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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MICHAEL EDWARD HOGARD, GOPI LINGAM, DEAN HU, BALAJI M. MANIAM, JAMES RITSON, ANDY H. UCHIDA, JOHN DAVID STIENMIER, and PAUL DAVID MCGREGOR

Appeal 2020–006394
Application 14/821,362
Technology Center 1700

BEFORE BEVERLY A. FRANKLIN, JEFFREY B. ROBERSTSON, and CHRISTOPHER C. KENNEDY, *Administrative Patent Judges.*

FRANKLIN, *Administrative Patent Judge.*

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the Examiner's decision to reject claims 1–4, 12–17, and 19–25. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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[1] We use the word Appellant to refer to "applicant" as defined in 37 C.F.R. § 1.42(a). Appellant identifies the real party in interest as Outset Medical, Inc. Appeal Br. 2.

CLAIMED SUBJECT MATTER

Claim 1 is illustrative of Appellant's subject matter on appeal and is set forth below:

1. A method of controlling a fluid level in a venous drip chamber of a dialysis system, the dialysis system having a blood pump and an air pump, the method comprising the steps of:

operating the blood pump in a first operating mode to flow saline in a first direction from a saline source, into a patient tubing set, into a venous drip chamber through a first port disposed at a bottom portion of the venous drip chamber, out of the venous drip chamber through a second port disposed at the bottom portion of the venous drip chamber, and into a dialyzer;

monitoring a saline fluid level in the venous drip chamber with at least one sensor;

operating the blood pump in a second operating mode to move blood in a second direction opposite to the first direction through a continuous pathway of the dialysis system, comprising moving blood with the blood pump from a patient into the patient tubing set via an arterial access point, moving blood with the blood pump through the dialyzer, moving blood with the blood pump into the venous drip chamber through the second port, moving blood with the blood pump out of the venous drip chamber through the first port, and moving blood out of the patient tubing set and back into the patient via a venous access point;

monitoring a blood fluid level in the venous drip chamber with the at least one sensor; raising the blood fluid level in the venous drip chamber by automatically pumping air out of the venous drip chamber with the air pump if the fluid level is below a level detected by the at least one sensor; and

lowering the blood fluid level by automatically pumping air into the venous drip chamber with the air pump if the blood fluid level is above a level detected by the at least one sensor.

Appeal Br. 9 (Claims Appendix).

REFERENCES

The prior art relied upon by the Examiner is:

Name	Reference	Date
Felding	US 2005/0040110 A1	Feb. 24, 2005
Chaung	US 2009/0038393 A1	Feb. 12, 2009
Folden	US 2009/0076433 A1	Mar. 19, 2009
Heyes	US 2010/0089807 A1	Apr. 15, 2010

THE REJECTIONS

1. Claim 1–3, 12–14, 16, 17, and 19 are rejected under 35 U.S.C. § 103 as being unpatentable over Heyes in view of Folden.

2. Claims 4 and 15 are rejected under 35 U.S.C. § 103 as being obvious over Heyes in view of Folden and in further view of Chaung.

3. Claims 20–25 are rejected under 35 U.SC. § 103 as being obvious over Heyes in view of Folden and in further view of Felding.

OPINION

We review the appealed rejections for error based upon the issues Appellant identifies, and in light of the arguments and evidence produced thereon. *Ex parte Frye*, 94 USPQ2d 1072, 1075 (BPAI 2010) (precedential) (cited with approval in *In re Jung*, 637 F.3d 1356, 1365 (Fed. Cir. 2011) ("[I]t has long been the Board's practice to require an applicant to identify the alleged error in the examiner's rejections."). Upon review of the evidence and each of the respective positions set forth in the record, we find that the preponderance of evidence supports Appellant's position in the record. Accordingly, we reverse each of the Examiner's rejections on appeal

essentially for the reasons set forth in the record by Appellant, and add the following for emphasis.

Appellant argues, *inter alia*, that the proposed modification (set forth in the rejection on pages 4–15 of the Answer) renders Heyes inoperable. Appeal Br. 6–7. Specifically, Appellant argues that Heyes' Figure 7 illustrates aperture 30 being above level sensor 44. Appeal Br. 6. Appellant argues that if saline flowed in the reverse direction through Heyes' bubble trap 34 (i.e., entering through port 38 and exiting through port 30), inlet lip 36 (which is the entry point to port 30) is positioned as shown in Figure 7 such that the saline level would have to be higher than upper level sensor 44. *Id.* Appellant argues that having no control of the fluid level within the chamber would cause the hydrophilic membrane that covers the vent in Heyes' bubble trap 34 to become wetted and non-useful. *Id.* As such, Appellant argues that it would not have been obvious to modify Heyes in view of Folden to have priming fluid flow in the reverse direction during priming because Heyes' bubble trap 34 would be rendered inoperable (via a wetted hydrophilic membrane) if flow was passed through in the opposite direction. Appeal Br. 7.

The Examiner's response is set forth on page 27 of the Answer. Therein, the Examiner states that the drawings of Heyes are not to scale and therefore Appellant's arguments regarding the location of port 30 is moot. The Examiner also states that even if port 30 is above level sensor 44, it would have been obvious to configure Heyes' bubble trap 34 so that the level sensor 44 prevents saline from contacting the hydrophilic membrane. Ans. 27–28.

In reply, Appellant states, *inter alia*, that it is wrong to state that because the drawings of Heyes are not indicated as being to scale, Appellant's position regarding Figure 7 is moot. Appellant agrees that Heyes does not indicate that its figures are drawn to scale; however, Appellant states that even when patent drawings are not drawn to scale, they may nevertheless be used to establish relative sizes and relationships between the various components which are clearly depicted in those drawings. *See, e.g., Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1565 (Fed. Cir 1991). Reply Br. 3. Appellant states that Appellant refers to Figure 7 of Heyes for its depiction of the relative positions/relationships between the aperture 30, the upper level sensor 44, and the hydrophilic membrane of bubble trap 34. *Id.* Appellant states that Appellant does not rely on "precise proportions" shown in Heyes' Figure 7. Instead, Appellant argues that the relative positions of the aperture 30, the upper level sensor 44, and the hydrophilic membrane make it clear that the bubble trap 34 is designed only for unidirectional flow. *Id.* We agree that it is error to view Appellant's position concerning Heyes' drawings as moot, for the reasons expressed by Appellant in the record. Patent drawings may not be disregarded for items that they clearly show. *In re Mraz*, 455 F.2d 1069, 1072 (CCPA 1972). We therefore agree with Appellant's interpretation of Figure 7 of Heyes.

In response to the Examiner's position that even if port 30 is above level sensor 44, it would have been obvious to have configured Heyes' bubble trap 34 so that the level sensor 44 prevents saline from contacting the hydrophilic membrane (Ans. 27–28), Appellant replies that modification of

Heyes' bubble trap 34 to operate bi-directionally amounts to a significant change in the function of the Heyes device. Reply Br. 3.

We are persuaded by Appellant's aforementioned arguments. The preponderance of the evidence favors Appellant's understanding that Heyes' bubble trap 34 is not for bi-directional flow for the reasons discussed by Appellant in the record. While the Examiner states that it would have been obvious to have modified Heyes' bubble trap 34 so that the level sensor 44 prevents saline from contacting the hydrophilic membrane, we agree with Appellant's position regarding change in function, and that "[i]f the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious." *In re Ratti*, 270 F.2d 810, 813 (CCPA 1959). Notably, Appellant's position in this regard is not adequately addressed by the Examiner in the record. Secondarily, that which is within the capabilities of one skilled in the art is not synonymous with obviousness. *In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992) (citing *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984) ("The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification." (citation omitted)); *cf. Ex parte Levengood*, 28 USPQ2d 1300, 1301-02 (BPAI 1993) ("At best, the examiner's comments regarding obviousness amount to an assertion that one of ordinary skill in the relevant art would have been able to arrive at appellant's invention because he had the necessary skills to carry out the requisite process steps. This is an inappropriate standard for

obviousness . . . . That which is within the capabilities of one skilled in the art is not synonymous with obviousness." (citation omitted)). In the instant case, the Examiner states that Heyes does not disclose the method by which the sytem is primed. Ans. 18. The Examiner then states that one skilled in the art would understand that Heyes' dialysis system would require priming. Ans 19. However, given that Heyes' system is for unidirectional flow, the suggestion is lacking in the applied art to use Folden's method of priming a dialysis system since Folden's technique requires bi-directional flow.

In view of the above, we reverse each rejection.

CONCLUSION

We reverse the Examiner's decision.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1–3, 12–14, 16, 17, 19	103	Heyes, Folden		1–3, 12–14, 16, 17, 19
4, 15	103	Heyes Folden, Chaung		4, 15
20–25	103	Heyes, Folden, Felding		20–25
Overall Outcome				1–4, 12–17, 19–25

REVERSED