

Roundtable I –

USPTO Subject Matter Eligibility Guidelines

Nov. 14, 2016

Richard Marsh, Jr., ABA-IPL

The ABA Post-Alice Task Force

- ▶ Formed to study how *Alice v. CLS Bank* is being applied at the PTO and in courts
- ▶ Over 100 volunteers representing diverse backgrounds, viewpoints, and experiences
- ▶ Partnership with Juristat

The ABA Post-Alice Task Force

- ▶ Patent Office focus:
 - ▶ Analyze applications in which the applicants overcame *Alice* rejections between July 2015 to November 2015
 - ▶ Analyze applications by workgroup to see if similar training results in consistent applications of section 101

Analysis – July 2015 to November 2015

- ▶ Over 400 cases analyzed:
 - ▶ Boilerplate rejections?
 - ▶ 41% of the office actions were deemed boiler plate
 - ▶ Interview? 57% of successful cases were interviewed
 - ▶ But note: About half the interview summaries made no mention of Alice issues

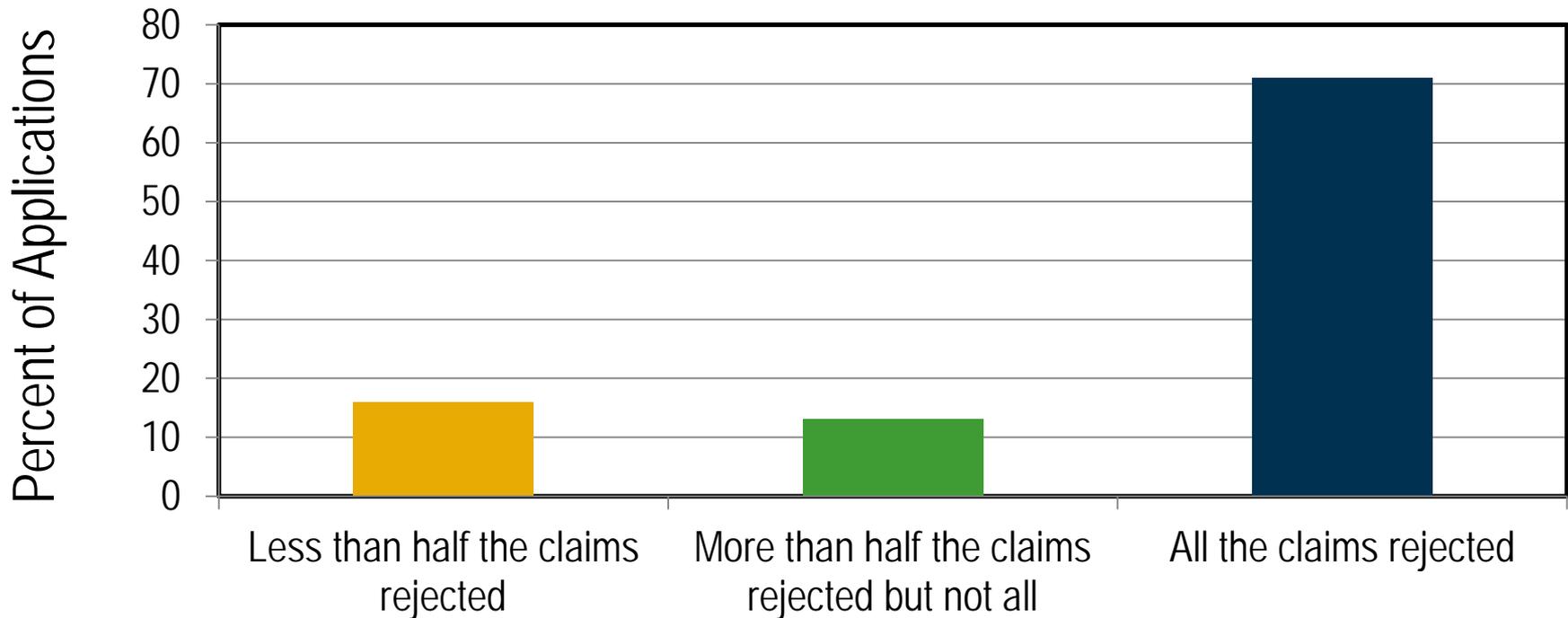
Analysis – July 2015 to November 2015

- ▶ Over 400 cases analyzed:
 - ▶ Did the applicants cite any specific examples from the guidelines in response to the rejections?
 - ▶ Most of the time (71%), no examples were cited
 - ▶ Did the applicants cite any specific cases in response to the rejections?
 - ▶ About half the time

Analysis – July 2015 to November 2015

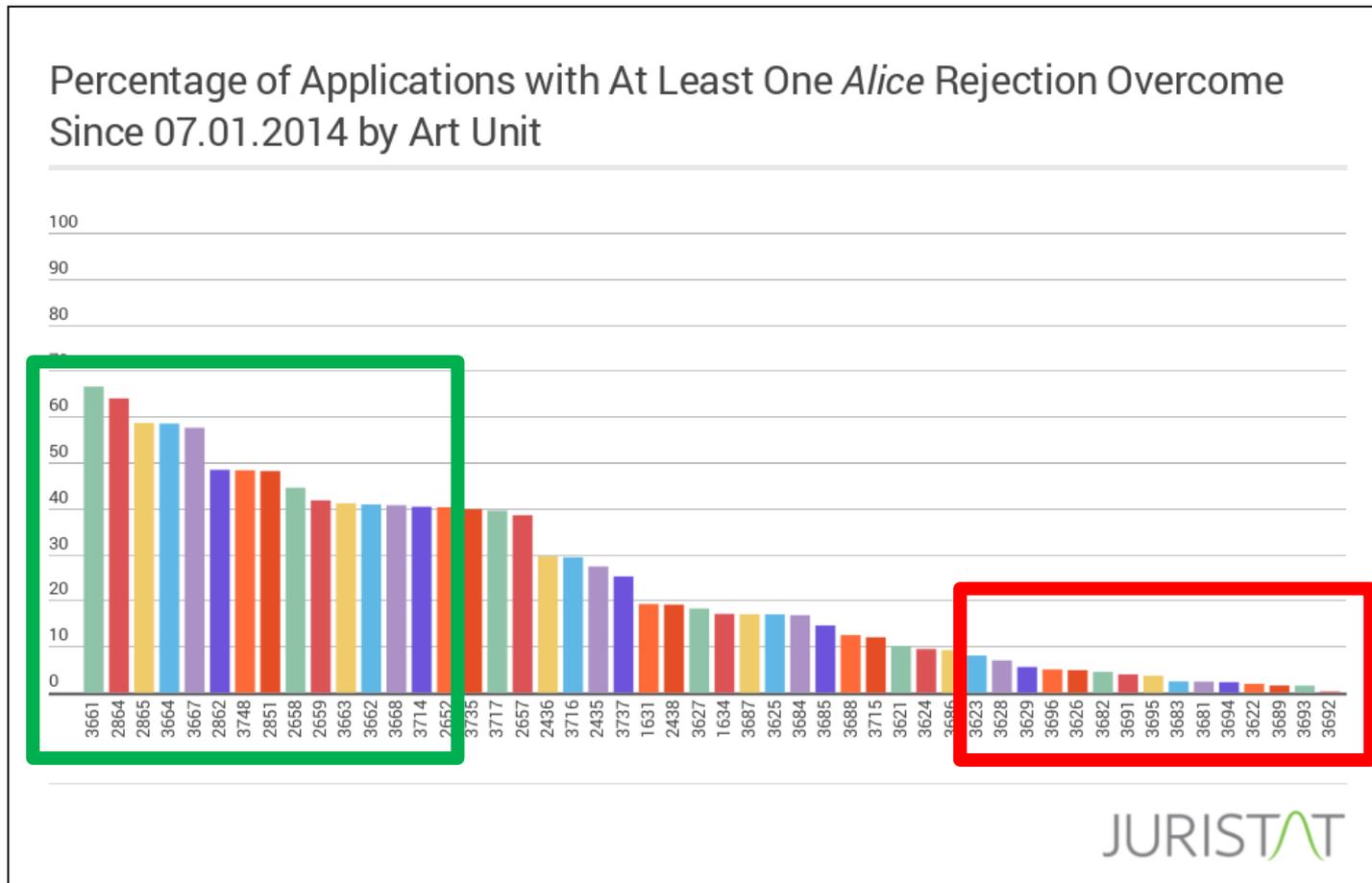
- ▶ How many claims in an application were rejected before overcoming *Alice*?

How Many Claims in an Application were Rejected?



Workgroup Focus

► Consistency within workgroups



Workgroup Focus

- ▶ Consistency within workgroups
- ▶ Workgroup 2860 (medical devices)
 - ▶ Variety of amendments, from significant technical details to “a processor”
 - ▶ §101 rejections overcome once prior art rejections overcome
- ▶ Workgroup 3760 (surgical techniques)
 - ▶ Amendments: Adding a specific sensor, a specific structure, etc.
- ▶ Workgroups 1640, 1660, 1670 (life sciences)
 - ▶ Amendments:
 - ▶ Replace naturally occurring substance with artificial counterpart
 - ▶ Limiting detection methods to specific methods or target groups

Questions?

Roundtable I –

USPTO Subject Matter Eligibility Guidelines

Nov. 14, 2016

Richard Marsh, Jr., ABA-IPL

USPTO § 101 Guidelines

Matt Levy

Patent Counsel

Computer & Communications Industry
Association

CURRENT APPROACH IS LIMITED

Current Guidelines

Uses comparisons to known examples:

“Examiners should not go beyond those concepts that are similar to what the courts have identified as abstract ideas.”

Drawbacks

- Unable to respond to unfamiliar abstract ideas
- Allows cherry-picking of examples
- Unhelpful in understanding examiner's reasoning

**LOOKING FOR TECHNICAL
IMPROVEMENT**

CAFC Has Identified Principle

- If there is a technical improvement, claim is patent-eligible
- See, e.g., *Bascom, Electric Power Group, McRO*
- Can be used at step 2A or 2B

Advantages

- Flexible, not limited to known examples
- Allows analysis of examiner's reasoning
- Consistent with CAFC case law



Cooper
Legal Group, LLC



35 U.S.C. § 101 Examination Practices: Key Problems and Recommendations

David Stein, Esq.

Vice-President, National Association of Patent Practitioners (NAPP)
Patent Attorney, Cooper Legal Group

The opinions expressed in this presentation are exclusively personal, and do not necessarily reflect the views of NAPP, Cooper Legal Group, or any client.
This presentation is not legal advice and does not create an attorney/client relationship.

Problem #1: Noncompliant Rejections

- USPTO *Interim Eligibility Guidance* is an excellent resource - detailed, accurate, and well-organized
- Even 2+ years after *Alice*, many 35 USC § 101 rejections are materially noncompliant with the *IEG*

Noncompliant § 101 Rejections, Example #1

Claims 1-19 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The claim(s) is/are directed to the abstract idea of using categories to organize, store and transmit information in a computer network. The additional element(s) or combination of elements in the claim(s) other than the abstract idea per se amount(s) to no more than: (i) mere instructions to implement the idea on a computer, and/or (ii) recitation of generic computer structure that serves to perform generic computer functions that are well-understood, routine, and conventional activities previously known to the pertinent industry. Viewed as a whole, these additional claim element(s) do not provide meaningful limitation(s) to transform the abstract idea into a patent eligible application of the abstract idea such that the claim(s) amounts to significantly more than the abstract idea itself. Therefore, the claim(s) are rejected under 35 U.S.C. 101 as being directed to non-statutory subject matter.

The claim as a whole, does not amount to significantly more than the abstract idea itself. This is because the claim does not affect an improvement to another technology or technical field; the claim does not amount to an improvement to the functioning of a computer itself; and the claim does not move beyond a general link of the use of an abstract idea to a particular technological environment.

The instant claims are rejected under 35 U.S.C. 101 in view of The Decision in *Alice Corporation Pty. Ltd. V. CLS Bank International, et al.* in a unanimous decision, the Supreme Court held that the patent claims in *Alice Corporation Pty. Ltd. V. CLS Bank International, et al.* (“Alice Corp.”) are not patent-eligible under 35 U.S.C. § 101.

Noncompliant § 101 Rejections, Example #2

- Claim 1 cites measuring, comparing, and evaluating metrics.
- “Measuring” and “comparing” are similar to concepts identified by the courts as abstract, such as using categories to organize, store, and transmit information in *Cyberfone*.
- “Evaluating” is an abstract idea in the context of organizing, storing, and transmitting information.

Noncompliant § 101 Rejections, Example #2

1. X XXXXXX XX XXXXXXXXXXXX XXXXXXXX XXXXXXXX XX XX XXXXXXXXXXX XX X XXXXXXXX XXXXXXXXXXX XX X XXXXXXX XX X XXXX XX X XXXXXXXXXXX XXXXXX X XXXXXXXXXXX, XXX XXXXXXX XXXXXXXXXXX:

XXXXXXXXXX XXXXXXXXXXXXXXXX XX XXX XXXXXXXXXXX XXXX XXXXX XXX XXXXXXXXXXX XX:

XXXXXXXXXX X XXXXXXX XXXX XX X XXXXXXXXXXXXXXX XX XXX XXXXXXXXXXX XX XXX XXXXXXX XXXX XXX XXXXXXX XX XXX XXXX;

XXXXXXXXXX XX XXXXX XXX XXXXXXXXXXX XX XXX XXXXXXXXXXX XXXX XXXX XXXXX XXX XXXXXXXXXXXXXXX XX XXX XXXXXXXXXXX XX XXX XXXXXXXXXXX XX XXXXXXXXXXX XX XXX XXXX;

XXX XXXXXXXXXXX XXXXXXXXXXX XX XXX XXXXXXXXXXX XXXX, **measure** X XXXXXXX XXXXXXX **metrics** XX XXX XXXXXXXXXXX XXXXX XXX XXXXXXX XXXXXXX XXX XXXXXXXXXXXXXXX XX XXX XXXXXXXXXXX XX XXX XXXXXXX XXX XXX XXXX;

compare XXX XXXXXXX XXXXXXX **metrics** XX XXX XXXXXXXXXXX XXXXXXXXXXX XX XXX XXXXXXXXXXX XXXXXXX XXX XXXXXXXXXXXXXXX XX XXX XXXXXXXXXXX XX XXX XXXXXXX XXX XXXXXXXXXXX XXXXXXX X XXXX XXXXXXXXXXX XXXXXXX XXXXXXX; XXX

XXX XXX XXXXXXXXXXX XX XXXXX XXX XXXXXXXXXXX XXXXXXX XXXXXXX X XXXX XXXXXXX XXXXXXX XXXXXXX, **evaluate** XX XXXXXXX XX XXX XXXX XXXXXXX XXXXXXX **metric** XX XXX XXXXXXXXXXX XXXXXXX XX XXX XXXXXXXXXXX XX XXXXXXXXXXX X XXXX XXXXXXX XXXXXXX XXXX XXXXXXXXXXXXXXX XX XXX XXXX XXXXXXX XXXXXXX XX XX XXXXX XXX XXXXXXXXXXX XX XXX XXXXXXX XXXXXXX XXX XXXXXXXXXXXXXXX XX XXX XXXXXXX XX XXX XXXXXXX XXX XXX XXXX; XXX

XXXXXX XXX XXXX XX XXX XXXX XXXXXXX XXXXXXX XXXX XXXXXXXXXXXXXXX XX XXX XXXX XXXXXXX XXXXXXX XX XXX XXXXXXXXXXXXXXX XX XXX XXXXXXX XX XXX XXXXXXX.

240-word claim boiled down to 6-word “abstract idea” (2.5%)

Noncompliant § 101 Rejections, Examples #3-7

- Dependent claims 2-18 do not add any limitations that would remedy the deficiencies outlined above and are rejected accordingly.
- Regarding claims 2-18, as they depend on claim 1, as they do not recite “significantly more” than what is recited in their parent claim, therefore they are also directed to an abstract idea.
- Dependent claims 2-6, 8-12, and 14-20 are rejected as ineligible subject matter under 35 U.S.C. 101 based on a rationale similar to the claims from which they depend.
- Claims 1-21 are directed to the abstract idea of xxxxx. The claims do not include additional elements that are sufficient to amount to significantly more than the judicial exception because the computing environment is a generic computer component that generally links the system to a particular technological environment. Accordingly, claims 1-21 are rejected under 35 USC 101 in view of *Alice Corp. v. CLS Bank*.
- All claims are rejected under 35 U.S.C. 101 because the claimed invention is directed to a judicial exception (*i.e.* an abstract idea) without significantly more.

Problem #1: Noncompliant Rejections

- Central message of Alice and the *IEG*: § 101 requires careful, thorough consideration and discussion of the eligibility of invention and claims
- Conversation is a two-way process - not possible when the examiner refuses to participate as the *IEG* requires, but treats § 101 as a “license to flush”

Noncompliant § 101 Rejections, Example #8

RESPONSE TO AMENDMENT

Applicant's amendments and arguments are NOT sufficient to overcome the 35 U.S.C. § 101 rejection set forth in the previous office action. Therefore, examiner maintains rejection of the claims under 35 U.S.C. § 101.

Problem #1: Noncompliant Rejections

- Recommendation: Enforce the *IEG* - supervisors should compel materially defective rejections to be withdrawn and rewritten

Problem #2: Opting Out of § 101

- Examiners are taking a pass on § 101 analysis
- “My SPE / art unit will never allow this claim”
- “35 USC § 101 is too difficult; you’ll have to appeal”
- [silence]

Problem #2: Opting Out of § 101

- Some examiners appear to feel powerless to perform analysis and make a decision
- Some examiners appear to feel no compelling responsibility to address § 101, particularly for making affirmative statements of patent eligibility

Problem #2: Opting Out of § 101

- Recommendation #1: Ensure that examiners feel supported for adequate § 101 rejections
- Recommendation #2: Ensure that examiners feel compelled to perform and explain § 101 analysis, especially in every notice of allowance

Problem #3: The Role of Appeals

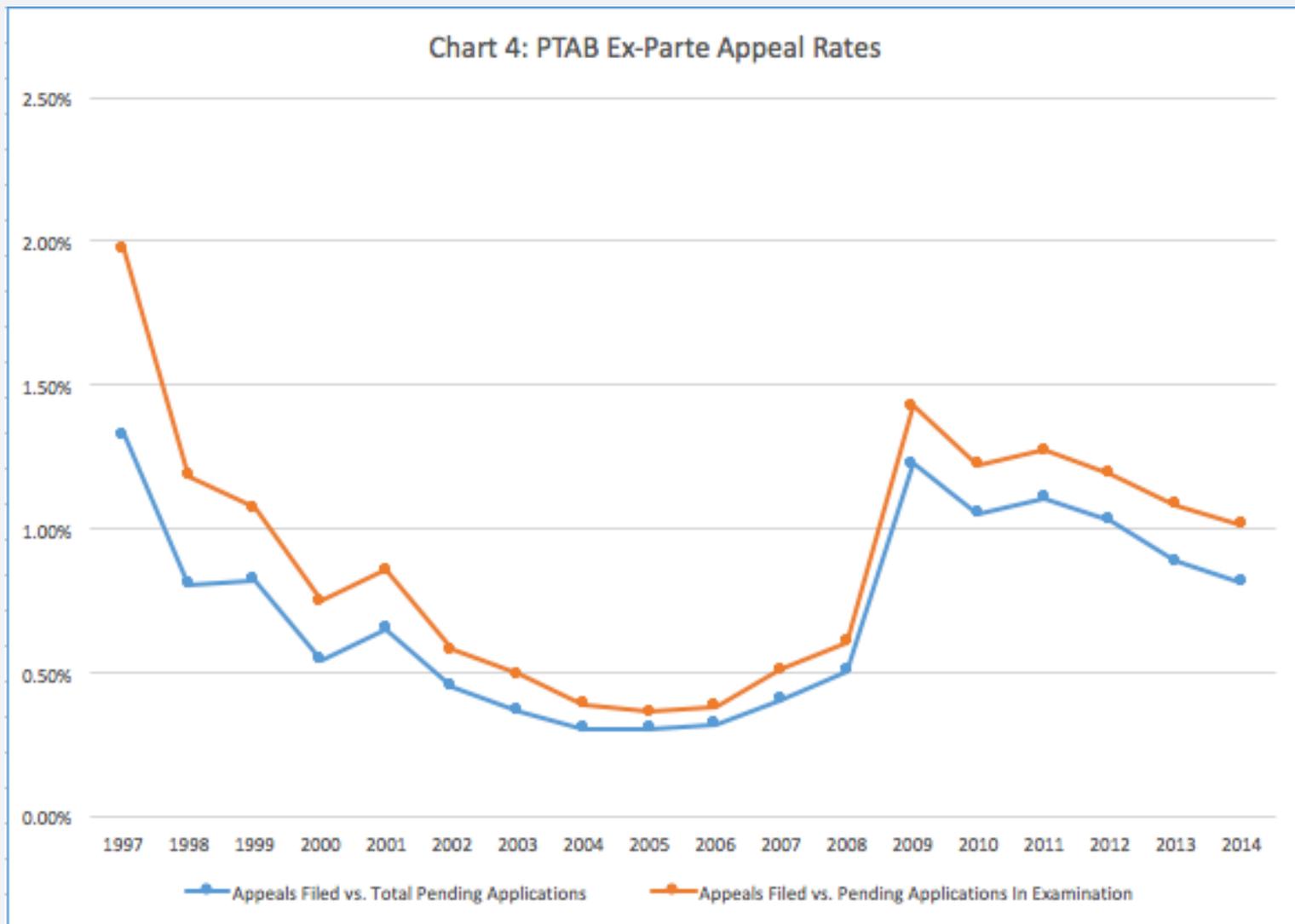
- Appeals are costly (\$2,800-\$4,100) and protracted (resolved via briefs: 6-12 months; resolved by board: 24-48 months) - painful for applicants, *even if they win*
- For examiners, appeals are a mere irritation *even if they lose*
- Discrepancy creates a problem of moral hazard:

Unlikelihood of appealed § 101 rejections
+ No significant consequence for losing appeal

Lots of deficient § 101 rejections

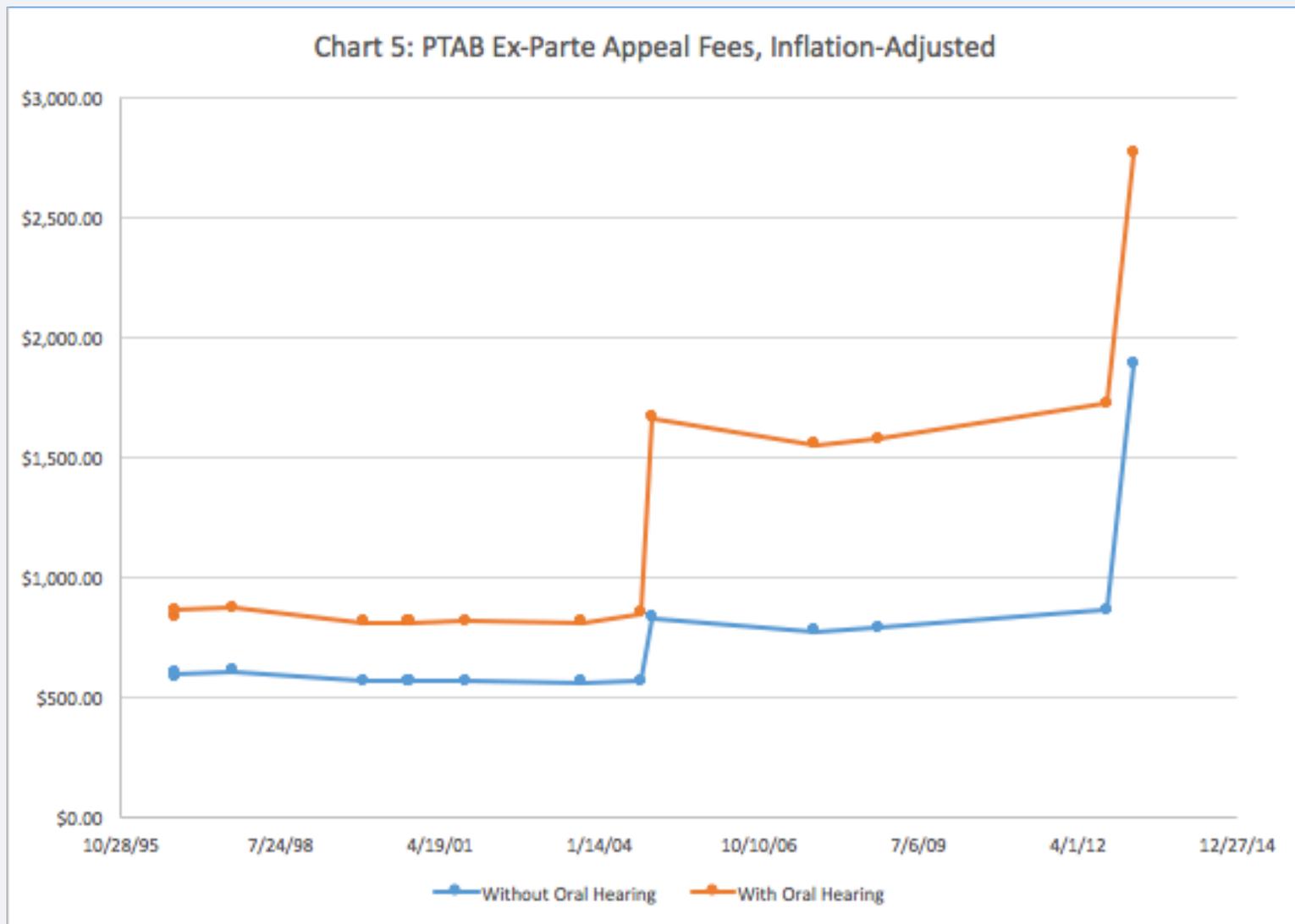
Problem #3: The Role of Appeals

- Appeals are over twice as common today as in 2004...



Problem #3: The Role of Appeals

- ...even though appeal fees are 2.5x as costly today



Problem #3: The Role of Appeals

- TC 3600 § 101 Appeal Data, three-year period:
 - 24,956 applications in process
 - 465 appeals (1.8% of in-process applications)
 - 434 appeals (93%) involved a § 101 rejection
 - 202 / 434 appeals (46.5%) involved no prior art rejection
 - 109 / 434 appeals (25.1%) never rejected on prior art
- Source: Robert Sachs, Fenwick & West /
Bilski Blog (<http://www.bilskiblog.com>)

Problem #3: The Role of Appeals

- Juristat appeal metrics: Some examiners lose 80%+ of appeals
- Example from Proactive Patents (<http://www.proactivepatents.com>):

Let's take a look at a real life example of a current USPTO examiner; for now we'll call him "Examiner A", who has six years of experience in Technology Center 2400 (Networking, Multiplexing, Cable, & Security), Examiner A proves to be a strong representation of USPTO examiners in this high-tech area. Reviewing the examiner's historical data, we can that Examiner A holds the following statistics:

- An overall allowance rate of 51%, compared to a Group Art Unit average of 62%
- Average number of office actions for issued patents is three (3), average office actions for abandoned applications is five (5), compared to a Group Art Unit issuance/abandonment average of two (2) office actions
- Applicant PTAB appeal win percentage is 90%, compared to a Group Art Unit average of 75%

Problem #3: The Role of Appeals

- Appeals are administratively heavy - should be reserved for tough cases and legitimate disagreements
- Instead, the appeal process is burdened with resolving deficient § 101 rejections - PTAB and clients bear the cost of examiners' errors

Problem #3: The Role of Appeals

- USPTO proposal: Increase appeal fees by 25%
- Undemocratic solution: Selectively penalizes applicants with small budgets, who have no recourse
- Hides and exacerbates fundamental problem of moral hazard - result: lower-quality § 101 rejections

Problem #3: The Role of Appeals

- Recommendation #1: Don't increase fees!
- Recommendation #2: Provide alternatives to appeal for challenging § 101 rejections (*e.g.*, P3 Program; special unit of Ombudsman's Office)
- Recommendation #3: Address moral hazard problem



Cooper
Legal Group, LLC



More Information:

National Association of Patent Practitioners

<http://www.napp.org>

Cooper Legal Group, LLC

<http://www.cooperlegalgroup.com>

The opinions expressed in this presentation are exclusively personal, and do not necessarily reflect the views of NAPP, Cooper Legal Group, or any client. This presentation is not legal advice and does not create an attorney/client relationship.



Subject Matter Eligibility in Molecular Diagnostics

Benjamin G. Jackson
Myriad Genetics



Current State of Guidelines

- Significant improvements over the various iterations
 - Genuine emphasis on examining the claim and all its limitations as an integrated whole
- PTO approach recognizes incremental nature of developments in s.101 law
 - Focus on subject matter clearly excluded by faithful yet narrow application of case law
 - Memos on latest cases (*McRO*, etc.) are helpful
 - Technology-specific examples are most helpful



Example 29 Appears to Broadly Exclude Diagnostic Inventions

- Comparing claims 1, 2 and 5 suggests methods of diagnosis *per se* are ineligible
 - Only reagents (claim 1) and treatment methods (claim 5) are eligible
 - How can measurement of an antibody (claim 1) be eligible but a further dependent claim applying that detection to diagnosis (claim 2) be ineligible?
- Very problematic for Molecular Diagnostic (MDx) inventions and for MDx industry



Excluding MDx from Patent System Is

- Unwise policy
 - MDx = Gateway to precision medicine
 - Lower costs, tailored care, better outcomes
- Not required or even permitted
 - SCOTUS has repeatedly refused to categorically exclude any type of invention (why are MDx inventions singled out?)
 - *Alice* says technical improvements to technological fields are eligible



Example 29 Takes Too Broad a View of “Laws of Nature”

- Claim 2, step c faulted for “*describ[ing] a correlation or relationship [that] is a consequence of natural processes*” ...
 - Everything is “*a consequence of natural processes*”
- What is the specific natural law or process (one-to-one causal link between JUL-1 and julitis) supposedly recited in the claim? There is none.
 - “*Applicant has discovered that the presence of a protein known as ‘JUL-1’ in a person’s body is indicative that the person has julitis*”
 - This is not a natural law; at most a statistical correlation



Example 29 Takes Too Broad a View of “Laws of Nature”

- PTO misinterprets this as “*similar to the naturally occurring correlation found to be a law of nature by the Supreme Court in Mayo*”
- *Mayo* did not involve a mere correlation, but instead a direct, causal/mechanistic link between drug and metabolites
 - Drug converted to metabolite according to clear, direct, well-understood biological mechanism (i.e., a natural law)
 - Other “natural law” examples from cases are also causal (e.g., gravity, $E=mc^2$)



Axiom in Field of Statistics

***Correlation does not
equal causation***



Illustration of this Axiom

- Correlation: US states w/ higher mean elevation tend to have lower obesity rates (e.g., Colorado, Utah, Idaho, Montana, Hawaii, California)

Sources: http://www.netstate.com/states/tables/state_elevation_mean.htm;
<http://www.livescience.com/50973-obesity-rates-full-rankings.html>

- Causation: So it must be a law of nature that lower elevation causes and higher elevation prevents obesity, right? Wrong.
 - Obesity is complex, caused by interplay of many factors (age, culture, income, elevation?)
 - Each factor may predict obesity with some statistical confidence, but none causes obesity



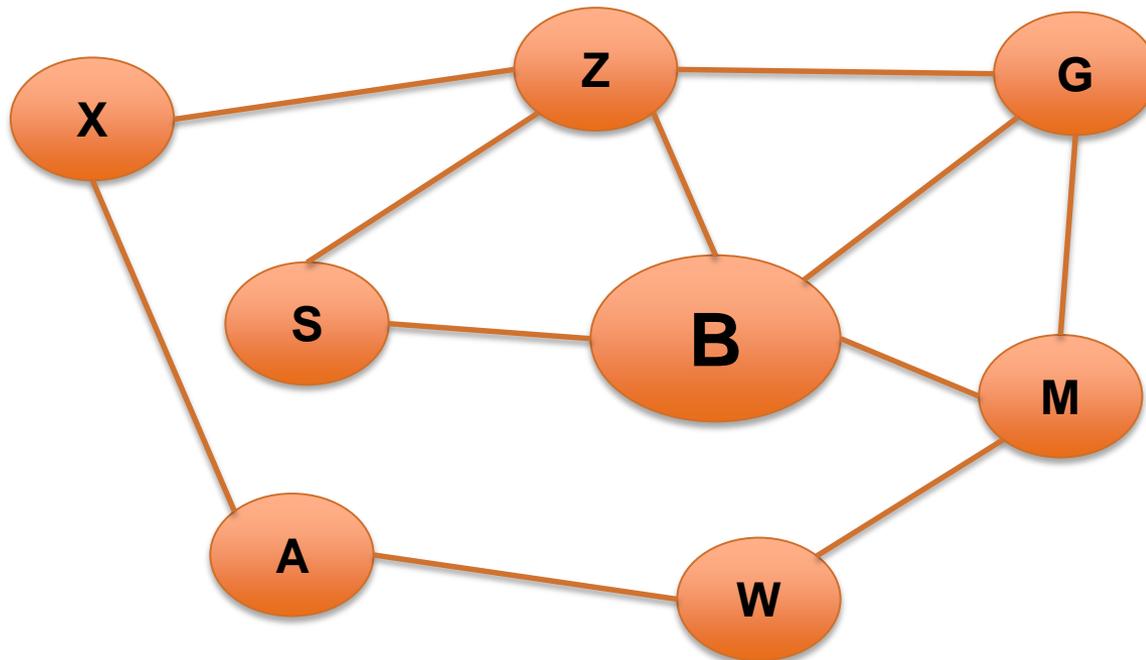
How MDx Really Works

- *Mayo*: direct, causal pharmacokinetic relationship between drug and metabolite
- *Myriad*: one-to-one biological causation between *BRCA1* mutations and breast cancer
- Modern MDx inventions are fundamentally different
 - Measure 100s or 1,000s of candidate biomarkers (may not be in biologically expected “pathway”)
 - Apply advanced statistical techniques to create a model/score integrating measurement(s)
 - E.g., $\text{Score} = A * [\text{GeneA}] + \log_2[\text{ProteinB}]$
 - Confirm model predicts disease with some desired (yet imperfect) level of statistical confidence



How MDx Really Works

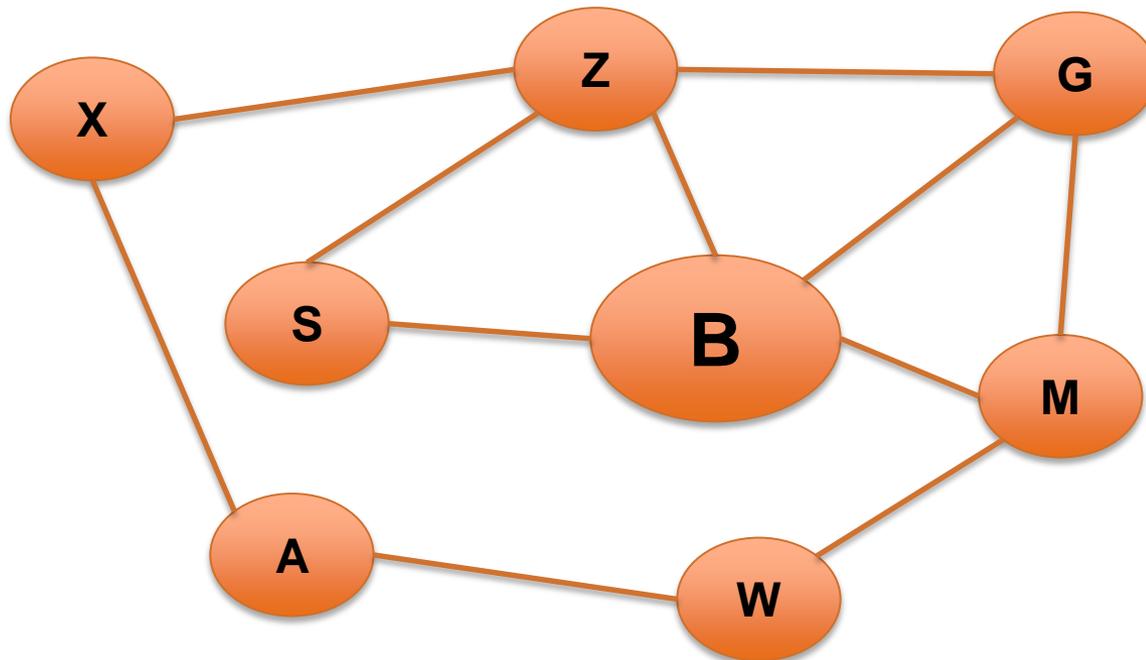
- An unimaginably complex web of natural laws dictates each biomarker's activities and effects in the person as a whole





How MDx Really Works

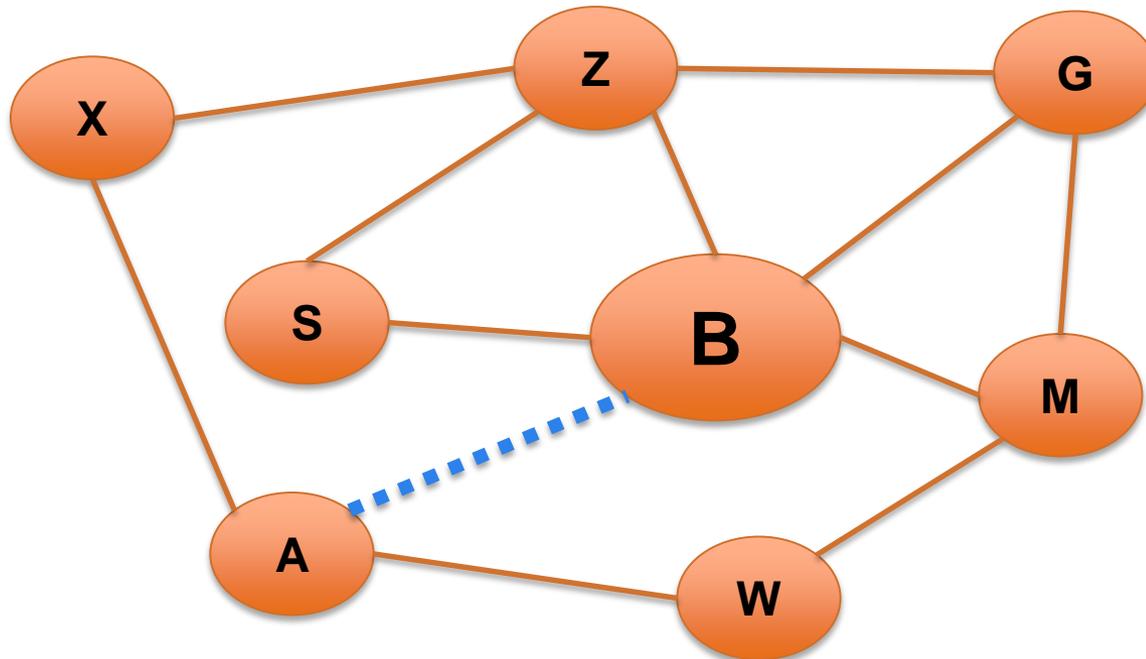
- In this example, solid lines indicate a direct mechanistic (i.e., biological) connection between the two biomarkers
- E.g., A is metabolized into X through a specific chemical reaction





How MDx Really Works

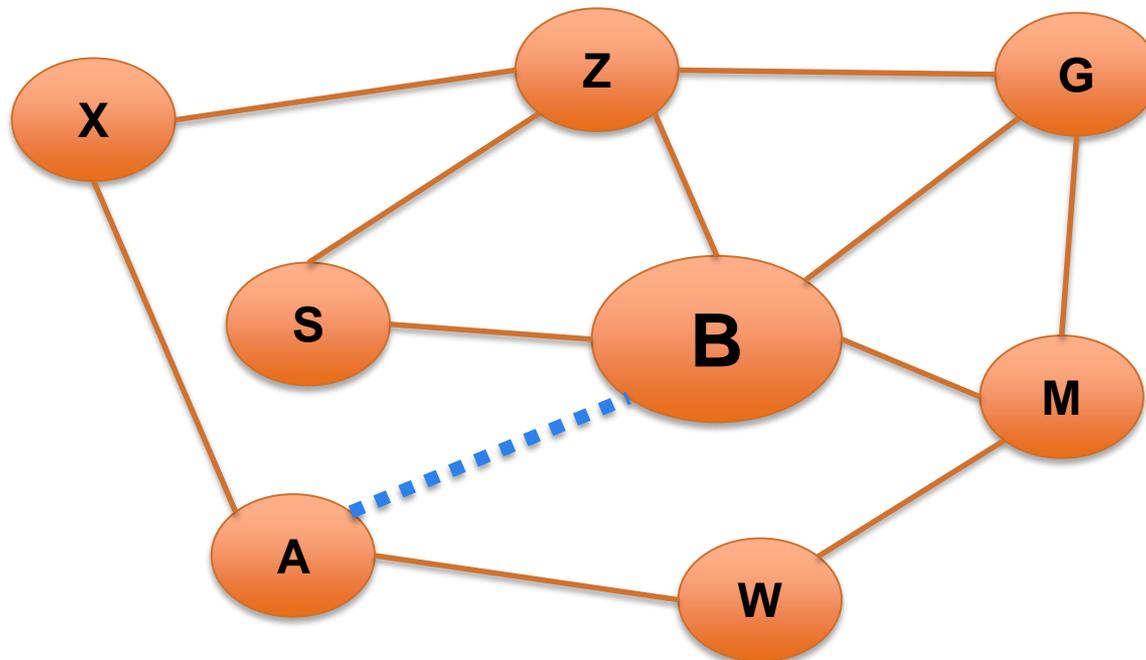
- Human ingenuity and intervention can, through our use of statistical analysis, **create** a brand new connection (blue dotted line)





How MDx Really Works

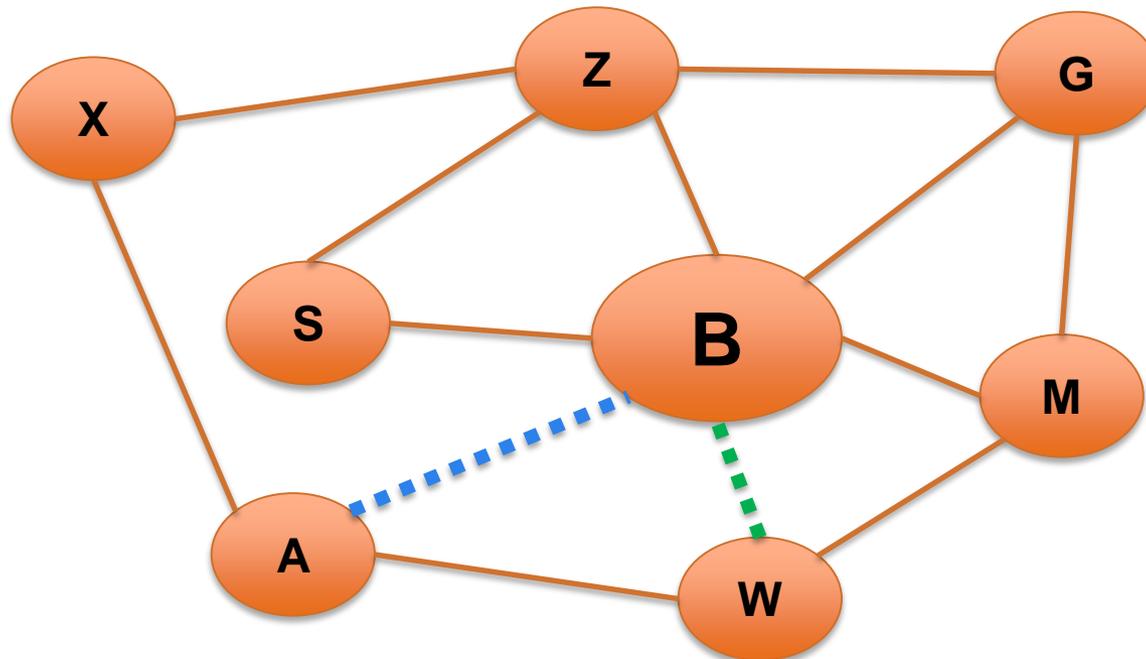
- It is not that there is NO link between A and B
- Biologically, they are connected through X and Z and this chain ($A \rightarrow X \rightarrow Z \rightarrow B$) is arguably a natural law (or 3 laws)
- But the inventor has created the direct, statistical link $A \rightarrow B$ where none existed; there is no such direct biological link





How MDx Really Works

- To the extent pre-emption is important in the analysis, this example shows that there are no such concerns
- Additional, different, or better analysis may likewise create a new statistical link between W and B





How MDx Really Works

- Multiple markers may contribute to the disease, some directly and some indirectly
- No single marker directly causes the disease (correlation does not equal causation)
- It is an act of “invention” worthy of a patent to create a brand new statistical link (as distinguished from a biological link) between one or more specific biomarkers and a specific disease feature



Path Forward

- Example 29 is a good start, but we need a lot more examples that represent realistic modern cases in MDx
 - Single markers without one-to-one causal link to diagnostic conclusion
 - Single markers whose predictive power is largely or entirely statistical (i.e., less than perfectly penetrant, sensitive and specific)
 - Multiple markers integrated into a panel
 - Statistical model integrating multiple inputs
 - Others?



Thank You

ROUNDTABLE ON PATENT SUBJECT MATTER ELIGIBILITY

- I. THE STRUCTURE OF THIS PRESENTATION**
- II. BACKGROUND / MOTIVATION / OBJECTIVE** *0.5 min*
 •my CV on below URL •30M US\$ lost by VoIP patent •I want my money back+++
- III. THE PERSPECTIVE OF SPL** (if MBA framework based) *1.0 min*
 •SPL is a "sub-physical" exact science, i.e. any SPL problem is of FFOL Maths
 •patents are principally "legally absolutely robust", i.e. risks only as to facts (*Teva!!!*)
- IV. THE PERSPECTIVE OF THE IEG** *2.0 min*
 PRINCIPALLY • NO PATENT CLARITY WITHOUT "ALL of Alice" incl. "inCs"
 Update the IEG text by • 2 sections explaining "inventive concepts"&"ALL of Alice"
 " any example by • 1 page quoting its "inCs" & applying "ALL of Alice" on them
 • invite any applicant to add this 1 page to its application
 PRINCIPALLY • NO SIGNIFICANT CHANGES FOR NEXT 10-20 YEARS
- V. THE INNOVATION EXPERT SYSTEM (IES)** *0.5 min*
 •Patent Biz is manufacture, •IES takes it to industrialization (•"inverse Ford")
 •IES automated training for users & examiners
- VI. FLAT QUESTIONS ANSWERING** *3.0 min*

Sigram Schindler – TU Berlin, TELES Patent Rights International GmbH
 USPTO – 14.11.2016

www.FSTP-Expert-System.com

The AMDOCS Dissent Stirs up the Key Deficiency of the CAFC's pro-PE *Alice* Decisions,
 thus showing:
The Time is Ripe for Ending the §101 Chaos – Properly and Finally!

Sigram Schindler
 TU Berlin & TELES Patent Rights International GmbH

AMDOCS^{1.a)} stirs up by its dissenting opinion ("D") the big deficiency of the CAFC's PE decisions, yet its majority opinion ("M") did not use it for progressing to meeting **ALL** *Alice* analysis's requirements.

Its D opinion^{b)} evidently is enabled by a deep concern: That all pro-PE "legal argument chains, LACs" in the CAFCs recent PE decisions^{c)} in absolutely no way confirm, its ETCI would "... **transform THE NATURE of the [originally nPE invention] claim into a patent-eligible application" that by an "**inventive concept**" is made "... **SIGNIFICANTLY MORE than a patent upon the ineligible concept itself**"^{c)}. This author fully shares this concern – not withstanding that the M opinion (almost) is correct.**

Indeed, none of these pro-PE CAFC decisions^{c)} uses in its LAC exactly these two key words defining this transformation of an nPE invention, prescribed by the *Alice* analysis for achieving its application's PE^[300,301]. This is an extremely unusual phenomenon in US SPL precedents about ETCIs^{d)}. Moreover, this indicates that none of these CAFC decisions' ETCIs (except that of *DDR*) has really been found to meet 100% of the requirements that the *Alice* analysis correctly recognized as necessary for excluding its threatening the US NPS^{e)} the way that *Alice* shall bar^{u)}. While these are legal errors justifying the above concern, transitionally this unfortunately occurs^{e)}.

Thus, AMDOCS calls for settling the PE problem as indicated by the CAFC's pro-PE decisions, concurring with the Supreme Courts' *Alice* analysis – as US economies require, now properly and finally.



THE CUSTOMER SUCCESS PLATFORM

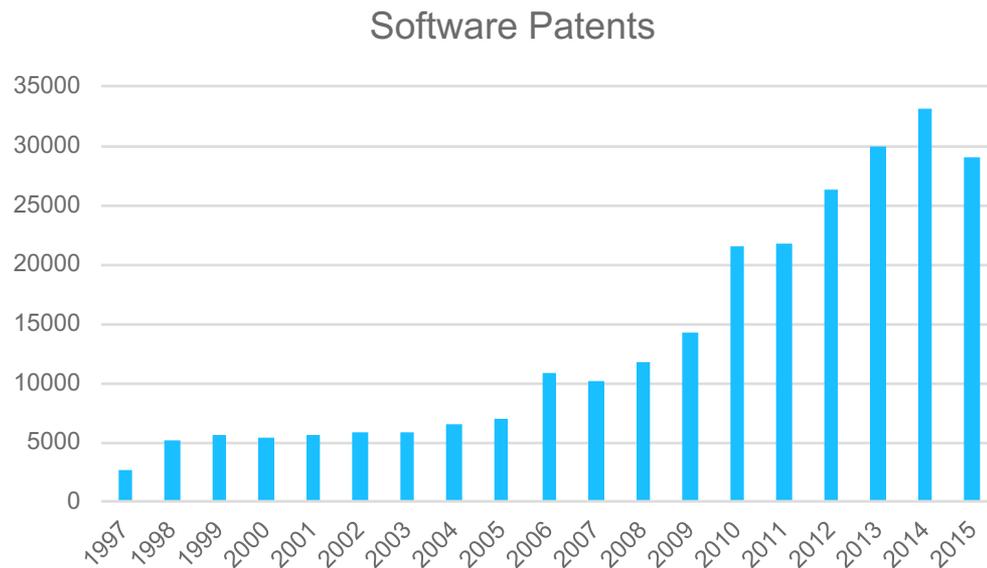
Salesforce's 101 Roundtable Comments

David Simon

Senior Vice President, Intellectual Property

Patent Issuances of Software Patents

Outside of Business Method Patents, Minor Impact



Total Decline: 4074

Class 705 Decline: 2715

Other Software: 4%

Source: <https://www.uspto.gov/web/offices/ac/ido/oeip/taf/cbcby.htm>

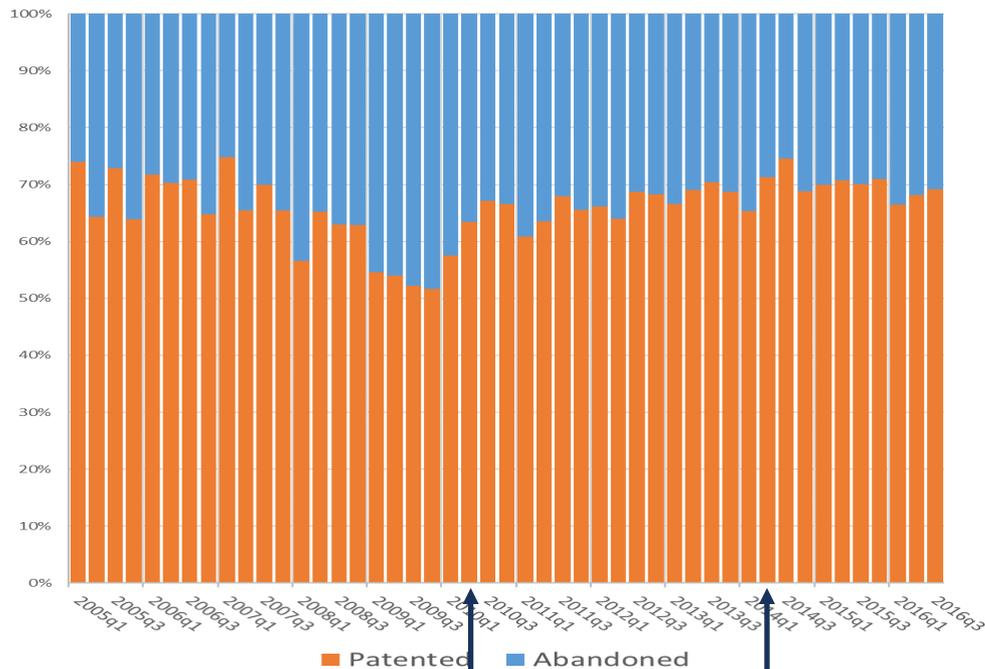
US Classes: 703-707, 709, 715-719, 726



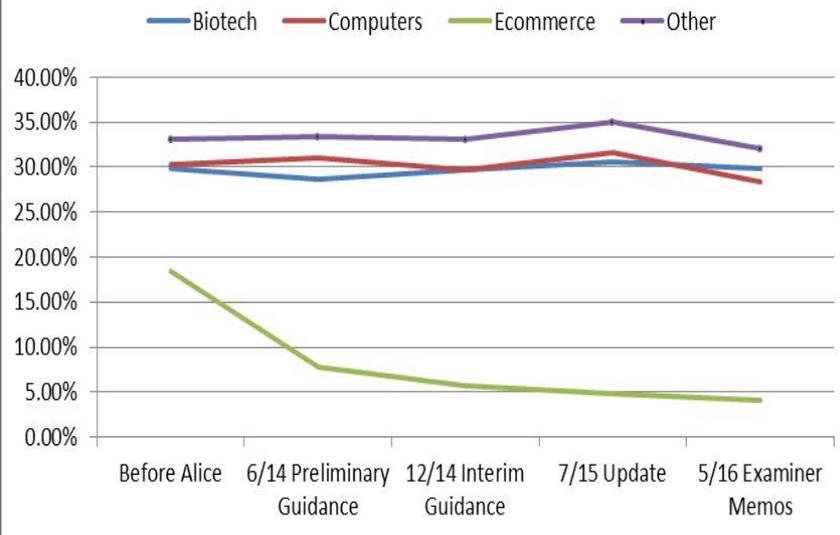
Overall PTO Allowance Rates are Largely Unchanged

Only Business Methods Dramatically Impacted

Disposals by Quarter



Percentages of Notices of Allowance (relative to All Office Actions)



<http://patentlvo.com/patent/2016/11/uspto-allowance-rate-2.html>

Bilski

Alice

<http://www.bilskiblog.com/blog/2016/10/alicestorm-update-turbulence-and-troubles-.html>



Life is no longer Grim for Patentees

Percentage of All 101 Decisions Resulting in Invalidity

	~Q3 '14-~Q2 '16	~Q3'16
All Courts	70%	60.5%
Federal Circuit	95%	83.3%
District Court	66%	53.4%
Patents	66%	45.4%

DDR Holdings 12/14

Enfish 5/16

Bascom 6/16

McRO 9/16

AmDocs 11/16

<http://www.bilskiblog.com/blog/2016/10/alicesform-update-turbulence-and-troubles-.html>

<http://www.bilskiblog.com/blog/2016/10/alicesform-update-turbulence-and-troubles-.html>



Guidelines

Guidelines are generally a reasonable interpretation of existing law

Guidelines should better emphasize developing a record

- Guidelines do require Examiner to set forth abstract idea & if applicable generic technology in typical PFC
- Guidelines provide sparse information on how the examiners should ensure that the record made by the applicant is clear

Recommendations for Guidelines (drawing from MPEP 2106):

- Guidelines should make clear argument is not evidence
- Examiners who have established a PFC should be empowered to force applicant's to either amend claims or make arguments about the claim limitations
- Examiners should be empowered to ask for proof

thank you

USPTO Subject Matter Eligibility Guidelines

Jason Sanders
Maschoff Brennan



Evidence should be required to support well-known, routine, conventional activity

- In *Alice*, the Supreme Court cited two references to support the conclusion that the claims recited well-known, routine, or conventional activity.
- The guidelines do not require any such evidence.
- Some Office Actions find the claims not anticipated and nonobvious yet are illogically found to be directed to well-known, routine, or conventional activity.
- This is consistent with the MPEP. Evidence is required for utility (MPEP 2107), obviousness (MPEP 2142), and for rejecting ornamental designs (MPEP 1504.01).
- This is consistent with holding by the Fed. Circuit (see In re Zurko, K/S HIMPP)
- In addition, without evidence it difficult to have an Examiner interview or prepare an appeal brief about whether something is well-known, routine, or conventional.
- If something is well-known, routine, or conventional then finding a reference stating as much should be a simple task.



Guidance is needed on the “Directed To” analysis

- Claims as a whole are often oversimplified
- Often structural claim elements are often ignored
- A single potentially abstract concept in a claim is frequently relied upon to show that the claim as a whole is abstract. This occurs in claims that include a number of structural elements.
- More guidance is needed on how to determine what a claim is directed to.



Claim-By-Claim 101 Examination

- Most patentable subject matter rejections do not include a claim-by-claim analysis. Instead, the independent claim is rejected, and the dependent claims are rejected based on the independent claims.
- Claim-by-claim analysis is consistent with examination procedures for prior art rejections (MPEP 2111.05 & 2143.03),
- A non-claim-by-claim analysis ignores the guidance to examine a “claim as a whole”. A dependent claim as a whole with the elements of the independent and dependent claims.
- A claim-by-claim analysis allows the examiner to determine whether a dependent claim amounts to “significantly more” (step 2B).
- A claim-by-claim analysis expedites prosecution by providing guidance about whether a dependent claim includes patent eligible subject matter.

1st Example of an Odd 101 Rejection

- An independent claim to a microscope having various optical elements arranged in a specific way and a computational unit configured to determine something based on data from the microscope.
- The independent claim was rejected as an abstract idea despite reciting structural elements with a processor.
- According to the Examiner, his supervisor would allow the independent claim if the processor is removed from the independent claim and made a dependent claim. This analysis flies in the face that the claim as a whole should be analyzed.



2nd Example of an Odd 101 Rejection

- A claim directed toward an internet based service that could only be performed through the Internet a la DDR Holdings.
- The claim was rejected as an abstract idea.
- The examiner allowed the claim when it was amended to simply include a database a la *Enfish*.

USPTO Subject Matter Eligibility Guidelines

Jason Sanders
Maschoff Brennan



Evidence should be required to support well-known, routine, conventional activity

- In *Alice*, the Supreme Court cited two references to support the conclusion that the claims recited well-known, routine, or conventional activity.
- The guidelines do not require any such evidence.
- Some Office Actions find the claims not anticipated and nonobvious yet are illogically found to be directed to well-known, routine, or conventional activity.
- This is consistent with the MPEP. Evidence is required for utility (MPEP 2107), obviousness (MPEP 2142), and for rejecting ornamental designs (MPEP 1504.01).
- This is consistent with holding by the Fed. Circuit (see In re Zurko, K/S HIMPP)
- In addition, without evidence it difficult to have an Examiner interview or prepare an appeal brief about whether something is well-known, routine, or conventional.
- If something is well-known, routine, or conventional then finding a reference stating as much should be a simple task.



Guidance is needed on the “Directed To” analysis

- Claims as a whole are often oversimplified
- Often structural claim elements are often ignored
- A single potentially abstract concept in a claim is frequently relied upon to show that the claim as a whole is abstract. This occurs in claims that include a number of structural elements.
- More guidance is needed on how to determine what a claim is directed to.



Claim-By-Claim 101 Examination

- Most patentable subject matter rejections do not include a claim-by-claim analysis. Instead, the independent claim is rejected, and the dependent claims are rejected based on the independent claims.
- Claim-by-claim analysis is consistent with examination procedures for prior art rejections (MPEP 2111.05 & 2143.03),
- A non-claim-by-claim analysis ignores the guidance to examine a “claim as a whole”. A dependent claim as a whole with the elements of the independent and dependent claims.
- A claim-by-claim analysis allows the examiner to determine whether a dependent claim amounts to “significantly more” (step 2B).
- A claim-by-claim analysis expedites prosecution by providing guidance about whether a dependent claim includes patent eligible subject matter.

1st Example of an Odd 101 Rejection

- An independent claim to a microscope having various optical elements arranged in a specific way and a computational unit configured to determine something based on data from the microscope.
- The independent claim was rejected as an abstract idea despite reciting structural elements with a processor.
- According to the Examiner, his supervisor would allow the independent claim if the processor is removed from the independent claim and made a dependent claim. This analysis flies in the face that the claim as a whole should be analyzed.



2nd Example of an Odd 101 Rejection

- A claim directed toward an internet based service that could only be performed through the Internet a la DDR Holdings.
- The claim was rejected as an abstract idea.
- The examiner allowed the claim when it was amended to simply include a database a la *Enfish*.

Re-thinking the eligibility of diagnostic methods under §101

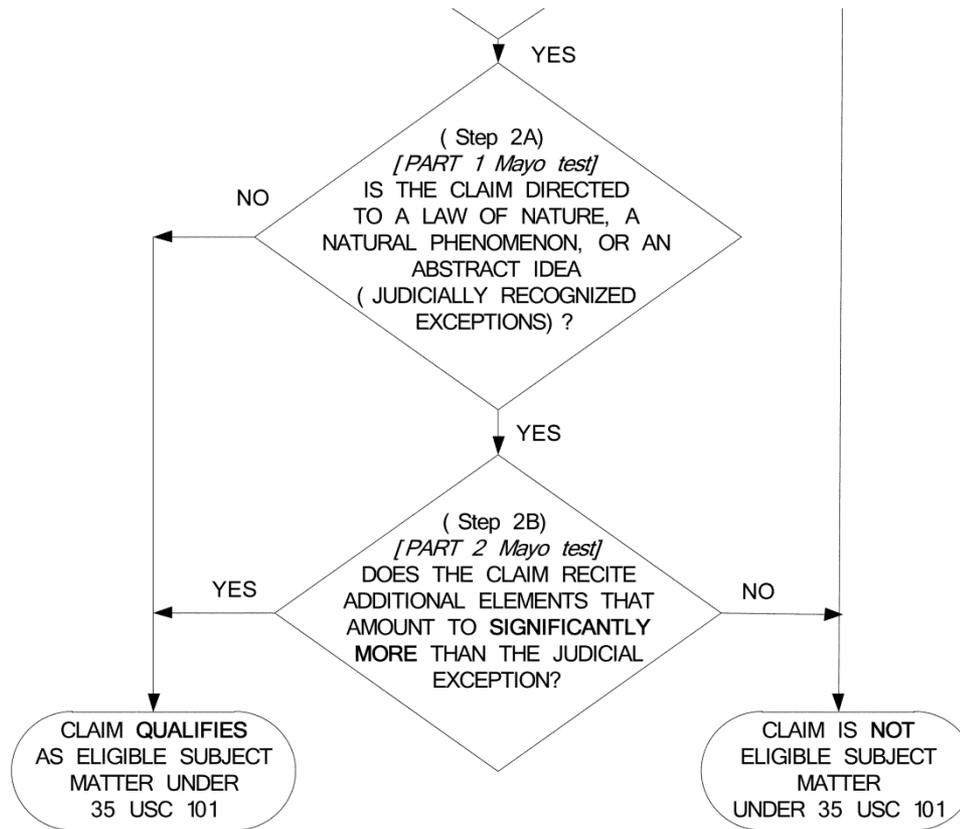
November 14, 2016
PTO Roundtable - Subject Matter Eligibility

PRESENTED BY: David A. Gass

Disclaimer

- This presentation is intended by the presenter to stimulate discussion of and improvements to the USPTO's Subject Matter Eligibility Guidelines.
- It does not necessarily represent the views of Marshall, Gerstein & Borun LLP or any of the firm's clients.

PTO Eligibility Algorithm (Step 2)



PTO “Directed to” Test –Step 2A

79 FR 74622 (Dec. 16, 2014)

- “A claim is directed to a judicial exception when a law of nature, a natural phenomenon, or an abstract idea is recited (i.e., **set forth or described**) in the claim.”
- Risk: *pre-emption of “judicial exception”*
- Safeguard: *“significantly more” analysis (“Step 2B”)*

PTO “Directed to” Test

79 FR 74622 (Dec. 16, 2014)

- *Should we test **all** claims for “significantly more”?*
 - “**at some level all inventions embody**, use, reflect, rest upon, or apply a law of nature, natural phenomenon, or abstract idea”
- *Answer: No!*
 - Some claims “**may recite** a judicial exception, **but** are directed to inventions that clearly **do not seek to tie up** the judicial exception” → “streamlined analysis”
- *Recent Federal Circuit Decisions:*
 - McRO v. Bandai et al.*, 120 USPQ 2d 1091 (9/13/2016)
 - Rapid Litigation Management v. CellzDirect* , 827 F.3d 1042 (7/5/2016)
 - Enfish v. Microsoft*, 822 F.3d 1327 (5/12/2016)

Hypothetical Claim to Diagnostic Method

1. A method comprising:
 - a) Analyzing a fluid/tissue sample from a patient;
 - b) Detecting/measuring MARKER **M** in the sample; and
 - c) Diagnosing DISEASE **D** in the patient from the presence/measurement of MARKER **M** in the sample.

USPTO analysis:

- “diagnosing ... describes a correlation or relationship” between **M** and **D**. “This limitation sets forth a judicial exception....”
- Must analyze claim for “significantly more”
 - See *PTO Life Science Training Example 29 (May 2016)*

“Diagnosing” Does Not “Describe” A Correlation

- “To properly interpret the claim, it is important to understand what the applicant has invented and is seeking to patent.” (79 F.R. 74622)
- A diagnostic invention is a technical solution to a medical problem. It uses the **M/D** correlation, but is not directed to it:
 - Diagnostic Input = patient sample;
 - Diagnostic Output = disease diagnosis
- Diagnosis is about an *individual*. The correlation is a characteristic of a *population*.

Diagnostic Patents Don't Preempt All Methods of Disease Diagnosis

- Typically, other tools exist (or can be developed) to diagnose Disease **D**:
 - Physical Examination?
 - Patient symptoms?
 - Biopsy?
 - Cell Culture?
 - Other Markers?

Diagnostic Patents Don't Preempt Innovation (They promote it!)

- Biomedical R&D:
 - Does **M/D** correlation provide insight into disease cause?
 - Can I use **M** to identify a new therapeutic target/pathway for **D**?
- Pharmaceutical R&D:
 - Can I use **M** to select the best treatment for **D**?
 - Can I use **M** to develop a new drug to treat **D**?
- Diagnostic R&D:
 - R&D to find a surrogate **M'** that is easier to measure?
 - R&D to find an **M₂** to improve sensitivity/specificity?
 - R&D to develop a new *prognostic* test to predict **D**?

“Preemption” Analysis Remains Relevant

- Federal Circuit considers (lack of) preemption in its “Directed To” (Step 2A) Analysis
 - See *McRO* or *CellzDirect*
- PTO Subject Matter Eligibility Decisions Memo dated 11/2/2016

Take-away's

- Recent Federal Circuit decisions require new scrutiny about whether **invention** is “directed to” a judicial exception. The fact that the words of a claim may describe a judicial exception is not conclusive.
- The acts of measuring a biomarker and diagnosing an individual patient are not directed to, and do not preempt, the correlation that underlies the diagnostic test
- Numerous avenues for research are *created* when an innovator discloses a diagnostic based on a new **M/D** correlation.



David A. Gass
Partner
Tel 312.474.6624
dgass@marshallip.com

- **Marshall, Gerstein & Borun LLP** is dedicated exclusively to the practice of IP law. The Firm assists clients worldwide in all phases of the IP life cycle, including securing rights, conducting transactions, and litigating and resolving disputes. Our centralized location, boutique size, and singular focus enhance efficiency, responsiveness, and decision-making, while reducing costs. *Chambers & Partners* has ranked Marshall Gerstein as having “one of the best biotechnology practices in the entire country.” *Corporate Counsel* magazine lists the Firm as a “Go-To Law Firm of the Top 500 Companies” for intellectual property and litigation. The Firm also is ranked as a top intellectual property law firm by *Managing IP*, *Fortune*, *Intellectual Property Today*, and *Intellectual Asset Management* magazines. Learn more at www.marshallip.com.



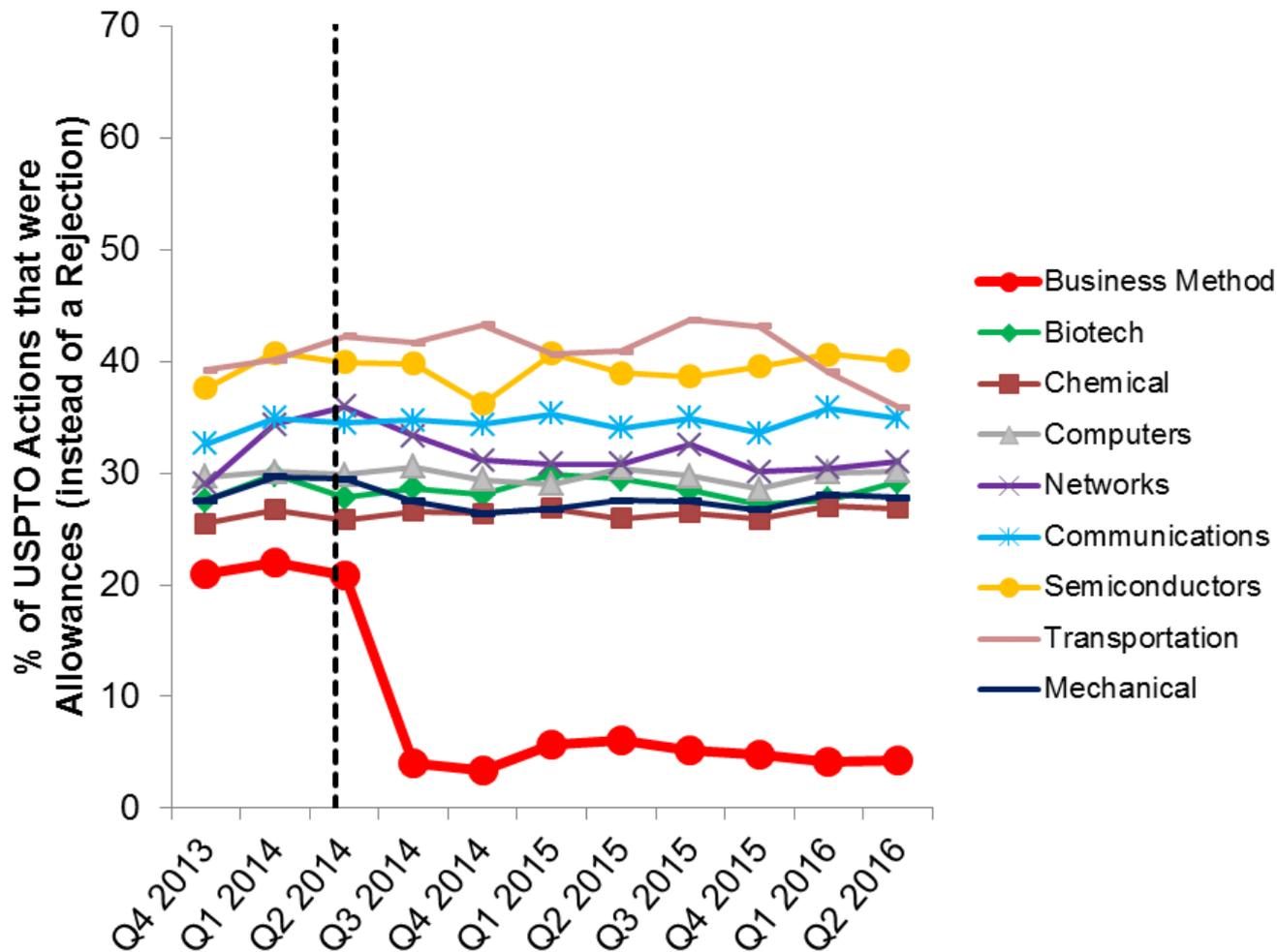
USPTO Roundtable

Subject Matter Eligibility Guidelines

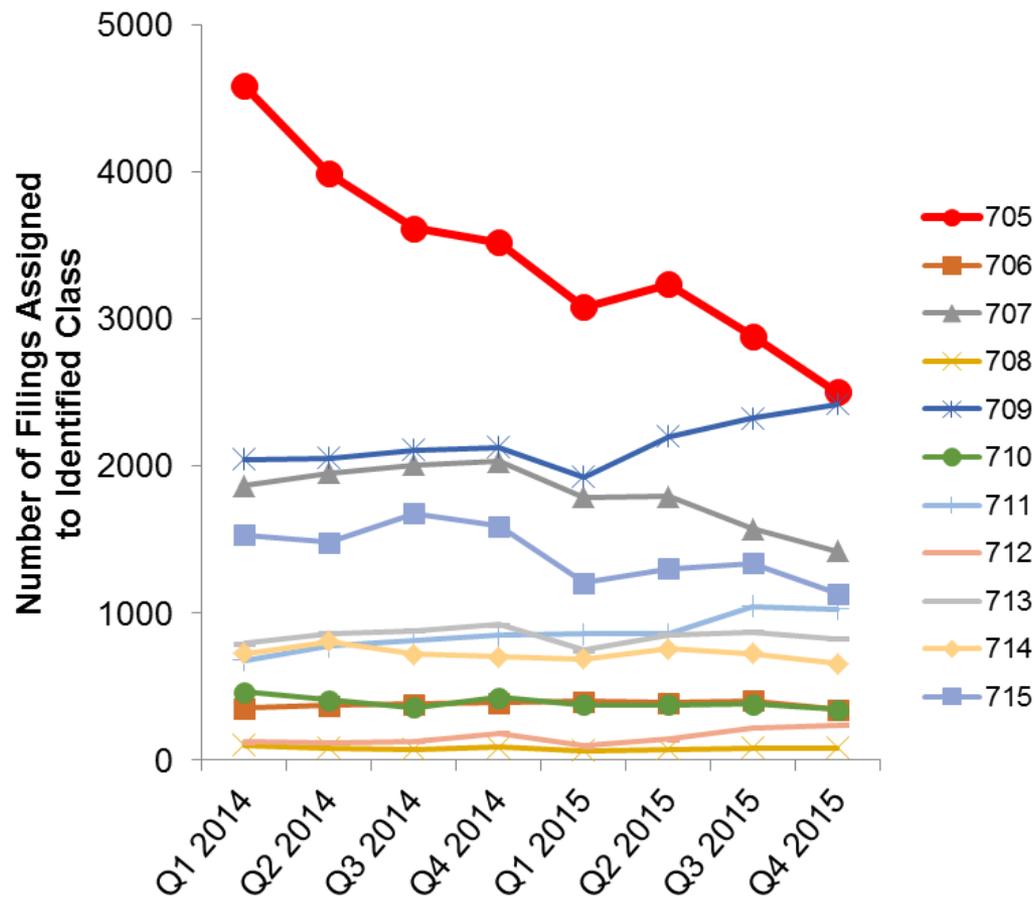
Presented by Sameer Vadera

November 14, 2016

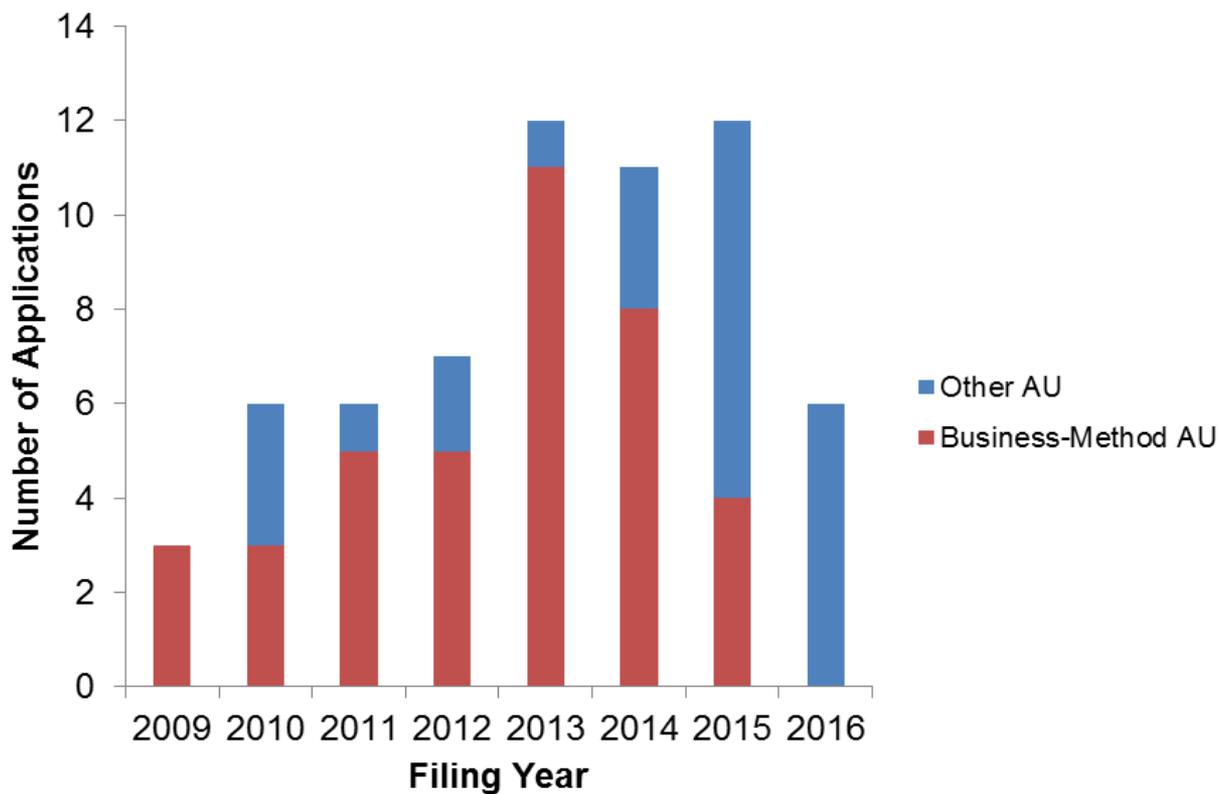
Business-Method Allowances Became Very Rare after *Alice*



Applicants are Filing Fewer Business-Method Patents



Case Study: Drafting New Applications for the Right AU



Ineligible Subject Matter Rejections under 35 USC §101

U.S. PATENT OFFICE
Presentation by

**Abe Hershkovitz
Hershkovitz & Associates, PLLC**

**2845 Duke Street
Alexandria, VA 22314, USA
patent@hershkovitz.net
www.hershkovitz.net**

Subject Matter Eligibility - PROBLEMS

- There is no consistency in applying subject matter eligibility rejections
- There is no justification of the rejections by actual analysis under Steps 2A or 2B
- There is improper dissection of claims and use of individual limitations to hold a claimed invention to be an abstract idea
- Non-precedential cases (Smartgene, Cyberfone, etc.) are cited as supporting the rejection even though the details of the claimed invention are completely different

Subject Matter Eligibility - PROBLEMS

- **Applicants are frustrated because groundless rejections are made, and arguments or claim amendments are being ignored, leaving Applicants with the feeling that *rejections cannot be overcome by any reasonable means***

Subject Matter Eligibility - TRAINING

- May 4, 2016 Office Memorandum on Subject Matter Eligibility:

...the Office action **must** provide **an explanation** as to **why** each claim is unpatentable, which **must be sufficiently clear and specific** to provide applicant **sufficient notice of the reasons for ineligibility and enable the applicant to effectively respond**. A subject matter eligibility rejection under Step 2 should:

identify the judicial exception by referring to **what is recited (i.e., set forth or described) in the claim** and **explain** why it is considered an exception;

identify any additional elements (**specifically point to claim features/limitations/steps**) recited in the claim beyond the identified judicial exception; and

explain the reason(s) that the additional elements taken individually, and also taken as a combination, do not result in **the claim as a whole** amounting to significantly more than the judicial exception.

- **THIS NOT BEING DONE IN THE OFFICE ACTIONS**

Subject Matter Eligibility - TRAINING

- **Too many §101 rejections contain only “boilerplate” language from the so-called Office “guidelines,” and no actual analysis is given in Office Action - UNSUPPORTED**
- **No intelligent discussion with Examiner about them is possible - UNRESOLVABLE**
- **Applicants are not informed what, if any, actual basis exists for these rejections, and so do not know what to do to overcome them - UNANSWERABLE**

Subject Matter Eligibility - TRAINING

- Examiners must make §101 rejections with the same reasonable explanations of *prima facie* “ineligibility” as in §103 “obviousness” rejections:
- Identify the explicit claim limitations that are an actual abstract idea, and give a factual analysis of why they are merely abstract, and why the claim as a whole is not substantially more

Subject Matter Eligibility - POLICY

- If Applicant traverses the grounds for rejection by a reasonable, factual explanation why there is no abstract idea, or the claim as a whole contains substantially more, or amends to overcome the rejection, then the Examiner must factually rebut the arguments and amendments, rather than just repeat verbatim the prior rejection with a conclusory statement that arguments are not persuasive
- All Actions that include a 101 rejection should require SPE review and signature

Subject Matter Eligibility - POLICY

- **When Office personnel other than Examiners [QUAS, SPE, etc.] help create/prepare the §101 rejections, they should thoroughly discuss them with the Examiner so the Examiner is knowledgeable with the rejection and can judge its validity, make changes, etc. If QUAS has input into rejection, why not include the QUAS at interviews?**
- **When Examiners do not understand the §101 rejections in their own Actions, there is no intelligent or reasonable discussion possible with Applicant.**

Subject Matter Eligibility – Suggestions

- **Examiners suggest claim changes to overcome 112 rejections, 102 and 103 rejections. Why not 101 rejections?**
- **Management should incentivize Examiners to take extra time needed to suggest claim changes that overcome the 101 rejection, e.g., reasonable time excluded as “non-examining time for 101 allowability investigation”, recognition points for “superior quality performance”, etc.**

Subject Matter Eligibility – Suggestions

- **Reexams and now Reissues are handled by specially trained CRU Examiners. What is an Abstract Idea? Does the claim recite more than just that, is there transformation? Do other limitations render the claim patentable? These questions pose difficulties that often exceed complexities faced in reexams or reissues. Why not create a CSMEU (Central Subject Matter Eligibility Unit) or CAU (pronounced “cow” for Central Abstract Unit) (joke) tasked with clearing all 101 rejections?**

7 Minutes to Convince You that “Significantly More” Means the “Machine or Transformation Test”

John Kasha

Member

Kasha Law LLC

My Focus

- Computer control of another device, instrument, or machine, or
- Analysis of data from another device, instrument, or machine, and
- A 101 rejection that the additional limitations are conventional or generic computer functions either alone or in combination

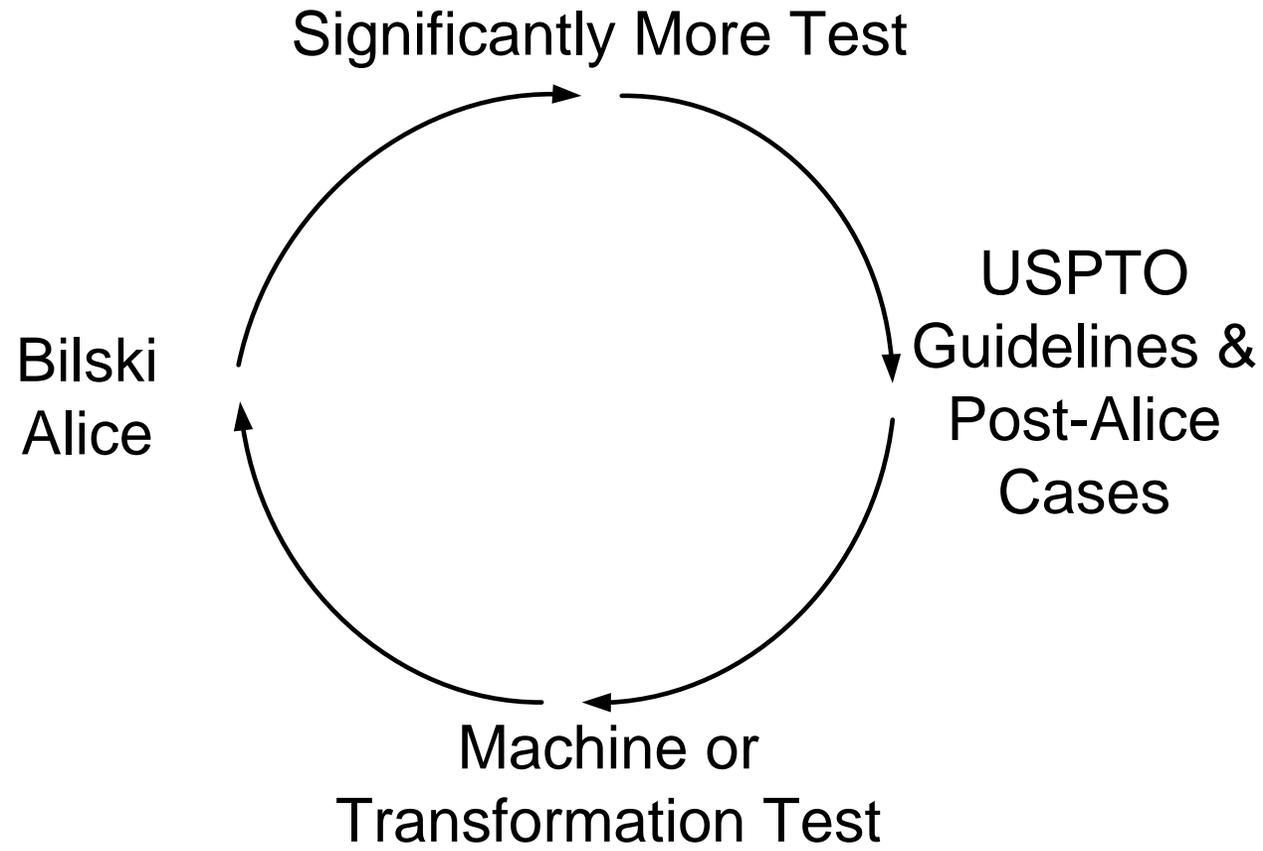
My Suggestion – The Lead

- Argue the combination of the limitations ties the abstract idea to machine or transformation
- Do not have to argue that the additional limitations are novel or nonobvious
- Compare the claim to *Diehr* and *Flook* and show how it is more like *Diehr* using the 3 factors described in *Mayo*
- I'll show this by discussing the *Diehr* Example in the USPTO Guidelines

Getting Around a 101 Rejection

- Before *Bilski* – Show it passes Machine or Transformation Test
- Before *Alice* – Show No Preemption
- Now – Show Significantly More
- My Argument – Significantly More really just again means Preemption and the Machine or Transformation Test

Graphically



How to do this in 7 minutes

- Look at the analysis of *Diehr* under the USPTO Guidelines
- Get a little help from *Mayo* and *Diehr*

Diehr Claim 1 – Look up Details Yourself

1. A method of operating a rubber-molding press ... comprising:
providing said computer ...
initiating an interval timer...
constantly determining ...
constantly providing ...
repetitively calculating ...
repetitively comparing ... and
opening the press automatically ...

USPTO Guidelines *Diehr* Example

- Goes through the analysis ad nauseam
- Statutory: YES
- Abstract Idea: Yes
- **Limitations (by themselves): conventional**

25. Rubber Manufacturing

The following illustrates an exemplary analysis using the 2014 IEG for actual and hypothetical claims modeled after the technology in Diamond v. Diehr, 450 U.S. 175 (1981) (Diehr). As the claims in this example are eligible, no written analysis would be provided in an

So Why is *Diehr* Eligible

- Is it because the combination is not conventional or generic? **No**
- It is because the combination adds “meaningful limitations on the use of the equation.”

Preemption

- Then the guidelines support preemption using the 3 factors mentioned in *Mayo's* analysis of *Diehr* and *Flook*

Mayo's 3 Diehr Factors

- Explains how variables are selected
- Claim contains disclosure of the underlying chemical process
- Claim contains disclosure of opening the press

Sound Familiar

- How variables are selected and how result of the abstract idea is used (opening the press) tie the abstract idea to the machine (the rubber molding press)
- The underlying chemical process – transforms uncured rubber to cured rubber
- **We again have the machine or transformation test**

Recap

- Significantly more does not mean the combination of limitations has to be unconventional or not generic.
- Indeed, the *Diehr* decision itself stated “it may later be determined that the ... process is not deserving of patent protection because it fails ... novelty under § 102 or nonobviousness under § 103.”

So Again - My Suggestion

- Argue the combination of the limitations ties the abstract idea to the machine or transformation
- Do not have to argue that the additional limitations are novel or nonobvious
- Compare the claim to *Diehr* and *Flook* and show how it is more like *Diehr* using the 3 factors described in *Mayo* (1. origin of variables ties to a machine, 2. a transformation of something, or 3. result ties to a machine)

Roundtable on

USPTO Subject Matter Eligibility Guidelines

“For Want of an Improvement, A Claim Was Lost”

Robert Sachs

Fenwick & West LLP

§ 101 Rejection Rates Before and After Guidance Memos

Tech Center	Apr-16	May-16	Jun-16	Jul-16	Aug-16	Sep-16	Oct-16
1600	13.19%	14.14%	13.83%	13.12%	13.50%	13.59%	11.71%
1700	1.11%	1.13%	1.29%	0.93%	0.86%	1.41%	1.23%
2100	15.68%	15.68%	15.24%	16.46%	15.43%	16.25%	18.41%
2400	19.66%	19.17%	18.05%	17.73%	17.33%	18.24%	18.01%
2600	11.93%	12.95%	12.87%	12.31%	11.71%	11.99%	12.50%
2800	4.63%	4.79%	5.06%	5.13%	5.42%	5.69%	4.60%
3600	6.18%	5.84%	5.00%	5.47%	5.93%	5.65%	5.87%
3600BM	91.99%	92.27%	92.66%	91.84%	90.91%	92.11%	91.77%
3700	7.36%	7.13%	8.23%	8.00%	7.56%	7.04%	7.30%

- Percent of Office Actions with Section 101 Rejections

Non-Final v. Final § 101 Rejection Rates

Tech Type	Action	Apr-16	May-16	Jun-16	Jul-16	Aug-16	Sep-16	Oct-16
Biology	Non-Final	13.62%	14.21%	14.98%	14.05%	14.03%	14.69%	12.81%
Biology	Final	12.43%	14.02%	11.87%	11.59%	12.66%	11.69%	9.42%
Chemistry	Non-Final	1.56%	1.89%	1.90%	1.36%	1.11%	2.06%	1.87%
Chemistry	Final	0.68%	0.23%	0.54%	0.37%	0.57%	0.51%	0.41%
Ecommerce	Non-Final	93.56%	91.97%	93.15%	92.99%	92.18%	92.65%	92.82%
Ecommerce	Final	89.72%	92.49%	91.87%	90.26%	89.23%	91.20%	89.73%
Electronics	Non-Final	14.14%	14.46%	14.34%	14.15%	13.95%	13.93%	13.70%
Electronics	Final	7.67%	7.47%	7.20%	7.58%	7.25%	8.21%	7.85%
Other	Non-Final	6.81%	6.95%	7.48%	7.82%	7.42%	6.97%	7.00%
Other	Final	5.96%	5.14%	5.28%	4.88%	5.11%	4.54%	5.06%

Selected Problems in the Application of the Guidance Memos

Problem 1: No Explanation Given for Abstract Idea

- May Memo: “When the examiner has determined the claim recites an abstract idea, the rejection **should identify the abstract idea** as it is recited (i.e., set forth or described) in the claim, **and explain why** it corresponds to a concept that the courts have identified as an abstract idea.”
- July 2015 Update: “[T]he examiner’s burden is met by clearly articulating the reason(s) why the claimed invention is not-eligible, for example by **providing a reasoned rationale that identifies** the judicial exception recited in the claim **and why** it is considered an exception”

Problem 2: Examiners Ignoring The Case Facts to Find Abstract Ideas

- May 4 Memo:
 - “Examiners should be familiar with any cited decision relied upon in making or maintaining a rejection to ensure that the rejection is reasonably tied to the facts of the case and to avoid relying upon language taken out of context. Examiners should not go beyond those concepts that are similar to what the courts have identified as abstract ideas.”

Example Rejections

- “[T]he claims [are] drawn to an abstract idea (i.e., certain methods of organizing human activity i.e. **game rules or mapping**)...Such an abstract idea being **similar to the kind of 'organizing human activity' at issue in Alice Corp.**”
- “**Game rules per se** are abstract ideas because they seek to preempt any and all embodiments using the rules. ***Gottschalk v. Benson*** 409 U.S. 63 (1972) **states that such patents are drawn to abstract ideas.**”

Example Rejections

- “Claim(s) 1-9 is/are directed to employee time entry... are similar to the concepts claimed: **Ambry, Myriad CAFC** - abstract idea found to be concepts relating to processes of comparing data that can be performed mentally such as comparing information regarding a sample or test subject to a control or target data.”
- “Claims 1 -13 are directed to the abstract idea of **processing payment requests for parking**...is a concept relating to the economy and commerce (“fundamental economic practices”) **similar to creating a contractual relationship of buySAFE.**”

Example Rejection

- **“The claims recite a method for operating a transportation service, including: operating first fleet vehicles, operating second fleet vehicles, directing a first vehicle to transport the first passenger in response to a service request initiated by the first passenger, directing a first fleet vehicle to pick up a second passenger, and modifying the instructions. This is similar to the kind of organizing human activity (creating a contractual relationship). It is similar to other concepts that have been identified as abstract by the courts, such as formulation and trading or risk management contracts in Alice Corp. The answer is YES. Therefore, independent claims 17 and 34 are directed to an abstract idea.**

buySAFE Claim

- A method, comprising:
- **receiving**, by at least one computer application program running on a computer of a safe transaction service provider, **a request from a first party for obtaining a transaction performance guaranty service** with respect to an online commercial transaction following closing of the online commercial transaction;
- **processing**, by at least one computer application program running on the safe transaction service provider computer, **the request by underwriting the first party in order to provide the transaction performance guaranty service to the first party**,
- wherein the computer of **the safe transaction service provider offers**, via a computer network, **the transaction performance guaranty service that binds a transaction performance guaranty to the online commercial transaction** involving the first party to guarantee the performance of the first party following closing of the online commercial transaction.

Problem 3: Examiners Never Surrender

- May Memo

“If applicant's claim amendment(s) and/or argument(s) **persuasively establish** that the claim is not directed to a judicial exception or is directed to significantly more than a judicial exception, the rejection should be withdrawn.”

- No explanation as to what counts as *persuasive*.
- Instead: Instructions focused on how to maintain rejection

Example 2B Analysis

- “The computer functions here are generic. For example, with respect to claim 1, the storing steps are the generic computer function of data storage, the **receiving steps are the generic** computer function of data input and/or transmission, **the retrieving step is the generic** computer function of data retrieval, the **sending step is the generic** computer function of data output and/or transmission, **the creating step** is the generic computer function of data storage, and the **providing step** is the generic computer function of data output and/or transmission.”

Looking At Verbs Only Makes All Software Claims Ineligible

- *DDR*: storing, receiving, identifying, retrieving, generating, transmitting, displaying
- *BASCOM*: generating, associating, receiving, executing, utilizing.
- *McRO*: obtaining, generating, evaluating, applying
- *Enfish*: configuring, indexing.

They're *Judicial Exceptions*, Not Administrative Ones

- “If the standard for determining if an idea is abstract includes finding a similar past abstract idea, then (presumably) "similar" here does NOT mean EXTREMELY similar because, otherwise, **how would "Meal planning" have ever made it on the list, with no other meal-planning ideas on the list?** Thus, Examiner does not believe the standard is so strict that (for example) another vehicle repair idea must be found on the list, in order for Applicant's idea to be found to be abstract.”

Recommendations

- The **cases** selected to show the abstract idea **must have claims reasonably related** to the rejected claims
- The explanation must be **more than simply a statement that the claims are similar** to those in a cited court case. A *reasoned explanation* is required.
- **All of the claim limitations** must be considered in Step 2B, not just the verbs. Follow the Federal Circuit
- If applicant provides a reasonable showing of eligibility, and rebuts the examiner's argument, the rejection should be withdrawn.

PTO Subject Matter Eligibility Roundtable 1

3 Recommendations to Improve the PTO's Guidance

Sunjeev S. Sikand
November 14, 2016

Use of Non-Precedential Opinions

- Nov. 2, 2016 memo: “Examiners should avoid relying upon or citing non-precedential decisions (e.g., *SmartGene*, *Cyberfone*) unless the facts of the application under examination uniquely match the facts at issue in the non-precedential decision.”
- But abstract idea examples 21 and 22 are still present and overgeneralized to set up false analogies.
 - Example 21 analysis states: “It is similar to other concepts that have been identified as abstract by the courts, such as using categories to organize, store and transmit information in *Cyberfone*, or comparing new and stored information and using rules to identify options in *SmartGene*.”

Recommendation 1

- PTO should amend the analyses of abstract idea examples 21 and 22 or withdraw those examples.
- “Uniquely match” standard is subjective.
 - Guidance should instruct examiners to not rely on non-precedential decisions at all.

Abstract Idea Example 23

- In example 23 (graphical user interfaces), the PTO concludes that broader claim 1 is not directed to an abstract idea.
- But the PTO concludes that narrower claim 4, which contains all of the elements of claim 1 and additional elements, is directed to an abstract idea.
- Adding a formula to a claim directed to otherwise patentable subject matter does not transform the claim into an ineligible abstract idea.
- Examining corps may erroneously believe that any “calculating” recitation means a claim is directed to a judicial exception under Step 2A.

Recommendation 2

- Graphical user interface calculations of example 23 are not akin to the mathematical algorithms (e.g., representative of a law of nature) that courts have previously found abstract.
 - PTO should determine that claim 4 of example 23 is not directed to an abstract idea.

Step 2B Ordered Combination

- Guidance memos and abstract idea examples 21 and 25 emphasize considering claim elements as an ordered combination.
- USPTO's Step 2B analysis of abstract idea example 21, claim 2 states:
 - “[S]ome of the limitations when viewed individually do not amount to significantly more than the abstract idea (such as storing subscriber preferences or transmitting an alert). However, when looking at the additional limitations as an **ordered combination**, the invention as a whole amounts to significantly more than simply organizing and comparing data [the alleged abstract idea].”
- But examiners continue to dissect claims to support a § 101 rejection and use boilerplate analyses.

Recommendation 3

- Nov. 2, 2016 memo correctly directs examiners to *BASCOM* for Step 2B analysis.
 - *BASCOM* court stated: “[I]nventive concept can be found in the non-conventional and non-generic arrangement of known, conventional pieces.”
- Examiners should provide a claim chart with language from precedential case law or other rationale articulating why each limitation is not significantly more.
- Guidance should also explicitly instruct examiners that allowable subject matter under §§ 102 and 103 must be considered under Step 2B.

Disclaimer

- The views presented may not necessarily reflect those of RatnerPrestia or its clients.

Questions, Comments, Concerns?
Thank You!

Sunjeev S. Sikand
RatnerPrestia, P.C.
ssikand@ratnerprestia.com

Roundtable I

USPTO - Alexandria, VA
November 14, 2016

Suzannah K. Sundby
Partner, Canady + Lortz LLP
Washington, DC

Well-Understood, Routine, and Conventional

Little guidance from courts and USPTO as to its scope and meaning as applied to 101 (in)eligibility determinations

In *Mayo*, Well-Understood, Routine, and Conventional (WURC)...

Was

- Determined as applied to the specific invention claimed
- Prior art actually
 - Administered thioguanine drugs to subjects, and
 - Determined levels of thioguanine drugs in said subjects

Was NOT

- Analyzed and applied at a generic high level, i.e., to ALL diagnostic method claims
- Did not consider whether prior art
 - Administered any drug to any subject, and
 - Determined levels of said any drug in said any subject (by any means)

However, Many Examiners...

4

- Assert a single claim element by itself as being WURC if it lacks absolute novelty and/or would have been obvious to a PHISITA
 - Absolute Novelty – If anyone performed (or used) the recited claim element for ANY reason, then it is WURC
 - PHISITA – If a Person Having the *Inventor's Skill and Information* in The Art would have performed (or used) the recited claim element, then it is WURC

Simply Wrong

5

No basis in our patent laws

So what is it?

6

If it is a “We know it when we see it” type of thing...

How can Examiners in all art groups evenly and consistently determine whether claim limitations are WURC from invention to invention?

Enablement and Written Description

Analyze whether the prior art in the given field of art provides (1) sufficient written description and (2) enabling support for the claimed invention *without the benefit of the inventor's own disclosure of the invention*

- If the state of the given field of art at the time of the invention (or EFF) does not
 - Provide written description support for the element as applied in the claim, it can't be WURC
 - Enable a PHOSITA to make or use the element as applied in the claim, it can't be WURC

- To be WURC, the prior art in the field of the invention, without the knowledge and skill of the inventor, must provide adequate enabling and written description support of the element as applied in the claim

In short

Doesn't mean the converse is true

9

- A claim reciting an element that is not WURC doesn't necessarily mean the claimed invention lacks enablement and written description support
 - As the inventor's own specification may adequately disclose what is not WURC

Sufficiency of Evidence of “Markedly Different” and “Significantly More”

Example 30, Claim 2:

A dietary sweetener comprising:
1-5 percent texiol; and
at least 90 percent water.

Example 30 States:

- The “Texas mint” plant is a relative of stevia, which has a thin liquid sap containing about 10% texiol
- [T]rained sensory panels reviewed formulations having varying concentrations of texiol in water, and found that the sensory perceptions of texiol’s sweetness and bitter aftertaste both increased with concentration, e.g., higher concentrations of texiol were perceived as having stronger sweet and bitter tastes.
- Based on the panel’s review, and from a consumer’s perspective, applicant discloses a preferred dietary sweetener comprising 1-5% texiol and at least 90% water.
- This preferred sweetener retains the naturally occurring texiol’s sweetness and bitter aftertaste.

- Claim 2 = 1-5% texiol

-
- Natural Occurring Sap = 10% texiol

$$\frac{1}{2}$$

And

- PREFERRED OVER 10% texiol by a sensory panel of experts and consumers
- RETAINS the sweetness and bitter aftertaste of 10% texiol

Simply Can't Be

15

If this type of evidence is insufficient to show
“Markedly Different”

What is?

Abstract Ideas and Diagnostic Inventions

When do transformative steps confer eligibility?

- *UURF v. Ambry* (2014)
 - We need not decide if Mayo is directly on point here because the method claims ... recite abstract ideas
 - We have already addressed ... in our own 2012 Myriad decision
- 2012 Myriad Decision of CAFC
 - Although the Court has now held that certain transformative steps are not necessarily sufficient under § 101 if the recited steps only rely on natural laws
 - [W]e once again, even in light of Mayo, arrive at the same conclusion of patent-eligibility because at the heart of claim 20 is a transformed cell, which is made by man, in contrast to a natural material

“Not Necessarily”

18

There are times where the opposite is true

“If and Only”

IF the recited steps ONLY rely on natural laws

Not “Only”

20

Things made by man

Claim 20: Cell made by man was thing transformed

Examples of Things Made By Man

21

- Monoclonal antibodies
- Probe comprising DNA fragments bound to detectable labels
 - Where the detectable labels are not naturally bound to the given DNA fragment
- Synthetically created DNA adaptors that allow high-throughput processing (sequencing, amplification, etc.)
- Synthetically created chemicals

Transformed Things

- A complex comprising a monoclonal antibody bound to an antigen
- The probe comprising the DNA fragment bound to the detectable label hybridized to a target DNA sample
- DNA adaptors ligated to target DNA samples
- Products of chemical reactions where synthetically made chemicals are the starting reactants

So Diagnostic Assays

23

Involving the transformation of tangible things made by man (not nature) should be found **eligible**

Squaring with *Ambry*

- At best, the ineligible claims of *Ambry* transformed a natural product with another natural product

Transforming to Analyze

- a sequence of a **BRCA1 gene** or **BRCA1 RNA** from a human sample or analyzing a sequence of **BRCA1 cDNA** made from mRNA from said human sample

Forming a Complex between

- a first sequence selected from the group consisting of a **BRCA1 gene** from said tumor sample, **BRCA1 RNA** from said tumor sample and **BRCA1 cDNA** made from mRNA from said tumor sample, and
- a second sequence selected from the group consisting of **BRCA1 gene** from a nontumor sample of said subject, **BRCA1 RNA** from said nontumor sample and **BRCA1 cDNA** made from mRNA from said nontumor sample

Ambry claims don't require that

Any sequence must be cDNA
(which is made by man)

- The meaning of “well-understood, routine, and conventional” and how it is to be determined evenly and consistently by Examiners for ALL inventions
- Examples of arguments and evidence sufficiently that support “Markedly Different” and “Significantly More”
- Examples eligible diagnostic biomarker assays (not treatment claims) requiring transformation of man-made tangible things

Disclaimer

- These materials and views expressed today reflect only the personal views of the author and do not necessarily represent the views of other members and clients of the author's organizations.
- These materials are public information and have been prepared solely for educational purposes to contribute to the understanding of U.S. intellectual property law. While every attempt was made to ensure that these materials are accurate, errors or omissions may be contained therein, for which any liability is disclaimed. These materials and views are not a source of legal advice and do not establish any form of attorney-client relationship with the author and Canady + Lortz LLP.



SCHWEGMAN
LUNDBERG • WOESSNER
A PROFESSIONAL ASSOCIATION | SLWIP.COM

PATENT PROTECTION FOR HIGH TECHNOLOGY





Diagnostic Tests – Is There Anything Left to Patent?

Warren D. Woessner, J.D., Ph.D.
Schwegman, Lundberg & Woessner
Minneapolis, MN

USPTO Round Table on Patent
Subject Matter Eligibility
November 14, 2016

The "Big Question"

- Are "simple" diagnostic claims PE– "If A, then B" patent-eligible? (Elevated Hcys = low cobalamin.)(Detection of receptor A or mutation B means treatment Y will be effective.)
- PTO – "No" (2014 and May 2016 Guidelines) (Detection "Good," Correlation "Bad.")
- Justice Breyer, "No" ("Metabolite Labs. Dissent")(2006)
- Fed. Cir.: "Maybe" – "Human ingenuity test" - if claim is drafted with specificity as to both the marker measured and the condition identified.
- Or will the court deny that the discovery and application of the utility of the correlation per se can provide the needed Mayo/Alice "inventive step," and that diagnosing is no more than "basic critical thinking" that is an "abstract idea."

Mayo Collab. Services v. Prometheus

- 132 S. Ct. 1239 (2012).
- Court reversed Fed. Cir. and held that claims to acquiring an indication of proper drug dosage based on determining if levels of metabolites fell within a predetermined range were patent ineligible as attempt to monopolize a "law of nature." (Correlation is between metabolite levels and efficacy or toxicity)
- Court stated that administration of drug and detection of metabolite levels are not natural laws.

The Supreme Court Punts P-E of Diagnostic Claims

- Court disregarded administration, measurement and indicating steps, as well as specific numerical limitations in the claims.
- The Mayo claims were method-of-medical-treatment claims. “Discovery” of the correlation between dosage and efficacy or side-effects was old.
- Court did not resolve the PE of "diagnostic claims":

"We need not determine here whether, from a policy perspective, increased protection for discoveries of diagnostic laws of nature is desirable."

Ariosa did not answer this question

- Appeal No. 2014-1139, 2014-1144 (Fed. Cir., June 12, 2015)
- U.S. Pat. No. 6,258,540 ("Non-invasive Prenatal Diagnosis")
- The primary diagnostic claim was very broad:

21. A method of performing a prenatal diagnosis, which method comprises the steps of:

[sampling, processing and detecting the presence of nucleic acid of foetal origin in maternal blood] and

(iv) providing a diagnosis based on the presence and/or quantity and/or sequence of the foetal nucleic acid.

(Claims 18-19 that recited specific diagnoses were not considered separately and are statements of intended use.)

Fed. Cir. applied the Mayo test.

- "Existence of cffDNA in maternal blood is a natural phenomenon" and so is "paternally inherited cffDNA."
"Thus the claims at issue...are generally directed to detecting the presence of a naturally occurring thing or a natural phenomenon." (Emphasis supplied)
- Held: "the practice of the method claims does not result in an inventive concept that transforms the natural phenomenon of cffDNA into a patentable invention."
- **BUT the recited "diagnosis" element was not mentioned at all.** "None of the remaining asserted dependent or indep. claims differ substantially from these claims."

Ariosa v. Sequenom

- Sequenom petitioned for re-hearing en banc but in Dec. 2015, it was denied (809 F.3d 1282).
- BUT Judges Lourie and Moore wrote concurrences, as did Judge Dyk. Judge Newman dissented.
- Cert. was denied on June 27, 2016.

Judge Linn Concurred (Barely)

- The broad language of Mayo discounting "conventional activity" conflicts with Diehr and was not necessary in view of the state of the art (Claim in Mayo was to an old use of an old compound).
- Mayo made me concur "even though here no one amplifying or detecting paternally inherited cffDNA using [blood] of pregnant mothers."
[because no one know it was there]

Judge Dyk: "Narrow is the Path to Salvation."

- In Myriad I and II, "we found genetic testing claims that sought to capture 'all comparisons between the patient's BRCA and the wild-type BRCA genes' to be overbroad and thus [not PE], noting that 'the covered comparisons are not restricted by the purpose of the comparison or the alteration being detected.'"
- "If the breadth of the claim is sufficiently limited to a specific application of the new law of nature discovered by the applicant and [actually] reduced to practice, I think that the novelty of the discovery should be enough to supply the necessary inventive concept....[O]nly diagnostic and therapeutic method patents limited in their claim scope would survive.... The claims of the '540 patent are overbroad." (Emphasis supplied)

Genetic Technol. Ltd. v. Meriel, LLC

- (Appeal no. 1215-, -1202, -1203 (Fed. Cir. April 8, 2016))
- Claims were to the use of law of linkage disequilibrium to the problem of detecting specific coding sequences of DNA.
- Claim 1 was directed to a method of detection of at least one coding region allele of a multi-allelic genetic locus via an amplification step and a detection step.
- Claim 15 reads: "The method of claim 9 wherein said allele is associated with a monogenic disease" (e.g., cystic fibrosis).
- The panel characterized the term "to detect an allele in the coding region" as a mental process step – a routine comparison that can be performed by the human mind."(Emp. supplied)

Does Judge Dyk have a legal hangover post-Ariosa?

- "The inventive concept necessary at step 2...cannot be furnished by the unpatentable law of nature (or natural phenomenon or abstract idea) itself. That is, under the Mayo/Alice framework, a claim directed to a newly discovered [PAIN] cannot rely on the novelty of that discovery for the inventive concept necessary for [PE]; instead the application must provide something inventive, beyond mere 'well-understood, routine conventional activity.'" [Citing Mayo, Myriad and Ariosa]
- The “two inventions” rule.

Rapid Litigation Mgmt. LTD v. Cellzdirect, Inc.

- Appeal no. 2015-1570 (Fed. Cir., July 5, 2016)(U.S. Pat. No. 7,604,929). Judges Moore, Stoll and Prost, Prost writing.
- Method to isolate "hardy hepatocytes" by subjecting hepatocytes, including pooled ones, to two freeze-thaw cycles, resulting in cryopreserved "hardy" hepatocytes that could be used without further selection of viable from non-viable ones.
- D.C. held claim was to law of nature - reversed

Rationale: Claims are directed to new and useful preservation technique

- Panel distinguished the method steps of Genetic Techs., Ariosa and Myriad I and II as involving nothing more than observing or identifying the ineligible concept.
- This contradicts the 2A eligibility of detection of JUL 1 (pp. 11-12).
- Mayo: Administration of drug and detection of metabolite levels are not natural laws.
- What outcome if claims were drawn to method to detect, identify or observe hardy hepatocytes?

Cellzdirect Panel Relied on Diehr

- "Just as in Diehr, it is the particular 'combination of steps' that is patentable here. 450 U.S. at 188. The inventors discovered that some percentage of hepatocytes can survive multiple freeze-thaw cycles and applied that discovery to improve existing methods for preserving hepatocytes. To require something more would be to discount the human ingenuity that comes from applying a natural discovery in a way that achieves a 'new and useful end.'" [citing Alice].

Vanda Pharms., Inc. v. Roxanne Labs., Inc.

D. Delaware. 2016. Judge Sleet upheld validity of method directed to a regimen for treating schizophrenia using Vanda's iloperidone.
(U.S. Pat. No. 8,586,610)

Claim 1. relied on two natural phenomena.

- (a) Determining whether or not patient is a CYP2D6 "poor metabolizer" of the drug by sampling and genotyping.
- (b) Administering less than 12 mg/day of the drug if patient is a poor metabolizer and >12 up to 24 mg/day if patient is not a poor metabolizer to lower risk of side effect (heart QTc prolongation.)

Claims argued to embody two laws of nature

- 1. That mutations in the CYP2D6 genes can alter enzymatic activity.
- That a patients' CYP2D6 enzymatic activity affects their metabolism of the drug.
- And argued that dose adjustment step was routine and conventional way to reduce side effects.

Judge wasn't buying it

- Judge had found the drug claims to be unobvious.
- This complete record gave Vanda a lot to work with to show its method was not routine.
- Expert testimony that attempts to generate regimens for structurally similar drugs didn't work. No prior art showing in vivo activity.
- Weight given to separating patients into two groups by genotyping a single enzyme, then adjusting the doses.
- Judge would not "discount the human ingenuity that comes from applying a natural discovery in a way that achieves a 'new and useful end.'"
- No preemption.

These are Conflicting Approaches

1. The discovery of the significance of the natural phenomenon and the use of human ingenuity to apply it *vs.*
2. A claim must contain “something more” or a further “inventive concept” in addition to 1) to satisfy s.101.



SCHWEGMAN
LUNDBERG • WOESSNER
A PROFESSIONAL ASSOCIATION | SLWIP.COM

PATENT PROTECTION FOR HIGH TECHNOLOGY

Thank you for your participation.

For more information please visit :
www.SLWip.com

MINNESOTA

1600 TCF Tower
121 South 8th Street
Minneapolis, MN 55402
612.373.6900

SILICON VALLEY

150 So. Almaden Blvd.
Suite 750
San Jose, CA 95113
408.278.4040

TEXAS

8911 Capital of Texas Highway
Suite 4150
Austin, TX 78759
512.628.9320

Thank you for your consideration

- Warren Woessner is a founding Principal of Schwegman Lundberg & Woessner in Minneapolis, MN. He received his Ph.D. and J.D. degrees from the University of Wisconsin – Madison. His practice focusses on client counseling in pharmaceuticals and biotechnology, with an emphasis on due diligence opinions and solutions for complex prosecution problems. He has spoken and published widely on issues in life sciences IP and chaired both the Chemical Practice and Biotechnology Committees of the AIPLA. Warren served two terms on the Amicus Committee and is a Fellow of the association. His IP Blog is patents4life.com.



Step 2A: Inconsistent Guidance Leads to Inconsistent Results

Roundtable 1: USPTO Subject Matter Eligibility Guidelines
David Easwaran



Preliminary Eligibility Instructions (PEI) (June 25, 2014)

- “determine whether the claim is directed to a judicial exception (i.e., law of nature, natural phenomenon, and abstract idea) using Part I of the two-part analysis”
- Part 1 (now called Step 2A):
 - “Determine whether the claim is directed to an abstract idea”
 - “Examples of abstract ideas...include:
 - Fundamental economic practices;
 - Certain methods or organizing human activities;
 - ‘[A]n idea of itself’; and
 - Mathematical relationships/formulas.”
 - “Claims that *include* abstract ideas ... should be examined under Part 2 below...” (emphasis added)
- **The PEI’s “directed to” test: evaluate whether the claim *includes* a judicially recognized exception**



Interim Eligibility Guidance (IEG) (December 16, 2014)

- “[D]etermine whether the claim *as a whole* is directed to a judicial exception”
- “To properly interpret the claim, it is important to understand what the applicant has invented and is seeking to patent”
- “A claim is directed to a judicial exception when [the judicial exception] is recited (i.e., set forth or described) in the claim”
- “[T]he application of the overall analysis is based on claims directed to judicial exceptions (defined as claims reciting the exception, i.e., set forth or described), rather than claims merely ‘involving’ an exception” (footnote 2)
- The IEG provided a streamlined eligibility analysis “[f]or claims that may recite a judicial exception, but are directed to inventions that clearly do not seek to tie up the judicial exception”
- **Inconsistency #1: the IEG introduced the “recited (i.e., set forth or described)” formulation, elevating Step 2A into an evaluation of whether the claim as a whole does *more* than involve or merely recite a judicially recognized exception**



The May 19 Memo (*Enfish* & TLI) (May 19, 2016)

- Based on *Enfish*, the “the ‘directed to’ inquiry applies a filter to claims, when interpreted in view of the specification, based on whether their character as a whole is directed to a patent ineligible concept”
- Also based on *Enfish*, “the Federal Circuit cautioned against describing a claim at a high level of abstraction untethered from the language of the claim when determining the focus of the claimed invention”
- But: “[i]n summary, ... examiners are to continue to determine if the claim recites (i.e., sets forth or describes) a concept that is similar to concepts previously found abstract by the courts”
- **Inconsistency #2: the May 19 Memo – unlike any prior guidance – stated that Step 2A should evaluate the *focus of the claimed invention*, yet alleged that the Step 2A guidance**



Rapid Litigation & Sequenom (July 14, 2016)

- Based on *Rapid Litigation Management*, “the ‘directed to’ analysis of a process claim ... requires an analysis of whether ‘the end result of the process, the essence of the whole, was a patent-ineligible concept”
- “This need to analyze the focus of the claims in Step 2A was also emphasized in the Federal Circuit's *Enfish* decision (discussed in the May 19, 2016 memorandum to examiners)”
- But: “[t]he USPTO's current subject matter eligibility guidance (set out in the 2014 Interim Eligibility Guidance, July 2015 Update, and the May 2016 memoranda to examiners) and training examples are consistent with these points”
- **Inconsistency #3: the July 14 Memo reiterated that Step 2A should evaluate the *focus* of the claimed invention, but *again* suggested that the earlier Step 2A guidance had not changed**



The November 2 Memo (*Bascom* and *McRO*) (November 2, 2016)

- “If applicant argues that a claim does not preempt all applications of the exception, an examiner should reconsider in Step 2A of the eligibility analysis whether the claim is directed to an improvement in computer-related technology or a specific way of achieving a desired outcome or end result”
- But the July 2015 Update stated that “the absence of complete preemption does not guarantee that a claim is eligible”
- And the May 4, 2016, Memo stated that “[q]uestions of preemption are inherent in and resolved by the two-part framework”
- **Inconsistency #4: the November 2 Memo acknowledged that non-preemption *should* be considered at Step 2A, despite contrary language in prior guidance**



Problems at Step 2A

- The guidance documents thus authorize multiple strategies at Step 2A, such as:
 - Evaluating whether a claim “includes” an exception (PEI)
 - Evaluating whether a claim “recites (i.e., sets forth or describes)” the exception (IEG)
 - Evaluating if an exception is the “focus” of a claim (May 19 Memo + July 14 Memo)
 - Considering preemption (November 2 Memo)
 - ...or not (July 2015 Update / May 4 Memo)
- Ostensibly, all of these strategies remain proper!
- Problem: the thicket of active guidance documents allows for inconsistent application of Step 2A between different Examiners and even between Office Actions from a single Examiner
- **Solution: the USPTO should clarify that the latest memos (May 19, July 14, and November 2) *supersede* all prior conflicting**



A Proposal For Improving Step 2A

- Step 2A should further be bifurcated into two sub-steps:
 - 1. Identifying the focus of each claim as a whole**
 - Identifying the *focus* of a claim is most consistent with the recent Federal Circuit cases, which perform the “directed to” inquiry after identifying:
 - i. the “character as a whole” of a claim (*Internet Patents Corp., Enfish, Electric Power, McRO, Affinity Labs v. DirecTV*)
 - ii. the “focus” of a claim (*Merial, TLI, Electric Power, Fairwarning IP, McRO, Affinity Labs v. DirecTV*),
 - iii. the “basic thrust” of a claim (*Bascom Global*)
 - iv. the “essence of the whole” of a claim (*Rapid Litigation Management*)
 - Isolating this sub-step will improve quality, consistency, and clarity of Examiner analysis
 - 2. Determining whether the identified focus is a judicially recognized exception**
 - Non-preemption (*McRO*) should be considered (and without needing to be affirmatively raised by the Applicant)



Thank you

david.easwaran@alston.com