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NOTE

THE DEGREE OF ALTERATION NECESSARY FOR PATENT ELIGIBILITY OF SYNTHETICALLY PRINTED DNA POST *MYRIAD* *GENETICS*

*Hannah Joy Coad*¹

ABSTRACT

Genetic engineering advancements are exponentially increasing, allowing for new organisms with unique DNA fingerprinting. It is now possible to 3D print synthetically created DNA molecules with functional nucleotides, which can be used to create new sequences of genes. These designed genes which do not naturally occur may be patent eligible. Post *Myriad Genetics*, lower courts have struggled to coherently apply a reasonable standard to evaluate whether a synthetically engineered gene is patent eligible, and thus, clarification is needed from Congress on this issue. This note evaluates the question: to what extent must DNA be altered through intron and exon splicing or through adding or deleting nucleotide sequences to render the strand patent eligible? Through evaluating pertinent and recent case analysis, one sees how currently there is a penumbra of ambiguity around the answer. Courts utilize both subjective and objective standards. These standards include that the patented DNA must be “materially different” from that which is a natural phenomenon, and the newly created DNA must be “distinguishable” from the original.

Under the landmark case, *Diamond v. Charkabarty*, the Supreme Court ruled that 35 U.S.C. § 101 includes patent protection for live man-made microorganisms. In subsequent years, this protection has extended to the process for creating clones, vaccines, DNA sequences used to create new organisms, and to growing human organs in mammals such as horses. Genetic engineering is a timely issue as global efforts, such as Genome Project-Write, seek international support on the project to recreate a human genome from scratch. This project, headed by the Center for Excellence for Engineering Biology, carries support of nearly 200 scientists affiliated with more than 100 institutions in 15 countries. The *New York Times* stated, “[I]t

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might be possible . . . to use a synthetic genome to create human beings without biological parents.” Under current patent law, a synthetically printed human genome with removed introns and disease-causing sequences may be patent eligible. The financial benefits to owning the intellectual property (IP) rights to such a genome and the growing public desire to design ones’ offspring further drive the race to this scientific development.

Under *Alice*’s two-part framework for analyzing patentability, the mere fact that cDNA is created through synthetic gene printing would not render the DNA patent eligible. It is legally insignificant how unique or innovative the process is which creates the product. The process must add or change something to the product itself. Utilizing gene printing would make it faster and more cost effective to print millions of potentially patentable genes.

The Supreme Court has recognized the potential risks of genetic engineering while at the same time acknowledged that barring patent grants in this field would do little to deter curious minds. While the debate continues as to the ethical implications of patenting synthetically printed human DNA, it is widely recognized that gene patents have done much to advance medical and biological research. A strong patent system is indispensable to a developed society and instrumental in propelling global advancement and cooperation. Thus, in its clarification on gene patenting, it is recommended that Congress carefully weigh the ethical implications of owning rights to the genetic information imprinted within a synthetically created genome while at the same time promoting protection to innovative researchers who are in the business of advancing science. While it is arguably an advantage to scientific development for laws to lag the vector of discovery, the time is ripe for Congress to clarify what would make a synthetically created gene patent eligible under § 101.

I. INTRODUCTION

Through scientific advancements, it is now possible to 3D print synthetic DNA molecules that can be used to create new living organisms. This note evaluates these developments under current patent precedent, while also considering the moral and ethical implications of patenting human DNA.²

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2. A patent is a right granted by the government to an inventor giving the exclusive right to foreclose others from making, using, selling, or importing the invention protected by the patent. The period of time in which an inventor has exclusive rights is 20 years. An inventor may obtain a utility patent on a process, machine, manufacture, composition of matter, or an improvement of any of these.

Kurt Saunders explains in his book, *Intellectual Property Law*, “[O]ngoing advances in biotechnology research and genetic engineering make it possible to imagine the creation of ‘designer’ genes and living organisms that may qualify for patent or trade secret protection.”³ It is the role of Congress, and not the courts, to define the limits of patentability, though the courts play an indispensable role of interpreting patent law and coloring in areas of ambiguity. One area needing particular clarification and legal development involves the extent to which DNA or cDNA must be altered from a naturally occurring DNA sequence to be deemed patent eligible. As *The New York Times* stated, “[I]t might be possible . . . to use a synthetic genome to create human beings without biological parents.”⁴

II. BACKGROUND ON PATENTABLE SUBJECT MATTER IN RELATION TO BIOLOGICAL SYSTEMS

A. *The Structure of Deoxyribonucleic Acid*

Deoxyribonucleic acid (DNA) consists of “two polynucleotide chains running in opposite directions,” which are “held together by hydrogen bonds between the bases.”⁵ The chains are complementary to each other, meaning that the “pairing of the bases is specific, adenine pairing with thymine and guanine with cytosine.”⁶ Nucleotides, the building blocks of DNA, have a phosphate-sugar portion, which contains a “5-prime” end and a “3-prime” end binding through hydrogen bonds.⁷ Human DNA contains 3 billion bases divided into twenty-three pairs of chromosomes.⁸ DNA has immense information-storing capacity with one gram of DNA storing the equivalent of fifty million DVDs worth of information.⁹ When a gene is expressed, it

3. *Id.* at 2.

4. Andrew Pollack, *Scientists Talk Privately About Creating a Synthetic Human Genome*, N.Y. TIMES (May 13, 2016), <https://www.nytimes.com/2016/05/14/science/synthetic-human-genome.html>.

5. F.H.C. Crick, *The Structure of DNA*, in A SYMPOSIUM ON THE CHEMICAL BASIS OF HEREDITY 532, 532 (William D. McElroy & Bentley Glass eds., 3d prtg. 1961), <https://ia801901.us.archive.org/3/items/in.ernet.dli.2015.502121/2015.502121.A-Symposium.pdf>.

6. *Id.*

7. *Roche Molecular Sys., Inc. v. Cepheid*, No. 14-cv-03228-EDL, 2017 U.S. Dist. LEXIS 113280, at *4 (N.D. Cal. Jan. 17, 2017), *aff'd*, 905 F.3d 1363 (Fed. Cir. 2018).

8. Umberto S.P. Melia et al., *Exons and Introns Characterization in Nucleic Acid Sequence by Time-Frequency Analysis*, in 32ND ANNUAL INTERNATIONAL CONFERENCE OF THE IEEE ENGINEERING IN MEDICINE AND BIOLOGY SOCIETY 1783, 1783 (2010), <https://upcommons.upc.edu/bitstream/handle/2117/10677/05626756.pdf>.

9. Robert Sanders, *New DNA Synthesis Technique Promises Rapid, High-Fidelity DNA Printing*, BERKELEY NEWS (June 18, 2018), <http://news.berkeley.edu/2018/06/18/new-dna-synthesis-technique-promises-rapid-high-fidelity-dna-printing/>.

unwinds to make a single-strand copy of pre-messenger RNA (pre-mRNA) that is then edited into mRNA.¹⁰

Introns, which are non-coding DNA, are not translated into proteins and therefore are removed.¹¹ These introns are spliced out from the exon segments; the exons contain the coding regions of the DNA.¹² The product is a continuous coding section of DNA, which can be translated into a protein for the cell.¹³ Some complex organisms' biological signals may allow some introns to remain in the RNA transcript, which become coding sequences.¹⁴ Two types of molecular machinery are utilized in splicing pre-messenger RNA.¹⁵ The first type is basal machinery, which consists of five small nuclear RNA molecules (sRNA), which form a spliceosome complex that is responsible for recognizing the sites where introns start and end.¹⁶ The second type of machinery is the gene regulation system, which "controls the process of splicing and cutting" by giving orders to the basal machinery.¹⁷

Complementary DNA (cDNA) is synthesized from mRNA in a reaction that is "catalyzed by the reverse transcriptase and DNA polymerase enzymes."¹⁸ cDNA is used to express certain proteins in cells during heterologous expression.¹⁹ The code in the cDNA will be transmitted for the protein to the cell.²⁰ The enzyme reverse transcriptase is used to generate cDNA by pairing RNA base pairs to DNA complements.²¹

Polymerase chain reaction (PCR) is a "well-understood" and "conventional" method of multiplying identical DNA strands for scientific research.²² DNA's double strands are separated, and primers are used to bind

10. Melia et al., *supra* note 8.

11. *Id.*

12. *Id.*

13. *Id.*

14. *Id.*

15. *Id.*

16. Melia et al., *supra* note 8.

17. *Id.*

18. *cDNA (Complementary DNA)*, HUMANGENES.ORG, <http://humangenes.org/cdna-complementary-dna> (last visited Oct. 3, 2019). "DNA polymerases are enzymes that synthesize new DNA by moving along the template strand and synthesizing a new strand of complementary DNA sequence by nucleotide polymerization in the 5' to 3' direction." Zoi Lygerou, *DNA Polymerases*, in *ENCYCLOPEDIA OF SYSTEMS BIOLOGY* 610, 610 (Werner Dubitzky et al. eds., 2013).

19. *cDNA (Complementary DNA)*, HUMANGENES.ORG, <http://humangenes.org/cdna-complementary-dna> (last visited Sept. 3, 2019).

20. *Id.*

21. *Id.*

22. *Roche Molecular Sys., Inc. v. Cepheid*, No. 14-cv-03228-EDL, 2017 U.S. Dist. LEXIS 113280, at *6 (N.D. Cal. Jan. 17, 2017), *aff'd*, 905 F.3d 1363 (Fed. Cir. 2018).

to the targeted segment of the strand to be copied which begins the process.²³ The enzyme polymerase binds to the strand of DNA beginning at the primer and adds nucleotides complementary to the DNA.²⁴ This amplification process exponentially increases the amount of identical DNA in the sample.²⁵

B. *Scientific Advancements in DNA Printing and Genome Project-Write*

Biotech companies now are printing and selling synthetic DNA.²⁶ This promising area of science enables the printing of base pairs, which make copies of DNA quickly and cheaply.²⁷ Synthetically printed DNA allows researchers quick access to custom made DNA strands, which are tailored to their specific needs.²⁸ Coding sequences are first placed on metal beads that emit different colors.²⁹ Next, a computer scans millions of pieces of DNA taking pictures to read the sequences.³⁰ The correct stretch of DNA is printed by firing a laser beam at a glass tray with millions of beads coated with DNA.³¹ The laser propels the bead with the DNA into the tray and sorts the DNA into the correct sequence.³²

Synthetically printed DNA used by drug companies in medical research has numerous other applications, such as growing synthetic tissues, engineering plants, or creating new organisms.³³ Austen Heinz, the CEO of Cambrian Genomics in San Francisco, “envisions a day when mass-produced DNA can genetically engineer people—or let anyone use DNA like computer code to design their own organisms.”³⁴ Heinz stated, “[A]s a race, or as a

23. *Id.*

24. *Id.*

25. *Id.* at *6–7.

26. Rob Stein, *DNA ‘Printing’ a Big Boon to Research, but Some Raise Concerns*, NPR (May 7, 2015, 4:56 PM), <https://www.npr.org/sections/health-shots/2015/05/07/404460240/dna-printing-a-big-boon-to-research-but-some-raise-concerns>; see also *Custom Oligos*, TRILINK BIOTECHNOLOGIES, <https://www.trilinkbiotech.com/custom-oligos> (last visited Sept. 3, 2019).

27. Stein, *supra* note 26.

28. *Id.*

29. *Id.*

30. *Id.*

31. *Id.*

32. *Id.*

33. Ian Sample, *Organisms Created with Synthetic DNA Pave Way for Entirely New Life Forms*, GUARDIAN (Jan. 24, 2017, 2:01 AM), <https://www.theguardian.com/science/2017/jan/23/organisms-created-with-synthetic-dna-pave-way-for-new-entirely-new-life-forms> (“[C]ells [created in laboratory experimentation] constitute a ‘stable form of semi-synthetic life’ and ‘lay the foundation for achieving the central goal of synthetic biology: the creation of new life forms and functions””).

34. Stein, *supra* note 26.

species we have a goal of improving who we are.”³⁵ UC Berkeley and Lawrence Berkeley National Laboratory have invented a new way to synthesize DNA that is more accurate and faster than previous methods and can produce DNA strands that are ten times longer than previous techniques.³⁶

The Center of Excellence for Engineering Biology has gained global support for the Human Genome Project-Write (GP-write).³⁷ Scientists believe that to understand humanity’s genetic blueprint, it is necessary to rebuild human genomes from scratch, which could be completed within ten years.³⁸ GP-write is an “international research project led by a multi-disciplinary group of scienti[sts]” and researchers who work on “genome-scale engineering, as well as transformative medical applications.”³⁹ The GP-write Consortium boasts that there are “nearly 200 scientists, affiliated with more than 100 institutions [or] companies in 15 countries” who have expressed interest in participating in GP-write.⁴⁰ Represented countries in the consortium include the USA, China, Israel, Germany, Japan, and Pakistan.⁴¹ With a global effort to rebuild a human genome, an international operation, such as the Center of Excellence for Engineering Biology, may seek patent filing assistance from the World Intellectual Property Organization, “a self-funding agency of the United Nations, with 192 member states.”⁴² This organization works under the Patent Cooperation Treaty, which was signed into international law in 1970.⁴³ It provides a unified patent filing procedure

35. *Id.*

36. Sanders, *supra* note 9.

37. Jef Boeke et al., *GP-write: A Grand Challenge Using DNA Synthesis, Gene Editing and Other Technologies To Understand, Engineer and Test Living Systems*, CTR. EXCELLENCE FOR ENGINEERING BIOLOGY 5 (May 9–10, 2017), <http://engineeringbiologycenter.org/wp-content/uploads/2017/10/GP-write-2017-summary.pdf>. In 2003, the Human Genome Project-Read was completed and recognized as one of the greatest feats of modern science. *The Human Genome Project*, NAT’L HUM. GENOME RES. INST., <https://www.genome.gov/human-genome-project> (last visited Sept. 7, 2019).

38. CTR. EXCELLENCE FOR ENGINEERING BIOLOGY, <https://engineeringbiologycenter.org> (last visited Sept. 4, 2019); *see also GP-write Consortium*, CTR. EXCELLENCE FOR ENGINEERING BIOLOGY, <http://engineeringbiologycenter.org/gp-write-consortium/> (last visited Sept. 4, 2019).

39. *GP-write Consortium*, *supra* note 38.

40. *Id.*

41. *Id.*

42. *Inside WIPO*, WORLD INTELL. PROP. ORG., <https://www.wipo.int/about-wipo/en/> (last visited Sept. 4, 2019).

43. *Summary of the Patent Cooperation Treaty (PCT) (1970)*, WORLD INTELL. PROP. ORG., https://www.wipo.int/treaties/en/registration/pct/summary_pct.html (last visited Sept. 4, 2019).

to protect inventions in its 192 contracting nation-states.⁴⁴ The international patent application is called an international application or a PCT application. The United States became a member of the treaty on January 24, 1978.⁴⁵

C. *Patentable Subject Matter Under 35 U.S.C. Chapter 10*

The first step in understanding the patent eligibility of synthetically printed DNA is evaluating the topic through the lens of the Constitution and statutory law. The U.S. Constitution includes the patent and copyright clause, which is the foundation of intellectual property (IP) rights.⁴⁶ It grants Congress the power to “promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”⁴⁷

To obtain a patent, an individual must show the claim is an invention and is, therefore, a patentable subject matter.⁴⁸ The invention must have utility, show novelty, be nonobvious, and have a written description adequate to embodiment.⁴⁹ Under 35 U.S.C. § 101, an inventor who “discovers any new and useful process, machine, manufacture, or composition of matter” may be able to obtain a patent.⁵⁰ Patentable subject matter includes that which is an improvement.⁵¹ 35 U.S.C. §102 covers the novelty requirement for patentability.⁵² The patent’s subject matter must not be contained in patented prior art, “described in a printed publication, or in public use.”⁵³ Under 35 U.S.C. § 103, the invention may not be obvious before the filing date of the claimed invention “to a person having ordinary skill in the art to which the claimed invention pertains.”⁵⁴ It is helpful to evaluate common-law interpretations of these sections.

44. See *Member States*, WORLD INTELL. PROP. ORG., <https://www.wipo.int/members/en/> (last visited Sept. 4, 2019).

45. See *The PCT Now Has 153 Contracting States*, WORLD INTELL. PROP. ORG., https://www.wipo.int/pct/en/pct_contracting_states.html (last visited Oct. 30, 2019).

46. U.S. CONST. art. I, § 8, cl. 8.

47. *Id.*

48. SAUNDERS, *supra* note 2, at 107.

49. *Id.*

50. 35 U.S.C. § 101 (2017).

51. *Id.*

52. 35 U.S.C. § 102 (2017).

53. *Id.*

54. 35 U.S.C. § 103 (2017).

D. *Patents on Live Organisms under Diamond*

In the landmark case, *Diamond v. Charkrabarty*, the Supreme Court held that live, man-made microorganisms are patentable under 35 U.S.C. § 101.⁵⁵ *Diamond* has become a cornerstone for gene patenting law, and thus an examination into the Court's rationale is helpful in understanding the potential patentability of synthetically printed DNA. In *Diamond*, a microbiologist filed for a patent assigned to General Electric Co. relating to the creation of man-made, genetically engineered bacteria specially designed to break down crude oil.⁵⁶ No naturally occurring organism had such a capacity.⁵⁷ The patent application had thirty-six claims, including the claim to the new bacteria itself derived from the genus *Pseudomonas*.⁵⁸ The bacteria contained "at least two stable energy-generating plasmids" ideal for decomposing crude oil.⁵⁹ Initially, the patent examiner rejected the microbiologist's claim based on the grounds that "living things . . . are not patentable subject matter under 35 U.S.C. §101."⁶⁰

The United States Patent and Trademark Office Board of Appeals affirmed the examiner's rejection of the application.⁶¹ However, the United States Court of Customs and Patent Appeals ultimately reversed, and its decision was upheld by the Supreme Court.⁶² The fact that the microorganism was alive was without legal significance in patent law, opening the door for the patentability of live organisms and larger mammals—including, potentially, humans.

The Court reasoned the microbiologist's microorganism constituted a manufacture or composition of matter under § 101, which was not a naturally occurring phenomenon, nor was it obvious.⁶³ The Court turned to legislative intent in interpreting "any" composition of matter as contemplating a wide scope of broad construction for patent protection.⁶⁴ The Court stated, "[C]omposition of matter' has been construed . . . to include 'all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture.'"⁶⁵

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

56. *Id.* at 305.

57. *Id.*

58. *Id.*

59. *Id.*

60. *Id.* at 306.

61. *Diamond*, 447 U.S. at 306.

62. *Id.* at 306, 318.

63. *Id.* at 309.

64. *Id.* at 308.

65. *Id.* at 308 (quoting *Shell Dev. Co. v. Watson*, 149 F. Supp. 279, 280 (D.D.C. 1957)).

The Court found the microorganism fell within this definition, having been created through human ingenuity and having a distinctive name, use, and purpose.⁶⁶

The petitioner had two main arguments on appeal.⁶⁷ The first argument rested on the fact that Congress had passed the Plant Patent Act and Plant Variety Protection Act.⁶⁸ In the petitioner's view, these acts would not have been necessary had Congress intended to grant patent protection to living things.⁶⁹ The Court rejected this argument.⁷⁰ The Court recognized that, by passing these acts, Congress intended to remove barriers believed to be in place to the patentability of cultivated plant types.⁷¹ In referring to these acts, the Court wrote, "Congress thus 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."⁷²

Petitioner's second argument was that at the time it passed § 101, Congress could not have intended the statute to include patents on living organisms and thus did not expressly authorize such protection.⁷³ Here, the Court turned to the broad terms of the statute, which has the statutory goal of promoting the arts and sciences.⁷⁴ The Court concluded, "Congress employed broad general language in drafting § 101 precisely because such inventions are often unforeseeable."⁷⁵ The statute was meant to adapt

66. *Id.* at 309–10.

67. *Diamond*, 447 U.S. at 310.

68. *Id.* at 313.

69. *Id.* at 311–12.

70. *Id.* at 311.

71. *Id.* at 312–13.

72. *Id.* at 313. Products of nature are not patent eligible:

[P]atents cannot issue for the discovery of the phenomena of nature. The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.

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

73. *Diamond*, 447 U.S. at 314.

74. *Id.* at 315.

75. *Id.* at 316.

alongside the progress of science.⁷⁶ Referencing the petitioner's argument, the Court wrote:

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 creates⁷⁷

The Court reasoned that regardless of its ruling on respondent's claims, scientific biomolecular research would continue, along with its inherent risks.⁷⁸ Since a large body of scientific research is conducted without knowledge of whether the end result will be patentable, the Court found that if it were to invalidate respondent's claim to the microorganism, it would do little to deter the creation of and experimentation with genetically engineered organisms.⁷⁹ Therefore, the Court held the bacterium was new "with markedly different characteristics from any found in nature and one having the potential for significant utility."⁸⁰ The discovery was the microbiologist's own handiwork engineered and altered from that found in nature.

The Court did not define that which would be "markedly different" from that of nature, leaving the question of how markedly different need the change be? This question is still largely unanswered. In his dissent, Justice Brennan expressed his view that the Court had expanded the meaning of § 101 beyond its legislative intent.⁸¹ In doing so, he stressed, the Court had granted patent protection to that which "uniquely implicates matters of public concern."⁸²

III. EVALUATING PATENTABLE SUBJECT MATTER UNDER *MYRIAD*, *MAYO*, AND THE *ALICE* FRAMEWORK

A. *Myriad and the Patentability of cDNA*

In *Association for Molecular Pathology v. Myriad Genetics, Inc.*, Myriad Genetics (Myriad) obtained several patents on the discovery of the location

76. *See id.*

77. *Id.*

78. *Id.* at 317.

79. *Diamond*, 447 U.S. at 317.

80. *Id.* at 310.

81. *Id.* at 321 (Brennan, J., dissenting).

82. *Id.* at 322.

of BRCA1 and BRCA2 sequences in genes.⁸³ Myriad contended not only that its patents were valid but that it owned an exclusive right to create BRCA cDNA.⁸⁴ The Supreme Court was tasked with resolving two key issues: Whether naturally occurring segments of DNA were patent eligible by virtue of its isolation from the rest of the human genome, and whether cDNA, which only contains protein coding information, was patent eligible.⁸⁵ The Court held naturally occurring DNA segments that are products of nature are not patent eligible under Title 35 U.S.C. § 101.⁸⁶ The Court explained the role of mutations, which cause small alterations of a single nucleotide in a strand of DNA.⁸⁷ While small changes may produce different amino acids, larger changes can result in the “elimination, misplacement, or duplication” of certain genes.⁸⁸ Some mutations are a naturally occurring part of the gene duplication process and are harmless, but other mutations may lead to diseases.⁸⁹ Myriad developed medical tests to detect the mutations in the BRCA1 and BRCA2 genes located on chromosomes 17 and 13.⁹⁰ Mutations to these sequences can increase the risk of breast and ovarian cancer.⁹¹ Women in the United States on average have a twelve to thirteen percent risk for breast cancer, but with certain mutations to key genes, the risk rises to between fifty and eighty percent.⁹²

Before Myriad’s breakthrough discovery, scientists knew that a woman’s heredity genes played a part in whether she would develop breast cancer.⁹³ However, scientists were uncertain where the gene was located.⁹⁴ Through its discovery, Myriad developed tests for detecting mutations in the BRCA1 and BRCA2 genes and sought composition patent claims which were of issue in the case.⁹⁵ The Court reasoned that mere isolation of BRCA1 and BRCA2,

83. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 579, 582 (2013).

84. *Id.* at 585.

85. *Id.* at 580.

86. *Id.*

87. *Id.* at 582.

88. *Id.*

89. *See, e.g.*, Bruce N. Ames, *Identifying Environmental Chemicals Causing Mutations and Cancer*, 20 *JURIMETRICS J.* 326, 326 (1980).

90. *Myriad*, 569 U.S. at 583.

91. *Id.* at 582–83.

92. *Id.* at 583.

93. *Id.*

94. *Id.*

95. *Id.* at 583–84.

“basic tools of scientific and technological work,” was comparable to discovering a law of nature or natural phenomena.⁹⁶

The Supreme Court further held that cDNA was patent eligible because it was not naturally occurring but was made within laboratory conditions and sufficiently altered.⁹⁷ Justice Thomas delivered the opinion of the Court:

cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA segments cDNA is not a “product of nature” and is patent eligible under § 101

. . . .

[We do not] consider the patentability of DNA in which the order of the naturally occurring nucleotides has been altered. Scientific alteration of the genetic code presents a different inquiry, and we express no opinion about the application of § 101 to such endeavors.⁹⁸

Justice Thomas left open for discussion the question of what constitutes patent eligible cDNA and to what extent DNA must be altered for it to be patent eligible.⁹⁹ In its conclusion, the Court made clear that merely isolation does not pass a gene claim into the realm of patent eligibility—the Court left unanswered questions concerning cDNA.¹⁰⁰ The Court pointed out that all three justices in the circuit court below, while expressing differing opinions as to the patentability of isolated DNA, agreed that the claims related to Myriad’s cDNA were valid.¹⁰¹ These circuit justices recognized that under § 101, cDNA was patent eligible since it was created in the laboratory and the introns had been removed from the larger segment.¹⁰² In his concurring opinion, Justice Scalia stated, “[cDNA] is a synthetic creation not normally present in nature” and therefore ought to be patent eligible in contrast to that DNA which is merely isolated and identical to the portion of the DNA in its natural state.¹⁰³ But to what degree must DNA or cDNA be altered to be

96. *Myriad*, 569 U.S. at 589 (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 92 (2012)) (internal quotation marks omitted).

97. *Id.* at 594–95.

98. *Id.* at 594–96.

99. *Id.* at 596.

100. *Id.*

101. *Id.* at 586–87.

102. *Myriad*, 569 U.S. at 588–89.

103. *Id.* at 596 (Scalia, J., concurring).

patent eligible?¹⁰⁴ How close can cDNA be to DNA while still maintaining its patent eligible status? The Supreme Court has yet to make a defining ruling, which has left district and circuit courts on their own to draw the line in an ever-changing scientific environment.¹⁰⁵

B. *Mayo's Combination of Abstract Ideas*

In *Mayo Collaborative Services v. Prometheus Laboratories*, the Supreme Court evaluated patent eligibility of a method for determining the proper dosage of thiopurine drugs, which were metabolized differently by patients.¹⁰⁶ Each patent claimed an administering step for the doctor to provide the patient with the drug and a determining step by which the doctor was to measure the resulting metabolite levels in the patient's blood.¹⁰⁷ Lastly, the patent described the metabolite concentration above which it was likely the patient would develop a side effect from the drug.¹⁰⁸ The Court held that Mayo's patents covered an ineligible subject matter since they recited laws of nature—the "relationships between concentrations of certain metabolites in the blood and the likelihood that a thiopurine drug dosage will prove ineffective or cause harm."¹⁰⁹ The Court ruled that laws of nature, natural phenomena, and abstract ideas¹¹⁰ are not patent eligible, and since the process for determining drug concentration, dosage, and evaluation of the results did not build off of previous science, Mayo's patents did not pass the test.¹¹¹

C. *Alice and the Two-Part Framework*

In *Alice Corporation v. CLS Bank International*, the Supreme Court evaluated several patents that Alice Corporation held for mitigating settlement risk, which is one of the risks assumed during an agreed-upon financial transaction.¹¹² A computer system was to act as a third-party

104. *Id.* at 596 (majority opinion).

105. *See id.*

106. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012).

107. *Id.* at 66.

108. *Id.*

109. *Id.* at 67.

110. *Id.* at 66. Early cases in the United States established that abstracts ideas are not patent ineligible. "A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right." *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1853). "An idea of itself is not patentable, but a new device by which it may be made practically useful is." *Rubber-Tip Pencil Co. v. Howard*, 87 U.S. (20 Wall.) 498, 507 (1874).

111. *Mayo*, 566 U.S. at 67.

112. *Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 208 (2014).

intermediary in the risk mitigation.¹¹³ The patents in the suit claimed three things: (1) a method to “exchang[e] financial obligations,” (2) a computer system to carry out this exchange, and (3) a computer-readable medium.¹¹⁴ Respondent, CLS Bank, which operated a global network facilitating currency transactions, stated that the patents held by Alice were invalid.¹¹⁵ In evaluating whether Alice’s patents were valid, the Court laid out a two-part framework for analyzing patent eligibility under § 101.¹¹⁶ The first step is for the court to decide if the subject matter at issue is “directed to a patent-ineligible concept.”¹¹⁷ If so, the second step is for the Court to determine whether the claim’s elements, taken in combination, form something new and “transform the nature of the claim’ into a patent-eligible application.”¹¹⁸

Applying this framework to Alice’s patents, the Court first found that the method did nothing more than implement an abstract idea on a generic computer.¹¹⁹ Taking the elements separately, the court found “creating and maintaining ‘shadow’ accounts, obtaining data, adjusting account balances, and issuing automated instructions” were not, by themselves, separately patent eligible.¹²⁰ Secondly, the Court considered whether these functions in the aggregate added something new or nonconventional, which may be patent eligible.¹²¹ The Court found that, viewed in the entirety, the claims added no improvement significant enough to transform the abstract ideas and conventional components into a patent-eligible invention.¹²² Therefore, Alice’s patents were held to be invalid.¹²³

V. ANALYSIS OF HOW SYNTHETICALLY-PRINTED DNA WITH REMOVED INTRONS AND DISEASE-CAUSING SEQUENCES WOULD BE TREATED UNDER CURRENT LAW

A. *Analysis of Synthetic DNA under Diamond, Myriad, Mayo, and Alice*

Synthesizing the rules laid out in *Diamond*, *Myriad*, *Mayo*, and *Alice* satisfies a critical step to analyzing the question: To what extent must synthetically printed DNA be altered to be patent eligible? Under *Diamond*,

113. *Id.*

114. *Id.*

115. *Id.*

116. *Id.* at 208–09.

117. *Id.* at 208 (citing *Mayo*, 566 U.S. 66, 77).

118. *Alice*, 573 U.S. at 208–09 (quoting *Mayo*, 566 U.S. 66, 79).

119. *Id.* at 209.

120. *Id.* at 209–10.

121. *Id.* at 210.

122. *Id.*

123. *Id.*

the Supreme Court ruled that the language of § 101, which included any “composition of matter,” encompassed the patentability of live organisms.¹²⁴ *Diamond* opened the gateway for a flood of patents on live organisms varying from plants and mammals to vaccines. Under *Myriad*, the Court held that cDNA was patent eligible because it was not naturally occurring since the introns had been removed from the sequence and therefore created a new strand.¹²⁵ Building off *Diamond*, *Myriad* held that synthetically printed DNA is patent eligible when sequences such as introns are removed, creating new nucleotide patterns.¹²⁶ The *Myriad* Court held that a lab could not have exclusive rights to isolate an individual’s BRCA1 and BRCA2 genes.¹²⁷ Recall that mutations to the BRCA1 and BRCA2 genes increased one’s chance of developing breast or ovarian cancer.¹²⁸ However, removing the BRCA1 and BRCA2 genes from a human genome, along with other alterations, may be considered enough change to move the sequence into the realm of patent eligibility.

The *Mayo* Court ruled that mere scientific relationships such as laws of nature and natural phenomena were not patent eligible.¹²⁹ Relationships and concentrations within biological systems are key to functionality, and though a new discovery may be groundbreaking, it is not patent eligible.¹³⁰

The Supreme Court’s two-part framework in *Alice* for analyzing patentability helps determine whether a scientific, multistep process is patent eligible. Two potential claims will be analyzed using this framework. The first claim is that a synthetically printed human genome would be patent eligible if it is a direct copy of a naturally occurring genome. The second claim is that a synthetically printed human DNA, which has been modified by removing such sequences as BRCA1, BRCA2, along with the removal of other naturally occurring sequences, would be patent eligible.

The first step under the *Alice* framework is to consider whether the step in and of itself would be patent eligible.¹³¹ The patent claim must be directed to and not just be based upon the intelligible concept.¹³² If the claim were based solely on the fact that the DNA was synthetically printed, it would not be directed to a patent eligible concept since synthetically printed DNA would not in itself be distinct from that which is in nature. However, the second

124. *Diamond v. Chakrabarty*, 447 U.S. 303, 307, 310 (1980).

125. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 594–95 (2013).

126. *Id.* at 577.

127. *Id.* at 585.

128. *Id.* at 576.

129. *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 92 (2012).

130. *Id.* at 66–67.

131. *Alice Corp. v. CLS Bank Int’l*, 573 U.S. 208, 217 (2014).

132. *Id.* at 218.

claim of altered DNA would pass the first step in the *Alice* framework, as the altered human genome would be different from that which is naturally occurring.

Step two of the *Alice* framework is only necessary if the claim does not pass the first step and if the claim is directed to an abstract idea. If the claim under step one is not directed to a patentable concept, it might still be saved under this second step if it contains an inventive concept. Synthetically printed DNA is an innovative concept, but it is not directed to an abstract idea. Instead, it is a means or a process of producing a physical product. Therefore, under *Alice*, the mere printing of the DNA would not render the product patent eligible. If the synthetically printed DNA were altered and transformed, it would be patent eligible. The question remains as to the degree of alteration necessary for it to be patent eligible. In other words, how close may the synthetically printed DNA be to a human's DNA while still being eligible for patent protection? To evaluate this question in more detail, it is helpful to carefully examine district and circuit court decisions post-*Myriad*.

B. *District and Circuit Court Interpretation After Myriad*

1. *Arisosa Diagnostics, Inc. v. Sequenom, Inc.* (California District Court)

In *Arisosa Diagnostics, Inc. v. Sequenom, Inc.*, Doctors Dennis Lo and James Wainscoat appealed on a patent claim for the discovery of cell-free fetal DNA (cffDNA).¹³³ CffDNA is present in maternal plasma and serum and was previously regarded by researchers as medicinal waste.¹³⁴ Doctors Lo and Wainscoat used known laboratory techniques to isolate a small fraction of paternally inherited cffDNA to determine characteristics in the fetus, which created an alternative for prenatal diagnosis with fewer risks.¹³⁵ This invention was commercialized by Sequenom as the MaterniT21 test and was challenged by Arisosa Diagnostics, who sold a similar Harmony Test used for non-invasive prenatal diagnostics.¹³⁶ The court held Arisosa's patent on the test invalid by using the *Mayo* framework.¹³⁷ The court reasoned that the patents explained methods such as PCR to amplify the cffDNA, which were "well-understood, routine, [and] conventional activities."¹³⁸ The natural

133. *Arisosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1373 (Fed. Cir. 2015).

134. *Id.*

135. *Id.*

136. *Id.* at 1373–74.

137. *Id.* at 1377.

138. *Id.*

phenomenon of the cffDNA was not transformed into a patentable invention by utilizing the methods in the claims.¹³⁹

2. *Genetic Technologies Ltd. v. Bristol-Myers Squibb* (Delaware District Court)

In *Genetic Technologies Ltd. v. Bristol-Myers Squibb*,¹⁴⁰ Genetype AG and Dr. Malcolm Simons discovered a correlation between variations in introns and alleles (coding regions in the DNA).¹⁴¹ A variation in the coding region of alleles can indicate particular traits or diseases.¹⁴² The court held that Dr. Simons' patent was not valid under *Alice* and *Mayo*.¹⁴³ The court reasoned that the invention claimed a process for amplifying and analyzing correlations in regions of DNA and thus considered whether any exceptions to a process applied.¹⁴⁴ The court, recognizing that organisms inherently contain a certain degree of variation, went on to state that the correlation preexists in the human body and involves a variation in linkage disequilibrium known as polymorphism, which is entirely a natural process inherited as a block.¹⁴⁵ The court analyzed whether Dr. Simons' patent satisfied the machine or transformation test, as mentioned in *Mayo* and *Bilski*. However, the court pointed out that the Supreme Court "neither said nor implied that the test trumps the 'law of nature' exclusion."¹⁴⁶ The plaintiff's claim that the process was patent eligible since it involved amplification, the use of primers,¹⁴⁷ and man-made DNA as the output, were

139. *Ariosa Diagnostics*, 788 F.3d. at 1376.

140. *Genetic Techs. Ltd. v. Bristol-Myers Squibb Co.*, 72 F. Supp. 3d 521, 525 (D. Del. 2014).

141. "An 'allele' is a genetic variation associated with a coding region. Groups of alleles may be inherited as a unit; these groups are sometimes referred to as haplotypes. Because the presence of these variations in the coding region may be associated with particular traits or diseases, it can be useful to detect whether certain alleles or haplotypes are present in an individual." *Genetic Techs. Ltd. v. Agilent Techs., Inc.*, 24 F. Supp. 3d 922, 926 (N.D. Cal. 2014) (internal citations omitted).

142. *Bristol-Myers Squibb Co.*, 72 F. Supp. 3d at 525.

143. *Id.* at 527–29.

144. *Id.* at 529.

145. *Id.* at 529–30.

146. *Id.* at 535.

147. A primer is a short, synthetic, single-stranded DNA molecule that binds specifically to an intended target nucleotide sequence[s]." *Univ. of Utah Research Found. v. Ambry Genetics Corp. (In re BRCA1- & BRCA2- Based Hereditary Cancer Test Patent Litig.)*, 3 F. Supp. 3d 1213, 1224 (D. Utah 2014) (citation omitted). The sequence of the primer is complementary to the DNA to which it binds and is used for starting the process of duplicating a DNA sequence utilizing polymerase chain reactions (PCR). This technique is commonly utilized in biochemical genetic research. *See id.*

unpersuasive since neither independently nor taken together did they add to the scientific body of knowledge.¹⁴⁸

Plaintiff, relying upon *Myriad* regarding cDNA, contended that amplified DNA is “man-made” because it is “molecularly distinct and distinguishable . . . from naturally occurring DNA from which it was derived.”¹⁴⁹ The court stated that the plaintiff misinterpreted *Myriad* and that the Court in that case court addressed the eligibility of “(i) ‘isolated native DNA,’ which it found ineligible and (ii) ‘cDNA,’ which it held was eligible on the basis that it was a synthesized DNA sequence from which the non-coding regions had been removed and, thus, did not occur in nature.”¹⁵⁰ Not all synthetic DNA is patent eligible, for amplified DNA and cDNA are distinctive—one merely duplicates naturally occurring DNA while the other removes introns from gene sequences.¹⁵¹

3. *In re* BRCA1-, BRCA2-Based Hereditary Cancer Test Patent Litigation (District Court of Utah)

Plaintiff, Myriad Genetics, brought suit after defendant, Ambry Genetics, announced it would begin to offer BRCA1 and BRCA2 testing.¹⁵² Plaintiff argued defendant’s genetic testing infringed on several of plaintiff’s patents claiming the right to synthetic DNA primers and methods for analyzing BRCA1 and BRCA2 sequences.¹⁵³ The court found that the concepts used by Myriad’s claim were well-understood, routine, and utilized conventional activity, including the use of biomarkers, amplification, sequencing, probing, and screening.¹⁵⁴ The court reasoned that there was a danger in allowing patent protection to cover the use of the laws of nature, as it risks “tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries.”¹⁵⁵

148. See *Genetic Techs. Ltd. v. Bristol-Myers Squibb Co.*, 72 F. Supp. 3d 521, 535 (D. Del. 2014) (citing Plaintiff’s brief).

149. *Id.* at 536.

150. *Id.*

151. *Id.*

152. *Univ. of Utah Research Found.*, 3 F. Supp. 3d at 1218.

153. *Id.* at 1219.

154. *Id.* at 1269.

155. *Id.* at 1270 (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 73 (2012)).

4. *Genetic Technologies Limited v. Agilent Technologies*
(District Court of California)

In *Genetic Technologies Limited v. Agilent Technologies*, the court refused to grant a motion to dismiss against defendant Agilent Technologies.¹⁵⁶ The court found that the plaintiff had not shown the defendant's patent did not claim "meaningfully limited applications of . . . natural law."¹⁵⁷ The contended patent involved variations in non-coding regions of DNA, which were correlated to the coding DNA, which the defendant stated were not universal but rather "specific, limited, and unconventional," changing over time through the evolutionary process.¹⁵⁸ The court acknowledged that merely discovered variations in genes were not patent eligible, and recognized that plaintiffs failed to provide evidence that these discoveries did not include an innovative or transformative step.¹⁵⁹ The court stated that the claims did not, "as a matter of law, fail the machine-or-transformation test," which states that a claim "may be meaningfully limited if: (1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing."¹⁶⁰ The plaintiff did not show that a primer pair cannot constitute a biomolecular machine.¹⁶¹

5. *In re Roslin Institute*

The Roslin Institute of Edinburgh (Roslin) in Scotland appealed from a final decision of the Patent Trial and Appeal Board (the Board),¹⁶² which "held that all of Roslin's pending claims . . . were unpatentable subject matter under 35 U.S.C. § 101."¹⁶³ The Court of Appeals for the Federal Circuit upheld the Board's decision that the claims were anticipated and obvious.¹⁶⁴

156. *Genetic Techs. Ltd. v. Agilent Techs., Inc.*, 24 F. Supp. 3d 922, 925 (N.D. Cal. 2014).

157. *Id.*

158. *Id.* at 928.

159. *Id.* at 933.

160. *Id.* at 932.

161. *Id.* at 933.

162. The Patent Trial and Appeal Board (PTAB) is a judicial board under the United States Patent and Trademark Office. The Board "conducts trials, including *inter partes*, post-grant, and covered business method patent reviews and derivation proceedings." See *Patent Trial and Appeal Board*, U.S. PAT. & TRADEMARK OFF., <https://www.uspto.gov/patents-application-process/patenttrialandappealboard> (last updated Oct. 28, 2019). The Board also hears appeals from adverse examiner decisions and decides interference cases. *Id.* Often, the Board will examine the validity of patent claims while the cases are pending in district or circuit courts.

163. *In re Roslin Inst. (Edinburgh)*, 750 F.3d 1333, 1334 (Fed. Cir. 2014).

164. *Id.* at 1334.

On July 5, 1996, Keith Henry Stockman Campbell and Ian Wilmut produced the first cloned mammal, Dolly the Sheep,¹⁶⁵ who was genetically identical to her donor sheep.¹⁶⁶ Utilizing somatic cell nuclear transfer, the scientists removed the nucleus of a somatic cell and implanted that nucleus into an enucleated oocyte.¹⁶⁷ Campbell and Wilmut obtained the '258 patent for the somatic method of cloning mammals, which was subsequently obtained by Roslin.¹⁶⁸ Roslin claimed the right to the cloned mammals themselves upon obtaining the '258 patent.¹⁶⁹ Two of Roslin's claims were as follows: "155. A live-born clone of a pre-existing, non-embryonic, donor mammal, wherein the mammal is selected from cattle, sheep, pigs, and goats. 164. The clone of any of claims 155-159, wherein the donor mammal is non-foetal."¹⁷⁰

In 2008, the Patent and Trademark Office (PTO) examiner issued a rejection of the patent claims because they contained non-patentable subject matter under §§ 101–103, and in 2013 the examiner's decision was reaffirmed by the Board.¹⁷¹ The Board concluded that the clones "may be called a composition of matter or a manufacture" under § 101.¹⁷² Moreover, the Board found that the subject of the patent did not possess "markedly different characteristics than any found in nature," and therefore, Roslin was not

165. Adam Greene writing for the George Washington Law Review describes the motivation for creating Dolly:

Dr. Ian Wilmut and his colleague Keith H.S. Campbell were attempting to create large herds of genetically-engineered farm animals. Sheep such as Dolly would be genetically engineered to produce human medicines in their milk. For example, a sheep whose milk included human insulin would provide an inexpensive and efficient means of manufacturing the medicine. The engineered livestock could also be created with "humanized" organs which could be transplanted into people.

Adam Greene, Note, *The World after Dolly: International Regulation of Human Cloning*, 33 GEO. WASH. INT'L L. REV. 341, 344–45 (2001) (footnotes omitted). Some scholars advocate strongly for continual development in the area of patents on cloned animals. "[T]he United States Patent and Trademark Office should no longer deny patents to genetically cloned animals, in particular livestock." Andrew Clark, Comment, *Does Dolly Deserve Defense: An Analysis of the Patentability of Cloned Livestock*, 15 J. HIGH TECH. L. 135, 136 (2014).

166. *In re Roslin Inst.*, 750 F.3d at 1334.

167. *Id.*

168. *Id.*

169. *Id.*

170. *Id.* at 1335.

171. *Id.*

172. *In re Roslin Inst.*, 750 F.3d at 1335.

entitled to rights over the cloned mammals.¹⁷³ In its opinion, the Board wrote: “[w]here . . . the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product.”¹⁷⁴ Key to the Board’s decision was that the clones were “indistinguishable from clones produced through prior art cloning methods”—the method of cloning was the same as prior art, and the product was naturally occurring.¹⁷⁵

Roslin contended that the cloned products were the product of human ingenuity and compositions of matter within the scope of § 101.¹⁷⁶ Roslin argued that environmental factors produce animals whose phenotypes are markedly different from those of the donor animals.¹⁷⁷ Further, Roslin stated the clones contain different mitochondrial DNA, which originates from the donor oocyte.¹⁷⁸ Mitochondria are the powerhouse of the cell which convert energy from the molecules in food into adenosine triphosphate (ATP) used in intracellular energy transfer.¹⁷⁹ Most of a cell’s DNA is packed into the chromosomes in the nucleus.¹⁸⁰ However, mitochondria contain DNA that differs from the DNA in the nucleus.¹⁸¹ Roslin claimed that the marked difference between the mitochondrial DNA of the cloned product from the parent mammal further added to the mammal’s patent eligibility.¹⁸²

The *Roslin* court considered *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, in which patents were sought for an inoculant to increase the nitrogen-fixing efficiencies of leguminous plants.¹⁸³ Because the patentee did not alter the bacteria in any way, the patent was invalidated because it involved “qualities . . . [which were] . . . the work of nature.”¹⁸⁴ Similarly, in *In re Roslin Institute*, the court found that the cloned mammal did not have “markedly

173. *Id.*

174. *Id.* (alterations in original).

175. *Id.*

176. *Id.* at 1337.

177. *Id.* at 1338.

178. *In re Roslin Inst.*, 750 F.3d at 1338.

179. *Mitochondrial DNA*, U.S. NAT’L. LIBR. OF MED. (Oct. 29, 2019), <https://ghr.nlm.nih.gov/mitochondrial-dna#definition>.

180. *Id.*

181. *Id.*

182. *In re Roslin Inst.*, 750 F.3d at 1338.

183. *Id.* at 1336; *see Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 128–29 (1948).

184. *In re Roslin Inst.*, 750 F.3d at 1336 (quoting *Funk Bros. Seed Co.*, 333 U.S. at 130).

different characteristics from any [farm animals] found in nature.”¹⁸⁵ Dolly was a genetically identical replica of the donor animal.¹⁸⁶ At the end of the opinion, the court added, “[t]o be clear, having the same nuclear DNA as the donor mammal may not necessarily result in patent ineligibility in every case.”¹⁸⁷ The court did not say when a mammal, having the same DNA as a parent donor, would be patent eligible.¹⁸⁸

6. *Roche Molecular Systems v. Cepheid*

In *Roche Molecular Systems v. Cepheid*, the U.S. District Court for the Northern District of California held assignor estoppel¹⁸⁹ did not bar defendant’s unpatentability arguments and that there was no structural difference between the claimed primers and those naturally occurring as part of the *rpoB* gene.¹⁹⁰ Roche claimed that one of Cepheid’s products infringed upon Roche’s patent titled, “Detection of a Genetic Locus Encoding Resistance to Rifampin in Microbacterial Cultures and in Clinical Specimens” (‘723 patent).¹⁹¹ The patent relates to methods of detecting mycobacterium tuberculosis (MTB) and for identifying MTB, which is resistant to the antibiotic “rifampin.”¹⁹² The patent also covers synthetic DNA molecules in the form of primers designed to perform the stated methods.¹⁹³

The inventors of the ‘723 patent found that the *rpoB* gene has position-specific signature nucleotides that are present in MTB.¹⁹⁴ The scientists created a test that could detect whether a sample of DNA contained MTB and could predict whether it would respond to the antibiotic.¹⁹⁵ This method, stated in claims 1–13, was faster and more accurate and had not been performed with the primers identified.¹⁹⁶ The patent claimed an intellectual

185. *Id.* at 1337 (quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980)) (alteration in original).

186. *Id.*

187. *Id.* at 1339.

188. *Id.*

189. “Assignor estoppel is an equitable doctrine that may be applied to prevent one who has assigned the rights to a patent (or patent application) from later contending that what was assigned is a nullity.” *Roche Molecular Sys. v. Cepheid*, No. 14-cv-03228-EDL, 2017 U.S. Dist. LEXIS 113280, at *17 (N.D. Cal. Jan. 17, 2017) (citation omitted).

190. *Id.* at *2–3.

191. *Id.* at *3.

192. *Id.*

193. *Id.*

194. *Id.* at *9.

195. *Roche Molecular Sys. v. Cepheid*, No. 14-cv-03228-EDL, 2017 U.S. Dist. LEXIS 113280, at *9 (N.D. Cal. Jan. 17, 2017).

196. *Id.* at *9–11.

property right to the discovered presence of the set of MTB-specific nucleotides present in the *rpoB* gene.¹⁹⁷

The court found that the primers were genetically indistinguishable from their respective sequences found in nature and were not like the cDNA found patentable under the *Myriad* analysis.¹⁹⁸ The court stated that “[e]ven groundbreaking discoveries can be deemed non-patentable if they arise from a newly discovered natural phenomenon combined with only routine and conventional steps.”¹⁹⁹

Appellant Roche Molecular Systems, Inc. (Roche) appealed the district court’s decision; the ruling below was affirmed in October 2018 by the United States Court of Appeals for the Federal Circuit.²⁰⁰ In its appeal, Roche argued that its primers were distinct from naturally occurring bacterial MTB DNA since they contained a 3-prime end and a 3-prime hydroxyl group.²⁰¹ This unique chemical structure allows the primers to bind to nucleotides beginning the binding process of a chain of DNA.²⁰² The circuit court affirmed the district court’s decision that, despite this chemical property, the genetic sequences were identical to those found in nature.²⁰³

Writing for the court, Circuit Judge Reyna stated a “DNA structure with a function similar to that found in nature can only be patent eligible as a composition of matter if it has a unique structure, different from anything found in nature.”²⁰⁴ In her concurring opinion, Circuit Judge O’Malley analyzed the case under *Myriad*, stating that the “possibility that an unusual and rare phenomenon might randomly create a molecule similar to one created synthetically through human ingenuity does not render a composition of matter nonpatentable.”²⁰⁵ Therefore, while a patent applicant may not receive protection on a claim covering a nucleotide sequence which is naturally occurring, if, by a rare occasion, nature produces a nucleotide sequence which happens to be the same as that which the scientist has created, the patent claim may still be valid.²⁰⁶

197. *Id.* at *9–10.

198. *Id.* at *44.

199. *Id.* at *28 (citing *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 57 (2013)).

200. *Roche Molecular Sys., Inc. v. Cepheid*, 905 F.3d 1363, 1365 (Fed. Cir. 2018).

201. *Id.* at 1369.

202. *Id.* at 1366.

203. *Id.* at 1369.

204. *Id.* (quoting *Univ. of Utah Research Found. v. Ambry Genetics Corp. (BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.)*, 774 F.3d 755, 761 (Fed. Cir. 2014)).

205. *Id.* at 1377 (O’Malley, J., concurring) (quoting *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 594 n.8 (2013)).

206. *Id.*

Justice O'Malley stated that key considerations on the patentability of cDNA include whether the sequence is a "materially different structure" than other strands naturally found or whether it is indistinguishable from natural DNA.²⁰⁷ What is "materially different" is not explicitly stated. An "indistinguishable" standard implicates that the slightest change to the original sequence would render a patentable sequence not naturally occurring. An indistinguishable standard utilizes objective reasoning. In contrast, a "materially different" standard implies a spectrum of change at which there is a point where "immaterial" changes into "materially different." At this point, the sequence becomes patentable. A "materially different" standard utilizes subjective reasoning. Thus, while scholarly opinions render insightful reasoning and guidance to courts below, they leave a spectrum of ambiguity as to what nucleotide sequences may be patented.

V. THE NEED FOR STATUTORY CLARITY FOR SYNTHETICALLY CREATED DNA

A. *Analysis under Modern Jurisprudence and a Proposed Means of Clarification*

In the aftermath of *Myriad*, modern jurisprudence shed some light on the further interpretation of *Myriad's* holding. In *Ariosa Diagnostics*, the District Court of California held that the amplification and detection of cffDNA through such procedures, like PCR, is conventional and directed to a patent ineligible subject matter.²⁰⁸ In *Genetic Technologies Limited*, the same court ruled that though the correlations between genomic variations in non-coding and coding regions of DNA are not patentable, certain applications or methods of DNA amplification may be patentable as long as they are meaningfully specific.²⁰⁹ Therefore, under *Genetic Technologies Limited*, applications or methods of DNA printing may be patent eligible apart and distinct from the products they produce.²¹⁰

In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litigation demonstrates how courts are cautious to over grant patents, which may tie up valuable information not unique to the claimant.²¹¹ In *In re Roslin Institute*, the Federal Circuit Court held that Dolly's clones could not be patented. Roslin recognized that the original sheep was a product of nature, but it contended that the copy was patent eligible because it was a "product

207. *Id.* at 1379 (emphasis removed).

208. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1377 (Fed. Cir. 2015).

209. *Genetic Techs. Ltd. v. Agilent Techs., Inc.*, 24 F. Supp. 3d 922, 933 (N.D. Cal. 2014).

210. *See id.*

211. *See In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 999 F. Supp. 2d 1377 (J.P.M.L. 2014).

of human ingenuity” and “not nature’s handiwork, but [its] own.”²¹² However, in its discussion, the court ruled that only discoveries with “markedly different characteristics from any found in nature” are eligible for patent protection.²¹³ Key to the court’s rationale was the finding that Roslin did not alter the genetic information in any way when it produced the clones.²¹⁴ It was the preservation of the exact donor DNA that made Campbell and Wilmut’s discovery so innovative.²¹⁵ Under the Federal Circuit’s holding in *In re Roslin Institute*, human DNA, created from as a clone from a donor human genome, would not be patent eligible apart from the alteration.²¹⁶ The very definition of a clone is that it is produced asexually and is genetically identical to that of its ancestor.²¹⁷ Therefore, no form of a clone is patent eligible unless it is formed from a human-engineered parent.

In *Roche Molecular Systems*, the District Court of California held that there was no structural difference between the claimed primers and rpoB gene segment rendering the ‘723 patent invalid.²¹⁸ Though these primers had been identified to hybridize to a specific signature nucleotide for MTB, the primers were a product of a natural phenomenon.²¹⁹ *Roche Molecular Systems* reiterates the importance to patentability that the gene sequence be altered from the original.²²⁰ However, courts utilize a range of standards stating that the patent will be invalidated if the strand is “indistinguishable”²²¹ from the parent or that the new strand must be a “materially different structure”²²² and contain “markedly different characteristics from any found in nature.”²²³ These subjective and objective standards in the aftermath of *Myriad* leave lower courts without clear guidelines. Before courts hear patent litigation, patent attorneys, along with scientists and investors, need clarity in what DNA patent claims are now valid under § 101.

212. *In re Roslin Inst. (Edinburgh)*, 750 F.3d 1333, 1337 (Fed. Cir. 2014).

213. *Id.* at 1336.

214. *Id.* at 1337.

215. *Id.*

216. *See id.*

217. *Id.*

218. *Roche Molecular Sys., Inc. v. Cepheid*, No. 14-cv-03228-EDL, 2017 U.S. Dist. LEXIS 113280, at *37, *65 (N.D. Cal. Jan. 17, 2017), *aff’d*, 905 F.3d 1363 (Fed. Cir. 2018).

219. *See id.* at *9–10.

220. *Id.* at *23.

221. *In re Roslin Inst. (Edinburgh)*, 750 F.3d at 1335.

222. *Roche Molecular Sys., Inc. v. Cepheid*, 905 F.3d 1363, 1379 (Fed. Cir. 2018).

223. *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980).

Congressional inaction to clarify patentability in this area has led to the variance in judicial interpretation.²²⁴ According to the Congressional Research Service, in regards to when a court may infer acquiescence, one of the most important factors is “congressional awareness that an interpretation has generated widespread attention and controversy.”²²⁵

The need for congressional clarification on what is patentable subject matter under § 101 has increasingly become a recognized need in the realm of genetic engineering.²²⁶ In his note, *A Myriad of Problems*, Jake Gipson writes that *Myriad* represents an “endemic of the problem—the Supreme Court’s failure to articulate a useful and meaningful guide on the limits of patentable subject matter. . . . Without any clear guidance from Congress or the courts, speculators are encouraged to gamble on the prospect of patent protection.”²²⁷ Gipson advocates for a framework based on § 103, which would dive deeper into the nonobvious inquiry of determining whether an invention is patentable.²²⁸

Dr. Torrance, in his article, *Synthesizing Law for Synthetic Biology*, explains how genetic engineering poses questions not just for patent law, but other forms of intellectual property as well.²²⁹ He argues synthetic DNA sequences may qualify for copyright protection as original works of law.²³⁰ Sequences may be eligible for trademark protection since genomes may contain “distinctive motifs capable of serving as legally effective indications of source.”²³¹ Dr. Torrance goes on to write about the uncertainty associated with other forms of IP protection and considers the arguments around open innovation.²³² Though Congressional clarification is necessitated primarily in the area of patent law, Congress may also consider tangential issues surrounding other forms of IP protection.

224. LARRY M. EIG, CONG. RESEARCH SERV., STATUTORY INTERPRETATION: GENERAL PRINCIPLES AND RECENT TRENDS 51 (2014), <https://fas.org/sgp/crs/misc/97-589.pdf>.

225. *Id.*

226. Jake Gipson, Note, *Patentable Subject Matter: A Myriad of Problems*, 65 ALA. L. REV. 815, 826 (2014).

227. *Id.* at 826–27 (footnote omitted).

228. *Id.* at 830.

229. Andrew W. Torrance, *Synthesizing Law for Synthetic Biology*, 11 MINN. J.L. SCI. & TECH. 629, 638–39 (2010).

230. *Id.*

231. *Id.* at 639.

232. *Id.* at 638–40.

B. *The Need for Legal Protection of DNA Integrity While Promoting Scientific Advancement*

1. *The Ethical Implications of Patenting Synthetically Printed Human DNA*

Nearly 30,000 human genes are patented in the United States.²³³ Sirena Rubinoff, in her article, *The Ethics of Patenting Genes and Animals*, writes, “Holding a genetic patent for diagnostic use or functional use does not give the patent holder outright ownership of a gene’s use.”²³⁴ Rubinoff goes on to write that while patent holders have a right to prevent others from utilizing the patented IP for research without approval, labs are generally not sued for studying a gene or using it in academic research.²³⁵

An important distinction must be made that DNA sequences or genes may be patented, while the human genome, currently, may not be patented.²³⁶ In this global debate, the European Union has codified a rejection of the “products of nature” doctrine in the Biotechnology Directive.²³⁷ This Directive states that substances isolated from nature cannot be excluded from patentability as a general principal.²³⁸

Altering genes of one species with sequences of another species is a common practice in scientific and medical research. The advancement of transgenic research proves to have practical benefits that would only be obtainable through more severe methods such as human research.²³⁹ In 2005,

233. Alyson L. Wooten, *International Conflicts over Patenting Human DNA*, 27 INTELL. PROP. LITIG. 7, 9–10 (2016).

234. Sirena Rubinoff, *The Ethics of Patenting Genes and Animals*, 266 MANAGING INTELL. PROP. 50, 51 (2017).

235. *Id.*

236. Donna M. Gitter, *International Conflicts over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623, 1628–29 (2001).

237. *Id.* at 1648.

238. *Id.*

239. The Helsinki Declaration sets forth ethical principles regarding human experimentation for research and has been adopted and developed by the World Medical Association. The Declaration contains seven principles summarized as follows:

- 1) human experimentation should always be conducted according to sound scientific principles;
- 2) the design of the experimentation should be set in advance and a protocol filed with an independent body;
- 3) experimentation should be conducted only by scientifically trained people;

Stuart Newman and Jeremy Rifkin submitted a patent application for two chimeras²⁴⁰ referred to as a humouse and a humanzee.²⁴¹ Despite the fact that the USPTO denied the application for the chimeras, the National Institutes of Health (NIH) has continued its work developing chimeras.²⁴² Chimeras are human-animal admixtures that contain the cells, tissue, and organs from two distinct sources in one living body.²⁴³ Chimeras naturally occur when human twins form inside of a womb.²⁴⁴ The twin embryos are fused at an early stage with each containing its own unique DNA while existing as one organism.²⁴⁵

Since the oncomouse was patented in 1988, over 660 animal patents have been granted—mice, frogs, and even horses have been implanted with human organs.²⁴⁶ Transgenic animals and animal chimeras with human cells are heavily sought after in research studies since they contain human cells and organs.²⁴⁷ Through utilizing chimeras, treatments for human conditions may be conducted on these test subjects without the need for expensive and risky

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- 4) the risk must be proportionate to the benefit;
 - 5) concern for the subject should prevail over scientific concerns;
 - 6) the effect on the integrity, privacy and psychology of the subject should be minimized; and
 - 7) the subjects must be advised of the procedure's alternatives and risks and experimentation should only occur once informed consent is obtained.

Barbara J. Gislason and Mercedes Meyer, *Humans and Great Apes: A Search for Truth and Ethical Principles*, 8 J. ANIMAL & NAT. RES. L. 1, 21 (2012). In contrast to human research, animal research is regulated by a lower standard which makes such research cheaper, faster, containing less risk, and more ethical.

240. Chimeras contain cells that originate from at least two different species. Human-animal chimeras contain human cells or even tissues or organs that are primarily human. Often, research is conducted utilizing human embryos and may disregard the welfare of the animals and the animal species involved. Chimeras can be used for animal-to-humans organ transplants or may be used for the study of neurologic or immune diseases such as AIDS drug testing. See *Chimeras*, UNIV. OF MINN., <https://www.ahc.umn.edu/img/assets/25857/chimeras.pdf> (last visited Nov. 6, 2019).

241. Rubinoff, *supra* note 234.

242. *Id.*

243. Shane Patrick McNamee, *Human-Animal Hybrids and Chimeras: What's in a Name?*, 6 J.AHR – EUR. J. BIOETHICS 45, 55 (2015) (discussing the distinction of a chimera compared to other human-animal combinations).

244. *Id.*

245. *Id.*

246. Rubinoff, *supra* note 234.

247. McNamee, *supra* note 243, at 55–56.

utilization of human test subjects.²⁴⁸ A key argument in favor of chimeras or transgenics is that humans share the vast majority of their DNA with other mammals, up to 99% the same DNA as that of chimpanzees.²⁴⁹ It is merely a fraction of a percentage that must be altered to change an organ in a mammal species, such as a mouse, to express a gene for the human counterpart.²⁵⁰ Though a full legal and ethical evaluation of chimeras and their counterparts are beyond the scope of this note, a comparison of other gene alteration methodologies prove helpful in thoughtfully considering the implications of altering synthetically printed human DNA.

Evolutionary researcher Dr. Andrew Torrance holds both a Ph.D. in biology and a J.D. from Harvard University.²⁵¹ In his article, *Patenting Human Evolution*, Dr. Torrance argues, “Genetic engineering allows the goals of artificial selection to be achieved more efficiently than traditional selective breeding programs. By inserting genes into the genome of an organism, such as a human, traits of that organism could be altered precisely and immediately within a single generation.”²⁵² He refers to genetic engineering as an “utterly transformative technology,” allowing for “enhanced” humans.²⁵³ Dr. Torrance argues that the current patent system presents a significant hurdle and restriction on advancements in biotechnology and the furthering of the human species.²⁵⁴ Dr. Torrance writes of a future where the natural process of having children will give way to a system of parents in a race to genetically enhance their offspring.²⁵⁵ He explains how “evolution stands on the verge of becoming fine-tuned and deliberate” through selective gene engineering, and that “the patent system enables private policing of a technology with strong implications for the evolutionary future of humanity.”²⁵⁶

Similar to Dr. Torrance’s outlook, Lee Silver, in his work, *Remaking Eden: How Genetic Engineering and Cloning Will Transform the American Family*, writes his projection of how genetic engineering will steadily be integrated

248. *Id.*

249. “Humans share 99% of their genes with chimpanzees, but only 98% with orangutans.” Gislason & Meyer, *supra* note 239, at 15.

250. *See id.*

251. Andrew W. Torrance, *Patenting Human Evolution*, 56 U. KAN. L. REV. 1075, 1075 n.* (2008).

252. *Id.* at 1084.

253. *Id.* at 1075.

254. *Id.* at 1075–76.

255. *Id.* at 1076–77.

256. *Id.*

into society as an acceptable and wanted form of enhancing human kind.²⁵⁷ Silver explains that at first, genetic engineering will be used to treat childhood diseases—the most likely widely accepted form of treatment to the largest portion of society.²⁵⁸ Once society's fear begins to subside, reprognetics will expand to treat diseases that impact adulthood.²⁵⁹ The next stage of adoption will be the treatment of the mind and the senses, such as treating alcohol addiction or mental diseases such as extreme aggression.²⁶⁰ The “final frontier” will proceed to development enhancements such as altering appearance or desirable cognitive attributes.²⁶¹ Lee Silver explains:

In the short term . . . most genetic enhancements will surely be much more mundane. They will provide little fixes to all of the naturally occurring genetic defects that shorten the lives of so many people. They will enrich physical and cognitive attributes in small ways. And as the years go by over the next two centuries, the number and variety of possible genetic extensions to the basic human genome will rise exponentially Extensions that were once unimaginable will become indispensable . . . to those parents who are able to afford them.²⁶²

Lee Silver explains the future impact of the availability of genetic enhancement upon society as developing a difference among those who are genetically enhanced and those who are not.²⁶³ He goes on to write, “The GenRich . . . all carry synthetic genes. Genes that were created in the laboratory and did not exist within the human species until twenty-first century reproductive geneticists began to put them there. The GenRich are a . . . hereditary class of [future] genetic aristocrats.”²⁶⁴ Genetic disparity may become the income disparity of the future.

Supporters of the world Silver envisions may argue that people strive to enhance their traits throughout a lifespan: they become faster, stronger, smarter, and carefully select a mate that will pass desirable traits to their offspring. Why not accelerate this process through selective genetic engineering thereby exponentially increasing the rate at which humanity

257. LEE M. SILVER, REMAKING EDEN: HOW GENETIC ENGINEERING AND CLONING WILL TRANSFORM THE AMERICAN FAMILY 152, 236–39 (Bard Printing 1998) (1997).

258. *Id.* at 277–78.

259. *Id.* at 278.

260. *Id.*

261. *Id.*

262. *Id.* at 280.

263. SILVER, *supra* note 257, at 296.

264. *Id.* at 5.

evolves? However, while a strong argument may be made for the desire to propel society forward, others may state that the ends of achieving an enhanced population do not justify the means of “playing” with human genomes. Here, Congress, along with the legal system, acts as a gateway for regulating this moral dilemma containing seemingly conflicting goals—the unprohibited promotion of science and genetic engineering with a respect for the sanctity of human life.

2. The Benefit of Gene Patents for Scientific Advancement

The benefits of patents on DNA are numerous, including encouraging investment and risk capital.²⁶⁵ This dynamic economic paradigm promotes competition and leads to an efficient allocation of resources while also maximizing consumer satisfaction and promoting scientific developments.²⁶⁶ According to the American Bar Association (ABA) Section of Patent Trademark and Copyright law, “Granting patents on animals and other higher life forms will stimulate the development of important new products that will increase the food supply and lower the costs of food production.”²⁶⁷ The publication goes on to state that transgenic patents will produce new life-saving pharmaceuticals and stimulate innovation in the biomedical sciences.²⁶⁸ Transgenics, true hybrids, and chimeras have significant benefits in biological, animal, and medical research, which arguably outweigh alternatives.²⁶⁹ Intellectual property rights on these living products help drive the medicinal industry, providing for safer, faster, and more economical chemical formulas utilized in medicine and industry.²⁷⁰

Transgenic organisms are those that contain genes from another species usually through recombinant DNA techniques resulting in a new species.²⁷¹ For example, the gene for the expression of Green Fluorescent Protein (GFP) has been isolated from jellyfish.²⁷² Through transgenics, the GFP gene has been inserted for commercial and scientific reasons into mice, goldfish, and other animals.²⁷³ In contrast to transgenics between animals, a more

265. Wooten, *supra* note 233, at 10.

266. Hazel V J Moir, What Are the Costs and Benefits of Patent Systems? 16 (Oct. 2008) (unpublished) (available for download at https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1409503&download=yes).

267. *Biosciences*, 1989 A.B.A. SEC. PAT. TRADEMARK & COPYRIGHT L. COMM. REP. 104.

268. *Id.*

269. McNamee, *supra* note 243, at 52–53.

270. *Biosciences*, *supra* note 267.

271. McNamee, *supra* note 243, at 52.

272. *Id.*

273. *Id.*

controversial issue is human transgenic embryos. These human embryos have non-human genes inserted and are often destroyed after a certain period.²⁷⁴ Transgenic animals begin with an animal DNA base and have a few genes altered to manifest certain human diseases such as Huntington's disease.²⁷⁵ Bio-pharming utilizes transgenic bacteria through recombinant DNA technology to insert human insulin production into e-coli.²⁷⁶ The product has resulted in mass production of synthetic human insulin.²⁷⁷

True hybrids are created through the inter-breeding of species created through the fertilization of an ovum/oocyte with the sperm of a different species.²⁷⁸ A common example of a true hybrid is a mule.²⁷⁹ There are both legal and ethical barriers to creating true hybrids, and many scientific benefits may be satisfied through transgenics.²⁸⁰ The mixing of genes through methods such as transgenics and synthetic DNA engineering proves a valuable area of development to biology, medicine, and industrial industries. These market sectors are propelled further through a strong patent and IP system, with certainty, reliability, and clarity playing a key role in decisions of investment.

VI. CONCLUSION

In the years following the Supreme Court's decisions in *Myriad*, *Mayo*, and *Alice*, lower courts have grappled with what constitutes genetically engineered patentable subject matter under 35 U.S.C. § 101. The realm of uncertainty caused by broad patent statutes and ambiguous court opinions leaves scientists, investors, and judges looking to indefinite precedent for answers on what claims ought to be protected. Advancing technological developments in synthetic DNA printing create a potential market for selectively engineering ones' offspring. In this process, questions pertaining to genetic patent eligibility are becoming increasingly relevant. Congress should clarify when synthetically printed genetically engineered genes would be patent eligible and lay down clear guidelines for courts and researchers alike. Clarity in this area would direct limited human and capital resources toward advancing science in a directed and more efficient manner. Congressional guidelines would work to reduce unnecessary disputes over ciphering which DNA sequences are patent eligible. Moral considerations must be balanced with liberal policies that allow for freedom of

274. *Id.*

275. *Id.*

276. *Id.* at 52–53.

277. McNamee, *supra* note 243, at 52–53.

278. *Id.* at 53.

279. *Id.*

280. *Id.*

experimentation within an ethical framework. The power to create is not always the power to destroy, for what we create may be something sacred.