

**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.

STEPHEN M. HASH, Baker Botts, LLP, Austin, TX, for plaintiff-cross-appellant Nuvo Pharmaceuticals (Ireland) Designated Activity Company. Also represented by JEFFREY SEAN GRITTON.

ALAN HENRY POLLACK, Windels Marx Lane & Mitten-dorf LLP, Madison, NJ, argued for all defendants-appellants. Defendants-appellants Dr. Reddy's Laboratories Inc., Dr. Reddy's Laboratories, Ltd. also represented by STUART D. SENDER.

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.

SAILESH K. PATEL, Schiff Hardin LLP, Chicago, IL, for defendants-appellees Lupin Ltd., Lupin Pharmaceuticals, Inc.

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

CLEVINGER, *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

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.

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]

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 ipsius 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

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.