

Myriad: A Look Into the Future of Genetic Patentable Subject Matter

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***Myriad*: A Look into the Future of Genetic Patentable Subject Matter**

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INTRODUCTION

In June 2013, the Supreme Court of the United States decided the *Association for Molecular Pathology v. Myriad Genetics* case.¹ That decision will change the future of patent eligible subject matter. The decision was one of the first cases the Supreme Court determined after the adoption of the America Invents Act of 2013 (“AIA”).² Specifically, the *Myriad* decision deals with 35 U.S.C. §101 and patent eligible subject matter related to gene patents.³ The circuit court initially held that both isolated DNA and synthetically created complimentary DNA (cDNA) were patent eligible subject matter under section

1. *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013).
2. Leahy-Smith America Invents Act, H.R. 1249, 112th Cong. (2011-12).
3. *Myriad Genetics, Inc.*, 133 S. Ct. 2107.

101 of the AIA.⁴ The Supreme Court reversed in part finding that isolated DNA, comprised of naturally occurring segments of DNA, is not patent eligible subject matter.⁵ However, the Supreme Court found that synthetically created cDNA was not naturally occurring because cDNA has been stripped of its non-coding intron component and contains only the coding exon portion of the DNA.⁶ Therefore, cDNA does not occur in nature and falls within the scope of patent eligible subject matter.⁷ There have been several district court cases⁸ and two circuit court cases⁹ that have analyzed subject matter eligibility in light of the *Myriad* decision.

This Comment is divided into two sections. The first section interprets and analyzes how district courts and circuit courts determine patentable subject matter under the guidance of the *Myriad* decision. The second section of the Comment approaches the issue from the perspective of a law student with a background in molecular and cellular biology. The second section attempts to understand and predict the future of patentable subject matter eligibility in light of the *Myriad* Supreme Court decision and its progeny.

I. MYRIAD AND PATENTABLE SUBJECT MATTER

The *Myriad* decision is the leading authority on gene patents subject matter eligibility.¹⁰ The Court in *Myriad* addressed the issue of patenting isolated genes and cDNA sequences.¹¹ Section 101 of the Patent Act¹² permits patents to be issued to “[w]hoever invents or discovers any new and useful . . . composition of matter,” “but laws of nature, natural phenomena, and abstract ideas are basic tools of scientific and technological work that lie beyond the domain of patent protection.”¹³ The *Myriad* subject matter analysis relies heavily on the Supreme Court’s analysis in *Mayo Collaborative Services*.¹⁴

4. Ass’n for Molecular Pathology v. USPTO, 689 F.3d 1303, 1328 (Fed. Cir. 2012).

5. *Myriad Genetics, Inc.*, 133 S. Ct. at 2119.

6. *Id.*

7. *Id.*

8. Genetic Techs. Ltd. v. Bristol-Myers Squibb Co., 72 F. Supp. 3d 521, 523 (D. Del. 2014); Ariosa Diagnostics, Inc. v. Sequenom, Inc., 19 F. Supp. 3d 938, 942 (N.D. Cal. 2013); *In re BRCA1- and BRCA2- Based Hereditary Cancer Test Patent Litig.*, 3 F. Supp. 3d 1213 (D. Utah 2014); Genetic Techs. Ltd. v. Agilent Techs., 24 F. Supp. 3d 922 (N.D. Cal. 2014); Genetic Techs. Ltd. v. Lab. Corp. of Am. Holdings, No. 12-1736-LPS-CJB, 2014 WL 4379587 (D. Del. Sept. 3, 2014).

9. *In re Roslin Inst. (Edinburgh)*, 750 F.3d 1333 (Fed. Cir. 2014); *In re BRCA1- and BRCA2- Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755 (Fed. Cir. 2014).

10. *See generally Myriad Genetics Inc.*, 133 S. Ct. 2107 (2013).

11. *Id.*

12. Leahy-Smith America Invents Act, H.R. 1249, 112th Cong. (2011-12).

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

14. *See generally Myriad Genetics Inc.*, 133 S. Ct. 2107 (2013).

The holding in *Myriad* is that isolated genes do not fall within the category of patentable subject matter because they are naturally occurring.¹⁵ However, the Court made the distinction that cDNA, which is synthetically created in a laboratory and is not naturally occurring, is patent eligible.¹⁶ Since the decision in June of 2013, several district courts have engaged in an analysis of patent eligible subject matter.¹⁷ Two federal circuit cases use the *Myriad* decision in the courts' holdings.¹⁸ In order to understand where the future of gene patents is going, we must first look to how the cases since the *Myriad* decision are interpreted and applied, both at the district and federal level.

*A. District Courts' Interpretation of Patentable Subject Matter
in Light of the Myriad Decision*

Several district court decisions have been decided since the outcome of the *Myriad* decision in June 2013, which cite to and interpret the analysis performed by the Supreme Court.¹⁹ The *Myriad* decision relies heavily on the analysis performed by the Supreme Court in *Mayo Collaborative*.²⁰ The question presented by the Supreme Court in *Mayo* is, "do the patent claims add enough to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws?"²¹ The Court in *Myriad* took up this analysis in its statement that isolated DNA was simply DNA that was isolated from a cell, which was naturally occurring and not patent eligible subject matter, but that cDNA was synthetically created in a laboratory and not occurring in nature therefore cDNA did fall within patentable subject matter.²²

15. *Id.*

16. *Id.*

17. *Genetic Techs. Ltd. v. Bristol-Myers Squibb Co.*, 72 F. Supp. 3d 521, 523 (D. Del. 2014); *Ariosa Diagnostics, Inc., v. Sequenom, Inc.*, 19 F. Supp. 3d 938, 942 (N.D. Cal. 2013); *In re BRCA1- and BRCA2- Based Hereditary Cancer Test Patent Litig.*, 3 F. Supp. 3d 1213 (D. Utah 2014); *Genetic Techs. Ltd. v. Agilent Techs., Inc.*, 24 F. Supp. 3d 922 (N.D. Cal. 2014); *Genetic Techs. Ltd. v. Lab. Corp. of Am. Holdings*, No. 12-1736-LPS-CJB, 2014 WL 4379587 (D. Del. Sept. 3, 2014).

18. *In re Roslin Inst. (Edinburgh)*, 750 F.3d 1333 (Fed. Cir. 2014).; *In re BRCA1- and BRCA2- Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755 (Fed. Cir. 2014).

19. *Bristol-Myers Squibb Co.*, 72 F. Supp. 3d at 523; *Ariosa Diagnostics, Inc.*, 19 F. Supp. 3d 938; *In re BRCA1- and BRCA2- Based Hereditary Cancer Test* 3 F. Supp. 3d 1213, 1217; *Agilent Techs., Inc.*, 24 F. Supp. 3d 922; *Genetic Techs. Ltd. v. Lab. Corp. of Am. Holdings*, No. 12-1736-LPS-CJB, 2014 WL 4379587 (D. Del. Sept. 3, 2014).

20. *See Myriad Genetics Inc.*, 133 S. Ct. 2107 (2013).

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

22. *See generally Myriad Genetics Inc.*, 133 S. Ct. 2107 (2013).

1. *Arisoa Dignostics, Inc. v. Sequenom, Inc.* (Northern District of California)

The district court case *Arisoa Diagnostics v. Sequenom, Inc.* involves claims that are similar to the isolated DNA claims of the Myriad patent.²³ The court stated that “he who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it . . . [t]his is true even if the discovery . . . [is] considered groundbreaking, innovative, or brilliant.”²⁴ “A process or method is not unpatentable simply because it contains a law of nature, a natural phenomenon, or an abstract idea.”²⁵ It is well settled in case law that “to be patentable, a process that focuses upon the use of a natural law, a natural phenomenon, or an abstract idea *must* contain other elements or a combination of elements, referred to as an ‘inventive concept.’”²⁶ In *Myriad*, the Court went even further in its analysis of what is considered naturally occurring stating that “[s]imply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable.”²⁷ “The [*Arisoa*] Court’s conclusion conforms [to] the relevant Supreme Court case law, in particular *Flook* and *Myriad*,” “even though *Myriad* involved composition claims rather than method claims.”²⁸

The fact that *Myriad* involves composition claims and *Arisoa* involves method claims does not change the analysis performed by the court.²⁹ “Although the Supreme Court [in *Myriad*] was not presented with method claims, the Court explained ‘had Myriad created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent.’”³⁰ Had Myriad sought protection for a method for DNA isolation of the BRCA1 and BRCA2 genes, the method would likely still be found to be ineligible subject matter. The method patent for Myriad’s isolated DNA would be found to be ineligible subject matter because “the processes used by Myriad to isolate DNA were well understood by geneticists at the time of Myriad’s patents.”³¹ Had the inventors in *Arisoa* “created an innovative method of performing DNA detection while searching for paternally inherited cffDNA . . . those claims would be patentable.”³²

23. *Arisoa Diagnostics, Inc.*, 19 F. Supp. 3d 938.

24. *Id.* at 948.

25. *Mayo Collaborative Servs.*, 566 U.S. at 70.

26. *Id.* See also *Parker v. Flook*, 437 U.S. 584 (1978).

27. *Arisoa Diagnostics, Inc.*, 19 F. Supp. 3d 938.

28. *Id.* at 950.

29. *Id.*

30. *Id.*

31. *Id.*

32. *Id.*

However, “the claims presently before the court simply rely on processes to detect DNA that—as Sequenom (inventor) concedes—were conventional techniques by those in the field at the time of the invention.”³³

From *Ariosa*, it is clear that the District Court of the Northern District of California places emphasis on the naturally occurring element of patentable subject matter.³⁴ *Ariosa* uses well-known Supreme Court cases in establishing the background for its understanding of *Myriad*.³⁵ Additionally, the *Ariosa* court does not solely rely on the holding and reasoning of the *Myriad* decision, but includes the reasoning from previous Supreme Court decisions in its determination of what constitutes patent eligible subject matter under section 101.³⁶

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

The District Court of Utah takes a similar approach to that of the Northern District of California in its interpretation and application of the *Myriad* decision. The District Court of Utah, in *In re BRCA1, BRCA2*, again uses previous Supreme Court decisions along with the *Myriad* analysis and specifically looks to the *Mayo* decision to aid in its analysis.³⁷ The language the court adopts from *Mayo* is “[p]atents drawn to be processes focused on patent ineligible subject matter may likewise be patent ineligible, unless the processes include an ‘inventive concept’ sufficient to ‘ensure that the patent in practice amount to significantly more than a patent upon the natural law itself.’”³⁸ The *In re BRCA1, BRCA2* court adopts much of the language from the *Myriad* decision.³⁹ Regarding the exceptions of section 101 patentable subject matter, the court says, “patents granted over these basic tools create ‘considerable danger’ and that their use would be ‘tied up,’ thereby ‘inhibit[ing] future innovations premised upon them.’”⁴⁰ Following the guidance laid out in *Mayo*, “[t]he Supreme Court cautions that these exceptions to section 101 should be applied with care, as ‘all inventions at some level embody, use, reflect, rest upon or apply laws of nature, natural phenomena, or abstract

33. *Id.*

34. *Id.* at 948.

35. *See generally* *Mayo Collaborative Servs. v. Prometheus Labs, Inc.*, 566 U.S. 66 (2012); *see also* *Parker v. Flook*, 437 U.S. 584 (1978).

36. *See generally* *Ariosa Diagnostics, Inc.*, 19 F. Supp. 3d 938.

37. *In re* BRCA1- and BRCA2- Based Hereditary Cancer Test Patent Litig., 3 F. Supp. 3d 1213, 1217 (D. Utah 2014).

38. *Id.* at 1258.

39. *Id.*

40. *Id.*

ideas.”⁴¹

The inventors in the *In re BRCA1, BRCA2* case argued that because their primer claims are drawn to synthetic DNA, their BRCA1 and BRCA2 primers are patent eligible.⁴² The district court rejected that argument because the inventor’s primer claims are drawn to patent ineligible products of nature.⁴³ Additionally, the inventors in this case argued that because the “Court [in *Myriad*] found patent ineligible only isolated . . . genomic, extracted DNA, then the Court must have in blanket fashion ‘affirmed the patent eligibility of synthetic DNA,’ finding that ‘unlike isolated human genes, synthetic DNA is man-made and not a product of nature.’”⁴⁴ The district court rejects this argument, specifically stating, “the only synthetic DNA the [*Myriad*] court expressly found patent eligible was cDNA, [and] even then, the Court held only that cDNA may be patent eligible under some circumstances:”

As a result, cDNA is not a ‘product of nature’ and is patent-eligible under section 101, except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA. In that situation, a short strand of cDNA may be indistinguishable from natural DNA.⁴⁵

The district court makes the inference in their conclusion that “if cDNA—which is clearly synthetic—is sometimes patent ineligible, then implicit in the Supreme Court’s decision is not all synthetic DNA is patent eligible.”⁴⁶ The *Myriad* Court focused on the fact that the cDNA’s contiguous sequence was altered in comparison to the sequence from which it was derived.⁴⁷ The district court goes further to explain that “this court’s best reading of [*Myriad*] is that the Court concluded cDNA sometimes can be sufficiently different from naturally occurring matter as to merit patent eligibility.”⁴⁸ However, non-cDNA isolated DNA is patent ineligible insofar as “the location and order of the nucleotides existed in nature.”⁴⁹ This district court reads the Supreme Court’s decision in *Myriad* to “harmonize” with lower court rulings in *Myriad*, that non-cDNA isolated DNA includes primers and probes.⁵⁰ Finally, the

41. *Id.* at 1259.

42. *Id.*

43. *Id.*

44. *Id.* at 1261.

45. *Id.* at 1262.

46. *Id.*

47. *Id.*

48. *Id.* at 1263.

49. *Id.*

50. *Id.*

district “court interprets [*Myriad*] to stand for the proposition that even synthetic, non-cDNA, isolated DNA is patent ineligible where it reflects the same nucleotide sequence as the genomic DNA.”⁵¹

The conclusion reached by the District Court of Utah in the *In re BRCA1, BRCA2* decision is consistent with *Myriad*. However, the Utah District Court expanded upon the language and interpretation of the Supreme Court language used in *Myriad*. Inferring from the language, using the lower court and Supreme Court *Myriad* decisions for guidance, and following the background of the *Mayo* Supreme Court patent case law, the District Court of Utah concluded that the key language of the phrase “synthetic” in the *Myriad* case is not dispositive in showing patent eligibility.⁵²

3. *Genetic Technologies Ltd v. Bristol-Myers Squibb Company* (District Court of Delaware)

The District Court of Delaware made its own interpretation of *Myriad* in October 2014.⁵³ In that case, the plaintiff, Genetic Technologies Ltd. (“GTG”),⁵⁴ made the argument that *Myriad* “stands for the proposition that ‘man-made DNA that is molecularly different from naturally occurring DNA is patent eligible in of itself.’”⁵⁵ The District Court, however, said that the plaintiffs misread *Myriad*.⁵⁶ The plaintiffs contend that amplified DNA is equivalent to cDNA and should fall within the category of patent eligible subject matter.⁵⁷

“GTG concedes that ‘like cDNA, the nucleotide sequence of amplified DNA is dictated by the naturally occurring DNA.’”⁵⁸ However, GTG argued that “the process of amplification does not copy the methylation status of the DNA and incorporates cytosines into the final product of the naturally occurring 5-methylcytosines.”⁵⁹ The district court stated that, “[an] attempt to liken amplified DNA to cDNA contradicts the reasoning of *Myriad* and related Federal Circuit precedent, which focuses on what the claims recite rather than unclaimed chemical differences identified post-hoc during litigation.”⁶⁰ The court goes even further to make its point, using language from the *Myriad*

51. *Id.*

52. *Id.*

53. *Genetic Techs. Ltd. v. Bristol-Myers Squibb Co.*, 72 F. Supp. 3d 521, 523 (D. Del. 2014).

54. *Id.*

55. *Id.* at 536.

56. *Id.*

57. *Id.*

58. *Id.*

59. *Id.*

60. *Id.*

decision, stating that the methylation argument brought by GTG does not make their product patent eligible.⁶¹ The Supreme Court language stated, “‘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,’ but rather ‘focus on the genetic information encoded in the BRCA1 and BRCA2 genes.’”⁶² The District Court distinguished this from the Supreme Court holding in *Myriad* because the “claims on cDNA presented no such problem because removal of the non-coding region sequence ‘unquestionably creates something new,’ even though the coding regions are retained.”⁶³ Claim 1 in this case recites a method for detecting a coding region allele using genomic DNA, which is then amplified.⁶⁴ “[T]he nucleotide sequence of amplified DNA is dictated by the naturally occurring DNA.”⁶⁵ “Therefore, although amplification is carried out in a laboratory by a human, it is a replication of the native DNA sequence, resulting in a mirror image of the naturally-occurring genetic information.”⁶⁶

The District Court of Delaware chose to focus on the functionality of the product as compared to the actual product itself. The methylation step while technically creating a “new” coding sequence does not alter the functionality of the coding process itself. Essentially, the court explained that all GTG did was add this methyl group marker; this addition did not change the overall structure or function of the sequence in question. Because the only change was a minimal methylation, the court did not view this as enough of an inventive step to cause the sequence to fall into the category of patent eligible subject matter.

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

The technology involved in this case includes a method claim “for analyzing variations in non-coding intron sequences to detect linked coding region alleles and haplotypes.”⁶⁷ Specifically, the claimed methods involve “amplifying genomic DNA with a primer pair that spans a non-coding region sequence” and use this primer pair to detect alleles.⁶⁸ Additionally, this case focused on whether the defendant’s motion to dismiss will survive the clear and

61. *Id.*

62. *Id.*

63. *Id.*

64. *Id.*

65. *Id.*

66. *Id.*

67. *Genetic Techs. Ltd. v. Agilent Techs., Inc.*, 24 F. Supp. 3d 922, 926 (N.D. Cal. 2014).

68. *Id.*

convincing standard.⁶⁹ The court ultimately denied the defendant's motion to dismiss on the grounds that Agilent did not show by clear and convincing evidence that the patent claims are not meaningfully limited applications of natural laws.⁷⁰

The court in *Agilent* only used the *Myriad* analysis twice.⁷¹ The way in which the court used the *Myriad* decision was to establish background on what the Supreme Court had said about DNA.⁷² This analysis does not shed much light on how the court applied the *Myriad* decision to the present case; instead it merely served to identify what introns are in the context of DNA.⁷³ The second mention of the *Myriad* case is more applicable to this paper as it relates to how the court interpreted footnote seventeen of the case.⁷⁴ Footnote seventeen states that "Agilent argues that, unlike cDNA, amplified DNA is not patent eligible under *Myriad*. Even so, GTG does not purport to have patented the amplified DNA itself, but rather methods utilizing amplified DNA."⁷⁵ The Court in *Myriad* was careful to point out that its decision did not reach any method claims or applications of natural laws.⁷⁶

The court, in denying the motion to dismiss, is going towards a finding that this case may involve subject matter that cannot be patented. More and more, courts are looking into naturally occurring elements of patents. In this case specifically, the court did not find clear and convincing evidence that the subject matter itself was not, generally speaking, naturally occurring.

B. Federal Circuits' Application of the Myriad Interpretation

The Federal Circuit has heard two cases arising out of the litigation following the *Myriad* decision.⁷⁷ Both of these cases will serve to help understand where the future of gene patents lies. Because patents cases are federally regulated, the Federal Circuit cases yield more insight as to how lower courts are ultimately interpreting and applying the *Myriad* decision. The first case heard in the Federal Circuit was *In re Roslin Institute*, decided May 8,

69. *Id.* at 927.

70. *Id.* at 923.

71. *Id.* at 926.

72. *Id.*

73. *Id.*

74. *Id.* at 933, n. 17.

75. *Id.*

76. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2119–2120 (2013).

77. *In re Roslin Inst. (Edinburgh)*, 750 F.3d 1333 (Fed. Cir. 2014); *In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755 (2014).

2014.⁷⁸ Roslin was subsequently followed by *In re BRCA1, BRCA2*, which was decided December 17, 2014.

1. *In re* Roslin Institute

This case is about the first large mammal cloned from an adult somatic cell: Dolly the sheep.⁷⁹ A clone is defined in this case as “an identical genetic copy of a cell, cell part, or organism.”⁸⁰ In order to achieve this scientific breakthrough, the scientists performed a technique known as somatic cell nuclear transfer.⁸¹ The patent at issue in this case, however, is not the somatic cell nuclear transfer technique.⁸² Inventors attempted to gain a patent on the actual clones themselves, which was rejected by an examiner at the United States Patent and Trademark Office.⁸³ The examiners rejected the claims because they were directed at non-statutory subject matter under section 101, and the examiners’ rejections were upheld by the Board of Examiners.⁸⁴ The Federal Circuit here undertook a de novo analysis of the Board’s rejection of patent eligibility.⁸⁵

The first analysis of the Federal Circuit points out that even before the *Myriad* decision, the Supreme Court’s opinions in *Chakrabarty* and *Funk Bros.*, “made clear that that naturally occurring organisms are not patentable.”⁸⁶ Roslin makes the argument that “copies (clones) are eligible for protection because they are ‘the product of human ingenuity’ and ‘not nature’s handiwork, but [their] own.’”⁸⁷ The Federal Circuit compares the clones made by Roslin to the isolated DNA in the *Myriad* case.⁸⁸ The Federal Circuit specifically stated that Roslin “‘did not create or alter any of the genetic information’ of its claimed clones, ‘[n]or did [Roslin] create or alter the genetic structure of [the] DNA’ used to make its clones.”⁸⁹

The Federal Circuit affirmed the Board’s finding that Roslin’s clones were unpatentable subject matter for several different reasons.⁹⁰ The key underlying theme to the affirmation of the rejection was the fact that the clones are

78. *In re Roslin Inst.*, 750 F.3d 1333.

79. *Id.* at 1334.

80. *Id.* at 1337.

81. *Id.*

82. *Id.*

83. *Id.* at 1338.

84. *Id.*

85. *Id.*

86. *Id.* at 1336.

87. *Id.* at 1337.

88. *Id.*

89. *Id.*

90. *Id.*

naturally occurring.⁹¹ The Federal Circuit stated, “the claims do not describe clones that have markedly different characteristics from the donor animals of which they are copies.”⁹² From this language, it is clear that the Federal Circuit is looking at the differences between the clones and the naturally-occurring sheep, concluding that there were no differences between them, and thus the clones did not fall within the category of patentable subject matter.

2. *In re* BRCA1, BRCA2

This case arises out of the initial *Myriad* Supreme Court decision.⁹³ It involves patents that were not considered in the *Myriad* decision.⁹⁴ At issue in this specific litigation are two types of claims, (1) composition of matter claims, and (2) method claims.⁹⁵ The composition of matter claims involve two DNA primers, which are “short, synthetic, single-stranded DNA molecule[s] that bind . . . specifically to . . . intended target nucleotide sequence[s].”⁹⁶ The method claims at issue involve comparisons between wild-type BRCA sequences and the patient’s BRCA sequences.⁹⁷ The Federal Circuit looks first to the composition of matter claims and then to the method claims.⁹⁸

The Supreme Court decision in *Myriad* guides the Federal Circuit in its analysis of the primer claims under section 101.⁹⁹ The Federal Circuit, in its analysis of the primer claims, articulates that primers “are not distinguishable from the isolated DNA found patent-ineligible in *Myriad* and are not similar to the patent-eligible cDNA.”¹⁰⁰ The Court goes further to explain that because the primers “contain the identical sequence of the BRCA sequence directly opposite to the strand they are designed to bind . . . they are structurally identical to the ends of DNA strands found in nature.”¹⁰¹ Additionally, the Court states “it makes no difference” that the primers are “synthetically replicated.”¹⁰² The Court again looks to the functionality when determining whether the primers are different from their naturally occurring counterparts.¹⁰³

91. *Id.* at 1339.

92. *Id.*

93. *In re* BRCA1- and BRCA2- Based Hereditary Cancer Test Patent Litig., 774 F.3d 755, 758 (Fed. Cir. 2014).

94. *Id.*

95. *See generally id.*

96. *Id.*

97. *Id.*

98. *Id.* at 759.

99. *Id.*

100. *Id.* at 760.

101. *Id.*

102. *Id.*

103. *Id.* at 760–61.

The Federal Circuit explains “the naturally occurring sequences at issue here do not perform a significantly new function.”¹⁰⁴ The Federal Court, in regards to functionality, reads the Supreme Court’s decision in *Myriad* to mean “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.”¹⁰⁵

II. CONCLUSION

Based on the District Court’s and Federal Circuit’s interpretation of *Myriad* regarding patentable subject matter it is reasonable to conclude that the court now looks to functionality in determining whether or not something is naturally occurring. In the District Court cases, this was illustrated when the court rejected the argument that a mere methylation created something new. The argument that the methylation added a methyl group essentially creating a “new” molecule did not hold weight because, in the court’s mind, the functionality was still the same. This move towards functionality being a part of the naturally occurring analysis is also starting to occur in the Federal Circuit. When looking at the *In re Roslin* and *In re BRCA1* cases, it is clear that courts are looking on a broader scale to determine whether the thing in question is naturally occurring. This will be important an important factor going forward in gene patentability.

The courts are essentially making the test of whether a matter is naturally occurring more difficult to overcome, in the sense that just because of the fact that the matter is made in a lab does not automatically preclude it from being considered naturally occurring. Quite the opposite, actually. The standard for showing something is not naturally occurring is becoming difficult to meet, especially now that courts are not looking just to the structure of the molecule or gene, but also the functionality. This can possibly be a dangerous road to travel down, because functionality is a very important part of patents. It is my opinion that adding a methyl group to a molecule, while maybe not changing the function of the molecule, substantially changes the molecule. This change, while not naturally occurring, is now seen by courts as not being enough to provide the molecule patent protection. I think that this is an erroneous interpretation and has the potential to cause devastating outcomes in the future regarding the patenting of genes and genetic products.

In conclusion, I caution the courts when applying this functionality test in making the determination of when something is naturally occurring. Functionality now plays an important part in the patent system, and creating a

104. *Id.*

105. *Id.* at 761.

more difficult hurdle in the gene patent sector could lead to stagnant innovation in a field that cannot afford to be stagnant.

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