No. _____

In the Supreme Court of the United States

HARITHA SAMARANAYAKE, JERE PIKKARAINEN, ANN-MARIE MAATTA AND SEPPO YLÄ-HERTTUALA,
Appellants and Petitioners
-against-

The HONORABLE ANDREI IANCU, in his official capacity as Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office,
Respondent

ON PETITION FOR A WRIT OF *CERTIORARI* TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF *CERTIORARI*

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Questions Presented

Whether, in *creating* the required evidentiary record *de novo* rather than merely *reviewing* the agency Record below, the Court of Appeals for the Federal Circuit exceeded its statutory jurisdiction under 35 U.S.C. § 144.

Whether 5th Amendment due process requires a litigant be afforded the opportunity to proffer rebuttal evidence in response to evidence newly-entered by a Federal Court.

List of Parties

A list of all parties to the proceeding in the court whose judgment is sought to be reviewed:

Haritha Samaranayake, Jere Pikkarainen, Ann-Marie Maatta and Seppo Ylä-Herttuala, *Petitioners*. The real party in interest is the assignee of the application, Gliotherapy Limited.

The Honorable Andrei Iancu, in his official capacity as Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office, *Respondent*.

Corporate Disclosure Statement

Gliotherapy Limited is a privately-held company. No public company owns, directly or indirectly, any of its stock.

Rule 14(b)(iii) List of Related Proceedings

The only related proceedings are the four decisions below:

The Court of Appeals for the Federal Circuit, Docket No. 2020-1158, *In re Haritha Samaranayake, Jere Pikkarainen, Ann-Marie Maatta And Seppo Ylä-Herttuala*, Decision on rehearing entered September 30, 2020; Decision on Appeal entered September 2, 2020.

Patent Trial & Appeal Board, Docket No. 2018-001996, *Ex parte Haritha Samaranayake, Jere Pikkarainen, Ann-Marie Maatta And Seppo Ylä-Herttuala*, Decision on rehearing entered September 4, 2019; Decision on Appeal entered May 30, 2019.

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Opinions Below

The opinion on rehearing of The Court of Appeals for the Federal Circuit is not reported and is reproduced in the Appendix ("App.") at 1a-2a. The two original opinions of The Court of Appeals for the Federal Circuit are not reported and are reproduced in the Appendix ("App.") at 11a-14a. The opinion on rehearing of The Patent Trial & Appeals Board (the "Board") is not reported and is reproduced at App. 21a-27a. The opinion of the Board is not reported and is reproduced at App. 31a-54a.

Jurisdiction

The Board enjoyed jurisdiction to hear the appeal under 35 U.S.C. § 134(a).

The Court of Appeals for the Federal Circuit enjoyed jurisdiction to hear an appeal under 35 U.S.C. § 141.

The Circuit entered judgment on September 2, 2020. A petition for rehearing was timely entered. The Circuit denied rehearing on September 30, 2020. This Court therefore enjoys jurisdiction under 28 U.S.C. § 1254(1).

Statutory Provisions Involved

U.S. CONSTITUTION, 5TH AMENDMENT: "No person shall … be deprived of life, liberty, or property, without due process of law."

35 U.S.C. § 144: "The Court of Appeals for the Federal Circuit shall review the decision from which an appeal is taken on the record before the Patent and Trademark Office."

5 U.S. C. § 706: "To the extent necessary to decision and when presented, the reviewing court shall decide

all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall- (1) compel agency action unlawfully withheld or unreasonably delayed; and (2) hold unlawful and set aside agency action, findings, and conclusions found to be-

* * *

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute"

Statement of the Case

Petitioners discovered a new way to treat malignant glioma, a particularly nasty form of cancer.

They filed a patent application on their invention. The patent examiner rejected their application.

Petitioners appealed to The Patent Trial & Appeal Board (the "Board"). Faced with such scrutiny, the examiner reversed position, conceded that the evidence of Record does not support rejection, and withdrew her rejections.

At the Board, however, the agency raised entirely new rejections. As support, the Board cited new extrinsic evidence. That evidence, however, was not in the Record on appeal.[1] Further, the agency's regulations largely bar new evidence after appeal. *See* 37 C.F.R. § 41.33(d). The agency thus did not enter its new evidence into the Record.

Responding to the Board's newly-raised evidence, Petitioners filed rebuttal evidence: a 106-page expert witness declaration explaining in painstaking detail how the Board misreads its own evidence. The Board, however, refused to consider it.

In summary, the Board considered evidence that was late-raised (and thus barred from entry), yetrefused to consider Petitioners' rebuttal evidence.

Petitioners thus appealed to The Court of Appeals for the Federal Circuit. In response, the agency served its *Certified List* of the contents of the agency Record on appeal. The agency's *Certified List* shows that the

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[1] The agency defines the "Record" as "the items listed in the content listing of the Image File Wrapper of the official file of the application." *See* 37 C.F.R. § 41.30.

Record on appeal does not include any of the agency's late-raised evidence. To fix that absence of evidence, the agency thus proffered that missing evidence - 100 pages of new documents - directly to the Circuit. Petitioners moved to strike or, in the alternative, for leave to proffer its 106-page expert witness declaration in rebuttal.

The Circuit admitted the agency's 100 pages of new evidence, denied Petitioners leave to enter its 106-page rebuttal evidence, and affirmed rejection based on the agency's 100 pages of new evidence.

The Circuit thus took several actions that are not merely erroneous, but dangerous.

First, in *creating* the required evidentiary record rather than merely *reviewing* the agency's Record, the Circuit exceeded its jurisdiction. *See* 35 U.S.C. § 144. Pointedly, the Circuit did so in spite of this Court's recent and unambiguous instruction to it that it "must review the PTO's decision on the same administrative record that was before the PTO." *See Kappos v. Hyatt*, 566 U.S. 431, 438 (2012). The Circuit similarly disregarded this Court's recent and unambiguous instruction to it that in this type of appeal, "there is no opportunity … to introduce new evidence" after appeal. *Id*. Troublingly, the Circuit does not even try to excuse its disregard for this Court's recent and unambiguous instruction.

Second, in *creating* the required evidentiary record rather than merely *reviewing* the agency's Record, the Circuit assumed the evidence-gathering, record-making function here reserved exclusively for the executive branch. *See Federal Radio Comm'n v. Nelson Bros. Bond & Mortgage Co*., 289 U.S. 266,

276-77 (1933). The Circuit thus violated our separation of powers. *See id.*

Third, in refusing Petitioners the opportunity to proffer rebuttal evidence to the Circuit's newly-entered evidence, the Circuit denied Petitioners due process of law under the 5th AMENDMENT.

Fourth, the Circuit fails to correctly apply the evidentiary standards of the Federal Administrative Procedure Act.

Federal agencies from the Army Corps of Engineers to the Securities & Exchange Commission must support their decisions with evidence *in the agency's record*.[2] In the instant case, The Court of Appeals for the Federal Circuit fails to follow this near-universal rule. Rather, the Circuit supports rejection with evidence that is not merely *absent from* the agency Record, but was expressly *barred from* entry into that Record because the agency improperly withheld it until after Petitioners appealed. Troublingly, the Circuit does not explain why the Patent Office should

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[2] *See e.g.*, Army Corps of Engineers v. Carlo Bianchi & Co., 373 US 709, 716 (1963); Dept of Commerce v. Eurodif SA, 129 S.Ct. 878, 886 n. 6 2009); Dept of Labor v. Brown-Pacific-Maxon, Inc., 340 US 504, 508 (1951); HUD v. Underwood, 487 US 552, 564-65 (1988); Rapanos v. EPA, 547 US 715, 786 (2006); Federal Reserve Bank v. First Lincolnwood Corp., 439 US 234, 253 (1978); FTC v. Indiana Federation of Dentists, 476 US 447, 454 (1986); Bowman Transp., Inc. v. Arkansas-Best Freight System, Inc., 419 US 281, 283-84 (1974) (ICC); Thomas Jefferson Univ. v. FDA, 512 US 504, 512 (1994); Consolo v. Federal Maritime Comm'n, 383 US 607, 619-20 (1966); Universal Camera Corp. v. NLRB, 340 US 474, 477 (1951); Social Security Admin. v. Perales, 402 US 389, 390 (1971); Citizens to Preserve Overton Park v. Sec'y of Transportation, 401 US 402 (1971); Steadman v. SEC, 450 US 91, 99 (1981).

be excused from complying with a rule that every other Federal agency follows. The Circuit's reliance on evidence absent from and indeed barred from the agency Record is not merely odd: it is dangerous. It allows - as here - the agency to arbitrarily reject applications on alleged extrinsic evidence, while denying patent applicants the right to rebut. The Circuit's odd rule poses an existential threat to the fair and efficient administration of the modern administrative state.

We first review the relevant procedural history. We then discuss the legal issues that procedural history raises.

Procedural History

Petitioners discovered a new way to treat malignant glioma, a particularly nasty form of brain cancer. On April 1, 2013, they filed a patent application on their invention. They then added to the agency Record[3] complete, legible copies of several hundred pages of relevant scientific literature.

The patent examiner then reviewed the application and the accompanying evidence of Record. On Aug. 4, 2015 the examiner rejected Petitioners' application. As support, the examiner reasoned that the application claims merely self-evident or "obvious" variants of the scientific papers of Record.

On August 12, 2015 the Applicant responded by explaining how, contrary to the examiner's analysis, the evidence relied on by the examiner shows that

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[3] The agency defines the "Record" as "the items listed in the content listing of the Image File Wrapper of the official file of the application." *See* 37 C.F.R. § 41.30.

the Petitioners' invention *is* patentable. On March 10, 2016 the patent examiner, parroting her earlier rationale, again rejected Petitioners' application.

On July 27, 2016, Petitioners filed an appeal brief with the Patent Trial & Appeal Board (the "Board"). Petitioners explained how the evidence relied on by the examiner contradicts rejection.

On Oct. 23, 2017, the Examiner filed her opening brief with the Board. Faced with Board scrutiny, the examiner reversed position. She conceded that the evidence of Record does not in fact support rejection. The examiner thus withdrew all of her prior rejections.

In their stead, however, the agency raised entirely new rejections. As support, it cited Ulasov[4] alone or together with Balmaceda, Brandes, Hegi (2008) and Yu. None of these documents, however, were in the agency Record on appeal.

The agency may introduce new evidence after appeal to the Board. To prevent sand-bagging an applicant with improperly concealed evidence, however, the agency can introduce new evidence after appeal if, and only if, it satisfies three preconditions. First, it must introduce its new evidence prior to the date appellants file their initial brief. *See* 37 C.F.R. § 41.33(d)(1). Second, it must concede that its new evidence overcomes all rejections. *Id*. Third, it must

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[4] For simplicity, I refer to these documents by author's last name only.

provide good and sufficient reasons why it did not earlier present its new evidence. *Id*.[5]

In the instant case, the agency failed to meet any of these three requirements. The agency did not mention its new evidence until Oct. 23, 2017 - over a year *after* Petitioners filed their initial brief. The agency argued that its late evidence does not overcome rejection. And the agency did not provide any reasons why it had withheld this evidence. The agency thus failed to satisfy any of the three elements required to permit entry of late-raised evidence. Thus, the agency's regulations say this late-raised evidence "will not be admitted." *See* 37 C.F.R. § 41.33(d)(2).

The agency's regulations bar the agency's late-raised evidence. *Id*. The agency thus did not enter into its Image File Wrapper copies of Ulasov, Balmaceda, Brandes, Hegi (2008) or Yu. Thus, the agency's Image File Wrapper does not include copies of Ulasov, Balmaceda, Brandes, Hegi (2008) or Yu. Thus, the Image File Wrapper content list does not list any of these documents. Those documents are therefore not part of the agency Record. *See* 37 C.F.R. § 41.30.

While the Record contains none of these documents, the Board nonetheless relied on them to support rejection. The Board thus relied on evidence that was (and remains) not merely *absent* from the Record, but is expressly *barred from* entry into the Record by 37 C.F.R. § 41.33(d).

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[5] If the agency cannot meet these three preconditions, then the proper procedure would have been for the Board to remand to the examiner, who then could enter the new evidence into the Record and afford the opportunity to respond.

Procedural due process requires an agency to consider evidence proffered to rebut newly-raised evidence. *See e.g., Ohio Bell Telephone Co.* v. *Public Utilities Comm'n,* 301 U.S. 292 (1937). Thus, in response to the Board's late-raised evidence, Petitioner proffered rebuttal evidence: a 106-page expert witness declaration explaining in painstaking detail how the Board misreads its own evidence. The Board flatly refused to consider that rebuttal declaration. *See* 26a.

Thus, the Board *considered* its own late-raised evidence, yet *disregarded* Petitioners' responsive rebuttal evidence. In refusing to consider Petitioners' rebuttal evidence, the Board failed to afford Petitioners due process. *See e.g., Ohio Bell Telephone Co.* v. *Public Utilities Comm'n,* 301 U.S. 292 (1937).

To justify its disregard for Petitioners' rebuttal evidence, the Board reasons that the agency's regulations largely bar patent applicants from entering new evidence after appeal to the Board. *See* 26a.

The regulations do indeed largely bar applicants from entering new evidence after appeal. *See* 37 C.F.R. § 41.33(d). But that same regulation also bars *the agency* from entering its late-raised evidence. *Id.* Thus, the Board waived its own compliance with its regulation, yet enforced that same regulation against applicant, barring it from proffering rebuttal evidence. *Heads-I-win; tails-you-lose.* This approach does not afford Petitioners due process. *See Ohio Bell.*

On November 4, 2019, Applicant appealed to The Court of Appeals for the Federal Circuit pursuant to 35 U.S.C. § 141(a).

On December 30, 2019, pursuant to 35 U.S.C. § 143, the agency served its *Certified List* of the contents of the agency Record. The agency's *Certified List* nowhere lists Balmaceda, Brandes, Hegi, Ulasov or Yu. The agency's *Certified List* confirms that Balmaceda, Brandes, Hegi, Ulasov and Yu are not of Record. *See* 37 C.F.R. § 41.30.

The agency cannot reject unless it supports rejection with substantial evidence of Record. *See Dickinson v. Zurko*, 527 U.S. 150, 152 (1999), *citing* 5 U.S.C. § 706(E). Thus, on December 31, 2019 Petitioners filed their initial brief with the Circuit, arguing that as a matter of law the Board's rejections are unsustainable because they are not supported by evidence *in the Record*.

On March 9, 2020, the agency tried to fix its fatal lack of evidence by proffering to the Circuit copies of Balmaceda, Brandes, Hegi, Ulasov and Yu - 100 pages of new evidence.

The statute granting the Circuit jurisdiction over this appeal, however, requires the Circuit to review the appeal "on the record before the Patent and Trademark Office." *See* 35 U.S.C. § 144. This court thus recently and unambiguously admonished the Federal Circuit that that in this type of appeal, "there is no opportunity … to introduce new evidence," so the Federal Circuit "must review the PTO's decision on the same administrative record that was before the PTO." *See Kappos v. Hyatt*, 566 U.S. 431, 438 (2012). The Circuit therefore does not enjoy jurisdiction to enter new evidence, nor to create a new evidentiary record independent of and significantly different from that at the agency. *See id*.

On March 12, 2020 Petitioners moved to strike the newly-proffered documents. The Circuit denied Petitioners' motion.

Alternatively, Petitioners requested the opportunity to proffer its 106-page expert witness declaration to rebut the agency's newly-proffered 100 pages of evidence. The Circuit denied this request.

The Circuit thus entered 100 pages of new evidence, denied Petitioners the opportunity to rebut, and affirmed rejection based on the newly-entered documents. In so doing, the Circuit committed several significant errors.

First, in entering 100 pages of new evidence, the Circuit exceeded its jurisdiction. In this type of appeal, the Circuit's jurisdiction is limited to reviewing "the record before the Patent and Trademark Office." *See* 35 U.S.C. § 144. The Circuit's error is particularly egregious here because its 100 pages of new evidence is not mere background. Rather, it is indispensible, and indeed often *the only* evidence ostensibly supporting most rejections.

Second, in *creating* the requisite evidentiary record in the first instance, the Circuit assumed the evidence-gathering, record-creating power that is here reserved exclusively to the executive branch. *See Federal Radio Comm'n v. Nelson Bros. Bond & Mortgage Co.*, 289 U.S. 266, 276-77 (1933). The Circuit thus violated the separation of powers. *See id.*

Third, in denying the Petitioners the opportunity to rebut the Circuit's 100 pages of new evidence, the Circuit denied Petitioners their 5TH AMENDMENT right to due process.

Fourth, in affirming rejection based on evidence that appears nowhere in the agency's Record, the Circuit disregarded the controlling legal standard under the Federal Administrative Procedure Act.

Reasons To Grant This Petition

The facts of this case are quite simple. Yet they raise fundamental problems with appellate jurisdiction, the separation of powers, 5TH AMENDMENT due process and the Federal Administrative Procedure Act. We discuss each in turn.

The Circuit Exceeds Its Jurisdiction

"It is a principle of first importance that the federal courts are courts of limited jurisdiction." Wright & Kane, LAW OF FEDERAL COURTS (6th ed. 2002) § 7 pg. 27; *see also e.g.*, *Bender v. Williamsport Area School Dist.*, 475 U.S. 534, 541 (1986). The jurisdiction of inferior Federal courts thus depends "entirely upon the action of Congress." *Cary v. Curtis*, 44 U.S. 236, 245 (1845). Thus, to ascertain an inferior court's jurisdiction, we must read the operative statute to determine how Congress invested - and withheld - jurisdiction. *Id.*; *Lockerty v. Phillips*, 319 U.S. 182, 187 (1943).

In the instant case, the Circuit enjoys jurisdiction pursuant to 35 U.S.C. § 144. That statute reads, "The Court of Appeals for the Federal Circuit shall review the decision from which an appeal is taken *on the record before the Patent and Trademark Office*." *See* 35 U.S.C. § 144 (emphasis mine). Congress thus here invested the Federal Circuit with quite limited jurisdiction here. The Circuit enjoys jurisdiction to review "the record before the Patent and Trademark Office" only. Congress pointedly *did not* invest the

Circuit with jurisdiction to admit new evidence and create a record independent of, and fundamentally different from, that of the agency.

Indeed, this Court recently admonished the Federal Circuit that in this type of appeal, "there is no opportunity … to introduce new evidence" at the Federal Circuit. *See Kappos v. Hyatt,* 566 U.S. 431, 438 (2012).

In the instant case, the Circuit did exactly what Congress and this Court told it to ***not*** do: it based its decision not on "the record before the Patent and Trademark Office," but on 100 pages of documents absent from, and indeed barred from, that Record. In basing its decision on 100 pages of documents found nowhere in the agency Record, the Circuit exceeded its jurisdiction. *See* 35 U.S.C. § 144; *Kappos*.

In the instant case, the Circuit's disregard of its jurisdiction is particularly egregious because the Circuit's 100 pages of new evidence is *indispensible*, and indeed *the only* evidence ostensibly supporting certain rejections.

The agency defines the Record on appeal as "the items listed in the content listing of the Image File Wrapper of the official file of the application." *See* 37 C.F.R. § 41.30. In response, the Board argued that while the agency's Image File Wrapper does not include copies of Balmaceda, Brandes, Hegi, Ulasov or Yu, and thus does not list any of these in its contents list, the agency constructively made these extrinsic documents of Record by providing a "full citation" to them. *See* 22a-23a. The agency, however, cites no authority for that proposition. *See id*.

The agency's inability to cite authority is not surprising because its position is belied by its own regulation. That regulation defines the agency Record on appeal as "the items listed in the content listing of the Image File Wrapper of the official file of the application." *See* 37 C.F.R. § 41.30. In the instant case, the Image File Wrapper does not include copies of Balmaceda, Brandes, Hegi (2008) Ulasov or Yu. The Image File Wrapper content listing thus does not list any of these documents. These documents are therefore not part of the agency Record on appeal. *See id*.

Providing a "full citation" to these documents does not change this. Merely providing a citation to an extrinsic document does not add a copy of that document to the Image File Wrapper. Providing a citation thus does not list that document in the Image File Wrapper content listing. Providing a "full citation" to these documents therefore fails as a matter of law to make them of Record. *See id*.

Furthermore, the Record includes only "the items listed in the content listing of the Image File Wrapper of the official file of the application …, *excluding amendments, Evidence, and other documents that were not entered*." *See* 37 C.F.R. § 41.30 (emphasis mine). In the instant case, the agency improperly withheld these documents until after appeal. The agency was thus barred from entering these documents into the Record on appeal. *See* 37 C.F.R. § 41.33(d). Thus, even assuming the agency had entered copies of these documents in the Image File Wrapper, those documents would not have been considered part of the Record on appeal. *See* 37 C.F.R. § 41.30.

Ulasov, Balmaceda, Brandes, Hegi (2008) and Yu are not part of the agency Record. *See* 37 C.F.R. § 41.33(d). In entering this 100 pages of new evidence for the first time, the Federal Circuit improperly exceeded its jurisdiction. *See* 35 U.S.C. § 144; *Kappos*.

The Circuit Violates the Separation of Powers

In reviewing agency action, a Federal court can resolve questions of law raised by the agency's evidentiary record. *See Federal Radio Comm'n v. Nelson Bros. Bond & Mortgage Co.*, 289 U.S. 266, 276-77 (1933). Federal courts cannot, however, "exercise functions which are essentially legislative or administrative." *Id.* at 275. For example, a Federal Court of Appeals creating its own evidentiary record separate from the agency record on appeal is an improper "attempt to vest in the Court an authority to revise the action of the [agency] from an administrative standpoint and to make an administrative judgment." *Id.* This violates the separation of powers.

In the instant case, the Circuit ignores this bedrock principle. Balmaceda, Brandes, Hegi, Ulasov and Yu are not in the agency Record. When the Circuit newly admitted those documents, the Circuit did not merely *review* the pre-existing agency record. Rather, the Circuit *created* a new evidentiary record fundamentally different from the agency's Record. In creating a new evidentiary record, the Circuit improperly misappropriated authority that here is vested exclusively in the executive branch. *See Federal Radio Comm'n*. at 276-77. The Circuit thus failed to respect our separation of powers. *See id.*

The Circuit Denies Due Process

No person shall be deprived of property without due process of law. U.S. CONST. 5TH AMENDMENT. Due process requires an opportunity to proffer rebuttal evidence. *See e.g.*, *Ohio Bell Telephone Co.* v. *Public Utilities Comm'n,* 301 U.S. 292 (1937), *Bowman Transp., Inc. v. Arkansas-Best Freight System, Inc.*, 419 US 281, 288 n. 4 (1974).

In the instant case the Circuit denied Petitioners' right to due process. The Circuit entered 100 pages of new evidence. In response, Petitioners asked to introduce rebuttal evidence (specifically, a 106-page expert-witness *Declaration* explaining in painstaking detail how the Circuit's newly-admitted documents fail to support rejection). The Circuit denied Petitioners' request. In entering 100 pages of new evidence while denying Petitioners the opportunity to rebut it, the Circuit failed to accord Petitioners due process. *See Ohio Bell* at 300; *Bowman Transp.* at 288 n. 4. The violation is particularly egregious here because the Circuit's 100 pages of new evidence is not mere background. Rather, it is *indispensible*, and indeed *the only* evidence ostensibly supporting most rejections. In denying Petitioners the opportunity to rebut the Circuit's 100 pages of new evidence, the Circuit denied Petitioners their right to due process. *See id.*

To justify its disregard of Petitioners' rebuttal evidence, the Circuit adopts the Board's rationale: that the agency's regulations largely bar applicants from entering new evidence after appeal. *See* 26a. That justification, however, fails as a matter of law.

The regulations largely bar *anyone* from entering new evidence after appeal. *See* 37 C.F.R. § 41.33(d).

If the Circuit chooses to disregard its own jurisdictional limits and allows itself to rely on new evidence, or if the Board chooses to disregard its own regulation and allows itself to rely on new evidence, then the Circuit (or the Board) must as a matter of law afford Petitioners the opportunity to rebut that new evidence. *See Ohio Bell* at 300; *Bowman Transp*. at 288 n. 4. Put another way, if a regulation denies Petitioners their Constitutional right to due process, it is the regulation - not the CONSTITUTION - which must yield.

The Circuit Misstates The Legal Standard Under the Administrative Procedure Act

This Court has (repeatedly) admonished the Federal Circuit that The Patent Office must comply with the Federal Administrative Procedure Act (the "APA"). The APA requires Federal agencies to support decisions with "substantial evidence … on the record of an agency." *See Dickinson v. Zurko*, 527 U.S. 150, 152 (1999), *citing* 5 U.S.C. § 706(E). The "substantial evidence" standard confines a Federal court's review to the administrative record. *See United States v. Carlo Bianchi & Co*., 373 US 709, 716 (1963); *Assoc. of Data Processing Service Org's, Inc. v. Board of Governors*, 745 F.2d 677, 684 (App. D.C. 1984) (SCALIA and GINSBURG, Circuit Judges) ("substantial evidence" under the Federal Administrative Procedure Act requires that substantial evidence be found in the record *at the agency*). This rule is particularly important for proceedings in the Patent Office because patent applications can (as here) involve extraordinarily complex technology, so it is crucial that everyone knows exactly what the facts and evidence are.

In the instant case, the agency's Record neither lists nor contains copies of Balmaceda, Brandes, Hegi, Ulasov or Yu. Those documents are therefore not part of the agency Record. *See* 37 C.F.R. § 41.30. Thus, neither the Circuit nor the agency supports its decision with evidence *in the agency Record*.

The Circuit tries to fix that flaw by entering the missing evidence in the first instance. That fix fails as a matter of law because a Circuit court must support an agency rejection with "the administrative record already in existence, not some new record made initially in the reviewing court." *See Camp v. Pitts*, 411 U.S. 138, 141 (1973). Thus, this Court recently admonished the Federal Circuit that "there is no opportunity" for the Circuit to enter new evidence in this type of appeal. *See Kappos v. Hyatt*, 566 U.S. 431, 438 (2012). To the contrary, this Court, reminding the Circuit of its limited statutory jurisdiction, instructed the Circuit that it "must review the PTO's decision on the same administrative record that was before the PTO." *Id*.

The Circuit, flatly disregarding this Court's recent, clear and express instruction to the contrary, entered 100 pages of new evidence. The Circuit's new evidence, however, does not change the Record *at the agency*. The Record *at the agency* did not - and as of this writing still does not - include copies of Balmaceda, Brandes, Hegi, Ulasov or Yu. Those documents are nowhere in the agency Record. Thus, neither the agency nor the Circuit can rely on them. *See Dickinson v. Zurko*, 527 U.S. 150, 152 (1999); *Kappos v. Hyatt*, 566 U.S. 431, 438 (2012).

The Circuit's Atypical Procedure Harms Medical Research

Malignant glioma has no cure. The inventors may have found one. Making the inventors' invention available commercially, however, will require significant further investment.[6] It will be difficult to convince investors to make that investment without in exchange providing some assurance that their investment is protected with a patent. The Circuit's posture here - rejecting the instant application on late-raised, extrinsic evidence, while refusing to even consider rebuttal evidence - makes that impossible. Brain cancer patients cannot be helped by a new cure if the Circuit kills off the cure in its infancy.

Summary

Petitioners respectfully ask the Court to grant *certiorari* to confirm that the Court of Appeals for the Federal Circuit's jurisdiction in appeals under 35 U.S.C. § 144 is limited to reviewing the evidence in the agency's Record below, confirm that due process requires both the Circuit the agency to consider evidence rebutting newly-raised evidence, and confirm that the Circuit must support rejection with substantial evidence in the Record at the agency.

Respectfully submitted on behalf of Petitioners by their attorneys,

PHARMACEUTICAL PATENT ATTORNEYS, LLC

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[6] *See generally*, Rick Mullin, *Cost To Develop New Pharmaceutical Drug Now Exceeds $2.5B*, CHEMICAL & ENGINEERING NEWS (Nov. 24, 2014).

J. Mark Pohl
Morristown, New Jersey
January 4, 2021

Appendix