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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/888,180 07/09/2004 Kimberly K. Leslie 310.00010101 3987

26813 7590 07/07/2009
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EXAMINER

WHALEY, PABLO S

ART UNIT	PAPER NUMBER
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1631

MAIL DATE	DELIVERY MODE
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07/07/2009 PAPER

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

The time period for reply, if any, is set in the attached communication.

DETAILED ACTION

Request For Continued Examination

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/29/2009 has been entered.

Status of Claims

Claims 1-3, 5-9, 11, 13, 20-23, and 41-50 are pending.

Claims 1-3, 5-9, 11, 13, and 20-23 are rejected.

Claims 4, 10, 12, 14-19, 24-40 are cancelled.

Priority

The application has been granted the benefit of priority to US Provisional Application 60/559,932 filed 04/06/2004 and US Provisional Applications 60/486,528 filed 07/11/2003.

Information Disclosure Statement

The information disclosure statement filed 04/29/2009 has been considered in full.

Withdrawn Rejections

The rejection of claims 32 and 33 under 35 U.S.C. 103(a) as being made obvious by Petricoin et al. (The Lancet, Feb. 12, 2002, Vol. 359, p. 572-577, IDS filed 05/02/2007), in view of Byrjalsen et al.

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(WO 98/10291; International Publication Date: 12 March 1998; IDS filed 2/24/2006) is withdrawn in view of applicant's amendments filed 04/07/2009.

Claim rejections - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 3, 11, 20-23, 45, and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2 and 3 recite reference protein profiles representing at least one and a plurality of biomarker polypeptides. It is unclear whether these biomarker polypeptides must be from those listed in Tables 3-7, or if they can be any biomarker polypeptide. Clarification is requested.

Claim 11, 20-23, 45, and 47 depend from cancelled base claims and therefore are rejected for being incomplete [See MPEP 608.01(n), Section V]. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-3, 5-9, 11, 13, 22-23 are rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter. These claims are rejected for the following reasons.

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The claimed subject matter is directed to a method for detecting endometrial pathology in a patient. A claimed process is statutory under 35 U.S.C. 101 if: (1) it is tied to a particular machine or apparatus of statutory subject matter under 35 U.S.C. §101 (i.e. a machine, manufacture, or composition of matter), or (2) it transforms a particular article into a different state or thing (In re Bilski, 88 USPQ2d 1385 Fed. Cir. 2008; In re Comiskey, Fed. Cir., No. 2006-1286).

Regarding the required tie to a particular machine or apparatus, the process required by the instant claims is not limited to a particular apparatus or machine. In particular, the claimed subject matter recites steps for obtaining a patient's sample, detecting polypeptides in the test sample to yield a profile, and providing a result to a user in a user readable format without requiring any specific machines for performing these steps. As a result, these limitations read on insignificant data gathering or post-solution activity, which is not considered sufficient to convert a process into statutory subject matter. The applicants may overcome the rejection by amendment of the claims to perform critical steps of the claimed invention using a specific computer, device, or processor having structure. The applicants are cautioned against introduction of new matter in an amendment.

Regarding the transformation test, the claimed subject matter does not recite a physical transformation of matter. For example, the claimed subject matter recites steps for obtaining a patient sample and detecting polypeptides to yield test protein profiles. However, these limitations do not require any assays for performing these steps and therefore do not explicitly result in a transformation of an article. This rejection could be overcome by amendment of the claims to recite a step wherein an article is reduced to a different state or thing (e.g. physical assay), or a step wherein data representing a physical object or substance that is obtained by a specific physical process is sufficiently manipulated or changed (e.g.. raw data into a particular visual depiction of a physical object on a display) [See In re Abele, 684, F.2d at 908-909, CCPA, 1982]. The applicants are cautioned against introduction of new matter in an amendment.

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It is noted that claims 20, 21, 41, and 42 are not rejected under 35 U.S.C. §101 because these claims require an explicit tie to a particular machine or apparatus and therefore are statutory subject matter.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached at 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pablo S. Whaley

Patent Examiner

Art Unit 1631

| /PW/

/SHUBO (Joe) ZHOU/

Primary Examiner, Art Unit 1631