UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

Orexo AB v. Actavis Elizabeth LLC

Orexo AB v. Actavis Elizabeth LLC, 903 F.3d 1265 (Fed. Cir. 2018) · No. 2017-1333 · Decided September 10, 2018

SUMMARY

The Federal Circuit reversed a district court's holding of obviousness for claims of a patent directed to an abuse-resistant sublingual tablet (Zubsolv®) for treating opioid dependence. The court held that the challenger failed to prove obviousness by clear and convincing evidence because no prior art reference taught or suggested using citric acid as a carrier particle for buprenorphine in an interactive mixture. The Federal Circuit found the district court's analysis was tainted by hindsight bias and improperly discounted objective indicia of nonobviousness, including the formulation's unexpected 66% improvement in bioavailability while maintaining the critical 4:1 buprenorphine-to-naloxone ratio.

CASE DETAILS

COURT	United States Court of Appeals for the Federal Circuit
WRITING FOR THE COURT	Newman; Hughes; Stoll
JURISDICTION	Federal
DECIDED	September 10, 2018
DOCKET	2017-1333
DISPOSITION	reversed_and_remanded
PROCEDURAL POSTURE	Appeal from a district court judgment of invalidity in Hatch-Waxman litigation.
STANDARD OF REVIEW	Following a bench trial, we review the district court's factual findings for clear error. Conclusions of law receive de novo determination.
PRECEDENTIAL VALUE	Published
PARTIES	Orexo AB, Orexo US Inc. v. Actavis Elizabeth LLC

TOPICS

patent law · standard of review · intellectual property · appellate procedure

PRACTICE AREAS

Intellectual Property · Patent Law

QUESTIONS PRESENTED

1. Whether claims 1, 3–6, and 8–10 of U.S. Patent No. 8,940,330 are invalid for obviousness under 35 U.S.C. § 103.

HOLDINGS

1. The claims are not invalid for obviousness because the prior art does not teach or suggest the specific combination of elements, and the evidence of unexpected results (66% improved bioavailability) supports nonobviousness.

KEY QUOTATIONS

> *"We reverse the judgment of invalidity of the '330 Patent, for we conclude that obviousness was not proved by clear and convincing evidence."* (at 2)

> *"There is no piece of prior art that was presented that says citric acid is a carrier particle or should be used as a carrier particle."* (at 13-14)

> *"The judgment of invalidity is reversed."* (at 17)

FACTUAL BACKGROUND

The '330 Patent claims a sublingual tablet composition for treatment of opioid dependence comprising microparticles of buprenorphine on carrier particles of citric acid, naloxone in a 4:1 ratio, and a disintegrant. This formulation (Zubsolv) provides 66% improved bioavailability and allows 29% lower dose compared to prior art Suboxone tablets. The prior art included Suboxone tablets (homogeneous mixture), Suboxone film (with citric acid but different structure), and the Orexo '443 Application (particles on carriers but not citric acid). The district court found the claims invalid as obvious, but the Federal Circuit reversed.

PROCEDURAL HISTORY

Orexo appealed the decision of the United States District Court for the District of Delaware holding claims 1, 3–6, and 8–10 of U.S. Patent No. 8,940,330 invalid for obviousness. The district court had ruled after a bench trial in an ANDA litigation.

DISPOSITION

reversed_and_remanded

REMAND INSTRUCTIONS

We remand for appropriate further proceedings.

CASES CITED

- In re Cyclobenzaprine Hydrochloride Extended-Release Capsule Patent Litig., 676 F.3d 1063 (Fed. Cir. 2012)
- InTouch Techs., Inc. v. VGO Commc'ns, Inc., 751 F.3d 1327 (Fed. Cir. 2014)

- KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398 (2007)
- Graham v. John Deere Co., 383 U.S. 1 (1966)
- Interconnect Planning Corp. v. Feil, 774 F.2d 1132 (Fed. Cir. 1985)
- In re Gordon, 733 F.2d 900 (Fed. Cir. 1984)
- Leo Pharm. Prods., Ltd. v. Rea, 726 F.3d 1346 (Fed. Cir. 2013)
- Orexo AB v. Actavis Elizabeth LLC, 217 F. Supp. 3d 756 (D. Del. 2016)