EXHIBIT A

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NOTE: This disposition is nonprecedential.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

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.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

Questions and Answers

Petitions for Rehearing (Fed. Cir. R. 40)
and
Petitions for Hearing or Rehearing En Banc (Fed. Cir. R. 35)

Q. When is a petition for rehearing appropriate?

A. Petitions for panel rehearing are rarely successful because they most often fail to articulate sufficient grounds upon which to grant them. For example, a petition for panel rehearing should not be used to reargue issues already briefed and orally argued; if a party failed to persuade the court on an issue in the first instance, a petition for panel rehearing should not be used as an attempt to get a second "bite at the apple." This is especially so when the court has entered a judgment of affirmance without opinion under Fed. Cir. R. 36. Such dispositions are entered if the court determines the judgment of the trial court is based on findings that are not clearly erroneous, the evidence supporting the jury verdict is sufficient, the record supports the trial court's ruling, the decision of the administrative agency warrants affirmance under the appropriate standard of review, or the judgment or decision is without an error of law.

Q. When is a petition for hearing or rehearing en banc appropriate?

A. En banc decisions are extraordinary occurrences. To properly answer the question, one must first understand the responsibility of a three-judge merits panel of the court. The panel is charged with deciding individual appeals according to the law of the circuit as established in the court's precedential opinions. While each merits panel is empowered to enter precedential opinions, the ultimate duty of the court en banc is to set forth the law of the Federal Circuit, which merit panels are obliged to follow.

Thus, as a usual prerequisite, a merits panel of the court must have entered a precedential opinion in support of its judgment for a suggestion for rehearing en banc to be appropriate. In addition, the party seeking rehearing en banc must show that either the merits panel has failed to follow identifiable decisions of the U.S. Supreme Court or Federal Circuit precedential opinions or that the merits panel has followed circuit precedent, which the party seeks to have overruled by the court en banc.

Q. How frequently are petitions for rehearing granted by merits panels or petitions for rehearing en banc accepted by the court?

A. The data regarding petitions for rehearing since 1982 shows that merits panels granted some relief in only three percent of the more than 1900 petitions filed. The relief granted usually involved only minor corrections of factual misstatements, rarely resulting in a change of outcome in the decision.

En banc petitions were accepted less frequently, in only 16 of more than 1100 requests. Historically, the court itself initiated en banc review in more than half (21 of 37) of the very few appeals decided en banc since 1982. This sua sponte, en banc review is a by-product of the court's practice of circulating every precedential panel decision to all the judges of the Federal Circuit before it is published. No count is kept of sua sponte, en banc polls that fail to carry enough judges, but one of the reasons that virtually all of the more than 1100 petitions made by the parties since 1982 have been declined is that the court itself has already implicitly approved the precedential opinions before they are filed by the merits panel.

Q. Is it necessary to have filed either of these petitions before filing a petition for certiorari in the U.S. Supreme Court?

A. No. All that is needed is a final judgment of the Court of Appeals. As a matter of interest, very few petitions for certiorari from Federal Circuit decisions are granted. Since 1982, the U.S. Supreme Court has granted certiorari in only 31 appeals heard in the Federal Circuit. Almost 1000 petitions for certiorari have been filed in that period.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

INFORMATION SHEET

FILING A PETITION FOR A WRIT OF CERTIORARI

There is no automatic right of appeal to the Supreme Court of the United States from judgments of the Federal Circuit. You must file a petition for a writ of certiorari which the Supreme Court will grant only when there are compelling reasons. (See Rule 10 of the Rules of the Supreme Court of the United States, hereinafter called Rules.)

Time. The petition must be filed in the Supreme Court of the United States within 90 days of the entry of judgment in this Court or within 90 days of the denial of a timely petition for rehearing. The judgment is entered on the day the Federal Circuit issues a final decision in your case. [The time does not run from the issuance of the mandate, which has no effect on the right to petition.] (See Rule 13 of the Rules.)

Fees. Either the $300 docketing fee or a motion for leave to proceed in forma pauperis with an affidavit in support thereof must accompany the petition. (See Rules 38 and 39.)

Authorized Filer. The petition must be filed by a member of the bar of the Supreme Court of the United States or by the petitioner representing himself or herself.

Format of a Petition. The Rules are very specific about the order of the required information and should be consulted before you start drafting your petition. (See Rule 14.) Rules 33 and 34 should be consulted regarding type size and font, paper size, paper weight, margins, page limits, cover, etc.

Number of Copies. Forty copies of a petition must be filed unless the petitioner is proceeding in forma pauperis, in which case an original and ten copies of the petition for writ of certiorari and of the motion for leave to proceed in forma pauperis. (See Rule 12.)

Where to File. You must file your documents at the Supreme Court.

Clerk
Supreme Court of the United States
1 First Street, NE
Washington, DC 20543
(202) 479-3000

No documents are filed at the Federal Circuit and the Federal Circuit provides no information to the Supreme Court unless the Supreme Court asks for the information.

Access to the Rules. The current rules can be found in Title 28 of the United States Code Annotated and other legal publications available in many public libraries.

Revised December 16, 1999