UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

NOTICE OF ENTRY OF JUDGMENT ACCOMPANIED BY OPINION

OPINION FILED AND JUDGMENT ENTERED: 12/22/2017

The attached opinion announcing the judgment of the court in your case was filed and judgment was entered on the date indicated above. The mandate will be issued in due course.

Information is also provided about petitions for rehearing and suggestions for rehearing en banc. The questions and answers are those frequently asked and answered by the Clerk's Office.

No costs were taxed in this appeal.

Regarding exhibits and visual aids: Your attention is directed Fed. R. App. P. 34(g) which states that the clerk may destroy or dispose of the exhibits if counsel does not reclaim them within a reasonable time after the clerk gives notice to remove them. (The clerk deems a reasonable time to be 15 days from the date the final mandate is issued.)

FOR THE COURT

/s/ Peter R. Marksteiner
Peter R. Marksteiner
Clerk of Court

17-1499, 17-1500, 17-1558, 17-1559 - Allergan Sales, LLC v. Sandoz, Inc.
United States District Court for the Eastern District of Texas, Case Nos. 2:15-cv-00347-JRG, 2:12-cv-00207-JRG

NOTE: This disposition is nonprecedential.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

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