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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte FRANZ FRANK, MARAL HAAR,
JÜRGEN MANIGEL, KAI KÜCK, SUSANNE STAHLKOPF,
MARCEL VOIGT, THOMAS BOUILLON,
MARTIN LUGINBÜHL, and PETER SCHUMACHER

Appeal 2017-000434
Application 13/005,810
Technology Center 3700

Before STEFAN STAICOVICI, EDWARD A. BROWN, and
ARTHUR M. PESLAK, *Administrative Patent Judges*.

PESLAK, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Franz Frank et al. ("Appellants") appeal under 35 U.S.C. § 134(a) from the Examiner's decision rejecting claims 38–42, 44–58, 62, and 64.[1] An oral hearing, pursuant to 37 C.F.R. § 41.47, was held on October 31, 2018. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM-IN-PART and ENTER A NEW GROUND OF REJECTION pursuant to our authority under 37 C.F.R. § 41.50(b).

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[1] Dräger Medical GmbH and Inselspital Bern, Direktion Lehre und Forschung are identified as the real party in interest. Appeal Br. 1.

THE CLAIMED SUBJECT MATTER

Appellants' invention "pertains to a process for monitoring a patient being anesthetized by means of at least one anesthetic with the use of a monitoring device." Spec. ¶ 2. Claim 38, reproduced below, is illustrative of the claimed subject matter.

> 38. An anesthetic process comprising the steps of:
> administrating a plurality of active anesthetic ingredients to a patient undergoing a painful procedure;
> determining a concentration of each of the active anesthetic ingredients at a site of action;
> determining an action of each of the active anesthetic ingredients from the determined concentrations of each active anesthetic ingredient at the site of action;
> determining an interaction relationship between each of the active anesthetic ingredients;
> combining the actions of the plurality of active anesthetic ingredients according to the interaction relationship to obtain a combined potency of all the plurality of active anesthetic ingredients;
> converting said combined potency to a Noxious Stimulus Response Index (NSRI), said NSRI being a one-dimensional parameter and having a full scale range with a first endpoint of said range indicating an alert and non-anesthetized patient, and with a second endpoint of said range indicating a deepest anesthesia;
> displaying the NSRI to an operator controlling said administering of the plurality of active anesthetic ingredients.

REJECTIONS[2]

1) Claims 38, 39, 56, 62, and 64 are rejected for failing to comply with the enablement requirement of 35 U.S.C. § 112, first paragraph.[3]
2) Claims 38, 39, 45, 56, 62, and 64 are rejected as indefinite under 35 U.S.C. § 112, second paragraph.
3) Claims 38–42, 45–52, 54, 55, 57, and 64 are rejected under 35 U.S.C. § 102(b) as anticipated by Noah D. Syroid et al. (*Development and Evaluation of a Graphical Anesthesia Drug Display*, 96 Anesthesiology, 565–74 (2002)) ("Syroid").
4) Claim 44 is rejected under 35 U.S.C. § 103(a) as unpatentable over Syroid.
5) Claims 53 and 56 are rejected under 35 U.S.C. § 103(a) as unpatentable over Syroid, Bouillon (US 2006/0081244 A1, published Apr. 20, 2006), and Andrews (US 6,186,977 B1, issued Feb. 13, 2001).

DISCUSSION

Rejection 1

The Examiner finds that "the specification, while being enabling for NSRI being calculated by equations 1 and 8, does not reasonably provide enablement for the term 'NSRI'" because equations 1 and 8 are not

[2] A rejection of claim 61 for failing to comply with the written description requirement of 35 U.S.C. § 112, first paragraph, was withdrawn in the Examiner's Answer. Ans. 7; Final Act. 2.

[3] The Examiner states that claims 59–63 would be allowable if rewritten to overcome the rejections under 35 U.S.C. § 112, second paragraph, and to include all limitations of the base claim and any intervening claims. Final Act. 8. Of these claims, however, only claim 62 is currently rejected.

commensurate with the scope of the claims. Final Act. 2–3. Appellants contend that NSRI is recited in the claims as "a parameter having a range with one endpoint that indicates an alert and non-anesthetized patient, and another endpoint that indicates a deepest anesthesia." Appeal Br. 11. Appellants argue that equations 1 and 8 in the Specification enable the claims and that one of "ordinary skill in the art, given the definition of NSRI in the claims, could convert the combined potency to a NSRI parameter using a different conversion than that described in equations 1 and 8, without undue experimentation." *Id.* Appellants submit that the preferred embodiment described in paragraph 30 of Appellants' Specification "is an inverted sigmoid function" and notes other types of inverted sigmoid functions are known in the art. *Id.*

The Examiner responds that Appellants' Specification defines NSRI "by equations 1 and 8 and no other definition or alternate method of calculating NSRI is provided such that NSRI can only be equations 1 and 8." Ans. 9. The Examiner asserts that "it would require undue experimentation to derive the NSRI parameter by another method." *Id*

When rejecting a claim under 35 U.S.C. § 112 for lack of enablement, the Examiner bears an initial burden of setting forth a reasonable explanation as to why the scope of protection provided by the claim is not adequately enabled by the description of the invention provided in the specification of the application. *See In re Wright*, 999 F.2d 1557, 1561–62 (Fed. Cir. 1993). The enablement provision in the first paragraph of 35 U.S.C. § 112 requires that the full scope of a claim be enabled. *ALZA Corp. v. Andrx Pharm., LLC*, 603 F.3d 935, 943 (Fed. Cir. 2010). Determining whether any necessary experimentation is undue involves consideration of many relevant

factors including, but not limited to: (1) the breadth of the claims; (2) the nature of the invention; (3) the state of the prior art; (4) the level of one of ordinary skill; (5) the level of predictability in the art; (6) the amount of direction provided by the inventor; (7) the existence of working examples; and (8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

The Examiner correctly notes that Appellants' Specification provides two equations that can be used to determine NSRI. Spec. ¶¶ 31, 45. Appellants, however, argue that undue experimentation is not required to determine NRSI by means other than equations 1 and 8 because, *inter alia*, one of ordinary skill in the art would understand that other methods of calculating NSRI are available and specifically directs us to other inverted sigmoid functions that it asserts are known in the art. The Examiner does not dispute that these other inverted sigmoid functions are known in the art or adequately explain why undue experimentation would be required to use these functions instead of equations 1 and 8. *See* Ans. 8–9. Even though calculating NSRI using other known inverted sigmoid functions may require some experimentation on the part of ordinarily skilled artisans, a disclosure may nonetheless be enabling despite the need for experimentation. The test is whether such experimentation is *undue*. *In re Angstadt*, 537 F.2d 498, 504 (CCPA 1976). The Examiner does not provide any analysis of the *Wands* factors to support the assertion that undue experimentation would be required. *See* Final Act. 2–3; Ans. 8–9.

In the absence of a persuasive analysis of the *Wands* factors, the Examiner fails to provide adequate reasoning to support the assertion that

undue experimentation would be required to determine NSRI by a method other than equations 1 and 8 in Appellants' Specification. Therefore, we do not sustain this rejection.

Rejection 2

Claims 38, 39, 56, 62, and 64

The Examiner rejects these claims as indefinite because "the metes and bounds of what constitutes NSRI are uncertain unless such term is defined by equations 1 and 8." Final Act. 3.

Appellants contend that NSRI is a one dimensional parameter "that has a full scale range with endpoints" and the endpoints of the recited range, "[a]n alert and non-anesthetized patient" and "deepest anesthesia" are well known in the art. Appeal Br. 14. Consequently, according to Appellants, because the "the metes and bounds are certain, these claims are not indefinite with regard to what constitutes NSRI." *Id.* The Examiner responds that "the metes and bounds of what constitutes NSRI are uncertain unless such term is defined by equations 1 and 8" and here "the end points . . . are unrelated to the formula used to determine the NSRI numerical parameter, but rather the formula defines the NSRI numerical parameter." Ans. 9. For the following reasons, we do not sustain this rejection.

"[W]e apply the approach for assessing indefiniteness approved by the Federal Circuit in *Packard*, i.e., '[a] claim is indefinite when it contains words or phrases whose meaning is unclear.'" *Ex parte McAward*, No. 2015-006416, 2017 WL 3669566, at *5 (PTAB Aug. 25, 2017) (precedential) (quoting *In re Packard*, 751 F.3d 1307, 1310, 1314 (Fed. Cir. 2014)). The language in 35 U.S.C. § 112, second paragraph, "of

'particular[ity]' and 'distinct[ness]' indicates[] claims are required to be cast in clear—as opposed to ambiguous, vague, indefinite—terms." *Packard*, 751 F.3d at 1313 (internal citations omitted). "The definiteness inquiry focuses on whether those skilled in the art would understand the scope of the claim when the claim is read in light of the rest of the [S]pecification." *Union Pacific Resources Co. v. Chesapeake Energy Corp.*, 236 F.3d 684, 692 (Fed. Cir. 2001). The breadth of a claim, however, is not to be equated with indefiniteness. *See, e.g.*, *In re Miller*, 441 F.2d 689, 693 (CCPA 1971).

In this case, Appellants' Specification explains that the "NSRI index corresponds to the probability of a reaction or response of the patient to a painful stimulus . . . NSRI equals 100 in case of an alert and non-anesthetized patient, and it has the value 0 in case of the deepest anesthesia." Spec. ¶ 32. As discussed, the Specification also provides 2 equations for determining NSRI. *See id.* ¶¶ 31, 45. Although the claimed term NSRI may be broad, we determine that the term is not unclear because one of ordinary skill in the art would understand the scope of NSRI when read in light of the Specification. Therefore, we do not sustain this rejection.

Claim 45

The Examiner determines that "'interaction term' is indefinite because the metes and bounds are uncertain and the instant Specification does not provide a means to determine it." Final Act. 3. Appellants respond that "interaction term" is not indefinite because the Specification provides several interaction terms that are combined with the anesthetic efficacy to

determine a combined potency. Appeal Br. 18–19 (citing Spec. pp. 15–18).[4] For the following reasons, we sustain the rejection of claim 45 as indefinite.

Claim 45, which depends from claim 38, provides that the combined potency "is determined based on a mean anesthetic efficacy of the active ingredients used and an interaction term." Claim 38 recites an "interaction relationship" is used "to obtain a combined potency." "[I]nteraction term" appears in paragraph 32 of Appellants' Specification in connection with determining the combined potency N. *See* Spec. ¶ 32. Appellants do not direct us to any special definition in the Specification of "interaction term" or any portion of the Specification that draws a distinction between an "interaction relationship" recited in claim 38 and an "interaction term" recited in claim 45. *Id.* It is unclear from the claims and Specification the metes and bounds of the phrase "interaction term." Further, it is unclear whether it is different than "interaction relationship" and, consequently, whether its inclusion in claim 45 adds any additional limitation to claim 38. Consequently, we agree with the Examiner that the term would be unclear to one of ordinary skill in the art after reading the claims and Specification. Therefore, we sustain the rejection of claim 45 as indefinite under 35 U.S.C. § 112, second paragraph.

Rejection 3

The Examiner finds that Syroid anticipates independent claims 38 and 64 including disclosing the step of "determining an interaction relationship between each of the active anesthetic ingredients." Final Act. 4 (citing Syroid, p. 566, 2:12–p. 567, 1:7, Fig. 2). Appellants contend that Syroid

[4] Appellants indicate a willingness to remove "interaction term" from claim 45 if prosecution continues. Appeal Br. 19.

does not anticipate claim 38 or claim 64 because it does not disclose "determining an 'interaction relationship.'" Appeal Br. 15. Appellants argue that the claims require "determining . . . how the active anesthetic ingredients actually 'interact.'" *Id.* According to Appellants, Syroid "does state that a combined effect is calculated . . . but this combined effect does not include determining an interaction relationship." *Id.* Further, because, according to Appellants, Syroid does not disclose "determining an interaction relationship," Syroid does not use the "interaction relationship to determine a combined potency." *Id.* at 16.

The Examiner responds that Appellants' Specification "teaches [that] the interactions can be additive." Ans. 11 (citing Spec. ¶ 25)[5]. Based on this teaching, the Examiner maintains the rejection because the broadest reasonable interpretation of "interaction relationship" includes adding the effects of the ingredients and the limitation is, therefore, "met by Syroid's teaching of using an additive property." *Id.* For the following reasons, we do not sustain the rejection of claim 38.

We agree with the Examiner that, based on paragraph 25 of the Specification, the broadest reasonable interpretation of "interaction relationship" encompasses adding the potency of the active ingredients, if appropriate, as well as taking into account synergistic or antagonistic effects of the ingredients in combination. *See* Spec. ¶ 25 ("the actions of the active ingredients being used are combined corresponding to the type of interaction of these active ingredients, for example, either additively, synergistically or antagonistically."). However, we do not agree with the Examiner's finding

[5] The Examiner refers to paragraph 33 of the Specification but that appears to be a typographical error.

that Syroid discloses determining an interaction relationship between each of the active ingredients using an additive property. Ans. 11. The Examiner relies on the following description in Syroid and Figure 2 to support this finding. Final Act. 4. Syroid provides that

> For simplicity, we calculate the combined effect using the sum of the predicted effect-site concentrations . . . [of] each drug (*i.e.*, the drug display does not incorporate drug-drug synergism or antagonism). If the total effect-site concentrations of all drugs are greater than 100%, then the contributions from each drug become a fraction of the total.

Syroid, p. 566, 2:12–p. 567, 1:7, Fig. 2. Although Syroid refers to summing the effects of the active ingredients, Syroid states that this is done for simplicity and does not incorporate any synergistic or antagonistic effects caused by ingredient interaction. Further, the percentages of the ingredients shown in Figure 2 of Syroid are reduced in the case where the total effect of all ingredients exceeds 100%. This supports Appellants' arguments that Syroid's summation does not disclose an actual interaction relationship between the individual ingredients because one of ordinary skill in the art would understand that a total effect greater than 100% does not account for antagonistic effects of the ingredients. The Examiner's finding that Syroid anticipates claim 38 and claim 64 is not supported by the requisite preponderance of the evidence. We, thus, do not sustain the rejection of independent claims 38 and 64 and of claims 39–42, 45–52, 54, 55, and 57 which depend from claim 38.

Rejection 4

Claim 44 depends from claim 38. Claims App. 4. The Examiner rejects claim 44 as unpatentable over Syroid. Final Act. 7–8. The Examiner's additional findings from Syroid in the rejection of claim 44 fail

to cure the deficiencies in the rejection of claim 38 discussed *supra*. *Id.* We, thus, do not sustain the rejection of claim 44 as unpatentable over Syroid.

Rejection 5

Claims 53 and 56 depend from claim 38. Claims App. 4–5. The Examiner rejects claims 53 and 56 as unpatentable over Syroid, Bouillon, and Andrews. Final Act. 8. The Examiner's findings based on the disclosure of Bouillon and Andrews fail to cure the deficiencies in the rejection of claim 38 discussed *supra*. *Id.* We, thus, do not sustain the rejection of claims 53 and 56.

NEW GROUND OF REJECTION

We enter a new ground of rejection of claims 40 and 41 as indefinite under 35 U.S.C. § 112, second paragraph.

Claim 40 depends from claim 38 and recites steps of "combining the actions for each of the active anesthetic ingredients in each class to determine a class potency," "determining an interaction relationship between the different classes of active anesthetic ingredients," and then "combining the class potencies according to the interaction relationship." Claims App. 3. Claim 38 recites "determining an interaction relationship between each of the anesthetic ingredients." *Id.* It is unclear which of the interaction relationships recited in claims 38 and 40 is used in claim 40 when combining the class potencies. In addition, claim 38 recites "converting said combined potency to a Noxious Stimulus Response Index." It is unclear, for claim 40, whether the class potency recited in claim 38 or the class potency recited in claim 40 is converted to a Noxious Stimulus Response Index. For these

reasons, we enter a new ground of rejection against claim 40 and claim 41, which depends from claim 40, as indefinite under 35 U.S.C. § 112, second paragraph.

DECISION

The Examiner's rejection of claims 38, 39, 56, 62, and 64 for failing to comply with the enablement requirement of 35 U.S.C. § 112, first paragraph, is reversed.

The Examiner's rejection of claims 38, 39, 56, 62, and 64 as indefinite under 35 U.S.C. § 112, second paragraph, is reversed.

The Examiner's rejection of claim 45 as indefinite under 35 U.S.C. § 112, second paragraph, is affirmed.

The Examiner's rejection of claims 38–42, 45–52, 54, 55, 57, and 64 under 35 U.S.C. § 102(b) is reversed.

The Examiner's rejections of claims 44, 53, and 56 under 35 U.S.C. § 103(a) are reversed.

We enter a NEW GROUND OF REJECTION of claims 40 and 41 as indefinite under 35 U.S.C. § 112, second paragraph.

FINALITY OF DECISION

This decision contains new grounds of rejection pursuant to 37 C.F.R. § 41.50(b). 37 C.F.R. § 41.50(b) provides "[a] new ground of rejection pursuant to this paragraph shall not be considered final for judicial review." 37 C.F.R. § 41.50(b) also provides:

When the Board enters such a non-final decision, Appellants, within two months from the date of the decision, must exercise one of the following

two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

> (1) *Reopen prosecution*. Submit an appropriate amendment of the claims so rejected or new Evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the prosecution will be remanded to the examiner. The new ground of rejection is binding upon the [E]xaminer unless an amendment or new Evidence not previously of Record is made which, in the opinion of the [E]xaminer, overcomes the new ground of rejection designated in this decision. Should the examiner reject the claims, . . . [Appellants] may again appeal to the Board pursuant to this subpart.
>
> (2) *Request rehearing*. Request that the proceeding be reheard under §41.52 by the Board upon the same Record. The request for rehearing must address any new ground of rejection and state with particularity the points believed to have been misapprehended or overlooked in entering the new ground of rejection and also state all other grounds upon which rehearing is sought.

Further guidance on responding to new grounds of rejection can be found in the MANUAL OF PATENT EXAMINING PROCEDURE § 1214.01 (9th Ed., Rev. 08.2017, Jan. 2018).

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-IN-PART; 37 C.F.R. § 41.50(b)