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IS DNA REALLY A NATURAL PRODUCT? IT'S TIME TO SEPARATE FACT FROM (LEGAL) FICTION: AN EXAMINATION OF DNA PATENTABILITY AS A BIOLOGICAL ALGORITHM IN THE POST-*MYRIAD* ERA

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INTRODUCTION

Patent law is arguably our nation's most complex paradox. It seeks to promote technological innovation by stifling follow-on competition, all for the benefit of an abstract legal fiction—the general public.[1] Yet, it is a necessary one. Indeed, the fundamental utilitarian policy which not only governs but drives the continued existence of a protected patent law regime is expressly located within the Constitutional framework itself.[2] But the implications of the intellectual property clause extend far beyond its textual roots.[3] Since the enactment of the first patent statute, adjudicators and policymakers alike have struggled to establish a uniform and consistent Constitutional application to the ever changing demands of a blooming technological society.[4] Within the onset of recent reinvigoration of patent law oversight by the Supreme Court, however, the biotechnology ("biotech") industry has experienced full force the complexity of this everlasting schism.[5]

* J.D. Candidate, Chicago-Kent College of Law, 2019. I would like to dedicate this note to my parents, who guide my intellectual pursuits, and to my sister Alex, who supported me throughout the writing process, who shares my love of molecular biology, and who is the Watson to my Crick. I would also like to thank the Chicago-Kent Law Review for their work.

1. Jeanne C. Fromer, *Patent Disclosure*, 94 IOWA L. REV. 539, 541 (2009).

2. U.S. CONST. art. I, § 8, cl. 8 ("To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.").

3. Jeanne C. Fromer, *The Intellectual Property Clause's External Limitations*, 61 DUKE L.J. 1329, 1332 (2012) (discussing the competing policy rationales needed to promote innovation, including the incentive to invent and the need for public disclosure of technological information).

4. Lisa C. Pavento et al., *International Patent Protection for HIV-Related Therapies: Patent Attorneys' Perspective*, 17 EMORY INT'L L. REV. 919, 921 (2003).

5. *See* Lisa Larrimore Ouellette, *Patentable Subject Matter and Nonpatent Innovation Incentives*, 5 U.C. IRVINE L. REV. 1115, 1117 (2015) ("[T]he boundaries of patentable subject matter [are] far from settled. This cautiousness in setting clear boundaries makes it difficult for researchers and investors to act with confidence in the patent system.").

Among the required criteria of patentability outlined by Congress, none may perhaps be more attuned to the essence of the invention than the qualified patentable subject matter requirement, codified in 35 U.S.C. § 101.[6] Despite its straightforward language, the interpretation of its significance to patents of different industries has been anything but crystalline.[7] Until recently, biotech patentees have enjoyed broad latitude in patent accessibility and protection, largely due to the Supreme Court's decision in *Diamond v. Chakrabarty* upholding the patentability of a genetically altered bacterium.[8] But the same Court that pioneered the liberal distribution of biotechpatent security rights also ushered in its downfall.[9] After its landmark decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, many biotech and pharmaceutical innovators are left confused and apprehensive for the future of biotech patent protection.[10] While certainly some distaste arises out of the explicit narrowing of patentability for gene patents,[11] the more substantive concerns arise over how to interpret the Supreme Court's reasoning in *Myriad*.[12] Without a clear standard moving forward, major biotech players will remain hesitant in researching and developing new technologies—technologies that ultimately benefit the public at large and promote advancement of general welfare. This is especially true considering the tremendous investment costs biotechnology and pharmaceutical companies sacrifice to obtain patent protection.[13] Additional insight is sorely needed.

This note attempts to reconcile the complexities implicated in *Myriad* by providing a standard to analyze the patentability of future gene patents. Specifically, this note seeks to establish clearer guidance through the tools already implemented by the Supreme Court. Throughout the roughly six decades of interpreting subject matter patentability, the Court has identified

6. 35 U.S.C. § 101 (2012).

7. Tun-Jun Chiang, *Competing Visions of Patentable Subject Matter*, 82 GEO. WASH. L. REV. 1858, 1886–88 (2014) (arguing that the product of nature exception as applied to human genes is dependent on one's underlying policy values).

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

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

10. *Id.*; Amelia Smith Rinehart, Myriad*: Lessons Learned*, 5 U.C. IRVINE L. REV. 1147, 1147–48 (2015).

11. Wing Yin Chan, *Should Isolated Human Genes be Patentable Subject Matter?*, 5 MANCHESTER REV. L. CRIME & ETHICS 64, 77–86 (2016).

12. Ouellette, *supra* note 5, at 1117.

13. Michael Beylkin, *Much Ado About Nothing: The Biotech and Pharmaceutical Industries Have Little to Fear in the Post-*eBay *World*, 6 J. ON TELECOMM. & HIGH TECH. L. 179, 197 (2007); CLAUDE BARFIELD & JOHN E. CALFEE, BIOTECHNOLOGY AND THE PATENT SYSTEM: BALANCING INNOVATION AND PROPERTY RIGHTS 15–23 (2007) (describing the costs associated with lengthy product development and regulatory approval, as well as the uncertainty in how well the developed products will perform in the market).

three exceptions to inventions which otherwise could be patentable under novelty and nonobviousness.[14] Of the three exceptions, the *Myriad* Court analyzed and ultimately held isolated DNA unpatentable under the "product of nature" exception to patentable subject matter, which withholds patentability for a naturally occurring entity.[15] Admittedly, at first glance the product of nature exception seems to be the logical choice, as DNA is a tangible entity that exists in nature apart from any manmade ingenuity. But the Court did not focus its DNA patentability analysis based on tangible differences. Instead, it focused primarily on the "genetic information" contained within the BRCA genes that were patented, and ultimately distinguished Myriad's cDNA analog patent because it sufficiently applied the knowledge contained in the BRCA gene beyond what naturally existed.[16] Perhaps the Court correctly applied the exception; yet no faithful product of nature analysis would depend on such an intangible concept such as the "genetic information" contained in a physical entity: the gene.

This is not to say the Court erred in its decision in *Myriad*. Quite the contrary, both as a legal and a policy matter, I believe the Court ultimately reached the correct result. But if the Court, or more generally society, is ready to look beyond the mere physicality of the genetic structures in gene patents, it should then instead view them as biological code analogous to electronic code. And this means taking appropriate measures to represent these changes in policy.

This note welcomes these new changes to biotechnological progress, and advocates their significance by applying future subject matter patentability analysis to gene patents using an "abstract idea" exception variant presented by the Court in *Alice Corp. v. CLS Bank International* and its progeny.[17] In doing this, the aim for this note is to allow for more clarity in future § 101 analysis, which will then alleviate many of the concerns expressed by biotechnology inventors who remain uncertain about whether the patent system will reward their efforts to protect their innovation. By analogizing the "genetic information" contained in gene patents to an abstract idea, this note necessarily attempts to explore various similarities between DNA and computer code and the implications of doing so. Not only will this analogy resolve ambiguity for gene patents, it will also fur-

14. Laws of nature, natural phenomena (also known as products of nature), and abstract ideas are not patent eligible, even if the invention itself is new and nonobvious, because the essence of the invention cannot be attributable to the inventor but to what already exists in nature. *See* CLS Bank Int'l v. Alice Corp., 717 F.3d 1269, 1283 (Fed. Cir. 2013).

15. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 596 (2013).

16. *Id.*

17. *See* Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347, 2354 (2014).

ther elaborate on the open-ended questions addressed by *Alice* in determining what exactly constitutes appropriate application of an abstract idea.

To accomplish these objectives, Part I briefly discusses the composition of DNA and its functional significance in the body. Part I also addresses the processes that comprise computer code. Part II then explores the history of subject matter patentability under § 101, specifically analyzing the judicially exempted bars to patentable subject matter as they are presented in *Myriad*. Part III advocates for the use of the abstract idea exception by way of the "quasi-algorithm" rule for future gene patents and conversely urge abandonment from the continued reliance of the product of nature exception in the context of gene patents. Finally, Part IV analyzes the various policy considerations that may result from the proposed change, including an application of the quasi-algorithm rule to various emerging contexts in biotechnology.

I. THE BUILDING BLOCKS OF GENETIC AND ELECTRONIC CODING STRUCTURE

A. DNA

DNA (known more formally as deoxyribonucleic acid) is integral to the functionality of multi-cellular organisms.[18] It comprises one of the subset of macromolecules that are manufactured in the body.[19] The buildings blocks of double helix DNA consist of nucleotides, which themselves consist of a chemical base bonded to a sugar and a phosphate molecule.[20] Nucleotides then become attached through polymerization of the phosphate molecules to create a vertical phosphate backbone.[21] The chemical bases which comprise a DNA strand consist of: A (adenine), G (guanine), C (cytosine), and T (thymine).[22] The chemical composition of these base pairs makes it such that A will always pair with T and similarly G will pair with C to create complementary DNA strands.[23] The "information" that a gene contains is a result of the aggregate sequencing of base pairs, much like the letter and words of this sentence contain an "informational" meaning when

18. See MICHAEL M. COX ET AL., MOLECULAR BIOLOGY: PRINCIPLES AND PRACTICE 259–91 (2012), for a discussion on the role of DNA in the body.

19. James Baggott & Sharon E. Dennis, *Macromolecules*, NETBIOCHEM (Jan. 1, 1995), https://library.med.utah.edu/NetBiochem/macromol.htm [https://perma.cc/B98T-MH9Q].

20. COX ET AL., *supra* note 18, at 177.

21. *Phosphate backbone*, SCITABLE, https://www.nature.com/scitable/definition/phosphate-backbone-273 [https://perma.cc/F3MF-PQF7].

22. COX ET AL., *supra* note 18, at 178.

23. *Id.* at 184.

compiled in the aggregate. This analogy also extends to the partial construction of sentence structure, as a sentence may mean different things when read left-to-right (or in most cases, nothing when read right-to-left, largely dependent on the language and custom) or when starting at the beginning of a sentence as opposed to somewhere in the middle. DNA is the same way.[24] A genetic transcript "sentence" may sequence for an entirely different gene than a part of that "sentence".[25] Or, like many cases in English grammar, a genetic "sentence" fragment may simply translate into unintelligible gibberish.[26]

Nearly all cells in the human body contain the same DNA, but what accounts for the wide diversity in cellular structure is how these cells express the information contained in stored DNA caches.[27] When DNA becomes a fully linked polymer, it then acts as a readable transcript upon which the body may use both to express coded genes within a DNA chain, and to regulate the expression by preventing or accelerating the production of expressed genes. This occurs in two independent steps. The first process, known as transcription, occurs by essentially transferring the information contained by a DNA molecule into an RNA (ribonucleic acid) transcript. An RNA molecule, unlike DNA, is single stranded.[28] This is because when DNA becomes prepped for transcription, the double strands unwind and form an elongation "bubble", in which only one complementary strand is read.[29] While the specific mechanisms of transcribing DNA into RNA are immaterial for understanding its biological purpose, it is important to note that in natural transcription, RNA synthesis is facilitated by an enzyme known as RNA polymerase, which creates new RNA bases to the growing chain until termination.[30] Thus, when the process is finished, the original DNA molecule is stored for later use, and a new RNA molecule containing the copy of the information present in the DNA molecule is then circulated for further expression.[31]

24. *See How do Cells Read Genes?*, GENETIC SCI. LEARNING CTR., https://learn.genetics.utah.edu/content/basics/dnacodes/ [https://perma.cc/XRZ5-56U8].

25. *Id.* (discussing how open reading frames can change the meaning of a DNA sentence); A.J.F. GRIFFITHS ET. AL, AN INTRODUCTION TO GENETIC ANALYSIS (7th ed. 2000), https://www.ncbi.nlm.nih.gov/books/NBK21950/ [https://perma.cc/S6R4-HPBN] (discussing how changing an open reading frame location can change the resulting protein). *But see* COX ET AL., *supra* note 18, at 594 (noting that the genetic code is non-overlapping, meaning that one amino acid is produced for each mRNA triplet).

26. *How do Cells Read Genes?*, *supra* note 24.

27. COX ET AL., *supra* note 18, at 586.

28. *Id.* at 49.

29. *Id.* at 529.

30. *Id.* at 516.

31. *Id.* at 540.

Translation is the second process. Its purpose is to convert the information contained in the intermediate RNA transcript into a practical and usable form.[32] Translation begins when a ribosome (a small organelle used to produce proteins) reads the RNA strand.[33] It does so by classifying the RNA base pairs into groups of three, and producing the appropriate amino acid[34] with the aid of additional tRNA (transfer RNA) molecules present in the cell.[35] Each triplet code corresponds to a different amino acid, with other codes used to signal initiation and termination.[36] When translation is finished, the RNA transcript may be used for subsequent translation or may then be targeted for degradation.[37] But the important product is the synthesis of a protein by the ribosome, which represents the physical embodiment of the information contained in the original DNA molecule.[38] The protein is then directed to perform whatever assignment is needed to sustain the cell.[39]

While a DNA molecule contains sequences that, when compiled, contain genes that can be expressed, it also contains a large amount of intermediate "junk sequences".[40] Junk sequences are also known as introns, and fill the gap between other coding sequences.[41] Introns are subsequently spliced out of a transcribed RNA molecule by intermediate processing that occurs before translation.[42]

The processes described above occur naturally in some form present in eukaryotic cells, including humans. However, beginning in the 1970s, molecular biologists discovered a way to reverse engineer DNA from an RNA template, creating a complementary DNA (cDNA) molecule.[43] cDNA contains the same information present in naturally synthesized DNA, but lacks the non-coding intron sequences that a natural DNA molecule pos-

32. *Id.* at 49.

33. Michael W. Davidson, *Ribosomes*, MOLECULAR EXPRESSIONS (Nov. 13, 2015), https://micro.magnet.fsu.edu/cells/ribosomes/ribosomes.html [https://perma.cc/5NUY-L6KM]; COX ET AL., *supra* note 18, at 619–20.

34. Amino acids are the building blocks of protein molecules, much like nucleotides are the building blocks of DNA.

35. Davidson, s*upra* note 33.

36. *Id.*

37. *Id.*

38. *Id.*

39. *See* COX ET AL., *supra* note 18, at 64.

40. *What is junk DNA, and what is it worth?*, SCI. AM. (Feb. 12, 2007), https://www.scientificamerican.com/article/what-is-junk-dna-and-what/ [https://perma.cc/98TS-FWWJ].

41. Alisa Lehman, *DNA Basics*, THE TECH MUSEUM OF INNOVATION (Jan. 24, 2013), http://genetics.thetech.org/ask-a-geneticist/junk-dna-not-so-junky [https://perma.cc/B32D-PBWU].

42. *Id.*

43. Matthias Harbers, *The Current Status of cDNA Cloning*, 91 GENOMICS 232, 233 (2008).

sesses.[44] The process can be conceptually understood to be the antithesis of transcription, in which the RNA molecule is read to create the complementary DNA base pairs that would normally be used to produce a RNA strand.[45] Unlike transcription, however, cDNA synthesis occurs by an enzyme known as reverse transcriptase, normally found in viruses.[46] In addition, cDNA is single-stranded, whereas naturally occurring DNA exists as a double stranded helix.[47]

B. Computer Code

Like in biological systems, for a computer to perform designated tasks, it must receive a set of coding instructions describing the task to be performed. The fundamental building blocks for computer functionality are integrated electrical circuits.[48] These circuits consist of electrical current that flows through logic gates via a piece of equipment known as a transistor.[49] Transistors are essentially electrical dams that direct the flow of current through a designated pathway with the ability to alternate pathways, much like water current in a dam.[50] When current flows through a logic gate, the gate is designated the number "1"; conversely, if no current flows, then the gate is represented by a "0".[51] This forms the basis for binary code, which consists of the sequences of all the aggregate logic gate representations.[52] Moreover, the "information" contained in binary sequences can be quantified by the grouping of eight numbers, also known as a "byte".[53]

In addition to binary code, computers also translate what is known as "source code". While binary code alone theoretically could perform computer tasks, humans cannot read long sequences of binary code.[54] Source code remedies this problem by crafting a "language" for programmers to

44. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 580 (2013).

45. *Id.* at 582 (describing that synthetic DNA begins with an mRNA transcript).

46. JOHN M. COFFIN ET AL., RETROVIRUSES (1997), https://www.ncbi.nlm.nih.gov/books/NBK19424/ [https://perma.cc/95QA-9SEF].

47. *Reverse Transcription (cDNA Synthesis)*, NEB BIOLABS, INC., https://www.neb.com/applications/cloning-and-synthetic-biology/dna-preparation/reverse-transcription-cdna-synthesis [https://perma.cc/A9VG-2RZT].

48. ALLAN R. HAMBLEY, ELECTRICAL ENGINEERING: PRINCIPLES AND APPLICATIONS 356, 359 (Marcia J. Horton et al. eds., 5th ed. 2011).

49. *Id.* at 601–06.

50. See *id.*, for a discussion on how field-effect transistors can be used to construct different logic gates.

51. IAN A. GROUT, INTEGRATED CIRCUIT TEST ENGINEERING: MODERN TECHNIQUES 42 (2006).

52. *Id.*

53. *Id.* at 42–44.

54. Pamela Samuelson, *CONTU Revisited: The Case Against Copyright Protection for Computer Programs in Machine-Readable Form*, 1984 DUKE L.J. 663, 683–86 (1984).

input commands to a computer, which then translates to the language into binary for the computer to comprehend and perform its assigned task.[55]

The structure of computers is defined by the hardware/software dichotomy. Hardware represents the physical embodiment of the computer, including the central processing unit and the motherboard.[56] In contrast, software is an intangible set of instructions that guides the hardware on how to perform its task.[57] In a technical sense, the functions of hardware and software are not exclusive, as both have the capability to perform the tasks delegated to the other.[58] But legally, the two are distinguishable. Software has the advantage of dual intellectual property protection: patents are available for the methodology, whereas copyright protects the expression of the software code.[59] Hardware, on the other hand, can gain only patent protection.[60]

The unique comparison between the building blocks of biological and electronic functionality raises interesting implications. Both DNA and binary code provide the basic information needed to build all subsequent complex functions. In this sense, the structural similarities between DNA and binary code establish the "fundamental relationship between human and machine."[61] Likewise, both RNA and source code can be thought of as intermediate carriers of the basic information. For one, both are designed to maximize the efficiency of the system by making translational processes much faster. But the analogy breaks down somewhat when considering how the basic code is processed. In biological systems, DNA is used only to transcribe its information to RNA, which does most of the active expression.[62] Though it contains the same information as DNA, RNA has evolved to perform several independent tasks that DNA alone could not.[63]

In contrast, while source code makes interfacing with the computer much easier, it is entirely dependent on the structural autonomy of the computer system. When a programmer inputs source code, it tells the com-

55. HAMBLEY, *supra* note 48, at 430.

56. William D. Duncan, *Ontological Distinctions Between Hardware and Software*, 12 APPLIED ONTOLOGY 5, 29–30 (2017).

57. *Id.*

58. *Id.* at 6–8.

59. Larry N. Woodard, *The West German Smorgasbord Approach to Intellectual Property Protection of Computer Software*, 15 J. MARSHALL J. COMPUTER & INFO. L. 883, 884 (1997).

60. *Id.*

61. Eugene Thacker, *Data Made Flesh: Biotechnology and the Discourse of the Posthuman*, 53 CULTURAL CRITIQUE 72, 73 (2003).

62. COX ET AL., *supra* note 18, at 516.

63. *See id.* at 568–71, 587–92.

puter to perform a task by translating the source code into binary code.[64] Essentially, source code only enhances the efficiency of the program, making it easier for programmers to communicate with computers.[65] Because hardware and software necessarily can accomplish the same functions, source code only serves the purpose of conveying the instructions to the computer.[66] But unlike RNA, which carries the instructions in its own medium, source code must first be translated to binary code for the computer to interpret the instructions.[67] Thus it is the central information medium carrier—binary code—that facilitates most of the active expression in computers.

II. THE CURRENT CLIMATE OF BIOTECH ELIGIBLE SUBJECT MATTER

A. Statutory Eligible Subject Matter

For any potential invention to receive patent protection, it must be a recognizable category suitable for patent eligibility. The designated categories of potential patentable subject matter are described in 35 U.S.C. § 101, which describes that "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor."[68] Thus, as long as an invention fits into any one of the above categories, it meets the statutory threshold for patent eligibility. In practice, the explicit text of § 101 rarely provides any serious challenge to a patent's validity.[69]

And yet, challenges to subject matter continue to be some of the most commonly litigated patentability issues for patent infringement lawsuits today.[70] This is because, according to modern jurisprudence, there exists implicit exceptions to what may actually be patent eligible.[71] As stated by the Supreme Court, inventions directed to "[l]aws of nature, natural phe-

64. Samuelson, *supra* note 54, at 683–85.

65. *Id.*

66. *Id.* at 686. Since computers can only read instructions that are given in binary code, source code is only helpful to the programmer in conveying instructions to the computer in a format that is understandable to the programmer. *Id.* (describing the process of translating source code to binary code via a compiler).

67. *Id.*

68. 35 U.S.C. § 101 (2012).

69. S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82-1923, at 6 (1952), *as reprinted in* 1952 U.S.C.C.A.N. 2394, 2399.

70. Nicholas Vincent, *Turning the Tide: Patent Subject Matter Eligibility at the Federal Circuit*, LEXOLOGY (May 24, 2017), https://www.lexology.com/library/detail.aspx?g=a704d311-e86d-420e-82b9-fe2e34c2a8e0 [https://perma.cc/XQ5D-4QGZ].

71. Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347, 2354 (2014).

nomena, and abstract ideas are not patent eligible."[72] These recognized exceptions have been present in jurisprudence in some form since at least the mid-nineteenth century, well before the enactment of modern day § 101.[73] One of the earliest cases questioning patent eligible subject matter involved a patent for an apparatus capable of producing pipes from metals.[74] The patent owners claimed not the individual parts, but the combination of the parts.[75] In reversing a judgment of infringement, the Court stated:

> 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. Nor can an exclusive right exist to a new power, should one be discovered in addition to those already known.[76]

B. The Myriad *Dispute*

The Court's decision in *Myriad* represents the keystone framework of the product of nature exception to the biotech industry. The respondent, Myriad Genetics, Inc., had recently discovered that two genes (BRCA1 and BRCA2) significantly increase the risk of breast cancer when mutated.[77] It later obtained patents both for the isolated DNA sequences of the BRCA genes, as well as the cDNA sequences it synthesized from the corresponding RNA transcript.[78] After a challenge to the § 101 subject matter of both patents, the district court granted summary judgment against Myriad, ruling both patents invalid as products of nature.[79] On first appeal, the Federal Circuit reversed but the Supreme Court vacated and remanded after its holding in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*[80] However, on remand, the Federal Circuit filed a myriad of opinions. The majority held that the isolated BRCA sequences were patent eligible, but focused on the act of isolating DNA as an inventive concept distinct from its natural form.[81] No judge gave any weight to the information value of the

72. *Id.*

73. *See* O'Reilly v. Morse, 56 U.S. 62, 113, 116 (1853) (holding that a claim directed to any system for transmitting information using electricity was barred as a "natural philosophy").

74. Le Roy v. Tatham, 55 U.S. 156, 156 (1852).

75. *Id.* at 159.

76. *Id.* at 175.

77. Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 582–83 (2013).

78. *Id.* at 583–84.

79. *Id.* at 586.

80. *Id. See also* 566 U.S. 66, 72–73 (2012) (holding diagnostic method patents for treating autoimmune diseases as unenforceable under 35 U.S.C. § 101 unpatentable subject matter).

81. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303, 1328–29 (Fed. Cir. 2012).

DNA sequences in its analysis to find an inventive concept. In addition, all judges agreed that the cDNA sequences were patent eligible.[82]

On second appeal, the Supreme Court rejected the Federal Circuit's holding that isolated DNA sequences could be patent eligible.[83] Specifically, the Court reasoned that the severing of chemical bonds could not in itself form an inventive concept because Myriad's claims were directed to the information contained in the genetic sequences, not on the tangible molecules.[84] Thus, the information naturally encoded within the BRCA genes remained unchanged notwithstanding the artificial isolation of those genes from the body. Strangely though, the Court felt differently with regards to cDNA patentability. The Court concluded that "cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA segments . . . [because] the lab technician unquestionably creates something new when cDNA is made."[85] On this basis, the Court held cDNA a sufficient application from DNA as a product of nature and thus was patent eligible.[86]

Although the Court's holding seems intuitively correct, the doctrinal basis on which it is founded is anything but consistent. First, the Court surprisingly omitted any application of the "inventive concept" doctrine it developed in *Mayo*[87]—the very case that warranted initial remand to the Federal Circuit—to Myriad's claims.[88] Instead, the Court extensively relied on the fundamental principle that "[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry."[89] Since this principle is exactly why the inventive concept doctrine was created, the Court essentially wipes the slate clean from any precedential guidance by *Mayo*.[90]

82. *Id.* at 1329, 1337, 1348 (Bryson, J., concurring) (finding that cDNA claims were patent eligible but concluding that isolated DNA claims were not).

83. *Myriad Genetics*, 569 U.S. at 591–93.

84. *Id.* at 593.

85. *Id.* at 594–95.

86. *Id.* at 595.

87. Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 72–73 (2012) ("A process that focuses upon the use of a natural law also contain[s] other elements or a combination of elements, sometimes referred to as an 'inventive concept,' sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself.")

88. Neither the phrase "inventive concept" nor the phrase "significantly more" appear anywhere throughout the Court's brief opinion. *Myriad Genetics*, 569 U.S. at 576. The Court did however, recite the discussion of the Federal Circuit's opinion in determining whether the act of isolating DNA was an "inventive act". *Id.* at 586–87.

89. *Id.* at 591.

90. The Court cites its decision in *Mayo* only three times throughout its opinion, and each of those citations are either directed towards the procedural history of the case or the basic fundamental

Instead, the Court drew an analogy to its iconic decision in *Diamond v. Chakrabarty*.[91] In *Chakrabarty*, the patent owner had artificially created a new living bacterium by infusing it with plasmids containing genes obtained from other sources.[92] As a result, this new bacterium was capable of breaking down crude oil, a property that no naturally occurring species of bacteria previously exhibited.[93] The Court held that the claimed bacterium was patent eligible under § 101, finding that the "human ingenuity" and research involved in creating the bacterium distinguished it from existing natural phenomena.[94]

The Court's reliance on *Chakrabarty* is expected, but problematic. While *Chakrabarty* stood for the rule that naturally derived phenomena could be patent eligible, the *Chakrabarty* court focused specifically on the "markedly different characteristics"—or physical properties—that differentiated the invention from properties found in nature.[95] What *Chakrabarty* did not explore was whether intangible characteristics implicated by the invention could be used to distinguish it from nature.

In contrast, this was the primary motivation used by the Court for holding isolated DNA unpatentable. As even the Court concedes, DNA present in the body contains a different chemical structure than isolated DNA in the laboratory.[96] This was readily explained and relied on by the Federal Circuit. Indeed, Judge Lourie, writing for the Federal Circuit, gave heavy weight to the cleaving of chemical bonds to create a "free-standing" molecule.[97] The Supreme Court could simply have held based solely on physical differences that the act of cleaving a biological molecule such as the BRCA gene was not sufficiently ingenious to grant patent protection. Admittedly, though, the reasoning would largely have rendered the distinctions unsatisfying, since the § 101 ingenuity standard was never meant to be a substantial bar to patentability (at least without encroaching into the separate obviousness patentability inquiry).[98] The Court essentially would be left to conclude the legal equivalent of 'we see that cleaving the chemical bonds makes the molecule different, but it's not enough.' And to some

policies surrounding the judicially created exceptions to patentability. *See id.* at 586 (procedural history), 589 (judicial exceptions to patentability), 594 (footnote support).

91. *Id.* at 590–91; Diamond v. Chakrabarty, 447 U.S. 303 (1980).

92. *Chakrabarty*, 447 U.S. at 305.

93. *Id.*

94. *Id.* at 309–10.

95. *Id.* at 310.

96. *Myriad Genetics*, 569 U.S. at 592.

97. Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office, 689 F.3d 1303, 1328 (Fed. Cir. 2012).

98. *See supra* note 69.

extent they do.[99] The problem is, however, they rely heavily on unprecedented grounds in doing so. The Court's central distinction is that isolated DNA patents cannot be valid because they inherently focus on the information contained in the DNA sequence, not the molecule itself.[100] The qualitative analysis of intangible characteristics like genetic information pushes this case beyond the realm of *Chakrabarty*.

Curiously, the Court took a different approach with cDNA patentability. The Court (rather conclusively) stated that cDNA is "unquestionably . . . something new,"[101] yet the Court remained silent as to what that "something new" is. It did not, for example, apply any formal two-step test to determine the presence of an inventive concept.[102] Moreover, the Court implied that its holding with respect to cDNA patent eligibility was directed to the physical structure of the cDNA molecule, a direct contrast to its earlier analysis with isolated DNA.[103] Whereas Myriad's isolated DNA claims were directed to the information encoded in sequences, now the Court seemed to hold Myriad's cDNA claims were directed to precisely the structural differences it rejected earlier. And it had to hold this way. A claim directed to a product of nature would make little sense if held otherwise, since the test is based on the markedly present characteristics claimed in the new invention. But this creates tension in the Court's reasoning. Essentially, this means that Myriad had directed its isolated DNA and cDNA claims to different properties: the former with the organizational sequence of nucleotides, and the latter to the physical structure of the cDNA molecule. While such a result could theoretically be possible, this was likely not Myriad's intention and not a fair interpretation of its claims.[104]

Interestingly, the Court expressly absolved any reliance on the application of information to further BRCA patents, and more broadly, to DNA sequences in general.[105] Yet the Court seemed to suggest otherwise when it clarified the narrow scope of its holding: the act of isolating genes does not

99. *Myriad Genetics*, 569 U.S. at 593 (rejecting the act of isolating DNA as an ingenious step because "Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA").

100. *Id.* at 593.

101. *Id.* at 595.

102. *See supra* text accompanying note 88.

103. *Myriad Genetics*, 569 U.S. at 595 (focusing on the splicing of introns that distinguishes cDNA from natural DNA).

104. *See id.* at 593. Based on the similarity in language of the claims at issue, the isolated DNA claims could not be directed to only the genetic information while the cDNA claims directed to the difference in physical structure. *Id.* at 583–85.

105. *Id.* at 596 ("Similarly, this case does not involve patents on new *applications* of knowledge about the BRCA1 and BRCA2 genes.") (emphasis added).

provide the novel ingenuity necessary to have a monopoly over the information encoded in those genes.[106] Its holding does leave open the possibility, however, that a novel approach to obtaining the information could be patentable.[107] While the exact relationship between "knowledge" of a gene and the "information" encoded within remains unclear, whatever amorphous distinction exists between them, they must be inherently intertwined. After all, how can one obtain and apply the knowledge of a gene without first learning the value of the information encoded within its nucleotides? In this way, the Court's holding seems irreconcilable with its reasoning: since DNA and cDNA are largely analogous molecules, they should be analyzed analogously. In other words, the entire presence of genetic information throughout this opinion creates confusion as to how precisely it can: (1) be reconciled with past precedent; and (2) how it should affect future decisions. The second prong will be discussed below.

III. THE QUASI-ALGORITHM RULE AS A SOLUTION TO *MYRIAD'S* TENSION

While it may seem that *Myriad* creates more problems than solutions, there is a way to formulate a rule for future DNA patentability cases post-*Myriad* that will overall benefit both the biotech industry and the general public, as well as incentivize follow-on innovation. Essentially, courts should be willing to see DNA not purely as a discrete biological entity, but as a "quasi-algorithm". I will refer to this rule as the "quasi-algorithm" rule.

Unlike claims directed to DNA manipulation, the Court is much more familiar with claims relating to mathematical processes. The Court in *Gottschalk v. Benson*, for example, invalidated a patent for an algorithm for the conversion of binary-coded decimal numerals into pure binary, because in effect the patent owner would be claiming a patent on the algorithm itself.[108] And more recently in *Alice*, the Court held that an algorithm for intermediate settlement was patent ineligible, because the invention essentially just translated a common and well known industry practice into a new medium (namely, a computer) without any detailed application of the practice.[109] But not all algorithms have been ruled patent ineligible. In *Diamond v. Diehr*, for example, the Court held that a method for rubber molding using the Arrhenius equation satisfied § 101 as being a sufficient applica-

106. *Id.* ("We merely hold that genes and the information they encode are not patent eligible under § 101 simply because they have been isolated from the surrounding genetic material.").

107. *Id.*

108. Gottschalk v. Benson, 409 U.S. 63, 68 (1972).

109. Alice Corp. v. CLS Bank Int'l, 134 S. Ct. 2347, 2360 (2014).

tion of a mathematical formula.[110] Though admittedly the Court has not developed a clear legal test outside of the *Mayo* framework for algorithms and other "abstract ideas," it has wrestled with digital technology patentability for over four decades.

But in legal terms, DNA fits well in a class of algorithmic legal fictions. DNA is not a categorical set of discrete steps in the traditional way. It does however, provide a method upon which a definite output is reached. Viewed this way, the entire processes of transcription and translation can be thought of as one biological algorithm, with the input being a specific gene and the output being the encoded protein. This algorithm can be simplified by just focusing on the information encoded within a gene, which essentially provides the instructions to perform all the necessary tasks. Thus, in order to be patent eligible under § 101, the question becomes not whether a DNA-based patent involves "markedly different characteristics" indicative of the *Chakrabarty* product of nature test,[111] but instead, whether the invention involves a sufficient application of the "DNA algorithm"—the information encoded to create a biological output. If the inventor alters the fundamental coding of the information just enough, she will create a new product or method beyond the processes "claimed" by nature.

In current § 101 jurisprudence, this rule would fit most cleanly within the "abstract idea" exception to patentable subject matter, most recently applied by the Court in *Alice*.[112] At its core, the exception bars patentability for any invention which centrally embodies "a principle in the abstract," a "fundamental truth," an "original cause", or a "motive."[113] It is easy to conceptualize theories or ideas as patent ineligible; based on the current state of patent law, no reasonable scientist would believe a research thesis would be patentable. What is much harder in practice is whether an application to an abstract idea is inventive enough to be patent eligible.[114] Courts (including the Supreme Court) have struggled with this analysis for decades, and the analysis of what exactly constitutes an "inventive concept" of an abstract idea would frustrate the purpose of this note. But while the principle is in itself abstract, the overall disposition is relatively clear—the

110. Diamond v. Diehr, 450 U.S. 175, 191–93 (1981).

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

112. *Alice*, 134 S. Ct. at 2354–55.

113. *Id.* at 2355 (citing Le Roy v. Tatham, 55 U.S. 156, 175 (1853)).

114. One emerging principle is that claiming an invention to a well-known process or algorithm by translating it into a computerized format is clearly not patent eligible. *See id.* at 2357.

Court gives patents directed to abstract ideas an enormous burden to satisfy, and thus rarely finds these patents inventive.[115]

Applying the quasi-algorithm rule to the claims in *Myriad* would very likely yield the same result as held by the Court, but would resolve some of the tension concerning what is actually being patented here. The claims at issue are the isolated BRCA sequences that Myriad labored to discover.[116] Applying step one of the *Alice* subject matter test, the claim is directed to the abstract idea of genetic information encoded within a gene. *Alice* step two then requires there to be an inventive concept after considering all the ingenious elements in their entirety. In this case, Myriad would need to show that the isolated gene sequences were a sufficient application of the DNA algorithm (as indicated by its claims). That is, did Myriad provide any additional ingenious elements to the already existing genetic information encoded within the BRCA genes that would either alter the algorithmic process or yield a different result?

This is a burden Myriad could not satisfy. In a sense, Myriad's claims sound hauntingly similar to claims that merely translated a process into a new medium, such as a computer. Stripping the claim to its ingenious elements, Myriad has not altered any of sequences, nor has it created a process by which the BRCA genes were produced another way that already existed. Myriad has simply isolated the sequences—essentially performing the equivalent of truncating a code and pasting it into a blank format.

Myriad's cDNA claims are also directed to the same abstract idea of genetic information, but the result is different. Applying step two, Myriad has both altered the process of the BRCA DNA algorithm, as well as obtaining a new output that exists outside any found in nature, even though the genetic information encoded within a cDNA molecule remains the same. While certainly the processes of creating cDNA via reverse transcriptase are well known in the biotechnology field, this is not an inquiry appropriate for § 101. The question is, rather, did the inventor herself use a process that is sufficiently different than what exists outside of nature?

115. *Compare Alice*, 134 S. Ct. at 2360 (patent for mitigating settlement risk invalid), *and* Bilski v. Kappos, 561 U.S. 593, 611–12 (2010) (patent for hedging price risk invalid), *and* Parker v. Flook, 437 U.S. 584, 594–95 (1978) (patent for updating alarms invalid), *and* Gottschalk v. Benson, 409 U.S. 63, 71–72 (1972) (patent for converting binary-coded decimal numerals into pure binary invalid), *with* Diamond, 450 U.S. at 191–93 (patent for curing rubber using Arrhenius equation valid).

116. *See* Ass'n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 584 (2013) (Claim 1 reads: "[a]n isolated DNA coding for a BRCA1 polypeptide," which has "the amino acid sequence set forth in SEQ ID NO:2." Claim 2 then reads: "[t]he isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1" where "SEQ ID NO:1 [is] the sequence of cDNA that codes for the BRCA1 amino acids listed in claim 1").

Myriad has arguably done so,[117] and the inquiry regarding the "newness" of the process would subsequently be analyzed under a § 103 examination.

IV. POLICY IMPLICATIONS

Ultimately, the goal driving any jurisprudential rule in patent law is how to best reconcile the *quid pro quo* exchange between the benefits gained by the patentee's contribution to society and the foreseeable market harms resulting from anti-competition. The biggest fear expressed by the Supreme Court throughout its § 101 jurisprudence has been the risk of giving patent rights for inventions that are preempted by what already exists in the public.[118] The problem with this approach to biotechnology is that it inherently is an unpredictable field.[119] What is preempted in biotechnology largely depends on perspective. Do we think of DNA as a tangible biological product? Or is it more prudent to focus on the intangible yet core utility of the molecule itself? The difficulty of these questions justify a narrow holding in *Myriad* moving forward.[120]

I believe the latter approach more appropriately categorizes the line between incentivizing innovation and *ex post* market control. Because patents directed to algorithms will most likely fail under § 101, this means that no one scientist can claim a monopoly over DNA without first disclosing some unique property actually created by the inventor himself. In terms of scientific advancement, this means that, absent special circumstances, DNA is fair game to all.[121] But if DNA is instead viewed more as a personal property right, then *Myriad* symbolizes a return to the traditional reluctance of government to commodify anything inherent to one's identity.[122] Among other noneconomic considerations are potential invasions to the

117. One interesting counterargument to Myriad's use of reverse transcriptase would be that the process of reverse gene encoding already exists in nature in the form of viral infections. Since viruses direct infected cells to recreate their genetic codes using reverse transcriptase, the argument is that Myriad is simply applying one natural phenomenon to another. The question then becomes whether the synthesis of one natural process (the BRCA DNA algorithm) to another independent one (viral DNA recreation) satisfies the "inventive concept" test. No such scenario has thus far been presented to the Court, and resolving this question is beyond the scope of this note.

118. O'Reilly v. Morse, 56 U.S. 62, 110 (1853); Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 72-–73 (2012).

119. Christopher M. Holman, *Unpredictability in Patent Law and its Effect on Pharmaceutical Innovation*, 76 MO. L. REV. 645, 674 (2011).

120. *See* Evan H. Tallmadge, Note, *Patenting Natural Products After Myriad*, 30 HARV. J.L. & TECH. 569, 572–73 (2017).

121. See Fazal Khan & Lindsay Kessler, *Genomics Unbound: The Scientific and Legal Case Against Patents Based on Naturally Occurring DNA Sequences*, 13 NEV. L.J. 668, 680–86 (2013), for a discussion on the harms of patents to natural DNA sequences.

122. Kelli Rockandel, *A Myriad of Reasons to Celebrate: Why the Invalidation of Isolated DNA Patents is a Victory for Personal Property Rights*, 38 VT. L. REV. 225, 225–26 (2013).

rights of privacy and reproductive liberties.[123] While patent law does not focus on such concerns, they should nonetheless be considered in the background of any patent dispute because they may carry economic consequences that chill innovation and also because a patent is inherently a positive property right granted by the sovereign.

Since *Myriad*, the biotechnology industry as a whole has not succumbed to the commercialization fears that proponents of gene patents once warned.[124] Before *Myriad*, the United States Patent and Trademark Office issued somewhere between 2,645 and 5,000 isolated DNA patents.[125] In addition, the Office "had granted 40,000 total DNA patents covering 20% of the human genome, of which 65% was owned or licensed by the private sector."[126] Presumably, most of those 5,000 patents are *de facto* invalid. Nonetheless, the industry has not seen any significant impact on follow-on innovation, as the industry was projected to be worth $414.5 billion in 2017.[127]

This is not to say *Myriad*'s far-reaching effects have not been felt in the industry itself. Soon after *Myriad* was decided, the Federal Circuit invalidated more method and BRCA patents in a subsequent infringement case brought by Myriad Genetics, Inc.[128] Prior to 2004, Myriad Genetics offered an open public database where it documented known mutations in the BRCA genes, and also offered free testing to patients who suffered from BRCA mutations.[129] Since losing patent protection to hundreds of gene patent claims from years of research, Myriad has closed its database, effectively removing it from the public and protecting its knowledge as a trade secret.[130] Though others are now free to use the BRCA genes without fear of infringement, the public has been deprived of comprehensive research on their function in the body. Thus, it is fair to say that the long-term

123. Lori B. Andrews & Jordan Paradise, *Gene Patents: The Need for Bioethics Scrutiny and Legal Change*, 5 YALE J. HEALTH POL'Y L. & ETHICS 403, 409–12 (2005).

124. Nikki Buck, *Greed is Good, for Patients: How the Biotechnology Industry Saves Lives, One Gene Patent at a Time*, 11 NW. J. TECH. & INTELL. PROP. 61, 77–79 (2013).

125. Charlotte A. Tschider, *Metaphor After* Myriad*: The Effect of Legal Rhetoric on Intellectual Property Protection for Biological Sequences*, 57 IDEA 519, 530 (2017).

126. *Id.*

127. *Id.*

128. *In re* BRCA1- and BRCA2-Based Hereditary Cancer Test Patient Litigation, 774 F.3d 755, 765 (Fed. Cir. 2014); John M. Conley et al., *Myriad after* Myriad*: The Proprietary Data Dilemma*, 15 N.C. J.L. & TECH. 597, 599 (2014).

129. Conley et al., *supra* note 128, at 600.

130. *Id.*

impact of *Myriad* on biotechnology innovation remains unknown even after approaching the case's five year anniversary.[131]

The last part of this note attempts to apply the quasi-algorithm rule in various domains of biotechnology. One integral field in biotechnology deals with protein expression and synthesis.[132] Proteins are versatile macromolecules that perform most of the cell's functions, and are now being synthetically made as an alternative to small drug molecules.[133] Before *Myriad*, protein patents typically took the form of either naturally isolated proteins, or synthetically created proteins made from recombinant DNA.[134]

It is very likely that naturally isolated proteins would not be patentable post-*Myriad*, as the protein itself resembles a naturally occurring product of nature. But even if courts looked beyond the physical structure of the protein and instead focus on its placement as the "output" of the DNA algorithm, such proteins would also not be patentable as abstract ideas. Similar to the analogy of isolated DNA patents, the inventor has not contributed anything substantive in applying or altering what already exists. Since *Myriad* expressly left open the question as to whether the methods of creating naturally occurring phenomena are patentable, it could be possible that the inventor has created something inventive. In that case, if the inventor had not simply isolated a naturally occurring protein, but actually synthesized and purified it through a non-conventional method, it could be patentable under the quasi-algorithm rule as a unique alteration of a naturally occurring algorithm. But such a result would conflict with earlier precedent holding that even when a product of nature is uniquely created, the product itself cannot be claimed as a patent.[135] Therefore, a better approach to the rule would look to the algorithm as a whole in determining if the end product—an isolated protein—is inventive enough as an output of the process. After *Myriad*, courts would likely answer this inquiry in the negative.

Applying the rule to synthetically created proteins would pose an interesting analysis. As a probabilistic matter, synthetically created proteins would be much more likely post-*Myriad* to be patentable under § 101. However, looking at them from the lens of their output of a DNA molecule,

131. Rinehart, *supra* note 10, at 1175. *See also* Peter S. Selness, *Personalized Medicine,* Mayo*, and the Uncertain Future of Integrated Health Care*, 18 MINN. L.J. SCI. & TECH. 787, 803–05 (2017) (discussing the impact of *Myriad* on the patentability of personalized medicine method patents).

132. *See generally* Priti Deka Phukan, *Patenting Proteins after* Myriad, 23 FED. CIR. B.J. 619, 619 (2014).

133. *Id.* at 639.

134. *Id.* at 639–40.

135. Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293, 293 (1884) (holding that a novel process that created a natural dye was patentable under the novelty patentability requirement but not a patent claiming the natural dye itself).

the likelihood of patentability would necessarily depend on how uniquely they were created, as well as their ultimate structural differences. Even a protein translated by artificial chimeric DNA with a function identical to a natural protein would necessarily depend on what steps the inventor did to "modify" the DNA algorithm that produces that natural protein. While a protein whose function is radically different would easily be patentable under § 101, it is important to keep in mind that, although § 101 encourages human ingenuity by emphasizing the differences between the invention and what exists in nature, biotechnology patents are more effective the closer they resemble the natural phenomenon they are imitating.

Another predominant area of biotechnology is the realm of gene-based diagnostic method patents.[136] Diagnostic patents as they existed before *Myriad* involved analyzing the effects of genes under controlled conditions as a way to diagnose a result (like a disease) on a patient.[137] The patentability of these patents took a huge blow from the *Mayo/Myriad* duo, as many of these patents skirted beyond the line of unpatentable laws of nature or abstract ideas.[138] Reception to broad diagnostic patent protection has generally been negative.[139] Critics argue that patent protection actually inhibits the "particularly acute need for follow-on innovation" unique to medical research.[140] Even after *Myriad*, however, diagnostic methods remain patentable so long as they otherwise meet the requirements of § 101.[141]

Under the quasi-algorithm rule, diagnostic patents would almost entirely fail under § 101. The inventor does not alter anything beyond the natural relationship that exists from the DNA to its clinical effect that is observed. Indeed, the inventor must rely on the natural expression of DNA, including the information in those genes, in order for his method to have any real value. No amount of creative claim drafting would be able to escape the fact that the method itself relies on the entirety of the naturally occurring, unmodified, DNA algorithm in order to achieve its desired re-

136. *See generally* Michael A. Sanzo, *The Patenting of Gene Based Diagnostic Assays in a Post* Mayo *and* Myriad *World*, 16 J. MARSHALL REV. INTELL. PROP. L. 1 (2016).

137. Duane C. Marks, *Diagnostic Method Patents: A Framework for Patent-Eligibility of Diagnostic Method Patents Post*-Mayo, USPTO, https://www.uspto.gov/sites/default/files/patents/announce/may9forum_marks.pdf [https://perma.cc/W3LU-6A26].

138. Sanzo, *supra* note 136, at 15–16.

139. *See generally Diagnostic Method Patents and Harms to Follow-on Innovation*, 126 HARV. L. REV. 1370 (2013); Sanzo, *supra* note 136; Morgan Medlin, Note, *Transformation of Diagnostic Method Patents: Why Changes in Biotechnology and the Law Make Evolution Necessary*, 23 S. CAL. INTERDISC. L.J. 627 (2014). *But see* Selness, *supra* note 131, at 798–803 (discussing the harms that result from minimal patent protection for personalized medicine method patients).

140. *Diagnostic Method Patents and Harms to Follow-on Innovation*, *supra* note 139, at 1377.

141. Marks, *supra* note 137, at 13–16.

sult. This is different from established case law, where such methods may be patentable if they apply a natural phenomenon in a unique and inventive way. But considering the general disdain for diagnostic patents and the problems they create on easy accessibility and follow-on innovation, this distinction may actually be more beneficial than the current law.[142]

A third impactful domain of biotechnology in recent years has been stem cell research.[143] Stem cells consist of embryonic stem cells (ES),[144] or induced pluripotent stem cells (iPS).[145] ES cells are obtained by *in vitro* fertilization, which essentially replicates natural fertilization under laboratory conditions.[146] iPS cells are obtained essentially by reprogramming other cells to act like embryonic cells.[147] As a matter of principle, iPS cell patents are generally more likely to pass § 101 than ES patents.[148]

Admittedly, the quasi-algorithm approach to stem cell patentability is difficult considering the limited focus on gene applications in stem cell development. However, because ES cells are essentially derived from natural processes, the DNA algorithm is undisturbed, and thus would suggest them to be unpatentable under a quasi-algorithm regime. Yet this raises a question of how substantial the DNA algorithm and the genetic coding information must be to the invention as a whole for it to be patentable under the quasi-algorithm rule. Should inventions that rely on natural processes of gene coding and expression (like stem cell technologies) be unpatentable merely because they adopt the DNA algorithm in its entirety, even if the algorithm itself is unsubstantial to the inventiveness of the invention? § 101 jurisprudence would say no, and it would be absurd to apply this rule in such a rigid way. Bringing this rule back into the stem cell context, stem cell patents might be patentable under the quasi-algorithm rule not because they creatively modify the DNA algorithm, but because they use the algorithm in an innovative way. In the ES cell context, however, this seems unlikely much like it was for isolated DNA patents: it is directed too closely to naturally products of nature. iPS cell patents, however, would likely meet this test, because they go beyond what already exists by repurposing the genetic information in natural somatic cells to act like another natural cell.

142. *Diagnostic Method Patents and Harms to Follow-on Innovation*, *supra* note 139, at 1382.

143. *See* Nicholas J. Diamond, *Stem Cells & the Trajectory of Section 101 Jurisprudence after* Myriad, 26 ALB. L.J. SCI. & TECH. 45, 67 (2016).

144. *Id.* at 68–69.

145. *Id.* at 69–70.

146. *Id.* at 68.

147. *Id.* at 69.

148. *Id.* at 74.

CONCLUSION

The application of recent (and confusing) § 101 jurisprudence to an already unpredictable biotechnology industry has resulted in a struggle to understand the lasting security of patent rights and future unpredictability of biotech patentability. In particular, the Court's *Myriad* decision highlighted the difficulties in how the patent system will view gene patents either as a tangible molecular entity, or as a coded informational sequence. The Court's limited guidance under *Myriad* indicates a shift in thinking under the latter approach. This note has endeavored to provide a doctrinal framework for reconciling the inherent ambiguity present in § 101 analysis and for future decisions moving forward. By analogizing the genetic information contained within a gene to a computer algorithm, we can more holistically qualify an inventor's ingenuity in gene patents. In the age of rapidly developing genetic and electronic technology, courts should not be restricted to classifying gene patents as directed to products of nature. Instead, when the essence of the invention goes to the genetic information in gene patents, courts should instead analogize the genetic algorithm as an application to an abstract idea under § 101 analysis. Only time will tell how lingering questions after *Myriad* will be resolved.