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BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte COLIN CRAIG McCULLOCH, CHRISTOPHER J. SEVINSKY, and FIONA GINTY

Appeal 2017-008682
Application 13/252,069[1]
Technology Center 1600

Before DONALD E. ADAMS, MICHAEL J. FITZPATRICK, and RACHEL H. TOWNSEND, *Administrative Patent Judges*.

TOWNSEND, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a method of analyzing tissue features, which have been rejected as being directed to patent ineligible subject matter, as anticipated, and for obviousness-type double patenting.[2] We have jurisdiction under 35 U.S.C. § 6(b).

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[1] Appellants identify the real party in interest as the General Electric Company. (Appeal Br. 2.)

[2] We note that the subject matter of this application is similar to that of Application 13/252,078, which is the subject of Appeal No. 2017-002258 and which Appellants note is a related appeal (Appeal Br. 2). In a decision issued simultaneously herewith, we affirm the rejections of the claims on appeal in Appeal No. 2017-004722, as being both directed to patent ineligible subject matter and as being obvious. Appellants also note that Application 13/252,072 is related. (*Id.*) That application was the subject of

We affirm.

STATEMENT OF THE CASE

Studying tissue specimens using labelled antibodies or antibody surrogates as biomarkers is well known, including testing "for the "expression of numerous biomarkers." (Spec. ¶¶ 3, 5.) "The techniques of tissue treatment and examination have been refined so that the level of expression of a given biomarker in a particular cell or even a compartment of the given cell such as the nucleus, cytoplasm or membrane can be quantitatively determined." (*Id.* ¶ 4.) "Commonly the treated tissue is examined with digital imaging and the level of different signals emanating from different biomarkers can consequently be readily quantified." (*Id.*) Appellants' Specification explains that

> [t]he invention relates generally to analyzing and visualizing the expression of biomarkers in individual cells, wherein the cells are examined in situ in their tissue of origin, to identify and understand patterns of expression that have an association with a diagnosis, a prognosis, or a response to treatment of a condition or a disease.

(Spec. ¶ 2.)

Claims 1, 5–13, and 30 are on appeal.[3] Claim 1 is representative and reads as follows:

> 1. A method of analyzing tissue features based on multiplexed biometric image data comprising:
>
> obtaining a tissue sample from a patient;

Appeal No. 2016-001180, in which the Board affirmed the Examiner's rejection of the claims as being both directed to patent ineligible subject matter and as obvious.

[3] Claims 14–29 have been withdrawn from consideration. (Appeal Br. 2.)

applying a multiplexing staining and destaining technique to the tissue sample and generating two or more images of the tissue sample during the multiplexing staining and destaining, wherein the two or more images comprise image data representative of biomarker concentration levels and location in the tissue of a plurality of biomarkers;

registering the two or more images to generate one or more overlay images;

quantifying the biomarker concentration levels and location to create a cell profile;

storing the cell profile;

establishing an association of relative biomarker concentration levels and location with at least one field of view in which individual cells are delineated, based on subcellular markers, and segmented into cell compartments generating cell profile data;

calculating, from the cell profile data, at least one cell feature based on the concentration levels of each of the plurality of biomarkers for a respective cell, wherein the at least one cell feature comprises a ratio based on a respective concentration level of each biomarker between cell compartments;

calculating a first moment for each respective at least one cell feature for each respective at least one field of view; and

examining the calculated first moments for an association with a second data set, wherein the second data set comprises cell profile data generated from a plurality of tissue samples drawn from a cohort of patients having a commonality.

(Appeal Br. 10.)

The following grounds of rejection by the Examiner are before us on review:

Claims 1, 5–13, and 30 under 35 U.S.C. § 101 as being directed to non-statutory subject matter. (Ans. 5–7.)

Claims 1, 5–13, and 30 under pre-AIA 35 U.S.C. § 102(e) as being anticipated by Sarachan et al.[4] (Final Action 2–5.)

Claims 1, 5–13, and 30 provisionally on the ground of non-statutory double patenting as being unpatentable over claims 1–20, 41, and 42 of copending Application No. 13/252,078. (Final Action 6–7.)

DISCUSSION

I

Patent Ineligible Subject Matter

The Examiner finds that the following steps of claim 1 are directed to the following abstract ideas:

> creating and storing a cell profile; calculating from the cell profile data for a cell feature and moments based on such cell feature; examining the calculated moments from cell imaging data for an association with a second dataset, which comprises all profile data generated from a plurality of tissue samples drawn from a cohort of patients having a commonality.

(Ans. 5.) The Examiner explains that these steps are deemed abstract because they are directed to "data storage, data processing based on mathematical calculation, and comparing information regarding a sample to a control." (*Id.* at 6).

The Examiner then determines that the following claim limitations are not abstract: obtaining a tissue sample; applying a multiplexing staining and destaining technique to the tissue sample and generating two or more images of the tissue sample during the multiplexing staining and destaining. (*Id.*) The Examiner explains, however, that "[t]hese steps are performed for the

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[4] Sarachan et al., US 2011/0091081 A1, published Apr. 21, 2011.

purpose of gathering image data so that it may be processed to determine whether there is an association between said data and a known set of cell profile data." (*Id.*) With respect to those steps, the Examiner notes that they "consist of well understood, routine and conventional activity already engaged [in] by the scientific community." (*Id.*) The Examiner further explains that these additional steps when considered, as a whole, "add nothing significant beyond the sum of their parts taken separately." (*Id.*) The Examiner concludes that, in light of the foregoing, the claim is not significantly different than the abstract idea and, thus, is patent ineligible under 35 U.S.C. § 101. (*Id.*)

Appellants contend that claim 1 is not abstract because it improves an existing technological process just as was the case with the claims in *McRO Inc. v. Bandai Namco Games America Inc.*, 837 F.3d 1299 (Fed. Cir. 2016). (Reply Br. 4–5.) In particular, Appellants assert that the prior art is improved "by replacing the subjective judgment of a human with the objective judgment of algorithm going through a different process than the human would." (*Id.* at 5.) Appellants explain that in the prior art:

> the user did not have a rigorous approach for selecting the appropriate number of groups. *See* [Spec. ¶ 15.] Users may inadvertently group cells with important distinctive characteristics being grouped together. *See id.* As a result, the process was less accurate and "difficult for a medical practitioner to understand." *See id*, [¶ 16].

(*Id.*) Appellants then explain that by calculating first moments "for an association with a second data set . . . [that] comprises cell profile data generated from a plurality of tissue samples drawn from a cohort of patients having a commonality," "improve[s the] predictive properties for patient survival." (*Id.*)

We do not find Appellants' argument persuasive and agree with the Examiner's findings and conclusions that claim 1 is patent ineligible under 35 U.S.C. § 101.

Section 101 provides that "[w]hoever 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." 35 U.S.C. § 101. In *Alice*, the Supreme Court articulated a two-step test for examining patent eligibility under § 101. *Alice Corp. Pty. Ltd. v. CLS Bank Intern'l*, 134 S. Ct. 2347 (2014). Step one involves determining whether the claims at issue are directed to a patent ineligible concept, and step two, reached only if the determination in step one is yes, considers the elements of each claim both individually and "as an ordered combination" to determine whether additional elements "transform the nature of the claim" into a patent eligible application. *Id.* at 2355 (internal quotation marks and citation omitted).

Regarding Appellants' reliance on *McRO*, we note that the claims in that case "were directed to the creation of something physical—namely, the display of 'lip synchronization and facial expressions' of animated characters on screens for viewing by human eyes. [*McRO*, 837 F.3d] at 1313. The claimed improvement was to how the physical display operated (to produce better quality images)." *SAP Am., Inc. v. Investpic, LLC*, 898 F.3d 1161, 1167 (Fed. Cir. 2018); *see also Affinity Labs of Tex., LLC v. DirectTV, LLC*, 838 F.3d 1253, 1262 (Fed. Cir. 2016) (noting that the claims in *McRO* were held patent-eligible because they made "a specific asserted improvement in computer animation"). Here, on the other hand, as Appellants explain, the improvement is not to something physical or an

improvement in computer technology, but to the "predictive properties for patient survival" that is achieved by a mathematical technique. (Reply Br. 5.) We find that the claims here are much more similar to those in *SAP* than those in *McRO*, which were found to be patent ineligible.

One of the claims at issue in *SAP* was as follows:

> 11. A method for providing statistical analysis of investment data over an information network, comprising the steps of:
>
> (a) storing investment data pertaining to at least one investment;
>
> (b) receiving a statistical analysis request corresponding to a selected investment;
>
> (c) receiving a bias parameter, wherein the bias parameter determines a degree of randomness in a resampling process; and,
>
> (d) based upon investment data pertaining to the selected investment, performing a resampled statistical analysis to generate a resampled distribution.

898 F.3d at 1165. The *SAP* court explained that "[t]he focus of the claims, . . . [including claim 11 recited above,] . . . is on selecting certain information, analyzing it using mathematical techniques, and reporting or displaying the results of the analysis." *Id.* at 1167. The Court explained that under the principles set forth in prior cases, claims such as these are directed at unpatentable abstract ideas. In particular, the Court stated:

> We have explained that claims focused on "collecting information, analyzing it, and displaying certain results of the collection and analysis" are directed to an abstract idea. *Electric Power[Group, LLC v. Alstom S.A.]*, 830 F.3d . . . [1350,] 1353 [(Fed. Cir. 2016)]. "Information as such is an intangible," hence abstract, and "collecting information, including when limited to particular content (which does not change its character as information), [i]s within the realm of abstract ideas." *Id.* (citing cases). So, too, is "analyzing information . . . by mathematical algorithms, without more." *Id.* at 1354 (citing cases, including *Parker v. Flook*, 437 U.S.

> 584 . . . (1978), and *Gottschalk v. Benson*, 409 U.S. 63 . . . (1972)). And "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." *Id.* (citing cases).

SAP, 898 F.3d at 1167. The *SAP* court explained that "[t]he claims in *McRO* thus were not abstract in the sense that is dispositive here." *Id.* "Here, in contrast [to *McRO*], the focus of the claims is not a physical-realm improvement but an improvement in wholly abstract ideas—the selection and mathematical analysis of information, followed by reporting or display of the results." *Id.* at 1168. Here, as in *SAP*, the focus of claim 1 is not a physical-realm improvement, but an improvement in wholly abstract ideas—the selection and mathematical analysis of information. Thus, as in *SAP*, under *Alice* step-one, we conclude that present claim 1 is directed at an abstract idea.

Turning to *Alice* step-two, Appellants argue that "the claims specifically recite steps that are different from, further limit, and improve upon, well-understood, routin[e], and conventional activities," and, thus, the claims recite "'significantly more' than an abstract idea." (Reply Br. 7.) Appellants appear to rely on the arguments it makes as to why Sarachan does not anticipate claim 1. (*Id.*) However, we do not find that lack of anticipation establishes that claim 1 is directed to something significantly more than an abstract idea. *See, e.g.*, *SAP*, 898 F.3d at 1162 (citing *Synopsys, Inc. v. Mentor Graphics Corp.*, 839 F.3d 1138, 1151 (Fed. Cir. 2016) ("[A] claim for a *new* abstract idea is still an abstract idea. The search for a § 101 inventive concept is thus distinct from demonstrating § 102 novelty."). "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) (emphasis added). There can be no dispute that claim 1 uses a generic computer to perform generic computer functions: calculating and comparing data.

According to Appellants, "Sarachan does not disclose using any calculated moments [of the determined ratios] to examine any associations with another data set." (Appeal Br. 7.) However, that step is simply a mathematical calculation, which is an abstract idea. An innovation that consists of using particular ineligible subject matter is insufficient to establish that the claims at issue are directed to a patent-eligible application of an abstract idea. *SAP*, 898 F.3d at 1162 ("an advance . . . [that] lies entirely in the realm of abstract ideas, with no plausibly alleged innovation in the non-abstract application realm . . . is ineligible for patenting"); *see also Synopsys*, 839 F.3d at 1152

> (To the extent the Asserted Claims add anything to the abstract idea (i.e., translating a functional description of a logic circuit into a hardware component description of the logic circuit), it is the use of assignment conditions as an intermediate step in the translation process . . . . But, given that the claims are for a mental process, assignment conditions, which merely aid in mental translation as opposed to computer efficacy, are not an inventive concept that takes the Asserted Claims beyond their abstract idea.).

Appellants further argue that claim 1 prevents preemption because it recites "specific characteristics of one of multiple possible approaches to biological data analysis." (Reply Br. 6, 8.) This argument is not found persuasive either because "the absence of complete preemption does not demonstrate patent eligibility." *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*,

788 F.3d 1371, 1379 (Fed. Cir. 2015). Where a patent's claims are deemed only to disclose patent ineligible subject matter under the two-step framework, as they are in this case, preemption concerns are fully addressed and made moot. *Id.*; *see also Intellectual Ventures I LLC v. Symantec Corp.*, 838 F.3d 1307, 1321 (Fed. Cir. 2016) ("A narrow claim directed to an abstract idea, however, is not necessarily patent-eligible . . . ."); *OIP Techs., Inc. v. Amazon.com, Inc.*, 788 F.3d 1359, 1362–63 (Fed. Cir. 2015) ("[T]hat the claims do not preempt all . . . [inventions in the field] or may be limited to [certain processes in the field] do[es] not make them any less abstract.").

Finally, Appellants argue that because claim 1 "is tied to a particular machine or apparatus" that "points to patent eligibility." (Reply Br. 8.) This argument is not persuasive because the machine that stores data and performs the analytical processing is a general purpose computer, and the use of such a generic computer element does not transform an otherwise abstract idea into patent-eligible subject matter. *See, e.g.*, *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 US 66, 84–85 (2012) ("[S]imply implementing a mathematical principle on a physical machine, namely a computer, . . . [i]s not a patentable application of that principle.") (describing *Gottschalk*, 409 U.S. at 64); *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1256 (Fed. Cir. 2014) ("[A]fter *Alice*, there can remain no doubt: recitation of generic computer limitations does not make an otherwise ineligible claim patent-eligible . . . . The bare fact that a computer exists in the physical rather than purely conceptual realm is beside the point.") (Internal quotation marks and citation omitted.) Furthermore, as the Specification indicates, machines for obtaining a tissue sample; applying a multiplexing staining and destaining technique to the tissue sample and

generating two or more images of the tissue sample during the multiplexing staining and destaining were known at the time of filing. (*See, e.g.*, Spec. ¶¶ 3–14.) Appellants do not assert that the machines used to gather the images for the data analysis are new or non-obvious. Thus, these limitations do not imbue the claim with an inventive concept. *Accord Berkheimer v. HP Inc.*, 881 F.3d 1360, 1370 (Fed. Cir. 2018) (holding claims lacked an inventive concept because they "amount to no more than performing the abstract idea of parsing and comparing data with conventional computer components"); *Affinity Labs*, 838 F.3d at 1262 (holding a claim lacked an inventive concept because it "simply recites the use of generic features . . . as well as routine functions . . . to implement the underlying idea").

Consequently, for all of the reasons discussed above, we sustain the Examiner's rejection of claim 1 under 35 U.S.C. § 101 as being directed to non-statutory subject matter.

Claims 5–13, and 30 have not been argued separately and, therefore, fall with claim 1. 37 C.F.R. § 41.37(c)(1)(iv).

II

Anticipation

The Examiner finds that Sarachan discloses a method

> that involves capturing data on the expression of biomarkers within the compartments of individual cells located within their tissue of origin, preserving this data on a cell by cell basis, analyzing this data to reveal pattern of expression, creating subsets of cells based on these patterns, visualizing the occurrence of these subsets on images of the tissues of origin and analyzing the occurrence of certain biomarkers in the subsets of cells for association to the diagnoses or prognoses of a condition or disease or to the response of treatment.

(Final Action 3.) The Examiner finds that Sarachan's method of analyzing the data involves "quantifying the biomarker concentration levels and location of said biomarkers to create a cell profile" and "calculating at least one cell feature based on the cell's expression of each of the plurality of biomarkers ([0037]-[0038]); calculating a first moment for each of the at least one cell feature for each of the at least one field view; and examining the calculated first moments for an association with second data set." (*Id.* at 3–4.) The Examiner contends that a second data set can be "of any sort, possibly an expression level of a biomarker" and that in carrying out the process described in Sarachan a person of "ordinary . . . [skill] in the art would look at the data including the calculated moment and a second data set . . . and think about whether there is any type of association." (Ans. 8–9.) The Examiner notes that "[w]hile grouping cells for having similar profiles, one would examine the calculated data and decide, either in one's mind or by running an algorithm, if there is an association between the data such that the cells may be grouped." (*Id.* at 9.)

Appellants contend that while Sarachan discloses determining ratios, it does not disclose "determining first moments of the ratios" and then using the first moment to find an association with a second data set step required by the claims. (Appeal Br. 6–7.) Instead, Appellants explain, Sarachan uses the ratio to group cells, and after having been grouped "a mean value of the attribute in the group may be determined." (*Id.*)

We agree with Appellants that Sarachan does not disclose examining the calculated first moments of ratios for an association with a second data set. Sarachan's general disclosure of creation of a database describes first moments may be calculated for biomarker measures obtained, i.e., "[t]he

data for a given biomarker across all the cells examined may not follow a distribution which readily lends itself to standard statistical treatment." (Sarachan ¶ 41.) Thus, the data set may be transformed using first moment determination. (*Id.*) Sarachan explains that the transformed "database may now be interrogated for groups of cells that have similar profiles of biomarker expression." (*Id.*) Sarachan notes that the cells can be grouped using the first moment data and a ratio between the expression level of two biomarkers but does not describe obtaining a first moment of the ratio. (Sarachan ¶ 43.) Example 1 of Sarachan describes a specific embodiment of data assessment in which intensity values were first standardized and then groups were created by using ratios. (Sarachan ¶¶ 59–63.) The ratios were then analyzed for an association with cells from controls or treated samples. (Sarachan ¶ 64.) We do not find any express disclosure in Sarachan examining the calculated first moments of ratios for an association with a second data set. Nor do we find that Sarachan's disclosure necessarily and inevitably discloses such an examination as required to establish an inherent disclosure. *In re Oelrich*, 666 F.2d 578, 581 (CCPA 1981) ("Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.") (Internal citation omitted.)[5]

For the reasons discussed, we do not sustain the Examiner's rejection of claim 1 as being anticipated by Sarachan. Because claims 5–13 and 30

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[5] We do not determine, here, whether such an analysis of the data would have been obvious from the disclosure of Sarachan, because that is not the rejection made by the Examiner.

ultimately depend from claim 1, we also do not sustain the Examiner's rejection of these claims as being anticipated by Sarachan.

III

Obviousness-Type Double Patenting

Appellants have not substantively argued the propriety of the non-statutory double patenting rejection made by the Examiner. (*See* Appeal Br. 4.) Consequently, we summarily affirm the Examiner's non-statutory double patenting rejection.

SUMMARY

We affirm the rejection of claims 1, 5–13, and 30 under 35 U.S.C. § 101 as being directed to non-statutory subject matter.

We reverse the rejection of claims 1, 5–13, and 30 under pre-AIA 35 U.S.C. § 102(e) as being anticipated by Sarachan et al.

We affirm the rejection of claims 1, 5–13, and 30 provisionally on the ground of non-statutory double patenting as being unpatentable over claims 1–20, 41, and 42 of copending Application No. 13/252,078.

TIME PERIOD FOR RESPONSE

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

AFFIRMED