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

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In re Application of	:	
Sphingotec GmbH	:	
Application No. 16/315,805	:	
Filed: 7 Jan 2019	:	DECISION ON PETITION
For: ADRENOMEDULLIN FOR	:	
ASSESSING CONGESTION IN A	:	
SUBJECT WITH ACUTE HEART	:	
FAILURE		

This is a decision on the petition under 37 CFR 1.181 filed April 7, 2023, requesting that the Director exercise supervisory authority and overturn the decision of April 6, 2023, by the Director of Technology Center 1600 (Technology Center Director), which Technology Center Director decision refused to issue a new and complete Office action rejecting claims 34 and 35.

The petition to review the decision of the Technology Center Director issued on April 6, 2023, is granted to the extent that the supervisory review has been undertaken. However, the petition to issue a new and complete Office action rejecting claims 34 and 35 is **DENIED**.

RELEVANT BACKGROUND

The above-identified application is a U.S. national stage application under 35 U.S.C. § 371 of PCT international application PCT/EP2017/067091, having an international filing date of July 7, 2017.

Prosecution in the above-identified application led to a Request for Continued Examination (RCE) being filed on August 30, 2022. The submission under 37 CFR 1.114 included an amendment to the claims, wherein claims 17, 18, 22, 25, and 28 were amended and claims 34 through 38 were added.

A non-final Office action was issued on December 20, 2022, and included, *inter alia,* a rejection of claims 17, 18, 21, 22, 25, 27, 28, and 34 through 38 under 35 U.S.C. § 103 as being unpatentable over any one of Gegenhuber et al. (J. Cardiac Failure 13(1): 42- 49, 2007) as evidenced by Morgenthaler et al. (Clin. Chem. 51(10): 1823-1829, 2005) or Ng et al. (U.S. Pat. No. 9,012,151) or Bergmann et al. (U.S. Pat. Pub. 2010/0159474) or Bergmann et al. (WO 2014/147153A1) in view of Ambrosy et al. (Eur. Heart J. 34: 835-843, 2013) and in light of Gheorghiade et al. (Eur. J. Heart Failure 12: 423-433, 2010).

A petition under 37 CFR 1.181 to the Technology Center Director was filed on January 26, 2023, requesting that a new and complete Office action be issued explaining why newly added claims 34 and 35 were rejected and clarifying the rejection of newly added claims 36 through 38.

A decision by the Technology Center Director was issued on April 6, 2023, dismissing the petition requesting that a new and complete Office action be issued.

The present petition was filed on April 7, 2023, requesting reconsideration of the petition decision issued on April 6, 2023.

STATUTES AND REGULATIONS

35 U.S.C. § 132(a) states:

> Whenever, on examination, any claim for a patent is rejected, or any objection or requirement made, the Director shall notify the applicant thereof, stating the reasons for such rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of his application; and if after receiving such notice, the applicant persists in his claim for a patent, with or without amendment, the application shall be reexamined. No amendment shall introduce new matter into the disclosure of the invention.

35 U.S.C. § 134 states:

> (a) PATENT APPLICANT. An applicant for a patent, any of whose claims has been twice rejected, may appeal from the decision of the primary examiner to the Patent Trial and Appeal Board, having once paid the fee for such appeal.
>
> (b) PATENT OWNER. A patent owner in a reexamination may appeal from the final rejection of any claim by the primary examiner to the Patent Trial and Appeal Board, having once paid the fee for such appeal.

37 CFR 1.104 provides, in part, that:

> (a) Examiner's action.
>
> (1) On taking up an application for examination or a patent in a reexamination proceeding, the examiner shall make a thorough study thereof and shall make a thorough investigation of the available prior art relating to the subject matter of the claimed invention. The examination shall be complete with respect both to compliance of the application or patent under reexamination with the applicable statutes and rules and to the patentability of the invention as claimed, as well as with respect to matters of form, unless otherwise indicated.

(2) The applicant, or in the case of a reexamination proceeding, both the patent owner and the requester, will be notified of the examiner's action. The reasons for any adverse action or any objection or requirement will be stated in an Office action and such information or references will be given as may be useful in aiding the applicant, or in the case of a reexamination proceeding the patent owner, to judge the propriety of continuing the prosecution.

(3) An international-type search will be made in all national applications filed on and after June 1, 1978.

(4) Any national application may also have an international-type search report prepared thereon at the time of the national examination on the merits, upon specific written request therefor and payment of the international-type search report fee set forth in § 1.21(e). The Patent and Trademark Office does not require that a formal report of an international-type search be prepared in order to obtain a search fee refund in a later filed international application.

(b) Completeness of examiner's action. The examiner's action will be complete as to all matters, except that in appropriate circumstances, such as misjoinder of invention, fundamental defects in the application, and the like, the action of the examiner may be limited to such matters before further action is made. However, matters of form need not be raised by the examiner until a claim is found allowable.

(c) Rejection of claims.

(1) If the invention is not considered patentable, or not considered patentable as claimed, the claims, or those considered unpatentable will be rejected.

(2) In rejecting claims for want of novelty or for obviousness, the examiner must cite the best references at his or her command. When a reference is complex or shows or describes inventions other than that claimed by the applicant, the particular part relied on must be designated as nearly as practicable. The pertinence of each reference, if not apparent, must be clearly explained and each rejected claim specified.

(3) In rejecting claims the examiner may rely upon admissions by the applicant, or the patent owner in a reexamination proceeding, as to any matter affecting patentability and, insofar as rejections in applications are concerned, may also rely upon facts within his or her knowledge pursuant to paragraph (d)(2) of this section.

37 CFR 1.181 provides that:

(a) Petition may be taken to the Director:

(1) From any action or requirement of any examiner in the *ex parte* prosecution of an application, or in *ex parte* or *inter partes* prosecution of a reexamination proceeding which is not subject to appeal to the Patent Trial and Appeal Board or to the court;

(2) In cases in which a statute or the rules specify that the matter is to be determined directly by or reviewed by the Director; and

(3) To invoke the supervisory authority of the Director in appropriate circumstances. For petitions involving action of the Patent Trial and Appeal Board, see § 41.3 of this title.

(b) Any such petition must contain a statement of the facts involved and the point or points to be reviewed and the action requested. Briefs or memoranda, if any, in support thereof should accompany or be embodied in the petition; and where facts are to be proven, the proof in the form of affidavits or declarations (and exhibits, if any) must accompany the petition.

(c) When a petition is taken from an action or requirement of an examiner in the *ex parte* prosecution of an application, or in the *ex parte* or *inter partes* prosecution of a reexamination proceeding, it may be required that there have been a proper request for reconsideration (§ 1.111) and a repeated action by the examiner. The examiner may be directed by the Director to furnish a written statement, within a specified time, setting forth the reasons for his or her decision upon the matters averred in the petition, supplying a copy to the petitioner.

(d) Where a fee is required for a petition to the Director the appropriate section of this part will so indicate. If any required fee does not accompany the petition, the petition will be dismissed.

(e) Oral hearing will not be granted except when considered necessary by the Director.

(f) The mere filing of a petition will not stay any period for reply that may be running against the application, nor act as a stay of other proceedings. Any petition under this part not filed within two months of the mailing date of the action or notice from which relief is requested may be dismissed as untimely, except as otherwise provided. This two-month period is not extendable.

(g) The Director may delegate to appropriate Patent and Trademark Office officials the determination of petitions.

37 CFR 41.31(a) provides that:

(a) *Who may appeal and how to file an appeal.* An appeal is taken to the Board by filing a notice of appeal.

(1) Every applicant, any of whose claims has been twice rejected, may appeal from the decision of the examiner to the Board by filing a notice of appeal accompanied by the fee set forth in § 41.20(b)(1) within the time period provided under § 1.134 of this title for reply.

(2) Every owner of a patent under *ex parte* reexamination filed under § 1.510 of this title before November 29, 1999, any of whose claims has been twice rejected, may appeal from the decision of the examiner to the Board by filing a notice of appeal accompanied by the fee set forth in § 41.20(b)(1) within the time period provided under § 1.134 of this title for reply.

(3) Every owner of a patent under *ex parte* reexamination filed under § 1.510 of this title on or after November 29, 1999, any of whose claims has been finally (§ 1.113 of this title) rejected, may appeal from the decision of the examiner to the Board by filing a notice of appeal accompanied by the fee set

forth in § 41.20(b)(1) within the time period provided under § 1.134 of this title for reply.

OPINION

Petitioner requests that a new and complete Office action be issued because: (1) the examiner failed to conduct an examination of independent claim 34 in the Office action issued on December 20, 2022; (2) petitioner is entitled to have all of the pending claims fully examined including the minor differences; (3) if the Office is taking the position that claim 35 is obvious for the reasons articulated in the rejection of claims 17 and 18, the Office should do so on the record; and (4) if the examiner is making a rejection which relies on the inherency doctrine with regard to claims 36 through 38, the Office action should be made clear and explicitly state such.

Petitioner's arguments have been considered but are not persuasive. A review of the Office action of December 20, 2022, reveals that the Office action complies with the notice requirement of 35 U.S.C. § 132(a) and meets the requirements of 37 CFR 1.104.

The notice requirement of 35 U.S.C. § 132(a) does not require that the rejection specify each and every feature of the claimed invention and where it can be found in the applied reference. As noted by the Federal Circuit, there has never been a requirement for an examiner to make an on-the-record claim construction of every term in every rejected claim and to explain every possible difference between the prior art and the claimed invention. All that is required to meet its *prima facie* burden of production is to set forth the statutory basis of the rejection and the reference or references relied upon in a sufficiently articulate and informative manner as to meet the notice requirement of 35 U.S.C. § 132(a). As stated in 35 U.S.C. § 132(a), the examiner must "notify the applicant," "stating the reasons for such rejection," "together with such information and references as may be useful in judging the propriety of continuing prosecution of his application." *See In re Jung*, 637 F.3d 1356, 1363 (Fed. Cir. 2011). This requirement of 35 U.S.C. § 132(a) "is violated when a rejection is so uninformative that it prevents the applicant from recognizing and seeking to counter the grounds for rejection." *See Chester v. Miller*, 906 F.2d 1574, 1578 (Fed. Cir. 1990) (*citing In re Wilke*, 314 F.2d 558, 562 (C.C.P.A. 1963)).

In the present application, the non-final Office action issued on December 20, 2022, included, *inter alia,* a rejection of claims 17, 18, 21, 22, 25, 27, 28, and 34 through 38 under 35 U.S.C. § 103 as being unpatentable over any one of Gegenhuber et al. (J. Cardiac Failure 13(1): 42- 49, 2007) as evidenced by Morgenthaler et al. (Clin. Chem. 51(10): 1823-1829, 2005) or Ng et al. (U.S. Pat. No. 9,012,151) or Bergmann et al. (U.S. Pat. Pub. 2010/0159474) or Bergmann et al. (WO 2014/147153A1) in view of Ambrosy et al. (Eur. Heart J. 34: 835-843, 2013) and in light of Gheorghiade et al. (Eur. J. Heart Failure 12: 423-433, 2010) and set forth the reasons for the rejection and how the references were being applied.

In the Office action of December 20, 2022, the examiner states the statutory basis for the rejection of claims 17, 18, 21, 22, 25, 27, 28, and 34 through 38 and provides an explanation as to how the cited references are being applied in the 35 U.S.C. § 103 rejection so as to be sufficiently informative; places petitioner on notice of the basis for the rejection of claims 34, 35,

and 36 through 38; and provides petitioner with the opportunity to recognize and respond to the rejection. For example, the Office action of December 20, 2022, explains that Bergmann et al. ('474) teach a method of preparing a sample comprising providing a bodily fluid [0044] obtained from a subject and a binder that binds to at least 5 amino acids of Pro-Adrenomedullin [0057] and that Bergmann et al. teach measuring the amount of adrenomedullin with an antibody ([0055]- [0060]) wherein the pro- adrenomedullin or fragments is at least 5 amino acids [0057]. The subject is a patient who has acute heart failure and that acute heart failure can either be new onset AHF or acute decompensated HF (see [0010] and [0049]). Bergmann et al. also teach MR-proADM that comprises amino acids 45 through 92 of preproADM (corresponding to SEQ ID NO:3 of the instant application) and that the levels in the sample are 0.5 through 5.0 pmol/L and most preferably 1.985 nml/L for MR-proADM (see [0064] and Figures 2 and 9).[1] The Office action also provides reasoning that while the cited references are silent as to the subjects being identified as suffering from residual congestion or other conditions/symptoms, the methods of the cited references utilize measurement of ADM for evaluating the status of the patients, such samples would be prepared to evaluate the subjects and would necessarily include those subjects identified and not identified as suffering from residual congestion.[2]

If petitioner believes that the examiner failed to establish a *prima facie* case as to any ground of rejection, then such an argument would be the basis for an appeal and not a petition. A review of the propriety of a rejection *per se* (and its underlying reasoning) is by way of an appeal as provided by 35 U.S.C. § 134 and 37 CFR 41.31, and not by way of petition under 37 CFR 1.181, even if a petitioner frames the issues as concerning procedure versus the merits. *See Boundy v. U.S. Patent & Trademark Office*, 73 USPQ2d 1468, 1472 (E.D. Va. 2004). As stated by the Court of Customs and Patent Appeals (a predecessor of the Federal Circuit), the adverse decisions of examiners which are reviewable by the Board are those which relate, at least indirectly, to matters involving the rejection of claims. *See In re Hengehold*, 440 F.2d 1395, 1404 (C.C.P.A. 1971). That a petitioner casts the argument as directed to a procedural requirement (rather than the merits of the rejection) does not untether the review of the *prima facie* case from the review of the merits of the rejection. *See In re Jung*, 637 F.3d 1356, 1363 (Fed. Cir. 2011) (applicant's procedural arguments concerning the *prima facie* case requirement are the same arguments that would have been made on the merits). An applicant dissatisfied with an examiner's decision in the second or subsequent rejection may appeal to the Patent Trial and Appeal Board. *See* 37 CFR 41.31(a)(1). It is well settled that the Director will not, on petition, usurp the functions or impinge upon the jurisdiction of the Patent Trial and Appeal Board. *See In re Dickerson*, 299 F.2d 954, 958 (C.C.P.A. 1962) (The Board will not ordinarily hear a question that should be decided by the Director on petition, and the Director will not ordinarily entertain a petition where the question presented is a matter appealable to the Board). *See also The Manual of Patent Examining Procedure* (MPEP) § 1201.

Since the Office action of December 20, 2022, complies with the notice requirement of 35 U.S.C. § 132(a) and meets the requirements of 37 CFR 1.104, a new Office action will not be issued.

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[1] Non-final Office action issued December 20, 2022, p.5.

[2] *Id.* pp.7 and 8.

DECISION

For the reasons stated above, the petition requesting a new and complete Office action be issued is **DENIED**.

This constitutes a final decision on the petition. No further requests for reconsideration will be entertained. Judicial review of this decision may be available upon entry of a final agency action adverse to the petitioner in the instant application (*e.g.,* a final decision by the Patent Trial and Appeal Board). *See* MPEP § 1002.02

The above-identified application is being forwarded to Technology Center 1600 for consideration of the reply filed on June 20, 2023, to the Office action issued on December 20, 2022.

/Robert W. Bahr/
Robert W. Bahr
Deputy Commissioner
for Patents