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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte GEORGE MANSOUR, CHRISTOPHER ZOLLINGER,
JONATHAN YEHL, and NEIL QUITOVIERA

Appeal 2019-001115
Application 14/319,617
Technology Center 3700

Before DANIEL S. SONG, CHARLES N. GREENHUT, and
JEREMY M. PLENZLER, *Administrative Patent Judges*.

GREENHUT, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant,¹ CareFusion 303, Inc.,
appeals from the Examiner's decision to reject claims 1–4, 6–9, 11, 13, 14,
16–21, 24 and 25. Final Act. 1. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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 Carefusion
303, Inc. Appeal Br. 1.

CLAIMED SUBJECT MATTER

The claims are directed to a system and method for compounding medication. Claim 1, reproduced below, is illustrative of the claimed subject matter:

1. A system comprising:

a removable, circular, rotatable transfer module having one or more transfer cartridges, each transfer cartridge having an access device;

a removable, circular, rotatable medication module having a medication container, wherein the access device of a selected transfer cartridge is configured to access the medication container; and

a removable, circular, rotatable filling module, wherein the transfer module is disposed between the filling module and the medication module, wherein the filling module comprises a first pump, and wherein the access device is configured to extend into the first pump, wherein the transfer module, the medication module, and the filling module are aligned circumferentially along a common axis of rotation.

REFERENCES

The prior art relied upon by the Examiner is:

Lasonde	US 5,697,407	Dec. 16, 1997
Credle, Jr. et al.	US 6,309,034 B1	Oct. 30, 2001
Angus et al.	US 9,327,958 B2	May 3, 2016
Uber, III et al.	US 2004/0254525 A1	Dec. 16, 2004

REJECTIONS²

Claims 1–4, 6–9, 11, 13, 14, 16–21, 24, and 25 are rejected under 35 U.S.C. § 112(a), as failing to comply with the enablement requirement. Final Act. 4.

² The written description rejection has been withdrawn. Ans. 2.

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Claims 1, 2, 6–9, 11, 13, 14, 16–18, 20, 21, 24, and 25 are rejected under 35 U.S.C. § 103 as being unpatentable over Lasonde, Angus and/or Credle. Final Act. 8.

Claims 3, 4, and 19 are rejected under 35 U.S.C. § 103 as being unpatentable over Lasonde, Angus, and/or Credle, and Uber. Final Act. 12.

OPINION

Enablement

The claims subject to this rejection are argued as a group for which claim 1 is representative under 37 C.F.R. § 41.37(c)(1)(iv).

The aspects of the claimed subject matter for which the Examiner concludes there is insufficient detail in the Specification to comply with the enablement requirement are: the pump, the means for rotating the medication module, and the fluidic circuit formed by the components. Final Act. 4–7. While the drawings are probably more than purely “artistic representations” as the Examiner submits (Final Act. 8; Reply Br. 3), for essentially the reasons articulated by the Examiner, we do agree with the Examiner that the figures coupled with the Specification lack the detail necessary to satisfy the enablement requirement of 35 U.S.C. § 112(a).

Neither the Examiner nor Appellant discusses in detail, or indicates there is any disagreement as to, the legal standards for analyzing compliance with the enablement requirements of 35 U.S.C. § 112(a). Accordingly, we need not reproduce those standards here and refer instead to MPEP § 2164.01 (discussing *inter alia In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988)).

In response to the Examiner’s determination with regard to the features identified above, Appellant essentially dismisses the Examiner’s

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position as related to unclaimed subject matter. App. Br. 13. The Examiner's mention of the so-called unclaimed subject matter was done to demonstrate the amount of speculation necessary for the skilled artisan to determine how to make the invention. It is true that meticulous details of certain common structures, which in appropriate circumstances may include pumps, for example, may not be necessary to enable or demonstrate possession of an invention. Reply Br. 3. Indeed, it is preferable to omit that which is already generally known to a skilled artisan. Here, however, the Examiner raised a reasonable "doubt [] about enablement because information is missing about one or more essential parts or relationships between parts which one skilled in the art could not develop without undue experimentation." MPEP § 2164.04 Appellant produces no rebuttal evidence, or argument to inform the Examiner or the Board how, based on the original disclosure, one skilled in the art would understand how to make and use a device including the parts and relationships for which the Examiner determines there is insufficient direction. Appellant points out the reference numerals where various claim elements can be found in the figures (App. Br. 12–13). This, without more, does little to explain their operation. Considering the pumps that are very poorly illustrated in Figures 3A-D, which Appellant relies on for support (App. Br. 11–12, 15), we, like the Examiner, are unable to discern the structure of any pump, either specifically taught by Appellant's disclosure, or generally known to a skilled artisan, such that a skilled artisan would be able to determine, and incorporate, the necessary pump, without resorting to undue experimentation. Likewise, it is unclear to us, and Appellant produces neither evidence nor explanation, as to how, and with respect to what, rotation of the medication module is effectuated. Perhaps most importantly the Examiner indicated that the fluidic pathway that allows

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the device to actually operate is not clear and Appellant's have not directed our attention to any aspects of the disclosure, supplied any external evidence, or even provided arguments, that explain the nature and operation of this pathway. We therefore disagree with Appellant's essentially unsupported assertion that "the amount of direction provided by the inventor is high." *See* App. Br. 14; Ans. 4. The fact that the amount of direction provided by the inventor is low, weighs in favor of undue experimentation and nonenablement.

Appellant's only other argument concerning the enablement requirement is that "any enabled use" suffices to satisfy this requirement and it suffices that even if one does not know how to operate the claimed invention for the purpose of compounding medication, the claimed invention is enabled for a use as retention device for medication, cartridges and pumps. App. Br. 14–15. However, the claim recites numerous elements that are associated with various functions beyond acting merely as a retention device. Similarly, the Specification associates these generically described elements with functions other than acting only as a retention mechanism. In some instances a description of a result to be achieved may be enough to allow the skilled artisan to work out the precise details of construction. However, there is no evidence or technical reasoning of record to demonstrate that that is the case here. Thus, as to Appellant's attempt to divorce the claim elements from the functions and results recited in the claims and disclosed in the Specification, we agree with the Examiner's assessment that, even under the standards for enablement quoted by Appellant (App. Br. 14), enabling what essentially amounts to a storage cabinet does not constitute enabling a use that "reasonably correlate[s] with

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the entire scope *of the claim*,” particularly when that claim is read, as all claims must be, in light of the Specification. *Id.*; Ans. 3;

Accordingly, for the foregoing reasons, we sustain the Examiner’s rejection under 35 U.S.C. § 112(a).

Obviousness

Regarding the first obviousness rejection listed above, the claims are argued as a group with the exception of claims 13, 16, 18 and 24. App. Br. 16–19. Arguments are not presented for the second obviousness rejection and we presume Appellant advocates those claims based only on dependency. The arguments for claims 13, 16, 18 and 24 do no more than point out what the claim recites coupled with the naked assertion that the claim is in a condition for allowance. App. Br. 18–19. We do not regard this form of argument to comply with the requirements to “explain why the examiner erred” under 37 C.F.R. § 41.37(c)(1)(iv). *See In re Lovin* 652 F.3d 1349, 1357 (Fed. Cir. 2011) “[37 C.F.R. § 41.37(c)(1)(iv)] requires more substantive arguments in an appeal brief than a mere recitation of the claim elements and a naked assertion that the corresponding elements were not found in the prior art.” We also note this Board does not “allow” claims of an application and cannot direct an examiner to pass an application to issuance. Rather, this Board’s primary role is to review adverse decisions of examiners including the findings and conclusions made by the examiner. *See Ex Parte Frye*, 94 USPQ2d 1072, 1077 (BPAI 2010) *citing* 37 C.F.R. § 41.50(a)(1) (“The Board, in its decision, may affirm or reverse the decision of the examiner in whole or in part on the grounds and on the claims specified by the examiner”). Accordingly, the obviousness rejections of the claims before us hinge on claim 1.

Appellant initially contends that by comparing Figure 1 of Lasonde with Figures 3A–D of the present application it can be seen that the device of Lasonde “is not at all similar to the system as claimed in claim 1.” App. Br. 16. A comparison of Figure 1 of Lasonde with Figures 3A–D of the present application may potentially reveal, that the device depicted in Lasonde is not at all similar to the device *depicted in Figures 3A–D of the present application*. However, without pointing to express or implicit limitations in claim 1 embodying the distinguishing features between Appellant’s disclosed invention and Appellant’s claimed invention, these alleged differences based on the figures are of little significance. “[T]he name of the game is the claim.” *In re Hiniker Co.*, 150 F. 3d 1362, 1369 (Fed. Cir. 1998).

Appellant next argues, misinterpreting the Examiner’s rejection, that the Examiner improperly relies on Lasonde’s piercing spikes as three different claim elements, the transfer module, the transfer cartridge, and the access device. App. Br. 17. The Examiner’s statement on the top of page 9 of the Final Action regarding the limitations in question is sufficiently clear. However, the Examiner provides additional explanation in the Answer demonstrating the error in Appellant’s argument:

The Final Action includes the finding that the structures (64, 65, 66, 58, 59, 60) of Lasonde collectively constitute a transfer module. The module (64, 65, 66, 58, 59, 60) of Lasonde has one or more individual cartridges (64, 65, 66). The cartridge (64) of Lasonde has an access device (spike portion; see Annotated Figure A below). This configuration falls within the scope of the claim language. Notably, in a manner exactly akin to the claim language and the disclosure of the pending application, the access device (spike portion) of Lasonde is a component of the cartridge (64) and the cartridge (64) is a component of the module (64, 65, 66, 58, 59, 60).

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Ans. 5–6 (Annotation omitted). As to the final argument presented in the Appeal brief, that elements 64–69 of Lasonde are a spike as opposed to elements including one, the Examiner correctly responds:

Figure 1 of Lasonde shows that the connector/administration spike (64) has a base portion and a spike portion, as indicated in Annotated Figure A above. The base portion is the portion that can be gripped and manipulated by a user, and the spike portion is the portion that actually penetrates into the container (20).

Ans. 6 (Annotation omitted). A “spike” sufficient to satisfy the claim language is, as the Examiner correctly points out, the penetrating portion of the connector elements. This is in no way negated by the fact that Lasonde attributes a descriptive name to the entire element, a “spike,” based on only an important sub-component of the element. *In re Neugebauer*, 330 F. 2d 353, 356 n.4 (CCPA 1964) (“In the construction of words, not the mere words, but the thing and the meaning, are to be inquired after.”)

Appellant does not articulate any further arguments regarding the issues discussed above in the Reply Brief. Rather, Appellant characterizes the clarification provided by the Examiner in the Answer as new contentions. Reply Br. 4–5. Although the Examiner explained in eight lines in the Answer what seemed apparent from the two lines in the Final Rejection, we cannot agree with Appellant that the Examiner’s clarification altered the thrust of the rejection or in any way deprived Appellant of adequate notice as to the basis for the Examiner’s rejection. As such, Appellant has not demonstrated “good cause” for introducing new arguments in the Reply Brief. *See* 37 C.F.R. § 41.41(b)(2). The additional arguments in the Reply Brief are mere unsupported assertions that the Examiner’s proposed combination would not have been successful or

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obvious. Reply Br. 5–6. As they are untimely, they need not be further addressed for purposes of this appeal. 37 C.F.R. § 41.41(b)(2).

For the foregoing reasons we sustain the Examiner’s obviousness rejections.

DECISION

The Examiner’s rejections are affirmed.

FINALITY AND RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED