Flagship Pioneering

IP Counsel Breakfast

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The Section 101 Landscape

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Agenda

- Background
- Latest USPTO Guidance on § 101 (October 17, 2019)
- Life Sciences Cases
- Mechanical Cases

Background on § 101

35 U.S.C. §101

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Exceptions to §101

- Natural phenomena
- Law of nature
- Abstract ideas

Background on § 101

Mayo v. Prometheus, 566 U.S. 66 (2012)

- Patent on drug dosing determined using patient metabolism found invalid – correlation between metabolites and efficacy is "natural law"
- A process reciting a law of nature is not patentable if it involves "well-understood, routine, conventional activity previously engaged in by researchers in the field"

Alice v. CLS Bank, 573 U.S. 208 (2014)

- Patent on financial-trading system found invalid – abstract idea merely implemented on computer patent ineligible without "something more"
- Bars patents on software and computer processes claimed at too high a level of abstraction from underlying computer process

Mayo/Alice Two-Step Test

Step 1 - Are the claims "directed to" patent-ineligible concept?

- If no, eligible.
- If yes, move to step 2.

Step 2 - Do the claims involve an "inventive concept" (i.e., do the elements taken individually and as an ordered combination transform the claim into a patent eligible application)?

§ 101 at the USPTO

New Guidance Published October 17, 2019

New USPTO Guidance for Section 101

- **New guidance to help clarify earlier guidance**
  - How to determine whether a claim recites a judicial exception
    - Abstract ideas
    - Product of Nature
    - Law of Nature/Natural Phenomenon
  - Groupings of abstract ideas
    - Mathematical concepts
    - Methods of organizing human activities
    - Mental Processes
  - Whether claim integrates a judicial exception into a practical application
  - New Examples
  - **But keep in mind - *Cleveland Clinic Found. et al. v. True Health Diagnostics LLC* (April 1, 2019) - Federal Circuit declined to give deference to USPTO § 101 guidelines**

New USPTO Guidance for Section 101

- **Whether a claim recites a judicial exception**
  - To “recite” a judicial exception means to “set forth” or “describe” an exception
  - “Set forth” means to explicitly include an abstract idea (using PTO groupings), product of nature (using markedly different analysis), or law of nature/natural phenomenon in a claim
  - “Describe” means to refer to a judicial exception without explicitly naming the exception
  - How to make this analysis is said to be described in the Examples
  - Multiple abstract concepts should be treated (by examiners) as one, if possible

New USPTO Guidance for Section 101

- **Groupings of abstract ideas**
  - Based on case law
  - Mathematical concepts include formulas, equations, mathematical relationships, and calculations, but a claim does not "recite" a mathematical concept if it is only based on or involves a mathematical concept (e.g., if the claim does not recite an algorithm that is noted in the specification)
  - Certain methods of organizing human activity
    - Not all such methods are abstract ideas
    - Abstract methods of organizing human activity include
      - Fundamental economic practices or principles
      - Commercial or legal interactions
      - Managing personal behavior or relationships between people

New USPTO Guidance for Section 101

- **Groupings of abstract ideas**
  - Mental Processes
    - Can be practically performed in the human mind (e.g., observations, evaluations, judgments, and opinions)
      - Method of calculating GPS position
      - Data encryption methods
    - Claims that recite use of a computer may still cover a mental process (e.g., if the claim recites a generic computer, or is merely using the computer as a tool to perform an abstract concept)
    - Both product claims and process claims can include a mental process
    - Claims that encompass a human performing steps mentally with the aid of a pen and paper still cover a mental process

New USPTO Guidance for Section 101

- **Evaluating whether a judicial exception is integrated into a practical application (Step 2A, Prong Two)**
  - **Step 2A** – whether a claim is "directed to" a judicial exception, should be determined without consideration of whether claim limitations are well-known, routine, or conventional
  - **Step 2A** is to be evaluated by examiners by using a two-prong inquiry
    - Prong One – does the claim "recite" a judicial exception?
    - Prong Two – a claim that recites a judicial exception is not "directed to" the judicial exception if the claim as a whole integrates the judicial exception into a practical application
- **Step 2B – Does the claim recite "significantly more"?**
  - This is where the examiner is to consider whether claim limitations are well-known, routine, or conventional

New USPTO Guidance for Section 101

- **Evaluating whether a judicial exception is integrated into a practical application (Step 2A, Prong Two)**
  - Claim integrates judicial exception into a practical application, if:
    - Improves technology, technical field, or functioning of computer
    - Effects particular treatment/prophylaxis for disease or medical condition
      - must be “particular” and not general/generic
      - must have more than a nominal or insignificant relationship to the judicial exception (must use law or nature or natural phenomenon in a “meaningful way”)
      - cannot be extra-solution activity or mere recitation of field of use
    - Implemented with a particular machine

New USPTO Guidance for Section 101

- **New Examples**
  - Example 43 – Treating Kidney Disease
  - Example 44 – Denveric Acid
  - Example 45 – Controller for Injection Mold
  - Example 46 – Livestock Management

New USPTO Guidance for Section 101

- **Example 43 - Treating Kidney Disease (method of treatment)**
- **Claim 1 -** a treatment method comprising:

  (a) calculating a ratio of C11 to C13 levels measured in a blood sample from a patient diagnosed with Nephritic Autoimmune Syndrome Type 3 (NAS-3) to identify the patient as having a non-responder phenotype;

  (b) administering a treatment to the patient having a non-responder phenotype.
- **Step 2A, Prong One** - No products of nature, but recites mathematical concept (calculation) and naturally occurring relationship – therefore recites judicial exceptions
- **Step 2A, Prong Two** – treatment too generic, fails to require particular application of the calculation – therefore does not integrate judicial exceptions into a practical application
- **Step 2B** – claim as a whole does NOT amount to "significantly more" (**claim is NOT eligible**, mere instruction to "apply" a judicial exception)

New USPTO Guidance for Section 101

- **Example 43 - Treating Kidney Disease (method of treatment)**
- **Claims 2 – 5:**

2. The method of claim 1, wherein the treatment is a non-steroidal agent capable of treating NAS-3.

Abstract idea of claim 1, but adds specific treatment without consideration of whether this is well-understood (**claim eligible**)

3. The method of claim 1, wherein the treatment is rapamycin.

Abstract idea of claim 1, but adds specific treatment (which does not "recite" a product of nature, though rapamycin is a natural product, because claim is focused on step (a) of claim 1)(**claim eligible**)

4. The method of claim 1, wherein the treatment is a course of plasmapheresis.

Abstract idea of claim 1, but adds particular treatment without consideration of whether this is well-understood (**claim eligible**)

5. A treatment method comprising administering rapamycin to a patient identified as having Nephritic Autoimmune Syndrome Type 3 (NAS-3).

Not considered to recite natural product, no other judicial exception (**claim eligible under Step 2A**)

New USPTO Guidance for Section 101

- **Example 44 – Denveric Acid (natural product)**

- **Claim 1** - A dosage unit comprising denveric acid in a container.

- **Step 2A, Prong One** – Product (denveric acid) as claimed is a protein product that is not markedly different from natural product – therefore recites judicial exceptions
- **Step 2A, Prong Two** – claim recites additional element of a container, but recited too generically and thus fails to meaningfully limit the claim – therefore does not integrate judicial exception into a practical application
- **Step 2B** – claim as a whole does NOT amount to "significantly more" (**claim is NOT eligible**, mere instruction to "apply" a judicial exception)

New USPTO Guidance for Section 101

- **Example 44 – Denveric Acid (natural product)**

- **Claim 2** - The dosage unit of claim 1, wherein the container is a wearable delivery device having a flexible patch-shaped housing, a needle assembly mounted on one side of the housing, a reservoir located inside the housing in which the denveric acid is stored, a dosage control button mounted on the opposite side of the housing from the needle assembly, and a delivery valve for dispensing a selected dosage of denveric acid from the reservoir to the needle assembly.

  Product of nature of claim 1, but adds specific delivery device ("particular machine") that is an integral part of the claim, without consideration of whether this is well-understood, routine, or conventional, and thus the device meaningfully integrates the product of nature into a practical application (**claim eligible**)

New USPTO Guidance for Section 101

- **Example 44 – Denveric Acid (natural product)**

- **Claim 3** - The dosage unit of claim 1, wherein the denveric acid is an intermediate-acting denveric acid.

  Abstract idea of claim 1, but recites specific modification of denveric acid that has a markedly different characteristic compared to the natural product, thus claim does not recite a product of nature under Step 2A, Prong One (**claim eligible**)

- **Claim 4** - The dosage unit of claim 1, further comprising protamine that is mixed with the denveric acid in the container in an amount of 0.75 mg to 1.5 mg protamine per every mg of denveric acid.

  Abstract idea of claim 1, but adds protamine to form a nature-based combination/mixture that has a markedly different functional property than denveric acid, and thus does not recite a product of nature under Step 2A, Prong One (**claim eligible**)

§ 101 at the Federal Circuit

Life Sciences

Athena v. Mayo (2019)

Athena Diagnostics v. Mayo Collaborative Servs., 915 F.3d 743 (Fed. Cir. 2019)

- 1. (not on appeal) 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 [MuSK].
- Claim 9 (on appeal), the most specific claim at issue, depends from claim 1 and requires:

  (1) contacting MuSK or an epitope thereof having a 125I label, with bodily fluid;

  (2) immunoprecipitating any antibody/MuSK complex; and

  (3) monitoring for the label on the complex, wherein the presence of the label indicates the presence of a MuSK-related disorder.

- **Key point**: Patent specification expressly admitted that the claimed methods employ "immunological assay techniques ***known per se in the art***"

Athena: Directed to Ineligible Subject Matter

- **Step One**, FC concluded that claims 7-9 were directed to "the correlation between the presence of naturally occurring MuSK autoantibodies in bodily fluid and MuSK-related neurological diseases" and the "claimed advance was only in the discovery of a natural law"
- **Step Two**, FC concluded that the additional steps of the claims require only admittedly standard techniques to be applied in a standard way
  - The specification of the '820 patent plainly states that iodination and immunoprecipitation are "known per se in the art"
- Federal Circuit affirmed grant of motion to dismiss on section 101 grounds – patent ineligible
- Lengthy dissent from Judge Newman, who would have held the claims patent eligible

Endo v. Teva (2019)

Endo Pharms., Inc. v. Teva Pharms. USA, Inc., 919 F.3d 1347 (Fed. Cir. 2019)

- Patent covers a method of using oxymorphone to treat pain in patients with impaired kidney functions
- The inventor discovered that patients with impaired kidney function need less oxymorphone than usual to achieve a similar level of pain management

Endo: Claim 1

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 ml/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.

Endo: Eligible Subject Matter

- FC stated that the method claims at issue were "legally indistinguishable" from the representative claims in *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals Int'l Ltd*
  - "The inventor here recognized the relationship between oxymorphone and patients with renal impairment, **but that is not what he claimed**. Rather, he claimed an ***application of that relationship***—specifically, a method of treatment including ***specific steps to adjust or lower the oxymorphone dose*** for patients with renal impairment."
- No preemption because the claims recited carrying out a dosage regimen based on the results of kidney function testing – did not cover a doctor just thinking about the natural law
- Federal Circuit reversed district court's grant of motion to dismiss on section 101 grounds

Other Recent Pharma 101 Cases

Genetic Veterinary Scis., Inc. v. Laboklin GmbH & Co., 933 F.3d 1302 (Fed. Cir. 2019) (**ineligible**)

- Patent was directed to methods for genotyping Labrador Retrievers for the purpose of determining if they are genetic carriers of hereditary nasal parakeratosis ("HNPK"), a disease that causes "crusts and fissures" to appear on a dog's nose at a young age

Natural Alternatives Int'l, Inc. v. Creative Compounds, LLC, 918 F.3d 1338 (Fed. Cir. 2019) (**eligible?, following *Vanda***)

- Patents generally related to the use of beta-alanine in a dietary supplement in methods of treatment to increase the anaerobic working capacity of muscle and other tissues
- FC said certain facts as to what was well-understood, routine, and conventional needed to be accessed on remand

Life Sciences Cases: Take Away Points

- Diagnostic method claims need to recite an "inventive concept" to transform the ineligible law of nature into a patent-eligible application. To establish an inventive concept, the claimed method steps need to do more than adapting a conventional assay to a newly discovered natural law
  - Avoid saying in the specification that any assay or technique mentioned in the claims is standard or routine
- Method of treatment claims reciting an ***application*** of a natural law can be patent eligible
  - Using a preamble "method of treating …" can be helpful, particularly where the claim involves dosage steps, but is not enough
  - Need to show particular, relevant, and/or improved treatment
- "Wherein" clauses setting forth what a correlation "indicates," with no required action taken, have generally been found ineligible

§ 101 at the Federal Circuit

Mechanical Arts

American Axle v. Neapco

Am. Axle Mfg. v. Neapco Holdings LLC, 939 F.3d 1355 (Fed. Cir. 2019)(U.S. Patent No. 7,774,911)

1. A method for manufacturing a shaft assembly of a driveline system, the driveline system further including a first driveline component and a second driveline component, the shaft assembly being adapted to transmit torque between the first driveline component and the second driveline component, the method comprising:

providing a hollow shaft member;

tuning at least one liner to attenuate at least two types of vibration transmitted through the shaft member; and

positioning the at least one liner within the shaft member such that the at least one liner is configured to damp shell mode vibrations in the shaft member by an amount that is greater than or equal to about 2%, and the at least one liner is also configured to damp bending mode vibrations in the shaft member, the at least one liner being tuned to within about ±20% of a bending mode natural frequency of the shaft assembly as installed in the driveline system.

American Axle v. Neapco

- **FC affirmed SJ that claims were invalid under § 101**

- **Step One: claims are directed to natural laws**
  - "the claims' general instruction to tune a liner amounts to no more than a directive to use one's knowledge of Hooke's law, and possibly other natural laws, to engage in an ad hoc trial-and-error process of changing the characteristics of a liner until a desired result is achieved"
  - Claims do not specify how to achieve such tuning
  - Claims provide no specific method to apply Hooke's Law
- **Step Two: no inventive concept**
  - "nothing in the claims qualifies as an 'inventive concept' to transform the claims into patent eligible matter"
  - The claimed steps are merely a "conventional, unbounded trial-and-error process" like "changing the mass or thickness of the liner, altering the location of the liner in the propshaft, or modifying any other physical attributes that will produce the claimed dual-attenuation"

American Axle v. Neapco

- **Dissent (J. Moore):**
  - Majority "expands § 101 well beyond its statutory gate-keeping function"; creates "validity goulash"
  - Majority has "outright reject[ed]" the second step of the *Alice/Mayo* test
  - This case is really about enablement, not eligible subject matter

Mechanical Arts Cases: Take Away Points

- Even claims to methods of physically manipulating structures can run afoul of 101
- If your invention relate to any judicial exception, make sure to include plenty of details in the specification for how to carry out your methods
- Draft claims to recite specific steps, and not just instructions to do something without including steps for how to achieve that something
- Avoid the use of too much functional or result-based language in your claims
- Include a mechanism in your claims to achieve the desired result

THANK YOU!

Presenter

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Peter Fasse is a Principal in the Boston office of Fish & Richardson. His practice emphasizes client counseling and patent prosecution in a wide variety of technologies, with an emphasis on healthcare, medical devices, and other biological and medical fields as well as various “green” technologies. Peter helps clients from start-ups to multinationals to develop competitive worldwide patent strategies and to establish solid and defensible patent portfolios. He performs competitive patent analyses, identifies third-party patent risks, and provides patentability and freedom-to-operate opinions. Peter also has experience in opposing and defending patents before the European Patent Office and in U.S. litigation and post-grant proceedings.

Mr. Fasse has experience in various fields including medical therapeutics, diagnostics, devices, and imaging, microfluidic systems, liquid biopsy, nucleic acid sequence analysis systems and software, cell culturing and bioprocessing, molecular biology, complex biomedical systems, optics, machine tools, and lasers. Specific applications relate to, e.g., cancer antibodies, RNAi and CRISPR therapeutics, engineered AAV systems, microfluidic analysis of circulating tumor and fetal cells, cell-free DNA analysis, next generation sequence analysis, CO2 laser systems, 3D printing, e.g., of tissues, human and bacterial genes and polypeptides, dendritic cell- and DNA- based vaccines, nanoparticle and vector-based delivery of therapeutic agents including AAV delivery of DNA to eye and ear tissues, automated blood analysis systems, nucleic acid probes, tissue engineering, infusion pumps, biochips, laser ablation devices, cellulose processing for ethanol production, CO2 recycling power plants, implantable drug delivery devices and microcapsules, ultrasound probes, wind and solar power, cytokines such as IL-8 and PF4, and diagnostic and therapeutic methods for, e.g., AIDS, cancer, autism, diabetes, psoriasis, and arthritis.

In litigation and European opposition matters, Mr. Fasse has represented clients in a variety of patent infringement suits and trade secret misappropriation cases. Specific subject matter at issue included, e.g., cancer therapeutics (Erbitux), cardiac biomarkers, cell culturing systems, methods of treating arthritis (CTL4Ig), dental implants, hook and loop fastener systems, computer-controlled medical infusion pumps, and fiberglass casting materials.

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