UNITED STATES PATENT AND TRADEMARK OFFICE

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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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Ex parte CHARLES J. VASKE, STEPHEN C. BENZ,
JOSHUA M. STUART, and DAVID HAUSSLER

_____

Appeal 2017-006133
Application 13/317,769[1]
Technology Center 1600

_____

Before DONALD E. ADAMS, ULRIKE W. JENKS, and
TIMOTHY G. MAJORS, *Administrative Patent Judges*.

ADAMS, *Administrative Patent Judge*.

DECISION ON APPEAL

This Appeal[2] under 35 U.S.C. § 134(a) involves claims 14–20, 33,

and 34 (Final Act.[3] 2). Examiner entered rejections under 35 U.S.C. § 101,

35 U.S.C. § 112, second paragraph, 35 U.S.C. § 103(a), and obviousness-

type double patenting. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] Appellants identify the real party in interest as "The Regents of the
University of California" (App. Br. 1).
[2] This Appeal is related to co-pending Appeal 2017-006005, Application
13/068,002 (*see* App. Br. 1).
[3] Office Action mailed February 17, 2016.

STATEMENT OF THE CASE

Appellants' disclosure is in the field of "computational biology" and "relates to analysis of pathways and pathway[] elements to provide dynamic pathway maps" (Spec. ¶ 3). Claim 14 is representative and reproduced below:

> 14. A processor-based method of generating a dynamic pathway map (DPM),
>
> comprising:
>
> accessing a model database that stores a probabilistic pathway model that comprises a plurality of pathway elements;
>
> assigning an influence level for at least one pathway of a first number of the plurality of pathway elements on the basis of known attributes;
>
> cross correlating the first number of the plurality of pathway elements;
>
> assigning an influence level for at least one pathway on the basis of assumed attributes;
>
> measuring a patient sample to identify measured attributes of the patient sample, based on a genome-scale assay;
>
> modifying the probabilistic pathway model by using a plurality of the measured attributes for a plurality of elements of the patient sample, via an analysis engine, the modifying comprising:
>
> > obtaining a factor graph representing states of entities in a cell and interactions between the entities, wherein the factor graph encodes a state of the cell using a random variable for each entity and wherein the factor graph has reference pathway activity information for a particular pathway, the reference pathway indicating deviations from the probabilistic pathway model; and
> >
> > formulating a treatment option for the patient based on the reference pathway activity of the factor graph, wherein at

least one of the above method operations is performed through a processor.

(App. Br. 32–33.)

The claims stand rejected as follows:

Claims 14–20, 33, and 34 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 13/068,002.

Claims 14–20, 33, and 34 stand rejected under 35 U.S.C. § 112, second paragraph.

Claims 14–20, 33, and 34 stand rejected under 35 U.S.C. § 103(a) as unpatentable over Liebman.[4]

Claims 14–20, 33, and 34 stand rejected under 35 U.S.C. § 101.

Obviousness-type Double Patenting:

Appellants do not contest and, thereby, waived appeal of the provisional obviousness-type double patenting rejection on this record (*see generally* Ans. 16). Therefore, we summarily affirm the provisional rejection of claims 14–20, 33, and 34 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of copending Application No. 13/068,002.

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[4] Liebman, US 2004/0167763 A1, published Aug. 26, 2004.

Definiteness:

ISSUE

Does the preponderance of evidence support Examiner's conclusion
that Appellants' claim 14 is indefinite?

ANALYSIS

Genomic-scale assay:

The method of Appellants' claim 14 requires, *inter alia*, the
measurement of "a patient sample to identify measured attributes of the
patient sample, based on a genome-scale assay" (App. Br. 32).

As Appellants explain, "[s]o long as the genome-scale assay can be
used in measuring a patient sample to identify measured attributes of the
patient sample, the genome-scale assay is suitable for practicing the claimed
method" (App. Br. 23). Although Examiner finds that Appellants'
Specification fails to provide a definition of the phrase "genomic-scale
assay," Appellants' contend that the phrase is "a term of art and therefore
not indefinite. A PubMed search for the term 'genome-scale' would yield
adequate support for this assertion" (Reply Br. 8). We find that Appellants
have the better position.

> Claims may use language that those skilled in the art
> understand without the need for explicit, detailed definitions in
> the written description. *See, e.g., W. L. Gore & Assoc., Inc. v.
> Garlock, Inc.*, 721 F.2d 1540, 1556–58, 220 USPQ 303, 315–16
> (Fed. Cir. 1983) (claims not indefinite because the evidence
> showed that those skilled in the art understood their scope even
> though the written description failed to disclose precise
> definitions of certain terms of art).

Atmel Corp., v. Information Storage Devices, Inc., 198 F.3d 1374, 1385
(Fed. Cir. 1999).

Obtaining a factor graph:

The method of Appellants' claim 14 requires, *inter alia*,

modifying the probabilistic pathway model by using a plurality of the measured attributes for a plurality of elements of the patient sample, via an analysis engine, the modifying comprising:

obtaining a factor graph representing states of entities in a cell and interactions between the entities, wherein the factor graph encodes a state of the cell using a random variable for each entity and wherein the factor graph has reference pathway activity information for a particular pathway, the reference pathway indicating deviations from the probabilistic pathway model.

(App. Br. 32.)

Examiner finds the phrase "obtaining a factor graph," as recited in Appellants' claim 14, indefinite and further finds that Appellants' Specification fails to provide a limiting definition of this phrase "such that one of ordinary skill in the art would know how to avoid infringement, i.e., what specific types of data are related by this particular graphs" (Final Act. 7). We are not persuaded.

Appellants' Specification discloses that

[t]his application is a continuation-in-part of US Non-provisional Patent Application Serial No. 13/068,002, . . . filed 29 April, 2011, which is incorporated by reference herein, and which is related to and claims priority from US Provisional Patent Application Serial No. 61/343,575 . . . filed 29 April, 2010, which is herein incorporated by reference in its entirety.

(App. Br. 1; *see* Reply Br. 8.) Examiner did not question the incorporation by reference of Appellants' *parent* Application Serial No. 13/068,002, into the disclosure of this Application.

As Appellants explain, "[t]he dynamic pathway map" disclosed in their Specification "is a factor graph or type of factor graph" and "support for the factor graph is given in [their] parent specification" (App. Br. 24–25 (citing ¶ 44 of this Specification and ¶¶ 83, 85, 146–150, and 153–155 of the Specification in their parent Application); *see also* Reply Br. 9). Thus, Appellants' contend, "[t]he factor graph as recited in the claim is []supported in [their] parent specification" (App. Br. 25).

Therefore, we are not persuaded by Examiner's assertion that "the term 'factor graph" is [] indefinite" because paragraph 44 "of the instant specification does not even mention the term 'factor graph'" and Appellants made reference to "an unspecified parent application" (Ans. 12). To the contrary, we find that Examiner failed to establish that a person of ordinary skill in this art would not understand the bounds of Appellants' claimed invention when read in light of Appellants' specification, including the subject matter incorporated by reference. *See Miles Laboratories Inc. v. Shandon Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993) ("The test for definiteness is whether one skilled in the art would understand the bounds of the claim when read in light of the specification").

Formulating a treatment option for the patient based on the reference pathway activity of the factor graph:

The method of Appellants' claim 14 requires, *inter alia*, "formulating a treatment option for the patient based on the reference pathway activity of the factor graph, wherein at least one of the above method operations is performed through a processor" (App. Br. 33).

Examiner finds the phrase "formulating a treatment option for the patient based on the reference pathway activity of the factor graph," as

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recited in Appellants' claim 14, "indefinite for failing to point out the requisite computational techniques that are included or excluded by the claim language" and further finds that Appellants' Specification fails to provide a limiting definition of the phase "such that one of ordinary skill in the art would know how to avoid infringement" (Final Act. 8). In this regard, Examiner finds that Appellants' "claim defines what a factor graph DOES, i.e. functional limitations, but fails to define what elements define it" (Ans. 12). We are not persuaded.

As Appellants explain, "[e]xplicit mathematical or computational techniques are not statutorily required in claims" and Examiner failed to establish that a person of ordinary skill in this art would not understand the bounds of Appellants' claimed invention when read in light of Appellants' specification, including the subject matter incorporated by reference (*see* Reply Br. 9; *see also* App. Br. 25). *See also Miles Laboratories Inc.*, 997 F.2d at 875.

CONCLUSION

The preponderance of evidence fails to support Examiner's conclusion that Appellants' claim 14 is indefinite. The rejection of claims 14–20, 33, and 34 under 35 U.S.C. § 112, second paragraph, is reversed.

Obviousness:

ISSUE

Does the preponderance of evidence relied upon by Examiner support a conclusion of obviousness?

FACTUAL FINDINGS (FF)

FF 1.   Liebman discloses that "Petri nets and stochastic activity nets (SANs) have been used as generalized systems models, and have been applied to the modeling of biochemical pathways" (Liebman ¶ 4).

FF 2.   Liebman

> relates to a method of evaluating a biological model, including the steps of: (a) representing the biological model within a computing system, in the form of a hierarchy of Petri nets or stochastic activity nets, wherein the nodes of the net represent biological or biochemical components, and the arcs correspond to the flow of biochemical components in the model; (b) recording a set of measurements of some of the biochemical components described by the model, wherein these measurements, are made on samples from one or more humans or other living organisms, wherein the set of patients is divided into subsets representing patients with a disease, various diseases, and/or healthy patients; (c) entering and storing those observations as a data set in the digital computer system, which performs the subsequent steps as automated computations; (d) optionally selecting for subsequent analysis a subset of the data set, based on patient demographic information or history of prior treatment; (e) for subset of the data, calculating the change of some or all measured variables with respect to the corresponding value of that variable for healthy patients or diseased patients in a different subset, and augmenting the data set with that information; (f) for each input to a network node, labeling the input with the expected effect of an increase in token flow at the input on each output of the node, either "increasing" or "decreasing"; (g) comparing in a qualitative or quantitative sense the pattern of increases and decreases of

measured biochemical levels in various disease states versus the
pattern of increases and decreases in flow rates of tokens
through the corresponding nodes; (h) marking the biochemical
variables and measurements for which the expected effect is an
increase while the biochemical measurements show a decrease,
or vice versa, the marking consisting of an annotation that the
model does not adequately describe the behavior of those
biochemical components; and (i) for models which are
consistent in that they have no markings from step (h) above,
further marking nodes whose outputs are connected, directly or
indirectly, to inputs of a relatively large number of nodes
compared to the average connectivity of the network, the
marking consisting of an annotation that the node is a potential
key regulatory factor.

(Liebman ¶ 9; *see also id.* at 7: col. 1, l. 25 – col. 2, l. 47.)

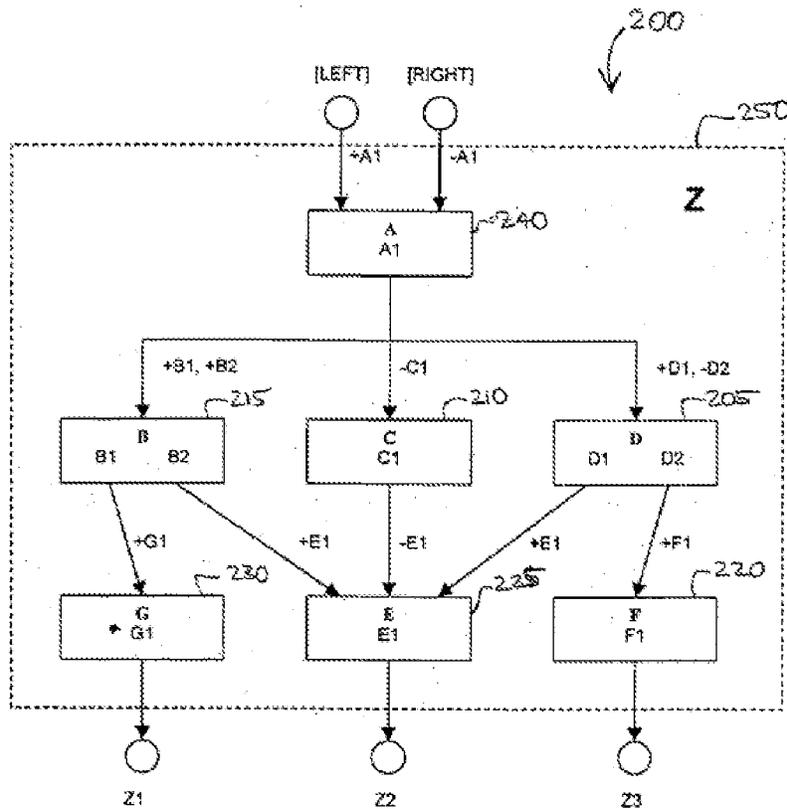FF 3. Liebman's Figure 3 is reproduced below:

Figure 3

Liebman's "FIG. 3 is [a] diagram illustrating the labeling of a model according to [Liebman's] . . . invention" (Liebman ¶ 15 (emphasis removed)).

> As shown in FIG. 3, a biological system 200 is described by a hierarchical set of Petri nets or Stochastic Activity Networks. At a given level of the hierarchy, each component is described as a labeled object with inputs and outputs. Each output is labeled with the place name and a number so that, for example, the two outputs of component D (205) are labeled D1 and D2. Inputs are labeled according to their effect on the outputs. For example, the label "+D1,-D2" indicates that an increase in token flow at this input will cause an increase in token flow at output D1, and a decrease in token flow at output D2.

(Liebman ¶ 39 (emphasis removed).)

FF 4. Liebman discloses that "[s]ome of the uses of [Liebman's] model evaluation techniques . . . include . . . [the] [a]bility to evaluate the change in protein expression levels as evidenced from proteomic or gene expression analysis of specific pathway components as to their impact on physiological response" (Lebman ¶¶ 46 and 51).

FF 5. Liebman discloses:

> The characteristics of the resulting model provide access to significant flexibility for further hypothesis evaluation. The incorporation of multiple SANs into one composed model allows the user to add and remove molecular species, reactions, pathways, etc. For example, to refine the model against the experimental data, it is easier to limit the analysis to only one or two SANs rather than the complete model to focus on a single reaction or group. In addition, parts of the system can be modeled or defined as appropriate. For example, the initiation SAN simplifies the representation of the actual process of coagulation initiation, i.e., the enzyme responsible for the activation of factor VII is not represented. The nature of the tool and the approach allows for the model to be developed with limited information and for inclusion of the missing

segments to the representation even after the crude model has
been initially refined. A system-wide refinement is a much
more limited process than the refinement of the initial model.

(Liebman ¶ 68.)

ANALYSIS

Examiner concludes that Liebman makes obvious Appellants' claimed
invention (*see* Final Act. 9–11; Ans. 14–16). Examiner's conclusion is
based, *inter alia*, on the following findings.

"Liebman teaches a method of evaluating a biochemical pathways
model[] using clinical data" (Ans. 15; *see* Final Act. 9). Examiner finds that
"Liebman teaches correlating nodes (i.e. pathway elements) with average
connectivity scores to identify specific sub-sets of nodes" (Ans. 15 (citing
Liebman's claims 3 and 4)). In this regard, Examiner reasons that because
Appellants' "[S]pecification neither defines nor sufficiently describes the
term 'pathway elements' to distinguish it from . . . Liebman, the above
teachings of Liebman meet [Appellants'] claim language for cross-
correlating the number of pathway elements, as [set forth in Appellants']
claim[s]" (Ans. 15).

Examiner finds that

> Liebman teaches labeling nodes with expected effects,
> assigning node scores, and assigning rate of change scores for
> variables associated with the data . . ., which broadly reads on
> assigning an influence level for at least one pathway (absent
> any limiting definition to the contrary), [because] the nodes
> defined the pathway, and correlating nodes with average
> connectivity scores to identify specific sub-sets of notes.

(Final Act. 9 (citing Liebman claims 1–4).) In this regard, Examiner finds
that Liebman's disclosure of

> calculating rates of change scores for expected pattern of
> increases and decreases in flow rates of tokens through the
> corresponding nodes . . . meets [Appellants'] claim language
> for assigning influence levels on the basis of known attributes,
> since the specification neither defines nor sufficiently describes
> the terms "influence level" or "attributes" to distinguish it from
> . . . Liebman.

(Ans. 15 (citing Liebman's claims 1 and 2).)

Examiner finds that "Liebman teaches recording (i.e. measuring) a set of measurements of biochemical components made on samples from one or more humans or other living organism patients" (Final Act. 9). Examiner recognizes, however, that "Liebman does not specifically teach modifying pathway models by obtaining a factor graph that encodes a state of the cell using variables and has reference pathway activity information that includes deviations from [a] probabilistic pathway model" (Final Act. 10). Nevertheless, Examiner finds that

> Liebman [] teaches representing (i.e. obtaining) models in the
> form of a hierarchy of Petri nets and stochastic activity nets . . .,
> wherein the nodes of the net represent biological or biochemical
> variables/components and the arcs correspond to the flow of
> biochemical components in the model, and wherein the data
> used to create the models is obtained from patients with a
> disease, various diseases, and/or healthy patients, i.e. it contains
> reference pathway information.

(Ans. 15–16 (citing Liebman's ¶ 39 and claim 5); *see also* Final Act. 10.) In this regard, Examiner reasons that

> absent any limiting definition for the term "factor graph" that
> would serve to distinguish from . . . Liebman, the examiner
> maintains that Liebman make[s] obvious the step of obtaining a
> factor graph, as [Appellants'] claimed, [because] [Appellants']

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> [S]pecification neither defines nor sufficiently describes the term "factor graph" to distinguish it from . . . Liebman.

(Ans. 16.)

We are not persuaded. As Appellants explain, Examiner's rationale does "not explicitly identify which element in Liebman allegedly corresponds with which element in [Appellants'] . . . claims and thus [] does not constitute a proper showing of all the limitations of the claims" (Reply Br. 9; *see also* App. Br. 27). We agree.

We recognize Examiner's assertion that "in view of the indefiniteness and lack of clarity in the instant claims, as set forth in the 35 USC 112 2nd rejections, [] Examiner had difficulty in properly interpreting the instant claims" (Ans. 14–16). We note, however, that analyzing claims based on "speculation as to meaning of the terms employed and assumptions as to the scope of such claims" is legal error. *In re Steele*, 305 F.2d 859, 862 (CCPA 1962).

Further, notwithstanding Examiner's assertion of indefinite claim language, we find no indefiniteness rejection on this record addressing the terms: "pathway elements," "influence level", or "attributes," which Examiner asserts are "neither define[d] nor sufficiently describe[d]" in Appellants' Specification (*see* Ans. 15; *cf. id.* at 12–14; Final Act. 7–8). In addition, although Examiner did find the term "factor graph" indefinite, as discussed above, Examiner failed to interpret this term in light of Appellants' disclosure (*see* Ans. 16; *cf. id.* at 12–13; Final Act. 7–8).

Nevertheless, we recognize Examiner's attempt to construe Appellants' claim terms broadly, but in doing so Examiner failed to clearly explain how Liebman teaches or suggests Appellants' claim limitations. As Appellants explain, however, "Examiner attempts to summarize portions of

cited Liebman paragraphs and claims, but does not specify which element in Liebman allegedly corresponds to which element in the present claims" (App. Br. 26; *see also* Reply Br. 9). We agree.

In this regard, we recognize that "[t]he inherent teaching of a prior art reference, a question of fact, arises both in the context of anticipation and obviousness." *In re Napier*, 55 F.3d 610, 613 (Fed. Cir. 1995). "To establish inherency, [however,] the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill.'" *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999) (citing *Continental Can Co. USA, Inc. v. Monsanto Co.*, 948 F.2d 1264, 1268 (Fed. Cir. 1991)). On this record, Examiner did not make such findings.

To the contrary, Examiner, at best, directed attention to various portions of Liebman and concluded that Liebman taught or suggested various elements of Appellants' claimed invention (*see* Final Act. 9–11; Ans. 14–16). "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).

> Absent some articulated rationale, a finding that a combination of prior art would have been "common sense" or "intuitive" is no different than merely stating the combination "would have been obvious." Such a conclusory assertion with no explanation is inadequate to support a finding that there would have been a motivation to combine.

In re Van Os, 844 F.3d 1359, 1361 (Fed. Cir. 2017).

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Therefore, we find that Examiner failed to establish an evidentiary basis on this record to support a conclusion of obviousness on this record (*see generally* App. Br. 26; Reply Br. 9).

CONCLUSION

The preponderance of evidence relied upon by Examiner fails to support a conclusion of obviousness. The rejection of claim 14–20, 33, and 34 under 35 U.S.C. § 103(a) as unpatentable over Liebman is reversed.

Subject Matter Eligibility:

ISSUE

Does the evidence of record support Examiner's finding that Appellants' claimed invention is directed to patent ineligible subject matter?

ANALYSIS

The scope of 35 U.S.C. § 101 "is subject to an implicit exception for 'laws of nature, natural phenomena, and abstract ideas,' which are not patentable." *Intellectual Ventures I LLC v. Capital One Financial Corp.*, 850 F.3d 1332, 1338 (Fed. Cir. 2017), citing *Alice Corp. Pty. Ltd. v. CLS Bank Int'l.*, 134 S. Ct. 2347, 2355 (2014); *see also Mayo Collaborative Services v. Prometheus Labs., Inc.*, 566 U.S. 66, 70 (2012) ("'[L]aws of nature, natural phenomena, and abstract ideas' are not patentable" (citation omitted, alteration original)).

Alice, sets forth the following two-step analysis for determining patent eligibility under Section 101:

> First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts [e.g., a law of nature, natural phenomenon, or abstract idea]. If so, we then ask, what else is there in the claims before us? . . . We have described

> step two of this analysis as a search for an inventive concept—
> i.e., an element or combination of elements that is sufficient to
> ensure that the patent in practice amounts to significantly more
> than a patent upon the ineligible concept itself.

Alice, 134 S. Ct. at 2355 (alterations, citations, and quotation marks omitted).

With respect to *Alice*'s first step, Examiner finds that, when considered as a whole, Appellants' claimed invention is "directed to gathering data (using routine and conventional techniques and/or instrumentations), and mathematically manipulating the data (using a general purpose computer) to generate additional data" (Final Act. 3; *see* Ans. 2–3). Thus, Examiner finds that Appellants' claimed invention is directed to an abstract idea, specifically "algorithmic concepts involving the mathematical manipulation of data" (Final Act. 3; *see* Ans. 3). Thus, Appellants' claimed invention comprises, at best, the steps of collecting, manipulating, and displaying data. "[A]n invention directed to collection, manipulation, and display of data [is] an abstract process." *Intellectual Ventures*, 850 F.3d at 1340; *see generally id.* at 1340–41.

> Without additional limitations, a process that employs
> mathematical algorithms to manipulate existing information to
> generate additional information is not patent eligible. "If a
> claim is directed essentially to a method of calculating, using a
> mathematical formula, even if the solution is for a specific
> purpose, the claimed method is nonstatutory." *Parker v. Flook*,
> 437 U.S. 584, 595[] (1978) (internal quotations omitted).

Digitech Image Techs., LLC v. Elecs. For Imaging, Inc., 758 F.3d 1344, 1351 (Fed. Cir. 2014). *See also FairWarning IP, LLC v. Iatric Systems, Inc.*, 839 F.3d 1089, 1093 (Fed. Cir. 2016) ("analyzing information by steps people go through in their minds, or by mathematical algorithms, without

more," are "essentially mental processes within the abstract-idea category).
We agree that Appellants' claimed invention involves an abstract idea.

Therefore, we turn to *Alice*'s second step, the "search for an inventive
concept—i.e., an element or combination of elements that is sufficient to
ensure that the patent in practice amounts to significantly more than a patent
upon the ineligible concept itself." *Alice*, 134 S. Ct. at 2355 (alterations,
citations, and quotation marks omitted). With respect to *Alice*'s second step,
Examiner finds that "the additional limitations recited in [Appellants']
claim(s) . . . do not amount to significantly more than the abstract idea"
(Final Act. 4; *see* Ans. 3–4). In this regard, Examiner finds that "[v]iewing
all the additional claim limitations individually, or as an ordered
combination, the claims(s) as a whole do (does) not add significantly more
to the abstract idea" (Final Act. 4; *see* Ans. 3–4 and 8). "Moreover,
[Examiner asserts,] all of the 'non-abstract' steps are recited at a high level
of generality and are considered routine and conventional data collection
steps, i.e. insignificant extra-solution activity" (Final Act. 5; *see* Ans. 3 and
9). We are not persuaded.

For the reasons set forth above with respect to the obviousness
rejection, Examiner failed to establish an evidentiary basis on this record to
support a finding that Appellants' claimed invention does not include "an
element or combination of elements that is sufficient to ensure that
[Appellants' claimed invention] in practice amounts to significantly more
than a patent upon the ineligible concept itself." *Alice*, 134 S. Ct. at 2355
(alterations, citations, and quotation marks omitted).

Therefore, we are compelled to reverse the rejection under 35 U.S.C.
§ 101 on this record.

CONCLUSION

The evidence of record supports Examiner's finding that Appellants' claimed invention is directed to patent ineligible subject matter. The rejection of claims 14–20, 33, and 34 under 35 U.S.C. § 101 is reversed.

TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

<u>AFFIRMED</u>