

# Information Technology and Biotechnology Breakout Session:

## New Pieces to the Patent Puzzle

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November 6, 2014  
IP Impact, Silicon Valley





**PATENT ELIGIBLE SUBJECT MATTER  
LIFE IN SOFTWARE/IT AFTER  
*ALICE CORPORATION V. CLS BANK*  
(AND OTHER RECENT 101 DECISIONS)**

## A Brief History with respect to Software and Biz Methods

- 1998: CAFC opens floodgates with *State Street*
- 2008: CAFC introduces M-O-T test in *Bilski*
- 2010: SCOTUS limits M-O-T and gives us vague “abstract idea” test in *Bilski*
- 2014: SCOTUS discounts significance of computerization/automation in *Alice*

# USPTO's (Over)Reaction to *Alice*

- Preliminary Guidelines and Examiner Training
- Dramatic increase in 101 rejections in classes 705 and 709
- Unwillingness to withdraw *Alice*-based rejections

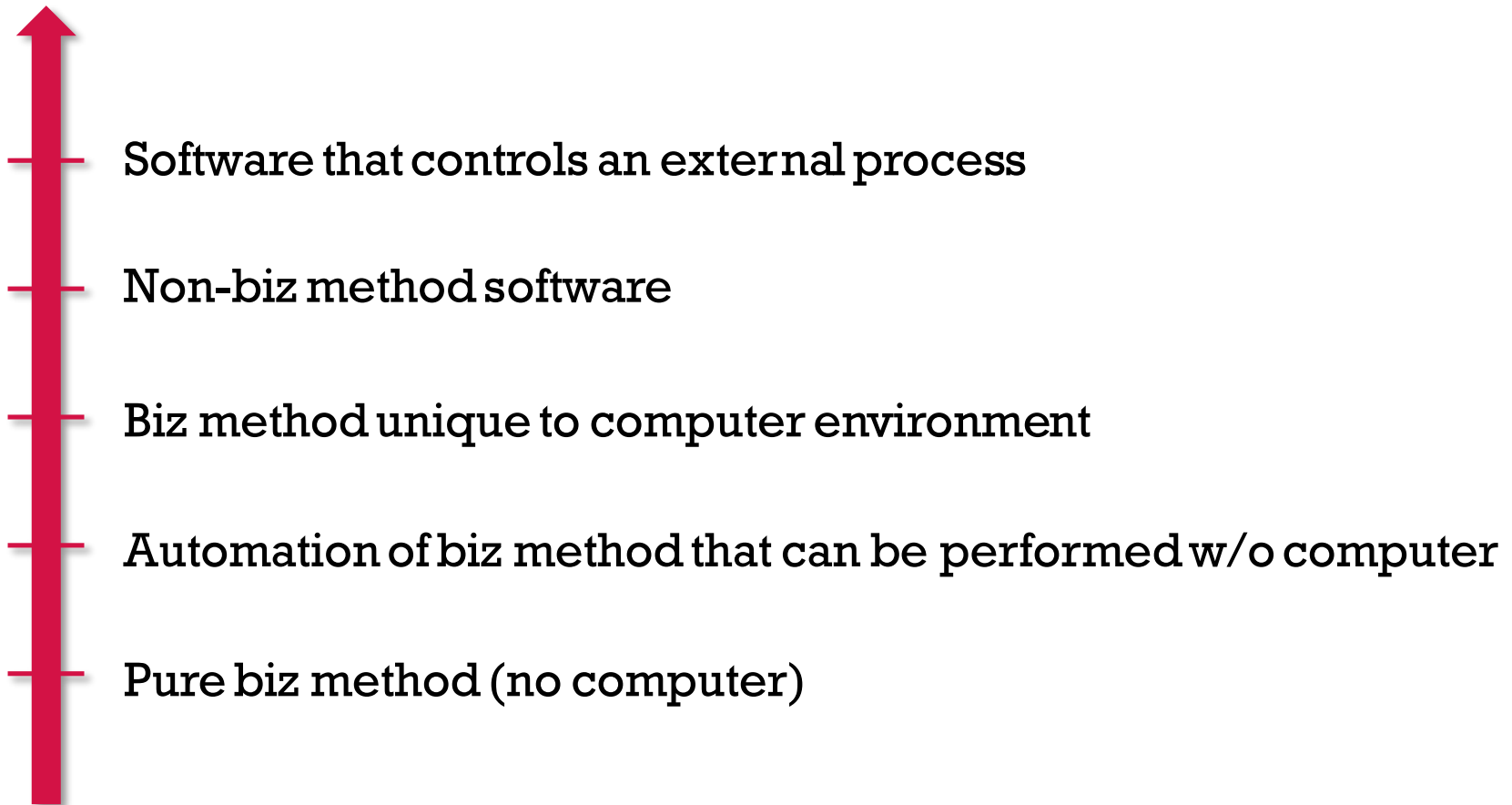
# Where Are We Now?

- Great uncertainty due to vague “abstract idea” test



- Additional cases needed

# Likelihood of Satisfying 101



# Responding to 101 Rejections by (Re)Applying the Mayo Framework – Part I

- What do you do when the Examiner asserts that your claims are directed to an abstract idea?
  - Argue that the Examiner has taken the abstraction of the claims too far and/or in a manner that SCOTUS (and the PTO guidelines) cautioned against
    - Examiner has ignored meaningful claim recitations
    - Examiner’s “abstraction” is an over-simplification of the claimed recitations
  - Argue that the claimed subject matter is not “**long prevalent**” or “**fundamental**” and thus, grant of the claims would NOT **preempt** use in all fields or effectively grant a monopoly over an abstract idea/fundamental practice
    - This is essentially a reverse 102/103 argument

# Responding to 101 Rejections by (Re)Applying the Mayo Framework – Part II

- What do you do when the Examiner determines, after considering your elements individually and in combination, that they do NOT transform the nature of the claim into a patent-eligible application?
  - Do not concede (even implicitly) that the claims recite an abstract idea, or over-emphasize Part II
  - Instead, argue that the elements amount to **significantly more** than a patent upon the abstract idea itself (assuming *arguendo*, that the claims simply recite an abstract idea)





**PATENT ELIGIBLE SUBJECT MATTER  
LIFE IN BIOTECH AFTER  
*MAYO V. PROMETHEUS AND MYRIAD*  
(AND OTHER RECENT 101 DECISIONS)**

# 101 – *Draft PTO Guidelines*

- *PTO Guidelines—Law of Nature, Nat. Phen., Nat. Prod. (Myriad/Prometheus—March, 2014)*
  - 3 part test applies to all claims (including abstract ideas, June 2014)
  - Q1--process, machine, manufacture, or composition of matter? If yes→
  - Q2--recite or involve one or more judicial exceptions? If yes→
  - Q3--significantly different than the judicial exception?

# 101 – *Draft PTO Guidelines*

- *PTO Guidelines*—“*Significantly Different*”--**toward eligibility**
  - a) initially appears to be a natural **product**, but after analysis... non-naturally occurring and markedly different in structure.
  - b) additional elements that impose meaningful limits on claim scope (others are not substantially foreclosed).
  - c) elements are more than nominally, insignificantly, or tangentially related to the judicial exception.
  - d) elements are more than apply or use the judicial exception.
  - e) elements include a particular machine or transformation of a particular article.
  - f) elements that is more than well-understood, purely conventional or routine in the relevant field.

# 101 – *Draft PTO Guidelines*

- *PTO Guidelines*—“*Significantly Different*”—**against eligibility**
  - g) product claim--a natural **product** that is not markedly different in structure from naturally occurring products.
  - h) high level of generality such that substantially all practical applications of the judicial exception are covered.
  - i) elements that must be used/taken by others.
  - j) elements that are well-understood/conventional/routine in the relevant field.
  - k) elements that are insignificant extra-solution activity.
  - l) elements that amount to nothing more than a mere field of use.

# 101 – *Draft PTO Guidelines*

- Comments from BIO Symposium (June Cohan, OPLA):
  - Will apply to more than DNA
  - Directed to vs. involving/reciting
  - *Significantly Different*—
    - “teaching tool”
    - “you won't see this term again”
  - Will drop/clarify 12 factors....

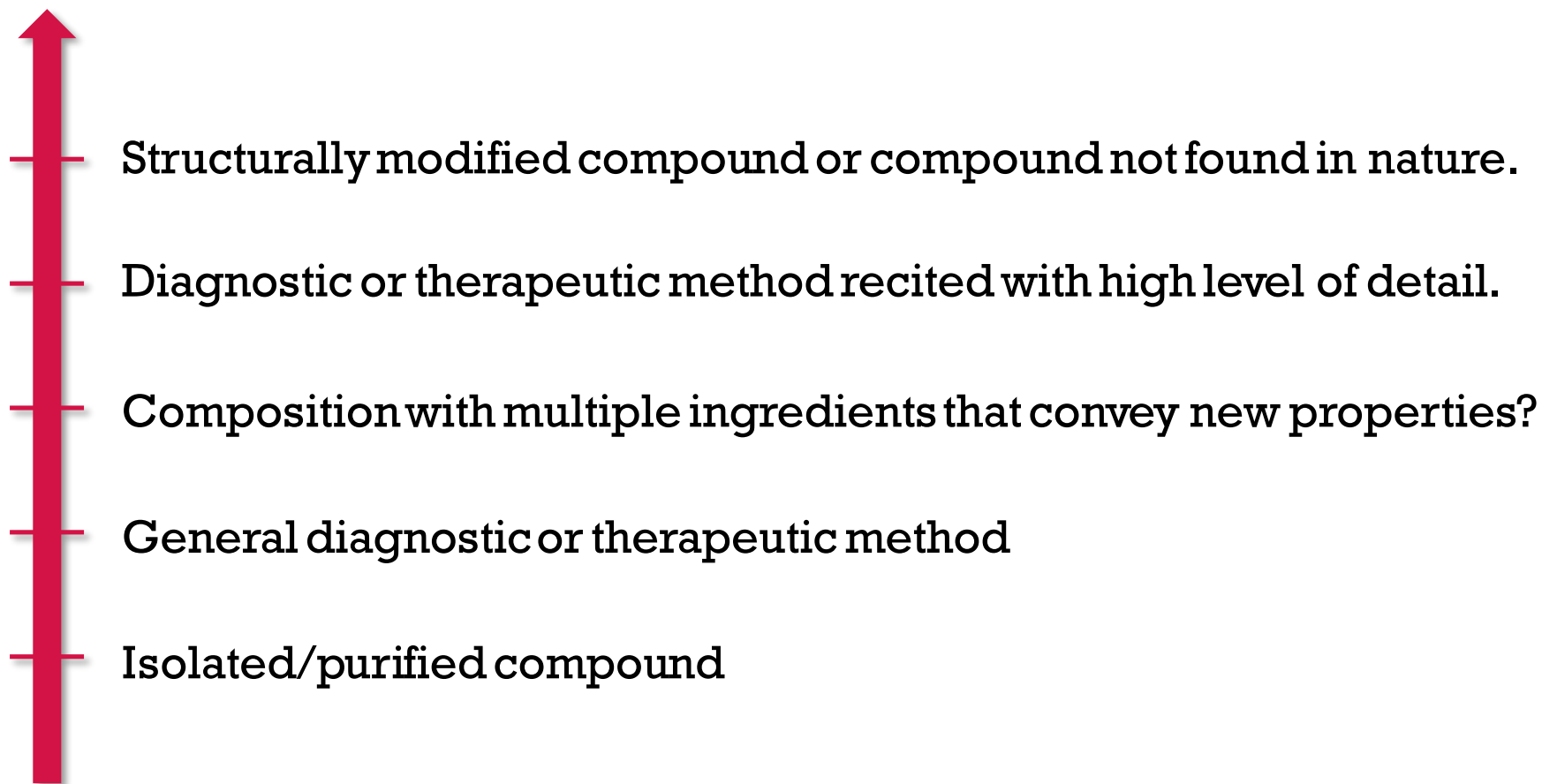
# PTO Examples

- Purified amazonic acid (N) vs. 5-methyl amazonic acid (artificial--Y)
- Combinations of bacteria—(N)
- Primer Pairs (N) vs. Mthd of using in PCR (Y)
- Mthd of diagnosing subject w/ misfolded protein by Ab (specific...NiN) (Y)
- Mthd of treatment using light: sunlight (N); syn light (N); filtered light/time/distance (Y)
- Mthd of ID mutant BRCA2...(AI....)

## What of?

- Isolated vs. Purified vs. Monoclonal
  - Antibiotics, proteins, etc.

# Likelihood of Satisfying 101



# Practice Points – Biotech Prosecution

- Effectively used as alternative “prior art”--discount/ignore elements in claims
- What is adequate to overcome... art?
  - Novel structural element?
  - Definitions
  - New steps vs. old steps for new purpose (from preamble to element).
  - Tie to unique initial or resulting step
    - But...distributed infringement
    - Beyond simple “extra-solution”
  - “Not occurring in nature” or “non-natural”
  - Novel function/characteristic (vs. PTO)



# Practice Points – Biotech Prosecution

- What is adequate to overcome... art?
  - Do not rely on unclaimed aspects
  - Amount/Concentration (vs. PTO)
  - Compositions (pharmaceutical carrier/buffer) (vs. PTO)
- PTO:
  - Examiner vs OPL
  - Guidelines—“in October or soon thereafter”

# Quotes from Myriad II—Oral Hearing

- **Judge Prost:** Is it your position that you should look at the entire claim?.... You take away the abstract idea or law of nature, look at the additional steps, and determine whether the additional steps are well-understood, routine, and conventional such that they add nothing significant.
- **Judge Dyk:** Function can't be the test, can it?

VS

- **Judge Dyk:** The Supreme Court was concerned about excluding all possible claims that would reward the invention here.



**DISTRIBUTED INFRINGEMENT  
LIFE AFTER  
*LIMELIGHT V. AKAMAI***

# A Brief History

- Definition: Two or more entities collectively perform all steps of a method claim, but no single entity performs all of them.
- Case law:
  - 2007: CAFC in *BMC v. Paymentech* introduces “direct or control” test and states that induced infringement requires a direct infringer
  - 2007-2012: Numerous decisions find no infringement due to divided infringement issues
  - 2012: CAFC addresses perceived unfairness by expanding induced infringement to cover divided infringement scenarios
  - 2014: Supreme Court in *Akamai* reverses CAFC and remands

# Where Are We Now?

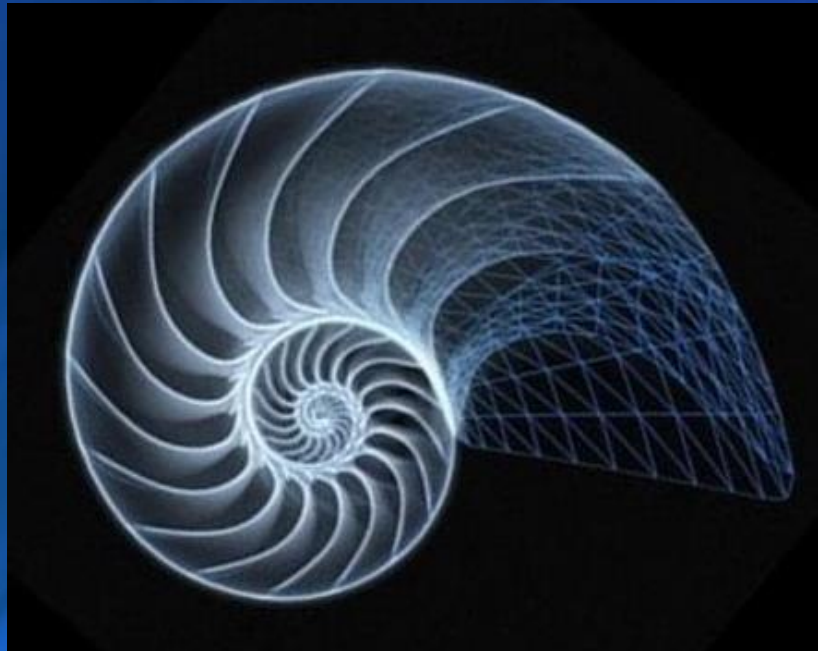
- Many accused infringers can again avoid liability where divided infringement issues exist
- CAFC may now address the perceived unfairness by revisiting the law of direct infringement (as suggested by SCOTUS)

# Practice Points – Software/IT Prosecution

- Draft claims for single infringer
  - From the perspective of the interesting actor, e.g., server side v. client side
  - Consider whether aspects of the claim can be obtained from a separate service or whether the invention itself can be spun into a separate service
- Draft claims that are directed to who will control/direct actions
  - The host/service provider? The manufacturer/owner of the end user device?
  - Who controls “the cloud”? Who controls a mobile app?
- Draft claims to refer obliquely to other parties
- Include server side claims to block the resulting functionality of those system claims being used in the U.S.

# Practice Points – Biotech Prosecution

- Draft claims for single infringer
  - Patient?
  - Treatment based on presence of characteristic, rather than testing for characteristic
  - Historical element vs steps to perform
- Who will control/direct actions
  - Hospital/Dr./Insurance
- Effect of functional limitations (“configured”, etc.) on subsequent options to block import of products?
  - e.g. import lyophilized forms, and claim requires “binds to”
- Trade Secret/Contracts?
- Downstream products--who owns



**INDEFINITENESS  
LIFE AFTER  
*NAUTILUS, INC. V. BIOSIG INSTRUMENTS***



# *Nautilus v. Biosig Instruments*

- **“Old” Fed. Cir. (high) standard:** claim satisfies § 112 if “amenable to construction” and not “insolubly ambiguous”
- **After *Nautilus*:** A patent is **invalid** for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with **reasonable certainty**, those skilled in the art at the time the patent was filed about the scope of the invention.

# Practice points – Biotech Prosecution

- Evolving terms in the art (at the time of filing)
  - Protein X in 2010 (isolated) vs 2011 (after sequenced) vs 2016 (after glycosylation pattern)
- Genus vs species for meaning of a term?
  - Terms with multiple definitions at time of filing, 1 definition or all?
    - Molecular Weight (*Teva Pharmaceuticals*)
    - CDRs
- Functionally defined or defining terms or degree
  - Hidden parameters that also could be defined?
    - How defining  $K_d$ ?
    - How defining “activity”
- “Product by process” or “product described by process” terms
  - Hidden parameters that also could be defined?

# Practice Points – Biotech Prosecution

- The claim is as precise as language allows (inherent limitation of language, “regard to the subject matter,” and provides notice)
- Deposits
- Definitions
  - Minor inconsistencies need not be a redefining of terms (*Ancora*)
    - Parallel definitions vs. serial definitions
  - Implicit/inherent definitions helpful (*Dan*)
- File History
  - Clarification of definition
- Continuations
- UPSTO currently uses “broadest reasonable interpretation”
  - *In re Packard*—*prima facie* approach

# Practice Points – Software/IT Prosecution

- Patent Drafting: Say what you mean
  - Consider including definitions
  - Include clear explanations of inventive concepts, including specific illustrative numerical parameters
  - Include at least one teaching claim (i.e., a claim that covers in greater detail, and as unambiguously as possible, what is important to the client)
  - Use dependent claims to further define claim terms
  - Include multiple claims to various embodiments

# CONCLUSION

U.S. Patent [19] [11] Patent [11] [45] Date of [45]

FOR [19] [11] Patent [11] [45] Date of [45]

Assistant Examiner— [19] [11] Patent [11] [45] Date of [45]

Attorney, Agent, or F [19] [11] Patent [11] [45] Date of [45]

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An elongate hollow [19] [11] Patent [11] [45] Date of [45]

tronic circuitry and [19] [11] Patent [11] [45] Date of [45]

ther end, a live electrode and a spaced common electro- [19] [11] Patent [11] [45] Date of [45]

de. The electronic circuitry includes a difference [19] [11] Patent [11] [45] Date of [45]

amplifier, and electromyogram signals detected by the [19] [11] Patent [11] [45] Date of [45]

electrodes are applied to opposite polarity inputs of the [19] [11] Patent [11] [45] Date of [45]

ier. As the electromyogram signals are [19] [11] Patent [11] [45] Date of [45]

equal amplitude and phase, the electro- [19] [11] Patent [11] [45] Date of [45]

will be subtracted from each other in [19] [11] Patent [11] [45] Date of [45]

mplifier to provide a substantially zero [19] [11] Patent [11] [45] Date of [45]

ectromyogram signals at the output of [19] [11] Patent [11] [45] Date of [45]

mplifier. However, electrocardiograph [19] [11] Patent [11] [45] Date of [45]

opposite phase, will be added in the [19] [11] Patent [11] [45] Date of [45]

ier so that the output of the difference [19] [11] Patent [11] [45] Date of [45]

stantially due to only the electrocardio- [19] [11] Patent [11] [45] Date of [45]

References Cit [19] [11] Patent [11] [45] Date of [45]

U.S. PATENT DOC [19] [11] Patent [11] [45] Date of [45]

4,319,581 3/1982 Cutter ..... [19] [11] Patent [11] [45] Date of [45]

4,513,753 4/1985 Tabata et al. [19] [11] Patent [11] [45] Date of [45]

4,825,874 5/1989 Uhlemann .. [19] [11] Patent [11] [45] Date of [45]

4,913,146 4/1990 DeCote, Jr. [19] [11] Patent [11] [45] Date of [45]

Primary Examiner—William E. K [19] [11] Patent [11] [45] Date of [45]

Claims, 10 Drawing Sheets [19] [11] Patent [11] [45] Date of [45]

# Conclusion

- Court's attempt to reduce scope
  - Similar to developments in § 112, W.D. over the last 20 years
  - Addressable during prosecution
- Drafting
  - Definitions
  - Larger number of narrower claims (support)
- Pending
  - Narrower claims (more)
- Issued:
  - Supp. Examination is available.

# Thank You

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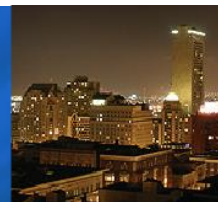
Orange County



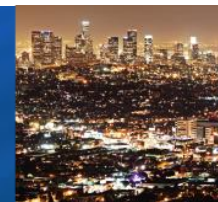
San Diego



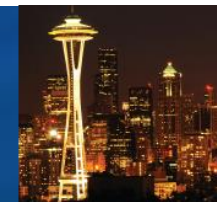
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