that is, a machine which will not operate to perform the intended purpose would not be called useful, and therefore would not be granted a patent." *Id*.

[39] *See 2106 Patent Subject Matter Eligibility*, USPTO (Mar. 30, 2020), *archived at* https://perma.cc/5N5X-MKCC (presenting the U.S. PTO's requirements for subject matter eligibility that must be met before receiving patent rights to an invention).

> First, the claimed invention must be to one of the four statutory categories. 35 U.S.C. 101 defines the four categories of invention

While subject matter eligibility is the primary requirement, inventions must also be "novel" and "nonobvious" for absolute patent protection.[40] A "novel" invention is one that is not already known to the public and is determined through a comparison of current inventions to the one in question.[41] The "nonobvious" requirement

> that Congress deemed to be the appropriate subject matter of a patent: processes, machines, manufactures and compositions of matter. The latter three categories define 'things' or 'products' while the first category defines 'actions' (i.e., inventions that consist of a series of steps or acts to be performed). Second, the claimed invention also must qualify as patent-eligible subject matter, i.e., the claim must not be directed to a judicial exception unless the claim as a whole includes additional limitations amounting to significantly more than the exception.

Id.

[40] *See* 35 U.S.C. § 102 (defining the novelty requirement as any invention that has not been previously published, used before, or available to the public). *See also* 35 U.S.C. § 103 (establishing the requirement of non-obviousness as any invention that is not readily apparent to anyone else with relevant knowledge). Non-obviousness is set forth as:

> A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.

Id.

[41] *See e.g.*, *General information concerning patents*, *supra* note 38 (affirming the USPTO's conditions for obtaining a patent, which include the need to be novel). *See also* John Gladstone Mills et al., PATENT L. BASICS § 7.1 (2019) (explaining that determining what qualifies as novel is a fact specific analysis that compares that which has already been invented to the current invention to ensure that no two identical or similar inventions are patented at the same time).

> The judgment that something is old or that it is new is subjective in the sense that it is made relative to and thus dependent upon one's prior experience. Objective or intrinsic refers to those qualities or attributes that are absolute and do not vary from observer to observer. The judgment that one object differs from another is independent of the prior experience of those making the comparison. Novelty is a question of fact.

Id.

expands on novelty by requiring that an invention neither be easily invented nor obvious to a knowledgeable person in the relevant field.[42]

To obtain subject matter eligibility, an invention must fall within one of the following four categories: processes, machines, articles of manufacture, and compositions of matter.[43] A "process" patent protects methods that consist of multiple steps or an arrangement that produces a finalized product.[44] A "machine" patent is for physical structures that consist of parts or devices whereas "articles of manufacture" are products that are made from raw material.[45] Finally, "compositions of matter" are chemical compounds or physical mixtures, whether it be through a chemical union or a mechanical mixture.[46] These categories cover all inventions that are eligible for patent protection, however broad exceptions exist under

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[42] *See* Gene Quinn, *Patentability: Nonobviousness Requirement of 35 U.S.C. 103*, IP WATCHDOG (June 17, 2017), *archived at* https://perma.cc/ZY7Q-LJV3 [hereinafter *Quinn - Patentability*] (articulating the nonobvious requirement and its implication on patent applications). An invention is considered obvious if the differences between the invention and prior art are such that the invention would be obvious at the time a patent application is filed. *Id.* The nonobvious element expands on the 'new' element by requiring that an invention would not be obvious to someone else knowledgeable in the relevant field given that if anyone else in the field could have invented it then it is obvious and unpatentable. *Id.*

[43] *See* 35 U.S.C. § 101 (requiring that an invention may obtain patent protection provided that it is a new process, machine, manufacture, or composition of matter). *See also* Ebrahim, *supra* note 21, at 15 (reaffirming that to be granted subject matter eligibility an invention must fit within one of the four statutory categories – process, machines, manufactures, or compositions of matter).

[44] *See* Mills et al., *supra* note 41, at § 6:2 (elaborating on a process patent as "consist[ing] of more than a single step, the arrangement, order, or sequence in which these component steps are to be performed may itself be of patentable significance"). *See also* Ebrahim, *supra* note 21, at 16 (elucidating on the two categories of a process patent which are a method of making something and a process that is a method of using something, both qualifying as process patents).

[45] *See General information concerning patents*, *supra* note 38, at 5 (explaining how the USPTO determines what can and cannot be patented). *See also* Ebrahim, *supra* note 21, at 16 (noting that a machine's novelty lies in its components whereas an article of manufacture is more broadly defined).

[46] *See Chakrabarty*, 447 U.S. at 308 (defining composition of matter as "all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids."). *See also 2106 Patent Subject Matter Eligibility*, *supra* note 39 (clarifying that "[i]t is also not necessary to identify a 'correct' category into which the claim falls, because although in many instances it is clear within which category a claimed invention falls, a claim may satisfy the requirements of more than one category.").

these categories that can affect whether an invention will be considered patent eligible.

These exceptions are broad and arguably could encompass almost every invention—if an invention falls under an exception it will be rendered patent ineligible.[47] For example, an invention that merely articulates an "abstract idea" or that simply repeats a "law of nature" or a "natural phenomenon" is patent ineligible.[48] The "abstract idea" exception ensures that an inventor cannot patent an idea such as a mathematical formula or physics equation, rather the idea must be in tangible form for it to even be considered patent eligible.[49] Moreover, the "laws of nature" or "natural phenomenon" exception stands as a

[47] *See* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) (establishing the rule that the laws of nature cannot be patented); *see also* Ebrahim, *supra* note 214, at 18 (reaffirming the exception of any invention that already exists in nature).

[48] *See* Alice Corp. Pty. v. CLS Bank Int'l, 573 U.S. 208, 218 (2014) (holding that "[a] principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right."). The *Alice* court made clear that any patent claim that espouses an abstract idea must add more to said application of the idea in order to be granted patent rights. *Id.* at 227. Absent any addition of something "significantly more," any claim over an abstract idea is invalidated. *Id.* at 225–26. *See also Funk Bros. Seed Co.*, 333 U.S. at 130 (establishing the exceptions – abstract idea, laws of nature, and natural phenomena –that invalidate patentability).

[49] *See* Mills et al., *supra* note 41, at § 1.24 (stating that ideas cannot be patented because patent law only protects inventions that have a tangible form).

> No patent confers a right to exclude others from the underlying idea which gave rise to the invention. The monopoly conferred by a patent attaches only to the embodiment of an idea in tangible form. Patent rights and rights in physical objects which possess the physical attributes called for by the claims of a patent are entirely distinct. The very motivation for having a patent system is to enlarge the fund of knowledge freely accessible to the public.

Id. *See also* Patent and Trademark Office, MANUAL OF PATENT EXAMINING PROC. § 2106.04(a) (9th ed. 2018) [hereinafter MPEP] (providing guidance as to how abstract ideas ought to be examined by identifying the claimed concept that may be an abstract idea and then comparing the concept to those that have been identified as abstract ideas by the courts). Notably, "[d]espite this long history, the courts have declined to define abstract ideas." *Id*. Instead, they have often identified abstract ideas by referring to earlier precedent, by comparing a claimed concept to the concepts previously identified as abstract ideas by the courts." *Id*. *See also* Eugene Molinelli, *For Abstract Ideas in Patent Eligibility Analysis, All Equations are NOT Equal*, USPTO (2019), *archived at* https://perma.cc/TNT7-ZY5T (clarifying that "that abstract ideas can be grouped as, mathematical concepts, certain methods of organizing human activity, and mental processes.").

barrier to those who wish to patent the discovery of plants, natural wonders, or any occurrence that is already present in nature.[50] While these requirements, under the Patent Act, are far more extensive and intricate, the primary focus for 3D bioprinting will be on the subject matter eligibility, as well as the potential exceptions to the Act.[51]

2. The Rights Conveyed to a Patent Holder and the Purpose of Patent Rights

Patent rights were conceived by the founding fathers as a means of ensuring inventors could exclude others from making, using, or selling their inventions.[52] The awarding of a patent protects an

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[50] *See Funk Bros. Seed Co*., 68 S. Ct. at 441 (pronouncing the laws of nature as beyond the scope of patentability as they are the very laws that ought to be available to everyone). The Supreme Court explained that:

> The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.

Id. See also MPEP, *supra* note 49, at 2106.4(b) (describing examples of laws of nature that cannot be patented such as Einstein's law that $E=mc^2$, Newton's discovery of gravity, or a cloned farm animal); Ebrahim, *supra* note 21, at 18 (expounding on the exception of laws of nature).

> The reason for this is that the patent system is designed to incentivize and reward inventive activity, and the discovery of preexisting items does not involve human-created ingenuity or development. In effect, one who goes into nature and simply brings a product of nature into the public domain does not have a discovery worth a patent.

Ebrahim, *supra* note 21, at 18.

[51] *See 2106 Patent Subject Matter Eligibility*, *supra* note 39 (determining that subject matter eligibility is focused on whether a particular invention fits within the meaning of patentability in a statutory category). The USPTO assesses whether an invention "is the claim to a process, machine, manufacture or composition of matter … [and] evaluation of this step should be made after determining what applicant has invented by reviewing the entire application disclosure and construing the claims in accordance with their broadest reasonable interpretation." *Id.*

[52] *See General information concerning patents*, USPTO (Oct. 2015), *archived at* https://perma.cc/2TWD-X4WC [hereinafter *USPTO Patent Overview*] (explaining that patent rights derive from the Constitution, which grants Congress the power to enact patent laws).

invention from infringement for twenty years, allowing the inventor to retain proprietary rights in her invention.[53] Should another decide to infringe on the inventor's patent right of exclusivity, the inventor has recourse—she can sue the infringing party to obtain an injunction as well as any damages caused by the infringement.[54] The ability to exclude others from infringing on an inventor's patent rights is a major incentive to obtain a patent but it may also tempt the holder to resort to complete monopolization thereby raising prices as high as possible.

In order to begin the patent approval process, an inventor has to decide whether to submit a provisional or a non-provisional patent application which, depending on the application, may determine how early a patent is ultimately published and available to the public.[55] Once the inventor has invented something worth patenting, she can submit a provisional patent application, allowing her a 12-month period to establish priority over others so that she can file her full application later on while still developing the invention into its final form.[56] Upon finalizing the invention, an inventor will file a non-

[53] *See* 35 U.S.C.A. § 154(a)(2) (West 2015) (codifying the twenty-year period during which an inventor has exclusive patent rights over the invention). Additionally, §154 grants a patent holder the right to exclude others from making, using, offering for sale, or selling the invention in the United States or importing the invention into the United States thereby ensuring that the patent holder has sole exclusive rights over the invention. *Id.* at § 154(a)(1).

[54] *See USPTO Patent Overview, supra* note 52 (explaining that "[t]he patentee may ask the court for an injunction to prevent the continuation of the infringement and may also ask the court for an award of damages because of the infringement.").

[55] *See Start With A Provisional Or A Non-Provisional Patent Application?*, ERICKSON L. GROUP (Mar. 1, 2020), *archived at* https://perma.cc/9EPY-J6VG (detailing the difference between a provisional and non-provisional patent application, which centers on the timing of when each is filed). *See also* John Calvert, *The Provisional Patent Application: What You Need to Know*, USPTO (Apr. 2010), *archived at* https://perma.cc/2532-89V9 (noting that a provisional patent application provides the inventor with an additional year to experiment, perfect an invention, find investors, determine sales potential, and any other additional considerations prior to obtaining a patent).

[56] *See* Gene Quinn, *Provisional Patents: What are they and why do you need them?*, IPWATCHDOG (Aug. 13, 2016), *archived at* https://perma.cc/28KD-5E95 [hereinafter *Quinn – Provisional Patents*] (elaborating on how a provisional patent application can ensure the inventor cements her position as the first to file).

> A provisional patent application will never itself mature into an issued patent, but in the right circumstance (and done properly) a provisional patent application can be a very useful tool for inventors. This is particularly true now that the United States is a

provisional patent application, which upon the expiration of the 12-month period of the previous application, sets in motion the patent application process that grants the patent rights and places the public on notice of the new invention.[57] The importance of publishing the patented invention is centered on the public domain principle, which ensures that unpatentable ideas remain readily available to everyone so that the public may use these ideas freely.[58] Patent law wrestles with the need to promote innovation while also protecting the public domain, which points to the urgency by which certain vital

> first to file country, which absolutely must be interpreted as inventors needing to file first before disclosing anything about their invention, offering it for sale or using the invention publicly.

Id.

[57] *See* Gene Quinn, *A beginner's guide to patents and the patents process*, IPWATCHDOG (Jan. 31, 2015), *archived at* https://perma.cc/BY7B-994B [hereinafter *Quinn – Beginner's Guide*] (pointing out that a non-provisional patent application is always needed in order to obtain a obtain a patent as this is the application that the patent examiner reviews for patentability); Gene Quinn, *What is a patent and where do patent rights come from?,* IPWATCHDOG (Feb. 20, 2016), *archived at* https://perma.cc/SS92-KGW2 [hereinafter *Quinn – Source of Patent Rights*] (narrating the inception of patent rights in the United States).

> Madison, known as the Father of the Constitution, was the primary proponent of strong rights and even convinced the skeptical Thomas Jefferson that without strong rights there would be insufficient incentive to take risks and innovate. So evident was the power to award patents that little information on the discussion had by the Founding Fathers during the Constitutional Convention was recorded. We do know that the Constitution itself grants to the Congress the power.

Quinn – Source of Patent Rights, supra.

[58] *See* Aronson v. Quick Point Pencil Co., 440 U.S. 257, 262, (1979) (articulating the purpose of patent law as a means of promoting innovation while also protecting the public domain).

> First, patent law seeks to foster and reward invention; second, it promotes disclosure of inventions, to stimulate further innovation and to permit the public to practice the invention once the patent expires; third, the stringent requirements for patent protection seek to assure that ideas in the public domain remain there for the free use of the public.

Id. at 262. *See also* Barry Sookman, *Law and Innovation: Is Intellectual Property a Path to Progress*, BARRY SOOKMAN (Apr. 13, 2014), *archived at* https://perma.cc/L2TP-Q3ZC (determining that "[t]he novelty requirement ensures that patent law does not impede innovation by ensuring that information in the public domain cannot be removed by patent law (or in the U.S.) State law.").

technological advancements ought to be scrutinized and even reserved for the public domain.[59]

3. The Supreme Court's Decisions on Patenting Nature

The Supreme Court has decided four cases concerning the patentability of nature that directly provide a clearer understanding of how the Patent Act ought to be interpreted in these instances.[60] Curiously, the U.S. Supreme Court held in *Diamond v. Chakrabarty,*[61] that a man-made genetically engineered bacterium was in fact patent eligible.[62] The Court reasoned that the genetically engineered bacterium had "markedly different characteristics from any found in nature and one having the potential for significant utility," given that the genetically engineered bacterium was modified to break down oil particles in the ocean.[63] According to the Court, the invention was

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[59] *See* Eimear Murphy, *Study Documents Public Domain's Importance to Innovation and Creativity*, INTELL.PROP. WATCH (Oct. 17, 2015), *archived at* https://perma.cc/V8HP-PFYY (expanding on the tension between innovation and the need to retain certain information in the public domain to make it available to all). It is worth noting that,

> [i]n the intellectual property system, there is an inherent balance that policymakers try to strike, WIPO Chief Economist Carsten Fink said, in his introduction to the event. On one hand, they give 'incentives towards creative and inventive activity,' and on the other hand, they recognize that 'creative works and inventions have public good characteristics and should be disseminated as widely as possible.

Id.

[60] *See* Gene Quinn, *The Supreme Court is More Interested in Being Right Than Shedding Light on 101* (Jan. 14, 2020), *archived at* https://perma.cc/JFL4-FU4L (discussing the four patent eligibility cases that the Supreme Court decided: *Mayo, Myriad, Alice* and *Bilski*).

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

[62] *See id.* at 309–10 (establishing the landmark decision on patent eligibility of natural organisms). *See also* Diamond v. Diehr, 450 U.S. 175, (1981) (explaining how a process patent claim also turns on whether a transformation has taken place to create something new that does not exist in nature). The Court elaborates that, "[t]ransformation and reduction of an article 'to a different state or thing' is the clue to the patentability of a process claim that does not include particular machines." *Id.* (quoting Gottschalk v. Benson, 409 U.S. 63, 70 (1972)).

[63] *See Chakrabarty*, 447 U.S. at 310 (establishing that the inventor's discovery was not "nature's handiwork" but rather his own thereby granting him patent eligibility). *See also* Matthew Varkey & Anthony Atala, *Organ Bioprinting: A Closer Look At Ethics*, 5 WAKE FOREST J. L. & POL'Y 275, 293 (2015) (laying out the potential

patent eligible because there's a clear difference between those discoveries that exist without the assistance of humans and those inventions that are unique, isolated, and not replicated by nature.[64] Still, the Court made certain to reaffirm the exception that "the laws of nature, physical phenomena, and abstract ideas" are not eligible for patenting.[65]

Moreover, the Supreme Court, in *Mayo Collaborative Servs. v. Prometheus Labs., Inc.,*[66] also addressed the possibility of patenting the process that helps doctors determine the proper dosage of thiopurine drugs to treat patients suffering from autoimmune diseases.[67] The Court held that such method was not patent eligible given that it merely applies "laws of nature" and gives instructions to doctors on how to apply said laws.[68] Notably, the reasoning hinged on the assertion that if a law of nature is not patentable, then a process utilizing such laws is also rendered ineligible, in order to be eligible the process has to add something greater to the laws of nature that goes beyond simply an effort to monopolize a law of nature.[69]

Consequently, the Supreme Court affirmed its nuanced adherence to the laws of nature exception in *Ass'n for Molecular*

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intellectual property ramifications that may arise from 3D bioprinting and the products of nature legal exception).

[64] *See Chakrabarty*, 447 U.S. at 309–10 (explaining that any invention that is unaided by man, thus naturally occurring in nature, remains patent ineligible). *See also* Xiaoban Xin, *Patent Eligibility of 3D Printed Organs*, 44 AIPLA Q. J. 143, 148–55 (2016) (outlining the landmark Supreme Court cases that interpret and explain the laws of nature exception).

[65] *See Chakrabarty*, 447 U.S. at 309 (setting forth the exception of the laws of nature).

[66] *See* Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 66 (2012).

[67] *See id.* at 69 (introducing the issue of whether a process by which drugs are administered ought to be patented given that it applies certain laws of nature).

[68] *See id.* at 72 (elaborating on the inability to patent the laws of nature). In discussing the ineligibility of the process seeking patenting, the Court explained that:

> [T]he steps in the claimed processes (apart from the natural laws themselves) involve well-understood, routine, conventional activity previously engaged in by researchers in the field. At the same time, upholding the patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries.

Id.

[69] *See id.* at 77 (affirming the principle that laws of nature ought not to be patented and neither should any process that fails to have additional features beyond just applying the law of nature).

Pathology v. Myriad Genetics, Inc.,[70] where the Court held that the mere isolation of a DNA sequence was unpatentable but that genes contained in the form of cDNA, which is a synthetic creation of DNA that complements RNA, was eligible since it was a synthetic creation by scientists that was not naturally occurring.[71] It is worth noting that the Court pointed out that the patenting of the laws of nature may very well stifle innovation rather than promote it, which ultimately goes against the rationale of patent law.[72]

Lastly, the Court in *Alice Corp. v. CLS Bank Int'l*,[73] held that a computer system that performed settlement risk mitigation was merely an abstract idea applied to a computer system therefore it fell within

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[70] *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).

[71] *See id.* at 580 (describing the Supreme Court's holding on the patentability of the isolation of DNA and cDNA). Moreover, cDNA is understood as "synthetically created DNA known as complementary DNA (cDNA), which contains the same protein-coding information found in a segment of natural DNA but omits portions within the DNA segment that do not code for proteins." *Id. See also* Matthew Ellis, *The Relationship and Differences in Genomic DNA and Complimentary DNA*, BIOCHAIN (Feb. 24, 2020), *archived at* https://perma.cc/FHU4-G46Q (detailing the process by which scientists use viral enzymes to make cDNA from RNA as they isolate RNA from the cells scientist are focused on).

> As a result, cDNA will only contain genes that are actively being used by a specific cell or tissue at a point in time. There is much less total information in cDNA than gDNA, but what information remains can be a lot more relevant to what a researcher is looking at since it doesn't contain sequences that are unnecessary to the functioning and replication of the DNA.

Id.

[72] *See* Ebrahim, *supra* note 21, at 47–48 (elaborating on the Supreme Court's reasoning in *Myriad*). *Myriad* contributed to a lack of clarity given that

> [R]equiring an invention to hold markedly different characteristics than nature would reduce inventors' incentive to innovate. This would be disadvantageous to innovation and slow advancements towards producing replica organs, which could be utilized for critical organ transplantation needs. Researchers and inventors can more easily replicate naturally occurring products that share characteristics with the invention at issue.

Id. See also Jennifer Gordon, *The Impact of Myriad and Mayo: Will Advancements in the Biological Sciences Be Spurred or Disincentivized? (Or Was Biotech Patenting Not Complicated Enough?*), NCBI (May 5, 2015), *archived at* https://perma.cc/2M2Z-2X8T (supporting the claim that innovation may be stifled because of Myriad). "The thinking in Myriad that isolated DNA is a patent-ineligible product of nature may well be extended to other purified natural substances. There are many useful substances in the natural world waiting to be discovered." *Id.*

[73] *See* Alice Corp. Ltd. v. CLS Bank Intern, 573 U.S. 208 (2014).

an exception that denies a claim of patentability.[74] Ultimately, whether it is an abstract idea or naturally occurring, the Supreme Court has made it clear that anything that fails to add to the storehouse of knowledge which is already available to everyone cannot be patented and monopolized.

C. Pharmaceutical Companies & Their Abuse of the Patent System

1. Pharmaceutical Companies' Manipulative Practices

Pharmaceutical companies have taken advantage of the patent system in order to tighten their grasp on their monopolization of vital drugs; thus, depriving individuals of the benefits of these scientific feats.[75] Accordingly, the abuse of the patent system by pharmaceutical companies can be succinctly exemplified by the patenting of insulin.[76] The drug was initially sold to a University for $3 and subsequently

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[74] *See id.* at 225–26 (affirming that "the claims at issue amount to "nothing significantly more" than an instruction to apply the abstract idea of intermediated settlement using some unspecified, generic computer"). *See also* Jordana R. Goodman, *Patenting Frankenstein's Monster: Exploring the Patentability of Artificial Organ Systems and Methodologies*, 15 NW. J. TECH. & INTELL. PROP. 35, 37 (2017) (furthering the notion that "[p]atents relying on subject matter concerning a law of nature can only be patentable if the claim as a whole amount to "significantly more" than the law of nature itself.").

[75] *See* Initiatives for Medicines, Access, & Knowledge, *Overpatented, Overpriced: How Excessive Pharmaceutical Patenting is Extending Monopolies and Driving up Drug Prices*, I-MAK (Feb. 1, 2020), *archived at* https://perma.cc/XP4U-WYT2 (reporting on the various practices companies partake in that ensure their control of profitable drugs). While patents only last for 20 years, "[t]here are 38 years of attempted patent protection blocking generic competition sought by drug makers for each of these top grossing drugs – or nearly double the twenty-year monopoly intended under U.S. patent law." *Id.*

[76] *See also* Lydia Ramsey*, The incredible history of insulin, a lifesaving drug that was discovered almost a century ago and is now at the center of the drug pricing outrage,* BUS. INSIDER (Apr. 11, 2019), *archived at* https://perma.cc/LFT2-H2V7 (exemplifying a historical example of how patents have been misused by companies for decades). The history of insulin is a prime example of how far things have devolved. *Id.*

> Banting and Best then began injecting insulin from animal pancreases into people to treat their diabetes. In 1922, a person with diabetes was given the first insulin injection. The team went on to win the Nobel Prize for the discovery of insulin in 1923, and later sold the patent for $3 to the University of Toronto.

Id.

resold to a pharmaceutical company, effectively causing the price of insulin to explode by 300%.[77] Pharmaceutical companies hold onto their patent rights by using practices like "evergreening" where the company files a new patent application of an older drug but only modifies it slightly so that it appears as a new invention.[78] In fact, it is simply the older drug disguised in new clothes.[79]

Celgene, a major pharmaceutical company, increased the prices of its drugs through evergreening, effectively extending its patent portfolio by an additional forty years.[80] The company's actions had the effect of forcing consumers to spend $45 billion more than

[77] *See id.* (reiterating the dramatic increase in the price of insulin once it was sold to a private company). Interestingly, the price of insulin has increased by 300% in the last decade. *Id.* The price of insulin has skyrocketed to the point that for some it means paying almost a mortgage's worth for a month's supply of the lifesaving medication. *Id.*

[78] *See* Roger Collier, *Drug patents: the evergreening problem*, CMAJ (June 11, 2013), *archived at* https://perma.cc/AC5G-DCMW (elucidating that "the sophisticated lifecycle plans brand-name companies have for their products — rolling out new versions when patents near expiry — are created primarily to help bottom lines rather than patients."). According to Patrick Kierans, the global head of pharmaceuticals and life sciences for Norton Rose:

> You are talking about extremely high risk to develop new therapies and compounds. Some are going to be revolutionary. Some are going to be incremental . . . The patent system, all the way back to the Statute of Monopolies (a British act passed in 1624), recognizes that it is good for the economy to encourage people to take these risks and to bring new things forward.

Id.

[79] *See* Allie Nawrat, *FROM EVERGREENING TO THICKETING: EXPLORING MANIPULATION OF THE PHARMA PATENT SYSTEM*, PHARMA TECH. FOCUS (Mar. 1, 2020), *archived at* https://perma.cc/6CRX-R834 (showing that researchers "found that 78% of drugs associated with new patents are not new drugs, but existing ones, and almost 40% of all drugs on the market had additional market barriers through further exclusivities."); *see also* Tahir Amin, *The problem with high drug prices isn't 'foreign freeloading,' it's the patent system*, CNBC (June 27, 2018), *archived at* https://perma.cc/TC4B-Y4TA (elaborating on the evergreening problem by explaining that drugs that are evergreened are essentially the same drug without anything new, non-obvious, or useful, which is required by law).

[80] *See* Alison Kodjak, *How A Drugmaker Gamed The System To Keep Generic Competition Away*, NPR (May 17, 2018), *archived at* https://perma.cc/UH9S-5XT6 (highlighting how Celgene was able to increase its drug prices as high as it wanted given the lack of competition in the market). Notably, "Celgene has kept generic competition at bay by constructing an almost impenetrable fortress of patents and grants of market exclusivity around Revlimid, and its sister drug Thalomid, while also taking steps to ensure that generic competitors can't get their hands on enough of the drugs to develop viable alternatives." *Id.*

they would have paid had there been a generic alternative.[81] Notably, already existing drugs that have had their patents extended by using the "evergreening" tactic have accounted for the largest price increases between 2005 and 2016.[82] The common argument made by pharmaceutical companies is that these price increases are needed in order to offset the high cost of researching and developing their drugs—yet a recent study found that the majority of the drug companies' revenue went straight into their pockets rather than to research and development.[83]

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[81] *See* Amin, *supra* note 79 (furthering that because of their abusive practices, Celgene has caught the attention of the FDA given that Celgene has refused to share samples with generics as a means of further cementing their monopoly). *See also* Shamard Charles, *No end in sight to rising drug prices, study finds*, NBC NEWS (May 31, 2019), *archived at* https://perma.cc/Y7WH-QFG3 (arguing that pharmaceutical companies have used the patent system to enrich themselves).

> The United States provides drug companies with the strongest patent protections in the world, but legal strategies in the pharmaceutical industry … abuse that liberty," the researchers wrote. "Reasonable drug costs for consumers must be balanced with incentives in the pharmaceutical industry to produce innovative drugs that improve and save lives.

Id.

[82] *See* Kevin Campbell, *Why Are Prescription Drug Prices Rising?,* U.S. NEWS (Feb. 6, 2019), *archived at* https://perma.cc/BFC8-2ZUE (showcasing how older drugs have accounted for the largest drug price increases that even exceed inflation rates and the rates of other developed drugs). *See also* Michael Erman, *Pharmaceutical companies celebrated New Year's by raising the prices on more than 250 drugs*, BUS. INSIDER (Jan. 1, 2020), *archived at* https://perma.cc/LZ7U-2EAM (providing examples of companies such as Bristol-Myers Squibb, Gilead, and Biogen that have increased the prices of their drugs at the start of the year).

[83] *See* Ezekiel Emanuel, *Big Pharma's Go-To Defense of Soaring Drug Prices Doesn't Add Up*, THE ATL. (Mar. 23, 2019), *archived at* https://perma.cc/5DKY-RLAS (shedding light on the fallacious argument made by drug companies that they spend the majority of their revenue on R&D).

> The most telling data on a disconnect between drug prices and research costs has received almost no public attention. Peter Bach, a researcher at Memorial Sloan Kettering, and his colleagues compared prices of the top 20 best-selling drugs in the United States to the prices in Europe and Canada. They found that the cumulative revenue from the price difference on just these 20 drugs more than covers all the drug research and development costs conducted by the 15 drug companies that make those drugs—and then some. To be more precise, after accounting for the costs of all research—about $80 billion a year—drug companies had $40 billion more from the top 20 drugs alone, all of which went

Whether through blocking generic drugs from entering the market, or filing various patents to extend their patent monopolies, pharmaceutical companies have reshaped our healthcare system through their manipulation of the patent system.[84] Patents were intended to reward innovation and promote the arts and sciences but the practices conducted by some companies have injected that original purpose with the corrosive effects of monopolization and overpricing.[85]

III. Premise

With the possibility of patenting 3D printed organs, comes a need to create boundaries so that patent rights won't be misused to drastically increase prices to unaffordable levels, like what is occurring with prescription drugs such as insulin. This section will explore how Congress has taken initiative to implement legislation with the purpose

> straight to profits, not research. More excess profit comes from the next 100 or 200 brand-name drugs.

Id.

[84] *See* Coalition Against Patent Abuse, *AbbVie's Humira: The poster child for how drug companies abuse the patent system to keep drug prices high. But only for Americans,* CAPA (Feb. 1, 2020), *archived at* https://perma.cc/8W82-MEJD (using AbbVie as an example of how pharmaceutical companies protect their monopolies). AbbVie has maintained a strong hold over its signature drug Humira because:

> [e]ven though Humira's patents were set to expire in 2016, which should have been when less costly generic versions would come to the market, a very few years before that expiration date, its maker, Abbvie, suddenly started applying for new patents. In these new patents – dozens and dozens of them – Abbvie was asserting that tiny, virtually meaningless changes to their drug and Humira's method of administration somehow represented significant new "inventions" and were worthy of new patents and new 20-year monopolies. This practice is commonly known as evergreening.

Id. See also Garrett Johnson & Wayne Brough*, Big Pharma is abusing patents, and its hurting Americans,* CNN (Sept. 13, 2020), *archived at* https://perma.cc/96Z3-WF55 (affirming the fact that pharmaceutical companies have engaged in strategic practices to secure continuous patent rights to control drug prices). By delaying the entry of generics into the market, companies further entrench their monopoly over drugs that could very well have an affordable alternative. *Id.*

[85] *See* Ladas & Parry, *A BRIEF HISTORY OF THE PATENT LAW IN THE UNITED STATES*, LADAS & PARRY (May 7, 2014), *archived at* https://perma.cc/ZP63-LY2Z (outlining the origins of our patent system as a means of promoting innovation); *see also Innovation & Monopoly*, OPEN MKT. INST. (Feb. 1, 2020), *archived at* https://perma.cc/2PSP-Y6YN (expanding on the tension between innovation and monopoly within the patents).

of impeding such monopolistic activity by large pharmaceutical corporations.

A. A Generic Approach to 3D Printed Human Organs

Currently, prescription drugs continue to face increasing competition from generic drugs.[86] While pharmaceutical companies continue to possess strong patent rights, the competition from generic drugs has begun to reduce over-pricing and pharmaceutical patent abuses currently taking place.[87] With this in mind, there is a possibility

[86] *See* The Hatch-Waxman Act of 1984, 21 U.S.C.S. § 355 (introducing the Hatch-Waxman Act of 1984). *See also A discussion on generic pharmaceutical drugs from an intellectual property perspective*, HEALIO: ORTHOPEDICS TODAY (Oct. 9, 2017), *archived at* https://perma.cc/XBY9-5EK2 [hereinafter *Discussion on Generic Pharmaceutical Drugs*] (providing an outline of how generic drugs are regulated and their effects on pharmaceutical company's patent rights). Because brand pharmaceutical companies leveraged their patent and regulatory rights, these companies fought to limit the availability of generic drugs in the market. *Id.* "As a result, Congress passed the Drug Price Competition and Patent Term Restoration Act in 1984, commonly referred to as the Hatch-Waxman Act." *Id. See also* Austin Frakt, *There Is No Single, Best Policy for Drug Prices*, N.Y. TIMES (July 15, 2019), *archived at* https://perma.cc/N69K-QPAQ (outlining an example of how one pharmaceutical company drastically increased the price of a lifesaving drug from $13.50 to $750 given the lack of competition). *See also* Michael Felberbaum, *FDA In Brief: New analysis highlights link between generic drug competition and lower drug prices, underscores importance of FDA efforts to spur generic drug development and market entry*, FDA (Dec. 13, 2019), *archived at* https://perma.cc/M4YM-JUQ3 (providing evidence that generic drugs lower drug prices thereby necessitating their entry into the market).

[87] *See* Erik Komendant*, Pharmaceutical Patent Abuse: To Infinity and Beyond!*, ASS'N. FOR ACCESSIBLE MED. (Nov. 16, 2019), *archived at* https://perma.cc/P8L2-8HUX (outlining a recent report that finds that the patent system may be used to build barriers to generic drug access). The study found that the top 12 brand drugs were protected by a total of 848 patents that ensured patent protection for almost 38 years thereby inhibiting any generic drug maker from entering the market in the near future. *Id. See also* Sarah Jane Tribble, *Drugmakers play the patent game to ward off competitors*, NBC NEWS (Oct. 2, 2018), *archived at* https://perma.cc/GL5P-WY99 (indicating that the patenting of small changes to currently patented drugs ensures continued patent protection to major brand pharmaceutical drugs). The process of patenting minor modifications expands the 10-year period of exclusive rights thereby extending those rights by continuously adding secondary patents to ensure generic drug makers are unable to develop alternatives once the exclusive period expires. *Id.*

of there being generic versions of 3D printed organs.[88] If one can fathom the possibility of generic 3D printed organs, similar to generic drug alternatives, the next step is to address the current landscape that generic drugs exist in and how this field ought to be reformed to pave the way for future generic 3D printed organs.

B. Current Legislative Efforts Designed to Thwart Deceptive Practices by Drug Companies

As pharmaceutical drug companies have erected various barriers to entry for competitors, especially generic drug manufactures, Congress has stepped in to assist generic drug makers in entering the market in order to alleviate the high costs of life saving drugs.

1. An Act to Publish the Process of Patented Drugs

The Biologic Patent Transparency Act ("BPT Act") was introduced to Congress as an effort to increase transparency by requiring patent holders to list all patents owned that could be reasonably asserted against a generic manufacturer.[89] The Bill seeks

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[88] *See* Adele Peters, *Scientist just took the next step on the quest to 3-D print new human organs*, FAST CO. (May 5, 2019), *archived at* https://perma.cc/FK6C-B9ZX (pointing out that an open-source system may prove invaluable to bioprinting given that it will allow other researchers and scientists to remain involved in developing bioprinted organs). "The researchers are also sharing open-source designs for their printer so others can also use it to get closer to the goal of a fully functioning organ." *Id.*

[89] *See* Elaine Blais et al., *Legislation To Watch: 9 Proposed Bills Impacting Biologics & Patent Disputes,* BIOSIMILAR DEV. (Oct. 29, 2019), *archived at* https://perma.cc/ZS3K-JX5Y (clarifying the purpose of the BPT Act as it seeks to ensure generic manufacturers have all the patent information they need to proceed in developing brand name alternatives).

> This bill could help biosimilar manufacturers prepare for litigation and could even guide strategy for development of biosimilar products by providing early notice of what aspects of the biologic product are protected by patents and the full scope of the brand-name manufacturer's patent portfolio that could be brought to bear in litigation.

Id. See also David Wallace, *US Bill Aims to Increase Transparency on Biologics*, PHARMA INTEL. (Nov. 16, 2019), *archived at* https://perma.cc/H2A2-454R (observing that the Biologic Patent Transparency Act would require companies to publicly disclose the web of patents they possess); *see also* Lisa Mandrusiak, *Biologic Patent Transparency Act - New Bill Aimed at Biologics*, OBLON (Mar. 12,

to address the practice of many pharmaceutical companies where they file a great number of patents in order to obfuscate any attempt of producing a generic alternative.[90] The BPT Act would create a disclosure list where the brand name company would be required to provide substantial additional information such as the name of the product, each patent held, the date of licensure and application number, the dosage form, route of administration, and any period of exclusivity held by the patented drug product.[91] Greater transparency creates a far more efficient marketplace, free from barriers to entry, and ultimately guaranteeing affordable generics available to all.

2. Allow for Greater Sample Availability

The Creating and Restoring Equal Access to Equivalent Samples Act ("CREATES Act") was recently included as a provision in the Further Consolidated Appropriations Act of 2020, which will now allow for the availability of generic drug samples to manufacturers who need them to produce alternatives to brand name

2019), *archived at* https://perma.cc/HRG8-HMUL (articulating the purpose of the Biologic Patent Transparency Act).

[90] *See* Biologic Patent Transparency Act, S. 659, 116th Congress § 2 (2019) (introducing the Biologic Patent Transparency Act and its components); Susan M. Collins & Tim Kaine, *Biologic Patent Transparency Act* (S. 659), COLLINS (Nov. 16, 2019), *archived at* https://perma.cc/L7A8-XL3S (furthering the purpose of the Biologic Patent Transparency Act). The Act:

> requires the manufacturers of approved products to disclose and list patents covering their products with the FDA. By requiring patent information to be published . . . the bill imposes transparency requirements that are similar to what are required for small molecule drugs under the Hatch-Waxman framework, which has proven successful in promoting the development and use of generic drugs.

Biologic Patent Transparency Act (S. 659), *supra*.

[91] *See* Mandrusiak, *supra* note 89 (noting that "[t]he bill is … designed to help reduce patent thickets associated with biologics and help promote competition in the marketplace."). *See also* Courtenay L. Brinckerhoff, *Will The Biologic Patent Transparency Act Shrink The Biosimilar Patent Dance Floor?*, FOLEY & LARDNER (May 7, 2019), *archived at* https://perma.cc/C38T-D5ZG (outlining the benefits of the Biological Patent Transparency Act as it helps generic drug companies in their development process by placing them on notice of any unknown patents currently held by the brand name company). *See* Omudhome Ogbru, *Biologics (Biologic Drug Class),* MEDICINENET (Nov. 17, 2019), *archived at* https://perma.cc/PXW8-HW8Z (defining a biologic as "[a] biologic drug (biologics) is a product that is produced from living organisms or contain components of living organisms.").

drugs.[92] Generic drug makers submit an abbreviated drug application showing that their generic version is the bioequivalent to the drug that has already been approved by the FDA.[93] However, this requires additional testing and using samples of the approved drug to prove that the generic version is similar to the approved drug.[94] To delay such access, pharmaceutical companies are curtailing this permissible process by refusing to give generic drug makers access to what they

[92] *See* CREATES Act of 2019, S. 340, 116th Cong. (2019) (establishing the CREATES Act as a provision within the Further Consolidated Appropriations Act). The provision reads that:

> [a]n eligible product developer may bring a civil action against the license holder for a covered product seeking relief under this subsection in an appropriate district court of the United States alleging that the license holder has declined to provide sufficient quantities of the covered product to the eligible product developer on commercially reasonable, market-based terms.

Id. See also CREATES Act Becomes Law, COVINGTON (Jan. 13, 2020), *archived at* https://perma.cc/CV8L-XKPV (announcing the passage of the CREATES Act as a provision in the Further Consolidated Appropriations Act of 2020). *See also* CREATES Act of 2019, S. 340 § 2 (providing a Senate bill that ultimately became law that seeks to facilitate access to samples that are necessary for generic drug development).

[93] *See* Wen Shen, *The CREATES Act of 2019 and Lowering Drug Prices: Legal Background & Overview*, CONG. RSCH. SERV. (Mar. 12, 2019), *archived at* https://perma.cc/W4RW-PHLM (explaining that generic drug manufacturers require samples of the patented drug in order to enter the market). Because some approved drugs are restricted from distributing samples, primarily because the drug company has placed their own restrictions and also invoke regulatory restrictions, such as those imposed by the FDA, to further deny access to samples. *Id.*

[94] *See* CREATES Act of 2019, S. 340 § 2 (detailing the process by which generic drug makers obtain samples of drugs they are seeking to develop into generic versions). The Bill explains that,

> [c]ontrary to the policy of the United States to promote competition in the market for drugs and biological products by facilitating the timely entry of lower-cost generic and biosimilar versions of those drugs and biological products, certain license holders are preventing generic product developers from obtaining quantities of the covered product necessary for the generic product developer to support an application for approval by the Food and Drug Administration.

Id. at § 2(5).

are already allowed to obtain.[95] The CREATES Act gives generic drug makers legal recourse when they are unable to obtain samples of the drug they are seeking to test in order to develop a generic version.[96]

3. Prohibit Pay for Delay Practices

To undermine the availability of prescription drugs by generic drug competitors, pharmaceutical companies pay generic drug manufactures large sums of money, even as much as $200 million, to delay their entry into the market thereby ensuring they can keep prices increasingly high.[97] This process, commonly known as "pay-for-

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[95] *See* Dean Clancy, *The Creates Act: Lower drug costs without price controls*, THE HILL (Jan. 18, 2018), *archived at* https://perma.cc/248T-D3KX (opining on the CREATES Act and its potential benefits). Generic drug makers are required, by the FDA, to extensively test a generic alternative, which includes obtaining a sample because they must:

> prove that a proposed alternative version of a drug is chemically identical to the original and just as safe. To do that, the would-be competitor needs to have, not just the formula for the patented drug, but also samples of that drug, and in sufficient quantities to carry out comprehensive comparison tests. To thwart competition, some drug makers simply refuse to sell the needed samples to their potential competitors, or overcharge for them, or slow-walk delivery.

Id.

[96] *See* Dena Bunis, *Bipartisan Bills in Congress Would Increase Access to Generics*, AARP (Mar. 21, 2019), *archived at* https://perma.cc/9CAH-S8W5 (elaborating on the CREATES Act and what it is intended to address). The CREATES Act gives generic drug companies the option of taking brand-name manufacturers to court in order to compel them to provide the samples necessary to develop generic counterparts. *Id.* "The measure would also keep brand-name companies from delaying a generic drug from getting to consumers by manipulating a Food and Drug Administration process designed to ensure that new drugs are safe." *Id.*

[97] *See* ASPE, *Expanding the Use of Generic Drugs*, ASPE (Dec. 1, 2010), *archived at* https://perma.cc/KQK9-HQWY (summarizing the ways in which companies may take steps to delay generic drug makers from providing alternative versions of the patented drug). *See also* Cmty. Catalyst, *Top Twenty Pay-For-Delay Drugs: How Drug Industry Payoffs Delay Generics, Inflate Prices and Hurt Consumers*, U.S. PIRG (July 2013), *archived at* https://perma.cc/4N77-TBG2 (warning that the pay-for-delay practices ensure that drug costs remain higher than the cost of generics, sometimes even as high as 10 times more expensive than their generic counterpart).

> The drug Provigil, prescribed for sleep disorders and multiple sclerosis-related fatigue, offers a case study: Experts expected a generic version of Provigil to go on the market in late 2005, but brand-name manufacturer Cephalon paid more than $200 million

delay," has slowed, if not outright halted, the availability of alternative prescription drugs.[98] In the hope of remedying this issue, Congress introduced The Preserve Access to Affordable Generics and Biosimilars Act of 2019 ("PAAGB Act"), a bipartisan bill to improve access to generic drugs and strengthen the process by which they enter the market.[99] The PAAGB Act would give the Federal Trade

> to four different generic drug manufacturers, who kept their generics off the market until 2012. In the meantime, many patients had to pay up to $1,200 each month for the drug, or manage without it.

Id. *See also* Robin Feldman, *Pharma companies fight behind-the-scenes wars over generic drugs*, STAT (June 16, 2017), *archived at* https://perma.cc/564C-ZPMT (detailing various practices undertaken by pharmaceutical drug companies to limit access to generic drug alternatives). "Given the value of holding off generic competition, drug companies string out a variety of delay games, one after another, each adding a little more time for the brand-name drug to flourish without generic competition." *Id.*

[98] *See* Gregory Jones et al., *Strategies that delay or prevent the timely availability of affordable generic drugs in the United States*, NCBI (Jan. 27, 2016), *archived at* https://perma.cc/H3VH-CWLW (indicating the various strategies used to ensure that generic drugs do not enter the market, including pay-for-delay); *see also* Erin Fox, *How Pharma Companies Game the System to Keep Drugs Expensive*, HARV. BUS. REV. (Apr. 6, 2017), *archived at* https://perma.cc/FFU4-RQV2 (explaining how generics are kept from entering the market whether it is through pay-for-delay or citizen petitions filed by pharmaceutical drug companies in an effort to stifle competition); *see also* ASPE, *supra* note 97 (highlighting the effects of pay-for-delay tactics). Pay-for-delay tactics have serious implications given that,

> [t]he FTC reports that there were 19 such agreements in fiscal year 2009, with each agreement on average delaying the availability of cost-saving generics by 17 months. The FTC also reported that, in January, 2010, such agreements were protecting at least $20 billion in sales of branded drugs from generic competition. The FTC estimated that pay-for-delay agreements cost American consumers $3.5 billion per year $35 billion over the next 10 years.

ASPE, *supra* note 97.

[99] *See* Andis Robeznieks, *Quick Take: Action on drug pricing gets massive bipartisan support*, AMA (Apr. 5, 2019), *archived at* https://perma.cc/5JRR-24Y7 (presenting current bipartisan efforts, such as the PAAGB, to address the access to generic drugs). Bills, both in the House and in the Senate, are being introduced to improve generic drug access as well as ending anti-competitive actions that use the patent system to create barriers to entry for generic drug makers. *Id.* *See also* Kelly Davio, *CBO Says Bill to Curb Pay-for-Delay Would Cut the Deficit by $613 Million Over 10 Years*, CTR. FOR BIOSIMILARS (May 10, 2019), *archived at* https://perma.cc/KZ5Q-2FJ6 (noting that the PAAGB would reduce the deficit by

Commission ("FTC") the authority to bring an enforcement action against any pharmaceutical company that enters into a "pay-for-delay" agreement with a generic drug maker and would also require companies to report their settlement agreements to the FTC to see if the settlement contains any pay-for-delay provisions.[100] By prohibiting said practice, generic drugs would become more readily available—creating a blueprint for future generic 3D printed organs in the future.

$613 million by 2029 given that direct spending would be reduced by $520 million and $93 million would be increased in revenues).

> While such deals are illegal under antitrust law, the proposed legislation would specifically target these agreements, especially as they arise to settle patent infringement cases. The bill would require that agreements that result from United States Patent Trial and Appeal Board proceedings be reported to the Federal Trade Commission (FTC) and the Department of Justice, and would establish the authority to levy penalties if a settlement is found to violate the law.

Id.

[100] *See* Preserve Access to Affordable Generics and Biosimilars Act of 2019, S. 64, 116th Cong. § 1 (2019) (introducing the PAAGB Act that seeks to end pay-for-play tactics employed by pharmaceutical companies); Preserve Access to Affordable Generics and Biosimilar Act, H.R. 2375, 116th Cong. § 2 (2019) (reaffirming the House version of S. 64). *See also* Betsy Lordan, *FTC Concludes that Impax Entered into Illegal Pay-for-Delay Agreement*, FTC (Mar. 29, 2019), *archived at* https://perma.cc/L8M8-LAK2 (exemplifying the Pay for Delay tactics used by drug companies to stifle competition). *See also* Emmarie Huetteman, *Klobuchar Wants To Stop 'Pay-For-Delay' Deals That Keep Drug Prices High*, KHN (Apr. 26, 2019), *archived at* https://perma.cc/6HPM-7KC2 (elaborating on how drug companies sue generic drug manufacturers to force them into settlement agreements that include payments to delay the generic drug manufacturer from entering the market). The FTC has found that the pay-for-delay deals have forced consumers to pay $3.5 billion dollars in higher drug costs every year. *Id. See also Nadler & Collins Introduce Preserve Access to Affordable Generics and Biosimilars Act, Legislation to Lower Prescription Drug Prices,* U.S. HOUSE COMM. ON THE JUDICIARY (Apr. 29, 2019), *archived at* https://perma.cc/DSP2-5XGY (expanding on why the PAAGB Act was introduced to the committee). Chairman Nadler explained that the "legislation addresses the critical need to lower the soaring cost of prescription drugs, which is jeopardizing the health and well-being of millions of American patients." *Id. See also* Steve Brachman, *Congress Adds TERM Act and No Combination Drug Patents Act to List of Drug Patent Bills Being Considered*, IP WATCHDOG (June 20, 2019), *archived at* https://perma.cc/4LYT-QE84 (adding the PAAGB to the list of bills that are currently being considered in Congress that seek to address drug patents).

IV. Analysis

A. 3-D Printed Organs are not Patent Eligible

While there is much to be said on the patentability of the process by which a human organ is printed using a 3D printer, this Note will primarily address the patentability of the actual 3D printed human organ.[101] While the Supreme Court has been clear in the non-patentability of the laws of nature, it has carved out certain parameters by which inventors may still obtain patentability when they apply said laws of nature.[102] Resultingly, a 3D printed human organ is at the heart

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[101] *See* Diamond v. Diehr, 450 U.S. 175 (1981) (elucidating on what makes a process patent eligible). The Court clarifies what is required of a process claim whereby:

> [a] process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made. The 'novelty' of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.

Id. See also Xin, *supra* note 64, at 164–70 (supporting the claim that 3D printed organs that are identical to human organs are patent ineligible). While there is a distinction between 3D printed organs that have alterations and those that are replicas of human organs, there is still a great challenge faced by both organs in obtaining their patent eligibility. *Id.* at 169–70. *See also* Ammar, *supra* note 19, at 298 (elaborating on the patentability of process). It is likely that the 3D bioprinting process will be patent eligible because "a process could be a method of making something such as a method for 3D printing a cell or an organ . . . [therefore] the process of bioprinting living organs themselves are patent eligible." *Id.*

[102] *See* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) (reiterating the prohibition against patenting nature). The Court reasoned that living things and organisms "are manifestations of laws of nature, free to all men and reserved exclusively to none." *Id. See also* Xin, *supra* note 64, at 150 (expanding on the Funk Bros. Seed Co. ruling). The Court explained that:

> . . . qualities were found to be a 'work of nature' and 'part of the storehouse of knowledge of all men … like the heat of the sun, electricity, or the qualities of metals … [f]or such a discovery to be considered an invention, the subject matter must 'come from the application of the law of nature to a new and useful end' which was not found in Funk. The Court refused, and refuses, to grant anyone a claim to the monopoly of a natural phenomenon.

Id. See also Diamond v. Chakrabarty, 447 U.S. 303, 303 (1980) (explaining the nuances to the laws of nature exception). The Court in *Chakrabarty* pointed out that the laws of nature ought not to be patented but should there be a creation that is a nonnaturallly occurring manufacture or composition of matter due to human ingenuity then said creation may very well be patent eligible. *Id.*

of the applicability of the laws of nature in patent law as these organs deal with composition of matter that exist in nature, yet also incorporate artificial manmade intervention.[103] This fusion of nature and human innovation gives life to the debate over the patentability of 3D printed organs.

To determine whether a 3D printed organ can be patented, *Chakrabarty* serves as a starting point. The Patent Act applies both the term "manufacture" and "composition of matter" as means of assessing whether a particular invention may be patented.[104] 3D printed organs fit the definition of manufacture because they are produced from raw materials such as human cells and thus are given "new forms, qualities, properties, or combinations, whether by hand-labor or by machinery."[105] Similarly, 3D printed organs qualify as "composition of matter" given that they are composite articles resulting from a chemical and biological union of human cells.[106] Given that the Court's analysis in *Chakrabarty* focused on the patentability of modified bacterium, one can apply a similar approach to the patentability of 3D printed organs— determining their fit within the subject matter eligibility requirements of the Patent Act as "manufacture" and "compositions of matter".[107]

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[103] *See* Ammar, *supra* note 19, at 291 (acknowledging the challenge of granting patent rights to living organisms such as 3D printed organs). There is a recognition that the use of human cells to print organs is contestable and, while the process may be patentable, the end product itself remains uncertain. *Id.* at 305. Ammar admits that "the patentability of the 3D bioprocess and bio ink is more significant that the patentability of the end product itself." *Id.*

[104] *See Chakrabarty*, 447 U.S. at 303 (using the canons of construction to define manufacture). The Court begins its analysis by determining what § 101 entails and uses these definitions as a starting point by which to interpret the applicable law. *Id.*

[105] *See id.* (establishing how the term 'manufacture' ought to be understood). The Court reads the term 'manufacture' in accordance with the dictionary definition as it begins to explore whether the creation in *Chakrabarty* is patent eligible. *Id.*

[106] *See id.* at 308 (defining composition of matter as "all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids"). Compositions of matter are relevant given that it is one of the means by which a creation may gain patent eligibility. *Id.*

[107] *See* 35 U.S.C.A. § 101 (West 1952) (focusing on the word "any"). *See also Chakrabarty*, 447 U.S. at 303 (pointing out that the word "any" in the Patent Act is important). By choosing the word "any," the Court interprets such usage as intentional by Congress in allowing a wide scope in determining patent eligibility. *Id.* at 308. The Court went on to look at committee reports accompanying the Act to determine congressional intent and found that Congress intended the Act to include

Although 3D printed organs may initially qualify within the parameters of the Patent Act, a 3D printed organ may still suffer the fate of being excluded from the Patent Act's purview due to the "law of nature" exception.[108] The debate focuses on the fine line between natural occurrences and human innovation that has been blurred with the blending of both 3D printing machinery and the very biological systems that sustain us.[109] Following the *Chakrabarty* Court's reasoning that a living organism that possesses markedly different characteristics from its naturally occurring form may very well be within the protection of the Patent Act—one can see how 3D printed organs fall outside this "markedly different characteristics" definition.[110] For example, when 3D printing a kidney or lung, the result will be a replica of what already exists in nature.[111] Each organ

"anything under the sun that is made by man." *Id.* at 309. Additionally, the Court expressly proclaimed that the subject-matter provision of the patent law was purposefully made to be broad in order to promote the progress of science and the arts as well as bringing forth social and economic benefits dreamed of by the founding fathers. *Id.* at 315.

[108] *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 577 (2013) (exemplifying a discovery that could fit under the Patent Act framework but is patent ineligible because it is a product of nature). Myriad split the baby as it deemed one DNA segment as patent ineligible while granting patent rights to cDNA. *Id.* The difference between the two rested on whether they were a product of nature. *Id.*

[109] *See* Varkey & Atala, *supra* note 63, at 294 (arguing that "patents for human organs will not be valid but it is not clear whether an artificial printed organ would be patent-eligible."). *See also Chakrabarty*, 447 U.S. at 313 (distinguishing between products of nature, whether alive or not, and man-made creations as a way of determining patentability). Inventions that lack human alterations and merely mimic that which is already in nature are undeserving of patent rights. *Id.* Congressional recognition of this distinction is what the Court used in determining whether the bacterium in Chakrabarty was patent eligible. *Id.*

[110] *See Chakrabarty*, 447 U.S. at 303 (differentiating those claims that are products of nature and those that have markedly different characteristics). In *Chakrabarty*, the patentee developed a new bacterium with "markedly different characteristics" from any found in the natural world thereby granting the patentee's creation patent rights. *Id.* at 310. The Court reasoned that "[h]is claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter—a product of human ingenuity 'having a distinctive name, character and use.'" *Id.* at 303.

[111] *See Myriad*, 569 U.S. at 577 (pointing out that in order to escape the law of nature exception there needs to be an alteration of some sort). In *Myriad*, the patentee did not alter the bacteria therefore the patentee remained constrained by the law of nature exception, which is directly applicable to the 3D bioprinting debate. *Id.*

that is printed, while using the patient's own unique cells, remains identical to all other naturally occurring organs already in existence.[112]

The challenge in determining whether a 3D printed organ possesses markedly different characteristics from any found in nature is exacerbated by the fact that the alteration of the cells is different to the alteration of bacteria in *Chakrabarty* as well as the modification of cDNA in *Myriad*.[113] The change of a human cell from mere tissue to growing cells, soon to become human kidneys, does not add anything new to the organ or change the very essence of the organ.[114] In both *Chakrabarty* and *Myriad*, the change in the living organism to something entirely different is what was key in granting both their patentability.[115] The apparent alchemy of 3D bioprinting appears to

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[112] *See* Lord, *supra* note 18 (providing a real example of a 3D bioprinted organ that has already been transplanted into a human). The printing of 3D organs has already begun given that a:

> . . . bladder was made using a sample of [the patient's] bladder tissue, and modified inkjet printer, presumably used to build a sort of scaffold/host for the cells. Incubated in lab condition, the new bladder was grown in 2 months, and then successfully transplanted into the patient. Massella is 1 of 10 people with a bioprinted bladder grown from his own cells. According to Dr. Atala, flat structures like skin are easiest to print, whereas tubular structures like blood vessels and hollow non-tubular organs like bladders are more complex. Solid organs like hearts, lungs, and kidneys, are the most difficult to bioprint as they have more cells per centimeter, though some researchers have had small successes in this field.

Id.

[113] *See Myriad*, 569 U.S. at 577 (explaining why cDNA was patent ineligible whereas a DNA sequence was not). The Myriad court elaborated that:

> cDNA is not a "product of nature," so it is patent eligible under § 101. cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA segments. Its creation results in an exons-only molecule, which is not naturally occurring. Its order of the exons may be dictated by nature, but the lab technician unquestionably creates something new when introns are removed from a DNA sequence to make cDNA.

Id.

[114] *See* Ebrahim, *supra* note 21, at 42 (determining that 3D bioprinted tissues are a product of nature). Because 3D bioprinted organs are "manufactured by natural growth through intrinsic self-assembly principles found in nature," there is a strong argument to be made that they lack patent eligibility. *Id.*

[115] *See Myriad*, 569 U.S. at 595 (ruling that the distinction between DNA and cDNA rested on the alteration of the latter). The *Myriad* court ruled that the DNA segment in question was a product of nature and not patent eligible, even if it had some human

support the claim that the modification of cells falls within the meaning of "markedly different characteristics," yet the final printed organ is a naturally occurring organ that already exists in nature.[116] Moreover, the lab technician does not create something new when she takes human cells as biological ink to print a kidney because the organ itself is not a new creation.[117] Whereas, in *Myriad*, the DNA was changed so that it retained naturally occurring exons yet excluded introns, the 3D printed organ is not modified to exclude or include any new characteristics.[118] While 3D printed organs require human handiwork in printing the organ itself, the scientist's involvement in the process does not alter the way in which the organ functions or will function once it is removed from the printer, which means that the scientist is merely a conduit for that which already exists in nature.[119] Simply

intervention, yet granted patent eligibility to cDNA because it was not "naturally occurring." *Id. See also Chakrabarty*, 447 U.S. at 310 (using the markedly different characteristics principle to grant patentability to the modified bacterium). The *Chakrabarty* court established the markedly different characteristics rule while also determining that the discovery was not nature's handiwork making it patentable despite including naturally occurring components. *Id.*

[116] *See id.* at 309 (affirming the patent ineligibility of that which is already in nature). The Court has made it clear that:

> . . . a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E = mc^2$; nor could Newton have patented the law of gravity. Such discoveries are "manifestations of . . . nature, free to all men and reserved exclusively to none."

Id.

[117] *See Myriad*, 569 U.S. at 577 (reaffirming the distinction between creating something new from nature versus merely using a product of nature). Whereas in *Myriad* the lab technician created something new with cDNA, the Court was clear in not granting the DNA sequence patent eligibility given that nothing new was created. *Id.*

[118] *See id.* at 590 (contrasting *Myriad* from the *Chakrabarty* ruling). The difference in *Myriad* was that it "did not create anything." *Id.* at 591. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of intervention. *Id.* The cDNA in *Myriad* was a new invention due to the role of human ingenuity in altering a naturally occurring phenomena. *Id.* at 590. *See also* Varkey & Atala, *supra* note 63, at 293 (extracting from the *Myriad* holding the heart of the patent eligibility in the cDNA). What made the cDNA patent eligible was the fact that it was synthetically created DNA thus shielding it from the natural product of nature exception. *Id.*

[119] *See* Ebrahim, *supra* note 21, at 45 (accepting that 3D bioprinted organs may be disqualified from patent eligibility). Given that the 3D bioprinting is printed in the hopes of being transplanted into a patient, this may ensure that said bioprinted organ

aiding the creation of a naturally occurring organism lacks the legal muster required under *Myriad* and *Chakrabarty*.[120] Much like a farmer aids the growth of her crops, a scientist helps the organ grow inside the printer, yet neither the farmer nor the scientist may claim patent rights for what nature has produced.

Some may argue that a 3D printed organ is distinct from the previous organ that the patient was forced to discard but if that discarded organ were to be a healthy and fully functioning organ then it would be identical to the organ taken out of the 3D printer.[121] The difference between the human organ that failed the patient and the one that will cure the patient fails to serve as a justification for why a 3D printed organ contains "markedly different characteristics."[122] There is a temptation to brand 3D printed organs as artificial creations devoid of natural characteristics, but ultimately the organ that is produced was designed and created using the laws of nature.[123]

While innovators and researchers may find discomfort in knowing their final printed organ may not be patent eligible, they can find solace in knowing that the process by which they printed the organ may very well be patentable, which will ensure the processes of printing is improved without commoditizing human organs

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may be "too human and…conceptually equivalent to a human organism" thereby denying it patent rights. *Id.*

[120] *See Myriad*, 569 U.S. at 577 (affirming that "extensive effort alone is insufficient to satisfy § 101's demands."). *See also Chakrabarty*, 447 U.S. at 303 (clarifying congressional intent behind the Patent Act). The Court made clear that the "distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions." *Id.* at 313.

[121] *See* Tran, *supra* note 8, at 159–60 (highlighting the benefits of bioprinting as they pertain to fixing defects and malfunctioning organs). The ability to fix genetic defects, such as "with bioprinting, an individual born with four fingers could print another hand with all five fingers as replacement … [or] an individual with mismatched teeth could get perfect teeth replacement instead of getting orthodontic braces." *Id.* at 160.

[122] *See* Ebrahim, *supra* note 21, at 42 (accepting that 3D bioprinted tissues lack markedly different characteristics). Because nature is "emulated inside of a 3D bioprinting" the 3D printed organ would not have the required markedly different characteristics to save it from the laws of nature exception. *Id.*

[123] *See Myriad*, 569 U.S. at 591 (ruling that the lack of human intervention rendered the DNA sequence patent ineligible). In *Myriad*, nothing new was created when the DNA was sequenced therefore "the composition was not patent eligible because the patent holder did not alter the bacteria in any way." *Id.* Ultimately, the DNA sequence could have been patent eligible, much like a 3D printed organ, if it became something new. *Id.*

themselves.[124] That being said, the final product that is a human heart, lung, or kidney, cannot be patentable because patent law has made sure to protect living organisms and natural occurrences from monopolization and commercialization.

B. Confronting 3D Printed Organ's Patentability by Applying the Generic Drug Approach

Since the patentability of human organs remains uncertain, there is still a way to ensure that 3D printed organs remain readily accessible to those in desperate need of them. To combat the abuse of patents used by pharmaceutical companies, generic drug makers have stepped in to offer affordable prescriptions that offer the same medical benefits.[125] Patent law gave pharmaceutical companies free reign over lifesaving drugs and it may very well give the same power to the owners of patents for 3D printed organs.[126] Should that be the case, it

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[124] *See Myriad*, 569 U.S. at 595 (noting how an innovative method could very well be patent eligible). The Court gives solace to the inventor in *Myriad* by explaining that, "[h]ad Myriad created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent." *Id.*

[125] *See* Felberbaum, *supra* note 86 (affirming the consequences of introducing generic drugs to the market). In its recent analysis, the FDA credited generic drugs for the significant decrease in drug prices. *Id.* Notably, "[t]he analysis looked at all drug products that had initial generic entry between 2015 and 2017 and showed that as competition increases, generic drug prices decline." *Id.*

[126] *See* Initiatives for Medicines, Access, & Knowledge, *supra* note 75 (expressing concern over drug companies' abuse of the patent system). The findings of the report revealed that there were efforts made by drug makers to abuse the patent system and use their patent rights to solidify their monopiles to raise drug prices and prevent others from encroaching on their monopolies. *Id.* Even worse, despite certain patents reaching their date of expiration, drug companies, such as Genetech and Amgen, have extended their hold on certain profitable drugs beyond the twenty-year limit. *Id. See also* Johnson & Brough, *supra* note 84 (providing an example of how the patent system is being abused). The problem can best be seen when one looks at Namenda:

> [A] drug produced by Forest Laboratories used to treat the confusion associated with Alzheimer's Disease. Forest Laboratories faced generic competition on Namenda starting in 2015. Instead of competing with a generic drug on the market, the company responded by changing its formulation of Namenda from a twice-daily pill to a once-daily version. This new version was patented with protection on the product extending to 2029. The

is imperative that there is a legislative framework in place to greet the arrival of 3D printed organs to prevent the kinds of abuses seen in the pharmaceutical industry and thereby stem the tide of inaccessibility.

A manner in which to facilitate the availability of 3D printed organs is to enact legislation in the future that draws inspiration from the BPT, CREATES, and PAAGB Acts. First, there will need to be a level of transparency that can be molded in the same fashion as the BPT Act, where 3D bioprinting companies will publish their patents to ensure they do not emulate the practices of pharmaceutical companies in over-patenting their inventions.[127] This proposed level of transparency would ensure that bioprinting companies publish "the marketing status, dosage form, route of administration, strength, and, if applicable, reference product, for each such biological product," without any delay or obfuscation.[128] Transparency will lead to greater competition so that a repetition of what Celgene has done, building a massive patent fortress to stifle generic competition and increase the price of a cancer drug, can be avoided.[129] Notably, a bioprinting

> actions of Forest Laboratories were a clear example of the company's attempt to game the patent system.

Id.

[127] *See* Biologic Patent Transparency Act § 2(a)(3) (setting forth the need to create a database that can be used by generic competitors to develop generic alternatives). The Act addresses the fact that "certain license holders are preventing generic product developers from obtaining quantities of the covered product necessary for the generic product developer to support an application for approval by the Food and Drug Administration." *Id. See also* Collins & Kaine, *supra* note 90, (explaining "[b]iologic medicines represent a new and promising era in treatments; yet, when competing products—'biosimilars'—attempt to enter the market, they often find it impossible to navigate the extensive portfolio of patents that protect the brand product due to a lack of readily accessible information.").

[128] *See* Biologic Patent Transparency Act § 2(a)(3) (outlining the required disclosures under the BPT that increase transparency). *See also* Khoury, *supra* note 6, at 5–6 (emphasizing the potential for 3D printing to revolutionize industries). One can best understand 3D printing's development as,

> The potential to be a paradigm-shifting factor is a combination between the popularization of such technologies . . . and the diffusion of a culture based on access to and reuse of knowledge…this type of open design through 3D printing is set to change the world, no less, and in the process Intellectual Property (IP) is expected to be greatly impacted by this.

Id.

[129] *See* Mandrusiak, *supra* note 89 (noting that one of the purposes behind the bill is to promote competition in the marketplace). *See also* Felberbaum, *supra* note 86

version of the BPT Act would defang bioprinting companies by prohibiting the bringing of infringement actions if the claimed patent is not disclosed, thereby ensuring brand name companies do not conveniently hide any patents that it may later use against generic manufacturers.[130]

Moreover, a 3D bioprinting version of the CREATES Act can make available samples of 3D printed organs for further testing and development.[131] This may be crucial in improving the quality of 3D printed organs and allowing those who have the means to do so to test new ways of perfecting 3D bioprinting.[132] A bioprinting version of the

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(reiterating the effect of generic drugs in lowering drug prices given the presence of greater competition); Kodjak, *supra* note 80 (shedding light on how Celgene has managed to "keep raising the price of Revlimid because the drug has no competition. It's been around for more than a decade and its original patent expires next year.").

> By preventing generic entry, Celgene has been able to continue reaping as much as $170 to $310 per dose for Thalomid and $430 per dose for Revlimid, or more than $200 million annually for Thalomid and $4 billion annually for Revlimid," said a 2014 lawsuit by the generic drug maker Mylan. Revlimid brought in $8.1 billion — or 63 percent — of Celgene's revenue in 2017. Those numbers are remarkable because both Revlimid and Thalomid are derived from a decades-old drug, thalidomide, that was once sold over the counter in Europe before it was pulled from the market.

Kodjak, *supra* note 80.

[130] *See* Biologic Patent Transparency Act § 2(a)(3) (requiring that: "a 'patent required to be disclosed' is any patent for which the holder of a biological product license . . . believes a claim of patent infringement could reasonably be asserted by the holder, or by a patent owner"). *See also* Brinckerhoff, *supra* note 91 (discussing the fact that the BPT Act requires brand companies to disclose all of the patents it believes an infringement claim could reasonably be asserted).

[131] *See* H.R. 1865 § 610 (presenting the CREATES Act as a means of promoting greater access to drug samples in an effort to generate greater generic market entry). *See also* Bunis, *supra* note 96 (elaborating on what the CREATES Act aims to achieve). The CREATES Act empowers generic drug makers to force pharmaceutical companies to hand over samples of their drugs when they refuse to do so. *Id.* Drug companies stall their regulatory requirement of handing over samples in an attempt to fend off generic drug competition. *Id.* This practice further strengthens the pharmaceutical company's hold over the profitable drug. *Id.*

[132] *See* Tran, *supra* note 8, at 160 (delivering potential side effects of 3D bioprinting). These risks remain unknown can range from malfunctions to unhealthy byproducts. *Id.* There will be a need for constant improvement in 3D bioprinting given that creating a human organ requires the mimicking of complex anatomical systems, which also creates potential risks of bioprinting. *Id. See also* American Institute of Physics, *supra* note 10 (providing ways in which 3D bioprinting has been improved).

Act would disincentivize brand name companies from inhibiting sample availability because the Act would force them to pay the attorney's fees and costs of bringing the civil action and "a monetary amount sufficient to deter the license holder from failing to provide . . . sufficient quantities of a covered product."[133] By increasing the availability of samples of the bioprinted organs, generic manufacturers would have one less barrier to entry thus enabling them to develop affordable alternatives that can be made available to everyone regardless of their net worth.

Much like the PAAGB Act, a bioprinting version would be needed to ensure that bio printing companies do not conspire to pay off generic bioprinters.[134] Drawing from the purpose of the PAAGB Act, a bioprinting version ought to enhance competition in the bioprinting market by "stopping anticompetitive agreements between manufacturers of brand name and generic drug products that . . . limit, delay, or otherwise prevent competition."[135] The need for an

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The use of physics to improve 3D bioprinting shows how this new technology works by trial and error thereby necessitating the sharing of information. *Id.*

[133] *See* H.R. 1865, *supra* note 92 (providing the legal remedies available to generic manufacturers who bring legal action against brand name companies that refuse to provide samples of their product for testing a development of generic competition). *See also* Clancy, *supra* note 95 (explaining that drug makers refuse to provide samples in order to thwart competition).

[134] *See* H.R. 2375, *supra* note 100 (reintroducing the PAAGB as an attempt to fend off unfair practices by drug companies such as paying off their generic competitors). *See also* House Judiciary Committee, *supra* note 100 (highlighting the importance of the PAAGB). Notably, the Act addresses pay-for-delay tactics given that they:

> prevent access to more affordable generic and biosimilar drugs, costing consumers and the government billions of dollars in higher drug costs. By establishing that pay-for-delay agreements are illegal under the antitrust laws, the Preserve Access to Affordable Generics and Biosimilars Act will lower drug prices by ending agreements that keep lower-priced generics from entering the market.

Id.

[135] *See* H.R. 2375, *supra* note 93 (articulating the purpose of the PAAGB that is designed to promote competition in the drug market). *See also* Lordan, *supra* note 100 (providing an example of a Pay for Delay occurrence). The case of Endo and Impax shows how, even though a generic competitor was ready to enter the market, a payment by Endo, the drug manufacturer, blocked consumer access to a lower-cost generic version. *Id*. *See also* Yanisky-Ravid & Kwan, *supra* note 16, at 929–30 (commenting on the need for a larger conversation on the ethical, moral, and legal issues surrounding 3D bioprinting). With the increasing capabilities of 3D bioprinting, there appears to be a lack of attention being paid by regulators at the

enforcement mechanism that would protect competition in the bioprinting market should mirror the PAAGB's forfeiture provision that would penalize companies that engage in pay-for-delay agreements in the amount of three times the value of the payment received by the generic manufacturer.[136] Bioprinting legislation that follows the PAAGB Act's footsteps will guarantee that 3D bioprinting companies do not take a page out of the pharmaceutical playbook and prevent the development and marketability of generic bioprinted organs.

V. Conclusion

The patent law system of the United States has driven great inventions that have shaped the very fabric of this country. Nevertheless, such a success in technological and intellectual advancement should not conceal the fact that certain industries have reaped great profits at the expense of everyday consumers, which begs the question of how can this be avoided in the future? With the advancement of 3D printed organs, the opportunity to save countless lives is a priceless possibility that should not be clouded by the insatiability of a few. As 3D bioprinting continues to grow at a rapid pace, the law should create boundaries by which the public can benefit from this innovation without fear of overpricing and other abuses that previous companies have employed without regard for desperate patients. If we allow life-saving human organs to become a commercialized commodity we will sentence all those who cannot afford these treatments to perpetually remain on the organ transplant waitlist until their number is called or their luck finally runs out.

federal level despite the rapid advancement, especially when it comes to the printing of internal and external body parts. *Id.*

[136] *See* H.R. 2375, *supra* note 100 (providing a forfeiture provision that would deter violations of the Act and offer equitable relief as deemed appropriate). Moreover, such remedies are in place to "support the purpose and intent of antitrust law by prohibiting anticompetitive practices in the pharmaceutical industry that harm consumers". *Id.*