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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte SIMON AIGNER, GABRIELE CHEMNITIUS, CARINA HORN, BERND LIMBURG, TIMO OTTENSTEIN, WOLFGANG PETRICH, MARKUS PLUM, CHRISTIAN RINGEMANN, and MARKUS SERR

Appeal 2018-001078
Application 14/744,971
Technology Center 1700

Before MICHAEL P. COLAIANNI, AVELYN N. ROSS, and MICHAEL G. McMANUS, *Administrative Patent Judges*.

McMANUS, *Administrative Patent Judge.*

DECISION ON APPEAL

The Examiner rejected claims 1–21 of Application 14/744,971 under 35 U.S.C. §§ 101, 102, and 103. Non-Final Act. (Feb. 21, 2017) 3–19. Appellant[1] seeks reversal of these rejections pursuant to 35 U.S.C. § 134(a). We have jurisdiction under 35 U.S.C. § 6(b).

For the reasons set forth below, we AFFIRM.

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[1] The Appellant is the Applicant, Roche Diabetes Care, Inc., which is also identified as the real party in interest. Appeal Br. 1.

BACKGROUND

The present application "relates generally to medicine/medical diagnostics and mathematics, and more particularly, it relates to methods of detecting an analyte concentration in a body fluid sample." Spec. 2. The Specification further states that it relates to "methods of characterizing a body fluid sample, as well a computer programs and devices that incorporate the same." *Id.*

Claim 1 is illustrative of the subject matter on appeal and is reproduced below:

> 1. A method for detecting an analyte in a body fluid sample, the method comprising the steps of:
>
> a) providing at least one optical measurement curve, wherein the optical measurement curve contains a plurality of measurement values recorded by monitoring a time development of at least one measurement value indicating a progress of a detection reaction of at least one test substance and the body fluid sample, wherein the measurement values contained in the optical measurement curve are acquired at differing points in time, and wherein the detection reaction is influenced by a set of state variables, each state variable characterizing at least one of a state of the body fluid sample and a condition of the detection reaction;
>
> b) providing a set of at least two different evaluation rules, each evaluation rule adapted to derive a characteristic value from the optical measurement curve, thereby deriving a set of characteristic values $X=\{X_i\}_{i=1...N}$ from the optical measurement curve, the set of characteristic values comprising at least one first characteristic value being derived from the optical measurement curve by using at least one first evaluation rule from the set of evaluation rules and at least one second characteristic value being derived from the optical measurement curve by using at least one second evaluation rule from the set of evaluation rules, the second evaluation rule being different from the first evaluation rule;

c) performing at least one multivariate analysis of the at least one first characteristic value and of the at least one second characteristic value by using at least one predetermined multivariate evaluation algorithm, the at least one multivariate evaluation algorithm adapted to derive at least one result from at least two variables, wherein the at least one first characteristic value and the at least one second characteristic value are used as the at least two variables, thereby deriving at least one estimate value for at least one target variable Y of the state variables; and

d) determining at least one analyte concentration by using the at least one target variable Y.

Appeal Br. (Claims App. A-1 to A-2).

REJECTIONS

The Examiner maintains the following rejections:

1. Claims 1–21 are under 35 U.S.C. § 101 as directed to patent ineligible subject matter. Final Act. 3–5.
2. Claims 1, 20, and 21 are rejected under 35 U.S.C. § 102(a) (pre-AIA) as anticipated by Dartmann[2]. *Id.* at 5–8.
3. Claims 1–19 are rejected under 35 U.S.C. § 102(b) (pre-AIA) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over, Schäfer et al.[3] *Id.* at 10–17.
4. Claims 20 and 21 are rejected under 35 U.S.C. §103(a) as obvious over Schäfer in view of Dartmann. *Id.* at 18–19.

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[2] WO 2011/131490 A2, published Oct. 27, 2011 ("Dartmann").

[3] US 5,420,042, issued May 30, 1995 ("Schäfer").

DISCUSSION

Rejection 1. The Examiner rejected claims 1–21 as directed to ineligible subject matter.

An invention is patent-eligible if it claims a "new and useful process, machine, manufacture, or composition of matter." 35 U.S.C. § 101. However, the Supreme Court has long interpreted 35 U.S.C. § 101 to include implicit exceptions: "[l]aws of nature, natural phenomena, and abstract ideas" are not patentable. *See, e.g., Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 216 (2014).

In determining whether a claim falls within an excluded category, we are guided by the Supreme Court's two-step framework, described in *Mayo* and *Alice*. *Id.* at 217−18 (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 75–77 (2012)). In accordance with that framework, we first determine what concept the claim is "directed to." *See Alice*, 573 U.S. at 219 ("On their face, the claims before us are drawn to the concept of intermediated settlement, i.e., the use of a third party to mitigate settlement risk."); *see also Bilski v. Kappos*, 561 U.S. 593, 611 (2010) ("Claims 1 and 4 in petitioners' application explain the basic concept of hedging, or protecting against risk.").

Concepts determined to be abstract ideas, and thus patent ineligible, include certain methods of organizing human activity, such as fundamental economic practices (*Alice*, 573 U.S. at 219−20; *Bilski*, 561 U.S. at 611); mathematical formulas (*Parker v. Flook*, 437 U.S. 584, 594--95 (1978)); and mental processes (*Gottschalk v. Benson*, 409 U.S. 63, 69 (1972)). Concepts determined to be patent eligible include physical and chemical processes, such as "molding rubber products" (*Diamond v. Diehr*, 450 U.S. 175, 192 (1981)); "tanning, dyeing, making waterproof cloth, vulcanizing India

rubber, smelting ores" (*id.* at 184 n.7 (quoting *Corning v. Burden*, 56 U.S. 252, 267–68 (1854))); and manufacturing flour (*Benson*, 409 U.S. at 69 (citing *Cochrane v. Deener*, 94 U.S. 780, 785 (1876))).

In *Diehr*, the claim at issue recited a mathematical formula, but the Supreme Court held that "a claim drawn to subject matter otherwise statutory does not become nonstatutory simply because it uses a mathematical formula." *Diehr*, 450 U.S. at 187; *see also id.* at 191 ("We view respondents' claims as nothing more than a process for molding rubber products and not as an attempt to patent a mathematical formula."). That said, the Supreme Court also indicated that a claim "seeking patent protection for [a] formula in the abstract ... is not accorded the protection of our patent laws,[] and this principle cannot be circumvented by attempting to limit the use of the formula to a particular technological environment." *Id.* at 191 (citing *Benson* and *Flook*); *see, e.g., id.* at 187 ("It is now commonplace that an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.") (emphasis in original).

If the claim is "directed to" an abstract idea, we tum to the second step of the *Alice* and *Mayo* framework, where "we must examine the elements of the claim to determine whether it contains an 'inventive concept' sufficient to 'transform' the claimed abstract idea into a patent eligible application." *Alice*, 573 U.S. at 221 (quotation marks omitted). "A claim that recites an abstract idea must include 'additional features' to ensure 'that the [claim] is more than a drafting effort designed to monopolize the [abstract idea].'" *Id.* (quoting *Mayo*, 566 U.S. at 77). "[M]erely requir[ing] generic computer implementation[] fail[s] to transform that abstract idea into a patent-eligible invention." *Id.*

The United States Patent and Trademark Office recently published revised guidance on the application of 35 U.S.C. § 101. USPTO's *2019 Revised Patent Subject Matter Eligibility Guidance* ("Guidance").[4] Under the Guidance, in determining what concept the claim is "directed to," we first look to whether the claim recites:

> (1) any judicial exceptions, including certain groupings of abstract ideas (i.e., mathematical concepts, certain methods of organizing human activity 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)).

Only if a claim (1) recites a judicial exception and (2) does not integrate that exception into a practical application, do we then look to whether the claim contains an "'inventive concept' sufficient to 'transform'" the claimed judicial exception into a patent-eligible application of the judicial exception. *Alice*, 573 U.S. at 221 (quoting *Mayo*, 566 U.S. at 82). In so doing, we thus consider whether the claim:

> (3) adds a specific limitation beyond the judicial exception that is not "well-understood, routine and 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.

See Guidance, 84 Fed. Reg. at 54–56.

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[4] *2019 Revised Patent Subject Matter Eligibility Guidance*, 84 Fed. Reg. 50-57 (January 7, 2019).

Guidance Step 2(a), Prong 1[5]

Pursuant to the Guidance, we begin by determining whether the claims recite any judicial exception(s) to patent eligibility. In this regard, the Examiner determined as follows:

> Claim 1 recites a method for detecting an analyte in a body fluid sample that includes steps of a) providing an optical measurement curve, b) providing a set of at least two evaluation rules, c) performing at least one multivariate analysis and d) determining at least one analyte concentration value. These steps describe a concept that is well known in the art for determining the concentration of an analyte in a sample that can be performed mentally or by any well-known generic computer and computer program and includes the use of mathematical techniques and relationships by manipulating existing information to generate additional information by evaluation rules. This idea is similar to the basic concept of manipulating information using mathematical relationships by converting numerical representation by Benson, *Gottschalk v. Benson*, 409 U.S. 63, 70, 175 USPQ 673, 676 (1972), which has been found by the courts to be an abstract idea. Therefore, the claim is directed to an abstract idea.

Non-Final Act. 3–4. We consider each limitation in turn. Step a) of claim 1 requires as follows:

> a) providing at least one optical measurement curve, wherein the optical measurement curve contains a plurality of measurement values recorded by monitoring a time development of at least one measurement value indicating a progress of a detection reaction of at least one test substance and the body fluid sample, wherein the measurement values contained in the optical measurement curve are acquired at differing points in time, and wherein the detection reaction is influenced by a set of state

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[5] Appellant presents argument regarding the patent eligibility of claim 1 under Step 2A and further asserts that "[c]laims 2–21 are patent eligible, at least because of the chain of dependency." Appeal Br. 6.

> variables, each state variable characterizing at least one of a state of the body fluid sample and a condition of the detection reaction.

Appeal Br. (Claims App. A-1). This claim element concerns providing an optical measurement curve. The optical measurement curve is indicated to contain a number of values recorded over time. That is, an optical measurement curve is a graphic representation of certain mathematical data recorded in sequence. *See* Spec. ¶ 75 ("the monitoring of the time development may include acquiring the respective measurement times, thereby generating the measurement curve, especially the optical measurement curve, including data pairs (R_i, t_i) and/or (t_i, $R_i(t_i)$)."). The Guidance indicates that "[m]athematical concepts— mathematical relationships, mathematical formulas or equations, mathematical calculations" fall within the abstract idea exception. Guidance at 52. The optical measurement curve of the claim indicates the mathematical relationship of certain measured data. Accordingly, we discern no error in the Examiner's determination that claim element a) recites abstract subject matter (mathematical relationships).

Step b) of claim 1 requires as follows:

> b) providing a set of at least two different evaluation rules, each evaluation rule adapted to derive a characteristic value from the optical measurement curve, thereby deriving a set of characteristic values $X=\{X_i\}_{I=1...N}$ from the optical measurement curve, the set of characteristic values comprising at least one first characteristic value being derived from the optical measurement curve by using at least one first evaluation rule from the set of evaluation rules and at least one second characteristic value being derived from the optical measurement curve by using at least one second evaluation rule from the set of evaluation rules, the second evaluation rule being different from the first evaluation rule.

Appeal Br. (Claims App. A-1).

The Specification indicates that "[t]he evaluation rule generally may be an arbitrary mathematical algorithm or may be an arbitrary combination of algorithms for deriving one or more numeric values from the optical measurement curve and/or from the measurement curve." *Id.* ¶ 88. The Specification further teaches that "[a]s used herein, 'different evaluation rules' means that an algorithm of the first evaluation rule may differ from the algorithm of the at least one second evaluation rule in at least one coefficient and/or in at least one parameter and/or in at least one other component defining the algorithm." *Id.* ¶ 87. Thus, claim element b) recites mathematical concepts considered to be abstract.

Step c) of claim 1 requires as follows:

> c) performing at least one multivariate analysis of the at least one first characteristic value and of the at least one second characteristic value by using at least one predetermined multivariate evaluation algorithm, the at least one multivariate evaluation algorithm adapted to derive at least one result from at least two variables, wherein the at least one first characteristic value and the at least one second characteristic value are used as the at least two variables, thereby deriving at least one estimate value for at least one target variable Y of the state variables.

Appeal Br. (Claims App. A-1). Claim element c) requires a multivariate analysis using at least one multivariate evaluation algorithm. The Specification indicates that the "multivariate analysis may include at least one mathematical operation." Spec. ¶ 123. Accordingly, claim element c) recites a mathematical concept considered to be abstract.

Step d) of claim 1 requires "determining at least one analyte concentration by using the at least one target variable Y." Appeal Br. (Claims App. A-1). In regard to this step, the Specification teaches that

> The target variable Y may be or may include a target variable Y being independent from the at least one analyte concentration. For example, the target variable Y being derived in step c) may be the at least one analyte concentration or if the target variable Y derived in step c) includes the analyte concentration, **nothing may have to be done in step d), or just a simple calculation**.

Spec. ¶ 137 (emphasis added). Thus, the Specification teaches that step d) may be "nothing" or "a simple calculation." *Id.* The Specification further teaches that, in some cases, step d) may require a correction algorithm and/or a transformation algorithm. *Id.* ¶ 138. The calculations and algorithms of step d) are mathematical concepts. Accordingly, step d) of claim 1 recites abstract subject matter.

In view of the foregoing, we do not discern error in the Examiner's determination that claim 1 recites abstract subject matter.

Guidance Step 2(a), Prong 2

Under Prong Two of the Revised Guidance, we must determine if the claims integrate the judicial exception into a practical application. That is, we determine whether a meaningful limit is imposed on the judicial exception, such that the claims are more than a drafting effort that monopolizes the judicial exception. This determination is made by identifying any additional claim limitations beyond the judicial exception and evaluating the additional limitations individually and in combination for determining whether they integrate the judicial exception into a practical application.

Appellant argues that the claims are to improvements in computer related technology. Appeal Br. at 11–16. Appellant asserts that "[t]he instant claims, when read in light of the specification, provide a robust analysis of improvements to the computer functionality itself." *Id.* at 12. This is firmly contradicted by the Specification. The Specification provides that "one of the steps or a plurality of the steps or even all of the steps may be performed by using a data processing device such as a computer, preferably a microcomputer and/or an application-specific integrated circuit (ASIC)." Spec. ¶ 70. The Specification further teaches that "[t]he [data] structures, which, after loading into a computer or computer network, such as into a working memory or main memory of the computer or computer network, may execute the methods as disclosed herein." *Id.* ¶ 174. That is, the Specification teaches a method "for which computers are invoked merely as a tool." *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1336 (Fed. Cir. 2016); *see also* MPEP § 2106.05(a), 9th Ed. (Rev. 08.2017).

Appellant additionally argues that the claims are to concepts inextricably tied to computer technology and, therefore, not abstract (*id.* at 16–17) and that the claims are directed to a solution to a problem in the software arts and are therefore not abstract (*id.* at 17–18). The same analysis applies to these arguments. It is apparent that the present claims concern analysis of a detection reaction where "computers are invoked merely as a tool."

Appellant further argues that gathering and combining data from a medical device is not abstract as it requires inputs from a physical device. *Id.* at 18–19. Appellant asserts that "claims 1-21 include input in the form of 'a sample analysis device ... at least one measuring unit ... [and] at least one

evaluation device,' and 'detecting an analyte in a body fluid sample' through the use of these input devices." *Id.* at 19.

Claim 1 requires "the optical measurement curve contains a plurality of measurement values recorded by monitoring a time development of at least one measurement value indicating a progress of a detection reaction of at least one test substance and the body fluid sample." This is mere pre-solution activity. *See Parker v. Flook*, 437 U.S. 584, 590 (1978) ("[t]he notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process exalts form over substance. A competent draftsman could attach some form of post-solution activity to almost any mathematical formula."); *see also* MPEP § 2106.05(g), 9th Ed. (Rev. 08.2017). Such detection reactions have long been known in the art. *See* Spec. 3–24.

The remaining limitations referred to by Appellant are recited in claim 20 (and claim 21 by dependency). Claim 20 is to a "sample analysis device" that includes a "measuring unit" that measures a detection reaction of a test substance and a sample so that an optical measurement curve is recorded. Appeal Br. (Claims App. A-6 to A-7). Claim 21 depends from claim 20 and further requires a "test element" that includes a "test substance" that "perform[s] the detection reaction." *Id.* (A-7). The Guidance instructs to identify "additional elements recited in the claim beyond the judicial exception(s)" and to determine if such additional elements "integrate the exception[s] into a practical application." *Guidance* at 54–55. Claims 20 and 21 recite such additional elements in such a manner that the recited abstract ideas are used "in conjunction with, a particular machine or manufacture that is integral to the claim." *See id.* at 55.

Appellant also argues that claim 1 and its dependents are not directed to an idea "of itself" or mathematical relationships or formulae. Appeal Br. 19–20. These arguments are addressed above.

We discern no additional elements (or combination of elements) recited in Appellants' claim 1 that integrate the judicial exceptions into a practical application. *See* 2019 Revised Guidance, *Revised Step 2A, Prong Two.* For example, Appellant's claimed additional elements (e.g.,) recited in claim 1 do not: (1) improve the functioning of a computer or other technology; (2) are not applied with any particular machine (except for generic computers and devices); (3) do not effect a transformation of a particular article to a different state; and (4) are not applied in any meaningful way beyond generally linking the use of the judicial exception to a particular technological environment, such that the claim as a whole is more than a drafting effort designed to monopolize the exception. *See* MPEP § 2106.05(a)–(c), (e)–(h), 9th Ed. (Rev. 08.2017).

In view of the foregoing, we determine that Appellant has not shown error in the Examiner's determination that claims 1–19 are directed to a judicial exception. We further determine that Appellant has shown error with regard to the Examiner's determination that claims 20 and 21 are directed to a judicial exception.

Guidance Step 2(b)

Appellant argues that claim 1 and its dependent claims recite additional elements that amount to "significantly more" than an abstract idea. Appeal Br. 20–24. Appellant asserts that "the claims in light of the specification represent an improvement in the functioning of the computer, as well as an improvement to the analyte detection technologies."

Id. at 21. This argument is similar to Appellant's argument above considered in regard to Prong 2 of Step 2(a) and is rejected for the same reasons. The Specification's teaching that "one of the steps or a plurality of the steps or even all of the steps may be performed by using a data processing device such as a computer, preferably a microcomputer and/or an application-specific integrated circuit (ASIC)" (Spec. ¶ 70) indicates that one may practice the method of the invention on a generic computer. *See also* Dartmann, 22:23–23:3 (describing use of a computer program to mathematically fit a curve to signal measurements and thereby determine concentration of an analyte).

Appellant further argues that claim 1 includes additional claimed elements effecting a transformation or reduction of a particular article to a different state or thing. Appeal Br. 22. In support, Appellant asserts that "[t]he claims in the instant application include multiple required concrete steps transforming the original input parameters or other data." *Id.* at 23. Such argument carries little weight. *See DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1256 (Fed. Cir. 2014) ("[I]n *Mayo*, the Supreme Court emphasized that satisfying the machine-or-transformation test, by itself, is not sufficient to render a claim patent-eligible, as not all transformations or machine implementations infuse an otherwise ineligible claim with an 'inventive concept.'").

Nor does our review of claim 1 reveal additional elements recited in the claims that provide significantly more than the abstract idea exception. Each step of claim 1 (a through d) requires an abstract mathematical step. Step a) may be seen as requiring the reaction of a test substance and a body fluid sample as well as some type of measuring device. Such steps are, however, well understood, routine, conventional activity in this field. *See*

Non-Final Act. 4; Spec. ¶¶ 11, 14, 16; Schäfer 1:8–61. Accordingly, Appellant has not shown that there are additional elements recited in the claims that provide significantly more than the abstract idea exception.

In view of the foregoing, Appellant has not shown error in the Examiner's rejection of claim 1 and dependent claims 2–19 as directed to ineligible subject matter.

Rejection 2. The Examiner rejected claims 1, 20, and 21 as anticipated by Dartmann. Non-Final Act. 5–8. In support of the rejection, the Examiner determined that Dartmann teaches two different evaluation rules adapted to derive a characteristic value from the optical measurement curve and performing a multivariate analysis of the first and second characteristic values. *Id.* at 6–7 (citing Dartmann, 18:29–19:2, 20:16–29, 79:1–6 (claim 8), and 80:16–27 (claim 12)). In the Answer, the Examiner indicated that "[i]n particular, one evaluation rule interpreted by the Examiner is the 'regularization on parameter a,' page 18 line 29-page 19 line 2. The other evaluation rule interpreted by the Examiner is the decision made by the decision tree of another parameter (y0, r, b, or n0), page 20 line 16-29." Answer 19. The Examiner further determined that Dartmann teaches the "multivariate analysis" limitation where it discloses "parameters are constrained during fitting to ensure robust and confident estimation of parameters for curves showing no amplification behavior or amplification behavior in the very end only. Constraints may be uni- or multivariate, linear or non-linear." *Id.* (citing Dartmann 19).

In its Appeal Brief, Appellant largely addresses the Examiner's findings from a previous Office Action. Appeal Br. 25–26. Appellant further provides a brief summary of its view of Dartmann but does not

specifically articulate error in the Examiner's analysis. *Id.* at 27. Appellant submitted a Reply Brief but does not address Dartmann therein. *See* Reply Br., generally.

Appellant argues that the rejection of claims 20 and 21 is procedurally deficient. Appeal Br. 28–29. As above, "the PTO carries its procedural burden of establishing a prima facie case when its rejection satisfies 35 U.S.C. § 132, in 'notify[ing] the applicant . . . by stating the reasons for [its] rejection, or objection or requirement, together with such information and references as may be useful in judging of the propriety of continuing the prosecution of [the] application.'" *In re Jung*, 637 F.3d 1356, 1362 (Fed. Cir. 2011) (quoting 35 U.S.C. § 132). Here, the Examiner informed Appellant of the basis of the rejection (35 U.S.C. § 102) and the specific portion of the reference (Dartmann) stated to anticipate. While the Rejection could have been more informative, the Examiner satisfied the procedural burden to establish a prima facie case.

Appellant does not put forward any substantive argument in opposition to the rejection of claims 20 and 21 apart from a general allegation that Dartmann does not teach the elements of claim 21. Appeal Br. 29. Accordingly, Appellant has not shown error in this regard. *See* 37 C.F.R. § 41.37(c)(1)(iv) (2012); *Hyatt v. Dudas*, 551 F.3d 1307, 1313–14 (Fed. Cir. 2008); *see also* Manual of Patent Examining Procedure (MPEP) § 1205.02, 9th ed. (Rev. 08.2017) ("If a ground of rejection stated by the examiner is not addressed in the appellant's brief, appellant has waived any challenge to that ground of rejection and the Board may summarily sustain it, unless the examiner subsequently withdrew the rejection in the examiner's answer.").

In view of the foregoing, Appellant has not shown reversible error in the Examiner's rejection of claims 1, 20, and 21 as anticipated by Dartmann.

Rejection 3. The Examiner rejected claims 1–19 as anticipated by or, in the alternative, obvious over, Schafer. As a preliminary matter, we reverse the Examiner's rejection on the basis of anticipation in view of the Examiner's concession that Schäfer does not teach a process "wherein the at least one first characteristic value and the at least one second characteristic value are used as the at least two variables, thereby deriving at least one estimate value for at least one target variable Y of the state variables" as required by claim 1. Answer 20. We consider the rejection on the basis of obviousness below.

Schäfer teaches that both a training run and an analysis run are performed. Abstract. In a training run (or multiple training runs), a sample with a known concentration of a given analyte is used to calibrate certain measurements. *See, e.g.*, Schäfer 10:66–11:68, 13:4–14:21 (claim 1). Subsequently, an analysis run is performed and information learned from the training run is used to interpret the results of the analysis run. *Id.*

Claim 1 requires providing evaluation rules and performing multivariate analysis as follows:

> b) providing a set of at least two different evaluation rules, each evaluation rule adapted to derive a characteristic value from the optical measurement curve, thereby deriving a set of characteristic values $X=\{X_i\}_I=_{1...N}$ from the optical measurement curve, the set of characteristic values comprising at least one first characteristic value being derived from the optical measurement curve by using at least one first evaluation rule from the set of evaluation rules and at least one second characteristic value being derived from the optical measurement curve by using at least one second evaluation rule from the set of evaluation rules,

> the second evaluation rule being different from the first evaluation rule
>
> c) performing at **least one multivariate analysis of the at least one first characteristic value and of the at least one second characteristic value** by using at least one predetermined multivariate evaluation algorithm, the at least one multivariate evaluation algorithm adapted to derive at least one result from at least two variables, wherein the at least one first characteristic value and the at least one second characteristic value are used as the at least two variables, thereby deriving at least one estimate value for at least one target variable Y of the state variables.

Appeal Br. (Claims App. A-1) (emphasis added).

Appellant argues that Schafer "does not teach or suggest that one could use multiple discriminator sets as variables in a single multivariate statistical technique." *Id.* at 33. Rather, Appellant contends, it teaches to apply multivariate statistical techniques to each discriminator set individually. *Id.*

As noted above, this is conceded by the Examiner. Non-Final Act. 11; Answer 20. In this regard, the Examiner states as follows:

> However, it would be obvious to one having ordinary skill in the art at the time the invention was made to modify the multivariate evaluation algorithm of Schaefer with a computer program adapted to derive at least one result from at least two variables, wherein the at least one first characteristic value and the at least one second characteristic value are used as the at least two variables thereby deriving at least one estimate value for at least one target variable Y of the state variables to manipulate the values obtained into a one dimensional space for deriving a single estimate value.

Non-Final Act. 11–12. Appellant does not address this finding. Accordingly, Appellant has not shown error in the foregoing and the rejection of claim 1 as obvious over Schäfer is affirmed.

Appellant separately appeals the rejection of claims 2–21 over Schäfer. Appeal Br. 34–45.

Appellant argues that the Examiner failed to establish a prima facie case of invalidity of claim 2. *Id.* at 35. Claim 2 is a Markush claim listing a number of "state variables." *Id.* (Claims App. A-2). In the rejection, one such state variable, "**alterations of the body fluid sample or of certain properties of the body fluid sample caused by pharmacological treatment of a donor of the body fluid sample**" is in bold text and followed by a citation to Schäfer. Non-Final Act. 12. While a more thorough explanation may be desirable, the rejection as issued fairly notified the applicant of the reason for the rejection and the reference relied upon. *See In re Jung* at 1362.

Appellant does not provide substantive argument against the rejection. Accordingly, Appellant has not shown error in this regard. *See* 37 C.F.R. § 41.37(c)(1)(iv) (2012).

Appellant additionally argues that claim 3 was rejected in error. Appeal Br. 36. Claim 3 depends from claim 2 and further requires that "the particulate component of the body fluid sample is a hematocrit." *Id.* (Claims App. A-2). The Examiner conceded that Schafer does not teach that the particulate component of the body fluid is a hematocrit (red blood cell content). Non-Final Act. 17. The Examiner found, however, that Schafer teaches analysis of urine and "it is well known that chemical analysis on biological sample include blood and urine." *Id.* The Examiner additionally cited to a portion of Schäfer that teaches that "[i]n chemical analysis, in particular with the **analysis of body fluids such as blood and urine**, **methods are commonly used** which are based on a specific binding reaction of two binding partners exhibiting biological affinity." Schäfer,

1:22–26 (emphasis added). On this basis, the Examiner concluded that claim 3 would have been obvious to one of ordinary skill in the art. Schäfer further teaches that "the invention has as its aim the creation of a method with which the analysis is possible in the case of an ambiguous evaluation curve C=f(X) with high reliability and **for a broad spectrum of different tests**." Schafer, 3:60–65 (emphasis added).

Appellant argues that the examples of Schäfer, which concern the testing of urine for albumin (Examples 1 and 3) and the testing of serum for ferritin (Example 2), would not provide sufficient reason to modify the teachings of Schäfer. Appeal Br. 36. This argument is insufficient to show error in the Examiner's determination. Schäfer teaches that it is applicable to a "broad spectrum of different tests" and that blood tests are known in the art. In view of such teachings, the Examiner's finding that one of skill in the art would have had reason to apply the teachings of Schäfer in the context of hematocrit testing is sufficiently supported. Accordingly, Appellant has not shown error in regard to the rejection of claim 3 as obvious over Schäfer.

Appellant additionally argues that claim 4 was rejected in error. Appeal Br. 36–7. Claim 4 depends from claim 1 and further requires that "the first evaluation rule may not be transformed into the second evaluation rule by a time transformation." *Id.* (Claims App. A-2).

The Examiner conceded that Schäfer "does not specifically disclose wherein the first evaluation rule may not be transformed into the second evaluation rule by a time transformation." Non-Final Act. 12. The Examiner finds, however, that "it would be obvious to one having ordinary skill in the art so that one of the evaluation rules are not transformed to maintain unaltered values to be observed for a point of reference, See Schafer et al, Column 13 line 10 - Column 14 line 2, Claim 1." *Id.*

This is inadequate analysis to support an obviousness rejection. "[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." *See In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). Here, the Examiner merely cited to a lengthy portion of Schäfer's claim 1. It is not apparent from review of the cited portion of Schäfer how the Examiner proposes to modify the claim so that "the first evaluation rule may not be transformed into the second evaluation rule by a time transformation." This falls short of the "articulated reasoning" required of the rejection.

Appellant additionally challenges the rejection of claim 5. Appeal Br. 37. Claim 5 depends from claim 1 and further requires that "the second evaluation rule differs from the first evaluation rule in at least one of: in at least one coefficient, in at least one parameter, and in at least one component related to the at least one predetermined multivariate evaluation algorithm." In rejecting claim 5, the Examiner repeated the claim language and then stated "See Schafer et al, Column 13 line 10 - Column 14 line 2, Claim 1, different discriminator sets." Non-Final Act. 12–13.

The cited portion of Schäfer includes the claim element "wherein the generating step (1)(c) for the at least one additional training run further includes generating a different discriminator set from the measurements of S(t) **by at least one of a different discriminator generation method and a different multivariate statistical technique**." Schäfer 13:54–58 (emphasis added). Here, it is possible to determine the portion of Schäfer relied upon, but the Examiner fails to provide even minimal analysis linking the reference to the claim at issue. Accordingly, the rejection of claim 5 falls short of the requisite "articulated reasoning."

Appellant additionally argues that claim 6 was rejected in error. Appeal Br. 37–38. Claim 6 depends from claim 1 and further requires that "a third evaluation rule is provided, wherein in step c), the at least one first characteristic value is derived from the first evaluation rule, and wherein in the at least one multivariate evaluation algorithm, the second evaluation rule or the third evaluation rule is used depending on the at least one first characteristic value." *Id.* (Claims App. A-2). In the rejection, the Examiner repeats the claim language then states that one of skill in the art would make such modification "to compare the target value of Y, taking into account different conditions of the sample." Non-Final Act. 13. This does not directly address the limitations at issue and is an inadequate explanation as to why one of skill in the art would have been motivated to make such a modification.

Appellant additionally argues that claim 7 was rejected in error. Appeal Br. 38. Claim 7 depends from claim 1 and further requires that

> the first characteristic value is determined by using a first time interval of the optical measurement curve, wherein the second characteristic value is determined by using a second time interval of the optical measurement curve, and wherein the first time interval of the optical measurement curve is different from the second time interval of the optical measurement curve.

Id. (Claims App. A-3). In support of the rejection, the Examiner repeats the claim's language then states "See Schafer et al, Schafer et al, Column 13 line 10 - Column 14 line 2, Column 7 line 26-66, Claim 1." Non-Final Act. 13. This does not directly address the limitations at issue and is an inadequate explanation as to how Schäfer teaches the limitation. Accordingly, the rejection of claim 7 is reversed. This applies equally to the rejection of claim 8 which depends from claim 7.

Appellant additionally argues that claim 9 was rejected in error. Appeal Br. 39. Claim 9 depends from claim 1 and further requires that "the at least two evaluation rules are adapted to derive the characteristic values from at least two derivatives of the optical measurement curve." *Id.* (Claims App. A-3). In support of the rejection, the Examiner repeats the claim's language then states "[s]ee Schafer et al, Column 13 line 10 -Column 14 line 2, Claim 1, Figure 1." Non-Final Act. 13. This does not directly address the limitations at issue and, given the complexity of the claim, is an inadequate explanation as to how Schäfer teaches the limitations at issue. Accordingly, the rejection of claim 9 is reversed.

Appellant additionally argues that claim 10 was rejected in error. Appeal Br. 39. Claim 10 depends from claim 1 and further requires that "the target variable Y comprises the at least one analyte concentration in the body fluid sample." *Id.* (Claims App. A-3). In support of the rejection, the Examiner repeats the claim's language then states "[s]ee Schafer et al, Column 14 line 17-21." Non-Final Act. 13. This does not directly address the limitations at issue and is an inadequate explanation as to how Schäfer teaches the limitations at issue. Accordingly, the rejection of claim 10 over Schäfer is reversed.

Appellant additionally argues that claim 11 was rejected in error. Appeal Br. 40. Claim 11 depends from claim 1 and further requires that "in step d), in addition to the at least one target variable Y, at least one electrochemical measurement value is used for determining the at least one analyte concentration, and wherein the electrochemical measurement value is determined by using at least one electrochemical measurement." In support of the rejection, the Examiner repeats the first clause of claim 11 and then cites to "Schafer et al, Column 14, line 17–21." Non-Final Act. 13–14.

The Examiner then recites the remainder of the claim and the following citation and limited analysis: "[s]ee Schafer et al, Column 4 line 23-43, Column 6 line 4-14, kinetic of the reaction and concentration, Figure 1." *Id.* at 14.

Appellant argues that the rejection of claim 11 is both procedurally and substantively defective. Appeal Br. 40. Appellant argues that the rejection is procedurally defective as the "Examiner did not provide any explanation of the rejection or how teachings of Shafer et al. were applied to these specifically-claimed elements." *Id.* Appellant argues that the rejection is substantively in error as Schäfer lacks any teaching regarding electrochemical measurement. *Id.*

Appellant's assertion regarding the absence of any explicit teaching regarding electrochemical measurement is corroborated by review of the sections cited by the Examiner. The Examiner does not further address this rejection in the Answer. Accordingly, Appellant has shown that this rejection lacks a proper basis and is therefore reversed. Claim 12 depends from claim 11 and is rejected on the same basis. Non-Final Act. 14. Accordingly, the rejection of claim 12 over Schäfer is reversed for the same reasons as claim 11.

Appellant additionally argues that claim 13 was rejected in error. Appeal Br. 41. Claim 13 depends from claim 1 and further requires that "the predetermined multivariate evaluation algorithm comprises at least one polynomial algorithm selected from:

$$Y = A \cdot X, (1);$$

$$Y = X^T \cdot A \cdot X, (2); \text{ and}$$

$$Y = X^T \cdot (X^T \cdot A \cdot X), (3),$$

wherein A is a one-dimensional, a two-dimensional or a three-dimensional evaluation tensor." *Id.* (Claims App. A-4).

In support of the rejection, the Examiner determined that "it would be obvious to one having ordinary skill in the art at the time the invention was made to modify the method . . . to optimally quantify the target variable." Non-Final Act. 14. This is insufficient to articulate a reason to modify the teachings of Schäfer. *See In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) ("[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.").

Appellant additionally argues that claim 14 was rejected in error. Appeal Br. 41–42. Claim 14 depends from claim 1 and further requires that

> the predetermined multivariate evaluation algorithm comprises at least one algorithm selected from:
>
> $$Y = \Sigma_i a_i \cdot X_i, \quad (4);$$
>
> $$Y = \Sigma_i a_i \cdot X_i + \Sigma_{i,j} a_{ij} \cdot X_i \cdot X_j, \quad (5); \text{ and}$$
>
> $$Y = \Sigma_i a_i \cdot X_i + \Sigma_{i,j} a_{ij} \cdot X_i \cdot X_j + \Sigma_{i,j,k} a_{ijk} \cdot X_i \cdot X_j \cdot X_k, \quad (6),$$
>
> wherein a_i, a_{ij}, are predetermined coefficients, and wherein i, j and k are, mutually independently, integers from 1 to N.

Id. (Claims App. A-4).

In support of the rejection of claim 14, the Examiner determined that "it would be obvious to one having ordinary skill in the art at the time the invention was made to modify the method . . . to take into account specific circumstances and different conditions of the method." Non-Final Act. 14–

15. This is insufficient to articulate a reason to modify the teachings of Schäfer. *See In re Kahn*, 441 F.3d at 988.

Appellant additionally argues that claim 15 was rejected in error. Appeal Br. 42–43. Claim 15 depends from claim 1 and further requires that "the at least one multivariate evaluation algorithm comprises a function involving at least one decision tree, and wherein the decision tree comprises at least one decision branch that allows selecting one out of at least two alternative procedures based on an assessment whether a predetermined condition may be fulfilled." *Id.* (Claims App. A-4).

In support of the rejection of claim 15, the Examiner determined that "it would be obvious to one having ordinary skill in the art at the time the invention was made to modify the method . . . to offer a decision between performing or not performing a specific procedure under a specific parameter with a specific parameter set or within a specific parameter range, under specific circumstances." Non-Final Act. 15. This is insufficient to articulate a reason to modify the teachings of Schäfer. *See In re Kahn*, 441 F.3d at 988. Accordingly, the rejection of claim 15 is reversed.

Appellant also argues that claim 16 was rejected in error. Appeal Br. 43–44. Claim 16 is reproduced below:

> 16. The method of Claim 1, wherein at least one of the two different evaluation rules is selected from the group consisting of:
>
> a) using a specific measurement value of the optical measurement curve or a derivative of the optical measurement curve at a predetermined point in time as the characteristic value;
>
> b) using a mean value of the optical measurement curve or a derivative of the optical measurement curve over a predetermined period of time as the characteristic value;

> c) using a characteristic point in time of the optical measurement curve or of a derivative of the optical measurement curve as the characteristic value;
>
> d) using a characteristic parameter of the optical measurement curve or of a derivative of the optical measurement curve as the characteristic value;
>
> e) using a fit parameter derived by at least one fitting process as the characteristic value, wherein the fitting process implies a fitting of at least one predetermined fit curve to at least a section of the optical measurement curve or of a derivative of the optical measurement curve; and
>
> [f]) using at least one value derived from a phase plot of at least two derivatives of different order of the optical measurement curve as the characteristic value, wherein the phase plot comprises at least one phase space curve.

Id. (Claims App. A-4 to A-5).

In support of the rejection of claim 16, the Examiner repeated the claim then cited to "Schafer et al, Column 4 line 4-44, Column 7 line 26-66, Claim 4-9." Non-Final Act. 15–16. The Examiner did not specify which two of the six possibilities is believed to be taught by Schäfer. The rejection does not directly address the limitations at issue and is an inadequate explanation as to how Schäfer teaches such limitations. The rejection of claim 16 is not addressed in the Examiner's Answer. Accordingly, the rejection of claim 16 is reversed.

Appellant also argues that claim 17 was rejected in error. Appeal Br. 44–45. Claim 17 depends from claim 1 and further requires that step b) of claim 1 include four recited substeps. *Id.* (Claims App. A-5 to A-6). For each substep of claim 17, the Examiner identified a portion of Schäfer found to teach the substep. Non-Final Act. 16. Appellant, referring to a previous

Final Office Action, asserts that "Appellant cannot reasonably determine which feature of Schafer et al. is believed to correspond with which feature recited in claim 17." Appeal Br. 44. Appellant additionally includes a general denial that Schäfer teaches the claimed elements. *Id.* at 44–45. As this does not address the citations to evidence in the operative Non-Final Rejection, it is insufficient to show error in the rejection.

Appellant additionally argues that claim 18 was rejected in error. Appeal Br. 45. Claim 18 requires the following steps:

> A) bringing the body fluid sample into contact with at least one test substance, thereby initiating a detection reaction of the test substance and the body fluid sample, wherein the detection reaction is influenced by a set of state variables, each state variable characterizing at least one of a state of the body fluid sample and a condition of the detection reaction;
>
> B) monitoring a time development of at least one measurement value indicating a progress of the detection reaction, thereby recording an optical measurement curve containing a plurality of the measurement values acquired at differing points in time;
>
> C) evaluating the optical measurement curve by using the method of Claim 1.

Id. (Claims App. A-6).

In the Non-Final Action, the Examiner repeated the claim then stated "[s]ee Schafer et al, Rejection of Claim 1, Example 1, Columns 10 and 11." Non-Final Act. 17. This is a succinct rejection to be sure. Given the nature of the limitations at issue, however, and the description of Example 1 in Schäfer, one can readily ascertain the teachings intended by the Examiner. Accordingly, Appellant has not shown error in this regard.

Appellant additionally argues that claim 19 was rejected in error. Appeal Br. 45. Claim 19 requires "[a] computer program comprising computer-executable instructions for performing the method of Claim 1 when the program is executed on a computer or a computer network." In support of the rejection, the Examiner cited to a portion of Schäfer which teaches as follows:

> Central determination by the manufacturer has the advantage that a particularly **powerful computer facility may be used**. If the optimized discrimination algorithm is independent of the manufacturing batch of the reagent kit, **one data transfer** of the information to the analytical unit, for example by **means of a diskette**, is sufficient. However if different manufacturing batches of the reagents vary to such an extent that the same optimized discrimination algorithm cannot be used for different batches, it is advisable that **the optimized discrimination algorithm** be determined separately for each batch and **be dispatched to the clinical laboratory on a suitable storage medium** with the packing of the test kit.

Schäfer, 9:27–40. Appellant argues that "[t]he Examiner did not provide any explanation of the rejection or how teachings of Shafer et al. were applied to these specifically-claimed elements" but does not present substantive argument regarding the claim. Appeal Br. 45. Given the nature of the limitations at issue and Schäfer's straightforward teachings regarding a computer facility and computer program storage, one can readily ascertain the teachings intended by the Examiner. Accordingly, Appellant has not shown error in this regard.

Rejection 4. The Examiner rejected claims 20 and 21 as obvious over Schäfer in view of Dartmann. Non-Final Act. 18–19. In support of the rejection of claim 20, the Examiner found that Schäfer teaches each element

"except for wherein the method is performed on a sample analysis device." *Id.* at 18. The Examiner finds that Dartmann teaches the claimed analysis device and cites to "Dartmann et al, page 22 line 1-22, Rejection of Claim 1, under 102(a)" in support thereof. *Id.*

The rejection lacks any statement as to why one of ordinary skill in the art would have had reason to combine the teachings of Schäfer and Dartmann. *Id.* Appellant argues that this is inadequate to state a rejection on the basis of obviousness. Appeal Br. 46. We accept such argument. *See In re Kahn*, 441 F.3d at 988.

Accordingly, the rejection of claims 20 and 21 as obvious over Schäfer in view of Dartmann is reversed.

CONCLUSION

The rejection of claims 1–19 as directed to ineligible subject matter is affirmed. The rejection of claims 20 and 21 as directed to ineligible subject matter is reversed. The rejection of claims 1, 20, and 21 as anticipated by Dartmann is affirmed. The rejection of claims 1–3, and 17–19 as obvious over Schäfer is affirmed. The rejection of claims 4–16 as obvious over Schäfer is reversed. The rejection of claims 20 and 21 as obvious over Schäfer in view of Dartmann is reversed.

As at least one rejection applicable to each claim at issue is affirmed, the Office Action as a whole is affirmed.

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

AFFIRMED