Aurora
Consulting

Patently Strategic Musings

ASHLEY SLOAT | February 22, 2022

WELCOME! – Format

- 10 Minutes Ice: Breaker
- 15-20 Minutes: Problem Solving
- 30-35 Minutes: New Material

Ice Breaker

- New people - introduce yourself
- **What song describes your life right now?**

Shared Problem Solving

- Fun Strategy Tidbits?
- Any problems you are encountering with the USPTO?
- Any practice issues arising?
- Any technical issues you are facing?

First Plague: Section 101

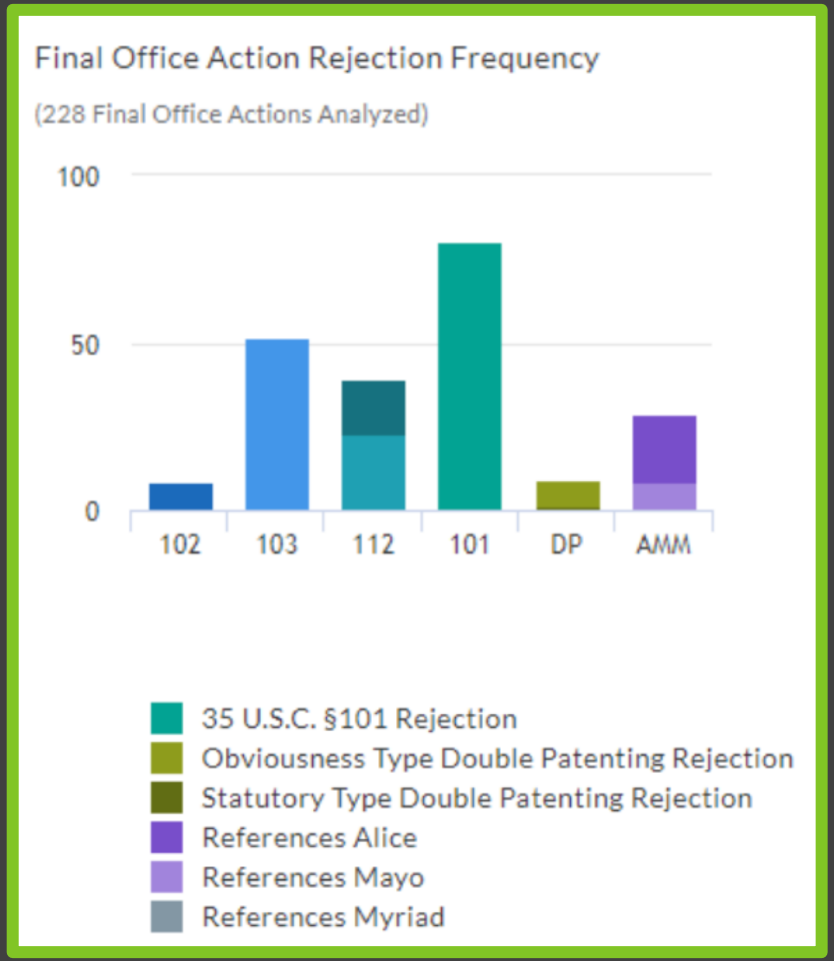
- **1631 Art Unit.** Molecular Bio, Bioinformatics, Nucleic Acids, Recombinant DNA/RNA, Gene Regulation

Last 5 yrs.

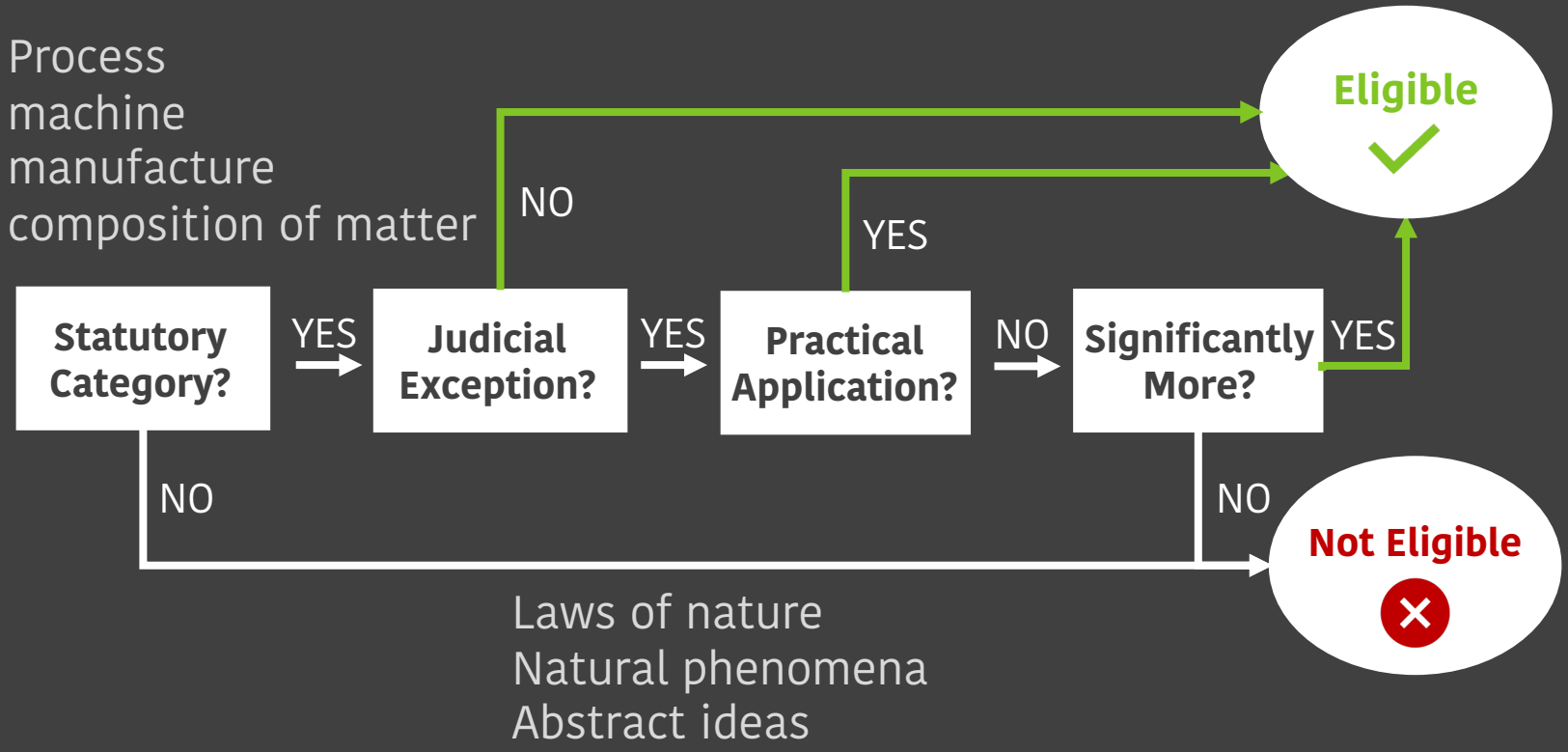
  - 59.7% allowance rate
  - 718 allowed patent applications
  - 485 abandoned applications
  - 80.7% of abandoned applications had a 101 rejection at final OA

The Reality of Past 5 Years

1631 Art Unit



Subject Matter Eligibility Guidance



Second Plague: Section 112

Death of the Genus Claim

- Field is nascent, unpredictable, rife with failure
  - Enzo Biochem v. Calgene (Fed. Circ. 1999)
  - Claimed antisense DNA technology
- Iterative trial-and-error lead by spec can still create enablement issue
  - Wyeth v. Abbott (Fed. Circ. 2010)
  - Rapamycin chemicals for treatment of restenosis
- Described screening process allowed for straightforward ID of working embodiments – still undue experimentation
  - Idenix Pharma v. Gilead (Fed. Circ. 2019)
  - 2-methyl nucleoside for treatment of HCV

Wands Factors

1. Quantity of experimentation necessary
2. Amount of direction or guidance presented
3. Presence or absence of working examples
4. Nature of the invention
5. State of the prior art
6. Relative skill of those in the art
7. Predictability or unpredictability of the art
8. Breadth of the claims

In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988).

Section 101 meets life sciences

- Mayo v. Prometheus Laboratories (Supreme Court 2012)
  - Relationship between metabolite concentration and likelihood of drug effectiveness
  - Determining **but not necessarily using** an improved treatment

MOT Claims: active treatment step

- **Eligible.** Claims with active treatment step
  - Vanda Pharmaceuticals v. West-Ward Pharmaceuticals (Fed. Cir. 2018)
  - Endo Pharmaceuticals Inc. v. Teva Pharms USA, Inc., 919 F.3d 1347 (Fed. Cir. 2019)

- **Ineligible.** detecting natural autoantibodies with conventional molecules and correlating with disease state
  - Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 915 F.3d 743 (Fed. Cir. 2019)

Vanda Pharmaceuticals v. West-Ward Pharmaceuticals (Fed. Cir. 2018) - ELIGIBLE

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.

Endo Pharmaceuticals Inc. v. Teva Pharms USA, Inc. (Fed. Cir. 2019) – ELIGIBLE

1. A method of treating pain in a renally impaired patient, comprising the steps of:

   a. providing a solid oral controlled release dosage form, comprising:

      i. about 5 mg to about 80 mg of oxymorphone or a pharmaceutically acceptable salt thereof as the sole active ingredient; and

      ii. a controlled release matrix;

   b. measuring a creatinine clearance rate of the patient and determining it to be

      (a) less than about 30 m[L]/min,

      (b) about 30 mL/min to about 50 mL/min,

      (c) about 51 mL/min to about 80 mL/min, or

      (d) above about 80 mL/min; and

   c. orally administering to said patient, in dependence on which creatinine clearance rate is found, a lower dosage of the dosage form to provide pain relief;

   wherein after said administration to said patient, the average AUC of oxymorphone over a 12-hour period is less than about 21 ng•hr/mL.

Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC (Fed. Cir. 2019) - INELIGIBLE

1. 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).

Natural Product Claims

- **Not eligible.** DNA primers with normal activity for detecting bacteria
  - Roche v. Cepheid (Fed. Cir. 2018)

- **Not eligible.** Naturally occurring DNA sequences
  - Association for Molecular Pathology v. Myriad Genetics (Supreme Court 2013)

- **Eligible.** Natural supplement in unnatural quantities
  - Natural Alternative v. Creative Compounds(Fed. Circ. 2019)

Roche Molecular Systems, Inc. v. Cepheid (Fed. Cir. 2018) - INELIGIBLE

1. A method for detecting Mycobacterium tuberculosis in a biological sample suspected of containing M. tuberculosis comprising:

(a) subjecting DNA from the biological sample to polymerase chain reaction [PCR] using a plurality of primers under reaction conditions sufficient to simplify a portion of a M. tuberculosis rpoB [gene] to produce an amplification product, wherein the plurality of primers comprises at least one primer that hybridizes under hybridizing conditions to the amplified portion of the [gene] at a site comprising at least one position-specific M. tuberculosis signature nucleotide selected, with reference to FIG. 3 (SEQ ID NO: 1), from the group consisting of:

a G at nucleotide position 2312, a T at nucleotide position 2313, an A at nucleotide position 2373, a G at nucleotide position 2374, an A at nucleotide position 2378, a G at nucleotide position 2408, a T at nucleotide position 2409, an A at nucleotide position 2426, a G at nucleotide position 2441, an A at nucleotide position 2456, and a T at nucleotide position 2465; and

(b) detecting the presence or absence of an amplification product, wherein the presence of an amplification product is indicative of the presence of M. tuberculosis in the biological sample and wherein the absence of the amplification product is indicative of the absence of M. tuberculosis in the biological sample.

Natural Alternatives v. Creative Compounds (Fed. Cir. 2019) - ELIGIBLE

1. A method of increasing anaerobic working capacity in a human subject, the method comprising:

a) providing to the human subject an amount of an amino acid to blood or blood plasma effective to increase beta-alanylhistidine dipeptide synthesis in the tissue, wherein said amino acid is at least one of:

i) beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide;

ii) an ester of beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide; or

iii) an amide of beta-alanine that is not part of a dipeptide, polypeptide or oligopeptide; and

b) exposing the tissue to the blood or blood plasma, whereby the concentration of beta-alanylhistidine is increased in the tissue,

wherein the amino acid is provided through a dietary supplement.

Drafting tricks to Avoid

- Extra-solution activity
- Limitations that have an insignificant relationship to the judicial exception
- General treatments or prophylaxis

Drafting Solutions

- **Practical applications**
  - Apply phenomenon in specific or unconventional way
  - Administering specific dose
- **Improvement over prior art methods**
- **Overcome a particular technical challenge**
- **Different claim types**
  - Method of treatment
  - Method of diagnosis
  - Method of detection

The other part of Section 101

- An invention's utility must be:
- Specific
  - Well-defined, avoids "general" statements of possible uses.
- Substantial
  - Provides a known and immediate "real world" benefit in its current form
- Credible
  - Consistent with known scientific principles and the facts of the case
- Failing utility necessarily fails enablement.

The USPTO is not the FDA

- Mere identification and demonstration of pharmacological activity associated with the treatment of specific conditions is sufficient.
  - Need not demonstrate that every (or any) embodiment is a commercially viable drug.

- *Nelson v. Bowler*, 626 F.2d 853, 856, 206 USPQ 881, 883 (CCPA 1980)
- *In re Jolles*, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980)
- *Cross v. Iizuka*, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985)
- *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995)

Specific but not substantial

***Brenner V. Manson*, 383 U.S. 519 (1966)**

- US Pat. 2,908,693 claimed a novel method of manufacturing 2-methyldihydrotestosterone (a known steroid) and related variants.
- No utility for the class was described or known at the time.
  - The possible use of similar compounds is presented. Claimed compounds not tested, nor is any further evidence provided.

Specific but not substantial

***Brenner V. Manson*, 383 U.S. 519 (1966)**

- Utility "is not satisfied by a showing that the compound yielded belongs to a class of compounds which scientists are screening of possible uses."
- Utility is not satisfied "by a showing that the process works, i.e., yields the intended product."
- "Use-testing" is not a use.

Neither specific nor substantial

***In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005)**

- Application 09/619,643 claimed five expressed sequence tags (ESTs) of the maize plant.
  - ESTs are short cDNA sequences useful in mapping genomes.
- The function and structure of the corresponding genes and proteins were unknown at the time of filing.
- Application states the common uses for ESTs as possible uses.

Neither specific nor substantial

***In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005)**

- Court upheld the rejection
- Proposed uses of the identified ESTs remain hypothetical and general
- Not specific:
  - Specification provided no guidance over why the claimed ESTs were more useful than ten thousands of ESTs present in the maize genome.
- Not substantial:
  - Specification lacked any evidence or demonstration that the ESTs succeeded at any of the proposed uses.
- “Use-testing” is not a use.