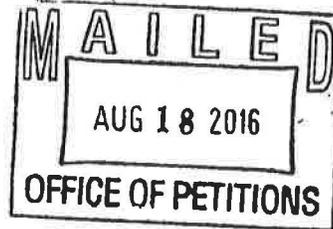




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In re Application of
Gary A. Hoffman *et al.*
Application No. 13/385,495
Filed: February 22, 2012
For: PRODUCTION AND USE OF HIGH
PRESSURE FOR CRYOPRESERVATION
AND CRYOFIXATION

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: DECISION ON PETITION
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This is a decision on the petition under 37 CFR 1.181 filed May 25, 2016, requesting that the Director exercise her supervisory authority and overturn the decision by a Technology Center 3700 Director (Technology Center Director) of May 16, 2016, which decision dismissed the petition under 37 CFR 1.181 of May 2, 2016 to withdraw the finality of the Office action of January 15, 2016.

The petition to withdraw the finality of the Office action of January 15, 2016 is **GRANTED**.

BACKGROUND

The above-identified application was filed on February 22, 2012.

A requirement for an election of species was mailed on September 10, 2014, and an election in reply to the requirement for an election of species of September 10, 2014 was filed on May 29, 2015.

A non-final Office action was mailed on July 6, 2015. The non-final Office action mailed on July 6, 2015 included, *inter alia*, the following rejections: (1) a rejection of claims 1 through 3, 5, 16, and 17 under 35 U.S.C. § 103 as being unpatentable over Kumar *et al.* (U.S. Patent No. 4,264,556) and Scheiwe *et al.* (U.S. Patent No. 4,327,799); (2) a rejection of claim 4 under 35 U.S.C. § 103 as being unpatentable over Kumar *et al.*, Scheiwe *et al.*, and Yerkes (notes from C. Yerkes posted on the University of Illinois Urbana-Champaign Internet Web site); (3) a rejection

of claims 6, 7 and 18 through 20 under 35 U.S.C. § 103 as being unpatentable over Kumar *et al.*, Scheiwe *et al.*, and Wisniewski (U.S. Patent Application Publication No. 2002/0110907); (4) a rejection of claim 11 under 35 U.S.C. § 103 as being unpatentable over Kumar *et al.*, Scheiwe *et al.*, and Arnitz *et al.* (U.S. Patent Application Publication No. 2011/0309086); (5) a rejection of claims 8, 9, 12, and 13 under 35 U.S.C. § 103 as being unpatentable over Kumar *et al.*, Scheiwe *et al.*, and Rubinsky (U.S. Patent Application Publication No. 2007/0042337); and (6) a rejection of claims 10, 14, an 15 under 35 U.S.C. § 103 as being unpatentable over Kumar *et al.*, Scheiwe *et al.*, Rubinsky, and Wisniewski.

A reply to the non-final Office action of July 6, 2015 was filed on October 6, 2015. The reply of October 6, 2015 included an amendment canceling claims 17 and 19, amending claims 1, 5, 8, 9, 10, 11, 20, and adding new claims 21 through 24.

A final Office action was mailed on January 15, 2016. The final Office action mailed on January 15, 2016 included, *inter alia*, the following rejections: (1) a rejection of claims 1 through 3, 5, 16, 18, 20 and 22 under 35 U.S.C. § 103 as being unpatentable over Studer *et al.* (U.S. Patent No. 6,758,362) and Leunissen (U.S. Patent Application Publication No. 2009/0011505); (2) a rejection of claim 4 under 35 U.S.C. § 103 as being unpatentable over Studer *et al.*, Leunissen, and Yerkes; (3) a rejection of claims 6 and 7 under 35 U.S.C. § 103 as being unpatentable over Studer *et al.*, Leunissen, and Wisniewski; (4) a rejection of claims 11 under 35 U.S.C. § 103 as being unpatentable over Studer *et al.*, Leunissen, and Arnitz *et al.*; (5) a rejection of claims 8, 9, 12, 13, and 23 under 35 U.S.C. § 103 as being unpatentable over Studer *et al.*, Leunissen; and Rubinsky; and (6) a rejection of claims 10, 14, an 15 under 35 U.S.C. § 103 as being unpatentable over Studer *et al.* Leunissen, Rubinsky, and Wisniewski.

A reply to the final Office action of January 15, 2016 was filed on March 14, 2016. The reply of March 14, 2016 included, *inter alia*, an argument that the finality of the Office action of January 15, 2016 was improper. An advisory action in response to the reply of March 14, 2016 was mailed on April 7, 2016. The advisory action of April 7, 2016, *inter alia*, refused to withdraw the finality of the Office action of January 15, 2016.

A petition to withdraw the finality of the Office action of January 15, 2016 was filed on May 2, 2016. The petition of May 2, 2016 was dismissed as untimely by a Technology Center 3700 Director in a decision mailed on May 16, 2016.

The instant petition was filed on May 25, 2016, and again requests the Director exercise her supervisory authority and withdraw the finality of the Office action of January 15, 2016.

A notice of abandonment was mailed on July 25, 2016, indicating that the reply of March 14, 2016 was not a proper reply under 37 CFR 1.113, and that the above-identified application was abandoned for failure to file a timely and proper reply under 37 CFR 1.113 to the final Office action of January 15, 2016.

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).

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 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 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.

OPINION

Petitioners first argue that the petition of May 2, 2016 should not have been dismissed as untimely because: (1) the petition of May 2, 2016 was filed within two months of the advisory

action of April 7, 2016; and (2) 37 CFR 1.181(f) is discretionary in that it provides only that a petition “may” be dismissed as untimely. Petitioners then argue that the finality of the Office action of January 15, 2016 is improper because the new ground of rejection (Studer *et al.* and Leunissen in place of Kumar *et al.* and Scheiwe *et al.*) could have been applied in the non-final Office action of July 6, 2016, and thus the new ground of rejection in the final Office action of January 15, 2016 was not necessitated by the amendment filed October 6, 2015.¹

A review of the record of the above-identified application reveals that petitioners filed a reply to the final Office action of January 15, 2016 on March 14, 2016 (within two months of that final Office action), arguing that the finality of the Office action of January 15, 2016 was improper, and that petitioners filed a petition to withdraw the finality of the Office action of January 15, 2016 on May 2, 2016, again within two months of the examiner’s response on April 7, 2016 to their request to withdraw the finality of the Office action of January 15, 2016. 37 CFR 1.181(c) provides that “[w]hen a petition is taken from an action or requirement of an examiner . . . , it may be required that there have been a proper request for reconsideration (§ 1.111) and a repeated action by the examiner.” Thus, petitioners’ actions in first seeking reconsideration by the examiner of the finality of the Office action of January 15, 2016 before filing the petition under 37 CFR 1.181 to withdraw the finality of the Office action of January 15, 2016 on May 2, 2016 were reasonable in light of this requirement of 37 CFR 1.181(c). Accordingly, it was not an appropriate exercise of discretion to dismiss the petition under 37 CFR 1.181 of May 2, 2016 to withdraw the finality of the Office action of January 15, 2016 as untimely under 37 CFR 1.181(f).

With respect to the merits of the petition to withdraw the finality of the Office action of January 15, 2016, current second action final practice is set forth in the Manual of Patent Examining Procedure (MPEP) as follows:

Second or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant’s amendment of the claims, nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p). Where information is submitted in an information disclosure statement during the period set forth in 37 CFR

¹ Petitioners also argue that Leunissen was submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(b), and is thus not “information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p)” under MPEP § 706.07(a); however, the new grounds of rejection in the Office action of January 15, 2016 being based upon information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p) does not appear to be the basis for the finality of the Office action of January 15, 2016.

1.97(c) with a fee, the examiner may use the information submitted, e.g., a printed publication or evidence of public use, and make the next Office action final whether or not the claims have been amended, provided that no other new ground of rejection which was not necessitated by amendment to the claims is introduced by the examiner. *See* MPEP § 609.04(b). Furthermore, a second or any subsequent action on the merits in any application will not be made final if it includes a rejection, on newly cited art, other than information submitted in an information disclosure statement filed under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p), of any claim not amended by applicant or patent owner in spite of the fact that other claims may have been amended to require newly cited art. Where information is submitted in a reply to a requirement under 37 CFR 1.105, the examiner may NOT make the next Office action relying on that art final unless all instances of the application of such art are necessitated by amendment.

For guidance in determining what constitutes a new ground of rejection, see MPEP § 1207.03(a).

A second or any subsequent action on the merits in any application or patent involved in reexamination proceedings should not be made final if it includes a rejection, on prior art not of record, of any claim amended to include limitations which should reasonably have been expected to be claimed. *See* MPEP § 904*et seq.* However, note that an examiner cannot be expected to foresee whether or how an applicant will amend a claim to overcome a rejection except in very limited circumstances (e.g., where the examiner suggests how applicant can overcome a rejection under 35 U.S.C. 112(b) or pre-AIA 35 U.S.C. 112, second paragraph).

A second or any subsequent action on the merits in any application or patent involved in reexamination proceedings may not be made final if it contains a new ground of rejection necessitated by the amendments to pre-AIA 35 U.S.C. 102(e) by the Intellectual Property and High Technology Technical Amendments Act of 2002 (Public Law 107-273, 116 Stat. 1758 (2002)), unless the new ground of rejection was necessitated by an amendment to the claims or as a result of information submitted in an information disclosure statement under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p).

When applying any 35 U.S.C. 102(a)(2) or pre-AIA 35 U.S.C. 102(e)/103 references against the claims of an application the examiner should anticipate that a statement averring common ownership may qualify the applicant for the exemption under 35 U.S.C. 102(b)(2)(C) or a statement of common ownership at the time the invention was made may disqualify any patent or application applied in a rejection under 35 U.S.C. 103 based on 35 U.S.C. 102(e). If such a statement

is filed in reply to the 35 U.S.C. 102(a)(2) or pre-AIA 35 U.S.C. 102(e)/103 rejection and the claims are not amended, the examiner may not make the next Office action final if a new rejection is made. *See* MPEP §§ 706.02(1)(3) and 2154.02(c). If a reference is disqualified under the joint research agreement provision of 35 U.S.C. 102(c) or pre-AIA 35 U.S.C. 103(c) and a new subsequent double patenting rejection based upon the disqualified reference is applied, the next Office action, which contains the new double patenting rejection, may be made final even if applicant did not amend the claims (provided that the examiner introduces no other new ground of rejection that was not necessitated by either amendment or an information disclosure statement filed during the time period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p). The Office action is properly made final because the new double patenting rejection was necessitated by amendment of the application by applicant.

Where the only changes in a rejection are based on treating the application to be subject to current 35 U.S.C. 102 rather than the version of 35 U.S.C. 102 in effect on March 15, 2013, (the pre-AIA version) or the reverse, and any prior art relied upon in the subsequent action was prior art under both versions of 35 U.S.C. 102, then the action may be made final. For example, if a first action relied upon a reference as being available under pre-AIA 35 U.S.C. 102(e) and the subsequent action relied only on the same reference under 35 U.S.C. 102(a)(2), then the subsequent action may be made final assuming no new requirements or non-prior art rejections were made. *See* MPEP § 809.02(a) for actions which indicate generic claims as not allowable.

In the consideration of claims in an amended case where no attempt is made to point out the patentable novelty, the examiner should be on guard not to allow such claims. *See* MPEP § 714.04. The claims may be finally rejected if, in the opinion of the examiner, they are clearly open to rejection on grounds of record.

Form paragraph 7.40 should be used where an action is made final including new grounds of rejection necessitated by applicant's amendment.

See MPEP § 706.07(a).

Petitioners' argument that the new ground of rejection (*Studer et al.* and *Leunissen* in place of *Kumar et al.* and *Scheiwe et al.*) was not necessitated by amendment because this ground of rejection could have been applied in the non-final Office action of July 6, 2016 has no basis in MPEP § 706.07(a).² The question is not whether the grounds of rejection in a final Office action

² Petitioners' reading of the "not necessitated by amendment" provision of MPEP § 706.07(a) to encompass, or include, a rejection in a final Office action that could have been applied in the

could have been applied in the non-final Office action, but whether the amendment made in reply to the prior non-final Office action necessitated the change in grounds of rejection. *See Ex parte Morris*, 159 USPQ 127, 128 (Dir. USPTO 1968).

Claims 1 and 8 as in the above-identified application were amended to replace “sample” with “biosample” in reply to the non-final Office action of July 6, 2016. Prior to this amendment, neither claim 1 nor claim 8 included any limitation suggesting that the term “sample” was limited to a “biosample.” Thus, this amendment (replacing “sample” with “biosample”) necessitated the new ground of rejection (Studer *et al.* and Leunissen in place of Kumar *et al.* and Scheiwe *et al.*) with respect to claims 1 and 8 in the final Office action of January 15, 2016 as the Kumar *et al.* technique is (as argued by applicant) suitable for some samples (metal, ceramic, plastic), but not for water-containing samples or biosamples. Therefore, the amendment to claims 1 and 8 necessitated the new ground of rejection of claims 1, 8, and the claims depending upon claims 1 and 8, in the final Office action of January 15, 2016.

Claim 10 in the above-identified application was amended to add “water-containing” before “sample” in the body of the claim in reply to the non-final Office action of July 6, 2016. Prior to this amendment, claim 10 recited “in a water-containing sample” (preamble), and “the sample” (several instances in the body of the claim). While the examiner declined to give patentable weight to the preamble of claim 10 in the non-final Office action of July 6, 2016, the “water-containing sample” in the preamble of claim 10 is the only antecedent for the term “the sample” in the body of claim 10. Therefore, this amendment (adding “water-containing” before “sample” in the body of claim 10) did not necessitate the new ground of rejection (Studer *et al.* and Leunissen in place of Kumar *et al.* and Scheiwe *et al.*) with respect to claim 10 in the final Office action of January 15, 2016. In addition, MPEP § 706.07(a) further provides that a second or any subsequent action should not be made final if it includes a rejection, on prior art not of record, of any claim amended to include limitations which should reasonably have been expected to be claimed. While an examiner is not expected to foresee whether or how an applicant will amend a claim to overcome a rejection except in very limited circumstances, in this situation it is readily apparent that the claim 10 could have been expected to be amended to expressly indicate that “the sample” is, as stated in the preamble of claim 10 prior to this amendment, a “water-containing sample.”

While the new grounds of rejection of claims 1, 8, and the claims depending upon claims 1 and 8, in the Office action of January 15, 2016 were necessitated by the amendment to claims 1 and 8

non-final Office action is not reasonable. If a new ground of rejection in an Office action is considered “not necessitated by amendment” if that ground of rejection could have been applied in the previous Office action, MPEP § 706.07(a) would preclude any new prior art based ground of rejection in response to an amendment that narrowed a claim in any manner, as any prior art based ground of rejection of a “narrower” claim will always be applicable *a fortiori* to the “broader” claim.

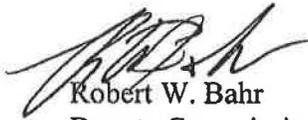
in the reply of October 6, 2015, the new grounds of rejection of claim 10, and the claims depending upon claim 10, in the Office action of January 15, 2016 were **not** necessitated by the amendment to claim 10 in the reply of October 6, 2015. Accordingly, MPEP § 706.07(a) does **not** authorize the finality of the Office action of January 15, 2016.

DECISION

For the reasons given above, the petition to withdraw the finality of the Office action of January 15, 2016 is **GRANTED**.

As the finality of the Office action of January 15, 2016 has been withdrawn, the reply of March 14, 2016 is a timely reply under 37 CFR 1.111 to the (now non-final) Office action of January 15, 2016. The notice of abandonment mailed on July 25, 2016 is hereby **vacated**.

The application is being forwarded to the Technology Center for treatment of the reply of March 14, 2016 as a reply under 37 CFR 1.111.



Robert W. Bahr
Deputy Commissioner for
Patent Examination Policy