This is a decision on the petition under 37 CFR 1.181 filed September 20, 2017, to invoke the supervisory authority of the Director to review the decision of September 5, 2017 of a Director of Technology Center 3600 (Technology Center Director), and to withdraw the finality of the Office action of April 20, 2017 and enter the amendment submitted with the reply of May 29, 2017.

The petition to withdraw the finality of the Office action of April 20, 2017, and to enter the amendment submitted with the reply of May 29, 2017, is **DENIED**.

**RELEVANT BACKGROUND**

The above-identified application was filed on January 14, 2014, and claims priority under 35 U.S.C. § 119 to provisional application No. 61/751,942, filed January 14, 2013.

A non-final Office action was issued on August 23, 2016. The Office action of August 23, 2016, included, *inter alia*, (1) a rejection of claims 1 through 3 and 10 through 15 under 35 U.S.C. § 101 as not being directed to patent eligible subject matter; (2) a rejection of claims 1, 10 through 13 under 35 U.S.C. § 112(b)¹ as being indefinite for failing to particularly point out and

¹ Section 4 of the Leahy-Smith America Invents Act (AIA) designated pre-AIA 35 U.S.C. § 112, ¶¶ 1 through 6, as 35 U.S.C. §§ 112(a) through (f), effective as to applications filed on or after September 16, 2012. *See* Pub. L. No. 112-29, § 4, 125 Stat. 284, 293-97 (2011). Section 3 of the AIA revised 35 U.S.C. §§ 102 and 103, effective as to applications ever having a claim with an
distinctly claim the subject matter regarded as the invention; (3) a rejection of claims 1 through 3 and 10 through 20 under 35 U.S.C. § 102(b) as being anticipated by Bengtsson et al. (U.S. Patent Application Publication No. 2010/0145262); (4) a rejection of claims 1 through 3 and 10 through 20 under 35 U.S.C. § 103(a) as being unpatentable over Bengtsson et al. in view of Steil et al. (U.S. Patent Application Publication No. 2008/0097289); and (5) an indication that claims 4 through 9 were withdrawn from consideration as being drawn to a non-elected invention (37 CFR 1.142(b)).


A final Office action was issued on April 20, 2017. The final Office action of April 20, 2017, included, inter alia, (1) a rejection of claims 1 through 15 under 35 U.S.C. § 101 as not being directed to patent eligible subject matter; (2) a rejection of claims 1, 4, and 7 through 13 under 35 U.S.C. § 112(b) as being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention; (3) a rejection of claims 1 through 20 under pre-AIA 35 U.S.C. § 102(b) as being unpatentable over Bengtsson et al.; and (4) a rejection of claims 1 through 20 under 35 U.S.C. § 103(a) as being unpatentable over Bengtsson et al. in view of Steil et al. The Office action of April 20, 2017, also stated, at page 15, that “[t]he Examiner would like to note that applicants filed several journal articles and NPL articles without a proper information disclosure statement and have not been considered. See MPEP section 609, 37 CFR 1.98, and 37 CFR 1.56.”

A reply under 37 CFR 1.116 (including a proposed amendment amending claims 1 through 3 and canceling claims 4 through 9) was filed on May 29, 2017. The reply of May 29, 2017, proposed effective filing date on or after March 16, 2013, or ever having a reference under 35 U.S.C. §§ 120, 121, or 365(c) to any patent or application that ever contained such a claim with an effective filing date on or after March 16, 2013. See Pub. L. No. 112-29, § 3, 125 Stat. at 285-293. The above-identified application was filed after September 16, 2012, but asserts priority to an effective filing date prior to March 16, 2013 for every claim ever contained in the above-identified application, and never contained a reference under 35 U.S.C. §§ 120, 121, or 365(c) to any other patent or application having a claim with an effective filing date on or after March 16, 2013. Therefore, this decision refers to the AIA version of 35 U.S.C. § 112, but the pre-AIA version of 35 U.S.C. §§ 102 and 103.
amendments to claims 1 through 3 and the cancelation of claims 4 through 9, and urged, *inter alia*, that—

The Final Action admits at p.15, lines 17-19 that the Examiner did not consider the references submitted with our Dec 23, 2016 Response, which are part of the evidentiary record in this application, submitted as evidence of patentability. This supporting evidence was required to be entered and considered with our Response. The Final Action is facially noncompliant with 35USC132(a). Accordingly, Applicants respectfully request and petition the Final Action be rescinded and supplanted with a 35USC132(a) compliant reexamination of this application, including due consideration of the evidentiary references submitted with our Dec 23, 2016 Response.

An advisory action was issued on June 8, 2017. The advisory action of June 8, 2017, refused entry of the after final reply of May 29, 2017, because the reply: (1) raised new issues that would require further consideration and/or search, and (2) was not deemed to have placed the application in better form for appeal by materially reducing or simplifying the issues on appeal.

A second reply under 37 CFR 1.116 was filed on June 8, 2017, and petitioners were advised that the reply of June 8, 2017 did not place the application in condition for allowance in an advisory action issued on June 23, 2017.

A petition under 37 CFR 1.181 to the Technology Center Director was filed on June 8, 2017, requesting that the finality of the Office action of April 20, 2017 be withdrawn and the amendment submitted with the reply of May 29, 2017 be entered. The petition of June 8, 2017 was denied by the Technology Center Director in a decision dated on September 5, 2017.

The instant petition was filed on September 20, 2017, again requesting that the finality of the Office action of April 20, 2017 be withdrawn and the amendment submitted with the reply of May 29, 2017 be entered. A notice of appeal to the Patent Trial and Appeal Board was also filed on September 20, 2017.

**STATUTE AND REGULATION**

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 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.
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 of 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 of the application, clearly stating the reasons in support thereof.

(c) Reply to a final rejection 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 1.116 provides that:

(a) An amendment after final action must comply with § 1.114 or this section.

(b) After a final rejection or other final action (§ 1.113) in an application or in an ex parte reexamination filed under § 1.510, or an action closing prosecution (§ 1.949) in an inter partes reexamination filed under § 1.913, but before or on the same date of filing an appeal (§ 41.31 or § 41.61 of this title):

(1) An amendment may be made canceling claims or complying with any requirement of form expressly set forth in a previous Office action;

(2) An amendment presenting rejected claims in better form for consideration on appeal may be admitted; or

(3) An amendment touching the merits of the application or patent under reexamination may be admitted upon a showing of good and sufficient reasons why the amendment is necessary and was not earlier presented.

(c) The admission of, or refusal to admit, any amendment after a final rejection, a final action, an action closing prosecution, or any related proceedings will not operate to relieve the application or reexamination proceeding from its condition as subject to appeal or to save the application from abandonment under § 1.135, or the reexamination prosecution from termination under § 1.550(d) or § 1.957(b) or limitation of further prosecution under § 1.957(c).

(d)(1) Notwithstanding the provisions of paragraph (b) of this section, no amendment other than canceling claims, where such cancellation does not affect the scope of any other pending claim in the proceeding, can be made in an inter partes reexamination proceeding after the right of appeal notice under § 1.953 except as provided in § 1.981 or as permitted by § 41.77(b)(1) of this title.

(2) Notwithstanding the provisions of paragraph (b) of this section, an amendment made after a final rejection or other final action (§ 1.113) in an ex
parte reexamination filed under § 1.510, or an action closing prosecution (§ 1.949) in an inter partes reexamination filed under § 1.913 may not cancel claims where such cancellation affects the scope of any other pending claim in the reexamination proceeding except as provided in § 1.981 or as permitted by § 41.77(b)(1) of this title.

(e) An affidavit or other evidence submitted after a final rejection or other final action (§ 1.113) in an application or in an ex parte reexamination filed under § 1.510, or an action closing prosecution (§ 1.949) in an inter partes reexamination filed under § 1.913 but before or on the same date of filing an appeal ((§ 41.31 or § 41.61 of this title), may be admitted upon a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented.

(f) Notwithstanding the provisions of paragraph (e) of this section, no affidavit or other evidence can be made in an inter partes reexamination proceeding after the right of appeal notice under § 1.953 except as provided in § 1.981 or as permitted by § 41.77(b)(1) of this title.

(g) After decision on appeal, amendments, affidavits and other evidence can only be made as provided in §§ 1.198 and 1.981, or to carry into effect a recommendation under § 41.50(c) of this title.

37 CFR 1.132 provides that:

When any claim of an application or a patent under reexamination is rejected or objected to, any evidence submitted to traverse the rejection or objection on a basis not otherwise provided for must be by way of an oath or declaration under this section.

**OPINION**

Petitioners argue that the final Office action of April 20, 2017 is facially noncompliant with 35 U.S.C. § 132(a) and thus necessarily non-final, and that the amendment submitted with the reply under 37 CFR 1.116 imposes no undue burden and narrows issues for appeal. Petitioners specifically contend that the final Office action of April 20, 2017 admits (at page 15, lines 17 through 19) that the examiner did not consider the references submitted with the reply of December 23, 2016, and that the failure to consider evidence of patentability submitted with the reply of December 23, 2016 renders the final Office action of April 20, 2017 non-compliant with 35 U.S.C. § 132(a). Petitioners request that the finality of the Office action of April 20, 2017 be withdrawn and that the amendment submitted with the reply of May 29, 2017 be entered.

The reply of December 23, 2016 (at page 2) states with respect to the rejection of claims 1, 10 through 13 under 35 U.S.C. § 112(b) as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention—

Model predictive control (MPC) is a term of art, and those skilled in the art understand that MPC is a process control that predicts the change in the
dependent variables of the modeled system that will be caused by changes in the independent variables. See, e.g. Qin et al., 2003; MPC Wikipedia entry; both attached). For example, in a chemical process, independent variables that can be adjusted by the controller are often either the setpoints of regulatory PID controllers (pressure, flow, temperature, etc.) or the final control element (valves, dampers, etc.). MPC controllers “strive” to maintain process conditions based on predictions. The “striving” is an inherent function of the control algorithm- it occurs whether the control is successful or not.

Those skilled in the art would understand an MPC controller that “strategically strives to maintain an 80-140 mg/dL glucose zone during the day, a 110-220 mg/dL zone at night, and a smooth transition of 2 hour duration in between” is modeling a dynamic system and making and using predictions to maintain the recited control parameters - that is the function/purpose/operation of the controller.

The reply of December 23, 2016 (at pages 2 through 3) states with respect to the rejection of claims 1 through 20 under 35 U.S.C. §§ 102 and 103—


An innovation over the time-invariant zone-MPC strategy [references 5,6,11, supra] is that the present invention is periodically time dependent w.r.t. the time of day. Specifically, during the night the blood-glucose target zone is raised, and the bound on the maximum insulin infusion rate is reduced, from the values employed during the day. The motivation for the former is to induce a rise of blood-glucose levels at night. The latter is enforced as a further safety mechanism and reduces the chance of controller induced hypoglycemia. Aspects of this invention were reported in the post-filing Gondhalekar et al., “Periodic-Zone Model Predictive Control for Diurnal Closed-Loop Operation of an Artificial Pancreas”, J Diabetes Science and Technology Volume 7, Issue 6, Nov 2013, attached. Specification, para 004.
With respect to petitioners’ arguments that the final Office action of September 5, 2017, does not comply with 35 U.S.C. § 132(a):

35 U.S.C. § 132(a) provides that “if a patent examiner finds that a patent application does not comply with the standards of patentability, the examiner will issue an office action with respect to the application, ‘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.’” Pfizer v. Lee, 811 F.3d 466, 469 (Fed. Cir. 2016). With respect to sufficiency of an Office action under 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 (Fed. Cir. 1990) (citations omitted).

A review of the final Office action of April 20, 2017 reveals that it contains sufficient information to place petitioners on notice of the bases for the rejection of claims 1 through 20 in the above-identified application. Specifically: (1) the explanation provided on pages 3 through 6 of the final Office action of April 20, 2017 contains sufficient information to place petitioners on notice of the basis for the rejection of claims 1 through 15 under 35 U.S.C. § 101 as not being directed to patent eligible subject matter to allow petitioners to recognize and respond to this rejection; (2) the explanation provided on pages 7 and 8 of the final Office action of April 20, 2017 contains sufficient information to place petitioners on notice of the basis for the rejection of claims 1, 4, and 7 through 13 under 35 U.S.C. § 112(b) as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention to allow petitioners to recognize and respond to this rejection; (3) the explanation provided on pages 10 and 11 of the final Office action of April 20, 2017 contains sufficient information to place petitioners on notice of the basis for the rejection of claims 1 through 20 under 35 U.S.C. § 102(b) or alternatively 35 U.S.C. § 103 as being unpatentable over Bengtsson et al. to allow petitioners to recognize and respond to this rejection; and (4) the explanation provided on pages 11 through 13 of the final Office action of April 20, 2017 contains sufficient information to place petitioners on notice of the basis for the rejection of claims 1 through 20 under 35 U.S.C. § 103 as being unpatentable over Bengtsson et al. and Steil et al. to allow petitioners to recognize and respond to this rejection. Accordingly, the Office action of April 20, 2017 satisfies the requirements of 35 U.S.C. § 132(a) in that it contain sufficient information as to place petitioners on notice of the bases for the rejection of their claims in the above-identified application.

The statement that an Office action that is noncompliant with 35 U.S.C. § 132(a) is necessarily non-final is a non-sequitur. Compliance of an Office action with 35 U.S.C. § 132(a) and finality of the Office action are distinct subjects: any Office action (final or non-final) may be noncompliant with 35 U.S.C. § 132(a). See Pfizer, 811 F.3d at 472-75 (determining whether a non-final restriction requirement complies with 35 U.S.C. § 132(a)). Finality of a second or
subsequent Office action is governed by MPEP § 706.07(a). Petitioners do not argue that the finality of the Office action of April 20, 2017 does not comply with MPEP § 706.07(a).

With respect to consideration of the documents submitted with the reply of December 23, 2016:

MPEP 609.05(c) provides, in part, that—

Occasionally, documents are submitted and relied on by an applicant when replying to an Office action. These documents may be relied on by an applicant, for example, to show that an element recited in the claim is operative or that a term used in the claim has a recognized meaning in the art. Documents may be in any form but are typically in the form of an affidavit, declaration, patent, or printed publication.

To the extent that a document is submitted as evidence directed to an issue of patentability raised in an Office action, and the evidence is timely presented, applicant need not satisfy the requirements of 37 CFR 1.97 and 37 CFR 1.98 in order to have the examiner consider the information contained in the document relied on by applicant. In other words, compliance with the information disclosure rules is not a threshold requirement to have information considered when submitted by applicant to support an argument being made in a reply to an Office action.

However, consideration by the examiner of the document submitted as evidence directed to an issue of patentability raised in the Office action is limited to the portion of the document relied upon as rebuttal evidence; the entirety of the document may not necessarily be considered by the examiner.

At the same time, the document supplied and relied on by applicant as evidence need not be processed as an item of information that was cited in an information disclosure statement. The record should reflect whether the evidence was considered, but listing on a form (e.g., PTO-892, or PTO/SB/08A and 08B) and appropriate marking of the form by the examiner is not required.

For example, if applicant submits and relies on three patents as evidence in reply to the first Office action and also lists those patents on a PTO/SB/08A and 08B along with two journal articles, but does not file a statement under 37 CFR 1.97(e) or the fee set forth in 37 CFR 1.17(p), it would be appropriate for the examiner to indicate that the teachings relied on by applicant in the three patents have been considered, but to line through the citation of all five documents on the PTO/SB/08A and 08B and to inform applicant that the information disclosure statement did not comply with 37 CFR 1.97(c).
The final Office action of April 20, 2017 states with respect to information submitted by petitioners in the reply of December 23, 2016 that—

The Examiner would like to note that applicants filed several journal articles and NPL articles without a proper information disclosure statement and have not been considered. See MPEP section 609, 37 CFR 1.98, and 37 CFR 1.56.

Petitioners are correct that compliance with the requirements of 37 CFR 1.97 and 37 CFR 1.98 is not a threshold requirement to have the articles they submitted in support of their arguments in the reply of December 23, 2016 considered vis-à-vis the patentability issues raised in the Office action of August 23, 2016 (and repeated in the final Office action of April 20, 2017). If an applicant, however, submits information in support of a patentability argument without complying with the requirements of 37 CFR 1.97 and 37 CFR 1.98, the examiner’s consideration of such information is limited to what is relied upon as rebuttal evidence, and such information is not treated as information that was contained in an information disclosure statement submitted in compliance requirements of 37 CFR 1.97 and 37 CFR 1.98. The sentence in the final Office action of April 20, 2017 simply informs petitioners that the articles submitted with the reply of December 23, 2016 are not being treated as submitted in an information disclosure statement in compliance with requirements of 37 CFR 1.97 and 37 CFR 1.98.

MPEP § 707.07(f) provides, in part, that:

In order to provide a complete application file history and to enhance the clarity of the prosecution history record, an examiner must provide clear explanations of all actions taken by the examiner during prosecution of an application.

Where the requirements are traversed, or suspension thereof requested, the examiner should make proper reference thereto in his or her action on the amendment.

As review of the final Office action of April 20, 2017 reveals that it does respond to petitioners’ arguments (petitioners’ arguments concerning the rejection of claims 1 through 15 under 35 U.S.C. § 101 as not being directed to patent eligible subject matter are addressed on pages 13 and 14 of the final Office action of April 20, 2017; petitioners’ arguments concerning the rejection of claims 1, 4, and 7 through 13 under 35 U.S.C. § 112(b) as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention are addressed on page 14 of the final Office action of April 20, 2017; and petitioners’ arguments concerning the rejection of claims 1 through 20 under 35 U.S.C. § 102(b) and/or 35 U.S.C. § 103 as being unpatentable over Bengtsson et al. and Steil et al. are also addressed on page 14 of the final Office action of April 20, 2017). The examiner specifically addressed petitioners’ interpretation of the MPC and MPC controller in the response to arguments section of the final Office action mailed April 20, 2017, on the bottom of page 14 and the top of page 15. In this section, the examiner explains the definition given to the term MPC controller and indicates the definition was derived from the specification. The examiner provides further detail in the advisory action dated June 8, 2017, by indicating that the references did not overcome the rejection and only taught prior art controllers. In other words, the examiner indicates that the evidence does not
provide a more specific definition than the specification that would warrant withdrawing the rejections given.

Thus, the final Office action mailed April 20, 2017, did consider the references to the extent that they were directed to an issue of patentability raised in the final Office action.

The final Office action of April 20, 2017 does not mention the articles by name, where it would have been preferable for the examiner to indicate that these articles have been considered for what they are relied upon in the reply of December 23, 2016. Nevertheless, it is clear from the record that the examiner has considered these articles to the extent required by MPEP § 609.05(c), but simply does not view the information in these articles to be germane to the reasons presented by the examiner for rejecting claims 1, 4, and 7 through 13 under 35 U.S.C. § 112(b) as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention, and rejecting claims 1 through 20 under 35 U.S.C. § 102(b) and/or 35 U.S.C. § 103 as being unpatentable over Bengtsson et al. and Steil et al. See advisory action of June 8, 2017 at page 3. The examiner was simply indicating in the final Office action of April 20, 2017 that the petitioners should file an Information Disclosure Statement that conformed with 37 CFR 1.98 if the petitioners would like the references to be considered in their entirety and not just for how they support petitioners’ rebuttal arguments.

Petitioners should note that differences in opinion between an applicant and the examiner concerning matters pertaining to the patentability of the invention are typical during the patent examination process and are not a proper basis for a petition under 37 CFR 1.181. See In re Jung, 637 F.3d 1356, 1363 (Fed. Cir. 2011) (applicant’s procedural arguments are the same arguments that would have been made on the merits). Petitioners are reminded that 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). 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.

2 37 CFR 1.132 and MPEP § 716 provide for the submission of evidence to traverse rejections or objections on a basis not otherwise provided for. The articles discussed in the reply of December 23, 2016 were not submitted under 37 CFR 1.132. While the articles discussed in the reply of December 23, 2016 are entitled to consideration, they do not have the status of an affidavit or declaration submitted under 37 CFR 1.132 for purposes of treatment under MPEP § 716.
With respect to petitioners’ arguments that the amendment filed April 20, 2017, presented no undue burden and reduces issues for appeal:

With respect to the amendment submitted with the reply of May 29, 2017:

MPEP §§ 714.12 and 714.13 provide, in part, that—

Once a final rejection that is not premature has been entered in an application, applicant or patent owner no longer has any right to unrestricted further prosecution. This does not mean that no further amendment or argument will be considered. Any amendment that will place the application either in condition for allowance or in better form for appeal may be entered. Also, amendments filed after a final rejection, but before or on the date of filing an appeal, complying with objections or requirements as to form are to be permitted after final action in accordance with 37 CFR 1.116(b). Amendments filed after the date of filing an appeal may be entered if the amendment complies with 37 CFR 41.33. See MPEP § 1206. Ordinarily, amendments filed after the final action are not entered unless approved by the examiner. See MPEP § 706.07(f), § 714.13 and § 1206.

An affidavit or other evidence filed after a final rejection, but before or on the same date of filing an appeal, may be entered upon a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented in compliance with 37 CFR 1.116(e). See 37 CFR 41.33 and MPEP § 1206 for information on affidavit or other evidence filed after appeal.

The prosecution of an application before the examiner should ordinarily be concluded with the final action. However, one personal interview by applicant may be entertained after such final action if circumstances warrant. Thus, only one request by applicant for a personal interview after final should be granted, but in exceptional circumstances, a second personal interview may be initiated by the examiner if in his or her judgment this would materially assist in placing the application in condition for allowance.

Many of the difficulties encountered in the prosecution of patent applications after final rejection may be alleviated if each applicant includes, at the time of filing or no later than the first reply, claims varying from the broadest to which he or she believes he or she is entitled to the most detailed that he or she is willing to accept.

* * * * *

It should be kept in mind that applicant cannot, as a matter of right, amend any finally rejected claims, add new claims after a final rejection (see 37 CFR 1.116) or reinstate previously canceled claims.
Except where an amendment merely cancels claims, adopts examiner suggestions, removes issues for appeal, or in some other way requires only a cursory review by the examiner, compliance with the requirement of a showing under 37 CFR 1.116(b)(3) is expected in all amendments after final rejection. An affidavit or other evidence filed after a final rejection, but before or on the same date of filing an appeal, may be entered upon a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented in compliance with 37 CFR 1.116(e). See 37 CFR 41.33 and MPEP § 1206 for information on affidavit or other evidence filed after appeal. Failure to properly reply under 37 CFR 1.113 to the final rejection results in abandonment. A reply under 37 CFR 1.113 is limited to:

- (A) an amendment complying with 37 CFR 1.116;
- (B) a Notice of Appeal (and appeal fee); or
- (C) a request for continued examination (RCE) filed under 37 CFR 1.114 with a submission (i.e., an amendment that meets the reply requirement of 37 CFR 1.111) and the fee set forth in 37 CFR 1.17(e). RCE practice under 37 CFR 1.114 does not apply to utility or plant patent applications filed before June 8, 1995 and design applications.

Further examination of the application may be obtained by filing a continued prosecution application (CPA) under 37 CFR 1.53(d), if the application is a design application. See MPEP § 201.06(d). Effective July 14, 2003, CPA practice does not apply to utility and plant applications.

An amendment filed at any time after final rejection, but before an appeal brief is filed, may be entered upon or after filing of an appeal brief provided the total effect of the amendment is to (A) remove issues for appeal, and/or (B) adopt examiner suggestions.

* * * * *

In the event that a proposed amendment does not place the case in better form for appeal, nor in condition for allowance, applicant should be promptly informed of this fact, whenever possible, within the statutory period. The refusal to enter the proposed amendment should not be arbitrary. The proposed amendment should be given sufficient consideration to determine whether the claims are in condition for allowance and/or whether the issues on appeal are simplified. Ordinarily, the specific deficiencies of the amendment need not be discussed. However, if the proposed amendment raises the issue of new matter, the examiner should identify the subject matter that would constitute new matter. If the proposed amendment presents new issues requiring further consideration and/or search, the examiner should provide an explanation as to the reasons why the proposed amendment raises new issues that would require further consideration and/or search. The reasons for nonentry should be concisely expressed. For example:
• (A) The claims, if amended as proposed, would not avoid any of the rejections set forth in the last Office action, and thus the amendment would not place the case in condition for allowance or in better condition for appeal.
• (B) The claims, if amended as proposed, would raise the issue of new matter.
• (C) The claims as amended present new issues requiring further consideration or search.
• (D) Since the amendment presents additional claims without canceling any finally rejected claims it is not considered as placing the application in better condition for appeal. *Ex parte Wirt*, 1905 C.D. 247, 117 OG 599 (Comm’r Pat. 1905).

The amendment under 37 CFR 1.116 of May 29, 2017 proposed to cancel claims 4 through 9 and add the limitation “wherein the controller is operably connected to an insulin pump in an artificial pancreas system or subsystem wherein the controller directs delivery of insulin by the pump” to each of independent claims 1, 2, and 3.

The amendment under 37 CFR 1.116 of May 29, 2017 was refused entry because: (1) it raises new issues that would require further consideration and/or search; and (2) it was not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal. *See* advisory action of June 8, 2017 at page 3. Specifically, the advisory action of June 8, 2017 indicates that:

The amendments to the claims change the scope of the dependent claims which create further consideration on the dependent claims, for example the scope of the method claims 10-20 are different due to the amendment of the independent claims made in the reply. Furthermore the amendments fail to simplify the issues for appeal as the claim amendments fail to further clarify the interpretation of the claims and help reduce the 112 issue.

*See id.*

The amendment under 37 CFR 1.116 of May 29, 2017 proposed to add the limitations from dependent claims 4, 5, and 6 (“wherein the controller is operably connected to an insulin pump in an artificial pancreas system or subsystem wherein the controller directs delivery of insulin by the pump”) to each of independent claims 1, 2, and 3, respectively.

Claims 10 and 13 depend directly upon claim 1, and claims 16 and 19 depend directly upon claims 10 and 13, respectively, claims 11 and 14 depend directly upon claim 2, and claims 17 and 20 depend directly upon claims 11 and 14, respectively and claims 12 and 15 depend directly upon claim 3, and claim 18 depends upon claim 12. Therefore, the examiner is correct that the amendment of claims 1, 2, and 3 to include the limitations of claims 4, 5, and 6 (which depend upon claims, 1, 2, and 3 respectively) would change the scope of claims 10 through 20, as claims 10 through 20 do not currently include the limitations of claims 4, 5, and 6. In addition, claims 10 through 15 are of a different statutory class of invention than claims 1 through 9; that is, claims 1 through 9 are directed to a device (a controller), where claims 10 through 20 are
directed to a process (a method comprising directing insulin delivery to a patient with type 1 diabetes). While there is no per se prohibition against a dependent claim being of a different statutory class than the claim upon which it depends (MPEP § 608.01(n) (“The fact that the independent and dependent claims are in different statutory classes does not, in itself, render the latter improper”)), use of this claim drafting approach will increase the complexity of the consideration of the impact that a change to a claim directed to a device will have on a claim to a dependent claim that a change to claim upon which it depends will have. Accordingly, petitioners have shown no error in the examiner’s position that: (1) the proposed amendment would raise new issues that would require further consideration; and (2) the proposed amendment would not place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

DECISION

For the reasons set forth above, the petition is granted to the extent that the Technology Center Director’s decision of September 5, 2017 has been reviewed; however, the petition is DENIED with respect to petitioners’ request to withdraw the finality of the final Office action mailed September 5, 2017 or to enter the amendment submitted with the reply of May 29, 2017.

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

The application is being referred to Technology Center 3600 for further processing.

Robert W. Bahr
Deputy Commissioner
for Patent Examination Policy