

United States Court of Appeals for the Federal Circuit

THE LARYNGEAL MASK COMPANY LTD. AND
LMA NORTH AMERICA, INC.,
Plaintiffs-Appellants,

v.

AMBU A/S, AMBU INC., AND AMBU LTD.,
Defendants-Cross Appellants.

2010-1028, -1062

Appeals from the United States District Court for the
Southern District of California in case No. 07-CV-1988,
Judge Dana M. Sabraw.

Decided: September 21, 2010

STEPHEN J. MARZEN, Shearman & Sterling LLP, of
Washington, DC, argued for plaintiffs-appellants. With
him on the brief were VICKI S. VEENKER and ADAM P.
NOAH. Of counsel on the brief were JOHN B. SGANGA, JR.,
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CHARLENE M. MORROW, Fenwick & West LLP, of
Mountain View, California, argued for defendants-cross

appellants. With her on the brief were DARRYL M. Woo and BRYAN A. KOHM, of San Francisco, California. Of counsel was JEFFREY V. LASKER.

Before RADER, *Chief Judge*, LOURIE and MOORE, *Circuit Judges*.

MOORE, *Circuit Judge*.

The Laryngeal Mask Company Ltd. and LMA North America, Inc. (collectively, LMA) appeal the district court's summary judgment that the Aura40™, AuraOnce™, and AuraStraight™ products made by Ambu A/S, Ambu Inc., and Ambu Ltd. (collectively, Ambu) did not infringe the asserted claims of U.S. Patent No. 7,156,100 ('100 patent) and that all claims were invalid for lack of written description under 35 U.S.C. § 112. We conclude that the district court erred in its construction of the claim term "backplate." Because its summary judgment of no infringement was predicated on this erroneous claim construction, we vacate. We further conclude that LMA has raised a genuine issue of material fact precluding summary judgment on the issue of written description, and we therefore vacate the court's judgment of invalidity and remand for further proceedings.

BACKGROUND

The '100 patent concerns laryngeal mask airway devices, which are artificial airway devices used to deliver anesthetic gases during surgery and to establish unobstructed airways in patients in emergency situations. '100 patent col.1 ll.10-13. As shown below, these devices include an airway tube [47] attached to a backplate [52], which is surrounded by an inflatable cuff [55]. The device is inserted into the patient's mouth and throat until the

far (distal) end of the cuff meets the opening of the esophagus [37]. The cuff is inserted in a deflated state. Once in place, the cuff is inflated using a cuff airway tube [62], forming a seal around the patient's laryngeal inlet and preventing gases from entering the esophagus. Anesthetic gas or air can then flow into the patient's laryngeal inlet via the airway tube [47].

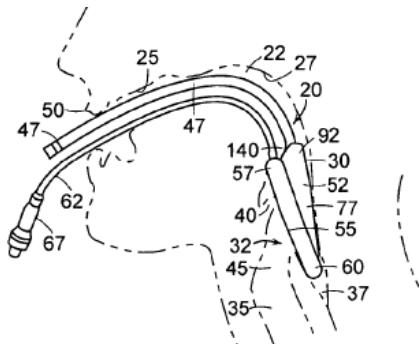


FIG. 2

'100 patent, fig. 2.

Laryngeal mask airway devices were pioneered in the 1980s by Dr. Archibald Brain, the inventor listed on the '100 patent. According to the '100 patent, one problem with prior art laryngeal mask airway devices is that during insertion, the leading edge of the deflated cuff will occasionally fold over on itself, allowing the more rigid distal end of the mask to catch the inside of the patient's throat. *Id.* col.1 ll.31-35. This can be unpleasant for the patient and may prevent the cuff from making a full seal around the patient's laryngeal inlet. *Id.* col.1 ll.46-40. The invention of the '100 patent seeks to minimize the risk that the deflated cuff will fold over on itself by adding a "reinforcing rib which serves to stiffen the leading end of the LMA-device during the course of the procedure for its insertion." *Id.* col.1 ll.47-54.

LMA filed suit against Ambu, asserting that certain of Ambu's laryngeal mask airway devices infringed claims 1 to 6 of the '100 patent. Ambu's accused products include its Aura40™, AuraOnce™, and AuraStraight™ laryngeal mask airway devices. The district court construed the disputed terms of the '100 patent. Relevant to this appeal, the court construed the claim term "backplate" as "the relatively rigid mask structure surrounded by the cuff and including a tube joint." *The Laryngeal Mask Co. v. Ambu A/S*, Civ. No. 07-CV-1988, D.I. 171, 7 (S.D. Cal. Mar. 17, 2009) (Claim Construction Order). The tube joint is the connection between the mask and the airway tube. *See, e.g.*, '100 patent figs. 2-3. The district court concluded that Ambu's accused devices¹ do not have a tube joint because the mask structure and the airway tube are integrally molded—they are one continuous piece rather than two pieces joined together by a joint. Because the accused products lacked a tube joint the district court concluded they lacked a backplate. *The Laryngeal Mask Co. v. Ambu A/S*, Civ. No. 07-CV-1988, D.I. 224, 5 (S.D. Cal. June 25, 2009) (Noninfringement Order). Therefore, the court granted summary judgment that Ambu's Aura40™, AuraOnce™, and AuraStraight™ products do not literally infringe claims 1 to 6 of the '100 patent. *Id.* at 6. The court also granted summary judgment of noninfringement under the doctrine of equivalents, concluding that it would vitiate the backplate limitation to equate a backplate that includes a tube joint to a backplate molded directly to an airway tube. *Id.* at 8.

¹ LMA also asserted that Ambu's AuraFlex™ device infringes the claims of the '100 patent, but this model is not integrally molded and was not part of the district court's summary judgment order.

The district court further granted Ambu's motion for summary judgment of invalidity for lack of written description. *The Laryngeal Mask Co. v. Ambu A/S*, Civ. No. 07-CV-1988, D.I. 476 (S.D. Cal. Sept. 25, 2009) (*Invalidity Order*). The court determined that the specification failed to adequately describe a mask having "at least a portion of the posterior portion of a wall of the cuff in the distal region being thicker and stiffer than other portions of the cuff," as required by claim 1. *Id.* at 4-6. The court thus concluded that claim 1 and its dependent claims were invalid under 35 U.S.C. § 112, ¶ 1. *Invalidity Order* at 7.

LMA appeals, challenging the court's claim construction and judgments of noninfringement and invalidity. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

This court reviews a grant of summary judgment *de novo*. *Immunocept, L.L.C. v. Fulbright & Jaworski, L.L.P.*, 504 F.3d 1281, 1286 (Fed. Cir. 2007). "Summary judgment is appropriate when there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law." *Id.*

I. Claim Construction

We review claim construction *de novo*. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1455-56 (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 art in question at the time of the invention when read in the context of the specification and prosecution history. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc).

Claims 1 to 6 are at issue. Claims 2 to 6 all depend from claim 1, which reads:

1. A laryngeal-mask airway device comprising:

a *backplate* defining a passage;

an inflatable cuff, the cuff defining a distal region and a central opening at least when inflated, the cuff being attached to the *backplate*, the cuff being insertable through a mouth of a patient to an inserted location within the patient, an airway extending from a laryngeal inlet of the patient, through the central opening, to the passage when the cuff is inflated and at the inserted location, at least a portion of the posterior portion of a wall of the cuff in the distal region being thicker and stiffer than other portions of the cuff.

'100 patent, claim 1 (emphasis added).

On appeal, LMA argues that the district court improperly read a tube joint limitation into the claims. LMA contends that the claim language requires only that the backplate "defin[e] a passage" and that the "cuff be[] attached to the backplate." LMA asserts that because the claims do not mention an airway tube, the claims need not clarify or explain how the airway tube will attach to the backplate.

LMA argues that the specification's repetition of the term tube joint does not justify adding it to the claims. LMA states that the "Summary of the Invention" describes "a mask attached to one end of the airway tube," and LMA asserts that this statement is broad enough to

include a mask that is integrally molded to an airway tube as well as devices with a tube joint. LMA Reply Br. 7.

LMA further argues that the prosecution history weighs against the addition of a tube joint limitation. LMA explains that during the final phase of prosecution, when pursuing claims directed to a mask having a reinforced cuff, it deleted the airway tube and tube joint language from the claims. LMA reiterates that the tube joint has nothing to do with the claimed invention. LMA asserts that because the terms “airway tube” and “tube joint” were deliberately deleted, it is improper to read these limitations back into the claims.

Ambu contends that backplate is a technical term coined by the inventor, Dr. Brain. Ambu does not argue that the plain and ordinary meaning of backplate includes a tube joint, but rather that Dr. Brain acted as his own lexicographer and defined backplate as a bowl containing a passage and a tube joint, fitted between the airway tube and the inflatable cuff. Ambu places great emphasis on the specification statement that: “The backplate 52 has a one-piece, integral spoon-shape including a bowl 90 and an external tube-joint 92 oriented proximally relative to the bowl, as shown in FIGS. 5 and 6.” ’100 patent col.6 ll.3-5. Ambu asserts that every figure, every embodiment, and every description of the backplate in the ’100 patent shows that the backplate is a separate structure from the airway tube and comprises a tube joint for connection to the airway tube. Ambu concludes that because “backplate” does not have a common meaning broader than that described in the ’100 patent, the patentee must have acted as his own lexicographer. Ambu further asserts that the prosecution history does not compel excluding the tube joint limitation. Ambu contends that by deleting

the tube joint language, LMA removed clarifying language from the claims, but LMA did not remove any limitation.

This is a difficult case of claim construction. We have a specification replete with discussion of a tube joint, which is the point of attachment between the mask structure and the airway tube. And we are mindful that the specification is the single best guide to the meaning of a disputed term. The preferred embodiment states that the backplate has a tube joint: It is this tube joint that connects the mask structure to the airway tube. *See, e.g.*, '100 patent figs. 2-3. Ambu is correct that the patent does not disclose an integrally molded mask/airway tube. Certainly, it would be improper to add a tube joint limitation to the claims at issue where none appears. *Kara Tech. Inc. v. Stamps.com Inc.*, 582 F.3d 1341, 1348 (Fed. Cir. 2009) (“The patentee is entitled to the full scope of his claims, and we will not limit him to his preferred embodiment or import a limitation from the specification into the claims.”). Ambu, however, does not ask this court to import the tube joint limitation into the claims generally, but rather argues that the claim limitation “backplate” should be construed to include a tube joint.

Although it is a close case, in light of the claim language, specification, and prosecution history, we conclude that the term backplate is not so limited. The claims themselves are limited to the mask structure. The claims require “a backplate defining a passage.” Claim 1 further defines that “the cuff ... [is] attached to the backplate.” There is no mention of the airway tube or how the backplate or mask structure would attach to the airway tube. The claims cover only a laryngeal mask airway device comprising the backplate and cuff.

Although there is ample discussion of the tube joint throughout the specification, there is only one place where the specification indicates that the tube joint is part of the backplate (in the preferred embodiment's description of Figures 5 and 6): "The backplate 52 has a one-piece, integral spoon-shape including a bowl 90 and an external tube-joint 92 oriented proximally relative to the bowl, as shown in FIGS. 5 and 6." '100 patent col.6 ll.3-5. This sentence, which as its language indicates, describes what is shown in Figures 5 and 6, is not enough to require every backplate to include a tube joint. To be his own lexicographer, a patentee must use a "special definition of the term [that] is clearly stated in the patent specification or file history." *Vitronics Corp. v. Conceptornic, Inc.*, 90 F.3d 1576, 1580 (Fed. Cir. 1996); *see also CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 ("[T]he claim term will not receive its ordinary meaning if the patentee acted as his own lexicographer and clearly set forth a definition of the disputed claim term in either the specification or prosecution history."). The specification does not clearly contain such a special definition. Although the preferred embodiment includes a backplate that contains a tube joint, we do not generally limit claims to the preferred embodiment. *Phillips*, 415 F.3d at 1323 ("[W]e have expressly rejected the contention that if a patent describes only a single embodiment, the claims of the patent must be construed as being limited to that embodiment."). The specification here does not clearly indicate the patentee's intent to give backplate a unique meaning different from its ordinary and customary meaning to one of skill in the art. *See Helmsderfer v. Brobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1381 (Fed. Cir. 2008) ("A patentee may act as its own lexicographer and assign to a term a unique definition that is different from its ordinary and customary meaning; however, a patentee

must clearly express that intent in the written description.”).

The Summary of the Invention uses the term backplate to refer to the mask structure. *See* '100 patent col.1 l.64 (referring to “the mask structure or backplate”). It describes the mask structure as “having a generally elliptical periphery provided with an inflatable cuff which surrounds the hollow interior of the mask into which the airway tube opens” *Id.* col.1 ll.59-61. It further explains that the laryngeal airway mask device comprises “a flexible airway tube and a mask attached to one end of the airway tube.” *Id.* col.1 ll.58. This indicates that the backplate will be connected or attached to the airway tube, but does not require that connection to be formed via a tube joint. We agree with LMA that this description is broad enough to include integrally molded devices as well as devices with a tube joint. The specification does not clearly convey the patentee’s intent to appoint a special meaning to the term backplate. Having concluded that the patentee did not act as his own lexicographer in this case by clearly defining a claim term, we must determine the ordinary meaning of backplate as used in these claims to one of skill in the art in light of the specification and prosecution history.

The prosecution history also indicates that the backplate is not required to have a tube joint. Just prior to issuance, the applicant deleted language concerning the airway tube and the tube joint. Reply to Office Action dated Oct. 19, 2005, at 2 (Apr. 19, 2006). The claims previously required that the backplate include a tube joint in the pharyngeal side of the mask. *See, e.g.,* U.S. Appl. No. 09/412,954, 19 (Oct. 5, 1999); Reply to Office Action of Dec. 15, 2004, 2 (Jun. 15, 2005). The applicant deleted this requirement from the claims. *See* Reply to Office

Action dated Oct. 19, 2005, 2 (Apr. 19, 2006). Following the amendment, the Examiner allowed the claims without any objection to or rejection of the deleted airway tube or tube joint language. *See* Notice of Allowance (Aug. 23, 2006).² Ambu asserts that LMA amended its claims in an effort to cover Ambu's recently marketed AuraOnce™ mask, which has a unitary structure lacking a tube joint. Regardless of why LMA amended its claims, we agree with LMA that it would be improper to read a tube joint limitation back into the backplate. *See Kister Instrumente AG v. United States*, 628 F.2d 1303, 1308 (Ct. Cl. 1980) ("[D]efendant's insist[e]nce upon this court's reading back into the claims limitations which were originally there and were removed during prosecution of the application through the Patent Office cannot be permitted.").

Although there was no dictionary or treatise definition introduced for backplate,³ there are two prior art patents also related to laryngeal mask devices which use the term. U.S. Patent No. 5,355,879 ('879 patent); U.S. Patent No. 5,305,743 ('743 patent). Both prior art patents list the same inventor as the patent at issue, Dr. Brain. Both of these patents disclose a backplate, but neither

² The Notice of Allowance contains an Examiner's amendment, but this amendment has nothing to do with the deleted tube joint limitation. The amendment clarified that the thicker and stiffer cuff reinforcement be located on the "posterior" portion of the cuff, rather than on a "first" portion of the cuff. Notice of Allowance (Aug. 23, 2006).

³ The failure to introduce a dictionary definition for the disputed claim term does not preclude a conclusion that there exists a plain meaning to one of skill in the art. We will not adopt a categorical rule that absence of a dictionary definition means that the applicant must be held to have acted as his own lexicographer and is therefore constrained to the preferred embodiment.

includes a tube joint. This prior art use of the term would further inform one of skill in the art as to the common meaning of the term backplate.

The term backplate has a somewhat self-descriptive nature. As the prior art patents indicate it is the plate on the back. In light of the claims, specification, prosecution history, and prior art patents, we conclude that one of skill in the art would understand the claimed backplate to be “the relatively rigid mask structure surrounded by the cuff.” We conclude that one of skill in the art would not conclude that the backplate must have a tube joint. We also conclude that the inventor did not act as his own lexicographer here and clearly require the backplate to have a tube joint. Because the district court’s judgment of noninfringement was based on an erroneous claim construction, we vacate that judgment and remand for further proceedings.

II. Written Description

The district court granted summary judgment that all claims of the ’100 patent were invalid for failure to satisfy the written description requirement of 35 U.S.C. § 112, ¶ 1. *Invalidity Order* at 7. “Compliance with the written description requirement is a question of fact.” *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1376 (Fed. Cir. 2009). Adequate written description requires that the applicant “convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the [claimed] invention.” *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563–64 (Fed. Cir. 1991) (emphasis omitted). Issued patents are presumed valid under 35 U.S.C. § 282, and thus Ambu must demonstrate by clear and convincing evidence that the claims at

issue are invalid for lack of written description. *ICU Medical*, 558 F.3d at 1376.

Claim 1 requires “at least a portion of the posterior portion of a wall of the cuff in the distal region being thicker and stiffer than other portions of the cuff.” ’100 patent, claim 1. The court construed this phrase according to its plain meaning and thus concluded that the phrase does not require that the “thicker and stiffer” cuff portion be connected to the backplate.⁴ *Claim Construction Order* at 9.

Ambu moved for summary judgment that the asserted claims thus construed were invalid for lack of written description because the specification nowhere describes a thicker and stiffer cuff portion that is not connected to the backplate. The court agreed, finding that the specification failed to describe such an embodiment. *Invalidity Order* at 5-6. LMA presented expert testimony that one of ordinary skill in the art would read the specification to describe a thicker and stiffer cuff portion disconnected from the backplate, but the court found the testimony “not helpful.” *Id.* at 6. It concluded that “[b]ased on the Court’s review of the specification, the ’100 patent does not meet the written description requirement.” *Id.* at 7.

On appeal, LMA argues that the specification adequately describes a thicker and stiffer cuff portion. LMA acknowledges that the specification does not describe an embodiment with the reinforced cuff region disconnected

⁴ Ambu’s devices contain a V-shaped stiffener that is located entirely within the cuff and not connected to the mask structure, and thus Ambu urged the court to construe the phrase to require that the thicker and stiffer cuff reinforcement be attached to a backplate. *Claim Construction Order* at 8.

from the backplate, but it argues that this does not render the claims invalid. LMA explains that the specification is silent as to whether the cuff reinforcement must be, or even should be, connected to the backplate. LMA further explains that the specification does not describe the invention in terms of the connection, extol any advantages of a connected cuff reinforcement, identify disadvantages of a disconnected cuff reinforcement, or identify a connection as a critical feature.

LMA further contends that factual disputes exist that render summary judgment of invalidity improper. LMA presented the testimony of two experts that one of ordinary skill in the art would read the specification as describing “at least a portion of the posterior portion of a wall of the cuff in the distal region being thicker and stiffer than other portions of the cuff,” as required by claim 1. This testimony focused on a statement in the specification that LMA refers to as the Cuff Wall Thickening Passage: “The distal rib 105a may be effectively constituted by a thickening of the posterior wall of the distal region 60a of the inflatable main-cuff 55a and, as shown, forms a distal extension of the bowl 90a of the backplate 52a.” ’100 patent col.8 ll.9-12. LMA stresses that “as shown,” this thicker and stiffer cuff portion is connected to the backplate, but LMA asserts that the “as shown” clause is not limiting.

LMA’s experts also cited the Summary of the Invention for support. *See* J.A. 3670; J.A. 3700. LMA’s experts opined that the Summary of the Invention refers broadly to a reinforcement in the distal end of the cuff, and then identifies a preferred embodiment in which the reinforcement extends from the backplate. J.A. 3671, 3700. Specifically, the Summary of the Invention explains that the present invention seeks to minimize the risk of the

deflated cuff folding over on itself during insertion “by incorporating into the cuff at its distal end a reinforcing rib which serves to stiffen the leading end of the LMA-device during the course of the procedure for its insertion.” ’100 patent col.1 ll.47-55. It also provides that “[i]n accordance with the invention . . . the device includ[es] a reinforcing rib incorporated into the distal end of the inflatable cuff.” *Id.* col.1 ll.56-63. LMA’s experts concluded that these statements describe the invention as having a reinforcement in the distal end of the cuff, but not as an extension of the backplate. *See* J.A. 3700. The Summary of the Invention further provides that “in a preferred aspect the mask structure or backplate which is of more rigid material than that of the soft and inflatable cuff formation has its back extended to the distal end of the cuff, in order to form the reinforcing rib.” ’100 patent col.1 ll.64-67. LMA’s experts contended that these statements, combined with the Cuff Wall Thickening Passage, provide support for the invention described in claim 1. LMA argues that, at a minimum, this testimony presents a genuine factual dispute on the issue of validity precluding summary judgment.

Ambu argues that “the district court properly found that the specification lacks any disclosure of a cuff stiffener detached from the backplate.” Ambu Br. 60. Ambu asserts that LMA’s position is based on an implausible interpretation of the specification and that its expert testimony plainly contradicts the specification.

We conclude that the district court erred in granting summary judgment that the patent was invalid for failing the written description requirement. The Summary of the Invention does not require that the cuff reinforcement be connected to the backplate. Rather, it describes a reinforcement incorporated into the distal end of the cuff.

'100 patent col.1 ll.47-63. The Summary of the Invention further states that “[i]n a preferred aspect,” the reinforcement extends from the backplate. *See id.* at col.1 ll.64-67. We agree with LMA that one of ordinary skill in the art could read these disclosures as providing for a cuff reinforcement in the distal region that need not be connected to the backplate. In addition, we agree with LMA that one of ordinary skill in the art could read the Cuff Wall Thickening Passage as disclosing a thickened cuff portion that need not be connected to the backplate. *Id.* col.8 ll.9-12. LMA has raised a genuine issue of material fact on this issue, and therefore we reverse the court’s grant of summary judgment and remand for further proceedings consistent with this opinion.

CONCLUSION

For the foregoing reasons, we vacate the court’s order of noninfringement and its judgment of invalidity for lack of written description and remand for further proceedings consistent with this opinion.

VACATED AND REMANDED

COSTS

No costs.