UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
14/049,453	10/09/2013	Mark Bearss	C00005809.USU1	9317

28390 7590 02/04/2020

MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
3576 UNOCAL PLACE
SANTA ROSA, CA 95403

EXAMINER
WIEST, PHILIP R

ART UNIT	PAPER NUMBER
3781	

NOTIFICATION DATE	DELIVERY MODE
02/04/2020	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

rs.patents.five@medtronic.com
rs.vasciplegal@medtronic.com

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte MARK BEARSS

Appeal 2019-003312
Application 14/049,453
Technology Center 3700

Before LINDA E. HORNER, JILL D. HILL, and LEE L. STEPINA, *Administrative Patent Judges.*

STEPINA, *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 1–11, 13–16, and 18–23.[2] We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM-IN-PART.

---

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

[2] Claims 12 and 17 have been cancelled. Appeal Br. 22 (Claims App.).

CLAIMED SUBJECT MATTER

The claims are directed to methods for managing patient blood fluid volume and hematocrit. Spec. ¶ 1.

Claim 1, reproduced below with emphasis added, is illustrative of the claimed subject matter.

> 1. A computer-implemented method comprising:
> receiving input regarding weight of a patient;
> receiving input regarding hematocrit of blood of the patient;
> setting a low hematocrit limit for the patient;
> calculating, based on the input regarding the weight of the patient, the input regarding the hematocrit of the blood of the patient, and the low hematocrit limit, a maximum volume of hematocrit-free fluid that the patient can receive into a blood compartment of the patient until the low hematocrit limit is reached; and
> *displaying the maximum volume of hematocrit-free fluid for a user to avoid*.

Appeal Br. 20 (Claims App.).

REFERENCE

The prior art relied upon by the Examiner is:

Name	Reference	Date
Janssenswillen	US 2013/0094996 A1	Apr. 18, 2013

REJECTIONS

I. Claims 1 and 16 are rejected under 35 U.S.C. § 112(a) as failing to comply with the written description requirement.

II. Claims 1 and 16 are rejected under 35 U.S.C. § 112(b) as indefinite.

III. Claims 1–11, 13–16, and 18–23 are rejected under 35 U.S.C. § 103 as unpatentable over Janssenswillen.

OPINION

Rejection I–Written Description

Appellant argues for the patentability of the claims subject to the first ground of rejection, i.e., claims 1 and 16, as a group. *See* Appeal Br. 9. We select claim 1 as representative of the group, and claim 16 stands or falls with claim 1.

The Examiner determines that the step of "displaying the maximum volume of hematocrit-free fluid for a user to avoid" in claim 1 is not supported by the original disclosure. *See* Final Act. 4–5. The Examiner finds that instead of providing written description for this limitation, "the [S]pecification repeatedly states that the system displays the amount of fluid that can be added to avoid reaching, or to just reach but not fall below, the threshold level." *Id.* (citing Spec. ¶¶ 7, 21, 29, 34, 38, 47). In other words, the Examiner finds that the Specification discloses displaying an amount of fluid that would be acceptable to add rather than an amount that would not be acceptable.

Appellant's Summary of the Claimed Subject Matter in the Appeal Brief indicates that paragraphs 7, 21, 31, 34, and 73 and Figure 2 satisfy the written description requirement for the limitation at issue in claim 1. Appeal Br. 4–5. In the Argument portion of the Appeal Brief, Appellant asserts that, in particular, paragraphs 31, 34, and 73 of the Specification support this limitation. *Id.* at 8–9.

In response, the Examiner reiterates the rejection and explains, "[t]he specification does not describe the step of displaying a maximum volume of hematocrit-free fluid for a user to avoid, which is the language required by the claims." Ans. 12.

In reply, Appellant contends that, contrary to the proper standard for satisfying the written description requirement, the Examiner is requiring literal support in the Specification. *See* Reply Br. 3 (citing *Eiselstein v. Frank*, 52 F.3d 1035, 1038 (Fed. Cir. 1995); *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). Appellant contends that the Specification provides "equivalent description" for the recitation at issue in paragraphs 31, 34, and 73. *Id.* at 4.

We agree with the Examiner's analysis. Paragraph 31 of the Specification states, in part, "[t]he FVL[3] is the volume of hematocrit-free fluid that may be added to the CPB circuit, which includes the PVB, the pump prime volume, and the IV volume, to avoid reaching, or to just reach but not fall below, the user-defined hematocrit low limit." Thus, as the Examiner determines (*see* Final Act. 4–5), the Specification describes an amount of fluid that is permitted to be added to the system without crossing the hematocrit low limit, i.e., an amount of fluid that may be added without causing the hematocrit level to drop below a user-defined threshold. Similarly, paragraph 34 of the Specification states, "[b]y displaying the FVL, a healthcare provider such as a member of the surgical or post-surgical team will know how much RBC-free fluid can be introduced into the patient's blood compartment to avoid reaching, or to just reach but not fall

[3] FVL = "fluid volume limit." Spec. ¶ 31.

below, the user defined low hematocrit limit." Paragraph 73 states, "[t]he method includes determining the maximum amount of a fluid that can be added to avoid reaching, or to just reach but not fall below, the low limit hematocrit; e.g., as depicted in and described above with regard to FIG. 5."[4] Emphasis omitted. A person of ordinary skill in the art would understand these portions of the Specification to indicate that the displayed fluid volume limit (FVL) is permissive in nature, i.e., it is what can be added to the fluid circuit, not something that is to be avoided, as recited in the final portion of claim 1.

Contrary to Appellant's argument, displaying a volume of fluid that is allowed to be added is not the equivalent of displaying a volume of fluid that should be avoided. This is true even if displaying the allowed volume would allow a user *to determine* the volume to avoid. In this regard, we note that claim 1 requires displaying a particular thing, namely, "the maximum volume of hematocrit-free fluid for a user to avoid." This language does not equate to reciting the display of other information that would be sufficient for a user to calculate the maximum volume of hematocrit-free fluid for a user to avoid, as implied by Appellant's assertions.[5] Accordingly, Appellant's arguments regarding Rejection I are unavailing, and we sustain

[4] The most pertinent portion of Figure 5 is step 135 in the depicted flowchart, which includes the text "Display amount that can be added."
[5] For example, under certain circumstances, informing a person that the result of a coin-flip is "heads" may be the equivalent of informing the person that the result is not "tails." Nonetheless, displaying the "heads" side of a coin on a screen is not the same as displaying the "tails" side.

the rejection of claims 1 and 16 as failing to comply with the written description requirement.[6]

Rejection II–Indefiniteness

The Examiner determines that the "displaying" step discussed above renders claim 1 indefinite because it implies avoiding providing the hematocrit-free fluid, but "the method also requires that the [hematocrit-free] fluid is added to the blood." Final Act. 5.

Appellant asserts that claim 1 specifies that "the maximum volume of hematocrit-free fluid is displayed for a user to avoid." Appeal Br. 10. Appellant contends that the Examiner's interpretation omits the words "maximum volume of" in the clause at issue, and that the "plain meaning" of this clause is that "the user should avoid *the maximum volume of hematocrit-free fluid displayed*." *Id.* at 11.

Appellant's argument is persuasive. As discussed above regarding Rejection I, claim 1 requires displaying the maximum volume of hematocrit-free fluid for a user to avoid. Contrary to the Examiner's position, in claim 1, it is this *volume* of fluid displayed, not the fluid itself, that is "for a user to avoid." Accordingly, we do not sustain the rejection of claim 1 as indefinite.

The Examiner rejected claim 16 for reciting language similar to that discussed above regarding claim 1. Final Act. 5. For the same reasons, we do not sustain the rejection of claim 16 as indefinite.

[6] Neither Appellant nor the Examiner addresses whether the rejection of independent claims 1 and 16 for failing to comply with the written description requirement implicates dependent claims 2–11, 13–15, and 18–23. *See* Final Act. 4–5; Appeal Br. 7–9.

Rejection III–Janssenswillen

The Examiner finds that Janssenswillen discloses many of the elements recited in claim 1, but does not disclose the "displaying" step. Final Act. 7. In comparing claim 1 to the prior art, the Examiner interprets this step as requiring that "the system displays the amount of fluid that can be added to avoid reaching, or to just reach but not fall below, the threshold level." Final Act. 5. To address the deficiency in Janssenswillen, the Examiner finds Janssenswillen discloses a hemodilution target (a low hematocrit limit for a patient) and a GUI that allows the display of other pertinent data. *Id.* at 7–8 (citing Janssenswillen ¶¶ 11–22, 93). The Examiner then discusses paragraphs 45, 46, and 93 of Janssenswillen and finds that "[e]ven if Janssenswillen does not explicitly and specifically require that the hematocrit limit/hemodilution target is displayed on the GUI, Janssenswillen clearly suggests that the volume of hematocrit-free fluid that can be received by the patient is an important variable in the procedure." *Id.* at 8. Based on these findings, the Examiner concludes it would have been obvious "to modify Janssenswillen's computer-implemented treatment method to display the volume of hematocrit-free fluid that can be received by the patient, because *doing so would allow the perfusionist to make informed decisions regarding the amount of hemodilution that can be tolerated by the patient*." *Id.* (emphasis added)

Appellant argues Janssenswillen does not disclose a volume of hematocrit-free fluid that can be received by the patient. Appeal Br. 14.

This argument does not apprise us of Examiner error because the rejection of claim 1 does not rely on Janssenswillen to explicitly teach this feature. Final Act. 7–8. Rather, the Examiner determines it would have

been obvious to modify the method disclosed by Janssenswillen to include this step. *See id.* at 8.

Appellant also contends that the Examiner's reasoning is not supported by rational underpinnings because Janssenswillen fails to disclose "allowing a perfusionist to make informed decisions regarding the amount of hemodilution that can be tolerated by the patient." Appeal Br. 17–18. Therefore, according to Appellant, the Examiner's reason for modifying the method disclosed by Janssenswillen is based on impermissible hindsight. *Id.* at 18.

We disagree with Appellant's argument on this point because the Examiner's reason for modifying the method taught by Janssenswillen does not rely on Janssenswillen explicitly teaching that a perfusionist makes decisions regarding the amount of hemodilution that can be tolerated by the patient. Rather, allowing this action to occur is the *benefit* that the Examiner determines would be the result of the proposed modification. *See* Final Act. 8. The Examiner's reasoning for the proposed modification is based on finding that Janssenswillen discloses real-time monitoring of certain variables to assist the perfusionist and that the volume of hematocrit-free fluid that can be received by a patient is an important variable in Janssenswillen's procedure. *See id.* We address these findings below.

Janssenswillen discloses that its hematocrit evolution graph generator monitors the evolution of a patient's hemodilution throughout the procedure. *See* Janssenswillen ¶¶ 45, 108. Paragraph 46 of Janssenswillen indicates that this graph enables the perfusionist to make "better[-]founded decisions based on accurate up-to-date information." Janssenswillen discloses a priming module able to determine priming constitution, volume, and flow to

achieve a hemodilution target. *See id.* ¶ 14; *see also id.* ¶ 65 (describing that the invention provides "a real monitor assisting the perfusionist during the procedure and enabling him to make better founded decisions throughout the whole procedure"). Accordingly, the Examiner's findings that "Janssenswillen teaches that real and theoretically calculated hematocrit levels are monitored throughout the treatment to enable the perfusionist to make better decisions based on accurate up-to-date information," and that Janssenswillen suggests that the volume of hematocrit-free fluid that can be received by the patient is an *important variable*, are supported by a preponderance of the evidence. These findings provide adequate underpinnings for the proposed modification to the method of Janssenswillen.

Appellant also argues that the Examiner does not address the "displaying" step in claim 1, and, therefore, has not established a prima facie case of obviousness. Appeal Br. 13–16. In this regard, Appellant quotes the Examiner's statement of the result of the proposed modification and contrasts it to the language in the displaying step, pointing out that what is displayed is the maximum volume of hematocrit-free fluid for a user to avoid (rather than what is permitted for a patient to receive). *Id.* at 13–14.

Appellant's argument is persuasive. The Examiner's claim interpretation does not comport with the plain language in the last line of claim 1. Specifically, the Examiner's interpretation of claim 1, set forth on page 5 of the Final Office Action, does not account for the requirement that what is displayed in the last step of claim 1 is something that is "for the user to avoid." Accordingly, we agree with Appellant that the Examiner has not set forth a prima facie case of obviousness. Consequently, we do not sustain

the rejection of claim 1, and claims 2–11, 13–15 depending, therefrom as unpatentable over Janssenswillen. The Examiner applies the same unreasonably broad claim interpretation in the rejection of independent claim 16 as unpatentable over Janssenswillen. *See* Final Act. 5, 10, 11. Therefore, for the same reasons, we do not sustain the rejection of claim 16, and associated dependent claims 18–23, as unpatentable over Janssenswillen.

CONCLUSION

Rejection I is affirmed, and Rejections II and III are reversed.

DECISION SUMMARY

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1, 16	112(a)	Written Description	1, 16	
1, 16	112(b)	Indefiniteness		1, 16
1–11, 13–16, 18–23	103	Janssenswillen		1–11, 13–16, 18–23
Overall Outcome			1, 16	2–11, 13–15, 18–23

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-IN-PART