

**MORAL COMPASS POINTING SOUTH: COMPARING THE
UNITED STATES' LACK OF A PATENT MORALITY
EXCLUSION WITH EUROPE AND JAPAN**

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The rapid growth of biotechnology has raised challenging questions of morality. Through their patent laws, the United States, Europe, and Japan have all grappled with these difficult questions. This Comment will explore the differences between these approaches and how the United States could strengthen its own evaluation of patentable subject matter by adopting strategies from both Europe and Japan. Through years of inconsistent case law in the United States, the seldomly used moral utility doctrine has not been invoked in decades, and when used in the past, was not effectively applied in a way that would be amenable to the complicated issues that arise with biotechnology. This Comment poses a solution to the United States' approach by enabling the United States Patent and Trademark Office to weigh the moral implications of inventions as a factor in evaluating whether to grant a patent. A balancing approach that weighs potential moral implications with net societal benefits for breakthrough biotechnology may be the best way for the United States to secure its position as an economic leader while promoting ethical patent regulation.

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I. INTRODUCTION

The growth of biotechnology has led to breakthroughs in medicine, agriculture, and many other areas that have significantly benefited society.¹ Its rapid growth has also led to the rise of challenging new moral questions. What if biotechnology was used to genetically modify human deoxyribonucleic acid (DNA)? Or to create organisms with a combination of both human and animal cells? What role should the patent system play in discouraging morally questionable behavior while promoting research and innovation? The United States, Europe, and Japan have all grappled with these difficult questions with varying approaches through their patent laws.² This Comment will explore the differences between these approaches and how the United States could adopt strategies from both Europe and Japan to strengthen its patent laws.

Biotechnology is broadly defined as the study or use of biological organisms, processes, cells, or cellular components in industrial, medical, agricultural, and

1. See Tucker Davey, *Benefits and Risks of Biotechnology*, FUTURE LIFE INST. (Nov. 14, 2018), <https://futureoflife.org/biotech/benefits-risks-biotechnology/> (discussing realized benefits of genetically engineered plants in agricultural industry and both potential and realized benefits in healthcare).

2. See Benjamin Coriat & Fabienne Orsi, *Establishing a New Intellectual Property Rights Regime in the United States: Origins, Content, and Problems*, 31 RSCH. POL. 1491, 1492–93 (2002) (discussing approaches to patent laws).

environmental engineering.³ Throughout history, people have used biotechnology to achieve significant technological advances in several areas such as agricultural techniques, vaccine and antibiotic development, and fermentation.⁴ Since the publication of physicist Erwin Schrödinger's *What is Life?*,⁵ biotechnology research has shifted to focus heavily on the microscopic level and decoding the chemical and genetic makeup of cells.⁶ Many of the most recent biotechnological developments involve tools using DNA sequencing, recombinant DNA, DNA synthesis, and genome editing.⁷

Although the rapid growth of these new biotechnologies has led to countless exciting solutions, they have also led to a host of pressing issues.⁸ For example, biotechnology allows food to grow without pesticides, require fewer nutrients, and withstand rapid climate change.⁹ Biotechnology also plays an integral role in cancer and heart disease treatments and in research to cure Alzheimer's disease.¹⁰ The rapid development of CRISPR/Cas⁹¹¹ technology could potentially enable people to safely edit DNA to cure genetic diseases.¹² While the benefits of biotechnology are clear, there are potential risks—including both intentional misuses and unintended consequences—that give rise to ethical and moral issues.¹³ Outside of gene editing, ethical issues arise in controversial areas such as medical procedures, embryonic stem cells, genetically modified transgenic animals, and methods of cloning animals.¹⁴ Of the many moral controversies surrounding biotechnology, the most

3. See *Biotechnology*, NATURE, <https://www.nature.com/subjects/biotechnology> (last visited Nov. 17, 2023) (defining biotechnology as a broad discipline with industrial and clinical applications).

4. *Id.*

5. Released in 1944, Erwin Schrödinger's *What is Life: With Mind and Matter and Autobiographical Sketches*, explored the boundaries of living organism through the lens of physics and chemistry. His work spurred the development of the emerging fields of molecular biology and molecular genetics. See Christina Moberg, *Schrödinger's What Is Life?—The 75th Anniversary of a Book that Inspired Biology*, 59 ANGEW. CHEM. INT. ED. 2550, 2551 (2020) (noting that Schrödinger's book is said to have been profoundly inspired pioneers of molecular biology and many other scientists for generations since).

6. See Julien Crockett, *Morality: An Important Consideration at the Patent Office*, 108 CAL. L. REV. 267, 279 (2021) (discussing how molecular biologists, such as James Watson and Francis Crick who discovered DNA's double helix structure, credit Schrödinger for inspiring their work).

7. See Davey, *supra* note 1 (explaining different tools of biotechnology).

8. See *id.* (discussing realized benefits of genetically engineered plants in agricultural industry and both potential and realized benefits in healthcare).

9. *Id.*

10. *Id.*

11. See *What Are Genome Editing and CRISPR-Cas9?*, MEDLINE PLUS, <https://medlineplus.gov/genetics/understanding/genomicresearch/genomeediting/> (last visited Nov. 18, 2023) (describing CRISPR-Cas9 as an exciting approach to genome editing that could be used to prevent genetic disease).

12. Davey, *supra* note 1.

13. See *id.* (discussing several examples of experiments and innovations that crossed ethical lines).

14. See Margo A. Bagley, *Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law*, 45 WM. & MARY L. REV. 469, 475 (2003) (identifying examples of morally questionable biotechnological inventions).

prevalent are questions about the mixing of human and animal species, denigration of human dignity, the destruction of human life, and the ownership of humans.¹⁵

Because biotechnology development is both research intensive and expensive, the patent system plays an essential role in its progress.¹⁶ Biotechnology companies spend 40–50% of their funds on research and development (R&D) and the promise of owning a patent incentivizes companies to make these investments.¹⁷ Often, patents are biotechnology companies' most important assets.¹⁸ Because of these financial incentives, increased interest in owning intellectual property rights has shifted the focus from institutional research towards a patent-focused approach.¹⁹ In other words, rather than focusing primarily on research for the purpose of growing knowledge, there has been an increased willingness to invest heavily in uncertain technologies with the hopes of obtaining patents.²⁰ The grant of a patent encourages disclosure and creates incentives for R&D of biotechnology inventions for commercial purposes.²¹

Patent laws play a key role in regulating new technologies. Emerging technologies are often heavily intertwined with patents because they are novel, valuable, and have industrial applicability.²² Additionally, patent offices tend to support uncertain and ambiguous technologies in fields such as biotechnology, where heavy investments in research and resources are essential to the success of the field.²³ The current patent system in the United States uses the “new, useful, and non-obvious” requirements to deal with these issues of ambiguity.²⁴ Rather than address morality issues within the assessment of the patentability of inventions, the United States patent system ignores morality and relies on a set of judicially created exceptions to exclude patents on things that may “tend to impede innovation more than it would promote [them].”²⁵

This Comment will focus on the intersection between the moral issues faced in

15. *Id.*

16. See *Intellectual Property Biotechnology: Everything You Need to Know*, UPCOUNSEL, <https://www.upcounsel.com/intellectual-property-biotechnology> (last visited Nov. 17, 2023) (quantifying importance of patent protection in biotechnology industry).

17. See *id.* (explaining biotechnology companies spend more of their revenues on R&D compared to R&D spending by other industries).

18. Carly Klein, *The Complications Around Patenting Biotechnology*, LABIOTECH.EU (June 25, 2022), <https://www.labiotech.eu/in-depth/biotechnology-patents-intellectual-property/>.

19. See Crockett, *supra* note 6, at 272 (noting some scholars argue U.S. patent system does not promote innovation and productivity as a result of the shift towards a patent-focused approach).

20. *Id.*

21. See Benjamin D. Enerson, *Protecting Society from Patently Offensive Inventions: The Risk of Reviving the Moral Utility Doctrine*, 89 CORNELL L. REV. 685, 688–89 (2004) (describing a “patent for disclosure” arrangement that incentivizes investment in R&D).

22. See Justine Pila, *Adapting the Ordre Public and Morality Exclusion of European Patent Law to Accommodate Emerging Technologies*, 38 NATURE BIOTECHNOLOGY 555, 555 (2020) (providing why biotechnology innovations are well designed for patent protection).

23. See *id.* (highlighting that patent officers support biotech companies because of their dependence on venture capital).

24. See generally 35 U.S.C. § 101–03 (providing rules for patentability).

25. *Alice Corp. Pty. Ltd. v. CLS Bank Intern.*, 573 U.S. 208, 216 (2014).

biotechnology patents and the United States' approach to them. Without a statutorily mandated morality clause, the United States exposes itself to the risks of emerging technologies with the potential to harm public morality and safety.²⁶ The United States should adopt a morality exclusion for patentability like many of the other patent leaders of the world. Part II will look at the history of the United States' exclusions to patentable subject matter and the lack of a morality exception in its patent laws. Part III will discuss other countries' patent systems and their morality exclusion doctrines. Part IV will discuss the need for the United States to adopt a morality exclusion and many of the policy reasons behind this approach. In the United States, the lack of a morality exclusion has led to uncertainty and prevents the patent system from having a safeguard against morally questionable technologies.

II. THE MORALITY CLAUSE AND EXCLUSIONS TO PATENTABILITY IN THE UNITED STATES

The United States has long been regarded as one of the strongest economic leaders in the world.²⁷ Part of this economic dominance is due to its strong patent laws that allow for innovation while protecting the investments made when developing new technologies.²⁸ The United States formerly had a morality exception to its patent laws that prevented inventions deemed detrimental to public morality and safety from being patented.²⁹ Biotechnology has made significant strides since the extinction of the United States' morality exception. Each day, scientists are pushing the boundaries of what is possible. With recent developments in technology and significant uncertainty surrounding a series of confusing court decisions about what inventions can receive patent protection, it is time for the United States to follow Europe's and Japan's lead in reviving the long-dormant morality exception.

A. *The History and Erosion of the United States' Morality Exclusion*

The United States' patent system is rooted in its Constitution.³⁰ Often referred to as the Intellectual Property Clause,³¹ Article I, Section 8, Clause 8 grants Congress

26. See *infra* Part IV.A for a full discussion of the issues with the U.S. approach to a morality clause in patent law.

27. *GPD (Current US\$) – United States*, WORLD BANK, <https://data.worldbank.org/indicator/NY.GDP.MKTP.CD?locations=US> (last visited Oct. 8, 2023).

28. See Marshall Phelps, *America's Patent System: An Amazingly Resilient Philosophy and Entity*, IPWATCHDOG (July 28, 2017), <https://ipwatchdog.com/2017/07/28/americas-patent-system-amazingly-resilient-philosophy-entity> (explaining that current patent approach created economically feasible system).

29. See *infra* Part II.A for a full discussion of the United States' use of morality exception in patent law.

30. See U.S. CONST. art. I, § 8, cl. 8 (“[The 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”).

31. See Malla Pollack, *What Is Congress Supposed to Promote?: Defining Progress in Article I, Section 8, Clause 8 of the United States Constitution, or Introducing the Progress Clause*, 80 NEB. L. REV. 754, 810 (2001) (noting usage of Copyright and Patent Clause, Intellectual Property Clause, Exclusive Rights Clause, and Progress Clause); see also *See ArtI.S8.C8.1 Overview of*

the power “to promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”³² Congress passed the Patent Act of 1790, which defined the subject matter of a U.S. patent as “any useful art, manufacture, engine, machine, or device, or any improvement therein not before known or used.”³³ The Patent Act required that patentable subject matter be useful and novel.³⁴ Three years later, Congress amended the language of the Patent Act to include patentable subject matter as “any new and useful art, machine, manufacture, or composition of matter.”³⁵

Historically, the United States evaluated the usefulness requirement of patentability and considered the morality of an invention within the context of the utility requirement.³⁶ Justice Story first articulated what was known as the “moral utility” doctrine³⁷ in *Lowell v. Lewis*, when he stated that U.S. patent laws require “that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society.”³⁸ For most of the history of the moral utility doctrine, courts cited this provision when rejecting patent applications for morally controversial inventions such as gambling machines and fraudulent articles.³⁹

Over the years, when determining patent eligibility, courts moved away from the moral utility doctrine and instead considered whether inventions could have any lawful useful application.⁴⁰ The Federal Circuit explicitly rejected the morality doctrine in 1999.⁴¹ The Court left open the possibility that Congress could declare certain inventions unpatentable based on a variety of reasons such as morality, but that decision lies outside the scope of the judicial branch.⁴²

Currently in the United States, there is no statutory morality requirement to obtain a patent.⁴³ While the moral utility doctrine has been referenced when defining utility within the scope of patents, the decreased reliance on this doctrine over the years indicates that it has become extremely unlikely to find a patent invalid on

Congress's Power Over Intellectual Property, CONSTITUTION ANNOTATED, https://constitution.congress.gov/browse/essay/artI-S8-C8-1/ALDE_00013060/ (last visited Nov. 18, 2023) (defining clause as Intellectual Property Clause).

32. U.S. CONST. art. I, § 8, cl. 8.

33. Patent Act of 1790, ch. 7, 1 Stat. 109–12 (April 10, 1790).

34. *See id.* (outlining requirements and rules of patents, such as them being unknown and useful).

35. Patent Act of 1790, ch. 7, 1 Stat. 109–12 (amended 1793).

36. *See Bagley*, *supra* note 14, at 488 (stating that Patent Act only permits “useful” inventions).

37. *Id.* at 489.

38. *Lowell v. Lewis*, 15 F.Cas. 1018, 1019 (C.C.D. Mass. 1817).

39. *Bagley*, *supra* note 14, at 489.

40. *See id.* at 489–90 (describing shift away from moral standards of patentability resulting from societal shifts and court’s reluctance to decide area which could be left to legislature).

41. *See Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366–67 (Fed. Cir. 1999) (stating that morality doctrine has not been applied broadly in recent years).

42. *See id.* at 1368 (explaining that Congress is free to decide patentability as it sees fit).

43. *See generally* 35 U.S.C. (governing U.S. patentability requirements).

morality grounds.⁴⁴ The reluctance to invalidate patents using morality leaves the United States in a difficult position should morally questionable patent applications arise in the near future.⁴⁵

B. Legislative Roots of Patentable Subject Matter

Patent subject matter eligibility—that is, what can be patented—remained relatively unchanged until Congress passed the Patent Act of 1952.⁴⁶ The Patent Act of 1952 codified years of case law on patent subject matter eligibility and set up the modern framework for what inventions could be patented in 35 U.S.C. § 101.⁴⁷ Congress updated the criteria for subject matter eligibility to grant patents to “whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof”⁴⁸ By choosing expansive categories for patentable subject matter (i.e., *any* new or useful improvement), Congress intended to give the patent laws wide scope.⁴⁹ While Congress sets the limits of patentability, the judicial branch interprets the law, guided by the legislative history and statutory intent.⁵⁰

The Supreme Court has developed three judicial exceptions to patentable subject matter within the framework of 35 U.S.C. § 101.⁵¹ The Court has held that laws of nature, physical phenomena, and abstract ideas are not patentable.⁵² These judicial exclusions are “part of the storehouse of knowledge of all men . . . free to all men and reserved exclusively to none.”⁵³ Additionally, patents on laws of nature and natural phenomena should be denied because they are not true inventions; they merely constitute discoveries of that which already existed in nature.⁵⁴

44. See Enerson, *supra* note 21, at 691–92 (describing Federal Circuit’s decreased reliance on the moral utility doctrine over the years).

45. See Crockett, *supra* note 6, at 298–300 (exploring different rationales behind including a morality provision as a requirement for patentability).

46. See John W. Cox & Joseph L. Vandegrift, *A Brief History of Supreme Court Interest in Patent-Eligible Subject Matter Under 35 U.S.C. § 101*, 19 J. TECH. L. & POL’Y 181, 183 (2014) (stating that Congress rarely amended patent statute).

47. See Sherry Knowles & Anthony Prosser, *Unconstitutional Application of 35 U.S.C. § 101 by the U.S. Supreme Court*, 18 J. MARSHALL REV. INTELL. PROP. L. 144, 151 (2018) (exclaiming that Congress finally passed the Patent Act of 1952 after years of refining patent code).

48. 35 U.S.C. § 101.

49. See *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980) (cautioning courts to not read into patent laws any limitations which legislature has not expressed).

50. See *id.* at 315 (reiterating that courts define what the law is).

51. See *id.* at 309 (explaining limits to broad patent rule interpretations).

52. *Id.*

53. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

54. See *Mayo Collaborative Servs. v. Prometheus Lab’ys, Inc.*, 566 U.S. 66, 72–73 (2012) (discussing rationale behind judicial exceptions to patentable subject matter).

C. Judicial Construction of 35 U.S.C. § 101: Exceptions and Biotechnology Patents

1. Pre-*Chakrabarty* and Judicial Exceptions to Patentability

Diamond v. Chakrabarty helped spark a revolution in the biotechnology industry,⁵⁵ but prior to the decision, patents falling under one of the judicial exceptions were analyzed on a case-by-case basis.⁵⁶ The Court's first foray into the modern construction of the judicial exceptions was *Funk Bros. Seed Co. v. Kalo Inoculant Co.*⁵⁷ In *Funk Bros.*, the patent involved product claims for a soil inoculant using different strains of bacteria in the roots of plants that enabled the plants to convert nitrogen from the air into organic nitrogenous compounds.⁵⁸ The inventor discovered that certain strains of each species of these bacteria could be mixed without harmful effect to the properties of the other strains.⁵⁹

Because the combination produced no new bacteria, no change in the species, no change in utility, and the species each had the same effect it always had, the Court held that the qualities of the discovered bacteria were natural phenomena and, thus, could not be patented.⁶⁰ The Court noted that if there was to be an invention from a discovery of natural phenomena, it "must come from the application of the law of nature to a new and useful end."⁶¹ By this, the Court meant an inventor must do something to change or apply a discovered law of nature rather than merely seek a patent for the discovery itself.

After Congress passed the Patent Act of 1952, the Court addressed patent eligibility under § 101 for the first time in *Gottschalk v. Benson*.⁶² Here, the patent under scrutiny was a process claim for a method using a mathematical formula for converting binary-coded decimal numbers into pure binary numerals.⁶³ The Court determined the algorithm was a set of procedures that were no more than a generalized formulation for programs to solve mathematical problems.⁶⁴ The Court relied on *Funk Bros.* regarding the § 101 judicial exceptions and applied the same general principles to the process claims here as it did to the product claims in *Funk*

55. See Matthew Jordan et al., *Forty Years Since Diamond v. Chakrabarty: Legal Underpinnings and its Impact on the Biotechnology Industry and Society*, GEO. MASON UNIV.: CTR. PROT. INTELL. PROP., Jan. 2021, at 1, 7 (detailing impact of *Diamond v. Chakrabarty* on biotechnology industry).

56. See Knowles & Prosser, *supra* note 47, at 160 (describing Court carving out judicial exceptions).

57. See generally *Funk Bros.*, 333 U.S. 127.

58. *Id.* at 128–29. Prior to the patent at issue here, it was the general practice to manufacture and sell inoculants containing only one species of bacteria because multiple strains would create an inhibitory effect that reduced their efficiency. *Id.* at 129–30.

59. *Id.* at 130.

60. *Id.* at 131.

61. *Id.*

62. 409 U.S. 63 (1972); Knowles & Prosser, *supra* note 47, at 157.

63. *Gottschalk*, 409 U.S. at 64.

64. *Id.* at 65.

*Bros.*⁶⁵ Because the mathematical formula at issue had no practical application except in connection with a computer, the Court invalidated the patent, as it would have resulted in patenting the mathematical formula itself, an abstract idea.⁶⁶ The Court emphasized that the transformation of an article to a different state or thing—the “machine-or-transformation”⁶⁷ test—is the clue to the patentability of processes.⁶⁸

In *Parker v. Flook*, the Court further clarified *Gottschalk* and provided more context for applying the judicial exceptions.⁶⁹ The claims here described a method of updating alarm limits in a catalytic conversion process by using a mathematical formula that automatically adjusted alarm limits based on a set of different variables.⁷⁰ The Court found, like in *Gottschalk*, that the claims did little more than apply a mathematical formula to well-known practices in the industry, and the invention was unpatentable because it was merely an abstract idea.⁷¹ Once the algorithm was assumed to be within the prior art, there was no inventive concept that would allow it to be patentable.⁷² There must be some application of the law of nature to a new and useful end to prevent a monopoly over a law of nature.⁷³

2. *Diamond v. Chakrabarty* and Patents on Living Things

The next case in the series of U.S. Supreme Court decisions addressing § 101 patent eligibility took place in 1980, when the Court analyzed whether a genetically engineered bacteria was patent eligible in *Diamond v. Chakrabarty*.⁷⁴ *Chakrabarty* marked the first time the Court analyzed whether a patent could be granted on a human-made living thing.⁷⁵ The claimed bacteria related to genetically engineered

65. *Id.* at 67–68.

66. *Id.* at 71–72.

67. *See generally* *Bilski v. Kappos*, 561 U.S. 593 (2010) (describing origins and applications of machine-or-transformation test and holding that it is not exclusive test for determining patentability of process).

68. *Gottschalk*, 409 U.S. at 70.

69. *Parker v. Flook*, 437 U.S. 584 (1978). The court clarified that *Gottschalk* applied the established rule that a law of nature cannot be the subject of a patent and described that the patentable subject matter exceptions are not explicitly mentioned in the language of § 101. *Id.* at 588–89.

70. *Id.* at 585. During a catalytic conversion process, different operating conditions (also known as process variables) are constantly monitored. *Id.* When any of the variables exceeds a predetermined alarm limit, an alarm may signal the presence of an abnormal condition within the process. *Id.*

71. *Id.* at 594–95. The process claims here contained three steps: “an initial step which merely measures the present value of the process variable (e.g., the temperature); an intermediate step which uses an algorithm to calculate an updated alarm-limit value; and a final step in which the actual alarm limit is adjusted to the updated value.” *Id.* at 585. “The only difference between the conventional methods of changing alarm limits and that described in respondent’s application rests in the second step -- the mathematical algorithm or formula.” *Id.* at 585–86.

72. *Id.* at 594.

73. *Id.* at 591.

74. *Diamond v. Chakrabarty*, 447 U.S. 303, 307 (1980).

75. *Crockett, supra* note 6, at 288.

bacterium capable of breaking down multiple components of crude oil.⁷⁶ The Court found that bacteria were patentable as a “composition of matter” within the scope of § 101.⁷⁷ In distinguishing the bacterium from natural phenomenon, the Court noted the human ingenuity involved in creating the bacterium.⁷⁸ Unlike the bacteria involved in *Funk Bros.*, Chakrabarty produced a new bacterium with markedly different characteristics from any found in nature.⁷⁹

The Court also had to grapple with a second issue: whether patents could be awarded on living things under § 101.⁸⁰ The Court held that living things could be patented.⁸¹ To reach that conclusion, the Court drew a distinction between products of nature and human-made inventions, rather than between living things and inanimate objects.⁸²

The petitioners argued that microorganisms cannot qualify as patentable subject matter without the express authorization of Congress.⁸³ Additionally, the petitioners argued that research similar to the one performed by Chakrabarty poses grave ethical and moral risks:

The briefs present a gruesome parade of horrors. Scientists, among them Nobel laureates, are quoted suggesting that genetic research may pose a serious threat to the human race, or, at the very least, that the dangers are far too substantial to permit such research to proceed apace at this time. We are told that genetic research and related technological developments may spread pollution and disease, that it may result in a loss of genetic diversity, and that its practice may tend to depreciate the value of human life. These arguments are forcefully, even passionately, presented; they remind us that, at times, human ingenuity seems unable to control fully the forces it creates—that with Hamlet, it is sometimes better “to bear those ills we have than fly to others that we know not of.”⁸⁴

The Court rejected petitioners’ arguments.⁸⁵ First, the Court observed that Congress had already spoken by passing § 101.⁸⁶ The Court’s job was merely to

76. *Chakrabarty*, 447 U.S. at 305. Before Chakrabarty’s invention of the bacteria in question, biological control of oil spills required the use of a mixture of naturally occurring bacteria that could each break down one component of the oil. *Id.* at 305 n.2. By breaking down the oil into similar substances, the decomposed oil could serve as food for aquatic life. *Id.* By breaking down multiple components of oil, Chakrabarty’s microorganism led to more efficient and rapid oil-spill control. *Id.*

77. *Id.* at 309–10.

78. *Id.*

79. *Id.*

80. *Id.* at 311. The Court discusses the 1930 Plant Patent Act and the 1970 Plant Variety Protection Act in connection with § 101 and determined that Congress had already addressed the issue. *See id.* at 310–12. The Court asserts that Congress, “recognized that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions.” *Id.* at 313.

81. *Id.* at 311.

82. *Id.*

83. *Id.* at 314.

84. *Id.* at 316.

85. *Id.* at 315–17.

86. *Id.* at 315.

interpret § 101 as including or excluding the genetically modified organism.⁸⁷ Second, as for the “parade of horrors,” the Court explained that the associated risks carry no weight in the analysis of patentable subject matter under § 101 because the courts are not equipped to evaluate these arguments.⁸⁸ The Court reasoned that the societal and policy evaluations should be left to the executive and legislative branches.⁸⁹ This case represented a significant shift in the analysis of patentability from a focus on whether something was *living* to a focus on whether something was a *product of nature* or *man-made*.⁹⁰

A great deal of uncertainty followed *Chakrabarty*, particularly surrounding patent applications involving life-forms.⁹¹ Shortly after the decision, the President’s Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research issued a report addressing some of the major ethical and social implications of biotechnology developments.⁹² While a host of issues, such as concerns about “playing God,” creating new life-forms, unknown consequences, and societal responsibilities, were raised,⁹³ the United States Patent and Trademark Office (USPTO) seemed reluctant to revive the moral utility doctrine.⁹⁴

The USPTO began granting patents on microorganisms, like the ones in *Chakrabarty*’s patent, but it remained unclear whether patents could be granted on animals.⁹⁵ The first case to bring clarity to this issue was *Ex parte Allen*, heard by the Board of Patent Appeals and Interferences.⁹⁶ The patent was for a method of producing sterilized oysters that could be harvested year-round as well as the oysters themselves.⁹⁷ The patent examiner rejected the patent under § 101 because oysters are living organisms, but on appeal the Board reversed, relying on *Chakrabarty*.⁹⁸

87. *Id.*

88. *Id.* at 316–17.

89. *Id.* at 317.

90. *See id.* at 313 (discussing how courts should approach patents involving living things).

91. *See* Anna Lumelsky, *Diamond v. Chakrabarty: Gauging Congress’s Response to Dynamic Statutory Interpretation by the Supreme Court*, 39 U. S.F. L. REV. 641, 656–58 (2005) (discussing patent activity in U.S. following *Diamond v. Chakrabarty*).

92. PRESIDENT’S COMM’N FOR THE STUDY OF ETHICAL PROBS. IN MED. & BIOMEDICAL & BEHAV. RSCH., *SPLICING LIFE: A REPORT ON THE SOCIAL & ETHICAL ISSUES OF GENETIC ENGINEERING WITH HUMAN BEINGS* (1982).

93. *Id.* at 51–79.

94. *See* Enerson, *supra* note 21, at 693–94 (discussing two patent cases in 1990s that involved morally controversial biotechnology and demonstrated USPTO’s reluctance to revive moral utility doctrine).

95. *See id.* at 696 (discussing 1988 patent for “Harvard Mouse,” first transgenic animal to be patented in United States).

96. *Id.* at 697; *Ex parte Allen*, No. 2 U.S.P.Q.2d 1425 (B.P.A.I. Apr. 3, 1987).

97. *Ex Parte Allen*, *supra* note 96, at 1425–26. Pacific oysters are unsuitable for consumption during their reproductive phase because they devote up to 80% of their body weight to gamete (sperm or eggs) production. *Id.* The method used here involves inducing polyploidy oysters (oysters having three or more sets of chromosomes instead of two) by fertilizing oyster eggs under controlled temperatures and applying hydrostatic pressure to the zygotes. *Id.* This method allows Pacific oysters to grow larger than they ordinarily would and ensures they can be harvested year-round. *Id.*

98. *Id.* at 1426–27.

The Board clarified that animals constituted eligible patentable subject matter when the subject matter includes human-made life-forms.⁹⁹

Shortly after *Ex parte Allen*, the USPTO released a statement clarifying its position¹⁰⁰ on subject matter involving living things.¹⁰¹ The USPTO stated: “The Patent and Trademark Office now considers non-naturally occurring, non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. § 101.”¹⁰² However, the USPTO also clarified that a patent could not be obtained on a claim of a human being because granting an exclusive property right in a human was prohibited by the Constitution.¹⁰³

The first instance of a patent on a higher life form came when researchers at Harvard University produced a genetically modified mouse that was highly susceptible to cancer by introducing an oncogene to trigger the growth of tumors.¹⁰⁴ The “oncomouse” was a “transgenic” animal—an animal created when DNA from other species has been artificially introduced into its genome.¹⁰⁵ Following its own guidelines on allowing patents on non-naturally occurring animals, the USPTO granted U.S. Patent No. 4,736,866 to Harvard University for “a transgenic non-human eukaryotic animal . . . whose germ cells and somatic cells contain an activated oncogene sequence introduced into the animal . . .”¹⁰⁶ Public outcry followed soon after because of the controversial ethical issue of whether it was morally right to own a property interest in a living being.¹⁰⁷ This resulted in a five-year unofficial moratorium on animal patents, after which the USPTO began granting patents to genetically engineered mice, followed by an influx of grants on many other animal patents.¹⁰⁸

Following the USPTO’s confirmation that animals, regardless of intelligence level, could be patented, Stuart A. Newman and Jeremy Rifkin sought to test the limits of patentable subject matter in genetically modified organisms.¹⁰⁹ Newman

99. *See id.* at 1427 (rejecting patent under § 103 for failing to meet non-obviousness requirements).

100. While the USPTO is authorized to provide guidance and establish procedures for patent applications, it has no rulemaking authority to establish substantive law. *See* 35 U.S.C. § 2 (establishing USPTO powers and duties).

101. USPTO, *Animals - Patentability*, 1077 OFF. GAZ. PAT. & TRADEMARK OFF. 24 (Apr. 21, 1987).

102. *Id.*

103. *Id.*

104. *See* WIPO, *Bioethics and Patent Law: The Case of the Oncomouse*, 3 WIPO MAGAZINE (June 2006), https://www.wipo.int/wipo_magazine/en/2006/03/article_0006.html (explaining creation of Oncomouse and issuance of patent in United States).

105. *Id.*

106. U.S. Patent No. 4,736,866 (filed June 22, 1984).

107. *See* Lumelsky, *supra* note 91, at 659–60 (analyzing aftermath of *Chakrabarty* and *Ex parte Allen*).

108. *Id.*

109. *See generally* Stuart A. Newman, *My Attempt to Patent a Human-Animal Chimera*, 27 L’OBSERVATOIRE DE LA GÉNÉTIQUE (Apr.–May 2006), https://www.nymc.edu/media/schools-and-colleges/nymc/pdf/newman/LObservatoire_Genetique_chimera.pdf (explaining Newman and Rifkin’s thought process and goals for applying for patent on human-animal chimera).

forecasted the evolution of biotechnology toward applications such as human cloning, human embryonic stem cells, and human-animal chimeras.¹¹⁰ To address this issue, Rifkin and Newman applied for a patent on embryos and full-term creatures containing both human and nonhuman cells.¹¹¹ Their objective in filing the patent was not to actually create animal-human chimeras, but to “help alert a wider public to what was coming down the road in terms of human applications of developmental biology.”¹¹²

In response to the chimera patent application, a USPTO press release stated that human-animal chimeras might not be patentable because of the public policy and morality components of § 101.¹¹³ However, when the USPTO first rejected the application, it did so under § 101 by concluding that patents on human beings were not within the Congressional intent of § 101, rather than a rejection based on moral grounds.¹¹⁴ Arguably, the USPTO wanted to reject the patent on morality grounds but did not believe it had the authority to do so, making the decision to reject under § 101 one of practicality. This reluctance to revive the moral utility doctrine has become a common theme of § 101 rejections, leading to unclear case law and policies.¹¹⁵

In its final rejection of the chimera patent application, the USPTO again stated that humans are not patentable subject matter.¹¹⁶ Two primary arguments were raised and subsequently rejected by the Patent Examiner: “(1) [The] claims are not directed to a human being or a human embryo but rather a man-made chimeric embryo, and (2) even if the claims cover human beings, the statute does not restrict patentability based on whether claims embrace a human being.”¹¹⁷

In rejecting these arguments, the Examiner stated that the presence of some non-human cells does not make a human embryo non-human.¹¹⁸ Specifically, the

110. *Id.*

111. *Id.* The term “chimera” has its roots in ancient mythology with creatures that were half-human and half-animal such as the minotaur in Greek mythology or the Egyptian gods with a human body and a beast head. Rodolphe Bourret et al., *Human-Animal Chimeras: Ethical Issues About Farming Chimeric Animals Bearing Human Organs*, 7 STEM CELL RSCH. & THERAPY 2016, at 1. In modern medicine, chimera has been used to describe a living organism that contains cells or tissues with different genotypes. *Id.* The definition takes on different meanings based on the field of use and can mean a combination of cells from different individuals, a combination of two DNA molecules from different individuals, or interspecies hybrids. *Id.*

112. Newman, *supra* note 109.

113. Ryan Hagglund, *Patentability of Human-Animal Chimeras*, 25 SANTA CLARA HIGH TECH. L. J. 51, 67 (2008).

114. *Id.* at 68.

115. See Press Release, Tillis, *Coons Introduce Landmark Legislation to Restore American Innovation*, THOM THILLIS (June 22, 2023), <https://www.tillis.senate.gov/2023/6/tillis-coons-introduce-landmark-legislation-to-restore-american-innovation> (proposing new legislation to fix growing consensus that patent eligibility case law has become inconsistent leading to widespread uncertainty in business and innovation communities).

116. Final Rejection, U.S. Patent App. No. 08/993,564, (USPTO Aug. 2, 2004) <https://patentcenter.uspto.gov/applications/08993564/ifw/docs> (Final Rejection).

117. *Id.* at 20.

118. *Id.* at 20–21.

Examiner found that utilizing the logic of this application, one could produce a creature that was entirely human because the embryos could produce an animal of one cell type or predominantly one cell type.¹¹⁹ In rejecting this patent, the USPTO failed to distinguish the composition of human and animal cells that would cross the threshold from a patentable man-made animal, such as the transgenic oncomouse containing human genetics, to a human being that cannot be patented.¹²⁰ The USPTO also stated it had already addressed the issue in past decisions and restated its belief that humans are not patentable subject matter.¹²¹ In 2011, Congress passed the America Invents Act (AIA), codifying the Weldon Amendment,¹²² and explicitly prohibiting “issuing a patent on a claim directed to or encompassing a human organism in any application” including patents directed at human embryos or fetuses.¹²³

3. Modern Framework Following *Alice/Mayo*

The statement in *Chakrabarty* acknowledging Congress’ intent to “include anything under the sun that is made by man”¹²⁴ as patentable subject matter allowed for a revolution in biotechnology in the United States where life-forms, plants, transgenic animals, and more were deemed patentable subject matter.¹²⁵ However, the Court appeared to narrow the scope of patentable subject matter in 2013 when it decided *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*¹²⁶ The patent in *Mayo* was for a process to help doctors that use thiopurine drugs to treat patients with autoimmune diseases determine whether the dosage level was too low or too high.¹²⁷ The claims involved (1) administering the drug thiopurine to a patient, (2) determining the concentration level of the drug in the blood, and (3) adjusting the dosage based on the determined concentration in the blood.¹²⁸

The Court held that the claims did nothing more than apply the law of nature that describes the relationship between thiopurine concentration levels and the drug’s efficacy.¹²⁹ The invention was prohibited by the natural law exception to § 101 because the claims did not transform the natural laws they relied on into patent-

119. *Id.* at 21.

120. *See* Hagglund, *supra* note 113, at 68–69 (discussing USPTO’s final rejection of chimera patent).

121. Final Rejection, *supra* note 116, at 21–22.

122. The Weldon Amendment was first adopted in 2003 and barred any use of USPTO funds to issue patents related to human cloning. Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 FED. CIR. B. J. 435, 511 (2012).

123. Leahy-Smith America Invents Act, Pub. L. No. 112–29, § 33(a), 125 Stat. 284, 340 (2011).

124. 447 U.S. 303, 309 (1980).

125. *See* Michele Wales & Eddie Cartier, *The Impact of Myriad on the Future Development and Commercialization of DNA-Based Therapies and Diagnostics*, COLD SPRING HARBOR PERSPS. MED., Dec. 2015, at 1, 2 (contextualizing shift from historically broad interpretation of patentable subject matter under § 101 to narrower scope following the *Mayo* and *Myriad* decisions).

126. 566 U.S. 66 (2012).

127. *Id.* at 73–74.

128. *Id.* at 74–75.

129. *Id.* at 72.

eligible *applications* of those laws.¹³⁰ Citing both *Flook* and *Bilski*,¹³¹ the Court found the patent claims did not contain the “inventive concept” required to grant more than a patent upon the natural law itself.¹³² As it had in past § 101 precedent, the Court discussed the balancing required in patent law to grant incentives for creation, invention, and discovery with the danger of impeding innovation through exclusivity.¹³³

Following *Mayo*, the Court had an opportunity to clarify its recent § 101 decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*¹³⁴ Myriad discovered the precise location and sequence of BRCA1 and BRCA2 genes;¹³⁵ mutations of these two genes can dramatically increase the risk of breast and ovarian cancer.¹³⁶ By discovering the two genes, Myriad was able to determine their typical nucleotide sequence, and subsequently develop medical tests to detect mutations in the BRCA1 and BRCA2 genes.¹³⁷ Myriad then sought and obtained patents on both the isolated segments of BRCA1 and BRCA2 DNA,¹³⁸ and the synthetically created cDNA¹³⁹ in the same gene regions.¹⁴⁰

The Supreme Court held the patent claims for the BRCA1 and BRCA2 genetic sequences were unpatentable.¹⁴¹ Because Myriad did not create or alter any of the

130. *Id.*

131. In *Bilski*, the claimed invention was for a series of steps explaining how commodities buyers and sellers in the energy market can hedge against the risk of price changes. 561 U.S. 593. The Court held the invention was ineligible for patent protection under § 101 because it was no more than a patent on an abstract idea. *Id.* at 608–09.

132. *Mayo*, 566 U.S. at 72–73.

133. *Id.* at 92.

134. 569 U.S. 576 (2013).

135. *Id.* at 582.

136. *Id.* at 583.

137. *Id.*

138. For a more detailed description of DNA and the process used by Myriad, the background information provided in the Court’s opinion is helpful:

DNA’s informational sequences and the processes that create mRNA, amino acids, and proteins occur naturally within cells. Scientists can, however, extract DNA from cells using well known laboratory methods. These methods allow scientists to isolate specific segments of DNA—for instance, a particular gene or part of a gene—which can then be further studied, manipulated, or used.

Id. at 582. To isolate DNA from the human genome, chemical bonds are severed and a non-naturally occurring molecule is created. *Id.* at 593. However, the isolated structure of the DNA is no different from its naturally occurring segment in the human genome. *Id.* at 590.

139. To contextualize the Court’s distinction between DNA and cDNA it is important to understand what cDNA is. “cDNA (copy or complementary DNA) is synthetic DNA that has been transcribed from a specific mRNA through a reaction using the enzyme reverse transcriptase. While DNA is composed of both coding and non-coding sequences, cDNA contains only coding sequences.” Oleg A. Shchelechkov, *cDNA (Copy DNA)*, NAT’L HUM. GENOME RES. INST., <https://www.genome.gov/genetics-glossary/Copy-DNA> (last updated October 5, 2023).

140. *Myriad*, 569 U.S. at 583–84.

141. *Id.* at 590–94.

genetic information encoded in the BRCA1 and BRCA2 genes, the discovery fell within the law of nature exception of § 101.¹⁴² While the discovery of the location of these genes was a significant medical breakthrough, the Court reiterated that “groundbreaking innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry.”¹⁴³ In contrast, the Court held that the cDNA claims were valid because the creation of cDNA results in an exons-only molecule that does not occur naturally.¹⁴⁴ The Court noted the creation of the cDNA by the lab technician and the fact that it is distinct from the naturally occurring DNA from which it was derived.¹⁴⁵

In the years since *Mayo* and *Myriad*, the Federal Circuit has struggled to effectively apply the § 101 patentable subject matter framework particularly when considering the Supreme Court’s subsequent¹⁴⁶—restatement of the framework as a two-part test in *Alice Corp. v. CLS Bank International*.¹⁴⁷ The test involves first determining whether the patent claims are directed toward a patent-ineligible concept (laws of nature, abstract ideas, or natural phenomenon).¹⁴⁸ If the patent is directed towards one of these concepts, the Court must then determine whether the additional claim elements “transform the nature of the claim” into a patent-eligible application.¹⁴⁹ The Court seeks to ensure that the patent contains the “inventive concept” necessary to prevent a patent on the ineligible concept itself.¹⁵⁰

In the view of many patent holders, the Supreme Court’s implementation of *Mayo/Alice* fails to provide objective, predictable criteria to determine patent eligibility.¹⁵¹ Historically, biotechnology has relied on inventive preparations based on naturally occurring substances.¹⁵² Because natural products and their derivatives form the basis for many biopharmaceutical innovations, representatives of the life sciences industry have argued that isolating a natural product should be sufficient for patent eligibility.¹⁵³

By continuing to use the judicially created exceptions for patentable subject matter instead of addressing morality concerns head-on through legislative action, the United States has weakened its patent system and is beginning to fall behind other countries. Additionally, the United States has no safeguard in place should a

142. *Id.* at 591.

143. *Id.*

144. *Id.* at 594.

145. *Id.* at 595.

146. See Allan Carlsen, *Illumina Inc. v. Ariosa Diagnostics, Inc.: A Misguided Redefining of Patentable Subject Matter Under the Mayo/Alice Test*, 94 TEMP. L. REV. 347, 359–64 (2022) (analyzing Federal Circuit’s decisions post *Mayo/Alice*, particularly those in biotechnology).

147. In *Alice Corp. v. CLS Bank International*, the Court clarified the framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim eligible applications of these exceptions. 573 U.S. 208, 217 (2014).

148. *Id.*

149. *Id.*

150. *Id.* at 217–18.

151. USPTO, PATENT ELIGIBLE SUBJECT MATTER: REPORT ON VIEWS AND RECOMMENDATIONS FROM THE PUBLIC 29–30 (2017), https://www.uspto.gov/sites/default/files/documents/101-Report_FINAL.pdf.

152. *Id.* at 29.

153. *Id.* at 35.

morally questionable and dangerous patent application meet the requirements of patentability in the near future.

III. INTERNATIONAL APPROACHES TO PATENTABLE SUBJECT MATTER

Morality exceptions as pre-grant mechanisms to prevent patentability are common throughout the world. These exceptions ensure countries' patent laws align with the cultural and ethical standards of their citizens. This Comment focuses on Europe and Japan because they represent two of the most powerful economies that effectively implement morality provisions within their patent laws without stifling innovation. To fully examine the effectiveness of the morality exceptions in Europe and Japan, this Comment will look at three innovative biotechnologies and how they were handled in both the United States and jurisdictions with morality exceptions.

A. Jurisdictions Using Patent Morality Exclusions

1. Trade-Related Aspects of Intellectual Property Rights (TRIPS)

The World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is the most comprehensive multilateral agreement on intellectual property.¹⁵⁴ It sets out minimum standards of protection, domestic procedures and remedies for enforcement, and dispute settlement procedures for parties with respect to intellectual property rights.¹⁵⁵ The TRIPS section on patentable subject matter contains an exception for member countries to exclude from patenting inventions that they deem “necessary to protect the *ordre public* or morality, including to protect human, animal or plant life or health to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.”¹⁵⁶ Article 27(3) also includes exceptions for diagnostic, therapeutic, and surgical methods for the treatment of both humans and animals, as well as exceptions for plants and animals other than microorganisms.¹⁵⁷

Because TRIPS grants WTO members freedom to exclude inventions from patentability based on morality,¹⁵⁸ but does not define morality or *ordre public*, countries have the discretion to apply these exceptions as they see fit based on the cultural norms of their respective societies.¹⁵⁹ By their very nature, definitions of conformity to moral principles are so intertwined with the sociocultural and religious

154. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), [hereinafter TRIPS Agreement] https://www.wto.org/english/docs_e/legal_e/27-trips_03_e.htm.

155. Overview: *The TRIPS Agreement*, WTO, https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited Nov. 17, 2023).

156. TRIPS Agreement, *supra* note 154, art. 27(2).

157. *Id.* at art. 27(3).

158. *Id.* at art. 27(2).

159. See Singh & Associates, *Ordre Public and Morality Exclusions from Patentability*, LEXOLOGY <https://www.lexology.com/library/detail.aspx?g=e1eff8bb-ae9d-4b20-bc95-68dd27f5aa07> (Sept. 29, 2012) (discussing ambiguity in definition of morality and *ordre public*).

values of different countries that it may prove difficult to provide objective definitions of these exclusions.¹⁶⁰

2. Europe

Unlike the United States, and in accordance with TRIPS, Europe has developed exclusions to patentable subject matter through legislation.¹⁶¹ Under the European Patent Convention (EPC),¹⁶² Europe explicitly excludes patents on inventions contrary to *ordre public* or morality, plant or animal varieties or biological processes for the production of plants or animals, and methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body.¹⁶³

Europe also provides a list of biotechnology inventions that may fall within the morality exceptions by categorically excluding the following from patenting: processes for cloning human beings, processes for modifying the germ line genetic identity of human beings, uses of human embryos for industrial or commercial purposes, processes for modifying genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and plants or animals exclusively obtained by means of biological process.¹⁶⁴ To give some guidance on how to apply the provisions against *ordre public* or morality, the European Patent Office (EPO) states that the provision is likely to be invoked only in rare and extreme cases.¹⁶⁵ The test to deny patent protection under this provision is “whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable.”¹⁶⁶

3. Japan

Japan has similar legislatively-defined patent morality exclusions.¹⁶⁷ Article 32

160. *See id.* (describing morality exclusions of different countries).

161. *See* Convention on the Grant of European Patents (European Patent Convention), art. 53, Oct. 5, 1973, 1065 U.N.T.S. 16208 [hereinafter European Patent Convention] (explicitly stating exceptions to patentability).

162. The EPC set up the European Patent Organization (EPO) which governs patent law between contracting states. *Legal Foundations*, EUR. PAT. OFF., <https://www.epo.org/about-us/foundation/legal-foundations.html> (last visited Nov. 17, 2023). The EPO consists of 39 member states, comprising all the member states of the European Union as well as Albania, North Macedonia, Iceland, Liechtenstein, Monaco, Montenegro, Norway, San Marino, Serbia, Switzerland, Türkiye, and the United Kingdom. *Id.*

163. EUR. PAT. ORG., *Implementing Regulations to the Convention on the Grant of European Patents*, Chapter V, Rule 28 (Feb. 1, 2023), <https://www.epo.org/en/legal/epc/2020/r28.html>; Eur. Pat. Org., *Guidelines for Examination in the European Patent Office*, Chapter II, Part G—Patentability, 4.1 (Mar. 2023).

164. *Id.* at Rule 28.

165. EUR. PAT. OFF., *Guidelines for Examination: 4.1 Matter Contrary to “Ordre Public” or Morality*, https://www.epo.org/en/legal/guidelines-epc/2023/g_ii_4_1.html (last visited Nov. 17, 2023).

166. *Id.*

167. *See* Japan Patent Act, Act No. 121 of April 13, 1959, last updated Act No. 42 of 2021, art. 32 [hereinafter Japan Patent Act] (defining unpatentable inventions in Japan).

of the Japan Patent Act states, “an invention that is likely to disrupt public order, corrupt public morals or harm public health may not be patented”¹⁶⁸ Unlike the European approach of describing a wide array of technologies that are contrary to *ordre public*, defining what dictates morality in Japan is not as straightforward.¹⁶⁹ The factors used to analyze whether something would disrupt public order are heavily influenced by religious, cultural, and traditional values of the public.¹⁷⁰ In Europe, these values are used to explicitly shape which inventions are unpatentable, while Japan gives little guidance to what may violate this provision. Some of the themes that contribute to morality are the closeness of man, nature, the significance of family, and the natural bond between Japanese religion and the Japanese nation.¹⁷¹ The Japanese approach focuses on the invention’s use and how it will affect public health.¹⁷²

Human beings are granted special respect because of the Japanese view that human beings are endowed with a capacity for spiritual activities.¹⁷³ The Japanese revere the unique identity of each human being, and that certainly plays a role in how patents are regulated through the morality clause.¹⁷⁴ However, the sanctity of human beings and their souls has not led to Japan having stricter patent laws in the biotechnology space.¹⁷⁵ In fact, the Japanese Patent Office often has a relaxed ethical standard so long as it does not believe there will be a violation to the sanctity of the human soul.¹⁷⁶ This has led to more relaxed standards in the area of stem cell research and patenting, as well as patents involving DNA modification.¹⁷⁷ Japan places a much higher reliance on novelty and obviousness rather than patentable subject matter, which is where most U.S. patent applications fail.¹⁷⁸

B. Applying Non-U.S. Jurisdiction Morality Exceptions to Specific Questions in

168. *Id.*

169. See Craig M. Borowski, *Human Cloning Research in Japan: A Study in Science, Culture, Morality and Patent Law*, 9 IND. INT’L & COMP. L. REV. 505, 518 (1999) (detailing historical, moral, and cultural implications of patent law in Japan).

170. See *id.* at 518–23 (discussing many religious and cultural influences on Japanese morality).

171. See *id.* at 518–19 (discussing influences on Japanese understanding of morality).

172. Gary Gregory, *What’s Immoral About Monsanto?: Strengthening the Roots of the Moral Utility Requirement by Amending the U.S. Patent Act*, 21 CARDOZO J. INT’L & COMP. L. 759, 785 (2013).

173. Borowski, *supra* note 169, at 523.

174. See *id.* at 528 (explaining how Japanese values of human life and unique identity are difficult to reconcile with human cloning).

175. See Borowski, *supra* note 169, at 531–33 (finding that, although Japan does not permit human cloning patents, they have few restrictions on animal cloning patents).

176. See Alice Yuen-Ting Wong & Aurélie Mahalatchimy, *Human Stem Cells Patents—Emerging Issues and Challenges in Europe, United States, China, and Japan*, 21 J. WORLD INTELL. PROP. 326, 342–44 (2018) (explaining how Japan is more liberal than other countries in granting stem cell patents, provided that claimed inventions do not involve destruction of human embryos).

177. See Eneda Hoxha, *Stemming the Tide: Stem Cell Innovation in the Myriad-Mayo-Roslin Era*, 30 BERKELEY TECH. L. J. 567, 608 (2015) (discussing how Japan’s patent regime has fewer regulations regarding stem cells and small DNA fragments than U.S. patent regime).

178. See *id.* (detailing debate surrounding patents for inventions that use hESCs).

Biotechnology

To examine the applicability of patent exclusions based on morality, this Comment will look at how morality exclusions are applied to patents on recent biotechnologies that have been deemed as immoral or against the public good in some countries. The purpose of the following section is to illustrate how other countries have effectively dealt with moral utility doctrines in modern biotechnology applications. By looking at how morality is applied in other countries, the United States can effectively adopt a similar approach to strengthen its patent laws.

1. Human Embryonic Stem Cell Patents

One of the more controversial areas in recent years has been the use of human embryonic stem cells (hESCs)¹⁷⁹ and whether patents should be granted on inventions involving the use of hESCs.¹⁸⁰ The morality of fetal research has long been a significant societal concern across many cultures.¹⁸¹ Because hESCs are human embryos and have the potential to develop into unique human individuals, research and patents involving their use bring up a host of ethical issues intertwined with respecting the dignity of human beings and other societal and religious concerns.¹⁸² To find a balance between the many positive applications of hESCs and potential ethical issues brought on by their use, countries have used the patent system to address research involving hESCs and their use.

The United States has historically been a leading country in allowing stem cell patents compared with other countries with strong patent and biotechnology systems.¹⁸³ Unlike many other countries, the United States' lack of a morality exclusion in its patent laws allowed for a wide range of stem cell patents; in the past, only patents directed toward or encompassing a human organism (including a human embryo) were denied.¹⁸⁴ In recent years, however, there has been some confusion surrounding hESC patents following the *Mayo* and *Myriad* decisions.¹⁸⁵ Rather than exclude certain stem cell patents as against public morality, the United States has only invalidated stem cell patents when they are deemed as already existing in nature and lacking the essential step of having any distinctive structural, functional, or other

179. In ideal conditions, hESCs differentiate into all types of cells and then develop into any human tissue (except the placenta), making them extremely valuable as a potential way to address diseases that cannot be cured with traditional techniques. Jiajav Chen & Wei Li, *Rethink the Patentability of Human Embryonic Stem Cell Research Findings: Relaxation Based on Benefit Weighing*, 16 STEM CELL REPS. 1868, 1868 (2021).

180. *Id.*

181. *See generally* Wong & Mahalatchimy, *supra* note 176 (discussing history and attitudes towards hESC research and patenting across different countries).

182. *See* Chen & Li, *supra* note 179, at 1868 (explaining that hESC research has long been controversial because of need to respect dignity of human beings).

183. *See* Gregory, *supra* note 172 (claiming United States and Japan are contemporary leaders in patents).

184. *See* Wong & Mahalatchimy, *supra* note 176, at 331–32 (explaining that before *Mayo* and *Myriad*, living organisms including animals, plants, and microorganisms were all patent-eligible, while patents directed to human organisms were prohibited).

185. *Id.*

properties from the natural cells in human bodies required by § 101.¹⁸⁶

Because of the monumental shift in § 101 patent eligibility in recent years, the future of hESC patents in the United States remains uncertain.¹⁸⁷ The ongoing debate centers around fundamental questions of whether hESCs constitute human organisms under the AIA—a question the United States Supreme Court has not yet addressed—and whether stem cells in general are products of nature, and, therefore, ineligible for patent protection.¹⁸⁸ The current dispute over stem cells also appears to ignore some of the biggest societal issues encapsulated by stem cell patents based on general public opinion, potential religious concerns, and concerns over human dignity.¹⁸⁹

In the European Union, the patent eligibility of hESCs is primarily a question decided on morality grounds.¹⁹⁰ Both the EPC and the Directive 98/44/EC on the Legal Protection of Biotechnological Inventions provide more clarity than the United States in the area of hESCs by directly prohibiting the patenting of “inventions that use human embryos for industrial or commercial purposes” as contrary to *ordre public* or morality.¹⁹¹ The European Court of Justice (ECJ) had a chance to clarify the moral exclusion with regard to stem cells in *Brüstle v. Greenpeace*. In this opinion, the ECJ defined the meaning of the term “human embryo,” defined the meaning of the phrase “use of human embryos for industrial or commercial purposes,” and answered the question of whether the destruction of a human embryo is a necessary condition of the technology to exclude it from patentability.¹⁹² The Court defined human embryos as any human ovum as soon as fertilized and cited to the underlying principles behind patenting of human embryos as contrary to *ordre public* or morality as they could affect respect of human dignity.¹⁹³ In determining the meaning of the phrase “use of human embryos for industrial or commercial purposes,” the Court recognized the value of research surrounding hESCs, but found any research leading to a patent application necessarily had an industrial or commercial nature to it and could not be patented

186. *Id.* at 334.

187. See Davey et al., *Interfacing of Science, Medicine and Law: The Stem Cell Patent Controversy in the United States and the European Union*, 3 FRONTIERS CELL & DEV. BIOLOGY, NOV. 2015, at 1, 4 (positing that hESC patents future is tremendously uncertain due to recent court cases).

188. See *id.* (explaining what matters for patentability purposes in U.S. is whether nucleotides or amino acids are in their natural form that exists in human body and if they are purified such that they are no longer in their natural form).

189. See NICOLAS RIGAUD, BIOTECHNOLOGY: ETHICAL & SOC. DEBATES 30–33 (2008) (discussing general public opinion, influential religious groups’, and non-religious associations’ concerns over research involving embryos).

190. See Davey et al., *supra* note 187, at 2 (examining how EU continues to strictly limit patent protection of hESCs on morality grounds).

191. European Patent Convention, *supra* note 161; Council Directive 98/44, art. 6. (2)(c) 1998 O.J. (L 213) 18 (EC).

192. See Case C–34/10, *Oliver Brüstle v. Greenpeace e.V.*, 2011 E.C.J. I–9849 ¶¶ 35, 36, 48 (clarifying exclusion of inventions based on moral reasoning).

193. See *id.* ¶¶ 32–38 (defining application of morality exclusion to human embryonic stem cells).

under the Legal Protection of Biotechnological Inventions.¹⁹⁴ For the third point, the Court found an invention is not patentable if its implementation requires either the prior destruction of human embryos or their prior use as a base material.¹⁹⁵

The European approach to patentability of hESCs is advantageous to the United States approach because it allows the courts to take an explicit existing exception and clearly define the limits of that exception. In the United States, there is currently a great deal of ambiguity regarding hESC patents because it is unclear how the Supreme Court's new approach to patent-eligible subject matter will apply to patents that were previously granted in the field.¹⁹⁶ Instead of looking at stem cell patents from a public morality approach, the United States must first determine whether the stem cells in question are fundamentally identical to naturally occurring cells in the human body to determine whether stem cells will fall under a § 101 exception to patentable subject matter.¹⁹⁷ The European approach is much simpler in practice as the Legislature has already defined what areas of technologies would be contrary to *ordre public* or morality and then the Court can easily define the limits of those technologies within the framework of morality.¹⁹⁸

The *Brüstle* decision has received a fair amount of criticism because it is unclear whether the definition given to a human embryo is consistent across different EU member states.¹⁹⁹ The ECJ had previously argued that where a difference of values, cultures, or religions between member states did not allow for harmonized legislation, the issue must be judged by different member states according to their own values.²⁰⁰ This highlights one of the primary criticisms of a morality exception: the morality of hESCs and ideas as to what constitutes a human embryo could also vary between countries based on cultural beliefs.²⁰¹ However, these questions of morality are best answered by the public opinion of their respective societies and variances between countries are not as important. This approach allows each country to determine how morally questionable patents should be viewed, considering both

194. *See id.* ¶¶ 39–46 (concluding that although aim of scientific research is distinguishable from industrial or commercial purposes, use of human embryos for purposes of research cannot be separated from patents and is therefore impermissible).

195. *See id.* ¶¶ 47–52 (finding that inventions must be regarded as unpatentable, even if patent claims do not concern use of human embryos, where implementation of inventions requires destruction of human embryos).

196. *See* Albert Wai-Kat Chan et al., *A Patent Perspective on US Stem Cell Research: What are the Implications of Recent US Supreme Court Decisions on the Patent Eligibility of Stem Cells?*, 32 NATURE BIOTECHNOLOGY (2014) (analyzing effect of *Mayo* and *Myriad* on stem cell patents in United States).

197. *Id.*

198. *See* Case C–34/10, *Oliver Brüstle v. Greenpeace e.V.*, 2011 E.C.J. I–9849 ¶¶ 35–48 (defining scope of human embryonic stem cells in accordance with Biotech Directive); *see also* EUR. PAT. OFF., *supra* note 165 (laying out test determining if patents would violate *ordre public*).

199. *See* Martin Heyer & Tade Matthias Spranger, *The European Court of Justice's Decision Regarding the Brüstle Patent and its Implications for the Legality of Stem Cell Research Within the European Union*, 22 STEM CELLS & DEV. 50, 52 (2013) (discussing differing definitions of “human embryo” across various EU member states).

200. *See id.* (detailing argument for member state's culture, morals, and values to be determinative).

201. *See id.* at 50–52 (discussing ECJ's deviation from prior precedent in *Brüstle*).

cultural norms and societal beliefs.

Even though the United States does not have to grapple with the questions of what its citizens will find morally acceptable based on its patent precedent, patent stem cell eligibility appears to be converging with the European approach of denial.²⁰² If both approaches are going to result in a denial of hESC patents, the European approach of clarity is preferred over the current ambiguity present in the United States approach.

In Japan, the morality provision prevents inventions where a human is produced through genetic manipulation.²⁰³ However, the Japanese Patent Act and Examination Guidelines do not clarify at what stage a human body is interpreted to be a human.²⁰⁴ Human embryos themselves are not explicitly unpatentable but applications involving a step where human embryos are destroyed have been rejected under Article 32.²⁰⁵ As long as the process does not involve the destruction of human embryos, stem cell patents typically do not face much resistance under the morality provision.

Japan is less restrictive than Europe on stem cell patentability and has issued patents on stem cell lines, manufacturing methods, uses of stem cells for drug production, and other applications.²⁰⁶ Japan's patent regime has little to no regulation regarding the patentability of stem cells despite the emphasis on morality as part of its patent laws.²⁰⁷ Because Japan has not deemed stem cells to be contrary to public morality, stem cell technology has been able to flourish under the existing clear guidelines on patentability.²⁰⁸

The Japanese approach is an illustrative case study of a country with a morality clause that does not limit innovation, and in fact encourages it. Stem cell researchers are assured their efforts will be rewarded with a patent and that those patents will stand up to scrutiny under any morality challenges. The United States takes a similar pro-innovation approach by refusing to deny stem cell patents on moral grounds; however, the uncertainty surrounding § 101 rejections inherently makes the patents weaker, as they may not gain future approval or may later be invalidated. By adopting a morality clause, the United States can still promote innovation in cutting-edge technologies like Japan has successfully managed to do. The Japanese focus on novelty and obviousness over patentable subject matter is successful because it gets to the core of what makes patent laws effective—the policy goal of promoting new innovative inventions.

202. See Davey et al., *supra* note 187, at 4 (concluding convergence of U.S. and E.U. laws regarding stem cell patent eligibility may be inevitable).

203. Wong & Mahalatchimy, *supra* note 176, at 341.

204. See *id.* at 340–43 (detailing Japanese Patent Act and Examination).

205. See *id.* (outlining Japan's approach to patentability using moral exclusions).

206. See *id.* (comparing Japanese patent exclusions and restrictions with that of Europe).

207. Hoxha, *supra* note 177, at 608.

208. See *id.* at 608–09 (discussing how Japan's targeted approach to its morality clause allows greater flexibility to scientists completing stem cell research and has led to rise in research compared to several other countries).

2. CRISPR Cas-9 and Genome Editing

Recent developments in CRISPR technology, a form of genome editing technology,²⁰⁹ has led to debates regarding issues of morality and ethics.²¹⁰ Some of the moral and ethical problems are the safety of the technology (as the risks are not fully known without more research), the risk of a “slippery slope” where genome editing may be used for non-therapeutic and enhancement purposes, the morality of curing genetic diseases, and the concern over genome editing for reproductive purposes.²¹¹ Additionally, much of the genome editing research involves the use of human embryos and their destruction, bringing up similar issues to those discussed above.²¹²

Patents play an important role in regulating the commercialization of human genome editing as they grant the exclusive right of commercial exploitation, and they also directly or indirectly dictate the direction of research efforts and activities.²¹³ Specifically, the pre-grant mechanism of including the *ordre public* or morality exception to patentability used by Europe and Japan may be used to prevent patents on human genomes found to be against the health and welfare of the public.²¹⁴

In the United States, human genome editing patents are not explicitly prevented or restricted, but they are subject to the same exceptions for laws of nature, natural phenomena, and abstract ideas to be patent-eligible subject matter.²¹⁵ Human genome sequencing technologies have not faced many of the issues brought up after *Myo* and *Myriad* under § 101, and much of the litigation surrounding these patents in the U.S. legal system revolves around issues of priority, novelty, and ownership, not whether they constitute patentable subject matter.²¹⁶

Rather than regulate gene editing through the patent system, the United States has incorporated an ethical approach to regulation through funding and market

209. See *What Are Genome Editing and CRISPR-Cas9?*, *supra* note 11 (providing a full description of CRISPR technology and its process).

210. See NAT'L HUM. GENOME RSCH. INST., *What Are the Ethical Concerns of Genome Editing?*, NAT'L INST. HEALTH, <https://www.genome.gov/about-genomics/policy-issues/Genome-Editing/ethical-concerns> (last updated Aug. 3, 2017) (providing overview of ethical concerns involved in genome editing now that CRISPR can potentially make such editing more accurate and easier in comparison to older technologies).

211. *Id.*

212. See *id.* (finding that many people have moral and religious objections to using human embryos for research).

213. See Duncan Matthews et al., *Balancing Innovation, 'Ordre Public' and Morality in Human Germline Editing: A Call for More Nuanced Approaches in Patent Law*, 29 EUR. J. HEALTH L. 562, 569 (2022) (detailing involvement of morality exception in granting patents and patents effect on human genome edit efforts and commercial exploitation).

214. See *id.* (explaining how pre-grant limitations allow national patent laws to contain mechanisms of public governance over technological innovation by excluding certain subject-matter from patentable invention).

215. See *supra* Part II.C for a discussion of the judicial exceptions to patentable subject matter under § 101.

216. Matthews et al., *supra* note 213, at 568.

restrictions.²¹⁷ The funding restrictions primarily consist of research grants that must adhere to ethical conditions, resulting in organizations like the National Institutes of Health (NIH) having a strong say in limits and types of research in the field of gene editing.²¹⁸ On the market restrictions side, the primary regulatory body is the Food and Drug Administration (FDA), where most of the biotechnological regulation is based upon safety rather than ethical concerns.²¹⁹ Under the current framework of the FDA, a science-based approach that weighs the benefits and risks is applied to evaluate the permissibility of gene editing technologies.²²⁰

3. Transgenic Animals

The European approach to Oncomouse patents granted in the United States²²¹ is an example of an effective way to apply a morality standard. Rather than inventing a bright-line rule as to the morality of patenting animals as contrary to morality or *ordre public*, the Court evaluated the patent by weighing the medical benefit to humans or animals against the suffering of the animals.²²² Rule 23d(d) of the EPC explicitly calls for this analysis within the scope of biotechnology patents and the *ordre public* or morality exception.²²³ By applying a balancing test between the medical benefit to humans or animals against the suffering of the animals, the Court was able to apply a nuanced approach to the morality exception, allowing it to consider all relevant evidence and make an informed decision regarding the morality of the patented invention.²²⁴ By acknowledging the difficulty in determining what was considered “moral” by the public, the Board determined that the balancing of benefits against the risks and harms would be an effective way to apply the morality exception to patents on animals.²²⁵ In evaluating this standard for the Oncomouse patent, the Court recognized that the mice would experience suffering, but found the substantial medical benefit of using mice instead of humans for cancer research outweighed this suffering.²²⁶

217. See Hannah Mosby, *Biotechnology's Great Divide: Strengthening the Relationship Between Patent Law and Bioethics in the Age of CRISPR-CAS9*, 19 MINN. J. L. SCI. & TECH. 565, 581–83 (2018) (detailing existing regulation methods of gene editing).

218. See *id.* (exploring different ways research grants can affect direction of gene editing research).

219. See *id.* (outlining central categories of gene editing restrictions).

220. U.S. DEP'T HEALTH & HUM. SERVS.: FOOD & DRUG ADMIN., HUM. GENE THERAPY PRODUCTS INCORPORATING HUM. GENOME EDITING: DRAFT GUIDANCE FOR INDUSTRY, 2 (2022).

221. See *supra* notes 104–08 and the accompanying text for a discussion on the U.S. approach to the Oncomouse patent.

222. *Harvard Coll. v. British Union for the Abolition of Vivisection (Transgenic Animals/HARVARD)*, Case T-0315/03–3.3.08, Judgment, Eur. Pat. Off. Tech. Bd. App., ¶ 5.1 (July 6, 2004).

223. See *id.* ¶ 8.1 (noting that patent cases must consider EPC Rule 23d(d), which requires denial of patent grants that concern modification of animal genetics that are likely to cause suffering without substantial medical benefits).

224. See *id.* ¶¶ 10.5–10.6 (noting that tests for assessment of cases regarding genetic material of animals weighs animal suffering and environmental risks against usefulness to mankind).

225. *Id.* ¶¶ 10.3–10.8.

226. *Id.* ¶ 13.2.

The Board also evaluated the public perception on using mice in cancer research.²²⁷ While the Board accepted that public opinion plays a role in the moral exception evaluation, it did not find this patent to meet the level of public disapproval that would prevent its patenting under the moral or *ordre public* exceptions.²²⁸ The public expressed unease about the patenting of animals, but similar to the balancing test applied by the Court, the public also recognized the importance of using animals for medical research.²²⁹

The European approach to balancing the benefits and risks of inventions that may be contrary to public morality is advantageous over the United States' approach because it explicitly allows the patent offices to take morality into account. Even Japan, which granted the Oncomouse patent,²³⁰ placed limits that could have prevented a morally repugnant invention if they considered transgenic animals met that ethical threshold. Without a morality exception, the United States must find a way to prevent a patent within one of the judicial exceptions or through other aspects of patent requirements beyond subject matter eligibility. Alternatively, the European approach allows for the law to evolve based on the public's perception of technology as it develops over time and is flexible enough to apply to technologies that may be unforeseen in the current biotechnology landscape.

IV. SHORTCOMINGS OF THE U.S. APPROACH AND VIABLE REMEDIES

A. *Issues with the U.S. Approach*

The purpose of the United States patent system is to foster technological innovation by providing incentives for continued R&D for the benefit of society.²³¹ However, by ignoring morality issues, the United States patent system overlooks potential technological harms that would conflict with this goal and consequentially be detrimental to the society the system aims to enhance.

The lack of clarity and protection over biotechnology patents in the last decade since the *Mayo* and *Myriad* decisions has opened the door to companies taking R&D elsewhere.²³² Because the biotechnology industry experienced a decrease in patent protection during this time, it has become a less attractive vehicle for investment, resulting in decreased funding and limited advancement in the field.²³³ The added

227. *See id.* ¶¶ 13.2.19–21 (discussing several public opinion polls that evaluated public perception of using mice in cancer research).

228. *See id.* (evaluating dichotomy in public perception of medical benefit to using animals for research versus public unease over patenting animals).

229. *See id.* (noting that, despite acceptance as beings that should not be abused, animals are still accepted as important in medical testing before resorting to human application).

230. Carolyn Brown, *Patenting Life: Genetically Altered Mice an Invention, Court Declares*, 163 CAN. MED. ASSOC. J. 867, 867 (2000).

231. *Patents*, WORLD INTELL. PROP. ORG., <https://www.wipo.int/patents/en/> (last visited Nov. 18, 2023).

232. *See* Nora J. McGuffey, *Praxair and the PTAB's Shadow Over Biotechnology Patents*, 20 UC DAVIS BUS. L.J. 111, 121 (2020) (explaining that biotechnology industries with little to no patent protection will receive less investment for research and development).

233. *Id.*

uncertainty also has the potential to drive R&D companies to turn to other forms of protection, such as trade secrecy, government grants and tax incentives, and protection outside the United States.²³⁴

One of the primary motivations behind the judicial exceptions to patentability is to ensure that patents do not tie up the tools of scientific and technological work by granting patents on laws of nature.²³⁵ However, the United States' use of judicial exceptions under this framework has gone too far and made it unclear what can be patented. While historically the United States was known for its generous patent standards of patent-eligible subject matter, there has been a change over the last decade.²³⁶ One study found the United States rejected over 1,700 patent applications on technologies that were not rejected in Europe.²³⁷ The Supreme Court's recent "failure to acknowledge the fundamental strength of biotechnology" puts the United States at a significant disadvantage unless its patent laws are altered to align with other countries.²³⁸ The recent uncertainty surrounding biotechnology patents has put the United States at risk of losing its reputation as a generous country for obtaining patents in the realm of patent-eligible subject matter.

Another big issue with the existing framework to patentable subject matter is the lack of input from the public on what is deemed morally acceptable. Underlying the patent system is an understanding that society approves of certain inventions and wants to promote and protect their existence and use.²³⁹ Under the current system, where there is a lack of consideration of ethical issues that may arise, the public is denied a meaningful opportunity to provide input on its approval or disapproval of morally questionable biotechnology.²⁴⁰ By failing to account for ethical implications at any point in the patenting process, there is a significant risk that the "social contract" of patents could be broken.²⁴¹

Morality clauses play an essential role in regulating ethical patents based on fundamental principles of human decency.²⁴² Human dignity, a founding principle

234. See David O. Taylor, *The Supreme Court's Revolution in Patent Eligibility Law: Alternative Protections for Biotechnology*, 37 NATURE BIOTECHNOLOGY 227, 229 (2019) (proposing alternative mechanisms to protect biotechnology investment following uncertainty in U.S. patent law).

235. See *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66, 86 (2012) (noting fears that granting laws of nature patents will inhibit future innovation and research).

236. See Taylor, *supra* note 234, at 229 (discussing changes in United States' attitude towards its standards for granting patents).

237. *Id.*

238. Gina Battaglia, *Rapid Advances in Biotechnology Bring Questions About Patentability*, BIORADIATIONS (May 11, 2016), <https://www.bioradiations.com/rapid-advances-in-biotechnology-bring-questions-about-patentability/>.

239. Mosby, *supra* note 217, at 585.

240. *Id.*

241. See *id.* at 584–86 (discussing impact on society of failing to account for ethical implications regarding the social contract between inventors and society to grant benefit on society in exchange for benefit of limited monopoly for inventor).

242. See María Carmelina Londoño-Lázaro & Juan F. Córdoba-Marentes, *Embedding Human Dignity Standards into Biotechnology Patents: The Role of Morality Clauses*, 12 EUR. J. RISK REGUL. 584, 592–593 (2021) (noting that ethical and moral attitudes of international legal system

of the international legal system, should be accounted for during an analysis of patentability to meet international standards.²⁴³ Specifically, in biotechnology, human dignity often serves as the basis for establishing the rights, conditions, and limitations of research that impacts humanity.²⁴⁴ From this fundamental principle, U.S. patent law needs to account for such an essential feature of biotechnological innovation to effectively promote progress while preventing potential abuses in the realm of risky, unknown science. Some of the potential risks associated with the failure to account for morality within patent law are the instrumentalization of human life, discrimination against certain genetic groups, and the commodification of human beings.²⁴⁵

The United States' judicially created exceptions to patentable subject matter are unnecessary as they could be predicated upon a morality exception. A provision for denying patents that are against public morals, like the European approach,²⁴⁶ could be in line with the judicially-created exceptions as against public morality. Within this framework, laws of nature, natural phenomena, and abstract ideas should be excluded from patentability following the same rationale that they would tie up the necessary information "free to all men,"²⁴⁷ essentially accomplishing the same goal with a foundation in legislation and clarity. By adopting a morality clause into its patent laws, the United States would more closely align itself with Europe and Japan to ensure uniformity. Additionally, this approach would enhance standards of morality to preserve human dignity and prevent potential abuses of unforeseen biotechnologies.

B. Solutions

The most effective way to ensure patents are evaluated for their potential abuses from a morality perspective would be to revive the moral utility doctrine,²⁴⁸ or to incorporate a morality standard for patentability through legislation like those used by other jurisdictions.²⁴⁹ By reviving the moral utility doctrine and applying it to modern biotechnology instead of using the current approach—judicial exceptions for laws of nature, abstract ideas, and natural phenomena²⁵⁰—the USPTO will be able to effectively evaluate the potential risks of developing biotechnologies before granting problematic technology a patent.

Because the USPTO is the first step in issuing a patent,²⁵¹ implementing a

have become criterion for moral analysis of inventions and patents).

243. *Id.* at 593.

244. *Id.* at 596.

245. *See id.* at 597–98 (discussing minimum threshold morality clauses should meet in biotechnology to preserve human dignity).

246. European Patent Convention, *supra* note 161, art 53.

247. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

248. *See supra* Part II.A for discussion of the history of the moral utility doctrine.

249. *See supra* Part III.A for full discussion of different morality standards used by other countries.

250. *Chakrabarty*, 447 U.S. at 309.

251. USPTO, *Patent Basics*, U.S. PAT. & TRADEMARK OFF., <https://www.uspto.gov/patents/basics> (last visited Nov. 19, 2023).

system to evaluate morality should be done at the patent examination phase before a patent is issued. To do so, Congress should amend the Patent Act to grant the USPTO power to deny patents based on a moral utility doctrine like the one provided in the TRIPS agreement.²⁵² Such an amendment would modernize the U.S. patent system to be consistent with those established in Europe and Japan and allow for input from the population regarding conduct contrary to public morality. The morality evaluation could also codify the exceptions to patentable subject matter and further clarify the guidelines for granting patents with regard to modern applications of biotechnology.

One potential issue with leaving the moral evaluation up to the USPTO is that patent examiners typically have technical backgrounds and may not be the best people to weigh in on complicated social policies such as morality.²⁵³ However, patent examiners are well-equipped to make these determinations—examiners are often experts in the technology and would be able to identify any potential morality issues that could come up if given proper guidance by Congress.²⁵⁴ This approach would allow Congress to fulfill the role of answering the question of “*should* society benefit” and the USPTO to continue to fulfill the role of answering the question of “*can* society benefit.”²⁵⁵ Patents that are improperly denied by examiners could be appealed to the Patent and Trial Appellate Board, ensuring that any patents that are improperly denied on morality grounds would be subject to review by a qualified board of patent judges.²⁵⁶ Any improper grants could be challenged in a variety of ways subject to review by similarly qualified judges.²⁵⁷

The USPTO could effectively incorporate a moral evaluation under a similar approach as Europe. The EPO provides guidance on what types of biotechnology would meet the threshold as contrary to *ordre public* or morality and Congress could follow a similar path.²⁵⁸ Additionally, the United States could remove any fear that the moral utility doctrine would be invoked too frequently by following Europe’s

252. TRIPS Agreement, *supra* note 154, art. 27(2).

253. See Enerson, *supra* note 21, at 720 (noting that patent law itself should not shape policy regarding what should be patentable and USPTO’s duty is only to decide whether inventions meet requirements).

254. See *Complete Guide to a Career as a Patent Examiner*, PAT. EDUC. SERIES, <https://www.patenteducationseries.com/patent-career/patent-examiner-career.html> (last visited Oct. 5, 2023) (noting that basic qualifications of a patent examiners include bachelor’s degrees in technical fields, such as science or engineering).

255. Enerson, *supra* note 21, at 720 (emphasis added).

256. 35 U.S.C. § 134; USPTO, *The Patent Trial and Appeal Board: Who Are They and What Do They Do?*, U.S. PAT. & TRADEMARK OFF., <https://www.uspto.gov/learning-and-resources/newsletter/inventors-eye/patent-trial-and-appeal-board-who-are-they-and-what> (last visited Nov. 19, 2023).

257. See Craig W. Kronenthal & H. Wayne Porter, *Three Ways to Challenge a Patent, TODAY’S GEN. COUNS.* (Jan. 2014), https://bannerwitcoff.com/_docs/library/articles/TGC.Kronenthal%20and%20Porter.pdf (establishing different mechanisms for challenging validity of patent after development of inter partes reviews (IPRs)).

258. EUR. PAT. OFF., *supra* note 165.

approach of invoking the doctrine only in rare circumstances.²⁵⁹

Following the approach of the EPO Oncomouse decision,²⁶⁰ the United States should perform the moral utility evaluation by weighing the potential harms and benefits to society.²⁶¹ A case-by-case balancing approach would allow the United States to account for the various interests at stake and evaluate potential misuses and risks of biotechnologies while also allowing the patent system to continue to promote innovation.²⁶² This approach could also be effectively applied to the exceptions to patentable subject matter as they currently exist within the framework of § 101.²⁶³ Rather than making a final determination of whether an invention is directed at laws of nature, natural phenomenon, or abstract ideas,²⁶⁴ courts and the USPTO could apply a more nuanced balancing test to determine the impact on future inventions if a patent is granted and weigh the potential harms against the benefits as a whole to society. Doing so would promote clarity and uniformity.

The idea of a balancing test for ethical standards is not novel in the United States. The FDA uses a similar approach in its evaluation of gene editing technologies and whether they should be granted approval.²⁶⁵ By addressing morality in both patent grants and FDA approval, the United States will effectively regulate technology throughout the lifecycle of biotechnology development. At the R&D phase, the FDA plays an insignificant role in regulation and approval,²⁶⁶ making the patent system a more effective means to ensure morally questionable research is stopped early. The United States should strive for consistency between technologies across different regulatory bodies rather than set different standards for patentability and FDA authorization.²⁶⁷ By ensuring different regulatory bodies have morality as a potential safety net in case biotechnology takes undesirable paths, the United States will be able to harmonize its laws within its own borders and with those of other economic leaders.

The United States could also follow the approach of Japan and include a morality provision that is hardly invoked. By combining the balancing approach of Europe and the relaxed application of Japan, the United States could have a “break in case of emergency” morality provision. By codifying clear standards of what is not patentable subject matter and leaving a broad morality exception in place to

259. *Id.*

260. See *supra* Section III.B.3 for full discussion of Oncomouse case in Europe.

261. *Harvard Coll. v. British Union for the Abolition of Vivisection (Transgenic Animals/HARVARD)*, Case T-0315/03–3.3.08, Eur. Pat. Off. Tech. Bd. App. (July 6, 2004).

262. Mosby, *supra* note 217.

263. 35 U.S.C. § 101 (1952).

264. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

265. U.S. DEP'T HEALTH & HUM. SERVS.: FOOD & DRUG ADMIN., *supra* note 220.

266. See Gregory Dolin, *Exclusivity Without Patents: The New Frontier of FDA Regulation for Genetic Materials*, 98 IOWA L. REV. 1399, 1449 (2013) (discussing balance needed between FDA and patenting because patents can be obtained on products that may not be marketed and sold without FDA approval).

267. See Abigail Perkins, *Gene[ie] in a Bottle: Regulating the Future of Man*, 21 TUL. J. TECH. & INTELL. PROP. 91, 103 (2019) (arguing Congress should grant FDA regulatory oversight of genetic technologies rather than rely on patent system to regulate them).

cover future inventions, the United States would have clear and complete patentability standards. In this way, it would strengthen its laws to limit confusion around patentable subject matter and emphasize the need to meet more important requirements of patentability, such as novelty and obviousness.

An approach that limits patentability in areas that the public finds morally unethical would also help to limit research in questionable areas of biotechnology.²⁶⁸ While denial of a patent does not prevent its use—and actually results in the invention ending up in the public domain—its denial serves as an effective mechanism to reduce investment in similar technologies where organizations know they will not be granted the luxury of a patent.²⁶⁹ By significantly deterring the economic incentive, commercial actors will be more reluctant to invest in an area and also run the risk of poor brand association if society has deemed those inventions as contrary to public morality.²⁷⁰

V. CONCLUSION

The United States has allowed the moral utility doctrine to fall dormant, and by doing so, has effectively abandoned an essential evaluation of patentability, especially considering the rapid development of biotechnology into previously unforeseen areas. Once an economic leader in patentability, the United States' failure to adopt morality standards consistent with TRIPS, Europe, and Japan puts it at risk of losing research and investment opportunities in an area ripe for investment and essential to developing better healthcare options.²⁷¹

Through years of inconsistent case law, the United States has attempted to evaluate patentable subject matter by deciding whether a patent would inhibit the use of fundamental tools for innovation. It has done so through judicially created exceptions denying patents if they are directed at laws of nature, natural phenomena, or abstract ideas, rather than approach the issue through legislation. The seldomly used moral utility doctrine has not been invoked in decades, and when used in the past, was not effectively applied in a way that would be amenable to the complicated issues that arise with biotechnology.

The TRIPS agreement allows countries to adopt a provision to deny patentability based on being contrary to *ordre public* or morality. While notions of what is considered moral may vary based on cultural differences between countries, many countries have adopted this morality standard and apply it in their patent laws based on the ethical expectations and requirements of their citizens. By having the option to deny patents as contrary to morality, these countries are well-equipped to deal with potential unforeseen consequences in the rapidly developing world of biotechnology.

268. Matthews et al., *supra* note 213, at 583.

269. *Id.*

270. *Id.*

271. The global biotechnology market is expected to be worth around 3.44 trillion by the year 2030. *Biotechnology Market Size to Worth Around US\$ 3.44 Trillion by 2030*, BIOSPACE (Apr. 25, 2022), <https://www.biospace.com/article/biotechnology-market-size-to-worth-around-us-3-44-trillion-by-2030/>.

In the last few decades, we have seen an influx of inventions that pose all kinds of ethical concerns, ranging from improper uses to unknown risks.²⁷² Some of the most prevalent in biotechnology involve the use of human embryonic stem cells, gene editing and therapies, and the creation of transgenic animals. These biotechnologies benefit humankind extraordinarily while also posing serious moral dilemmas regarding their use. By following the approach of other countries, the United States can learn from its past mistakes and clarify its patent laws on modern biotechnology to encourage innovation while also providing safeguards against their potential misuse.

This Comment poses a solution to the United States' approach by enabling the USPTO to weigh the moral implications of inventions as a factor in evaluating whether to grant a patent. To do so, Congress must first adopt morality standards, like those legislatively governed in Europe and Japan, and provide the USPTO with the proper guidance and tools to effectively implement this system. A balancing approach that weighs potential moral implications with net societal benefits for breakthrough biotechnology may be the best way for the United States to secure its position as an economic leader while promoting ethical patent regulation.

272. See Abu Sadat Mohammad Nurunnabi et al., *Societal Concerns with Biotechnology and Necessity of Regulation*, 10 BANGL. J. BIOETHICS 7, 9 (2019) (demonstrating many societal concerns that have arisen because of increased research and development in field of biotechnology).