160 F.4th 1305
United States Court of Appeals, Federal Circuit.

DUKE UNIVERSITY, Allergan Sales, LLC, Plaintiffs-Appellees

v.

SANDOZ INC., Defendant-Appellant

2024-1078
|
Decided: November 18, 2025

Synopsis

Background: Owner of patent claiming method of treating hair loss brought action against alleged infringer. After jury found alleged infringer had failed to prove patent invalid and awarded owner $39 million in infringement damages, the United States District Court for the District of Colorado, Raymond P. Moore, J., 2023 WL 9227019, denied alleged infringer's motions for judgment as a matter of law and for a new trial. Alleged infringer appealed.

Holdings: The Court of Appeals, Stark, Circuit Judge, held that:

[1] written description of invention, which was claimed as subgenus of prostaglandin analogs, failed to describe representative number of species of subgenus;

[2] written description failed to satisfy common-structural-features test for adequate written description;

[3] disclosure of prostaglandin hairpin, as common structural feature, failed to identify how hairpin was unique to claimed subgenus, as opposed to entire genus described in patent specification;

[4] disclosure of prostaglandin hairpin failed to provide sufficient guidance to account for variation at action end of structure; and

[5] disclosure of prostaglandin hairpin failed to provide sufficient guidance to account for variation in position occupied by phenyl group.

Reversed.

Procedural Posture(s): On Appeal; Motion for Judgment as a Matter of Law (JMOL)/Directed Verdict.

West Headnotes (16)

[1] **Courts** Particular questions or subject matter

When a district court denies a motion for judgment as a matter of law, the Court of Appeals reviews its decision under the law of that court's regional circuit.

[2] **Federal Courts** Taking case or question from jury; judgment as a matter of law

The Tenth Circuit applies de novo review to a district court's denial of a motion for judgment as a matter of law.

[3] **Federal Courts** Taking case or question from jury; judgment as a matter of law

A district court's refusal to grant judgment as a matter of law may be reversed only if the evidence is such that without weighing the credibility of the witnesses the only reasonable conclusion is in the moving party's favor.

[4] **Patents** Questions of law or fact

Whether a patent provides adequate written description for a claim presents a question of fact. 35 U.S.C.A. § 112(a).

[5] **Patents** Disclosure as directed to one skilled in the art

Patents Possession of claimed invention

A patent provides adequate written description for a claim if the patent specification discloses that a person of ordinary skill in the art would conclude the inventor possessed the full scope of the invention at the time of their patent application. 35 U.S.C.A. § 112(a).

[6] **Patents** Weight and sufficiency

Like all patent invalidity defenses to infringement, lack of adequate written description must be proven by clear and convincing evidence. 35 U.S.C.A. § 112(a).

[7] **Patents** Disclosure as directed to one skilled in the art

Patents Possession of claimed invention

An inventor may obtain a patent only if she discloses the invention to the public, in sufficient enough detail that a person of ordinary skill in the art will understand that the inventor truly possessed the invention as claimed. 35 U.S.C.A. § 112(a).

[8] **Patents** Written Description Requirement

The purpose of the written description requirement for patentability is to prevent a patent applicant from later asserting that he invented that which he did not. 35 U.S.C.A. § 112(a).

[9] **Patents** Genus and species

To satisfy the written description requirement for patentability, the written description of an invention claimed as a genus of chemical compounds requires description not only of the outer limits of the genus but also of either a representative number of members of the genus or structural features common to the members of the genus, in either case with enough precision that a relevant artisan can visualize or recognize the members of the genus. 35 U.S.C.A. § 112(a).

[10] **Patents** Particular products or processes

Written description of invention claimed as subgenus of prostaglandin F (PGF) analogs to grow hair failed to describe representative number of species of subgenus, so as to satisfy written description requirement for patentability, where patent did not expressly disclose a single embodiment of claimed subgenus. 35 U.S.C.A. § 112(a).

[11] **Patents** Genus and species

To meet the written description requirement for patentability of an invention claimed as a genus of chemical compounds by sufficiently disclosing structural features common to all members the genus, the patent must provide sufficient blaze marks to direct a skilled artisan to the claimed genus. 35 U.S.C.A. § 112(a).

[12] **Patents** Particular products or processes

Written description of invention claimed as subgenus of prostaglandin F (PGF) analogs to grow hair failed to satisfy common-structural-features test for adequate written description, and thus patent claim directed to subgenus was invalid, where patent, at best, disclosed two prostaglandin hairpin structures with a menu of available atoms, moieties, and functional groups from which a skilled artisan could populate specific positions on those structures. 35 U.S.C.A. § 112(a).

[13] **Patents** Particular products or processes

Disclosure of prostaglandin hairpin, as common structural feature of invention claimed as subgenus of prostaglandin F (PGF) analogs to grow hair, failed to identify how hairpin was unique to claimed subgenus, as opposed to entire genus described in patent specification, and thus failed to satisfy common-structural-features test for adequate written description; specification disclosed characteristic prostaglandin hairpin structure shared by all compounds disclosed therein, billions of compounds contained such generic hairpin structure, and a person of ordinary skill in the art would not be able to visualize thousands of compounds claimed from among billions of prostaglandin compounds described in specification, based on written description of widely shared hairpin structure. 35 U.S.C.A. § 112(a).

[14] **Patents** Particular products or processes

Disclosure of prostaglandin hairpin, as common structural feature of invention claimed as subgenus of prostaglandin F (PGF) analogs to grow hair, failed to provide sufficient guidance to account for variation at action end of structure, and thus failed to satisfy common-structural-features test for adequate written description, even though patent specification disclosed 13 options for such end position; options were themselves large categories within which numerous other options existed, yielding a vast number of options for end position, options that specification noted were either "preferred" or "more preferred" directed a skilled artisan away from, rather than toward, claimed subgenus, and methods for synthesis taught by specification did not indicate preferred options. 35 U.S.C.A. § 112(a).

[15] **Patents** Particular products or processes

Disclosure of prostaglandin hairpin, as common structural feature of invention claimed as subgenus of prostaglandin F (PGF) analogs to grow hair, failed to provide sufficient guidance to account for variation in position occupied by phenyl group in claimed subgenus, and thus failed to satisfy common-structural-features test for adequate written description, even though patent specification disclosed that position consisted of eight categories of options, including an aromatic group, and identified phenyl as most preferred aromatic group; categories required additional embedded choices, and guidance that phenyl was most preferred aromatic group only applied once a skilled artisan had selected aromatic group from among eight categories, which nothing in specification directed artisan to do. 35 U.S.C.A. § 112(a).

[16] **Patents** In general; utility

US Patent 9,579,270. Invalid.

Appeal from the United States District Court for the District of Colorado in No. 1:18-cv-00997-RM-KLM, Judge Raymond P. Moore.

Attorneys and Law Firms

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William M. Jay, Goodwin Procter LLP, Washington, DC, argued for defendant-appellant. Also represented by Gabriel Ferrante, New York, NY; Vishal C. Gupta, Step-toe LLP, New York, NY; Robert Kappers, Chicago, IL.

Before Dyk, Stoll, and Stark, Circuit Judges.

Opinion

Stark, Circuit Judge.

***1308** Sandoz Inc. ("Sandoz") appeals from a judgment of the U.S. District Court for the District of Colorado, holding that Sandoz failed to prove claim 30 of U.S Patent No. 9,579,270 (the "'270 patent") invalid for lack of adequate written description. We reverse.

I

Plaintiffs-appellees Duke University and Allergan Sales, LLC (collectively referred to herein as "Allergan") together own all rights in the '270 patent and certain related patents. The '270 patent issued in 2017 and has a priority date of 2000. It is entitled, "Compositions and Methods for Treating Hair Loss Using Non-Naturally Occurring Prostaglandins," and relates generally to treating hair loss using compositions containing prostaglandin F ("PGF") analogs. '270 pat. abstract.

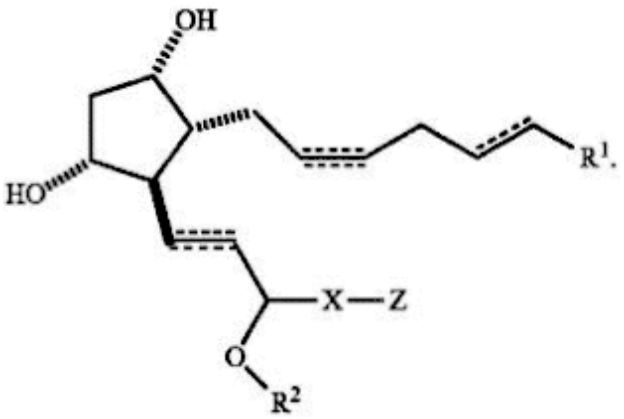
As the district court explained:

> The '270 Patent describes a method for growing hair by topically applying a chemical compound known as a prostaglandin. Prostaglandins are molecules that bind to certain receptors on cells in a living body and change how such cells function. The human body produces a variety of prostaglandins; the general type at issue here is known as prostaglandin F or PGF. Within the general category of PGF are many variants, some naturally-occurring and some synthesized. These variants are referred to as PGF analogs. Analogs differ from one another by virtue of various molecules that can attach to [the] base structure of the prostaglandin and which change its pharmacological properties. For example, the prostaglandin is much like a charm bracelet to which different charms can be attached at different points.

J.A. 5-6.

At issue in this appeal is claim 30 of the '270 patent. When read together with claims 17, 24, and 25, from which it depends, claim 30 recites:

> A method of growing hair, wherein the method comprises topically applying to mammalian skin a safe and effective amount of a composition comprising:
>
> ... an active ingredient selected from the group consisting of a prostaglandin F analog of the following structure:



> and pharmaceutically acceptable salts thereof;
>
> wherein R^1 is C(O)NHR^3 [i.e., an amide];
>
> R^2 is a hydrogen atom;
>
> R^3 is methyl, ethyl, or isopropyl;
>
> X is selected from the group consisting of —C≡C—, a covalent bond, —CH=C=CH—, —CH=CH—, —CH=N—, —C(O)—, —C(O)Y—, and —$(CH_2)_n$—, wherein n is 2 to 4;
>
> Y is selected from the group consisting of a sulfur atom, an oxygen atom, and NH;
>
> and Z is phenyl.

'270 pat. at 66:65-67:54.

Allergan markets Latisse®, an FDA-approved topical solution for treatment of eyelash hair loss by stimulating hair growth. J.A. 10078-79. Latisse® consists of a 0.03% bimatoprost ophthalmic solution. J.A. 16. Bimatoprost is a PGF analog with an ethyl amide at its action end (the "C1 end" or "C1 location" and also known as the "R^1" position), and phenyl at the omega end, which is also referred to as the "Z" position. [1]

Sandoz manufactures and sells a generic version of Latisse®. In 2018, Allergan sued Sandoz, alleging its generic drug product infringes claim 30 of the '270 patent. J.A. 77. Sandoz stipulated to infringement but challenged the validity of the claim. J.A. 1-2, 7783.

***1309**

During a five-day jury trial, Sandoz attempted to prove that claim 30 of the '270 patent is invalid for lack of adequate written description. In support of its contention, Sandoz presented the testimony of its expert, Dr. Clayton Heathcock. Dr. Heathcock opined that claim 30 lacks sufficient written description because "the Claim describes over 4,000 compounds that can cause hair to grow" but does not identify "a single" specific embodiment of the claim in the specification or disclose sufficient common structural features of the compounds encompassed by the claim. J.A. 10448-56. Allergan countered Sandoz's evidence with testimony from its own expert, Dr. Allen Reitz, who opined that the '270 patent "adequately describes the use of amides for growing hair ... with three types of prostamides with a phenyl ring at the end of the omega chain." J.A 10679.

The jury found Sandoz had failed to prove that claim 30 was invalid for obviousness, ***1310** lack of enablement, or lack of adequate written description and awarded Allergan $39 million in infringement damages. J.A. 8514-15. Sandoz filed a motion for a new trial and for judgment as a matter of law, both of which the district court denied. J.A. 37-50. Sandoz timely appealed. The district court had jurisdiction under 28 U.S.C. § 1338(a), and we have jurisdiction pursuant to 28 U.S.C. § 1295(a).

II

[1] **[2]** **[3]** When a district court denies a motion for judgment as a matter of law, we review its decision under the law of that court's regional circuit. *See* *Promega Corp. v. Life Techs. Corp.*, 875 F.3d 651, 659 (Fed. Cir. 2017). This case arises out of the Tenth Circuit, which applies de novo review to a district court's denial of a motion for judgment as a matter of law. *See* *Stroup v. United Airlines, Inc.*, 26 F.4th 1147, 1156 (10th Cir. 2022). Thus, "a district court's refusal to grant judgment as a matter of law may be reversed only if the evidence is such that without weighing the credibility of the witnesses the only reasonable conclusion is in the moving party's favor." *Id.* (quoting *Elm Ridge Expl. Co., LLC v. Engle*, 721 F.3d 1199, 1216 (10th Cir. 2013) (internal brackets and quotation marks omitted).

[4] **[5]** **[6]** Whether a patent provides adequate written description for a claim presents a question of fact. *See* *Gen. Hosp. Corp. v. Sienna Biopharmaceuticals, Inc.*, 888 F.3d 1368, 1371 (Fed. Cir. 2018). That question is whether the patent specification discloses that a person of ordinary skill in the art would conclude "the inventor possesse[d] the full scope of the invention" at the time of their patent application. *LizardTech, Inc. v. Earth Res. Mapping, Inc.*, 424 F.3d 1336, 1345 (Fed. Cir. 2005); *see also* 35 U.S.C. § 112(a) ("The specification shall contain a written description of the invention ...."); *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1124 (Fed. Cir. 2008) ("[T]o satisfy the written description requirement for a claimed genus, a specification must describe the claimed invention in such a way that a person of skill in the art would understand that the genus that is being claimed has been invented, not just a species of the genus."). Like all invalidity defenses, lack of written description must be proven by clear and convincing evidence. *See* *Vasudevan Software, Inc. v. MicroStrategy, Inc.*, 782 F.3d 671, 682 (Fed. Cir. 2015). Thus, Sandoz's "burden on appeal is doubly high," as it "must show that no reasonable jury could have failed to conclude that [its] case had been established by clear and convincing evidence." *Boehringer Ingelheim Vetmedica, Inc. v. Scherlng-Plough Corp.*, 320 F.3d 1339, 1353 (Fed. Cir. 2003).

III

While Sandoz raises multiple issues on appeal,[2] we need address only one: its contention that the district court should have granted judgment as a matter of law that claim 30 of the '270 patent is invalid for lack of adequate written description. Sandoz argues that claim 30 covers the use of a specific subgenus of PGF analogs to grow hair, but that the specification fails to show a skilled artisan that the inventors ***1311** were in possession of that full subgenus, including the specific embodiment at issue in this litigation, bimatoprost. According to Sandoz, the specification does not provide a single example of an actual compound claimed by claim 30 and also fails to identify sufficient commonalities of structure to provide a skilled artisan with the necessary "blaze marks" to lead them to the claimed compounds. Because we agree with Sandoz that no reasonable juror could have found that Sandoz failed to prove, by clear and convincing evidence, that claim 30 lacks adequate written description, we reverse the district court's judgment.

[7] **[8]** The written description requirement "reflects the basic premise of the patent system[:]" an inventor may

"obtain[ ] a patent" only if she "discloses [the] invention" to the public, in sufficient enough detail that a person of ordinary skill in the art will understand that the inventor truly "possessed the invention as claimed." *Regents of the Univ. of Minn. v. Gilead Scis., Inc.*, 61 F.4th 1350, 1355 (Fed. Cir. 2023). "The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not." *Id.* (quoting *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1330 (Fed. Cir. 2003) (internal quotation marks omitted).

Sandoz contends that the specification of the '270 patent is written so broadly that it encompasses a "universe of billions of compounds," while claim 30 is limited to roughly 1,620 of these potential compounds. According to Sandoz, the patent fails to provide skilled artisans with the information they need to identify and obtain this subgenus of claimed compounds. Based on the vast discrepancy between the written description and the actual scope of the claim, Sandoz continues, the pertinent artisan would conclude that the named inventors did not actually possess the invention claimed in claim 30.

Certain premises underlying Sandoz's written description contentions are uncontested. Allergan's expert, Dr. Reitz, agreed at trial that the specification is written in such a manner – with multiple open positions on its chemical structure, each of which could be filled in various ways – that it could encompass billions of compounds. *See* J.A. 10708 (Dr. Reitz agreeing "billions of compounds are represented by [the specification's] backbone, based on the types of substituents"). Experts for both sides agreed that the number of compounds actually claimed by claim 30 is far smaller: either 4,230, which was Sandoz's expert's view, or 1,620, as Allergan's expert opined. J.A. 10676, 10690-91, 10707. Thus, any reasonable juror had no choice but to find that the specification broadly described billions of compounds, while claim 30 was directed to between just 1,620 and 4,230 of such compounds. In order to have adequate written description, the specification of the '270 patent needs to allow a skilled artisan to understand how to identify this subgenus of claimed compounds.

[9] We have considered similar patents with some frequency. As we have previously held:

> Written description of an invention claimed as a genus of chemical compounds, as here ... requires description not only of the outer limits of the genus but also of either a representative number of members of the genus or structural features common to the members of the genus, in either case with enough precision that a relevant artisan can visualize or recognize the members of the genus.

Regents, 61 F.4th at 1356; *see also* *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350-52 (Fed. Cir. 2010). In other words, the specification must provide sufficient ***1312** indication as to how a skilled artisan would narrow the disclosed universe of billions of compounds described in the specification to the subset of just 1,620-4,230 compounds actually claimed.

[10] Based on the evidence introduced at trial, no reasonable juror could find anything other than clear and convincing evidence that the '270 patent fails to describe either (i) a representative number of species of claim 30's subgenus or (ii) structural features common to all members of that subgenus. Allergan does not even argue that the patent satisfies the first of these alternatives, since the '270 patent does not expressly disclose even a single embodiment of claim 30. *See, e.g.*, '270 pat. at col. 8 (showing that only disclosed embodiment containing C(O)NHR^3 at C1 end and phenyl in Z position does not contain methyl, ethyl, or isopropyl in R^3 position, thus falling outside of claim 30); *see also* J.A. 7939 (jury instruction, which was limited to common structural features test); J.A. 10743-47 (parties discussing whether jury should be instructed on representative number instruction, with court stating "there's been no evidence that this ... theory" applies.).

[11] Allergan solely relies on the proposition that the patent nonetheless sufficiently discloses structural features common to all members of the claimed subgenus. To meet the written description requirement in this manner, the patent must "provide sufficient blaze marks" to direct a skilled artisan

to the claimed subgenus. *Regents*, 61 F.4th at 1356-58. That is, the specification must "provide[ ] adequate direction which reasonably would lead persons skilled in the art to" the compounds actually claimed in claim 30. *Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570 (Fed. Cir. 1996) (internal brackets and quotation marks omitted).

[12] Allergan insists that the specification of the '270 patent satisfies this common-structural-features test because it discloses three features that are common to all members of the claimed subgenus: "[i] the characteristic prostaglandin hairpin, [ii] ... with amides at the C1 position ... [iii] connected to the unsubstituted phenyl ring at the omega [action] end." Ans. Br. at 49 (bracketed numerals added). No reasonable juror could agree.

As we explain in more detail below, the '270 patent, at best, discloses two prostaglandin hairpin structures and a menu of available atoms, moieties, and functional groups from which a skilled artisan could populate the R^1, R^2, R^3, R^4, X, Y, and Z positions of those structures. '270 pat. at 7:34-8:67. Under our precedent, this is inadequate. *See, e.g.*, *In re Ruschig*, 379 F.2d 990, 995 (CCPA 1967) (finding inadequate written description where specification leaves skilled artisan needing "to select[ ] from the myriads of possibilities encompassed by the broad disclosure, with no guide indicating or directing that th[e] particular selection[s] should be made rather than any of the many others which could also be made").

[13] Start with the prostaglandin hairpin. It was undisputed at trial that this is a "generic" feature. *See* J.A. 10670 (Allergan's Dr. Reitz); J.A. 10574 (Sandoz's Dr. Hla); J.A. 10486 (Sandoz's Dr. Heathcock: "That's the basic carbon skeleton of all prostaglandins."). Both parties' experts agreed that the specification discloses a characteristic prostaglandin hairpin structure shared by all compounds disclosed in the specification. *See* J.A. 10517-18 (Dr. Heathcock agreeing specification contains "a characteristic backbone ... with an R group attached at C1"); J.A. 10670 (Dr. Reitz explaining prostaglandin has "characteristic hairpin turn, including the linker," with R^1 being "the important position"); ***1313** J.A. 10668 (Dr. Reitz describing hairpin as "common"). Billions of compounds contain this generic hairpin structure. J.A. 10708 (Dr. Reitz testifying that "billions of compounds are represented by th[e] backbone"). Allergan failed to identify how this common structural feature was unique to the claimed subgenus, as opposed to the entire genus described in the specification. Thus, Allergan has not introduced evidence to show that a person of ordinary skill in the art would be able to "visualize" the thousands of compounds claimed in claim 30, from among the billions of prostaglandin compounds described in the specification, based on the written description of the widely shared hairpin structure.

[14] Second, the hairpin structure does not provide sufficient guidance to account for the variation at the R^1 and Z positions. A reasonable juror would necessarily have found that the specification fails to provide sufficient blaze marks with respect to the C1 position. Allergan argues that "the specification undisputedly discloses *only 13 options* for [this] action end," with one of those options being the claimed amide, $C(O)NHR^3$. Ans. Br. at 51 (emphasis in original). But the characterization of the specification's disclosures for C1 as containing merely "13 options" is not correct, as most of the 13 options are themselves large categories within which numerous options exist. In reality, the specification's guidance with respect to the C1 position resembles a path with 13 branches, and most of those branches lead to additional branches, yielding in the end a vast number of options for C1.[3]

In particular, the specification teaches:

> R^1 is selected from the group consisting of [1] C(O)OH, [2] C(O)NHOH, [3] $C(O)OR^3$, [4] CH2OH, [5] $S(O)2R^3$, [6] $C(O)NHR^3$, [7] $C(O)NHS(O)2R^3$, [8] tetrazole, [9] a cationic salt moiety, [10] a pharmaceutically acceptable amine or [11] ester comprising 2 to 13 carbon atoms, and a [12] biometabolizable amine or [13] ester comprising 2 to 13 carbon atoms.

'270 pat. at 8:9-15 (internal numbering added). A skilled artisan would understand that only four of these 13 options (C(O)OH, C(O)NHOH, CH2OH, and tetrazole) are singular items; the other nine options are categories, each requiring additional choices within them. Thus, selecting one of

Allergan's "13 options" would, for nine of the branches on the path, be merely the first decision an artisan would need to make before having to make other decisions just to determine what to place at C1.

For example, one of the patent's disclosed options (number [3] above) is C(O)NHR^3. The inclusion of the substituent R^3 as a component of this option requires a further choice to be made (after choosing C(O)NHR^3 from among the 13 options for C1), because the specification discloses no fewer than 12 further *categories* from which the artisan must select to ***1314** fill the R^3 position. *See* '270 pat. at 8:10-17; *see also id.* at 5:22-36 (defining one of the 12 categories, the "heterogenous group," as "a saturated or unsaturated chain containing 1 to 18 member atoms," which may be straight or branched in multiple spots, with or without (double and triple) bonds). Hence, even assuming a person of ordinary skill chose C(O)NHR^3 from among the "13 options" for C1, just to fill in the C1 position she would still have to (i) select 1 of 12 categories for the R^3 position, and then (ii) select a specific molecule from whichever category of those 12 she chose. While Dr. Reitz told the jury "any ordinary chemist could look at the functional groups, understand what's intended, understand permutations that could result," J.A. 10670, and therefore might know not to pursue every one of the possible combinations the specification allows to be placed at C1 and its R^3 component, the incontestable fact is that the specification describes far more than just "13 options" for C1.

And as we have previously held: "Following [such a] maze-like path, each step providing multiple alternative paths, is not a written description of what might have been described if each of the optional steps had been set forth as the only option." *Regents*, 61 F.4th at 1357. Or, as we have similarly put it, "one cannot disclose a forest in the original application, and then later pick a tree out of the forest and say 'here is my invention.' " *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1326 (Fed. Cir. 2000). Instead, satisfaction of the written description requirement with a patent like the '270 patent requires disclosure of sufficient "blaze marks directing the skilled artisan to that tree." *Id.*; *see also* *Regents*, 61 F.4th at 1356. The specification does not do so, and therefore fails to adequately direct the skilled artisan to the proper selection at the C1 position in order to arrive at the subgenus of compounds claimed by claim 30.

Furthermore, the only blaze marks provided by the specification for this C1 selection point *away from* the combinations as recited in claim 30. A specification's description of "preferred embodiments do[es] blaze a trail through the forest." *Fujikawa*, 93 F.3d at 1571. The specification of the '270 patent calls out five of its 13 options for C1 as either "prefer[red]" or "more prefer[red]." '270 pat. 8:10-18. Notably, however, those five do *not* include C(O)NHR^3, which is the option a skilled artisan would need to choose to reach the claimed invention. This means that the "preferred" and "more preferred" blaze marks direct a skilled artisan *away from*, rather than toward, the claimed subgenus, which would again lead the artisan to conclude the inventors did not actually possess what they claimed. *See generally* J.A. 10454 (Dr. Heathcock opining that specification describes carboxylic acid and esters as more preferred and does not note any preference for C1-alkylamides like bimatoprost).

If a skilled artisan were to ignore these blaze marks preferring five of the other "13 options" for C1, and remain on the nonpreferred C(O)NHR^3 path, the specification then provides help by teaching that R^3 in this group is "preferably ... selected from the group consisting of methyl, ethyl, and isopropyl," '270 pat. at 8:30-31. But Allergan has not identified any persuasive reason why an artisan who ignored the first set of blaze marks, effectively directing her away from C(O)NHR^3, would then follow the blaze marks given for the R^3 location of this non-preferred group.

In a final effort to identify part of the written description that would assist an ordinarily skilled artisan at the C1 position, Allergan points to portions of the specification that teach methods for compound ***1315** synthesis, including four examples of synthesizing compounds containing amides. Allergan argues this discussion would steer a skilled artisan to the placement of an amide at C1, and therefore direct that artisan to the right choice, C(O)NHR^3, out of the alleged "13 options" elsewhere called out (which we addressed above) as available for C1. *See* J.A. 10673-74 (Dr. Reitz testifying that specification points to amides at C1 because of their mentions in description of synthesis process); J.A. 10451 (Dr. Heathcock agreeing these disclosures are in specification); *see also* J.A. 10525 (Dr. Heathcock: "They definitely say [in the patent] that you can make an amide, but they didn't really

give any explicit instructions on how to do that, although they did for sulfonamide."). In each of the four synthesis schemes disclosed, however, C1 can be any of the same variants listed above – that is, any of the "13 options," nine of which are categories requiring further embedded choices – but one ends up with an amide only if one selects option number six from that list, C(O)NHR[3]. And while the syntheses described as Formulas I and III of the specification call out amides as examples of the optional C1 manipulation, even these formulas do not indicate that amides should be preferred at C1. Moreover, Allergan's expert, Dr. Reitz, admitted that two specific examples provided in the synthesis schemes, which use sulphonamides or hydroxamic acid, are not within the scope of the '270 patent's claims. J.A. 10696-97.

[15] Finally, we turn to Allergan's arguments about what the specification describes at the Z position. Claim 30's compounds require a phenyl group at Z. J.A. 10675. While Allergan contends that "the specification discloses only eight categories of options for Z, and ... expresses a preference for phenyl," Ans. Br. at 55, in fact the specification makes clear that (as with C1) each of these eight categories requires additional embedded choices:

> Z is selected from the group consisting of a carbocyclic group, a heterocyclic group, *an aromatic group*, a heteroaromatic group, a substituted carbocyclic group, a substituted heterocyclic group, a substituted aromatic group, and a substituted heteroaromatic group.

'270 pat. at 8:48-53 (emphasis added). While the specification does identify phenyl as the most preferred aromatic group, *see id*. at 4:2-3, this guidance is only pertinent once the artisan selects an aromatic group from among the eight initially described options, which nothing in the specification directs such an artisan to do. *See* J.A. 10675 (Dr. Reitz opining that *when* "Z is selected from an aromatic group," a skilled artisan "would know that a phenyl is [an] aromatic group" and "the most preferred aromatic group is phenyl," but not identifying a reason why an artisan would select an aromatic group in the first place).[4]

Allergan's argument that "at least ten of the patent's example compounds employ unsubstituted phenyl at the omega end," Z, Ans. Br. 52, does not overcome these problems. The specification lists 95 example compounds and gives no reason to prefer the ten examples containing phenyl. ***1316** Ten is not even the greatest number of appearances of a compound at the omega end; flurobenzene is used at Z in 18 of the 95 example compounds disclosed in the patent.

Thus, even accepting that the specification guides a skilled artisan towards the hairpin structure, leaving only variability at the C1 and Z ends to be navigated, the specification does not provide sufficient "blaze marks" to guide a skilled artisan to a PGF analog with an amide at the C1 position and a phenyl at the Z position, which are both required elements of the compounds comprising claim 30's subgenus. To the contrary, as in *Fujikawa*, 93 F.3d at 1571, the specification of the '270 patent does not "direct one to the proposed tree in particular, and does not teach the point at which one should leave the trail to find it." Instead, the specification may only reasonably be viewed as a mere " 'laundry list' disclosure of every possible moiety for every possible position," making it inadequate to satisfy the written description requirement of 35 U.S.C. § 112(a). *See id.*

Thus, this is a case in which the appellant has overcome the doubly high burden of persuading us to overturn a jury verdict of no invalidity. The multiple, branching paths of the '270 patent's specification are clear on the face of the patent, were explained in detail by Sandoz's expert, and their existence was not disputed by Allergan's expert. Given our precedent, any reasonable juror would have found, by clear and convincing evidence, that a person of ordinary skill in the art, reviewing the specification of the '270 patent, would be unable to visualize or recognize the members of the subgenus claimed by claim 30 based upon the specification's disclosures. The specification fails to provide the relevant artisan with sufficient blaze marks or structural commonalities among the claimed compounds to lead her to conclude that the inventor actually possessed the claimed invention.

Therefore, we reverse the judgment of the district court that claim 30 is not invalid for lack of a written description. *See, e.g.*, *BASF Plant Sci., LP v. Commonwealth Sci. & Indus. Rsch. Org.*, 28 F.4th 1247, 1269 (Fed. Cir. 2022) (reversing judgment of adequate written description where "jury had no reasonable basis to reject [accused infringer's] evidence ... of

inadequate written-description support"); *Idenix Pharms. LLC v. Gilead Scis. Inc.*, 941 F.3d 1149, 1164 (Fed. Cir. 2019) (reversing same where patent "fail[ed] to provide sufficient blaze marks to direct a POSA to the specific subset" of claimed compounds).

IV

We have considered Allergan's remaining arguments with respect to written description and find them unpersuasive. Accordingly, for the reasons set out above, we conclude that no reasonable factfinder, taking the evidence in the light most favorable to Allergan, could have found anything other than clear and convincing evidence that claim 30 of the '270 patent is invalid for lack of adequate written description. The judgment of the district court is reversed.

REVERSED

All Citations

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Footnotes

1 Like the parties, we use C1 position and R^1 interchangeably throughout this opinion. We do the same for omega end and Z.

2 Sandoz's other principal arguments on appeal are that Allergan should have been collaterally estopped from litigating its obviousness defense due to prior decisions of this court, that the district court's instruction to the jury on teaching away was prejudicially flawed, and that claim 30 was not enabled. Because we have determined that claim 30 is invalid, *infra*, we need not resolve these additional issues.

3 Allergan insists that Sandoz's expert, Dr. Heathcock, "agreed that the specification discloses only 13 possibilities for the action end, one of which is an amide." Ans. Br. at 17 (citing J.A. 10518-19) (internal quotation marks omitted); *see also id.* at 55 (asserting that "[Dr.] Heathcock repeatedly conceded" this point). No reasonable juror could have found that Dr. Heathcock admitted the 13 options listed are *only 13* and do not have embedded within them additional options. At no point, even in the cross-examination highlighted by Allergan, did Dr. Heathcock testify there are "only" 13. To the contrary, he consistently made clear that while he could visualize each of the "functional groups" listed for R^1 (i.e., C1), he further explained that it "would be hard, because there's so much variety with the Rs." J.A. 10519; *see also* J.A. 10520 (Allergan counsel acknowledging Dr. Heathcock "said there's variability in these– in each one of these 13").

4 The specification further recites a preference for Z being selected from among a "group consisting of furanyl, thienyl, and phenyl." '270 patent at 4:59-63. However, for that blaze mark to be pertinent to the skilled artisan, she would need to have already chosen a —C#C— bond for the X position. *See id.* at 8:54-63. Such a —C#C— bond is just one of as many as 15 options for X, *see id.* at 8:41-47; and it is the only one that if selected contains a blaze mark pointing to phenyl. Therefore, the skilled artisan must first reach a conclusion regarding X, the linker, before the specification may, but in most cases will not, prompt her to prefer phenyl.