United States Court of Appeals for the Federal Circuit

THE GENERAL HOSPITAL CORPORATION,
Appellant

v.

SIENNA BIOPHARMACEUTICALS, INC.,
Appellee

2017-1012

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. 106,037.

Decided: May 4, 2018

PHILIPPE BENNETT, Alston & Bird LLP, New York, NY, argued for appellant. Also represented by WALTER SCOTT; AOIFE BUTLER, Chicago, IL; PETER CARL LAURO, BRIAN LANDRY, Saul Ewing Arnstein & Lehr LLP, Boston, MA.

BRENTON R. BABCOCK, Knobbe, Martens, Olson & Bear, LLP, Irvine, CA, argued for appellee. Also represented by EDWARD M. CANNON.

Before MOORE, REYNA, and TARANTO, *Circuit Judges.*

MOORE, *Circuit Judge*.

General Hospital Corp. ("GHC") appeals the Patent Trial and Appeal Board's dismissal of an interference determining it lacked standing because claims of U.S. Patent Application No. 13/789,575 lacked sufficient written description under § 112 of the Patent Act. It further appeals the Board's denial of its contingent motion to add a new claim. We vacate the Board's termination of the interference and remand for further proceedings.

BACKGROUND

The claims at issue relate to methods of removing hair using nanoparticles to damage hair follicles. GHC is the named applicant on the '575 application, and Sienna Biopharmaceuticals, Inc. ("Sienna") owns U.S. Patent No. 8,821,941. On October 8, 2015, at GHC's suggestion, the Board declared an interference. The Board identified claim 1 of the '941 patent as the sole count. Claim 1 is directed to a method of localizing thermal damage to a hair follicle by applying a composition comprising a plurality of unassembled plasmonic nanoparticles to a skin surface. Relevant to this appeal, claim 1 requires "the unassembled plasmonic nanoparticles have a concentration of 10^9 to 10^{23} particles per ml of the composition, wherein said concentration is sufficient to, after exposure to irradiation, induce thermal damage in the hair follicle."

The Board identified claims 65–67 of the '575 application and claims 1–20 of the '941 patent as corresponding to that count. Claim 65 is representative of the '575 claims. Like claim 1, it is directed to a method of localizing thermal damage to a hair follicle by applying a composition comprising a plurality of unassembled plasmonic nanoparticles to a skin surface. In claim 65, "the unassembled plasmonic nanoparticles have a concentration of about 6.6×10^{11} particles per ml of the composition." The Board construed "about" as it appears in claim 65 to mean "within 10%." Therefore, "about 6.6×10^{11} particles per

ml" encompasses of a range of at most from 5.94×10^{11} to 7.26×10^{11} particles per ml.

Sienna moved for a determination that claims of the '575 application were unpatentable for failure to meet the written description requirement. The disclosure in the '575 application describes formulations by reference to optical density (OD) rather than particles per ml. The parties disputed the proper extinction coefficient to be used in converting optical density to concentration in particles per ml. The Board accepted an extinction coefficient of 4.2, crediting the testimony of Sienna's expert Dr. Tao over the testimony of GHC's expert Dr. Dmochowski. Applying this coefficient, the Board found no concentrations disclosed in the '575 disclosure were between 5.94×10^{11} and 7.26×10^{11} particles per ml. The Board, therefore, found claims 65–67 lack written description support and are unpatentable under § 112.

GHC moved to add new claim 74 expressly limiting the nanoparticles to have "an Optical Density of 250 O.D. when measured at a wavelength of about 810 nm." The Board denied this motion, determining that GHC did not show interference-in-fact with Sienna claim 1, or correspondence to Count 1, and failed to provide supporting evidence that this claim was patentable.

GHC appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

I

Sufficiency of written description is a question of fact, reviewed for substantial evidence. *Inphi Corp. v. Netlist, Inc.*, 805 F.3d 1350, 1354 (Fed. Cir. 2015). In determining whether the written description requirement is met, we consider "whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter

as of the filing date." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc).

As a preliminary matter, the parties dispute the proper construction of the claim term "about." "We review the Board's claim construction de novo except for subsidiary fact findings, which we review for substantial evidence." *Perfect Surgical Techniques, Inc. v. Olympus Am., Inc.*, 841 F.3d 1004, 1012 (Fed. Cir. 2016). Here, the Board properly construed "about" to mean "within 10%." The '575 application defines "about," giving a broadest value of 10%:

> Unless otherwise specifically stated or obvious from context, as used herein, the term "about" is understood as within a normal tolerance in the art, for example within 2 standard deviations of the mean. About can be understood as within 10%, 9%, 8%, 7%, 6%, 5%, 4%, 3%, 2%, 1%, 0.1%, 0.05%, or 0.01% of the stated value. Unless otherwise clear from context, all numerical values provided herein are modified by the term about.

Although the specification and prosecution history of the '941 patent do not expressly define "about," the Board considered Dr. Tao's testimony that a range of 10% is consistent with the use of the word "about" in the '941 specification. None of the intrinsic or extrinsic evidence cited by GHC supports GHC's construction that "about" includes ± 20% variation. Moreover, GHC waived its argument that the broadest reasonable interpretation of "about" was ± 20%. In the interference, GHC only contested Sienna's proposed construction by generally denying that the broadest reasonable interpretation was "within 10%." J.A. 812. GHC did not present an alternative construction or explain why it disagreed with Sienna's proposed construction. Although GHC's expert Dr. Dmochowski stated in a declaration that a skilled artisan would have considered a 20% variation to be acceptable,

the Board expressly stated that it would not consider this testimony because GHC did not rely on it or argue Dr. Tao's 10% variation was incorrect. We conclude that the Board properly determined that the claim limitation "about 6.6×10^{11} particles per ml" encompasses of a range of at most from 5.94×10^{11} to 7.26×10^{11} particles per ml.

Given this claim construction, substantial evidence supports the Board's findings that none of the disclosed values in the '575 application fall within 10% of the claimed value. Claims 65–67 of the '575 application, which include the "about 6.6×10^{11} particles per ml" limitation, are not original claims. The '575 application broadly discloses that "the composition comprises plasmonic particles that have an optical density of at least about 1 O.D." J.A. 3164. GHC has identified seven specific compositions in the '575 application, which it argues have optical densities of 132, 144, 250, 275, 300, 715, and 780. When converted to particles per ml, these optical densities give values of 4.10×10^{11}, 4.46×10^{11}, 7.77×10^{11}, 8.44×10^{11}, 9.31×10^{11}, 22×10^{11}, and 24×10^{11} particles per ml.

The disclosure of a broad range of values does not by itself provide written description support for a particular value within that range. Instead, where a specification discloses a broad range of values and a value within that range is claimed, the disclosure must allow one skilled in the art to "immediately discern the limitation at issue in the claims." *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000). In *Purdue Pharma*, we affirmed a district court finding that a claim requiring a pharmacokinetic concentration ratio (C_{max}/C_{24}) above 2 was not supported by sufficient written description where the specification (1) included examples of ratios above and below 2; (2) did not emphasize the C_{max}/C_{24} ratio as an aspect of the invention; and (3) "disclose[d] a multitude of pharmacokinetic parameters, with no blaze marks direct-

ing the skilled artisan to the C_{max}/C_{24} ratio or what that ratio should exceed." *Id.* at 1326.

Here, the specification discloses a range of optical densities and several discrete values within that range. The specification broadly states that in one embodiment the particles have an optical density of *at least* "about 1 O.D.," J.A. 3164, which GHC argued corresponds to less than 1×10^{11} particles per ml. The specification does not expressly identify a maximum concentration, and GHC did not argue any upper limit to the range disclosed other than "some value greater than 9.31×10^{11}." J.A. 804. Several of the discrete values provided in the specification are even higher than that. As we stated in *Purdue Pharma*, "one cannot disclose a forest in the original application, and then pick a tree out of the forest and say here is my invention." *Purdue*, 230 F.3d at 1326. The disclosure of a range of concentrations from less than 1×10^{11} particles per ml to some unidentified maximum, does not provide written description support for the claimed concentration of "about 6.6×10^{11} particles per ml," nor does the disclosure of particular discrete values within that range, none of which are the claimed value.

While GHC argues the written description requirement is met because when a 10% variability is applied to both the claimed value and one of the disclosed values, the ranges overlap, this argument is unavailing. The specification discloses an optical density of 250 OD, which GHC argues corresponds to 7.77×10^{11} particles per ml. GHC argues a 10% variability should be applied to this value, generating a range from 6.99×10^{11} to 8.55×10^{11} particles per ml. Because this range overlaps with the claimed range of "about 6.6×10^{11} particles per ml" or from 5.94×10^{11} to 7.26×10^{11} particles per ml, GHC argues the written description requirement is met. This argument relies on language in the specification that states "[u]nless otherwise clear from context, all numerical values provided herein are modified by the term

about." J.A. 92. Even if we accept GHC's argument that the specification may be read to convert each disclosed value into a range with 10% variation, GHC's argument still fails, as a disclosed range that minimally overlaps with the claimed range does not provide written description support for the claimed range. In *Eiselstein v. Frank*, 52 F.3d 1035, 1040 (Fed. Cir. 1995), we determined that the range of "about 45–55% . . . is not the same as a very different 10% range, viz., 50–60%." There, half of each range overlapped with the other. Here, the overlap is even less. Whether written description support exists for the claimed "6.6×10^{11} particles per ml" in light of the disclosures in the '575 specification is a question of fact. We conclude that substantial evidence supports the Board's determination that the examples provided in the specification do not provide written description support for the claim term. Accordingly, the Board did not err in its analysis, and substantial evidence supports its finding of a lack of sufficient of written description.

II

The Board also denied GHC's contingent motion to amend to add new claim 74, determining that GHC failed to show claim 74 was patentable and failed to meet its burden of showing the proposed claim interferes with any of Sienna's claims. We review the Board's denial of a motion to amend to determine if it is arbitrary or capricious. *Veritas Techs. LLC v. Veeam Software Corp.*, 835 F.3d 1406, 1408 (Fed. Cir. 2016).

The Board's determination that GHC failed to meet its burden to show that the claim 74 is patentable was arbitrary and capricious. GHC certified it was not aware of any reason why the claim was not patentable. The Board stated GHC failed to direct it to evidence supporting the certification, but it did not engage in a substantive analysis of the claim's patentability or identify any particular ground on which GHC failed to establish patenta-

bility. The Board has adopted a Standing Order for conducting interferences, which in accordance with Board practice, was entered into the docket. *See In re Sullivan*, 362 F.3d 1324, 1328 (Fed. Cir. 2004) (affirming the use of the Standing Order). The Standing Order expressly instructs the moving party to "certify" that it is not aware of any reason why the claim is not patentable. Standing Order ¶ 208.5.1. It explains that "[a] certification that is inconsistent with the prosecution history of an involved or benefit file will be accorded no weight unless the inconsistency is explained." *Id.* Here, the Board did not point to any inconsistency with the prosecution history or otherwise challenge the merits of the certification, but still afforded the certification no weight. Given GHC's compliance with the Standing Order, the Board acted arbitrarily and capriciously in holding GHC failed to show the proposed claim was patentable absent evidence of inconsistency with the prosecution history.

The Board's determination that GHC had not established claim 74 interferes with any of Sienna's claims was not in accordance with our controlling precedent. Neither the parties nor the Board dispute that proposed claim 74 covers a particular species of the genus set forth in the '941 claim. Nevertheless, the Board determined GHC had not met its burden because it had not provided evidence that a skilled artisan "would have considered it obvious to have chosen the narrow range of nanoparticle diameter and optical density recited in its proposed claim 74."

Where a prior art patent discloses a range of values, showing a claimed value falls within that range meets a party's burden of establishing the narrower claim would have been obvious where there is no reason to think the result would be unpredictable. *See, e.g.*, *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 738 (Fed. Cir. 2013) (holding where the claimed value fell within prior art range, burden of production switched to the party opposing the obviousness challenge, while burden of proof

remanded with challenger); *Alcon Research, Ltd. v. Apotex Inc.*, 687 F.3d 1362, 1368 (Fed. Cir. 2012) (holding a prior art reference disclosing a range of concentrations expressly disclosed a particular concentration within that range). In doing so, we have stated that "[t]he normal desire of scientists or artisans to improve upon what is already known provides the motivation to determine where in a disclosed set of percentages is the optimum combination of percentages." *In re Peterson*, 315 F.3d 1325, 1330 (Fed. Cir. 2003); *accord In re Applied Materials, Inc.*, 692 F.2d 1289, 1295 (Fed. Cir. 2012). Although such a showing may not ultimately be sufficient to establish obviousness where other facts cut against that conclusion, *see, e.g.*, *Peterson*, 315 F.3d at 1331–32 (considering teaching away and unexpected results), here, neither the Board nor Sienna has pointed to any such facts. The cases cited by the Board are distinguishable. In *In re Baird*, 16 F.3d 380 (Fed. Cir. 1994), the prior art that disclosed a generic molecular formula indicated a preference leading away from the claimed compounds. *Id.* at 382–83. Moreover, we have suggested that when a reference discloses various structures rather than a range of values, optimization is not as likely to be routine. *See Genetics Inst., LLC v. Novartis Vaccines & Diagnostics, Inc.*, 655 F.3d 1291, 1306 (Fed. Cir. 2011). The other case cited by the Board involved a question of anticipation, not obviousness. *See Atofina v. Great Lakes Chem. Corp.*, 441 F.3d 991, 999–1000 (Fed. Cir. 2006). It is not disputed that the values in the proposed claim fall within the ranges in claim 1 of the '941 patent. Under the circumstances of this case, GHC has put forth sufficient evidence to establish proposed claim 74 would have been rendered obvious by claim 1 of the '941 patent.

CONCLUSION

For the foregoing reasons, we affirm the Board's finding that claims 65–67 are unpatentable for lack of sufficient written description. We vacate the Board's denial of

GHC's contingent motion to add a new claim and remand for further proceedings.

AFFIRMED IN PART AND VACATED AND REMANDED IN PART

COSTS

No costs.