No. 2018-1019

IN THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

INO THERAPEUTICS LLC, MALLINCKRODT HOSPITAL PRODUCTS INC., MALLINCKRODT HOSPITAL PRODUCTS IP LTD.,

Plaintiffs-Appellants,

v.

PRAXAIR DISTRIBUTION INC., PRAXAIR INC.,

Defendants-Appellees.

On Appeal from the United States District Court for the District of Delaware, No. 1:15-cv-00170-GMS Honorable Gregory M. Sleet

RESPONSE TO PETITION FOR REHEARING EN BANC

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CERTIFICATE OF INTEREST

Counsel for Appellees Praxair Distribution Inc. and Praxair Inc. certify the following:

1. Full Name of Party Represented by me	2. Name of Real Party in interest represented by me is:	3. Parent corporations and publicly held companies that own 10% or more of stock in the party
Praxair Distribution, Inc.	N/A	Praxair, Inc., a wholly owned subsidiary of Linde plc, a publicly traded corporation
Praxair, Inc.	N/A	A wholly owned subsidiary of Linde plc, a publicly traded corporation

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court (and who have not or will not enter an appearance in this case) are:

MORGAN, LEWIS & BOCKIUS LLP: Colm Connolly, Margaret McGreal, Jennifer Dienes, Jesse Dyer, Caroline Lourgos

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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).

District of Delaware cases: 1:16-cv-00944, 1:16-cv-01168, 1:16-cv-00592

/s/ William R. Peterson
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Dated: October 31, 2019

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

TABLE OF AUTHORITIES
(continued)

Page(s)

RULES

INTRODUCTION

This Court should deny Mallinckrodt's petition for rehearing en banc. In a nonprecedential opinion limited to the unusual facts of the case before it, the panel majority correctly applied the *Mayo*/*Alice* framework and this Court's precedent to affirm the district court's judgment that the asserted claims are ineligible under Section 101. En banc review would neither resolve a disagreement among the Court's decisions nor answer any exceptionally important question.

Mallinckrodt overstates the issue as "selective administration" of drugs. A patentee who invents a new method of treatment—giving new drugs, new dosages, or new treatments to selected patients—will be unaffected by the decision.

As the panel majority recognized, the representative claim sets out two patient types: (1) patients who receive a routine and conventional treatment; and (2) patients who receive no treatment at all. Rather than "selective administration," the asserted claims are better described as "non-administration."

This case is particularly ill-suited for the en banc court to discuss broad legal principles because Mallinckrodt's eligibility arguments conflict with its infringement theory. Although Mallinckrodt now argues that the claims cover only a possible response to knowledge of the natural law, before the district court, Mallinckrodt asserted that informing doctors of the natural law would induce them to practice the claimed methods.

The majority's analysis under *Mayo* and *Alice* is sound. Examining the claims as a whole, the majority recognized that they are "directed to" a natural phenomenon: "A neonate patient's body will react to [inhaled nitric oxide or 'iNO'] gas in a certain way depending on whether or not the patient has a congenital heart condition called LVD." Maj. 9-10.

The claim's "administering" step is not directed to a new use for an old drug, dosage regimen, or any means of treating the underlying condition. As the majority explained, "[t]he patent claim does no more than add an instruction to withhold iNO treatment from the identified patients; it does not recite giving any affirmative treatment for the iNO-excluded group, and so it covers a method in which, for the iNO-excluded patients, the body's natural processes are simply allowed to take place." Maj. 9.

In the second step, "apart from the natural phenomenon itself," the claim "involves only well-understood, routine, and conventional steps." *Id*. This conclusion flows from the undisputed fact that each recited step, including the "administering" step and its dosage of iNO, was conventional (having been disclosed in Mallinckrodt's now-expired patents). This analysis follows the Supreme Court's decision in *Mayo* and this Court's precedent.

Mallinckrodt asks this Court to "create a protective rule that seems to suit the needs of" selective treatment or personalized medicine, a request that the Supreme

Court explicitly rejected in *Mayo*. *See Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 91-92 (2012) ("recogniz[ing] the role of Congress in crafting more finely tailored rules where necessary"). And the majority's decision is "limited to the particular claims and issue and is driven by the particular circumstances"—it does not render "method of treatment claims," "selective treatment claims," or "precision treatment" claims per se ineligible. To the contrary, the decision acknowledges that "new and inventive methods of treatment in personalized medicine remain patent eligible." Maj. 22.

This nonprecedential decision, limited to the specific and unusual circumstance of claims covering a method of nontreatment, does not warrant rehearing en banc.

BACKGROUND

For 20 years, Ikaria (acquired by Mallinckrodt during this litigation) enjoyed a monopoly on and reaped enormous profits from nitric oxide gas to treat newborn infants ("neonates") experiencing hypoxic respiratory failure ("HRF"). Appx1288; Appx1476; Appx1477; Appx13389-13398.

Unwilling to accept the Patent Act's limited 20-year monopoly, Ikaria sought to extend its monopoly: "dissuade competitive entry" by "maintain[ing] iNO patent protection… beyond 2013." Appx18502.

In 2004, Ikaria commissioned the "INOT22 Study" in hopes of discovering new medical uses for iNO. Appx1483. During the study, Ikaria claimed to have observed patients with left ventricular dysfunction ("LVD") experiencing an increased rate of serious adverse events, including pulmonary edema, when treated with iNO.[1] Appx1517-1518; Appx13770.

Ikaria did not attempt to develop a new treatment based on this observation. Instead, it patented claims that cover nothing more than **not** treating patients with LVD. As Named Inventor Dr. James Baldassarre testified, the invention was an "observation." Appx18117; Appx1516-1518; Appx1520.

[1] Internal correspondence attributed the serious adverse events to "inexperience of the operators and the use of general anesthesia," not iNO treatment. Appx13673.

Seeking to compete in providing iNO gas, Appellee Praxair Distribution, Inc. filed an Abbreviated New Drug Application with FDA for approval of a generic iNO gas.

In response, Mallinckrodt sued Praxair for induced infringement. Its theory: because the FDA-approved label noted a correlation between LVD and adverse events, Appx18567-18578 (current INOmax label), Praxair would necessarily induce doctors to practice the claimed methods. *See, e.g.*, Appx25618.

After a seven-day bench trial, the district court found the asserted method claims ineligible under Section 101. Maj. 7. On appeal, a majority of the panel affirmed the district court's Section 101 conclusion in a 24-page, nonprecedential opinion.

REASONS FOR DENYING THE PETITION

En banc review is disfavored and granted only if it is necessary to maintain uniformity of this Court's decisions or if the proceeding involves a question of exceptional importance. Fed. R. App. P. 35(a); *see* Fed. Cir. IOP 13(2); *Sony Elecs., Inc. v. U.S.*, 382 F.3d 1337, 1339 (Fed. Cir. 2004).

When a panel opinion "is not viewed as having changed the law," disagreement with the panel's decision "is not a sufficient reason for en banc review." *Dow Chem. Co. v. Nova Chems. Corp. (Canada)*, 809 F.3d 1223, 1227–28 (Fed. Cir. 2015) (Moore, J., joined by Newman, O'Malley, and Taranto, JJ., concurring in denial of rehearing en banc). The majority's nonprecedential decision could not have changed the law because this Court "will not give . . . nonprecedential dispositions the effect of binding precedent." Fed. Cir. R. 32.1(b), (d).

The purpose of en banc rehearing is not "to second-guess the panel on the facts of a particular case." *In re Dillon*, 919 F.2d 688, 700 n.3 (Fed. Cir. 1990) (Newman, J., joined by Cowen and Mayer, JJ., dissenting). The "rare intervention" of en banc rehearing "should be reserved for real conflicts as well as cases of exceptional importance." *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1311 (Fed. Cir. 2006) (Michel, C.J., and Mayer, J., concurring). That "rare intervention" is unwarranted here.

I. The Panel's Step One Analysis is Soundly Grounded in Precedent.

A. The majority correctly determined that claim 1 is directed to a natural phenomenon.

At Step One, the majority examined the claim as a whole and correctly concluded that it is directed to observing a natural phenomenon: that "[a] neonate patient's body will react to iNO gas in a certain way depending on whether or not the patient has a congenital heart condition called LVD." Maj. 9-10.

The majority's analysis focused on the words of the claim. Maj. 10-11, 15-16. Step One requires "a probing inquiry, which demands a careful reading of the claim language in relation to the particular natural phenomenon in each case." Maj. 11.

The majority concluded that "the focus of the invention is screening for a particular adverse condition that, once identified, requires iNO treatment be withheld." Maj. 11. It reasoned that "[t]he exclusion step merely restates the natural law," because it expressly recites "'excluding the second patient from treatment with inhaled nitric oxide, based on the determination that the second patient has left ventricular dysfunction, so is at particular risk of increased PCWP leading to pulmonary edema upon treatment with inhaled nitric oxide.'" Maj. 10. In other words, the "exclusion step" instructs a physician to observe that "[a] neonate patient's body will react to iNO gas in a certain way depending on whether or not the patient has a congenital heart condition called LVD." Maj. 9.

Although the claim includes an "administering" step, Pet. 10, the majority recognized that the claim's focus "is not on a new way of actually treating the underlying condition." Maj. 11. Indeed, the claim fails to recite any "way of reducing the risk of pulmonary edema while providing *some* level of treatment to those patients." *Id.*

This conclusion is hardly surprising: Named Inventor Dr. Baldassarre described the invention as an "observation." *See* Appx18117; Appx1516-1518; Appx1520. Praxair's expert testified that "the 'standard observation' that a dysfunctional ventricle, in combination with increased blood flow, could cause a backup of venous blood, and, in turn, edema," is a natural phenomenon "taught to first year medical students." Maj. 9.

"[T]he claim is directed to detecting the presence of LVD in a patient and then doing nothing but leaving the natural processes taking place in the body alone for the group of LVD patients." Maj. 10. That "broad directive to exclude all neonatal patients with LVD from iNO treatment (while continuing to treat other patients according to the established dose), collapses into a claim focused on the natural phenomenon." Maj. 13.

B. The majority's conclusion is consistent with Supreme Court precedent and this Court's decisions.

The majority's conclusion follows from the Supreme Court's decision in *Mayo*. The claims in *Mayo* were directed to "relationships between concentrations

of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm." 566 U.S. at 77. Mallinckrodt's argument—that any application of a natural law in treatment is automatically eligible under Section 101—cannot be harmonized with *Mayo*. If Mallinckrodt were correct, then the *Mayo* patentee simply needed to claim not administering thiopurine to patients with high concentrations of metabolites. *But see Mayo*, 566 U.S. at 72 (patent eligibility cannot "depend simply on the draftsman's art"). Neither authority nor logic supports Mallinckrodt's position that a law of nature is transformed into a patent-eligible application by stating the law of nature and adding the words "apply it in treatment."

The majority correctly determined that the claims are directed to the natural relationship between LVD and the risk of serious adverse events with iNO treatment in neonates. Maj. 9-10. That relationship is the consequence of how a neonate with LVD naturally processes iNO. Maj. 3-4, 10. Thus, the claims are based on entirely "natural processes." Maj. 3, 11.

The majority's decision is equally consistent with this Court's decision in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Ltd.*, 887 F.3d 1117, 1121 (Fed. Cir. 2018). Maj. 13. The decisions' consistency should not be surprising, given that decisions of the same district judge—Gregory M. Sleet—

were affirmed in both cases. Like the panel majority, Judge Sleet recognized no inconsistency in holding these claims ineligible and those in *Vanda* eligible.

In *Vanda*, the claims were directed to treating schizophrenia by administering iloperidone in particular dosing ranges based on a natural relationship—i.e., metabolism of iloperidone by the CYP2D6 enzyme. 887 F.3d at 1121. Rather than identify a correlation and claim "apply it in treatment" (or claim "do not apply the standard treatment to patients with a particular enzyme"), the *Vanda* inventors invented a new method of treatment through specific dosages: "requir[ing] a treating doctor to administer iloperidone in the amount of either (1) 12 mg/day or less or (2) between 12 mg/day to 24 mg/day, depending on the result of a genotyping assay." *Id.* at 1135. These claims constitute "a new way of using an existing drug that is safer for patients because it reduces the risk of QTc prolongation." *Id*.

In contrast, Mallinckrodt's claim 1 "does not recite a specific method of treating the disease using an improved set of specific doses in light of th[e] [natural phenomenon's] discovery." Maj. 12-13. Indeed, claim 1 does not recite *any* method of treating neonatal patients having LVD. Maj. 13.

Mallinckrodt wrongly suggests that the "the claim in *Vanda* had a broader preemptive scope than Mallinckrodt's." Pet. 11. According to Mallinckrodt, the claim in *Vanda* "claimed *all* doses of 12 mg/day or less, whereas Mallinckrodt's claims cover only a single, specific course of action." *Id.*

In truth, Mallinckrodt's claims would cover **any treatment** given to patients with LVD other than the known, conventional treatment. Imagine that an inventor developed an innovative new drug for neonates with HRF and LVD. Administering this drug would run afoul of Mallinckrodt's claim because the patient would be excluded from iNO treatment. This is the danger in claiming inaction—by claiming "do not administer inhaled nitric oxide," Mallinckrodt covers "providing any conceivable known or unknown treatment other than inhaled nitric oxide." The breadth and the preemptive effect are extraordinary.

As a result, the asserted claims, like those in *Mayo*, "tie up the doctor's subsequent treatment decision" by covering any use of the natural law, unlike the *Vanda* claims that covered only a specific and inventive treatment. *Vanda*, 887 F.3d at 1135 (quoting *Mayo*, 556 U.S. at 86). The majority correctly concluded that "as far as the record shows, this claim is broadly preemptive of uses of the natural phenomenon." Maj. 21.

Moreover, as the majority explained, "[p]reemption is sufficient to render a claim *ineligible* under § 101, but it is not necessary." Maj. 21 (quoting *Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC*, 915 F.3d 743, 752 (Fed. Cir. 2019)); *see Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1379 (Fed. Cir. 2015) ("Where a patent's claims are deemed only to disclose patent ineligible

subject matter under the *Mayo* framework, as they are in this case, preemption concerns are fully addressed and made moot.").

Endo and *Natural Alternatives* illustrate the same principle: if a claim recites observing a naturally occurring correlation or relationship, uses only routine techniques to do so, and does not make any use of that correlation or relationship other than to observe it, then the claim is directed to only the natural law itself.

The *Endo* claims are not directed to ineligible subject matter because they apply a natural law to claim a method of treating a particular condition with specific doses of the drug. *Endo Pharm. Inc. v. Teva Pharm. USA, Inc.*, 919 F.3d 1347, 1353 (Fed. Cir. 2019). Although the treatment steps are based on the results of kidney function, the claims recite carrying out a specific dosing regimen to achieve a specific treatment outcome. *Id.* at 1353-54.

In *Natural Alternatives*, the district court determined that the claims are directed to the natural law: "ingesting certain levels of beta-alanine, a natural substance, will increase the carnosine concentration in human tissue and, thereby, increase the anaerobic working capacity in a human" and "aid in regulating hydronium ion concentration in the tissue." *Nat. Alts. Int'l, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338, 1344 (Fed. Cir. 2019).

This Court reversed, explaining that "[t]he claims not only embody this discovery, they require . . . actually administer[ing] the dosage form claimed in the

manner claimed, altering the athlete's physiology to provide the described benefits." *Id.* at 1344. "The claim used a particular dose of a substance to obtain a specific 'benefit' by 'altering the subject's natural state.'" Maj. 14 (quoting *Nat. Alts.*, 918 F.3d at 1345).

The majority explained the critical difference between these claims and Mallinckrodt's claims. Maj. 14-15. Claim 1 does not "actually integrate or leverage natural laws to an eligible method of treatment for a particular disease." Maj. 15. "[A]s far as the claim specifies, the [LVD] patient's state may remain unchanged and natural bodily processes may proceed." *Id.*

Similarly, although the cells in *CellzDirect* were naturally able to survive multiple freeze cycles, the claims added a second freeze cycle to allow for a higher percentage of viable cells at the end of the process. *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc*., 827 F.3d 1042, 1051 (Fed. Cir. 2016).

In contrast, Mallinckrodt did not claim a new laboratory method or improved process. As the majority explained, claim 1 "simply sets out an observation of the adverse event, and then instructs the physician to withhold iNO treatment." Maj. 16. This is not "acting on" a natural law; it is passively observing.

Mallinckrodt further argues that "[a]lternatives to withholding iNO might have included administering a lower dose to those patients, adjusting dosing interval, increasing monitoring for adverse effects, or taking compensatory measures to offset

those effects." Pet. 12. But these eligibility arguments conflict with Mallinckrodt's infringement theory: that Praxair, by selling iNO with a label warning of the correlation between LVD and adverse effects, induced infringement of its method claims. Appx25618.

At trial, Mallinckrodt presented evidence that any doctor who knew of the correlation would either not treat the patient or (at the least) discontinue treatment after a side effect developed. Appx1778; Appx25829. Mallinckrodt cannot have it both ways—arguing for eligibility that withholding treatment is merely one among many responses to knowledge of this natural law, while arguing for infringement that it is the only response to that the natural law. Such unusual facts and inconsistent arguments make this case ill-suited for broad pronouncements of law and en banc review.

This observation of a natural phenomenon is not patent eligible under this Court's precedent. *See, e.g.*, *Athena,* 915 F.3d at 752-53 ("Claiming a natural cause of an ailment and well-known means of observing it is not eligible for patent because such a claim in effect only encompasses the natural law itself."); *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1360-61 (Fed. Cir. 2017) (claims that recite observing naturally occurring biological correlations "with no meaningful non-routine steps in between" are directed to a natural law); *Ariosa*, 788 F.3d at 1376 (claims "generally directed to detecting the presence of a naturally

occurring thing or a natural phenomenon, cffDNA in maternal plasma or serum" are ineligible as "begin[ing] and end[ing] with a naturally occurring phenomenon").

C. The majority correctly rejected Mallinckrodt's pleas for a categorical exception to this Court's § 101 precedent and Mallinckrodt's fears of categorical ineligibility.

Ultimately, Mallinckrodt appears to urge the adoption of a categorical exception to eligibility requirements for method of treatment claims, "selective treatment claims," or "precision treatments." Pet. 2, 5, 7-10, 12-14. But the Supreme Court has refused to "depar[t] from established general legal rules" to create "a new protective rule that seems to suit the needs of one field," lest it "produce unforeseen results in another." *Mayo*, 566 U.S. at 92.

The majority explained that the "draftsman's decision to pen a claim as a 'protocol' does not exempt those claims from being scrutinized under the Supreme Court's controlling two-part test." Maj. 17. The same is true for "a method of treating" patients, "selective treatment claims," or "precision treatments." Although "method claims are generally eligible subject matter, method claims that are directed only to natural phenomena are directed to ineligible subject matter." *Cleveland Clinic*, 859 F.3d at 1360.

Rooted in precedent and limited to the facts of this case, the majority's nonprecedential decision is not the watershed described by Mallinckrodt. "[N]ew and inventive methods of treatment in personalized medicine remain patent

eligible." Maj. 22. The majority did not hold "that every treatment that contemplates adverse events—whether known or newly discovered—will lack claim elements that prove transformative." Maj. 22 n.6.

Rather, the majority limited its holding to the particular circumstances of the case: "[H]ere, proceeding with the prior art treatment for [HRF] while offering no solution for neonatal patients with LVD does not transform these particular claims [into a patent-eligible application of a natural phenomenon]." *Id*. The decision does not render any method of treatment claims—or even "selective treatment claims"—per se ineligible. Pet. 7. Step One continues to "demand[] a careful reading of the claim language in relation to the particular natural phenomenon in each case." Maj. 11.

II. The Majority Correctly Determined that the Well-Known Steps Recited in the Claims Do Not Add an Inventive Concept Under Step Two.

At Step Two, the majority properly analyzed the recited steps, "individually and as an ordered combination, to determine whether they contain an 'inventive concept' sufficient to 'transform the claimed naturally occurring phenomena into a patent-eligible application.'" Maj. 17.

First, for the "identifying" step, the majority explained that "[t]he specification . . . makes it clear that identifying patients who have hypnoxic respiratory failure and are candidates for 20 ppm of iNO treatment is routine and conventional in the art." Maj. 18.

Second, the majority analyzed the two "determining" steps: determining that a first patient does not have LVD; and determining that a second patient has LVD. It concluded that these steps were similarly "known to those skilled in the medicinal arts, and such techniques for example may include assessment of clinical signs and symptoms of heart failure, or echocardiography diagnostic screening." Maj. 18-19.

Third, the majority concluded, and Mallinckrodt does not dispute, that it was routine and conventional to "administer[]" a 20 ppm dose of iNO to a patient without LVD. Maj. 3, 11, 18.

Finally, the majority considered the "excluding" step, which directs physicians to "exclud[e]" a patient with LVD from treatment with iNO based on her increased risk of adverse events. Maj. 19.

The majority correctly concluded that "this 'do not treat' step essentially embodies the natural phenomenon at issue in this case—the insight that nitric oxide will adversely affect a neonate with LVD." *Id.* It fails to provide any inventive concept "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself." *Alice Corp Pty. Ltd v. CLS Bank Int'l*, 573 U.S. 208, 217-18 (2014) (quoting *Mayo*, 566 U.S. at 73).

Nor do the claims add anything inventive as an ordered combination. Maj. 20. Because "[a]nyone who wants to use the natural phenomenon must first identify 'candidates for inhaled nitric oxide gas treatment' and determine whether a given

patient has the LVD heart condition," Maj. 20, the combined steps amount to little "more than an instruction to doctors to apply the applicable laws when treating their patients." *Mayo*, 566 U.S. at 79-80.

Nevertheless, Mallinckrodt again argues that the claims satisfy Step Two because not treating LVD patients with iNO results in substantial benefits, "capable of reducing severe adverse events by as much as 90%." Pet. 14-15.

But this argument is misplaced. Maj. 21. "Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry." *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 591 (2013). Discovering BRCA1 and BRCA2 genes in *Myriad* was surely beneficial, but this advancement did not transform the claims into patent-eligible subject matter. *Id.*

The same is true here. Any benefits that Mallinckrodt touts result solely from the "phenomenon itself—not an inventive application of it." Maj. 21. Mallinckrodt did not invent a new way of detecting LVD or titrating an iNO dose. Maj. 19. In fact, Mallinckrodt acknowledges that the benefits it maintains should confer patent eligibility are those that "stem from the underlying natural law." Pet. 14 n.1.

At bottom, the "inventive concept" and any of its benefits that Mallinckrodt identifies are "furnished by the unpatentable law of nature (or natural phenomenon or abstract idea) itself." Maj. 18 (quoting *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1376 (Fed. Cir. 2016)). The claims are not patent eligible.

CONCLUSION

In a nonprecedential opinion limited to the specific facts and unusual claims before it, the majority correctly concluded that the claimed method is directed to a natural phenomenon and that the elements, individually and as an ordered combination, do not contain an inventive concept. Mallinckrodt's petition should be denied.

Dated: October 31, 2019

Respectfully submitted,

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PROOF OF SERVICE

I hereby certify that on October 31, 2019, I electronically transmitted this Response to Petition for Rehearing En Banc to the Clerk of the Court using the Court's ECF system. I further certify that counsel of record for Appellants are being served with a copy of this Response by electronic means via the Court's ECF system, or by email, as follows:

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CERTIFICATE OF COMPLIANCE WITH RULE 32

1. This response complies with the type-volume limitations of Federal Circuit Rule 35(e)(4) because this response contains 3,898 words, excluding the parts of the response exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b).

2. This response complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this response has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in Times New Roman 14 point font.

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Dated: October 31, 2019