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IP Theory – SAWR

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1. **UNDER CURRENT UNITED STATES JURISPRUDENCE, TRANSGENIC HUMAN CLONES SHOULD BE ENTITLED TO PATENT PROTECTION.**

The United States has historically given a relatively wide berth to those seeking patent protection, and understandably so. First codified at the federal level in the Constitution, this right to intellectual property protection is seen as fundamentally crucial to progress. Specifically, Article I, Section 8 of the United States Constitution states that “Congress shall have Power [...] to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” This right to intellectual monopoly, however, necessarily requires limitations.

United States patentable subject matter includes “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”[[1]](#footnote-1) Current United States Patent Office (USPTO) policy dictates that no patent protection be given to a claim attempting to patent a law of nature, a natural phenomenon, or a naturally occurring relation or correlation. Additionally any claim directed to or encompassing a human organism is presumed invalid.[[2]](#footnote-2) Specifically, the Manual of Patent Examining Procedure (MPEP) § 2105, as well as the America Invents Act (AIA), each codify this rule.

Under current United States jurisprudence, however, non-naturally occurring non-human multicellular organisms, including animals, have been granted patent protection.[[3]](#footnote-3) Consequently, current USPTO guidelines reinforce this broad interpretation of the patentable subject matter.[[4]](#footnote-4) Thus, this paper will show that, unless the United States undertakes drastic policy changes, the current trend of patentable subject matter will lead to the patentability of the transgenic human. Specifically, just as the the Court in *Chakrabarty* interpreted 35 U.S.C. §101 broadly to include non-naturally occurring multicellular organisms[[5]](#footnote-5), the language proscribing the patentability of a human organism is particularly vulnerable to a narrow interpretation that excludes the transgenic human organism. Additionally, this paper will discuss the possible ramifications of a patent grant for a claim consisting of a transgenic human organism.

1. **Current United States Laws and Jurisprudence Affirm The Natural Products Exception To Patentability But Provide An Exception When The Product Is Markedly Different From Naturally Occurring Products.**
2. ***Title 35 Of The United States Code §101 Provides A Specific Rebuttable Of The Patentability Of Laws Of Nature, Naturally Occurring Phenomena and Abstract Ideas.***

As stated above, 35 U.S.C. §101 cites four categories of patentable subject matter: process, design, manufacture, or composition of matter.[[6]](#footnote-6) Additionally, the Court has always held that “laws of nature, natural phenomena, and abstract ideas” are not patentable subject matter under § 101 of the Patent Act.[[7]](#footnote-7) The subject matter within these categories remains free because, as the Court has stated, these categories encompass “part of the storehouse of knowledge of all men…free to all men and reserved exclusively to none.”[[8]](#footnote-8) Additionally, the USPTO has unequivocally stated that “patenting natural products would, therefore, be in contravention of over 150 years of Supreme Court precedent and USPTO’s interpretation of Myriad, and would be a violation of fundamental common law principles, the public domain, and the public trust doctrine.” [[9]](#footnote-9)

The public storehouse of knowledge and the public domain are exemplified by the idea of the commons, a notion from Anglo-Saxon tradition relating to the granting of a public right to use certain parcels of land.[[10]](#footnote-10) The idea of the public commons was criticized heavily in an effort to promote the agricultural revolution and private land ownership. For example, the theory of the tragedy of the commons warns that with each member of the commons acting rationally in their own interests, the commons will eventually be depleted.[[11]](#footnote-11)

Intellectual property, however, differs from real property in the sense that any area of exclusivity is artificial, not natural. Thus, the subject matter incorporated under the laws of nature, natural phenomena and abstract ideas must necessarily remain open to all because they are intrinsic parts of the universe and nothing to do with human invention.[[12]](#footnote-12) To grant ownership over one of these areas and thereby exclude others from use would be unethical.[[13]](#footnote-13)

In *Association for Molecular Pathology v. Myriad Genetics, Inc.*, the Supreme Court emphasized and elaborated on the separation of naturally occurring phenomena from patentability. In that case, Myriad Genetics, Inc. obtained patents for the sequences of the BRCA1 and BRCA2 genes after discovering their location. Mutations of these genes dramatically increase the risk of breast and ovarian cancer.[[14]](#footnote-14) The Association for Molecular Pathology argued that the patent claims were invalid because they covered products of nature.

Ultimately, the Court held that the naturally occurring DNA segments comprising the BRCA1 and BRCA2 genes were not patent eligible merely because Myriad isolated them, but cDNA (synthetically created exons-only DNA known as complementary DNA) was patentable because it is not naturally occurring.[[15]](#footnote-15)

In holding so, the Court emphasized the need to maintain the separation of laws of nature, natural phenomena, and abstract ideas from patentability as they comprise the “basic tools of scientific and technological work,” and entitling individuals to a monopoly over them would “inhibit future innovation premised upon them.”[[16]](#footnote-16) The court went on, however, to note that the rule against patents on naturally occurring things has its own limits because, at some level, all inventions necessarily “embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas,” and “too broad an interpretation of this exclusionary principle could eviscerate patent law.”[[17]](#footnote-17)

1. ***The United States Supreme Court Has Held That While Natural Products Are Excluded From Patent Protection, Non-Naturally Occurring Organisms May Be Entitled To Protection.***

In deciding *Myriad*, the court discussed its previous decision in *Diamond v. Chakrabarty*. In that case a scientist, Chakrabarty, added four plasmids to a bacterium enabling it to break down components of crude oil. There the Court held that the modified bacterium was patentable, explaining that the claim encompassed a “nonnaturally occurring manufacture or composition of matter - a product of human ingenuity ‘having a distinctive name, character [and] use.’”[[18]](#footnote-18) The Court supported its holding by stating that the bacterium had “markedly different characteristics from any found in nature.”.[[19]](#footnote-19) Additionally, the Court reasoned that Congress’ choice of the terms “manufacture” and “composition of matter” signaled that the patent laws be given a broad interpretation.[[20]](#footnote-20) Manufacture, the Court held, was a term that broadly encompassed “the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or machinery.” Along the same lines, composition of matter was broadly held to encompass “all compositions of two or more substances and … all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids.”[[21]](#footnote-21)

Petitioner in this case argued that the 1930 Plant Patent Act and the 1970 Plant Variety Protection Act, which excluded bacteria from their protection, signaled Congress’ intent to leave all other living organisms out of the scope of patentability. The Court, however, dismissed this argument on the basis that nothing in the legislative history gave any reason for excluding bacteria from the scope of patentability. [[22]](#footnote-22) Additionally, the petitioner attempted to argue that because genetic engineering technology was so new, any consequences were unforeseen and thus, should be left to congress to decide. Again, the Court found this argument unconvincing because congress had technically spoken as to the scope of patentable subject matter through the passage of 35 U.S.C. §101 and it was now appropriate for the judiciary to weigh in.[[23]](#footnote-23) Thus, this landmark case was the first instance of a living organism receiving patent protection in the United States and exemplifies the Court’s later emphasis in *Myriad*, that a living organism is only eligible for patent protection so long as it falls within the umbrella of non-naturally occurring non-human multicellular organisms, including animals.

Following the Supreme Court’s reasoning in *Chakrabarty*, the USPTO Board of Patent Appeals determined that animals are patentable subject matter under 35 U.S.C. §101 in *Ex parte Allen*.[[24]](#footnote-24) There, the Board decided that a polyploid oyster could have been patentable under §101 if all the necessary criteria had been satisfied. Following the decision, the Commissioner issued the notice: Animals - Patentability, stating that the PTO would consider nonnaturally occurring, nonhuman, multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. §101.[[25]](#footnote-25)

1. **Transgenic Mammals Have Been Granted Patent Protection In The United States.**

Animals and organisms are deemed “transgenic” when they contain artificially introduced DNA into their genome from another species.[[26]](#footnote-26) They have generally been developed for purposes of medical research, enhanced food production (GM crops), or in order to produce needed proteins and organs.[[27]](#footnote-27) Many ethical issues are flagged by the development of the transgenic animal are important to take note of when discussing the issuance of patents for these animals. Any issuance of a patent in this highly charged area carries the United State’s ethical, as well as legal endorsement. Specifically, the United States effectively signals its implicit approval of an invention by its grant of a patent because protection is only granted for any “new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.”[[28]](#footnote-28)

On April 12, 1988, the USPTO issued a patent to Harvard University which claimed “a transgenic non-human mammal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said mammal, or an ancestor of said mammal, at an embryonic stage.[[29]](#footnote-29) This was the first ever patent granted on an animal. The “oncomouse” was genetically designed to be highly susceptible to cancer through the introduction of the oncogene, which triggers tumor growth, making it highly useful in cancer research.[[30]](#footnote-30) In the actual patent, the scope of the claim is fairly broad, including any mammal within its scope. Specifically, the claim covers “a transgenic, non-human eukaryotic animal whose germ cells and somatic cells contain an activated oncogene sequence introduced into the animal.”[[31]](#footnote-31)

Opponents to the grant of patents on animals and animal varieties raised two major issues. First, they argued that higher order animals, such as mammals, should be exempt from patentability even if they do meet the standards set forth by the patent system of novelty or industrial applicability and use. Second, they argued that moral issues raised by the suffering caused to transgenic animals should be taken into account when granting patent protection.[[32]](#footnote-32) The United States apparently dismissed any of these concerns by granting the patent application. It should be noted though, that the patent does explicitly exclude humans from its claim. Additionally, this claim fell in line with current jurisprudence because it sought to protect a “nonnaturally occurring manufacture or composition of matter - a product of human ingenuity ‘having a distinctive name, character [and] use.’”[[33]](#footnote-33)

Conversely, the Canadian Supreme Court invalidated the patent as a natural product in Harvard College v. Canada (Commissioner of Patents).[[34]](#footnote-34) Initially, the Canadian patent examiner rejected the claims to the transgenic animal described in the claim because it did not fit the definition of an invention, but allowed claims for the process of obtaining the oncomouse.[[35]](#footnote-35) In 2002, the Supreme Court of Canada held that higher life forms were not patentable because they were not a “manufacture or composition of matter within the meaning of invention” of the Canadian Patent Act. The Court reached this conclusion by reasoning that a manufacture was interpreted as a non-living mechanistic product or process. It found that the words “machine” and “manufacture” do not imply a conscious, sentient living creature. Additionally, the Court held that a composition of matter encompassed the mixing or combination of ingredients or substances by a person, and that the formation of an adult mouse is a complex process which requires no human intervention. Specifically, the body of a mouse “is composed of various ingredients or substances, but it does not consist of ingredients or substances that have been combined or mixed together by a person.” [[36]](#footnote-36)

Here, although the Court held that the actual body of the mouse did not fall into the patentable definitions, it stated that microorganisms, or oncogene-injected eggs that were capable of maturing into the oncomouse, may be a mixture of ingredients and thus patentable under Canadian Law..[[37]](#footnote-37) Additionally, the Canadian Supreme Court endorsed the same argument that failed in *Chakrabarty*. Specifically, the Court held that because no mention of mammals was made in the Canadian Patent Act of 1869, it was up to Parliament to debate and deliberate over the contentious social and moral issues raised by the patenting of such life forms.

On the other hand, the European Patent Office (EPO), granted the patent to the oncomouse in 2004. The EPO, which follows the standards of the European Patent Convention (EPC), applied a utilitarian test. Article 53(a) of the EPC prohibits patents for inventions “"the publication or exploitation of which would be contrary to *ordre public* or morality". Further, Article 53(b) excludes patents on "animal varieties or essentially biological processes for the production of…animals."[[38]](#footnote-38) Thus, in order to proceed with validation of the patent, the EPO concluded that the exclusion of animal varieties did not constitute a ban on on patenting animals per se. Additionally, the EPO concluded that the oncomouse was not an animal variety and thus did not fall within the exclusion. [[39]](#footnote-39) In addressing the morality exception, the EPO’s utilitarian test weighed the potential benefits of such a claim against any negative impact it would have. Namely, the EPO weighed the suffering of the oncomice against the possible benefits to human medicine. [[40]](#footnote-40) Ultimately, the EPO concluded that the benefit of furthering cancer research was a significant medical benefit that outweighed the moral concerns about suffering caused to the oncomice. It should be noted, however, that during the judicial process, the patent was amended to solely encompass mice in its application.[[41]](#footnote-41)

1. **Under Current United States Jurisprudence, Transgenic Humans May Be Entitled To Patent Protection Unless Significant Policy Changes Are Implemented.**

The United States has effectively held that non-human, transgenic mammals should be entitled to patent protection because they are a product of human ingenuity “having a distinctive name, character [and] use.”[[42]](#footnote-42) Thus, transgenic humans that exhibit the same sort of traits - are a product of human ingenuity and have a distinct name, character and use - as the protectable transgenic mammals, should be entitled to the same sort of patent protection.

In the area of the human organism patent, the PTO’s stance is quite specific. The Leahy-Smith America Invents Act (AIA), states that “notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism.”[[43]](#footnote-43) Additionally, the legislative history of the AIA adds to this statement by stating that the PTO has “already issued patents on genes, stems cells, animals with human genes, and a host of non-biologic products used by humans, but it has not issued patents on claims directed to human organisms, including human embryos and fetuses. My amendment would not affect the former, but would simply affirm the latter.” Here, the PTO has undisputedly excepted human organisms from the scope of patentable subject matter.

Although the PTO has clearly stated its stance on the patentability of human organisms, the same line of reasoning used in *Chakrabarty*, *Myriad*, *Ex parte Allen* and the grant of the Harvard oncomouse patent could logically be extended to a patent application claiming a transgenic human organism. Namely, in the same way that the United States Supreme Court validated Chakrabarty’s patent application for his crude-oil digesting bacterium on the basis that it would never be found in nature in that form, had markedly different characteristics from any found in nature, and had the potential for significant utility[[44]](#footnote-44), a transgenic human organism could be developed with markedly different characteristics from any found in nature with the potential for significant utility. For example, one could imagine the development of a transgenic human that was capable of a significantly longer lifespan, withstanding disease, or even capable of regrowing limbs. Each of these traits could arguably be said to be markedly distinct from any of those found in nature and could logically provide great potential for significant utility.

In the United States, a patent has already been granted for a sort of genetic engineering of human organisms, which basically amounts to selective breeding. The company 23andMe was awarded a patent in 2013 for “gamete donor selection”. This selection process is accomplished through a genetic and computer technologies that would enable parents to handpick a sperm or egg donor with whom they would be likely to produce a child born with certain desirable traits.[[45]](#footnote-45) The company adamantly holds that it does not plan to use the technology beyond application as a “Family Traits Inheritance Calculator”, but the language of the patent grant provides sufficiently wide berth for 23andMe to do so itself, or license the technology out to other who wish to do so. [[46]](#footnote-46)Gamete selection differs significantly from the type of genetic engineering involved in creating an transgenic human organism. Namely, although this sort of carefully calculated cross breeding and genetic engineering would each result in an organism with new features, the former would fail to meet the standards set forth by the PTO. Specifically, the resulting organism from cross breeding would likely not exhibit traits undiscoverable in nature, or that necessarily provide the potential for significant utility. Some examples could be theorized, however, including cross breeding to achieve children completely immune to specific diseases or mitochondrial disorders (as 23andMe hopes to do). Yet, these would not be markedly different from those children born naturally with that trait. Although there are key differences in the two technologies, the patent award to 23andMe arguably sets the stage for the next logical step - the transgenic human patent.

Recently, the German company TissUse has “developed methods to generate and use subunits of human organs to achieve miniaturized constructs representative of human organs for use in the chip. It comprises two independent circulatory networks at the scale of a microscope glass slide.”[[47]](#footnote-47) Detractors view this as creating genetically modified humans in the same vein as genetically modified plants. These “micro-humans” would replace the need for using animals in laboratory testing. According to TissUse, the technology would closely simulates the activity of multiple human organs in their true physiological context at the smallest possible biological scale.[[48]](#footnote-48) Basically, the “micro-human” would be comprised of a miniature scale version of interating human organs that are stimulated by smartphone-sized microchips. The company’s technology has yet to be approved by regulators, but the implications are clear. In the context of United States patent law and the reasoning stated in *Chakrabarty* and more recently in *Myriad*, this genetically modified “micro-human” could be seen as having markedly different characteristics from those found in nature - they are the size of microchips - and could logically be deemed to provide potential for significant utility. and thus, be patent eligible. Specifically, the technology would allow for much more specialized, efficient, and relevant drug testing which could enhance the medical field by leaps and bounds and simultaneously cut down on the use of animals in laboratory testing. One could imagine the Court, in light of all the recent decisions leading up to the allowance of transgenic mammal patents, construing the AIA’s language narrowly to remove the transgenic human organism from its exception.

The more likely scenario for the grant of a transgenic human organism patent would be similar to the type of end-result endorsed by 23andMe’s technology. Concerned parents would make a viable consumer base for technology that developed genetically modified human children who were less susceptible to disease, birth defects, and the aging process. The technology would be markedly different from the simple gamete selection proposed by 23andMe. Specifically, the transgenic human organism that would be most likely to receive patent protection would be one who had foreign DNA that coded for some specific benefit(s) artificially introduced before fertilization. This would present a slew of intellectual property issues. For example, should a child claimed under this patent choose to procreate before the patent term expiration, the patented genetic material passed down to the subsequent child would be impermissibly copied and transmitted. This, however, would severely limit the patented individual’s most precious right to procreate. Thus, Congress would likely have to engage in a careful analysis of the benefits and risks associated with the grant of such a patent, much like the EPO did with its utilitarian analysis of the Harvard oncomouse.

1. **IF MORAL REPUGNANCE IS THE ONLY BARRIER TO SUCH PATENTS, IT IS A THIN BARRIER SUSCEPTIBLE TO EROSION.**

Additionally, if moral repugnance is the only barrier to such patent protection, it is a thin barrier that is particularly susceptible to erosion. As exemplified by the decisions in *Chakrabarty* and *Ex parte Allen*, the USPTO and the Supreme Court gave no heed to the moral repugnance argument of patenting of higher order organisms, including animals. Transgenic animals are routinely subjected to pain and suffering for the betterment of medical research. It could be easy then, to imagine a company sidestepping even the issue of pain and suffering by developing a transgenic human organism that is effectively braindead or just merely a husk that developed organs necessary for medical research testing on humans. These human test subjects would not feel pain and could effectively be treated as not some lesser sort of human organism that is entitled to patent protection in line with the principles outlined by the Supreme Court and the USPTO.

Humans, by evolution, feel and react to stimuli the same way most other vertebrates do, including chimpanzees, dogs, and mice. The decision to disregard this fact with respect to higher order mammals only sets the stage for the next logical step of disregarding these concerns with respect to transgenic human organisms.

1. 35 U.S.C. §101 (West). [↑](#footnote-ref-1)
2. http://www.uspto.gov/patents/law/exam/101\_training\_aug2012.pdf [↑](#footnote-ref-2)
3. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) [↑](#footnote-ref-3)
4. http://www.uspto.gov/patents/law/exam/101\_training\_aug2012.pdf [↑](#footnote-ref-4)
5. *Supra*, note 3. [↑](#footnote-ref-5)
6. *Supra*, note 1. [↑](#footnote-ref-6)
7. Mayo Collaborative Services v. Prometheus Laboratories, Inc., 132 S. Ct. 1289, 1290 (2012) [↑](#footnote-ref-7)
8. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948). [↑](#footnote-ref-8)
9. USPTO, Comments on USPTO’s Guidance on the Proposed Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, And/Or Natural Products (July 30, 2014), *available at* http://www.uspto.gov/patents/law/comments/mm-a-cfs20140730.pdf (last accessed September 20, 2014) [↑](#footnote-ref-9)
10. http://www.councilforresponsiblegenetics.org/genewatch/GeneWatchPage.aspx?pageId=305 [↑](#footnote-ref-10)
11. Lloyd, William Forster, *Two Lectures on Population* (1833). [↑](#footnote-ref-11)
12. *Supra*, note 9. [↑](#footnote-ref-12)
13. *Id.* [↑](#footnote-ref-13)
14. *Assn. for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2109 (2013) [↑](#footnote-ref-14)
15. *Id.* [↑](#footnote-ref-15)
16. *Id.* [↑](#footnote-ref-16)
17. *Id.* at 2116. [↑](#footnote-ref-17)
18. *Supra*, note 3, at 305, 309-310. [↑](#footnote-ref-18)
19. *Id.* [↑](#footnote-ref-19)
20. *Chakrabarty*, at 306. [↑](#footnote-ref-20)
21. *Id*, at 309. [↑](#footnote-ref-21)
22. *Id.* at 313. [↑](#footnote-ref-22)
23. *Id*. at 2211. [↑](#footnote-ref-23)
24. *Ex parte Allen,* 2 USPQ2d 1425 (Bd. Pat. App. & Inter. 1987) [↑](#footnote-ref-24)
25. Animals - Patentability, 1077 O.G. 24, April 21, 1987, http://www.uspto.gov/web/offices/pac/mpep/s2105.html [↑](#footnote-ref-25)
26. http://www.wipo.int/wipo\_magazine/en/2006/03/article\_0006.html [↑](#footnote-ref-26)
27. *Id*. [↑](#footnote-ref-27)
28. *Supra*, note 1. [↑](#footnote-ref-28)
29. U.S. Patent No. 4,736,866 [↑](#footnote-ref-29)
30. http://www.wipo.int/wipo\_magazine/en/2006/03/article\_0006.html [↑](#footnote-ref-30)
31. *Supra*, note 26. [↑](#footnote-ref-31)
32. *Supra*, note 27. [↑](#footnote-ref-32)
33. *Supra*, note 3 at 305, 309-310. [↑](#footnote-ref-33)
34. Harvard College v. Canada (Commissioner of Patents), 4 SCR 45, 2002 SCC 76 (2002) [↑](#footnote-ref-34)
35. http://www.wipo.int/wipo\_magazine/en/2006/03/article\_0006.html [↑](#footnote-ref-35)
36. *Supra*, note 31. [↑](#footnote-ref-36)
37. *Id*. [↑](#footnote-ref-37)
38. http://www.wipo.int/wipo\_magazine/en/2006/03/article\_0006.html, Board of Appeal of the European Patent Office, Decision of 6 July 2004, T 315/03 [↑](#footnote-ref-38)
39. http://www.wipo.int/wipo\_magazine/en/2006/03/article\_0006.html [↑](#footnote-ref-39)
40. *Supra*, note 24. [↑](#footnote-ref-40)
41. *Id*. [↑](#footnote-ref-41)
42. *Supra*, note 3. [↑](#footnote-ref-42)
43. Leahy-Smith America Invents Act (AIA), Pub. L. 112-29, [**sec. 33(a)**](http://www.uspto.gov/web/offices/pac/mpep/mpep-9015-appx-l.html#aiasec33limitonissuance), 125 Stat. 284, [↑](#footnote-ref-43)
44. *Supra* note 3. [↑](#footnote-ref-44)
45. http://www.genengnews.com/gen-news-highlights/designer-baby-patent-awarded-to-23andme/81248945/ [↑](#footnote-ref-45)
46. *Id.* [↑](#footnote-ref-46)
47. http://www.tissuse.com/technology.html [↑](#footnote-ref-47)
48. *Id.* [↑](#footnote-ref-48)