No. 24-

IN THE

Supreme Court of the United States

MATTHEW T. MCLEAY,

Petitioner,

v.

COKE MORGAN STEWART, ACTING UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND ACTING 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

RYAN S. HINDERLITER
KUTAK ROCK LLP
2405 Grand Boulevard,
Suite 600
Kansas City, MO 64108
(816) 960-0090
ryan.hinderliter@
kutakrock.com

BARTHOLOMEW L. MCLEAY
Counsel of Record
DWYER ARCE
KUTAK ROCK LLP
The Omaha Building
1650 Farnam Street
Omaha, NE 68102
(402) 346-6000
bart.mcleay@
kutakrock.com
dwyer.arce@
kutakrock.com

Counsel for Petitioner

120455

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

QUESTION PRESENTED

This Court has made clear "in both civil and criminal cases, in the first instance and on appeal," it relies on the "parties to frame the issues for decision and assign to courts the role of neutral arbiter of matters the parties present." *Greenlaw v. United States*, 554 U.S. 237, 243 (2008).

It also has explained "litigation is a winnowing process, and the procedures for preserving or waiving issues [on appeal] are part of the machinery by which courts narrow what remains to be decided." *Exxon Shipping Co. v. Baker*, 554 U.S. 471, 487 n.6 (2008).

The question presented is:

> Whether a court of appeals may sua sponte revive an argument the government has impliedly waived on appeal and rely on the waived argument in ruling in the government's favor.

PARTIES TO THE PROCEEDINGS BELOW

Petitioner Matthew T. McLeay ("McLeay") is an individual.

Respondent is Coke Morgan Stewart, Acting Under Secretary of Commerce for Intellectual Property and Acting Director of the United States Patent and Trademark Office ("PTO").

RELATED PROCEEDINGS

In re McLeay, No. 2023-2338, 2025 WL 516809 (Fed. Cir. Feb. 18, 2025).

Ex Parte Matthew McLeay, No. APPEAL 2023-001665, 2023 WL 2596784, at *1 (P.T.A.B. Mar. 20, 2023).

TABLE OF CONTENTS

Table of Contents

Table of Contents

TABLE OF APPENDICES

TABLE OF CITED AUTHORITIES

Page

CASES:

Page

Page

Page

Page

Page

STATUTES AND OTHER AUTHORITIES:

Page

PETITION FOR A WRIT OF CERTIORARI

Petitioner respectfully petitions this Court for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The decision of the United States Court of Appeals for the Federal Circuit ("Federal Circuit") is reported at *In re McLeay*, No. 2023-2338, 2025 WL 516809 (Fed. Cir. Feb. 18, 2025). App. 1a. The decision of the United States Patent and Trademark Office, Patent Trial and Appeal Board ("Board") is reported at *Ex Parte Matthew McLeay*, No. APPEAL 2023-001665, 2023 WL 2596784, at *1 (P.T.A.B. Mar. 20, 2023) ("Board Decision"). App. 32a.

JURISDICTION

On February 18, 2025, the Federal Circuit affirmed the decision of the Board. App. 1. On March 25, 2025, the Federal Circuit denied panel rehearing. App. 50a. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

The relevant statutory provisions are those found at 35 U.S.C. § 112(a), providing:

> (a) In General.--The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to

> which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.

STATEMENT

For more than a half century the federal courts of appeals have been without a general principle to guide them in exercising their discretion regarding implied waiver. *See Exxon Shipping Co. v. Baker*, 554 U.S. 471, 487 (2008) ("We have previously stopped short of stating a general principle to contain appellate courts' discretion [in addressing issues raised for the first time on appeal] … and we exercise the same restraint today" (citing *Singleton* v. *Wulff*, 428 U.S. 106, 120 (1976))).

This unrestricted discretion has resulted in divergent rulings and differing standards for implied waiver in appellate practice under federal law, creating an identifiable 4-2-1 split in the federal courts of appeals.

This case involves a patent claim and invites the opportunity for the Court to revisit the patent bargain. It is of course a vital exchange designed to protect the public. But it also is important to protect the inventor. This is particularly true for the small inventor who comes forward to answer the call of the government during a global health crisis. This scenario arose for McLeay, the inventor in this appeal, shortly before the coronavirus pandemic exploded on the world scene. As the country braced for impact, McLeay and others were implored by the federal government to quickly identify simple and

adaptable medical solutions to meet the anticipated punch of COVID19. McLeay has been a solo medical practitioner, researcher, and inventor. He answered the call.

McLeay's invention was new and simple as the government ordered. It has two ingredients, one of which is water. The other is an FDA-approved drug, ribavirin. McLeay's invention converts the ribavirin and water into an aerosol mist and delivers the drug using a device known as a nebulizer. This general regimen of treating a patient with a nebulizer is commonplace in medicine and routinely applied by physicians, especially pulmonologists who are true experts in the use of nebulizers to treat lung disease.

McLeay's invention is unique because it repurposes ribavirin. While FDA-approved, ribavirin has a checkered history in producing side effects when delivered to a patient by pill or injection. McLeay made the surprising discovery that ribavirin delivered in aerosolized form would be effective in combatting coronavirus without the adverse side effects. Even more encouraging, aerosolized ribavirin delivers a far greater amount of ribavirin deep into the lung and successfully eradicates the disease where it is found. McLeay's invention is medically ideal for a pandemic because it can be administered outside overburdened hospital systems and is a welcome option for individuals seeking a vaccine alternative. There is no dispute McLeay's invention works.

The legal issues in this petition fit neatly into this history. The government admitted on appeal a "skilled artisan would have known how to deliver aerosolized ribavirin to a patient's lungs." PTO Fed. Cir. Brief at 12. The government also impliedly waived other issues on

appeal, appearing to save the parties time and expense in litigating them. One such issue involves the government foregoing a dispute on the "breadth of the claim" and by also not challenging the patent specification's "written description." McLeay's patent should be granted even if these matters were disputed, but the appeal was certainly streamlined with them removed. Or so McLeay thought.

Without warning or any indication, the Federal Circuit on its own resuscitated both "breadth of the claim" and "written description" arguments. It also ignored another instance in which implied waiver was shown based on the government's concession that skilled physicians would know how to deliver aerosolized ribavirin to a patient's lungs with a nebulizer and know also the medical device's limits. The Federal Circuit relied on these waived arguments in affirming the Board's Decision. The waived arguments became the winning arguments on appeal.

This Court should answer the question presented and resolve the 4-2-1 split in the courts of appeals. It also should identify an appropriate standard for implied waiver in appellate practice under federal law. At minimum, the rule should not allow a court of appeals to sua sponte revive an argument impliedly waived by the government that assures the government a court victory—as was done here.

The petition should be granted.

STATEMENT OF THE CASE

A. Implied Waiver Jurisprudence

1. No General Principle

Waiver consists of the "intentional relinquishment or abandonment of a known right or privilege." *Johnson v. Zerbst*, 304 U.S. 458, 464 (1938). "What suffices for waiver depends on the nature of the right at issue." *New York v. Hill*, 528 U.S. 110, 114 (2000)). "Whether a particular right is waivable … and whether the defendant's choice must be particularly informed or voluntary, all depend on the right at stake." *United States v. Olano*, 507 U.S. 725, 733 (1993).

"As a general proposition, the law can presume that an individual who, with a full understanding of his or her rights, acts in a manner inconsistent with their exercise has made a deliberate choice to relinquish the protection those rights afford." *Berghuis v. Thompkins*, 560 U.S., 370 (2010). Citing *Berghuis*, members of this Court have proposed a refined description of the "prototypical case" of "implied waiver," expressing it as "relevant course of conduct [that] signals an intention to relinquish the right at issue." *Hemphill v. New York*, 595 US 140, 157 (2022) (Alito, J., concurring).

This Court has observed "litigation is a winnowing process, and the procedures for preserving or waiving issues [on appeal] are part of the machinery by which courts narrow what remains to be decided." *Exxon Shipping Co. v. Baker*, 554 U.S. 471, 487 n.6 (2008) (internal citations omitted). But this Court has "stopped short of stating a general principle" on implied waiver

under federal law that would provide guidance in appellate proceedings. *Id.* at 488.

This is problematic. And it is unsurprising the void has been filled with different standards for determining implied waiver under federal law. This dichotomy has led to inconsistent results dependent solely on where a litigant is found. Only this Court has authority to resolve this issue. Respectfully, it should.

2. Principle of Party Presentation Is Not Uniformly Applied

This Court has explained a party's conduct constituting "waiver" is not the same as "forfeiture." *Hamer v. Neighborhood Hous. Servs. of Chi.*, 583 U.S. 17, 20 n.1 (2017). It is "'an abuse of discretion' ... for a court 'to override a … deliberate waiver.'" *Wood v. Milyard*, 566 U.S. 463, 472-73 (2012).

The difference between waiver and forfeiture continues to perplex lower courts and create uncertainty. *Compare United States v. Burke*, 504 U.S. 229, 246 (1992) (Scalia, J., concurring in the judgment) (it is "more than just a prudential rule of convenience"), *with Davis v. United States*, 512 U.S. 452, 464 (1994) (Scalia, J., concurring) ("refusal to consider arguments not raised is sound prudential practice").

Respectfully, this Court's jurisprudence on waiver and forfeiture has created some of the confusion. *See Greenlaw v. United States*, 554 U.S. 237, 243 (2008) ("[I]n both civil and criminal cases, in the first instance and on appeal, we follow the principle of party presentation");

Wood v. Milyard, 566 U.S. 463, 473 n.5 (2012) ("[W]e made clear in [*Day v. McDonough*, 547 U.S. 198, 202 (2006)] that a federal court has the authority to resurrect only forfeited defenses"); *United States v. Sineneng-Smith*, 590 U.S. 371, 376 (2020) (quoting *Day*, 547 U.S. at 202, for the proposition the "party presentation principle is supple, not ironclad …. [A] federal court ha[s] 'authority, on its own initiative,' to correct a party's … 'miscalculation' … absent 'intelligent waiver'").

This Court's decision almost a century ago in *Hormel v. Helvering*, 312 U.S. 552 (1941), also continues to cloud whether the judiciary can grant relief to the government based on a waived argument. *Id*. at 55657. *Hormel* concluded a court is empowered to act "as justice may require" when reviewing a waived argument following a federal board's decision, but it also found precedent does not allow the government to present a new issue under a statute after expressly waiving any reliance on the statute. *Id*. at 556-57.

Lower federal courts of appeals and commentators have criticized sua sponte decision-making by the judiciary and questioned a court's authority to do so. *Thomas v. Crosby*, 371 F.3d 782, 793 (11th Cir. 2004) ("The conditions under which a court may consider a nonjurisdictional matter *sua sponte* … have caused a great deal of confusion among jurists"). *Compare United States v. Dowdell*, 70 F.4th 134, 140 (3d Cir. 2023) ("[W]e cannot reach waived arguments"), *with United States v. Campbell*, 26 F.4th 860, 872 (11th Cir. 2022) (en banc) ("Waiver [means only that] … courts must respect that decision" of a litigant) (emphasis added). *See* Barry A. Miller, *Sua Sponte Appellate Rulings: When Courts*

Deprive Litigants of an Opportunity to Be Heard, 39 San Diego L. Rev. 1253, 1260 (2002) ("[T]he Supreme Court has never squarely decided whether due process prevents an appellate court from raising new issues without giving the parties a chance to be heard[.]").

A vigorous minority of the Eleventh Circuit *en banc* decision in *Campbell* exemplifies the strain created by the absence of a guiding standard and the angst building over the rise of "judicial issue creation" theory:

> Today's decision … contravenes foundational commitments of our adversarial system and its constituent party-presentation principle, obscures the critical distinction between the oft-confused concepts of "waiver" and "forfeiture," and fails to meaningfully limit the circumstances in which appellate courts can engage in what commentators have called "judicial issue creation."
>
> …
>
> The party-presentation principle serves dueprocess interests by ensuring that a party has advance notice and an opportunity to be heard before a court decides an issue that may sink his case.

United States v. Campbell, 26 F.4th 860, 893, 895 (11th Cir. 2022) (en banc) (Newsom and Jordan, JJ., dissenting).

B. Background – Patent Enablement

1. Governing Law

"The Congress shall have Power … To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8. "The authority of Congress is exercised in the hope that '[t]he productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens.'" *Diamond v. Chakrabarty*, 447 U.S. 303, 307 (1980) (internal citation omitted).

Section 112, paragraph 1 of Title 35 is the statutory section for patent enablement, and it includes discussion of written description: "The [patent] specification shall contain a written description of the invention, and ... enable any person skilled in the art to which it pertains ... to make and use the ... invention." 35 U.S.C. § 112(a). *Amgen Inc. v. Sanofi*, 598 U.S. 594, 615-16 (2023) ("There is one statutory enablement standard[.]").

A patent specification is not "necessarily inadequate just because it leaves the skilled artist to engage in some measure of adaptation or testing." *Id.* at 611. Nor is a patent invalid merely because the invention has inoperative embodiments in the range of the claim. *See also Hildreth v. Mastoras*, 257 U.S. 27, 34 (1921) ("The machine patented may be imperfect in its operation; but if it embodies the general principle and works ... it is

enough"); *see also United Therapeutics Corp. v. Liquidia Techs., Inc.*, 74 F.4th 1360, 1369-70 (Fed. Cir. 2023) ("[Plaintiff] asserts[ ] claims are not required to carve out all possible inoperative embodiments …. We agree with [Plaintiff] that the claims are adequately enabled[.]").[1]

In *Amgen* this Court unanimously explained that there is a stark difference between a patent holder making a claim over an entire class or category of matter (genus) versus making a "particular" or specific (species) invention. "If a patent claims an *entire class* of processes, machines, manufactures, or compositions of matter, the patent's specification must enable a person skilled in the art to make and use the *entire class*." 598 U.S. at 610 (emphasis added). While focused on the genus class in the antibodies case before it, this Court commented about the narrow species claim also present: "[W]e do not doubt that Amgen's specification enables the 26 exemplary antibodies." *Id.* at 612.

This Court in *Amgen* identified genus-species distinctions again and again, reminding lower courts an inventor is entitled to a patent for a narrow and specific invention even when the inventor may be denied a broader genus claim. *Id.* at 607 ("Morse's patent included eight claims, and this Court had no trouble upholding seven of them—those limited to the telegraphic structures and systems he had designed[.]" (citing *O'Reilly v. Morse*,

1. McLeay identified *United Therapeutics Corp.* to the Federal Circuit below as a "highly instructive" case, citing it in two briefs and during oral argument, but it was not discussed by the Federal Circuit Petitioner Fed. Cir. Opening Brief at 34, 43, 54-55; Petitioner Fed. Cir. Reply Brief at 4, 7,14-16, 18, 21; Fed. Cir. Reh'g Pet. at 12.

56 U.S. 62 (1853))); *id.* at 609 ("'[I]nstead of confining themselves to carbonized paper, as they might properly have done, and in fact did in their third claim, [Sawyer and Man] made a broad claim for every fibrous and textile material" (citing *Consol. Elec. Light Co. v. McKeesport Light Co.*, 159 U.S. 465 (1895))); *id.* at 610 ("Perkins was entitled to its patent on the specific starch glue it had invented…. But just as Morse could not claim all means of telegraphic communication, and Sawyer and Man could not claim all fibrous and textile materials for incandescence, Perkins could not claim all starch glues made from whatever starch happened to perform as well as animal glue[.]" (citing *Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245 (1928))).

2. "Breadth of the Claim" Arguments

For nearly four decades, the Federal Circuit has relied on what have been called the *Wands* factors, identified in its seminal case, *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988), for determining whether enablement is lacking based on "undue experimentation." *In re Wands*, 858 F.2d at 737. One of the *Wands* factors is "breadth of the claim." *Id.*

3. Written Description in Federal Circuit

"Since its inception, [the Federal Circuit] has consistently held that § 112, first paragraph, contains a written description requirement separate from enablement … [T]he test … is whether the disclosure … conveys ... the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en

banc); *Alcon Research Ltd. v. Barr Lab'ys, Inc.*, 745 F.3d 1180, 1191 (Fed. Cir. 2014) ("written description is about whether …what was claimed corresponds to what was described").

4. Waived and Forfeited Arguments

In the Federal Circuit, a court commits an "abuse of discretion" if it holds a "patent invalid on a ground never advanced by [the adverse party]." *Astellas Pharma, Inc. v. Sandoz Inc.*, 117 F.4th 1371, 1378 (Fed. Cir. 2024) (citation omitted). The *Wands* factors are illustrative, not mandatory, but the Federal Circuit has indicated it does not raise *Wands* factors on its own for the benefit of a party. *In re Starrett*, No. 20222209, 2023 WL 3881360, at *5 (Fed. Cir. June 8, 2023) (the court limits its review to specific *Wands* factors raised and does not go further on its own when the party itself "fails to address any of the other *Wands* factors").

C. Factual Background

1. In General

McLeay is a physician who has been active "in the private practice of Pulmonary/Critical Care Medicine" and is "triple boarded in Internal Medicine, Pulmonary, and Critical Care Medicine through the American Board of Internal Medicine." Fed. Cir. App. 942. McLeay has been an active "research investigator with expertise in new drug formulations and treatment modalities" directed toward "lung disease." Fed. Cir. App. 942. McLeay has "several granted patents and patent applications" and is the inventor in this case. Fed Cir. App. 942.

The invention is a pharmaceutical drug with only two ingredients, ribavirin and water, delivered in aerosolized liquid form. Fed. Cir. App. 26. The invention is used for treating patients suffering from SARSCoV2 (coronavirus) known to cause COVID19. Fed. Cir. App. 451.

Ribavirin is a wellknown and generally safe antiviral agent used for more than a halfcentury and formally approved by the Food and Drug Administration ("FDA") decades ago. Fed. Cir. App. 395, 955, 957. But there is reported history of "side effects associated with oral or intravenous ribavirin" use. Fed. Cir. App. 447449, 959. A narrow prior use of aerosolized ribavirin for a viral lung disease (RSV) shows it does not have the same negative record as oral and intravenous use. Fed. Cir. App. 447.

In January 2020, after becoming aware of requests by the federal government for help from medical drug inventors to identify potential drugs to resist the advancing coronavirus pandemic, McLeay postulated that aerosolized ribavirin would be effective in treating SARSCoV2. Fed. Cir. App. 446, 605, 955961.

At the time of his application, McLeay was aware SARSCoV2 contained an obstructive protein that he believed, without full information, his peers may have doubts about whether his invention would be effective. Fed. Cir. App. 448. McLeay included negative history in his application on this basis but also, most importantly, McLeay stated in the specification his proposed use of aerosolized ribavirin for SARSCoV2 is a "surprising discovery" allowing for "deep" deposit of the drug "into the lower airways" (and thus effectively neutralizing or overwhelming the obstructive protein). Fed. Cir. App.

446450, 605, 957-58. McLeay was later proven right in his conclusion. Fed. Cir. App. 962.

McLeay's invention is a species claim (not a genus claim) and is narrowly described in his application in pertinent part: "A method of treating a SARSCoV2 lung infection … by … a liquid aerosol … comprising >50% (w/w) [51 percent or more of] water and <50% (w/w) [49 percent or less of] ribavirin, … delivered … with a nebulizer." Fed. Cir. App. 3 (McLeay's claim is referred to as claim 20).

The Specification includes a background section stating: "The COVID19 pandemic has created an urgent need for rapid and easy to administer therapies, … [and McLeay] has made the surprising discovery that [ribavirin aerosol is] effective in treating COVID19 …." Fed. Cir. App. 446.

On July 23, 2021, outside researchers (Messina) published a study showing successful results for "COVID19 [patients who] … received treatment with … ribavirin aerosol" and the researchers credited a reference in prior article co-authored by McLeay for identifying the proper dosage, formulation, and administration and the researchers ultimately selected a 10 percent formulation recommended in the prior art reference. Fed. Cir. App. 945, 957, 958, 964, 972, 975 n.18.

The prior art research co-authored by McLeay also showed a range of three dosages (2%, 6% and 10%) within the range limit "up to 49.9%" as successful in delivering the same amount of ribavirin drug deep into the "lower airways" of a patient on a nebulizer. Fed. Cir. App. 957-58.

2. Examiner's Action and Board Decision

On February 9, 2022, the Examiner issued a final Office Action rejecting claim 20 in McLeay's application. Fed. Cir. App. 40. The Examiner stated in summary fashion, among other things, "Breadth of claim limitation … was not fully enabled by the disclosure." Fed. Cir. App. 41. McLeay appealed under 35 U.S.C. § 141(a).

On March 22, 2023, the Board entered the Board Decision affirming the "Examiner's conclusion that undue experimentation would be required to practice the claimed invention … [and] rejection of claim 20 under the enablement provision of 35 U.S.C. § 112(a) is affirmed." Fed. Cir. App. 38. The Board generally "adopt[e]d" the *Wands* factors found by the Examiner but, unlike the Examiner, it did not identify "breadth of the claim" as a specific ground. Fed. Cir. App. 27. The Board also separately acknowledged the sufficiency of written description in McLeay's specification, while vaguely commenting on its "enabling description:" "We find … that although … portions of Appellant's Specification may provide written descriptive support for … claim 20, they do not provide an enabling description of the claimed subject matter for the reasons set forth by Examiner." Fed. Cir. App. 32. McLeay appealed to the Federal Circuit as authorized by 35 U.S.C. § 134.

D. PTO Concessions on Appeal

1. Breadth of Claim and Description Waived

On appeal, McLeay set forth and addressed all *Wands* factors, including "breadth of the claim," observing

the Examiner "essentially skipped" the latter factor when evaluating enablement of his invention for undue experimentation. McLeay Fed. Cir. Brief at 39. McLeay also referred to the absence of any "deficiency in the written description" and noted the Board acknowledged the "'Specification may provide written descriptive support for … claim 20.'" McLeay Fed. Cir. Brief at 42 n.26.

In its opposition brief, PTO identified a few *Wands* factors, but it conspicuously excluded "breadth of the claim" as a factor providing support for the Board's Decision. PTO Fed. Cir. Brief at 12-14. PTO also effectively agreed "written description" in McLeay's specification is not a subject of the appeal, stating: "McLeay's written-description argument is irrelevant for the enablement rejection here." PTO Brief at 20 n.6, citing McLeay's Brief at 56-57 (referring to an "adequately described" example).

Regarding whether a satisfactory "enabling description" of McLeay's invention exists, PTO made a further substantial concession in the appeal by admitting "it is undisputed … a skilled artisan would have known how to deliver aerosolized ribavirin to a patient's lungs." PTO Fed. Cir. Brief at 12.

In reply, McLeay pointed out PTO's "how-to" admission on enablement and that "PTO quotes … *Wands* factors," but excludes the "breadth of the claim" factor in support of undue experimentation. McLeay Fed. Cir. Reply Brief at 19, 21. McLeay further noted PTO's argument presented "a disguised written description deficiency, not an enablement shortfall," adding that any suggested sua sponte action by the court would be "antithetical to the

well-worn 'principle of party presentation.'" Petitioner Fed. Cir. Reply Brief at 7.

2. *Holland Furniture* Precedent

McLeay argued multiple times on appeal *Holland Furniture* is a controlling precedent for this case, explaining "*Amgen* … reaffirms, the patentability of the inventor's simple patent in *Holland Furniture*, which comprised only two ingredients, one of which is 'three parts or less' of water," closely analogous to McLeay's invention. Petitioner Fed. Cir. Brief at 51; Petitioner Fed. Cir. Reply Brief at 9.

E. Federal Circuit Opinion

The Federal Circuit affirmed the Board's Decision for lack of enablement based on an alleged need for undue experimentation. App. 8a. The primary invalidating ground according to the Federal Circuit is the overreaching "breadth of the claim." App. 2a (finding specification "does not enable the full scope of the claims"); App. 4a (finding "scope of the claim is not "useful or operative""); App. 7a ("claim 20's fatal flaw … is [there is] substantial evidence … that practicing the full scope of the claimed range would require undue experimentation").

The Federal Circuit specifically declared "breadth of the claim" to be "[p]articularly relevant" for its decision: "Particularly relevant here, the Examiner found that the breadth of the claims was not fully enabled by the Application because there is insufficient disclosure of the claimed composition." App. 2a. As noted, however, unlike other *Wands* factors it identified on appeal, PTO did not

include "breadth of the claim" as a basis for affirming the Board's Decision. Petitioner Fed. Cir. Reply Brief at 19, 21.

The Federal Circuit flatly rejected PTO's use of an "efficacy" argument in an enablement analysis but then puzzlingly concluded: "McLeay has failed … the how-to-use aspect of the enablement requirement because … the full scope of the claim is not "useful or operative."" App. 7a. In reaching this conclusion, the Federal Circuit also did not acknowledge McLeay's claim 20 is operable only with use of a "nebulizer" to deliver aerosolized ribavirin to a patient. App. 2a. The Federal Circuit likewise ignored PTO's admission "it is undisputed … a skilled artisan would have known how to deliver aerosolized ribavirin to a patient's lungs." PTO Fed. Cir. Brief at 12.

The Federal Circuit further identified alleged failures in written description to support its decision. App. 6a (noting "up-to-50% range of ribavirin recited by claim 20"); App. 7a (finding "Application does not disclose that the full range recited in claim 20 is effective"). The Federal Circuit omitted mention, however, that PTO impliedly, if not expressly, waived written description on appeal. PTO Fed. Cir. Brief at 20 n.6.

The Federal Circuit without specificity rejected McLeay's arguments related to implied waiver and the application of *Holland Furniture*, concluding: "We have considered McLeay's remaining arguments but find them unpersuasive." App. 8a.

F. Petition for Rehearing

On March 3, 2025, McLeay filed a petition for panel rehearing. Reh'g Pet. at 1 n.2. McLeay argued PTO's

inclusion of certain *Wands* factors in support of its position, while deliberately excluding "breadth of the claim," should have caused the Federal Circuit to conclude PTO's argument about not enabling the "full scope of the claimed range" was waived. Reh'g Pet. at 8. McLeay also argued the Federal Circuit improperly revived "written description" arguments waived by PTO. Reh'g Pet. at 2.

McLeay asked the Federal Circuit to reconsider his argument based on his species claim and find he is "entitled to the protection of a patent" for a range of 10% to 49% in the same way as the composition in *Holland Furniture* allowed a patent based on "three parts of water or less" and one part "starch" (mathematically a greater range of 25% to 99%). Reh'g Pet. at 1-2.

REASONS FOR GRANTING THE WRIT

This petition presents the single question of whether a court of appeals may sua sponte revive an argument the government has impliedly waived on appeal and rely on the waived argument in ruling in the government's favor. The lower federal courts of appeals have known they have been without guidance on implied waiver in appellate practice under federal law for a half century, since *Singleton v. Wulff*, 428 U.S. 106, 120 (1976).[2]

Several federal courts of appeals, applying this Court's decision in *Exxon Shipping*, do recognize an appellate-briefing waiver is part of a "winnowing process"

2. *United States v. Dowdell*, 70 F.4th 134, 142 (3d Cir. 2023) ("The Supreme Court has … explicitly declined to articulate any general rule regarding waiver.").

on appeal[3] but some also believe they have "discretion" to sua sponte "consider" waived arguments.[4]

This Court's decision not to provide a general principle on implied waiver in the past half century has resulted in disparate decisions in the lower federal courts of appeals, including the Federal Circuit below in a separate case, dividing the courts into a 4-2-1 split. This Court should resolve the question presented and answer the question in the negative.

A. There Is a Circuit Split 4-2-1

1. Three Separate Rules

The First Circuit[5] and Ninth Circuit[6] describe the test for implied waiver as requiring a "showing of purpose"

---

3. *Muhler Co. v. State Farm Fire & Cas. Co.*, No. 20-1800, 2022 WL 327005, at *2 (4th Cir. Feb. 3, 2022) ("litigation is a winnowing process"); *In re Syngenta AG MIR 162 Corn Litig.,* 111 F.4th 1095, 1112 (10th Cir. 2024) ("appellate-briefing waiver is part of the 'winnowing process'").

4. *Sniado v. Bank Austria AG*, 378 F.3d 210, 213 (2d Cir. 2004) ("we have discretion to consider waived arguments"); *Freeman v. Pittsburgh Glass Works, LLC*, 709 F.3d 240, 249 (3d Cir. 2013) ("it is within our discretion to … consider a waived issue…."); *Brown v. Nucor Corp.*, 785 F.3d 895, 920 (4th Cir. 2015) ("if a 'miscarriage of justice would otherwise result'") (cleaned up); *see also Bechtold v. City of Rosemont*, 104 F.3d 1062, 1068 (8th Cir. 1997) ("court may exercise its discretion").

5. *Jardines Bacata, Ltd. v. Diaz-Marquez*, 878 F.2d 1555, 1559 (1st Cir. 1989) ("To prove a case of implied waiver of a legal right, ... there must be a clear, unequivocal and decisive act of … showing a purpose to abandon or waive the legal right....").

6. *Arizona v. Tohono O'odham Nation*, 818 F.3d 549, 559 (9th Cir. 2016) ("clear, decisive and unequivocal conduct which indicates a purpose to waive the legal rights involved").

to "waive the legal right" with "clear, decisive and unequivocal" conduct. The other two courts in the four court majority, the Second Circuit[7] and Third Circuit,[8] require the same purpose-based showing for implied waiver, but they articulate the standard using slightly different words, stating, for example, the proof requires "clear and unequivocal" conduct showing the parties who waive are "aware of their rights and [have] made the conscious choice … to waive them" anyway (hereinafter, "purpose" test).[9]

In the second group are the Third Circuit[10] and Federal Circuit,[11] which instead require proof of conduct

---

7. *NLRB v. New York Tel. Co.*, 930 F.2d 1009, 1011 (2d Cir. 1991) ("parties were aware of their rights and made the conscious choice …to waive them"); *Mooney v. City of New York*, 219 F.3d 123, 131 (2d Cir. 2000) ("[T]he conduct … must be clear and unequivocal ….").

8. *In re Wedgewood Realty Grp.*, 878 F.2d 693, 699 (3d Cir. 1989) ("[the party's] 'own actions were clearly inconsistent with an intention on his part to insist on his rights'"); *Daye v. Pennsylvania*, 483 F.2d 294, 298 (3d Cir. 1973) ("must be clear and unequivocal").

9. *NLRB*, 930 F.2d at 1011.

10. *In re Wedgewood Realty Grp.*, 878 F.2d 693, 699 (3d Cir. 1989) ("[the party's] 'own actions were clearly inconsistent with an intention on his part to insist on his rights").

11. *Core Wireless Licensing SARL v. Apple Inc.*, 899 F.3d 1356, 1365 (Fed. Cir. 2018) ("patentee's conduct was so inconsistent with an intent to enforce its rights as to induce a reasonable belief that such right has been relinquished" (internal quotation marks omitted)).

"inconsistent with an intent to enforce [the] rights" (hereinafter, "inconsistent acts" test).[12]

Finally, and most closely aligned with this Court's prior decisions on implied waiver, the Sixth Circuit,[13] citing recent observations from this Court's decision in *Hemphill*, states implied waiver under federal law is established merely by showing "the relevant course of conduct *signals* an intention to relinquish the right at issue," with the court strongly emphasizing such conduct need not be "explicit"[14] (hereinafter, the "signals" test) (emphasis added).

Other courts of appeals have discussed implied waiver under federal law in conclusory fashion, but those cases cannot be categorized into the 4-2-1 split. For example, the Eleventh Circuit, beyond *Campbell* (already discussed), has stated in vague terms that implied waiver under federal law exists when "acts, conduct, or circumstances … make out a clear case."[15] The Tenth Circuit, with even less clarity, states implied waiver under federal law is based on both "action or inaction."[16]

---

12. *Id.*

13. *Walker v. United States*, 134 F.4th 437 (6th Cir. 2025).

14. *Walker*, 134 F.4th at 440-41 ("there is one important thing [waiver] need not be: explicit").

15. *Griffin v. Coca-Cola Refreshments USA, Inc.*, 989 F.3d 923, 935 (11th Cir. 2021) ("'the acts, conduct, or circumstances relied upon to show waiver must make out a clear case'" of intentional relinquishment).

16. *Vreeland v. Zupan*, 906 F.3d 866, 876 (10th Cir. 2018) ("waiver of a particular right via some other action or inaction").

2. The Three Rules Reach Three Different Results Under the Same Basic Facts

Application of the three rules identified in the 4-2-1 split discussed here bring about three different results when analyzed under the same basic facts. Review of the Sixth Circuit decision in *Walker* provides a good starting point for demonstrating the differences.

In *Walker*, defendant (Walker) delivered a letter to the court asking for additional time to seek habeas relief based on an approaching statutory deadline. 134 F.4th at 439. The government responded to the letter stating Walker's request should be denied because Walker's "claim was meritless anyway." *Id.* at 445. The government did not mention a statute of limitations defense at the time. *Id.* Walker later filed for relief out of time and the district court concluded his request was time-barred. *Id*. On appeal, Walker argued the government's conduct demonstrated it waived the defense. *Id.* The Sixth Circuit agreed with Walker and reversed. Quoting the "signals" test from *Hemphill*, which it also correlated to language in its own precedent ("There are no 'magic words' required for showing intent to waive"), the Sixth Circuit held:

> Looking objectively at the record, these facts show that the government understood the timeline for Walker's motion and knew not only that timeliness was at issue in this case, but specifically that it could make a viable statute of limitations argument. Yet the government chose not to pursue it.

Id. at 446.

The Sixth Circuit also found it could theorize the government's motivation for waiver under its signals test: "We can discern strategic reasons why the government might have chosen this course of action" to be to "avoid responding to the potentially thorny question of [procedure at issue]." *Id.*

This result in *Walker* applying the "signals" test would not have occurred under either of the "inconsistent acts" test or the "purpose" test for implied waiver identified by the other courts of appeals in the 4-2-1 split.

The Third Circuit in *Wedgewood* applied the "inconsistent acts" test. *In re Wedgewood Realty Grp., Ltd.*, 878 F.2d 693, 698 (3d Cir. 1989). In *Wedgewood*, after a debtor filed a bankruptcy petition, a secured creditor (WIF) filed a motion seeking relief from the automatic stay and later delivered two letters to the bankruptcy court, the latter which the debtor argued impliedly waived WIF's right to raise "timeliness objections" regarding the automatic stay. *Id.* The Third Circuit agreed with WIF, stating: "[I]mplied waiver is generally not found unless the creditor takes some action which is inherently *inconsistent* with adherence to the time constraints." *Id.* (emphasis added). The Third Circuit then held: "Here, WIF's actions were not inconsistent with … the time limitations." *Id.* at 699.

The "purpose test" used in the Ninth Circuit and three other courts in its group require more for implied waiver than the Sixth Circuit. In *Arizona v. Tohono O'odham Nation*, 818 F.3d 549 (9th Cir. 2016), the state of Arizona and others (plaintiffs) were involved in a gaming compact with an Indian tribe (the "Nation"). *Id.* Plaintiffs later brought a lawsuit against the Nation seeking to enjoin its

plan to conduct gaming on a certain parcel of property. *Id.* A meeting took place in which the Nation's representatives were present, and a handout was distributed indicating, according to plaintiffs, the Nation had waived its right to conduct gaming as planned. *Id.*

The district court found plaintiffs' evidence "did not bar the Nation from gaming" and the Nation also did not waive its right because its representatives were present when a "handout" favoring plaintiffs' position was distributed. *Id.* at 555, 558. The Ninth Circuit, applying its "purpose" test for implied waiver affirmed the district court's ruling, stating:

> An implied waiver of rights will be found where there is "clear, decisive and unequivocal" conduct which indicates a purpose to waive the legal rights involved.…
>
> There is nothing in the record that shows that representatives of the Nation either drafted or distributed the handout or were primary speakers at this meeting.

Id. at 559-60 (cleaned up).

Unlike the Sixth Circuit, where these facts expectedly would be viewed as signals of implied waiver, they were found to be insufficient in the Ninth Circuit under the "purpose" test for implied waiver.

These three examples alone show the circuit split is real, and consequential to litigants. The question presented should be decided by this Court.

B. Other Legal Authorities on Waived Rights on Appeal

Legal scholars and commentators have long criticized the uncertainty associated with sua sponte relief given by courts for waived arguments on appeal, observing it is "notoriously confused, abstruse, and disjointed—indeed, scholars have been consistently despairing in their assessments"[17] of this judicial state of affairs.[18] Based on the arbitrary nature and unchecked power given to lower courts in this circumstance, scholars have less-than-affectionately referred to this paradigm as the "gorilla rule."[19]

As previously noted, some jurists and commentators also disapprovingly refer to this approach as "judicial issue creation" theory,[20] while others give the methodology praise and approval.[21]

---

17. John F. Muller, *The Law of Issues*, 49 Wake Forest L. Rev. 1325, 1372 (2014) ("This state of affairs affords appellate courts broad leeway to decide, beyond public view, when they wish to consider variations on the arguments made below[.]").

18. Jeffrey M. Anderson, *Right for Any Reason*, 44 Cardozo L. Rev. 1015, 1050 (Feb. 2023).

19. Robert J. Martineau, *Considering New Issues on Appeal: The General Rule and the Gorilla Rule*, 40 Vanderbilt L. Rev. 1023 (1987).

20. *United States v. Campbell*, 26 F.4th 860, 895 (11th Cir. 2022) (Newsom and Jordan, JJ., dissenting) (rejecting "judicial issue creation" theory).

21. Barry A. Miller, *Sua Sponte Appellate Rulings: When Courts Deprive Litigants of an Opportunity to be Heard*, 39 San Diego L. Rev. 1253, 1259 (2002) (citing authorities).

In any event, there is an identifiable divide in the courts of appeals on the general principle to be applied in circumstances in which implied waiver under federal law is considered. This chasm is unsurprising since, for the past half century, and reaffirmed again a few decades ago, the outcome has been by this Court's design.[22]

The federal court of appeals have applied the foregoing three different rules for years. Without a general principle from this Court evaluating implied waiver under federal law for appellate practice, the Federal Circuit was bound to apply its own, respectfully, mistaken, "inconsistent acts" rule. This is the wrong test to be applied, especially given the benefit to litigants of having rules that encourage reduction of the issues to be tried.[23]

C. The Federal Circuit's Decision Is Wrong

1. Waived Arguments Should Not Be Revived

The Federal Circuit affirmed the Board's Decision for lack of enablement applying the *Wands* factors to determine whether undue experimentation would be required. App. 34a. The Federal Circuit declared the

22. *Exxon Shipping Co. v. Baker*, 554 U.S. 471, 487 (2008) (reaffirming *Singleton*).

23. The signals rule is not intended to address every situation. For example, implied waiver discussed here is not intended to apply to waiver of impartiality of a judge or tribunal. *See, e.g.*, *Liljeberg v. Health Servs. Acquisition Corp.*, 486 U.S. 847, 859 n.8 (1988) ("455(b)(4) requires disqualification no matter how insubstantial the financial interest"); *Parker v. Connors Steel Co.*, 855 F.2d 1510, 1527 n.18 (11th Cir. 1988) ("Grounds for disqualification under § 455(b) cannot be waived by the parties.").

"breadth of the claim" factor to be "particularly relevant" to its decision. App. 2a. Respectfully, the Federal Circuit's opinion is flawed because the "breadth of the claim" argument was waived by PTO. Petitioner Fed. Cir. Reply Brief at 19, 21.

The same is true for the Federal Circuit's conclusion that "McLeay has failed … the how-to-use aspect of the enablement requirement because … the full scope of the claim is not 'useful or operative.'" App. 7a. As an initial matter, the Federal Circuit itself shredded PTO's howto-use argument for applying "efficacy" arguments in an "enablement inquiry." App. 8a. After doing so, however, the Federal Circuit failed to recognize that any remaining filament of PTO's how-to-use claim disappeared with PTO's admissions on appeal—amounting to waiver—that "it is undisputed … a skilled artisan would have known how to deliver aerosolized ribavirin to a patient's lungs" and would have performed the task with a "nebulizer." PTO Fed. Cir. Brief at 4, 12.

Finally, the Federal Circuit transformed certain alleged failures in written description in McLeay's specification into alleged enablement deficiencies. PTO Brief at 20 n.6; *see, e.g.*, App. 6a ("up-to-50% range of ribavirin recited by claim 20"); App. 7a ("Application does not disclose that the full range recited in claim 20 is effective[.]"). The Federal Circuit erred in doing so.

Judges on the Federal Circuit have indicated there should not be any "importation" of enablement requirements into "written description" requirements and vice versa. *See Biogen Int'l GmbH v. Mylan Pharms. Inc.*, 28 F.4th 1194, 1200 (Fed. Cir. 2022) (Lourie, J.,

dissenting) ("The … point of error is the … importation of extraneous legal considerations into the written description analysis.").

A failure to fully describe a range consistent with what is claimed is a written description failure, not an enablement deficiency, under Federal Circuit precedent. *Indivior UK Ltd. v. Dr. Reddy's Lab'ys S.A.*, 18 F.4th 1323, 1329 (Fed. Cir. 2021) ("[T]here is no written description support for the range of 'about 48.2 wt % to about 58.6 wt %'"); *RAI Strategic Holdings, Inc. v. Philip Morris Prods. S.A.*, 92 F.4th 1085, 1088 (Fed. Cir. 2024) (citing cases) (in "'determining whether the written description requirement is met, …[a] broader range does not describe the narrower range"); *Gen. Hosp. Corp. v. Sienna Biopharms., Inc.*, 888 F.3d 1368, 1372 (Fed. Cir. 2018) ("The disclosure of a broad range of values does not by itself provide written description support for a particular value within that range.").

PTO's conduct shows it more than signaled an intent to relinquish its right to raise written description on appeal when it stated: "[Any] written-description argument is irrelevant for the enablement rejection here." PTO Fed. Cir. Brief at 20 n.6. The Federal Circuit also erred in resuscitating the waived written description argument sub silentio and using it to conclude there is substantial evidence to affirm the Board's Decision of undue experimentation. [24]

24. McLeay does agree with PTO there is written description support for McLeay's invention. (PTO Brief at 20 n.6). Any inoperability in the claimed range due to required use of a nebulizer would be known to pulmonologists and thus have no bearing on enablement. *Hildreth v. Mastoras*, 257 U.S. 27, 34, (1921); *United*

2. Federal Circuit Ignored Binding Precedent in Reaching Its Decision

Although reminded multiple times during the appeal, the Federal Circuit did not consider binding precedent from this Court in *Holland Furniture*, which, again, was reaffirmed in *Amgen*, a decision alone that can resolve this case.[25] McLeay respectfully submits, upon remand, once the waived arguments are properly excised from the analysis, the Federal Circuit will be in a position again to apply this Court's precedent in *Holland Furniture*.

McLeay pressed consideration of *Holland Furniture* in part because the Federal Circuit concluded the "fatal flaw ... is … practicing the full scope of the claimed range" (a gap between 10% and 49%) of a ribavirin-water combination. App. 8a. *Holland Furniture* is closely analogous if not on point with this case. Reh'g Pet. at 10.

In *Holland Furniture*, plaintiff (Perkins) filed an action seeking to enjoin defendant (Holland) from infringing a patented invention for "starch glue" used for wood veneering. 277 U.S. at 247. Perkins' "patent disclose[d]" disparaging remarks showing use of "ordinary starch" with water is "unsuitable" for making "starch glue." *Id.* at 256, 254. This Court observed "Perkins' real invention ... was ... use of a particular kind of starch as an ingredient" in combination with "three parts or less of water," which

---

Therapeutics Corp. v. Liquidia Techs., Inc., 74 F.4th 1360, 1369 (Fed. Cir. 2023) ("inoperative embodiments" known to "skilled artisan" does not affect enablement).

25. *See* Petitioner Fed. Cir. Opening Brief at 51; Petitioner Fed. Cir. Reply Brief at 8-9; App. 5a; Reh'g Pet. at 10-12.

mathematically identifies a claimed range of 25% to 99% for the starchwater combination. *Id.* at 249, 255. *See also* Reh'g Pet. at 10 & n.6). *Holland Furniture* found Perkins was "entitled to the protection of a patent" as described. *Holland Furniture Co.*, 277 U.S. at 255.

As McLeay explained to the Federal Circuit, when this Court in *Amgen* discussed *Holland Furniture*, it was mostly focused on the "genus" claim, describing it as distinguishable from a species claim, and it also noted Perkins, the inventor in *Holland Furniture*, was denied a patent of a genus claim because it went "beyond the specific starch glue" involved and so would require "elaborate experimentation." *Amgen*, 598 U.S. at 609-10. Reh'g Pet. at 11.

Like the remarks in *Holland Furniture* about "ordinary starch" being "unsuitable" for a starch glue as "disclose[d]" in Perkins' patent, McLeay includes remarks about oral and intravenous use of ribavirin in his specification. Fed. Cir. App. 957. Also, like recognition given in *Holland Furniture* that "Perkins' real invention" was use of a new "particular kind of starch," the specification explains McLeay made a "discovery" about using ribavirin in a very particular way, namely, having it directly "delivered to the lungs" in aerosol form using a nebulizer. Fed. Cir. App. 449-450. Like Perkins in *Holland Furniture*, McLeay's invention, as acknowledged by the Federal Circuit, has been proven to work. Fed. Cir. App. 973.

The most significant commonality of McLeay's invention with *Holland Furniture* relates to the so-called "fatal flaw." App. 8a. The Federal Circuit defines the

fatal flaw as an alleged gap between "10% [and] as high as 49.99%," in the claimed range of the ribavirin-water combination. App. 7a. This gap is less than the claimed range in the starch-water combination approved in *Holland Furniture* of "three parts or less of water" and "one" part starch (mathematically calculated to be a range of 25% to 99% starch). The Federal Circuit did not discuss *Holland Furniture* despite multiple requests to do so.

D. The Question Presented Is Important and the Petition Is the Right Vehicle for Deciding It

This case is a strong vehicle for this Court to address the important question presented in this petition on implied waiver in appellate proceedings. Lower federal courts of appeals have been without even a general principle for a half century and three identifiable rules have emerged in a 4-2-1 circuit split. There is no reasonable basis after this many decades and the divergent opinions involved that this Court should await further percolation of the issue.

The petition allows this Court to narrowly and definitively set forth a general principle to guide the federal courts of appeals on the application of implied waiver under federal law. This uniformity will bring about fairness to litigants who must now accept different rules of practice based on where they are located.

This petition is presented in the factual context of an individual inventor who answered the government's call for assistance and then relied on its response in court to make decisions regarding the litigation. Sua sponte action by courts, especially in favor of the government in this circumstance, is not only inherently unfair, but financially

impactful to parties because they move the goalposts and undermine the "winnowing process" described by this Court.

This petition provides an opportunity for this Court to give relief to such litigants, but it also allows the Court to give clarity and guidance on appellate practices for government agencies, corporations, and individuals alike. This also concerns a subject matter of appellate procedure for which this Court alone is the preeminent expert.

E. The Issue Is Squarely Presented

The Federal Circuit's decision squarely presents the important question here related to implied waiver in the federal courts of appeals for appellate practice.

This is a clean and manageable case. The truly operative facts are few and largely undisputed and the precise issue to be decided by this Court is narrow and procedural in nature. Unlike large cases with expansive and daunting trial and appellate records, this case will arrive at this Court with a thin record and an easily manageable docket.

This Court's specific disposition of this case also is expected to be narrow and straightforward. Specifically, if the petition is granted, McLeay will ask this Court to adopt the "signals" rule described herein as the proper test for determining implied waiver for appellate practice under federal law. Once this Court selects the proper rule, the only additional expected action is for the Court to remand the case to the Federal Circuit with instructions to determine whether implied waiver is established under the

new rule and to enter a judgment without giving weight to the waived arguments previously considered.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

Ryan S. Hinderliter
Kutak Rock LLP
2405 Grand Boulevard,
Suite 600
Kansas City, MO 64108
(816) 960-0090
ryan.hinderliter@
kutakrock.com

Bartholomew L. McLeay
Counsel of Record
Dwyer Arce
Kutak Rock LLP
The Omaha Building
1650 Farnam Street
Omaha, NE 68102
(402) 346-6000
bart.mcleay@
kutakrock.com
dwyer.arce@
kutakrock.com

Counsel for Petitioner

APPENDIX

TABLE OF APPENDICES

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT, FILED FEBRUARY 18, 2025

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2023-2338

IN RE: MATTHEW MCLEAY,

Appellant

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. 17/231,735

Decided: February 18, 2025

Before MOORE, *Chief Judge*, STOLL, *Circuit Judge*, and GILSTRAP, *Chief District Judge*.[1]

GILSTRAP, *Chief District Judge*.

Matthew McLeay appeals from a decision of the United States Patent Trial and Appeal Board (the "Board"). The Board affirmed an Examiner's rejection of claims 20-24 of U.S. Patent Application No. 17/231,735 (the "Application") as unpatentable for lack of enablement under 35 U.S.C. § 112(a). For the reasons provided below, we affirm.

1. Honorable Rodney Gilstrap, Chief Judge, United States District Court for the Eastern District of Texas, sitting by designation.

Appendix A

BACKGROUND

On April 15, 2021, McLeay filed the Application. The Application discloses using ribavirin, amongst other medications, for the treatment of certain respiratory conditions. The Application included 20 method of treatment claims, including three independent claims. Appx83-85. McLeay amended claim 20, which as amended recites the following:

> 20. A method of treating a SARS-CoV-2 lung infection in a patient in need thereof comprising administering to a lung of said patient by inhalation a liquid aerosol composition comprising >50% (w/w) water and <50% (w/w) ribavirin, wherein said liquid aerosol is delivered to the lung with a nebulizer.

Appx3 (alteration removed).[2] Claims 21-24 each depend from claim 20.

During prosecution, the Examiner issued a Final Office Action that rejected claims 20-24 for lack of enablement. Particularly relevant here, the Examiner found that the breadth of the claims was not fully enabled by the Application because there is insufficient disclosure of the claimed composition. Appx988. Further, the Examiner found that the Application admits "that the use of ribavirin in treating COVID-19 is not expected to be successful by

2. All limitations of claim 20 were disclosed in the Application as-filed. *See* Appx84-85.

skilled pulmonologists and infectious disease specialists." Appx989. In view of this finding, the Examiner found that "[o]ne skilled in the art cannot readily anticipate the effect of administering to the lung infected with SARS-CoV-2 an aerosolized liquid comprising >50% water and <50% ribavirin, and thus there is lack of predictability in the art." Appx990. The Examiner also found that the Application fails to disclose whether the claimed compound is effective in treating a SARS-CoV-2 lung infection in a patient. Appx990-91. Finally, the Examiner found that the quantity of experimentation needed to make or use the claimed invention "would be significant." Appx991.

In the Final Office Action, the Examiner also rejected McLeay's argument that the prior art reference Gilbert and McLeay[3] discloses how to make, use, and administer the claimed composition. The Examiner found that Gilbert and McLeay "teaches treatment of influenza A virus infections using MegaRibavirin aerosol, and the treatment of influenza A is not indicative of its effectiveness against SARS-CoV-2 lung infection." Appx993. McLeay also argued that Messina,[4] a post-filing date reference, established that the administration "of aerosolized ribavirin according to the subject patent application as disclosed in the written description has been

3. Brian E. Gilbert and Matthew T. McLeay, *MegaRibavirin Aerosol for the Treatment of Influenza A Virus Infections in Mice*, 78 Antiviral Res. 223-29 (2008) (Appx955-61).

4. Messina et al., *Ribavirin Aerosol in the Treatment of SARS-CoV-2: A Case Series*, 10 Infect. Dis. Ther. 2791-804 (2021) (Appx962-75).

demonstrated to be efficacious in the treatment of [five] patients with COVID-19." Appx945. The Examiner found this argument unpersuasive since Messina does not enable the full scope of the claims (*i.e.*, a composition comprising less than 50% ribavirin). Appx56-57.

McLeay appealed the Examiner's decision to the Board. The Board found "that a preponderance of the evidence supports Examiner's analysis of the *Wands* factors and adopt[ed] them as" their own. Appx27. The Board further denied McLeay's rehearing request and did not modify its decision. Appx2.

McLeay timely appeals to this court. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

"Whether a claim satisfies the enablement requirement is a question of law that may be based on underlying factual findings." *Medytox, Inc. v. Galderma S.A.*, 71 F.4th 990, 996 (Fed. Cir. 2023) (citing *Alcon Rsch. Ltd. v. Barr Lab'ys, Inc.*, 745 F.3d 1180, 1188, 1190 (Fed. Cir. 2014)). We review the Board's legal conclusions de novo and its factual findings for substantial evidence. *In re Kotzab*, 217 F.3d 1365, 1369 (Fed. Cir. 2000). "If the evidence in record will support several reasonable but contradictory conclusions, we will not find the Board's decision unsupported by substantial evidence simply because the Board chose one conclusion over another plausible alternative." *In re Jolley*, 308 F.3d 1317, 1320 (Fed. Cir. 2002).

Appendix A

Section 112(a) provides in relevant part that

> [t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.

35 U.S.C. § 112(a). "The specification must enable the full scope of the invention as defined by its claims, allowing for a reasonable amount of experimentation." *Baxalta Inc. v. Genentech, Inc.*, 81 F.4th 1362, 1364-65 (Fed. Cir. 2023) (quoting *Amgen Inc. v. Sanofi*, 598 U.S. 594, 610-12, 143 S. Ct. 1243, 215 L. Ed. 2d 537 (2023)) (cleaned up).

I

McLeay argues the Board erred in concluding that undue experimentation is required to practice the claimed invention. To start, the Board found that a person of ordinary skill in the art would not have expected that ribavirin would be effective in treating a SARS-CoV-2 lung infection, and therefore, the quantity of experimentation needed to practice the claimed method, absent some disclosure to the contrary, would be considerable. Appx45. The Board's fact findings are supported by substantial evidence, including that the Application itself recognized that Ribavirin's "use in treating COVID-19 is not expected by skilled pulmonologists and infectious disease specialists to be successful in treating COVID-19." Appx447-49

(collecting articles that concluded that ribavirin would not be effective for treating patients infected with COVID-19).

Nor do the portions of the Application cited by McLeay provide guidance to a person of ordinary skill in the art as to how to arrive at the claimed invention without undue experimentation. Notably, McLeay relies upon "Example 7" of the Application, which is titled "Coronavirus infection" and describes treating a single patient exhibiting "symptoms of fever" with dry powder ribavirin. Appx478-79. The Board found that the Application's Example 7 does not describe treating a SARS-CoV-2 lung infection with the composition recited in claim 20, as it fails to describe treatment "with a liquid aerosol comprising >50% (w/w) water and < 50% of said ribavirin and excipient." Appx31. This finding is supported by substantial evidence. Appx478-79.

Additionally, McLeay advances arguments substantially similar to those rejected by the Board that references outside the Application enable claim 20. This court is similarly unpersuaded by these arguments. With respect to the Gilbert and McLeay prior art reference and the post-filing Messina reference, neither discloses the up-to-50% range of ribavirin recited by claim 20. At best, these references disclose 2%, 6%, and 10% ribavirin. Gilbert and McLeay discloses treating patients infected with influenza A—not a SARS-CoV-2 lung infection—with compositions comprising 2%, 6%, and 10% doses of ribavirin. Appx958. Messina discloses treating patients infected with a SARS-CoV-2 lung infection, but only with a composition comprising 10% ribavirin. Appx964.

There is no disclosure of record, pre-or post-Application filing, that administration of a liquid aerosol composition comprising over 10% ribavirin—let alone one as high as 49.99% ribavirin—may effectively treat a SARS-CoV-2 lung infection. Accordingly, substantial evidence supports the Board's conclusion that the Application does not disclose that the full range recited in claim 20 is effective for treating a SARS-CoV-2 lung infection.[5]

II

This court has held that "[e]nablement is closely related to the requirement for utility." *In re '318 Pat. Infringement Litig.*, 583 F.3d 1317, 1323 (Fed. Cir. 2009). Moreover, this Court has held that "[i]f a patent claim fails to meet the utility requirement because it is not useful or operative, then it also fails to meet the how-to-use aspect of the enablement requirement." *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1358 (Fed.Cir.1999). Here, the Board correctly found that McLeay has failed to show that claim 20 meets the how-to-use aspect of the enablement requirement because, as explained above, the full scope of the claim is not "useful or operative." This requirement prevents McLeay from "patenting [] a mere research proposal" for possibly effective amounts of ribavirin for treating a SARS-CoV-2 lung infection. *'318 Pat. Litig.*, 583 F.3d at 1324.

---

5. McLeay does not separately argue that the Board erred with respect to dependent claims 21-24.

However, we reject the Board's overbroad contention that the claim is not enabled because the Application "lacked any evidence of ribavirin's efficacy against COVID-19." Appellee's Br. at 24. While utility informs a court in making an enablement determination, a claim's utility alone should not end the enablement inquiry. In this case, claim 20's fatal flaw is that there is substantial evidence for the Board's fact findings underlying its conclusion that practicing the full scope of the claimed range would require undue experimentation.

CONCLUSION

We have considered McLeay's remaining arguments but find them unpersuasive. For the reasons stated above, we affirm the Board's finding that claims 20-24 are not enabled.

AFFIRMED

APPENDIX B — REQUEST FOR REHEARING OF THE UNITED STATES PATENT AND TRADEMARK OFFICE, FILED APRIL 15, 2021

UNITED STATES PATENT
AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL
AND APPEAL BOARD

Ex parte MATTHEW MCLEAY

Appeal 2023-001665
Application 17/231,735
Technology Center 1600

Before DONALD E. ADAMS, JOHN E. SCHNEIDER, and RACHEL H. TOWNSEND, *Administrative Patent Judges.*

ADAMS, *Administrative Patent Judge.*

DECISION ON REQUEST FOR REHEARING

Appellant[1] requests rehearing of our DECISION ON APPEAL affirming the rejection of claims 20-24 under the enablement provision of 35 U.S.C. § 112(a).[2]

---

1. We use the word Appellant to refer to "applicant" as defined in 37 C.F.R. § 1.42(a). Appellant identifies the real party in interest as "Matthew McLeay" (Appellant's July 11, 2022, Appeal Brief ("Appeal Br.") 4).

2. *Ex Parte Matthew McLeay,* No. 2023-001665, 2023 WL 2596784 (PTAB Mar. 20, 2023) ("Decision").

Appendix B

Because we do not modify our Decision, Appellant's May 22, 2023, rehearing request ("Req. Reh'g") is DENIED. [3]

STATEMENT OF THE CASE

Appellant's disclosure:

> [R]elates to pharmaceutical formulations and methods using Verteporfin Ribavirin and/or Gemcitabine for use in the treatment of diseases by various routes of administration including inhalation, intratumoral, topical and/or systemic injection administration ... [and] more specifically to the use of Verteporfin, Ribavirin, Gemcitabine, and/or combinations thereof as an inhaled dry powder treatment for COVID-19 and/or other lung infections, cancer and other noncancer applications, which may be combined with other therapies such as photodynamic therapy and/or sonodynamic therapy.

(Spec. ¶ 2.) Appellant's claim 20 is reproduced below:

> 20. A method of treating a SARS-CoV-2[4] lung infection in a patient in need thereof

3. This DECISION ON REQUEST FOR REHEARING incorporates the Decision and is final for the purpose of judicial review. 37 C.F.R. § 41.52(a)(1).

4. Appellant explained that novel Coronavirns nCoV 2019 was a precursor name for SARS-CoV-2 (*see* Decision at *1 (citing Appeal Br. 11)).

> comprising administering to a lung of said patient by inhalation a liquid aerosol composition comprising >50% (w/w) water and <50% (w/w) ribavirin, wherein said liquid aerosol is delivered to the lung with a nebulizer.

(Appeal Br. 14.)

Claims 20-24 stand rejected under the enablement provision of 35 U.S.C. § 112(a).

ISSUES

Appellant identifies the following points believed to have been misapprehended or overlooked by the Board. 37 C.F.R. § 41.52 (A "request for rehearing must state with particularity the points believed to have been misapprehended or overlooked by the Board.").

> I. "The non-confidential information before the Board should have led the Board to the opposite conclusion" than the preponderance of evidence on this record supports Examiner's conclusion that Appellant's Specification failed to provide an enabling disclosure of the subject matter set forth in Appellant's claimed invention and that undue experimentation would have been required to practice Appellant's claimed invention (Req. Reh'g 2; *cf.* Decision at *1, *8).

II. "The Board failed to accept Appellant's statement in his sworn declaration[5] that he provided the clinical trial parameters and protocols used in the study described in the Messina[6] reference" and "Appellant was not given any information before the Decision that the ... [Patent and Trademark Office ("PTO")] had any question about his role in providing clinical trial parameters and protocols used in the Messina study" (Req. Reh'g 2 (citing Messina 11: col. I); *Gf* Decision at *6-*7); Ans. 16;[7] Advisory Act. 5;[8] *see generally* Decision *1-*8).

III. "The Messina reference identifies a treatment study supporting Appellant's invention disclosed to Bausch[9] and further supports enablement of the present claims

---

5. Declaration of Matthew McLeay, M.D., M.S., signed December 22, 2021 ("McLeay Deel.").

6. Messina et al., *Ribavirin Aerosol in the Treatment of SARS-CoV-2: A Case Series,* 10 Infect. Dis. Ther. 2791-804 (2021).

7. Exaininer's October 21, 2022, Answer.

8. Examiner's June 14, 2022, Advisory Action.

9. McLeay makes reference to "the Bausch Health Team" (McLeay Decl. ¶ 16); *see also* Messina 2802 (Messina discloses that "[s]tudy medication and equipment for drug administration were provided by Bausch Health, Milan, Italy" and that "[f]unding for publication fees and technical editorial and medical writing assistance was provided by Bausch Health, Bridgewater, NJ, USA.")).

> based on the specification, prior art, and expertise and knowledge of persons skilled in the art" (Req. Reh'g 3; *c.f* Decision at *1-*8).

ANALYSIS

I

Appellant contends that "[t]he non-confidential information before the Board should have led the Board to the opposite conclusion" than the preponderance of evidence on this record supports Examiner's conclusion that Appellant's Specification failed to provide an enabling disclosure of the subject matter set forth in Appellant's claimed invention and that undue experimentation would have been required to practice Appellant's claimed invention (Req. Reh'g 2; *cf.* Decision at *1, *8). In particular, Appellant contends:

> The Gilbert and McLeay reference,[10] [which Appellant's briefings relied upon in support of enablement,] is cited within the Messina reference at page [2801], column 1 of Messina and further described and summarized at page [2791], the abstract, and page [2802], column 1.

(Req. Reh'g 2 (citing McLeay Decl. ¶¶ 16-17); *cf.* Decision at *2-*3.) We are not persuaded.

---

10. Brian E. Gilbert and Matthew T. McLeay, *MegaRibavirin Aerosol for the Treatment of Influenza A Virus Infections in Mice,* 78 Antiviral Res. 223-29 (2008).

Appendix B

The totality of the evidence on this record was carefully considered with due consideration to the persuasiveness of the findings of Examiner and the arguments of the Appellant. *See In re Oetiker,* 977 F.2d 1443, 1445 (Fed. Cir. 1992) ("[P]atentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument."). As we discuss in further detail below, the preponderance of evidence on this record was found to support Examiner's conclusion that Appellant's Specification failed to provide an enabling disclosure of the subject matter set forth in Appellant's claimed invention and that undue experimentation would have been required to practice Appellant's claimed invention (*see* Decision at *1-8).

With respect to Appellant's citation to paragraphs 16-17 of the McLeay Declaration, we note that the Decision did not overlook this evidence and addressed both paragraphs (*see* Decision at *6).

We acknowledge Appellant's citation of page 2801, column 1 of Messina, which cites the Gilbert and McLeay reference (Req. Reh'g 2). For clarity, we reproduce the relevant paragraph of Messina in full below:

> *An experimental dosing regimen of aerosolized ribavirin was developed for the treatment of SARS-CoV-2 infection in order to deliver medication in a shorter treatment period.* The

Appendix B

> FDA-recommended dosing for patients with respiratory syncytial virus is a solution of 20 mg/mL with continuous aerosol administration for 12-18 h per day for 3-7 days [11]. Research using animal models demonstrated that the use of a higher concentration ribavirin solution (60 mg/mL) could significantly reduce treatment time [16, 17]. *Ribavirin 100 mg/mL administered using a more efficient nebulizer was effective in reducing mortality in a lethal influenza A virus mouse model [18].* Administration of ribavirin aerosol 100 mg/mL for 30 min is estimated to deliver 1760 μg/mL to the alveolar lining fluid, which is approximately 64 times the half maximal response (EC_{50}) of 26.7 μg/mL observed against a clinical isolate of SARS-CoV-2 in vitro (data on file). Administration of ribavirin aerosol as recommended in the treatment of respiratory syncytial virus (20 mg/mL over 12 h) [11] results in an estimated dose of 10.9 mg/kg, whereas administration in the compassionate use study (ribavirin aerosol 100 mg/mL for 30 min) results in an estimated dose of 5.1 mg/kg, which represents approximately half the systemic exposure (data on file).

(Messina 2801 (emphasis added; alteration original); *see also id.* at 2803-04 (Messina identifies endnote: 11

as Virazole,[11] 16 as Gilbert,[12] 17 as Wyde,[13] and 18 as Gilbert and McLeay).) Thus, Messina disclosed that with consideration of FDA-recommended dosing guidelines in addition to a number of other documents, including Gilbert and McLeay, "[a]n experimental dosing regimen of aerosolized ribavirin was developed for the treatment of SARS-CoV-2 infection in order to deliver medication in a shorter treatment period" (Messina 2801).[14] In addition, we note that the paragraph quoted above is the only portion of Messina that cites the Gilbert and McLeay document (*see also* Advisory Act. 5 (Examiner finds that "in the extensive acknowledgment section at the end of the Messina publication, no mention is made of [A]pplicant's contribution to the study (the only mention made was the reference to Gilbert and McLeay [at page 2801 of Messina].")).

---

11. "Virazole (ribavirin for inhalation) Solution, USP [product monograph]. Leval, Quebec, Canada: Bausch Health Canada Inc; 2020" (Messina 2803).

12. Gilbert et al., *Further studies with short duration ribavirin aerosol for the treatment of influenza virus infection in mice and respiratory syncytial virus infection in cotton rats,* 17 Antiviral Res. 33-42.

13. Wyde et al., *Efficacy of high dose-short duration ribavirin aerosol in the treatment of respiratory syncytial virus infected cotton rats and influenza B virus infected mice,* 7 Antiviral Res. 211-20 (1987).

14. *See In re Hedges,* 783 F.2d 1038, 1039-40 (Fed. Cir. 1986) (Identifying in a reference "of record ... disclosures pertinent to the same arguments for which [Appellant] cited the reference[]" does not constitute a new ground of rejection.).

Although Appellant directs attention to Messina's Abstract and the first column of Messina's page 2802, we find no discussion of Appellant or the Gilbert and McLeay document at these portions of Messina. For the foregoing reasons, as well as those set forth in the Decision, we are not persuaded by Appellant's contention that Messina "identifies a treatment study supporting Appellant's invention disclosed to Rausch Health[] and further supports enablement of the present claims based on the specification, prior art, and expertise and knowledge of persons skilled in the art[]" (Req. Reh'g 3 (footnotes omitted); *cf.* Decision at *6-*7.).

We are not persuaded by Appellant's contention that the Board "surprisingly offered no account of the otherwise inexplicable coincidence that dosages of the ribavirin composition tested in the Messina study were the ***same*** dosages disclosed in the earlier Gilbert and McLeay reference" for the treatment of influenza A virus infection in mice (Req. Reh'g 2 (citing Messina 2801: col. l); *cf.* Decision at *2 (citing Final Act. 8) ("Examiner explained, Gilbert and McLeay discloses the 'treatment of influenza A virus infections using MegaRibavirin aerosol, and the treatment of influenza A is not indicative of its effectiveness against SARS-CoV-2 lung infection [and] [i]t is the Examiner's understanding that influenza and COVID-19 are caused by different viruses.'")). As the Decision explained:

> The how to use prong of enablement "incorporates as a matter of law the requirement of 35 U.S.C. § 101 that the specification disclose

as a matter of fact a practical utility for the invention." *Rasmusson v. SmithKline Beecham Corp.,* 413 F.3d 1318, 1322-23 (quoting *In re Cortright,* 165 F.3d 1353, 1356 (Fed. Cir. 1999)); *see also* Ans. 11-12. The measure of proof required to establish that practical utility is not simply that the therapeutic method claimed is "not implausible." *Rasmusson,* 413 F.3d at 1325.

> If mere plausibility were the test for enablement under section 112, applicants could obtain patent rights to "inventions" consisting of little more than respectable guesses as to the likelihood of their success. When one of the guesses later proved true, the "inventor" would be rewarded the spoils instead of the party who demonstrated that the method actually worked. That scenario is not consistent with the statutory requirement that the inventor enable an invention rather than merely proposing an unproved hypothesis.

Id.

(Decision at *3.)[15]

15. We note that Appellant's rehearing request does not address the confusion on this record as to whether "Example 7 of its Specification is prophetic" (Decision *6). Appellant's rehearing request also does not address, *inter alia,* the additional deficiencies

Further, "[w]hen rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application." *In re Wright,* 999 F.2d 1557, 1561-62 (Fed. Cir. 1993). On this record, the PTO met its burden (*see* Decision at *1-8). "If the PTO meets this burden, *the burden then shifts to the applicant* to provide suitable proofs indicating that the specification is indeed enabling." *Wright,* 999 F.2d at 1562 (emphasis added). We, therefore, decline Appellant's invitation to carry its burden (*see* Req. Reh'g 2 (citing Messina 2801: col. 1) (Appellant contends that the Board "surprisingly offered no account of the otherwise inexplicable coincidence that dosages of the ribavirin composition tested in the Messina study were the ***same*** dosages disclosed in the earlier Gilbert and McLeay reference" for the treatment of influenza A virus infection in mice.)).

For the reasons set forth in the Decision and discussed above, we are not persuaded by Appellant's contention that "[t]he non-confidential information before the Board should have led the Board to the opposite conclusion" than the preponderance of evidence on this record supports Examiner's conclusion that Appellant's Specification failed

---

relating to Appellant's reliance on Example 7 of its Specification to support the enablement of its claimed invention (*see id.* at *4-*6). *Cf.* 37 C.F.R. § 41.52 (A "request for rehearing must state with particularity the points believed to have been misapprehended or overlooked by the Board.").

to provide an enabling disclosure of the subject matter set forth in Appellant's claimed invention and that undue experimentation would have been required to practice Appellant's claimed invention (Req. Reh'g 2; *cf.* Decision at *1, *8). An applicant dissatisfied with the outcome of a Board decision is entitled to appeal the decision, *see* 35 U.S.C. §§ 141 and 145, but is not entitled to have the same issue decided multiple times on the same record.

II

Appellant contends that "[t]he Board failed to accept Appellant's statement in his sworn declaration that he provided the clinical trial parameters and protocols used in the study described in the Messina reference" and "Appellant was not given any infonnation before the Decision that the ... [PTO] had any question about his role in providing clinical trial parameters and protocols used in the Messina study" (Req. Reh'g 2 (citing Messina [2801]: col. 1)). In particular, Appellant contends that "Examiner properly did not advance such an assertion in the face of Appellant's declaration" (Req. Reh'g 2). We are not persuaded.

The evidence on this record establishes that *Examiner found:*

> [A]lthough the [McLeay] [D]eclaration stipulates (Paragraph 16) that Dr. McLeay disclosed the clinical trial parameters and protocols used in the Messina publication under confidentiality provisions, *there was no indication from the*

Appendix B

> *[McLeay] [D]eclaration that Dr. McLeay himself carried out (or directed) those case studies described in Messina* (and thus there was no (post-filing) data submitted in the form of a declaration signed by Dr. McLeay).

(Ans. 16 (emphasis added).) The evidence on this record further establishes that *Examiner found:*

> McLeay's Declaration only states that he "disclosed" the clinical trial parameters and protocols used in the Messina, 2021 study to the Bausch Health Team and Chief Medical Officer on March 9, 2020 under confidentiality provisions *(McLeay's Declaration does not indicate that the studies (or the experiments) in the Messina publication were conducted or supervised by or under the control of applicant).* Furthermore, *in the extensive acknowledgment section at the end of the Messina publication, no mention is made of [A]pplicant's contribution to the study* (the only mention made was the reference to Gilbert and McLeay [at page 2801 of Messina, which discussed the treatment of influenza A virus infection in mice]).

(Advisory Act. 5 (emphasis added).) Therefore, we are not persuaded by Appellant's contention that "Appellant was not given any information before the Decision that the . . . [PTO] had any question about [McLeay's] role in providing clinical trial parameters and protocols used in the Messina

study" (Req. Reh'g 2; *cf.* Advisory Act. 5; Ans. 16). For the foregoing reasons, we are not persuaded by Appellant's contention regarding a remand to Examiner to establish facts already present on this record or, alternatively, provide Appellant with an opportunity to respond to Examiner's findings that Appellant previously failed to address (*see* Req. Reh'g 2 (Appellant contends that "the Board . . . could have remanded the issue to the Examiner to ask for an additional filing to be made by Appellant or even to make further inquiry about whether there could be any supplemental information bearing on the subject. That was not done.")).[16]

Further, the weight and credibility accorded each item of evidence, including declarations, is an issue of fact within the discretion of the Board. *Velander v. Garner,* 348 F.3d 1359, 1371 (Fed. Cir. 2003). On this record, McLeay declared: "I disclosed the clinical trial parameters and protocols used in the Messina, 2021 study to the [Bausch] Health Team and Chief Medical Officer on March 9, 2020 under confidentiality provisions" (Decision at *6 (citing McLeay Deel. ¶ 16)). McLeay, however,

16. *See, e.g., Hyatt v. Dudas,* 551 F.3d 1307, 1313-14 (Fed. Cir. 2008) (The Board may treat arguments appellant failed to make for a given ground of rejection as waived.); *see also* 37 C.F.R. § 41.37(c)(1)(iv) ("Except as provided for in (37 C.F.R.] §§ 41.41, 41.47 and 41.52, any arguments or authorities not included in the appeal brief will be refused consideration by the Board for purposes of the present appeal."); MPEP § 1205.02 ("The fact that appellant may consider a ground to be clearly improper does not justify failure to point out to the Board the reasons for that belief, including an explanation of why the examiner erred as to the ground of rejection.").

offered no evidence to corroborate that testimony. The record was, therefore, carefully explored to identify an evidentiary basis to corroborate McLeay's testimony. No such corroborating evidence was found (*see generally* Advisory Act. 5; Ans. 16; Decision at *6). Instead, the record established that Messina made no mention of McLeay in the acknowledgment section of its document and cites "Minnesota Department of Health. Aerosol-generating procedures and patients with suspected or confirmed COVID-19. St. Paul: Minnesota Department of Health; 2020" (Decision at *6 (citing Messina 2802-03: § ACKNOWLEDGEMENTS; Messina 2804); *see also* Advisory Act. 5; *see generally* Ans. 16)). Further, as discussed above, Messina disclosed that with consideration of FDA-recommended dosing guidelines in addition to a number of other documents, "[a]n experimental dosing regimen of aerosolized ribavirin was developed for the treatment of SARS-CoV-2 infection in order to deliver medication in a shorter treatment period" (Messina 2801).

"[T]he Board is entitled to weigh the declarations and conclude that the lack of fachrnl corroboration warrants discounting the opinions expressed in the declarations." *In re Am. Acad. of Sci. Tech Ctr.,* 367 F.3d 1359, 1368 (Fed. Cir. 2004); *cf. P Tech, LLC v. Intuitive Surgical, Inc.,* No. 2022-1102, 2022 WL 17688149 at *3 (Fed. Cir. Dec. 15, 2022) (unpublished) (The "Board did not abuse its discretion in affording expert testimony regarding a lack of motivation to combine little weight after finding that the expert 'd[id] not cite any evidence to corroborate [his] opinion'" (alteration original)).

For the foregoing reasons, we are not persuaded by Appellant's contention that "[t]he Board[] assert[ed] that unsworn 'Acknowledgments' in Messina's publication should be given presumptive priority over Appellant's sworn declaration" (Req. Reh'g 2). To the contrary, the preponderance of evidence on this record failed to support McLeay's testimony, which "appears to take credit for Messina's contribution to the art" (Decision at *6; *see also* Messina 2801 (Messina disclosed that with consideration of FDA-recommended dosing guidelines in addition to a number of other documents, "[a]n experimental dosing regimen of aerosolized ribavirin was developed for the treatment of SARS-CoV-2 infection in order to deliver medication in a shorter treatment period."); Advisory Act. 5 (Examiner found "McLeay's Declaration does not indicate that the studies (or the experiments) in the Messina publication were conducted or supervised by or under the control of applicant" and that "in the extensive acknowledgment section at the end of the Messina publication, no mention is made of [A]pplicant's contribution to the study."); Ans. 16 (Examiner found "no indication from the [McLeay] [D]eclaration that Dr. McLeay himself carried out (or directed) those case studies described in Messina."); *cf.* McLeay Decl. ¶ 16 (McLeay declared: "I disclosed the clinical trial parameters and protocols used in the Messina, 2021 study to the [Bausch] Health Team and Chief Medical Officer on March 9, 2020 under confidentiality provisions.")).

Further, as stated above, a "request for rehearing must state with particularity the points believed to have been misapprehended or overlooked by the Board." 37

C.F.R. § 41.52. Appellant's rehearing request does not contest the finding that:

> Examiner directs attention to several references cited and discussed in the background section of Appellant's Specification support[ing] a finding that, at the time Appellant's claimed invention was made, those of skill in this art would not have reasonably expected that ribavirin would be effective in the treatment of 2019-nCoV and, importantly, would not have recommended the use of ribavirin for 2019-nCoV treatment.

(Decision at *3 (citing Ans. 4; Final Act. 4; Spec. ¶¶ 6-12).) Appellant's rehearing request does not contest the finding that Appellant's Specification discloses that ribavirin's "use in treating COVID-19 is not expected by skilled pulmonologists and infectious disease specialists to be successful in treating COVID-19" (Decision at *3 (citing Spec. ¶ 5)). Appellant's rehearing request does not contest that

> Appellant failed to establish that its disclosure overcomes the evidence of non-enablement provided by the disclosures of the prior art, made at the time of Appellant's claimed invention, that expressly teach that ribavirin has undesirable side effects in patients with respiratory disorders, which reduces ribavirin's potential as an antiviral against SARS-CoV-2 and is not recommended as a treatment for 2019-nCoV (Spec. ¶¶ 6, 11). As Examiner explains, "it is unclear from reading . . .

Appendix B

> [Appellant's] [S]pecification whether . . . [a] liquid aerosol composition comprising >50% (w/w) water and <50% (w/w) ribavirin was even effective in treating SARS-CoV-2 lung infection in a patient" (Ans. 5).

(Decision at *3 (alteration original) (citing Spec. ¶¶ 6, 11; Ans. 5).)

Appellant's rehearing request also does not contest Examiner's finding "that the 'additional drugs or treatments used in Messina in addition to the aerosol ribavirin were not disclosed in ... [Appellant's] [S]pecification as originally filed'" (Decision at *7 (alteration original) (citing Ans. 19); *see also id.* (The Board agreed "with Examiner's finding that the post-filing date, Messina, reference does not disclose a method of treating a SARS-CoV-2 lung infection in a patient in need thereof that is commensurate in scope with Appellant's claim 20 and, therefore, does not make up for the deficiencies in Appellant's nonenabling disclosure") (citing *Genentech Inc. v. Novo Nordisk AIS,* 108 F.3d 1361, 1365 (Fed. Cir. 1997) (quoting *In re Wright,* 999 F.2d at 1561) ("To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'")). As the Decision explained:

> We recognize Appellant's attempt to fill the foregoing evidentiary void in the enabling disclosure of its claim 20 by contending that its claimed method recites the transitional term "comprising" and, therefore, encompasses the

> additional active agents and steps set forth in Messina's, post-filing date, therapeutic protocol (Appeal Br. 12[17]). Stated differently, Appellant appears to contend that simply by using the transitional term comprising Appellant can usurp the inventive contribution of others that actually enabled a specific method of treating a SARS-CoV-2 lung infection in a patient using a specific therapeutic regimen that includes ribavirin in combination with other active agents that were not disclosed in Appellant's Specification. We are not persuaded. *See In re Glass,* 492 F.2d 1228, 1232 (CCPA 1974) ("It is an applicant's obligation to supply enabling disclosure without reliance on what others may publish after he has filed an application on what is supposed to be a completed invention. If he cannot supply enabling information, he is not yet in a position to file."); *Genentech,* 108 F.3d at [1366] ("Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable . . . Tossing out the mere germ of an idea does not constitute enabling disclosure.").

(Decision *7.)

---

17. Appellant contended that "[c]laim 20 of the present application claims the method of treating a SARS-CoV-2 lung infection in a patient using 'comprising' language, meaning claim 20 claims a method including at least the elements listed in the claim . . . Accordingly, the Applicant contends that the Messina reference does disclose the invention as claimed in claim 20" (Appeal Br. 12).

Appendix B

Notwithstanding Appellant's contentions to the contrary, following the preponderance of evidence on this record to a holding in favor of Examiner does not demonstrate a "personal slight toward Appellant," that "the Board made unreasonable, incorrect, and unfair assumptions about Appellant's role in providing clinical trial parameters and protocols used in the Messina study," or "engaged in speculation about Appellant's contribution related to the Messina reference" (Req. Reh'g 2-3). To the contrary, the totality of the evidence on this record was carefully considered with due consideration to the persuasiveness of the findings and arguments of Examiner and Appellant, respectively. *See Oetiker,* 977 F.2d at 1445 ("[P]atentability is determined on the totality of the record, by a preponderance of evidence with due consideration to persuasiveness of argument."). The preponderance of evidence on this record was found to support Examiner's conclusion that Appellant's Specification failed to provide an enabling disclosure of the subject matter set forth in Appellant's claimed invention and that undue experimentation would have been required to practice Appellant's claimed invention (Decision at *1-*8).

In addition, we are not persuaded by Appellant's characterization of our finding with respect to paragraph 16 of the McLeay Declaration as "pivotal" to our holding (Req. Reh'g 2). To the contrary, paragraph 16 of the McLeay Declaration was merely one item among the totality of the evidence considered on this record. As stated above, the weight and credibility accorded each item of evidence, including declarations, is an issue of fact

within the discretion of the Board. *Velander,* 348 F.3d at 1371; *see also Am. Acad. of Sci. Tech Ctr.,* 367 F.3d at 1368 ("[T]he 'Board has broad discretion as to the weight to give to declarations offered in the course of prosecution[, and) . . . the Board is entitled to weigh the declarations and conclude that the lack of factual corroboration warrants discounting the opinions expressed in the declarations.'").

III

Appellant contends that "[t]he Messina reference identifies a treatment study supporting Appellant's invention disclosed to Bausch and further supports enablement of the present claims based on the specification, prior art, and expertise and knowledge of persons skilled in the art" (Req. Reh'g 3). We are not persuaded (*see* Decision at *1-8; *see generally id.* at *7 ("As Examiner explains: . . . Messina['s] study does not correlate with the scope of the broadest claim (i.e., instant claim 20 which recites a liquid aerosol composition comprising ribavirin in the amount of less than 50 wt.% and water in the amount of greater than 50 wt.%)." (emphasis omitted))). *See In re Fisher,* 427 F.2d 833,839 (CCPA 1970) ("The scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.").

As stated above an applicant dissatisfied with the outcome of a Board decision is entitled to appeal the decision, *see* 35 U.S.C. §§ 141 and 145, but is not entitled to have the same issue decided multiple times on the same record.

Appendix B

CONCLUSION

Appellant's rehearing request of the rejection of claims 20-24 under the enablement provision of 35 U.S.C. § 112(a) is DENIED.

APPELLANT'S REQUESTED EDITS

Appellant requests "at minimum, the Board should, upon rehearing, modify the Decision to strike ... [certain portions] before entering any order on Appellant's request for rehearing" (Req. Reh'g 3; *cf. id.* at 1-2). We decline Appellant's request to modify the Decision.

Appendix B

DECISION SUMMARY

Outcome of the Decision on Rehearing:

Claim(s)	35 U.S.C. §	Reference(s)/ Basis	Denied	Granted
20–24	112	Written Description	20–24	

Final Outcome of Appeal after Rehearing:

Claim(s) Rejected	35 U.S.C. §	Reference(s)/ Basis	Affirmed	Reversed
20–24	112	Written Description	20–24	

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

DENIED

APPENDIX C — DECISION ON APPEAL OF THE UNITED STATES PATENT AND TRADEMARK OFFICE, FILED APRIL 15, 2021

UNITED STATES PATENT
AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL
AND APPEAL BOARD

Ex party MATTHEW MCLEAY

Appeal 2023-001665
Application 17/231,735
Technology Center 1600

Before DONALD E. ADAMS, JOHN E. SCHNEIDER, and RACHEL H. TOWNSEND, *Administrative Patent Judges.*

ADAMS, *Administrative Patent Judge.*

DECISION ON APPEAL

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 20–24 (*See* Final Act.[2] 1). We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

---

1. We use the word Appellant to refer to "applicant" as defined in 37 C.F.R. § 1.42(a). Appellant identifies the real party in interest as "Matthew McLeay" (Appellant's July 11, 2022, Appeal Brief ("Appeal Br.") 4).

2. Examiner's February 9, 2022, Final Office Action.

Appendix C

STATEMENT OF THE CASE

Appellant's disclosure:

> [R]elates to pharmaceutical formulations and methods using Verteporfin Ribavirin and/or Gemcitabine for use in the treatment of diseases by various routes of administration including inhalation, intratumoral, topical and/or systemic injection administration . . . [and] more specifically to the use of Verteporfin, Ribavirin, Gemcitabine, and/or combinations thereof as an inhaled dry powder treatment for COVID-19 and/or other lung infections, cancer and other noncancer applications, which may be combined with other therapies such as photodynamic therapy and/or sonodynamic therapy.

(Spec. ¶ 2.) Appellant's claim 20 is reproduced below:

> 20. A method of treating a SARS-CoV-2 lung infection in a patient in need thereof comprising administering to a lung of said patient by inhalation a liquid aerosol composition comprising >50% (w/w) water and <50% (w/w) ribavirin, wherein said liquid aerosol is delivered to the lung with a nebulizer.

(Appeal Br. 14.)

Claims 20–24 stand rejected under the enablement provision of 35 U.S.C. § 112(a).

Appendix C

ISSUE

Does the evidence of record support Examiner's conclusion that undue experimentation would be required to practice the claimed invention?

ANALYSIS

Appellant does not separately argue the claims on Appeal. We, therefore, focus our analysis on Appellant's representative claim 20, reproduced above.

Appellant's claim 20 is directed to a method of treating a SARS-CoV-2 lung infection in a patient. As Appellant explains, "[t]hose skilled in the art recognize that 'novel Coronavirus nCoV 2019' was a precurser [sic] name for SARS-CoV-2 before it was permanently named" (Appeal Br. 11).

After considering the factors set forth in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988), Examiner found that Appellant's Specification fails to provide an enabling disclosure of the subject matter set forth in Appellant's claimed invention (*see* Final Act. 3–7; Ans.[3] 3–7). We find that a preponderance of the evidence supports Examiner's analysis of the Wands factors and adopt them as our own.

Appellant contends that "medical physicians with sufficient skill and experience/expertise in pulmonology and infectious diseases clearly know how to identify a

3. Examiner's October 21, 2022, Answer.

patient having a SARS-CoV-2 lung infection" (Appeal Br. 9). Appellant further contends that "[m]edical physicians with sufficient skill and experience and/or expertise in pulmonology and infections [sic] diseases would clearly recognize that the process of administering a liquid aerosol composition to a patient's lung by inhalation is the same no matter what type of lung infection the patient has" (*id.*; *see also id.* at 8 (Appellant directs attention to Gilbert and McLeay[4] for a disclosure of "aerosol ribavirin dosage, formulation, and administration of aerosol ribavirin for pulmonary routes in patients, namely for treatment of influenza A and respiratory syncytial virus (RSV)."); McLeay Decl.[5] ¶ 13 (McLeay declares that "[t]he administration of nebulized ribavirin to treat viral lung infection is enabled by the disclosure of Gilbert and McLeay . . . for *the treatment of influenza A virus infection* in mice" (emphasis added))). Appellant, therefore, contends:

> [B]ased on the disclosure within the present application coupled with the information known in the art at the time of filing (namely, as described in Gilbert and McLeay), physicians are enabled to treat a SARS-CoV-2 lung infection in a patient by administering a liquid aerosol composition to the patient's lungs by

4. Brian E. Gilbert and Matthew T. McLeay, *MegaRibavirin Aerosol for the Treatment of Influenza A Virus Infections in Mice*, 78 Antiviral Res. 223–29 (2008).

5. Declaration of Matthew McLeay, M.D., M.S., signed December 22, 2021.

> inhalation as claimed in claim 20 without undue experimentation. Undue experimentation would not be necessary because the process of administering a liquid aerosol composition to a patient's lungs by inhalation is the same as is known in the art.

(Appeal Br. 9.) We are not persuaded.

As Examiner explained, Gilbert and McLeay discloses the "treatment of influenza A virus infections using MegaRibavirin aerosol, and the treatment of influenza A is not indicative of its effectiveness against SARS-CoV-2 lung infection [and] [i]t is the Examiner's understanding that influenza and COVID-19 are caused by different viruses" (Final Act. 8). We are not persuaded by Appellant's contention that Examiner's finding:

> [I]s erroneous because the effectiveness of the claimed method is not relevant to the enablement requirement under § 112(a). The enablement requirement requires that a person skilled in the art knows **how to carry out the method** as claimed based on the disclosure of the patent application and what is known in the art, **not** the predicted **effectiveness** of the method for its intended purpose.

(Appeal Br. 10.)

"The legal question of enablement involves an assessment of whether a patent disclosure would have

enabled one of skill in the art at the time the application was filed to make and use the claimed invention without undue experimentation." *Adang v. Fischoff*, 286 F.3d 1346, 1355 (Fed. Cir. 2002) (citing *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384 (Fed.Cir.1986)); *In re Swartz*, 232 F.3d 862, 863 (Fed. Cir. 2000). On this record, we find that Appellant's Application was filed April 15, 2021 claiming benefit to a parent Application filed January 17, 2021, and two provisional Applications, the earliest of which was filed January 17, 2020.

The how to use prong of enablement "incorporates as a matter of law the requirement of 35 U.S.C. § 101 that the specification disclose as a matter of fact a practical utility for the invention." *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318, 1322–23 (quoting *In re Cortright*, 165 F.3d 1353, 1356 (Fed. Cir. 1999)); *see also* Ans. 11–12. The measure of proof required to establish that practical utility is not simply that the therapeutic method claimed is "not implausible." *Rasmusson*, 413 F.3d at 1325.

> If mere plausibility were the test for enablement under section 112, applicants could obtain patent rights to "inventions" consisting of little more than respectable guesses as to the likelihood of their success. When one of the guesses later proved true, the "inventor" would be rewarded the spoils instead of the party who demonstrated that the method actually worked. That scenario is not consistent with the statutory requirement that the inventor enable

> an invention rather than merely proposing an unproved hypothesis.

Id..

On this record, Examiner directs attention to several references cited and discussed in the background section of Appellant's Specification to support a finding that, at the time Appellant's claimed invention was made, those of skill in this art would not have reasonably expected that ribavirin would be effective in the treatment of 2019-nCoV and, importantly, would not have recommended the use of ribavirin for 2019-nCoV treatment (*see* Ans. 4; *see also* Final Act. 4; Spec. ¶¶ 6–12). Further, as Examiner, explains, "[A]ppellant himself states that the use of ribavirin in treating COVID-19 is not expected to be successful by skilled pulmonologists and infectious disease specialists" (Ans. 3–4; *see* Spec. ¶ 5 (Appellant discloses: "The drug Ribavirin is a nucleoside analogue and has been approved for use in a nebulizer to treat respiratory syncytial virus (RSV) infections. Its use in treating COVID-19 is not expected by skilled pulmonologists and infectious disease specialists to be successful in treating COVID-19.)).[6]

---

6. We recognize Appellant's contention that the references it cited in its Specification were provided to "support **nonobviousness** of the present invention, **not a lack of enablement**" (Appeal Br. 10). We are not persuaded. The reference disclosures Appellant provided in its Specification are part of the record before this Panel and weigh in favor of a finding of non-enablement. Appellant's reason for including these disclosures in its Specification is not relevant.

Appendix C

We recognize Appellant's contention that "[a]ny part of the specification can support an enabling disclosure, even a background section that ***discusses, or even disparages***, the subject matter disclosed therein" (Appeal Br. 8 (citing MPEP § 2164.01)). On this record, however, Appellant failed to establish that its disclosure overcomes the evidence of non-enablement provided by the disclosures of the prior art, made at the time of Appellant's claimed invention, that expressly teach that ribavirin has undesirable side effects in patients with respiratory disorders, which reduces ribavirin's potential as an antiviral against SARS-CoV-2 and is not recommended as a treatment for 2019-nCoV (Spec. ¶¶ 6, 11). As Examiner explains, "it is unclear from reading . . . [Appellant's] [S]pecification whether . . . [a] liquid aerosol composition comprising >50% (w/w) water and <50% (w/w) ribavirin was even effective in treating SARS-CoV-2 lung infection in a patient" (Ans. 5). In this regard, Examiner finds:

> Even though Example 7 of . . . [Appellant's] [S]pecification is titled "Coronavirus Infection", the example simply states that the 67-year-old female who had no previous lung disease developed *fever for 2 days.* There is no mention of *a lung infection* which instant liquid aerosol composition is supposed to treat. Also, there is no indication that she was positively diagnosed with SARS-CoV-2 (this is in contrast to all the other examples in which appellant provided detailed diagnostic information as to what the patient was suffering from). Thus, it is unclear whether the composition in Example 7 was

> being used for treating a SARS-CoV-2 lung infection or not.

(Ans. 5–6.) Examiner further finds that Example 7 of Appellant's Specification:

> [D]oes not describe inhalation of *a liquid aerosol composition comprising water (greater than 50%) and ribavirin (less than 50%)* using a nebulizer but instead describes *a dry powder inhalation* composition containing ribavirin. No guidance was provided for practicing instant invention (i.e., administering a liquid aerosol composition comprising >50% water and <50% ribavirin with a nebulizer to treat SARS-CoV-2 lung infection) as to the proper dosage, frequency of administration and duration of treatment. *Furthermore*, Example 7 seems anecdotal, involving *just one patient* . . . [and] there is *no other working example* . . . [in Appellant's] [S]pecification that is drawn to treating SARS-CoV-2 lung infection using a liquid aerosol composition comprising >50% water and <50% ribavirin.

(*Id.* at 6; *see also id.* at 15 (Examiner finds that Example 7 of Appellant's Specification employs a "*dry powder inhalation* method instead of a liquid aerosol inhalation (using a nebulizer) as required" by Appellant's claim 20).) We find no error in Examiner's findings.

Appendix C

Appellant contends that support for the elements of claim 20 is found in at least paragraphs 16–19, 21, 40, 43, 45, 51, 53, 55, 57, 59, 61, 65, 67, 71, 73, 79, 81, 83, 85, 87, and 89 of its Specification (Appeal Br. 10–11; *see also id.* at 11 (Appellant contends that "[a]dditional support can be found in the patent claims as originally filed, most specifically original claims 16 and 20")). We find, however, that although these portions of Appellant's Specification may provide written descriptive support for Appellant's claim 20, they do not provide an enabling description of the claimed subject matter for the reasons set forth by Examiner (*see* Final Act. 3–7; Ans. 3–7).

Appellant contends:

> To the extent that Examiner contends that the term "coronavirus" in the title of Example 7 did not mean SARS-CoV-2 coronovirus, the Applicant directs the Board's attention to "Example 7: Coronavirus infection" and paragraph [00066] of U.S. Provisional Patent No. 62/962,382, filed January 17, 2020 (the ['387 Provisional), to which the present application claims priority and which is incorporated by reference in its entirety into the present patent application. The '387 Provisional states that the 67-year-old female nonsmoker with no previous lung disease of Example 7 was "admitted with cough, fever and shortness of breath for the past day and tested positive (*e.g.*, PCR) for **novel Coronavirus nCoV 2019** and CXR reveals mild interstitial infiltrates" (emphasis added).

(Appeal Br. 11; *see also* McLeay Decl. ¶ 10 (McLeay declares that his "intention with the use of the heading 'Coronavirus Infection' [as set forth in Example 7 of the Specification] was to indicate a patient infected with the SARS-CoV2 virus and suffering from COVID-19 or 2019 Novel Coronavirus"). In support of the foregoing, McLeavy declares that "[n]early every mention of the term 'coronavirus' in the [S]pecification is associated with the 2019 novel coronavirus" (McLeay Decl. ¶ 11). We are not persuaded.

Appellant's disclosure makes a total of three references to coronavirus outside of the background section of its Specification, which, as discussed above, supports a finding of non-enablement. First, Appellant discloses the invention provides a solid dry powder form or aerosol form of Ribavirin for use in treating . . . a viral lung infection such as, *e.g.*, coronavirus or influenza virus" (Spec. ¶ 51). Second, Appellant discloses "[i]n another aspect, the invention provides a solid dry powder form or aerosol form of combined Veterporfin, Ribavirin, and Gemcitabine for use with or without perflubron in treating . . . a viral lung infection, preferably SARS CoV-2 coronavirus or influenza virus" (Spec. ¶ 79). Third, as discussed above, the title of Appellant's Example 7 refers to a "Coronavirus Infection" (Spec. 33). As discussed above, however, there is no evidence in Example 7 to support a finding that the patient treated actually had a SARS-CoV-2 lung infection.

Thus, of the three references to the term coronavirus, outside the background section of Appellant's Specification,

only *one* refers to SARS CoV-2 coronavirus (*see* Spec. ¶ 79). It is clear, therefore, that when Appellant intended to refer to SARS CoV-2 coronavirus, Appellant did so by name. The *single* reference to a treatment of SARS CoV-2 coronavirus, however, relates to an embodiment of Appellant's claimed invention that is *not* claimed. Specifically, the *only* disclosure of a treatment of SARS CoV-2 coronavirus in Appellant's Specification, relates to an embodiment, wherein a solid dry powder form or aerosol form of *a combination of Veterporfin, Ribavirin, and Gemcitabine for use with or without perflubron* is contemplated for use "in treating . . . a viral lung infection, preferably SARS CoV-2 coronavirus or influenza virus" (Spec. ¶ 79).

For the foregoing reasons, we are not persuaded by McLeay's statement that it "is apparent and clear to the ordinarily skilled virologist or pulmonologist when reading the specification," that Appellant's "intention with the use of the heading 'Coronavirus Infection'[, in Example 7 of its Specification,] was to indicate a patient infected with the SARS-CoV2 virus" (McLeay Decl. ¶ 10).

In addition, we note that Appellant does not dispute Examiner's finding that Appellant's reference to paragraph 66 of Provisional Application 62/962,382 appears to be a reference to paragraph 66 of Provisional Application 62/967,777 ("the '777 Provisional"), filed January 30, 2020 (Ans. 14). Next, we agree with Examiner's finding:

> [I]t is not clear whether or not those two examples (i.e., Example 7 in present

> specification and Example 7 in the '777 Provisional) are even correlated. Example 7 in [the] present [S]pecification simply states that the 67-year-old female nonsmoker having no previous lung disease develops symptoms *of fever for 2 days* (and there is no mention of lung infection or diagnosis of COVID-19) whereas Example 7 of '777 Provisional states that the 67-year-old female nonsmoker and no previous lung disease is admitted with *cough, fever* and shortness of breath for *the past day* and tested positive for COVID-19.

(Ans. 14–15.) Further, even if we credit Example 7 of Appellant's Specification with the disclosure of Example 7 in the '777 Provisional, we find that Examiner has the better position. Specifically, as Examiner explains, like Example 7 of Appellant's Specification, Example 7 of the '777 Provisional employs a "*dry powder inhalation* method instead of a liquid aerosol inhalation (using a nebulizer) as required" by Appellant's claim 20 (Ans. 15).

We also recognize that Appellant appears to assert that Example 7 of its Specification is prophetic (*see* Appeal Br. 12 (Appellant contends that "[p]ost-filing evidence is allowed by the USPTO and may be used in an application to support *prophetic examples* to rebut a rejection based on lack of enablement." (emphasis added)). Appellant did not, however, dispute Examiner's finding that Appellant "never indicated that . . . Example 7 [of its Specification] was a prophetic example" and "there is no indication [in Example 7 of Appellant's Specification] that the example is

describing an experiment involving ribavirin that has yet to be performed (except for the last statement concerning verteporfin and gemcitabine 'Verteporfin and Gemcitabine dpi could be *substituted for* the Ribavirin'" (Ans. 17–18 (citing MPEP § 608.01(p)(II)) (emphasis added); *cf.* McLeay Decl. ¶ 17 (McLeay declares that the Specification describes "[t]he successful effective treatment of patients[, plural,[7]] suffering from COVID-19 with the aerosolized ribavirin.")).

For the foregoing reasons, we are not persuaded that Example 7, or any other portion, of Appellant's Specification provides an enabling description of the specific method set forth in Appellant's claim 20.

McLeay declares that Messina,[8] a post-filing date reference, established that the administration "of aerosolized ribavirin according to the subject patent application as disclosed in the written description has been demonstrated to be efficacious in the treatment of [five] patients with COVID-19" (McLeay Decl. ¶ 15). In addition, although we find no mention of McLeay in the "Acknowledgments" section of Messina's publication, McLeay appears to take credit for Messina's contribution to the art declaring: "I disclosed the clinical trial parameters and protocols used in the Messina, 2021 study to the

7. We find no evidence on this record to support a finding that more than one patient was treated in Example 7 of Appellant's Specification.

8. Messina et al., *Ribavirin Aerosol in the Treatment of SARS-CoV-2: A Case Series*, 10 Infect. Dis. Ther. 2791–804 (2021).

Baushch Health Team and Chief Medical Officer on March 9, 2020 under confidentiality provisions" (McLeay Decl. ¶ 16; *cf.* Messina 2802–03: § ACKNOWLEDGEMENTS; Messina 2804 (Messina cites "Minnesota Department of Health. Aerosol-generating procedures and patients with suspected or confirmed COVID-19. St. Paul: Minnesota Department of Health; 2020.")). We are not persuaded.

As Examiner explains:

> [The] five patients in the case studies in Messina were not just given aerosol ribavirin. Three of the five patients were initially treated empirically with antibiotics and one of those three also received corticosteroids and other antiviral medications. Only two patients received no antiviral or immunomodulating treatments other than ribavirin (see under DISCUSSION). The Messina publication also points out (see under Safety and Tolerability) that all patients received low-molecular weight heparin throughout hospitalization except for Patient 5, who received prophylaxis with enoxaparin and an antiplatelet agent to reduce thromboembolic risk. *Also*, the only concentration of aerosol ribavirin used was 100 mg/ml (i.e., about 10% of ribavirin). *Thus, the showing of Messina study does not correlate with the scope of the broadest claim (i.e., instant claim 20 which recites a liquid aerosol composition comprising ribavirin in*

> *the amount of less than 50 wt.% and water in the amount of greater than 50 wt.%).*

(Ans. 18; *see also id.* at 19 (Examiner finds that the "additional drugs or treatments used in Messina in addition to the aerosol ribavirin were not disclosed in . . . [Appellant's] [S]pecification as originally filed").) We agree with Examiner's finding that the post-filing date, Messina, reference does not disclose a method of treating a SARS-CoV-2 lung infection in a patient in need thereof that is commensurate in scope with Appellant's claim 20 and, therefore, does not make up for the deficiencies in Appellant's non-enabling disclosure. *Genentech Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993)) ("To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'").

We recognize Appellant's attempt to fill the foregoing evidentiary void in the enabling disclosure of its claim 20 by contending that its claimed method recites the transitional term "comprising" and, therefore, encompasses the additional active agents and steps set forth in Messina's, post-filing date, therapeutic protocol (Appeal Br. 12). Stated differently, Appellant appears to contend that simply by using the transitional term comprising Appellant can usurp the inventive contribution of others that actually enabled a specific method of treating a SARS-CoV-2 lung infection in a patient using a specific therapeutic regimen that includes ribavirin in combination with other active

agents that were not disclosed in Appellant's Specification. We are not persuaded. *See In re Glass*, 492 F.2d 1228, 1232 (CCPA 1974) ("It is an applicant's obligation to supply enabling disclosure without reliance on what others may publish after he has filed an application on what is supposed to be a completed invention. If he cannot supply enabling information, he is not yet in a position to file."); *Genentech*, 108 F.3d at ("Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. . . . Tossing out the mere germ of an idea does not constitute enabling disclosure.").

CONCLUSION

The evidence of record supports Examiner's conclusion that undue experimentation would be required to practice the claimed invention. The rejection of claim 20 under the enablement provision of 35 U.S.C. § 112(a) is affirmed. Claims 21–24 are not separately argued and fall with claim 20.

DECISION SUMMARY

In summary:

Claim(s) Rejected	35 U.S.C. §	Reference(s)/ Basis	Affirmed	Reversed
20–24	112	Written Description	20–24	

Appendix C

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). See 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED

APPENDIX D — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT, FILED MARCH 25, 2025

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

2023-2338

IN RE: MATTHEW MCLEAY,

Appellant

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. 17/231,735

Before MOORE, *Chief Judge*, STOLL, *Circuit Judge*, and GILSTRAP, *Chief District Judge*.[1]

PER CURIAM.

ORDER

Matthew McLeay filed a petition for panel rehearing.

Upon consideration thereof,

IT IS ORDERED THAT:

1. Honorable Rodney Gilstrap, Chief Judge, United States District Court for the Eastern District of Texas, sitting by designation.

Appendix D

The petition for panel rehearing is denied.

FOR THE COURT

/s/ Jarrett B. Perlow
Jarrett B. Perlow
Clerk of Court

March 25, 2025
Date