Appeal No. 2019-1419

UNITED STATES COURT OF APPEALS
THE FEDERAL CIRCUIT

ILLUMINA, INC., SEQUENOM INC.,

Plaintiffs-Appellants,

v.

ARIOSA DIAGNOSTICS, INC., ROCHE SEQUENCING SOLUTIONS, INC., ROCHE MOLECULAR SYSTEMS, INC.,

Defendants-Appellees.

Appeal from the United States District Court for the Northern District of California, Case No. 3:18-cv-02847-SI, Judge Susan Illston

PLAINTIFFS-APPELLANTS' RESPONSE TO DEFENDANTS-APPELLEES' PETITION FOR PANEL REHEARING AND REHEARING EN BANC

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CERTIFICATE OF INTEREST

Counsel for Plaintiffs-Appellants Illumina, Inc. and Sequenom, Inc. certify:

1. The full name of every party or amicus represented by us is:

   Illumina, Inc.
   Sequenom, Inc.

2. The name of the real party in interest represented by us is:

   Illumina, Inc.
   Sequenom, Inc.

3. All parent corporations and any public companies that own 10 percent or more of the stock of the parties represented by us are:

   N/A
   Laboratory Corporation of American Holdings

4. The names of all law firms and the partners or associates that appeared for the parties now represented by us in the trial court or are expected to appear in this Court are:

   Edward R. Reines
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   Christopher S. Lavin
   Zachary D. Tripp

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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). (The parties should attach continuation pages as necessary.)

   None.

TABLE OF CONTENTS

Page

CERTIFICATE OF INTEREST i

TABLE OF CONTENTS ii

TABLE OF AUTHORITIES iii

OPPOSITION TO PETITION FOR REHEARING AND REHEARING EN BANC 1

STATEMENT 3

REASONS TO DENY PETITION 8

CONCLUSION 18

CERTIFICATE OF SERVICE 19

CERTIFICATE OF COMPLIANCE 20

TABLE OF AUTHORITIES

Page(s)

FEDERAL CASES

Alice Corp. Pty. Ltd. v. CLS Bank Int'l,
573 U.S. 208 (2014) ..... *passim*

Ariosa Diagnostics, Inc. v. *Sequenom, Inc.*,
788 F.3d 1371 (Fed. Cir. 2015) ..... *passim*

Association for Molecular Pathology v. Myriad Genetics, Inc.,
569 U.S. 576 (2013) 2

Ecolochem, Inc. v. Southern Cal. Edison Co.,
227 F.3d 1361 (Fed. Cir. 2000) 16

Rapid Litigation Management Ltd. v. *CellzDirect Inc.*,
827 F. 3d 1042 (Fed. Cir. 2016) ..... *passim*

Warner-Jenkinson Co. v. Hilton Davis Chemical Co.,
520 U.S. 17 (1997) 16

Water Techs. Corp. v. Calco, Ltd.,
850 F.2d 660 (Fed. Cir. 1988) 16

STATUTES

35 U.S.C. § 101 ..... 1, 8, 15

OPPOSITION TO PETITION FOR REHEARING AND REHEARING EN BANC

This case involves a fact-specific application of the test under *Alice Corp. Pty. Ltd. v. CLS Bank Int'l,* 573 U.S. 208 (2014), with the panel correctly holding that the patented enrichment methods here are "new and useful process[es]," within the meaning of 35 U.S.C. § 101. The methods are for enriching a maternal blood sample so that the output has more fetal DNA and can be used for fetal genetic testing. The inventors discovered that fetal DNA fragments in a mother's blood tend to be shorter than fragments of her own DNA. They then applied that knowledge to create a new and useful process for enriching a maternal blood fraction by using size-based differentiation to filter out DNA fragments longer than specified thresholds—approximately 500 or 300 base pairs—to facilitate fetal genetic testing on the output. Notably, no law of nature or natural phenomena dictates those thresholds. The inventors themselves chose them so that the output would be useful for fetal genetic testing, *i.e.*, so the process removes enough longer DNA, which is often maternal, but leaves behind enough genetic material so the fetal DNA can be tested. That process is not "directed at" the phenomenon that fetal DNA tends to be shorter; it applies knowledge of that phenomenon to create a useful enrichment method.

The panel's decision that these methods are patent-eligible breaks no new legal ground and instead is fact-specific and correct. In particular, it does not conflict with any decision of this Court or the Supreme Court. Indeed, the panel itself distinguished *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013), and *Ariosa Diagnostics, Inc.* v. *Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), and instead found the enrichment methods here to be analogous to the enrichment methods this Court upheld in *Rapid Litigation Management Ltd.* v. *CellzDirect Inc.*, 827 F. 3d 1042 (Fed. Cir. 2016).

Judge Reyna dissented, finding that the only "claimed advance" was the discovery that fetal DNA fragments tend to be shorter and finding that these methods are directed at that phenomenon and lack limitations making it patent-eligible. Diss. 7. But the petition for rehearing does not mention the "claimed advance," and instead characterizes the panel decision as being much broader than it actually is. Further review is unwarranted.

STATEMENT

1. The question presented is whether claims 1–2, 4–5, and 9–10 of U.S. Patent 9,580,751 (the "'751 patent") and claims 1–2 and 10–14 of U.S. Patent 9,738,931 (the "'931 patent") are claims for a "process," within the meaning of Section 101. The patents cover "methods of preparing a fraction of cell-free DNA that is enriched in fetal DNA." Op. 4.

It was previously known that blood plasma contains small fragments of DNA outside of any cell, known as "cell free" or "extracellular" DNA, and that a pregnant woman's plasma contains fragments of both her own DNA *and* small amounts of DNA from the fetus. *Id.* at 3. The presence of fetal DNA in maternal blood created the possibility of non-invasive fetal genetic testing. Researchers and clinicians faced a practical problem, however: "[T]he major proportion (generally >90%) of the extracellular DNA" in a mother's blood is her own DNA. *Id.* That made it "difficult, if not impossible," to "distinguish and separate the tiny amount of fetal DNA from the vast amount of maternal DNA." *Id.* In essence, there was a signal-to-noise problem.

The inventors of the '751 and '931 patents devised a process for solving that problem. First, they discovered that fetal cell-free DNA tends to be shorter than maternal cell-free DNA. Specifically, their study found that "the majority of the

circulatory extracellular fetal DNA has a relatively small size of approximately 500 base pairs or less, whereas the majority of circulatory extracellular maternal DNA in maternal plasma has a size greater than approximately 500 base pairs." *Id.* at 3-4; *see* Appx32 tbl. 1 (size distributions from underlying study). They applied that knowledge by creating methods for using size discrimination—with specified length parameters—to filter out longer fragments and thereby produce an output enriched in fetal DNA. The inventors selected size thresholds of approximately 300 or 500 base pairs to enrich the fraction for fetal genetic testing. *See* Op. 4.

Claim 1 of the '751 patent is for:

> A method for preparing a deoxyribonucleic acid (DNA) fraction from a pregnant human female useful for analyzing a genetic locus involved in a fetal chromosomal aberration, comprising:
>
> (a) extracting DNA from a substantially cell-free sample of blood plasma or blood serum of a pregnant human female to obtain extracellular circulatory fetal and maternal DNA fragments;
>
> (b) producing a fraction of the DNA extracted in (a) by:
>
> (i) size discrimination of extracellular circulatory DNA fragments, and
>
> (ii) selectively removing the DNA fragments greater than approximately 500 base pairs, wherein the DNA fraction after (b) comprises a plurality of genetic loci of the extracellular circulatory fetal and maternal DNA; and
>
> (c) analyzing a genetic locus in the fraction of DNA produced in (b).

Id. at 4-5. Claim 1 of the '931 patent uses a size parameter of approximately 300 base pairs rather than 500 base pairs. *Id.* at 5. Dependent claims include additional

laboratory steps, including centrifugation, chromatography, and use of microarrays. *Id.* at 5-6.

2. Plaintiffs-appellants own the '751 and'931 patents. On May 15, 2018, they brought this infringement action against Ariosa Diagnostics, Inc., Roche Sequencing Solutions, Inc., and Roche Molecular Systems, Inc. (collectively "Roche"). The district court granted summary judgment to Roche, holding that the claims were not for patentable subject matter. The court determined the claims were "more analogous" to those in *Ariosa* than those in *CellzDirect*. Appx11.

3. This Court reversed and remanded, holding that "the claims of the '751 and '931 patents are directed to patent-eligible subject matter." Op. 15. At the outset, the Court observed that this is neither a "diagnostic" case nor a "method of treatment" case, but instead a "method of preparation" case. *Id.* at 8. To determine whether the methods are patentable, the Court then stated the two-step *Alice* test, under which a court first asks whether the claims are "directed to" a law of nature or natural phenomenon. *Id.* at 7. "[I]f—and only if—they are," the court asks whether claim limitations transform it into a patent-eligible application. *Id.* at 7-8. Applying that test, the court determined that the claims are not "'directed to' the natural phenomenon." *Id.* at 8-9.

First, the Court explained that the phenomenon is "that cell-free fetal DNA tends to be shorter than cell-free maternal DNA in a mother's bloodstream." *Id.* at 9. Second, the Court determined that the claims "are *not* directed to that natural phenomenon but rather to a patent-eligible method that utilizes it," namely, a "method[] for preparing a fraction of cell-free DNA that is enriched in fetal DNA." *Id.* at 10. "The methods include specific process steps—size discriminating and selectively removing DNA fragments that are above a specified size threshold—to increase the relative amount of fetal DNA as compared to maternal DNA in the sample." *Id.* "Those process steps change the composition of the mixture, resulting in a DNA fraction that is different from the naturally-occurring fraction in the mother's blood." *Id.*

The Court distinguished *Myriad* on the ground that it involved a claim for a preexisting gene, not "a process for isolating it." *Id.* at 12. The Court distinguished *Ariosa* because it involved claims for the mere knowledge that cell-free fetal DNA exists and a method to see that it exists. *Id.* at 11. "Here, in contrast, the claims are directed to more than just the correlation between a DNA fragment's size and its tendency to be either fetal or maternal," and they "do not merely cover a method for detecting whether a cell-free DNA fragment is fetal or maternal based on its size."

Id. Rather, they "remove[] some maternal DNA from the mother's blood to prepare a fraction of cell-free DNA that is enriched in fetal DNA." *Id.* at 11-12.

The Court found *CellzDirect* instructive. *Id.* at 12. The inventors there discovered a phenomenon (some hepatocytes survive freezing and thawing), then "exploited that phenomenon in a patent-eligible method" for enriching a sample to have a greater proportion of viable hepatocytes by subjecting them to multiple freeze-thaw cycles. *Id.* at 12-13. "So too here," the Court stated. *Id.* at 13. The inventors "used their discovery to invent a method of preparing a fraction of DNA that includes physical process steps to selectively remove some maternal DNA in blood to produce a mixture enriched in fetal DNA." *Id.*

Judge Reyna dissented. Judge Reyna found it significant that the written description labels "surprising" the finding that cell-free fetal DNA "tends to be shorter than cell-free maternal DNA." Diss. 7. In his view, that discovery was the only claimed advance and the claims were "directed to" that phenomenon.

REASONS TO DENY PETITION

Roche contends (Pet. 2-3) that the panel's decision conflicts with *Myriad* and *Ariosa*. But the panel distinguished *Myriad* and *Ariosa*, finding *CellzDirect* instead to be analogous because (like *CellzDirect* but unlike *Myriad* or *Ariosa*) the claims here are for a new, specific enrichment process. The panel's determination that this case is more like *CellzDirect* than *Myriad* or *Ariosa* is factbound, does not conflict with any decision of this Court or the Supreme Court, and is correct: The claims are not directed at a natural phenomenon. They apply knowledge of a phenomenon to create a process for producing a novel substance (an enriched blood fraction) that overcomes a barrier to non-invasive fetal genetic testing. That enrichment process is a "process." 35 U.S.C. § 101. Review is unwarranted.

1. Roche contends that "the panel held that the *mere separation* of one natural product (smaller cell-free DNA) from another (larger cell-free DNA) is enough to survive a § 101 challenge, without regard to the inventiveness of that separation." Pet. 7 (emphasis added); *id.* at 8 ("[T]he separation of naturally occurring materials, standing alone, is not patent eligible."). But the panel held no such thing. This case does not involve "mere separation" or separation "standing alone." The panel held that "the claims of the '751 and '931 patents are directed to patent-eligible subject matter." Op. 15. Those claims are for specific, defined processes with numerical

thresholds for creating a new enriched substance—a fraction with more fetal DNA—that is useful for genetic testing. The Court's holding that this enrichment process is a patentable "process" is both case-specific and correct.

First, notwithstanding the Court's observation that Roche had failed "to clearly identify the natural phenomenon that forms the basis of its challenge" and indeed that Roche's articulation was a "moving target," *id.* at 9, Roche still has not identified the phenomenon. That omission is striking because one cannot determine whether a patent is "directed to" a natural phenomenon without knowing what the phenomenon is. Here, the Court correctly identified it: It is the fact "that cell-free fetal DNA tends to be shorter than cell-free maternal DNA in a mother's bloodstream." *Id.*; accord Diss. 7 (describing the phenomenon as being that cell-free fetal DNA "tends to be shorter than cell-free maternal DNA").

As the panel explained, the claims are not "directed to" that tendency, "but rather to a patent-eligible method that utilizes it," namely, a "method[] for preparing a fraction of cell-free DNA that is enriched in fetal DNA." Op. 10. They claim specific steps for creating an enriched fraction that is "different from the naturally-occurring fraction in the mother's blood" in that it contains more fetal DNA, overcoming a practical problem that had impeded fetal genetic testing from maternal blood. Contrary to Roche's suggestions (Pet. 7), the claims do not recite in abstract

terms the idea of using size to separate "larger" fragments from "smaller" fragments. They specifically identify the selective removal of longer DNA from a maternal sample to enrich the fraction in fetal DNA, for use in fetal genetic testing. Op. 4. And they specify thresholds—approximately 500 base pairs or 300 base pairs—for performing the useful enrichment.

Notably, no natural law dictates that fetal cell-free DNA is always shorter than maternal cell-free DNA—and much less dictates a uniform cutoff at approximately 500 (or 300) base pairs. Nor is there a natural law that, in any given person's blood, most fetal fragments will be shorter than those thresholds whereas most maternal fragments will be longer. *See id.* To the contrary, in any given sample, there is a distribution above and below those thresholds—and there is significant variability in the distributions from person to person. *See* Appx32 tbl. 1. For example, in a sample from one woman, 22% of the fragments shorter than 300 base pairs were determined to be fetal; from another woman, the figure was 87%. *Id.* And in one sample, 12.5% of the fragments between 1000 and 1500 base pairs—considerably longer than the thresholds here—were determined to be fetal. *Id.* The 500/300 thresholds thus are not preexisting laws of nature. They are man-made figures *the inventors themselves selected* to make this enrichment process useful: They reflect a judgment that those thresholds increase the proportion of fetal DNA enough, while

leaving enough of the sample behind that the fraction is "useful for analyzing a genetic locus involved in a fetal chromosomal aberration." Op. 4. The claims thus are not directed at the tendency of fetal DNA to be shorter. They apply knowledge of that phenomenon to create a useful enrichment process.

Indeed, even if the claims were "directed at" fetal cell-free DNA's tendency to be shorter, they would still be patent eligible at *Alice* step two because they include limitations that "transform the nature of the claim into a patent-eligible application." *Id.* at 8 (quoting *Alice*, 573 U.S. at 217). Namely, the specified thresholds of approximately 500 (or 300) base pairs make clear that the claims are not seeking to monopolize the mere tendency of fetal DNA to be shorter. The inventors instead applied their knowledge of that phenomenon in a specific way, to create an enriched fraction that overcomes the prior difficulty in "distinguish[ing] and separat[ing] the tiny amount of fetal DNA from the vast amount of maternal DNA." *Id.* at 3.

The claims in turn do not preempt the natural phenomenon. As noted above, they define specific processes for enriching maternal blood in fetal DNA, using specified, human-selected size thresholds. The claims do not cover size differentiation outside that context or other mechanisms for differentiating fetal from maternal cell-free DNA. Even in this context, they do not preempt use of different thresholds (say, approximately 1500 base pairs), nor size filtering to enrich the

portion of *maternal* DNA by excluding smaller fragments. And it does not reach other as-yet-unknown applications of the knowledge that maternal cell-free DNA tends to be longer. Quite simply, these claims are for a new and useful process, not a preexisting natural phenomenon.

As the panel explained, *CellzDirect* is analogous. *Id*. at 12. In *CellzDirect*, the inventors discovered that some hepatocytes survive multiple freeze-thaw cycles, then obtained a patent on a process for increasing the proportion of viable hepatocytes by subjecting them to multiple freeze-thaw cycles so that the output would be more than 70% viable. *See* 827 F.3d at 1046. The process did not claim any advance in the conventional steps of freezing or thawing. This Court upheld the claims at step one, concluding that they "are directed to a new and useful laboratory technique for preserving hepatocytes." *Id.* at 1048. The inventors "exploited" their knowledge of a natural phenomenon by creating a "patent-eligible method" for enriching a sample so that it has a greater proportion of a desired property. Op. 13. "So too here." *Id.* The inventors did not patent the phenomenon that cell-free fetal DNA tends to be shorter; they used their discovery to invent a lab technique for enriching a sample in fetal DNA. *Id*. at 15. Moreover, the claims here specify size thresholds (500 or 300 base pairs) for the enrichment. In *CellzDirect*, this Court upheld process patents even without specifying similar thresholds (such as requiring

cryopreservation to occur within specified temperature ranges), and instead merely with an instruction to repeat the process until the output is more than 70% viable.

Roche contends (Pet. 15) that the *CellzDirect* claims lacked an "analyzing" step and "culminated in cryopreserved hepatocytes with specific properties that … are not naturally occurring and can be used for treatment." But adding an "analyzing" step to an otherwise patentable process does not make it any less of a "process." Moreover, the processes *do* culminate in output "with specific properties that … are not naturally occurring and can be used for treatment." *Id.* The enriched serum has properties (more fetal DNA) that "are not naturally occurring" and "can be used for treatment." Indeed, the whole point of the method is to alter a natural substance so that it can be used for diagnosis and treatment. *See* Op. 4.

2. Roche contends (Pet. 7) that the panel's decision conflicts with *Myriad* and *Ariosa*. But in its brief on appeal, Roche recognized that neither decision was directly on point. *See* Roche Br. 23 (contending merely that the case "closely resemble[s]" *Ariosa*); *see id.* at 30 ("much closer" to *Ariosa* than *CellzDirect*). In any event, the panel distinguished *Myriad* and *Ariosa* on the facts. Roche quotes the Supreme Court's statements that "a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated," and that "separating [a] gene from its surrounding genetic material is not an act of invention."

Pet. 2-3 (quoting *Myriad*, 569 U.S. at 580, 591). But Roche is taking those statements out of context. In *Myriad*, the Court held that a preexisting gene does not become patentable merely because it was isolated—but "expressly declined to extend its holding to method claims reciting a process used to isolate DNA." Op. 12; *see Myriad*, 569 U.S. at 595-596 (emphasizing that "there are no method claims before this Court" and that "this case does not involve patents on new applications of knowledge" about particular genes).

This case involves "the opposite situation." Op. 12. It *only* presents method claims and they are for "new applications of knowledge": the inventors exploited their knowledge that maternal DNA fragments tend to be longer to invent a method for enriching a fraction, using man-made size thresholds, so that it can be used in testing fetal DNA. To put it another way, the claim in *Myriad* was analogous to an effort to patent the genetic material in isolated cell-free fetal DNA itself—as in *Ariosa*—not a new method for enriching a sample so that fetal DNA may be usefully analyzed in the first place.

Ariosa is likewise inapposite. As the Court explained in *CellzDirect*, "[t]he existence and location of [cell-free fetal DNA] is a natural phenomenon; identifying its presence was merely claiming the natural phenomena itself." 827 F.3d at 1048; *see* Op. 11. "Here, in contrast, the claims are directed to more than just the

correlation between a DNA fragment's size and its tendency to be either fetal or maternal," and they "do not merely cover a method for detecting whether a cell-free DNA fragment is fetal or maternal based on its size." Op. 11. "Rather the claimed method removes some maternal DNA from the mother's blood to prepare a fraction of cell-free DNA that is enriched in fetal DNA." *Id.* at 11-12. The panel's conclusion that these claims are patentable under Section 101 thus does not conflict with any decision of this Court or the Supreme Court.

Roche contends (Pet. 16) that the decision "further complicate[s]" this Court's jurisprudence. But that is based on the premise that the panel "classif[ied] patent claims into *per se* categories for purposes of the § 101 analysis." *Id.* It did not. The majority described this a "method of preparation case," "not a diagnostic case" or "method of treatment" case. Op. 8. But that is descriptive, not prescriptive. Indeed, if attaching a label were enough, the Court could have stopped there. The Court instead conducted a full *Alice* inquiry, concluding (correctly) that these claims are for patent-eligible enrichment processes that apply (but are not directed at) natural phenomena. The Court thus did not hold that methods of preparation are always eligible or that mere separation is always enough. It applied *Alice* to "conclude that the claims of the '751 and '931 patents are directed to patent-eligible subject matter."

Id. at 15. That fact-specific holding will not complicate this Court's jurisprudence, as the Court made clear that the *Alice* test remains the lodestar.

Roche's pond water hypothetical (Pet. 11) is also misplaced. The claims here do not resemble a mere instruction to "filter larger material from a sample of pond water before analyzing a microorganism contained therein." *Id.* They are more like a method to use an approximately 5-micron diameter filter on water from a specific kind of brackish pond, to enrich the proportion of a particular microorganism that had previously been too diffuse to study. Such a claim may be obvious or insufficiently enabled, but it is still a "process" within Section 101—not a patent directed at the microorganism itself or its size.

Indeed, removing bacteria from water is commonly known as water purification. Section 101 plainly encompasses processes for water purification, notwithstanding that the starting point (dirty water) and ending point (clean water) are both natural substances and purification mechanisms involve application of laws of nature and natural phenomena. Cf. *Ecolochem, Inc. v. Southern Cal. Edison Co.*, 227 F.3d 1361 (Fed. Cir. 2000) (reversing judgment of invalidity as to methods of purifying water); *Water Techs. Corp. v. Calco, Ltd.*, 850 F.2d 660 (Fed. Cir. 1988) (upholding infringement of method for purifying water); *see also Warner-Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17 (1997) (doctrine of equivalents as to

a method of purifying dye). Roche's sweeping position that "separation of naturally occurring materials, standing alone, is not patent eligible" (Pet. 8) thus would cast a cloud of uncertainty over a vast array of patents on processes like purifying water, cleaning air, enriching gas, refining oil, filtering noise, and "thousands of others that recite processes to achieve a desired outcome." *CellzDirect*, 827 F.3d at 1048. The correct approach is not to ask whether a method involves "separation of naturally occurring materials, standing alone." It is to apply *Alice* and ask whether it is "directed to" a law of nature and, if so, has limitations establishing that it applies a law of nature. That is exactly the approach the panel followed here.

3. Finally, this would be a poor vehicle for considering arguments about *Alice* step one. As set forth above, even if the claims were directed at fetal DNA's tendency to be shorter, they would satisfy *Alice* step two because claims limitations establish that they apply that tendency to create a useful enrichment process. Moreover, broad arguments about Section 101 would not address all the claims. For example, dependent claims include the use of microarrays, which had not previously been used with cell-free DNA. *See* Op. 13 n.1. Further review is unwarranted.

CONCLUSION

The petition for rehearing should be denied.

Respectfully submitted,

Dated: May 1, 2020

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I hereby certify that on May 1, 2020, I filed or caused to be filed copies of the foregoing with the Clerk of the United States Court of Appeals for the Federal Circuit via the CM/ECF system and served or caused to be served a copy on all counsel of record by the CM/ECF system.

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CERTIFICATE OF COMPLIANCE

The undersigned certifies that this brief complies with the type-volume limitation of Federal Rule of Federal Circuit Rule 32(a) or Federal Rule of Federal Circuit Rule 28.1. This brief contains 3,877 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f).

The undersigned further certifies that this brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) or Federal Rule of Federal Circuit Rule 28.1 and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6). This brief has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in Times New Roman 14-point font.

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