# Patent protection in AI and life science/biotechnology
## Comments from US perspective

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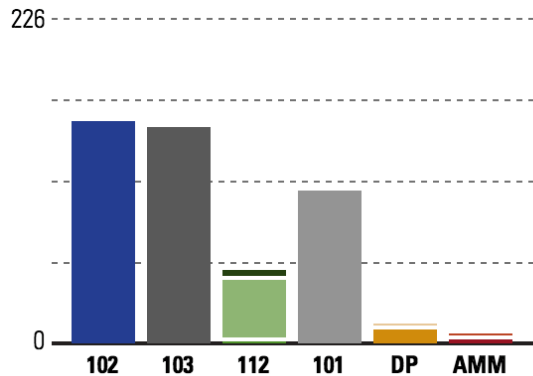Of Counsel, Seed IP Law Group

# Challenges

- US Isolation
  - Patent eligibility (*Mayo, Myriad, Alice*)
  - Definiteness - Functional claiming
  - Written description
- PCT Application-PPH
  - Same description and drawings
  - Identical or similar claims - Priority
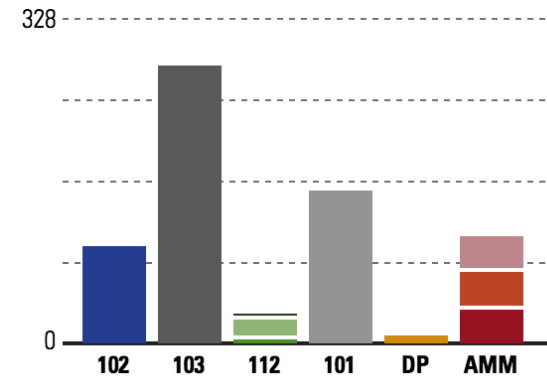
# *Mayo-Myriad-Alice* Impact



**First Office Action Rejection Frequency**
(226 First Office Actions Analyzed)

**Non-final Office Action Frequency**
(455 Non-Final Office Actions Analyzed)
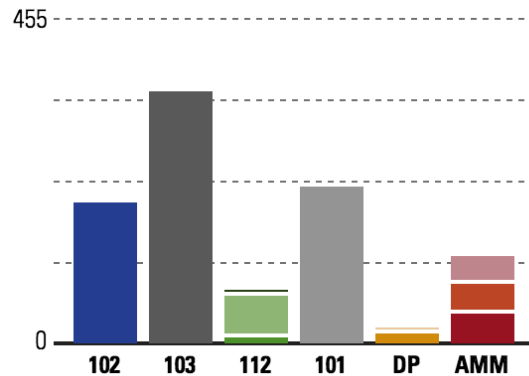
**Final Office Action Frequency**
(328 Final Office Actions Analyzed)

REASONS FOR REJECTION

102 ■ 35 U.S.C. §102 Rejection
103 ■ 35 U.S.C. §103 Rejection
112 ■ 35 U.S.C. §112 First Paragraph Rejection
   ■ 35 U.S.C. §112 Second Paragraph Rejection
   ■ 35 U.S.C. §112 Fourth Paragraph Rejection

■ 35 U.S.C. §112 Fifth Paragraph Rejection
■ 35 U.S.C. §112 Sixth Paragraph Rejection
101 ■ 35 U.S.C. §101 Rejection
DP ■ Obviousness Type Double Patenting Rejection
■ Statutory Type Double Patenting Rejection

AMM ■ References Alice
■ References Mayo
■ References Myriad

Tara Krarouski, The Most Important Patent Examiner Statistic (Dec. 13, 2016)
http://knowledge.reedtech.com/intellectual-property-all-posts/the-most-important-patent-examiner-statistics-besides-allowance-rates
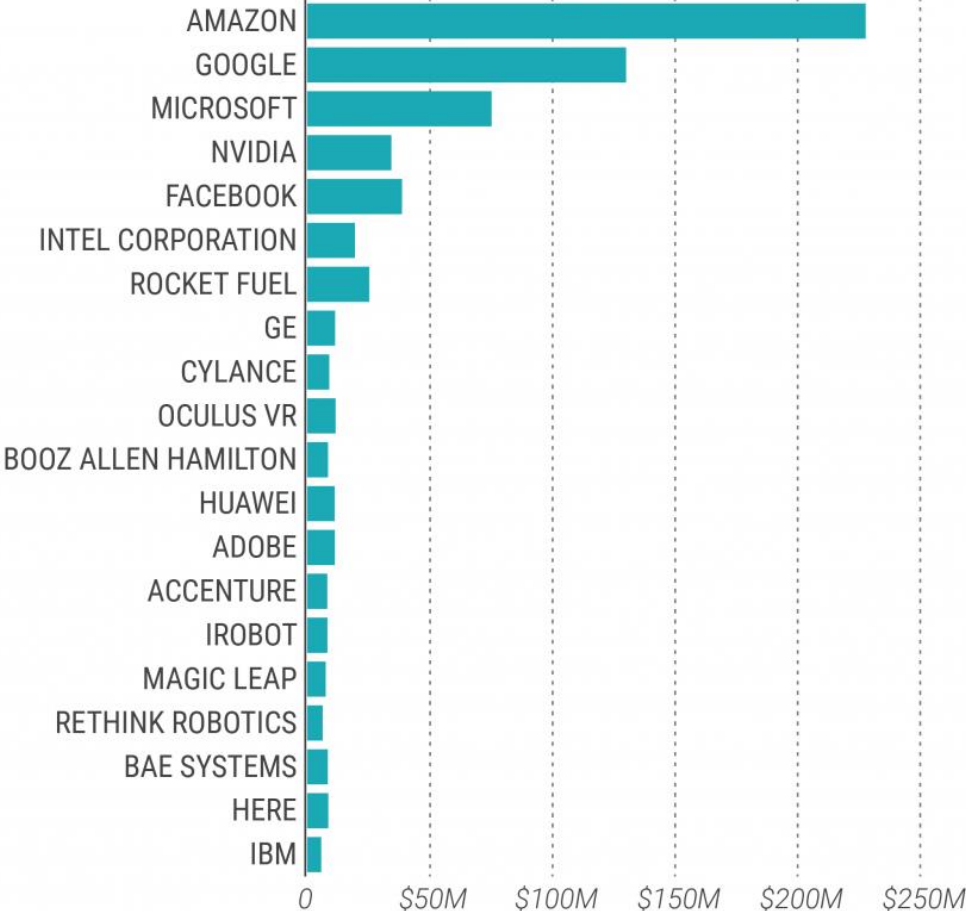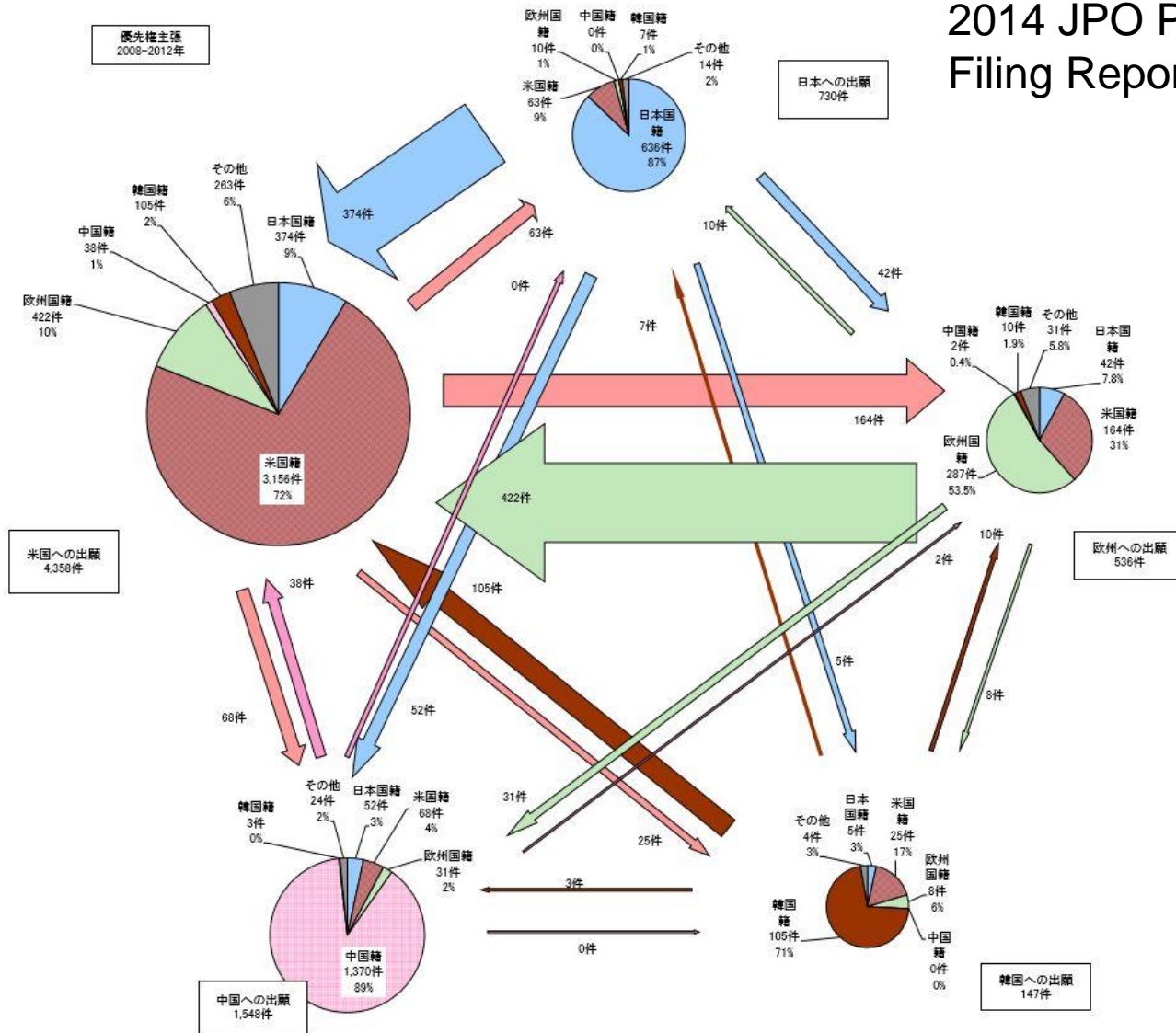
# Patent Protection in AI

## Overcoming Eligibility and Indefiniteness Rejections

# Top 20 Companies Investing in AI Talent

No other company comes close to matching the $227.8 million that hiring and salary firm Paysa estimates Amazon will spend hiring artificial intelligence talent.

| Company | Investment |
|---|---|
| AMAZON | |
| GOOGLE | |
| MICROSOFT | |
| NVIDIA | |
| FACEBOOK | |
| INTEL CORPORATION | |
| ROCKET FUEL | |
| GE | |
| CYLANCE | |
| OCULUS VR | |
| BOOZ ALLEN HAMILTON | |
| HUAWEI | |
| ADOBE | |
| ACCENTURE | |
| IROBOT | |
| MAGIC LEAP | |
| RETHINK ROBOTICS | |
| BAE SYSTEMS | |
| HERE | |
| IBM | |

0    $50M    $100M    $150M    $200M    $250M

2014 JPO Patent Filing Report: AI
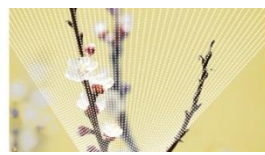
# Patent Eligibility
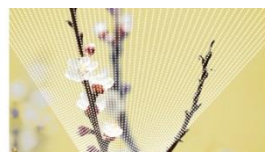
- Artificial Intelligence
  - Enabling a machine to mimic cognitive functions: Learning and problem solving
  - Such functions provided by specially programmed software
    - Data library
    - Algorithms: Mathematical and statistical tools to mimic the ability of human brain or behavior
    - Human machine interface

# *Alice Corp. v. CLS Bank Int'l*

- Two Step Analysis
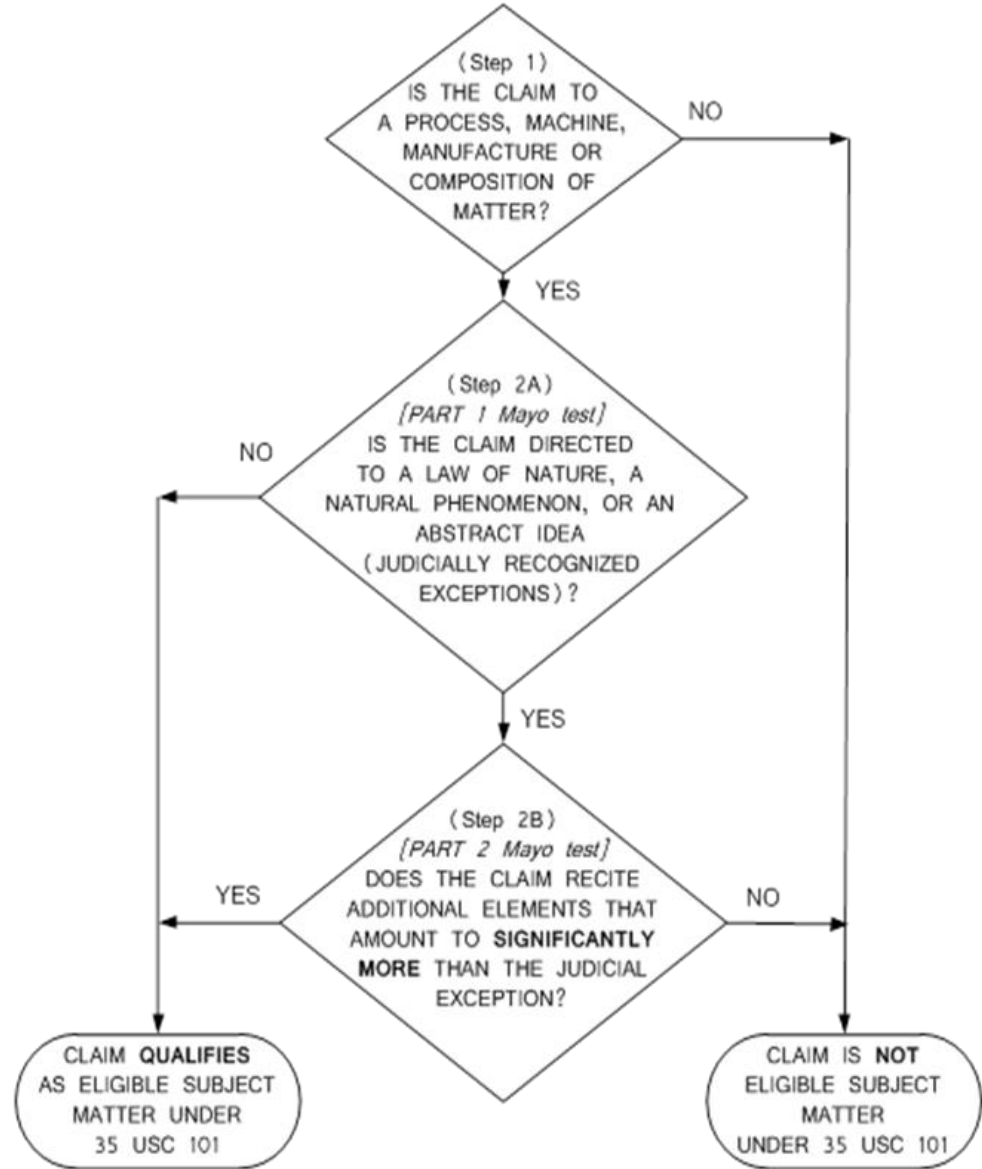  1. Determine whether claim recites a patent-ineligible concept (i.e., law of nature, abstract idea or natural phenomena . . .)
     - Fundamental economic practices;
     - Certain methods of organizing human activities;
     - "[A]n idea of itself; and
     - Mathematical relationships/formulas
  2. Determine whether claim contains "meaningful limitations" ensuring it amounts to "significantly more" than the abstract idea.

## Evaluating Subject Matter Eligibility

Examiners are to:

1. Review the disclosure to identify what applicant considers as the invention.

2. Determine if the claim falls into a statutory category.

3. Identify the judicial exception recited in the claim (if any).

4. Determine if the claim as a whole recites significantly more than the judicial exception itself.

(Step 1)
IS THE CLAIM TO A PROCESS, MACHINE, MANUFACTURE OR COMPOSITION OF MATTER? — NO

YES

(Step 2A)
[PART 1 Mayo test]
IS THE CLAIM DIRECTED TO A LAW OF NATURE, A NATURAL PHENOMENON, OR AN ABSTRACT IDEA (JUDICIALLY RECOGNIZED EXCEPTIONS)? — NO

YES

(Step 2B)
[PART 2 Mayo test]
DOES THE CLAIM RECITE ADDITIONAL ELEMENTS THAT AMOUNT TO **SIGNIFICANTLY MORE** THAN THE JUDICIAL EXCEPTION? — YES / NO

CLAIM **QUALIFIES** AS ELIGIBLE SUBJECT MATTER UNDER 35 USC 101

CLAIM IS **NOT** ELIGIBLE SUBJECT MATTER UNDER 35 USC 101

9

# Human Machine Interface

- *DDR Holdings v Hotels.com* (Fed. Cir. 2014)
  - Claims relating to e-commerce system and method providing hosts with transparent, context sensitive e-commerce supported pages, through the claimed interconnectivity, accomplish the process of displaying composite webpages with a look and feel of the source web page.

  - Held: Claims are eligible under the two step analysis

# Human Machine Interface

Step1: Not directed to an abstract idea

- The claimed solution is necessarily rooted in computer technology in order to overcome a problem specifically arising in the realm of computer networks.

Step 2: Significantly more or Inventive Concept

- The claims at issue here specify how interactions with the Internet are manipulated to yield a desired result—a result that overrides the routine and conventional sequence of events ordinarily triggered by the click of a hyperlink. …When the limitations of the '399 patent's asserted claims are taken together as an ordered combination, the claims recite an invention that is not merely the routine or conventional use of the Internet.
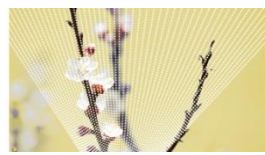
# Data Library

- *Enfish v. Microsoft,* 2016 U.S. App. LEXIS 8699 (Fed. Cir. 2016)

  – Fact: P holds a patent directing to a self-referential database implemented by a general purpose computer and sued Microsoft for infringement. Dist. Ct. found claims being drafted in means-plus-function format but found them invalid.

  – Held: The asserted means-plus-function claims directing to a self-referential table for a computer database are not directed to an abstract idea and thus patent eligible.

# Data Library

A Representative Claim:

A data storage and retrieval system for a computer memory, comprising:

means for configuring said memory according to a logical table, said logical table including:

a plurality of logical rows, each said logical row including an object identification number (OID) to identify each said logical row, each said logical row corresponding to a record of information;

a plurality of logical columns intersecting said plurality of logical rows to define a plurality of logical cells, each said logical column including an OID to identify each said logical column; and

means for indexing data stored in said table

# Data Library

Step 1- Not directed to an Abstract Idea: Here, the claims are not simply directed to *any* form of storing tabular data, but instead are specifically directed to a *self-referential* table for a computer database.

– The necessity of describing the claims in such a way is underscored by the specification's emphasis that "the present invention comprises a flexible, self-referential table that stores data"

Step 2-Not necessary: Because the claims are not directed to an abstract idea under step one of the *Alice* analysis, we do not need to proceed to step two of that analysis.

# Algorithms

- *McRO, Inc. v. Bandai Namco* (Fed. Cir. 2016)
  - Fact: P holds two patents which are directed to an improvement on a prior method of synchronizing pre-recorded voices with facial expressions of animated three-dimensional characters. Dist. Ct. found all asserted claims invalid for directing to an abstract idea.
  - Held: Representative claim was *not* "directed to" an abstract idea. Therefore, it and the other asserted claims were patent eligible even though the claimed process used computer software to automate a task humans previously performed.
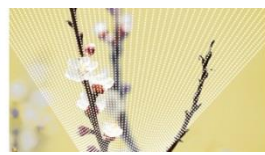
# Algorithms

Step 1- Not directed to an Abstract Idea: Here, the claims are limited to rules with specific characteristics.

- The claims themselves set out <span style="color:red">meaningful requirements</span> for the first set of rules: the ordered combination of claimed steps, using unconventional rules that relate sub-sequences of phonemes, timings, and morph weight sets.

- Claims are not directed to an abstract idea if they focus on a specific means or method that <span style="color:red">improves the relevant technology</span> or are instead directed to a result or effect that itself is the abstract idea and merely invoke generic processes and machinery.

Step 2-Not necessary

# Means-Plus-Function Claims

- Claim Construction: MPF Limitations

  1. Identify the claimed function in a MPF limitation

  2. Determine what structure, if any, is disclosed in the specification for the claimed function

- Definiteness Determination - Stringent

  - Whether the specification adequately discloses a structure to perform the function

    - Three requirements: 1) adequate disclosure of a structure; 2) all functions; and 3) link between the claimed function and the disclosed structure
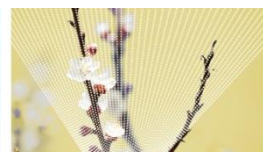
# Means-Plus-Function Claims

Heightened Disclosure Requirement

- <u>Indefiniteness</u>: Computer Software Inventions
  - Sufficient disclosure: A specialized function performed by the computer must be supported in the specification; and the algorithm that the computer uses to perform the claimed specialized function must also be disclosed
    - *Specialized functions* are functions other than those commonly known in the art, often described by courts as requiring "special programming" to perform the function on a general purpose computer or computer component
    - *Non-specialized functions* are functions known by those of ordinary skill in the art as being commonly performed by a general purpose computer or computer component
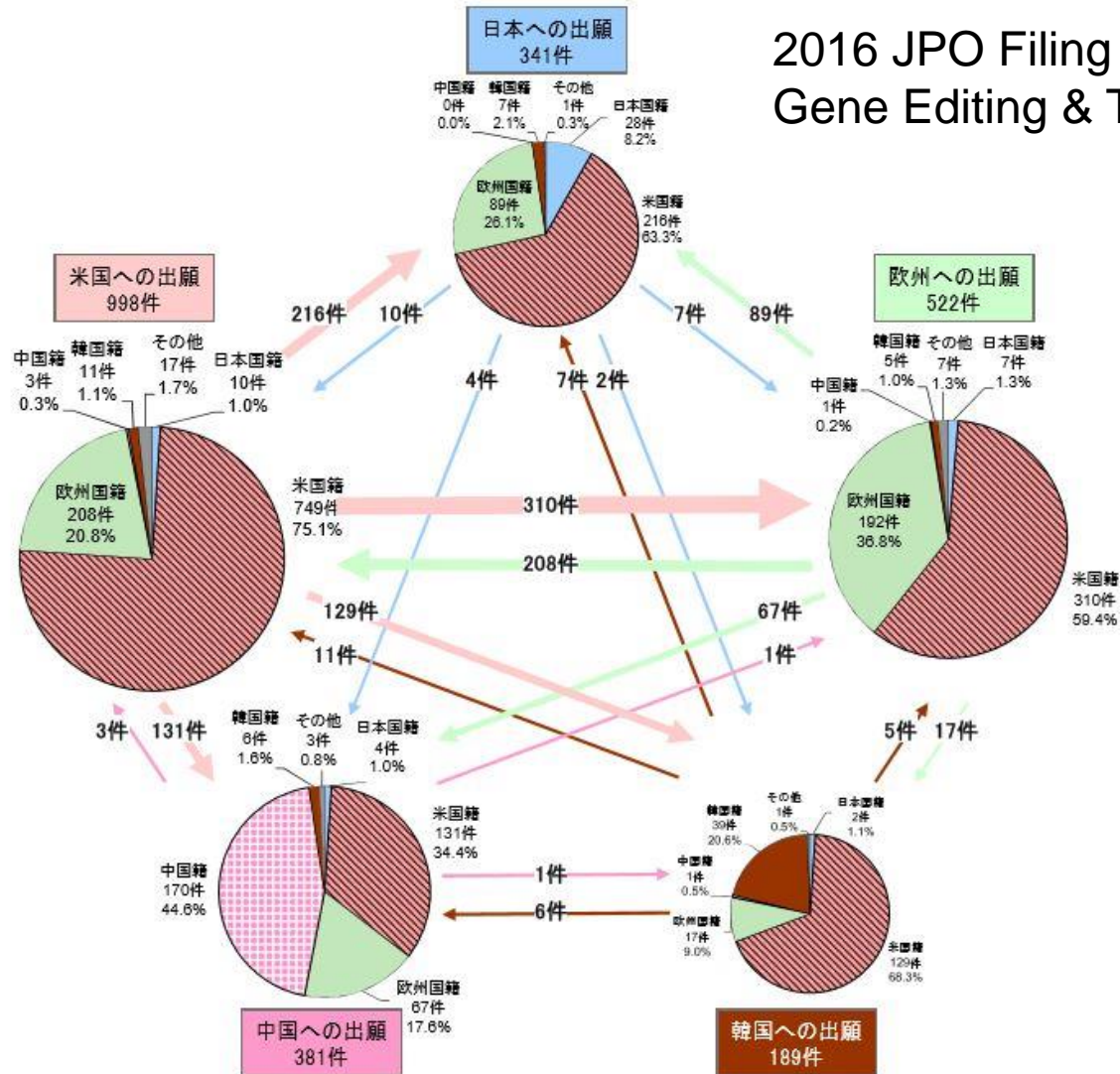
# Patent Protection in Life-Science/Biotech

## Overcoming Mayo-Myriad Eligibility Rejections

| Rank of Score Statistic | Companies | Total Revenue, 2015 (USD Million) | Revenue Growth 2014-15 (%) | Operating Expense Ratio, 2015 (%) | Income per share, 2015 (USD) | R&D by Sales Ratio, 2015 (%) | Income per employee, 2015 (USD Thousand) | Market Cap, 2016 (USD Billion) | Asset Turnover Ratio, 2015 (%) |
|---|---|---|---|---|---|---|---|---|---|
| 1 | Gilead Sciences Inc. (U.S.) | 32,639.00 | 31.13 | 32.00 | 12.37 | 9.23 | 4079.88 | 138.1 | 63.01 |
| 2 | Celgene Corp. (U.S.) | 9,256.00 | 20.67 | 75.64 | 2.02 | 39.94 | 1327.79 | 86.40 | 34.15 |
| 3 | Biogen Inc. (U.S.) | 10,763.80 | 10.93 | 54.56 | 15.38 | 18.70 | 1464.46 | 61.90 | 55.20 |
| 4 | Amgen Inc. (U.S.) | 21,662.00 | 7.97 | 60.90 | 9.15 | 18.79 | 1210.17 | 122.4 | 30.25 |
| 5 | Regeneron Pharmaceuticals, Inc. (U.S.) | 4,103.73 | 45.55 | 69.49 | 6.17 | 39.49 | 954.36 | 42.40 | 73.28 |
| 6 | Shire Plc (U.S.) | 6,416.70 | 6.55 | 77.88 | 2.25 | 24.37 | 1156.58 | 42.28 | 38.65 |
| 7 | CSL Ltd. (Australia) | 6,129.00 | 8.90 | 27.98 | 2.69 | 10.01 | 383.06 | 37.00 | 81.72 |
| 8 | Novozyme (Denmark) | 1,993.51 | 12.38 | 31.20 | 1.31 | 95.11 | 307.40 | 14.40 | 73.83 |
| 9 | Vertex Pharmaceuticals Inc. (U.S.) | 1,032.34 | 77.86 | 145.23 | 2.31 | 96.47 | 529.40 | 21.40 | 41.29 |
| 10 | Alexion Pharmaceuticals Inc. (U.S.) | 2,604.05 | 16.58 | 70.44 | 0.68 | 27.24 | 890.58 | 35.8 | 19.88 |
| 11 | Illumina, Inc. (U.S.) | 2,219.76 | 19.25 | 42.19 | 3.19 | 18.09 | 482.56 | 21.10 | 59.99 |
| 12 | Grifols International, S.A. (Spain) | 4,167.88 | 17.26 | 24.66 | 0.83 | 6.00 | 282.82 | 13.6 | 40.08 |
| 13 | United Therapeutics Corp. (U.S.) | 1,465.76 | 13.76 | 52.31 | 14.17 | 16.72 | 9161.01 | 5.40 | 66.63 |
| 14 | BioMarin Pharmaceutical Inc. (U.S.) | 889.90 | 20.51 | 112.44 | -1.07 | 71.33 | 412.37 | 15.20 | 24.05 |
| 15 | Agilent Technologies (U.S.) | 4,038.00 | -0.25 | 49.46 | 1.20 | 8.17 | 2243.33 | 14.48 | 54.57 |

2016 JPO Filing Report:
Gene Editing & Therapies
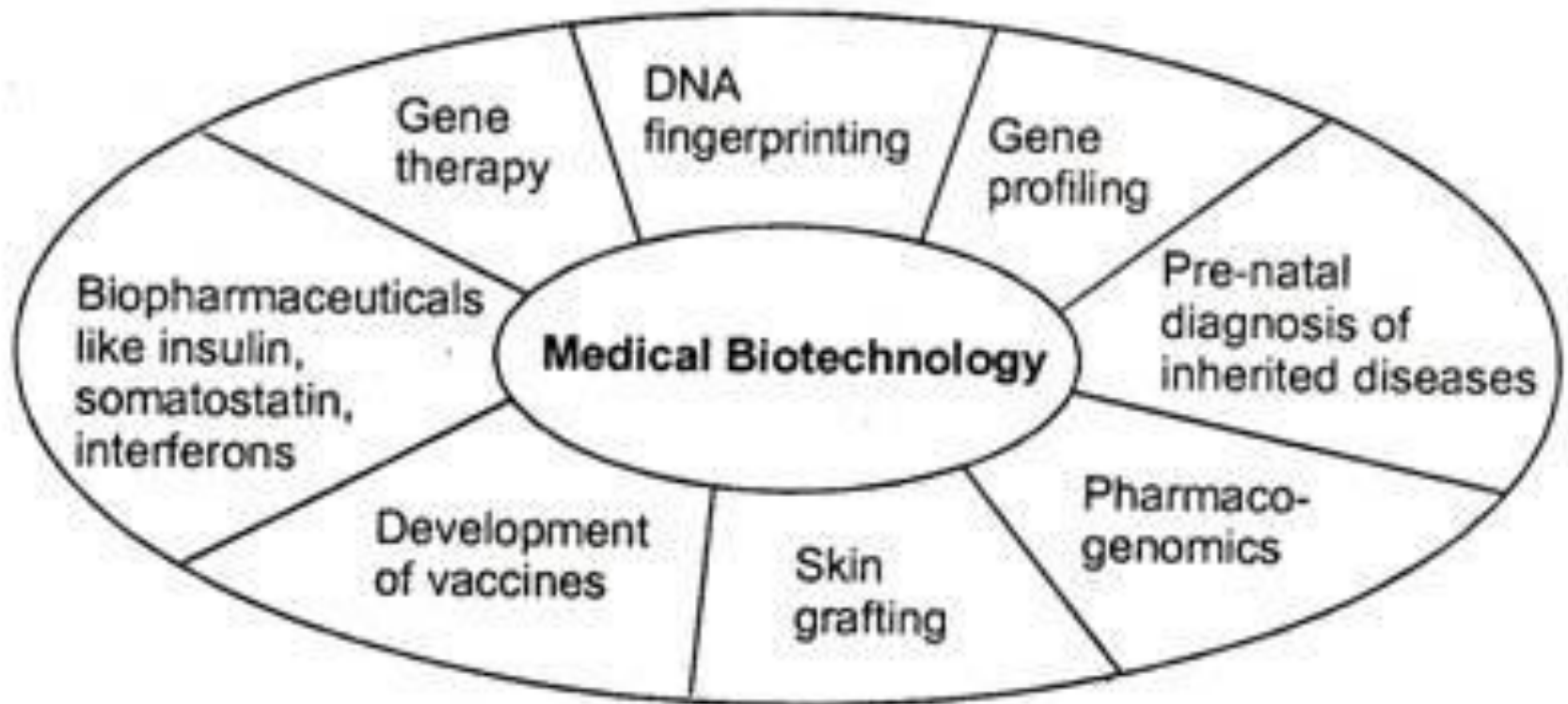
# Patent Eligibility

Major difference from EPC & JPL

- No statutory exclusion
  - Invention contrary to ordre public or morality
  - Plant or animal variety
  - Surgical, therapeutic or diagnostic method on human (or animal) body

# Patent Eligibility

- Common law exclusions
  - *Mayo v. Prometheus* (2012): Two step analysis
    - Gene therapies and personalized medicine
  - *AMP v. Myriad* (2013): Natural Product
    - Isolated DNA and natural products
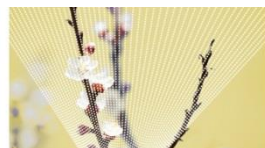
# *Mayo-Myriad* Impact

| AU Group | Technology |
|---|---|
| 1610 | Organic Compounds: Bio-Affecting, Body Treating, Drug Delivery, Steroids, Herbicides, Pesticides, Cosmetics, and Drugs |
| 1620 | Organic Chemistry |
| 1630 | Molecular Biology, Bioinformatics, Nucleic Acids, Recombinant DNA and RNA, Gene Regulation, Nucleic Acid Amplification, Animals and Recombinant Plants, Combinatorial/Computational Chemistry |
| 1640 | Immunology, Receptor/Ligands, Cytokines, Recombinant Hormones, and Molecular Biology Thereof |
| 1650 | Fermentation, Microbiology, Isolated and Recombinant Proteins/Enzymes |
| 1660 | Plants |
| 1670 | Cross-section of TC1600 subject matter uniting technology from the organic, nucleic acid, protein, and antibody arts, with a general focus on the pharmacological, diagnostic, and therapeutic aspects |

Table 2. Technologies associated with each art unit group in the biotechnology and organic chemistry TC 1600.

Trends in Subject Matter Eligibility for Biotechnology Inventions, IP Watchdog, July 12, 2015
http://www.ipwatchdog.com/2015/07/12/trends-in-subject-matter-eligibility-for-biotechnology-inventions/id=59738/
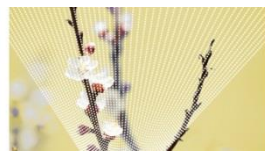
# *Mayo-Myriad* Impact
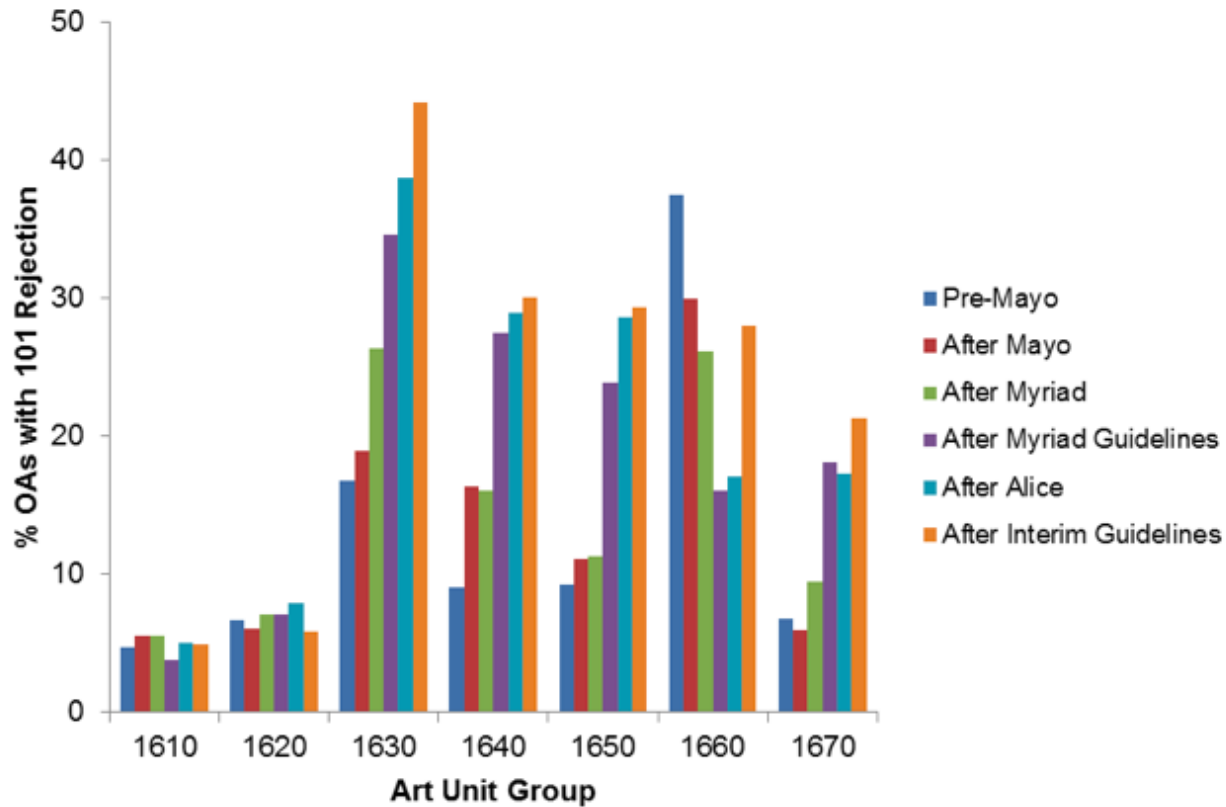
# Gene Therapy

**_Ariosa v. Sequenom_** (Fed. Cir. 2015)

- <u>Facts</u>:  _Sequenom_ obtained a patent on a method for using cell-free fetal DNA (cffDNA) in a pregnant mother's blood plasma to identify paternal genes by (1) amplifying the cffDNA from the maternal plasma and (2) detecting the presence of paternally-inherited DNA. Ariosa and other competitors filed declaratory judgment actions alleging non-infringement.  The District Court found the asserted claims invalid for lack of eligibility and Sequenom appealed.

- <u>Held</u>:  The claims directed to the cffDNA detecting method are directed to a natural phenomenon and thus not eligible.

# Gene Therapy

## 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.

# Gene Therapy

1. The asserted claims are directed to a natural phenomenon (cffDNA in maternal blood; paternally inherited cffDNA)

2. Additional steps do not transform the natural phenomenon into eligible subject matter because the amplifying and defecting steps were well-understood, routine and conventional activities in 1997.

   ❖ The dependent claims are focused on the use of the natural phenomenon in combination with well-understood, routine, and conventional activity.

# Gene Therapy

- *Sequenom* claims are issued at EPO & JPO
  - EP 0994963
    - A detection method performed on a maternal serum or plasma sample from a pregnant female, which method comprises detecting the presence of a nucleic acid of fetal origin in the sample, wherein said nucleic acid is a paternally inherited sequence which is not possessed by said pregnant female.
      - The patentee overcome an opposition at the EPO Board of Appeal

# Gene Therapy

- ***Genetic Techs. v. Merial*** (Fed. Cir. 2016)

Failed Mayo Analysis:

A method for detection of at least one coding region allele of a multi-allelic genetic locus comprising:

 a) amplifying genomic DNA with a primer pair that spans a non-coding region sequence, said primer pair defining a DNA sequence which is in genetic linkage with said genetic locus and contains a sufficient number of non-coding region sequence nucleotides to produce an amplified DNA sequence characteristic of said allele; and

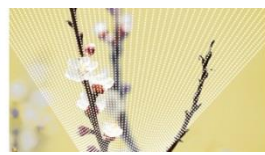b) analyzing the amplified DNA sequence to detect the allele

# Personalized Medicine

- USPTO Eligibility Guidelines

  <u>Eligible claim examples</u>

  - A method of treating a patient with julitis, the method comprising administering an effective amount of anti-TNF antibodies to a patient suffering from julitis

  - 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.

# Personalized Medicine

- PTAB inconsistent with USPTO Guidelines
  - Ex Parte Chattier
    - A method comprising applying at least one DDD condition therapeutic to a patient based on at least one DDD altered risk associated biological marker determined to be present in said patient.  Not eligible
  - Ex Parte Altwood
    - A method comprising 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, and the patient has a single nucleotide polymorphism (SNP)…rs4073366, wherein the patient is homozygous for the cytosine allele (C-allele) or the patient is homozygous for the guanine allele (G-allele) at the polymorphic position of rs407336 …. Not elgible

# Regenerative Medicine

***In re Roslin Institute***  (Fed. Cir. 2014)

- <u>Facts</u>:  Roslin Institute of University of Edinburgh obtained a patent on a method for cloning mammals from an adult cell.  It also tried to patent on the cloned mammals made by the patented method.  USPTO rejected the product claims for anticipation and obviousness.

- <u>Held</u>: Roslin's claimed clones are exact genetic copies of patent ineligible subject matter, products of nature and thus are not eligible for patent protection.

# Thank You!

If you have a question or comment

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