IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CAREDX, INC. and THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY, Plaintiffs, v. NATERA, INC., Defendant.	Civil Action No. 19-0567-CFC-CJB CONSOLIDATED
CAREDX, INC. and THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY, Plaintiffs, v. EUROFINS VIRACOR, INC., Defendant.	Civil Action No. 19-1804-CFC-CJB

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MEMORANDUM OPINION

September 28, 2021
Wilmington, Delaware

COLM F. CONNOLLY
CHIEF JUDGE

Plaintiffs CareDx, Inc. and the Board of Trustees of the Leland Stanford Junior University (collectively, CareDx) have sued Defendants Natera, Inc. (C.A. No. 19-0567) and Eurofins Viracor, Inc. (C.A. No. 19-1804) for patent infringement. On December 1, 2020, I denied Natera's and Eurofins's motions for summary judgment of invalidity of the asserted patents under 35 U.S.C. § 101. C.A. No. 19-0567, D.I. 115; C.A. No. 19-1804, D.I. 76. I subsequently decided, after identifying material facts that may not be genuinely in dispute, to reconsider summary judgment of invalidity of the asserted patents on my own pursuant to Federal Rule of Civil Procedure 56(f)(3) and the Court's inherent authority.[1] I held an evidentiary hearing and permitted the parties to submit briefing after the

[1] Pursuant to Federal Rule of Civil Procedure 56(f)(3), "[a]fter giving notice and a reasonable time to respond, the court may consider summary judgment on its own after identifying for the parties the material facts that may not be genuinely in dispute." Under Third Circuit law, which governs the procedures by which this case is handled, a district court may revisit a prior decision *sua sponte* so long as it has not entered a final judgment depriving it of jurisdiction to reconsider the issue. *DeFranco v. Wolfe*, 387 F. App'x 147, 155 (3d Cir. 2010); *see also Escanio v. United Parcel Serv.*, 538 F. App'x 195, 199 (3d Cir. 2013) (judge may revisit earlier interlocutory denial of summary judgment). "In order to revisit a prior decision, the Court must explain on the record the reasoning behind its decision to reconsider the prior ruling, and it must take appropriate steps so that the parties are not prejudiced by reliance on the prior ruling." *DeFranco*, 387 F. App'x at 156.

hearing. I have now determined, for the reasons set forth below, that there are no genuine disputes of material fact and that summary judgments in Defendants' favor are warranted because the asserted patents claim patent-ineligible subject matter and are therefore invalid under § 101. *See* Fed. R. Civ. P. 56(a) ("The court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.").

I. THE ASSERTED PATENTS

CareDx has asserted three patents: U.S. Patent Numbers 8,703,652 (the #652 patent) (asserted against Natera and Eurofins); 9,845,497 (the #497 patent) (asserted against Natera); and 10,329,607 (the #607 patent) (asserted against Natera). As described by CareDx in the operative Amended Complaint against Natera, all three patents disclose "method[s] for determining organ transplant rejection" that "allow[ ] doctors to assess rejection through blood tests and without invasive biopsies." C.A. No. 19-0567, D.I. 74 ¶ 1.[2] An important determinant of the success or failure of an organ transplant is whether, and the extent to which, the recipient's body "rejects" the organ and attacks it with the body's immune system. Early detection of rejection is crucial to a transplant operation's success and the recipient's survival.

[2] Unless otherwise noted, all docket citations that follow will be to C.A. No. 19-0567.

The methods disclosed in the patents, to use CareDx's words, "detect [ ] particular concentrations of donor-specific, cell-free DNA in the bodies of donor recipients . . . ." D.I. 15 at 3. The linkage between concentrations of the organ donor's cell-free DNA (cfDNA) found in the recipient's blood after the organ transplant and the likelihood that the recipient will reject the newly transplanted organ was "long-known" before 2009, when the applications for the asserted patents were filed with the United States Patent and Trademark Office (PTO). D.I. 176 at 2. According to CareDx, attempts to detect the concentration of donor-specific cfDNA as of 2009 were "deficient," and the methods claimed by the asserted patents "improved on these deficiencies [*sic*] through the use of innovative, highly precise assays capable of detecting tiny increases in donor-specific DNA, thereby allowing doctors to recognize the onset of organ rejection before the damage becomes irreversible." D.I. 15 at 2.

The three asserted patents share a single written description and are all titled "Non-invasive Diagnosis of Graft Rejection in Organ Transplant Patients." Each patent has a priority date in November 2009. The shared written description states that the claimed "invention describes sensitive and non-invasive methods . . . for diagnosing or predicting transplant status or outcome (e.g. transplant rejection)."

#657 patent at 3:52–55.[3] A detection method is said to be "sensitive" in two respects. Sensitivity can refer to the smallest absolute amount of change that can be detected by a method, Tr. of May 17, 2021 Hr'g at 96:25–97:14; or it can refer to the method's ability to correctly identify a patient with a particular disease, *id.* at 111:9–22.

CareDx alleged in its operative complaints that claim 1 of each asserted patent is "representative." See D.I. 74 ¶¶ 20, 23, 26; C.A. No. 19-1804, D.I. 1 ¶ 17. Defendants assert, and CareDx does not dispute, that claim 1 in each patent is sufficiently similar to the respective patent's other claims to be deemed a representative claim for determining whether the patent claims patent-eligible subject matter.

Claim 1 of the #652 patent recites:

> A method for detecting transplant rejection, graft dysfunction, or organ failure, the method comprising:
>
> > (a) providing a sample comprising cell-free nucleic acids from a subject who has received a transplant from a donor;
> >
> > (b) obtaining a genotype of donor-specific polymorphisms or a genotype of subject-specific polymorphisms, or obtaining both a genotype of donor-specific polymorphisms and subject-specific polymorphisms, to establish a polymorphism profile for detecting donor cell-free nucleic acids,

[3] For the sake of simplicity, I will identify only the #652 patent when citing to the patents' shared written description.

wherein at least one single nucleotide polymorphism (SNP) is homozygous for the subject if the genotype comprises subject-specific polymorphisms comprising SNPs;

(c) multiplex sequencing of the cell-free nucleic acids in the sample followed by analysis of the sequencing results using the polymorphism profile to detect donor cell-free nucleic acids and subject cell-free nucleic acids; and

(d) diagnosing, predicting, or monitoring a transplant status or outcome of the subject who has received the transplant by determining a quantity of the donor cell-free nucleic acids based on the detection of the donor cell-free nucleic acids and subject cell-free nucleic acids by the multiplexed sequencing, wherein an increase in the quantity of the donor cell-free nucleic acids over time is indicative of transplant rejection, graft dysfunction or organ failure, and wherein sensitivity of the method is greater than 56% compared to sensitivity of current surveillance methods for cardiac allograft vasculopathy (CAV).

Claim 1 of the #497 patent recites:

A method of detecting donor-specific circulating cell-free nucleic acids in a solid organ transplant recipient, the method comprising:

(a) genotyping a solid organ transplant donor to obtain a single nucleotide polymorphism (SNP) profile of the solid organ transplant donor;

(b) genotyping a solid organ transplant recipient to obtain a SNP profile of the solid organ transplant recipient, wherein the solid organ transplant recipient is selected from the group consisting of: a kidney transplant, a heart transplant, a liver

transplant, a pancreas transplant, a lung transplant, a skin transplant, and any combination thereof;

(c) obtaining a biological sample from the solid organ transplant recipient after the solid organ transplant recipient has received the solid organ transplant from the solid organ transplant donor, wherein the biological sample is selected from the group consisting of blood, serum and plasma, and wherein the biological sample comprises circulating cell-free nucleic acids from the solid organ transplant; and

(d) determining an amount of donor-specific circulating cell-free nucleic acids from the solid organ transplant in the biological sample by detecting a homozygous or a heterozygous SNP within the donor-specific circulating cell-free nucleic acids from the solid organ transplant in at least one assay, wherein the at least one assay comprises high-throughput sequencing or digital polymerase chain reaction (dPCR), and

wherein the at least one assay detects the donor-specific circulating cell-free nucleic acids from the solid organ transplant when the donor-specific circulating cell-free nucleic acids make up at least 0.03% of the total circulating cell-free nucleic acids in the biological sample.

Claim 1 of the #607 patent recites:

A method of quantifying kidney transplant-derived circulating cell-free deoxyribonucleic acids in a human kidney transplant recipient, said method comprising:

(a) providing a plasma sample from said human kidney transplant recipient, wherein said human kidney transplant recipient has received a kidney transplant from a kidney transplant donor, wherein said plasma sample from said human kidney transplant recipient comprises kidney transplant-

derived circulating cell-free deoxyribonucleic acid and human kidney transplant recipient-derived circulating cell-free deoxyribonucleic acid;

(b) extracting circulating cell-free deoxyribonucleic acid from said plasma sample from said human kidney transplant recipient in order to obtain extracted circulating cell-free deoxyribonucleic acid, wherein said extracted circulating cell-free deoxyribonucleic acid comprises said kidney transplant-derived circulating cell-free deoxyribonucleic acid and human kidney transplant recipient-derived circulating cell-free deoxyribonucleic acid;

(c) performing a selective amplification of target deoxyribonucleic acid sequences, wherein said selective amplification of said target deoxyribonucleic acid sequences is of said extracted circulating cell-free deoxyribonucleic acid, wherein said selective amplification of said target deoxyribonucleic acid sequences amplifies a plurality of genomic regions comprising at least 1,000 single nucleotide polymorphisms, wherein said at least 1,000 single nucleotide polymorphisms comprise homozygous single nucleotide polymorphisms, heterozygous single nucleotide polymorphisms, or both homozygous single nucleotide polymorphisms and heterozygous single nucleotide polymorphisms, and wherein said selective amplification of said target deoxyribonucleic acid sequences is by polymerase chain reaction (PCR);

(d) performing a high throughput sequencing reaction, wherein said high throughput sequencing reaction comprises performing a sequencing-by-synthesis reaction on said selectively-amplified target deoxyribonucleic acid sequences from said extracted circulating cell-free deoxyribonucleic

acid, wherein said sequencing-by-synthesis reaction has a sequencing error rate of less than 1.5%;

(e) providing sequences from said high throughput sequencing reaction, wherein said provided sequences from said high throughput sequencing reaction comprise said at least 1,000 single nucleotide polymorphisms; and

(f) quantifying an amount of said kidney transplant-derived circulating cell-free deoxyribonucleic acid in said plasma sample from said human kidney transplant recipient to obtain a quantified amount, wherein said quantifying said amount of said kidney transplant-derived circulating cell-free deoxyribonucleic acid in said plasma sample from said human kidney transplant recipient comprises using markers distinguishable between said human kidney transplant recipient and said kidney transplant donor, wherein said markers distinguishable between said human kidney transplant recipient and said kidney transplant donor comprises single nucleotide polymorphisms selected from said at least 1,000 single nucleotide polymorphisms identified in said provided sequences from said high throughput sequencing reaction, and wherein said quantified amount of said kidney transplant-derived circulating cell-free deoxyribonucleic acid in said plasma sample from said human kidney transplant recipient comprises at least 0.03% of the total circulating cell-free deoxyribonucleic acid from said plasma sample from said human kidney transplant recipient.

Thus, the methods disclosed in the representative claims have four steps for detecting a donor's cfDNA in a transplant recipient:

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.[4]

The patents' written description expressly states that the techniques referred to in these steps are, "unless otherwise indicated, conventional techniques of immunology, biochemistry, chemistry, molecular biology, microbiology, cell biology, genomics, and recombinant DNA, which are within the skill of the art." #652 patent at 5:36–40. Nowhere in the written description do the patents "otherwise indicate" that any of these techniques are nonconventional. On the contrary, the written description is replete with characterizations of the techniques in terms that confirm their conventionality.[5] Thus, according to the patents

[4] Defendants, in their supplemental § 101 opening brief, provided this summary of the steps of the method disclosed in the independent claims. *See* D.I. 175 at 8. CareDx does not dispute this summary, *see* D.I. 176; and CareDx's expert—Dr. Brian Van Ness—characterized the claims in essentially the same way, *see* Tr. of May 17, 2021 Hr'g at 169:19–170:5, 174:10–23, 175:25–176:10, 176:22–177:8.

[5] *See, e.g.*, #652 patent at 9:8–14 (stating that "[d]etection, identification and/or quantitation of the donor-specific markers (e.g. polymorphic markers such as SNPs) can be performed using real-time PCR, chips (e.g., SNP chips), high through-put shotgun sequencing of circulating nucleic acids (e.g. cell-free DNA), as well as other methods known in the art"); *id.* at 10:11–12 (stating that to obtain cfDNA samples "any technique known in the art may be used, e.g. a syringe or other vacuum suction device"); *id.* at 13:51–52 (stating that step 2 of claimed

themselves, the recited techniques disclosed in the claimed methods of detection were conventional as of 2009.

II. RELEVANT PROCEDURAL HISTORY OF THE CASE

CareDx filed its original complaint against Natera in March of 2019, alleging that Natera's kidney transplant rejection test infringed the #497 and #652 patents. D.I. 1. Five months later, CareDx filed its complaint against Eurofins, alleging that Eurofins's various organ transplant rejection tests infringed the #652 patent. C.A. No. 19-1804, D.I. 1. Defendants each moved to dismiss the complaints on the ground that the patents asserted against them were invalid under § 101 for claiming patent-ineligible subject matter. *See* D.I. 10; C.A. No. 19-1804,

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methods can be performed "using existing genotyping platforms know[n] in the art"); *id.* at 15:6–8 (stating that techniques recited in step 2 of claimed methods "can be accomplished through classic Sanger sequencing methods which are well known in the art"); *id.* at 13:58–61 (stating that "[c]ompanies (such as Applied Biosystems, Inc.) currently offer both standard and custom-designed TaqMan probe sets for SNP genotyping that can in principle target any desired SNP position for a PCR-based assay"); *id.* at 20:31–34 (stating that genotyping recited in claimed methods "may be performed by any suitable method known in the art including those described herein such as sequencing, nucleic acid array or PCR"); *id.* at 15:22–65 (discussing commercial high-throughput sequencing products); *id.* at 14:58–67 (citing articles from 2006 and 2007 as supporting the statement that "digital PCR is a much more accurate and reliable method to quantitate nucleic acid species"); *id.* at 18:55–19:2 (stating that "[m]ethods for quantifying nucleic acids," including high-throughput genotyping, "are known in the art"); *id.* at 21:5–9 (stating that "[t]he presence or absence of one or more nucleic acids from the transplant donor in the transplant recipient may be determined by any suitable method known in the art including those described herein such as sequencing, nucleic acid arrays or PCR").

D.I. 7. The motions were referred to the Magistrate Judge, who issued in both actions a single Report and Recommendation in which he recommended that I deny the motions. *See* D.I. 53.

Defendants each filed objections to the Magistrate Judge's recommendation. While the objections were pending before me, CareDx amended its complaint against Natera to add a claim for infringement of the #607 patent, which had issued in June 2019. *See* D.I. 74. Because the filing of the Amended Complaint mooted the motion to dismiss, I issued an Order in the Natera action vacating the Report and Recommendation (in that case), denying without prejudice Natera's motion to dismiss, and stating that Natera was free to file a motion to dismiss the Amended Complaint. Natera subsequently filed a second motion to dismiss, alleging that all three patents asserted against it were invalid under § 101. *See* D.I. 76.

In the meantime, I issued an Order adopting the Magistrate Judge's recommendation to deny the motion to dismiss in the Eurofins action. I stated in the Order:

> Eurofins argued in support of its motion to dismiss that the claims of the [#652 patent] are directed to a natural phenomenon (i.e., the correlation between transplant rejection and the presence of naturally occurring cfDNA) and therefore are not eligible for patenting under 35 U.S.C. § 101. The Magistrate Judge disagreed, concluding that the claims are directed to a "purportedly new, unconventional combination of steps" to detect that natural phenomenon. [C.A. No. 19-1804,] D.I. 30 at 9. Although language in the written description[] of the . . .

> asserted patent[ ] suggests that the patented steps are neither new nor unconventional, *see generally Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 757 (Fed. Cir. 2019) (claims that "recite only a natural law together with conventional steps to detect that law, . . . are ineligible under § 101"), I agree with the Magistrate Judge that it would be premature to make at this time a definitive ruling on whether the claims recite patent eligible subject matter. Accordingly, I will adopt the recommendation of the Magistrate Judge and deny Eurofins['s] motion to dismiss.
>
> Because the patents' specifications raise doubts about the patents' validity, and mindful of my obligation to facilitate the "just, speedy, and inexpensive determination of every action and proceeding," Fed. R. Civ. P. 1, I will entertain in this case early dispositive motion practice and, to that end, will convene a teleconference with the parties to discuss scheduling.

C.A. No. 19-1804, D.I. 53 at 2–3.

As evident from my observation in the Order that the written description of the asserted patents "suggests that the patented steps are neither new nor unconventional" and my citation of *Athena Diagnostics*, I had serious doubts that the Magistrate Judge's recommendation was correct. I was, however, mindful that the state of § 101 law is, to use the words of various Federal Circuit judges,

"fraught,"[6] "incoherent,"[7] "unclear, inconsistent[,] . . . and confusing,"[8] and "indeterminate and often lead[ing] to arbitrary results."[9, 10] And so I was especially

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[6] *See Athena Diagnostics,* 927 F.3d at 1337 (Hughes, J., concurring in the denial of the petition for rehearing en banc) ("The multiple concurring and dissenting opinions regarding the denial of en banc rehearing in this case are illustrative of how fraught the issue of § 101 eligibility, especially as applied to medical diagnostics patents, is.").

[7] *See Interval Licensing LLC v. AOL, Inc.*, 896 F.3d 1335, 1348 (Fed. Cir. 2018) (Plager, J., concurring in part and dissenting in part) (observing that the "incoherent body of doctrine" surrounding § 101 "renders it near impossible to know with any certainty whether [an] invention is or is not patent eligible" and that "the state of the law is such as to give little confidence" in the court's decisions).

[8] *See The State of Patent Eligibility in America, Part I: Hearing Before the Subcomm. on Intellectual Property of the S. Comm. on the Judiciary*, 116th Cong. 2 (2019) at 2 (retired Federal Circuit Chief Judge Paul Michel describing recent § 101 cases as "unclear, inconsistent with one another and confusing" and acknowledging that "courts alone created this problem").

[9] *See Smart Sys. Innovations, LLC v. Chicago Transit Auth.*, 873 F.3d 1364, 1377 (Fed. Cir. 2017) (Linn, J., dissenting in part and concurring in part) (characterizing § 101 jurisprudence as "indeterminate and often lead[ing] to arbitrary results").

[10] *See also Berkheimer v. HP Inc.*, 890 F.3d 1369, 1374 (Fed. Cir. 2018) (Lourie J., concurring in the denial of rehearing en banc) ("[Section 101] needs clarification by higher authority."); Daryl Lim, *The Influence of Alice*, 105 Minn. L. Rev. Headnotes 345, 346 (2021) (describing the standards for deciding patent eligibility as being "virtually indiscernible"); James Nurton, *Iancu Calls on Federal Circuit to Fix Section 101 Problem*, IP Watchdog (May 2, 2019) (former PTO director Andrei Iancu stating that "[r]ecent [§ 101] case law has created significant confusion"); *State of Patent Eligibility, Part I* at 1–2 (former PTO director David Kappos stating that "patent eligibility law truly is a mess" and calling Federal Circuit decisions "irreconcilable [and] incoherent").

reluctant to overrule a § 101 decision of a well-respected colleague at the motion to dismiss stage.

On the other hand, I recognized (and remain of the view) that "[f]ailure to recite statutory subject matter is the sort of basic deficiency that can, and should, be exposed at the point of minimum expenditure of time and money by the parties and the court." *OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359, 1364 (Mayer, J., concurring) (internal quotation marks and citation omitted). And I shared (and continue to share) Judge Mayer's view that "addressing 35 U.S.C. § 101 at the outset not only conserves scarce judicial resources and spares litigants the staggering costs associated with discovery and protracted claim construction litigation, it also works to stem the tide of vexatious suits . . . ." *Id.*

These competing concerns led me to a middle ground. I decided to follow the Magistrate Judge's recommendation and deny the motions to dismiss; but, at the same time, I stayed all aspects of the case except for expert discovery and summary judgment practice related to Defendants' § 101 challenge to the asserted patents. Natera thus withdrew its motion to dismiss, the parties engaged in expert discovery related to patent eligibility, and both Defendants filed motions for summary judgment of invalidity of the asserted patents under § 101.

The Scheduling Orders of both cases require that a concise statement of facts accompany any motion for summary judgment. The concise statements must

detail the facts "essential for the Court's determination of the summary judgment." D.I. 45 at 14. As explained in the Scheduling Orders, the concise statements of fact "play an important gatekeeping role in the Court's consideration of summary judgment motions," and, as a result, "a party shall reference only the material facts that *are absolutely necessary* for the court to determine the limited issues presented in the motion for summary judgment (*and no other*)." D.I. 45 at 14 n.1, 14–15 (emphasis added). In the concise statement of facts submitted with each summary judgment motion, Defendants each alleged as an undisputed, essential fact that "[n]either the written description nor the claims of the Patents disclose nonconventional techniques for performing genotyping and/or multiplex/high-throughput sequencing, individually or in combination." D.I. 102 ¶ 23. In support of this alleged fact, the Defendants relied on the written description of the asserted patents and the opinions of their shared expert, Dr. John Quackenbush. D.I. 102 ¶ 23 and cited exhibits. CareDx denied that the patents' claims disclosed only conventional techniques and cited in support of its position opinions of its own expert, Dr. Brian Van Ness, as well as six scientific articles that discussed the nascent nature of some of the specifically disclosed techniques. D.I. 104 ¶ 23 and cited exhibits. Faced with competing expert testimony on a fact the Defendants identified as being "absolutely necessary" for my determination, I denied the

summary judgment motions in orders issued on December 1, 2020. D.I. 115; C.A. No. 19-1804, D.I. 76.

On January 13, 2021, Defendants moved for certifications of interlocutory appeals from these orders. In their joint opening brief filed in support of their certification requests, Defendants cited Federal Circuit case law that appeared on its face to hold that the articles and expert testimony relied on by CareDx in opposition to the summary judgment motions are incapable, as a matter of law, of raising a genuine issue of material fact in light of the statements in the patents' shared written description that the disclosed techniques in the claimed detection methods were, in fact, conventional.

Defendants had not made this argument in their summary judgment briefing, *see* D.I. 123; D.I. 136; Tr. of April 20, 2021 Hr'g at 5–14; and they had repeatedly cited in that briefing the opinions of their expert about the conventionality of the disclosed techniques, *see* D.I. 101 at 2–3, 14, 29–30; C.A. No. 19-1804, D.I. 62 at 3, 17–18. Accordingly, during a telephonic hearing on April 20, 2021, I denied the certification motions on the grounds that the parties had not put before me (and thus I had not addressed) the issue for which certification of the appeals was sought. Tr. of April 20, 2021 Hr'g at 14. But in light of the case law cited in support of the certification motions, it occurred to me that I may have prematurely decided that summary judgment in Defendants' favor was not warranted. It also

occurred to me that I had the authority to decide questions of fact underlying Defendants' § 101 challenge. *See Mortgage Grader Inc. v. First Choice Loan Servs. Inc.*, 811 F.3d 1314, 1325 (Fed. Cir. 2016) ("The mere existence in the record of dueling expert testimony does not necessarily raise a genuine issue of material fact" that precludes summary judgment.); *cf. Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249–50 (Fed. Cir. 2008) (affirming grant of summary judgment of indefiniteness based on intrinsic evidence and noting in dictum that conflicting expert testimony does not preclude a finding of indefiniteness); *Capital Sec. Sys., Inc. v. NCR Corp.*, 725 F. App'x 952, 958–59 (Fed. Cir. 2018) (affirming district court's decision granting summary judgment of indefiniteness despite expert testimony that an artisan of ordinary skill would understand the disputed claim term with reasonable certainty); *HIP, Inc. v. Hormel Foods Corp.*, 796 F. App'x 748 (Fed. Cir. 2020) (summarily affirming district court's decision granting summary judgment of indefiniteness despite expert testimony that an artisan of ordinary skill would understand the disputed claim term with reasonable certainty).

For these reasons, and cognizant of my obligation to administer the Federal Rules of Civil Procedure "to secure the just, speedy, and inexpensive determination of every action", Fed. R. Civ. P. 1, I ruled *sua sponte* at the April 20 hearing that I would reconsider my denial of the previous summary judgment motions and

schedule a hearing for the parties to adduce any evidence they thought I should consider in addressing the validity of the asserted patents under § 101. Tr. of April 20, 2021 Hr'g at 14–29. I then held in May 2021 an evidentiary hearing during which the parties presented competing expert testimony. And I permitted briefing after the hearing on any topic the parties wished to address related to the asserted patents' validity under § 101.

III. PATENT-ELIGIBLE SUBJECT MATTER

Section 101 of the Patent Act defines patent-eligible subject matter. It provides: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101.

There are three judicially created limitations on the literal words of § 101. The Supreme Court has long held that laws of nature, natural phenomena, and abstract ideas are not patentable subject matter. *Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014). These exceptions to patentable subject matter arise from the concern that the monopolization of "the[se] basic tools of scientific and technological work" "might tend to impede innovation more than it would tend to promote it." *Id.* (internal quotation marks and citations omitted).

But "an invention is not rendered ineligible for patent simply because it involves" a law or phenomenon found in nature or an abstract idea. *Alice*, 573 U.S. at 217 As the Court noted in *Alice,* "[a]t some level, 'all inventions ... embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.'" *Id.* (citation omitted). Applications of these concepts to "new and useful end[s]" remain eligible for patent protection. *Id.* (citation omitted).

Alice famously

> set forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts. First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts. If so, we then ask, "[w]hat else is there in the claims before us?" To answer that question, we consider the elements of each claim both individually and "as an ordered combination" to determine whether the additional elements "transform the nature of the claim" into a patent-eligible application. We have described step two of this analysis as a search for an "'inventive concept'"—*i.e.*, an element or combination of elements that is "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself."

Alice, 573 U.S. at 217–18 (citations omitted). Thus, under *Alice*, when faced with a § 101 challenge to a patent, the court first asks whether the asserted claims are "directed to" a patent-ineligible concept. If the answer to the "directed to" question (i.e., step one of the *Alice* inquiry) is no, then the patent is not invalid under § 101. If the answer to that question is yes, then the court proceeds to step

two of the *Alice* inquiry and asks whether the individual or combined elements of the asserted claims contain an inventive concept.

In *Athena Diagnostics*, the Federal Circuit held that at step one of the *Alice* inquiry claims are directed to a natural law if they "recite only [a] natural law together with standard techniques for observing it." 915 F.3d at 752. This holding is consistent with at least two other Federal Circuit decisions. *See Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1048 (Fed. Cir. 2016) (holding that claims are "directed to" a patent-ineligible concept "when they amount[] to nothing more than observing or identifying the ineligible concept itself"); *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1361 (Fed. Cir. 2017) (holding that method-of-detection claims were "directed to a natural law" at step one of the *Alice* inquiry where the claims "use[d] well-known techniques to execute the claimed method" and had "no meaningful non-routine steps"). Thus, under binding Federal Circuit case law, methods-of-detection claims are directed to a patent-ineligible concept if they "only involve detecting a natural law 'with no meaningful non-routine steps.'" *Athena*, 915 F.3d at 752 (quoting *Cleveland Clinic*, 859 F.3d at 1361). Accordingly, where a patent claims a method for detecting a natural phenomenon, whether the patent is "directed to" a natural phenomenon for purposes of *Alice* step one turns on whether the claimed methods of detection are standard or routine.

In *Berkheimer*, however, the Federal Circuit held that "[t]he second step of the *Alice* test is satisfied when the claim limitations involve more than performance of well-understood, routine, [and] conventional activities previously known to the industry." 881 F.3d at 1367 (internal quotation marks and citations omitted). This description of the test for *Alice* step two sounds a lot like—in my mind, exactly like—the description of the test for *Alice* step one articulated by the Federal Circuit in *Athena* and *Cleveland Clinic* for method-of-detection claims. And, indeed the Federal Circuit has recognized that the two steps of the *Alice* inquiry overlap. *See Amdocs (Isr.) Ltd. v. Openet Telecom, Inc.*, 841 F.3d 1288, 1294 (Fed. Cir. 2016) ("Recent cases, however, suggest that there is considerable overlap between step one and step two, and in some situations this analysis could be accomplished without going beyond step one."); *Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1353 (Fed. Cir. 2016) ("[T]he two stages involve overlapping scrutiny of the content of the claims[, and] . . . there can be close questions about when the inquiry should proceed from the first stage to the second." (citations omitted)); *see also Smart Sys. Innovations*, 873 F.3d at 1382 n.2 (Linn, J., dissenting in part and concurring in part) (expressing "serious[] doubt" that "the boundary between steps one and two can somehow be defined").

It follows, then, that where a patent claims a method for detecting a natural phenomenon, the dispositive inquiry under both steps of the *Alice* inquiry is

whether the asserted method uses more than standard or conventional techniques of detection. And under either step, as the Supreme Court held in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, where the asserted

> claims inform a relevant audience about certain laws of nature; [and] any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately[,] . . . the steps are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities.

566 U.S. 66, 79–80 (2012).

IV. ANALYSIS

The parties essentially agree, and I find, that the asserted claims are directed to detecting a donor's cfDNA in a transplant recipient. *See* #652 patent at claim 1 (claiming "[a] method for detecting transplant rejection . . . or organ failure."); #497 patent at claim 1 (claiming "[a] method of detecting donor-specific circulating cell-free nucleic acids in a solid organ transplant recipient"); #607 patent at claim 1 (claiming "[a] method of quantifying kidney transplant-derived circulating cell-free deoxyribonucleic acids in a human kidney transplant recipient"). In CareDX's words:

- "[T]he claims are directed to new processes for detecting [a donor's] []cfDNA." C.A. No. 19-0567, D.I. 68 at 9.

- "The inventors [of the asserted patents] improved on these deficiencies [in the prior art] through the use of innovative, highly precise assays capable of detecting tiny increases in donor-specific cell free DNA . . . ." D.I. 15 at 2; C.A. No. 19-1804, D.I. 15 at 1.

- "[T]he plain language of the claims and the specification of the asserted patents establish that the claims are directed to specific, concrete methods of detecting particular concentrations of donor-specific, cell-free DNA in the bodies of donor recipients . . . ." C.A. No. 19-0567, D.I. 15 at 3.

- "Claim 1 of [the #]497 patent, for example, is directed to 'a method of detecting donor-specific circulating cell-free nucleic acids in a solid organ transplant recipient.'" D.I. 15 at 10.

- "[T]he challenged claims recite a series of specific, non-conventional laboratory techniques for detecting cell-free DNA with a high degree of sensitivity, in a manner that improves upon prior art methods of attempting such detection." D.I. 15 at 13.

- "[T]he claims of the asserted patents are directed to specific, novel processes for detecting donor-specific cell free DNA . . . ." D.I. 15 at 15.

It is undisputed that donor-specific cfDNA and the correlation donor-specific cfDNA has with organ rejection are natural phenomena.[12] Because the asserted claims are directed to the detection of these natural phenomena, the

[12] The correlation between donor-specific cfDNA and organ rejection could also be described as a natural law. I need not parse the differences between a natural law and a natural phenomenon since both concepts are patent-ineligible subject matter. For ease of reference, I will refer to both donor-specific cfDNA and the correlation donor-specific cfDNA has with organ rejection as natural phenomena.

dispositive inquiry under both steps of the *Alice* inquiry is whether the claimed methods of detection are conventional (i.e., standard or routine).

In this case, the written description of the asserted patents makes clear that the claimed detection methods are conventional. It expressly states that

> [t]he practice of the present invention employs, unless otherwise indicated, conventional techniques of immunology, biochemistry, chemistry, molecular biology, microbiology, cell biology, genomics and recombinant DNA, which are within the skill of the art.

#652 patent at 5:36–40. As noted above, nothing in the written description "otherwise indicates" that any of the techniques recited in the claims are nonconventional. To the contrary, as discussed above, there are numerous characterizations of the specific techniques in the written description that confirm their conventionality. *See supra* note 5.

The patentee's unequivocal and binding admission in the written description that the recited detection methods are conventional ends the matter before me. *See Mayo*, 566 U.S. at 79 (affirming summary judgment of invalidity under § 101 of patents directed to natural laws where, "[a]s the patents state, [the claimed] methods for determining metabolite levels were well known in the art"); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1377 (Fed. Cir. 2015) (affirming summary judgment of invalidity under § 101 of patents directed to a natural phenomenon where "[t]he specification of the '540 patent confirms that the

preparation and amplification of DNA sequences in plasma or serum were well-understood, routine, conventional activities performed by doctors in 1997"); *Cleveland Clinic*, 859 F.3d at 1360–63 (affirming dismissal pursuant to Rule 12(b)(6) on the grounds that the asserted patents directed to a natural phenomenon were invalid under § 101 where "[t]he specifications of the testing patents confirm that known testing methods could be used to detect MPO, and that there were commercially available testing kits for MPO detection," and "the claims here instruct that MPO levels be detected or determined using any of these known techniques"); *SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1170 (Fed. Cir. 2018) (affirming Rule 12(c) judgment on the pleadings that the asserted patent directed to an abstract idea was invalid under § 101 where the patent's "invocation" of "generic parallel processing components" "amount[ed] to a recitation of what is well-understood, routine, and conventional" (internal quotation marks and citation omitted)); *see also Mortgage Grader*, 811 F.3d at 1325 (recognizing that "it is also possible, as numerous cases have recognized, that a § 101 analysis may sometimes be undertaken without resolving fact issues," and that "[t]he mere existence in the record of dueling expert testimony does not necessarily raise a genuine issue of material fact"); *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 890 F.3d 1354, 1356 (Fed. Cir. 2018) (Moore, J., concurring in the denial of the petition for rehearing en banc) ("In a situation where the

specification admits the additional claim elements are well-understood, routine, and conventional, it will be difficult, if not impossible, for a patentee to show a genuine dispute.").[13]

CareDx argues that "the specification['s] admi[ssion] that the claimed techniques are routine and conventional appears verbatim in myriad patents and patent applications covering different technologies that are not limited to DNA sequencing applications," D.I. 176 at 20 n.6; and it insists that "[i]t would be unfair to read this widely repeated passage in biotech patents referencing generic publications about biochemistry basics to be some sort of supposed voluntary confession that there is no inventive concept in the specification," D.I. 176 at 19–20. It should come as no surprise that CareDx cites no case law to support this argument, and I reject it out of hand.

The idea that a patentee is bound by the words it uses in its patent—whether in the claims or elsewhere in the specification—is a fundamental tenet of the patent law.[14] The PTO relies on the patent applicant's representations when it decides

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[13] The Magistrate Judge did not address in his Report and Recommendation the fact that the written description of the asserted patents expressly characterized the recited detection techniques as conventional.

[14] *See Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1117 (Fed. Cir. 2004) ("[A] patentee who notifies the public that claim terms are to be [understood] beyond their ordinary meaning to one of skill in the art will be bound by that notification, even where it may have been unintended."); *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1362 (Fed. Cir.

whether to issue a patent; and the patentee's words in the claims and written description put the public on notice of the scope of the claimed invention.[15] Accordingly, as the Supreme Court recently noted,

> the patent law[] demand[s] . . . honesty from patent applicants. In applying for a patent, the inventor must ordinarily submit an oath—a statement attesting that he is "the original inventor" of the "claimed invention." And the inventor must comply with "a duty of candor and good faith" in the patent process, including "a duty to disclose" to the PTO all information he knows "to be material to patentability."

Minerva Surgical, Inc. v. Hologic, Inc., 141 S. Ct. 2298, 2309 n.3 (2021) (citations omitted). After the patent issues, courts rely on the patentee's representations in

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2007) ("Admissions in the specification regarding the prior art are binding on the patentee for purposes of a later inquiry into obviousness."); *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1570 (Fed. Cir. 1988) ("A statement in the patent that something is in the prior art is binding on the applicant and patentee for determinations of anticipation and obviousness."); *Sjolund v. Musland*, 847 F.2d 1573, 1577–79 (Fed. Cir. 1988) (the patent specification admitted that certain matter was prior art, and thus "the jury was not free to disregard [that matter]" and "must have accepted [it] as prior art, as a matter of law").

[15] *See McClain v. Ortmayer*, 141 U.S. 419, 423–24 (1891) ("Nothing is better settled in the law of patents than that the patentee may claim the whole or only a part of his invention, and that, if he only describe and claim a part, he is presumed to have abandoned the residue to the public. The object of the patent law in requiring the patentee to 'particularly point out and distinctly claim the part, improvement, or combination which he claims as his invention or discovery' is not only to secure to him all to which he is entitled, but to apprise the public of what is still open to them. The claim is the measure of his right to relief, and, while the specification may be referred to to [*sic*] limit the claim, it can never be made available to expand it.")

the specification when they construe the claims that define the metes and bounds of the monopoly the patent confers on the patentee. Competitors rely on those representations to ascertain and design around infringement. The demand that the patentee be forthright in the application that ultimately takes the form of the issued patent's written description is so fundamental that a patent can be deemed unenforceable if a court determines that the patentee made false representations to the PTO in or during the prosecution of the patent application with a specific intent to mislead. *See Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011) (en banc). There is therefore nothing unfair about holding CareDx to its representations in the patent's written description.

It is of no moment that CareDx's representation that the recited techniques are conventional "appears in myriad patents." As a logical matter, the number of times a representation is made has no bearing on its truthfulness. But in any event, there is a reason why patentees frequently represent to the PTO that techniques recited in their patents are conventional. Section 112 of the Patent Act requires that the specification provide sufficient explanation of the claimed invention to enable an artisan of ordinary skill to make and use the invention. To avoid or overcome an objection by the PTO that the requested patent lacks adequate detail to satisfy § 112, patent applicants will often expressly represent that recited techniques are conventional. Having done that here, CareDx cannot now avoid the

consequences that flow from its representation. Indeed, it would be unfair to Defendants to let it do so.

In the supplemental brief it filed after the May 2021 evidentiary hearing, CareDx argues that the patents "otherwise indicate[]" that some of the individual techniques are nonconventional. D.I. 176 at 21. But CareDx mischaracterizes the written description. For example, CareDx cites nine lines of the written description as evidence that the patents' "discussion of digital PCR," a sequencing technique recited in the #497 claims, "describes [digital PCR] as an emerging technique" and "expressly directs the reader to inventor Quake's landmark 2006 journal article" "[t]o teach how to use d[igital] PCR with the claimed inventions." D.I. 176 at 21–22 (citing #652 patent at 14:55–64). This assertion by CareDx is simply false. Here is what the cited text actually says:

> In some embodiments, digital PCR or real time PCR to quantitate the presence of specific polymorphisms that have already been identified in the initial genotyping step pre-transplantation. Compared with the quantitative PCR techniques used in some of the earlier cited work, digital PCR is a much more accurate and reliable method to quantitate nucleic acid species including rare nucleic acid species, and does not require a specific gender relationship between donor and recipient. (Warren, L., Bryder, D., Weissman, L L., Quake, S. R., Proc Natl Acad Sci, 103, 17807-17812 (2006)).

#652 patent at 14:55–64. The fact that digital PCR is more accurate and reliable than earlier PCR techniques does not mean that digital PCR was an emerging

technique as of 2009. In fact, the cited text does not characterize digital PCR as "an emerging technique," nor does it direct the reader to the Quake article to learn how to use digital PCR.

CareDx also argues that a "lengthy discussion of next generation sequencing (NGS) in the specification also indicates vividly that this technology is not routine, conventional, or well-understood." D.I. 176 at 22. CareDx claims that this discussion "identifies a series of new NGS systems over several columns and then teaches extensively about them with copious citation to patent *applications* and other contemporaneous literature." D.I. 176 at 22 (emphasis in original). But this "lengthy discussion," does not suggest in any way, let alone "vividly" indicate, that NGS was nonconventional as of 2009. The discussion identifies commercial sequencing machines and gives high-level descriptions of how they work, referring to sensitivity and error rate concepts that CareDx's expert, Dr. Van Ness, admitted were "known and accepted in the art." Tr. of May 17, 2021 Hr'g at 264:18–265:18; *see also id.* at 249:23–255:6. Dr. Van Ness was correct when he testified at the evidentiary hearing that the asserted patents' specifications "don't get into the details and describe the individual methods for each of th[e] sequencing platforms that are described in the patent[s]." *Id.* at 225:17–21. He was also correct that no such details are claimed—an important fact since "features that are

not claimed are irrelevant as to step 1 or step 2 of the *Mayo/Alice* analysis," *Am. Axle & Mfg., Inc. v. Neapco Holdings LLC*, 939 F.3d 1355, 1363 (Fed. Cir. 2019).

CareDx argues, too, that the patents' written description "unambiguously state[s] that the[] [inventors] applied a never-before-used combination of techniques to better measure the correlation and specifically contrast their invention with how the prior art attempted to conquer the very same long-standing problem." D.I. 176 at 20 (citing #652 patent at 7:48–52; 8:45–50). But this assertion is also not true. CareDx cites in support of this assertion nine lines from the patents' written description. Here is what those lines actually say:

> In some embodiments, the invention provides methods, devices, compositions and kits for detection and/or quantitating circulating nucleic acids, either free in plasma or from circulating cells, for the diagnosis, prognosis, detection and/or treatment of a transplant status or outcome.
>
> * * * *
>
> In some embodiments, the invention provides a universal approach to noninvasive detection of graft rejection in transplant patients which circumvents the potential problems of microchimerism from DNA from other foreign sources and is general for all organ recipients without consideration of gender.

#652 patent at 7:48–52; 8:45–50. There is no suggestion, let alone "unambiguous statement," in these cited excerpts—or anywhere else in the asserted patents—that the claimed methods employ "a never-before-used combination of techniques."

CareDx seems to argue that the novelty of the application of the recited techniques to the detection of donor-specified cfDNA makes the techniques nonconventional. In CareDx's words, "[a]s applied to cfDNA, the claimed techniques were not routine in 2009." D.I. 180 at 8; *see also* D.I. 176 at 2 (describing "the purported invention" of the asserted patents as "the never-before-taught *application of different combinations of particular laboratory techniques to better measure* the correlation" of donor-specific cfDNA and organ rejection (emphasis in the original)). The Supreme Court in *Mayo*, however, "made clear that transformation into a patent-eligible application requires more than simply stat[ing] the law of nature [in this case, cfDNA] while adding the words apply it." *Ariosa*, 788 F.3d at 1377 (internal quotation marks omitted) (quoting *Mayo*, 566 U.S. at 72). And *Alice* step two's requirement of "additional features that must be new and useful" is simply not met in this case because the asserted method claims recite standard detection techniques applied to naturally occurring phenomena. *Roche Molecular Sys., Inc. v. CEPHEID*, 905 F.3d 1363, 1372 (Fed. Cir. 2018).

CareDx also argues that it is the combination of the recited techniques that is nonconventional. D.I. 176 at 2, 28. But the asserted patents do not claim an ordered combination of the recited techniques. The recited techniques, "when viewed as a whole, add nothing significant beyond the sum of the[] [techniques] taken separately[,]" and therefore the recited techniques are "not sufficient to

transform unpatentable natural correlations into patentable applications of those regularities." *Mayo*, 566 U.S. at 80; *see also Alice*, 573 U.S. at 217 ("[W]e consider the elements of each claim both individually and 'as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." (quoting *Mayo*, 566 U.S. at 78–79)).

Finally, CareDx argues that extrinsic evidence establishes that the recited detection techniques were not conventional. *See* D.I. 176 at 25–28. CareDx cites no case in which a court allowed a patentee to avoid a declaration of a patent's invalidity by offering extrinsic evidence that contradicted an unambiguous admission in an asserted patent's written description. I can't imagine CareDx could find such a case. Permitting CareDx to now nullify with extrinsic evidence an unambiguous representation it made to the PTO to secure its patents and exclude competitors like Defendants from making or using the claimed invention would be fundamentally at odds with the basic principles underlying our patent system.

In *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996), the Federal Circuit held that when construing the claims of a patent

> where the public record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. The claims, specification, and file history, rather than extrinsic evidence, constitute the public record of the patentee's claim, a record on which the public is entitled to rely. In other words, competitors

> are entitled to review the public record, apply the established rules of claim construction, ascertain the scope of the patentee's claimed invention and, thus, design around the claimed invention. *See Markman*, 52 F.3d at 978–79, 34 USPQ2d at 1329. Allowing the public record to be altered or changed by extrinsic evidence introduced at trial, such as expert testimony, would make this right meaningless. *See Southwall*, 54 F.3d at 1578, 34 USPQ2d at 1678 ("A patentee may not proffer an interpretation for the purposes of litigation that would alter the indisputable public record consisting of the claims, the specification and the prosecution history, and treat the claims as a 'nose of wax.'" (quoting *Senmed, Inc. v. Richard-Allan Med. Indus., Inc.*, 888 F.2d 815, 819 n.8, 12 USPQ2d 1508, 1512 n.8 (Fed.Cir.1989))).

I see no reason why the holding of *Vitronics* should be limited to claim construction and not apply here. Allowing CareDx to alter by extrinsic evidence the unambiguous public record it established with the claims and written description of the asserted patents would make Defendants' right to design around meaningless. It would also reward CareDx for being dishonest—either when it told the PTO that the recited techniques were conventional or when it insisted before this Court that they were not.[16]

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[16] Ironically, the testimony of CareDx's expert that I found most credible and compelling at the evidentiary hearing confirms the conventionality of the recited techniques in the asserted method claims:

> THE COURT: [Y]ou would agree that every disclosed technique is routine and conventional in some application. Your point is, it's just not the application of this patent?

V. CONCLUSION

For the reasons discussed above, I find that the claims of the asserted patents are invalid as a matter of law under § 101 for claiming patent-ineligible subject matter. Accordingly, pursuant to Federal Rule of Civil Procedure 56(f)(3), I will enter summary judgments in Defendants' favor.

The Court will issue Orders consistent with this Memorandum Opinion

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> THE WITNESS: I think that's an accurate statement.
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> * * * *
>
> THE COURT: So the application to what? What am I applying the disclosed techniques to?
>
> THE WITNESS: Applying it to the detection of donor-derived DNA in a recipient receiving an organ transplant . . . .

Tr. of May 17, 2021 Hr'g at 261:12–17; 263:11–15.