United States Court of Appeals for the Federal Circuit

HAEMONETICS CORP., Plaintiff-Appellee,

v.

BAXTER HEALTHCARE CORP. AND FENWAL INC., Defendants-Appellants.

2009-1557

Appeal from the United States District Court for the District of Massachusetts in Case No. 05-CV-12572, Judge Nathaniel M. Gorton.

Decided: June 2, 2010

THOMAS J. PARKER, Alston & Bird LLP, of New York, New York, argued for plaintiff-appellee. Of counsel on the brief was MARGARET H. PAGET, Sherin & Lodgen LLP, of Boston, Massachusetts. Of counsel were JAMES W. MATTHEWS and KATY E. KOSKI, Sherin & Lodgen LLP, of Boston, Massachusetts; and KAMRAN JIVANI, Alston & Bird LLP, of Atlanta, Georgia.

GREGORY A. CASTANIAS, Jones Day, of Washington, DC, argued for defendants-appellants. With him on the

brief were LUKE A. SOBOTA and PAUL R. GUGLIUZZA; and JOHN J. NORMILE, of New York, New York.

Before LOURIE, GAJARSA, and MOORE, Circuit Judges.

LOURIE, Circuit Judge.

Baxter Healthcare Corp. and Fenwal Inc. (collectively, "Fenwal") appeal from the decision of the United States District Court for the District of Massachusetts granting judgment as a matter of law ("JMOL") that asserted claim 16 of U.S. Patent 6,705,983 ("the '983 patent") is not indefinite, from the district court's denial of JMOL that claim 16 was either anticipated by prior invention or obvious, and from the court's award of prospective remedies. Because the district court erred in its construction of "centrifugal unit" in claim 16, thereby affecting the court's other determinations, we reverse in part, vacate in part, and remand.

BACKGROUND

Haemonetics Corp. ("Haemonetics") and Fenwal both manufacture and sell centrifuge devices designed to separate red blood cells ("RBCs") from human blood by apheresis. In contrast to manual collection, in which an individual donates whole blood, apheresis involves collecting RBCs directly from a donor connected to an automated centrifuge system. The system separates and collects RBCs from the donor's drawn blood before returning the remaining blood components to the donor, thus yielding up to double the volume of RBCs from a single donation compared to manual collection. An important feature of apheresis centrifuge devices is portability since approximately 70 to 80% of blood collection in the United States takes place on mobile blood drives. Haemonetics sells two portable RBC apheresis devices suitable for use on mobile blood drives: the $MCS^{\circledast}+$, introduced in 1995, and the CymbalTM, introduced in 2007. In 2003, Fenwal introduced its portable RBC apheresis device, the $ALYX^{\circledast}$ system.

Haemonetics is the owner by assignment of the '983 patent, which claims a compact blood centrifuge device for separating and collecting components in a liquid such as blood. The '983 patent describes a centrifugal device comprising (1) a vessel in which blood components are separated in a separation chamber and (2) tubing through which blood flows in and out of the vessel. The tubing connects the spinning vessel to a non-rotating support structure, forming a question mark-shaped loop around the vessel.

Figure 1 of the '983 patent illustrates the claimed centrifugal device.

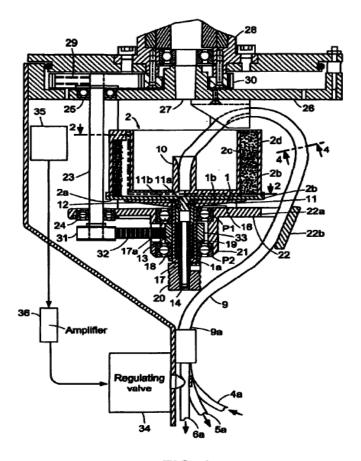


FIG. 1

Figure 1 shows the configuration of the vessel, marked as number 2, and its associated tubing, numbers 4a, 5a, and 6a, which are enclosed in tubular component 9. The vessel and the tubes comprise the mobile unit that connects to the centrifugal rotor, number 1, and that the user discards after each use. *See* '983 patent col.5 ll.1-7.

On December 22, 2005, Haemonetics brought suit against Fenwal in the United States District Court for the

District of Massachusetts,¹ alleging infringement of the '983 patent by Fenwal's ALYX[®] centrifugal system. After claim construction and summary judgment motions, Haemonetics limited its allegation of infringement to claim 16. Fenwal counterclaimed that claim 16 was invalid as indefinite, as anticipated by prior invention, and as obvious.

Claim 16 claims a centrifugal unit that includes a centrifugal component, which the parties agree refers to the vessel, and a plurality of tubes. It reads as follows:

A centrifugal unit comprising a centrifugal component and a plurality of tubes, said unit to turn around an axis to separate the components of a liquid, blood in particular, with such plurality of tubes displaying a single tubular component wherein said unit includes:

a base in the form of a disk;

an external cylindrical wall extending from the base;

an internal cylindrical wall extending from the base and separated by the external wall so as to define a ring-shaped separation chamber among each other;

a tubular housing almost extending coaxially to said rotating axis from the base to receive an end of a tubular unit; and

a plurality of channels extending radially in the base of the *centrifugal unit*, with each channel providing communication between a respective

¹ Haemonetics initially brought suit against Baxter Healthcare Corp. and Baxter International Inc. Haemonetics later added Fenwal Inc. as a defendant in March 2007 when Fenwal became an independent corporation as a result of Baxter's divestiture of its transfusion therapies business, which included the ALYX[®] centrifugal system.

tube of the tubular unit and the separation chamber, with the *centrifugal unit* having a radius between 25 and 50 mm and a height between 75 and 125% of the radius.

Id. claim 16 (emphases added).

On August 16, 2007, the district court issued a claim construction order and construed the term "centrifugal unit" as used in claim 16. The court held, and the parties agreed, that "centrifugal unit" as used in the claim's first line means "the combination of both the vessel and the tubing." Haemonetics Corp. v. Baxter Healthcare Corp., 517 F. Supp. 2d 514, 518 (D. Mass. 2007). Nevertheless, the court construed the claim's remaining two references to "centrifugal unit," including the final one in the context of the "height" and "radius" limitations, to mean only the vessel. Id. at 519-20. The court relied on claim 16's use of identical dimensions to the patent's other independent claims, which the parties agreed used "centrifugal unit" to refer exclusively to the vessel. Id. at 519. The court reasoned that, because the vessel and the tubing together are always larger than the vessel alone, giving "centrifugal unit" a construction that includes the tubing in the context of the dimensional limitations "would yield an absurdity." Id.

Following claim construction, the case proceeded to trial before a jury. At the close of evidence, the district court granted without opinion Haemonetics's motion for JMOL that claim 16 was not indefinite. The jury then found claim 16 infringed and not invalid, and awarded Haemonetics over \$11.3 million in lost profits damages and over \$4.3 million in reasonable royalty damages. The district court denied Fenwal's motions for JMOL on anticipation and obviousness without opinion, then entered a permanent injunction to begin on December 1, 2010, and finally ordered Fenwal to pay a 10% royalty on sales of the infringing kits made after the jury verdict of infringement.

Fenwal timely appealed. We have jurisdiction pursuant to 19 U.S.C. $\frac{1295(a)(1)}{12}$.

DISCUSSION

I.

We begin with the district court's construction of the claim term "centrifugal unit." Claim construction is an issue of law, *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977-78 (Fed. Cir. 1995) (en banc), which this court reviews de novo, Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1454-55 (Fed. Cir. 1998) (en banc). The words of a claim are generally given their ordinary and customary meaning as understood by a person of ordinary skill in the relevant art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312-13 (Fed. Cir. 2005) (en banc).

Fenwal argues that the district court erred in construing "centrifugal unit" in the body of claim 16 to refer to just the vessel when the plain language of the claim's preamble defines the unit as comprising a vessel and a According to Fenwal, the district plurality of tubes. court's construction violates black letter claim construction law by either rendering superfluous "comprising a centrifugal component" or rendering "centrifugal unit" redundant with "centrifugal component." Instead, Fenwal asserts, "centrifugal unit" should be construed to refer to the vessel and its associated tubing throughout claim 16, a construction that tracks the specification's description of such an embodiment at column 3, lines 21 through 22, and which accomplishes the invention's goal of creating a small, portable apheresis machine.

Haemonetics responds that the specification makes clear that "centrifugal unit" in the context of the dimensional limitations refers to the vessel alone, as Fenwal concedes for claims 1 and 20. To reconcile this construction with claim 16's first use of the term, which expressly defines "centrifugal unit" as comprising a centrifugal component and a plurality of tubes, Haemonetics asserts that the claim preamble does no more than state the claimed invention's intended field of use. Converselv. Haemonetics argues that Fenwal's construction of "centrifugal unit" in the body of claim 16 to include the tubing nonsensically alters the unit's dimensional limitations: excludes every embodiment in the specification; and ignores that the invention's goals, *i.e.*, small size, light weight, and economic disposability, depend on the vessel having the claimed height and radius range.

We agree with Fenwal. Patent claims function to delineate the precise scope of a claimed invention and to give notice to the public, including potential competitors, of the patentee's right to exclude. Bicon. Inc. v. Straumann Co., 441 F.3d 945, 950 (Fed. Cir. 2006). This notice function would be undermined, however, if courts construed claims so as to render physical structures and characteristics specifically described in those claims superfluous. Id.; see also Elekta Instrument S.A. v. O.U.R. Scientific Int'l, Inc., 214 F.3d 1302, 1307 (Fed. Cir. 2000) (holding that the claim language "extending between latitudes 30°-45°" did not include latitudes between 14° and 43° because that would "render[] the reference to 30° superfluous"). As such, we construe claims with an eve toward giving effect to all of their terms, Bicon, 441 F.3d at 950, even if it renders the claims inoperable or invalid, see Chef Am., Inc. v. Lamb-Weston, Inc., 358 F.3d 1371, 1374 (Fed. Cir. 2004) ("[W]here, as here, claims are susceptible to only one reasonable interpretation and that interpretation results in a nonsensical construction of the claim as a whole, the claim must be invalidated." (quoting *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357 (Fed. Cir. 1999))); *Elekta Instrument*, 214 F.3d at 1309 (same).

In this case, claim 16's beginning and, in our view, controlling language could hardly be clearer. Claim 16 "A centrifugal unit comprising a centrifugal states: component and a plurality of tubes" It does not merely state the intended field of use in a preamble, as Haemonetics argues. Rather, it unambiguously defines "centrifugal unit" as "comprising" two structural components: a centrifugal component and a plurality of tubes. The claim then further recites, not the centrifugal component and not a centrifugal unit, but "the centrifugal unit" as "having a radius between 25 and 50 mm and a height between 75 and 125% of the radius." Reading "the centrifugal unit" in the context of the dimensional limitations to refer exclusively to the vessel, as the district court did, ignores the antecedent basis for "the centrifugal unit," see Process Control, 190 F.3d at 1356-57, and fails to give effect to the claim language "comprising a centrifugal component," see Bicon, 441 F.3d at 950.

Furthermore, the specification defines "centrifugal unit" in the context of the height and radius limitations in two different embodiments, one that tracks the language of claim 1, in which the parties agree that "centrifugal unit" refers to the vessel alone, and one that tracks the language of claim 16. Specifically, the specification describes a "first embodiment" in which a centrifugal device "includes a centrifugal unit with a center and a rotation axis." '983 patent col.2 ll.50-53. In this embodiment, which tracks the language of claim 1, a plurality of tubes connects to the centrifugal unit, and the "centrifugal unit has a radius between 25 and 50 mm and a height between 75 and 125% of the radius." *Id.* col.2 ll.53-65. The specification also describes "another embodiment" in which a centrifugal unit "includes a centrifugal component *and* a plurality of tubes," tracking the language of claim 16. *Id.* col.3 ll.20-22 (emphasis added). Again, the "centrifugal unit has a radius between 25 and 50 mm and a height between 75 and 125% of the radius." *Id.* col.3 ll.33-35.

The patentee's inconsistent use of identical height and radius limitations for two different embodiments thus indicates that "the centrifugal unit" in the context of the dimensional limitations must have different meanings in the context of different claims. Compare Process Control, 190 F.3d at 1356-57 (holding that "a discharge rate" and "the discharge rate" in the same claim maintained the same meaning because the written description did not clearly redefine the term in the different contexts so as to put one skilled in the art on notice), with Epcon Gas Sys., Inc. v. Bauer Compressors, Inc., 279 F.3d 1022, 1031 (Fed. Cir. 2002) (construing the term "substantially" differently in the same claim in the context of language of approximation-"substantially constant"-versus language of magnitude-"substantially below"). In other words, the description of two embodiments with each tracking the language of different independent claims most reasonably supports a construction in which "centrifugal unit" has one meaning in claim 1 and another in claim 16. See Wilson Sporting Goods Co. v. Hillerich & Bradsby Co., 442 F.3d 1322, 1327-29 (Fed. Cir. 2006) (holding that the claim term "gap" had different meanings in different claims based on those claims' different geometrical contexts).

Haemonetics argues, and the district court concluded, that because the vessel with the tubing is larger than the vessel alone, construing "centrifugal unit" in the context of the dimensional limitations to include the tubing "would yield an absurdity." *Haemonetics*, 517 F. Supp. 2d at 519. Maybe so, but we do not redraft claims to contradict their plain language in order to avoid a nonsensical result. *See, e.g., Elekta Instrument*, 214 F.3d at 1309. *Cf. Ultimax Cement Mfg. Corp. v. CTS Cement Mfg. Corp.*, 587 F.3d 1339, 1348 (Fed. Cir. 2009) (holding that construing "soluble calcium sulfate anhydride" to mean "soluble anhydrous calcium sulfate" did not rewrite the claim but "merely restate[d] its plain meaning" in light of the specification and the knowledge in the art).

Claim 16 defines "centrifugal unit" to include a plurality of tubes and defines the dimensional limitations of that centrifugal unit. An "error" may have occurred in drafting claim 16, as Haemonetics's counsel indicated during the district court's claim construction hearing, J.A. 923, but it is what the patentee claimed and what the public is entitled to rely on. See Process Control, 190 F.3d at 1357 ("Where, as here, the claim is susceptible to only one reasonable construction, . . . we must construe the claims based on the patentee's version of the claim as he himself drafted it."); Hoganas AB v. Dresser Indus., Inc., 9 F.3d 948, 951 (Fed. Cir. 1993) ("It would not be appropriate for us now to interpret the claim differently just to cure a drafting error . . . That would unduly interfere with the function of claims in putting competitors on notice of the scope of the claimed invention.").

We thus reverse the district court's claim construction and hold that "centrifugal unit" in claim 16 consistently means a vessel and a plurality of tubes, irrespective of its meaning in claim 1.

II.

Related to the construction of "centrifugal unit" in claim 16, Fenwal also appeals the district court's grant of JMOL that claim 16 was not indefinite. As with claim construction, we review a decision on indefiniteness *de novo*. *Datamize*, *LLC v*. *Plumtree Software*, *Inc.*, 417 F.3d 1342, 1347 (Fed. Cir. 2005).

The Patent Act requires that a patent's specification "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, ¶ 2. "Because the claims perform the fundamental function of delineating the scope of the invention, the purpose of the definiteness requirement is to ensure that the claims delineate the scope of the invention using language that adequately notifies the public of the patentee's right to exclude." *Datamize*, 417 F.3d at 1347 (internal citations omitted).

Yet, because claim construction frequently poses difficult questions over which reasonable minds may disagree, proof of indefiniteness must meet "an exacting standard." *Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249 (Fed. Cir. 2008). "Only claims 'not amenable to construction' or 'insolubly ambiguous' are indefinite." *Id.* at 1250 (quoting *Datamize*, 417 F.3d at 1347). A claim is not indefinite merely because parties disagree concerning its construction. An accused infringer must thus demonstrate by clear and convincing evidence that one of ordinary skill in the relevant art could not discern the boundaries of the claim based on the claim language, the specification, the prosecution history, and the knowledge in the relevant art. *Id.* at 1249-50.

The district court held that claim 16 is not indefinite as a matter of law but did not provide a reason for its conclusion. Fenwal argues that the court erred in that conclusion and that claim 16 is indefinite because the terms "radius" and "height" used to define the centrifugal unit can be measured at several different places, and the patent does not disclose which is correct. Fenwal, however, rests its argument exclusively on the district court's erroneous construction of "centrifugal unit" in the context of the dimensional limitations to refer to the vessel alone. Specifically, Fenwal points to conflicting evidence at trial regarding whether one skilled in the art would understand "radius" and "height" to refer to the interior dimensions of the vessel, as Fenwal argued, or the exterior dimensions of the vessel, as Haemonetics argued. While Fenwal does identify in passing additional radius and height measurements that include the tubing, Fenwal does not argue or point to any evidence indicating whether or not including the tubing in the construction of "centrifugal unit" makes the radius and height measurements discernable to one of skill in the art and where around the tubing the measurements are to be made.

Haemonetics also argues the issue of indefiniteness based only on the district court's incorrect claim construction. As a result, this court lacks any evidence in the record or any argument by the parties directed to where the height or radius are to be measured when the centrifugal unit includes not only the circular vessel but also the off-set, question mark-shaped tubes. Given the change in the unit's shape in claim 16 under this court's construction of "centrifugal unit" and the absence of any basis on which to decide the issue in the first instance, we vacate the district court's grant of JMOL and remand for a determination of the meaning of "radius" and "height" under the correct claim construction of "centrifugal unit" and of whether claim 16 is definite.

III.

Fenwal also appealed the jury's finding that the '983 patent was not invalid due to anticipation or obviousness

and the district court's award of prospective remedies. Again, because the jury's verdict on invalidity and infringement relied on the district court's incorrect claim construction, we vacate the verdict and the award of prospective remedies and remand for proceedings consistent with this opinion.

CONCLUSION

For the foregoing reasons, we reverse in part, vacate in part, and remand.

REVERSED IN PART, VACATED IN PART, and REMANDED