NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

ALLERGAN SALES, LLC,
Plaintiff-Cross-Appellant

v.

SANDOZ, INC., ALCON LABORATORIES, INC., ALCON RESEARCH, LTD.,
Defendants-Appellants

2017-1499, 2017-1500, 2017-1558, 2017-1559

Appeals from the United States District Court for the Eastern District of Texas in Nos. 2:12-cv-00207-JRG, 2:15-cv-00347-JRG, Judge J. Rodney Gilstrap.

Decided: December 22, 2017

JONATHAN ELLIOT SINGER, Fish & Richardson, PC, San Diego, CA, argued for plaintiff-cross-appellant. Also represented by SUSAN E. MORRISON, ROBERT M. OAKES, Wilmington, DE; DEANNA JEAN REICHEL, Minneapolis, MN.

JOHN C. O'QUINN, Kirkland & Ellis LLP, Washington, DC, argued for defendants-appellants. Also represented

by SEAN M. MCELDOWNEY, CALVIN ALEXANDER SHANK; BRYAN SCOTT HALES, Chicago, IL.

Before MOORE, MAYER, and HUGHES, *Circuit Judges.*

HUGHES, *Circuit Judge.*

Allergan Sales, LLC sued generic drug manufacturers under the Hatch-Waxman Act, alleging infringement of U.S. Patent Nos. 7,030,149, 7,320,976, and 8,748,425. The U.S. District Court for the Eastern District of Texas found the asserted claims not invalid but only claims of the '425 patent infringed. We find no reversible error in the district court's finding of no invalidity. Nevertheless, because we find that the accused proposed generic drug contemplates administering dosages of a specific composition that is not claimed in any of the patents, we affirm-in-part and reverse-in-part.

I

Allergan holds the approved new drug application for Combigan®, which is used to lower intraocular pressure in glaucoma and ocular hypertension patients. Combigan® is a "fixed combination" ophthalmic solution consisting of 0.2% brimonidine tartrate and 0.68% timolol maleate for twice-daily dosage.

Allergan claims that the '149, '976, and '425 patents cover Combigan®. These patents share a common specification, which describes: (1) a "Brimonidine Tartrate 0.20% (w/v)" and "Timolol Maleate 0.68% (w/v) (Equivalent to 0.50% (w/v) timolol)" pharmaceutical composition; and (2) a clinical study using that composition for twice daily administration. *See, e.g.*, J.A. 347–50. In particular, Allergan claims that claim 4 of the '149 patent, claim 1 of the '976 patent, and claims 1–8 of the '425 patent protect Combigan® and its administration.

Claim 4 of the '149 patent recites a method of reducing the number of daily administrations of 0.2% brimonidine and 0.5% timolol in a single composition from three times a day to two times a day "without loss of efficacy." J.A. 350.

Claim 1 of the '976 patent recites a method of administering "a therapeutically effective amount" of composition comprising 0.2% brimonidine and 0.5% timolol twice daily. J.A. 356.

Claim 1 of the '425 patent recites administering twice daily a single combination comprising 0.2% brimonidine tartrate and 0.5% timolol free base to "reduce[] the incidence of one or more adverse events" listed in the claim. J.A. 366. Claims 2–8 of the patent depend from claim 1, each specifically reciting only one of the adverse events enumerated in claim 1. *Id.*

Sandoz, Inc., Alcon Laboratories, Inc., and Alcon Research, Ltd. (collectively, Sandoz) filed and maintained an abbreviated new drug application (ANDA) with the U.S. Food and Drug Administration, seeking its approval to market generic versions of Combigan®. Allergan sued Sandoz for direct, induced, and contributory infringement, asserting numerous patents in three different actions, only the last two of which proceeded to a consolidated bench trial on the '149, '976, and '425 patents.

The district court found the asserted claims of the patents not invalid as obvious. The court also found that claim 4 of the '149 patent satisfies the written description requirement. The court finally determined that Sandoz's ANDA does not infringe claim 4 of the '149 patent or claim 1 of the '976 patent, but does infringe claims 1–8 of the '425 patent.

Sandoz appeals the district court's no-invalidity and infringement determinations. Allergan cross-appeals the

finding of non-infringement. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

II

We review the district court's legal determinations de novo and factual findings for clear error. *Braintree Labs., Inc. v. Novel Labs., Inc.*, 749 F.3d 1349, 1358 (Fed. Cir. 2014). Obviousness is a question of law that we review de novo, and we review any underlying factual questions for clear error. *Honeywell v. United States*, 609 F.3d 1292, 1297 (Fed. Cir. 2010). "Whether a claim satisfies the written description requirement is a question of fact that, on appeal from a bench trial, we review for clear error." *Alcon Res. Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1190 (Fed. Cir. 2014). Infringement is a question of fact that we review for clear error. *Id.* at 1186.

A

Sandoz first argues that all asserted claims are invalid as obvious. A claim is invalid if, at the time the invention was disclosed, a person having ordinary skill in the art would have found the patented invention obvious in light of the prior art. *See* 35 U.S.C. § 103; *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398, 415–16 (2007). But patents are presumed to be valid and overcoming that presumption requires clear and convincing evidence. 35 U.S.C. § 282; *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011).

The district court found the asserted claims not invalid as obvious, reasoning that Sandoz presented substantially the same arguments and evidence in an earlier dispute with Allergan in which we held that claim 4 of the '149 patent recited an efficacy limitation that is neither suggested nor inherent in any prior art in the record. J.A. 74–76; *see also Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286, 1293–94 (Fed. Cir. 2013). Relying on that precedential decision, the court found that all asserted claims

recited analogous efficacy limitations, neither suggested nor inherent in prior art produced by Sandoz. J.A. 163.

Sandoz contends that the court erred because the asserted claims merely recite the inherent results of administering an obvious combination. We disagree. As we concluded in the earlier dispute regarding claim 4 of the '149 patent, the concomitant administration of brimonidine and timolol ophthalmic composition twice daily is obvious in view of the prior art. *See* J.A. 122–25; *Allergan*, 726 F.3d at 1294. Each asserted claim, however, expressly recites an additional efficacy limitation that further restricts the method of administering the composition twice daily: (1) "without loss of efficacy" in claim 4 of the '149 patent, *see* J.A. 350; (2) "a therapeutically effective amount" in claim 1 of the '976 patent, *see* J.A. 356; and (3) "reduc[ing] the incidence of one or more adverse events" in claim 1 of the '425 patent,[1] *see* J.A. 366. *See also Allergan*, 726 F.3d at 1293. Those efficacy limitations are not disclosed by any prior art reference in the record. To the contrary, the prior art shows that the combination dosed twice daily produces a loss of efficacy in the afternoon. J.A. 107–116; *see also Allergan*, 726 F.3d at 1294. The efficacy limitations are also not inherent in the administration of the ophthalmic composition, a finding adequately supported by the record. *See, e.g.*, J.A. 2572–75, 3007–09, 3117–19, 3243–45. Accordingly, the asserted claims merely recite those administrations of the composition that satisfy the efficacy limitations—but not those that end up in, for example, a loss of efficacy, examples of which abound in the prior art offered by Sandoz.

In light of the foregoing, the district court did not err by finding that Sandoz failed to present clear and convinc-

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[1] Claims 2–8 include similar limitations, but each claim specifically recites only one of the adverse events enumerated in claim 1. *See* J.A. 366.

ing evidence to overcome the presumption that the asserted claims are valid.

B

Sandoz next argues that claim 4 of the '149 patent is invalid for lack of written description in the specification based on its expert testimony that the claim encompasses hundreds of brimonidine and timolol combinations.

The written description requirement provides that a patentee's application for a patent must "clearly allow persons of ordinary skill in the art to recognize that [he] invented what is claimed." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (quoting *Vas–Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991)). "[T]he test for sufficiency is 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." *Id.* Relevant here, a sufficient description of a genus requires the "disclosure of either a representative number of species falling within the scope of the genus or structural features common to the members of the genus so that one of skill in the art can visualize or recognize the members of the genus." *Id.* at 1350. Even a single representative embodiment can support written description of a claimed genus. *See, e.g.*, *Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1073 (Fed. Cir. 2005); *Bilstad v. Wakalopulos*, 386 F.3d 1116, 1124–25 (Fed. Cir. 2004).

Claim 4 of the '149 patent recites 0.2% brimonidine and 0.5% timolol. J.A. 350. Given the construction of the terms brimonidine and timolol to include their free base and salt forms, *see* J.A. 1594, 1597, the district court correctly credited Allergan's expert testimony at trial that a person of ordinary skill in the art would have understood the claim to encompass only *six* possible combinations of brimonidine and timolol and their respective free base and salt forms, *see* J.A. 150—not, as Sandoz claims,

hundreds of combinations. More critically, the specification discloses one of those six possible combinations, 0.2% brimonidine tartrate and 0.68% timolol maleate composition. *See* J.A. 347. Tellingly, Sandoz's expert failed to identify any additional composition beyond that particular combination. J.A. 150–51. It was also undisputed at trial that the only salt of brimonidine available as of the filing of the '149 patent was brimonidine tartrate and that only one salt of timolol actually available—timolol maleate. J.A. 151–52. The specification therefore discloses a representative—indeed, the sole—embodiment of the claimed genus and a person of ordinary skilled in the art, reading the specification, would have immediately discerned the claimed limitation. Accordingly, the district court did not err by finding that the claim satisfies the written description requirement.

C

Sandoz finally argues that the district court erred in finding infringement of claims 1–8 of the '425 patent. Allergan asserted only literal infringement of those claims. "To establish literal infringement, every limitation set forth in a claim must be found in an accused product, exactly." *Advanced Steel Recovery, LLC v. X-Body Equip., Inc.*, 808 F.3d 1313, 1319 (Fed. Cir. 2015) (quoting *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir. 1995)).

The district court found that the proposed generic contains 0.5% timolol free base and therefore infringed the claims of the '425 patent. J.A. 116–18, 158. That finding is erroneous for two related reasons. Claims 1–8 are narrowly and specifically drawn, reciting administration of 0.2% brimonidine tartrate and 0.5% timolol free base. J.A. 366. Both Combigan® and the proposed generic, however, contain 0.68% timolol maleate, an ophthalmic compound distinct from 0.5% timolol free base. *See, e.g.*, J.A. 2786–87 (Sandoz's expert explaining why the pro-

posed generic does not contain 0.5% timolol free base). The district court relied on the equivalency of the two compounds in finding literal infringement—that is, 0.5% timolol free base recited in claims 1–8 as chemically equivalent to 0.68% timolol maleate contained in the proposed generic. *See* J.A. 117, 158. Because chemical equivalency is not sufficient for literal infringement of these claims, the court clearly erred.

The Hatch-Waxman Act provides for a technical infringement upon submission of an ANDA, but only "for a drug claimed in a patent." 35 U.S.C. § 271(e)(2)(A). Here, Combigan® contains a 0.2% brimonidine tartrate and 0.68% timolol maleate solution, as its FDA-approved label makes clear. J.A. 2310; *see also* J.A. 116–17. But claims 1–8 of the '425 patent expressly recite 0.5% timolol free base, not 0.68% timolol maleate. Therefore, as a matter of law, Combigan® is not the "drug claimed in" the '425 patent, and Sandoz's ANDA does not infringe under § 271(e)(2)(A). *See also Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1354 (Fed. Cir. 2003) ("[I]t is not an act of infringement to submit an ANDA for approval to market a drug for a use when neither the drug nor that use is covered by an existing patent.").

In sum, the district court erred by finding that Allergan showed literal infringement of claims 1–8 of the '425 patent.

D

Allergan argues on its cross-appeal that the district court erred in finding that Sandoz's proposed generic does not infringe claim 4 of the '149 patent and claim 1 of the 976 patent. Allergan again asserted only literal infringement with respect to those claims. Both the claims specifically recite 0.2% brimonidine. But the proposed generic contains 0.2% brimonidine titrate, a distinct pharmaceutical compound that reduces to 0.132% brimonidine—indeed, Allergan's expert confirmed so. J.A.

2710–11; *see also* J.A. 117. As such, the district court did not err by finding that Allergan failed to show literal infringement of claim 4 of the '149 patent and claim 1 of the '976 patent.

III

We have considered remaining arguments and find them unpersuasive. Accordingly, we affirm the district court's finding of no invalidity of the asserted claims and non-infringement of the claims of the '149 and '976 patents, but reverse the finding of infringement of claim 1 of the '425 patent.

AFFIRMED-IN-PART AND REVERSED-IN-PART

No costs.