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INTRODUCTION

At a very high level, the United States, through the US Patent and Trademark Office, will issue patents to qualifying inventors in order to incentivize technological advancements.[1] These patents grant the patent owners the right to exclude others from making, using, selling, or offering to sell the invention for a period of time.[2] In effect, the patent owner is granted a significant financial incentive–a monopoly over the invention–in exchange for developing the invention and disclosing it to the public. The power to issue such patents stems from Congress's Constitutional power "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[3]

Importantly, the Constitution provides that the power to issue patents is limited to "promot[ing] the Progress of . . . useful Arts."[4] This intuitively means that certain inventions should not qualify for a patent, because the grant of a monopoly on that invention would not promote progress. For example, granting a patent–and thus a monopoly–for an old, widely used, publicly available machine would generally not promote progress.

This also gives insight into the fundamental purpose of the patent law system as envisioned by the framers of the Constitution. The framers understood that the public benefits when technological advancements are made, and that this public benefit justifies the grant of a limited monopoly. In general, monopolies have a negative impact on the public because they decrease market competition and drive costs up. However, incentivizing the creation of beneficial inventions, or at least incentivizing faster development of such inventions, has been viewed as worth the cost. Because this cost has to be justified, patent rights are only available for those inventions that promote progress.[5] In other words, the value of the patent is not determined by the time, effort, or labor that went into development but rather is determined by the results of that

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[1] *See, e.g.,* Stanford University v. Roche Molecular Systems Inc., 563 U.S. 776 (2011).

[2] 35 U.S.C. §271(a) (2010).

[3] U.S. CONST. art. I, § 8, cl. 10.

[4] *Id.*

[5] Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 10-11 (1966) (holding that patents claiming only obvious subject matter are invalid) ("[T]he underlying policy of the patent system [is] that 'the things which are worth to the public the embarrassment of an exclusive patent,' ... must outweigh the restrictive effect of the limited patent monopoly.") (quoting letter from Thomas Jefferson to Isaac McPherson (Aug. 1813)).

labor. The resulting innovation must be such that it promotes "progress" as defined by Congress and by the courts.

To protect this goal, Congress and the Judiciary have established specific criteria to determine which inventions qualify for a patent and which do not. The Congressional criteria for patentability, detailed in 35 U.S.C §§101-03, states that an invention must be novel, useful, and nonobvious.[6] In addition to these requirements, the Judiciary requires that the invention not be classified as a law of nature, natural phenomenon, or abstract idea.[7] As mentioned, the purpose of each of these criterion is to ensure that patents are granted only to inventions that "promote the Progress of . . . useful Arts."

As new technologies emerge, it is unclear whether these judicially created criteria still serve that purpose or whether the criteria are overly expansive such that truly useful inventions are insufficiently incentivized. This Note looks specifically at 3D printed biomaterials–designed to replicate naturally occurring cells, tissues, and organs–to determine if this technology is patentable under the current system of judicially created exceptions, if it should be, and if there are better alternative forms of intellectual property protection such that a change to the current patent system is unnecessary. Part I discusses the relevant background of 3D printed biomaterials. Part II discusses judicial exceptions to patentability generally. Part III analyzes the patentability of 3D printed biomaterials under the current system of judicial exceptions. Part IV argues that judicial exceptions should be removed as they exist currently. Part V discusses the implications of such a change.

I. THE BACKGROUND OF 3D PRINTED BIOMATERIALS

Traditional manufacturing processes are often subtractive processes. For example, if a manufacturer wished to make a key, she would likely start with a block of metal and machine away unwanted material until the final product reflected the shapes and grooves required for the part to correctly interact with the lock. Any removed material would then be discarded or reused.

3D printing, on the other hand, is an additive process.[8] It requires that material is added layer by layer until the desired shape is formed. Imagine, for example, mig welding the shape of the letter 'A' onto a block of steel. The 'A' would be slightly raised relative to the block because material has been added. Imagine then continuing to lay layers of

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[6] 35 U.S.C §§ 101-03 (2011) (stating with respect to novelty and utility, "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.") (stating with respect to nonobviousness, "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.").

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

[8] JOHN JORDAN, 3D PRINTING 3-5 (2019).

additional weld on top of that same 'A' until the letter had a significant thickness away from the block. This is a very basic and exaggerated example of 3D printing. The general benefit of this manufacturing is that the final shape "grows" with each layer. This means that material generally does not need to be removed or wasted like subtractive manufacturing, and it means that more complex shapes and structure are achievable without additional tooling beyond the "printer."

Most 3D printing is done with computer aided manufacturing ("CAM").[9] This means that the product is designed on a computer, software is used to convert the final product into a series of step-by-step instructions that define each layer, and those instructions are sent to a 3D printer which reads the instructions, prints the layers, and ultimately grows the final product.[10]

Modern developments in biotechnology have shown that this process can be used to manufacture biomaterials such as tissues and, potentially, full organs.[11] In the case of burn victims, for example, doctors have been able to 3D print skin and skin grafts to replace the damaged tissue.[12] For this process, a number of skin cells are first collected from the patient.[13] Then, those cells are replicated and grown in vivo. That product is then supplemented with additional biomaterials for support and printability, thereby forming a sort of "bio-ink."[14] That ink is then processed through a 3D printer which "prints" the bio-ink, layer by layer, until it forms a structure that is similar to and compatible with skin tissue.[15] This living, 3D-printed tissue is then grafted onto the patient. Since the tissue was made from the patient's own skin cells and printed in a structure compatible with human skin, the patient's body should accept the 3D printed tissue graft, and the patient's own skin should grow into it.[16]

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[9] Tadeusz Mikolajczyk et al., *CAD CAM System for Manufacturing Innovative Hybrid Design Using 3D Printing*, TWELFTH INT'L CONF. INTERDISC. ENG'G 22 (2019).

[10] *Id.*

[11] Dr. Edith Bracho-Sanchez, *Researchers 3D-Print Heart From Human Patient's Cells*, CNN (April 17, 2019, 4:19 PM), https://www.cnn.com/2019/04/15/health/3d-printed-heart-study/index.html. ("The process of printing the heart involved a biopsy of the fatty tissue that surrounds abdominal organs. Researchers separated the cells in the tissue from the rest of the contents, namely the extracellular matrix linking the cells. The cells were reprogrammed to become stem cells with the ability to differentiate into heart cells; the matrix was processed into a personalized hydrogel that served as the printing 'ink.'").

[12] Peng He et al., *Bioprinting of Skin Constructs for Wound Healing*, BURNS & TRAUMA (2018) ("Extensive burns and full-thickness skin wounds are difficult to repair. Autologous split-thickness skin graft (ASSG) is still used as the gold standard in the clinic. However, the shortage of donor skin tissues is a serious problem. A potential solution to this problem is to fabricate skin constructs using biomaterial scaffolds with or without cells. Bioprinting is being applied to address the need for skin tissues suitable for transplantation, and can lead to the development of skin equivalents for wound healing therapy. . . . The process of skin bioprinting involves collecting skin tissues from patients by skin biopsy and culturing them in vitro to obtain enough number of cells; Cultured skin cells are then mixed with biomaterials and delivered to a three dimensional (3D) bioprinter for fabrication of customized skin.").

[13] *Id.*

[14] *Id.*

[15] *Id.*

[16] *Id.*

These developments create a multitude of potential intellectual property rights. There are potential rights in the "ink," or the biomaterial fed into the printer, in the printer itself, in the software and computer codes, and in the final product. This paper will focus on the intellectual property rights associated with the final, 3D printed, biomaterial product.

This final product, although it is created from a highly innovative, non-natural process, looks substantially similar to the work of Mother Nature. It is made from an assembly of cells just like any human tissue or human organ. In fact, the closer this product resembles its naturally occurring counterpart, the more successful it will be for use in patients.[17]

Any differences between the 3D printed product and the naturally occurring product are incidental; they are either designed differences in order to make the biomaterial suitable for 3D printing, or they are differences resulting from a limitation in the technology. These differences do not exist in order for the 3D printed material to function differently than natural tissue. In fact, just the opposite is true. Whatever the reason for the differences, the ultimate goal is to mimic the natural tissue as closely as possible so that the product is accepted by the patient's body and compatible with it. In other words, the goal is for the 3D printed product to match the characteristics of the natural tissue *despite* any differences between the two. In this way, inventors use human ingenuity and human invention to mimic a product of nature. And, products of nature, alternatively called natural phenomena, are one of the three judicially created exceptions to patentability.

II. JUDICIAL EXCEPTIONS TO PATENTABILITY

The Constitutional power conferred on Congress to award patents and other forms of monopoly rights is as follows: "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[18] This power includes the express limitation that such rights are to be granted only when they "promote . . . Progress."[19] To ensure this limitation is satisfied, the Judiciary has created three categorical exceptions to patentability: laws of nature, natural phenomena, and abstract ideas.[20] The laws of nature exception, as the name suggests, includes natural and physical laws such as gravity. The natural phenomena exception includes natural materials, such as iron,

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[17] Karthik Tappa and Udayabhanu Jammalamadaka. *Novel Biomaterials Used in Medical 3D Printing Techniques*, 9(1) J. FUNCTIONAL BIOMATERIALS (2018) ("Only with the recent advancements in developing novel biodegradable materials has the use of 3D printing in medical and pharmaceutical fields boomed. Today, additive manufacturing technology has wide applications in the clinical field and is rapidly expanding. It has revolutionized the healthcare system by customizing implants and prostheses, building biomedical models and surgical aids personalized to the patient, and bioprinting tissues and living scaffolds for regenerative medicine. . . . An ideal 3D printing biomaterial should be biocompatible, easily printable with tunable degradation rates, and *morphologically mimic living tissue*.") (emphasis added).

[18] U.S. CONST. art. I, § 8, cl. 10.

[19] *Id.*

[20] *See, e.g.*, Diamond v. Chakrabarty, 447 U.S. 303 (1980), *supra* note 7.

and living products of nature, such as plants and animals. And, the abstract ideas exception includes concepts such as human thoughts and mathematical equations. These exceptions, when applicable, will bar an invention from patent eligibility regardless of whether or not the congressional requirements dictated in 35 U.S.C §§101-03 have been met.[21]

These judicially created exceptions to patentability are put in place to distinguish between what has been truly invented versus merely discovered. As stated in *Diamond v. Chakrabarty*, "[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.'"[22] Discoveries, such as the newly discovered material that the *Chakrabarty* court used in its hypothetical, as opposed to inventions, are already in the public domain even if they are unknown or not yet discovered by the public.[23] Since the discovery is pre-existing, it is free for anyone to discover and use, and because of this, the judiciary has decided that monopolies over discoveries do not "promote progress" as is required under the Constitution.[24] In other words, the judiciary will limit patent protection rights to true inventions versus mere discoveries.

A. Natural Phenomena

With respect to natural phenomena, which generally extends to natural materials and organisms, this distinction between discovery and invention means that not all materials and not all organisms will fall into this category. If the phenomenon in question is a mere discovery, it will be precluded from patentability by this categorical exception. If, however, it is a true invention, it may still be patentable.

This distinction is most readily seen by comparing *Funk Bros. Seed Co. v. Kalo Inoculant Co.* and *Diamond v. Chakrabarty*. In *Funk Bros.*, the patented technology in question was a mixture of specific strains of bacteria that was capable of inoculating leguminous plant seeds.[25] Prior to discovering this specific mixture, it was known that each strain of bacteria was effective only for certain types of leguminous plants.[26] Generally, this would mean that mixed cultures of bacteria could inoculate a greater range of leguminous plants; however, as strains were

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[21] *Id.*

[22] *Chakrabarty*, 447 U.S. at 309 (quoting Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948)).

[23] Mere discoveries of natural phenomenon are not patentable because nature is already within the public domain, and that which belongs to the public should not be taken from it. "'Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work.' And monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it." Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 71 (2012) (quoting Gottschalk v. Benson, 409 U.S. 63, 67 (1972)).

[24] *Id.*

[25] Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948).

[26] *Id.* at 129.

mixed, the interactions between the strains of bacteria inhibited their ability to inoculate the plants.[27] This caused the mixed cultures to be less effective. Upon further research, the researchers at Kalo Inoculant Co. discovered that a very specific mixture of strains of bacteria was able to inoculate the plants without the different strains inhibiting each other's effectiveness.[28] In other words, the specific combination played well together. Kalo Inoculant Co. patented that combination, and this suit followed.[29]

Ultimately the Court found that the bacteria combination was not patentable.[30] It was excluded under the judicial exception of natural phenomena.[31] Here, the inventors had not changed the naturally occurring qualities of the bacteria. They merely discovered the existence of those qualities and sought to commercialize them. Therefore, they did not 'invent' for the purposes of obtaining a patent.[32]

In contrast, in *Diamond v. Chakrabarty*, Chakrabarty was able to obtain a patent on bacteria.[33] This clarified that the judicial exception regarding natural phenomena was not about distinguishing between living and nonliving material but rather between inventions and mere discoveries.

In this case, the bacteria strain in question was genetically modified.[34] The genetic code of the bacteria was engineered such that this new strain of bacteria was capable of breaking down crude oil.[35] The goal of this genetic modification was to create a form of bacteria that would clean up oil spills.[36] Here, the genetic modification, made by Chakrabarty, "produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility."[37] No naturally occurring bacteria exhibited the same ability to break down crude oil. This genetic property was fundamentally new, or "markedly different."

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[27] *Id.* at 129–130.
[28] *Id.* at 130.
[29] *Id.* at 128.
[30] *Id.* at 132.
[31] *Id.*
[32] "Discovery of the fact that certain strains of each species of these bacteria can be mixed without harmful effect to the properties of either is a discovery of their qualities of non-inhibition. It is no more than the discovery of some of the handiwork of nature and hence is not patentable. The aggregation of select strains of the several species into one product is an application of that newly discovered natural principle. But however ingenious the discovery of that natural principle may have been, the application of it is hardly more than an advance in the packaging of the inoculants. Each of the species of root-nodule bacteria contained in the package infects the same group of leguminous plants which it always infected. No species acquires a different use. The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee." Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 131 (1948).
[33] Diamond v. Chakrabarty, 447 U.S. 303, 310 (1980).
[34] *Id.*
[35] *Id.* at 305.
[36] *Id.*
[37] *Id.* at 310.

The court emphasized that the patent act contains very few limitations.[38] The section reads, "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title," and that passage was intended to be broad.[39] Ultimately, it was meant to "include anything under the sun that is made by man."[40] The court reasoned that, while bacteria in general might be categorized as natural phenomena, the "markedly different characteristics" exhibited by Chakrabarty's bacteria were decidedly non-natural.[41] They were the exclusive result of his human ingenuity.

This test for "markedly different characteristics" became the test to distinguish between inventions and discoveries, or, in other words, between patentable subject matter and natural phenomenon. This helps ensure that inventors are incentivized for disclosure to the public of true inventions which "promote the progress of science" as opposed to being rewarded for their labor in making a discovery. By not drawing the line between living and nonliving material, but rather between natural phenomena and "markedly different characteristics," the patent system is able to reward and incentivize true inventions that may have natural qualities but are the "product of human ingenuity."

B. Markedly Different Characteristics

With *Chakrabarty*, the Court articulated that the relevant test for the judicial exception of natural phenomena was "markedly different characteristics:" a living organism or living material could still be patent eligible if, as the result of human ingenuity, the material exhibited markedly different characteristics than the product of nature.[42] The question that was not answered, however, was how much difference is required to be markedly different. To apply this test to 3D printed biomaterials, it matters whether "markedly different" means 'does not exist in nature' or whether it means 'acts differently than products of nature.' As previously described, 3D printed biomaterials have a cellular structure different than naturally occurring tissue, yet the goal of the final product is to act as similarly to nature as possible. The ideal 3D printed biomaterial would be functionally indistinguishable from the corresponding natural material.

In *Association for Molecular Pathology v. Myriad Genetics, Inc.*, the Court addressed this question.[43] In the case, the Court considered whether isolated DNA sequences were eligible for patent protection.[44] Isolated DNA sequences are shortened forms of naturally occurring DNA

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[38] *Id.* at 307.
[39] *Id.* (quoting 35 U.S.C. § 101).
[40] *Chakrabarty*, 447 U.S. at 309 (quoting S. REP. No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. REP. No. 1923, 82d Cong., 2d Sess., 6 (1952) (internal quotations omitted).
[41] *Chakrabarty*, 447 U.S. at 310.
[42] *Id.*
[43] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013).
[44] *Id.*

molecules. Importantly, these shortened forms, separated from the rest of the DNA molecule, do not exist in nature.[45] However, the shortened form is identical to and unchanged from the relevant DNA segment that is found as part of the full DNA molecule.[46] In this case, the Court found that this did not pass the "markedly different" test and was therefore not patent eligible.[47]

Prior to this case, it had been generally accepted that isolated DNA sequences, since nature does not produce DNA in these shortened forms, were different enough from naturally occurring DNA.[48] So, the courts, up until this point, found that isolated DNA sequences did not fall within the judicial exception to patentability. In *Myriad*, however, the Court reached the opposite conclusion.[49] The Court based its finding on the fact that, even though the DNA could not be found in this form in nature, the reason these isolated sequences were valuable was due to their natural properties and not due to any change in characteristic that occurred in the isolation process:

> Nor are Myriad's claims saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule. Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA. Instead, the claims understandably focus on the genetic information encoded in the BRCA1 and BRCA2 genes.[50]

In effect, the "markedly different characteristics" test, as articulated by the Court, is not whether the product as a whole is nonnaturally occurring bur rather whether the inventive concept sought to be captured is new and different. This can generally be broken into two questions: (1) is the subject matter different than products found in nature, and (2) is the benefit of the patent derived from those differences or is the benefit derived from the naturally occurring characteristics? In *Myriad*, the benefit sought to be claimed was a function of the naturally occurring sequence of the DNA segment and not a function of the nonnaturally occurring segmentation itself.[51]

Importantly, in *Myriad*, the Court clarified what kinds of advancements would still be patent eligible and would not fall under the judicially created exceptions:

> It is important to note what is *not* implicated by this decision. First, there are no method claims before this Court. Had Myriad created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent. . . . Similarly, this case does not involve patents on

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[45] *Id.*
[46] *Id.* at 595.
[47] *Id.* at 591.
[48] *Id.* at 594.
[49] *Id.* at 593.
[50] *Id.* at 593.
[51] *Id.* at 579.

> new *applications* of knowledge about the BRCA1 and BRCA2 genes. . . . Nor do we consider the patentability of DNA in which the order of the naturally occurring nucleotides has been altered. Scientific alteration of the genetic code presents a different inquiry, and we express no opinion about the application of § 101 to such endeavors. We merely hold that genes and the information they encode are not patent eligible under § 101 simply because they have been isolated from the surrounding genetic material.[52]

This emphasizes that benefits derived from *changes* relative to a naturally occurring phenomenon are still patent eligible. In effect, this withholds patent eligibility from inventors that make trivial, nonnaturally occurring changes to a natural phenomenon in order to claim a monopoly on the naturally occurring and useful characteristics of that natural phenomenon. It also further emphasizes the difference between mere discovery and true invention. Characteristics inherent to the underlying natural phenomenon are discovered, whereas characteristics resulting from a human-made change are invented. In the case of *Myriad*, the benefit of the DNA sequence was not invented by the researchers, it was only discovered.

C. New Applications of Otherwise Ineligible Concepts

Explicitly left undecided by the *Myriad* Court was the patent eligibility of new applications of natural phenomena, laws of nature, and abstract ideas. Because the patentee in *Myriad* had attempted to patent the isolated DNA sequence alone, not an application of the DNA sequence or the DNA sequence as used in a process, the issue never arose in the case.

In *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, however, the patent at issue was the *application* of an abstract idea.[53] Because the patent was for an application, the Court determined under which circumstances applications of concepts that otherwise fall under a judicial exception to patentability can nonetheless be patent eligible.[54]

The abstract idea in *Mayo* was a mathematical function for determining the proper dosage of thiopurine drugs to treat autoimmune diseases.[55] The patent claims included a method for calculating the appropriate drug dosage using that function and an "administering" step to administer that dosage to the patient.[56] The Court ultimately determined that this was insufficient.[57] They found that, in order to give rise to patent eligibility, there had to be a sufficient "inventive concept" beyond the natural phenomenon, law of nature, or abstract idea. A

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[52] Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 595–96 (2013) (emphasis in original).
[53] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 72 (2012).
[54] *Id.* at 90–91.
[55] *Id.* at 72.
[56] *Id.* at 76.
[57] *Id.* at 78.

generic step stating to "apply" or "administer" what was otherwise a judicially recognized exception was not enough.[58]

This was an attempt to balance between two competing goals. By drawing the line between an "inventive concept" and lack thereof instead of drawing the line between an "application" and lack thereof, the Court sought to focus the test on *what* is being claimed versus *how* it is being claimed. The Court sought to ensure that valuable inventions not be excluded from patent law simply because they contain or rely on a natural principle[59] while also ensuring that ineligible patents cannot circumvent the categories of ineligibility by simply reciting an 'apply' step.[60] As the Court stated, "[t]he prohibition against patenting abstract ideas 'cannot be circumvented by attempting to limit the use of the formula to a particular technological environment' or adding 'insignificant postsolution activity.'"[61]

This was reaffirmed in *Alice Corp. v. CLS Bank Int'l.*, which articulated the test from *Mayo* as a two-step framework:

> First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts. If so, we then ask, "[w]hat else is there in the claims before us?" To answer that question, we consider the elements of each claim both individually and "as an ordered combination" to determine whether the additional elements "transform the nature of the claim" into a patent-eligible application. We have described step two of this analysis as a search for an "'inventive concept'"–*i.e.,* an element or combination of elements that is "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself."[62]

Although the wording has changed from "markedly different" to an "inventive concept" that "amounts to significantly more," this inquiry is fundamentally the same as that articulated by the Court in *Myriad*. Like the precedent cases, *Alice* focuses only the final product or process being claimed and asks whether that final product includes something "significantly more" than the natural phenomenon, law of nature, or abstract idea.

The goal here seems to still be to distinguish between human invention and mere discovery, yet noticeably missing from the analysis is

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[58] *Id.* at 72–73 ("[The precedent cases] insist that a process that focuses upon the use of a natural law also contain other elements or a combination of elements, sometimes referred to as an "inventive concept," sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself.")

[59] *Id.* at 71. "The Court has recognized, however, that too broad an interpretation of this exclusionary principle could eviscerate patent law. For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas. Thus, in Diehr the Court pointed out that "'a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm.'" *Id.*

[60] *Id.* at 72–73.

[61] *Id.* (quoting Diamond v. Diehr, 450 U.S. 175, 191–192 (1981)).

[62] Alice Corp. Pty. v. CLS Bank Int'l, 573 U.S. 208, 217–18 (2014) (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66 (2012) (internal citations omitted).

a question about how the product came to be. There is no evaluation into whether the end product is the result of inventive processes or could exist without human ingenuity–this is clear from *Myriad*.[63] Also missing from the analysis is any inquiry into who is responsible for the benefit of the invention. In *Myriad*, nature was responsible for the precise sequence of the genes that were isolated.[64] Similarly, in *Funk Bros.*, nature was responsible for the noninhibiting characteristics of the specific strains of bacteria used in the combined bacteria culture.

Since the patentee in *Myriad* did not rearrange nucleotides to create a strand of DNA that may or may not have already existed in nature, the question was never asked. Similarly, the patentee in *Funk Bros.* had not altered the genes of the bacteria. So, the inquiry did not focus around "who is responsible" but rather "what was created." Following the line of cases through *Alice*, the relevant question today is whether the end product itself includes an "inventive concept" that amounts to "significantly more" than the ineligible concept itself. This question again focuses on the "what" of the final product instead of directly asking the question that seems to be on the Court's mind: is this a product of true invention or mere discovery?

III. PATENTABILITY OF 3D PRINTED BIOMATERIALS

The goal of 3D printed biomaterials is to create living material, nonnaturally, that resembles the corresponding natural material as closely as possible. 3D printed skin tissue is created from a culture of cells grown from a portion of the patient's own skin. A 3D printed organ would need to be virtually indistinguishable from the patient's own organ in order for the body to accept the replacement. These inventions, though made by man, are designed to mimic nature in cases where the natural product is unavailable or damaged. As stated earlier, any differences between the 3D printed product and the naturally occurring product are incidental; they are either designed differences in order to make the biomaterial suitable for 3D printing, or they are differences resulting from a limitation in the technology. The goal is for the 3D printed product to match the characteristics of the natural tissue *despite* any differences between the two.

A. Applying the Judicial Exception for Natural Phenomena

In deciding whether a 3D printed biomaterial is a patent eligible concept, the Alice test would ask (1) is this directed to a patent ineligible concept, and (2) is there an inventive concepts that amounts to significantly more than the patent ineligible concept itself? Answering these questions would indicate that this product is ineligible for patent protection. The invention is directed to a product of nature–the tissue,

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

[64] *Id.* at 591.

organ, etc.–and, ideally, nothing more is added. There would be no "markedly different" characteristics from the natural phenomenon.[65]

B. Congressional Criteria for Patentability

Even if the invention was not excluded by a judicially created exception to patentability, in order to obtain patent protection, the invention would need to satisfy the congressional requirements found in the Patent Act. The criteria for patentability under the Patent Act, codified in 35 U.S.C §§101-03, states that an invention must be novel, useful, and nonobvious.[66]

The usefulness of 3D printed biomaterials is clearly evident: it solves the problems of insufficient organ donations, of finding donors that match the patient, and of transporting donated organs while they are still viable.[67] The novelty and nonobviousness requirements are prior art specific. As long as the limitations specified in the claims are novel as compared to the prior art and more than an obvious extension from that prior art, the subject matter would be patentable. Here, that would be dependent on the specific claims and the research that has already been done and publicized in the field.

These criteria could be met by new innovations in the 3D printed biomaterial field. Assuming a limitation that required a cellular structure to be 'printed' in a given way, the claim would be novel and nonobvious as compared to naturally occurring human tissue. One could not, however, claim patent rights over human skin cells in the abstract. Human skin cells in the abstract already exist in nature and in the public domain. They would therefore not be novel on their own.

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[65] Tabrez Y. Ebrahim, *3D Bioprinting Patentable Subject Matter Boundaries*, 41 SEATTLE U. L. REV. 1, 42 (2017) ("At first glance, it can appear that 3D bioprinted living tissues (whether for organ transplants, in vivo skin repair, or wearable microbiomes) are nothing more than an assembly of cells organized in a 3D structure. However, 3D bioprinted tissues are manufactured by natural growth through intrinsic self-assembly principles found in nature. In such cases, where nature is emulated inside of a 3D bioprinter, the resulting product would arguably not have markedly different characteristics because nature is directing the creation. However, human ingenuity is arguably the cause for the precision, automation, and deposition of the bioink particles inside of a 3D bioprinter that produce 3D bioprinted materials.").

[66] 35 U.S.C. §§ 101-03 (2011) (stating with respect to novelty and utility, "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."); *Id.* (stating with respect to nonobviousness, "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.").

[67] The utility requirement is generally considered to be a low bar. It requires only that there is an identifiable benefit and that it is capable of use. *See, e.g.*, Bedford v. Hunt, 3 F. Cas. 37 (C.C. D. Mass. 1817) (No. 1,217) ("The law . . . does not look to the degree of utility; it simply requires that it shall be capable of use . . . .").

IV. WHETHER 3D PRINTED BIOMATERIALS SHOULD BE PATENTABLE

If the goal of the US Patent Law system is to incentivize human innovation for the general benefit of the public, then 3D printed biomaterials should be patentable.

Again, these judicially created exceptions to patentability are enforced only to ensure that the patent system falls within the Constitutional grant of authority "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[68] Specifically, the exceptions to patentability are meant to effectuate the limitations "to promote the Progress of . . . useful Arts" and to secure the patent rights to "Inventors."[69]

The thrust of these Constitutional limitations was to ensure that true products of human ingenuity were protected while ensuring that mere discoveries were not awarded monopolies. Mere discoveries fail to benefit the public sufficiently to warrant the grant of patent protection because discoveries are by definition, already in the public domain; they are just, as yet, undiscovered. As stated since the inception of the patent law system in the United States, "the underlying policy of the patent system [is] that 'the things which are worth to the public the embarrassment of an exclusive patent,' . . . must outweigh the restrictive effect of the limited patent monopoly."[70] While mere discoveries of information that already existed in the public domain were never meant to be patentable, true inventions were always meant to be covered by patent protection. That is why the Patent Act was written broadly and has been construed broadly.[71]

Congress enacted the Patent Act and specified that patent protection would be made available to "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof . . ."[72] This language was enacted in 1952, and the House Report accompanying the bill clarified that this language was intended to capture "anything under the sun made by man" so long as it met the criteria of being new, useful, and nonobvious.[73]

"The idea that an invention must be 'made by man' was used to distinguish 'a philosophical principle only, neither organized or capable of being organized' from a patentable manufacture."[74] As the Court stated

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[68] U.S. CONST. art. I, § 8, cl. 10.

[69] *Id.*

[70] Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 10–11 (1966) (quoting letter from Thomas Jefferson to Isaac McPherson (Aug. 1813)).

[71] *See, e.g.*, In re Bilski, 545 F.3d 943 (2008).

[72] 35 U.S.C. § 101 (2011).

[73] H.R. 1923, 116th Cong. (1st Sess. 2019), at 7 ("A person may have 'invented' a machine or a manufacture, which may include anything under the sun made by man, but it is not necessarily patentable under section 101 unless the conditions of the title are fulfilled.").

[74] In re Bilski, 545 F.3d 943, 976 (Dyk, J., concurring) (quoting Hornblower v. Boulton, 8 T.R. 95, 98 (K.B. 1799)).

in *Chakrabarty*, "[t]he Act embodied Jefferson's philosophy that 'ingenuity should receive a liberal encouragement.'"[75]

As is, 3D printed biomaterials do not meet the judicial requirements for patent eligibility. The invention is directed to a product of nature–human cells, tissues, organs, etc.–and, ideally, nothing more is added to the final product. There would be no "markedly different" characteristics from the natural phenomenon; the natural product and the human engineered version would be functionally and biologically equivalent.

However, if the goal of the patent system is to incentivize the disclosure of inventions that are the product of human ingenuity, then arguably, here, the patent system is failing. 3D printed biomaterials are not created by nature, nor are they already in the product domain. They are "markedly different," not in how they function or in what they are made from, but in how they are created and the problems they can solve.

Like the engineered strain of bacteria at issue in *Chakrabarty*, these biomaterials are not "unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter–a product of human ingenuity."[76] The success of these materials is attributable not just to natural processes, but largely to human invention. These materials *could not* exist without human invention. And, the natural equivalent cannot solve the problems that the 3D printed materials can. 3D printed biomaterials and organs, as compared to their natural counterparts, have the added utility of solving problems of insufficient organ donors in general, insufficient donated organs that match the patient in need, and limitations relating to transportation of donated organs while they are still viable.

These 3D printed biomaterials provide a significant benefit to the greater public, require a substantial amount of investment and ingenuity, and, as such, are exactly the kinds of inventions that the patent system was intended to incentivize.

A. Other Forms of Intellectual Property as Incentives

In lieu of the patent system, inventors could rely on trade secret law to protect their inventions. Trade secret law derives its basis from the English common law, and in the United States today, the Uniform Trade Secrets Act protects trade secrets from misappropriation.[77] Functionally, it makes trade secret misappropriation a tort claim. While it does not protect trade secrets against voluntary disclosure, even if that disclosure is unintended, it does give the owner of a trade secret an avenue to recover damages when their trade secret has been unlawfully misappropriated.[78] A trade secret can be any information when that

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[75] Diamond v. Chakrabarty, 447 U.S. 303, 308–09 (1980) (quoting 5 Writings of Thomas Jefferson 75–76 (Washington ed. 1871)).

[76] *Chakrabarty*, 447 U.S. at 303.

[77] UNIF. TRADE SECRETS ACT, 14 U.L.A. 537 (1985).

[78] *See, e.g.*, David W. Slaby James Gregory, *Trade Secret Protection: An Analysis of the Concept "Efforts Reasonable Under the Circumstances to Maintain Secrecy"*, 5 SANTA CLARA COMPUTER & HIGH TECH. L.J. 321, 322 (1989).

information provides a commercial benefit or advantage, when that information is actually secret and has not been disclosed, and when reasonable measures have been put in place to continue to keep that information secret.[79] "Reasonable measures" generally means that the party protecting the trade secret has taken affirmative steps to institute both security measures and confidentiality procedures.[80]

While the evidentiary requirements of a trade secret misappropriation claim may vary from state to state, like most tort claims, in general, a plaintiff must establish (1) the existence of a trade secret; (2) the acquisition of a trade secret as a result of a confidential relationship; and (3) the unauthorized use of a trade secret.[81]

The goals of trade secret law are fundamentally different than patent law. Unlike patent law, the focus is not in the technology or the information, but rather on the nature of the relationship between the parties in question. The goal is to protect employers who maintain commercially advantageous information within the bounds of a confidential business relationship.[82] In this way, it is functionally much more similar to agency laws such as the protection against insider trading.

However, while trade secret law might provide sufficient protection to encourage researchers to continue to develop 3D printed biomaterials, it does not incentivize disclosure. In fact, it incentivizes the exact opposite. And, it would potentially provide to successful researchers an unlimited monopoly over their invention.

The patent system, on the other hand, incentives inventors not only to invest the time and money into developing the inventions at the start, but it also promotes disclosure to the public. These disclosures provide multiple additional public benefits. First, they ensure that the monopolies over the relevant technologies are time limited. Thus, all patented technologies after their expiration are available to the public to make, use, and sell. Additionally, they allow other researchers to continue to develop and improve the technology. Since the patent system incentivizes an earlier disclosure, researchers arguably have access to the relevant knowledge sooner, allowing their subsequent improvements and innovations to also come sooner. In this way, patents promote progress not only through their own value but also indirectly through the value of

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[79] *See, e.g.*, *id.* at 323 ("Secrecy is an illusive and critical requirement for the trade secret owner. In determining whether the secrecy element has been met by the claimant, courts will look to whether the information was generally known or available and whether the information was generally known or available and whether reasonable efforts were undertaken by the claimant to maintain secrecy. It is clear that the trade secret owner must take some affirmative steps to maintain secrecy; a plan of taking no special precautions for fear of arousing undue interest in the information is sure to fail.") (citing Junkunc v. S.J. Advanced Technology & Mfg. Corp., 498 N.E.2d 1179 (1986); J.T. Healy & Son, Inc. v. James A. Murphy & Son, Inc., 260 N.E.2d 723 (1970)).

[80] *See, e.g.*, *id.* at 327 (citing Electro-Craft Corp. v. Controlled Mot., Inc. 332 N.W.2d 890 (Minn. 1983)).

[81] *See, e.g.*, 88 Ohio Jur. 3d *Trade Secrets* § 1.

[82] *See, e.g.*, 88 Ohio Jur. 3d *Trade Secrets* § 2 ("The protection afforded by trade secret laws is not a function of property interests or contract rights but of equitable principles of good faith applicable to confidential relationships.") (citing Niemi v. NHK Spring Co., Ltd., 543 F.3d 294 (6th Cir. 2008).

subsequent inventions–inventions which are only possible when information is accessible and disseminated.

If trade secrets provided sufficient incentives for technological development such that trade secrets alone could "promote . . . useful arts," then there would have been no reason to establish the patent system at all.

B. Other Hurdles to Patentability

One additional hurdle to patentability of 3D printed biomaterials is Section 33 of the America Invents Act. Section 33 states that "notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism."[83] This provision has not yet been interpreted by the courts, so it is not yet clear what the full scope of "directed to or encompassing a human organism" includes. Because the words "directed to," "encompassing," and "human organism" in Section 33 are undefined, the courts are free to interpret this broadly or narrowly.[84] In a narrow interpretation, this section could mean only that a full human organism or the clone of a human organism could not be patented. In a broad interpretation, however, "directed to . . . a human organism" could include patents for any aspect of a human organism. This broad interpretation may make 3D printed biomaterials not eligible for patent protection regardless of whether or not such patents are excluded by a judicially created exception to patentability. However, the legislative history indicates that this section was only meant to exclude from patentability full human organisms at any stage of development, including but not limited to human embryos or genetically modified human embryos.[85]

Unlike judicial exceptions to patentability, however, Section 33 seems to stem from concerns regarding patenting, cloning, altering, or genetical engineering human organisms and human embryos. This then has less to do with the substantive requirements of patent eligibility and more to do with potential moral challenges. With this understanding, and with the legislative history, it seems unlikely that 3D printed biomaterials or 3D printed organs will be considered ineligible for patent protection on the basis of this provision.

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[83] Leagy- Smith America Invetns Act of 2011, Pub. L. No. 112-29, § 33, , 125 Stat. 340.

[84] EDWARD D. MANZO, AMERICA INVENTS ACT--A GUIDE TO PATENT LITIGATION AND PATENT PROCEDURE §4.2 (2018) ("Section 33 of the AIA bars the USPTO from issuing patents "directed to or encompassing a human organism." The AIA did not provide a definition of "human organism" in 35 U.S.C. § 100 or anywhere else. One may ask how broadly "human organism" should be construed and whether AIA Section 33 prohibits a future patent claiming to a human gene, a grown living organ, or other subject matter."). *See also*, Tabrez Y. Ebrahim, *3d Bioprinting Patentable Subject Matter Boundaries*, 41 SEATTLE U. L. REV. 1, 28 (2017).

[85] *Id.* at §4.4 ("The Congressional Record extension remarks . . . suggest that Congress did not intend in Section 33 to limit . . . obtaining patents on . . . cells, tissues, organs (including synthetic organs), or other bodily components produced by human intervention. . . . On the other hand, Congress *did* intend to prohibit any patent having a claim . . . encompassing . . . a human organism at any stage of development") (citing 157 Cong. Rec. E1184 (daily ed. June 23, 2011) (statement of Rep. L. Smith)).

V. IMPACT OF REMOVING JUDICIAL EXCEPTIONS

If the judicial exceptions to patentability were removed, there would be no initial hurdle for patentees to show that their inventions comprise an inventive step that is significantly more than a natural phenomenon, law of nature, or abstract idea. Patentees would still have to show, however, that they meet all of the criteria set forth in 35 USC §§101-03. This means that the invention would still have to be a "process, machine, manufacture, or composition of matter" that is new, useful, and nonobvious.[86]

A. Substantive Impact

Ultimately, this change would have very little substantive impact on the types or quality of inventions that are considered patentable. Inventions that are substantively no more than an abstract idea, laws of nature, or natural phenomenon would all continue to be unpatentable under the requirements of 35 USC §§101-03 because they are not novel concepts or are, at least, obvious variations as compared to the underlying ineligible concept.

Mere discovery of a new bacteria or natural phenomenon, for example, would not be patentable because that natural phenomenon existed in nature prior to the discovery, and nature is already within the public domain.[87] The novelty requirement ensures that that which is already in the public domain not be taken from it.

Of course, novelty requires that each limitation in the patent claim is disclosed in the prior art. Therefore, a small change to the natural phenomenon, law of nature, or abstract ideas would not be deemed ineligible for patent protection with the novelty test alone. These sorts of insignificant changes, however, would be captured under the nonobviousness requirement of 35 U.S.C. §103. And, ultimately, the nonobviousness requirement would likely succeed in withholding patent eligibility from the same sorts of innovations that are currently kept out of the patent system with the *Mayo* and *Alice* test.

The current two-part framework dictated by *Mayo* and *Alice* to determine patentability of these judicially created exceptions is not dissimilar from the obviousness test. Under *Mayo* and *Alice*, the test is (1) whether the invention is directed to a judicially created exception and (2)

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[86] 35 U.S.C §§ 101-03 (2011) (stating with respect to novelty and utility, "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.") (stating with respect to nonobviousness, "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.").

[87] *See, e.g.*, In re Cruciferous Sprout 301 F.3d 1343 (Fed. Cir. 2002) (holding that the previously undiscovered benefit of gluosinolates, which are naturally occurring in broccoli sprouts, are novel and therefore are not patent eligible because broccoli–and nature in general–are already in the public domain).

if so, whether there is the addition of an "inventive concept" sufficient to make the invention nonetheless patentable.[88] This "inventive concept" could be equivalently captured by the obviousness test. The obviousness test requires that there is an additional element or limitation beyond the existing prior art that would be nonobvious to a person having ordinary skill in the art.[89]

Comparing this to the patent for the isolated DNA segment in *Mayo*, this patent would likely have been found to be obvious in light of the prior art. The prior art in this case would include the naturally occurring DNA structure that dictated the order of the nucleotides, and it would have included the well-established and well-understood practice of isolating a pertinent segment of DNA.[90] For a person having ordinary skill in the art then, upon knowing both the relevant DNA segment and the process to isolate it, it would have been obvious to combine the two.

What would not be obvious, however, is the research, ingenuity, precision, and engineering that are required to 3D print viable biomaterials. While this practice may become obvious with time, as the field grows and practices for successfully 3D printing biomaterials become better understood, they would likely not be found obvious now. Therefore, eliminating the judicially created exceptions to patentability would allow Congress to incentivize the research, development, and disclosure of innovations in 3D printed biomaterials without compromising the overarching Constitutional requirement that awarded patents must "promote the Progress of . . . useful Arts."

B. Practical Impact

Although the substantive impact to the quality of innovations that are eligible for patent protection is likely to be negligible, removing the judicially created exceptions to patentability would have significant practical impacts on evidentiary burdens during litigation.

Currently, in order to invalidate a patent, the primary evidentiary burden falls on the alleged infringer. This is because issued patents enjoy a presumption of validity. Therefore, the burden falls on the alleged infringer to make a prima facie showing that the patent is directed to ineligible subject matter. Only after making such a showing does the burden shift to the patentee. Once the burden shifts, the burden is on the patentee to show the addition of an inventive concept that amounts to "significantly more" than the ineligible concept alone. In this current system, the alleged infringer does not need to show the absence of an inventive concept. Once the alleged infringer makes the initial showing that the patent in question is directed to ineligible subject matter, the burden switches.

With a change in the jurisprudence to remove judicially created exceptions to patentability, however, even more burden would be

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[88] Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 72–73 (2012); Alice Corp. Pty. v. CLS Bank Int'l, 573 U.S. 208, 217–18 (2014).

[89] Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 10–11 (1966).

[90] *See Mayo*, 566 U.S. at 74–75.

shouldered onto the alleged infringer. With this change, the evidentiary burden would fall on the alleged infringer not just to show the *existence* of a natural phenomenon or other exception prior to the patent's effective filing date but also to show that the patent claims are either obvious or not novel in light of the ineligible concept. Comparing this to the *Mayo* and *Alice* two-step framework, the alleged infringer would effectively have to show, not only that the patent claims are directed to ineligible matter, but also that there is no addition of an inventive concept. In other words, the alleged infringer would need to show that anything beyond the ineligible material is obvious.

The requirement of nonobviousness, as previously described, requires that there is an additional element or limitation in the patent claims beyond the existing prior art that would be nonobvious to a person having ordinary skill in the art. Typically, for an alleged infringer to invalidate a patent for obviousness, the alleged infringer must make a showing that the prior art teaches, suggests, or motivates a person having ordinary skill in the art to make the modification or combination disclosed in the patent claims.

In effect, while the substantive requirement for patents would remain similar, the procedural impact would make the effected patents more difficult to challenge. Importantly, with an elimination of all judicially created exceptions, this change would impact more than just 3D printed biomaterial patents. It would shift the evidentiary burden for all patents directed to judicially ineligible concepts. This would include 3D printed biomaterials but would also include software, algorithms, business methods, et cetera. The questions then become whether, as a society, we want the grey-area patentable subject matter patents, such as various software systems and algorithms, to be harder or easier to challenge and whether the benefits of incentivizing patents such as 3D printed biomaterials outweighs the cost of making grey-area patents harder to challenge if indeed it is better for society if those patents are easier to challenge.

VI. CONCLUSION

The goal of 3D printed biomaterials is to create living material, nonnaturally, that resembles the corresponding natural material as closely as possible. These inventions, though made by man, are designed to mimic nature in cases where the natural product is unavailable or damaged. As is, 3D printed biomaterials do not meet the judicial requirements for patent eligibility because they fall into the category of natural phenomena, which is one of the judicially created exceptions to patentability.

These exceptions are put in place to ensure that patent rights are granted only to innovations that sufficiently benefit society. Specifically, the Constitution grants Congress the power "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and

Discoveries."[91] This grant of power to Congress to secure to inventors the exclusive right to their discoveries is expressly limited by the requirement that it promote the progress of useful Arts.

In interpreting this limitation, the courts have created exceptions to patentability. Specifically, natural phenomena, laws of nature, and abstract ideas have been categorized as patent ineligible subject matter. The test for patent eligibility, as articulated in *Mayo* and *Alice* is (1) whether the invention is directed to a judicially created exception and (2) if so, whether there is the addition of an "inventive concept" sufficient to make the invention nonetheless patentable.

3D printed biomaterials are clearly directed to a product of nature or natural phenomenon–human cells, tissues, organs, etc. are natural phenomena–and, ideally, in the creation of a 3D printed biomaterial, nothing more is added to the final product. There would be no "markedly different" characteristics from the natural phenomenon; the natural product and the human engineered version would be functionally and biologically equivalent.

However, if the goal of the patent system is to incentivize the disclosure of inventions that are the product of human ingenuity, then arguably, here, the patent system is failing. 3D printed biomaterials are not created by nature, nor are they already in the product domain. They are "markedly different," not in how they function or in what they are made from, but in how they are created and the problems they can solve.

Like the engineered strain of bacteria at issue in *Chakrabarty*, these biomaterials are not "unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter–a product of human ingenuity."[92] The success of these materials is attributable not just to natural processes, but largely to human invention. These materials *could not* exist without human invention. And, the natural equivalent cannot solve the problems that the 3D printed materials can. 3D printed biomaterials and organs, as compared to their natural counterparts, have the added utility of solving problems of insufficient organ donors in general, insufficient donated organs that match the patient in need, and limitations relating to transportation of donated organs while they are still viable.

These 3D printed biomaterials provide a significant benefit to the greater public, require a substantial amount of investment and ingenuity, and, as such, are exactly the kinds of inventions that the patent system was intended to incentivize.

If the judicial exceptions to patentability were removed, there would be no initial hurdle for patentees to show that their inventions comprise an inventive step that is significantly more than a natural phenomenon, law of nature, or abstract idea. Patentees would still have to show, however, that they meet all of the criteria set forth in 35 USC §§101-03.

Because these criteria require that all patents be new, useful, and nonobvious, there would be little substantive impact by removing the

[91] U.S. CONST. art. I, § 8, cl. 10.
[92] Diamond v. Chakrabarty, 447 U.S. 303 (1980).

judicial exceptions to patentability. Inventions that are little more than an abstract idea, law of nature, or natural phenomenon would all continue to be unpatentable under the requirements of 35 USC §§101-03 because they are not novel concepts or are, at least, are obvious variations as compared to the underlying ineligible concept.

What would not be obvious, however, is the research, ingenuity, precision, and engineering that are required to 3D print viable biomaterials. While this practice may become obvious with time, as the field grows and practices for successfully 3D printing biomaterials become better understood, they would likely not be found obvious now. Therefore, eliminating the judicially created exceptions to patentability would allow Congress to incentivize the research, development, and disclosure of innovations in 3D printed biomaterials without compromising the overarching Constitutional requirement that awarded patents must "promote the Progress of . . . useful Arts."[93]

[93] U.S. CONST. art. I, § 8, cl. 10.