

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte Medical Components, Inc.

Appeal 2008-1974
Application 10/857,427
Technology Center 3700

Decided: August 28, 2008

Before JAMESON LEE, RICHARD TORCZON, and SALLY C.
MEDLEY, *Administrative Patent Judges*.

LEE, *Administrative Patent Judge*.

DECISION ON APPEAL

A. Statement of the Case

This is a decision on appeal by the real party in interest, Medical Components, Inc. (MC), under 35 U.S.C. § 134(a) from a final rejection of claims 17-21 and 25-28. We have jurisdiction under 35 U.S.C. § 6(b).

References Relied on by the Examiner

Humbert	US 4,846,223	Jul. 11, 1989
Manska	US 5,156,186	Oct. 20, 1992

The Rejections on Appeal

The Examiner rejected claims 17-21 and 25-28 under 35 U.S.C. § 112, second paragraph.

The Examiner rejected claims 17-21, 25, 27, and 28 under 35 U.S.C. § 102(b) as anticipated by Manska.

The Examiner rejected claim 26 under 35 U.S.C. § 103(a) as unpatentable over Manska and Humbert.

B. Principles of Law

A claim is indefinite if, when read in light of the specification, it does not reasonably apprise those skilled in the art of the scope of the invention. *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1342 (Fed. Cir. 2003).

The analysis of a claim rejection based on prior art should not be performed where it is necessary to engage in speculation as to the meaning of claim terms and assumptions as to the scope of a claim. *See In re Steele*, 305 F.2d 859, 862 (CCPA 1962).

C. Analysis

The invention relates to a connector for a medical device wherein the connector forms a fluid passage and incorporates a sealing device therein for selectively restricting fluid flow through the passage. (Spec. 3:¶ 6.)

Claim 17 is the independent claim and is reproduced below (Claims App'x):

17. A connector for being secured to a catheter that extends into a venous opening of a patient, comprising:

a body having a proximal end, a distal end adapted to be secured to a proximal end of a catheter lumen, and an axially extending passage extending therethrough between the proximal end and the distal end, fluidly connecting the proximal end and the distal end, wherein the proximal end includes a fitting for releasably connecting the connector to an external device, the body further having a valve body extending laterally with respect to the axially extending passage to lateral ends, with the valve body containing a cylinder-receiving passage; and

a cylinder rotatably disposed within the cylinder-receiving passage of the valve body and being rotatable between a first position and a second position,

wherein the cylinder includes an opening extending generally diametrically therethrough, and further includes first and second ends at least one of which includes an actuating section, and the first and second ends, including the at least one actuating section, extend only minimally beyond the lateral ends of the valve body,

wherein when the cylinder is in the first position, the proximal end of the body is in fluid communication with the distal end of the body and wherein, when the cylinder is in the second position, the proximal end of the body is not in fluid communication with the distal end of the body.

MC must show error in the Examiner's decision rejecting claims 17-21 and 25-28.

Rejections under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 17-21 and 25-28 as indefinite under 35 U.S.C. § 112, second paragraph based on a limitation appearing in

independent claim 17. Claims 19 and 27 were further rejected as indefinite based on limitations added by each of those claims. We address the indefiniteness rejections of claims 17, 19, and 27 separately.

The rejection of claim 17 as indefinite

The Examiner rejected independent claim 17 as being indefinite because of a lack of clarity of the limitation in claim 17 of “first and second ends, including the at least one actuating section, extend only minimally beyond the lateral ends of the valve body.” (Claims App’x 11:14-16.) The Examiner explained (Ans. 3:8-12):

The examiner is unsure as to the degree of the relative term “minimally” and as to the nature of “the lateral ends of the valve body”. It is unclear as to the relative degree and criticality of the term “minimally” in view of the handles (236) in Figure 6, which extend away from the valve body. It is unclear as to the claimed structure.

MC argues that (App. Br. 4:9-15):

The artisan of routine skill would understand that "only minimally" with respect to the first and second ends clearly means only to the extent necessary to include a flange that overlaps the end surface of the valve body and thus secure the cylinder within the valve body since the cylinder is to be held rotatably therewithin, and with respect to the actuating section, only to the extent necessary to enable actuation thereof, that is, to enable rotation thereof to be performed (i.e., by tool engagement therewith or manual engagement therewith).

The claim itself does not provide any context for determining what constitutes a minimal extension or an upper bound beyond which the extension cannot be regarded as minimal. MC has not directed us to any portion of the specification as originally filed that describes the term “only minimally” or reveals an objective standard for determining its scope.

In the above-quoted arguments, it is urged that the meaning of “only minimally” would be clear to a person of ordinary skill in the art. The meaning is said to be linked to the functions of the first and second ends securing the cylinder and the rotating actuating section. However, MC’s claim does not relate the term “only minimally” to any function of the claimed structure. MC has also not pointed to any part of the specification in which that term is disclosed to be interrelated with functional characteristics. Furthermore, MC submitted no declaration from a technical witness to the effect that a person of ordinary skill in the art would understand the term “only minimally” to be associated with any particular function. It is only the argument made in the Appeal Brief that urges such a meaning for that term. Argument of counsel cannot take the place of evidence lacking in the record. *Estee Lauder Inc. v. L’Oreal, S.A.*, 129 F.3d 588, 595 (Fed. Cir. 1997). MC has not directed us to evidence that the “only minimally” limitation would have the alleged meaning as argued by MC to a person of ordinary skill in the art.

A claim is indefinite if, when read in light of the specification, it does not reasonably apprise those skilled in the art of the scope of the invention. *Amgen Inc.*, 314 F.3d at 1342. For the reasons discussed above, a person of ordinary skill would not be reasonably apprised of the scope of the “only minimally” limitation of claim 17.

We sustain the Examiner’s rejection of independent claim 17 and the dependent claims 18-21 and 25-28 under 35 U.S.C. § 112, second paragraph, as indefinite.

The rejection of claim 19 as indefinite

Claim 19 depends from claim 17 and is indefinite for the same reasons claim 17 is indefinite. Furthermore, the Examiner pointed to additional reasons why claim 19 is indefinite. Claim 19 introduces the additional limitations (Claims App'x 12:4-9):

wherein the cylinder has a tab extending therefrom a small distance in a direction orthogonal to the catheter, and wherein body comprises a first stop portion disposed along an outer diameter of the cylinder and a second stop portion disposed a predetermined arcuate distance around the outer diameter of the cylinder from the first stop, and wherein the tab is movably disposed between the first stop portion and the second stop portion.

The Examiner based the rejection on two limitations relating to the tab extending : (1) “a small distance,” and (2) “in a direction orthogonal to the catheter.”

We consider first the “small distance” limitation. The Examiner found that term unclear and stated “[t]he term ‘small’ is a relative term and needs to be fully defined with respect to the distance as used in claim 19.” (Ans. 8:5-6.)

MC argues that “[t]he artisan of routine skill would understand that the tab of the cylinder is joined to the cylinder and extends from the cylinder for a small distance (i.e. having a small length)...”(App. Br. 4:21-22.) MC further argues “[t]he ‘small distance’ is only enough for the tab to physically abut the stop, and the claim provides the context for understanding ‘small distance’.” (App. Br. 5:1-3.)

We take MC’s argument to be that the scope of “small distance” is determined by the operation of the tab in moving between and engaging the stops. According to MC, a small distance means that which is only enough

for the tab to act as claimed. However, a tab that extends a distance greater than one that is “only enough” to abut the stop is still capable of abutting and moving in the manner specified in the claim, and still extends only a “small distance” as compared to an even larger extension. Small does not equate to only enough. The claim reveals no such indication; the specification does not define the term as such; and MC submitted no declaration evidence tending to establish that it is conventional for one with ordinary skill in the art to equate “small distance” to a length that is “only enough” and no more.

As noted before, a claim is indefinite if, when read in light of the specification, it does not reasonably apprise those skilled in the art of the scope of the invention. *Amgen Inc.*, 314 F.3d at 1342. MC has not pointed us to sufficient evidence to establish the standard that a person of ordinary skill in the art would use to establish the measure for determining what constitutes a “small distance.” Without an objective standard for the meaning of “small,” the scope of the claim is indefinite.

We turn now to the “in a direction orthogonal to the catheter” limitation. In rejecting claim 19 based on that limitation, the Examiner stated (Ans. 3:15-18):

It is also unclear as to what is “in a direction orthogonal to the catheter”. It is unclear if the tab is located a small distance in a direction orthogonal to the catheter or if the tab is extending from the cylinder in a direction orthogonal to the catheter.

The Examiner also stated (Ans. 9:2-10):

The limitation "the cylinder has a tab extending therefrom a small distance in a direction orthogonal to the catheter" in claim 19 is readable in different ways and needs to be clarified. In a first interpretation, the tab is extending from the cylinder with the tab being located a small distance in a direction orthogonal from the

catheter. In a second interpretation, the cylinder has a tab with the tab extending a small distance in a direction orthogonal to the catheter from the surface of the cylinder. If the second interpretation is used, another issue arises with respect to the limitation "in a direction orthogonal to the catheter" because that as the tab rotates during actuation, the angle the tab makes with respect to the catheter changes and is therefore deviating from a direction orthogonal to the catheter.

MC disputes that the "in a direction orthogonal to the catheter" limitation renders the claim indefinite within the meaning of 35 U.S.C. § 112, second paragraph. We agree with MC.

The limitation of claim 19 that the tab is extending "in a direction orthogonal to the catheter" defines the direction of the extension in relation to the catheter, i.e. orthogonal to the catheter. As noted above, the Examiner found that the limitation has two defined interpretations. Rather than suggesting that the limitation is indefinite, that finding provides that the limitation simply has a scope that is broad enough to encompass two embodiments. Breadth in scope does not equal indefiniteness. *In re Miller*, 441 F.2d 689, 693 (CCPA 1971).

In the above-quoted statements, the Examiner justifies the indefiniteness rejection based on the "in a direction orthogonal to the catheter" limitation by describing a situation where the tab extension deviates from the orthogonal direction. That is not a matter of indefiniteness. The claim calls for the tab to extend "in a direction orthogonal to the catheter." That limitation clearly encompasses tabs that extend in a direction orthogonal to the catheter and excludes those where the extension of the tab deviates or is not in a direction orthogonal to the catheter. The limitation does not render the claim indefinite.

The rejection of claim 27 as indefinite

Claim 27 depends from claim 17 and is indefinite for the same reasons claim 17 is indefinite. Furthermore, claim 27 was also separately rejected under 35 U.S.C. § 112, second paragraph as indefinite. Claim 27 introduces the additional limitations (Claims App'x 12:23 to 13:2):

wherein the cylinder further comprises a manually-engageable [sic] protrusion disposed on the first end of the cylinder and extending a small distance in a direction orthogonal to the catheter, and wherein the protrusion is sized to allow a user to grasp it to operate the cylinder between the open position and the closed position.

For reasons similar to those for claim 19, the Examiner based the indefiniteness rejection of claim 27 on the limitations relating to “a small distance” and “in a direction orthogonal to the catheter.”

We again consider first the “small distance” requirement. As with claim 19, the Examiner also found the term “a small distance” in claim 27 to be unclear and stated “[t]he term ‘small’ is a relative term and needs to be fully defined with respect to the distance as used in claim 27.” (Ans. 9:20-21.)

MC argues (App. Br. 5:11-14):

...the remainder of the claim gives the clear meaning to “a small distance”: “wherein the protrusion is sized to allow a user to grasp it to operate the cylinder between the open position and the closed position”, i.e., a distance only large enough to enable manual engagement of the protrusion for actuation/rotation thereof.

MC urges that the “small distance” of the protrusion’s extension is limited to one that is “only large enough” to be grasped and operated by a user. However, the claim does describe a protrusion extension that is “only large enough” as alleged. The claim calls for a protrusion that extends a

small distance and is sized to allow a user to grasp and operate it. There is nothing either explicit or intrinsic to the “sized” limitation that provides an objective standard for measuring the claimed “small distance.” MC does not explain why the sizing of the protrusion to be grasped and operated in the manner recited sets an upper bound for the small distance of the protrusion’s extension, i.e. one that is “only large enough.” A protrusion that is some size larger than “large enough” is also sized to allow a user to grasp it in the manner claimed. Would the extension of that larger sized protrusion still be considered a “small distance?” MC does not point to either a portion of the specification or any declaration evidence that establishes an objective standard for determining the meaning of “small.” Without an objective standard for the meaning of “small,” the scope of the claim 27 is indefinite.

With regard to the limitation in claim 27 of “in a direction orthogonal to the catheter,” for similar reasons as those discussed above for claim 19, we do not agree with the Examiner that it renders the claim indefinite. In claim 27, the direction of the extension of the protrusion is clearly indicated as orthogonal to the catheter.

We sustain the indefiniteness rejection of claims 17-21 and 25-28 under 35 U.S.C. § 112, second paragraph.

Rejections over prior art

The Examiner rejected independent claim 17 and dependent claims 18-21 and 25-28 as unpatentable over prior art. As discussed above, we sustain the indefiniteness rejection of claims 17-21 and 25-28. The analysis of a claim rejection based on prior art should not be performed where it is necessary to engage in speculation as to the meaning of claim terms and assumptions as to the scope of a claim. *See In re Steele*, 305 F.2d at 862.

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Accordingly, we do not reach the merits of the rejection of claims 17-21 and 25-28 over prior art.

D. Conclusion

The rejection of claims 17-21 and 25-28 under 35 U.S.C. § 112, second paragraph is **affirmed**.

We do not reach the merits of the rejection of claims 17-21, 25, 27, and 28 under 35 U.S.C. § 102(b) as anticipated by Manska, and we do not reach the merits of the rejection of claims 26 under 35 U.S.C. § 103(a) as unpatentable over Manska and Humbert.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

AFFIRMED

SD

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