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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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*Ex parte* MICHAEL DONOVAN, DOUG POWELL, and FAISAL KHAN

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Appeal 2017-005993  
Application 12/821,664  
Technology Center 1600

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Before RICHARD M. LEBOVITZ, RICHARD J. SMITH, and  
TIMOTHY G. MAJORS, *Administrative Patent Judges*.

MAJORS, *Administrative Patent Judge*.

DECISION ON APPEAL

Appellants<sup>1</sup> submit this appeal under 35 U.S.C. § 134 involving claims to methods of administering a course of treatment to a subject with a cancer type. The Examiner rejected the claims as anticipated and for lack of eligible subject matter. We have jurisdiction under 35 U.S.C. § 6(b).

We REVERSE.

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<sup>1</sup> Appellants identify the Real Party in Interest as the Fundação D. Anna Sommer Champalimaud E Dr. Carlos Montez Champalimaud. App. Br. 3.

## STATEMENT OF THE CASE

According to the Specification, “[i]n the U.S. – 211,000 women [are] diagnosed with Breast cancer each year of which 42,000 over-express HER2.” Spec. 2:26–27. Moreover, “less than 35% of these HER2 over-expressors respond to trastuzumab (Herceptin) therapy and of the initial responders, 25% of metastatic breast cancer patients develop resistance to trastuzumab.” *Id.* at 2:27–29. The Specification, thus, states that “a need exists to better predict the response to therapy.” *Id.* at 2:29–30.

Appellants’ “invention relates to the identification of biomarkers associated with breast cancer,” and more specifically, “the invention provides a multiplex immunofluorescent quantitative assay for Her-2 in formalin fixed paraffin embedded breast tumor samples.” *Id.* at 5:16–17. As the Specification explains, the “invention further provides systems and apparatuses that use clinical information, molecular information and computer-generated morphometric information in a predictive model for predicting the occurrence, response to treatment, or survivability of a subject with breast cancer.” *Id.* at 5:20–23. Further, the “systems methodology represents an integrative platform which relies on principles of machine learning to combine clinical data, with quantitative biomarker characteristics.” *Id.* at 5:24–26; *see id.* at 5:29–31 (“Mathematical models are incorporated to threshold and then normalize individual and multiple (bio) markers in a given tissue section which allows for an accurate assessment of any given marker across multiple patient samples.”).

Claims 39, 40, 42–44, 46–49, 51–54, 57–59, 65 and 66 are on appeal. Independent claim 65 is illustrative and is reproduced below:

65. A method for administering a course of treatment to a subject with a cancer type comprising the steps of:

A. measuring, using an immunofluorescence imaging device having a connection to a computing device configured to execute code in a processor, at least a plurality of protein expression levels of the subject by contacting a formalin fixed paraffin embedded tissue sample of the subject to antibodies of Her2, Her2-ECD, cytokeratin and p95HER2;

B. capturing an image of the tissue sample with the immunofluorescence imaging device and analyzing the image with an image analysis device to determine plurality of protein expression levels present in the sample;

C. automatically storing the plurality of protein expression levels measured by the image analysis device in a subject dataset in a memory of the computing device wherein the subject dataset includes clinical and biographic data relating to the subject;

D. calculating, using the computing device, a protein expression level of p95HER2 for the subject according to a function (1);

i. where function (1) =  $p95HER2 = (Her2 + pHer2) - Her2-ECD$ ;

E. providing a machine learning application with a population dataset from a data storage device, wherein the machine learning application is configured to generate an effective treatment model using a linear discriminant analysis on the population dataset, wherein the population dataset includes data relating to each member of the population obtained at least two different points in time, wherein each member is diagnosed with the same cancer type and similar clinical features as the subject and the data obtained at the at least two different points in time relating to each member includes:

i. at least one data value corresponding to treatment resistance status, []

ii. at least one data value corresponding to treatment status;

iii. at least one data value corresponding to the health outcome,

iv. and the protein expression levels for each individual as obtained by:

1. contacting a formalin fixed paraffin-embedded tissue sample of each member of the population with antibodies to Her2, Her2-ECD, cytokeratin, p95HER2 and p95HER2 for each member of the population dataset, and
2. deriving the protein expression level of p95HER2 of each member of the population dataset according to function (1);

F. evaluating the subject dataset with the effective treatment model, wherein the evaluation yields a value related to a probability that the subject will have a resistance to at least one treatment for the cancer type;

G. generating, using a treatment module configured as instructions for the computer, a output data object that includes at least information indicating a course of treatment for the subject that does not include any treatment where the probability that the subject will have resistance is above a given threshold.

App. Br. 22–23 (Claims App'x).

The claims stand rejected as follows:

- I. Claims 39, 40, 42–44, 46–49, 51–54, 57–59, 65 and 66 under 35 U.S.C. § 101 for lack of patent eligible subject matter.
- II. Claims 39, 40, 42–44, 46–49, 51–54, 57–59, 65 and 66 under 35 U.S.C. § 102(e) as anticipated by Singh.<sup>2</sup>

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<sup>2</sup> Singh et al., US 8,163,499 B2, issued Apr. 24, 2012.

## I. SUBJECT MATTER ELIGIBILITY

### 1. *Supreme Court Eligibility Framework*

An invention is patent-eligible if it claims a “new and useful process, machine, manufacture, or composition of matter.” 35 U.S.C. § 101.

Nevertheless, the Supreme Court has interpreted § 101 to include certain implicit exceptions: “[l]aws of nature, natural phenomena, and abstract ideas” are not patentable. *Alice Corp. v. CLS Bank Int’l*, 573 U.S. 208, 216 (2014).<sup>3</sup>

The Supreme Court has further established a two-step framework, described in *Mayo* and *Alice* for assessing whether a claim falls within one of those excepted, patent-ineligible, categories. *Id.* at 217–218 (citing *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 75–77 (2012)). Under that framework, the Supreme Court explains, first “we determine whether the claims at issue are directed to one of those patent-ineligible concepts.” *Id.* “If so, we then ask, “[w]hat else is there in the claims before us?”” *Id.* (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 78 (2012)). In answering this second question, the Court explains,

we consider the elements of each claim both individually and as an ordered combination to determine whether the additional elements transform the nature of the claim into a patent-eligible application. . . . We have described step two of this analysis as a

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<sup>3</sup> For instance, 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 v. Kappos*, 561 U.S. 593, 611 (2010)); mathematical formulas (*Parker v. Flook*, 437 U.S. 584, 594–95 (1978)); and mental processes (*Gottschalk v. Benson*, 409 U.S. 63, 69 (1972)).

search for an inventive concept—*i.e.*, an element or combination of elements that is sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.

*Id.* (internal citations and quotation marks omitted).

## 2. *Subject Matter Eligibility Guidance*

The Patent Office recently published revised guidance on the application of § 101 in proceedings taking place before the Office. 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. 51 (Jan. 7, 2019) (hereafter “Revised Guidance”). Under that guidance, we first look to whether the claim recites:

- (1) Step 2A – Prong One: 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) Step 2A – Prong Two: additional elements that integrate the judicial exception into a practical application (*see* MPEP<sup>4</sup> § 2106.05(a)–(c), (e)–(h)).<sup>5</sup>

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<sup>4</sup> All Manual of Patent Examining Procedure (MPEP) citations herein are to MPEP Rev. 08.2017, January 2018.

<sup>5</sup> We acknowledge that some of the considerations at Step 2A, Prong Two, properly may be evaluated under Step 2 of *Alice* (Step 2B of the Office guidance). For purposes of maintaining consistent treatment within the Office, we evaluate them under Step 1 of *Alice* (Step 2A of the Office guidance). *See* 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. at 55 n. 25, 27–32. “As before, Step 1 of the USPTO’s eligibility analysis entails considering whether the claimed subject matter falls within

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:

(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.

*See* 2019 Revised Patent Subject Matter Eligibility Guidance, 84 Fed. Reg. at 56 (“Step 2B: If the Claim Is Directed to a Judicial Exception, Evaluate Whether the Claim Provides an Inventive Concept”).

3. *Examiner’s §101 Rejection – Alice/Mayo Steps 1 and 2*

a. *Guidance Step 2A – Prong One*

Although the Examiner does not, in the rejection on appeal, delineate between the different steps in the eligibility analysis (either under the *Alice/Mayo* framework or the then-existing Office guidance),<sup>6</sup> the Examiner concludes that all of the pending claims “are drawn to detecting the judicial exception of naturally occurring levels of HER2, HER2-ECD, cytokeratin, phosphorylated HER2 (pHER2), and p95HER2 in cancer and a prognosis.” Final Act. 2. Accordingly, we understand the Examiner to have rejected the

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the four statutory categories [e.g., process, machine, etc.]” and the Revised Guidance “does not change Step 1 . . . analysis.” *Id.* at 53–54.

<sup>6</sup> The 2019 Revised Patent Subject Matter Eligibility Guidance, discussed above, was not published and available to the Examiner at the time the particular § 101 rejection on appeal was made final (Dec. 10, 2015).

claims, at least partly, for being directed to a natural phenomenon or law of nature. Considering the Examiner's conclusion in view of the Office's recent guidance (Step 2A, Prong 1), we note claim 65's recitation of "protein expression levels of . . . Her2, Her2-ECD, cytokeratin and p95HER2" in a subject's tissue sample. *See* claim 65 (portion of step (A), and portion of step (E)(iv)(1) regarding protein expression levels in samples from population members).<sup>7</sup>

The Examiner further asserts that the "steps of storing numerical values in a computer dataset, mathematical manipulation and evaluation of data, and generating treatment modules are considered a law of nature in the form of a mathematical algorithm or an abstract idea." *Id.* at 3–4; *see also id.* at 5–6 ("mathematical manipulation of protein expression data to develop a treatment module for patients, however the manipulation of data to produce theoretical treatment modules is an abstract idea"). Hence, viewing the Examiner's assertions through the lens of the Office's recent guidance, the Examiner appears to further find that some of the claimed steps include abstract ideas for reciting mathematical concepts or relationships related to expression levels of certain protein biomarkers.

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<sup>7</sup> Claim 65 may include a drafting error insofar as it appears to indicate that the expression levels of p95HER2 is measured (e.g., through fluorescent imaging), yet other elements of claim 65 indicate that the expression level of p95HER2 is separately calculated or derived with a computing application performing function (1). *See* claim 65, steps (D) and (E)(iv)(2); *see* Reply Br. 3–4 (arguing that p95HER2 is derived from other measured protein values, thus eliminating the need to directly measure p95HER2 expression levels).

We find that some elements of the claims recite at least some judicially excepted subject matter. As noted above, the claims do recite measuring “expression levels” of naturally occurring proteins (e.g., “Her2, Her2-ECD, cytokeratin,” etc.), which may be overexpressed in subjects with cancer. *See, e.g.*, claim 65; Spec. 1:13–14 (“HER2 is a member of the epidermal growth factor receptor family and is amplified / over-expressed in approximately 15-20% of breast cancers.”). Thus, such step is simply identifying the naturally occurring relationship between expression levels and a disease or non-diseased state.

Moreover, as the Examiner suggests, some of the claim limitations recite or rely upon mathematical relationships. For example, claim 65 recites calculating a subject’s protein expression level of p95HER2 according to the function:  $p95HER2 = (Her2 + pHer2) - Her2-ECD$ . *See* claim 65 (step (D)(i)); *see also* claim 65 (step (E) (reciting, *inter alia*, generating a model “using linear discriminant analysis”).

*b. Guidance Step 2A – Prong Two*

Under Prong 2, the Patent Office “evaluate[s] whether the claim as a whole integrates the recited judicial exception into a practical application of the exception.” *See* Revised Guidance 54. As the Revised Guidance further explains, “[a] claim that integrates a judicial exception into a practical application will apply, rely on, or use the judicial exception in a manner that imposes a meaningful limit on the judicial exception.” *Id.* Such practical application may be evidenced, for example, by “an additional element [that] implements a judicial exception with, or uses a judicial exception in

conjunction with, a particular machine or manufacture that is integral to the claim.” *Id.* at 55.

Beyond the limitations that the Examiner indicates include patent ineligible natural laws and abstract ideas, the Examiner determines that some of the other claimed steps recite only “routine laboratory procedures,” such as antibody assays. Final Act 3. Such “[r]outine data gathering,” the Examiner asserts, does not add any “meaningful limitation” to the claims. Final Act. 3. Other claim elements, the Examiner asserts are known. *Id.* (citing “known and conventional treatments for breast cancer including trastuzumab”); *see also, e.g.*, claim 47 (reciting administration of immunotherapy, including trastuzumab or bevacizumab).<sup>8</sup>

Appellants argue that the claims are not merely directed to naturally-occurring expression levels of Her2, Her2-ECD, pHER2, and cytokeratin. App. Br. 6. To the contrary, Appellants contend, “[t]he claims include specific hardware and structural limitations,” such as “an imaging device and an immunofluorescence biomarker assay,” which “render the subject matter as directed to more than just a natural correlation.” *Id.* at 7. According to Appellants, the claims require “a collection of analytic tools

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<sup>8</sup> The Examiner, in the Final Rejection on appeal as well as in the Answer, does not provide separate § 101 analysis for the dependent claims (or any separate response to Appellants’ arguments identifying certain limitations in the dependent claims that Appellants contend confer eligibility to those claims). *See, e.g.*, App. Br. 7, 9 (regarding “morphometric data acquisition tools” and “use of morphometric imaging devices,” as allegedly required for dependent claim 43).

specifically arranged and ordered to make practical use of measured biomarker data.” *Id.*

Moreover, Appellants argue, the claims require, *inter alia*, a “machine learning application” that “evaluate[s] the effects that the presence of multiple biomarkers within a population have on that population’s resistance to specific cancer treatments, using linear discriminant analysis on the population data to generate statistical models.” *Id.* at 9;<sup>9</sup> *see* claim 65 (“the machine learning application is configured to generate an effective treatment model using linear discriminant analysis . . .”). Then, Appellants contend, a machine learning application “evaluates the subject data [with the effective treatment model] and makes a determination that a subject with a cancer type, compared to previous subjects with the same cancer type, will derive a clinical benefit from a selected treatment.” *Id.* (“treatment is determined that has a high probability of effectiveness [i.e., excludes treatments where probability of resistance is above a given threshold]”); *see* claim 65. Although such steps may involve computer functionalities, Appellants contend, that does not doom the claims to abstraction (citing *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1338 (Fed. Cir. 2016) (“[W]e are not persuaded that the invention’s ability to run on a general-purpose computer dooms the claims.”)).

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<sup>9</sup> Although Appellants make some of these arguments in the context of whether the claims recite “significantly more” than the ineligible subject matter (i.e., *Alice*, Step 2; Revised Guidance Step 2B), Appellants’ arguments are also germane to *Alice* Step 1 and the Revised Guidance’s “integrated into a practical application” inquiry.

The Examiner responds that the claimed method fails to recite a practical application of a law of nature or natural phenomenon. Ans. 8–9. The Examiner asserts that the mathematically manipulated expression data that is processed is never applied to perform a physical step. *Id.* Moreover, the Examiner asserts, the complexity of the computer algorithm (i.e., analysis of multiplexed protein expression values) “does not render the manipulation of data on a computer any less abstract.” *Id.* at 9–10 (“the instant claims do not confine an abstract idea to a useful application because the claims do not recite administration of any specific cancer treatment based on any specific threshold biomarker value”).

Having considered the Examiner’s rejection and Appellants’ arguments in response, we conclude the claims are patent eligible because they include additional elements sufficient to integrate the judicial exception into a practical application.

As Appellants point out, claim 65 requires hardware and computing features that interoperate in specific ways to carry out the claimed method. Claim 65 requires “an immunofluorescence imaging device,” and further specifies that this imaging device is connected to a “computing device.” Claim 65 further requires an “image analysis device” that determines expression levels in the captured sample images. Even accepting *arguendo* that certain limitations such as “immunofluorescence” or antibody assays are routine or conventional (an inquiry generally addressed under Step 2B of the Revised Guidance), or merely “data gathering” as the Examiner asserts, claim 65 requires more than that.

Claim 65 requires the computing device and a machine learning application that are also configured to carry out specific operations in furtherance of generating an effective course of treatment for the subject with cancer. Those operations include, *inter alia*, calculating p95HER2 expression levels with the computer according to a particular function. The machine learning application, on the other hand, is configured to generate an effective treatment model using population data according to a specific statistical functionality (linear discriminant analysis) and relying on particular inputs (e.g., data for each member of the population taken at two different times, data values corresponding to treatment resistance and health outcomes, and both measured and derived protein expression levels for a plurality of biomarkers). Hence, as with the incorporation of particular “rules” in the claims of *McRO*, we find that the specific operations and inputs employed by the recited machine learning application in generating an effective treatment model impose meaningful limits to the claims beyond any judicial exception. *McRo, Inc. v. Bandai Namco Games America Inc.*, 837 F.3d 1299, 1315 (Fed. Cir. 2016).<sup>10</sup> Further, upon evaluation of the

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<sup>10</sup> In *McRO*, the court further observed that “[t]here has been no showing that any rules-based lip synchronization process must use rules with the specifically claimed characteristics.” *McRo*, 837 F.3d at 1315. As discussed, *infra*, concerning the rejection under § 102, the Examiner did not show on this record that generating treatment models with a machine learning application was known or conventional, nor that such a method would require the particular operations and inputs as claimed by Appellants here. To the extent certain inputs and operations may be characterized as broad, the Federal Circuit has noted that § 101 does not render claims reciting a “genus” of rules unpatentable. *Id.* at 1313 (indicating that breadth

measured and calculated subject dataset in relation to the effective treatment model generated by the machine learning application, the computing device includes programming (i.e., instructions) in the form of a treatment module to generate a course of treatment for the cancer subject—excluding ineffective treatments where resistance is probable.<sup>11</sup> The Examiner provides no support or authority for the notion that a “physical step,” outside the aforementioned hardware and specific computer operations/steps must be made in order to demonstrate a sufficient practical application of the invention claimed.

To be sure, some of the features recited in the claims invoke mathematics or require computer operations that might be characterized as abstract. That a claim may rely on or recite such patent-ineligible features is, however, unsurprising. Indeed, the Supreme Court has long recognized that all inventions, at some level, embody or apply laws of nature, natural phenomena, and abstract ideas and, thus, we must “tread carefully in

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of claim scope under such circumstances is principally addressed under § 112).

<sup>11</sup> Insofar as the Examiner suggests that the claims could be made more specific by identifying particular treatments and threshold values, the Examiner is correct. Ans. 9. For example, claim 65 might (as in some of the dependent claims) recite that the cancer type is breast cancer and that the therapy is administration of immunotherapy including trastuzumab and bevacizumab. *See, e.g.*, dependent claims 46, 47, and 54. Reciting, in the claims, more specific disease conditions and administration of specific agents may be a further indication of a practical application. *See, e.g., Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals*, 887 F.3d 1117, 1134 (Fed. Cir. 2018) (claims reciting administration of the drug iloperidine to the schizophrenic patient based on analysis of the patient’s genotype).

construing this exclusionary principle lest it swallow all of patent law.” *Alice*, 134 S. Ct. at 2354. To that end, as part of the analysis, we must neither overgeneralize the claim nor overemphasize limitations that might recite a natural law or an abstract idea dissected from the whole. *Id.*; *Thales Visionix Inc. v. U.S.*, 850 F.3d 1343, 1347 (Fed. Cir. 2017) (“[We] ensure at step one that we articulate what the claims are directed to with enough specificity to ensure the step one inquiry is meaningful”). We consider the claim elements individually *and as a whole*. And, when we consider claim 65 as a whole, including the series of orchestrated steps requiring specific interoperation of hardware and specially configured computing modules that generate effective treatment models and courses of treatment for cancer, we find, contrary to the Examiner’s conclusion, that the alleged ineligible subject matter is integrated into a practical application.

Having reached the decision above, we need not analyze claim 65 under Step 2B of the Revised Guidance or Step 2 of *Alice*. See Revised Guidance 51; *Thales*, 850 F.3d at 1349 (“Because we find the claims are not directed to an abstract idea, we need not proceed to step two”).

For the above reasons, we conclude that claim 65 (and dependent claims 39, 40, 42–44, 46–49, and 51–54) are not patent-ineligible under 35 U.S.C. § 101. We reach the same conclusion for claim 66 (and dependent claims 57–59), for similar reasons. Although claim 66 does not recite certain elements in claim 65 (e.g., “an immunofluorescence imaging device”), claim 66 includes other limitations that are more specific implementations than in claim 65 (e.g., Step (E) evaluating the subject dataset with the effective treatment model by identifying a hyperplane that

separates first and second classes of disease resistance). Moreover, as noted above, the Examiner provided no separate analysis under § 101 for any of the pending claims. *See supra* n.9.

## II – ANTICIPATION

The Examiner also rejected claims 39, 40, 42–44, 46–49, 51–54, 57–59, 65 and 66 as anticipated by Singh. Final Act. 7–9; Ans. 5–6. According to the Examiner, Singh teaches methods of screening breast cancer patient samples for expression levels and activation states of tumor proteins in the HER2 pathway. Ans. 4. Further, the Examiner finds, Singh teaches creating expression profiles for selection of appropriate therapy, such as trastuzumab therapy. *Id.* at 4–5. According to the Examiner, Singh teaches the measured proteins may include HER2, phosphorylated HER2, p95HER2, and cytokeratins, and that detection can occur using immunofluorescence. *Id.* at 5. Moreover, the Examiner finds, Singh teaches expression profiles that correspond to treatment outcomes “can be stored in a computer database.” *Id.* at 4–5.

Regarding “steps C-G of claim 65 and steps B-F of claim 66,” the Examiner asserts that such steps “are a mathematical manipulation of data and abstract idea where no physical steps occur, no material/structural limitations are recited, [and] therefore do not distinguish the instantly claimed method from that taught by the prior art.” *Id.* at 5–6.

On the record before us, we are unpersuaded that the Examiner has met the burden to show, by a preponderance of the evidence, that the appealed claims are anticipated by Singh. *In re Oetiker*, 977 F.2d 1443,

1445 (Fed. Cir. 1992) (The Examiner “bears the initial burden . . . of presenting a *prima facie* case of unpatentability.”).

As an initial matter, we note that the Examiner, after discussing what Singh allegedly describes, provides a single block cite identifying at least ten figures, eight examples, over ten tables, more than fifteen columns of text from Singh’s specification, and all sixty-five of Singh’s claims. From these myriad disclosures (including descriptions of several distinct embodiments), the Examiner does not clearly or sufficiently identify in Singh a cohesive anticipatory disclosure that meets all the limitations for each of the claims. To anticipate, “it is not enough that the prior art reference discloses part of the claimed invention, which an ordinary artisan might supplement to make the whole, or that it includes multiple, distinct teachings that the artisan might somehow combine to achieve the claimed invention.” *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1371 (Fed. Cir. 2008). Under these circumstances, the Board declines the Examiner’s invitation to piece together an anticipation rejection from those many and varied disclosures.

In addition to the above, the Examiner’s dismissal of several steps of the claims as allegedly including “mathematical manipulation of data and abstract idea[s]” is not warranted. Ans. 5–6. As Appellants point out, there is no authority or basis for the Examiner, in effect, ignoring such steps of the appealed method claims. App. Br. 14. Inasmuch as the Examiner contends that “Examiner did consider and address” those steps in the rejection, we are unpersuaded. Ans. 11–12. The Examiner responds that “[t]he computer provided by Singh et al reasonably comprises a ‘machine learning application’ and ability to perform or use mathematical analysis as claimed.”

*Id.* at 12. But the pending claims recite methods and require various computer elements operate or be configured to operate in particular ways. An ability for Singh's computer to be so configured (even assuming that's true) is not enough to establish anticipation. Singh also appears to merely disclose that results (i.e., suitability of certain drug treatments) may be recorded or stored in a computer. *See, e.g.*, Singh 24:1–12 (“the methods of the present invention may further comprise recording or storing the results of step (d) [determining whether the anticancer drug is suitable or unsuitable for the treatment of the breast tumor] in a computer database or other suitable machine or device for storing information, e.g., at a laboratory”). That does not describe all the computer functionalities and operations that are claimed, and the Examiner provides no sufficient and persuasive evidence otherwise.

For the above reasons, the anticipation rejection of claims 39, 40, 42–44, 46–49, 51–54, 57–59, 65 and 66 is reversed.

#### SUMMARY

We reverse the rejections for ineligible subject matter and anticipation on appeal.

REVERSED