Biotech Patent Eligibility: Why we *Care* about Conventionality

CareDx, Inc. v. Natera, Inc., 40 F.4d 1371 (Fed. Cir. 2022)

Michael J. Moedritzer[*]

ABSTRACT

While the cfDNA advancements of CareDx hold significant promise and life saving potential in the field of molecular diagnostics, the Federal Circuit's decision in *CareDx, Inc. v. Natera, Inc*. to invalidate the patent was justifiable. The court correctly held that these inventions were directed to a natural phenomena and combined conventional techniques. The foundation of the patent system does not motivate these federally funded academic innovations and risk unwarranted high healthcare costs. With the recent White House mandate requiring tax payer funded research to be publicly available, there is also less risk for the use of trade secrets in these types of academic innovations.

*Michael Moedritzer, University of Missouri B.S. 2019, University of Missouri J.D. 2024. I would like to thank Professor Dennis Crouch for his insight and guidance and Ryan Hasenbeck for his editing skills.

I. INTRODUCTION

The patent system has been crucial in the technological and scientific progress that our country has seen over its history.[1] However, a patent system that allows protection over the fundamental tools of scientific research can hinder future research.[2] Finding the correct balance of patent eligibility is crucial to maintain the integrity of this system. In the words of Thomas Jefferson, we must draw "a line between the things which are worth to the public the embarrassment of an exclusive patent, and those which are not."[3]

A recent decision in the United States Court of Appeals for the Federal Circuit may have massive implications for the biotechnology–or biotech–industry. Ever since *Diamond v. Chakrabarty* in 1980, biotech innovators have relied on patent protection to ensure profits and investment to expand research into molecular biology. However, patent eligibility for biological diagnostic methods has been called into question in the last decade. The influence of the *Alice* test has limited the ability to patent inventions that involve laws of nature or natural phenomena. In the recent case of *CareDx, Inc. v. Natera, Inc.*, the patent eligibility of diagnostic methods was even further constricted.

However controversial the *Alice* test has become in limiting the ability to patent innovations involving biotechnology and computer software, the court in *CareDx* correctly determined that the diagnostic method was not patent eligible. There is a potential to tie up future scientific progress if the patent system allows for overly broad patent protection on fundamental biological research methods. The court correctly determined that the patent in *Care Dx,* was not eligible under 35 U.S.C. § 101.

II. CAREDX, INC. V. NATERA, INC.

In *CareDx, Inc. v. Natera, Inc.*, Stanford owned patents '652, '497, and '607.[4] The patents shared the same specification for a "Non-Invasive Diagnosis of Graft Rejection in Organ Transplant Patients."[5] Stanford had developed a method of precisely detecting levels of cell-free DNA ("cfDNA") within a person's blood.[6] This method can be used to detect the status of an organ transplant and predict if the organ is being rejected by a patient's body.[7] When an organ transplant is being rejected, the immune system of the organ recipient will begin to break down the organ cells, releasing cfDNA.[8] By accurately quantifying the amount of donor cfDNA in a patient's blood, one can predict whether the patient's immune system is rejecting the organ.[9]

1.James Yang, *Purpose of the Patent* System, OC PAT. LAW. (Apr. 11, 2018), https://ocpatentlawyer.com/lesson/purpose-benefits-patent-system.

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

3. Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813) (accessible at https://founders.archives.gov/documents/Jefferson/03-06-02-0322).

4. CareDx, Inc. v. Natera, Inc., 40 F.4d 1371, 1372 (Fed. Cir. 2022).

5. *Id.*

6. *Id.* at 1372–73.

7. *Id.* at 1373.

8. *Id.* at 1372–73.

9. *Id.* at 1373.

The court summarized patents '652, '497, and '607 as:

1. "'obtaining' or 'providing' a 'sample' from the recipient that contains cfDNA;

2. 'genotyping' the transplant donor and/or recipient to develop 'polymorphism' or 'SNP' 'profiles;'

3. 'sequencing' the cfDNA from the sample using 'multiplex' or 'high-throughput' sequencing; or performing 'digital PCR;' and

4. 'determining' or 'quantifying' the amount of donor cfDNA."[10]

Stanford exclusively licensed the use of these three patents to CareDx.[11] CareDx then filed infringement suits against Natera–a clinical genetic testing company–and Eurofins Viracor–a clinical diagnostics and biopharma services company–for allegedly using this exclusive method for their organ transplant rejection tests.[12] Both Defendants moved to dismiss the complaints for failure to state a claim as patents '652, '497, and '607 allegedly lacked patent-eligible subject matter.[13]

This motion was referred to a magistrate judge, who concluded "the claims were a 'purportedly new, unconventional combination of steps' to detect natural phenomena."[14] The court adopted the magistrate judge's recommendation, but noted that "the language in the written description of the asserted patent[ ] suggests that the patented steps are neither new nor unconventional" and the "specifications raise[d] doubts about the patents' validity."[15]

Following expert discovery, Natera and Eurofins each moved for summary judgement of ineligibility, which was ultimately denied by the district court because of a factual dispute as to the conventionality of the techniques performed in the claim.[16] Defendants then moved for an interlocutory appeal from the order denying summary judgment.[17] The court then "stated it would reconsider its summary judgement decision in view of case law cited in the certification motions."[18]

The district court then granted the motion for summary judgment based on patent ineligibility, stating the claims were "directed to the detection of natural phenomena" and "the claims recited only conventional techniques."[19] CareDx then appealed the district courts grant of the summary judgment motions.[20]

The court of appeals reviews the issue of patent eligibility *de novo*.[21] The court acknowledged that Congress contemplated the scope of patent eligibility to be wide,

10. *Id.* at 1375.
11. *Id.*
12. *Id.*
13. *Id.*
14. *Id.* (quoting CareDx, Inc. v. Natera, Inc., 563 F. Supp. 3d 329, 337 (D. Del. 2021).
15. *Id.* (quoting CareDx, Inc. v. Natera, Inc., 563 F. Supp. 3d 329, 337 (D. Del. 2021).
16. *Id.*
17. *Id.*
18. *Id.*
19. *Id.* at 1375–76.
20. *Id.* at 1376.
21. *Id.*

but that there are important implicit exceptions.[22] In order to not monopolize the basic tools of science and technology, "'laws of nature, natural phenomena, and abstract ideas' are not patentable."[23] While these components of nature are not in themselves patent eligible, applications and uses of these laws of nature *can* be eligible.[24] To determine the eligibility of these kinds of patents, the court uses a two-step test established in *Alice Corp. Pty. Ltd v. CLS Bank Int'l* and *Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc.*[25]

Using the first step of the *Alice* test, the court examined "whether the claims are 'directed to' a law of nature or natural phenomenon."[26] Then, if the claims are directed to a law of nature, the court "examine[s] whether the limitations of the claim apart from the law of nature or natural phenomenon, considered individually or as an ordered combination, 'transform the nature of the claim' into a patent-eligible application."[27]

CareDx emphasized that the patent's claim was not the discovery of the correlation between the rejected organ and the cfDNA levels in the patient's blood–rather, it was the "improved measurement methods spelled out in the claims as superior to the inadequate prior measurement techniques."[28] Prior to this method, cfDNA was not able to be measured at useful levels for diagnostic measurements of this kind. CareDx states that the patent protection is not for the increase in the cfDNA that shows the organ failure, but it is for the measurement technique itself.[29]

CareDx asserted that the district court incorrectly combined step one with step two and focused primarily on conventionality and that there was no basis in the law for this type of one-step analysis.[30] Regarding step two of the *Alice*/*Mayo* test, CareDx said that using digital PCR and next-generation sequencing to increase the precision of the measurement technique was an adequate inventive breakthrough that satisfies the second prong.[31]

Natera and Eurofins argued that the patent's claims were directed to the detection of natural phenomena.[32] The claims direct to the detection of the organ donor's cfDNA in the blood of the transplant recipient and the correlation between these elevated levels and the risk for organ rejection.[33] They argued that these claims are indistinguishable from diagnostic method claims that the Supreme Court has found ineligible that use conventional measurement techniques to detect natural phenomena.[34] They believed that the district court correctly interpreted the word "detecting" in the claims to conclude that they were directed to natural phenomenon.[35]

The court agreed with Natera and Eurofins that this is not a claim involving a new method of preparation or measurement technique, but rather a patent that

22. *Id.*
23. *Id.* (quoting Mayo Collaborative Servs. v. Prometheus Lab'ys, Inc., 566 U.S. 66, 70 (2012)).
24. *CareDx, Inc.*, 40 F.4d at 1376.
25. *Id.*
26. *Id.* (quoting Alice Corp. Pty. Ltd. v. CLS Bank Intern., 573 U.S. 208, 208 (2014)).
27. *Id.* (quoting *Mayo Collaborative Servs.*, 566 U.S. at 78).
28. *Id.* at 1377.
29. *See id.*
30. *Id.*
31. *Id.*
32. *Id.*
33. *Id.*
34. *Id.*
35. *Id.*

applies "conventional measurement techniques to detect a natural phenomenon[.]"[36] The court compared it to a new and improved method of detecting fetal cfDNA fragments, which was held to be ineligible.[37] The court further described how the claims are indistinguishable from other claims that the Supreme Court had held to be patent ineligible.[38]

CareDx further argued that the claims are not directed to natural phenomena, but rather to improved laboratory techniques.[39] But the court saw the claims as "conventional use of existing techniques to detect naturally occurring cfDNA."[40] Because of this, the court affirmed the district court's holding as to the step one analysis of the *Alice*/*Mayo* test.[41]

The court also agreed with the district court's analysis for step two of the *Alice*/*Mayo* test. It held that the claims added nothing inventive to the diagnostic method because they recite standard, well-known techniques in a logical combination for the purpose of the test.[42] The court stated that even the specification admits that "each step in the purported invention requires only conventional techniques and commercially available technology."[43] Finding that the claims were directed to natural phenomena and that there was not a sufficient inventive step to overcome the *Alice*/*Mayo* test, the court affirmed the district court's decision holding that the patents were ineligible.[44]

III. EVOLUTION OF THE *ALICE* TEST

A. Diamond v. Chakrabarty: Opening the Door to Biotech

Throughout the last 40 years, the ability to patent various types of biotechnology and abstract inventions has been a subject of interest for the courts. In 1980, *Diamond v. Chakrabarty* addressed whether a genetically engineered new bacteria could be eligible for patent protection.[45] Ananda Chakrabarty was able to genetically engineer a type of bacteria that was able to break down many of the components of crude oil during an oil spill.[46] When applying for a patent the patent examiner rejected the claim because the bacteria was a product of nature and because living things were not within the scope of patentable subject matter under 35 U.S.C § 101.[47]

The Supreme Court disagreed. The Court acknowledged that Congress grants this temporary monopoly in order to foster a "positive effect on society through the introduction of new products and processes of manufacture into the economy . . .

36. *Id.* at 1377–78.
37. *Id.* at 1378.
38. *Id.*
39. *Id.* at 1379.
40. *Id.*
41. *Id.* at 1379–80.
42. *Id.* at 1380.
43. *Id.*
44. *Id.*

45. *See* Diamond v. Charkrabarty, 447 U.S. 303 (1980).
46. *Id.* at 305.
47. *Id.* at 306.

and better lives for our citizens."[48] Looking at the history of patent law, the Court determined that the language of 35 U.S.C. § 101 should be broad in its scope and coverage.[49] Looking at the congressional reports about the 1952 Patent Act, the intended subject matter was to "include anything under the sun that is made by man."[50] However, it acknowledged that there are limits in patent law. Laws of nature, physical phenomena, and abstract ideas have long been determined to be ineligible for patents, as they are "manifestations of . . . nature, free to all men and reserved exclusively to none."[51]

The Court determined that–as Chakrabarty had engineered the bacteria rather than simply discovering the microorganism–the language of 35 U.S.C. § 101 encompasses genetically engineered bacteria.[52]

This case opened up the doors to biotechnology being more present in the patent system. The ability to patent genetically engineered living organisms and the results of molecular biology innovation allowed biologists to influence the medical field more directly.[53]

B. Mayo Collaborative Services v. Prometheus Laboratories, Inc.: The Initial Test

Since then, biotechnology has had a profound impact on the healthcare field.[54] But around thirty years later, in *Mayo Collaborative Services v Prometheus Laboratories, Inc.*, the test for whether an invention is natural phenomena became more defined.[55] In *Mayo*, Prometheus Laboratories was the exclusive licensee of two patents, which encompassed a manner of determining whether the dosage of a thiopurine drug was within a healthy range.[56] The patented claims essentially directed a doctor to administer the drug, to measure the resulting metabolites, then compare that concentration to certain level guidelines.[57]

The Supreme Court once again acknowledged that the scope of the patent system is broad, but that "'[l]aws of nature, natural phenomena, and abstract ideas' are not patentable."[58] The Court made it clear that "one must do more than simply state the law of nature while adding the words 'apply it'" for the invention to be patent eligible.[59] The Court needed to determine whether the patent covering the process that helps doctors use these thiopurine drugs to treat their patients with autoimmune diseases determine whether the dosage was too high or too low, was able to be patented.[60] Prometheus's process must have adequately transformed the unpatentable

48. *Id.* at 307.
49. *Id.* at 307–08.
50. *Id.* at 309.
51. *Id.* (quoting Funk Bros. Seed Co. v. Kalo Inoculant Co, 333 U.S. 127, 130 (1948)).
52. *Charkrabarty*, 447 U.S. at 318.

53. Ronald Evens, *The Evolution of Biotechnology And Its Impact On Health Care*, 34 HEALTH AFFS. 210, 217 (2015).
54. *Id.* at 211.
55. *See* Mayo Collaborative Servs. v. Promethus Lab'ys, Inc., 566 U.S. 66 (2012).
56. *Id.*
57. *Id.*
58. *Id.* at 70.
59. *Id.* at 72.
60. *Id.*

natural phenomena into something that would be patent eligible. The Court here held that the transformation was insufficient to render this process patent eligible.[61]

The Court emphasized that a process that focuses on a law of nature must contain an inventive concept or other elements that ensure that the process is significantly more than patenting the law of nature itself.[62] Looking at the patent, the claim revolved around a patient's body metabolizing the thiopurine drug, resulting in certain metabolites circulating throughout their bloodstream.[63] It had been known prior to this patent that these metabolites circulate through the blood and that they could be measured, but the precise correlation between the levels and the dosage was not known.[64]

After analyzing prior case law on patentability, the court determined that the claims here "add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field."[65] The conventional nature of the process combined with the focus on a natural phenomenon made these claims ineligible for patent protection.[66]

C. Alice Corp. Pty. Ltd. V. CLS Bank Intern.: Further Defining the Test

The test for patent eligibility for inventions that relate to law of nature was then further refined in *Alice Corp. Pty. Ltd. v. CLS Bank Intern.* In *Alice*, the petitioner was the assignee of patents which were designed to use a computer system as a third-party intermediary to facilitate the exchange of financial obligations between parties.[67] The scheme was used to mitigate "settlement risk[.]"[68] The Supreme Court once again was tasked with determining whether a process that focused on an abstract idea could be protected under existing patent law.

The patent claims used this computerized process to limit the risk that only one party will satisfy its obligation in an agreed upon financial exchange.[69] The system did this by creating "shadow" credit and debit records that "mirror the balances of the parties' real world accounts at 'exchange institutions'" then used these to instruct the financial institutions to "carry out the 'permitted' transactions in accordance with the updated shadow records[.]"[70] By doing this, the method of exchanging obligations mitigated the risk that only one party will perform.[71]

In 2007, CLS Bank International filed a suit against Alice Corp. seeking declaratory judgement stating that the patents at issue are invalid.[72] The Supreme Court cited *Mayo* in its attempt to balance policy considerations surrounding its decisions to limit the patentability of natural phenomena. The Court did not want to

61. *Id.*
62. *Id.* at 72–73.
63. *Id.* at 73.
64. *Id.*
65. *Id.* at 82.
66. *Id.*
67. Alice Corp. Pty. Ltd. v. CLS Bank Intern., 573 U.S. 208, 212 (2014).
68. *Id.*
69. *Id.* at 213.
70. *Id.* at 213–14.
71. *Id.* at 214.
72. *Id.*

inhibit the future progress and discovery by tying up the use of the "building blocks of human ingenuity" but also did not want to let these exclusionary principles "swallow all of patent law."[73]

The Supreme Court then articulated the current *Alice*/*Mayo* test: first, courts must "determine whether the claims at issue are directed to a patent-ineligible concept."[74] If the claims are directed to a patent-ineligible concept, then courts must "examine the elements of the claim to determine whether it contains an '"inventive concept"' sufficient to 'transform' the claimed abstract idea into a patent-eligible application."[75]

In this case, the Court determined that the claims at issue were directed to the abstract idea of intermediated settlement, a "fundamental economic practice long prevalent in our system of commerce."[76] Moving on to step two of the analysis, the Court concluded that "merely requir[ing] generic computer implementation" fails to sufficiently transform this abstract idea into a patent-eligible invention.[77]

D. Berkheimer and Aatrix: Component about Facts or Conventionality

Four years later, the Court of Appeals for the Federal Circuit decided two patent cases in the same week that further altered the *Alice* test. On February 8, 2018, the court added a fact-finding component to the *Alice* test.[78] In *Berkheimer*, the court once again needed to decide whether an invention was patent eligible under 35 U.S.C. § 101.[79]

The patent at issue in *Berkheimer* was a method of archiving a digital item in a processing system.[80] The patent system "parses files into multiple objects and tags the objects to create relationships between them."[81] The unique architecture of the system "eliminates redundant storage of common text and graphical elements, which improves system operating efficiency and reduces storage costs."[82] Mr. Berkheimer appealed the grant of summary judgment holding his patent invalid for ineligibility under 35 U.S.C. § 101.[83]

The court looked to whether there is any genuine dispute of material fact that would have disallowed the summary judgment order.[84] It then stated that even though patent eligibility is ultimately a question of law, that the "inquiry may contain underlying issues of fact."[85] But prior to this analysis, the court must use step one of the *Alice* to determine whether it is directed at an abstract concept. The

73. *Id.* at 216–17.
74. *Id.* at 218.
75. *Id.* at 221.

76. *Id.* at 218–19.
77. *Id.* at 221.
78. Berkheimer v. HP Inc., 881 F.3d 1360, 1368 (Fed. Cir. 2018).
79. *Id.* at 1365.
80. *Id.* at 1366.
81. *Id.* at 1362.
82. *Id.* at 1362–63.
83. *Id.* at 1362.
84. *Id.* at 1365.

85. *Id.*

district court found that it was directed to the abstract concept of "using a generic computer to collect, organize, compare, and present data for reconciliation prior to archiving."[86]

The court of appeals must look to prior similar decisions to determine if it is directed at a patent ineligible concept because the Supreme Court has not defined what it means to be directed to an abstract concept.[87] Looking at similar claims, the court determined that the claim is not directed to a patent eligible improvement in technology, rather it found that it was similar to computer technology cases that had been directed to an abstract concept.[88]

Moving on to step two of the *Alice* test, the court added a new dimension of the analysis. The court says that step two of the *Alice* test is satisfied when the claims "involve more than performance of 'well-understood, routine, [and] conventional activities previously known to the industry.'"[89] But the question of whether the elements of a claim are well-understood, routine, and conventional remains a question of fact.[90]

The court eventually finds that the summary judgment was improper because "[w]hether something is well-understood, routine, and conventional to a skilled artisan at the time of the patent is a factual determination."[91] The court emphasized that many cases of patent eligibility have been decided on summary judgment and this decision does not cast any doubt on those.[92] When there is no dispute of material fact as to the conventionality of a claim, then summary judgment is proper in patent eligibility cases.[93]

In a similar case, decided six days later, the court reversed the dismissal of an infringement suit under a F.R.C.P. 12(b)(6) motion.[94] Here the patent at issue describes a data processing system that allows a user to manipulate form data and create viewable forms and reports on a computer.[95] At the district court level, Defendant moved to dismiss the complaint under 12(b)(6), which was granted because one claim was directed to an intangible concept and the rest did not have an adequate inventive concept under *Alice* step two.[96]

The court here disagreed. While it is permissible to decide patent eligibility at a 12(b)(6) stage, the court stated that this is only permissible when there are not factual allegations that must be considered when determining the question of law.[97] Here, the court reaffirmed its stance in the previous case, that the *Alice* step two test is satisfied when it is shown that the elements in the claim go beyond well-known, routine, and conventional additions that an artisan in the field would know.[98] It also

86. *Id.* at 1366.
87. *See id.* at 1365.
88. *Id.* at 1366.
89. *Id.* at 1367 (quoting Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat'l Ass'n, 776 F.3d 1343, 1347 (Fed. Cir. 2014)).
90. *Id.* at 1368.
91. *Id.* at 1369.
92. *Id.* at 1368.
93. *Id.*
94. Aatrix Software, Inc. v. Green Shades Software, Inc., 882 F.3d 1121, 1130 (Fed. Cir. 2018).
95. *Id.* at 1123.
96. *Id.* at 1124.
97. *Id.* at 1125.
98. *Id.* at 1128.

further emphasized that there are underlying questions of fact in this determination that need to be resolved before a 12(b)(6) motion to dismiss should be granted.[99]

The court was careful to say that this judgment is only for the standard of a 12(b)(6) motion and that, importantly, a summary judgment standard would be different.[100] But in this case, viewing the facts in the light most favorable to the plaintiff, the court determined that the dismissal was inappropriate because there were underlying questions of fact that were not sufficient for dismissal.[101]

The various recent decisions on this matter have vast implications for the field of biotechnology. The *Alice*/*Mayo* framework could possibly make it practically unfeasible to acquire any type of molecular diagnostic method that does not involve the invention of a new machine or genetic testing method. This framework has brought out many policy questions as well: Should these molecular diagnostic techniques be patent eligible at all? Are these inventions even motivated by the patent system? Will this defeat the purpose of natural law patent ineligibility by encouraging trade secrets?

IV. SUMMARY OF ARGUMENT

The improvements to the technique of quantifying cfDNA achieved in this Stanford laboratory are undoubtably important to the field of molecular diagnostics. This discovery is going to save lives and further the ability to diagnose many other methods of disease detection and prevention. While the usefulness of this method is unquestionable, the court was correct to hold the patent claimed was an ineligible concept. It correctly held that this was an invention directed to a natural phenomenon and was a combination of conventional techniques that were not discovered by the former patent holder.

This type of discovery also is not motivated by the patent system. The patent system is in place to spur innovation and allow others to build off the previous monopolies.[102] To be worthy of the "embarrassment" of a legal monopoly, the system needs to motivate the innovation and that innovation needs to motivate further progress in itself. While the appellant adamantly disagrees, fundamental biological research in university laboratories is not primarily motivated by the patent system. This research is federally funded and innovations from these labs are not spurred by the incentive of a monopoly.

Patent ineligibility for innovations in molecular diagnostics that do not introduce an innovative concept also produce better results for the health of the nation. These discoveries have the potential to save vast amounts of lives, but one of the biggest problems facing our nation today is the monumental cost of health care.[103] Adding patent protection to diagnostic methods that do not sufficiently innovate

99. *Id.*
100. *Id.* at 1130.

101. *Id.*
102. Yang, *supra* note 1.

103. *See* Alex Montero et al., *Americans' Challenges with Health Care Costs*, KAISER FAM. FOUND. (July 14, 2022), https://www.kff.org/health-costs/issue-brief/americans-challenges-with-health-care-costs.

would result in the embarrassment of undeserved legal monopolies and increased health care costs.

Traditionally, patent ineligibility could increase the risk of trade secrets emerging. If this became more prevalent in the field of fundamental molecular biology research, this would result in new basic research methods being kept from other scientists. While this could have a negative effect on such a powerful field of innovation, this likely will not actually occur. The majority of fundamental biological research, similar to diagnostic methodology, is done in university research laboratories. This type of research, including the research done by the Stanford University researchers, is federally funded.

The National Security Presidential Memorandum (NSPM)-33 is a recent regulation from the Biden administration.[104] This regulation mandates that federally funded scientific research must be disclosed to the public.[105] This requirement forecloses the potential issue of trade secrets in the fundamental scientific research field.

The court in *CareDx* was correct in its assessment that patents '652, '497, and '607 were ineligible for protections. The field is not motivated by the patent system, it would result in heightened health care costs funded by federal tax dollars, and the recent Biden regulation solves the potential issue of non-disclosure.

V. THE APPLICATION OF THE *ALICE* TEST WAS CORRECT

The *Alice* test, while controversial, has become the legal standard for whether biotech is patentable. The test is frequently criticized for indeterminate and unpredictable,[106] with some even saying that "there is now less clarity on the basic question of patent eligibility than at almost any other time in American patent law."[107] But in this case, it resulted in the correct outcome.

The *Alice* Test was created to establish a "safe harbor from Section 101 abstract idea scrutiny . . . if the claimant establishe[d] that the claim is directed to a solution of a technological problem."[108] But patent holders can become worried about inconsistencies of decision making when it comes to biotechnological patents.[109]

For example, the *Alice* step one has had some confusion. There is inherent vagueness that comes with the phrase: "directed to a natural phenomenon or abstract idea."[110] In *BASCOM Glob. Internet Servs., Inc. v. AT&T Mobility LLC*, the court only was able to look to precedent because the Supreme Court has not determined what an "abstract idea" consists of. There has been some guidance given to courts analyzing innovations under the *Alice* test:

---

104. *An Update on Research Security: Streamlining Disclosure Standards to Enhance Clarity, Transparency, and Equity*, THE WHITE HOUSE, (Aug. 31, 2022), https://www.whitehouse.gov/ostp/news-updates/2022/08/31/an-update-on-research-securitystreamlining-disclosure-standards-to-enhance-clarity-transparency-and-equity.

105. *Id.*

106. Daryl Lim, *The Influence of Alice*, 105 MINN. L. REV. 345, 358 (2021).

107. Jeffrey A. Lefstin, *The Three Faces of Prometheus: A Post-Alice Jurisprudence of Abstractions*, 16 N.C. J. L. & TECH. 647, 649 (2015).

108. Donald S. Chisum, *The Supreme Court's Alice Decision on Patent Eligibility of Computer-Implemented Inventions: Finding an Oasis in the Desert*, PATENTLY-O (June 23, 2014), https://patentlyo.com/patent/2014/06/eligibility-implemented-inventions.html.

109. Lim, *supra* note 106, at 355.

110. *See* CareDx, Inc. v. Natera, Inc., 40 F.4th 1371, 1375–76 (Fed. Cir. 2022).

> At some level, "all inventions… embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." Thus, an invention is not rendered ineligible for patent simply because it involves an abstract concept.[111]

But, "[t]hat formulation plainly contemplates that the first step of the inquiry is a meaningful one, i.e., that a substantial class of claims are not directed to a patent-ineligible concept."[112] As nearly all inventions in the physical world incorporate some aspect of the laws of nature into their function, the test needs to be narrowed further. Boiling down the test to its basic questions, courts have begun to ask: in the light of the specification, is the "character as a whole is directed to excluded subject matter[?]"[113]

The court in *CareDx* concluded that the patents at issue were directed towards a natural phenomenon. Because the Supreme Court has given little guidance to this prong of the test. In the majority of cases the courts have had to look to prior case law to determine whether the patent is directed to an abstract concept or a law of nature.[114] Viewing the patent in the light of other biotech cases, the claim was directed to the quantities of cfDNA in a patient's blood resulting from the cellular breakdown of rejected organs. In light of these patent specifications, the court decided that the character as a whole was directed to the amount of cfDNA and this was the measurement of natural phenomenon.

The conventionality analysis, while usually done in step two of the analysis, was permissibly used after finding that the patent was directed to an abstract concept. As the patent itself calls the types of methods used as "conventional" and every biological method conducted was of public knowledge in the molecular biological community. Essentially the Stanford laboratory claimed a method of detecting fragments of DNA in the blood using conventional techniques, and while this may be impressive, it is not patent eligible.

VI. THIS INNOVATION IS NOT MOTIVATED BY THE PATENT SYSTEM

Historically, the courts have been careful about not expanding the patent system beyond the bounds necessary to spur innovation. In the case where innovation comes without the motivation of the patent system, the country should spare itself of the embarrassment of a legal monopoly.

The federal government provides more funding for fundamental research to higher education than any other sector.[115] In fact, academic institutions perform around 60% of federally funded basic research.[116] In 2018, academic research institutions performed nearly $80 billion in research and development, and nearly two

---

111. Alice Corp. Pty. Ltd. v. CLS Bank Intern., 573 U.S. 208, 217 (2014) (quoting Mayo Collaborative Servs. V. Prometheus Labs., Inc., 566 U.S. 66, 71 (2012)).
112. Enfish, LLC v. Microsoft Corp., 822 F.3d 1327, 1335 (Fed. Cir. 2016).
113. Internet Pats. Corp. v. Active Network, Inc., 790 F.3d 1343, 1346 (Fed. Cir. 2015).
114. *See* Aatrix Software, Inc. v. Green Shades Software, Inc., 882 F.3d 1121, 1124 (Fed. Cir. 2018). *See also* Berkheimer v. HP Inc., 881 F.3d 1360, 1367 (Fed. Cir. 2018).

115. *Academic R&D in the United* States: *Science and Engineering Indicators*, NAT'L SCI. FOUND., https://ncses.nsf.gov/pubs/nsb20202/academic-r-d-in-the-united-states (last visited Jan. 19, 2023).
116. *Id.*

thirds of that research was in fundamental, basic research.[117] This fundamental research on molecular biology and genetic techniques and diagnostic tools is crucial for the furtherance of science, but it is not motivated by the patent system.

This fundamental research itself is the building block that the court is so adamantly opposed to allowing patent protection over. This is in no way suggesting that most biotech should be patent ineligible but using publicly known technology to detect a naturally occurring phenomenon in the blood should be available to other researchers without paying a monopoly premium.

Proponents of the patent eligibility in cases such as this argue that the patents are motivated by the patent system. They view the capital invested in convincing the medical system to use their product after the patent is issued as sufficient to warrant the legal protection. However, labor or investment in developing is generally insufficient to establish patent eligibility,[118] so investment in marketing the product following patent issuance should not be enough to constitute the embarrassment of a legal monopoly.

VII. THIS PATENT INELIGIBILITY WILL NOT CAUSE DISCLOSURE PROBLEMS

Whenever an inventor believes that patent protection will not best protect their interests, then there is always the option to keep the details the invention a trade secret.[119] This option however can inhibit the progress of future inventors, because the innovative concepts are not disclosed to the public. So, by making various forms of innovation patent ineligible it begs the question of whether this patent ineligibility may inhibit future progress through the use of trade secrets in science.

Incentivizing scientific progress is one of the main objectives of the patent system.[120] So, if this decision would cause those in the field to hide the details of their innovations with trade secrets, this would achieve the exact opposite result the court intends.

Fortunately, the courts do not have to worry about this potential consequence. The White House Office of Science and Technology Policy recently established new policy guidance that effectively solves this problem.[121] This new policy guidance says that all taxpayer funded scientific research will have to be immediately available to the public at no cost.[122] This policy is praised by the scientific leaders who believe this will spur even further innovation.[123]

Because of this new policy, the vast amount of fundamental scientific research that is funded federally will be available to the public without the worry of trade secrets or incentivizing disclosure through the patent system. This new policy

117. *Id.*
118. Lim, *supra* note 106, at 349.
119. Daniel C. Munson, *The Patent-Trade Secret Decision: An Industrial Perspective*, 78 J. PAT. & TRADEMARK OFF. SOC'Y 689, 689–90 (1996).
120. U.S. CONST. Art. 1. Sec. 8. Cl. 8.
121. *What They Are Saying: White House Federally Funded Research Guidance Hailed as a Win for Innovation and* Equity, THE WHITE HOUSE (Sept. 30, 2022), https://www.whitehouse.gov/ostp/news-updates/2022/08/31/what-they-are-saying-white-house-federally-funded-research-guidance-hailed-as-a-win-for-innovation-and-equity.
122. *Id.*
123. *Id.*

solves the potential problems that may have resulted from limiting patent protection on fundamental diagnostic research.

VIII. CONCLUSION

The work done to produce the patents assigned to CareDx were great achievements that will inevitably save lives. But the court was correct in invalidating the patents for ineligibility. The court properly used the *Alice* test to determine that this was directed to an ineligible concept and solely used conventional methodology. The federally funded research was not motivated by the patent system and there is no danger of non-disclosure because of the new policy guidance. The potential hinderance on future scientific research was solved with a balance of patent ineligibility and new disclosure policy for federally funded research.