No. 19-____

IN THE

Supreme Court of the United States

NUVO PHARMACEUTICALS (IRELAND) DESIGNATED ACTIVITY COMPANY, AND HORIZON MEDICINES LLC,

Petitioners,

v.

DR. REDDY'S LABORATORIES INC., DR. REDDY'S LABORATORIES, LTD., MYLAN, INC., MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LIMITED, LUPIN LTD., AND LUPIN PHARMACEUTICALS, INC.

Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

Whether the Federal Circuit erred by holding that, whenever the prior art teaches away from a pharmaceutical composition, the written description of a patent claiming that composition can satisfy 35 U.S.C. § 112 only if it discloses either experimental data proving efficacy or a detailed theory of why the composition works sufficient to show that it would be effective.

PARTIES TO THE PROCEEDING

Petitioners Nuvo Pharmaceuticals (Ireland) Designated Activity Company and Horizon Medicines LLC were Plaintiffs-Cross-Appellants below.

Respondents Dr. Reddy's Laboratories Inc., Dr. Reddy's Laboratories, Ltd., Mylan, Inc., Mylan Pharmaceuticals Inc., and Mylan Laboratories Limited were Defendants-Appellants below.

Respondents Lupin Ltd. and Lupin Pharmaceuticals, Inc. were Defendants-Appellees below.

RULE 29.6 CORPORATE DISCLOSURE STATEMENT

Petitioner Nuvo Pharmaceuticals (Ireland) Designated Activity Company is a public corporation listed on the Toronto Stock Exchange and is a wholly owned subsidiary of Nuvo Pharmaceuticals Inc.

Petitioner Horizon Medicines LLC's parent corporation is Horizon Pharma PLC.

RELATED PROCEEDINGS

Pozen Inc., et al. v. Dr. Reddy's Laboratories Inc., et al. No. 17-2473 (the additional cases included in this consolidated appeal are: Nos. 17-2481, 17-2484, 17-2486, 17-2487, 17-2488, 17-2489, 17-2491, 17-2492 & 17-2493) (Fed. Cir. May 15, 2019);

Pozen, Inc., et al. v. Actavis Laboratories FL, Inc., et al., Appeal No. 17-1604 (the additional cases included in this consolidated appeal are: Nos. 17-1605, 17-1606, 17-1607, 17-1608, 17-1610, 17-1611, 17-1612, 17-1613, 17-1614, 17-1615 & 17-1616) (Fed. Cir. Mar. 5, 2018);

Horizon Pharma, Inc. at al. v. Dr. Reddy's Laboratories Inc. et al., C.A. Nos. 3:11-cv-2317 & 3:13-cv-0091 (D.N.J. July 21, 2017);

Horizon Pharma, Inc. et al. v. Lupin Ltd. et al., C.A. No. 3:11-cv-4275 (D.N.J. July 21, 2017);

Horizon Pharma, Inc. et al. v. Mylan Pharmaceuticals et al., C.A. No. 3:13-cv-4022 (D.N.J. July 21, 2017);

Horizon Pharma, Inc. et al. v. Actavis Laboratories FL., Inc. et al., C.A. Nos. 3:13-cv-3038, 3:15-cv-3322, 3:15-cv-8523, 3:15-cv-8524, 3:16-cv-426 & 3:16-cv-4916 (D.N.J. Feb. 8, 2017).

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PETITION FOR A WRIT OF CERTIORARI

Horizon Medicines LLC and Nuvo Pharmaceuticals (Ireland) Designated Activity Company respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The opinion of the U.S. Court of Appeals for the Federal Circuit (Pet. App. 1a) is reported at *Nuvo Pharmaceuticals (Ireland) Designated Activity Company v. Dr. Reddy's Laboratories, Inc.*, 923 F.3d 1368 (Fed. Cir. 2019). The district court's opinion is unreported and reproduced at Pet. App. 33a.

JURISDICTION

The judgment of the U.S. Court of Appeals for the Federal Circuit was entered on May 15, 2019. Pet. App. 118a. A petition for rehearing *en banc* was denied on July 30, 2019. Pet. App. 120a. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATUTORY PROVISIONS INVOLVED

Section 112, ¶ 1 of Title 35 of the United States Code[1] provides in relevant part:

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[1] The applications resulting in the patents-in-suit were filed before the enactment of the Leahy-Smith America Invents Act ("AIA"). Accordingly, the pre-AIA version of 35 U.S.C. § 112 governs this case.

> 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.

INTRODUCTION

This case raises the fundamental question of whether an inventor may obtain a patent on a new and nonobvious pharmaceutical composition before conducting clinical trials to prove its efficacy or otherwise providing a detailed theory as to why the composition works.

This Court has recognized the requirement of 35 U.S.C. § 112 that inventions be described in "full, clear, concise, and exact terms" is "part of the delicate balance the law attempts to maintain between inventors, who rely on the promise of the law to bring the invention forth, and the public, which should be encouraged to pursue innovations, creations, and new ideas beyond the inventor's exclusive rights." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., Ltd.*, 535 U.S. 722, 731 (2002) (citation omitted). To strike this balance, the written description standard requires that the specification "reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598

F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). The disclosure meets this requirement if it "allows one skilled in the art to visualize or recognize the identity of the subject matter purportedly described." *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1190 (Fed. Cir. 2014).

Until now, nothing more has been required. The written description requirement has never required actual reduction to practice, an explanation of why the invention will work, or experimental data demonstrating effectiveness. *Allergan Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1308-09 (Fed. Cir. 2015); *Alcon*, 745 F.3d at 1190-91; *Ariad*, 598 F.3d at 1352. Indeed, an invention need not be reduced to practice before filing and even inventions that are purely prophetic may be entitled to patent protection if the patent specification shows that the inventor possessed the claimed subject matter. *See, e.g.*, *Ariad*, 598 F.3d at 1352.

The Federal Circuit's decision in this case upends these settled principles and imposes a heightened written description standard on pharmaceutical inventions. According to the Federal Circuit, whenever the prior art teaches away from a new and nonobvious pharmaceutical composition, the patent specification must contain disclosures in the form of data or a detailed theory as to why it would work.

Not only is this new standard a departure from precedent, which has never required experimental data or a detailed theory of *why* an invention works, but it also conflates the distinct enablement and written description inquiries under § 112. The

Federal Circuit, in its *en banc* opinion in *Ariad*, held that written description is "a separate requirement" from the enablement inquiry. *Ariad*, 598 F.3d at 1345. As the court explained, the specification must also "describe how to make and use the invention (*i.e.*, enable it), but that is a different task." *Id.*

Here, the Federal Circuit held that, where the prior art teaches away from a claimed composition, the patent specification must both show possession and *additionally* must persuade a person skilled in the art that the invention would work to quell any skepticism based on the prior art. This, however, is an enablement issue that is not relevant to written description. The Federal Circuit's heightened written description standard thus departs from precedent holding that "whether the patentee has proven to the skilled reader that the invention works … is an enablement issue," apart from whether the invention has been described sufficient to show possession. *Alcon*, 745 F.3d at 1191. By characterizing the question of whether the specification overcame a skilled artisan's skepticism as a written description issue, the Federal Circuit improperly conflates these distinct inquiries and injects confusion into a settled area of law.

The Federal Circuit's inconsistent application of § 112 when analyzing written description shows the court's internal division on this issue. Different Federal Circuit panels, when faced with similar facts, reach opposite conclusions as to whether a patent satisfies the written description standard. This Court's guidance is needed to fix the Federal Circuit's

inconsistency and bring uniformity to its application of § 112.

This Court has counseled that "courts must be cautious before adopting changes that disrupt the settled expectation of the inventing community." *Festo*, 535 U.S. at 739. The Federal Circuit's opinion here does just that by creating a heightened written description standard for pharmaceutical compositions. Under this heightened standard, inventors will be required to expend significantly more resources to obtain experimental data before seeking patent protection. This will be especially harmful to the pharmaceutical and biotechnology industries, where it is necessary to seek patents for early-stage inventions long before establishing efficacy in humans through expensive and time-consuming clinical trials. The Federal Circuit's decision imperils those inventions because requiring efficacy data to show possession of a composition will discourage life science companies from pursing new therapies.

Worse still, the Federal Circuit's new written description requirement will disproportionality harm the most innovative new products. Under the court's heightened standard, the more an invention departs from the conventional wisdom reflected in the prior art, the more disclosure will be necessary to overcome a skilled artisan's skepticism.

STATEMENT OF THE CASE

I. The Claimed Invention

The patents-in-suit, U.S. Patent Nos. 6,926,907 and 8,557,285, claim combination dosage forms containing two ingredients: (1) a non-steroidal anti-inflammatory drug ("NSAID") surrounded by enteric coating to prevent its release below pH 3.5; and (2) an uncoated proton pump inhibitor ("PPI"), at least some of which releases immediately. These dosage forms address the unmet medical need for an arthritis medicine or a pain reliever that did not have the gastrointestinal side effects associated with the typical NSAID products. Pet. App. 230a.

NSAIDs have been widely accepted as effective agents for controlling pain, but their use can lead to the development of gastrointestinal lesions, such as ulcers and erosions, in susceptible individuals. *Id.* at 230a. It was thought that these lesions are caused by the acidic conditions of patients' stomachs and upper small intestines. *Id.* The inventor of the patents-in-suit, Dr. John Plachetka, sought to reduce these gastrointestinal side effects, and he developed the claimed pharmaceutical compositions to do so.

At the time of invention, others had unsuccessfully tried to reduce NSAID-induced gastrointestinal injury. One such approach involved combining an NSAID with an enteric-coated PPI. Enteric-coated PPIs, however, often did not take effect for several hours, and thus did not inhibit acid quickly enough to prevent gastrointestinal injury. *Id.* at 231a. Despite this problem, no one suggested using

an uncoated PPI. And in fact, the art taught away from using an uncoated PPI, teaching instead that PPIs must be enteric coated to prevent degradation by stomach acid.

Dr. Plachetka departed from this conventional wisdom when he invented the claimed compositions, which combine an NSAID with an *uncoated* PPI. He designed the claimed compositions to achieve "coordinated release" of the two drugs, in which the uncoated PPI would immediately release and begin neutralizing the stomach acid but the enteric-coated NSAID would release only at a pH of 3.5 or above, where the risk of gastrointestinal injury was diminished.

Claim 1 of the '285 patent, reproduced below, is illustrative:

> A pharmaceutical composition in unit dosage form comprising therapeutically effective amounts of:
>
> (a) esomeprazole, wherein at least a portion of said esomeprazole is not surrounded by an enteric coating; and
>
> (b) naproxen surrounded by a coating that inhibits its release from said unit dosage form unless said dosage form is in a medium with a pH of 3.5 or higher;
>
> wherein said unit dosage form provides for release of said esomeprazole such that upon introduction of said unit dosage form into a medium, at least a portion of said

> esomeprazole is released regardless of the pH in the medium.

The specification demonstrates both that the inventor possessed the idea of using an uncoated PPI and that doing so would be effective. It begins by introducing the compositions as "a single, coordinated, unit-dose product that combines: a) an agent that actively raises intragastric pH to levels associated with less risk of NSAID-induced ulcers; and b) an NSAID." *Id.* at 234a. The specification discloses that this coordinated release involves first releasing an amount of an acid inhibitor effective to raise gastric pH then subsequently releasing an effective amount of an NSAID once the pH of the gastrointestinal tract has risen. *Id.* at 238a.

The specification discloses amounts of both the acid inhibitor and NSAID that are "effective" within the meaning of the claims. For example, the specification states that the NSAID must be "in an amount effective to reduce or eliminate pain or inflammation." *Id.* at 236a. It then identifies that naproxen is "[t]he most preferred NSAID . . . in an amount of between 50 mg and 1500 mg, and more preferably, in an amount of between 200 mg and 600 mg." *Id.* at 236a-237a.

The specification similarly details the effectiveness and amounts of the acid inhibitor of the claimed dosages. It explains that there is "an acid inhibitor present in an amount effective to raise the gastric pH of a patient to at least 3.5 . . . ." *Id.* at 235a. It also identifies omeprazole and esomeprazole as

"preferred agents that may be effectively used as acid inhibitors" in the claimed dosages. *Id.*

Not only does the specification disclose the PPIs that "may be effectively used," it also discloses the amounts to be used in the claimed dosage forms. For example, it states that PPIs "will typically be present at about 5 mg to 600 mg per unit dose." *Id.* at 247a. As to its preferred acid inhibitors, omeprazole and esomeprazole, the specification discloses that omeprazole would be present in the composition "in an amount of between 5 mg and 50 mg, with about 10 or 20 mg being preferred" and that esomeprazole would be present in an amount of "5-100 mg, with about 40 mg being preferred." *Id.*

The specification also includes exemplary formulations of the claimed dosages, including the "effective" amount of acid inhibitor. For instance, Example 6 recites a four-layer tablet comprising the PPI omeprazole in the outermost layer and an enteric-coated NSAID at the core. Example 6 explains that "omeprazole is released first and then the core erodes and releases" the NSAID. *Id.* at 266a. Example 6 also discloses the amount of omeprazole that will be effective to raise gastric pH. It states that the omeprazole "raises the pH of the gastrointestinal tract to above 4" and the "typical effective amount of omeprazole in the dosage form may vary from 5 mg to 50 mg." *Id.* at 265a.

The specification of the patents-in-suit thus discloses problems associated with traditional enteric-coated PPIs, a specific formulation within the claims with immediate-release uncoated PPIs, and

the "typical effective amount" of the uncoated PPIs that should be used to achieve the benefits of the claimed compositions. These disclosures demonstrate that the inventor possessed the claimed invention, including that the uncoated PPI in the claimed dosage forms would be effective at raising the gastric pH.

II. District Court Proceedings

This case arises from Respondents' Abbreviated New Drug Application, seeking to market generic versions of the innovator drug VIMOVO®. After a six-day bench trial, the district court held that the asserted claims were not invalid, rejecting Respondents' arguments as to obviousness, written description, and enablement.

The district court first rejected Respondents' various obviousness arguments, which were the primary focus of the district court proceedings. For example, the district court concluded that, based on the evidence presented at trial, a skilled artisan "would not have been motivated to use an uncoated PPI given numerous prior art references reflecting a widely-held understanding that the acid lability of PPIs, particularly in a solid dosage form, would generally require an enteric coating." Pet. App. 99a. The district court thus held the claimed compositions to be nonobvious.

The district court then rejected Respondents' contention that, because the claimed use of uncoated PPI was nonobvious, the patents must necessarily lack written description support for that limitation. *Id.* at 108a-111a. Respondents argued that, because a

skilled artisan would have understood the prior art as teaching away from the claimed invention, he or she would not believe the inventor had possession of the claimed dosage form without experimental data proving that the claimed composition would be effective.

The district court found that "[t]he '285 patent specification contains various disclosures describing the immediate release of an acid inhibitor as a component of the invention." *Id.* at 109a-110a (citation omitted). It noted the specification described that the "acid inhibitor is in one or more layers outside of the core which do not contain any NSAID. These layers are not surrounded by any enteric coating and, upon ingestion of the tablet or capsule by a patient, release the acid inhibitor into the patient's stomach." *Id.* at 110a. The court also found that the "early release of the acid inhibitor is repeatedly described" and that the "immediate release of an uncoated acid inhibitor is explicitly distinguished in the specification from enteric coated PPI formulations that delay the absorption of the acid inhibitor." *Id.*

The district court also concluded that the specification enabled a skilled artisan to make and use the claimed compositions, which Respondents did not challenge on appeal. The court rejected Respondents' argument that the claimed dosage forms were not enabled simply because the patents do not contain experimental data testing uncoated PPIs and that, without experimental data, the patent specification is nothing more than an "unsupported 'suspicion' that the invention would work." *Id.* at 105a. Relying on testimony from both parties' experts,

the court found that the specification teaches a skilled artisan how to make the claimed tablets and that the "patents themselves disclose their intended use." *Id.* at 106a. The district court thus stated that "[t]here appears to be no serious dispute between the parties that the Asserted Patents disclose how to make and use the claimed invention." *Id.* at 105a.

The district court concluded that, "in light of the disclosures in the specification describing the immediate release of an uncoated PPI and the potential disadvantages of enteric coated PPI formulations," the claims met the requirements of § 112. *Id.* at 110a-111a. It explicitly stated that "[t]he lack of experimental testing data or a detailed analysis on why an uncoated PPI might prove effective does not require us to find otherwise." *Id.* at 111a.

III. The Federal Circuit's Opinion

The Federal Circuit reversed the district court's factual finding that the specification contained sufficient written description to support the uncoated PPI claim limitation. Despite the specification's disclosures that the acid inhibitor is "present in an amount effective to raise the gastric pH of a patient to at least 3.5" and its identification of preferred acid inhibitors and the specific amounts to be used in the claimed dosages, the Federal Circuit characterized the specification as "fatally flawed" for "provid[ing] nothing more than the mere claim that uncoated PPI might work, even though persons of ordinary skill in the art would not have thought it would work." Pet. App. 24a. Ultimately, the court found that the

inventor failed to show possession because a skilled artisan "would not have expected uncoated PPI to raise gastric pH." *Id.* at 30a-31a.

In its opinion, the Federal Circuit cited, but declined to follow, its precedents holding that neither experimental data nor a detail theory is required to show possession. The Federal Circuit stated that "the record evidence demonstrates that a person of ordinary skill in the art would not have known or understood that uncoated PPI is effective." *Id.* at 23a. The court accepted Respondents' argument that, if the prior art taught away from the claimed invention, the specification lacked written description support because it did not include experimental data showing efficacy or a detailed description of why the dosage form would work. The court thus concluded that "there is nothing in the specification of the patents-in-suit showing 'that the inventor *actually invented* the invention claimed.'" *Id.* at 23a (citation omitted).

Petitioners filed a petition for *en banc* rehearing and the Federal Circuit requested a response from Respondents. On July 30, 2019, the court denied Petitioners' rehearing request. Pet. App. 120a.

REASONS FOR GRANTING THE PETITION

This case shows the irreconcilable conflict that exists within the Federal Circuit regarding what disclosure is required to satisfy the written description requirement of 35 U.S.C. § 112. The Federal Circuit's opinion creates a new, heightened written description standard that is squarely at odds with long-standing precedent stating that a patent

specification need only show that the inventor had possession of the claimed invention. Indeed, an invention need not actually be reduced to practice before filing. *Ariad*, 598 F.3d at 1352. Neither is the specification required to include an explanation of why the invention will work. *Allergan*, 796 F.3d at 1308-09. And the Federal Circuit has never required experimental data demonstrating effectiveness. *Id.* The contradictory outcome in this case when compared to these precedents shows that the Federal Circuit needs guidance in order to apply § 112 correctly and consistently.

I. The Federal Circuit's New Heightened Written Description Standard Departs from Precedent by Requiring Experimental Data Proving Efficacy

The Federal Circuit's opinion upends years of written description case law. In doing so, it improperly creates a heightened written description requirement that finds no support in § 112.

The Federal Circuit's opinion acknowledges, but declines to follow, clear precedents stating that neither experimental data nor a detailed theory of why the invention will work is required to satisfy the written description requirement. The court recognized, for example, that "case law does not require experimental data demonstrating effectiveness." Pet. App. 23a (citing *Allergan*, 796 F.3d at 1309). It similarly conceded that that written description "does not require theory or explanation of how or why a claimed composition will be effective." *Id.* (citing *Allergan*, 796 F.3d at 1308-09). And the

court further acknowledged that an invention need not even have been reduced to practice to satisfy the written description requirement. *Id.* (citing *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 926 (Fed. Cir. 2004)); *see also Ariad*, 598 F.3d at 1352.

Under a proper application of § 112, the specification must simply "allow[] one skilled in the art to visualize or recognize the identity of the subject matter purportedly described," to satisfy the written description requirements of § 112. *Alcon*, 745 F.3d at 1190 (quoting *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 968 (Fed. Cir. 2002)). No experimental data or detailed theory is required.

Despite recognizing this established written description law, the Federal Circuit nevertheless reversed the district court's written description finding because the patent lacked experimental data demonstrating effectiveness or a more detailed theory of why the claimed compositions would work. The court accepted Respondents' argument that, where a patentee prevails on obviousness by showing that a skilled artisan would have understood the prior art as teaching away from a claimed invention, the specification must contain disclosures to overcome that teaching away in the form of experimental data or a detailed theory of why the invention will work. Pet. App. 23a-24a. The court explained that, despite the specification's disclosures of effective amounts of uncoated PPI, "a person of ordinary skill in the art would not have known or understood that uncoated PPI is effective," (*id.* at 23a), and "would not have expected uncoated PPI to raise gastric pH," (*id.* at 30a-31a).

This reasoning is a departure from precedent, most notably in *Allergan* and *Alcon*. In *Allergan*, for example, a generic drug company argued that pharmaceutical composition claims directed to a method of lowering intraocular pressure lacked written description support because the specification failed to disclose efficacy data. *Allergan*, 796 F.3d at 1308. The generic challenged enablement, arguing that "the specifications contain no actual efficacy … data; rather they merely provide a research proposal." *Id.* at 1309-10. As Respondents did here, the generic company argued that, if the prior art taught away from the claimed compositions such that they were nonobvious, then the claims must lack written description support.

Contrary to the outcome here, the Federal Circuit in *Allergan* flatly rejected this argument and concluded that the claims met both the written description and enablement standards of § 112. Although the claims recited specific clinical effects of lowering interocular pressure and reducing hyperemia, the Federal Circuit nevertheless held that "efficacy data are generally not required in a patent application. Only a sufficient description enabling a [skilled artisan] to carry out the invention is needed." *Id.* at 1310. The court also explained that there was no tension between the obviousness and § 112 inquiries because "the specifications here provide sufficient guidance to the skilled artisan." *Id.*

The Federal Circuit similarly declined to follow its decision in *Alcon*. Pet. App. 26a-28a. The claims at issue in *Alcon* involved methods of "enhancing the chemical stability" of a composition comprising a

"therapeutically-effective amount" of a pharmaceutical drug. *Alcon*, 745 F.3d at 1184. In finding that the specifications contained sufficient disclosures to establish possession, the Federal Circuit rejected the generic challenger's argument that the specifications failed to disclose the claimed stability data, explaining that "[t]here is no requirement that the disclosure contain 'either examples or an actual reduction to practice.'" *Alcon*, 745 F.3d at 1190 (citation omitted). Instead, the Federal Circuit explained that written description asks only whether a skilled artisan "can recognize that what was claimed corresponds to what was described; it is not about whether the patentee has proven to the skilled reader that the invention works, or how to make it work, which is an enablement issue." *Id.* at 1191 (citing *Ariad*, 598 F.3d at 1352).

The decision here contravenes *Alcon* by requiring a disclosure that not only shows possession of the claimed invention, but that also overcomes a skilled artisan's skepticism caused by prior-art teaching away from using uncoated PPI. Under this heightened standard, the court ignored disclosures of typical amounts of PPIs to be used in the claimed compositions, including disclosure of amounts that would be "effective." *See* Pet. App. 23a ("[T]here is nothing in the specification of the patents-in-suit showing 'that the inventor *actually invented* the invention claimed.'").

The Federal Circuit's conflicting statements about the specification's disclosures show that only clinical data showing effectiveness of uncoated PPI or a more detailed theory of why the invention works are

enough to meet the new written description standard. The court concluded, for example, that disclosures of specific amounts of PPI that are "typical" were insufficient because they did not specify that the amounts would be therapeutically effective. *See, e.g.*, Pet. App. 21a-23a. Yet the court also found disclosures of amounts of PPI that would be "effective" to be insufficient. For instance, the court discounted Example 6, which discloses an exemplary formulation including a specified range of uncoated, immediate-release PPI that was described as the "typical effective amount." *Id.* at 22a-23a. According to the Federal Circuit, this disclosure was insufficient because it was merely an "ipsis verbis" recitation of the claim limitations. *Id.* at 22a. The Federal Circuit thus rejected some disclosures as failing to expressly specify effectiveness while rejecting disclosures of "effective" amounts as insufficient because they used the same language recited in the claims.

Against this backdrop, it is difficult to discern what disclosures *aside from experimental data or a detailed theory* could possibly have satisfied the Federal Circuit that the inventor possessed the claimed invention. The court's opinion creates a heightened written description standard, at least where the patentee successfully establishes that the claims would not have been obvious because they went against prior-art teachings. This standard conflicts with the Federal Circuit's holdings in *Alcon*, *Allergan*, and *Ariad*, and it evidences the division within the Federal Circuit regarding the proper standard for analyzing written description.

II. The Federal Circuit Improperly Conflates Enablement and Written Description

The Federal Circuit improperly imported enablement inquiries into the written description determination, contrary to precedent holding that these inquiries are separate and distinct. *See Ariad*, 598 F.3d at 1351 ("Since its inception, this Court has consistently held that § 112, first paragraph, contains a written description requirement separate from enablement . . . .").

The Federal Circuit has stated unequivocally that written description "is not about whether the patentee has proven to the skilled reader that the invention works, or how to make it work, which is an enablement issue." *Alcon*, 745 F.3d at 1191. Written description instead only asks "whether the skilled reader of the patent disclosure can recognize that what was claimed corresponds to what was described." *Id.*

The Federal Circuit violated its precedents by considering as part of the written description analysis whether a skilled artisan would *believe* the patent's disclosures that certain amounts of uncoated PPI would be effective in the claimed dosage forms. *Alcon* makes clear that that question is instead an enablement question. The district court rejected Respondents' enablement challenge, stating that there "appears to be no serious dispute between the parties that the Asserted Patents disclose how to make and use the claimed invention." Pet. App. 105a. Respondents declined to challenge the district court's enablement holding on appeal.

Although the Federal Circuit blurred the lines between the distinct *legal inquiries*, it disregarded the common facts that support both the district court's enablement holding and its finding that the specification provides written description support for the claimed compositions. The Federal Circuit has recognized that enablement and written description "usually rise and fall together," such that "a recitation of how to make and use the invention across the full breadth of the claim is ordinarily sufficient to demonstrate that the inventor possesses the full scope of the invention, and vice versa." *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005). Here, the specification's disclosure of how to make and use the claimed compositions also shows that the inventor had full possession of the claims, including the notion that the recited amounts of uncoated PPI would be effective to raise gastric pH.

By characterizing a skilled artisan's skepticism as a written description, rather than enablement issue, the Federal Circuit improperly conflated the two statutory requirements and sidestepped the district court's uncontested findings regarding enablement.

III. The Federal Circuit's New Heightened Written Description Requirement Will Disrupt Public Policy and Stifle Innovation

The Federal Circuit's heightened written description standard will harm innovation by imposing a higher burden on inventions that depart from the prior art. This new standard will force innovators to incur significantly more expenses before

being able to obtain patent protection, and thus it will disincentivize innovation. This is especially problematic for the pharmaceutical and biotechnology industries, where new inventions are routinely described in patent applications before efficacy in human patients is proven through clinical trials.

As the Federal Circuit has recognized, the pharmaceutical industry "relies on patent protection in order to recoup the large sums it invests to develop life-saving and life-enhancing drugs." *In re Bilski*, 545 F.3d 945, 1005-06 (Fed. Cir. 2008) (Mayer, J., dissenting). Indeed, it costs an estimated $1.86 billion in out-of-pocket research and development expenses to develop a new pharmaceutical drug, and "fewer than one in five drug candidates that make it out of the laboratory survive this tortuous process and reach the marketplace in the form of FDA-approved pharmaceuticals." *Id.* at 1006 (quoting Jay Dratler, Jr., *Alice in Wonderland Meets the U.S. Patent System,* 38 Akron L. Rev. 299, 313-14 (2005)); *see also* Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. of Health Econ. 20, 31 (May 2016). Given these costs, the Federal Circuit has acknowledged that "[o]nly patent protection can make the innovator's substantial investment in development and clinical testing economically rational." *Bilski*, 545 F.3d at 1006 (quoting Dratler, 38 Akron L. Rev. 313-14).

The promise of patent protection similarly drives innovations in the field of diagnostic medicine, where inventions are "very expensive to develop but relatively cheap to reproduce." *Athena Diagnostics,*

Inc. v. Mayo Collaborative Servs., LLC, 927 F.3d 1333, 1356 (Fed. Cir. 2019) (Moore, J., dissenting) (citation omitted). Industry leaders in this field "make clear that absent dependable patent protection, companies will not move forward with diagnostic innovations." *Id.* As a result, the Federal Circuit has recognized that "[w]ithout the possibility of patent protection to recoup the high costs of research and development associated with diagnostic techniques and kits, the impact can only be that there will be fewer advances in diagnostic medicine." *Id.*

The Federal Circuit has recognized that, if experimental data were necessary before patent filing, "the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas . . . ." *In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995). Under the Federal Circuit's new written description standard, innovators will be forced to choose whether to file a patent application before completing all testing, such as clinical trials, risking the result here, or instead delay filing until after testing and risk losing patent protection.

The Federal Circuit's new heightened standard disregards these longstanding policy considerations and will harm the most innovative technological developments. Under the new written description standard, the more an invention differs from the prior art, the more experimental data or detailed theory must be included to overcome a skilled artisan's skepticism that the claimed invention will work. As a

result, the Federal Circuit's new standard will disproportionately harm the most innovative new developments, which face the most skepticism for their great departure from the prior art. This is directly contrary to the goal the patent system is designed to foster.

* * * * *

The Federal Circuit's decision creates a heightened written description standard requiring either experimental data proving efficacy or a detailed explanation of why the claimed invention would work. This standard reveals a division within the Federal Circuit, with some panels departing from the long-standing precedent stating that such disclosures are not required. It also improperly conflates the written description and enablement inquiries, which are two distinct legal requirements, and will disproportionately harm the most novel inventions.

CONCLUSION

For these reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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OCTOBER 2019