

Article

PATENTING FRANKENSTEIN’S MONSTER: EXPLORING THE PATENTABILITY OF ARTIFICIAL ORGAN SYSTEMS AND METHODOLOGIES

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The conception of Frankenstein’s monster bridges the ever-narrowing divide between man and machine. Long before Congress codified Section 33(a) of the America Invents Act (“AIA”), Mary Shelley’s vague description of the monster’s creation has left people wondering: what defines a human organism? Through an analysis of patent law and scientific progress in the development of artificial organ systems, this paper explores the boundaries of patentable subject matter in the United States and attempts to clarify Congress’s determination that “no patent may issue on a claim directed to or encompassing a human organism.” Though patent law should incentivize development of artificial human tissues and organs, Section 33(a) of the AIA stands to limit scientific progress. Either judicial or legislative action must clarify the term “human organism” to balance the need for artificial organ development, while hindering unethical scientific development of artificial humans.

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INTRODUCTION

Every Frankenstein movie, book, comic strip, and television show demonstrates that, in biotechnology, “just because something can be done does not mean that it should be done.”¹ Scientific progress in the fields of tissue engineering and organ transplantation have far surpassed Mary Shelley’s crude description of stitching body parts together to form a human being.² Yet, patent law regarding artificial human engineering remains as unclear as *Frankenstein’s* definition of “Alive.”³ To truly promote the science of tissue engineering while avoiding incentivizing human experimentation, laws regarding the patentability of “human organisms” must be clarified.

Patentable subject matter should “include anything under the sun that is made by man.”⁴ However, the discovery of something that pre-exists in nature, whether it is an element, law, or principle, cannot be the subject of a patent without further application.⁵ These discoveries “are manifestations of [the] laws of nature, free to all men and reserved exclusively to none.”⁶

¹ 157 CONG. REC. E1178 (daily ed. June 23, 2011) (statement of Rep. Smith).

² See MARY WOLLSTONECRAFT SHELLEY, *FRANKENSTEIN; OR, THE MODERN PROMETHEUS* 32 (Wisehouse Classics 2015) (1831) (“The dissecting room and the slaughter-house furnished many of my materials; and often did my human nature turn with loathing from my occupation, whilst, still urged on by an eagerness which perpetually increased, I brought my work near to a conclusion.”).

³ See generally *FRANKENSTEIN* (Universal Pictures 1931).

⁴ *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (quoting S. REP. NO. 82-1979 at 5 (1952); H.R. REP. NO. 82-1923 at 6 (1952)).

⁵ See *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2110 (2013) (“groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry.” (citing *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948))).

⁶ *Funk Bros. Seed Co.*, 333 U.S. at 130.

Patents relying on subject matter concerning a law of nature can only be patentable if the claim as a whole amounts to “significantly more” than the law of nature itself.⁷ For example, the creation of an artificial equivalent of an existing, natural product is not a patentable invention.⁸ Because the law of nature and embodiments of that law have existed before the artificial equivalent, the natural embodiment is “prior art,” thus barring the artificial creation from patent-eligibility.⁹ However, if a device or material that is created through the use of scientific or mathematical principles is useful and novel, with substantial differences from what exists in nature, the device or material could be patentable.¹⁰

This line between patentable subject matter and laws or phenomena of nature may seem clear, but it has become far too blurry in the world of biotechnology. With the progress of CRISPR-Cas9¹¹, *in vitro* fertilization¹², and artificial organ creation¹³, the ability to imitate nature in a laboratory has become less science fiction and more realistic possibility.

Not only can scientists clone animals¹⁴, but scientists can now grow artificial tissues¹⁵, print organs¹⁶ and bones¹⁷, and even transplant artificial

⁷ See *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2360 (2014) (“Instead, 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.” (citing *Mayo Collaborative Services v. Prometheus Labs.*, 132 S. Ct. 1289, 1298 (2012))); *Le Roy v. Tatham*, 55 U.S. 156, 175 (1852) (requiring “a practical result and benefit not previously attained” (quoting *Househill Co. v. Neilson*, Webster’s Pat. Cases 673, 683 (1842) (House of Lords))).

⁸ See *In re Roslin Inst. (Edinburgh)*, 750 F.3d 1333, 1339 (Fed. Cir. 2014) (calling a clone unpatentable because it is a “time-delayed version[] of [a] donor mammal[]” and already exists in nature); see also *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293 (1884); *General Electric Co. v. De Forest Radio Co.*, 28 F.2d 641 (3d Cir. 1928); Michael D. Davis, *The Patenting of Products of Nature*, 21 RUTGERS COMPUTER & TECH. L. J. 293, 323–34.

⁹ See *Myriad Genetics, Inc.*, 133 S. Ct. at 2109 (determining that isolated and purified DNA was not made “with markedly different characteristics from any found in nature” (citing *Chakrabarty*, 447 U.S. at 310)); *In re Roslin Inst.*, 750 F.3d at 1339. Prior art is evidence that the claimed invention in the patent application has already existed.

¹⁰ *Parker v. Flook*, 437 U.S. 584, 590 (1978) (“[A] process is not unpatentable simply because it contains a law of nature or a mathematical algorithm.”).

¹¹ See generally Eric S. Lander, *The Heroes of CRISPR*, 164 CELL 18, 18–22 (2016) (giving a narrative perspective of the gene-editing invention, CRISPR); *CRISPR Timeline*, BROAD INSTITUTE, <https://www.broadinstitute.org/what-broad/areas-focus/project-spotlight/crispr-timeline> [<https://perma.cc/R4ST-KYJ7>] (providing a timeline of CRISPR-Cas9 progress).

¹² See Bradley J. Van Voorhis, *In Vitro Fertilization*, 356 N. ENGL. J. MED. 379 (Jan. 25, 2007); *Timeline: The History of In Vitro Fertilization*, PBS: WGBH, <http://www.pbs.org/wgbh/americanexperience/features/timeline/babies/> [<https://perma.cc/GYG9-W5UY>] (providing a timeline history of *in vitro* fertilization).

¹³ See Aleem Ahmed Khan, *Emerging Technologies for Development of Humanized Bio-artificial Organs*, 6 J. MED. ALLIED SCI. 1 (Jan. 31, 2016) (providing an overview of new techniques to create artificial organs).

¹⁴ See, e.g., X Cindy Tian et al., *Cloning Animals by Somatic Cell Nuclear Transfer – Biological Factors*, 1 REPROD. BIOL. & ENDOCRINOL. 98 (Nov. 13, 2003) (discussing cloning of mammals); see

tissue into animals.¹⁸ In years to come, scientists may progress from creating artificial tissues to artificial organs to artificial organ systems.¹⁹ These imitations of organs and organ systems are valuable for medical experimentation, pharmaceutical experimentation, and organ transplantation.²⁰ When artificial organs are transplanted into natural humans, the line between man and patentable subject matter will become more blurred than ever before. The creation of Frankenstein's monster, an artificial man, is coming closer every day.

However, the law is at an impasse. Though in recent years, the Supreme Court, the Federal Circuit, and Congress have all endeavored to codify and clarify patent law, their combined actions often leave scientists and lawyers with more questions than answers.²¹ Through an exploration of the American Invents Act, 35 U.S.C. § 101, and Section 33(a), this paper shows where the progress of science is promoted and where it is hindered

also I. Wilmut et al., *Viable Offspring Derived from Fetal and Adult Mammalian Cells*, 385 NATURE 810 (Feb. 27, 1997) (publishing the results of cloning a sheep).

¹⁵ See, e.g., Sean V. Murphy & Anthony Atala, *3D Bioprinting of Tissues and Organs*, 32 NATURE BIOTECHNOLOGY 773 (Aug. 2014) (presenting current and future predictions in the field of tissue and organ engineering).

¹⁶ See *id.*

¹⁷ See Leon S. Dimas et al., *Tough Composites Inspired by Mineralized Natural Materials: Computation, 3D Printing, and Testing*, 23 ADVANCED FUNCTIONAL MATERIALS 4269 (2013), (discussing producing a synthetic material with fracture behavior similar to bone).

¹⁸ See e.g., Jeremy J. Song et al., *Regeneration and Experimental Orthotopic Transplantation of a Bioengineered Kidney*, 19 NATURE MEDICINE 646 (May 2013) (discussing producing and transplanting a lab-grown kidney into a rat).

¹⁹ As of the publication of this paper, scientists have not developed artificial organ systems capable of human transplantation. However, the field of artificial organ development is progressing in that direction. See, e.g., Vivien Marx, *Tissue Engineering: Organs from the Lab*, 522 NATURE 373 (June 18, 2015) (discussing the progress of organ engineering through scaffolds and microchips).

²⁰ See LEONID GRININ & ANTON GRININ, *THE CYBERNETIC REVOLUTION AND FORTHCOMING EPOCH OF SELF-REGULATING SYSTEMS* 56 (Uchitel Publishing House 2016); see also Tyler Irving, *'Person-on-a-chip' – U of T Engineers Create Lab-grown Heart and Liver Tissue for Drug Testing and More*, UNIVERSITY OF TORONTO ENGINEERING (Mar. 7, 2016), <http://news.engineering.utoronto.ca/person-on-a-chip-u-of-t-engineers-create-lab-grown-heart-and-liver-tissue-for-drug-testing-and-more/> [<https://perma.cc/QZR4-LDT3>] (showing that lab-grown heart and liver tissues can be used for drug testing and may have future applications in repairing and replacing damaged organs).

²¹ See *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2120 (2013) ("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."); see also Erin Coe, *The Battle for Patent Law: Federal Circuit Looks to Hold the Line as Supreme Court Eyes IP*, LAW360 (July 9, 2016), <https://www.law360.com/articles/814461/the-battle-for-patent-law> [<https://perma.cc/LC7C-7PT4>] ("Is a patent obvious or not? Can [an infringing product] be enjoined or not? Is a patent eligible or not? The Supreme Court has sown extensive confusion in the law, partly by being unclear and particularly by being eager to knock down Federal Circuit-created standards as unduly rigid." (alteration in original) (quoting former Federal Circuit Chief Judge Paul Michel)).

under current patent law.²² The vague determination that claims directed to human organisms are not patentable only hinders the progress of artificial organ development.²³ Either judicial or legislative action must clarify the term “human organism” to balance the need for artificial organ development, while hindering unethical scientific development of artificial humans.

Section II of this paper discusses the rights of patent owners and how, though patents convey no positive rights, patents do provide incentives to research in a particular scientific field. Section III of this paper discusses the evolution of patentable subject matter under 35 U.S.C. § 101 and in the Leahy-Smith America Invents Act, both in the Supreme Court and under federal law. Section IV of this paper discusses what is considered “settled” by the United States Patent and Trademark Office (“USPTO”) as patentable and unpatentable subject matter. Section V analyzes the current unsettled patent law of biotechnology, specifically showing that both scientists and policy makers are striving to incentivize scientific progression while hindering unethical experimentation with artificial human creation. Section VI proposes a definition of human organism under patent law to incentivize creating artificial organs for donation without simultaneously incentivizing creating artificial humans.

I. WHAT IS A PATENT: THE RIGHTS OF PATENT OWNERS

To understand the implications of determining patentable subject matter, the definition of a patent and the rights it conveys to its assignee or owner must be explored. The negative right of exclusion can prevent others from making, using, selling, or offering to sell a patent. Though patents do not grant the right to make or use the claimed subject matter, the incentives of patent ownership discussed herein can be sufficient for scientists to research artificial creation of human tissues.

A patent is a “special privilege designed to serve the public purpose of promoting the ‘Progress of Science and useful Arts.’”²⁴ It runs contrary to the general rule discouraging monopolies, allowing the patent owner(s)

²² See Leahy-Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284 (2011) (codified as amended in various sections of 35 U.S.C.); 35 U.S.C. § 101 (2012).

²³ See Leahy-Smith America Invents Act § 33(a) (“Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism.” The law provides no definition of the term “human organism.”).

²⁴ Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co., 324 U.S. 806, 816 (1945) (referencing U.S. CONST. art. I, § 8).

“the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States.”²⁵

A patent conveys no positive rights.²⁶ A patent owner has no right to make, use, sell, or offer to sell his or her invention.²⁷ This must be understood: an inventor who patents an invention may not be able to use his or her invention.²⁸ The United States Patent and Trademark Office (“USPTO”) is not granting the patent owner the right to positively use the claimed invention in commerce.²⁹ A person can pay for the best patent on his or her invention and no amount of money will allow them to use the invention they patented.³⁰ A patentee must be cautious before proceeding to use his or her invention; parts of the person’s invention, the process of making parts of the person’s invention, or using that person’s invention in a particular way might be patented by someone else.³¹

A patent conveys “a negative right of exclusion.”³² A patent allows the owner to prevent others from making, using, offering to sell, or selling a patented invention throughout the duration of the patent term.³³ This means

²⁵ 35 U.S.C. § 154 (2013) (patent owners may also exclude others from “importing the invention into the United States, and, if the invention is a process . . . exclude others from using, offering for sale or selling throughout the United States, or importing into the United States, products made by that process.”).

²⁶ See DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW 4-5 (3d ed. 2004) (“[A] patent gives an inventor the right to exclude. A patent does not give the inventor the positive right to make, use, or sell the invention.” The text further quotes Judge Rich’s comparison of patents to property rights in real property. It explains that real property conveys “a right to use that carries with it a logically subordinate right to exclude. That right to exclude exists to ensure the owner’s full enjoyment of the right to use.” This right to use is a positive right, whereas a right to exclude others from using is a negative right.).

²⁷ *Id.*

²⁸ If a patent only conveys a negative right to exclude, it is possible that using the patented invention may infringe on the negative right to exclude conveyed previously to another inventor.

²⁹ See *Patent Process Overview*, U.S. PATENT AND TRADEMARK OFFICE, <https://www.uspto.gov/patents-getting-started/patent-process-overview#step1> [<https://perma.cc/2E96-38U7>] (providing a beginner’s guide to the patent process, including how the USPTO grants and rejects patent applications).

³⁰ The United States does not have compulsory licensing in all areas of patents. Compulsory licensing would either allow someone to produce a product or process without the patent owner’s permission or create a set price for a patent owner to license the product.

³¹ If somebody else also possesses a negative right to exclude, that person can prevent a subsequent patent owner’s ability to produce or use the invention in the subsequent patent.

³² See, e.g., *Chicago & A. Ry. Co. v. Pressed Steel Car Co.*, 243 F. 883, 890 (7th Cir. 1917) (explaining that a patent license is only an immunity from suit by the licensor and is not granting the “right to make, use, and sell” the entirety of the invention).

³³ See, e.g., *Clouding IP, LLC v. Google Inc.*, 61 F. Supp. 3d 421, 428 n.6 (D. Del. 2014) (“The core exclusionary right of a patent is the negative right of a ‘patentee’ to ‘exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States.’” (citing 35 U.S.C. § 154 (2013))); see also 35 U.S.C. § 271 (2010).

that, when the USPTO grants a patent, the owner can exclude others from making, using, selling, or offering to sell the invention claimed in the patent. Essentially, in exchange for publicly teaching a person of ordinary skill in the art how to make and use the invention, the patent owner may prevent everyone else from using the patented claims for the life, or term, of the patent.³⁴ Currently, a patent term is 20 years from the time of filing the patent application.³⁵

Ownership of a patent is different than the freedom to operate – the freedom to use the patent claim.³⁶ A patent can be used to prevent other companies from operating because patents convey those negative rights. Someone who owns a patent can make anyone who wants to make or use a claim in a patent license that patent from the owner.³⁷ However, a patent owner may not be able to make and use the contents of their own patent. That freedom to operate is determined by other patent owners: owners of patents that may overlap with the patent at issue.³⁸

A person can obtain a patent for any “new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement.”³⁹ This improvement can, and often does, include improvements on currently patented inventions. For example, Person A patented a table, claiming (1) a horizontal table top and (2) four table legs. Assume for the sake of argument that Person A invented the table: no table had ever existed before and, therefore, the invention and patent on the invention is completely new.⁴⁰ During the term of Person A’s patent, no one can make or use the table claimed in Person A’s patent. However, during this term, Person B invented and patented a table claiming (1) a horizontal table top (2) four table legs, and (3) a hole in the horizontal table top (for an umbrella). Person B could obtain a patent on this new invention because the hole in the horizontal table top is a new and useful improvement.

³⁴ See 35 U.S.C. § 154 (2013).

³⁵ See *id.* (“[S]uch grant [of a patent] shall be for a term beginning on the date on which the patent issues and ending 20 years from the date on which the application for the patent was filed in the United States . . .”).

³⁶ See, e.g., Dov Greenbaum, *New Rules, Different Risk: The Changing Freedom to Operate Analysis for Biotechnology*, 11 N.C.J.L. & TECH. ON. 139 (2010) (analyzing freedom to operate agreements in biotechnology).

³⁷ See 35 U.S.C. § 154 (2013).

³⁸ See *What Does “Freedom to Operate” Mean?*, PATENT LENS, www.bios.net/daily/pententlens/2768.html [<https://perma.cc/NK6K-2HNQ>] (providing a beginner’s guide to freedom to operate agreements and explaining that a freedom to operate agreement determines “whether a particular action, such as testing or commercializing a product, can be done without infringing valid intellectual property rights of others.”).

³⁹ 35 U.S.C. § 101 (2012).

⁴⁰ See Section III for further discussion about novelty in patent law.

However, Person B would not be free to make and use a table with four legs and a hole in the center of the table top because it would infringe on Person A's patent. Person B would have to license Person A's patent or wait until Person A's patent expired to make and use her patented invention. Person B could also try to "design around" Person A's patent by making a table that did not have every element of Person A's patent claim. For example, if Person B made a table with three legs instead of four, Person B would not be subject to pay licensing fees to Person A to make and use the three-legged table.

When evaluating a patent in the biotechnology space, there is a "distinction between a claim to a product, device, or apparatus, all of which are tangible items, and a claim to a process, which consists of a series of acts or steps."⁴¹ Product claims "cover what a device is, not what a device does."⁴² Contrastingly, a process "consists of acts or steps, rather than tangible things. A process, therefore, has to be carried out or performed."⁴³ Typically, a claim to a product is more valuable than a claim to a process because, when determining if a person infringed the patent, product infringement is easier to prove than process infringement.⁴⁴ "To infringe a method claim, a person must have practiced all steps of the claimed method."⁴⁵ Additionally, "the sale of an apparatus capable of performing the patented method is not a sale of the method. A method claim is directly infringed only by the entity usurping the patented method."⁴⁶

As discussed in further detail below in Section IV, patent incentives in the field of organ transplant and artificial tissue development are limited.⁴⁷ Currently, patent owners cannot sue doctors for practicing patented medical

⁴¹ See *In re Kollar*, 286 F.3d 1326, 1332 (Fed. Cir. 2002) (highlighting the difference between product and process claims).

⁴² Peter Strand, *What's the Use? Understanding Method vs. Apparatus Use Infringement*, LEXOLOGY (Jun. 28, 2012), <http://www.lexology.com/library/detail.aspx?g=df5ab67a-9322-44bd-bf2a-db71cbb77169> [https://perma.cc/V4LT-Z8M7] (quoting *Kollar*, 286 F.3d at 1332).

⁴³ See *id.*

⁴⁴ See *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1311 (Fed. Cir. 2006) ("Method claims are only infringed when the claimed process is performed, not by the sale of an apparatus that is capable of infringing use."); see also Dan L. Burk, *The Problem of Process in Biotechnology*, 43 HOUS. L. REV. 561 (Summer 2006) (discussing offshore processes and obviousness of a process as barriers to prove both validity of patents and infringement of those patents).

⁴⁵ See *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1317 (Fed. Cir. 2009); *Joy Techs., Inc. v. Flakt, Inc.*, 6 F.3d 770, 775 (Fed. Cir. 1993) (explaining that a method claim is infringed when someone practices the patented method); 35 U.S.C. § 271 (2010).

⁴⁶ Strand, *supra* note 42.

⁴⁷ See 35 U.S.C. § 287(c) (2011) (limiting remedies available to patent owners of surgical procedure patents by exempting medical practitioners and health care entities from infringement liability); for further detail, see Section IV(B).

methods.⁴⁸ Furthermore, though many patents have been sought and granted for methods to grow artificial tissues, a product patent for an artificial tissue would be considered far more valuable.⁴⁹ To collect damages for directly infringing a method patent, the petitioner must prove that all steps of the patented method were performed by a third party, or substantially performed under a doctrine of equivalents test.⁵⁰ Producing the product, such as an artificial tissue, would not necessarily be sufficient proof to collect damages from a process patent. However, if the patent were directed to that artificial tissue and not the method of creation, proving infringement would be far easier.

II. AN EVOLUTION OF 35 U.S.C. § 101: WHAT ARE SECTIONS 101 AND 33(A)?

The object of this section is to discuss the present state of patent law under 35 U.S.C. § 101 and Section 33(a). This delves into a brief history of the America Invents Act and codifying the policy that human organisms are not patentable. Furthermore, this section demonstrates the power of the Supreme Court and Federal Circuit to interpret patentable subject matter. The section concludes by showing the difference between patentability of method and product claims of biotechnological developments.

“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof,” is entitled to a patent, subject to the additional requirements of Title 35 of the United States Code.⁵¹ 35 U.S.C. § 101 outlines the requirements related to patentable subject matter.

Categorizing patentable subject matter has been a hotly contested issue, with four Supreme Court cases and a legislative overhaul of the patent system in the past decade alone.⁵² Patentable subject matter must

⁴⁸ See 35 U.S.C. § 287 (2011).

⁴⁹ See, e.g., *Shields v. Halliburton Co.*, 493 F. Supp. 1376, 1389 (W.D. La. 1980), *aff'd*, 667 F.2d 1232 (5th Cir. 1982) (explaining that generally, all steps of a method patent must be performed to infringe. However, if one step is omitted, infringement could be found under the doctrine of equivalents); *PSN Illinois, LLC v. Ivoclar Vivadent, Inc.*, 525 F.3d 1159, 1167–68 (Fed. Cir. 2008) (“Under the all-elements rule, ‘an accused product or process is not infringing unless it contains each limitation of the claim, either literally or by an equivalent.’” (citing *Freedman Seating Co. v. Am. Seating Co.*, 420 F.3d 1350, 1358 (Fed. Cir. 2005))). To prove infringement of a process patent, the plaintiff must show that a separate entity performed all steps of a patented process. Contrastingly, to prove infringement of a product patent, the plaintiff only needs to show that every element of a claim exists in a product created by or sold by the defendant.

⁵⁰ See *id.*

⁵¹ 35 U.S.C. § 101 (2012).

⁵² See *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354 (2014); *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013); *Mayo Collaborative Services v.*

satisfy two conditions under 35 U.S.C. § 101: (1) the claimed invention “must be directed to one of the four statutory categories, and (2) must not be wholly directed to subject matter encompassing a judicially recognized exception.”⁵³ Essentially, any process, machine, manufacture, or composition of matter that is not a law of nature, natural phenomena, or abstract idea has the potential to be patentable.⁵⁴ Indeed, as recently as 2012, the Court explained that statutory subject matter included “anything under the sun that is made by man.”⁵⁵

The Court’s emphasis that subject matter must be made by man to qualify as patentable has been examined by the courts as far back as 1852 in *Le Roy v. Tatham*.⁵⁶ Judicial exceptions, namely laws of nature, natural phenomena, and abstract ideas, are not patentable subject matter, even if *discovered* by man.⁵⁷ Courts have determined that these exceptions do not fulfill a statutory category of patentable subject matter.⁵⁸ Because laws of nature, natural phenomena, and abstract ideas are not a process, machine, manufacture, or composition of matter, they are not patentable.

This is not to say that living creatures are not patentable under United States law. Patents have issued to such subject matter as bacteria⁵⁹, genetically engineered animals⁶⁰, cloning techniques⁶¹, and *in vitro* fertilization techniques.⁶² The line between patentable subject matter and a “law of nature” is blurred in the biotechnology space. This line is

Prometheus Labs., 132 S. Ct. 1289, 1304 (2012); *Bilski v. Kappos*, 561 U.S. 593 (2010); Leahy-Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284 (2011).

⁵³ MANUAL OF PATENT EXAMINING PROCEDURE § 2106 (2015).

⁵⁴ *See id.*; *see also Alice Corp.*, 134 S. Ct. at 2354.

⁵⁵ *Mayo Collaborative Services*, 132 S. Ct. at 1304 (citing H.R. REP. No. 1923, at 6 (1952)).

⁵⁶ *Le Roy v. Tatham*, 55 U.S. 156, 175 (1852) (“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.”); *see also Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948) (“[m]anifestations of laws of nature” are “part of the storehouse of knowledge . . . free to all men and reserved exclusively to none.”).

⁵⁷ *See Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (“a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter.”).

⁵⁸ *See id.*; *see also Alice Corp.*, 134 S. Ct. at 2354 (“‘Laws of nature, natural phenomena, and abstract ideas are not patentable’” (citing *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013))).

⁵⁹ *See, e.g.*, U.S. Patent No. 8,465,755 (issued Jun. 18, 2013) (patenting recombinant *Salmonella* bacterium).

⁶⁰ *See, e.g.*, U.S. Patent No. 9,113,616 (issued Aug. 25, 2015) (patenting a genetically modified mouse).

⁶¹ *See, e.g.*, U.S. Patent No. 6,700,037 (issued Mar. 2, 2004) (patenting a method of preparing a cloned porcine embryo).

⁶² *See, e.g.*, U.S. Patent No. 4,589,402 (issued May 20, 1986) (patenting a method of *in vitro* fertilization).

continuously clarified and altered both by legislative action and judicial interpretation.

A. Where the Law Stands Judicially: What is Patentable?

In recent years, both legislative action and judicial interpretation have imposed additional subject matter limitations through an interpretation of the four categories in 35 U.S.C. § 101. Recently, transitory forms of signal transmission, contractual agreements between parties, data *per se*, and, most notably, a human *per se* are all outside the four statutory categories of 35 U.S.C. § 101.⁶³ To explore the future of 35 U.S.C. § 101 as applied to biotechnology and artificial tissue, the cases of *Diamond v. Chakrabarty*, *Mayo Collab. Services v. Prometheus Labs.*, and *Association for Molecular Pathology v. Myriad Genetics* must be discussed.⁶⁴ These cases collectively show that not only is the Supreme Court capable of judicially interpreting the four categories of subject matter, but the Court has actively and recently added to judicial exceptions of both method and product patents.

Diamond v. Chakrabarty expressly rejected the argument that “micro-organisms cannot qualify as patentable subject matter until Congress expressly authorizes such protection.”⁶⁵ The *Chakrabarty* Court held that Ananda Chakrabarty’s human-made genetically modified bacterium was patentable because it had a “property which is possessed by no naturally occurring bacteria.”⁶⁶ Discussing patentable subject matter under § 101, the Court explained that “discoveries are ‘manifestations of . . . nature, free to all men and reserved exclusively to none.’”⁶⁷ In other words, discoveries are not patentable under § 101. The Court reviewed the three basic judicial exceptions to patentable subject matter under § 101, namely, “laws of nature, physical phenomena, and abstract ideas.”⁶⁸ The micro-organism in question, however, “plainly qualifies as patentable subject matter” because this is a “non-naturally occurring manufacture or composition of matter—a product of human ingenuity.”⁶⁹ Essentially, *Chakrabarty* established that

⁶³ MANUAL OF PATENT EXAMINING PROCEDURE § 2106 (2015); *see also* *Digitech Image Tech., LLC v. Electronics for Imaging, Inc.*, 758 F.3d 1344, 1350 (Fed. Cir. 2014) (data *per se*); *In re Ferguson*, 558 F.3d 1359, 1364 (Fed. Cir. 2009) (cert. denied) (a contractual agreement); *In re Nuijten*, 500 F.3d 1346, 1357 (Fed. Cir. 2007) (transitory forms of signal transmission); *Leahy-Smith America Invents Act*, Pub. L. No. 112-29, § 33(a), 125 Stat. 284, 340 (2011) (a human *per se*).

⁶⁴ *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013); *Mayo Collaborative Services v. Prometheus Labs.*, 132 S. Ct. 1289 (2012); *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

⁶⁵ *Chakrabarty*, 447 U.S. at 314.

⁶⁶ *Id.* at 303.

⁶⁷ *See id.* at 309 (citing *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)).

⁶⁸ *Id.*

⁶⁹ *Id.*

living matter is patent eligible if it is manmade.⁷⁰ Not only are some micro-organisms patentable under United States law, but also the Court can determine whether a micro-organism qualifies as patentable subject matter without Congressional authorization.⁷¹

The *Mayo v. Prometheus* decision controversially limited 35 U.S.C. § 101 subject matter in method claims, explaining that the process for personalized medicine dosing was not eligible for patent protection because the claims “effectively claim natural law or natural phenomena.”⁷² The patent claims relied on “the relationships between concentrations of certain metabolites in the blood and the likelihood that a . . . drug dosage will prove ineffective or cause harm.”⁷³ The Court found that the steps of administering drugs, measuring a patient’s metabolite levels, and other additional steps in the claimed processes were not “sufficient to transform the nature of the claims” and render them patentable subject matter.⁷⁴ After this case explicitly limited 35 U.S.C. § 101 by requiring method claims to have elements beyond routine and convention to be considered patentable subject matter, many looked to Congress to resolve technical amendments through the America Invents Act (“AIA”) and to reverse this limitation.⁷⁵ As explained below, the AIA did not overturn this ruling and, thus, the limitation remained.

Though *Chakrabarty* showed that micro-organisms made by man can be patented under 35 U.S.C. § 101, the ruling in *Association of Molecular Pathology v. Myriad Genetics* limited the decision.⁷⁶ *Myriad Genetics* determined the validity of gene patents under United States law,

⁷⁰ See *id.* at 310 (“Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature’s handiwork, but his own; accordingly it is patentable subject matter under § 101.”).

⁷¹ See *id.* at 314 (“It is, of course, correct that Congress, not the courts, must define the limits of patentability; but it is equally true that once Congress has spoken it is ‘the province and duty of the judicial department to say what the law is.’” (citing *Marbury v. Madison*, 1 Cranch 137, 177 (1803))). The Court explained that after Congress passed 35 U.S.C. § 101, the Court can construe the language of Congress and can use legislative history and statutory purpose to interpret ambiguities in the law.

⁷² *Mayo Collaborative Services v. Prometheus Labs.*, 132 S. Ct. 1289, 1305 (2012).

⁷³ *Id.* at 1291.

⁷⁴ *Id.* (further claiming that the doctor’s step of measuring a patient’s metabolite levels “is not normally sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law” (citing *Parker v. Flook*, 437 U.S. 584, 590 (1978))).

⁷⁵ See, e.g., Gene Quinn, *Killing Industry: The Supreme Court Blows Mayo v. Prometheus*, IPWATCHDOG (Mar. 20, 2012), www.ipwatchdog.com/2012/03/20/supreme-court-mayo-v-prometheus/id=22920/; Dennis Crouch, *Punishing Prometheus: The Supreme Court’s Blunders in Mayo v. Prometheus*, PATENTLYO (Mar. 26, 2012), patentlyo.com/patent/2012/03/punishing-prometheus-the-supreme-courts-blunders-in-mayo-v-prometheus.html.

⁷⁶ *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013); *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

specifically looking at isolated DNA sequences.⁷⁷ These DNA sequences were used for diagnostic breast cancer examinations.⁷⁸ The Court held, much like in *Mayo v. Prometheus*, that the human intervention necessary to produce the isolated DNA sequences did not, in itself, render the subject matter patentable.⁷⁹ Justice Thomas explained that Myriad's claims were not "saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule."⁸⁰ The Court simultaneously held that synthetically created gene sequences that do not exist in nature are patent eligible.⁸¹

Frustratingly, the *Myriad* decision left a wide gray area between synthetic and natural creation. The Supreme Court justices did not "consider the patentability of DNA in which the order of the naturally occurring nucleotides" was altered in the DNA.⁸² Though the Court determined that naturally occurring, isolated DNA was not patentable and completely synthetic creations were patentable, the gray area of editing DNA and, more broadly, changing natural materials, was not explained. Moreover, the Court did not discuss imitation of naturally occurring substances through synthetic means, including the field of tissue engineering.⁸³

⁷⁷ See *Myriad Genetics, Inc.*, 133 S. Ct. at 2111 ("we hold that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring.").

⁷⁸ See *id.* at 2111 ("This case involves patents filed by Myriad after it made one such medical breakthrough. Myriad discovered the precise location and sequence of what are now known as the BRCA1 and BRCA2 genes.").

⁷⁹ See *id.* at 2110.

⁸⁰ *Id.* The ruling in *Myriad Genetics* seemed to conflate two separate requirements for patent eligibility, namely 35 U.S.C. § 101 and 35 U.S.C. § 102. In addition to the subject matter requirements under 35 U.S.C. § 101, claims are not patent eligible if they are not novel under 35 U.S.C. § 102. Typically, the novelty of a claim should be examined under 35 U.S.C. § 102, where the court looks to whether "the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public." However, as was established in *Diamond v. Chakrabarty* and affirmed in *Myriad Genetics*, something classified as a product of nature is not patent eligible under 35 U.S.C. § 101, regardless of novelty under 35 U.S.C. § 102.

⁸¹ See *id.* at 2111 ("We also address the patent eligibility of synthetically created DNA known as complementary DNA (cDNA) . . . cDNA is patent eligible because it is not naturally occurring.") The Court also explained that, even if the products of isolating and purifying DNA were not patentable, the "innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes" could have been patentable as a method patent. *Id.* at 2119.

⁸² See *id.* at 2120 ("Scientific alteration of the genetic code presents a different inquiry, and we express no opinion about the application of § 101 to such endeavors.").

⁸³ See *id.*

B. Where the Law Stands Legislatively: What is Patentable?

Legislative actions have also limited patentable subject matter categories, particularly through codifying policies in the United States Patent and Trademark Office (“USPTO”). For more than twenty years, the USPTO “had an internal policy that human beings at any stage of development are not patentable subject matter under 35 U.S.C. Section 101.”⁸⁴ Though the USPTO had long prevented patenting of human beings, this policy was only recently codified by the Leahy-Smith America Invents Act Section 33(a) in 2011, which states as follows: “Notwithstanding any other provision of the law, no patent may issue on a claim directed to or encompassing a human organism.”⁸⁵

This codification was not meant to alter currently patentable subject matter under § 101.⁸⁶ Instead, “Codifying the Weldon amendment [Section 33(a)] simply continues to put the weight of the law behind the USPTO policy.”⁸⁷ According to legislative interpretation, this “only affects patenting human organisms, human embryos, human fetuses, or human beings.”⁸⁸ It does not have any “bearing on stem cell research or patenting genes.”⁸⁹

Though the Congressional record does provide some clarity as to the legislative purpose of Section 33(a), namely to render subject matter such as human embryos and human fetuses unpatentable, it does little to define the term “human organism.”⁹⁰ Human organism must have a different and broader definition than “human” because both embryos and fetuses are not considered human under current United States law.⁹¹ The definitional ambiguity certainly does not affect beginning-of-life research projects such as *in vitro* fertilization and stem-cell research because these research areas

⁸⁴ 157 CONG. REC. E1177 (daily ed. Jun. 23, 2011) (statement of Rep. Smith).

⁸⁵ Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284, 340 (2011).

⁸⁶ 157 CONG. REC. E1179 (daily ed. Jun. 23, 2011) (statement of Rep. Weldon) (citing a letter from James Rogan, Undersecretary and Director of the U.S. Patent Office, stating “Given that the scope of Representative Weldon’s amendment does not alter the USPTO policy on the non-patentability of human life-forms at any stage of development and is fully consistent with our policy, we support its enactment.”).

⁸⁷ 157 CONG. REC. E1177 (daily ed. Jun. 23, 2011) (statement of Rep. Smith).

⁸⁸ 157 CONG. REC. E1178 (daily ed. Jun. 23, 2011) (statement of Rep. Smith) (citing a July 22, 2003 speech in the House of Representatives of Hon. Dave Weldon).

⁸⁹ *Id.*

⁹⁰ 157 CONG. REC. E1177-E1180 (daily ed. Jun. 23, 2011).

⁹¹ See 1 U.S.C. § 8 (2013) (“‘person’, ‘human being’, ‘child’, and ‘individual’, shall include every infant member of the species *homo sapiens* who is born alive at any stage of development.”). Fetuses and embryos have not been born and, therefore, are not included under the present definition of “human being.” See below, Section V.

had the guidance of USPTO policy under which to pursue patents.⁹² The frustratingly missed clarification lies in the growing field of artificial organ creation: where does the boundary between human organism and organ system lie?

III. SETTLED PATENTABLE SUBJECT MATTER AT THE USPTO

To delve into the gray area of patentability in the biotechnological space, it is first important to understand definitively patentable subject matter in the USPTO.⁹³ Specifically when looking at subject matter that may define a human organism, two fields should be explored: in vitro fertilization and techniques regarding organ transplants. Combined, these fields present the closest available analog to the creation of a human organism in Section 33(a).

A. Creating a Living Creature Through Fertilized Eggs

In vitro fertilization is a process wherein egg and sperm are combined outside of a body.⁹⁴ The process was originally developed by Robert G. Edwards and Dr. Patrick Steptoe as a procedure to treat human infertility.⁹⁵ Edwards has received a Nobel Prize in Physiology or Medicine in 2010 for his work.⁹⁶ This was a major breakthrough in the fertility world, with over five million children to date being born because of developments in *in vitro* fertilization.⁹⁷ Certainly, patent law should—and does—support this type of breakthrough in medical technology.⁹⁸ Still, not everything about *in vitro* fertilization is patentable.

⁹² 157 CONG. REC. E1178 (daily ed. Jun. 23, 2011) (statement of Rep. Smith).

⁹³ Specifically referring to current laws and judicial rulings as of February 1, 2017.

⁹⁴ See generally *In Vitro Fertilization (IVF): Overview*, MAYO CLINIC, www.mayoclinic.org/tests-procedures/in-vitro-fertilization/home/ovc-20206838 (last visited Jan. 18, 2017) (providing a beginner's guide to *in vitro* fertilization); A.H. DeCherney, *In Vitro Fertilization and Embryo Transfer: A Brief Overview*, 59 YALE J. OF BIOL. AND MEDICINE 409 (1986) (providing an advanced overview of *in vitro* fertilization).

⁹⁵ See Martin H. Johnson, *Robert Edwards: The Path to IVF*, 23 REPROD. BIOMED. ONLINE 23 (2011).

⁹⁶ 2010 Press Release for Nobel Prize in Physiology or Medicine (Oct. 4, 2010) (on file with Nobel Media AB). Patrick Steptoe died before he could share in the prize. Walter Sullivan, *Dr. Patrick Steptoe is Dead at 74; Opened Era of 'Test Tube' Babies*, N.Y. TIMES, Mar. 23, 1988.

⁹⁷ See Emma Innes, *Five Million Babies Have Now Been Born by IVF – and Half Since 2007, New Figures Confirm*, DAILY MAIL (Oct. 16, 2013, 6:08 AM), <http://www.dailymail.co.uk/health/article-2462640/Five-million-babies-born-IVF--HALF-2007.html>.

⁹⁸ See *Diamond v. Chakrabarty*, 447 U.S. 303, 307 (1980); Jennifer Carter-Johnson, *Designing Children: Patents and the Market are not Sufficient Regulation*, MSU BIOETHICS (Nov. 20, 2014), <https://msubioethics.com/2014/11/20/designing-children> (explaining that *Chakrabarty* “recognized that patents may incentivize technology that needs regulation.”).

The black and white aspects of patentability of *in vitro* fertilization technology primarily lie in the differences between product and method claims. To obtain a patent, an inventor must contribute something new to society, as an invention is only patentable to whoever “invents or discovers new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”⁹⁹ A process, or method claim, regarding *in vitro* fertilization would be directed to a method of performing *in vitro* fertilization.¹⁰⁰ This could include methods of preparing egg and sperm to be combined, inserting a fertilized egg into a woman, or preparing the uterus to receive a fertilized egg.¹⁰¹ Contrastingly, a product claim with regards to *in vitro* fertilization would be directed to the product of the method: namely the growing fetus.

Patent claims for methods of *in vitro* fertilization are allowable under 35 U.S.C. § 101 as patentable subject matter.¹⁰² These include patents for introducing peripheral blood mononuclear cells before transferring an embryo into a patient’s uterus, a temperature controlling method for use in *in vitro* fertilization, and a method of fertilizing germ cells.¹⁰³ Though these may rely on a law of nature—namely, that when an egg and sperm meet, the egg can become fertilized and grow into a fetus—the method’s steps comprise “significantly more” than that law of nature.¹⁰⁴ Scientific ingenuity and years of experimentation come into play when patenting a method of *in vitro* fertilization because, without relying on scientific techniques that do not readily occur in nature, the woman being implanted with the fertilized egg would not become pregnant.

⁹⁹ 35 U.S.C. § 101 (2012).

¹⁰⁰ See, e.g., U.S. Patent No. 4,589,402 (issued May 20, 1986) (patenting a method of *in vitro* fertilization).

¹⁰¹ See *id.* (claiming a method of *in vitro* fertilization inducing ovulation, combining ovum and spermatozoa, and transferring the conceptus into the uterus).

¹⁰² See *id.*

¹⁰³ See U.S. Patent No. 8,137,967 (issued Mar. 20, 2012) (claiming a method of *in vitro* fertilization of a cell in an ovary called an “oocyte”); U.S. Patent No. 6,694,175 (issued Feb. 17, 2004) (claiming a method of monitoring the body temperature of a human embryo during *in vitro* medical care); U.S. Patent App. No. 13/655,257 (filed Oct. 18, 2012) (claiming a method of *in vitro* fertilization for a female patient, including introducing “an effective amount of a composition comprising peripheral blood mononuclear cells” into the uterus).

¹⁰⁴ See *Alice Corp. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2353 (2014) (explaining that, to determine whether claims are patent-eligible under 35 U.S.C. § 101, the court must first identify the judicial exception represented in the claim “and then determine ‘whether the balance of the claim adds ‘significantly more.’” (quoting *Mayo Collaborative Services v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012))).

The product of this method, otherwise known as the fetus, is not patentable and has never been patentable.¹⁰⁵ This seems like a logical result: a human should not be able to patent another human. Though there are many reasons behind this eventual result, the two main reasons in patent law are as follows: 1) the product already exists in nature and 2) it would be unethical to allow a human to patent another human, and current United States patent policy reflects this unethical result.¹⁰⁶

The first reason that fetuses are not patentable is that the product, the fetus, already exists in nature.¹⁰⁷ Outside of the subject matter eligibility requirements under 35 U.S.C. § 101, a person cannot get a patent on something that is not new or novel.¹⁰⁸ Under 35 U.S.C. § 102, if a product or process already exists in nature, it cannot later be patented.¹⁰⁹ As previously discussed in Section III(A), naturally occurring human genes, even those isolated from the human body, are not patentable because they are naturally occurring.¹¹⁰ For the same reason, a fetus would not be patentable. Even if the fetus in question has a combination of genes that would not exist but for the method applied, the method being *in vitro*

¹⁰⁵ 157 Cong. Rec. E1179 (daily ed. Jun. 23, 2011) (statement of Rep. Smith) (explaining the United States Patent and Trademark Office “has not issued patents on claims directed to human organisms, including human embryos and fetuses.”).

¹⁰⁶ See 35 U.S.C. § 101 (2012); 35 U.S.C. § 102 (2015) (“A person shall be entitled to a patent unless . . . the claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention”); see also DRJ Macer, *Patent or Perish? An Ethical Approach to Patenting Human Genes and Proteins*, 2 THE PHARMACOGONOMICS J. 361 (2002) (describing ethical dilemmas with human patenting, including incentivizing unethical research, harming human moral order including the environment, Article 4 of the Universal Declaration on the Human Genome and Human Rights, and government price controls).

¹⁰⁷ See *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980) (explaining that “handiwork of nature” is not patentable subject matter, but a product with “markedly different characteristics from any found in nature” is patentable subject matter).

¹⁰⁸ See 35 U.S.C. § 102 (2015) (explaining that a condition for patentability is that the claimed invention was not in public use or “otherwise available to the public before the effective filing date of the claimed invention”) (emphasis added). Though the Court has recognized that “the § 102 novelty inquiry” may sometimes overlap the “§ 101 patent-eligibility inquiry,” this paper is directed to patent eligibility under 35 U.S.C. § 101. *Mayo Collaborative Services v. Prometheus Labs.*, 132 S. Ct. 1289, 1304 (2012). For a more in-depth analysis of the Court’s conflation of 35 U.S.C. § 101 and § 102, see Teige P. Sheehan, *Mayo v. Prometheus: The Overlap Between Patent Eligibility and Patentability*, 21 BRIGHT IDEAS: N.Y. STATE BAR ASS’N 1 (Fall 2012).

¹⁰⁹ See *id.*; see also *Diamond v. Diehr*, 450 U.S. 175, 189-190 (1981) (explaining that 35 U.S.C. § 102 “covers in detail the conditions relating to novelty,” and it could be “an amplification and definition of ‘new’ in section 101”); *In re Bergstrom* 427 F.2d 1394 (C.C.P.A. 1970).

¹¹⁰ See *Alice Corp. v. CLS Bank Int’l*, 134 S. Ct. 2347, 2353 (2014) (explaining that the Supreme Court has “long held that [35 U.S.C. § 101] contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable” (quoting *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2116 (2013))).

fertilization, the result of that method cannot be patented in the wake of *Prometheus* and *Myriad Genetics*.¹¹¹

Additional support for not allowing products of *in vitro* fertilization to be patented can be found in *In re Roslin Institute*.¹¹² In this case, the Federal Circuit determined that cloned animals were unpatentable subject matter.¹¹³ Though genetically modified animals can be patented under United States patent law, a clone of an animal cannot be patented.¹¹⁴ As acknowledged in *In re Roslin Institute*, “naturally occurring organisms are not patentable.”¹¹⁵ Though there are methods relating to selecting materials to be combined which will eventually form a living being, “the natural organism itself [is] unpatentable because its ‘qualities are the work of nature’ unaltered by the hand of man.”¹¹⁶

A fetus, likewise, is a product “unaltered by the hand of man.”¹¹⁷ Because the fertilized egg has not been modified, with the exception of a natural fertilization process, the product of that fertilization is no different than any other fetus or human existing in society.¹¹⁸ The discovery does not possess “markedly different characteristics from any found in nature.”¹¹⁹ Therefore, the subject matter is unpatentable.

The second reason that a fetus is unpatentable is spelled out in United States policy and law. Specifically Section 33(a) and, before that, general USPTO policy did not allow for the patentability of human embryos or fetuses.¹²⁰ Though the definition of human organism is not specifically laid out in United States law, it is safe to say that fetuses and humans certainly

¹¹¹ *Myriad Genetics*, 133 S. Ct. at 2120; *Prometheus Labs.*, 132 S. Ct. 1289 (2012).

¹¹² *In re Roslin Inst. (Edinburgh)*, 750 F.3d 1333 (Fed. Cir. 2014).

¹¹³ See *id.* at 1339 (stating that “a time-delayed version of a donor mammal,” otherwise known as a clone, simply has a “time-delayed characteristic” of the donor mammal, rather than a different characteristic of the mammal. Therefore, the clones “are unpatentable subject matter under § 101.”).

¹¹⁴ *Id.* at 1336 (citing *Diamond v. Chakrabarty*, 447 U.S. 303 (1980); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948)).

¹¹⁵ *Id.*

¹¹⁶ *Id.* (citing *Funk Bros. Seed Co.*, 333 U.S. at 130).

¹¹⁷ *Id.*

¹¹⁸ But see Section V (discussing genetic modification and artificial tissues). The above scenario assumes that the *in vitro* fertilization did not also include genetically modifying the spermatozoan (sperm), ovum (egg), or zygote (fertilized egg).

¹¹⁹ *Id.* (citing *Chakrabarty*, 447 U.S. at 310).

¹²⁰ 157 CONG. REC. E1179 (daily ed. Jun. 23, 2011) (remarks of Rep. Smith) (stating that the Section 33(a) amendment “provides congressional support for the current U.S. Patent and Trademark policy against patenting human organisms, including human embryos and fetuses.”).

fall within the category.¹²¹ Therefore, the patent office has always had a policy to categorically deny patents directed to human fetuses or humans.¹²²

B. Medical Techniques in Organ Transplants

Though the American Medical Association “vigorously condemn[s] the patenting of medical and surgical procedures,” their campaign to amend 35 U.S.C. § 101 over the past two decades has been largely unsuccessful.¹²³ Unlike other countries, the United States allows for inventors to patent medical methodologies and surgical procedures.¹²⁴ However, patents of medical methodologies and surgical procedures are not as valuable as other method patents.¹²⁵ 35 U.S.C. § 287 limits remedies available to patent owners of surgical procedure patents.¹²⁶ 35 U.S.C. § 287 reads, in relevant part, as follows:

¹²¹ See *id.*; see also MANUAL OF PATENT EXAMINING PROCEDURE § 2105 (2015).

¹²² See *id.*; 157 CONG. REC. E1180 (daily ed. June 23, 2011) (remarks of Rep. Smith) (Explaining that the Weldon Amendment “should not be construed to affect claims directed to or encompassing subject matter other than human organisms, including but not limited to claims directed to or encompassing the following: cells, tissues, organs, or other bodily components that are not themselves human organisms (including, but not limited to, stem cells, stem cell lines, genes, and living or synthetic organs); hormones, proteins or other substances produced by human organisms; methods for creating, modifying, or treating human organisms, including but not limited to methods for creating human embryos through in vitro fertilization, somatic cell nuclear transfer, or parthenogenesis; drugs or devices (including prosthetic devices) which may be used in or on human organisms.” The Weldon amendment should be construed as Congressional approval “for the long-standing USPTO policy of refusing to grant any patent containing a claim that encompasses *any member of the species homo sapiens at any stage of development*” (quoting James Rogan (Nov. 20, 2003) (emphasis added))).

¹²³ See Robert Gunderman & John Hammond, *The Limited Monopoly: “Under the Knife”—Patenting Surgical Procedures*, 10 ROCHESTER ENGINEER 1 (Feb. 2009) (citing American Medical Association, *Resolutions*, PROC. AM. MED. ASS’N ANNUAL MEETING 390 (1994), www.ama-assn.org/ama/pub/about-ama/our-history/ama-historical-archives/the-digital-collection-historical-ama-documents.page).

¹²⁴ See, e.g., *Ex Parte Scherer*, 103 U.S.P.Q. 107, 110 (Pat. Off. Bd. App. 1954) (overruling the examiner’s decision that a medical method claim of injecting fluid into the human body is not patentable because “the only useful result . . . is dependent on the reaction of the human body to the injected fluid.” The court stated that the “utility of the injection of medicaments as a mode of administering medicaments cannot be denied. Consequently, the method . . . must be considered as useful within the provisions of 35 U.S.C. 101.”); U.S. Patent No. 5,080,111 (issued Jan. 14, 1992) (patenting a method of making a surgical incision).

¹²⁵ See David B. Gornish, *Medical Method Patents*, LAW 360 (Sept. 7, 2006, 12:00 AM), <https://www.law360.com/articles/9766/medical-method-patents> [<https://perma.cc/H2CF-G8UQ>] (explaining that useful processes and methods can be patentable. Though “the United States is one of the only countries which considers medical methods to be patentable subject matter,” 35 U.S.C. § 287(c) limits medical method patents. § 287(c) “exempts licensed medical professionals (e.g. doctors) and related healthcare entities (e.g. hospitals) from liability for infringement of medical method patents.”).

¹²⁶ See *id.*; 35 U.S.C. § 287 (2011) (explaining that if a medical practitioner infringes a patent, the patent owner cannot collect an infringement remedy from the medical practitioner or the health care entity, such as a hospital, with respect to the medical activity performed by the medical practitioner);

(c) With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271(a) or (b), the provisions of sections 281, 283, 284, and 285 shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity . . . (c)(3) This subsection does not apply to the activities of any person, or employee or agent of such a person . . . who is engaged in the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services . . . where such activities are: (A) directly related to the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services. . . .¹²⁷

Under 35 U.S.C. § 287, a patentee cannot collect infringement remedies, including civil trial, injunction, damages, and attorney's fees, as a result of a medical practitioner "infringing" the patented medical activity.¹²⁸ In other words, if a doctor performs the patented procedure, the patent owner cannot sue for damages.

However, this does not revoke the patentability of the medical procedures under 35 U.S.C. § 101.¹²⁹ Though a patent owner of a medical procedure patent certainly cannot collect damages from a medical professional, the owner can collect damages in an industrial setting.¹³⁰ In business, research "that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications," is susceptible to patent

see also Leisa Talbert Peschel, *Revisiting the Compromise of 35 U.S.C. § 287(c)*, 16 TEX. INTELL. PROP. L.J. 299, 306-310 (Winter 2008) (providing a legislative history summary of 35 U.S.C. § 287).

¹²⁷ 35 U.S.C. § 287 (2011); see also 35 U.S.C. § 271(a) (2010) (direct infringement); 35 U.S.C. § 271(b) (2010) (infringement by active inducement); 35 U.S.C. § 281 (1952) (remedy for infringement of a patent); 35 U.S.C. § 283 (1952) (injunction); 35 U.S.C. § 284 (2012) (damages); 35 U.S.C. § 285 (1952) (attorney fees). This only exempts 35 U.S.C. § 271(a) and (b), meaning that a patent owner can collect from medical practitioners or health care providers under 35 U.S.C. § 271 (c) for matters related to contributory infringement.

¹²⁸ See *id.*; see also Gornish, *supra* note 125 (explaining that a surgeon who performs an infringing surgery "would be insulated from infringement liability under § 287(c)." Patented medical methods where "the only persons or entities that are likely to directly infringe a patented medical method cannot be held liable for infringement . . . [are] essentially worthless.").

¹²⁹ See Gornish, *supra* note 125 ("[T]here are two phases of the patent process: (1) procurement and (2) enforcement. Procurement (i.e., patent prosecution) involves applying for and obtaining a patent from the government. Enforcement is how the patent holder uses an issued patent to exclude others from practicing the patented invention, and/or obtain damages for infringement." 35 U.S.C. § 287 limits enforcement, not procurement, of a patent.).

¹³⁰ See 35 U.S.C. § 287 (2011) (protecting only "a medical practitioner's performance of a medical activity" and not a person "engaged in the "commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter . . . where such activities are . . . directly related to the commercial development, manufacture, sale, importation, or distribution of a machine, manufacture, or composition of matter or the provision of pharmacy or clinical laboratory services.").

infringement suit.¹³¹ Therefore, if infringing medical procedures are used in business rather than in medical practice, the patent owner could sue the infringer for damages.

The exploration of and monetary incentives behind organ transplant extend far beyond medical procedures. Though the field of organ transplant originated with medical procedures, the field has now become intertwined with artificial tissue development.¹³² As discussed in more detail below, artificial tissues can be used as replacements for natural tissues.¹³³ As a replacement, artificial tissues could be transplanted into a human as a substitute for an organ or tissue donation.¹³⁴ However, because these tissues, unlike natural tissues, could be commoditized and produced in industry, industrial facilities would be practicing the methods of transplanting tissues. Therefore, methodologies related to organ transplant not only remain patentable under United States law, but are also rapidly becoming valuable patents.

IV. UNSETTLED PATENTABLE SUBJECT MATTER: THE GREY LINE OF ARTIFICIAL HUMAN ORGANISMS

This section looks to dissect the struggle of differentiating between artificial creation of a human organism and progressive scientific experimentation in creating human tissues. As the creation of artificial human organs bridges the gap between science fiction and fact, scientists, legislators, and ethicists are working to simultaneously incentivize scientific progress and discourage unethical experimentation. Their intentions can be united through defining the term "human organism" in Section 33(a) to effectively discourage unethical experimentation.

A. A Scientist's Perspective: Defining the "Progress of Science" Through Researchers and Ethicists

To better define the difference between ethical experimentation and monstrous unethical research, look to the scientists. The consequences of incentivizing the creation of an artificial human are recognized far outside of the legal space. The scientific community as a whole regularly works to

¹³¹ *Madey v. Duke University*, 307 F.3d 1351, 1362 (Fed. Cir. 2002).

¹³² See *Tissue Engineering*, 18 NATURE BIOTECHNOLOGY IT56, IT56-IT58 (2000) (discussing the history and future of the tissue engineering industry).

¹³³ See, e.g., Alessandro Gonfiotti, et al., *The first tissue-engineered airway transplantation: 5-year follow-up results*, 383 THE LANCET 238, 238-44 (2014) (discussing the progress of the tissue-engineered, artificially created trachea after the first transplantation in 2009).

¹³⁴ See *id.* (showing that the trachea could be grown in a laboratory and inserted into a person. This process is in lieu of using the tissue or organs of an organ donor).

de-incentivize pursuits that are ethically questionable at best. Unethical and socially unacceptable scientific studies regarding human experimentation are often heavily criticized before publication, may be denied publication from top journals, and may lose grant funding.¹³⁵ Though, like patents, this cannot stop a scientist from finding his or her own funding and engaging in privatized experiments, removing incentives reduces the impact of those studies before science and the law have come to a consensus concerning procedure after such a study is successful.¹³⁶ Patent law should work in parallel with ethicists and scientists to collectively incentivize innovation while discouraging unethical artificial human experimentation.

Research scientists often rely on government grants, private grants, and funding from foundations to fund their research.¹³⁷ With federal grants dwindling with recent budgetary cuts, the competition to receive grants has only become stiffer.¹³⁸ The culture of the academic scientific world is based on a “publish or perish” philosophy.¹³⁹ The amount of publications and, more importantly, the prestige these publications afford the scientists, correlates both to the amount of funding the scientist’s laboratory may receive and the career success of that scientist.¹⁴⁰

Like legal or medical journals, scientific journals have a known ranking system. Journals that have a high-impact, meaning that the articles published in those journals are cited more frequently in a three year time

¹³⁵ See Karen Young Kreeger, *Reproduction Research Held Back by Diffuse Rules, Charged Politics* THE SCIENTIST (1997), available at <http://www.the-scientist.com/?articles.view/articleNo/18343/title/Reproduction-Research-Held-Back-By-Diffuse-Rules--Charged-Politics/> [<https://perma.cc/86BP-QGYM>] (explaining that Mark Hughes, a professor at Georgetown University, “used agency funds, in part, to conduct genetic tests on DNA derived from human embryos destined for in vitro fertilization” and, as a result, lost his funding).

¹³⁶ See *id.*

¹³⁷ See Paula E. Stephan, *The Economics of Science*, 34 J. ECON. LIT. 1199, 1225 (Sept. 1996) (“U.S. Scientists are responsible for raising their own funds through the submissions of proposals to funding agencies.”).

¹³⁸ See Art Jahnke, *Who Picks Up the Tab for Science?*, BOSTON U. (2015) <http://www.bu.edu/research/articles/funding-for-scientific-research/> [<https://perma.cc/HWY2-ANHX>] (“[s]ince the 2010 apex, cuts to discretionary spending have clipped R&D funds by 15.4 percent in inflation-adjusted spending”); Bob Grant, *Follow the Funding*, THE SCIENTIST (May 2015), <http://www.the-scientist.com/?articles.view/articleNo/42799/title/Follow-the-Funding/> [<https://perma.cc/8V7N-E4WU>] (showing that laboratories unable to fund salaries and experiments with dwindling National Institutes of Health funding).

¹³⁹ See Danielle Fanelli, *Do Pressures to Publish Increase Scientists’ Bias? An Empirical Support from US States Data*, PLOS (2010), <http://dx.doi.org/10.1371/journal.pone.0010271> [<https://perma.cc/WEG5-T768>] (explaining that “The growing competition and ‘publish or perish’ culture in academia might conflict with the objectivity and integrity of research, because it forces scientists to produce ‘publishable’ results at all costs.”).

¹⁴⁰ See *id.* (explaining “bibliometric parameters to evaluate careers (e.g. number of publications and the impact factor of the journals they appeared in)” are integral to a scientist’s career in academia).

period, are considered more prestigious.¹⁴¹ For example, *Nature Reviews Molecular Cell Biology* has an impact factor of 32.928 for 2015, meaning that each article published since 2012 in the journal was cited, on average, 32.928 times at the end of the 2015 year.¹⁴² Comparatively, a lower-impact journal, such as *Trends in Biochemical Sciences* had an impact factor of 10.183 in 2015.¹⁴³

The higher the impact of a paper often correlates with the prestige of the study.¹⁴⁴ This, however, often leads to a cyclical turn of events. The more attention a paper gains in the scientific world, the better.¹⁴⁵ Therefore, scientists want to publish in a journal that has a high impact factor, because that increases the likelihood of a particular paper being a high impact paper. In turn, more scientists read and reference studies in high impact journals because they are considered more prestigious.¹⁴⁶ Though many have published articles explaining that the impact factor of a journal may not be the most accurate way to measure the value or import of the article, the impact factor is nevertheless one of the most emphasized components when choosing a publication journal.¹⁴⁷

To discourage unethical scientific experiments and, thus, both decrease the likelihood of independent funding for experiments and the readership for results of unethical experiments, high impact journals will refuse to publish unethical scientific pursuits regardless of overall scientific value.¹⁴⁸ Journal editors recognize that article selection encourages

¹⁴¹ See *id.* (showing that the impact factor is an important aspect when evaluating the prestige of a publication).

¹⁴² *Scimago Journal & Country Rank*, SCIMAGO LAB (2016), <http://www.scimagojr.com/journalrank.php?category=1312> [<https://perma.cc/5R45-HHDX>].

¹⁴³ *Id.*

¹⁴⁴ See Kamil Mizera, *The Big IF: Is Journal Impact Factor Really So Important?*, OPEN SCIENCE (June 7, 2013) (“Despite many negative voices and evidence, the impact factor is still doing well and is one of the most influential criteria when establishing the prestige and career of a scientist.”).

¹⁴⁵ See *id.* (showing that paper authors care about having the most citations from their respective publications and, therefore, are still publishing at high impact factor journals).

¹⁴⁶ See *id.* (showing that despite Open Access publications having a wide audience, scholars “usually prefer to publish (or try to publish) in the traditional way, in journals with Impact Factors.”).

¹⁴⁷ *Id.*

¹⁴⁸ David Cyranoski & Sara Reardon, *Chinese Scientists Genetically Modify Human Embryos*, NATURE NEWS (Apr. 22, 2015), <http://www.nature.com/news/chinese-scientists-genetically-modify-human-embryos-1.17378> [<https://perma.cc/7NJM-DZA4>] (showing that the high impact journals, *Nature* and *Science* refused to publish a paper about modifying human embryos. Though the research may have been properly vetted, the ethical concerns associated with experimenting on the human embryo became an overwhelming factor in denying the lead scientists a publication.” Huang says that the paper [about modifying human embryos] was rejected by *Nature* and *Science*, in part because of ethical objections.”).

scientists to pursue further paths of research related to a publication.¹⁴⁹ Without high impact publications, progress will become slower and, perhaps, the field of inquiry will die altogether. With regards to the development of an artificial human, high impact journals such as *Science*, *Cell*, and *Nature* are refusing to publish certain experimental results, demonstrating that the scientific community recognizes that questionably-ethical experiments regarding the creation of artificial humans are no longer simply science fiction.¹⁵⁰ By rejecting articles for publication regarding gene-editing and head transplantation, as discussed below, scientists are showing that there are limits to what should be encouraged for the purposes of the “Progress of Science.”¹⁵¹

Recently, scientists have discovered a breakthrough system for gene editing known as “clustered regularly interspaced short palindromic repeats” or “CRISPR” for short.¹⁵² Gene editing techniques can be used for everything from medicine to crop seed enhancement to germline editing.¹⁵³ Overall, the CRISPR-Cas9 system enables scientists to remove, add, or alter sections of a DNA sequence faster, cheaper, and more accurately than previous DNA editing techniques.¹⁵⁴ Changing a section of DNA allows scientists to study the function of that section of DNA, which can be useful for learning about almost anything involving how a cell works, whether that be a plant cell, animal cell, bacterial cell, or fungal cell.¹⁵⁵ However, with almost every scientific discovery regarding life, it is possible for research to take a dangerous and unethical turn.

¹⁴⁹ See *id.*; see also Daniel Cressey & David Cyranoski, *Human-embryo Editing Poses Challenges for Journals*, NATURE NEWS (Apr. 28, 2015), www.nature.com/news/human-embryo-editing-poses-challenges-for-journals-1.17429 [<https://perma.cc/N4BJ-ME4H>] (explaining that there are “complex ethical concerns and potential societal impacts” associated with studies on the human germline (quoting Emilie Marcus, editor-in-chief of *Cell*)).

¹⁵⁰ See Cressey, *supra* note 149 (explaining that gene-editing of human embryos is complicated and that journals, such as *Cell*, require “high technical and ethical standards” to publish); see also *Journal Info*, (2016) www.bioxbio.com/if/html/NATURE.html [<https://perma.cc/PZ66-L3A9>] (Nature 2015 impact factor: 38.138; Science 2015 impact factor: 34.661; Cell 2015 impact factor: 28.710).

¹⁵¹ See U.S. CONST. art. 1, § 8.

¹⁵² See, e.g., *What is CRISPR-Cas9?*, GENOME CAMPUS (Dec. 19, 2016), www.yourgenome.org/facts/what-is-crispr-cas9 (providing a beginner’s guide to CRISPR); Alex Reis, et al., *CRISPR/Cas9 and Targeted Genome Editing: A New Era in Molecular Biology*, 1 NEB EXPRESSIONS (2014), <https://www.neb.com/tools-and-resources/feature-articles/crispr-cas9-and-targeted-genome-editing-a-new-era-in-molecular-biology> [<https://perma.cc/4U9V-LG3G>] (providing a more advanced guide to CRISPR).

¹⁵³ See *id.*

¹⁵⁴ See *id.*

¹⁵⁵ See *What is CRISPR-Cas9?*, *supra* note 152 (looking at the applications and implications of CRISPR-Cas9).

Though the CRISPR-Cas9 system is useful in many contexts, the use of the system to edit human reproductive (germline) cells has become a cause for concern in the scientific community.¹⁵⁶ Scientists have been using CRISPR-Cas9 to edit non-reproductive (somatic) cells for over a decade.¹⁵⁷ However, the ability to edit human germline cells, otherwise known as egg and sperm cells, grants scientists the ability to essentially create genetically modified humans.¹⁵⁸

Germline modifications are different than somatic modifications because germline modifications are heritable.¹⁵⁹ This means that, if the germline modification results in a viable human that can reproduce, that human can pass on the germline modification to offspring.¹⁶⁰ As of now, scientists cannot predict what effect this will have on future generations.¹⁶¹ Encouraging research on germline modification could result in “unsafe or unethical uses of the technique,” including changing skin color, intelligence, or athletic ability.¹⁶²

The scientific outcry with regards for discouraging human germline editing occurs on two main levels, the individual level and the community level. Many scientists have called for a voluntary moratorium to “discourage human germline modification and raise public awareness of the difference between [genome editing in somatic cells and in germ cells].”¹⁶³ Essentially, each scientist would voluntarily stop researching CRISPR-Cas9 applications on germline cells.¹⁶⁴ Though this may work on a small-scale basis, individual moratoriums are not going to stop scientific

¹⁵⁶ See Edward Lanphier, et al., *Don't Edit the Human Germ Line*, NATURE (Mar. 12, 2015), <http://www.nature.com/news/don-t-edit-the-human-germ-line-1.17111> [<https://perma.cc/SXQ6-PUBE>].

¹⁵⁷ See Rodolphe Barrangou, *CRISPR Provides Acquired Resistance Against Viruses in Prokaryotes*, 315 SCIENCE 1709 (2007).

¹⁵⁸ See Lanphier, *supra* note 156.

¹⁵⁹ See David Cyranoski & Sara Reardon, *Chinese Scientists Genetically Modify Human Embryos*, NATURE NEWS (Apr. 22, 2015), <http://www.nature.com/news/chinese-scientists-genetically-modify-human-embryos-1.17378> [<https://perma.cc/7NJM-DZA4>].

¹⁶⁰ See *id.* (noting concerns about “inheritable genetic modification[s].”).

¹⁶¹ See *id.* (explaining that “genome editing in human embryos using current technologies could have unpredictable effects on future generations.”).

¹⁶² See *id.* (“Researchers have also expressed concerns that any gene-editing research on human embryos could be a slippery slope towards unsafe or unethical uses of the technique.”). Though the idea with editing germ cells is to reduce risk of cancer or handicaps, this could lead to people who are less accepting of people with disabilities in society. Creating these “designer babies” could create a rift between those able to afford CRISPR modification and those who cannot. Furthermore, eliminating strands of DNA we know may cause cancer may have untold consequences when a person reproduces. There is no way for certain to verify that these untold consequences will not come to light without human reproduction.

¹⁶³ See Lanphier, *supra* note 156.

¹⁶⁴ See *id.*

research on a large scale. The lure of a high impact human germline editing paper would be enough for some scientists to override this voluntary cessation of research.¹⁶⁵ Thus, the journal editors and funding agencies must also disincentivize human germline modification for this to have a large impact.

In 2015, Chinese researchers led by Junjiu Huang edited the genome of human embryos.¹⁶⁶ Huang recognized the potential ethical concerns with his research and used “non-viable embryos . . . obtained from fertility clinics” to modify a human gene.¹⁶⁷ Though the embryos could not produce a live birth if implanted into a human through *in vitro* fertilization, scientists and journals worldwide recognized that experiments on human embryos—viable or not—is ethically questionable.¹⁶⁸

Nature and *Science*, two of the highest impact scientific journals in the world, rejected the paper and refused to publish the results.¹⁶⁹ Huang explained that the rejection was based, in part, on ethical objections.¹⁷⁰ Though the results were published in a Beijing-based journal, *Protein & Cell*, a refusal of publication from *Nature* and *Science* will dissuade other scientists from pursuing research on human embryos regardless of ethical concerns.¹⁷¹ *Protein & Cell*, an online journal with an impact factor of 3.817 cannot compare in prestige to *Nature* and *Science*.¹⁷² The perception of paper quality in journals with low impact factors is, in turn, lower than papers published in high impact journals. As a result of subject matter rejection from top science journals, other scientists are dissuaded from pursuing or continuing human embryo gene editing studies – at least for the time being.

¹⁶⁵ See, e.g., Richard Gray, *Surgeon Behind World's First Human Head Transplant Says the Operation Could Take Place in the UK Next Year*, DAILYMAIL.COM (Nov. 23, 2016, 12:21PM), <http://www.dailymail.co.uk/sciencetech/article-3949888/Controversial-surgeon-world-s-human-HEAD-transplant-reveals-virtual-reality-help-prepare-patients.html> [<https://perma.cc/FF26-UCAQ>] (explaining that there is a neurosurgeon who will attempt to transplant a human head, but scientists are skeptical, in part, because the experiments the neurosurgeon has performed so far are not proven to work for humans. The journals cited are not peer-reviewed and are not evidence-based publications).

¹⁶⁶ See Puping Liang, et al., *CRISPR/Cas9-mediated Gene Editing in Human Trippronuclear Zygotes*, 6 PROTEIN CELL 363 (2015).

¹⁶⁷ David Cyranoski & Sara Reardon, *Chinese Scientists Genetically Modify Human Embryos*, NATURE NEWS (Apr. 22, 2015), <http://www.nature.com/news/chinese-scientists-genetically-modify-human-embryos-1.17378> [<https://perma.cc/T7ZE-YY5M>] (modifying a human gene to prevent a potentially fatal blood disorder).

¹⁶⁸ See *id.*

¹⁶⁹ See *id.* (“Huang says the paper was rejected by *Nature* and *Science*”).

¹⁷⁰ See *id.*

¹⁷¹ See Liang, *supra* note 166.

¹⁷² See *Impact Factor of Protein & Cell*, BIOXBIO, (2016) www.bioxbio.com/if/html/PROTEIN-CELL.html [<https://perma.cc/7QF9-3Y2J>].

Furthermore, funding organizations, including the National Institute of Health (NIH) are refusing to fund gene editing studies of human embryos.¹⁷³ Days after Huang's paper was published in *Protein & Cell*, the NIH released a statement entitled "Statement on NIH funding of research using gene-editing technologies in human embryos."¹⁷⁴ Though the NIH recognized that gene editing can be used to improve scientific "understanding of gene function and advance potential therapeutic applications to correct genetic abnormalities," the NIH will categorically refuse funding gene-editing technologies in human embryos.¹⁷⁵ The NIH explained that altering the human germline has been debated over many years and the scientific community has reached an almost universal consensus that altering the human germline is "a line that should not be crossed."¹⁷⁶ Cited factors included safety issues, ethical issues about affecting future generations of humans without their consent, and "lack of compelling medical applications justifying the use of CRISPR/Cas9 in embryos."¹⁷⁷ Without funding from the NIH, many laboratories will simply lack the ability to perform scientific studies and, thus, will lose yet another incentive to experiment on human embryos.¹⁷⁸

The scientific community does not just recognize the need to disincentivize an artificial or mutated human by means of embryo modifications. In recent years, an Italian neurosurgeon named Dr. Sergio Canavero has spoken about performing "the first human head transplant" in 2017, pending "ethical approval and the funding to do it."¹⁷⁹ However, many scientists have argued against pursuing such experiments, explaining

¹⁷³ Francis S. Collins, *Statement on NIH Funding of Research Using Gene-editing Technologies in Human Embryos*, NATIONAL INSTITUTES OF HEALTH (Apr. 28, 2015), <https://www.nih.gov/about-nih/who-we-are/nih-director/statements/statement-nih-funding-research-using-gene-editing-technologies-human-embryos> [<https://perma.cc/JWP5-2NPZ>] ("NIH will not fund any use of gene-editing technologies in human embryos.").

¹⁷⁴ *Id.*

¹⁷⁵ *Id.*

¹⁷⁶ *Id.*

¹⁷⁷ *See id.* ("These include the serious and unquantifiable safety issues, ethical issues presented by altering the germline in a way that affects the next generation without their consent, and a current lack of compelling medical applications justifying the use of CRISPR/Cas9 in embryos.").

¹⁷⁸ *But see* Bob Grant, *Follow the Funding*, THE SCIENTIST (May 1, 2015), <http://www.the-scientist.com/?articles.view/articleNo/42799/title/Follow-the-Funding/> [<https://perma.cc/PKK9-LL5Y>] (showing that scientists will adapt to fund their laboratories, rather than assume their experiments will eventually be funded).

¹⁷⁹ *See* Prakash Chandra, *Meet Sergio Canavero, the Neurosurgeon Who Will Carry Out First Human Head Transplant Next Year*, ECONOMIC TIMES PANACHE (May 14, 2016), <http://economictimes.indiatimes.com/magazines/panache/meet-sergio-canavero-the-neurosurgeon-who-will-carry-out-first-human-head-transplant-next-year/articleshow/52263142.cms> [<https://perma.cc/VUP2-9FLH>].

the ethical costs far outweigh the scientific benefits.¹⁸⁰ Furthermore, many explain that Dr. Canavero's experiment "has been mostly about publicity rather than the production of good science."¹⁸¹ Papers concerning Dr. Canavero's research are being published in journals which are guest-edited, rather than peer-edited.¹⁸² Without being published in a peer-reviewed journal, meaning a journal where other neuroscientists and researchers would examine Canavero's results, these experiments are merely "science through public relations."¹⁸³ The lack of peer reviewed journal publications casts doubt on the veracity of Dr. Canavero's results and, potentially, the source of future funding of his experiments.¹⁸⁴ The ethical outcry by both journal publications and by individual scientists seems to be slowing the progress on Dr. Canavero's endeavors.¹⁸⁵

Through the examples of CRISPR human embryo editing and head transplantation, the scientific community has demonstrated two facts: science is progressing towards artificially creating humans and the scientific community is attempting to stop progress of questionably ethical human experimentation. By removing incentives of funding and journal publication, it has become harder for scientists to progress in experiments related to human genetic modification. United States law, and patent law in particular, must become more transparent before it can have the same effect of deterring experimentation in this space.¹⁸⁶ To effectively dissuade creation of a human organism, the term "human organism" must become better defined under current United States law and in the United States patent system.

¹⁸⁰ See, e.g., Anto Cartolovni & Antonio G. Spagnolo, *Ethical Considerations Regarding Head Transplantation*, 6 SURG. NEUROL. INT. 103 (2015) (explaining that the patient "will be exposed to far greater and unknown risks than the benefits of the procedure." These include immunosuppressive drugs, genetic inheritance, and using organs that "could be useful to someone else that needs a heart or liver that could save his/her life.").

¹⁸¹ See Sam Wong, *Head Transplant Carried Out on Monkey, Claims Maverick Surgeon*, NEW SCIENTIST (Jan. 19, 2016) (quoting Thomas Cochrane, a neurologist at Harvard Medical School's Center for Bioethics), <https://www.newscientist.com/article/2073923-head-transplant-carried-out-on-monkey-claims-maverick-surgeon/> [<https://perma.cc/9GJH-H5GD>].

¹⁸² See *id.* (explaining that the research has not been published in a peer-reviewed journal).

¹⁸³ *Id.*

¹⁸⁴ See *id.*

¹⁸⁵ See *id.* (as of 2017, Canavero has not been granted funding or approval for the proposed experimental surgery).

¹⁸⁶ The ambiguity of "human organism" in Section 33(a) requires clarification before examiner and USPTO rejections can be truly effective against an inventor attempting to patent artificial human products.

B. *Products of Life: The Current Problems with Patenting Artificial Tissues*

The divide between necessary scientific research and potentially unethical experimentation comes to a crux with artificial copying of human organisms. Though the patent system strives to incentivize research, it often falls short of fully supporting biotechnology. Due to ambiguous language, conflicting legislation, and unclear court opinions, research attempting to mimic nature cannot be properly promoted within the current confines of the patent system.

Under the current patent system, scientists can obtain patents for artificial tissues, even those comprising human cells.¹⁸⁷ These tissues are considered patentable for one main reason: the artificial tissues are different than naturally occurring tissues.¹⁸⁸ Scientists are in the process of developing artificial tissues and artificial organs.¹⁸⁹ These organs are eventually meant to be compatible with human organs.¹⁹⁰ That is, natural organ donations may eventually become a thing of the past. The object of many of these research projects is to create organs for those on organ donation waiting lists.¹⁹¹ The problem lies in this progression: scientists are working to replicate a natural product. The closer scientists get to replication of a natural product, the further scientists get to patent protection of their invention.

¹⁸⁷ See, e.g., U.S. Patent App. No. 14/153,535 at 4 (Notice of Allowance issued Sept. 27, 2016) (claiming in Claim 4 “an artificial tissue construct . . . comprising alveolar primary epithelial cells . . . wherein the alveolar primary epithelial cells . . . are human cells.”).

¹⁸⁸ See Yasuhiko Tabata, *Biomaterial Technology for Tissue Engineering Applications*, 6 J. OF THE ROYAL SOCIETY INTERFACE S311, S314 (2009) (comparing natural and synthetic biomaterials used in tissue engineering-based regeneration therapy); Yalda A.Kharaz, et al., *Proteomic Differences Between Native and Tissue-engineered Tendon and Ligament*, 16 PROTEOMICS 1547, 1550-1552 (Apr. 8, 2016) (discussing the differences between engineered and natural tissues).

¹⁸⁹ See, e.g., Anthony Atala, *Tissue Engineering of Artificial Organs*, 14 J. OF ENDOUROLOGY 49, 49-51 (2009) (discussing tissue engineering efforts for tissue and organs within the urinary system); see also U.S. Patent No. 5,750,329 (issued May 12, 1998) (patenting methods and compositions for an artificial lung organ culture system).

¹⁹⁰ See *id.* (“Trials of urethral tissue replacement with processed collagen matrices are in progress, and bladder replacement using tissue engineering techniques are currently being arranged. Recent progress suggests that engineered urologic tissues may have clinical applicability in the future.”); see also Alexandra Ossola, *Scientists Grow Full-sized, Beating Human Hearts from Stem Cells* POPULAR SCIENCE (Mar. 16, 2016) <http://www.popsi.com/scientists-grow-transplantable-hearts-with-stem-cells> (showing that growing artificial organs will combat organ shortage problems).

¹⁹¹ See *The Surprising Future of Artificial Organ Transplants*, Brandvoice, FORBES (Sept. 26, 2016, 10:23 AM), <http://www.forbes.com/sites/oppenheimerfunds/2016/09/26/the-surprising-future-of-artificial-organ-transplants/#af9323f43963> [<https://perma.cc/BGA4-YNSW>] (providing an overview of artificial organ research done thus far and explaining that “[s]cientists are finding newer, cheaper and safer pathways to create artificial organs — pathways that could reduce the wait for organ transplants and transform surgery as we know it.”).

As explained above, according to 35 U.S.C. § 101 and § 102, if a product or process already exists in nature, it cannot later be patented.¹⁹² If scientists are able to create exact replicas of organs or human tissues, their inventions are not patentable under current law.¹⁹³ The process to create the artificial tissue could be patentable, but the actual product may not be. The more similar the artificial organ is to a real organ, the less likely the invention would be patentable.¹⁹⁴ The distinction between patentable and not patentable artificial tissue replication becomes murkier every day. With the addition of Section 33(a), the USPTO can impose additional hurdles to biotechnology inventors.¹⁹⁵

Currently, the USPTO has not rejected many current patents based on Section 33(a).¹⁹⁶ However, the file history of US 8,821,541 shows that Section 33(a)—not § 102—can be used to prevent the patentability of tissues.¹⁹⁷ In the file history of ‘541, the inventor patented an apparatus for anchoring a surgical suture to a bone.¹⁹⁸ During the examination of the

¹⁹² 35 U.S.C. § 101 (2012); 35 U.S.C. § 102 (2015).

¹⁹³ See *id.* (showing that, if something already exists in nature before an inventor applies for a patent, the material is not patentable; see also *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013)).

¹⁹⁴ See *Myriad Genetics, Inc.*, 133 S. Ct. at 2118 (showing that isolated and purified DNA is not patent-eligible, even with laboratory intervention).

¹⁹⁵ See Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284, 340 (2011) (reading in relevant part: “Notwithstanding any other provision of the law, no patent may issue on a claim directed to or encompassing a human organism.” Without properly defining the term “human organism,” but showing that this is a necessary amendment to patent laws and, specifically 35 U.S.C. § 101 laws, the difference between “human organism” and a “product of nature” is unclear and can be an additional barrier to patent applicants outside of typical § 101 law.).

¹⁹⁶ This was first searched through “Harvard Dataverse,” providing a compilation of all rejections of patent applications until December 11, 2015. See Michael Frakes & Melissa Wasserman, *Replication Data For: Is the Time Allocated to Review Patent Applications Inducing Examiners to Grant Invalid Patents? Evidence from Micro-Level Application Data*, HARVARD DATAVERSE (2015), <https://dataverse.harvard.edu/dataset.xhtml?persistentId=doi:10.7910/DVN/ABE7VS> [<https://perma.cc/D2RB-VAEQ>]. After searching 200 randomized rejections under 35 U.S.C. § 101 and finding nothing, this was then searched through docketalarm.com, a search database, to determine if any post-grant proceedings, including litigations, inter partes reviews, and post-grant reviews, were conducted on patents rejected under Section 33(a). DOCKET ALARM, www.docketalarm.com (last visited Jan. 25, 2017). Out of the 77 search results, three post-grant proceedings were conducted on patents rejected under Section 33(a). These are summarized as follows: US Patent App. No. 13/672,422 (filed Nov. 8, 2012) (Aug. 17, 2016 Final Rejection rejecting claims reciting the “neck of a user” under Section 33(a) and suggesting an amendment reciting the term “adapted to the neck of a user” to ameliorate the rejection); U.S. Patent No. 8,821,541 (issued Sept. 2, 2014) (discussed below, notes 197-200); U.S. Patent No. 7,454,002 (reissue U.S. App. No. 14/567,016 (filed Dec. 11, 2014)) (Apr. 12, 2016 Non-Final Rejection rejecting claim 30 reciting that a receiver “is coupled to the user” and, therefore, positively claims the user). Only the U.S. Patent No. 8,821,541 rejection remotely discusses patenting a human organism. All other rejections amount to little more than draftsman errors.

¹⁹⁷ U.S. Patent No. 8,821,541 (issued Sept. 2, 2014).

¹⁹⁸ See *id.* (patenting a “suture anchor with insert-molded rigid member”).

application, the examiner rejected claim 34, which recited a suture anchor “wherein at least one suture strand has a length sufficient to tie tissue.”¹⁹⁹ The examiner stated “Claim 34 is positively claiming the tissue which is a human organism” and, thus it is “excluded from the scope of patentable subject matter under 35 U.S.C. § 101.”²⁰⁰ Regardless of the validity of the examiner’s rejection, the statement that tissue is a human organism demonstrates that Section 33(a) requires clarity.²⁰¹ By allowing an examiner to reject a claim to a tissue as a “human organism,” the uncertainty behind the business of artificial organ creation grows larger.

Herein lies the problem with artificial tissue creation and, eventually, artificial organ and organ system creation. If patent law were used to incentivize creation of an artificial organ, the law should render the artificial product patentable and not just the process of creating the organ. However, patent law does not incentivize creating exact replicas of DNA or animals that already exist in nature.²⁰² If the object of creating an artificial organ is to replicate one already found in nature, then, as science gets closer and closer to the ultimate object, the products become less and less likely to be patentable subject matter.²⁰³ Even if the product would be different than what currently exists in nature, the definition of Section 33(a) with regards to a human organism is so broad that, ultimately, no bio-manufactured organ could be patentable.²⁰⁴

¹⁹⁹ See Non-final Rejection of Application No. 11/518,872, 9 (non-final rejection issued Feb. 21, 2014) (Application of U.S. Patent No. 8,821,541 (issued Sept. 2, 2014)) (it should be noted that this rejection was most likely directed to claim 33, not claim 34), as is evident from the patent file history).

²⁰⁰ See *id.* (showing that 33(a) is considered in the USPTO to be a subset of 35 U.S.C. § 101).

²⁰¹ See *id.*; see also 157 CONG. REC. E1179 (daily ed. Jun. 23, 2011) (statement of Rep. Weldon) (citing a letter from James Rogan, Undersecretary and Director of the U.S. Patent Office, stating “Given that the scope of Representative Weldon’s amendment [Section 33(a)] does not alter the USPTO policy on the non-patentability of human life-forms at any stage of development and is fully consistent with our policy, we support its enactment.”). If Section 33(a) was not meant to alter USPTO policy, then the claims should have been otherwise allowable under 35 U.S.C. § 101 because tissues, even those comprising human cells are considered patentable. See, e.g., U.S. Patent App. No. 14/153,535 (Notice of Allowance issued Sept. 27, 2016) (claiming in Claim 4 “an artificial tissue construct . . . comprising alveolar primary epithelial cells . . . wherein the alveolar primary epithelial cells . . . are human cells.”).

²⁰² See 35 U.S.C. § 101; see also *Ass’n for Molecular Pathology v. USPTO*, 689 F.3d 1303, 1351 (2012) (explaining that “[T]here is no magic to a chemical bond that requires us to recognize a new product when a chemical bond is created or broken.” This shows that, even if DNA or a tissue is created synthetically in a laboratory, if it matches what already exists in nature, the synthetically created biologic material is not patentable.).

²⁰³ See *id.* (showing that, the closer scientists get to replicating naturally occurring DNA, the harder it would be to patent the product).

²⁰⁴ See Amanda H. Russo, *Association for Molecular Pathology v. Myriad Genetics, Inc. and Its Impact on the Patentability of “Designer” Genes*, 4 NYU J. INTELL. PROP. & ENT. L. 37, 40 (2014) (“Unfortunately, the AIA never expressly defines any of the terms in [33(a)] so it is not entirely clear what specific subject matter would fall under the prohibition.”); Andrew Armstrong, *3D Printed Human Organs and the Debate on Applicable Patent Law*, IPWATCHDOG (Oct. 7, 2015),

C. Defining a “Human Organism”: An Exploration of the Term “Human” in Other Areas of United States Law

To provide clarity to Section 33(a) and promote ethical experimentation, there must be a clear, precise definition of “human organism” that encompasses the legislative intent behind Section 33(a). To produce such a definition, Congress can look to other areas of United States law for template definitions of a human. Certainly, the Congressional record behind the adoption of Section 33(a) unambiguously demonstrates that the term “human organism” has a different meaning in patent law than in other legal areas.²⁰⁵ Congressmen claim that human embryos fall under the patent definition of “human organism.”²⁰⁶ However, under current criminal law statutes, dropping a petri dish full of artificially inseminated cells does not constitute murder of a human being. Nevertheless, because patent law does not give a clear definition of “human organism,” other areas of the law should be used for context and insight. Through looking to laws concerning *in vitro* fertilization and brain-dead individuals, the definition of “human organism” in patent law can be designed to incentivize artificial organ development and discourage human experimentation. Two main statutes can be used for guidance: 1 U.S.C. § 8 (defining a living human) and the Uniform Death Determination Act (defining when a body ceases to be a living human).²⁰⁷

1 U.S.C. § 8 defines a “person” and “human being” as including “every infant member of the species homo sapiens who is born alive at any stage of development.”²⁰⁸ It clarifies that “born alive . . . means the complete expulsion or extraction from his or her mother of that member, at any stage of development, who after such expulsion or extraction breathes

<http://www.ipwatchdog.com/2015/10/07/3d-printed-human-organs-and-the-debate-on-applicable-patent-law/id=62307/> [<https://perma.cc/S5B6-BMZT>] (explaining that using a definition for human organism, “any living entity containing one or more cells belonging to the species homo sapiens” would render a “bioprinted organ ineligible for patenting.”); *see also* 157 CONG. REC. E1179 (daily ed. June 23, 2011) (statement of Rep. Smith) (“The term ‘human organism’ includes an organism of the human species that incorporates one or more genes taken from a nonhuman organism . . . However, it does not include non-human organism incorporating one or more genes taken from a human organism.”).

²⁰⁵ *See, e.g.*, 1 U.S.C. § 8 (2002) (defining “person” and “human being”); *see also* Cruzan v. Dir., Missouri Dep’t of Health, 497 U.S. 261, 266 (1990) (defining occurrence of human death); Uniform Determination of Death Act (1981), *available at* <http://www.uniformlaws.org/shared/docs/determination%20of%20death/udda80.pdf> [<https://perma.cc/7984-32PD>].

²⁰⁶ 157 CONG. REC. E1179 (daily ed. June 23, 2011) (statement of Rep. Smith) (stating that a human embryo is an “organism.”).

²⁰⁷ *See* 1 U.S.C. § 8 (2002); Uniform Determination of Death Act (1981), *available at* <http://www.uniformlaws.org/shared/docs/determination%20of%20death/udda80.pdf>. The Uniform Determination of Death Act has been adopted by 41 states thus far. *See, e.g.* Okla. Stat. Ann. Tit. 63, § 3122 (West).

²⁰⁸ 1 U.S.C. § 8 (2002).

or has a beating heart, pulsation of the umbilical cord, or definite movement of voluntary muscles. . . .”²⁰⁹ This limits a human being to 1) a homo sapien 2) who is born and 3) (who is born) alive.

In terms of end-of-life care in the United States, the Uniform Determination of Death Act explains “An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead.”²¹⁰ In other words, if brain function stops, the body is no longer alive. Medical professionals are legally allowed to withdraw life support without criminal repercussions.²¹¹

The following chart provides a summary of the requirements to be considered a human being under 1 U.S.C. § 8 and the requirements to be considered dead under the Uniform Determination of Death Act.

<u>1 U.S.C. § 8</u> ²¹²	<u>Uniform Determination of Death Act</u> ²¹³
Every infant member of the species homo sapien . . . at any stage of development	
Complete expulsion or extraction from his or her mother	
Breathes OR has a beating heart,	Irreversible cessation of circulatory and respiratory functions
Pulsation of the umbilical cord OR definite movement of voluntary muscles	Irreversible cessation of all functions of all the entire brain

Chart 1: Topical Definitions of “Human” or “Living Human” in Other Areas of United States Law

Through analyzing the legislative history of Section 33(a), the definition of a human being in 1 U.S.C. § 8 cannot simultaneously be used

²⁰⁹ *Id.*

²¹⁰ See Uniform Determination of Death Act (1981), available at <http://www.uniformlaws.org/shared/docs/determination%20of%20death/udda80.pdf>; Okla. Stat. Ann. tit. 63, § 3122 (West 2017).

²¹¹ See Robert M. Sade, *Brain Death, Cardiac Death, and the Dead Donor Rule*, 107 J.S.C. MED. ASS’N 146, 147 (2011) (“Although withdrawal of life support (not the patient’s disease) causes death, it is not a legally or morally culpable act.”).

²¹² 1 U.S.C. § 8 (2002).

²¹³ Uniform Determination of Death Act (1981), available at <http://www.uniformlaws.org/shared/docs/determination%20of%20death/udda80.pdf>; Okla. Stat. Ann. Tit. 63, § 3122 (West 2017).

for the term “human organism.” The terms “born” and “alive” were simply not contemplated definitional aspects of “human organism” as construed in patent law.²¹⁴

Because “no member of the human species is an ‘invention’ or property to be licensed for financial gain,” Congress intended the term “human organism” to encompass human embryos.²¹⁵ Human embryos are not born and are not alive. They have not been expelled or extracted from a mother. Furthermore, even if a human embryo was implanted into a uterus and developed until just before the embryo formed a fetus, it is not possible for the most developed human embryo to be extracted from the uterus alive.²¹⁶ The embryo, as extracted, would not breathe, have a beating heart, pulsation of the umbilical cord, or movement of voluntary muscles.²¹⁷

Section 33(a) was adopted to “not allow . . . researchers to gain financially by granting them an exclusive right to practice . . . ghoulish research,” such as creating male-female hybrid embryos.²¹⁸ Cellular research certainly goes beyond what is contemplated as human under 1 U.S.C. § 8.²¹⁹ Scientists who are experimenting are not murdering or battering embryos. Scientists cannot be prosecuted for murder when experimenting with fertilized embryos.²²⁰ In fact, scientists can let fertilized

²¹⁴ See 157 CONG. REC. E1177 – E1180 (daily ed. June 23, 2011) (demonstrating through absence that congressmen debating Section 33(a) did not discuss when a human organism was born or when a human organism was considered alive).

²¹⁵ See *id.* at E1177.

²¹⁶ See KEITH L. MOORE & T.V.N. PERSAUD, *ESSENTIALS OF EMBRYOLOGY AND BIRTH DEFECTS*, 6 (7th ed. 2008) (explaining that at the end of the embryonic period at eight weeks, “the beginnings . . . of all essential structures are present.” However, fetuses are not viable until “22 weeks after fertilization, but the chance of survival is not good until the fetus is several weeks older.”).

²¹⁷ See *id.* at 2, 191-194, 245 (explaining that the embryonic period ends at week eight of pregnancy; the embryo develops heart tubes and umbilical arteries but not a fully developed heart; showing the progression of the musculoskeletal system of the embryo – none of these are functional outside of the womb); Pregnancy Timeline, *BBC News* (Dec. 23, 2004, 13:42 GMT), <http://news.bbc.co.uk/2/hi/health/4121411.stm> [<https://perma.cc/9F3R-DZYH>] (showing a beginner’s guide to fetal development and explaining that an embryo is a mass of cells before the second month of pregnancy. That embryo develops into a fetus around the second month); M.A. Hill, *Respiratory System Development*, EMBRYOLOGY (Jan. 23, 2017), https://embryology.med.unsw.edu.au/embryology/index.php/Respiratory_System_Development [<https://perma.cc/P7R9-HP96>] (explaining that though lungs begin to form as an embryo, by the time the embryo develops into a fetus, these lungs are buds, “an outgrowth from the ventral wall of the foregut” and are not functional).

²¹⁸ 157 CONG. REC. E1178 (daily ed. June 23, 2011) (statement of Rep. Smith).

²¹⁹ 1 U.S.C. § 8 (2002) (discussing the definition of a human after birth, but not discussing development of a human *in utero* or by synthetic means).

²²⁰ But see Ann A. Kiessling, *What Is an Embryo?: A Rejoinder*, 37 CONN. L. REV. *1, *8 (2004) (showing that this issue is contested, arguing “that if embryos have the moral status of persons born, then destroying them for any reason is murder” (referencing Harold T. Shapiro, *What Is an Embryo?: A Comment*, 36 CONN. L. REV. 1093, 1097 (2004))).

embryos expire without any criminal ramifications.²²¹ The same cannot be said for humans. A scientist cannot poke or prod another human with a needle, nor can a scientist ignore another human until he or she expires.²²² Therefore, the definition of “human organism” under the Leahy-Smith America Invents Act Section 33(a) must be broader than the definition of “person” and “human being” under 1 U.S.C. § 8.

Nothing grown in a lab will ever be considered “born,” unless scientists determine that an artificial uterus is the best way to develop cells.²²³ However, this seems unlikely as it would go against the years of progress in cell growth experiments, which currently use scaffolds and molds to shape and form artificially grown tissues.²²⁴ Therefore, there must be a way to distinguish “human organisms” without requiring birth in a patent context. The current problem is the uncertainty behind this distinction. Looking to end-of-life definitions under United States law helps to provide a bit of clarity between the definition of a human and the potential definition of a “human organism.”

The Uniform Determination of Death Act provides a far better template to create a working definition of human organism under Section 33(a). If the definition of death were applied in reverse, meaning that nothing became “alive” until it fulfilled the criteria listed under the Act, Congress could promote experimentation with artificial organs while still preserving the legislative intent to discourage human embryonic experiments. This would have the added benefit of avoiding the complicated viability arguments entangling abortion.²²⁵

²²¹ *Frisina v. Women & Infants Hosp. of R.I.*, No. CIV. A. 95-5827, 2002 WL 1288784, at *4-5 (R.I. Super. Ct. May 30, 2002) (explaining that frozen embryos were not considered “‘persons’ for constitutional purposes” (quoting *Kass v. Kass*, 696 N.E.2d 174, 179 (N.Y. 1998))); *see also* Amber N. Dina, *Wrongful Death and the Legal Status of the Preivable Embryo: Why Illinois is on the Cutting Edge of Determining a Definitive Standard for Embryonic Legal Rights*, 19 REGENT. U.L. REV. 251, 264-66 (2006) (discussing the possibility of civil penalties for an embryo bank for wrongfully destroying embryos without permission).

²²² *See First Oak Brook Corp. Syndicate v. Comly Holding Corp.*, 93 F.3d 92, 94 (3d Cir. 1996) (defining battery as “harmful or offensive contact between or among two or more persons”); *see also* S. John Campanie, 1989 N.Y. Op. Att’y Gen. (Inf.) 98 (1989) (defining “[a] death caused by unlawful act or criminal neglect” as a death that a coroner can investigate).

²²³ *See* 1 U.S.C. § 8 (2002) (defining a human as “born alive” as “the complete expulsion or extraction from his or her mother.”).

²²⁴ *See* Dietmar W. Huttmacher, *Scaffolds in Tissue Engineering Bone and Cartilage*, 21 BIOMATERIALS 2529 (2000) (explaining the use of scaffold designs to artificially design musculoskeletal tissue, bone, and cartilage).

²²⁵ *See* Yaniv Heled, *On Patenting Human Organisms or How the Abortion Wars Feed into the Ownership Fallacy*, 36 CARDOZO L. REV. 241, 256 (2014) (explaining that “the mingling of sex, embryo research, and the context of the abortion debate generated sufficient outrage to persuade Congress to reenact the Weldon Amendment[Section 33(a)] time and again until it finally found a permanent home in Section 33 of the America Invents Act”); *see also* 157 CONG. REC. E1178-E1181

The first requirement of the Uniform Determination of Death Act is “irreversible cessation of circulatory and respiratory functions.”²²⁶ Applying this definition of life, unlike the definition in 1 U.S.C. § 8, to an embryo does not specifically require a heart or lungs.²²⁷ Though an embryo may possess the beginnings of a circulatory and respiratory system, an embryo does not have a functional heart or lungs at the end of its development process.²²⁸ Therefore, a template definition of a “human organism” requiring “circulatory and respiratory functions” would unquestionably apply to an embryo.²²⁹ Additionally, it would exclude artificial organ development, except experiments creating a combination of a cardiovascular and respiratory system.²³⁰

Furthermore, by the end of the embryonic period and the beginning of the fetal development period, “rudimentary structures of the brain and central nervous system are established.”²³¹ Therefore, the second prong of the Uniform Determination of Death Act could be fulfilled by a human.²³² Artificial tissues do not have a brain or central nervous system.²³³ Until scientists develop an artificial brain, artificial respiratory system, or artificial circulatory system that can be implanted into a human, no definition of “alive” could overshadow scientific research and deny research facilities well-deserved patents. The individual organ systems would be patentable under this definition, but the human body receiving the

(daily ed. June 23, 2011) (discussing that embryos are not patentable and showing that viability of an embryo does not play into the definition of a “human organism” for patent subject matter purposes).

²²⁶ See Uniform Determination of Death Act (1981), available at <http://www.uniformlaws.org/shared/docs/determination%20of%20death/udda80.pdf>.

²²⁷ See 1 U.S.C. § 8 (2002) (requiring a “person” or “human being” to have a beating heart or breathe).

²²⁸ See Keith L. Moore & T.V.N. Persaud, *Essentials of Embryology and Birth Defects*, 191–94 (7th ed. 2008) explaining that the embryonic period ends at week eight of pregnancy; the embryo develops heart tubes and umbilical arteries but not a fully developed heart).

²²⁹ See *id.* (showing that, though embryos do not have viably formed hearts or lungs, embryos do develop circulatory and respiratory functions).

²³⁰ If scientists artificially developed a working cardiovascular and respiratory system, connected these systems, and attached this system to a brain, the overall combination of systems may not be patentable subject matter under Section 33(a) if the definition of “human organism” used the template of the Uniform Determination of Death Act. This development, however, is far from where science has progressed in the present state.

²³¹ See Joan Stiles & Terry L. Jernigan, *The Basics of Brain Development*, 20 NEUROPSYCHOL. REV. 327, 328 (2010).

²³² See Uniform Determination of Death Act (1981), available at <http://www.uniformlaws.org/shared/docs/determination%20of%20death/udda80.pdf> (requiring “irreversible cessation of all functions of the entire brain, including the brain stem.” If this were to be interpreted broadly, any organism with human central nervous system development could be construed to fall under the definition of “human organism.”).

²³³ Unless the artificial tissues in question are brain tissues or nervous system tissues.

implant would still remain unpatentable, as the combination of functioning organ systems would fulfill the definitional basis of a “human organism”. Adopting informed definitions of “human organism” from the realm of end-of-life care rather than from “beginning of life” definitions would help to clarify patentability in biotechnology.²³⁴

The objective of patent law is to incentivize innovation.²³⁵ To incentivize innovation, particularly in the high-cost world of biotechnology, those funding the industry should be able to predict whether an eventual product or method, if successful, would become profitable.²³⁶ This profit can be derived from a patent—the ability to exclude others from making or using the new product or method.²³⁷ With this ability can come lucrative licensing deals, which can be used to fund future research and development.²³⁸ With ambiguity in the law come uncertain investors: would investing in artificial organ development be investing in unpatentable technology? Through clarifying the term “human organism” by exploring both the above definitions of human life and the scientific objectives and concerns regarding artificial human development, discussed below, artificial tissue development can be investigated while hindering unethical experimentation on humans and fetuses.

V. INCENTIVIZING RESEARCH: DEFINING A “HUMAN ORGANISM” WITH A LEGAL AND SCIENTIFIC LENS: AN EXPLORATION OF THE TERM “HUMAN” IN OTHER AREAS OF UNITED STATES LAW

This section addresses policy concerns of both scientists and legislators in tissue engineering patents. To promote innovation, legislators must adopt a clear and strong patent system. This includes allowing businesses to obtain patents that will clearly stand in a court of law. To clarify the murky subject matter concerns in 35 U.S.C. § 101 and Section

²³⁴ At least for the definition of “human organism” as used in Section 33(a) for patentability purposes.

²³⁵ See *Siemens Med. Solutions USA, Inc. v. St.-Gobain Ceramics & Plastics, Inc.*, 647 F.3d 1373, 1375 (Fed. Cir. 2011) (“At its heart, the patent system incentivizes improvements to patented technology.”).

²³⁶ See *Cal. Inst. of Tech. v. Hughes Commc’ns Inc.*, 59 F. Supp. 3d 974, 986 (C.D. Cal. 2014) (“In order to best incentivize innovation, however, patent law must be predictable, consistent, and uniform.”).

²³⁷ See Andrew Beckerman-Rodau, *Patent Law - Balancing Profit Maximization and Public Access to Technology*, 4 COLUM. SCI. & TECH. L. REV. 1, 12 (2002) (explaining that patent rights are “used by an enterprise to make a profit.”).

²³⁸ See, e.g., *Wis. Alumni Research Found. v. Intel Corp.*, 656 F. Supp. 2d 898, 903 (W.D. Wis. 2009) (explaining that research at the university is supported “by patenting and licensing university inventions and by returning the proceeds of that licensing to fund additional research at the university.”).

33(a) that have emerged in the past decade, scientists and legislators must collectively arrive at a consensus to properly define “human organism” to promote ethical experimentation in biotechnical organ engineering.

At a recent international conference discussing the future of life-patenting, Dr. Calum MacKellar asked whether Dr. Frankenstein should have been permitted to patent his creation.²³⁹ Congress has answered this question with a resounding . . . maybe. As explained during the adoption of Section 33(a), “no member of the human species is an invention.”²⁴⁰ Human beings are not meant to be “property to be licensed for financial gain.”²⁴¹ The object of Section 33(a) was to disincentivize the commodification of human life and to not allow “profiteers to financially gain from the biology and life of another human person.”²⁴² With the ever-blurring line between man and man-made man—from *in vitro* fertilization to the creation of artificial organs—the question of the patentability of Frankenstein’s monster has become only more obscure.

Though the intention behind Section 33(a) was to prevent patenting of a claim directed to or encompassing a human organism, there is no law that clarified the definition of “directed to” or “human organism.”²⁴³ Through examining the legislative history behind Section 33(a), two facts become abundantly clear: 1) legislators did not want embryos to become patentable and 2) legislators did not contemplate the effects Section 33(a) could have on human tissue engineering.²⁴⁴ With the increasingly murky judicial rulings behind 35 U.S.C. § 101, the lack of clear definitions for Section 33(a) will slow the development of artificial tissues and artificial organs.²⁴⁵

²³⁹ See Rob Vischer, *Patents on Life: The Future of Life-Patenting*, MIRROR OF JUSTICE (Sept. 5, 2015), <http://mirrorofjustice.blogspot.com/mirrorofjustice/2015/09/patents-on-life-the-future-of-life-patenting.html> (referencing the International Conference for Patents on Life: Through the Lenses of Law, Religious Faith, and Social Justice, UNIVERSITY OF CAMBRIDGE (Sept. 4-5, 2015), available at <http://www.vhi.st-edmunds.cam.ac.uk/events/past-events/conferences/patents-conference-2015>).

²⁴⁰ 157 CONG. REC. E1177 (daily ed. June 23, 2011) (statement of Rep. Smith).

²⁴¹ *Id.*

²⁴² See *id.*

²⁴³ See *id.* at E1178 (“Even the European Union prevents patents on human embryos.”).

²⁴⁴ See *id.* at E1178-E1181 (discussing that embryos are not patentable, while failing to discuss “human organs” or “tissues”).

²⁴⁵ See Ryan Davis, *Patent Eligibility Confusion Reigns Post-Alice, Experts Say*, LAW360 (Mar. 26, 2015, 7:45 PM), <https://www.law360.com/articles/636273/patent-eligibility-confusion-reigns-post-alice-experts-say> [https://perma.cc/73BG-6CTF] (showing that the Court did not clarify patentable subject matter under § 101 in the recent case of *Alice Corp. v. CLS Bank Int’l*, 134 S. Ct. 2347 (2014)); Heidi Ledford, *Myriad Ruling Causes Confusion*, NATURE NEWS (June 18, 2013), <http://www.nature.com/news/myriad-ruling-causes-confusion-1.13226> [https://perma.cc/Z6ED-T2HC] (showing that the Court also did not clarify patentable subject matter in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013)).

Though some economists may find that patents do not promote innovation in all fields of research, patents do provide clear incentives to innovate in the field of biotechnology and pharmaceuticals.²⁴⁶ “[T]he existence and strength of the patent system affects the organization of industry.”²⁴⁷ A working patent system requires clear laws and strong patents to function.²⁴⁸ A patent is worth the investment only if it can stand up in court.²⁴⁹ With unclear laws regarding the patentability of subject matter changing quickly and without direction in the last decade, investments in patentable biotechnology could be on the verge of decline.²⁵⁰

To hedge this possibility, legislators must clarify the law with regard to patentable technology. Most specifically, if the law is to truly prevent unethical experimentation and simultaneously fulfill the Constitutional requirement to “Promote the Progress of Science”, the definition of human organism must be clarified.²⁵¹ No court has issued a ruling construing Section 33(a).²⁵² Legislators should develop a further unambiguous record before the history of Section 33(a) becomes too convoluted to cleanly clarify.

²⁴⁶ See Bronwyn H. Hall, *Patents and Patent Policy*, 23 OXFORD REV. ECON. POL’Y 568, 576 (2007) (“if there is an increase in innovation due to patents, it is likely to be centered in the pharmaceutical, biotechnology, and medical instrument areas”); Halla Thorsteindottir, et al., *Conclusions: Promoting Biotechnology Innovation in Developing Countries*, 22 NATURE BIOTECHNOLOGY DC48, DC49 (2004) (“In India, the patenting laws have encouraged the country’s biotechnologists to invent around existing patents and to come up with processes that reduce production costs.”).

²⁴⁷ Hall, *supra* note 246 at 577.

²⁴⁸ See *id.* (“Thus the bottom line from the empirical evidence is that the patent system provides clear incentives for innovation”).

²⁴⁹ Businesses will only license (get permission to use) a patent if that patent would not be invalidated in a court of law. If it would be easy to invalidate the patent and, thus, free the technology for all to use, businesses with the means to sue will sue. A business would not obtain a patent if it was too easy to invalidate because it would not be worth the original investment if no entity licenses the patented technology.

²⁵⁰ See Amanda Liverzani, *Fate of Software Patents Still Unclear Following SCOTUS Decision in Alice v. CLS Bank*, JOLT DIGEST (June 28, 2014), <http://jolt.law.harvard.edu/digest/fate-of-software-patents-still-unclear-following-scotus-decision-in-alice-v-cl-s-bank> [<https://perma.cc/2Z6A-NSWL>] (showing that the Supreme Court “declined to articulate a definitive test” for the subject matter patentability of software and “intellectual property practitioners and technology companies [were] anxiously awaiting clarification” on the subject); Richard Baker, *Where Do We Stand One Year After Alice*, LAW360 (June 17, 2015, 8:27 PM), <https://www.law360.com/articles/668773/where-do-we-stand-one-year-after-alice> [<https://perma.cc/CM2M-RYA8>] (explaining that the “secondary market for software and business method patents dried up in the past year as buyers avoid the risks of ineligibility under § 101”, “business method patents issued have declined by greater than 60% over similar pre-Alice periods”).

²⁵¹ See U.S. CONST. art. I, § 8, cl. 8.

²⁵² As of Jan. 27, 2017 (searching databases of next.westlaw.com and advance.lexis.com)

Now is the time to act. The category of human organism is hybridizing. Far from an artificial hip replacement or *in vitro* fertilization, the biotechnological improvements are expanding into what was originally considered pure science fantasy: the creation of a human. Experiments in implantable tissues and artificial organs are underway.²⁵³ Future experiments in human tissue transplanting could go beyond life-saving procedures, with new procedures being developed to make stronger bones and better muscles.²⁵⁴ If these go further than simple organ transplantation, stepping into the world of human improvements, the line between human organism and human engineered devices will become even vaguer with time.

If the goal of patent law is truly to promote innovation, the patent law space must prioritize unambiguous legislative text. In the past decade, multiple Court rulings in subject matter patent law have left the scientific community wanting.²⁵⁵ In fact, patent law is recognized to be such a difficult and tedious matter for judges to decide uniformly that a patent pilot program has been established to help judges specialize. Though courts may create a definition of “human organism” under 33(a) based on legislative history, the job is best left up to the legislature and scientists.

Promoting science with patents can only go so far without the assistance of the science community. The goal to promote science without incentivizing unethical experimentation necessitates input from scientists. Luckily, commentary with regard to moral issues behind developing an artificial human or experimenting on human embryos goes far beyond the legal realm. Scientists are trying to prevent unethical experimentation in gene-editing and transplant methodologies.²⁵⁶ Their efforts, however, can only go so far without legal backing. If patents are enough to incentivize scientists to break with moral impositions in their field, then the United States patent law will be undermining scientific efforts.

Science cannot succeed devoid of law. Nor can law be devoid of science. For too long, legislative history and judicial precedent have been created in the patent world without a true understanding of the implications

²⁵³ See, e.g., Anthony Atala, *Tissue Engineering of Artificial Organs*, 14 J. OF ENDOUROLOGY 49, 49-51 (2009) (discussing tissue engineering efforts for tissue and organs within the urinary system); see also U.S. Patent No. 5,750,329 (issued May 12, 1998) (patenting methods and compositions for an artificial lung organ culture system); see also, *supra* Section V(A).

²⁵⁴ See, e.g., Leon S. Dimas et al., *Tough Composites Inspired by Mineralized Natural Materials: Computation, 3D Printing, and Testing*, ADVANCED FUNCTIONAL MATERIALS (2013) (discussing producing a synthetic material with fracture behavior similar to bone).

²⁵⁵ See *supra* note 245.

²⁵⁶ See Edward Lanphier, et al., *Don't Edit the Human Germ Line*, NATURE (Mar. 12, 2015), <http://www.nature.com/news/don-t-edit-the-human-germ-line-1.17111> [<https://perma.cc/SU6L-LKYL>].

and the science affected by those policies.²⁵⁷ If the goal of defining a “human organism” is to dissuade scientists from experimenting on human embryos, the true definition of an embryo should be incorporated into the law. Instead of shying away from defining before-birth and after-birth fetuses and humans due to a complicated moral and theological system, the complexities of life should be embraced by the legal and scientific communities.²⁵⁸

Isolating law from science cannot be the policy of the patent system. To ameliorate concerns about creating an unclear definition of “human organism” under Section 33(a), a committee should form with scientists, ethicists, and lawmakers to assess the current state of patent law in biotechnology. Together this committee can work toward finding an acceptable definition of “human organism” that neither hinders scientific exploration nor promotes unethical procedures.

This definition should use the template provided by the Uniform Determination of Death Act, wherein a “human organism” would need to have either both circulatory and respiratory functions or functional central nervous system.²⁵⁹ If the mutual goal of the scientific and legal communities is to discourage experimentation upon fertilization of an egg, but encourage experimentation in artificial tissue engineering, the definition of a “human organism” cannot be informed by the definition of a human being.²⁶⁰ Rather, this definition must be informed by a negative: a definition of something possessing human tissue, but not possessing the essential qualities of life. The Uniform Determination of Death Act provides this very template by explaining when life stops.²⁶¹ Defining “human organism” using the Uniform Determination of Death Act template

²⁵⁷ See Jeff Guo, *The Supreme Court Reveals its Ignorance of Genetics*, NEW REPUBLIC (June 13, 2013), <https://newrepublic.com/article/113476/supreme-court-genetics-ruling-reveals-judges-ignorance> [<https://perma.cc/AQ7M-CU43>] (showing that the *Myriad Genetics* decision contains improper rationales as related to science and “saying that cDNA is patentable but natural DNA isn’t misunderstands the central complaint about gene patents”).

²⁵⁸ See Yaniv Heled, *On Patenting Human Organisms or How the Abortion Wars Feed into the Ownership Fallacy*, 36 CARDOZO L. REV. 241, 256 (2014) (reviewing the complexities of Section 33(a) in the context of the abortion debate).

²⁵⁹ See Uniform Determination of Death Act (1981), available at <http://www.uniformlaws.org/shared/docs/determination%20of%20death/udda80.pdf>.

²⁶⁰ See 1 U.S.C. § 8 (2002) (defining a “human being” as possessing a “beating heart”, “breathing”, having an “umbilical cord”, and being able to naturally move “voluntary muscles.” An embryo does not possess any of the above as viable characteristics).

²⁶¹ See Uniform Determination of Death Act (1981), available at <http://www.uniformlaws.org/shared/docs/determination%20of%20death/udda80.pdf> (looking broadly to an organism with “circulatory and respiratory functions” and a brain “including the brain stem”, which are characteristics that an embryo arguably possesses, but tissues do not necessarily possess).

would encompass human embryos, but would not hinder experimentation with regard to artificial tissues and organs.²⁶²

Through providing this clear definition, progress in bioengineering can advance unhindered by future ambiguous legislative and judicial actions. The definition could clarify the murky laws of patentable subject matter for scientists and lawmakers alike. Bringing both certainty and transparency to patent law can better inform both scientists and businesses. This can help push research toward ethical progress in the field of organ transplantation. A committee including both scientists and legislators has the most potential to form a cohesive, unambiguous definition of “human organism” under Section 33(a). Together, this committee would promote scientific progress in biotechnology and prevent the patentability of the ultimate ethical concern: Frankenstein’s monster.

²⁶² *See id.*

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