United States Court of Appeals for the Federal Circuit

06-1087

NICHOLS INSTITUTE DIAGNOSTICS, INC.,

Plaintiff- Appellee,

v.

SCANTIBODIES CLINICAL LABORATORY, INC.,
and SCANTIBODIES LABORATORY, INC.,

Defendants-Appellants.

DECIDED: September 20, 2006

Before MAYER, RADER, and LINN Circuit Judges.

LINN, Circuit Judge.

Scantibodies Clinical Laboratory, Inc. and Scantibodies Laboratory, Inc. (collectively "Scantibodies") appeal from an order of the United States District Court for the Southern District of California denying Scantibodies' motion for partial summary judgment of invalidity of Nichols' U.S. Patent No. 6,030,790 (the "'790 patent") and granting Nichols Institute Diagnostics, Inc.'s ("Nichols") cross-motion for partial summary judgment of no invalidity of the '790 patent. Nichols Inst. Diagnostics, Inc. v. Scantibodies Clinical Lab., Inc., No. 02-CV-46 (S.D. Cal. May 3, 2005). Scantibodies

also appeals from post-trial orders for judgment as a matter of law ("JMOL") that the '790 patent is valid and infringed. Because the district court erred in denying partial summary judgment that the '790 patent is anticipated and granting partial summary judgment that the '790 patent is not anticipated, we reverse the grant of summary judgment of no anticipation, hold that all of the asserted claims (i.e., independent claim 17 and its dependent claims 20 through 25) are anticipated under 35 U.S.C. § 102, and direct entry of judgment for Scantibodies. We therefore need not, and do not, reach the remaining issues on appeal regarding infringement and alternate grounds for invalidity.

I. BACKGROUND

Human Parathyroid Hormone ("hPTH") is a protein comprised of 84 amino acids that plays an important role in regulating calcium metabolism. Various fragments of hPTH may circulate in the bloodstream; however, to be biologically active, a fragment of hPTH must include the first two amino acids and must be at least 34 amino acids long. The amount of biologically active hPTH circulating in a patient's bloodstream may be measured by creating antibodies that bind to specific amino acid sequences, also referred to as peptides, of hPTH and then incorporating those antibodies into a well-known immunoassay test.

In September of 1994, Dr. Marcus Magerlein and five of his colleagues published an abstract disclosing that they created ten antisera, labeled K1 through K10, each of which contained a mixture of antibodies that bound to specific peptides of a fragment of hPTH that contained amino acids 1 through 37 (represented as hPTH 1-37). See M. Magerlein et al., Abstract, Immunological Detection of Human Parathyroid Hormone 1-37 (hPTH 1-37), the Physiologically Circulating Fragment of hPTH, Eur. J. Pharm. Sci. 2

(1994) (the "abstract"). The abstract explains that, when used in well-known assay tests, the disclosed sera "provide the possibility to specifically detect the physiologically circulating fragment of human PTH in serum." The abstract discloses that some of the sera, namely sera labeled K1 through K3, bound predominantly to hPTH peptides having the first two amino acids. Because the antibodies in the K1 through K3 sera bound predominantly to peptides containing the first two amino acids, and the antibodies in the other sera bound to peptides of hPTH containing blocks of amino acid sequences through 37, the sera could be used in combination to specifically detect hPTH fragments that include the first two amino acids and are 37 amino acids long.

The abstract was published and distributed to the public on September 12, 1994. It was not until after that date that the authors of the abstract discovered that, to be biologically active, a fragment of hPTH must have both the first two amino acids and be at least 34 amino acids long. Thus, it was not until after the abstract was published that the authors recognized the significance of the disclosure in the abstract.

On September 22, 1995, Dr. Magerlein and his colleagues filed the patent application that is the subject of this litigation. The '790 patent discloses compositions of antibodies that selectively bind to specific peptide sequences of hPTH 1-37, methods of using the antibodies to detect biologically active hPTH, and immunoassay test kits containing the antibodies to assist in the diagnosis of biologically active hPTH. Independent claim 17 and its dependent claims 20 through 25 are at issue in this appeal. At the trial court, and on appeal, the parties treated claim 17 as representative. Claim 17 recites:

> A composition comprising an antibody or antibody fragment and a suitable carrier: wherein the antibody or antibody

> fragment selectively binds a peptide of human parathyroid hormone (hPTH) selected from the group consisting of peptides having SEQ. ID Nos. 1-6.

'790 patent, col. 26, ll. 29-34. The peptides having the sequence identification numbers 1 through 6, (i.e., SEQ. ID Nos. 1-6) are hPTH 1-10, hPTH 1-9, hPTH 1-8, hPTH 1-7, hPTH 1-6, and hPTH 1-5, respectively.

Nichols is the exclusive licensee of the '790 patent. Scantibodies manufactures and sells test kits for hPTH that contain antibodies the bind to peptides of hPTH 1-9 and hPTH 1-12. On January 8, 2002, Nichols sued Scantibodies, alleging that Scantibodies' hPTH 1-9 and hPTH 1-12 antibodies literally infringed claims 17 and 20-25 of the '790 patent. Scantibodies counterclaimed that the '790 patent is invalid and not infringed.

Scantibodies twice sought summary judgment that the abstract anticipates the '790 patent. The district court denied both motions. On June 2, 2003, in the first order denying Scantibodies's summary judgment motion on anticipation, the district court held that Scantibodies had "not proven by clear and convincing evidence that the abstract [expressly] describes the same antibodies as those in the patent" because the antibodies described in the abstract "predominantly" bind to hPTH peptides with the first two amino acids, whereas the antibodies disclosed in the patent "selectively" bind to hPTH peptides with the first two amino acids. See Nichols Inst. Diagnostics, Inc. v. Scantibodies Clinical Lab., Inc., No. 02-CV-46 (S.D. Ca. Jun. 2, 2003).

On May 3, 2005, in the second order denying Scantibodies's summary judgment motion on anticipation, the district court considered whether the abstract discloses the claimed antibodies inherently. See Nichols Inst. Diagnostics, Inc. v. Scantibodies Clinical Lab., Inc., No. 02-CV-46 (S.D. Ca. May 3, 2005). The district court recognized

that the sera disclosed in the abstract contained a mixture of antibodies and noted that "there is no dispute that the [claimed antibody] was present in the K2 serum." Id., slip op. at 9. Nevertheless, the district court concluded that the abstract did not inherently anticipate the claimed antibody because the claimed antibody "differentiates between biologically active and inactive hPTH," whereas the abstract "does not disclose or suggest the means of differentiating between biologically active and inactive hPTH." Id.

The case proceeded to trial. The jury found that Scantibodies's hPTH 1-9 antibody infringes claims 15 and 21, but that Scantibodies's hPTH 1-12 antibody does not infringe. The jury also found that the patent was invalid for failure to disclose the best mode, and for lack of enablement and written description. After trial, the parties each filed motions for JMOL, Nichols contesting the jury's finding that the '790 patent is invalid and not infringed by the hPTH 1-12 antibody, and Scantibodies contesting the jury's finding that the hPTH 1-9 antibody infringes claims 15 and 21. On August 30, 2005, the trial court granted Nichols's motions and denied Scantibodies's motion. On November 16, 2005, the trial court granted Nichols's motion for permanent injunction, but stayed the motion pending this appeal.

Scantibodies timely appealed. We have jurisdiction over this appeal pursuant to 28 U.S.C. §§1292(a)(1).

II. DISCUSSION

A. Standard of Review

This court reviews a district court's grant or denial of summary judgment under the law of the regional circuit. Chamberlain Group, Inc. v. Skylink Techs., Inc., 381 F.3d 1178, 1191 (Fed. Cir. 2004). Under the law of the United States Court of Appeals for

the Ninth Circuit, this court reviews the grant or denial of summary judgment without deference. See DeBoer v. Pennington, 206 F.3d 857, 863 (9th Cir. 2000) (stating that the Ninth Circuit reviews both a denial and grant of summary judgment de novo).

Anticipation is a question of fact. SmithKline Beecham Corp. v. Apotex Corp., 403 F.3d 1331, 1343 (Fed. Cir. 2005) (quotation omitted). "However, without genuine factual disputes underlying the anticipation inquiry, the issue is ripe for judgment as a matter of law." Id. Whether an asserted anticipatory document qualifies as a "printed publication" under § 102 is a legal conclusion based on underlying factual determinations. N. Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 936 (Fed. Cir. 1990).

B. Analysis

Scantibodies argues that the district court erred in granting Nichols's cross-motion for summary judgment of no anticipation on two grounds. First, Scantibodies argues that the district court erroneously limited the asserted claims to an antibody that will detect biologically active hPTH. Second, Scantibodies argues that, because it is undisputed that the antiserum disclosed in the abstract contained the claimed antibody, and because it was well known how to isolate the claimed antibody from the other antibodies in the disclosed serum, the abstract inherently anticipates the asserted claims.

Nichols counters that, although the abstract discloses the K2 antibody, the abstract does not disclose the "selective" binding capability of the claimed antibody; rather, the abstract discloses only that the K1 through K3 sera show "predominant" binding to hPTH peptides having the first two amino acids. Nichols also contends that

the abstract does not anticipate because it was not until after the abstract was submitted that the inventors appreciated the significance of the claimed antibody, namely that it could be used to detect biologically active hPTH. Nichols also asserts that the abstract is not a "printed publication" under 35 U.S.C. § 102(b) because it was not adequately indexed.

Turning first to the issue whether the abstract is a "printed publication" under 35 U.S.C. § 102(b), whether a given reference is a "printed publication" depends on whether it was "publicly accessible" during the relevant period. In re Wyer, 655 F.2d 221, 226 (C.C.P.A. 1981). The parties do not dispute that the abstract was published in the European Journal of Pharmaceutical Sciences and mailed to subscribers, including scientists, attendees of industry-related conferences, universities and libraries on September 12, 1994. It is also undisputed that at least one library, the British Library Document Supply Centre, received an original copy of the abstract on September 16, 1994 and that such copy "would have been available for public use from that date." Given these undisputed facts regarding the distribution of the abstract directly in to the hands of the interested public, we hold that the abstract was sufficiently publicly accessible to be considered a printed publication under 35 U.S.C. § 102(b). See Cooper Cameron Corp. v. Kvaerner Oilfield Products, Inc., 291 F.3d 1317 (Fed. Cir. 2002) (holding that a document that was distributed to three members and six participants to a joint venture project was prior art); see also Wyer, 655 F.2d 221; Klopfenstein, 380 F.3d 1345 (Fed. Cir. 2004). In re Cronyn, 890 F.2d 1158 (Fed. Cir. 1989), cited by Nichols, does not compel a different result. In that case, a single copy of a research thesis was sent to one library and was indexed only by the student's name,

which bore no relationship to the subject of the thesis. In this case, multiple copies of the abstract were distributed directly to multiple interested members of the relevant public.

We also hold, for the reasons below, that the abstract anticipates the asserted claims, because no reasonable juror could have found that the abstract does not inherently disclose the claimed antibody. SmithKline, 403 F.3d at 1343. The abstract itself and the testimony of Dr. Magerlein conclusively demonstrate that the abstract expressly or inherently discloses each element of the asserted claims. The abstract states that the authors have obtained antibodies and that "the different regions of hPTH 1-37 are covered by the produced antibodies. Furthermore, the combinations of two antibodies in a two-side assay are tested." The abstract also discloses that sera mixture K1 through K3, which contains the K2 antibody, shows predominant binding to peptides having the first two amino acids. Dr. Magerlein testified, and Nichols does not dispute, that the K2 antibody is the same as the claimed antibody. See Magerlein Deposition at 271-72, Nichols Inst. Diagnostics, Inc. v. Scantibodies Clinical Lab., Inc., No. 02-CV-46 (Aug. 10, 2004) ("[T]he antibody that was used for the assay [described in the '790 patent] was isolated from the antiserum K2."); id. at 310 ("The test described or referenced here [in the '790 patent] contains the K2 antibody that was isolated from the K2 antiserum."). Dr. Magerlein also testified that the claimed antibody was isolated from the K2 antiserum using affinity purification, which was well-known in the art. See id. at 291 (testifying that affinity purification was "well known" and that "any expert skilled in the art . . . would know about that technique"); Transcript of Magerlein Cross Examination at vol. 6, p. 94, Nichols Inst. Diagnostics, Inc. v. Scantibodies Clinical Lab.,

Inc., No. 02-CV-46 (Aug. 30, 2005), (testifying that "[t]his assay [described in the '790 patent] used the K-2 antibody obtained by affinity purification of this antiserum disclosed here in this abstract"). It is thus beyond dispute that the K2 antibody disclosed in the abstract is the claimed antibody and the claimed antibody could be isolated from the K1 through K3 sera by a technique that was well-known in the art.

Nichols nevertheless maintains that that the abstract does not anticipate because the abstract discloses only that the K1 through K3 sera shows "predominant" binding to hPTH peptides having the first two amino acids, whereas the claimed antibody requires "selective" binding to hPTH peptides having the first two amino acids. Nichols acknowledges that the reason the K1 through K3 sera disclosed in the abstract show only "predominant" binding is because the K1 through K3 sera contain a mixture of antibodies. The claims however, recite the binding properties of the isolated K2 antibody, not the K1 through K3 sera. It is undisputed that, once the K2 antibody is isolated from the K1 through K3 sera, using well-known purification methods, the isolated K2 antibody necessarily will exhibit the claimed "selective" binding. Because the K2 antibody, which is contained in the K1 through K3 sera, necessarily has the claimed binding properties, the abstract inherently anticipates. See Schering, 339 F.3d at 1377 (holding that "a prior art reference may anticipate without disclosing a feature of the claimed invention if that missing characteristic is necessarily present, or inherent, in the single anticipating reference"). Because the abstract inherently meets each and every element of the asserted claims, the asserted claims are anticipated and hence invalid. Id. at 1379.

Nichols's argument that the abstract does not anticipate because the significance of the claimed antibody was not known until after the abstract was submitted is without merit. "[I]nherent anticipation does not require a person of ordinary skill in the art to recognize the inherent disclosure in the prior art at the time the prior art is created." SmithKline, 403 F.3d at 1343 (citations omitted); see also Schering, 339 F.3d at 1377 (holding that "inherent anticipation does not require that a person of ordinary skill in the art at the time would have recognized the inherent disclosure"); MEHL/Biophile Int'l Corp. v. Milgraum, 192 F.3d 1362, 1366 (Fed. Cir. 1999) ("Where . . . the result is a necessary consequence of what was deliberately intended, it is of no import that the article's authors did not appreciate the results.").

CONCLUSION

For the above reasons, the decision of the district court is reversed.