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In re Application of:
JONATHAN LIM ET AL.
Application No.: 14/623,904
Filed: February 17, 2015
Title: **MOLECULES FOR ADMINISTRATION**
TO ROS1 MUTANT CANCER CELLS

ON PETITION

This is a decision on the petition filed October 6, 2016, requesting that the Director exercise her supervisory authority to review the decision of August 15, 2016 by the Director of Technology Center 1600 (Technology Center Director), whose decision refused to withdraw the Office action of June 7, 2016 and its finality.

The petition is granted to the extent that the examiner will be directed to either—

- (1) Issue a new Office action (which may be final) setting a new time period for reply and containing only the rejections set forth in the final Office action of September 16, 2016 and does not include any reference to or discussion of Valent¹ in the body of the Office action; or
- (2) Issue a new non-final Office action setting a new time period for reply that contains the rejections set forth in the final Office action of September 16, 2016 and includes Valent in the statement of the rejection.

BACKGROUND

The above-identified application was filed on February 17, 2015.

A non-final Office action was mailed on October 16, 2015. The Office action of October 16, 2015 included: (1) a rejection of claims 1, 3, 4, 6, 7, 9, 10, and 12 through 19 under 35 U.S.C. § 112(a) for failure to comply with the requirement for a written description of the invention; and

¹ Valent et al., Eur. J. Hum. Genet (1997), Vol. 5(2), pp. 102-104.

(2) a rejection of claims 1 through 19 under 35 U.S.C. § 103 as being unpatentable over Lombardi et al. WO 2009/013126 (Lombardi); Bendiera et al. WO 2008/074749 (Bendiera); Hout et al. WO 2013/119950 (Hout); Greco et al., *Molecular and Cellular Endocrinology* (2010), Vol. 321 (1), pp. 44-49 (Greco); and Lipska et al., *BMC Cancer* (2009), 9:436, pp. 1-9 (Lipska).

A reply to the Office action of October 16, 2015 was filed on January 8, 2016. The reply of January 8, 2016 traversed the rejections of claims 1 through 19 in the Office action of October 16, 2015 and added a new claim 20.

A non-final Office action was mailed on February 4, 2016. The Office action of February 4, 2016 included a rejection of claims 1 through 20 under 35 U.S.C. § 103 as being unpatentable over Lombardi, Bendiera, Hout, Greco and Lipska.

A reply to the Office action of February 4, 2016 was filed on May 17, 2016. The reply of May 17, 2016 traversed the rejections of claims 1 through 20 in the Office action of February 4, 2016.

A final Office action was mailed on June 7, 2016. The final Office action of June 7, 2016 included a rejection of claims 1 through 20 under 35 U.S.C. § 103 as being unpatentable over Lombardi, Bendiera, Hout, Greco, and Lipska. The final Office action of June 7, 2016 does not include Valent et al., *Eur. J. Hum. Genet* (1997), Vol. 5(2), pp. 102-104 (Valent), in the statement of the rejection, but references Valent in the body of the Office action for the proposition that deregulated genes ROS1, NTRKI, NTRK2 and NKRT3, are (were) well-known in the art prior to the time the invention was made.

A petition under 37 CFR 1.181 was filed on July 5, 2016, requesting, *inter alia*, that the Office action of June 7, 2016 and its finality be withdrawn. The petition of July 5, 2016 was denied by the Technology Center Director in the decision of August 15, 2016.

A second final Office action was mailed on September 16, 2016.² The final Office action of September 16, 2016 included a rejection of claims 1 through 20 under 35 U.S.C. § 103 as being unpatentable over Lombardi, Bendiera, Hout, Greco, and Lipska. The final Office action of September 16, 2016 does not include Valent in the statement of the rejection, but again references Valent in the body of the Office action for the proposition that deregulated genes ROS1, NTRKI, NTRK2 and NKRT3, are (were) well-known in the art prior to the time the invention was made. The Office action of September 16, 2016 also included a copy of Valent.³

² The Office action of September 16, 2016 is entered into the United States Patent and Trademark Office (USPTO) Patent Application Locating and Monitoring (PALM) system as a "Letter Restarting Period for Response" (NRES), but the Office action of September 16, 2016 is an Office action under 35 U.S.C. § 132.

³ The USPTO's Image File Wrapper (IFW) records for the above-identified application include the following documents in the search notes for September 16, 2016: (1) Greco et al., *Chromosome 1 Rearrangements Involving the Genes TPR and NTRK1 produce Structurally Different Thyroid-Specific TRK Oncogenes* (1997) (Greco); and (2) Tognon et al., *The chimeric*

The instant petition was filed on October 6, 2016, and requests that the Director exercise her supervisory authority to review the decision of August 15, 2016 by the Technology Center Director, whose decision refused to withdraw the Office action of June 7, 2016 and its finality.

STATUTE AND REGULATION

35 U.S.C. § 132 provides that:

(a) 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.

(b) The Director shall prescribe regulations to provide for the continued examination of applications for patent at the request of the applicant. The Director may establish appropriate fees for such continued examination and shall provide a 50 percent reduction in such fees for small entities that qualify for reduced fees under section 41(h)(1).

35 U.S.C. § 134 provides that:

(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 1.113 provides that:

(a) On the second or any subsequent examination or consideration by the examiner the rejection or other action may be made final, whereupon applicant's, or for *ex parte* reexaminations filed under § 1.510, patent owner's reply is limited to appeal in the case of rejection of any claim (§ 41.31 of this title), or to amendment as specified in § 1.114 or § 1.116. Petition may be taken to the Director in the case of objections or requirements not involved in the rejection of

protein tyrosine kinase ETV6-NTRK3 requires both Ras-Erk1/2 and PI3-kinase-Akt signaling for fibroblast transformation, Cancer Research 61, 8909-8916 (Dec. 15, 2001) (Tognon).

any claim (§ 1.181). Reply to a final rejection or action must comply with § 1.114 or paragraph (c) of this section. For final actions in an *inter partes* reexamination filed under § 1.913, see § 1.953.

(b) In making such final rejection, the examiner shall repeat or state all grounds of rejection then considered applicable to the claims in the application, clearly stating the reasons in support thereof.

(c) Reply to a final rejection or action must include cancellation of, or appeal from the rejection of, each rejected claim. If any claim stands allowed, the reply to a final rejection or action must comply with any requirements or objections as to form.

37 CFR 1.181(a) provides that:

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.

OPINION

Petitioners contend *inter alia* that: (1) the examiner has failed to set forth a clear and correct Office action, and has failed to adequately address petitioners' arguments and exhibits; (2) the examiner has failed to make Valent of record, or provide a copy of Valent⁴; (3) the finality of the Office action of June 7, 2016 (and ostensibly the Office action of September 16, 2016) is improper; and (4) the Technology Center Director decision of August 15, 2016 mischaracterizes the petition of July 5, 2016 and includes extraneous material for which there is no clear mechanism for petitioners to address as part of the prosecution history of this application. Petitioners request *inter alia* that the Director: (1) reverse and vacate the Technology Center Director decision of August 15, 2016; (2) withdraw the finality of and vacate the Office action of June 7, 2016, and September 16, 2016; (3) require the examiner to issue a new non-final Office action that adequately addresses petitioners' arguments and exhibits, and sets a new time period for reply.

⁴ The request to make Valent of record and for a copy of Valent is moot inasmuch as the Office action of September 16, 2016 made Valent of record and included a copy of Valent.

Petitioners' contention that the examiner has failed to set forth a clear and correct Office action, and has failed to adequately address petitioners' arguments and exhibits:

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 1.191, and not by way of petition under 37 CFR 1.181, even if the 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). An applicant dissatisfied with an examiner's decision in the second or subsequent rejection may appeal to the Patent Trial and Appeal Board (formerly the Board of Patent Appeals and Interferences). *See* 37 CFR 43.31(a)(1). As stated by the Court of Customs and Patent Appeals (a predecessor of the U.S. Court of Appeals for 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 (CCPA 1971). 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 (CCPA 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* MPEP 1201.

With respect to the procedural aspects of 35 U.S.C. § 132:

Section 132 merely ensures that an applicant "at least be informed of the broad statutory basis for [the rejection of] his claims, so that he may determine what the issues are on which he can or should produce evidence." Section 132 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 (1990) (citations omitted).

The Office actions issued in the above-identified application have been reviewed. The Office actions of October 16, 2015, February 4, 2016, June 7, 2016, and September 16, 2016 each satisfies the notice requirements of 35 U.S.C. § 132, in that each Office action is sufficiently informative as to place petitioners on notice of the basis for the rejection(s) so as to allow petitioners to recognize and counter the rejection(s). *See id.* Accordingly, none of the Office actions of October 16, 2015, February 4, 2016, June 7, 2016, and September 16, 2016 violate the procedural requirements of 35 U.S.C. § 132.

While petitioners consider the Office actions to be inadequate in addressing petitioners' arguments and exhibits,⁵ the Office action of September 16, 2016 does acknowledge and respond to the exhibits submitted by petitioners. *See* Office action of September 16, 2016 at 9. With respect to the sufficiency of the examiner's response to petitioners' arguments and exhibits, the correctness and underlying reasoning of an examiner's consideration of an applicant's

⁵ Petitioners are reminded that evidence submitted to traverse a rejection or objection on a basis not otherwise provided for must be by way of an oath or declaration under 37 CFR 1.132.

arguments, exhibits, or evidence goes directly to a rejection of the pending claims under 35 U.S.C. § 103 and is appropriate for the applicant's substantive challenge to the rejection. *See In re Jung*, 637 F.3d 1356, 1363 (Fed. Cir. 2011). Since the correctness and underlying reasoning of the examiner's consideration of petitioners' arguments and exhibits goes directly to the rejections of the pending claims under 35 U.S.C. § 103, any review of the correctness and underlying reasoning of the examiner's consideration of petitioners' arguments and exhibits is by way of an appeal as provided by 35 U.S.C. § 134 and 37 CFR 1.191, and not by way of petition under 37 CFR 1.181.

To the extent that petitioners consider the Office actions (or the decision of August 15, 2016) to contain inaccurate or unsupported or extraneous information or statements, petitioners have the opportunity to provide whatever clarification of the prosecution history is considered necessary by explaining the inadequacy of the Office action or pointing out inaccuracies or unsupported or extraneous information or statements included in the Office action in the reply to that Office action. Similarly, petitioners may point out inaccuracies or unsupported or extraneous information or statements that petitioners may want considered by the Patent Trial and Appeal Board (PTAB) in any appeal in the above-identified application in any appeal brief in the above-identified application.

Petitioners place considerable reliance upon the examiners use of the phrase "superseded" in the Office actions of February 4, 2016 and June 7, 2016. Petitioners are correct that the MPEP provides no discussion (or definition) of "superseding" an Office action, but that is because "superseded" has no particular significance in the context of the USPTO issuing a new Office action, other than that the most recent Office action supersedes any former Office actions by setting forth the examiner's current position on the patentability of the claims, as well as on any other applicable objections or requirements. The phrase "superseded" does not suggest that any previous Office action has been vacated or rendered a nullity, or have any other significance.

Petitioners' contentions based upon the Enhanced Patent Quality Initiatives (EPQI) and the actions taken as a consequence of petitioners contacting the Patents Ombudsman Program have also been considered, but are not deemed persuasive. Neither of these programs create any basis for relief via petition under 37 CFR 1.181 that does not already exists under the patent statutes, regulations, and examining procedures.

Petitioners' contentions concerning Valent and the finality of the Office actions of June 7, 2016 and September 16, 2016:

The Office actions of June 7, 2016 and September 16, 2016 reference Valent in the body of the Office action for the proposition that deregulated genes ROS1, NTRK1, NTRK2 and NKRT3, were well-known in the art prior at the time the invention was made. This use of Valent goes directly to the factors that underpin an obviousness analysis (scope and content of the prior art and level of ordinary skill in the art). *See Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966). When a reference is relied on to support a rejection, whether or not in a minor capacity, that reference should be positively included in the statement of the rejection. *See In re Hoch*, 428 F.2d 1341, 1342 n.3 (CCPA 1970). That the reference to Valent occurs in the response to

petitioners' arguments section of the Office actions of June 7, 2016 and September 16, 2016 and is in response to petitioners' argument is of no moment. *See In re Biedermann*, 733 F.3d 329, 338 (Fed. Cir. 2013) (a new ground of rejection is not negated by the fact that the new reference is cited in response to an applicant's argument). Valent is being applied in the Office actions of June 7, 2016 and September 16, 2016 to support the examiner's case of unpatentability of claims 1 through 20 under 35 U.S.C. § 103, and thus must appear in the statement of the rejection to be referenced in the body of an Office action in the manner it is being applied in the Office actions of June 7, 2016 and September 16, 2016.⁶ *See, e.g., Ex parte Raske*, 28 USPQ2d 1304, 1304-05 (Bd. Pat. App. & Int. 1993) (backdoor use of references to 'show the general state of the art' improper).

Petitioners' request, however, that the Office action of June 7, 2016 or September 16, 2016 be vacated is unwarranted. The patent laws provide that an applicant may reply to an Office action "with or **without** amendment" (35 U.S.C. § 132), and may appeal to the Patent Trial and Appeal Board if any of the "claims has been twice rejected" (35 U.S.C. § 134), thus indicating that the patent laws do not expect that every USPTO Office action will be correct in every respect. The vacatur of an Office action is an extreme measure that is warranted only in unusual situations (e.g., an Office action signed by an employee who does not have the authority to issue that type of Office action, the issuance of an Office action in the wrong application, or the issuance of an Office action containing language not appropriate for inclusion in an official U.S. government document). The above-identified application simply does not present a situation that would warrant vacatur of the Office action of June 7, 2016 or September 16, 2016.⁷

DECISION

The petition is **granted** to the extent that the examiner will be directed to either: (1) issue a new Office action (which may be final) setting a new time period for reply and containing only the rejections set forth in the final Office action of September 16, 2016, but with the reference to Valent removed from the body of the Office action; or (2) issue a new non-final Office action setting a new time period for reply that contains the rejections set forth in the final Office action

⁶ A different result might be warranted if an Office action references such a document for some other reason, such as referring to a dictionary or patent document to explain a general or art-recognized meaning of a term appearing in the claim or in the prior art.

⁷ Petitioners' comments concerning patent term adjustment are noted. Petitioners are reminded that the patent term adjustment provisions compensate applicants for certain reductions in patent term that are not the fault of the applicant, and not to guarantee the correctness of the USPTO's every decision. *See Pfizer v. Lee*, 811 F.3d 466, 476 (2016). Nevertheless, discussions of patent term adjustment in the above-identified application is premature at this point as the USPTO is not obliged to make a patent term adjustment determination or provide notice of that determination to the applicant until the date of issuance of the patent. *See* 35 U.S.C. § 154(b)(3)(B)(i). If petitioners are dissatisfied with that patent term adjustment determination, they may at that point seek reconsideration of the patent term adjustment determination. *See* 35 U.S.C. § 154(b)(3)(B)(ii) and 37 CFR 1.705.

of September 16, 2016 and includes Valent in the statement of the rejection (such new non-final Office action may also include any other rejections that are deemed appropriate).

The petition, however, is **denied** in all other respects, including: (1) vacating any of the Office actions of October 16, 2015, February 4, 2016, June 7, 2016, and September 16, 2016 or the decision of August 15, 2016; or (2) requiring the examiner to provide a further discussion of petitioners' arguments and exhibits.

This decision moots the petition under 37 CFR 1.182 for expeditious review of the petition filed on October 6, 2016.

This decision becomes a final agency action upon entry of a final decision by the Patent Trial and Appeal Board. *See* MPEP § 1002.02. No further reconsideration of this decision on petition will be entertained.

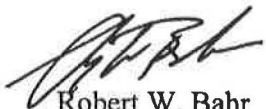
The above-identified application is being returned to Technology Center 1600 for correction of the PALM system entry for the Office action of September 16, 2016 to a "Final Rejection" (CTFR) and issuance of either:

(1) new Office action (which may be final) setting a new time period for reply and containing only the rejections set forth in the final Office action of September 16, 2016, but with the reference to Valent removed from the body of the Office action; or

(2) a new non-final Office action setting a new time period for reply that contains the rejections set forth in the final Office action of September 16, 2016 and includes Valent in the statement of the rejection.

The Office action issued in response to this decision should cite Greco and Tognon (the documents in the search notes for September 16, 2016) on a Notice of References Cited (PTO-892) and include a copy of these documents.

Telephone inquiries concerning this decision may be directed to Vincent N. Trans whose telephone number is (571) 272-3613.



Robert W. Bahr
Deputy Commissioner for
Patent Examination Policy
Petitions Officer