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ON JANUARY 13, 2020 THE U.S. SUPREME COURT ORDERED AS FOLLOWS:

- THE GOOD

  DENIED CERT IN *HIKMA V. VANDA*, LETTING FEDERAL CIRCUIT RULING STAND

- THE BAD

  YET IT WOULD NOT TAKE UP*ATHENA V. MAYO* (OR ANY OTHER CASE) TO CLARIFY 35 U.S.C. §101 LAW

- THE UGLY

  APPLICATION OF 101 LAW REMAINS MURKY, AT LEAST IN THE BIOTECH AND PHARMA AREAS

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I. *Hikma V. Vanda*

The Federal Circuit held that patent claims directed to methods of treatment are patent eligible, even if the claims involve "personalized medicine." *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals International Ltd.*, 887 F.3d 1117, 1134–36 (Fed. Cir. 2018). Specifically, a method claim of treating patients with schizophrenia requiring first determining whether the patient is a CYPD2D6 poor metabolizer is patent eligible. One such claim is reproduced below.

> 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; 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.

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The Federal Circuit reasoned that, unlike the *Mayo* claims, requiring only the observation of a natural law and optimizing treatment based on that observation, the *Vanda* claims require one to administer a drug to alter a patient's condition, i.e., a novel method of treating a disease. As such, the claims at issue are NOT directed to a patent-ineligible concept (step 1 of the two-step *Alice* test).

By not granting *certiorari*, the Supreme Court lets the holding of this case stand.

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II. Athena v. Mayo

The Federal Circuit held that a method claim of diagnosing a neurological disorder is patent ineligible. *Athena Diagnostics, Inc.* v. *Mayo Collaborative Servs.*, *LLC*, 915 F.3d 743 (Fed. Cir. 2019). An exemplary Athena diagnostic method claim is reproduced below.

> A method for diagnosing neurotransmission or developmental disorders related to muscle specific tyrosine kinase (MuSK) in a mammal comprising the step of detecting in a bodily fluid of said mammal autoantibodies to an epitope of muscle specific tyrosine kinase (MuSK).

In denying *en banc* re-hearing[1], Judges Dyk, Hughes, and Chen stated that the Athena diagnostic claims would be patent eligible, but for Supreme Court case law. Judges Moore, O'Malley, Wallach, Stoll, and Newman, in dissenting, stated that the Athena diagnostic method claims should be patent eligible, even under Supreme Court precedent, and should thus be heard *en banc*.

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[1] *Athena Diagnostics, Inc.* v. *Mayo Collaborative Servs.*, *LLC*, 927 F.3d 1333 (Fed. Cir. 2019).

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This case would be the right case for the Supreme Court to take on to clarify whether virtually all diagnostic method claims are patent ineligible, as the claims here are all directed to observing a law of nature, or whether some diagnostic method claims (such as Athena's) are and other such claims are not (such as the claims in *Mayo*).

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III. Where Are We Now?

What is patent eligible and what is not?

Regarding claims that are not directed to methods of diagnosis, the *Charkarbarty*'s microbe, transformed by plasmids and with novel properties, is patent eligible. Also, a method of treatment claim is patent eligible, even if some of the method steps involve determining a particular patient's response or status.[2]

Although made by man, isolated DNA molecules are not, unless they are cDNA molecules. A mixture of several bacteria is not patent eligible. All method of diagnosis claims may be patent ineligible, unless there is also a treatment component.

[2] More than one party may perform the steps of the claimed methods, thus removing a direct infringement cause of action.

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