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Patents

Subject Matter Eligibility for Biotechnology Patents in the United States

BY Z. YING LI AND SIEW YEN CHONG

The U.S. patent law permits the patenting of a ''new and useful process, machine, manufacture, or composition of matter'' and any related ''new and useful improvement.'' 35 U.S.C. § 101 (''Section 101''). But that broad provision is constrained by legal precedents set by the Supreme Court and lower federal courts. The Supreme Court has held that laws of nature, natural phenomena, and abstract ideas are not patent-eligible subject matter, but their novel and useful applications are. *See, e.g.*, *O' Reilly v. Morse*, 56 U.S. 62, 112-120 (1853); *Am. Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1 (1931); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948); *Diamond v. Diehr*, 450 U.S. 175 (1981); and *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). How to distinguish a patent-ineligible law of nature from a patent-eligible application thereof, however, is a challenging task for courts and patent practitioners alike.

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This paper provides an overview on the current legal landscape on this issue with respect to biotechnology patents, especially in the field of personalized medicine (''PM''). As discussed below, a number of patents claiming methods of diagnosis or prognosis using biomarkers have been invalidated under Section 101 in recent years. However, some recent legal developments suggest that all is not lost for PM inventions. We believe that the courts and the U.S. Patent and Trademark Office (USPTO) have begun to finesse their approaches to subject matter eligibility after the seemingly sweeping Supreme Court decisions in *Mayo*, *Myriad*, and *Alice*. With careful consideration and skillful drafting, patent claims to PM inventions can pass the patent-eligibility test under Section 101.

I. The Supreme Court's Two-Step Test for Subject Matter Eligibility

In 2012, the Supreme Court addressed patent eligibility in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. 66 (2012), and set forth a two-part analysis for assessing patent eligibility.

The Prometheus patents litigated in *Mayo* claimed methods of optimizing therapeutic efficacy of a drug that would metabolize to 6-thioguanine (6-TG). The

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methods included the steps of (1) administering the drug to a patient and (2) determining the level of 6-TG in the patient, wherein the level indicated whether a physician should adjust the dosage of the drug accordingly. *See* Appendix. A unanimous Court held that these methods were not patent-eligible subject matter.

In the first part of its analysis, the Court noted that the Prometheus claims set forth a law of nature, namely, the relationship between a drug's metabolite levels and its efficacy. *Mayo*, 566 U.S. at 77 (''[t]he relation is a consequence of the way in which thiopurine compounds are metabolized by the body—entirely natural processes. And so, a patent that describes that relation sets forth a natural law.'').

In the second part of its analysis, the Court asked whether the Prometheus claims ''do significantly more than simply describe these natural relations.'' *Id.* The Court answered this question in the negative. It found that the administering step, the determining step, and the subsequent dosage reconsideration in light of the metabolite level ''add nothing specific to the laws of nature other than what is *well-understood, routine, conventional activity, previously engaged by those in the field*.'' *Id*. at 82 (emphasis added). The Court held that as a result, the Prometheus claims did not claim patent-eligible subject matter.

Notably, the Court made a comment, albeit in passing, on the distinction between the Prometheus patents and other biotechnology patents: ''Unlike, say, a typical patent on a new drug or a new way of using an existing drug, the patent claims do not confine their reach to particular applications of those laws.'' *Id.* at 87. Many legal scholars and practitioners consider this comment as the Court's attempt at providing some assurance on the patentability of ''typical'' biopharma inventions.

II. The Federal Circuit's Application of the *Mayo* Test

Since the *Mayo* decision, the Court of Appeals for the Federal Circuit (CAFC) has applied the *Mayo* two-part test to biotechnology patents on multiple occasions. (CAFC decisions related on natural substances such as *Myriad* and its progeny are not discussed herein). In most cases, the Court found the challenged patents to be invalid under Section 101. *See, e.g., Cleveland Clinic Foundation v. True Health Diagnostics LLC, 859 F.3d 1352* (Fed. Cir. 2017); *Genetic Techs., Ltd. v. Merial LLC*, 818 F.3d 1369 (Fed. Cir. 2016), *cert. denied*, 137 S. Ct. 242 (2016); *In re BRCA1-and BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755 (Fed. Cir. 2014). A high-profile case is *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015), *cert. denied*, 136 S. Ct. 2511 (2016).

In *Ariosa*, the CAFC found that a method of screening paternally inherited cell-free fetal DNA (cffDNA) present in a pregnant woman's serum was not patent-eligible subject matter. *See* Appendix. First, the CAFC determined under the *Mayo* Step 1 analysis that the claims at issue were directed to a natural phenomenon—paternally inherited cffDNA is naturally present in the maternal blood stream. *Id.* at 1376. Next, the CAFC proceeded with the *Mayo* Step 2 analysis, i.e., asking whether ''the elements of each claim both individually and 'as an ordered combination' . . . 'transform the nature of the claim into a patent-eligible application' '' of the natural phenomenon. *Id.* at 1375 (citation omitted). The CAFC noted that amplifying and analyzing DNA using PCR was ''well-understood, conventional and routine'' and concluded that the claims were thus directed to patent-ineligible subject matter. *Id.* at 1377.

The *Ariosa* decision was surprising to many in the biotechnology industry and in the patent bar: The invention was considered groundbreaking in neonatal screening and yet it could not be protected by a patent.

After a slew of decisions in which the CAFC found biotechnology patents to be directed to patent-ineligible subject matter, the innovator community breathed a collective sigh of relief when the Court paused that trend in *Rapid Litigation Management Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042 (Fed. Cir. 2016).

In *Rapid Litigation*, the inventors of the patent in suit discovered that a fraction of hepatocytes are capable of surviving multiple freeze-thaw cycles. The patent claimed a method of producing cryopreserved hepatocytes based on this discovery. *See* Appendix. In performing the *Mayo* Step 1 analysis, the Court characterized the claimed process as ''directed to'' a new and useful laboratory technique and not to a natural law. In particular, the Court stated:

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. . . . The same is not true here. . . . The . . . claims are like thousands of others that recite processes to achieve a desired outcome, e.g., *methods of producing things, or methods of treating disease*. That one way of describing the process is to describe the natural ability of the subject matter to undergo the process does not make the claim ''directed to'' that natural ability. If that were so, we would find patent ineligible methods of, say, producing a new compound . . ., treating cancer with chemotherapy . . . , or treating headaches with aspirin. *Id.* at 1048-49 (emphasis added).

In its *Mayo* Step 2 analysis, the *Rapid Litigation* Court stated that:

It is true that, at step two, a claim that recites only ''well-understood, routine, conventional activity already engaged in by the scientific community'' will not be patent eligible. . . . That is not to say, however, that all process claims that employ only independently known steps will be unpatentable. To the contrary, in examining claims under step two, we must *view them as a whole,* considering their elements ''both individually and as *an ordered combination*.'' *Id.* at 1051 (citation omitted; emphasis added).

Thus, unlike diagnostic or prognostic methods whose innovative aspect resides in the discovery of a natural phenomenon such as a biomarker, the CAFC appears to favor methods of producing and preparing things, which involve transformative steps. By that token, methods of treatment, which also involve transformative steps (improving the health of patients), may be received more favorably than pure methods of diagnosis or prognosis as well. (As used herein, methods of diagnosis or prognosis refer to the use of biomarkers for diagnosis or prognosis, where the methods do not involve any unique and/or new technical steps or tools.)

In the most recent CAFC decision on subject matter eligibility, where the diagnostic methods were held invalid under Section 101, the method-of-treatment claims were not challenged under Section 101. *Cleveland*, *supra*. It remains to be seen how the CAFC will analyze PM treatment claims under Section 101. It is

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worth noting that Judge Dyk made the following remarks with regard to personalized medicine: ''Singling out a particular subset of patients for treatment (for example, patients with a particular gene) may reflect a new and useful invention that is patent eligible despite the existence of prior art or a prior art patent disclosing the treatment method to patients generally.'' *Prometheus Labs. v. Roxane Labs*, 805 F.3d 1092, 1099 (Fed. Cir. 2015). Although this comment was made in the context of an obviousness analysis, it is reasonable to argue that a treatment method that is not obvious under Section 103 also should pass muster under Section 101 because an unobvious method cannot be ''routine'' or ''conventional.''

III. Lower Courts' Application of the *Mayo* Test

The district courts have applied the *Mayo* two-step analysis in many cases. The outcomes of these cases vary and are highly fact-specific. However, there appears to be a continuous trend that methods of diagnosis or prognosis are found patent ineligible, while method claims reciting treatment steps may be found patent eligible. In this section, we discuss three cases that are informative as to how the district courts may analyze claims related to biomarkers.

In *Esoterix Genetic Laboratories LLC v. Qiagen, Inc.*, 133 F. Supp. 3d 349 (D. Mass. 2015), the claims at issue were directed to a method of determining efficacy of gefitinib or erlotinib on cancer patients by screening for certain EGFR gene variants. *See* Appendix. The U.S. District Court for the District of Massachusetts found those claims to be invalid under the *Mayo* analysis. In particular, the Court noted that the claims were directed to a natural law—the correlation between certain EGFR mutations and a patient's responsiveness to EGFR tyrosine kinase inhibitors—and that the drugs recited in the claims were ''well-known'' and ''conventional.'' *Id.* at 358-9.

By contrast, the U.S. District Court for the District of Delaware came to a different conclusion in another genotyping case. *Vanda Pharmaceuticals, Inc. v. Roxane Laboratories, Inc.*, 203 F. Supp.3d, 412 (D. Del. 2016). In that case, the claims at issue were directed to a ''method of treating a patient'' by genotyping the patient and based on the result, giving the patient the schizophrenia drug iloperidone at a specific dosage of 12 mg/day. *See* Appendix. While acknowledging that the claims ''depend upon laws of nature,'' the Court nonetheless held that ''the claims incorporate some additional step sufficient to transform the claims, making them valid.'' *Id.* at 428-29. Specifically, the Court noted that the dosage step applied only to a subpopulation of genotyped patients and in a highly specified way, and that the process of using this genetic test to inform the dosage adjustment recited in the claims was ''*not routine or conventional*.'' *Id.* at 429. Citing *Rapid Litigation*, the Court stated that ''*a particular combination of steps can lead to valid patent claims that depend upon a natural relationship*.'' *Id.* (internal quotation marks omitted; emphasis added).

Interestingly, the district court judge presiding over *Vanda* recently ruled against several treatment patents under 35 U.S.C. § 101.
Mallinckrodt Hosp. Prods. IP Ltd. v. Praxair Distrib., Inc.,
No. 15-170-GMS, 2017 BL 311273 (D. Del. Sep. 5, 2017).
In *Mallinckrodt*, the patents in suit were directed to methods of treating patients in need of inhaled nitric oxide (iNO) by first determining whether the patients have left ventricular dysfunction (LVD), and then treating only those not having LVD and excluding those with LVD, as LVD increases the risk of pulmonary edema from the treatment. *See* Appendix. The Court found that every step in the claims—diagnosing LVD and administering iNO (a commonly used vessel dilator) at the previously recommended pressure of 20 ppm—were ''routine'' and ''conventional.'' The Court held that the novel realization that patients with LVD should not receive iNO treatment, while valuable, was not worthy of patent protection. *Id.* at *17-18.

One reason that accounts for the different outcomes between *Vanda* and *Mallinckrodt* may be that the treatment steps in *Vanda* had elements (specific dosages) that made the steps less ''routine'' and ''conventional,'' whereas the *Mallinckrodt* claims were much more general. The divergent outcomes in the two cases illustrate the highly fact-specific nature of Section 101 analysis. But overall, it appears that claims directed purely to methods of diagnosis or prognosis have a high rate of failure under Section 101 in district courts.

IV. The USPTO's Application of the *Mayo* Test

The Patent Trial and Appeal Board (PTAB) at the USPTO has also issued a number of decisions on the Section 101 issue in the biotechnology area. Some of the applications at issue claimed methods of using biomarkers to stratify patient populations; and the Board held that those claims failed under *Mayo* because the recited treatment steps in the claims were well known and routine and did not add significantly more to the natural law recited in the claims. *See, e.g., Ex Parte Gleave*, No. 2013-009646, 2016 BL 297687 (P.T.A.B. Aug. 30, 2016); *Ex Parte Van Criekinge*, No. 2015-002378, 2016 BL 324969 (P.T.A.B. Sept. 22, 2016); *Ex Parte Atwood*, No. 2015-001611, 2016 BL 266197 (P.T.A.B. Aug. 16, 2016); *Ex Parte Axtell*, No. 2015-00156, 2016 BL 408396 (P.T.A.B. Nov. 30, 2016).

These biomarker decisions, however, appear to run contrary to the USPTO's May 2016 guidelines on subject matter eligibility of life sciences patent applications (''Guidelines''). The portion most relevant to biomarker inventions in the Guidelines is Example 29 (''Diagnosing and Treating Julitis''). In the hypothetical fact pattern of this Example, julitis, a fictitious disease, is conventionally treated with anti-TNF antibodies; but for unknown reasons, some patients do not respond well to this treatment. The fictitious inventor has discovered that JUL-1 is a reliable biomarker for julitis and can accurately separate patients who truly have julitis and are therefore responsive to conventional anti-TNF treatment from patients who are misdiagnosed as having julitis and therefore do not respond to anti-TNF treatment.

A sample claim in this Example is directed to a treatment method based on this discovery:

6. A method of diagnosing and treating julitis in a patient, said method comprising:

a. obtaining a plasma sample from a human patient;

b. detecting whether JUL-1 is present in the plasma sample;

c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected; and

d. administering an effective amount of anti-tumor necrosis factor (TNF) antibodies to the diagnosed patient.

The Guidelines indicate that this hypothetical claim would be found patent eligible under Section 101. The Guidelines explain that while the claim depends on a natural law—the correlation of biomarker JUL-1 and the disease julitis—and each step was well known and routine, the claim as a whole is patent eligible because the *combination of the diagnosis and treatment steps is ''not routine and conventional*.''

The analysis of this Example is similar to that in *Rapid Litigation*, which was decided two months after the issuance of the Guidelines. Both focus on the analysis of the *combination of claim elements*, rather than looking at each claim element individually and determining whether each element itself was well-known, routine, and conventional. Thus, this Example will provide helpful guideposts to patent applicants for charting the territory of Section 101 for their biomarker inventions.

V. Outlook for the Patentability of Biomarker Inventions

Based on our analysis of case law, recent PTAB decisions, and the USPTO Section 101 Guidelines, we are of the view that inventions relying on the discovery of a biomarker (e.g., a certain genotype) may be eligible for patents if the claims to them are carefully drafted. Besides reciting the biomarker, the claims should include additional claim elements that transform the natural phenomenon to a patent-eligible application thereof.

Our analysis of the current legal landscape indicates that method claims reciting a biomarker relationship may be patentable under Section 101 if they also recite claim elements that are not ''well known, routine, and conventional.'' For method-of-treatment claims, this can be achieved by, for example, reciting a drug that has not yet been widely used or known (e.g., not yet approved by the Food and Drug Administration). This also can be achieved by reciting specific elements that limit the treating step, for example, dosing regimen (*see Vanda*). The recitation of a specific drug, formulation, or dosing regimen may help assuage any concern of a court or a patent examiner that a broad claim reciting a biomarker relationship would potentially preempt the entire field from relying on this relationship and preclude others from treating patients identified by these biomarkers, even though the treatment uses different drugs.

Appendix: List of Court and PTAB Decisions

Case
Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 661 (2012)
Patent/Application at Issue
U.S. Pat. 6,355,623 (exemplary)
Representative Claim
1. 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 $8x10^8$ 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 $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.
Court/PTAB Holding
invalid

Case
Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371 (Fed. Cir. 2015)
Patent/Application at Issue
U.S. Pat. 6,258,540
Representative Claim
1. A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises
amplifying a paternally inherited nucleic acid from the serum or plasma sample and
detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.
Court/PTAB Holding
invalid

Case
Rapid Litigation Management Ltd. v. CellzDirect, Inc., 827 F.3d 1042 (Fed. Cir. 2016)
Patent/Application at Issue
U.S. Pat. 7,604,929
Representative Claim
1. A method of producing a desired preparation of multi-cryopreserved hepatocytes, said hepatocytes being capable of being frozen and thawed at least two times, and in which greater than 70% of the hepatocytes of said preparation are viable after the final thaw, said method comprising:
(A) subjecting hepatocytes that have been frozen and thawed to density gradient fractionation to separate viable hepatocytes from nonviable hepatocytes,
(B) recovering the separated viable hepatocytes, and
(C) cryopreserving the recovered viable hepatocytes to thereby form said desired preparation of hepatocytes without requiring a density gradient step after thawing the hepatocytes for the second time, wherein the hepatocytes are not plated between the first and second cryopreservations, and wherein greater than 70% of the hepatocytes of said preparation are viable after the final thaw.
Court/PTAB Holding
not invalid

Case
Esoterix Genetic Laboratories LLC v. Qiagen, Inc.,133 F.Supp.3d 349 (D. Mass. 2015)
Patent/Application at Issue
U.S. Pat. 7,294,468
Representative Claim
1. A method for determining an increased likelihood of pharmacological effectiveness of treatment by gefitinib or erlotinib in an individual diagnosed with non-small cell lung cancer comprising:
obtaining DNA from a non-small cell lung cancer tumor sample from the individual; and
determining the presence or absence of at least one

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nucleotide variance in exon 18, 19, or 21 of the epidermal growth factor receptor (EGFR) gene in the DNA,
wherein the presence of at least one nucleotide variance selected from:
1) An in-frame deletion in exon 19 of the EGFR gene consisting of a deletion within codons 746 to 753 that results in amino acid changes comprising a deletion of at least amino acids leucine, arginine, and glutamic acid at position 747, 748, and 749 of SEQ ID NO:512;
2) A substitution in exon 21 that results in an amino acid change consisting of a substitution of arginine for leucine at position 858 (L858R) of SEQ ID NO:512, or a substitution in exon 21 that results in an amino acid change consisting of a substitution of glutamine for leucine at position 861 (L861Q) of SEQ ID NO:512; or
3) A substitution in exon 18 that results in an amino acid change consisting of a substitution of cysteine for glycine at position 719 (G719C) of SEQ ID NO:512
indicates an increased likelihood of pharmacological effectiveness of treatment by gefitinib or erlotinib in the individual.

Court/PTAB Holding
invalid

Case
Vanda Pharmaceuticals, Inc. v. Roxane Laboratories, Inc., 203 F.Supp.3d 412 (D. Del. 2016)

Patent/Application at Issue
U.S. Pat. 8,586,610 (exemplary)

Representative Claim
1. A method for treating a patient with iloperidone, wherein the patient is suffering from schizophrenia, the method comprising the steps of:
determining whether the patient is a CYP2D6 poor metabolizer by: obtaining or having obtained a biological sample from the patient; and performing or having performed a genotyping assay on the biological sample to determine if the patient has a CYP2D6 poor metabolizer genotype; and
if the patient has a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient in an amount of 12 mg/day or less, and
if the patient does not have a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient in an amount that is greater than 12 mg/day, up to 24 mg/day,
wherein a risk of QTc prolongation for a patient having a CYP2D6 poor metabolizer genotype is lower following the internal administration of 12 mg/day or less than it would be if the iloperidone were administered in an amount of greater than 12 mg/day, up to 24 mg/day.

Court/PTAB Holding
not invalid

Case
Mallinckrodt Hosp. Prods. IP Ltd. v. Praxair Distrib., Inc., No. 15-170-GMS, 2017 BL 311273 (D. Del. Sep. 5, 2017)

Patent/Application at Issue
U.S. Pat. 8,795,741 (exemplary)

Representative Claim
1. A method of treating patients who are candidates for inhaled nitric oxide treatment, which method reduces the risk that inhalation of nitric oxide gas will induce an increase in pulmonary capillary wedge pressure (PCWP) leading to pulmonary edema in neonatal patients with hypoxic respiratory failure, the method comprising:
(a) identifying a plurality of term or near-term neonatal patients who have hypoxic respiratory failure and are candidates for 20 ppm inhaled nitric oxide treatment;
(b) determining that a first patient of the plurality does not have left ventricular dysfunction;
(c) determining that a second patient of the plurality has left ventricular dysfunction, so is at particular risk of increased PCWP leading to pulmonary edema upon treatment with inhaled nitric oxide;
(d) administering 20 ppm inhaled nitric oxide treatment to the first patient; and
(e) excluding the second patient from treatment with inhaled nitric oxide, based on the determination that the second patient has left ventricular dysfunction, so is at particular risk of increased PCWP leading to pulmonary edema upon treatment with inhaled nitric oxide.

Court/PTAB Holding
invalid

Case
Ex Parte Gleave, 2016 BL 297687 (P.T.A.B. 2016)

Patent/Application at Issue
Application 12/423,359

Representative Claim
6. A method for treating cancer in a patient diagnosed as suffering from cancer comprising the steps of:
(a) obtaining a sample of cancerous tissue from the patient;
(b) evaluating the sample of cancerous tissue to determine an expression level of functional phosphatase and tensin homologue deleted from chromosome 10 (PTEN); and
(c) in the case where the expression level of functional PTEN is below a threshold level, administering to the patient a therapeutic composition comprising as an active agent a composition effective to inhibit the expression of heat shock protein 27 (hsp27).

Court/PTAB Holding
not patentable

Case
Ex Parte Van Criekinge, 2016 BL 324969 (P.T.A.B. 2016)

Patent/Application at Issue
Application 12/303,153

Representative Claim
1. A method comprising:
(a) performing an assay on a test sample containing colorectal cells or nucleic acids from colorectal cells from a subject with adenoma, wherein the assay assesses if epigenetic silencing of at least one gene selected from the group consisting of NM_145059.1, NM_183244.1, NM_145341.2, NM_080672.3, NM_002630, NM_003383, NM_005504, NM_016269, NM_006988, NM_021637, NM_001888, NM_014899 NM_145341, NM_001752, NM_014142, NM_01145, NM_016013, NM_017590, NM_152429, NM_138340, NM_052968, NM_183244, NM_199423, NM_015111, NM_002181, NM_005637, NM_030790, NM_018144, NM_004232, NM_030912, NM_145059, NM_033338, NM_006834, NM_003014, NM_001343, NM_000963, NM_004385, and NM_002899 has occurred;
(b) identifying the subject with adenoma as needing colorectal cancer treatment where the assay detected epigenetic silencing in step (a); and
(c) selecting an appropriate therapeutic-treatment strategy for the subject with adenoma identified in step (b) when epigenetic silencing of at least one gene from step (a) is detected, wherein selecting the appropriate therapeutic treatment strategy comprises administering a

treatment regime is selected from the group consisting of: endoscopic polypectomy or resection, chemotherapy, and radiation.

Court/PTAB Holding

not patentable

Case

In Ex Parte Atwood, 2016 BL 266197 (P.T.A.B. 2016)

Patent/Application at Issue

Application 13/691,048

Representative Claim

42. A method for administering treatment to a patient at risk for developing Alzheimer's disease (AD) or a patient diagnosed with AD, wherein the patient is homozygous or heterozygous for an Apolipoprotein E4 (APOE4) allele, the method comprising:

(a) treating a sample from the patient with reagents that detect a single nucleotide polymorphism (SNP) ... consisting of ... rs4073366 ...; and

(b) administering AD treatment to the patient if ... the patient is determined to be homozygous for the cytosine allele (C-allele) or the patient is determined to be homozygous for the guanine allele (Gallele) at the polymorphic position of rs4073366 ....

Court/PTAB Holding

not patentable

Case

Ex Parte Axtell, 2016 BL 408396 (P.T.A.B. 2016)

Patent/Application at Issue

Application 13/026,181

Representative Claim

1. A method for assessing prognosis for responsiveness of a human multiple sclerosis patient to an IL-17 inhibitor, comprising:

analyzing a blood sample from said patient with an antibody-based assay for the presence of IL-17F and IL-7 to provide a quantitative dataset for IL-17F and IL-7 to detect whether altered levels of IL-17F and IL-7 relative to a control are present;

assessing responsiveness to an IL-17 inhibitor by comparing the quantitative dataset for IL-7 and IL-17F to a control dataset, wherein increased levels of IL-17F and decreased levels of IL[-]7 relative to a control indicates that the patient is responsive to an IL-17 inhibitor; and

providing to the multiple sclerosis patient an assessment of the prognosis for responsiveness to an IL-17 inhibitor.

14. The method of claim 1, further comprising administering an IL-17 inhibitor to a patient assessed as a responder to IL-17 inhibitors.

Court/PTAB Holding

not patentable

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