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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte BART JACOB BAKKER,
HENDRIK JAN VAN OOIJEN,
and RENE VAN DEN HAM

Appeal 2020-000940
Application 14/434,286
Technology Center 3600

Before JAMES P. CALVE, MICHELLE R. OSINSKI, and WILLIAM A. CAPP, *Administrative Patent Judges*.

CALVE, *Administrative Patent Judge*.

DECISION ON APPEAL

STATEMENT OF THE CASE

Pursuant to 35 U.S.C. § 134(a), Appellant[1] appeals from the decision of the Examiner to reject claims 1–4, 6–8, 10, 11, 13, 14, and 16–24, which are all pending claims.[2] Appeal Br. 6. We have jurisdiction under 35 U.S.C. § 6(b).

We AFFIRM.

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[1] "Appellant" refers to "applicant" as defined in 37 C.F.R. § 1.42. Appellant identifies Koninklijke Philips Electronics N. V. as the real party in interest. Appeal Br. 2.

[2] Claims 5, 9, 12, and 15 are cancelled. Appeal Br. 2.

CLAIMED SUBJECT MATTER

Claims 1, 16, and 18 are independent. Claim 1 is reproduced below.

> 1. An apparatus that determines whether an anticoagulant is to be administered to a patient based on an estimation value of thrombosis risk of the patient based on patient-specific input features, the apparatus comprising:
>
> a data interface that receives the input features;
>
> a processor that:
>
> calculates the estimation value by applying a decision support algorithm as a function of numerical values derived from the received input features;
>
> compares the estimation value to a threshold value;
>
> if the estimation value exceeds the threshold value, prescribe an anticoagulant to the patient;
>
> if the estimation value does not exceed the threshold value, do not prescribe the anticoagulant to the patient and
>
> a user interface that outputs the estimation value and, if the estimation value exceeds the threshold, outputs the prescription of an anticoagulant treatment to be administered to the patient;
>
> wherein the input features include a combination of at least one clinical risk factor and at least one protein concentration of the patient.

REJECTIONS

Claims 10, 11, 13, 14, 16, and 17 are rejected under 35 U.S.C. § 112(a) for lack of written description.

Claims 1–4, 6–8, 10, 11, 13, 14, and 16–24 are rejected as directed to a judicial exception to 35 U.S.C. § 101.

Claims 1, 2, 6, 8, 16–19, and 22–24 are rejected under 35 U.S.C. § 102 as anticipated by Mann (US 2009/0298103 A1, pub. Dec. 3, 2009).

ANALYSIS

Claims 10, 11, 13, 14, 16, and 17 for Lack of Written Description

The Examiner determines that adding "administer an anticoagulant treatment to the patient" in claim 16 introduces new matter. Final Act. 3. The Examiner finds the Specification recites "[s]pecifically, the proposed solution may be used to decide, per patient, whether or not to administer anticoagulant treatment based on estimated thrombosis risk." *Id.* (quoting Spec. 2, last two lines). The Examiner determines that this passage "teaches suggesting whether or not to administer the treatment, it's not describing or reciting how to administer the treatment." Ans. 3.

Appellant argues that this passage of the Specification supports this limitation because the description of "deciding whether or not to administer an anticoagulant treatment necessarily reflects to one of skill in the art that the applicants had possession of the ability to administer the treatment at the time the specification was filed." Appeal Br. 6; Reply Br. 2. Appellant also argues that administering an anticoagulant treatment is well-known in the art and need not be described further where the original disclosure disclosed whether or not to "administer anticoagulant treatment." Reply Br. 2.

As an initial step, we interpret this limitation. MPEP ¶ 2163 II.A.1. We interpret this limitation to mean to treat a patient with an anticoagulant. We do not interpret this limitation to mean "to provide the patient an oral medication" as the Examiner does. Final Act. 3. Claim 16 does not recite a method of administering an anticoagulant treatment to a patient. Instead, it recites a method of calculating an estimation value and using that value to determine *whether* to administer an anticoagulant treatment to a patient.

The Background of the Invention makes clear that it is known in the art to administer anticoagulant treatment for thrombosis. The problem is deciding whether to administer treatment. Spec. 1:11–24. The uncertainty causes unnecessary thromboses in high risk patients who do not receive treatment and bleeding in low risk patients who receive unnecessary anticoagulant treatment. *Id.* at 1:25–2:2. The invention object is increasing the accuracy of thrombosis risk estimation for patients. *See id.* at 2:14–15.

Claim 16 recites such a method of determining *whether* to administer anticoagulant treatment to a patient, not *how* to do so. If an estimation value for a patient exceeds a threshold value, claim 16 recites a step of "administer an anticoagulant treatment to the patient; otherwise, do not administer the anticoagulant to the patient." Appeal Br. 17 (Claims App.).

This method calculates a thrombosis estimation value of a patient to "help[] the physician to stratify the patients that are treated or examined for conditions that are known to increase thrombosis risk, into high and low risk categories." *Id.* at 2:28–30. "[T]he proposed solution may be used to decide, per patient, *whether or not to administer anticoagulant treatment* based on estimated thrombosis risk." *Id.* at 2:30–31 (emphasis added). The clinical decision support system processor 20 calculates a thrombosis risk score (R) based on input patient risk factors. If the score exceeds a threshold value (T), *anticoagulant therapy is indicated for the patient* whose risk values have been entered into the calculation. *Id.* at 6:24–26. "Otherwise, preventive anti-coagulation therapy is indicated as not advisable." *Id.* at 6:26. The clinical decision support system "can be accessed by a clinician who needs to *make a decision about patients' anticoagulation treatment*." *Id.* at 7:1–3 (emphasis added).

The Patent Laws require "[t]he specification shall contain a written description of the invention." 35 U.S.C. § 112(a). The written description must reasonably convey to a skilled artisan that the inventor had possession of the *claimed subject matter* as of the filing date. *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (citations omitted).

As our reviewing court has instructed us:

> [T]he level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology. *Id.* For generic claims, we have set forth a number of factors for evaluating the adequacy of the disclosure, including "the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue."

Ariad, 598 F.3d at 1351 (citation omitted). The Examiner has not explained why the written description is inadequate in terms of these factors and in fact agrees that the Specification supports a method to determine *whether* or not to administer anticoagulant treatment as recited in claim 16. *See* Ans. 3.

Appellant's Figure 4 illustrates user interface 30, which displays a patient's calculated risk score (RS) of 0.1 compared to a threshold level (T) of 0.5. The risk scale (RV) indicates that the patient's score of 0.1 qualifies as a low risk of thrombosis. Spec. 11:10–24. This visualization allows a clinician to quickly assess a patient's thrombosis risk and provides enhanced support for a treatment decision. *Id.* at 11:25–27. We determine that the Specification sufficiently describes the method step of "if the estimation value exceeds the threshold value, administer an anticoagulant treatment to the patient" as recited in claim 16 and its dependent claims 10, 11, 13, 14, and 17. Thus, we do not sustain this rejection.

Patent Eligibility under 35 U.S.C. § 101

Examiner's Determination

The Examiner finds that the claims recite making a determination by obtaining patient-specific input features, calculating an estimation value, and comparing the estimation value to a threshold. Final Act. 4. The Examiner determines that these steps recite a mental process that medical professionals can perform in their heads. *Id.*; Ans. 3–4. The Examiner also determines that the claims are directed to a mathematical concept of a decision support algorithm. Ans. 3–4.

The Examiner determines that the judicial exception is not integrated into a practical application because applying the decision support algorithm as a function of numerical values derived from input features is done on a generic computer and processor that do not add a meaningful limitation or provide an inventive concept. *See* Final Act. 4; Ans. 4. The Examiner also determines that the claims lack additional elements that are significantly more than the judicial exception, and administration of an anticoagulation treatment if an estimation value exceeds a threshold value is extra-solution activity. Final Act. 4; Ans. 4.

Appellant's Contentions

Appellant argues that calculating an estimation value of thrombosis risk by applying a decision support algorithm as a function of numerical values derived from patient-specific input features cannot be performed in a medical professional's head. Appeal Br. 7. Appellant argues Example 37 of the 2019 Revised Subject Matter Eligibility Guidance, 84 Fed. Reg. 50 (Jan. 7, 2019) recites a similar determining step that requires a processor and cannot be applied practically in the mind. *Id.*

Appellant argues that there is no known algorithm for determining a value of thrombotic risk based on a numerical value associated with at least one clinical risk factor and at least one protein concentration and therefore a medical professional reviewing clinical risk factors and protein blood test results as a mental process cannot convert clinical risk factors into numerical values that can be combined with numerical values of protein concentrations to calculate an estimation value of thrombotic risk as claimed. Appeal Br. 8; Reply Br. 3. Appellant further argues that the decision support algorithm is created using "machine learning" that uses "hidden models" that are "tuned" to provide a reliable prediction. Reply Br. 3.

Appellant asserts that even if the claims recite a mental process, the claims integrate the mental process into a practical application by improving the accuracy of identifying patients with high thrombotic risk for whom anticoagulant therapy should be administered. Appeal Br. 8–9. Appellant contends that this improvement to technology or a technical field constitutes a practical application of the abstract idea. *Id.* at 9.

Appellant asserts that the dependent claims impose further substantial limitations to the abstract idea of calculating and comparing numbers. *Id.* at 9–10. For example, Appellant contends that claims 3, 4, 13, 14, 20, and 21 "limit the calculating step to specific clinical risk factors." *Id.* at 10. Appellant argues that claims 7 and 10 "add an additional optimization that minimizes prediction error associated with the estimated thrombosis risk value." *Id.* Appellant argues that claim 11 "adds an additional training and optimizing step to train and validate the calculation of the thrombotic risk value." *Id.*

Principles of Law

Section 101 of the Patent Act states:

> 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.

35 U.S.C. § 101. This provision contains an implicit exception: "Laws of nature, natural phenomena, and abstract ideas are not patentable." *Alice Corp. Pty. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014).

To distinguish patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications, we first determine whether the claims are directed to a patent-ineligible concept. *Id.* at 217. If they are, we consider the elements of each claim, individually and "as an ordered combination," to determine if additional elements "'transform the nature of the claim' into a patent-eligible application" as an "inventive concept" sufficient to ensure the claims in practice amount to significantly more than a patent on the ineligible concept itself. *See id.* at 217–18.

The USPTO has issued guidance about this framework. 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 50 (Jan. 7, 2019) ("Revised Guidance"). Under the Revised Guidance, to determine whether a claim is "directed to" an abstract idea, we evaluate whether the claim recites (1) any judicial exceptions, including certain groupings of abstract ideas listed in the Revised Guidance (i.e., mathematical concepts, certain methods of organizing human activities such as a fundamental economic practice, or mental processes); and (2) additional elements that integrate the judicial exception into a practical application (*see* MPEP §§ 2106.05(a)–(c), (e)–(h) (9th ed. rev. 08.2017 Jan. 2018) ("MPEP")). *Id.* at 52–55.

Only if a claim (1) recites a judicial exception and also (2) does not integrate that exception into a practical application, do we then consider whether the claim (3) adds a specific limitation beyond the judicial exception that is not "well-understood, routine, conventional" in the field (*see* MPEP § 2106.05(d)) or (4) simply appends well-understood, routine, conventional activities previously known to the industry, specified at a high level of generality, to the judicial exception. *Id.* at 56.

Grouping of Claims

Because Appellant argues independent claims 1, 16, and 18 as a group (Appeal Br. 7–9), we select claim 1 as the representative claim of the group. *See* 37 C.F.R. § 41.37(c)(1)(iv).

Appellant's arguments summarizing dependent claim limitations and asserting, without any analysis, that these dependent claims impose further meaningful limits on the abstract idea (*see* Appeal Br. 9–10) do not present cognizable argument for the separate patentability of those claims. *See* 37 C.F.R. § 41.37(c)(1)(iv) ("A statement which merely points out what a claim recites will not be considered an argument for separate patentability of the claim."); *see also In re Lovin*, 652 F.3d 1349, 1357 (Fed. Cir. 2011) (holding that the Board reasonably interpreted 37 C.F.R. § 41.37(c)(1)(vii), which is the predecessor to § 41.37(c)(1)(iv), "to require more substantive arguments in an appeal brief than a mere recitation of the claim elements and a naked assertion that the corresponding elements were not found in the prior art").

Therefore, we address Appellant's patent-eligibility arguments in regards to independent claim 1. Claims 2–4, 6–8, 10, 11, 13, 14, and 16–24 stand or fall with claim 1.

Step 1: Is Claim 1 Within a Statutory Category?

Claim 1 recites an "apparatus" which is within a statutory category of 35 U.S.C. § 101, namely, a machine. Therefore, we next consider whether claim 1 considered as a whole recites a judicial exception.

Step 2A, Prong 1: Does Claim 1 Recite a Judicial Exception?

We determine claim 1 recites an abstract idea. The Revised Guidance enumerates this abstract idea as (1) mathematical concepts—mathematical calculations and (2) mental processes—concepts that can be performed in the human mind. *See* Revised Guidance, 84 Fed. Reg. at 52.

The invention calculates an estimation value of thrombosis risk based on patient-specific input features. Spec. 1:1–3. The calculation provides a "patient-specific measure to estimate the personal thrombosis risk and facilitate an informed choice on whether or not to treat." *See id.* at 1:15–17. The focus is to reduce uncertainty about patient specific risk of thrombosis that causes unnecessary thromboses in high risk patients who do not receive anticoagulant treatment and bleeding in relatively low risk patients who receive unnecessary anticoagulant treatment. *Id.* at 1:25–2:2.

The Specification describes this innovation as implemented on a computer-based "clinical decision support system (CDSS)," which is

> any software designed to directly aid in clinical decision making in which characteristics of individual patients are matched to a computerized knowledge base for the purpose of generating patient-specific assessments or recommendations that are then presented to clinicians for consideration and decision making.

Id. at 1:4–8. CDSSs are used to improve the quality of health care by supporting clinical decision making. *Id.* at 1:8–10.

The preamble recites this concept as embodied in an "apparatus that determines whether an anticoagulant is to be administered to a patient based on an estimation value of thrombosis risk of the patient based on patient-specific input features." Appeal Br. 15 (Claims App.).

The Specification describes this "apparatus" as a CDSS that involves a clinical decision support algorithm and/or software. Spec. 5:19–21, Fig. 1. Appellant's Figure 1, which we reproduce below, illustrates an exemplary CDSS configuration as a schematic block diagram.

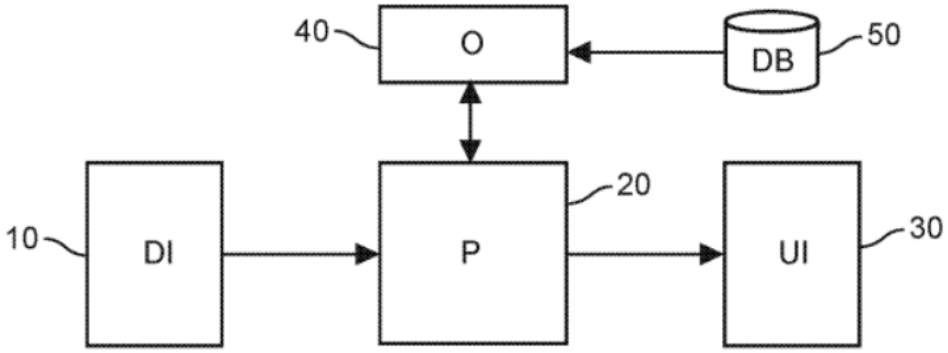

FIG. 1

Appellant's Figure 1 above illustrates a CDSS, which comprises data interface (DI) 10, processor (P) 20, user interface (UI) 30, optimization unit (O) 40, and database (DB) 50. *Id.* at 5:19–30.

The first limitation of claim 1 recites "a data interface that receives the input features." Appeal Br. 15 (Claims App.). The final limitation recites "wherein the input features include a combination of at least one clinical risk factor and at least one protein concentration of the patient." *Id.*

The Specification describes the *clinical risk factors* as immobilization within the last three months, surgery within the last month, family history of venous thrombosis, pregnancy, or puerperium within the last three months, current use of estrogens, and obesity. Spec. 6:1–13.

The Specification describes *protein concentrations* as concentration of the coagulation protein FVIII, FXI, and TFPI. *Id.* at 6:14–16.

Receiving or collecting data pertaining to the "input features" recites an abstract mental process or steps people can and have performed in their minds. *See* Revised Guidance, 84 Fed. Reg. at 52 n.14; *Content Extraction and Transmission LLC v. Wells Fargo Bank, N.A.*, 776 F.3d 1343, 1347 (Fed. Cir. 2014) (holding steps of collecting data, recognizing certain data in the collected data set, and storing the recognized data in a memory recited functions that humans always have performed); *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1067 (Fed. Cir. 2011) (holding the idea of collecting and comparing known information recited a mental step).

> The next limitations recite functions performed by "a processor" as
>
> calculates the estimation value by applying a decision support algorithm as a function of numerical values derived from the received input features;
> compares the estimation value to a threshold value;
> if the estimation value exceeds the threshold value, prescribe an anticoagulant to the patient;
> if the estimation value does not exceed the threshold value, do not prescribe the anticoagulant to the patient

Appeal Br. 15 (Claims App.).

We determine that calculating an estimation value (described as a risk score in the Specification) using a generic "decision support algorithm" as a function of numerical values derived from the input features recites an abstract mathematical calculation that can be performed as a mental process in the human mind or by using pen and paper to make the calculations. Similarly, comparing the estimation and threshold values also recites a mental process that can be performed in the human mind.

The Specification describes these functions as processor 20 calculates a numerical risk score based on numerical values derived from input features using a "clinical decision support algorithm." Spec. 6:19–22; *see* 5:19–27 (processor 20 applies an interpretative algorithm). If the risk score exceeds a threshold, anti-coagulation therapy is indicated for the patient whose values were input. *Id.* at 6:19–26. Otherwise, therapy is not indicated. *Id.* at 6:26.

The Specification provides no description of the algorithm or process by which a risk score ("estimation value") is calculated. Appeal Br. 4 (citing Spec. 6:19–25 as support for this claimed subject matter). The Specification describes the "input features" and their "numerical values" as follows:

> immobilization (plaster cast, extended bed rest at home for at least 4 days, hospitalization) within the last three months (e.g. "1" for true, "0" for false);
> surgery within the last month (e.g. "1" for true, "0" for false);
> family history of venous thrombosis (considered positive if at least one parent, brother, or sister experienced venous thrombosis (e.g. "l" for true, "0" for false));
> pregnancy or puerperium within the last three months (e.g. "1" for true, "0" for false);
> current use of estrogens (oral contraceptives or hormone replacement therapy (e.g. "1" for true, "0" for false));
> obesity (body mass index over 30 (e.g. "1" for true, "0" for false));
> concentration (U/mL) of the coagulation protein FVIII in blood;
> concentration (U/mL) of the coagulation protein FXI in blood; and
> concentration (ng/ml) of the coagulation protein TFPI in blood.

Spec. 6:4–16.

The risk score is a number between one and zero. One is the highest thrombosis risk. Zero is the lowest risk. *Id.* at 6:19–22. The risk score is compared to a threshold value between zero and one. The threshold may be fixed or adjustable to bias results. Low thresholds indicate higher risk and potential overtreatment. High thresholds do the opposite. *Id.* at 6:27–33.

These limitations recite mental processes that can be performed in the human mind by simply comparing a risk score to a threshold to determine if the risk score exceeds the threshold. *See Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1354 (Fed. Cir. 2016) ("[W]e have treated analyzing information by steps people go through in their minds, or by mathematical algorithms, without more, as essentially mental processes within the abstract-idea category."). The claim in *Electric Power* received input data measurements and analyzed the data based on "limits, sensitivities and rates of change for one or more measurements." *Id.* at 1351–52.

So too, in *Intellectual Ventures I LLC v. Capital One Bank (USA)*, 792 F.3d 1363, 1367 (Fed. Cir. 2015), a method of storing a user identity profile in a database and then "tracking financial transactions to determine whether they exceed a pre-set spending limit" was determined to involve an abstract idea. Here, comparing an estimation value to a threshold value to determine if the estimation value exceeds the threshold value recites a similar abstract idea as identified above.

Essentially, the processor replicates mental processes of doctors and clinicians. The Specification describes the computer-based clinical decision support system aiding clinical decisions by matching traits of patients to a computerized knowledge base to generate patient-specific assessments for clinicians to consider in decision-making. Spec. 1:4–10.

When recited at such an abstract, high level of generality as claim 1 does here, the claim recites an abstract idea as identified above. Similar claims to such computerization of human mental processes and functions have been held to be abstract ideas by our reviewing court.

In *University of Florida Research Foundation, Inc. v. General Elec. Co.*, 916 F.3d 1363 (Fed. Cir. 2019), the court held a method of receiving patient physiologic treatment data, converting the data to a specific format, performing at least one programmatic action on the data, and presenting the results in a graphical user interface recited an abstract idea because it merely replaced "pen and paper methodologies" with "data synthesis technology." *Id.* at 1367. The court held that:

> This is a quintessential "do it on a computer" patent: it acknowledges that data from bedside machines was previously collected, analyzed, manipulated, and displayed manually, and it simply proposes doing so with a computer. We have held such claims are directed to abstract ideas.

Id. Here, claim 1 similarly collects data about a patient as "input features" through a generic data interface, calculates an "estimation value" using a generic decision support algorithm and "numerical values derived from the received input features," and "compares the estimation value to a threshold value" to determine if the estimation value exceeds the threshold or not.

The Specification admits that clinical risk factors such as immobility and contraceptive use are known in the art and used to estimate and diagnose thrombosis risk. Spec. 2:2–6. Guidelines based on clinical risk factors have been used to estimate thrombosis risk. *Id.* at 2:6–8. Protein measurements such as a thrombin generation assay are used to estimate thrombotic risk. *Id.* at 2:8–10. Thus, the claimed "input features" are known data types.

The court in *In re Grams*, 888 F.2d 835 (Fed. Cir. 1989) held similar claims where the sole physical process step was performing clinical tests on individuals to obtain input data and the remaining steps essentially recited a mathematical algorithm for solving a given type of mathematical problem recited an abstract idea of a mathematical algorithm. *Id.* at 837, 840. Like claim 1 here, the claim in *Grams* recited a method of diagnosing abnormal conditions of an individual by performing clinical laboratory tests on the individual to obtain a set of parameter values and comparing the values to predetermined values to determine if the individual's condition is abnormal. *Id.* at 836. Here, claim 1 similarly receives data as "input features" through a generic data interface, calculates an "estimation value," and compares that value to a "threshold value" to decide whether to prescribe an anticoagulant.

In *In re Meyer*, 688 F.2d 789 (CCPA 1982), the court held that claims reciting a mathematical algorithm that represented the mental processes that neurologists follow in examining patients and comparing responses to what should be received recited an abstract idea. *Id.* at 793, 795–96. Replacing thinking processes of a neurologist with a computer was abstract. *Id.* at 795.

Similarly, in *SmartGene, Inc. v. Advanced Biological Labs., SA*, 555 F. App'x 950 (Fed. Cir. 2014), the court held a claim to using a computing device with basic functionality for comparing stored and input data and *rules* replicated the mental processes that doctors routinely perform. *Id.* at 954–55. Here, claim 1 compares an "estimation value" calculated by a generic decision support algorithm (a rule) from numerical values of "input features" to a threshold value. Doctors routinely compare patient data from tests and examinations to thresholds to diagnose medical conditions as *Grams* and *Meyer* indicate. *See Grams*, 888 F.2d at 836; *Meyer*, 688 F.2d at 793, 795.

As also indicated by these cases, mere recitation of an algorithm as part of the claimed process is not sufficient to render the claim non-abstract.

Here, the "decision support algorithm" is applied so the processor "calculates the estimation value" "as a function of numerical values derived from the received input features." Appeal Br. 15 (Claims App.).

The Specification describes this process generically as well. Indeed, it indicates that the clinical decision support system uses "a clinical decision support algorithm and/or software." Spec. 5:19–21. "[T]he processor 20 calculates a numerical function of the . . . numerical inputs by applying the clinical decision support algorithm." *Id.* at 6:19–21.

The Specification also describes an "interpretative clinical decision support algorithm," which may be a complex mathematical function that takes numerical (or Boolean) values for the nine input features (described above in this decision) as input and uses them in a series of non-linear calculations to return a numerical value between zero and one. *Id.* at 7:6–9. In addition, a "numerical function" can use a combination of "classifier functions that are common in the field of machine learning, such as neural network functions or support vector machines or Bayesian network." *Id.* at 7:9–12. Classifiers are optimized by optimization unit 40 and database 540 of subjects (thrombosis patients and health controls) whose numerical values for the nine input features are available. *Id.* at 7:12–14.

None of these features of the decision support algorithm are claimed. Claim 1 requires "at least one clinical risk factor" and "at least one protein concentration" without reciting any of the nine input features described in the Specification (*id.* at 6:4–16). Argument regarding an algorithm created by machine learning is not commensurate with claim 1. *See* Reply Br. 3.

"Absent claim language carrying a narrow meaning, the PTO should only limit the claim based on the specification or prosecution history when those sources expressly disclaim the broader definition." *In re Bigio*, 381 F.3d 1320, 1325 (Fed. Cir. 2004)); *see In re Hiniker*, 150 F.3d 1362, 1368 (Fed. Cir. 1998) ("Although operational characteristics of an apparatus may be apparent from the specification, we will not read such characteristics into the claims when they cannot be fairly connected to the structure recited in the claims."); *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994) ("Although an inventor is indeed free to define the specific terms used to describe his or her invention, this must be done with reasonable clarity, deliberateness, and precision."). Appellant asserts no definition or disclaimer for claim 1.

These claim construction tenets govern our patent-eligibility analysis. *See Ericsson Inc. v. TCL Commc'n Tech. Holdings Ltd.*, 955 F.3d 1317, 1325 (Fed. Cir. 2020) (holding that the specification must always yield to the claim language when identifying the true focus of a claim); *see also Two-Way Media Ltd. v. Comcast Cable Commc'ns, LLC*, 874 F.3d 1329, 1340 (Fed. Cir. 2017) ("As with claim 1 of the '187 patent, the problem is that no inventive concept resides in the claims.").

The claimed "user interface" "outputs the estimation value" resulting from these mental processes and mathematical calculation as extra-solution activity. *See Elec. Power*, 830 F.3d at 1354 ("And we have recognized that merely presenting the results of abstract processes of collecting and analyzing information, without more (such as identifying a particular tool for presentation), is abstract as an ancillary part of such collection and analysis."). The "user interface" is generic rather than one that organizes icons as in claim 2 of Example 37 of the 2019 Patent Eligibility Guidelines.

The Specification indicates that the calculated risk score (estimation value) is shown as a number or other graphical representation on a computer screen or user interface 30 in comparison to the threshold. Spec. 8:6–15. Appellant's Figure 4 is reproduced below to illustrate this user interface.

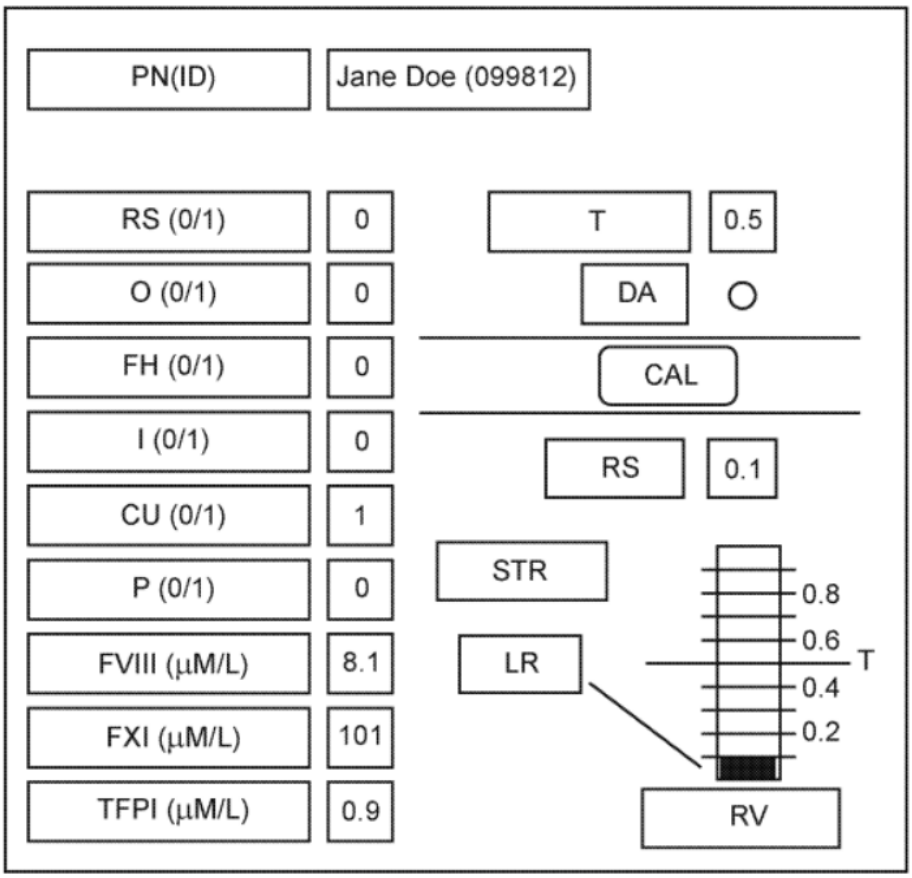

FIG. 4

Appellant's Figure 4 above illustrates user interface 30 of Figure 1 with nine "input features" including binary values ("0" or "1") for recent surgery (RS), obesity (O), family history (FH), immobility (I), contraceptive use (CU), and pregnancy (P), and protein concentrations. *Id.* at 11:10–18.

The patient's calculated risk score (RS) is 0.1, which is graphed with the Threshold (T) value of 0.5 on graphical visualization (RV) to indicate that the calculated risk score qualifies as a low risk (LR). *Id.* at 11:18–25.

We find no description of the user interface outputting a prescription. *See id.* at 6:19–33, 8:6–9:14. The Specification indicates the visualization illustrated in Figure 4 allows quick assessment by a clinician and provides enhanced support for a treatment decision. *Id.* at 11:25–27.

Figure 4 illustrates why the other limitations recite an abstract idea. A person can collect input features as binary values or protein concentrations as a mental process. Use of the decision support algorithm to calculate an estimation value recites a mathematical calculation and comparison of that value to a threshold value is a mental process that doctors may perform in their minds to diagnose medical conditions and thrombosis risk.

Such steps also are similar to claims that recited a mental process in *CyberSource Corporation* v. *Retail Decisions, Inc.*, 654 F.3d 1366 (Fed. Cir. 2011). There, the claims recited a method of detecting credit card fraud in online transactions. The first step obtained information about transactions that used an Internet address identified with a credit card transaction and "can be performed by a human who simply reads records of Internet credit card transactions from a preexisting database." *CyberSource*, 654 F.3d at 1372. The second step constructed a map of credit card numbers and can be performed by a person writing down a list of credit card transactions made from an IP address. *Id.* ("There is no language in claim 3 or in the '154 patent's specification that requires the constructed 'map' to consist of anything more than a list of a few credit card transactions."). The third step used the map of credit card numbers to determine if a credit card transaction was valid. It can be performed in the human mind by a person observing that numerous transactions used different credit cards with different user names and billing addresses originating at the same IP address. *Id.* at 1373.

Comparing the estimation and threshold values recites an abstract mental step. *See In re BRCA1- and BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755, 763 (Fed. Cir. 2014) (holding that claims to comparing two different nucleotide sequences recited an abstract mental step). The Revised Guidance provides the following guidance:

> If a claim, under its broadest reasonable interpretation, covers performance in the mind but for the recitation of generic computer components, then it is still in the mental processes category unless the claim cannot practically be performed in the mind.

Revised Guidance, 84 Fed. Reg. at 52 n.14; *see also Intellectual Ventures I LLC* v. *Symantec Corp.,* 838 F.3d 1307, 1318 (Fed. Cir. 2016) (''[W]ith the exception of generic computer implemented steps, there is nothing in the claims themselves that foreclose them from being performed by a human, mentally or with pen and paper.'').

Appellant's argument that claim 1 cannot recite a mental process because there is no known arithmetic algorithm for determining a value of thrombotic risk based on a numerical value associated with at least one clinical risk factor and at least one protein concentration is not persuasive. *See* Appeal Br. 8. First, the claimed "decision support algorithm" is recited at a high level of generality as being applied to calculate an estimation value from numerical values derived from received input features. As claimed, such a broad mathematical calculation is amenable to mental processing. Even if we could read limitations from the Specification into claim 1, there are no such details to be found regarding this algorithm and its operation.

Second, the calculation of the estimation value recites the abstract idea of mathematical calculations. Revised Guidance, 84 Fed. Reg. at 52.

As our reviewing court held in similar circumstances involving a claim to performing mathematical calculations and techniques on input data:

> The claims in this case are directed to abstract ideas. The focus of the claims, as reflected in what is quoted above, is on selecting certain information, analyzing it using mathematical techniques, and reporting or displaying the results of the a analysis. That is all abstract.

SAP Am., Inc. v. Investpic, LLC, 898 F.3d 1161, 1167 (Fed. Cir. 2018) (also holding that "analyzing information . . . by mathematical algorithms, without more" is an abstract idea as is merely presenting results of abstract processes as an ancillary part of the collection and analysis of information).

Even if claim 1 recited a new algorithm, the claim is still abstract. "The 'novelty' of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter." *Diamond v. Diehr*, 450 U.S. 175, 188–89 (1981); *see Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 88–90 (2012) (the patent eligibility of an abstract idea does not depend on its alleged novelty or non-obviousness); *SAP America*, 898 F.3d at 1163 ("No matter how much of an advance in the finance field the claims recite, the advance lies entirely in the realm of abstract ideas, with no plausibly alleged innovation in the non-abstract application realm. An advance of that nature is ineligible for patenting."); *Two-Way Media*, 874 F.3d at 1340 (Fed. Cir. 2017) (holding that "[e]ligibility and novelty are separate inquiries.").

Accordingly, we determine that claim 1 recites the abstract idea of mathematical concepts—mathematical calculations and mental processes—concepts performed in the human mind as identified above.

Step 2A, Prong Two: Integration into a Practical Application

We next consider whether claim 1 recites additional elements that integrate the abstract idea into a practical application. Revised Guidance, 84 Fed. Reg. at 54 (Revised Step 2A, Prong Two). We determine that claim 1 lacks any such additional elements because any additional elements recited in claim 1 do not improve a computer or other technology. They do not implement the abstract idea in conjunction with a particular machine or manufacture that is integral to the claim. They do not transform or reduce a particular article to a different state or thing. They do not apply the abstract idea in a meaningful way beyond linking it to a particular environment. *See* Revised Guidance, 84 Fed. Reg. at 55 and MPEP sections cited therein).

Appellant argues that the system improves the accuracy of identifying patients with high thrombotic risk to whom coagulation therapy should be administered and therefore is a practical application of the calculating and comparing of numbers. Appellant also argues that using numerical values of clinical risk factors in combination with numerical values of protein concentrations to calculate a thrombosis risk value imposes substantial limits on the calculating and comparing process. Appeal Br. 9.

This argument is not persuasive because "[i]nformation as such is an intangible" and collecting, analyzing, and displaying that information, without more, is an abstract idea. *See Interval Licensing LLC v. AOL, Inc.*, 896 F.3d 1335, 1344–45 (Fed. Cir. 2018) (quoting *Elec. Power Grp.*, 830 F.3d at 1353–54 and citing similar decisions holding that displaying different types or sets of information from various sources on a generic display is abstract absent a specific improvement to the way computers or other technologies operate).

In addition, "[i]t has been clear since *Alice* that a claimed invention's use of the ineligible concept to which it is directed cannot supply the inventive concept that renders the invention 'significantly more' than that ineligible concept." *BSG Tech LLC v. Buyseasons, Inc.*, 899 F.3d 1281, 1290 (Fed. Cir. 2018); *see id.* at 1291 ("As a matter of law, narrowing or reformulating an abstract idea does not add 'significantly more' to it."); *see also RecogniCorp, LLC v. Nintendo Co.*, 855 F.3d 1322, 1327 (Fed. Cir. 2017) ("Adding one abstract idea (math) to another abstract idea (encoding and decoding) does not render the claim non-abstract."); *Synopsys, Inc. v. Mentor Graphics Corp.*, 839 F.3d 1138, 1151 (Fed. Cir. 2016) ("But, a claim for a *new* abstract idea is still an abstract idea."); *Versata Dev. Grp., Inc. v. SAP Am., Inc.*, 793 F.3d 1306, 1335 (Fed. Cir. 2015) (holding claims that improved an abstract idea but did not recite the supposed computer improvements were not patent eligible).

Finally, there is no indication that the apparatus, as claimed, improves the accuracy of identifying thrombotic risk in patients. The Specification indicates the clinical decision support system provides increased accuracy because "[t]he smallest set of risk factors and protein concentrations that together have an optimal predictive value for thrombosis risk are selected and a numerical algorithm is created that translates the numerical values of the chosen factors and concentrations to a single numerical value specifying thrombotic risk." Spec. 2:14–23. The Specification identifies this set of risk factors as six (6) clinical factors and three (3) protein concentrations. *Id.* at 6:1–16. However, claim 1 calculates an estimation value based only on at least *one clinical risk factor* and at least *one protein concentration*. Thus, any improved accuracy from using particular risk factors is not claimed.

The Specification indicates an estimation value can be based on some of the input features but does not indicate which ones to use. *Id.* at 6:19–21. Figure 4 uses all nine. Even if claim 1 recited a particular input feature, they are data values that are measured in different ways. *See id.* at 13–16.

Furthermore, the accuracy of any thrombotic risk prediction depends not only on a calculation performed by a generically-claimed algorithm on a generically-claimed risk factor and protein concentration, but it also depends on the threshold value that is established. Claim 1 recites no parameters for that value. The Specification indicates that the threshold value can be set as a fixed value or tuned by the user at user interface 30 to balance sensitivity and specificity of the system. *Id.* at 6:27–29. Low threshold values set a bias toward indications of high risk (i.e., they are more likely to be exceeded by an estimated value), while high threshold values have the opposite effect and tend to under treatment. *Id.* at 6:29–32. "The specific choice of T is the responsibility of the user, e.g. clinician, and may be subject of a clinical study, but is not further discussed here." *Id.* at 6:32–33.

Therefore, we are not persuaded that merely inputting a clinical risk factor and a blood concentration factor and calculating an estimation value based on their "numerical values" necessarily improves the accuracy of the thrombotic risk estimation or any other technology, as recited in claim 1.

The Specification indicates machine learning may be used to exploit patterns hidden in numerical data values to predict an output. *See id.* at 8–9. Claim 1 does not recite machine learning, and generic machine learning used to optimize parameters (*see id.* at 7–10), by itself, does not integrate claim 1. *See id.* at 7–10; *OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359, 1362–63 (Fed. Cir. 2015) (holding generic price optimization is an abstract idea).

The "apparatus," "data interface," "processor," and "user interface" are recited as generic elements that perform generic functions. The data interface receives data "input features." The processor performs calculations and analyzes/compares numerical values. The user interface outputs results of the abstract calculations and comparisons performed by the processor.

Claim 1 recites the use of these components as tools that implement the abstract idea. This implementation is not sufficient to integrate the abstract idea into a practical application. *See Alice*, 573 U.S. at 223 ("[T]he mere recitation of a generic computer cannot transform a patent-ineligible abstract idea into a patent-eligible invention."); *Elec. Power*, 830 F.3d at 1354 (holding that the focus of the claims is on certain abstract ideas that use computers as tools); *Bancorp Svcs., L.L.C. v. Sun Life Assur. Co. of Canada (U.S.)*, 687 F.3d 1266, 1278 (Fed. Cir. 2012) ("[T]he use of a computer in an otherwise patent-ineligible process for no more than its most basic function––making calculations or computations—fails to circumvent the prohibition against patenting abstract ideas and mental processes."); *Accenture Glob. Servs., GmbH v. Guidewire Software, Inc.*, 728 F.3d 1336, 1345 (Fed. Cir. 2013) ("Accenture attempts to limit the abstract idea of claim 1 by applying it in a computer environment and within the insurance industry. However, those types of limitations do not 'narrow, confine, or otherwise tie down the claim.' As we . . . recently held, simply implementing an abstract concept on a computer, without meaningful limitations to that concept, does not transform a patent-ineligible claim into a patent-eligible one."). "[T]he complexity of the implementing software or the level of detail in the specification does not transform a claim reciting only an abstract concept into a patent-eligible [one]." *Accenture*, 728 F.3d at 1345.

> The Specification describes the apparatus as follows:
>
> [T]he apparatus may be implemented as a discrete hardware circuitry with discrete hardware components, as an integrated chip, as an arrangement of chip modules, or as a signal processing device or chip controlled by a software routine or program stored in a memory, written on a computer readable medium, or downloaded from a network, such as the Internet.

Spec. 4:17–21. The processor, data interface, and user interface also are described generically in the Specification in addition to being claimed as generic components. *Id.* at 5:19–6:33. Therefore, claim 1 does not link the abstract idea to a particular machine that is integral to the claim.

Nor does claim 1 effect a treatment of thrombosis as Appellant argues. Reply Br. 4–5. Claim 1 does not recite a method of treating thrombosis with anticoagulants. Outputting a generic prescription does not effect a treatment either. *See Classen*, 659 F.3d at 1068; *see also Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.*, 887 F.3d 1117, 1135 (Fed. Cir. 2018).

The mere data gathering and extra-solution activity recited in claim 1 does not integrate the abstract idea into a practical application. *See* Revised Guidance, 84 Fed. Reg. at 55 n.33; MPEP § 2106.05(g); *Elec. Power*, 830 F.3d at 1355 ("But merely selecting information, by content or source, for collection, analysis, and display does nothing significant to differentiate a process from ordinary mental processes.").

The decision in *Classen Immunotherapies* illustrates the distinction. Claim 1 of the '283 patent recited steps of collecting and comparing data for immunization results without applying the data for immunization purposes and thus recited an abstract mental step. *Classen*, 659 F.3d at 1067. Other patents recited a specific application of immunization steps in accordance with a lower-risk schedule that were held to be patent-eligible. *Id.* at 1068.

The claims of the '139 and '739 patent recited methods of lowering the risk of chronic immune-mediated disorder by including the physical step of immunization on a determined schedule. *Id.* at 1066. Therefore, these claims recited a physical implementation of the mental step recited in the '283 patent. *Id.* at 1067. Requiring the act of immunization with a lower-risk schedule moved the abstract idea to specific patent-eligible application. *Id.* at 1068. The exemplary claim of the '739 patent recited a method of immunizing a mammalian subject by immunizing the subject according to a subject immunization schedule that administered at least one infectious disease-causing organism associated immunogen of a lower risk schedule in accordance with the lower risk screened immunization schedule. *See id.* at 1060–61.

In contrast to these claims in *Classen*, claim 1 recites an apparatus that performs data collection and analysis using mathematical calculations and mental processes with an extra-solution step of outputting a prescription that is not described in the Specification. There is no method or step of treating thrombosis in claim 1 or administering an anticoagulant treatment according to a schedule. Claim 1 does not effect a particular treatment as Appellant contends. *See* Reply Br. 4. The Specification provides no description of any such anticoagulant treatment to be administered to a patient. Instead, the system determines *whether* to administer an anticoagulant treatment to a patient (*id.*) as an extra-solution activity of the mathematical calculations and mental processes recited in the claim without imposing a meaningful limitation on the claim.

Accordingly, we determine that claim 1 does not include additional elements that integrate the abstract idea into a practical application.

Step 2B: Does Claim 1 Include an Inventive Concept?

We next consider whether claim 1 recites elements, individually, or as an ordered combination, that provide an inventive concept. *Alice*, 573 U.S. at 217–18. The second step of the *Alice* test is satisfied when the claim limitations involve more than performance of well-understood, routine, and conventional activities previously known to the industry. *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1367 (Fed. Cir. 2018); *see* Revised Guidance, 84 Fed. Reg. at 56 (explaining that the second step of the *Alice* analysis considers whether a claim adds a specific limitation beyond a judicial exception that is not "well-understood, routine, conventional" activity in the field).

Individually, the limitations of claim 1 recite aspects of the abstract idea or insignificant extra-solution activity identified above. As an ordered combination, the limitations add nothing that is not the sum of the individual parts. Even if the steps are groundbreaking, innovative, or brilliant, that is not enough for eligibility. *See Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 591 (2013); *accord SAP Am., Inc. v. InvestPic, LLC*, 898 F.3d 1161, 1163 ("No matter how much of an advance in the finance field the claims recite, the advance lies entirely in the realm of abstract ideas, with no plausibly alleged innovation in the non-abstract application realm. An advance of that nature is ineligible for patenting.").

Accordingly, we determine that claim 1 does not recite any elements, individually or as an ordered combination, that provide an inventive concept sufficient to transform the abstract idea into patent eligible subject matter. Thus, we sustain the rejection of claim 1 and claims 2–20, which fall with claim 1 as directed to a judicial exception under 35 U.S.C. § 101.

Claims Anticipated by Mann

The Examiner relies on Mann to disclose an apparatus, method, and non-transitory computer readable medium in independent claims 1, 16, and 18 to include obtaining input features of at least one clinical risk factor and at least one protein concentration of the patient and calculating an estimation value by applying a decision support algorithm as a function of numerical values derived from the input features. Final Act. 5–7. The Examiner cites paragraph 32, 34, 37, and 112 as disclosing the claimed "input features" of a protein concentration *and* at least one clinical risk factor. *Id.*

Appellant argues that Mann discloses that hemostatic risk is related to the level of thrombin in a patient's blood and thus determines the amount of thrombin based on concentrations of three blood factors in samples taken from a patient without considering clinical risk factors. Appeal Br. 10–13; Reply Br. 5–7. Appellant also argues that Mann does not consider clinical risk factors "because Mann believes that the levels of protein in a patient sufficiently captures the patient's clinical history." Appeal Br. 11 (citing Mann ¶ 30). Appellant contends that paragraph 34 of Mann uses the concentrations of three blood factors in a biologic sample taken from the subject to determine hemostatic risk in the patient. *Id.*

In response, the Examiner points out that Mann also describes risk factors such as acute coronary syndrome event and in vitro fertilization for thromboembolic complications. Ans. 5 (citing Mann ¶¶ 32, 37, 270–72). Appellant responds that Mann does not estimate thrombosis risk based on a combination of such clinical risk factors and protein concentrations. Reply Br. 5–7. Appellant argues that Mann determines thrombosis risk based only on blood protein factors for coagulation measured in blood samples. *Id.*

The calculation of an estimation value of thrombosis risk is based on numerical values derived from input features that "include a *combination* of at least one clinical risk factor *and* at least one protein concentration." Appeal Br. 15–18 (Claims App.) (emphasis added).

Mann's description of acute coronary syndrome event and in vitro fertilization risk factors corresponds to the claimed "clinical risk factors" that are used as input features to calculate an estimation value of thrombosis risk. The Specification describes the clinical risk factors as including patient immobilization in the last three months, surgery in the last month, family history of venous thrombosis, pregnancy, use of estrogens, and obesity. *See* Spec. 6:1–13. However, Mann's teachings cited by the Examiner do not use these or any other clinical risk factors to estimate a patient's thrombosis risk.

Paragraphs 32, 34, 37, and 112, which are cited to disclose the input features (*see* Final Act. 5–6), do not use clinical risk factors to calculate a thrombosis risk as required by the claims. Paragraph 32 describes a method of assessing hemostatic risk by simulating, in silico, thrombin concentration based on biological input of a sample taken from a subject. Paragraph 34 describes determining concentrations of three blood factors in a biological sample taken from the subject. Paragraph 37 describes generating as output a thrombin concentration that is taken to be indicative of blood coagulation. Paragraph 112 describes inputting patient-specific concentrations of pro- and anti-coagulants. We find no disclosure of the use of clinical risk factors such as acute coronary syndrome event or in vitro fertilization to estimate a thrombosis risk in combination with the blood concentration factors. Mann estimates thrombosis risk based on blood protein concentrations without considering clinical risk factors. Thus, we do not sustain this rejection.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/ Basis	Affirmed	Reversed
10, 11, 13, 14, 16, 17	112(a)	Written Description		10, 11, 13, 14, 16, 17
1–4, 6–8, 10, 11, 13, 14, 16–24	101	Eligibility	1–4, 6–8, 10, 11, 13, 14, 16–24	
1, 2, 6, 8, 16–19, 22–24	102	Mann		1, 2, 6, 8, 16–19, 22–24
Overall Outcome			1–4, 6–8, 10, 11, 13, 14, 16–24	

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a). *See* 37 C.F.R. § 1.136(a)(1)(iv).

AFFIRMED