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In re Application of  
Luc Montagnier  
Application No. 13/731,481  
Filed: December 31, 2012  
For: HIGHLY SENSITIVE METHOD FOR  
DETECTION OF VIRAL HIV DNA  
REMAINING AFTER ANTIRETROVIRAL  
THERAPY OF AIDS PATIENTS

DECISION ON PETITION

This is a decision on the petition filed on April 10, 2017 under 37 CFR 1.181, requesting that the Director exercise her supervisory authority over the primary examiner, and *inter alia*, withdraw and strike the examiner's answer mailed on April 4, 2017 and reopen prosecution in the above-identified application.

The petition to withdraw or strike the examiner's answer of April 4, 2017 and to reopen prosecution in the above-identified application is **DENIED**.

**RELEVANT BACKGROUND**

The above-identified application was filed on December 31, 2012.

A non-final Office action was mailed on January 29, 2015. The Office action of January 29, 2015 included, *inter alia*: (1) a rejection of claims 1 through 10 under 35 U.S.C. § 112(b)<sup>1</sup> for

<sup>1</sup> Section 4 of the Leahy-Smith America Invents Act (AIA) designated 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, effective as to applications having any claim with an effective filing date on or after March 16, 2013. See Pub. L. No. 112-29, § 3, 125 Stat. at 285-293. Since the above-identified application was filed after September 16, 2012, but has only claims with an

failure to comply with its definiteness requirement; (2) a rejection of claims 1 through 10 under 35 U.S.C. § 101 for failure to comply with its utility requirement; and (3) a rejection of claims 1 through 10 under 35 U.S.C. § 112(a) for failure to comply with its enablement requirement. The Office action of January 29, 2015 held claims 11 through 18 and 21 through 23 withdrawn from consideration as drawn to a non-elected invention (37 CFR 1.142).

A reply under 37 CFR 1.111 (a reply to a non-final Office action) to the non-final Office action of January 29, 2015, including an amendment to the claims, was filed on April 29, 2015.

A final Office action was mailed on June 2, 2015. The Office action of June 2, 2015 included, *inter alia*: (1) a rejection of claims 1 through 10 under 35 U.S.C. § 112(b) for failure to comply with its definiteness requirement; (2) a rejection of claims 1 through 10 under 35 U.S.C. § 101 for failure to comply with its utility requirement; and (3) a rejection of claims 1 through 10 under 35 U.S.C. § 112(a) for failure to comply with its enablement requirement. The Office action of June 2, 2015 held claims 11 through 18 and 23 through 26 withdrawn from consideration as drawn to a non-elected invention (37 CFR 1.142).

A reply to the final Office action of June 2, 2015 was filed on September 2, 2015 including an amendment to the claims and a request for reconsideration. Petitioner was advised in an advisory action mailed on September 23, 2015 that: (1) the reply of September 2, 2015 is being treated as a reply under 37 CFR 1.116 (an after final reply); (2) the reply of September 2, 2015 did not place the above-identified application in condition for allowance; and (3) the amendment filed on September 2, 2015 would be entered for purposes of appeal.

A request for continued examination under 37 CFR 1.114, an amendment to the claims, and a declaration under 37 CFR 1.132 was filed on December 2, 2015.

A non-final Office action was mailed on March 14, 2016. The Office action of March 14, 2016 included: (1) a rejection of claims 1 through 11, 13 through 16 and 23 through 26 under 35 U.S.C. § 101 for failure to comply with its utility requirement; (2) a rejection of claims 1 through 11, 13 through 16 and 23 through 26 under 35 U.S.C. § 112(a) for failure to comply with its utility and enablement requirements; (3) a rejection of claims 1 through 11, 13, 16 and 24 through 26 under 35 U.S.C. § 102(b) as being anticipated by Montagnier (WO 2007/068831).

A reply to the non-final Office action of March 14, 2016 was filed on June 14, 2016, including an amendment to the claims.

A final Office action was mailed on June 22, 2016. The final Office action of June 22, 2016 included: (1) a rejection of claims 1 through 11, 13 through 16 and 23 through 26 under 35

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effective filing date prior to March 16, 2013, this decision refers to the AIA version of 35 U.S.C. § 112, but to the pre-AIA version of 35 U.S.C. § 102.

U.S.C. § 101 for failure to comply with its utility requirement; (2) a rejection of claims 1 through 11, 13 through 16 and 23 through 26 under 35 U.S.C. § 112(a) for failure to comply with its utility and enablement requirements; (3) a rejection of claims 1 through 11, 13, 16 and 24 through 26 under 35 U.S.C. § 102(b) as being anticipated by Montagnier (WO 2007/068831); (4) a rejection of claims 1 through 11, 13, 16 and 24 through 26 under 35 U.S.C. § 102(e) as being anticipated by Montagnier (U.S. Patent No. 8,736,250); (5) a rejection of claims 1 through 11, 13, 16 and 24 through 26 under 35 U.S.C. § 102(e) as being anticipated by Montagnier (U.S. Patent No. 9,029,165); (6) a rejection of claims 1 through 11, 13, 16 and 24 through 26 under 35 U.S.C. § 102(e) as being anticipated by Montagnier (U.S. Patent No. 9,316,610); (7) a rejection of claims 1 through 11, 13, 16 and 24 through 26 on the ground of judicially created obviousness-type double patenting as being unpatentable over claims 1 through 20 of U.S. Patent No. 8,736,250 to Montagnier; (8) a rejection of claims 1 through 11, 13, 16 and 24 through 26 on the ground of judicially created obviousness-type double patenting as being unpatentable over claims 1 through 19 of U.S. Patent No. 9,029,165 to Montagnier; and (9) a rejection of claims 1 through 11, 13, 16 and 24 through 26 on the ground of judicially created obviousness-type double patenting as being unpatentable over claims 1 through 20 of U.S. Patent No. 9,316,610 to Montagnier.

A reply to the final Office action of June 22, 2016 (a request for reconsideration) was filed on August 23, 2016. Petitioner was notified in an advisory action mailed on August 29, 2016 that the request for reconsideration filed on August 23, 2016 did not place the application in condition for allowance.

A second reply to the final Office action of June 22, 2016 (including a declaration) was filed on September 1, 2016. Petitioner was notified in an advisory action mailed on September 6, 2016 that the reply of September 1, 2016 did not place the application in condition for allowance and that the declaration filed on September 1, 2016 would not be entered.

A third reply to the final Office action of June 22, 2016 was filed on September 7, 2016. Petitioner was notified in an advisory action mailed on September 15, 2016 that the reply of September 7, 2016 did not place the application in condition for allowance.

A petition under 37 CFR 1.181 was filed on August 22, 2016, and the petition of August 22, 2016 was denied by the Technology Center Director in a decision mailed on September 16, 2016.

A renewed petition under 37 CFR 1.181 was filed on November 15, 2016, and the petition of November 15, 2016 was denied by the Technology Center Director in a decision mailed on November 23, 2016.

A notice of appeal and pre-appeal brief request for review were filed on November 22, 2016. A notice of panel decision from pre-appeal brief review stating that the application would proceed

to the Board of Patent Appeals and Interferences (now Patent Trial and Appeal Board (PTAB)) was mailed on December 14, 2016. An appeal brief was filed on January 23, 2017.

An examiner's answer was mailed on April 4, 2017. The examiner's answer of April 4, 2017 maintained the following rejections: (1) the rejection of claims 1 through 11, 13 through 16 and 23 through 26 under 35 U.S.C. § 101 for failure to comply with its utility requirement; and (2) the rejection of claims 1 through 11, 13 through 16 and 23 through 26 under 35 U.S.C. § 112(a) for failure to comply with its utility and enablement requirements.

The instant petition under 37 CFR 1.181 was filed on April 10, 2017, and requests that the Director exercise her supervisory authority over the primary examiner, and *inter alia*, withdraw and strike the examiner's answer mailed on April 4, 2017 and reopen prosecution in the above-identified application.

#### **STATUTE AND REGULATION**

35 U.S.C. § 132(a) provides that:

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.

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 1.181(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.

37 CFR 1.181(f) provides that:

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.

37 CFR 41.31 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 § 41.02(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.

(b) The signature requirements of §§ 1.33 and 11.18(a) of this title do not apply to a notice of appeal filed under this section.

(c) An appeal, when taken, is presumed to be taken from the rejection of all claims under rejection unless cancelled by an amendment filed by the applicant and entered by the Office. Questions relating to matters not affecting the merits of the invention may be required to be settled before an appeal can be considered.

(d) The time periods set forth in paragraphs (a)(1) through (a)(3) of this section are extendable under the provisions of § 1.136 of this title for patent applications and § 1.550(c) of this title for ex parte reexamination proceedings.

### OPINION

Petitioner asserts that the examiner's actions represent a failure to follow proper and enunciated United States Patent and Trademark Office (USPTO) procedures. Petitioner specifically argues that the examiner is misinterpreting the claims by failing to consider the claims as presented and by misquoting the claims thus altering the meaning of the claim language. Petitioner further argues that the examiner is relying upon his own beliefs, bias, and prejudices, and giving weight to selected portions of the evidence of record without a sound basis, and that the examiner has not provided a proper analysis of the claims with respect to the utility requirement of 35 U.S.C. § 101 and enablement requirement of 35 U.S.C. § 112(a) as outlined in section 2107.02(IV) of the Manual of Patent Examining Procedure (MPEP). Petitioner also argues that the actions taken in the above-identified application violate the Appointments Clause (U.S. CONST. art. II, § 2, cl. 2) and the First Amendment (U.S. CONST. amend. I). Petitioner requests a review of the prosecution history of the above-identified application for a determination of whether the administrative process was respected, whether the examiner acted in an arbitrary and capricious manner, and whether the position of the USPTO is properly being presented by the examiner. Petitioner requests that the Director employ her supervisory authority to withdraw and strike the examiner's answer and take other appropriate action.

The instant petition was filed on April 10, 2017, more than two (2) months after the final Office action of June 22, 2016, and more than two (2) months after the Technology Center Director decision of November 23, 2016. To the extent that petitioner is requesting administrative review under 37 CFR 1.181 of any of the Technology Center Director decision of November 23, 2016, Technology Center Director decision of September 16, 2016, Office action of June 22, 2016, Office action of March 14, 2016, Office action of June 2, 2015, or Office action of January 29, 2015, such request is **denied** as no longer timely. See 37 CFR 1.181(f) (petitions not filed within two months of the mailing date of the action or notice from which relief is requested may be dismissed as untimely).

Petitioner's contentions concerning the examiner's interpretation of claims and whether there is sufficient evidence to support the examiner's position concerning the patentability of the claims ultimately go to the merits of the rejections. Petitioner is 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).<sup>2</sup> 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). 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.

Differences in opinion between an applicant and the examiner as to the nature of the invention, scope of the claims, adequacy of the disclosure, scope and content of the prior art, or sufficiency and weight of the evidence are typical during the patent examination process. Petitioner is free to challenge the reliability, accuracy, and weight of the evidence by a reply under 37 CFR 1.111 or on appeal to the PTAB. *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). With respect to petitioner's arguments concerning the examiner's (alleged) failure to comply with the utility examination guidelines in MPEP § 2107.02 in formulating the rejections under 35 U.S.C. §§ 101 and 112(a), the USPTO's utility examination guidelines—

establish the policies and procedures to be followed by Office personnel in the evaluation of any patent application for compliance with the utility requirements of 35 U.S.C. 101 and 35 U.S.C. 112(a), or pre-AIA 35 U.S.C. 112, first paragraph.

These Guidelines have been promulgated to assist Office personnel in their review of applications for compliance with the utility requirement. The Guidelines do not alter the substantive requirements of 35 U.S.C. 101 and 35 U.S.C. 112, nor are they designed to obviate the examiner's review of applications for compliance with all other statutory requirements for patentability. The Guidelines do not constitute substantive rulemaking and hence do not have the force and effect of law. Rejections will be based upon the substantive law, and it is these rejections which are appealable. Consequently, any perceived failure by Office personnel to follow these Guidelines is neither appealable nor petitionable.

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<sup>2</sup> While petitioner asserts that an examiner's actions in rejecting claims 1 through 11, 13 through 16 and 23 through 26 is an abuse of discretion and arbitrary and capricious, characterizing a rejection as "an abuse of discretion" or as "arbitrary and capricious" (rather than as merely "in error") does not transform a rejection of the claims from an appealable matter to a petitionable matter.

See MPEP § 2107; *see also Utility Examination Guidelines*, 66 *Fed. Reg.* 1091, 1098 (Jan. 5, 2001) (Rejections will be based upon the substantive law, and it is these rejections which are appealable. Consequently, any perceived failure by Office personnel to follow these Guidelines is neither appealable nor petitionable.). Accordingly, a petition under 37 CFR 1.181 is not the appropriate forum for this disagreement between an applicant and the examiner.<sup>3</sup>

With respect to petitioner's First Amendment arguments, the USPTO is placing no restrictions on petitioner's expression or beliefs. While petitioner characterizes the circumstances of the above-identified application as one in which the application is being rejected due to petitioner's beliefs, a review of the above-identified application reveals that the examiner is rejecting claims 1 through 11, 13 through 16 and 23 through 26 due to the examiner's position that the subject matter of these claims do not comply with the utility requirement of 35 U.S.C. § 101 and the utility and enablement requirements of 35 U.S.C. § 112(a). That is, the examiner is not rejecting claims otherwise considered by the examiner to define patentable subject matter simply because the examiner disagrees with petitioner's views, beliefs, or opinions. Rather, petitioner and the examiner simply have opposing viewpoints (opinions or beliefs) concerning the patentability of claims 1 through 11, 13 through 16 and 23 through 26, which are nothing more than the typical disagreements between an applicant and the examiner that exist in an application that is subject to appeal. As noted by petitioner, the issue is not petitioner's or the examiner's views, beliefs, or opinions, but whether the examiner has established a *prima facie* case of unpatentability in rejecting claims 1 through 11, 13 through 16 and 23 through 26 for failure to comply with the utility requirement of 35 U.S.C. § 101 and the utility and enablement requirements of 35 U.S.C. § 112(a).<sup>4</sup> As discussed previously, whether the examiner has established a *prima facie* case of unpatentability in rejecting claims 1 through 11, 13 through 16 and 23 through 26 is reviewable 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. In any event, the conflicting viewpoints between petitioner and the examiner simply do not implicate the First Amendment.

Petitioner appears to argue that the examiner has shown sufficient bias to warrant directing the Technology Center Director to assign an application to a new examiner. An applicant seeking to invoke the Director's supervisory authority to direct the Technology Center Director to assign an application to a new examiner must demonstrate improper conduct amounting to bias (or the appearance of bias) against the applicant on the part of the examiner. *See In re Ovshinsky*, 24 USPQ2d 1241, 1251-52 (Comm'r Pats. 1992). A difference of opinion between the examiner

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<sup>3</sup> An applicant may, of course, raise the issue of an examiner's failure to follow the MPEP with the examiner's supervisor (or Technology Center Director).

<sup>4</sup> In addition, the examiner's expression of views, beliefs, or opinions in the Office actions in the above-identified application do not amount to the government establishing an official religion, favoring one religion over another, preferring religion over non-religion, or non-religion over religion.



and the applicant as to the patentability of one or more claims does not evidence bias, abuse, or any other improper conduct on the part of the examiner, much less that the examiner's replacement is justified. The decision to find a claim patentable or unpatentable is ultimately a judgment call over which reasonable people can disagree. *See Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969). The circumstances of the above-identified application do not indicate improper conduct amounting to bias or the appearance of bias on the part of the examiner so as to warrant directing the Technology Center Director to transfer the above-identified application to a new examiner.<sup>5</sup>

With respect to petitioner's arguments concerning the Appointments Clause and 35 U.S.C. § 3(b)(3), USPTO personnel who exercise the authority of a principal or inferior officer have been appointed by the Secretary of Commerce (or by the President with Senate confirmation in the case of the Director). Primary examiners do not exercise the authority of a principal or inferior officer. Specifically, primary examiners do not engage in USPTO policy making or in the exercise of significant discretion or authority, do not take testimony, conduct trials, or rule on the admissibility of evidence (other than timeliness), and do not have the power to enforce compliance with discovery orders. In addition, the adverse decisions of primary examiners are not final USPTO decisions (the Board's decisions are the final USPTO decisions), and a primary examiner's factual findings and legal conclusions are subject to *de novo* review by the Board. *See Jung*, 637 F.3d at 1365 (while an appellant must identify to the Board what the examiner did wrong, the Board reviews the examiner *de novo*).

### **DECISION**

For the previously stated reasons, the petition to withdraw or strike the examiner's answer of April 4, 2017 and to reopen prosecution in the above-identified application 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.

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<sup>5</sup> It is brought to petitioner's attention that the rejections in the above-identified application were considered in a Pre-Appeal Brief Review and that two supervisory patent examiners from Technology Center 1600 conferred in the examiner's answer of April 4, 2017 (at page 29), which suggest that the examiner's actions in the above-identified application are not so atypical as to warrant granting the extraordinary request to direct the Technology Center Director to assign an application to a new examiner.

Petitioner is reminded that the appeal forwarding fee (37 CFR 41.20(b)(4)) must be paid no later than June 5, 2017 (within **two (2) months** from the mailing date of the examiner's answer of April 4, 2017: June 4, 2017 being a Sunday) in order to avoid dismissal of the appeal. *See* 37 CFR 41.45. Extensions of time under 37 CFR 1.136(a) are not applicable to this time period. *See* 37 CFR 41.45(c).

Petitioner is also reminded that a reply brief may be filed no later than June 5, 2017 (within **two (2) months** from the mailing date of the examiner's answer of April 4, 2017: June 4, 2017 being a Sunday). *See* 37 CFR 41.41(a). Extensions of time under 37 CFR 1.136(a) are not applicable to this time period. *See* 37 CFR 41.41(c).

Telephone inquiries concerning this decision should be directed to Vanitha Elgart at 571.272.7395.

A handwritten signature in black ink, appearing to read 'R. W. Bahr', is positioned above the printed name.

Robert W. Bahr  
Deputy Commissioner for  
Patent Examination Policy