2019 PAT. APP. LEXIS 9982

Patent Trial and Appeal Board

October 28, 2019, Decided

Appeal 2019-003328 ; Application 15/282,562 [1] ; Technology Center 1600

USPTO Bd of Patent Appeals & Interferences; Patent Trial & Appeal Bd Decs.

Reporter
2019 PAT. APP. LEXIS 9982 *

Ex parte SCOTT EASTMAN and ERIC SASSO

Notice:

[*1] ROUTINE OPINION. Pursuant to the Patent Trial and Appeal Board Standard Operating Procedure 2, the opinion below has been designated a routine opinion.

Core Terms

biomarkers, concentrate, disease, natural law, patent, statistically, correlate, regimen, recite, therapeutic, inflammatory, subject matter, corresponding, patient, teach, laws of nature, autoimmune, diagnose, marker, practical application, method of treatment, arthritis, additional element, ordinary skill, patent-eligible, diagnostic, ineligible, clinical, juvenile, routine

Panel: Before ULRIKE W. JENKS, RACHEL H. TOWNSEND, and MICHAEL A. VALEK, Administrative Patent Judges.

Opinion By: RACHEL H. TOWNSEND

Opinion

TOWNSEND, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under *35 U.S.C.* § 134 involving claims to a method for treating a subject having juvenile idiopathic arthritis, which have been rejected as being directed to patent ineligible subject matter and as being obvious. We have jurisdiction under *35 U.S.C.* § 6(b).

We affirm.

STATEMENT OF THE CASE

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[1] We use the word "Appellant" to refer to "Applicant" as defined in 37 C.F.R. § 1.42. Appellant, Crescendo Bioscience, which is a wholly owned subsidiary of Myriad Genetics, Inc. identifies itself as the real party in interest. (Appeal Br. 3.)

Appellant's Specification states that Juvenile Idiopathic Arthritis (JIA) "is the most common rheumatic disease affecting children and adolescents." (Spec. P 4.) Appellant's Specification also notes that "[p]resentation, severity, and course of disease vary widely, from a benign self-limiting course, to severe, unremitting disease resulting in progressive joint destruction, skeletal deformity, growth retardation, possible blindness, and long-term disability." (*Id.*) The Specification further states that "[n]o existing single biomarker or multi-biomarker test produces results demonstrating a high association with level of JIA disease activity." (*Id.* P 7.) Appellant's invention is directed at "using the biomarkers to measure disease activity in a subject." (*Id.* P 8; *see also* PP 9-12, P 35 ("The present teachings relate generally to diagnostic applications of biomarkers associated with subjects having inflammatory and/or autoimmune diseases, such as for example JIA, and that are useful in determining or assessing disease or flare activity.").) The Specification does not provide for any particular method of treatment for JIA other than to assess biomarkers prior to any treatment. (*Id.* P 12.)

Claims 1, 2, **[*2]** and 4-8 are on appeal. [2] Claim 1 is representative and reads as follows:

> 1. A method for treating a subject having juvenile idiopathic arthritis (JIA) the method comprising:
>
> providing a test sample comprising a sample of bodily fluid taken from the mammal;
>
> determining a sample concentration for a combination of three or more biomarkers selected from the group comprising C-reactive protein (CRP); epidermal growth factor (EGF); interleukin 6 (IL-6); leptin (LEP); matrix metalloproteinase-1 (MMP1); matrix metalloproteinase-3 (MMP3); resistin (RETN); serum amyloid (SAA); tumor necrosis factor receptor, type 1 (TNF-R1); vascular cell adhesion molecule-1 (VCAM1); vascular endothelial growth factor A (VEGF-A); and YKL-40;
>
> determining whether the sample concentration is statistically significantly greater than a combination of concentrations of corresponding control biomarkers that are indicative of JIA; and
>
> administering a JIA therapeutic regimen if the sample concentration is statistically significantly greater than the combination of concentrations **[*3]** of corresponding control biomarkers.

(Appeal Br. 18.)

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

Claims 1, 2, and 4-8 under *35 U.S.C.* § 101 as being directed to patent-ineligible subject matter.

Claims 1, 2, 4-6, and 8 under *35 U.S.C.* § 103(a) as unpatentable over Cavet. [3]

Claim 7 under *35 U.S.C.* § 103(a) as unpatentable over Cavet and Shimizu. [4]

DISCUSSION

Patent Ineligible Subject Matter

The Examiner finds that claims 1, 2, and 4-8 are directed to a natural law:

> The relationship between concentrations of IL-6, MMP-3 and YKL-40, or a combination thereof, in a subject and the presence or absence of JIA is a natural law.

(Final Action 5).

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[2] Claims 10-20 remain pending but are withdrawn from consideration as being directed to a non-elected invention. (Final Action 2.)

[3] Cavet et al., US 2011/0137851 A1, published June 9, 2011.

[4] Shimizu et al., *Distinct subsets of patients with systemic juvenile idiopathic arthritis based on their cytokine profiles*, 61 Cytokine 345-348 (2013).

The Examiner notes that the method of treatment is dependent upon the diagnostic steps of determining the concentrations of the biomarkers and assessing whether the concentration is statistically significantly greater than controls which are indicative of JIA. (*Id.*) The Examiner notes that methods of determining these biomarkers in samples were known in the art. (*Id.* at 5-6.)

The Examiner finds that no specific treatment protocol is recited in the claims **[*4]** and that "[t]reatment after diagnosis is a routine and obvious step in the medical arts; thus the claim, as amended, adds only a conventional step [recited at a high degree of generality] and nothing significantly different than the judicial exception." (*Id.* at 6-7.)

Appellant does not argue the claims separately. We analyze claim 1 as representative. We agree with the Examiner's factual findings and conclusion that claim 1 is directed to patent ineligible subject matter.

35 U.S.C. § 101 defines patent-eligible subject matter. The Supreme Court has carved out exceptions to what would otherwise appear to be within the literal scope of § 101. *Alice Corp. Pty. Ltd. v. CLS Bank Int'l, 573 U.S. 208, 216 (2014)*. One of these exceptions are claims "directed to" laws of nature. *Id.* This appeal involves the law of nature exception to patent eligibility under section 101.

The Supreme Court has established a two-step framework for "distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts." *Id. at 217*. "First, we determine whether the claims at issue are directed to" a patent-ineligible concept. *Id.* If so, "we consider the elements of each claim both individually and 'as **[*5]** an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application." *Id.* (quoting *Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 78-79 (2012)*).

The United States Patent and Trademark Office (PTO) issued the *2019 Revised Patent Subject Matter Eligibility Guidance* ("Guidance"), indicating how the PTO would analyze patent eligibility under the Supreme Court's two-step framework. *84 Fed. Reg. 50-57 (January 7, 2019)*. Applying the Guidance, we agree with the Examiner that the pending claims are directed to patent ineligible subject matter.

STEP 2A, Prong One:

Under the Guidance, in determining what concept a claim is "directed to" in step one of the Supreme Court's two-step framework, we first look to whether the claim recites any judicial exceptions, such as a law of nature. Guidance, 84 Fed. Reg. at 52, 54 (Step 2A, Prong One).

In *Mayo*, the Supreme Court found that a claim was directed to a natural law, where the claim required administering a drug and determining the levels of a metabolite following administration, where the level of metabolite was indicative of a need to increase or decrease the dosage of the drug. *Mayo, 566 U.S. at 74*; *Athena Diagnostics, Inc. v. Mayo Collaborative Servs. LLC, 915 F.3d 743, 750, 753-54 (Fed. Cir. 2019)* (noting that detecting the presence of a label in a method for diagnosing neurotransmission or developmental disorders related to MuSK comprising contacting labeled MuSK with a bodily fluid, immunoprecipitating **[*6]** any antibody/MuSK labeled complex, monitoring for the label, and noting the presence of the label is indicative of a neurotransmission or developmental disorder related to MuSK, involves "the correlation between the presence of naturally-occurring MuSK autoantibodies in bodily fluid and MuSK-related neurological diseases" that "exists in nature apart from any human action.").

Appellant does not dispute that claim 1 involves a natural law. (*See, e.g.*, Appeal Br. 8 ("Appellant submits that the claims under appeal are patent eligible because the claims recite the application of a therapeutic regimen.").) The claim requires comparing the sample concentration biomarkers against concentrations of corresponding control biomarkers that are indicative of JIA and "determining whether the sample concentration is statistically significantly greater" than the control and thus indicative of JIA or not significantly greater and thus not indicative of JIA. This "determining" step recites a natural law, i.e., the correlation between the concentration of certain naturally occurring compounds, which are the biomarkers, and the presence of JIA.

STEP 2A, Prong Two:

Having made the determination that claim 1 recites a **[*7]** natural law, under the Guidance, we next examine whether there are additional elements *beyond* the natural law that integrates the judicial exception into a practical application. Under the Guidance, this is referred to as the "Prong Two" inquiry under "Step 2A." Guidance, 84 Fed. Reg. at 54-55. That is, under the Prong Two analysis we look to whether the claim as a whole "appl[ies], rel[ies] on, or use[s] the judicial exception in a manner that imposes a meaningful limit on the judicial exception." *Id.*

The additional steps here include the data gathering to determine the levels of biomarkers in a test sample and compare the levels to a control. The Specification does not indicate any particular method of determining is required; rather it explains that this determination can be done by immunoassay or clinical chemistry to assess the presence and concentration of the biomarkers. (Spec. PP 10, 11, 105.) The determination of the statistical significance of the amount of the biomarker as compared to control also is not required to be by a particular method. Many methods are described in the Specification. (*See, e.g.*, PP 72-78.) As our reviewing court has explained application of "conventional techniques to detect [the] . . . **[*8]** natural law" are not a particular application of the natural law. *See* Athena, 915 F.3d at 751. Similar to the "determining" step in *Mayo*, here the first "determining" step tells the person performing the method to determine the concentration of biomarkers through whatever process that person wishes to use. *See* Mayo, 566 U.S. at 79. The second "determining" step, which is an identification of the correlation, simply notes that a particular conclusion can be drawn in light of the correlation: "rather like Einstein telling linear accelerator operators about his basic law and then trusting them to use it where relevant." *Id. at 78*.

Limitations that are indicative of integration into a practical application can include the particular application of a natural law to effect a particular treatment or prophylaxis for a disease or medical condition. *See, e.g.,* VandaPharms. Inc. v. West-Ward Pharms. Int'l Ltd., 887 F.3d 1117, 1134-35 (Fed. Cir. 2018). While Appellant's claim is purportedly a method of treatment, as the Examiner explains, the method steps do not require that a treatment be administered. (Ans. 9.) That is, "[t]he skilled artisan is directed to do nothing if the concentration of the combination of biomarkers is not statistically significantly greater than a combination of control biomarker concentrations." (*Id.* at 10 (emphasis omitted).) In particular, the claim requires "determining a sample concentration for a combination" of particular biomarkers, and "determining whether the sample concentration is statistically significantly greater than a combination of concentrations of corresponding control biomarkers that are indicative of JIA." The administration of a JIA therapeutic regimen is only a required step "if the sample concentration is statistically significantly greater than the combination of concentrations of corresponding control biomarkers." (Appeal Br. 18 (Claim 9).) Consequently, under certain scenarios the claimed method merely results in detection of the biomarker and no action is to be taken based on the information ascertained in the detection of the natural correlation. In other words, if a certain condition precedent is not met, the additional step of administering a treatment is not performed. Indeed, Appellant agrees that such is the case stating:

> the appealed claims **[*9]** **apply** the relationship of the biomarker expression levels by instructing a skilled artisan whether or not to treat with a JIA therapeutic regimen based on whether the sample concentration is statistically significantly greater than a combination of control biomarker concentrations.

(Appeal Br. 9.) [5]

[5] In its Reply Brief, Appellant contends that claim 1 does not encompass the lack of treatment because the preamble of the claim states a "method for treating." (Reply Br. 3.) However, the preamble "expression does not result in a manipulative difference in the steps of the claim" and is thus deemed to be only a statement of purpose and intended result. Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc., 246 F.3d 1368, 1376 (Fed. Cir. 2001). Appellant's additional argument in the Reply Brief that one of ordinary skill in the art would interpret claim 1 at issue to encompass only treatment being performed on confirmed high risk patients (Reply Br. 2-3) is belied by the claim language which requires administration of a therapeutic only "if the sample concentration is statistically significantly greater than the combination of concentrations of corresponding control biomarkers."

This is similar to claims in *Ex parte Schulhauser*, Appeal No. 2013-007847 (PTAB Apr. 28, 2016) (precedential), where the Board concluded that **[*10]** in a method claim where the additional steps need only be performed if certain conditions precedent were met, the claim covered the method where the additional steps need not be performed. We conclude that this principle applies to claim 1 on appeal here. As such, like the claims found patent-ineligible in *Mayo*, Appellant's claim involves acquiring information to observe the natural law, but do not require any particular use of the acquired information to, e.g., alter a patient's condition. Mayo, 566 U.S. at 79-80 (claims ineligible where they merely "tell doctors to gather data from which they may draw an inference in light of the correlations").

Appellant argues that "there is doubt that *Schulhauser* is readily applied outside the 'context of both method claims and system claims' in the electronic/mechanical arts." (Reply Br. 5.) We disagree. The legal issue as to the broadest reasonable construction of claims that include conditional language addressed in *Schulhauser* is not limited by or to a particular technology. The analysis is universally applicable: conditional limitations in a method claim are not limiting under a broadest reasonable interpretation, because the claim covers at least two possibilities--one in which **[*11]** the condition is satisfied and one in which the condition is not satisfied.

Second and apart from the fact that treatment is not always required by the claim, to the extent treatment is administered because "the sample concentration is statistically significantly greater than the combination of concentrations of corresponding control biomarkers," there is no *particular* treatment required. The Guidance suggests that a claim including "an additional element that applies or uses a judicial exception to *effect a particular treatment or prophylaxis* for a disease or medical condition" would be a practical application. Guidance, 84 Fed. Reg. at 55 (citing *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659F.3d 1057, 1066-68 (Fed. Cir. 2011); and Vanda, 887 F.3d at 1135) (emphasis added). On the other hand, the Guidance also suggests that a claim including "[a]n additional element [that] merely recites the words 'apply it' (or an equivalent) with the judicial exception," does not integrate the judicial exception into a practical application. *Id.* (citing Alice, 573 U.S. at 222-26; Gottschalk v. Benson, 409 U.S. 63 (1972); and Credit Acceptance Corp. v. Westlake Servs., 859 F.3d 1044 (Fed. Cir. 2017). *See also* Mayo, 566 U.S. at 72, 81 (claiming a law of nature or natural phenomenon and also reciting steps that must be taken to apply the laws in question is not patent-eligible); *October 2019 Update: Subject Matter Eligibility* at 14 (October 18, 2019), available at https://www.uspto.gov/sites/default/files/documents/peg_oct_2019_update.pdf ("October 2019 Guidance Update").

Here, the claim says to administer **[*12]** a JIA therapeutic regimen "if the sample concentration is statistically significantly greater than the combination of concentrations of corresponding control biomarkers." That language, on its face, does not require the use or application of the natural law to effect the therapeutic regimen chosen. And even if the claim were interpreted to recite a regimen based on the natural correlation between the markers and JIA, the administering step is stated at such a high level of generality, we conclude that it is merely the equivalent of an instruction to apply it. Thus, claim 1 does not apply or use the natural correlation to "effect a particular treatment or prophylaxis." *See* October 2019 Guidance Update at 14.

The level of generality stands in contrast to the claims found patent-eligible in cases like Vanda and Natural Alternatives Int'l v. Creative Compounds LLC, 918 F.3d 1338, 1345 (Fed. Cir. 2019). The claims at issue in *Vanda* that were found *not* to be directed to a law of nature, but to a method of treatment, required performing one of two specific therapies for schizophrenia with specific daily doses of iloperidone based on a patient's genetic disposition. Id. at 1134 (holding that claims including a limitation of genotyping to determine if a patient is a CYP2D6 poor metabolizer and then administering a drug in either case **[*13]** but in certain amounts depending upon whether the patient is or is not a CYP2D6 poor metabolizer). The Federal Circuit characterized the *Vanda* claims as being directed to "a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome." Vanda, 887 F.3d at 1136.

In *Natural Alternatives*, the Federal Circuit explained that the method claims at issue "contain a dosage limitation by virtue of the 'effective' limitation" and

> [t]he claims not only embody this discovery [that administering certain quantities of beta-alanine to a human subject alters that subject's natural state to produce greater levels of creatine which results in specific

> physiological benefits for athletes engaged in certain intensive exercise,] they require that an infringer actually administer the dosage form claimed in the manner claimed, altering the athlete's physiology to provide the described benefits.

918 F.3d at 1344, 1346. Appellant's claim 1 is not directed to a specific method of treatment using a specific compound at a specific dose based on the natural law. Thus, the claimed method is not a practical application of the natural law.

Furthermore, we find, as the Examiner did, that considering the steps **[*14]** of claim 1 together as an ordered combination adds nothing to the law of nature that is not already present when the steps are considered separately. We conclude, therefore, that the claims do not recite additional elements that integrate the exception into a practical application of that exception. The process steps here merely tell those "interested in the subject about the correlations that the researchers discovered." *Mayo, 566 U.S. at 78*.

STEP 2B

Step 2B requires that we look to whether the claim "adds a specific limitation beyond the judicial exception that [is] not 'well-understood, routine, conventional' in the field." (*See* MPEP § 2106.05(d) (9th ed., rev. 08.2017 (Jan. 2018)).). The Examiner found, and Appellant does not dispute, that determining the concentrations of the biomarkers at issue in samples was known in the art. (Final Action at 5-6 (citing references).) The Examiner further found, and Appellant does not dispute, that "[t]reatment after diagnosis is a routine and obvious step in the medical arts." (*Id.* at 6.)

Based on the foregoing, therefore, we conclude that claim 1 is directed to a judicial exception without significantly more, and therefore, is not eligible for patent protection.

Claims 2 and 4-8 have not been argued separately and therefore fall with claim 1. *37 C.F.R. § 41.37(c)(1)(iv) (2017)*.

II

Non-Obviousness

In response to a restriction requirement, Appellant elected the biomarkers IL6, MMP3, and YKL-40 for examination. (Final Action 2.) The Examiner finds that Cavet teaches a method of measuring inflammatory disease activity by measuring the levels of at least two biomarkers, including IL6, MMP3, and YKL-40, **[*15]** in a sample and comparing the levels to constituent levels of those markers in samples and making a clinical assessment thereon. (*Id.* at 9.) The Examiner explains that "[t]he disease activity to be measured may include juvenile idiopathic arthritis [paragraph 0105]." (*Id.*) The Examiner also finds that Cavet teaches that using multiple serum biomarkers "are necessary for the accurate clinical assessment of disease activity in subjects [paragraph 0014]." (*Id.*) The Examiner further finds that

> [t]he reference discloses that measurement of the biomarkers would aid in accurately classifying subjects by disease activity, in order to establish their optimal treatment regimen [paragraph 0009], thus suggesting a therapeutic regimen would follow diagnosis of JIA.

(*Id.*) The Examiner concludes that one of ordinary skill in the art would have found it obvious to modify Cavet to include assaying for the elected biomarkers with a reasonable expectation of success "because the reference teaches that such a method is successful in diagnosing an inflammatory disease such as JIA, and one would be aware that measuring additional biomarkers would provide useful diagnostic information." (*Id.* at 10.)

The Examiner further explains that while the "[e]xamples presented deal with diagnosis and treatment of rheumatoid arthritis" (RA), the art demonstrates that the symptoms presented in JIA and RA are similar and the treatment regimens (including NSAID therapy and methotrexate) are similar. (Ans. 15-17.) Thus, according to the Examiner "one of ordinary skill, aware of the **[*16]** success in utilizing the markers to diagnose and plan a

treatment regimen to treat rheumatoid arthritis, would be motivated to apply methods taught by Cavet to diagnose and treat JIA." (*Id.* at 17.)

Appellant argues that Cavet mentions JIA once in a paragraph defining autoimmune disease where JIA is mentioned as one of thirty-seven autoimmune disorders, and does not "describe[] any sort of success in diagnosing an inflammatory disease or even administering a JIA therapeutic." (Appeal Br. 13.) Appellant further argues that "Cavet does not describe the use of the recited biomarkers to identify individuals with JIA." (*Id.* at 15.) Thus, according to Appellant "[t]here is simply no indication whatsoever, not even in the definition of an autoimmune disorder in Cavet, that indicates to a skilled artisan any success of the presently claimed invention." (*Id.* at 13.) Appellant further explains that the prior art references the Examiner cites to for establishing the similarity of JIA and RA do not "provide knowledge sufficient to select particular biomarkers disclosed in Cavet, which are used for RA, to be used in a method for treating JIA." (Reply Br. 7.) The Appellant argues that the similarity of symptoms and treatment therapeutics does not help to predict *a priori* a specific group of biomarkers from Cavet that would be useful in identifying JIA and treating that inflammatory disease. (*Id.* at 7-8.) In particular, Appellant notes that "NSAIDS, which include aspirin and ibuprofen, are also used as analgesics and antipyretics, and methotrexate is also used for psoriasis" which Appellant urges establishes that the "superficial level of fact finding does not predict a biomarker solution and does not justify prima facie obviousness." (*Id.* at 9.)

We agree with Appellant that the Examiner has failed to establish a prima facie case of obviousness as to the elected invention. We agree with the Examiner that Cavet is not limited to its preferred embodiment (Ans. 14-15), which includes methods of diagnosing RA disease activity so as to provide appropriate and optimized treatment for patients (Cavet PP 4, 9, 14). However, we agree with the Appellant that the mere similarity of symptoms of disease and overlap of treatment modalities does not establish a reasonable expectation of selecting the specific biomarkers claimed as relevant **[*17]** to an assessment of JIA. (Appeal Br. 7-8.)

That is because Cavet teaches that, even as to RA,

> [d]eveloping biomarker-based tests (e.g., measuring cytokines), e.g. specific to the clinical assessment of RA, has proved difficult in practice because of the complexity of RA biology--the various molecular pathways involved and the intersection of autoimmune dysregulation and inflammatory response.

(Cavet P 13.) The Examiner has not established with any evidence that RA and JIA, which both involve arthritic conditions with autoimmune etiologies or components (Ans. 15), share any of the same or similar biochemical pathways in their autoimmune dysregulation and inflammatory response.

Cavet only discloses that the DAIMRK group of biomarkers is a set of biomarkers that is "strongly associated with inflammatory disease, and especially RA, when used in particular combinations." (Cavet P 174.) Moreover, regarding the "Biological Significance of the DAIMRK Group of Markers," Cavet teaches that

> [t]he methodology employed in selecting the DAIMRK biomarkers thus resulted in a set of markers especially useful in quantifying RA disease activity, by providing the clinician with a unique and **[*18]** broad look at RA disease biology.

(*Id.* P 177.) And, while a diversity of pathways are represented, that diversity is relevant to RA and "the clinical assessment of individual subjects, despite the heterogeneity of the pathology of the disease assessed." (*Id.* P 176.) In other words, the DAIMRK biomarkers are specific to RA and there is no teaching of how one of ordinary skill in the art would know which of those markers would reasonably correlate to JIA. While it may be the case that one of ordinary skill in the art could have used the "Model Development Process" described in Cavet (*id*. PP 181-188) to assess what biomarkers are relevant to JIA, that the described process would be promising to try does not establish obviousness. *In re Kubin, 561 F.3d 1351, 1359 (Fed. Cir. 2009)* (identifying two categories of obvious-to-try situations that do not equate to prima facie obviousness under § 103: when what was "obvious to try" was (a) to vary all parameters or try every available option until one succeeds, where the prior art gave no indication of critical parameters and no direction as to which of many possibilities is likely to be successful; or (b) to explore a new technology or general approach in a seemingly promising field of experimentation, where the prior art gave only general guidance as to the particular form or method of achieving the claimed invention.); *In re Eli Lilly & Co., 902*

F.2d 943, 945 (Fed. Cir. 1990) ("An 'obvious-to-try' situation exists when a general disclosure may pique the scientist's curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claimed result would be obtained if certain directions were pursued.").

There is no particular combination of disclosed biological markers in Cavet that is noted to be associated with JIA. Picking one of a finite number of known solutions to a known problem is obvious. KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 421 (2007): That is not the case here. Consequently, even though Cavet generically suggests a genus of biomarkers from the DAIMRK biomarkers from which to select at least two biomarkers in a diagnostic method for inflammatory disease that completely overlaps the biomarkers claimed (Cavet PP 15, 19), we do not agree with the Examiner that Cavet provides a reasonable expectation that any combination of these biomarkers or any other biomarkers from the DAIMRK genus would reasonably be expected to have a correlation to diagnosing JIA.

Thus, we reverse the Examiner's rejection of claims 1, 2, 4-6, and 8 as being obvious over Cavet.

The Examiner's rejection of claim 7 over Cavet and Shimizu does not rectify the problem discussed above regarding claim 1. Thus, we also reverse the Examiner's rejection of claim 7 as being obvious over Cavet and Shimizu.

CONCLUSION

In summary:

Claims Rejected	35 U.S.C. §	Reference(s)/Basis	Affirmed	Reversed
1, 2, and 4-8	101	Eligibility **[*19]**	1, 2, and 4-8	
1, 2, 4-6, and 8	103	Cavet		1, 2, 4-6, and 8
7	103	Cavet and Shimizu		7
Overall Outcome				1, 2, and 4-8

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

USPTO Bd of Patent Appeals & Interferences; Patent Trial & Appeal Bd Decs.

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