

REMARKS

With this Response, no claims are amended. Claims 4, 7-8, 11, 14-15, 18-19, 21 and 23-24 are withdrawn as directed to non-elected species. Although a final rejection has been issued, Applicant believes no search is required given that there are no claim amendments and no remaining rejections based on the prior art. Thus, Applicant respectfully requests entry of this Amendment and reconsideration of the claimed invention.

I. Information Disclosure Statement

Applicant thanks the Examiner for acknowledging the Supplemental IDS statement filed September 19, 2014. Applicant respectfully requests that the Examiner consider the Supplemental IDS statement herewith.

II. Examiner Interview

Applicant thanks the Examiner for attending the telephonic interview with Applicant's representative Ramin Akhavan on October 30, 2014. Applicant's representative confirmed an election of the species of claim 22.

III. Election

The Examiner has withdrawn claims 23-24 from further consideration as being drawn to a nonelected species, allegedly being no allowable generic or linking claim. Office Action, p. 2.

Upon the allowance of a generic claim, Applicant requests consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. As Applicant believes generic claim 1 is allowable with this Response, Applicant requests reconsideration of all withdrawn claims.

IV. Priority

Applicant appreciates the Examiner acknowledging respectfully that the pending claims have priority at least as early as October 14, 2008.

V. Claim Rejections under 35 U.S.C. § 101

The Examiner rejected claims 1-3, 5-6, 9-10, 12-13, 16-17, 20 and 22 under 35 U.S.C. § 101 alleging that “the claim(s) as a whole, considering all claim elements both individually and in combination, do not amount to significantly more than an abstract idea.” Office Action, p. 3. Applicant respectfully traverses the rejection. The alleged abstract idea identified by the Examiner comprises “a system comprising a database and instructions for inputting molecular profile data and using said data to identify a therapeutic agent with a likely benefit and to generate a report.” *Id.*

On December 16, 2014, the USPTO guidance issued updated guidelines for determining subject matter eligibility under 35 U.S.C. 101 in view of recent decisions by the U. S. Supreme Court (the “Guidance”). The Guidance directs the Examiner to use a two-part analysis to determine subject matter eligibility for claims involving abstract ideas: 1) determine whether the claim is directed to an abstract idea; and 2) if an abstract idea is present in the claim, determine whether the claim recites additional elements that amount to significantly more than the abstract idea itself. Guidance, pp. 9-10. The Guidance clarifies that it is “important to consider the claim as whole” because “[i]ndividual elements viewed on their own may not appear to add significantly more to the claim, but when combined may amount to significantly more than the exception.” *Id.* at p. 21. Claims that may recite a judicial exception but are directed to inventions that clearly do not seek to tie up the judicial exception may undergo a streamlined eligibility analysis. *Id.* at Section I.B.3.

a. Streamlined Eligibility Analysis Reveals that the Claims Recite Statutory Subject Matter

The Guidance explains that, “[f]or purposes of efficiency in examination, a streamlined eligibility analysis can be used for a claim that may or may not recite a judicial exception but, when viewed as a whole, clearly does not seek to tie up any judicial exception such that others cannot practice it.” Guidance, p. 24. In the instant matter, the Examiner states that “[t]he claim(s) is/are directed to the abstract idea of a system comprising a database and instructions for inputting molecular profile data and using said data to identify a therapeutic agent with a likely benefit and to generate a report.” Office Action, p. 3. Here, Applicant’s claimed invention should be afforded such streamlined eligibility analysis for at least the reason that the claims recite specific combinations of biomarkers that clearly do not tie up all manner of “a system comprising a database and instructions for inputting molecular profile data and using said data to identify a therapeutic agent with a likely benefit and to generate a report.” For example, such a system can be constructed with a subset of the instantly claimed markers and/or analysis

techniques, with completely different markers and/or analysis techniques, and/or for a different disease or cancer. Accordingly, Applicant respectfully requests that the Examiner reconsider the claims under the streamlined eligibility analysis and withdraw this rejection.

b. Full Eligibility Analysis also Reveals that the Claimed Invention Recites Statutory Subject Matter

The Guidance also provides “a number of considerations [identified by the Supreme Court] for determining whether a claim with additional elements amounts to significantly more than the judicial exception itself.” Guidance, p. 21. Analysis under these considerations also reveals that the instant invention recites patentable subject matter for at least the following reasons.

First, the claims recite numerous “[l]imitations that may be enough to qualify as ‘significantly more’ when recited in a claim with a judicial exception...” See Guidance, p. 21. For example, the claims provide “[i]mprovements to another technology or technical field.” Guidance, p. 21 (citation removed). Indeed, the claimed invention provides improvements in the fields of science and medicine. For example, the claimed invention provides improvements in the treatment of cancer victims, which is a wholly separate field from a system, database and instructions. In addition, the claims are applied “with, or by use of, a particular machine.” See *id.* (citation removed). With respect to this factor, the Guidance cites to the Supreme Court’s characterization of the machine-or-transformation test as “a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101.” Instant claim 1 recites a device configured to assay a plurality of molecular targets. Such a device is a *machine*, and the *machine* is one that *transforms* a biological sample from the individual. The transformation is both physical, *e.g.*, via chemical contact and/or reaction, and also computational by turning the sample into the molecular profile test values. Claims 20 and 22 (and withdrawn claims 18, 19, 21, 23 and 24) further recite specific analysis methods that require certain devices and perform sample transformation. Third, for similar reasons, the claims provide a device that effects “a transformation or reduction of a particular article to a different state or thing.” See *id.* at p. 22. In this case, the claims provide a device that *transforms* a biological sample, not only via reaction, but into molecular profile test values. Such molecular profile test values are a wholly different state or thing from the biological sample. Fourth, the claimed invention recites “a specific limitation other than what is well-understood, routine and conventional in the field” and adds “unconventional steps that confine the claim to a particular useful application.” Indeed, the Examiner withdrew the previous rejection under 35 U.S.C. § 103(a), acknowledging that “applicant’s arguments with regards to the references not suggesting that the RRM1

and PTEN are linked to the likely benefit of therapeutic agents in [uterine] cancer were found persuasive.” Office Action, p. 5. For this reason the claims necessarily recite “unconventional” elements that go beyond “what is well-understood, routine and conventional in the field.” Indeed, as the linkage of RRM1 and PTEN to the likely benefit of therapeutic agents in uterine cancer is non-obvious, it is also unconventional.

In addition to the above, the claims recite more than various “[l]imitations that were found not to be enough to qualify as “significantly more” when recited in a claim with a judicial exception...” See Guidance, p. 22. First, the claims recite more than “mere instructions to implement an abstract idea on a computer.” For example, the claims require a device configured to assay a plurality of molecular targets. Second, the claims recite more than “well-understood, routine and conventional activities previously known to the industry...” such as “a generic computer to perform generic computer functions that are well-understood, routine and conventional...” See *id.* at pp. 22-23. In addition to the assay device, the claims recite an unconventional panel of biomarkers for uterine cancer, as acknowledged by the Examiner in the Office Action at p. 5. See discussion above. Third, the claims recite more than “*mere* data gathering in conjunction with a law of nature or abstract idea.” See Guidance, p. 23 (emphasis supplied). In the Office Action, the Examiner alleged that the “device to assay a plurality of targets is directed towards a step [that] has been considered *merely* data gathering, i.e. determine molecular profile test values.” Office Action, p. 5 (emphasis supplied). As a threshold matter, any data gathering in claim 1 is not *merely* insignificant activity but is performed by transforming a biological sample into such values for a panel of specific and unconventional markers. Moreover, the remaining claim elements are not merely abstract, such as a specific and unconventional panel of markers. Fourth, the instant claims do more than “[g]enerally link[] the use of the judicial exception to a particular technological environment or field of use.” See Guidance, p. 23. Indeed, the claims are linked to the fields of science and medicine intrinsically and not as an afterthought.

Accordingly, the claimed invention: 1) provides improvements to another technology or technical field; 2) recites a machine that transforms a sample in accord with the machine-or-transformation test; 3) transforms one article into another; and 4) provides a non-conventional panel of targets for uterine cancer treatment options. Similarly, the claims recite more than: 1) general instructions to implement an abstract idea on a computer; 2) routine and conventional activities; 3) *mere* data gathering in conjunction with the alleged abstract idea; and 4) general linkage to a field of use. Taken together, analysis of these considerations reveals that the claimed invention amounts to significantly more than any alleged abstract

idea itself. As the claims comply with the Guidance, Applicant respectfully requests that the Examiner reconsider and withdraw this rejection.

VI. Claim Rejections under 35 U.S.C. § 103(a)

Applicant appreciates the Examiner for withdrawing the prior rejection under 35 U.S.C. § 103(a). Office Action, p. 5. Applicant notes the Examiner states that Applicant's arguments with respect to *prostate* cancer were found persuasive. *Id.* However, the instant claims are directed to *uterine* cancer. This Response assumes that the Examiner intended to state uterine cancer throughout the Office Action.

CONCLUSION

Applicant submits that this Response fully addresses the Final Office Action mailed November 12, 2014. Applicant believes that the pending claims are under condition for allowance. Applicant respectfully solicits the Examiner to expedite the prosecution of this patent application to issuance. Should the Examiner have any questions, the Examiner is encouraged to telephone the undersigned at (571) 261-9809.

FEE AUTHORIZATION

The Commissioner is authorized to charge any additional fees which may be required, including petition fees and extension of time fees, to Deposit Account No. **50-4961** (Docket No.: 37901-715.307).

Respectfully submitted,

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