United States Court of Appeals for the Federal Circuit

2007-1513

IMPAX LABORATORIES, INC.,

Plaintiff-Appellant,

v.

AVENTIS PHARMACEUTICALS INC.,

Defendant-Appellee.

C. Kyle Musgrove, Kenyon & Kenyon LLP, of Washington, DC, argued for plaintiff-appellant. With him on the brief were Michael M. Shen and Aimee N. Soucie, Steven J. Lee, of New York, New York, and Philip J. McCabe, of San Jose, California.

Paul H. Berghoff, McDonnell Boehnen Hulbert and Berghoff LLP, of Chicago, lllinois, argued for defendant-appellee. With him on the brief were James C. Gumina, Curt J. Whitenack, and Aaron F. Barkoff.

Appealed from: United States District Court for the District of Delaware

Judge Joseph J. Farnan, Jr.

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2007-1513

IMPAX LABORATORIES, INC.,

Plaintiff-Appellant,

v.

AVENTIS PHARMACEUTICALS INC.,

Defendant-Appellee.

Appeal from the United States District Court for the District of Delaware in case no. 02-CV-00581, Judge Joseph J. Farnan, Jr.

DECIDED: October 3, 2008

Before RADER, SCHALL, Circuit Judges, and ZOBEL, District Judge *.

RADER, Circuit Judge.

The United States District Court for the District of Delaware held that United States Patent No. 5,236,940 (the '940 patent) does not qualify as an enabling prior art reference and thus does not anticipate claims 1-5 of U.S. Patent No. 5,527,814 (the '814 patent). Because the trial court correctly determined that the '940 patent is not an enabling prior art reference and that it therefore does not anticipate claims 1-5 of the '814 patent, this court affirms.

I

The '814 patent relates to the use of riluzole to treat amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease). Aventis Pharmaceuticals Inc. (Aventis) owns the '814

* Honorable Rya W. Zobel, District Judge, United States District Court for the District of Massachusetts, sitting by designation.

patent and sells riluzole under the trade name RILUTEK. On May 16, 2001, Impax Laboratories, Inc. (Impax) filed with the Food and Drug Administration (FDA) an Abbreviated New Drug Application (ANDA) pursuant to 21 U.S.C. 355(j) seeking approval to market generic riluzole tablets. On June 25, 2002, Impax sued Aventis in the district of Delaware for a declaratory judgment that Impax did not infringe, induce infringement of, or contribute to the infringement of the '814 patent. In its suit, Impax alleged that the '814 patent was invalid and unenforceable.

After a bench trial, the district court determined that Impax did not prove that the '814 patent was unenforceable due to inequitable conduct nor show that claims 1-5 were anticipated by prior art. Impax Labs., Inc. v. Aventis Pharms. Inc., 333 F. Supp. 2d 265 (D. Del. 2004). On March 16, 2005, the court entered final judgment against Impax.

Impax appealed that decision. This court affirmed-in-part, vacated-in-part, and remanded to the district court. Impax Labs., Inc. v. Aventis Pharms. Inc., 468 F.3d 1366, 1384 (Fed. Cir. 2006). On remand, the trial court examined the asserted prior art, the '940 patent, for evidence that it enables the use of riluzole to treat ALS and thus qualifies as enabling prior art. Impax Labs., Inc. v. Aventis Pharms. Inc., 496 F. Supp. 2d 428, 433 (D. Del. 2007). In the event that it qualifies as enabling prior art, the trial court also received the opportunity to determine if the disclosure anticipates claims 1-5 of the '814 patent. Id. Addressing those questions, the district court determined that the '940 patent does not enable a person of ordinary skill in the art to treat ALS with riluzole and therefore does not anticipate claims 1-5 of the '814 patent. Id. Impax timely appealed the district court's remand decision to this court.

II

An issued patent enjoys a presumption of validity. Impax Labs., 468 F.3d at 1378. Thus, a party challenging patent validity has the burden to prove its case with clear and convincing evidence. Id. When the examiner considered the asserted prior art and basis for the validity challenge during patent prosecution, that burden becomes particularly heavy. See Hewlett-Packard Co. v. Bausch & Lomb Inc., 909 F.2d 1464, 1467 (Fed. Cir. 1990).

In order to anticipate a claimed invention, a prior art reference must enable one of ordinary skill in the art to make the invention without undue experimentation. Finisar Corp. v. DirecTV Group, Inc., 523 F.3d 1323, 1336 (Fed. Cir. 2008) (citing In re Omeprazole Patent Litig., 483 F.3d 1364, 1379 (Fed. Cir. 2007)). In other words, the prior art must enable the claimed invention. Minn. Mining & Mfg. Co. v. Chemque, Inc. (3M), 303 F.3d 1294, 1301 (Fed. Cir. 2002). The "undue experimentation" component of that equation examines (1) the quantity of experimentation; (2) the amount of direction or guidance present; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims. In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

Whether a prior art reference is enabling presents a question of law based upon underlying factual findings. 3M, 303 F.3d at 1301. This court reviews the ultimate question of enablement without deference while reviewing the underlying factual inquiries for clear error. Elan Pharms., Inc. v. Mayo Found. Med. Educ. & Research, 346 F.3d 1051, 1054 (Fed. Cir. 2003). Under the clear error standard, the district

court's findings will not be overturned in the absence of a definite and firm conviction that a mistake has been made. Impax Labs., 468 F.3d at 1375.

A

The first time this case was before the district court, the trial court found that: (1) formula I encompasses a particularly large number of compounds; (2) riluzole was not meaningfully discussed in the treatment of medical conditions associated with the effects of glutamate; (3) the language of the '940 patent itself created "substantial uncertainty" regarding use of glutamate inhibiting compounds in the treatment of ALS; and (4) the language in the '940 patent discussing conditions implicating glutamate is speculative, at best. In other words, the district court found that the disclosure of the '940 patent did not put one of ordinary skill in the possession of the invention. See id. at 1384-85 (Rader, J., concurring-in-part). This court remanded for a specific determination on whether the '940 patent enables a person of ordinary skill in the art to treat ALS with riluzole without regard to the efficacy of such treatment. Id. at 1384.

On remand, the district court made additional factual findings on that specific question. The district court found that excessive experimentation would have been necessary to practice the invention. Specifically the trial court opined that formula I of the alleged prior art discloses hundreds or thousands of compounds and several diseases. Moreover, nothing in the '940 patent would direct one skilled in the art to recognize that riluzole could be used to treat ALS. The trial court rejected the notion that "the mere mention of riluzole is sufficient to put one skilled in the art in the possession of the claimed invention." Impax Labs., 496 F. Supp. 2d at 432.

The district court also did not find the dosage information in the disclosure to teach a proper treatment. Instead the trial court noted that "the dosage guidelines are broad and not specific to any of the hundreds of formula I compounds of the claimed invention or to any of the listed diseases." Id. at 433. Moreover, the '940 patent ties the dosing information to "the compounds of the invention" and specifically excludes riluzole from the invention. Id. at 432-33. Finally, the trial court also noted the absence of working examples.

In view of these findings, the district court found that one of ordinary skill in the pharmaceutical arts would have needed extensive experimentation to link riluzole with the treatment of ALS. Id. at 433. The district court then reached the ultimate conclusion that the '940 patent does not enable claims 1-5 of the '814 patent and thus, it is not anticipatory.

This court does not find error, let alone clear error, in the district court's factual findings. Weighing the Wands factors, the trial court's findings properly support its conclusion that an ordinarily skilled artisan would have needed to experiment unduly to gain possession of the invention. As shown by the trial court, the '940 patent's dosage guidelines are broad and general without sufficient direction or guidance to prescribe a treatment regimen. The alleged prior art also contains no working examples. Finally, nothing in the '940 patent would have led one of skill in the art to identify riluzole as a treatment for ALS. In sum, each component of the claimed invention—identifying riluzole as a treatment for ALS and devising dosage parameters—would require undue experimentation based on the teachings of the '940 patent. Because the '940 patent

does not enable a person of ordinary skill in the art to treat ALS with riluzole, it does not anticipate claims 1-5 of the '814 patent.

B

As this court explained during the first appeal, when an accused infringer asserts that a prior art patent anticipates specific patent claims, the infringer enjoys a presumption that the anticipating disclosure also enables the claimed invention. Impax Labs., 468 F.3d at 1382. However, the patentee may overcome that presumption with persuasive evidence showing that the prior art patent does not enable the claimed invention. Id. On appeal, Impax argues that the district court's silence regarding the initial presumption of enablement to both claimed and unclaimed material is reversible legal error. For this proposition, Impax cites this court's opinion in Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1355-56 (Fed. Cir. 2003).

To the contrary, in Amgen, the district court placed an affirmative burden of proving the prior art reference's enablement of the claimed invention on the alleged infringer. Id. This court assigned error to that shifting of the burden. In this case, the district court correctly placed the burden of proving non-enablement on the patentee. The patentee then met that burden with persuasive evidence that the '940 patent does not enable claims 1-5 of the '814 patent. The district court did not need to specifically articulate its correct burden-shifting framework. In this case, as the district court found, the record shows sufficient evidence to overcome the presumption of enablement.

III

Because the district court applied the proper enablement standard and correctly determined that the ’940 patent is not an enabling prior art reference and that it does not anticipate claims 1-5 of the ’814 patent, this court affirms.

AFFIRMED