17-2473, 17-2481, 17-2484, 17-2486,
17-2489, 17-2491, 17-2492, 17-2493

IN THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

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

Plaintiffs-Cross-Appellants,

v.

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

Defendants-Appellants,

LUPIN LTD., LUPIN PHARMACEUTICALS, INC.,

Defendants-Appellees.

Appeals from the United States District Court for the District of New Jersey in Nos. 3:11-cv-02317-MLC-DEA, 3:13-cv-00091-MLC-DEA, 3:13-cv-04022-MLC-DEA, Judge Mary L. Cooper.

PETITION FOR REHEARING EN BANC

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June 14, 2019

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Nuvo Pharmaceuticals **v.** Dr. Reddy's Laboratories Inc.

Case No. 17-2473

THIRD AMENDED CERTIFICATE OF INTEREST

Counsel for the:
☐ (petitioner) ■ (appellant) ☐ (respondent) ☐ (appellee) ☐ (amicus) ☐ (name of party)

Horizon Medicines LLC (cross-appellant)

certifies the following (use "None" if applicable; use extra sheets if necessary):

1. Full Name of Party Represented by me	2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:	3. Parent corporations and publicly held companies that own 10% or more of stock in the party
Horizon Medicines LLC	Horizon Medicines LLC	Horizon Pharma plc

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

Danielle C. Pfifferling of Finnegan, Henderson, Farabow, Garrett & Dunner LLP; John E. Flaherty, Ravin R. Patel, and Guillermo C. Artiles of McCarter &English, LLP; Susan M. Krumplitsch, and Ellen A. Scordino of Cooley LLP.

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. *See* Fed. Cir. R. 47. 4(a)(5) and 47.5(b). (The parties should attach continuation pages as necessary).

Pozen Inc. v. Dr. Reddy's Laboratories Inc., Appeal 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); Pozen, Inc. v. Actavis Laboratories FL, Inc., Appeal No. 17-1604 (the additional cases included are: Nos. 17-1605, 17-1606, 17-1607, 17-1608, 17-1610, 17-1611, 17-1612, 17-1613, 17-1614, 17-1615 & 17-1616); Horizon Pharma, Inc. at al. v. Dr. Reddy's Laboratories Inc. at al., C.A. Nos. 11-2317 & 13-91 (USDC-DNJ); Horizon Pharma, Inc. et al. v. Lupin Ltd. et al., C.A. No. 11-4275 (USDC-DNJ); Horizon Pharma, Inc. et al. v. Mylan Pharmaceuticals et al., C.A. No. 13-4022 (USDC-DNJ); Horizon Pharma, Inc. et al. v. Actavis Laboratories FL., Inc. et al, C.A. Nos. 13-3038, 15-3322, 15-8523, 15-8524, 16-426 & 16-4916 (USDC-DNJ).

4/10/2019
Date

/s/ James B. Monroe
Signature of counsel

Please Note: All questions must be answered

James B. Monroe
Printed name of counsel

cc: Counsel of Record

Reset Fields

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Nuvo Pharmaceuticals (Ireland) Designated Activity Company, et al **v.** Dr. Reddy'sLaboratories Inc., et al

Case No. 17-2473

CORRECTED
CERTIFICATE OF INTEREST

Counsel for the:
☐ (petitioner) ■ (appellant) ☐ (respondent) ☐ (appellee) ☐ (amicus) ☐ (name of party)

Nuvo Pharmaceuticals (Ireland) Designated Activity Company, (Cross Appellant)

certifies the following (use "None" if applicable; use extra sheets if necessary):

1. Full Name of Party Represented by me	2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:	3. Parent corporations and publicly held companies that own 10% or more of stock in the party
Nuvo Pharmaceuticals (Ireland)	NONE	Nuvo Pharmaceuticals Inc.
Designated Activity Company		wholly owns Nuvo Pharmaceuticals (Ireland)
		Designated Activity Company. Nuvo Pharmaceuticals Inc. is a
		public company listed on the Toronto Stock Exchange

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

Baker Botts L.L.P.: Stephen Hash, Jeffrey Gritton

FORM 9. Certificate of Interest

Form 9
Rev. 10/17

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. See Fed. Cir. R. 47. 4(a)(5) and 47.5(b). (The parties should attach continuation pages as necessary).

Pozen Inc. v. Dr. Reddy's Laboratories Inc., Appeal 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); Pozen, Inc. v. Actavis Laboratories FL, Inc., Appeal No. 17-1604 (the additional cases included are: Nos. 17-1605, 17-1606, 17-1607, 17-1608, 17-1610, 17-1611, 17-1612, 17-1613, 17-1614, 17-1615 & 17-1616); Horizon Pharma, Inc. at al. v. Dr. Reddy's Laboratories Inc. at al., C.A. Nos. 11-2317 & 13-91 (USDC-DNJ); Horizon Pharma, Inc. et al. v. Lupin Ltd. et al., C.A. No. 11-4275 (USDC-DNJ); Horizon Pharma, Inc. et al. v. Mylan Pharmaceuticals et al., C.A. No. 13-4022 (USDC-DNJ); Horizon Pharma, Inc. et al. v. Actavis Laboratories FL., Inc. et al, C.A. Nos. 13-3038, 15-3322, 15-8523, 15-8524, 16-426 & 16-4916 (USDC-DNJ).

01/15/2019
Date

/s/Stephen M. Hash
Signature of counsel

Please Note: All questions must be answered

Stephen M. Hash
Printed name of counsel

cc: All Counsel of Record - See Attached

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STATEMENT OF COUNSEL

Based on my professional judgment, I believe the panel decision is contrary to the following decision(s) of the Supreme Court of the United States or the precedent(s) of this Court:

- *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293 (Fed. Cir. 2015)
- *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180 (Fed. Cir. 2014)
- *Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co.*, 598 F.3d 1336 (Fed. Cir. 2010) (en banc)

/s/ *James B. Monroe*
James B. Monroe
Attorney of record for Plaintiff-Cross-Appellant Horizon Medicines LLC

I. PRELIMINARY STATEMENT

The panel's opinion upends years of this Court's written description precedent. The panel held that, where a patentee prevails on obviousness by proving 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.

This opinion creates a heightened written description standard that contradicts this Court's precedents stating that a patent specification must only show that the inventor had possession of the claimed invention and *does not* need to disclose data

proving efficacy or explain why an invention will work. *See, e.g.*, *Alcon*, 745 F.3d at 1190-91; *Allergan*, 796 F.3d at 1309; *Ariad*, 598 F.3d at 1351-52. Indeed, an invention need not actually be reduced to practice before filing. *Ariad*, 598 F.3d at 1352.

Although the panel acknowledged these precedents, it nonetheless declined to follow them. Instead, it reversed the district court's written description finding based on the absence of experimental data or detailed theory in the patent specification to overcome teaching away in the prior art. This decision departs from this Court's clear guidance 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. It also improperly flips the clear-and-convincing burden, forcing patentees to prove their claims are not invalid.

The panel's heightened written description standard will harm innovation by imposing a higher burden on the most novel inventions. This is particularly true for pharmaceutical and biotechnology companies, who often must describe inventions in patent applications long before establishing efficacy in humans through expensive and time-consuming clinical trials. Requiring not only proof that the inventor possessed the claimed invention, but also data showing that it is effective, may thus discourage these companies from pursuing important new therapies. Worse, the panel's new written description standard will disproportionately harm the most

innovative drugs, which often reflect the greatest departure from the conventional wisdom and thus face the strongest skepticism in the field. The more an invention diverges from prior-art approaches, the more experimental data will be required to overcome any teaching away or skepticism.

The panel erred by creating a new, heightened written description standard that conflicts with this Court's precedents. En banc consideration is needed to maintain the uniformity of this Court's written description decisions.

II. STATEMENT OF FACTS

A. The Claimed Pharmaceutical Compositions

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 an enteric coating that prevents its release below pH 3.5; and (2) an uncoated proton pump inhibitor ("PPI"), at least some of which releases immediately. These dosage forms were designed to reduce the incidence of gastrointestinal toxicity caused by NSAIDs, which was thought to occur due to acidic conditions in the gastrointestinal tract.

At the time of invention, others had tried many unsuccessful approaches to reducing gastrointestinal injury by combining an NSAID with an acid inhibitor, such as an enteric-coated PPI. The patents-in-suit disclose the shortcomings of these approaches. For example, enteric-coated PPIs may not take full effect for several

hours, or even days, and thus did not inhibit acid fast enough to alleviate gastrointestinal injury. Despite this problem, no one ever suggested using uncoated PPI. On the contrary, the prior art taught that PPIs must be enteric coated to prevent degradation by stomach acid and taught away from using uncoated PPI.

The inventor conceived of a novel way to reduce gastrointestinal side effects by bucking this conventional wisdom, combining an enteric-coated NSAID with an immediate-release, *uncoated* PPI. These dosage forms were designed to permit coordinated release of the two drugs, such that the uncoated PPI would immediately release and begin neutralizing stomach acid, and the enteric-coated NSAID would release only at a pH where risk of gastrointestinal injury would be reduced. Despite the prior-art teachings that uncoated PPIs would not be effective, the inventor reasoned that using an uncoated, immediate-release PPI would allow him to get "the right amount of acid inhibition at the right time when you're going to deliver this pain reliever." Appx9926[41:4-13].

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

> 1. 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

[1] Although the '907 and '285 patent claims differ, the panel did not distinguish between them on appeal.

> (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 of the medium.

Appx213[22:8-18].

The patent specification's disclosures show both that the inventor possessed the idea of using uncoated PPI *and* that doing so would be effective. For example, they state that the invention involves "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" with an NSAID. Appx204[3:11-20]. The specification further states that the claimed compositions "contain[] an acid inhibitor present in an amount effective to raise the gastric pH of a patient to at least 3.5 . . . when one or more unit dosage forms are administered." Appx204[3:29-33]. The specification identifies PPIs such as omeprazole and esomeprazole as "preferred agents that may be effectively used as acid inhibitors" in the claimed invention. Appx204[3:44-47].

Not only does the specification disclose that PPIs "may be effectively used," but it also discloses amounts of PPIs that can be used in the claimed dosage forms. It states, for example, that PPIs "will typically be present at about 5 mg to 600 mg

per unit dose." Appx206[8:5-6]. The specification further states that the typical amount of the PPI esomeprazole ranges from 5-100 mg, with about 40 mg being preferred.[2] Appx206[8:5-14].

Example 6 in the specification specifically recites using an "Immediate Release" PPI in combination with an enteric-coated NSAID. Appx210-211[16:1-17:47]. It discloses that the dosage form has a layer containing the PPI omeprazole "in an effective amount which is released from the dosage form as soon as the film coat dissolves." Appx210[16:33-37]. It further discloses that the immediate-release PPI "raises the pH of the gastrointestinal tract to above 4" and that the "*typical effective amount* of omeprazole [PPI] in the dosage form may vary from 5 mg to 50 mg." Appx210[16:35-39] (emphasis added).

The patent specification thus describes not only problems associated with traditional enteric-coated PPIs, but also a specific formulation falling within the claims with immediate-release PPI, including the "typical effective amount" of uncoated PPI. Plaintiffs' experts cited these disclosures in concluding that the specification provided support for every element of the claims. These disclosures

[2] VIMOVO®, the drug covered by the patents-in-suit, is marketed in dosage forms with 20 mg of esomeprazole combined with either 375 or 500 mg of naproxen. The amount of uncoated PPI in the marketed product thus falls squarely within the range disclosed in the patent specifications.

and testimony show that the inventor possessed the claimed invention, including that uncoated PPI would be effective in the claimed dosage forms.

B. The District Court Found That Defendants Failed to Provide Clear and Convincing Evidence That the Specification Did Not Adequately Describe the Uncoated PPI Limitation

Based on these disclosures, the district court found that Defendants failed to satisfy their high burden of proving by clear and convincing evidence that the patents-in-suit lacked written description support for the uncoated PPI limitation. Appx81-84. The court properly applied the standard enunciated in *Ariad*, which requires the specification to convey to a skilled artisan that the inventor possessed the claimed subject matter. 598 F.3d at 1351-52. It rejected Defendants' argument that, if they lost on obviousness because the prior art taught away from using uncoated PPI, then the patents-in-suit lack written description support for that limitation because a skilled artisan would not have expected uncoated PPI to work. Appx81-84. The court concluded that, contrary to Defendants' arguments, the specification did not need to disclose experimental data proving the efficacy of uncoated PPIs or a detailed theory about why uncoated PPIs would work, and thus that Defendants failed to carry their burden of establishing lack of written description. Appx83.

III. ARGUMENT IN SUPPORT OF REHEARING EN BANC

A. Requiring Experimental Data Showing Efficacy or a Theory of Why the Invention Will Work Conflicts with the Court's Precedents in *Alcon*, *Allergan*, and *Ariad*

Contrary to this Court's precedents, the panel reversed the district court's written description finding because the patent specification does not contain experimental data demonstrating effectiveness or a more detailed theory of why the claimed compositions would work. The panel accepted Defendants' argument that, if the prior art would have led a skilled artisan to be skeptical that uncoated PPI would work, the patents must lack written description because they allegedly lack experimental data or a detailed theory to overcome this teaching away and persuade the skilled artisan the uncoated PPI in the claimed invention would be effective. Slip op. 18. The panel stated, for example, that the inventor failed to show possession of the claimed invention because a skilled artisan "would not have expected uncoated PPI to raise gastric pH." Slip op. 24.

Despite recognizing this Court's precedents holding that neither experimental data nor a detailed theory is required, the panel stated that "[n]evertheless, . . . the record evidence demonstrates that a person of ordinary skill in the art would not have known or understood that uncoated PPI is effective." Slip op. 18. The panel thus concluded that "there is nothing in the specification of the patents-in-suit showing

'that the inventor *actually invented* the invention claimed.'" Slip op. 18-19 (citation omitted).

The panel improperly enacted a new written description standard requiring either experimental data or a detailed theory of why the invention will work, at least for inventions that overcome obviousness based on skepticism in the field or a lack of reasonable expectation of success. In doing so, the panel's opinion contradicts the very cases it cites, which hold that written description does not require experimental data, working examples, a detailed theory of why the invention will work, or an actual reduction to practice. The panel acknowledged, for example, that "[i]t is true that our case law does not require experimental data demonstrating effectiveness." Slip op. 18 (citing *Allergan*, 796 F.3d at 1309). Indeed, *Allergan* explains that there "is no rigid requirement that the disclosure contain 'either examples or an actual reduction to practice' . . . ." 796 F.3d at 1308 (quoting *Ariad*, 598 F.3d at 1352). Again citing *Allergan*, the panel similarly acknowledged that written description "does not require theory or explanation of how or why a claimed composition will be effective." Slip op. 18 (citing *Allergan*, 796 F.3d at 1308-09). Instead, it requires only that a patent's disclosure "allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 323 F.3d 956, 968 (Fed. Cir. 2002).

Allergan presents very similar facts to those here, further demonstrating the panel's departure from this Court's precedents. In *Allergan*, a generic drug company argued that pharmaceutical composition claims lacked written description because the specification "does not disclose any efficacy . . . data of a formulation" within the claims. 796 F.3d at 1308. The company alternatively framed this as an enablement challenge, arguing that "the specifications contain no actual efficacy . . . data; rather they merely provide a research proposal." *Id.* at 1309-10. It thus argued that, "if the claims are held to be nonobvious, then they must fail the enablement requirement because the district court found . . . that the prior art taught away from the claimed invention." *Id.* at 1310.

The Court rejected these challenges and concluded that the district court did not err in finding that the specification provided adequate written description and that the generic company failed to prove nonenablement. Even though the challenged claims recited certain clinical effects (e.g., "*lowers intraocular pressure and results in less hyperemia*," *id.* at 1300), the Court nonetheless held that "efficacy data are generally not required in a patent application. Only a sufficient description enabling a [skilled artisan] to carry out an invention is needed." *Id.* at 1310. *Allergan* establishes that where, as here, a patent claims pharmaceutical compositions that are effective and the specification discloses an example of a formulation within the scope of the claim, including amounts of both components

that will be "effective," the patent's disclosures allow a skilled artisan to "recognize the identity" of the claimed dosage forms. No more is needed. The panel's opinion requires disclosures that *Allergan* expressly says are not required.

The panel similarly cited, but declined to follow, the Court's decision in *Alcon*. Slip op. 21-22. As in *Allergan*, the Court in *Alcon* stated that, to establish written description, there is "no requirement that the disclosure contain 'either examples or an actual reduction to practice." 745 F.3d at 1190-91. Even though the claims in *Alcon* required a "therapeutically-effective amount" of a drug, the Court nonetheless explained 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." *Id.* at 1191. Instead, the written description inquiry asks whether a skilled artisan "can recognize that what was claimed corresponds to what was described." *Id.* (citing *Ariad*, 598 F.3d at 1352).

The panel contravened the Court's precedent in *Alcon* by requiring disclosure sufficient to overcome a skilled artisan's skepticism caused by prior-art teachings that uncoated PPI would not be effective. Slip op. 18 ("[T]he record evidence demonstrates that a person of ordinary skill would not have known or understood that uncoated PPI is effective."). The panel further characterized the specification's disclosures, including of "effective" amounts of immediate-release (uncoated) PPI, as "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." Slip op. 19 (emphasis added). And the panel stated that the specification's alleged failure to overcome this skepticism made it "fatally flawed." *Id.* This reasoning directly contradicts *Alcon*'s recitation of the correct written description standard, which does not require a patent to persuade a skilled artisan that the claimed invention would be effective.

The conflicting statements in the panel's opinion demonstrate that only clinical data showing effectiveness of uncoated PPI or a detailed theory of the invention could satisfy the panel's heightened written description standard. The panel concluded that the disclosures of specific amounts of PPI that are "typical" were insufficient because the specification does not disclose that those amounts would be therapeutically effective. *See, e.g.*, slip op. 17-18. On the other hand, the panel discounted Example 6, which discloses an exemplary formulation with a specific range of "Immediate Release" (i.e., uncoated) PPI described as a "typical effective amount." According to the panel, the disclosure in Example 6 that a specific range of uncoated PPI will be "effective" also fails because it is simply an ipsis verbis recitation of what is in the claim. Slip op. 18.

The panel thus found some portions of the specification insufficient because they recite amounts of PPI without explaining that they would be "therapeutically effective," while it found other disclosures insufficient because their recitation of

specific "effective" amounts of uncoated PPI simply repeated what is in the claim. Against this backdrop, it is difficult to discern what disclosures *aside from experimental data or a detailed theory* could possibly have shown that the inventor possessed the claimed invention. The panel's opinion thus creates a heightened burden for written description, at least where a patentee successfully argues that the claims would not have been obvious because they went against prior-art teachings. This heightened burden conflicts with the Court's prior holdings in *Allergan* and *Alcon* and deviates from the proper standard recited in *Ariad*.

B. The Panel Opinion Contradicts *Alcon*'s Guidance That Whether a Skilled Artisan Would Believe a Claimed Invention Would Work Goes to Enablement, Not Written Description

The panel's opinion further conflicts with *Alcon* by characterizing the question of whether a skilled artisan would believe that a claimed invention would work as a written description issue rather than an enablement issue. 745 F.3d at 1191 (stating 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"). As discussed above, the written description standard in *Ariad* asks whether a skilled artisan would understand that the inventor had possession of the claimed invention, not whether that invention would work. The panel's inquiry into whether the specification's disclosures overcame a skilled artisan's skepticism thus should not have been considered as part of the written description analysis.

This error is particularly harmful because, here, the district court held that the patents were enabled, 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." Appx79. Defendants declined to challenge that holding on appeal.

Further, to the extent that the written description and enablement inquiries overlap in certain instances, the same disclosures that the district court found taught a skilled artisan how to make and use the claimed compositions show that the inventor had possession of those compositions. Indeed, as this Court has held, "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 disclosure of how to make and use the claimed compositions *also* shows that the inventor had possession of the full scope of the claims. A skilled artisan would have known *exactly* what the inventor was claiming because the specification teaches how to make the claimed compositions and use them to reduce gastrointestinal injury. These disclosures show that the inventor possessed both the idea of making the claimed compositions, including uncoated PPI, and that using them would be effective.

This is not the type of case where the specification enables, but fails to sufficiently describe, an overbroad genus containing a vast number of species. In such cases, the Court has concluded that the scope of the right to exclude "overreach[es] the scope of the inventor's contribution to the field of art as described in the patent specification" because the claims cover a broad genus, but the inventor only describes a small number of species that is insufficient to describe the full genus. *AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1299 (Fed. Cir. 2014) (quoting *Ariad*, 598 F.3d at 1353-54). Here, by contrast, the claims recite compositions with two ingredients: enteric-coated NSAID and uncoated PPI. They thus bear little resemblance to cases where a claimed genus containing thousands or even millions of species is supported by disclosure of no more than a handful of species. Here, a skilled artisan could immediately envision the full scope of the claims and would understand that the inventor was claiming a dosage form combining enteric-coated NSAID with immediate-release, uncoated PPI that would accomplish the patents' goal of reducing gastrointestinal injury.

C. This Decision Imperils Numerous Patents, Particularly in the Pharmaceutical and Biotechnology Fields

The panel's heightened written description standard will harm innovation by imposing a higher burden on inventions that depart from the prior art and thus are nonobvious. It will especially hurt biotechnology and pharmaceutical companies by impairing their ability to patent important new drugs. Inventions in these fields are

routinely described in patent applications before efficacy in humans is proven through clinical trials. Indeed, countless pharmaceutical patents claim using a safe and effective amount of a composition, even though clinical testing is not complete.

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) (en banc) (Mayer, J., dissenting). As the Court has recognized, "[o]nly patent protection can make the innovator's substantial investment in development and clinical testing economically rational." *Id.* (quoting Jay Dratler, Jr., *Alice in Wonderland Meets the U.S. Patent System*, 38 Akron L. Rev. 299, 313–14 (2005)). This substantial investment—an estimated $1.86 billion in out-of-pocket research and development expenses—takes on even greater significance because "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.*; *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).

As the Court has recognized, 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). The panel's new written description standard will force companies to choose whether to file a patent application before completing clinical trials, risking the result here, or instead delay filing until after clinical trials and risk losing patent protection for their invention.

More problematic still, the panel's holding requires pharmaceutical patent owners to meet a higher burden on written description when they succeed in proving nonobviousness, which the district court in this case recognized as a "catch-22." The more an invention differs from the prior art, the more experimental data the specification must disclose to overcome teaching away and prove to a skilled artisan that the invention will work. As a result, the panel's opinion will disproportionately harm the most innovative new drugs by imposing a higher written description burden on inventions that reflect the greatest departure from conventional wisdom, and thus face the greatest skepticism.

IV. CONCLUSION

The panel's decision creates a heightened written description standard requiring either experimental data proving effectiveness or detailed theory of why a claimed invention would work. It conflicts with this Court's precedents stating that such disclosures are not required. The en banc Court should rehear this case to resolve the conflict between this opinion and *Allergan*, *Alcon*, *Ariad*, and other similar cases.

Date: June 14, 2019

Respectfully submitted,

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ADDENDUM

United States Court of Appeals for the Federal Circuit

NUVO PHARMACEUTICALS (IRELAND) DESIGNATED ACTIVITY COMPANY, HORIZON MEDICINES LLC,
Plaintiffs-Cross-Appellants

v.

DR. REDDY'S LABORATORIES INC., DR. REDDY'S LABORATORIES, LTD., MYLAN, INC., MYLAN PHARMACEUTICALS INC., MYLAN LABORATORIES LIMITED,
Defendants-Appellants

LUPIN LTD., LUPIN PHARMACEUTICALS, INC.,
Defendants-Appellees

2017-2473, 2017-2481, 2017-2484, 2017-2486, 2017-2489, 2017-2491, 2017-2492, 2017-2493

Appeals from the United States District Court for the District of New Jersey in Nos. 3:11-cv-02317-MLC-DEA, 3:13-cv-00091-MLC-DEA, 3:13-cv-04022-MLC-DEA, Judge Mary L. Cooper.

Decided: May 15, 2019

JAMES B. MONROE, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Washington, DC, argued for

plaintiffs-cross-appellants. Plaintiff-cross-appellant Horizon Medicines LLC also represented by CHARLES COLLINS-CHASE.

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ANDREW DUFRESNE, Perkins Coie LLP, Madison, WI, argued for all defendants-appellants. Defendants-appellants Mylan, Inc., Mylan Pharmaceuticals Inc., Mylan Laboratories Limited also represented by AUTUMN N. NERO; DAN L. BAGATELL, Hanover, NH; SHANNON BLOODWORTH, Washington, DC.

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Before PROST, *Chief Judge*, CLEVENGER and WALLACH, *Circuit Judges*.

CLEVENGER, *Circuit Judge*.

Dr. Reddy's Laboratories, Inc., Mylan Pharmaceuticals, and Lupin Pharmaceuticals (collectively, "the Generics") appeal from the final judgment of the United States District Court for the District of New Jersey following a bench trial upholding the asserted claims of U.S. Patent Nos. 6,926,907 ("the '907 patent") and 8,557,285 ("the '285 patent") as nonobvious under 35 U.S.C. § 103, enabled

under 35 U.S.C. § 112, and adequately described under § 112. Nuvo Pharmaceuticals, Inc. and Horizon Pharma (collectively, "Nuvo") cross-appeal from the district court's grant of summary judgment of noninfringement to Dr. Reddy's, concluding that one of its drug products will not infringe the claims of the '907 patent. For the reasons set forth below, we reverse the appeal and dismiss the cross-appeal.

BACKGROUND

I

Non-steroidal anti-inflammatory drugs, also known as NSAIDs, control pain. Common NSAIDs include, among others, aspirin and naproxen. While NSAIDs control pain, they also have the undesirable side effect of causing gastrointestinal problems such as ulcers, erosions, and other lesions in the stomach and upper small intestine. Some theorize that the undesirable side effect is tied to the combination of NSAID with the presence of acid in the stomach and upper small intestine. So, to treat the side effect, some practitioners began prescribing acid inhibitors to be taken by a patient along with the NSAID. The NSAID treats the pain while the acid inhibitor reduces the acidity in the gastrointestinal tract, which is achieved by increasing the pH level in the tract. Common acid inhibitors include, among others, proton pump inhibitors ("PPIs") like omeprazole and esomeprazole.

The combination therapy had complications. First, stomach acid degraded the PPI before it could reach the small intestine. To fix that issue, an enteric coating that wears off after a certain amount of time has elapsed was placed around the PPI. Second, if the NSAID was released before the acid inhibitor had enough time to raise the pH level in the tract, patients would continue to suffer gastrointestinal damage. To address those complications, Dr. John Plachetka invented a new drug form that coordinated the release of an acid inhibitor and an NSAID in a single

tablet. The tablet contained a core of an NSAID like naproxen in an amount effective to treat pain, an enteric coating around the NSAID that prevents its release before the pH increases to a certain desired level, and an acid inhibitor like PPI around the outside of the enteric coating that actively works to increase the pH to the desired level. Dr. Plachetka's invention contemplates using some amount of uncoated PPI to allow for its immediate release into a patient's stomach and upper small intestine. Dr. Plachetka recognized problems associated with uncoated PPI, namely that without a coating, the PPI is at risk of destruction by stomach acid—thereby undermining the therapeutic effectiveness of the PPI.

Dr. Plachetka received the '907 patent on his invention, which he assigned to Pozen Inc. He also received the '285 patent, which is a division of an abandoned application that was a division of another application that itself was a continuation-in-part of the application that resulted in the '907 patent. The '285 patent is also assigned to Pozen. The two patents bear the same title, "Pharmaceutical Compositions for the Coordinated Delivery of NSAIDs," and have nearly identical specifications.

Claim 1 of the '907 patent and claim 1 of the '285 patent are representative. They read as follows:

> 1. A pharmaceutical composition in unit dosage form suitable for oral administration to a patient, comprising:
>
> > (a) an acid inhibitor present in an amount effective to raise the gastric pH of said patient to at least 3.5 upon the administration of one or more of said unit dosage forms;
> >
> > (b) a non-steroidal anti-inflammatory drug (NSAID) in an amount effective to reduce or eliminate pain or inflammation in said

> patient upon administration of one or more of said unit dosage forms;
>
> and wherein said unit dosage form provides for coordinated release such that:
>
> i) said NSAID is surrounded by a coating that, upon ingestion of said unit dosage form by said patient, prevents the release of essentially any NSAID from said dosage form unless the pH of the surrounding medium is 3.5 or higher;
>
> ii) at least a portion of said acid inhibitor is not surrounded by an enteric coating and, upon ingestion of said unit dosage form by said patient, is released regardless of whether the pH of the surrounding medium is below 3.5 or above 3.5.

'907 patent col. 20 ll. 9–32.

> 1. 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 of the medium.

'285 patent col. 22 ll. 9–19.

The shared specification discloses that the invention "is directed to a pharmaceutical composition in unit dosage form suitable for oral administration to a patient" that "contains an acid inhibitor present in an amount effective to raise the gastric pH of a patient to at least 3.5, preferably to at least 4, and more preferably to at least 5, when one or more unit dosage forms are administered." '907 patent col. 3 ll. 19–25.[1] It discloses exemplary acid inhibitors like PPIs, which the patents teach includes omeprazole and esomeprazole. It recites amounts of omeprazole between 5 and 50 mg and amounts of esomeprazole between 5 and 100 mg, "with about 40 mg per unit dosage form being preferred." *Id.* at col. 7 ll. 9–13. The specification discloses that "[t]he pharmaceutical composition also contains a non-steroidal anti-inflammatory drug in an amount effective to reduce or eliminate pain or inflammation." *Id.* at col. 3 ll. 39–41. It provides that "[t]he most preferred NSAID is naproxen 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 col. 3 ll. 48–50.

The specification teaches methods for preparing and making the claimed drug formulations, including in tablet dosage forms. It provides examples of the structure and ingredients of the drug formulations that comport with the invention. It is undisputed that there is no experimental data demonstrating the therapeutic effectiveness of any amount of uncoated PPI and coated NSAID in a single dosage form. Appellant's Opening Br. 23, 33; Appellee's Resp. Br. 35, 43; Oral Arg. at 34:08–40, http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2017-2473.mp3. Furthermore, although the specification expressly provides that PPIs are "enteric coated to avoid destruction by

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[1] Because the '907 and '285 patents have nearly identical specifications, we cite to the '907 patent only unless stated otherwise.

stomach acid," there is no alternative disclosure explaining that uncoated PPI could still be effective to raise pH. '907 patent col. 2 l.6; Oral Arg. at 34:08–39:28.

Pozen ultimately sold its rights to the '907 and '285 patents to Nuvo Pharmaceuticals, and Horizon Pharma maintained its previously obtained license under those patents. Nuvo makes and sells a drug called Vimovo®, which is a commercial embodiment of the '907 and '285 patents. The Generics want to market a generic version of Vimovo®. They submitted Abbreviated New Drug Applications ("ANDAs") to the U.S. Food and Drug Administration ("FDA") seeking approval to market products covered by the claims of the '907 and '285 patents. Dr. Reddy's also submitted a second ANDA covering a product slightly different than Vimovo® because it contains a small amount of uncoated NSAID in the outer layer of the tablet, which is separate from the enteric-coated NSAID that releases only when the pH rises to about 5.5.

II

Nuvo sued the Generics in the United States District Court for the District of New Jersey to prevent their ANDA products from going to market, if approved, before the expiration of the '907 and '285 patents. Nuvo alleged that all the Generics' ANDA products will infringe claims 5, 15, 52, and 53 of the '907 patent and claims 1–4 of the '285 patent.[2] The Generics stipulated to infringement, except with respect to Dr. Reddy's second ANDA product, which it alleged will not infringe the claims of either patent. The Generics defended against the infringement assertions by alleging that the asserted patents are invalid as obvious over the prior art under 35 U.S.C. § 103 and for lack of enablement and an adequate written description under 35 U.S.C. § 112.

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[2] All the asserted claims of the '907 and '285 patents are dependent on claim 1 of those respective patents.

Dr. Reddy's moved for summary judgment of noninfringement, arguing that its second ANDA product does not infringe the asserted claims of the '907 patent. It argued that, because the claims of the '907 patent prevent "essentially any NSAID" from being released from the unit dosage form until the pH reaches at least 3.5, its second ANDA product containing some amount of NSAID in the outer layer that is released immediately, regardless of the pH, cannot infringe those claims. Nuvo countered that the phrase "essentially any NSAID" in the claim language prevents only NSAID in the core of the tablet from being released before the pH rises to 3.5 or higher and that the claimed invention allows for a small amount of additional NSAID to be released immediately. The district court agreed with Dr. Reddy's and granted its summary judgment motion.

The court then held a six-day bench trial on the validity of the '907 and '285 patents, as well as Dr. Reddy's contention that its second ANDA product does not infringe the asserted claims of the '285 patent. It concluded that none of the asserted claims are obvious over the prior art because it was nonobvious to use a PPI to prevent NSAID-related gastric injury, and persons of ordinary skill in the art were discouraged by the prior art from using uncoated PPI and would not have reasonably expected it to work. It also determined that the asserted claims of both patents are enabled because the specification teaches how to make and use the invention and expert testimony demonstrated that an ordinarily skilled artisan would have accepted the usefulness of an NSAID–PPI combination therapy for treating pain.

The district court went on to reject all three of the Generics' written description arguments. First, the court rejected the "comprising" written description argument. The Generics argued that, because of the "comprising" language in the '285 patent's claims, they allow for the drug formulation to include some uncoated naproxen that is

released immediately regardless of the pH, which is not supported by the specification and goes against the concept of coordinated release that is at the heart of the patent's invention. The court disagreed because it viewed uncoated naproxen as a less preferred embodiment of the claimed invention and thus found that the invention was supported by the general disclosure in the specification.

Second, the district court rejected the "inhibit" written description argument. The Generics contended that, although the patent discloses only delayed release formulations, the claims of the '285 patent recite a broader undescribed invention, namely sustained release as opposed to coordinated release of naproxen. That is because the claims cover any formulation having a coating that merely "inhibits" the release of naproxen before the pH reaches 3.5 or higher, which would include sustained release drugs that immediately discharge naproxen albeit at a slower rate than is typical. The court disagreed that the word "inhibits" meant that the claims contemplated sustained release drug formulations and thus concluded that the claims do not lack written description support on that basis.

Third, the district court rejected the "efficacy" written description argument. The Generics argued that, if they lose on their obviousness contention, then the claims lack written description support for the claimed effectiveness of uncoated PPI because ordinarily skilled artisans would not have expected it to work and the specification provides no experimental data or analytical reasoning showing the inventor possessed an effective uncoated PPI. Nuvo responded that experimental data and an explanation of why an invention works are not required, the specification adequately describes using uncoated PPI, and its effectiveness is necessarily inherent in the described formulation. The court rejected the notion that effectiveness does not need to be described because it is necessarily inherent in the claimed drug formulation. It also held that the

specification of the '907 and '285 patents did not disclose information regarding the efficacy of uncoated PPI. But the court nonetheless concluded that the claims were adequately described because the specification described the immediate release of uncoated PPI and the potential disadvantages of coated PPI, namely that enteric-coated PPI sometimes works too slowly to raise the intragastric pH. The district court did not explain why the mere disclosure of immediate release uncoated PPI, coupled with the known disadvantages of coated PPI, is relevant to the therapeutic effectiveness of uncoated PPI, which the patent itself recognized as problematic for efficacy due to its potential for destruction by stomach acid.

Finally, the district court held that Dr. Reddy's second ANDA product infringes the claims of the '285 patent because it satisfies all the limitations recited in those claims.

The Generics now appeal the first "comprising" and third "efficacy" written description rulings. They do not appeal the obviousness holding, the enablement decision, or the second "inhibit" written description issue. Nuvo cross-appeals the district court's grant of summary judgment of noninfringement. We have jurisdiction to decide the appeals under 28 U.S.C. § 1295(a)(1).

DISCUSSION

The Generics' appeal and Nuvo's cross-appeal present three main issues. First, the Generics argue that the district court clearly erred when it concluded that the specification of the '907 and '285 patents adequately describes the claimed effectiveness of uncoated PPI. The Generics emphasize the circumstances in which the written description issue arises in this case. The asserted claims recite the therapeutic effectiveness of uncoated PPI, but the prior art taught away from such effectiveness. In those circumstances, the Generics argue that satisfaction of the written description requirement requires either supporting experimental data, or some reason, theory, or alternative

explanation as to why the claimed invention is possessed by the inventor, and that mere recitation of claim language in the specification cannot suffice. Second, the Generics argue that the district court clearly erred when it concluded that the specification of the '907 and '285 patents adequately describes uncoated naproxen. Finally, Nuvo argues that the district court should not have granted summary judgment of noninfringement in favor of Dr. Reddy's because it incorrectly construed the term "essentially any NSAID" in the claims of the '907 patent to prevent even small amounts of uncoated NSAID in the unit dosage form.

Whether a claim satisfies the written description requirement is a question of fact. *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1308 (Fed. Cir. 2015). Therefore, on appeal from a bench trial, we review a written description determination for clear error. *Id.* "Under the clear error standard, the court's findings will not be overturned in the absence of a 'definite and firm conviction' that a mistake has been made." *Scanner Techs. Corp. v. ICOS Vision Sys. Corp. N.V.*, 528 F.3d 1365, 1374 (Fed. Cir. 2008) (quoting *Pfizer, Inc. v. Teva Pharm. USA, Inc.*, 518 F.3d 1353, 1366 (Fed. Cir. 2008)).

Our analysis begins and ends with the "efficacy" written description issue.

I

The written description requirement of 35 U.S.C. § 112, ¶ 1 provides, in pertinent part, that "[t]he specification shall contain a written description of the invention."[3] That requirement is satisfied only if the inventor "convey[s]

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[3] Because the applications resulting in the '907 and '285 patents were filed before the enactment of the Leahy–Smith America Invents Act ("AIA"), Pub. L. No. 112–29, § 4(c), 125 Stat. 284, 296–97 (2011), we apply the pre-AIA version of 35 U.S.C. § 112.

with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention,' and demonstrate[s] that by disclosure in the specification of the patent." *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1348 (Fed. Cir. 2011) (quoting *Carnegie Mellon Univ. v. Hoffmann–La Roche Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008)). "The essence of the written description requirement is that a patent applicant, as part of the bargain with the public, must describe his or her invention so that the public will know what it is and that he or she has truly made the claimed invention." *AbbVie Deutschland GmbH & Co. v. Janssen Biotech, Inc.*, 759 F.3d 1285, 1298 (Fed. Cir. 2014).

The Generics argue that the district court clearly erred when it concluded that the claimed effectiveness of uncoated PPI in the '907 and '285 patents is supported by adequate written description. Their argument is straightforward. The '907 and '285 patents claim uncoated PPI effective to raise the gastric pH to at least 3.5, the district court found upon Nuvo's insistence as part of its obviousness analysis that ordinarily skilled artisans would not have expected uncoated PPIs to be effective, and nothing in the specification would teach a person of ordinary skill in the art otherwise.

Nuvo counters that the district court correctly concluded that the claimed uncoated PPI is supported by adequate written description. It argues that the claims do not require any particular degree of efficacy of the uncoated PPI itself, it is enough that the specification discloses making and using drug formulations containing effective amounts of PPI and NSAID, and experimental data and additional explanations demonstrating the invention works are unnecessary.

The district court held that the Generics failed to prove by clear and convincing evidence that the asserted claims of the '907 and '285 patents are invalid for lack of written

description. But its analysis does not support its conclusion. The district court, after finding that the specification lacks "information regarding the efficacy of uncoated PPIs," said it was enough that the specification described the immediate release of uncoated PPI and the potential disadvantages of enteric-coated PPI formulations. J.A. 82–83. But that disclosure it pointed to in no way provides support for the claimed efficacy of uncoated PPI. Even if the district court thought that it was enough that the patents taught how to make and use drug formulations containing uncoated PPI, it flatly rejected Nuvo's argument "that the efficacy of uncoated PPIs need not be described because it is 'necessarily inherent' in a formulation." J.A. 83. Nevertheless, because we review the district court's decision for clear error, we will scour the record created below for evidence supporting the district court's written description finding.

A

At trial, the parties and the district court understood that the plain words of the patents claim effectiveness of uncoated PPI. Beyond the plain language of the claims, the district court was not asked to define further the effectiveness limitation. The parties and the district court also understood that written description of effective uncoated PPI is required. Nuvo nonetheless for the first time on appeal, and as its lead argument, contends that we can affirm the district court's written description finding because the claims do not recite an efficacy requirement for uncoated PPI. The Generics of course disagree. We read Nuvo's appellate brief as presenting at least five arguments aimed at either recharacterizing the written description dispute or rewriting the claim language. We reject them all as meritless.

Claim 1 of the '907 patent recites "[a] pharmaceutical composition in unit dosage form suitable for oral administration to a patient, comprising: . . . an acid inhibitor

present in an amount *effective to raise the gastric pH of said patient to at least 3.5* upon the administration of one or more of said unit dosage forms" and wherein "at least a portion of said acid inhibitor is not surrounded by an enteric coating . . . ." '907 patent col. 20 ll. 9–29 (emphasis added). Claim 1 of the '285 patent recites "[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 "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 of the medium." '285 patent col. 22 ll. 9–19 (emphasis added). The claim also recites "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," which means the esomeprazole must be acting to raise the pH to effect the release of the naproxen from the dosage form. *Id.* at col. 22 ll. 13–15. Both patents-in-suit therefore recite claims requiring amounts of uncoated PPI effective to raise the gastric pH to at least 3.5. No argument was made below that the claims of the '907 patent should be treated any differently than those of the '285 patent with respect to the efficacy limitation. And the district court treated the claims the same with respect to that limitation. So we do not treat them differently on appeal either.

First, Nuvo argues that there is no requirement that the dosage form as a whole be effective to raise the gastric pH. While we agree, we do not understand the Generics to be arguing that the claims require the entire drug to be effective to raise the gastric pH to a certain level. Instead, the uncoated PPI must effectively do so.

Second, Nuvo contends that the claims do not require an effective amount of the combined uncoated PPI and coated naproxen in a single dosage form, but only amounts

of each component effective on their own. The Generics respond that Nuvo's argument is divorced from the claim as a whole, which requires coordinated release achieved by an effective amount of uncoated PPI that raises the gastric pH to at least 3.5 and an effective amount of naproxen that is released to treat pain when the pH reaches the desired level. Nuvo's argument was not raised below and thus is forfeited. *See TVIIM, LLC v. McAfee, Inc.*, 851 F.3d 1356, 1363 (Fed. Cir. 2017) ("[A] party may not introduce new claim construction arguments on appeal or alter the scope of the claim construction positions it took below. Moreover, litigants waive their right to present new claim construction disputes if they are raised for the first time after trial.").

Third, Nuvo argues that the claims do not require that the uncoated PPI be effective to raise the gastric pH to a certain level, but only that the dosage forms contain an effective amount of uncoated PPI. The Generics disagree. Nuvo forfeited the argument by not raising it below. Additionally, it is nonsensical to read the claims to require effective amounts of uncoated PPI without specifying the result effectively achieved. Claim 1 of the '907 patent expressly states that the PPI, which is uncoated, must be effective to raise the gastric pH to at least 3.5. Claim 1 of the '285 patent at least impliedly requires the same since the naproxen is only released when the pH reaches at least 3.5 and the uncoated esomeprazole is the only other agent available in the dosage form to achieve that goal.

Fourth, Nuvo contends that the '907 patent allows multiple dosage forms rather than a single dosage form to satisfy any perceived efficacy requirement, so the specification does not need to show an effective amount of uncoated PPI in one dosage form. We disagree. As stated above, Nuvo forfeited any argument that the '907 and '285 patents should be treated differently with respect to the efficacy requirement by not raising it to the district court. And the '285 patent does not allow for more than one dosage form.

Even if it were true that the '907 patent allows more than one dosage form to effectively raise the gastric pH to at least 3.5 using uncoated PPI, the specification would still need to provide support for the notion that uncoated PPI is effective.

Last, Nuvo argues that the Examiner interpreted the '907 patent claims as merely requiring certain amounts of PPI and NSAID effective on their own rather than requiring an overall efficacy for the combined drug. The Generics counter that the Examiner never considered the effectiveness of uncoated PPI because it was not a claim limitation at the time of the initial rejection. We already rejected Nuvo's argument that the difference between a dosage form as a whole containing an effective amount of uncoated PPI and an effective amount of uncoated PPI as a component meaningfully impacts the written description analysis. And we also already rejected its argument that the Generics were contending that Nuvo had to demonstrate the overall effectiveness of the entire drug combination. Furthermore, the argument is forfeited because it was not presented below. Finally, the Examiner appears to have interpreted the claims to require an amount of PPI, whether coated or uncoated, effective to raise the gastric pH to the desired level. We agree with that understanding and written description support must be provided for that limitation.

In sum, the parties appear to have assumed before the district court that the claims require a therapeutically effective amount of uncoated PPI that can raise the gastric pH to at least 3.5. We see no reason to change course on appeal. Because the parties' assumption at the trial court is a fair reading of the claim language, we will proceed as everyone did before the district court and search the specification for written description support for the efficacy of uncoated PPI.

B

Nuvo argues that credible expert testimony from its witness, Dr. Williams, identified written description support in the specification for the claimed dosage forms comprising an effective amount of uncoated PPI. Specifically, Nuvo points to Dr. Williams's testimony that every limitation of the asserted claims in the '907 and '285 patents has adequate written description support in the shared specification.

Dr. Williams identified four parts of the specification that he thought provide written description support for amounts of uncoated PPI, and specifically esomeprazole, effective to raise the gastric pH of a patient to at least 3.5. He pointed to the specification's statement that "[t]he composition contains an acid inhibitor present in an amount effective to raise the gastric pH of a patient to at least 3.5." *See* J.A. 10787 (quoting '907 patent col. 3 ll. 21–23), 10797 (similar). He also pointed to the claims themselves for written description support. *See* J.A. 10787 (citing '907 patent col. 20 ll. 9–32, 42–45), 10798 (similar). He then said the sixth example in the specification provides support for uncoated PPI because it includes "omeprazole immediate release" in the title and provides that a layer of the composition embodied in the example "contains an acid inhibitor in an effective amount which is released from the dosage form as soon as the film coat dissolves," where the acid inhibitor is the PPI omeprazole. J.A. 10788–89 (quoting '907 patent col. 14 ll. 40–41, col. 15 ll. 1–3). His last piece of support from the specification was its statement that "[p]roton pump inhibitors will typically be present at about 5 milligrams to 600 milligrams per dose" and "[e]someprazole is 5 to 100 milligrams." J.A. 10798 (quoting '907 patent col. 7 ll. 7–13).

The Generics argue that the parts of the specification Dr. Williams identified are not enough to satisfy the written description requirement. They argue that the

specification provides only typical dosage amounts of uncoated PPI and the use of uncoated PPI in a drug formulation, but it never discusses or explains its efficacy. We agree with the Generics that Dr. Williams's testimony does not identify parts of the specification sufficient to satisfy the written description requirement. The statements he points to recite the claim limitation by simply calling generally for effective amounts of uncoated PPI, but our precedent clearly establishes that is not enough.

We have expressly rejected the "argument that the written description requirement . . . is necessarily met as a matter of law because the claim language appears *in ipsis verbis* in the specification." *Enzo Biochem, Inc. v. Gen–Probe Inc.*, 323 F.3d 956, 968 (Fed. Cir. 2002). We explained that "[t]he appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy" § 112, ¶ 1 because it may not both put others on notice of the scope of the claimed invention and demonstrate possession of that invention. *Id.* at 968–69.

It is true that our case law does not require experimental data demonstrating effectiveness. *Allergan*, 796 F.3d at 1309; *see also In re '318 Patent Infringement Litig.*, 583 F.3d 1317, 1324 (Fed. Cir. 2009) ("Typically, patent applications claiming new methods of treatment are supported by test results. But it is clear that testing need not be conducted by the inventor."). It also does not require theory or explanation of how or why a claimed composition will be effective. *Allergan*, 796 F.3d at 1308–09. Moreover, we have repeatedly stated that the invention does not actually have to be reduced to practice. *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 926 (Fed. Cir. 2004).

Nevertheless, as the Generics point out and Nuvo cannot reasonably dispute, the record evidence demonstrates that a person of ordinary skill in the art would not have known or understood that uncoated PPI is effective. And there is nothing in the specification of the patents-in-suit

showing "that the inventor *actually invented* the invention claimed." *Centocor*, 636 F.3d at 1348 (emphasis added); *accord Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). There must be some description, such as a constructive reduction to practice, establishing that the inventor "was in possession of the . . . claimed invention, including all of the elements and limitations." *Univ. of Rochester*, 358 F.3d at 926 (quoting *Hyatt v. Boone*, 146 F.3d 1348, 1353 (Fed. Cir. 1998)). Patents are not rewarded for mere searches, but are intended to compensate their successful completion. *Ariad*, 598 F.3d at 1353. That is why the written description requirement incentivizes "actual invention," *id.*, and thus "[a] 'mere wish or plan' for obtaining the claimed invention is not adequate written description," *Centocor*, 636 F.3d at 1348 (quoting *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1566 (Fed. Cir. 1997)).

In light of the fact that the specification provides 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, the specification is fatally flawed. It does not demonstrate that the inventor possessed more than a mere wish or hope that uncoated PPI would work, and thus it does not demonstrate that he actually invented what he claimed: an amount of *uncoated* PPI that is *effective* to raise the gastric pH to at least 3.5. That conclusion is confirmed by the inventor's, Dr. Plachetka's, own testimony at trial during which he admitted that he only had a "general concept of coordinated delivery with acid inhibition" using uncoated PPI at the time he filed his first patent application. J.A. 9942, 10000–01. Although Dr. Plachetka said he thought he "put a rationale in [the specification] as to why [uncoated PPI] would work," he did not identify any particular part of the specification supporting that understanding. J.A. 9997. And his only support in the specification for "a rationale explaining why [he] thought the uncoated PPI would be effective for

treating gastric related injury" was that, in its "entire context," he explained "why the coordinated delivery system would be of benefit for patients." *Id.* Although inventor testimony cannot establish written description support where none exists in the four corners of the specification, it illuminates the absence of critical description in this case.[4]

C

Nuvo's final arguments are that it is enough to satisfy the written description requirement that the specification of the '907 and '285 patents teaches how to make and use the claimed invention, and that we should accept the therapeutic effectiveness of uncoated PPI as a matter of

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[4] At oral argument, Nuvo also encouraged us to find written description support for the therapeutic effectiveness of uncoated PPI based on testimony of Dr. Kibbe, the Generics' expert. Oral Arg. at 50:51–52:26. But in that part of the trial transcript Nuvo directed us to, Dr. Kibbe only discussed what the patent claims require and he never testified about the written description support in the specification for the efficacy of uncoated PPI. Furthermore, although Dr. Kibbe later confirmed during his trial testimony that he thought "an enteric-coated NSAID surrounded by an uncoated PPI would be effective for treating chronic pain," his confirmation was ambiguous because he qualified it with "I think I have got that right. I'm not sure." J.A. 10513. Even if we accepted his statement that uncoated PPI would be effective for treating chronic pain, the district court rejected the notion that ordinarily skilled artisans would have used uncoated PPI in its obviousness analysis, and his testimony only speaks to treating pain and not to raising the gastric pH to at least 3.5. Dispositively, Dr. Kibbe's testimony is irrelevant to the written description inquiry, because it does not point to any disclosure in the specification to which the testimony could relate.

inherency. The Generics respond that Nuvo is wrong because that only satisfies the enablement requirement, which is separate and distinct from the written description requirement. As for inherency, the Generics note that the district court rejected that ground for written description support, and assert that Nuvo has not made out a case for inherent disclosure.

1.

Teaching how to make and use an invention does not necessarily satisfy the written description requirement. We have recognized that the enablement requirement, which requires the specification to teach those skilled in the art how to make and use the claimed invention without undue experimentation, is separate and distinct from the written description requirement. *Ariad*, 598 F.3d at 1343–51. And the fact that an invention may be enabled does not mean it is adequately described, and vice versa. *Univ. of Rochester*, 358 F.3d at 921–22. That is because "[t]he purpose of the written description requirement is broader than to merely explain how to 'make and use' [the invention]." *Id.* at 920. The focus of the written description requirement is instead on whether the specification notifies the public about the boundaries and scope of the claimed invention *and* shows that the inventor possessed all the aspects of the claimed invention. *Id.* at 926.

Nuvo cites our decision in *Alcon Research Ltd. v. Barr Laboratories, Inc.*, 745 F.3d 1180 (Fed. Cir. 2014), to support its position that it is enough that the patents teach making and using the claimed combination drug formulation. The Generics argue that case is distinguishable. We agree that *Alcon* does not save the claims of the '907 and '285 patents.

In *Alcon*, patent claims were directed to a method for enhancing the chemical stability of an aqueous solution containing a therapeutically effective amount of a known drug. 745 F.3d at 1184. We held that the claims were

adequately described because the disclosure in the specification demonstrated that the inventor possessed and actually invented the claimed stability enhancing features of the method. *Id.* at 1191. We noted that the patent referenced the unexpected nature of the discovery, gave exemplary formulations, and disclosed data showing stability testing using the claimed invention. *Id.*

The factual circumstances in *Alcon* are markedly different than the facts presented here. Unlike the specification of the patent at issue in *Alcon*, the specification of the '907 and '285 patents does not provide any data showing that uncoated PPI is effective in raising the gastric pH of a patient to at least 3.5. Even though we said in *Alcon* that "written description is about whether the skilled reader of the patent disclosure can recognize that what was claimed corresponds to what was described" and "is not about whether the patentee has proven to the skilled reader that the invention works, or how to make it work," we found that the written description requirement was satisfied at least in part by accelerated stability testing data showing the claimed effect. *Id.* Under those circumstances, it was not necessary for the patentee to demonstrate or otherwise "prove" beyond the data disclosed in the specification that the invention works. Here, there is no similar hook or disclosure in the specification that an ordinarily skilled artisan can rely on to understand that the inventor possessed effective uncoated PPI.

2.

Our case law has recognized that, under a narrow set of circumstances, the written description requirement may be satisfied without an explicit disclosure if the claimed features are necessarily inherent in what is expressly described. *See, e.g.*, *Allergan*, 796 F.3d at 1309 ("A claim that recites a property that is necessarily inherent in a formulation that is adequately described is not invalid as lacking written description merely because the property itself is

not explicitly described."); *Yeda Research & Dev. Co. v. Abbott GmbH & Co. KG*, 837 F.3d 1341, 1345 (Fed. Cir. 2016) ("Under the doctrine of inherent disclosure, when a specification describes an invention that has certain undisclosed yet inherent properties, that specification serves as adequate written description to support a subsequent patent application that explicitly recites the invention's inherent properties."); *cf.* Manual of Patent Examining Procedure § 2163 (9th ed. Rev. 3, Jan. 2018) (recognizing that inherency may satisfy the written description requirement).

Nuvo cites our decision in *Allergan* to support its position that the claimed efficacy of uncoated PPI is necessarily inherent in the specification's explicit disclosure of methods for making and using drug formulations containing uncoated PPI. The Generics contend that, like *Alcon*, *Allergan* is also factually distinguishable. We agree.

In *Allergan*, the patentee claimed a drug combination effective for reducing intraocular pressure that included 0.01% bimatoprost and 200 ppm benzalkonium chloride ("BAK"). 796 F.3d at 1300. But the prior art taught away from the claimed combination of ingredients and the specification did not explicitly describe its clinical efficacy. *Id.* at 1298, 1305–07, 1309. While we upheld the nonobviousness of the claimed invention given the unexpected results of and teaching away from increasing the amount of BAK to decrease the amount of intraocular pressure, we also held that the claims were supported by adequate written description. *Id.* at 1305, 1309. We reasoned that the parties did not dispute that "the inherent properties of a formulation comprising 0.01% bimatoprost and 200 ppm BAK produce the claimed clinical profile." *Id.* at 1309. It was enough that the specification described the formulation, its components, and how to make and use it. *Id.* at 1308–09. Moreover, there were experimental results for similar drug formulations demonstrating a trend in their clinical effectiveness, even if the data were not specifically related to the exact formulation claimed. *Id.* at 1299–300.

Here, unlike in *Allergan*, whether uncoated PPI is inherently effective in raising the gastric pH to at least 3.5 is disputed. And there is no written disclosure that in any way relates to the efficacy of immediately released PPI. Neither party has identified any evidence in the record that uncoated PPI necessarily is effective in a certain amount, consistent with the specification, to raise the gastric pH to 3.5 or higher. Nor can we find any evidence in the record demonstrating the inherency of the claimed feature. That failure of proof thus dooms Nuvo's inherency argument.

D

Written description analyses are highly fact specific. *See Amgen Inc. v. Sanofi*, 872 F.3d 1367, 1377 (Fed. Cir. 2017) ("[E]ach case involving the issue of written description must be decided on its own facts." (alterations and internal quotation marks omitted) (quoting *Noelle v. Lederman*, 355 F.3d 1343, 1349 (Fed. Cir. 2004))); *Vas–Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562 (Fed. Cir. 1991) ("The CCPA's 'written description' cases often stressed the fact-specificity of the issue."). Based on the specific facts of certain cases, it is unnecessary to prove that a claimed pharmaceutical compound actually achieves a certain result. But when the inventor expressly claims that result, our case law provides that that result must be supported by adequate disclosure in the specification. In this case, the inventor chose to claim the therapeutic effectiveness of uncoated PPI, but he did not adequately describe the efficacy of uncoated PPI so as to demonstrate to ordinarily skilled artisans that he possessed and actually invented what he claimed. And the evidence demonstrates that a person of ordinary skill in the art reading the specification would not have otherwise recognized, based on the disclosure of a formulation containing uncoated PPI, that it would be efficacious because he or she would not have expected uncoated PPI to raise gastric pH. Under those facts, the patent claims are invalid for lack of adequate written description pursuant to § 112, ¶ 1.

II

Because we hold that the '907 and '285 patents are invalid for lack of an adequate written description given that the shared specification does not adequately describe the claimed effectiveness of uncoated PPI, we do not need to address the Generics' alternative argument that the patents are also invalid under § 112, ¶ 1 for failing to adequately describe uncoated, immediate release naproxen. Similarly, because we conclude that the asserted claims are invalid, Nuvo's cross-appeal challenging the district court's grant of summary judgment of noninfringement with respect to Dr. Reddy's second ANDA product and the '907 patent is moot.

CONCLUSION

For the reasons stated above, we reverse the district court's determination that the asserted claims of the '907 and '285 patents are not invalid for lack of an adequate written description. Those claims are invalid. We dismiss as moot Nuvo's cross-appeal challenging the district court's grant of summary judgment of noninfringement to Dr. Reddy's with respect to its second ANDA product and the now-invalidated '907 patent claims.

REVERSED AS TO 17-2473, 17-2481, 17-2484, 17-2486; DISMISSED AS TO 17-2489, 17-2491, 17-2492, 17-2493.

COSTS

No costs.

CERTIFICATE OF SERVICE

I hereby certify that I served a copy of the foregoing **PETITION FOR REHEARING EN BANC** on counsel of record on June 14, 2019, by Electronic Means (by E-mail or CM/ECF).

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CERTIFICATE OF COMPLIANCE

This rehearing petition complies with the type-volume limitation of Federal Rule of Appellate Procedure 35(b)(2). This petition contains 3,898 words, excluding the parts of the document that are exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 35(c)(2). This petition complies with the typeface and type style requirements of Federal Rule of Appellate Procedure 32(a) because this motion has been prepared in a proportionally spaced typeface using Microsoft Word in Times New Roman 14-point font.

Dated: June 14, 2019

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