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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

Ex parte JÖRG J. GORONZY and CORNELIA M. WEYAND¹

Appeal 2015-000312
Application 13/231,282
Technology Center 1600

Before JOHN G. NEW, TAWEN CHANG, and JOHN E. SCHNEIDER,
Administrative Patent Judges.

NEW, *Administrative Patent Judge.*

DECISION ON APPEAL

SUMMARY

Appellants file this appeal under 35 U.S.C. § 134(a) from the Examiner's Non-Final Rejection of claims 1 and 4–8 as unpatentable under 35 U.S.C. § 101 as being directed to non-statutory subject matter

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

We AFFIRM.

¹Appellants state the real party-in-interest is Board of Trustees of the Leland Stanford Junior University. App. Br. 2.

NATURE OF THE CLAIMED INVENTION

Appellants' invention is directed to compositions and methods for the diagnosis and treatment of rheumatoid arthritis. Abstract.

REPRESENTATIVE CLAIM

Independent claim 1 is representative of the claims on appeal and recites:

1. A method for determining the predisposition of a patient that has shown symptoms of rheumatoid arthritis for increased risk of development overt rheumatoid arthritis, the method comprising:

(i) determining the expression of one or both of B-Raf and K-ras in a cell population comprising T cells obtained from said patient to provide a determination of expression levels;

(ii) comparing the determination of expression levels obtained in step (i) with a determination of expression levels of one or both of B-Raf and K-ras of a normal control cell population; and

(iii) providing a determination of a predisposition of the patient to increased risk of development of overt rheumatoid arthritis when the comparing of step (ii) shows increased expression of one or both of B-Raf and K-ras relative to the normal control cell population.

App. Br. 15.

We agree with, and adopt, the Examiner's findings and conclusion that the appealed claims are unpatentable as being directed to non-statutory subject matter. We address below the arguments raised by Appellants.

ISSUE

Appellants argue that the Examiner erred in concluding that the claims are directed to non-statutory subject matter because the steps recited in the

claims are not sufficient to ensure the claim amounts to significantly more than a law of nature and the general instruction simply to “apply it.” App. Br. 3.

ANALYSIS

Appellants argue that their claimed invention is distinguishable from that which the Supreme Court held unpatentable in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289 (2012). App. Br. 3–5. According to Appellants, in *Mayo* the Court held that the claims in question involved well-understood, routine, conventional activity previously engaged in by researchers in the field, and that the claims disproportionately tied up the use of the underlying natural laws.² *Id.* at 4. In contrast to the

² The representative claim in *Mayo* recites:

A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6–thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6–thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6–thioguanine less than about 230 pmol per 8×10^8 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6–thioguanine greater than about 400 pmol per 8×10^8 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

Mayo, 132 S.Ct. at 1295.

comparing and providing steps of Appellants' claims on appeal, Appellants assert, the final clauses of the *Mayo* claim (the "wherein" clauses) were not integrated into the claim and therefore did not apply, rely on, or use any natural principle. *Id.*

Specifically, Appellants argue, the "wherein" clauses of the *Mayo* claim contained the phrase "indicates a need to," which allegedly does not actually require anything of the one performing the method and instead simply stated the law of nature itself. App. Br. 5. Appellants contend that this lack of integration was critical because the "wherein" clauses therefore provided no actual limitations to the claims and the only steps that were limiting (steps (a) and (b)) were routinely carried out in the art, in the same order, in the same patient population, and for the same purpose. *Id.*

In contrast to the Court's findings in *Mayo*, Appellants argue, the claims of the instant appeal integrate all the steps of the claimed method. App. Br. 6. Appellants assert the "providing a determination" step specifies that when performing the method, one determines the predisposition of a patient by determining the expression of B-Raf and/or K-ras in a cell population from the patient, comparing that expression to expression from normal control cells, and determining that there is a predisposition to increased risk of development of overt rheumatoid arthritis when the comparing step shows increased expression in the cells from the patient relative to control cells. *Id.* Appellants argue the claims on appeal are distinguishable from the claims in *Mayo* because the comparing and providing steps are explicitly integrated into the claim as a whole, thus providing limitations that one would perform when practicing the method. *Id.*

Appellants further contend that the pending claims are a clear and useful patent eligible application of any asserted natural principle. App. Br. 6. Appellants assert that a method that includes a step of providing a patient with a determination of whether they have a predisposition to increased risk of development of overt rheumatoid arthritis is an a useful, real-world application that has major implications for how that person will subsequently live. *Id.*

Appellants next point to the twelve factors used to determine the eligibility of subject matter under 35 U.S.C. §101, as set forth by the Office in its *Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products*, March 4, 2014. App. Br. 6. We have reviewed Appellants' analysis of these factors, but we find them neither persuasive nor properly reflective of current law or the USPTO's analysis protocols on subject matter eligibility, as set forth by the Director in the *2014 Interim Guidance on Patent Subject Matter Eligibility*, December 10, 2014, and subsequently updated in 2015 and 2016 (the "Interim Guidance").

As an initial matter, we agree with the Examiner that the limitations of the claims on appeal, as exemplified by claim 1, are analogous to the claims at issue in *Mayo* and, consequently, dictate the same outcome. *See* Ans. 5. Specifically, the instant claims are directed to determining the elevated levels of expression of B-Raf and K-ras that indicate a predisposition to increased risk of development of overt rheumatoid arthritis. Appellants do not dispute that this is a phenomenon of nature, i.e., that it occurs naturally in the body. As in *Mayo*, the claims on appeal require an assay to detect the phenomenon and a treatment based upon the outcome of that assay, i.e.,

“determining the expression of one or both of B-Raf and K-ras in a cell population comprising T cells obtained from said patient.” Appellants do not argue that the assay is separately novel and their Specification discloses that such assays are well known in the art. *See Spec.* ¶¶ 53–62.

Consequently, we apply the two-part test set forth in the Interim Guidance for claims involving phenomenon of nature. *See Interim Guidance* 9–25; 35–37. First, we look to whether the claims on appeal are directed to a statutory category. In this instance, we conclude that they are: the claims are explicitly directed to a method or process. Next, we determine whether the claims are directed to a judicially-created exception, in this instance, a natural law or phenomenon of nature. Although the claims require a non-novel assay to determine the phenomenon, the phenomenon itself, elevated levels of expression of B-Raf and K-ras by T-cells, occurs naturally in patients with a disposition to increased risk of development of overt rheumatoid arthritis. *See Spec.* ¶¶ 8–10; *see also* Ans. 12. Consequently we find that the claims are directed to a phenomenon of nature and therefore falls within one of the judicially-created exceptions.

Having determined that the claims are directed to a phenomenon of nature, we look to the claim as a whole to determine whether any element, or combination of elements, is sufficient to ensure that the claim amounts to significantly more than the exception. *See Interim Guidance* 36. The “assay” step refers to the activities of the relevant audience, *viz.*, physicians who treat patients with a predisposition to developing rheumatoid arthritis. The claims direct these physicians to the recited proteins which, when expressed at elevated levels in T-cells, are associated with a predisposition to development of overt rheumatoid arthritis. *See Spec.* ¶¶ 4–11. The

audience is a pre-existing audience and is certainly well established; moreover, the assays recited in the claims are well known in the art and can be routinely performed. *Id.* The “identifying” step tells the doctor to determine whether T-cell expression of B-Raf and K-ras is elevated compared to a control group.

Therefore, as in *Mayo*, the claims inform a relevant audience about a certain phenomenon of nature (specifically here, a correlation between elevated T-cell expression of B-Raf and K-ras in patients with a disposition to increased risk of development of overt rheumatoid arthritis), and the additional steps of the claims consist merely of “well understood, routine, conventional activity already engaged in by the scientific community.” *Mayo*, 32 S.Ct. at 1298; *see Spec.* ¶¶ 4–11. These steps, when viewed as a whole, add nothing significantly inventive beyond the sum of their parts taken separately. The claims therefore do not amount to significantly more than the natural law itself and we consequently affirm the Examiner’s rejection.

Furthermore, our reviewing court has recently explained:

In recent cases, we found claims “directed to” a patent-ineligible concept when they amounted to nothing more than observing or identifying the ineligible concept itself. For example, in *Genetic Technologies*, the claim recited methods for detecting a coding region of DNA based on its relationship to non-coding regions. *Genetic Techs., Ltd. v. Merial L.L.C.*, 818 F.3d at 1369, 1373–74 (Fed. Cir. 2016). Because the relationship between coding and non-coding sequences was a law of nature, the claim amounted to nothing other than identifying “information about a patient’s natural genetic makeup.” *Id.* at 1375. Likewise in *Ariosa*, the claims recited methods for detecting paternally inherited cffDNA in the blood or serum of a pregnant female. *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1373–74 (Fed. Cir. 2015),

cert. denied, No. 15–1102, — U.S. —, 136 S.Ct. 2511, — L.Ed.2d —, 2016 WL 1117246 (June 27, 2016). The existence and location of cffDNA is a natural phenomenon; identifying its presence was merely claiming the natural phenomena itself. *Id.* at 1376. And in *In re BRCA*, the claims recited methods for screening human germline for an altered BRCA1 gene by comparing the target DNA sequence with wild-type sequence. *In re BRCA1– & BRCA2–Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755, 761–62 (Fed. Cir. 2014). But comparing two sequences to detect alterations is a patent-ineligible “abstract mental process.” *Id.* at 763. Although the claims in each of these cases employed method steps, the end result of the process, the essence of the whole, was a patent-ineligible concept.

Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc., 827 F.3d 1042, 1048 (Fed. Cir. 2016).

In the appeal presently before us, the relationship between elevated expression of B-Raf and K-ras and an increased disposition to develop overt rheumatoid arthritis is a natural phenomenon and the claimed invention consists of nothing more than observing or identifying the non-eligible natural phenomenon. As such, although this relationship may perhaps be a discovery, it is not a patentable invention. We consequently affirm the Examiner’s rejection of the claims as being directed to non-statutory subject matter.

DECISION

The Examiner’s rejection of claims 1 and 4–8 as unpatentable under 35 U.S.C. § 101 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)(1). *See* 37 C.F.R. § 1.136(a)(1)(iv).

Appeal 2015-000312
Application 13/231,282

AFFIRMED