APPENDICES

APPENDIX A

NOTE: This disposition is nonprecedential.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

ALLERGAN SALES, LLC,
Plaintiff-Cross-Appellants

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,

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

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