Nos. 22-1027, 22-1028

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

CAREDX, INC., THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY, *Plaintiffs-Appellants*,

v.

NATERA, INC., *Defendant-Appellee*

CAREDX, INC., THE BOARD OF TRUSTEES OF THE LELAND STANFORD JUNIOR UNIVERSITY, *Plaintiffs-Appellants*,

v.

EUROFINS VIRACOR, INC. *Defendant-Appellee*.

Appeal from the United States District Court for the District of Delaware Case Nos. 1:19-cv-00567-CFC-CJB, 1:19-cv-01804-CFC-CJB

EUROFINS VIRACOR'S RESPONSE TO APPELLANTS' COMBINED PETITION FOR PANEL REHEARING AND REHEARING EN BANC

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CERTIFICATE OF INTEREST

As required by Federal Circuit Rule 47.4, I certify the following:

1. Represented Entities: Provide the full names of all entities represented by undersigned counsel in this case. Fed. Cir. R. 47.4(a)(1).

Eurofins Viracor, Inc., n/k/a Eurofins Viracor LLC

2. Real Parties in Interest: Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. Fed. Cir. R. 47.4(a)(2).

Not applicable.

3. Parent Corporations and Stockholders: Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. Fed. Cir. R. 47.4(a)(3).

Eurofins Clinical Testing US Holdings, Inc.; Eurofins Scientific SE

4. Legal Representatives: List all law firms, partners, and associates that (a) appeared from the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

Not applicable.

5. Related Cases: Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5).

Federal Circuit Case No. 22-1027 (CareDx, Inc. v. Natera, Inc.)

6. **Organizational Victims and Bankruptcy Cases:** Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

Not applicable.

Dated: November 14, 2022 Respectfully submitted,

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'652 patent	U.S. Patent No. 8,703,652
cfDNA	cell-free DNA
Eurofins	Appellee Eurofins Viracor LLC, f/k/a Eurofins Viracor, Inc.
PCR	Polymerase chain reaction

INTRODUCTION

CareDx claims its patents are eligible for protection under 35 U.S.C. § 101 because of the various discoveries it did not make. As CareDx acknowledges—indeed, emphasizes—the core of the '652 patent involves "a *long-known* natural phenomenon": After an organ transplant, an increase in donor cfDNA in the recipient's blood is correlated with organ rejection. Rehearing Petition ("Pet.") 1 (emphasis added). That patent (the only one asserted against Eurofins) claims the application of a class of conventional measurement techniques to observe that correlation. Thus, CareDx argues that it is eligible for patent protection because it applied a known measurement technique (which it did not invent) to a known natural phenomenon (which it did not discover)—an application that it refers to, somewhat misleadingly, as an "improved laboratory measurement method[]." Pet. 1.

The panel rejected those arguments based on a straightforward application of binding Supreme Court precedent, as well as a host of follow-on cases from this Court. As the panel explained, the claimed methods here "are indistinguishable from other diagnostic method claims the Supreme Court found ineligible in *Mayo* [Collaborative Services v. Prometheus Laboratories, 566 U.S. 66 (2012)], and that [this Court] found ineligible on multiple occasions." Op. 15. Indeed, following Mayo, this Court has "consistently" invalidated highly similar "diagnostic claims ... as directed to ineligible subject matter." Illumina, Inc. v. Ariosa

Diagnostics, Inc., 967 F.3d 1319, 1325 (Fed. Cir. 2020); see, e.g., Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 915 F.3d 743 (Fed. Cir. 2019); Genetic Veterinary Scis., Inc. v. LABOKLIN GmbH & Co. KG, 933 F.3d 1302 (Fed. Cir. 2019); Roche Molecular Sys., Inc. v. CEPHEID, 905 F.3d 1363 (Fed. Cir. 2018); Cleveland Clinic Found. v. True Health Diagnostics LLC, 859 F.3d 1352 (Fed. Cir. 2017); Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015).

CareDx does not ask this Court to overrule these prior precedents. Nor could it, given the Supreme Court's on-point decision in *Mayo*. Rather, CareDx attempts to distinguish this case factually, proposing an exceedingly narrow (and counterintuitive) distinction: that unlike the patentees in these other cases, CareDx did *not* discover the underlying natural phenomenon. Thus, it says, the patentees were the first to apply a known technique to a particular context. But that is true in *every* comparable diagnostic case: even where the patentee also discovered the underlying correlation, the patentee is necessarily the first to apply a particular measurement technique to detect the correlation. And in every comparable diagnostic case, this Court has rejected CareDx's precise argument. The panel's decision is thus entirely consistent with well-established caselaw.

Notwithstanding this precedent, CareDx identifies two issues that it believes warrant en banc review. First, CareDx argues that the Court should consider "whether a patent in which the claimed advance is a new and improved laboratory

measurement method is patent-eligible at step one." Pet. 2. But this case does not present that question, because the patentees of the '652 patent did not invent a new and improved laboratory method. Rather, they applied *concededly conventional* laboratory techniques to observe a *known* natural phenomenon. This Court has repeatedly held that applying known techniques in a new context to observe a known natural phenomenon is not eligible for patent protection, unlike inventing a new technique.

Second, CareDx argues that the panel erred by "exclud[ing] human-made improvements [that] employ existing tools." Pet. 3. To start, this merely reinforces that the '652 patent does not in fact involve a new and improved laboratory technique—it uses "existing tools." Even putting that aside, the first application of a known measurement technique to a natural phenomenon (a situation presented by all of this Court's prior diagnostic cases) does not render an invention eligible for patent protection. Under CareDx's approach, a patentee could bypass § 101 entirely merely by using a known measurement technique to detect a natural correlation. That is plainly not the law, and CareDx has notably not cited any caselaw in support of its novel approach.

In short, the panel's decision is entirely consistent with Supreme Court precedent, with this Court's precedent, and with fundamental principles of patent eligibility. CareDx expressly asks for an exception to those principles for this case—

an exception that this Court has already rejected and that CareDx does not even try to ground in any of this Court's cases. There is no need for en banc review for this Court to address a straightforward application of prior caselaw.

BACKGROUND

The '652 patent recites well-known diagnostic methods to detect donor cfDNA in the bodily fluids of a transplant recipient. Representative claim 1 comprises four steps, each described at a high level of generality: (a) providing a sample containing cfDNA from a transplant recipient; (b) obtaining a genotype of donor-specific and/or subject-specific polymorphisms to create a polymorphism profile; (c) multiplex sequencing the cfDNA in the sample and analyzing the results using the polymorphism profile to detect donor and recipient cfDNA; and (d) monitoring the quantity of donor cfDNA, where an increase in the quantity of donor cfDNA over time—any increase—indicates organ rejection. (27:39-28:40). As the panel explained, these steps are performed using one of any number of conventional techniques in the art. Op. 13-14 & n.1. Thus, contrary to CareDx's repeated assertions, the patent does not claim either a new measurement technique or an inventive combination of steps; CareDx repurposes those phrases to describe the application of known measurement techniques to the particular context of detecting any increase in cfDNA.

The district court granted summary judgment to Eurofins (as well as to co-

defendant Natera), holding the claims-in-suit ineligible under both prongs of the *Alice/Mayo* analysis. The court concluded that the claims were directed to the detection of natural phenomena—*i.e.*, "donor-specific cfDNA and the correlation donor-specific cfDNA has with organ rejection." Appx95. The court further determined that it was clear from the face of the patent that "the recited detection methods are conventional." Appx96.

This Court affirmed in a straightforward opinion. As the panel explained, this case does not involve "a method of preparation or a new measurement technique." Op. 13. Rather, the patents "apply conventional measurement techniques to detect a natural phenomenon—the level of donor cfDNA and the likelihood of organ transplant rejection." Op. 15.

At step one, the court reviewed the claim language and concluded that the "claims recite methods for detecting natural phenomena." Op. 16. At step two, the panel rejected CareDx's argument that the "claimed advance" is an "improved, human-devised method for measuring increases in donor cfDNA," noting that "CareDx does not actually claim any improvements in laboratory techniques." Op. 17; see Op. 14 n.1. Rather, "the actual claims of the patent merely recite" using "conventional techniques and off-the-shelf technology" to "detect naturally

occurring cfDNA," and therefore add nothing inventive at step two. Op. 17.1

ARGUMENT

This straightforward decision is not a candidate for rehearing en banc. The panel's opinion is a direct application of on-point Supreme Court and Federal Circuit caselaw: It breaks no new ground, extends no precedent, and has no independent effect beyond cases this Court has already decided. CareDx's attempts to distinguish prior cases simply underscore that its proposed approach is inconsistent with them, and with fundamental principles of patent-eligible subject matter.

I. The panel decision is entirely consistent with an unbroken line of caselaw.

A. This case is controlled by Supreme Court precedent.

The claimed methods here "are indistinguishable from other diagnostic method claims the Supreme Court found ineligible in *Mayo*." Op. 15. As in *Mayo*, CareDx's patent directs doctors to collect data from which they can draw a conclusion in light of a previously discovered law of nature—here, "any increase signals organ rejection." *See Mayo*, 566 U.S. at 80. *Mayo* thus dictates the outcome of this case, and there is nothing for this Court to rehear.

The patent at issue in *Mayo* claimed a method for "optimizing therapeutic efficacy" of a drug by titrating the amount of the drug to the concentration of certain

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¹ The panel also rejected, as "without merit," CareDx's various procedural objections to the district court's handling of the case. Op. 18-19.

metabolites in the patient's blood. 566 U.S. at 73-75. Scientists had previously discovered that the metabolite levels "were correlated with the likelihood that a particular dosage of" the drug might be harmful or ineffective. *Id.* at 73-74. The patent attempted to harness that natural correlation by directing doctors to "determin[e]" the level of metabolites through standard laboratory techniques, "wherein" metabolites above a certain level indicate a need to administer more of the drug, and metabolites below a certain level indicate the need to administer less. *Id.* The "upshot" is that these steps "simply tell doctors to gather data from which they may draw an inference in light of the correlations." *Id.* at 79.

So too here. Claim 1 of the '652 patent recites using standard laboratory techniques ("obtaining a genotype" and "multiplex sequencing") to "detect" the amount of donor cfDNA in a sample, "wherein" any increase in the amount of donor cfDNA over time signals organ rejection or failure. Appx131. Drawing that inference from standard measurements is not patent-eligible.²

B. This Court has held ineligible a string of comparable patents.

This Court has consistently applied *Mayo* to invalidate patents that claim the use of a known laboratory technique to observe a natural phenomenon. In *Ariosa*, this Court held ineligible a closely analogous method: making a diagnosis by

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² While retired Judge Michel disagrees with the *Alice/Mayo* test, *see* Amicus Br. 9-12, revisiting binding Supreme Court precedent is of course not a basis for rehearing en banc.

detecting the presence of a certain subset of cell-free DNA using common laboratory techniques (including PCR). 788 F.3d at 1373, 1376. In *Cleveland Clinic*, this Court invalidated claims directed to a method for observing the correlation between a specific enzyme and cardiovascular disease. 859 F.3d at 1360. The method claimed "seeing' [the enzyme] already present in a bodily sample and correlating that to cardiovascular disease"—just as CareDx claims "seeing" the cfDNA level and correlating it to organ failure. *Id.* at 1360-61. The same was true in *Roche*, which disclosed using PCR to detect a signature nucleotide in a sample and infer that the sample contained a certain bacterium. 905 F.3d at 1370. And true again in *Athena*, when the Court held ineligible claims directed to standard techniques for observing the relationship between autoantibodies and neurological disease. 915 F.3d at 752.

In short, this case breaks no new ground. As the panel explained, the "claims here are equally as ineligible as those" in *Mayo*, *Ariosa*, and "multiple" other cases. Op. 15-16. CareDx's petition does not challenge these precedents; it does not even mention several of them. Because the panel's decision follows ineluctably from these prior precedents, there is no basis to take this case en banc.

II. CareDx attempts to distinguish prior caselaw on the basis that its patent is *less* inventive.

CareDx's primary basis for avoiding *Mayo*, and all of the caselaw following it, is to argue that this patent is different from every previous one because, while it uses conventional laboratory tools, it claims their application in a "new context."

Pet. 14-15. CareDx insists that, unlike in previous cases, it can claim an "improved" method of measurement—by which it actually means the application of a conventional method to measure a particular phenomenon. *See id.* While CareDx argues that this issue is relevant to both steps of the *Alice/Mayo* framework, at bottom it raises only one point. At step one, CareDx argues that the panel erred by failing to recognize that "the claims are directed to an improvement upon prior art measurement methods"—applying them in a different context. Pet. 13. And at step two, it likewise argues that the patent is eligible for protection because the claim "is for an improved method for measuring a known phenomenon." Pet. 15.

CareDx presents no basis for rehearing the panel's analysis of either step en banc, for two independent reasons. First, CareDx's objection to the panel's decision rests on an exceedingly narrow, case-specific, and ultimately meaningless distinction between this case and a wall of prior precedent. Second, even if the Court were writing on a blank slate, this case would not squarely present the issue CareDx seeks to have this Court address.

A. This Court has repeatedly rejected CareDx's proposed approach.

CareDx describes as "precedent-setting" the question whether applying "existing laboratory tools in a new context" is sufficient for patent protection under the *Alice/Mayo* framework. Pet. v. But the precedent on this question has already been set: This Court has repeatedly held that transferring conventional techniques

to a new setting does not bypass § 101. In *Roche*, for example, the Court rejected the patentee's argument that it was entitled to protection because it was "not routine or conventional to use PCR (or any other genetic test) to detect the presence of" a certain enzyme, and "unprecedented to perform PCR using the type of primer specified in" the claims. 905 F.3d at 1372. While the underlying laboratory technique (PCR, and more generally genetic testing) was conventional, the patentee argued that it had never before been used to measure this particular phenomenon. *See id.* This Court agreed with the patentee's factual premise—the inventors were indeed "the first to use PCR to detect [the enzyme]." *Id.* Nevertheless, because the patent claimed "standard PCR methods applied to a naturally occurring phenomenon," the *Alice/Mayo* requirement "of additional features that must be new and useful [was] simply not met." *Id.* (internal quotation marks omitted).

This Court made the same point in *Athena*, where the patentee argued that the claimed steps were "unconventional" because they had not yet been applied to detect the correlation at issue. 915 F.3d at 754. "Even accepting that fact," the Court held that "performing standard techniques in a standard way to observe" a new correlation was insufficient for patent protection. *Id.* "Rather, to supply an inventive concept the sequence of claimed steps must do more than adapt a conventional assay to a newly discovered natural law." *Id.* Likewise, in *Ariosa*, the Court invalidated a patent despite agreeing that the inventors "combined and utilized man-made tools of

biotechnology in a new way that revolutionized prenatal care." 788 F.3d at 1379.

CareDx does not ask this Court to overrule this well-established precedent. Rather, it suggests these cases are distinguishable because the patentees there had also discovered the natural phenomenon at issue. In other words, CareDx argues that, even if the discoverer of an unknown natural phenomenon cannot get a patent for applying conventional measurement techniques to observe it, someone who *did not discover* the phenomenon should be able to get a patent for applying conventional measurement techniques to observe a *known* natural phenomenon. Pet. 16-17.³

That makes little sense. The patents in *Mayo* and this Court's cases necessarily claimed the use of a technique to measure a natural phenomenon. *See*, *e.g.*, *Mayo*, 566 U.S. at 79 ("the 'determining' step tells the doctor to determine the level of the relevant metabolites in the blood, through whatever process the doctor or the laboratory wishes to use"). Otherwise, identification of the natural phenomenon would be of little use as a diagnostic tool. This Court's decisions invalidating similar method-of-detection patents thus hold that (1) identification of

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³ In passing, CareDx notes that it "strongly disagrees" with the panel's conclusion that the measurement methods "require only conventional techniques and off-the-shelf technology." Pet. 14 (discussing Op. 17). That factual, case-specific argument would not be appropriate for full-court review. And CareDx's disagreement is baseless: as the panel correctly recognized, "the written description is replete with characterizations of the claimed techniques in terms that confirm their conventionality." Op. 14 & n.1, 17.

the natural law is not itself patent-eligible; *and* (2) application of a known measurement technique to observe that natural law is not patent-eligible. *See*, *e.g.*, *Athena*, 915 F.3d at 751 ("As in *Cleveland Clinic* and *Ariosa*, we conclude that claims 7-9 are directed to a natural law because the claimed advance was only in the discovery of a natural law, and that the additional recited steps only apply conventional techniques to detect that natural law."). Because CareDx does not suggest that it discovered the natural law, its argument is limited to the second step—making its eligibility argument weaker, not stronger.⁴

CareDx responds that the patentees in *Mayo*, *Ariosa*, *Athena*, and *Cleveland* did not rely on the "inventiveness of the measurement method." Pet. 16-17. *But* neither did CareDx. As CareDx acknowledges, its patent does not claim a new measurement method; it discloses only applying conventional measurement techniques to a new context. *See*, e.g., Pet. 14 (explaining that the patent applies "existing tools to a different context"). CareDx attempts to recast its patent as claiming a new laboratory technique, like a patent on PCR. But in that context, the patentee is entitled to protection for *inventing* the new technique. That is not what

⁴ CareDx also criticizes the panel for failing to identify the "claimed advance" at step one of the *Alice/Mayo* test. Pet. 12 (citing *CosmoKey Solutions GmbH & Co. v. Duo Security LLC*, 15 F.4th 1091 (Fed. Cir. 2021)). That is incorrect. As the panel explained, it "agree[d]" that "CareDx's asserted claims are directed to detecting natural phenomena." Op. 12-13. Thus, the *only* circuit precedent CareDx claims this case contradicts (Pet. v) is simply inapposite.

happened here. Rather, the patentees applied existing techniques to detect a particular natural phenomenon, much like focusing a microscope on a new target.⁵

As a result, this case is no different from this Court's prior diagnostic decisions, in which the patentee was necessarily the first to apply a conventional technique to measure a particular phenomenon. *See, e.g., Athena*, 915 F.3d at 754 (rejecting the patentee's argument "that the claimed steps were unconventional because they had not been applied to detect [certain] autoantibodies prior to Athena's discovery of the correlation between [the] autoantibodies" and the disorder at issue). In this case, the Court merely held—as it has "repeatedly held" in the past—that "applying standard techniques in a standard way to observe natural phenomena does not provide an inventive concept." Op. 18. That well-grounded holding in no way hinges on whether the phenomenon at issue is known or newly discovered, and there is no reason to take this case en banc to revisit this well-established precedent.⁶

Finally, CareDx's insistence that the panel failed to consider the "combination" of claims is merely a rehash of this same argument. Pet. 14-15.

⁵ Judge Michel's amicus brief likewise rests on the incorrect assumption that this is "an invention that is directed to a new and improved diagnostic measurement method." Amicus Br. 3. But, again, there is no "new and improved diagnostic measurement method." *See* Op. 13-14 & n.1.

⁶ Nor is there any reason for panel rehearing. Briefly, as a near-afterthought, CareDx asserts that the panel should reconsider "extend[ing] *Athena* to the new and different context of improved measurement methods." Pet. 17. That is incorrect for the reasons explained in text.

CareDx suggests that the panel "dissect[ed]" the claims," rather than considering them "as a whole," contrary to *Diamond v. Diehr*, 450 U.S. 175, 188 (1981). But CareDx's patent recites a "combination" only in the sense that it teaches the application of conventional techniques to a particular context. As discussed above, such an application cannot provide the requisite "inventive" concept. *E.g.*, *Ariosa*, 788 F.3d at 1379.

B. CareDx's patent does not directly present the issue it asks this Court to address.

Even if CareDx were correct that this Court had not yet (repeatedly) addressed the application of a conventional technique to measure a natural phenomenon, this case is a poor vehicle to consider the issue. Because the '652 patent does not claim a particular measurement technique with any meaningful degree of detail, it is little different from a patent that merely discloses the observation of a particular phenomenon (rather than, as CareDx suggests, a particular approach for doing so).

The '652 patent claims its measurement step at the highest level of generality: "multiplex sequencing" of the sample, followed by "analysis of the sequencing results" to observe the natural phenomenon and look for any increase over time. Appx131 (27:41-67). That is all: The patent does not claim any particular type or method of multiplex sequencing, nor does it provide any particular instructions for using multiplex sequencing in this context. Rather, the written description is replete with high-level directives to use conventional, commercially available means.

Appx122 (9:8-14), Appx125 (15:22-16:41), Appx128 (21:5-8); note 3, *supra*. Consider, also, the two other patents that CareDx asserted only against Natera, which replace multiplex sequencing with high-throughput sequencing or digital polymerase chain reactions, while similarly failing to provide any particular instructions for use in this context. Op. 3-8. So in full, CareDx is claiming the detection of cfDNA using either multiplex sequencing *or* high-throughput sequencing *or* digital PCR—the suite of conventional methods for genetic sequencing. *See* Op. 14 n.1.

These claims are materially equivalent to the claims in *Mayo*, which simply directed doctors to select a known process for determining the level of metabolites. 566 U.S. at 79. While CareDx repeatedly harps on the difficulties scientists had in quantifying cfDNA prior to 2009, these patents did little more than direct doctors to use a broad class of then-existing tools for genetic sequencing. As a result, this case does not present the question of how the analysis might evolve if, as CareDx seems to contemplate, a patentee were the first to apply a particular measurement technique in a novel context—in other words, if there were something inventive about the recognition that a technique could be used in a particular context. Rather, the patents here disclose applying a broad class of existing genetic-sequencing techniques to an entirely expected context: sequencing a type of DNA. Thus, even were the Court inclined to consider whether application of a particular measurement method to a

new context might in certain contexts be sufficient to warrant protection, the '652 patent does nothing materially more than "simply state the law of nature while adding the words 'apply it," *Mayo*, 566 U.S. at 72.

As a result, CareDx's concerns regarding the viability of diagnostic patents are misplaced. Again, the patentees here did not invent anything in the patent: They did not discover the natural phenomenon, nor did they discover any of the claimed measurement techniques. Granting CareDx patent protection for applying an accepted sequencing technique to do precisely what that technique is intended to do (sequence DNA) would dramatically alter this Court's § 101 jurisprudence. Indeed, if an inventor could claim patent protection by being the first to apply a known technique to a new context, *every* natural phenomenon could be patent-eligible in pieces—one for each conventional technique used to observe it. That rule is flatly inconsistent with the Supreme Court's precedent, this Court's precedent, and general principles of patent eligibility, and there is no basis for this Court entertain it en banc.

CONCLUSION

For the foregoing reasons, CareDx's petition for rehearing should be denied.

⁷ The breadth of CareDx's claims means their preemptive scope would be dramatic—but even assuming CareDx is right that its patent does not preempt *all* uses of the natural correlation between cfDNA and organ rejection, that sort of preemption is "not necessary" to show that a claim is ineligible for patent protection. *Athena*, 915 F.3d at 752.

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This brief complies with the type-volume limitation of Federal Rule of

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November 14, 2022

/s/ William M. Jay William M. Jay

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CERTIFICATE OF SERVICE

I, William M. Jay, hereby certify that on November 14, 2022, the foregoing document was filed with the Court and served on counsel of record for Appellant by the CM/ECF system.

/s/ William M. Jay William M. Jay