

No. 2019-1222

In the
United States Court of Appeals
for the
Federal Circuit

23ANDME, INC.,
Plaintiff-Appellant,

v.

ANCESTRY.COM DNA, LLC,
ANCESTRY.COM OPERATIONS INC.,
ANCESTRY.COM LLC,
Defendants-Appellees.

*On Appeal from the United States District Court for the
Northern District of California,
Case No. 18-cv-02791-EMC
(Hon. Edward M. Chen)*

23ANDME, INC.'S PETITION FOR REHEARING EN BANC

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CERTIFICATE OF INTEREST

Pursuant to Federal Circuit Rule 47.4, counsel for Appellant 23andMe, Inc.

certifies as follows:

1. The name of the party I represent is: 23andMe, Inc.
2. The real parties in interest are: 23andMe, Inc.
3. The parent corporation or publicly held corporation that owns 10% or more of the stock of the parties in interest is: None
4. The following law firms, partners, and associates have appeared for 23andMe, Inc. below or are expected to appear for 23andMe, Inc. in this Court:

McDermott Will & Emery: William G. Gaede, III, Bhanu K. Sadasivan, Sami Sedghani, Paul W. Hughes, M. Miller Baker and Brent A. Hawkins
5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. *See* Fed. Cir. R. 47.4(a)(5) and 47.5(b): None

Dated: November 4, 2019

/s/ William G. Gaede

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STATEMENT OF COUNSEL

Based on my professional judgment, I believe this appeal requires an answer to the following precedent-setting questions of exceptional importance:

1. Whether this Court has now carved out a categorical exception to claims incorporating natural correlations, even where the claims recite novel techniques, in contravention of Supreme Court and this Court's precedent.
2. Whether courts may now circumvent *Alice* step two analysis at the motion to dismiss stage despite undisputed factual allegations on the novelty of the claims.

Based on my professional judgment, I believe the panel's decision is contrary to the following precedent of the Supreme Court and this Court: *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66 (2012); *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042 (Fed. Cir. 2016); *McRO, Inc. v. Bandai Namco Games Am. Inc.*, 837 F.3d 1299 (Fed. Cir. 2016); *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121 (Fed. Cir. 2018); *Cellspin Soft, Inc. v. Fitbit, Inc.*, 927 F.3d 1306 (Fed. Cir. 2019).

/s/ William G. Gaede

William G. Gaede

INTRODUCTION

Claim 12 of U.S. Patent No. 8,463,554 (the “554 Patent”) provides a novel and specific method for relatives to find each other in a large database. It does so by finding and applying DNA information of the database users in an unusual and innovative way to identify and estimate the chromosomal DNA segments that may be from a common ancestor, using that data in a new way to predict if, and how closely, the two users are related, and notifying the relative of the relationship.

This Court’s and the Supreme Court’s precedent draws a clear line that innovative methods for finding and manipulating DNA information are patentable under the Supreme Court’s *Myriad* decision, while under its *Mayo* decision and this Court’s diagnostic cases, routine steps for detecting DNA or other natural subject matter are not. Under this precedent, 23andMe meticulously and separately pled the specific and unconventional combination of steps that, whether under *Alice* Step 1 or 2, render dependent Claim 12 patent eligible.

The district court fundamentally erred on a motion to dismiss by not separately addressing Claim 12 with its multiple and unique limitations and simply invalidating Claim 12. The district court described the asserted claims (*e.g.* Claim 7) at a high level of abstraction as nothing more than comparing DNA to determine relationship, when the claims recite several concrete steps as listed above. With no evidence that the claimed advancement recite routine, well-understood or conventional

techniques, the opinion undermines the presumption of validity by summarily adjudicating claims through hindsight bias without a complete record.

The panel's use of a summary affirmance mechanism in this case, if anything, confirms the need for the en banc court's review as the egregious errors in the district court's opinion cannot go uncorrected. If permitted to stand, the panel's affirmance of the district court's invalidation of 23andMe's dependent Claim 12 may well serve as a death knell for the patent eligibility of DNA based method claims that employ unconventional and new techniques.

STATEMENT OF THE CASE

The '554 Patent discloses new and useful techniques for, per its title, "[f]inding relatives in a database." Appx41. Finding unknown relatives has clear utility—whether in expanding a family tree, adoptees finding relatives, or finding a relative where a family record is unavailable.

As the '554 Patent explains, before 23andMe's invention, existing techniques were ineffective in identifying close relatives (10 generations or less) and used Y chromosome DNA or mitochondrial DNA. Appx57, 1:21-34. The claimed invention does not utilize these old techniques, but instead employs new unconventional techniques that were not in the art, as 23andMe's Complaint alleged, *infra*. Appx76-78.

Claim 12 provides an innovative way for relatives to find each other by using the relative's DNA information in a database in an unconventional manner, harnessing that information to predict a degree of relationship, and notifying the relatives of the specific relationship. Collectively, Claim 12's limitations and the claims it depends from impose several specific, new, and unconventional ordered steps:

(1) Determine whether a DNA segment shared between two users is IBD ("identical by descent"), *i.e.*, whether the shared DNA segment is likely inherited from a common ancestor. Appx57, 2:36-40. IBD is not a static gene in a specific location, unlike BRCA-1 and -2 genes at issue in the *Myriad* and *In re BRCA1 and BRCA2* cases. Appx57, 2:32-36; Appx62, 11:4-8. Nor is IBD simply derived from a comparison of common recombinable DNA between two users.¹ This is so because humans share 99.5% of their DNA, and therefore a shared recombinable DNA sequence is not automatically an IBD.

Claim 12 recites the steps to identify a DNA segment as IBD. The human genome has markers called SNP (Single Nucleotide Polymorphisms) that tend to vary in different individuals. Appx57, 2:46-51. At a particular SNP location on a genome, a user can have one of three possible combinations, AA, BB, AB,

¹ Recombinable DNA is autosomal and X-chromosomal DNA. It does not include DNA in the Y-chromosome or mitochondrial DNA. Appx57, 2:32-36.

depending on whether they inherit an A allele from each parent, a B allele from each parent or an A and a B allele from the two parents. If the user inherits the same allele, whether AA or BB, it is a homozygous call and if she inherits AB, it is a heterozygous call.² Appx59, 6:25-29.

Claim 12 teaches a new way to use this SNP information to identify IBD.³ If at a particular SNP location, both users have AA, then it is a homozygous call. But if one user has AA and the other BB, then it is an *opposite* homozygous call. Claim 12 recites identifying *consecutive opposite* homozygous calls, *i.e.*, two opposite homozygous calls, and evaluating the distance between the two opposite homozygous calls to determine whether the region is an IBD. Appx53, Fig. 6; Appx59-60, 6:32-7:32. The specification teaches that if the distance between the

² Such homozygous or heterozygous calls can be made using “standard SNP based genotyping technology.” Appx59, 6:14-16. But that is not what Claim 12 is directed to. Rather, what is innovative is the way the patent teaches *how* to use the “calls” information.

³ “12. The method of claim 7, wherein identifying one or more IBD regions includes:
identifying consecutive opposite-homozygous calls in a SNP sequence of the first user and in a SNP sequence of the second user, wherein the first user and the second user have opposite-homozygous calls at a given SNP location where the first user and the second user do not share an allele;
determining, based at least in part on a distance between the consecutive opposite-homozygous calls, whether a region between the opposite-homozygous calls is an IBD region.”

Appx62, 11:38-49.

calls is greater than 10cM (centiMorgan (“cM”) is a measure of genetic distance), then the region is deemed an IBD. Appx60, 7:2-8. As the specification teaches, up to 650,000 SNPs may be used in the Claim 12 method. Appx58, 3:15-17.

(2) Claim 7, from which Claim 12 depends, recites how to use the IBD information to determine whether the two users are related and the degree of their relationship. Appx62, 11:1-19. A single IBD region is typically insufficient to determine relationship such as grandparent and/or uncle relationships. Hence, the IBD information is manipulated, by summing the lengths of the IBD regions or calculating the percentage of DNA shared in the IBD regions, and the manipulated IBD information is utilized to estimate the degree of relative relationship. For example, the specification teaches that if the two users have IBD_{half} (sum of the lengths of the IBD region) that is approximately half the total length of all autosomal chromosomes and many shared segments, then the users may have grandparent/grandchild relationship. Appx60, 7:36-41, 49-52.

(3) Notify the user, using the database, of the predicted degree of relative relatedness to another user in the database (*e.g.*, second cousin).⁴

⁴ See independent Claim 1. Appx61, 10:47-48.

23andMe's Complaint separately and expressly pled Claim 12's unconventional steps to identify IBD regions. For example:

- “The ‘554 Patent further claims, *inter alia*, a certain and specific way to identify the IBD regions. For example, and as exemplified in Claim 12, the patent claims identifying sequence of small nucleotide polymorphisms (SNPs) in two individuals. An individual's genome may have ~650,000 SNPs. A call can be made for each particular SNP as heterozygous, *i.e.* has two different alleles, with one from each parent (example, AB), or homozygous, *i.e.* has the same alleles (example, AA or BB). The process of IBD identification includes identifying consecutive opposite-homozygous calls in the SNP sequences of the two individuals and determining whether a region between the two opposite-homozygous calls is an IBD region, based at least on the distance between the two opposite homozygous calls.” Appx77, ¶20.
- “Such techniques . . . are novel, non-obvious and involve more than the performance of well-understood, routine and conventional activities previously known in the industry.” Appx78, ¶22.

23andMe separately argued patent eligibility of Claim 12 during the motion to dismiss proceeding in at least three different places in its briefing:⁵

- The asserted dependent claims “impose additional concrete techniques and applications which were neither routine nor conventional, such as . . . identifying consecutive opposite homozygous calls in Single Nucleotide Polymorphisms (SNPs) sequence and at least in part based on the distance between the consecutive opposite-homozygous call, whether it is an IBD region (claim[] 12).” Appx707.
- “The Complaint further alleges a specific way to identify relatedness using SNPs as in claim 12. ECF No. 1 at ¶ 20. These specific applications and techniques to calculate relative relatedness in genetic database are specifically described in the specification. *See* ’554 Patent, Fig. 5 & 6, 7:17-32; 7:36-38; claim 12.” Appx708.
- “The dependent claims further secure patent eligibility. For example, claim 12 requires identification of IBD regions by ‘identifying consecutive opposite-homozygous calls in a SNP sequence of the first user and in a SNP sequence of the second user . . .’ ’554 Patent, claim

⁵ 23andMe further argued Claim 12 separately in its appeal briefs. *See* 23andMe’s Blue Brief, Argument Sections A.1.b, A.2 and C and Grey Brief, Argument Sections I.A.2.b, I.B.1, and III.

12; ECF No. 1 at ¶ 20. . . . These are not meaningless embellishments of claims 7 or 27 but rather require additional specific requirements which are neither conventional nor routine.” Appx 713.

Nowhere did 23andMe argue that the broader Claim 1 or dependent Claim 7 were representative of dependent Claim 12.

On a Rule 12(b)(6) motion to dismiss, the district court held all twelve asserted claims invalid because: (1) under *Alice* Step 1, the claims “are ‘directed to’ a law of nature because the focus of the claims is a correlation that exists in nature – *i.e.*, the more recombinable DNA information that is shared between two people, the closer the degree of relationship,” and (2) under *Alice* Step 2, the only “unconventional feature” is the “requirement that specific DNA information be compared,” which simply restates the correlation that exists in nature. Appx21-22 & 25.

The district court’s opinion failed to address any of Claim 12’s dependent limitations defining the unconventional way to estimate IBD, the Complaint’s allegations that these techniques were new and novel, nor the specific arguments on Claim 12 advanced in 23andMe’s opposition to the motion to dismiss. Appx9-26.

23andMe also pled that Claim 7 was patent eligible, alleging steps there as new and unconventional. Appx77-78, ¶¶19 & 22. Sharing an IBD segment does not automatically make two users relatives, nor provide an estimation of the degree of relatedness. As alleged, Claim 7 solves this problem in a new way to estimate

relative relationships where (a) the IBD segments are identified across the two genomes, and (b) their lengths are summed or the percentage of DNA shared in the IBD segments determined as a calculation tool to identify a predicted degree of relationship. Appx62, 11:1-19; Appx77-78, ¶¶19 & 22. The specification did not identify these new steps as being routine or conventional. The district court refashioned these steps as simply a reflection of the natural correlation that more shared DNA equals a closer relative relationship. Appx24.

The district court only in a footnote addressed preemption and did not dispute that the specific scientific building blocks were not preempted by 23andMe's claims, nor that the claims did not preempt all uses of IBD, or all ways for relatives to find each other. Appx26, n.9, Appx713-14.

REASONS FOR GRANTING REHEARING EN BANC

A. RULE 36 AFFIRMANCE IS IMPROPER IN THIS CASE

By summarily affirming the lower court's judgment under Rule 36, the panel left uncorrected the district court's failure to address patent eligibility of Claim 12. Without a panel opinion, 23andMe is left with no explanation for unpatentability of Claim 12, even though the claim recites an unconventional technique that precedent dictates should render it patent eligible.

Rule 36 is an insufficient mechanism to resolve substantial cases—especially when significant property rights are at stake. *See, e.g., Straight Path IP Litigation*

Group, LLC, v. Apple, Inc., No. 19-253 (S. Ct.) (pending). In these circumstances, when key questions of patent rights remain unresolved, the Court should provide an opinion.

B. CLAIM 12 RECITES A NOVEL AND UNCONVENTIONAL METHOD

With respect to Claim 12, the district court erred in three ways: it erred substantively at both steps 1 and 2 of the *Alice* analysis, and it erred procedurally by resolving fact-bound questions at the Rule 12(b)(6) stage. Each of these points is a basis for reversal. Ultimately, Claim 12 is directed to a new and unconventional technique to identify the IBD. Appx77, ¶20; *see generally* Appx76-78, ¶¶17-22.

1. Claim 12 Defines a New and Unconventional Way To Identify IBD that Renders the Claim Directed to Patent Eligible Subject Matter under *Alice* Step 1

The Supreme Court has recognized that a method claim involving searching for genes or specific DNA segments does not doom it to patent ineligibility. As the Supreme Court said in *Myriad*, “[h]ad Myriad created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent.” *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 595 (2013).

The Supreme Court’s *Mayo* decision does not undo its *Myriad* pronouncements on patent eligibility for method claims that use new techniques to search for DNA information, here IBD. The administering and detection steps of

the *Mayo* claim were purely conventional and insufficient to render the claim a patent eligible application of the law of nature. *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66, 78-79 (2012).

Those observations have been equally true in this Court's diagnostic detection cases, which involved the use of routine assays. *See Athena Diagnostics, Inc. v. Mayo Collaborative Svcs, LLC*, 915 F.3d 743, 751 (Fed. Cir. 2019); *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1361 (Fed. Cir. 2017), *cert. denied*, 138 S. Ct. 2621 (2018); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1377-78 (Fed. Cir. 2015), *cert. denied*, 136 S. Ct. 2511 (2016).

Claim 12 of the '554 Patent is different. It does not claim naturally occurring SNPs in the DNA. It does not claim homozygous or heterozygous alleles in the DNA. Nor does it claim the use of routine assays.

Consistent with *Myriad*, it claims a narrow method to utilize the underlying SNP information to identify IBD by a new and unconventional combination of steps. *See McRO, Inc. v. Bandai Namco Game America Inc.*, 837 F.3d 1299, 1315 (Fed. Cir. 2016) (“The claimed process uses a combined order of specific rules that renders information into a specific format that is then used and applied to create desired results: a sequence of synchronized, animated characters.”). “While the result [IBD] may not be tangible, there is nothing that requires a method ‘be tied to a

machine or transform an article' to be patentable.” *Id.* (citing *Bilski v. Kappos*, 561 U.S. 593, 603 (2010)).

In particular, Claim 12 is directed to a new and innovative series of ordered rules to determine whether a DNA segment is an IBD. This involves identifying a particular type of calls in SNP sequences, consecutive opposite homozygous calls, followed by evaluating the distance between them to identify the IBD regions.

Such useful and new methods that apply unconventional and ordered rules are patent eligible under this Court’s precedent. *See, e.g., Rapid Litigation Management Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1048 (Fed. Cir. 2016); *McRO*, 837 F.3d at 1314; *Thales Visionix Inc. v. United States*, 850 F.3d 1343, 1348-49 (Fed. Cir. 2017); *see generally, Diamond v. Diehr*, 450 U.S. 175 (1981).

2. Claim 12’s New and Unconventional Method Is Patent Eligible Under *Alice* Step 2

Even if Claim 12 were deemed as directed to patent ineligible subject matter, these unconventional limitations satisfy the requirements of step 2 of the *Alice* analysis. This includes the steps of utilizing consecutive opposite homozygous calls and distance to identify IBD. This was a new way of identifying IBD regions that had not been done before, as alleged in the Complaint.

Nothing in the district court’s opinion shows that it undertook a proper *Alice* Step 2 analysis. The court did not examine the limitations within Claim 12, nor address whether they are unconventional. Appx24-25. In neglecting to do this

analysis, it failed to account for the specific allegations in the Complaint and in the motion to dismiss opposition that such specific steps were unconventional, supplying the inventive concept apart from any natural correlation. *See, supra*, Appx77-78, ¶¶20 & 22, Appx707-08 & 713.

The specification teaches the inventive way of identifying IBD regions recited in Claim 12, raising at a minimum factual issues on inventive concept that precluded judgment. *See, e.g.*, Appx59-60, 6:32-7:32; Appx52, Fig. 5; *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1369 (Fed. Cir. 2018). The specification does not describe these specific steps to identify IBD as known in the art or routine, conventional or well-understood. Simply inferring that Claim 12's specific steps amount to nothing more than stating a correlation that more similar DNA means a closer relative relationship turns a blind eye to Claim 12's specific limitations⁶ and the inherent factual issues.

3. Dismissal Was Improper at the Rule 12(b)(6) Stage

As a procedural matter, dismissal was improper at this early stage because there was no clear statement in the record that Claim 12's specific methods were well-understood, routine or conventional. *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121, 1127-28 (Fed. Cir. 2018); *Natural Alternatives Int'l*

⁶ "As long as what makes the claims inventive is recited by the claims, the specification need not expressly list all the reasons why this claimed structure is unconventional." *Cellspin Soft, Inc. v. Fitbit, Inc.*, 927 F.3d 1306, 1317 (Fed. Cir. 2019).

v. Creative Compounds, LLC, 918 F.3d 1338, 1347 (Fed. Cir. 2019). Given that undisputed fact, Ancestry did not meet its clear and convincing burden to show unpatentability. *Cellspin*, 927 F.3d at 1318; *see generally Microsoft Corp. v. i4i Ltd. Partnership*, 564 U.S. 91 (2011).

23andMe expressly alleged the innovativeness of the Claim 12 technique for finding relatives, identified the improvements disclosed in the specification that are captured in the claims, and explained how the claimed methods are improvements over the prior art. *See, e.g., Appx76-78, ¶¶17-22*. There further were no clear contrary statements in the specification upon which to establish a clear and convincing record. *Cf. Genetic Technologies Ltd. v. Merial LLC*, 818 F.3d 1369, 1377 (Fed. Cir. 2016). The district court and the panel's affirmance erred by failing to credit the Complaint's specific and undisputed allegations that the subject matter of Claim 12 represents a new and unconventional method.⁷

C. THE REMAINING IBD CLAIMS RECITE SPECIFIC, CONCRETE STEPS FOR FINDING RELATIVES

Likewise, Claim 7, representative of Claims 14, 22 and 31 (the IBD claims), is patent eligible. It recites a novel and innovative way to find relatives: (a) identify

⁷ There was no merit to Ancestry's argument that 23andMe had not separately pled and raised Claim 12 before the district court when there were specific allegations in the Complaint addressed to Claim 12, and its Opposition separately argued Claim 12. *See pp. 7-9, supra*. This argument cannot provide a reasoned basis for the panel's affirmance under FRAP 36.

IBD regions; (b) manipulate IBD information by summing the length of the IBD segments and/or determining the percentage of shared DNA in the IBD regions; (c) make a prediction on the degree of relatedness based on that calculation; and (d) notify the first user through the database about the possibility of a relative.

Under *Alice* Step 1, the district court erred by recasting Claim 7's limitations as nothing more than the more DNA shared between two individuals, the closer is the degree of relationship.⁸ Appx21-22. But the focus of the claims was not to a correlation that relatives share more DNA, but to a technological advancement that uses DNA information in a new and unconventional way to allow two relatives in a database to find each other. The claims harness the user's naturally occurring DNA information to produce a technological improvement to finding a relative—estimate a user's degree of relationship with another user by summing the lengths of, or calculating the percentage of DNA shared in, the IBD regions and notify the user about the potential relative. Claims that “harness[] a natural law to produce a technological improvement” are patent eligible. *Cf. Athena*, 915 F.3d at 751. Further, by requiring a user to be notified about a potential relative, the claims do

⁸ As this Court has warned, “describing the claims at such a high level of abstraction and untethered from the language of the claims all but ensures that the exceptions to § 101 swallow the rule.” *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1337 (Fed. Cir. 2016).

not preempt any research activity that uses these techniques or other ways of identifying relatives.

Turning to *Alice* Step 2, the district court rewrote the IBD claims to conclude: “the only alleged unconventional feature of 23’s claims is the requirement that specific DNA information be compared to determine a relative relationship.” Appx25. But the claims teach, and the Complaint alleges, concrete, *unconventional* techniques to determine relationship, unlike the conventional techniques employed in the claims at issue in *Cleveland Clinic*, *Ariosa* or *Athena*. Nothing in the Patent or its prosecution history describes the specific steps in Claim 7 as known in the art or routine, conventional or well-understood. The district court erred by deciding that “[t]he actual technique employed in claim 7 is not novel,” Appx24, not only indulging in hindsight bias, but without giving 23andMe the benefit of presumption of validity. On this record, invalidation and dismissal under Rule 12(b)(6) was improper.

CONCLUSION

For the foregoing reasons, 23andMe requests that the Court reconsider en banc the panel’s decision and vacate and reverse the judgment below.

Dated: November 4, 2019

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ADDENDUM

NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

23ANDME, INC.,
Plaintiff-Appellant

v.

**ANCESTRY.COM DNA, LLC, ANCESTRY.COM
OPERATIONS INC., ANCESTRY.COM LLC,**
Defendants-Appellees

2019-1222

Appeal from the United States District Court for the
Northern District of California in No. 3:18-cv-02791-EMC,
Judge Edward M. Chen.

JUDGMENT

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THIS CAUSE having been heard and considered, it is

ORDERED and ADJUDGED:

PER CURIAM (PROST, *Chief Judge*, WALLACH and
HUGHES, *Circuit Judges*).

AFFIRMED. See Fed. Cir. R. 36.

ENTERED BY ORDER OF THE COURT

October 4, 2019
Date

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

CERTIFICATE OF COMPLIANCE

Pursuant to Fed. Cir. R. 35(b)(2)(A), I certify that the foregoing petition contains 3820 words, as counted by Microsoft Word 2016.

/s/ William G. Gaede, III

William G. Gaede, III

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the appellate CM/ECF system. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

Dated: November 4, 2019

/s/ William G. Gaede

William G. Gaede, III