Patent Office Practice and Policy

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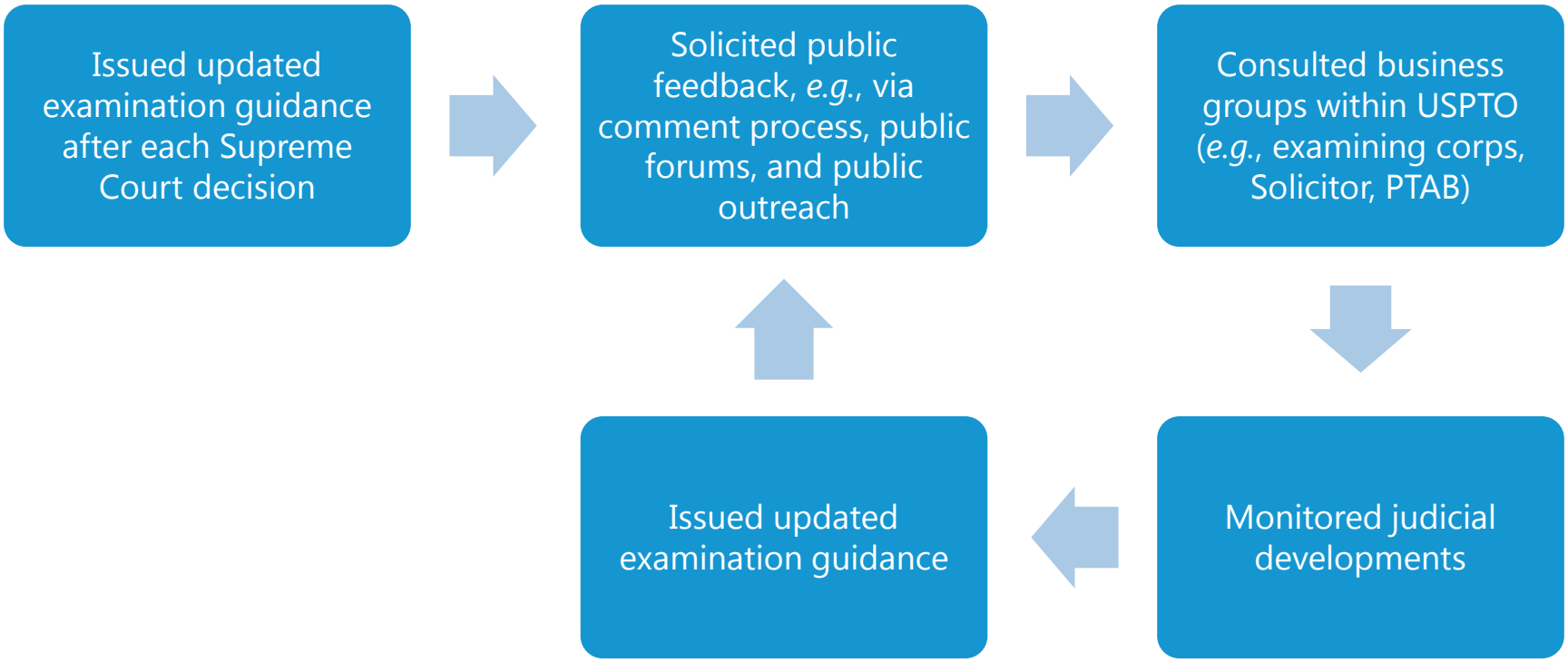
OFFICE ELIGIBILITY GUIDANCE

35 U.S.C. § 101 – Judicial Exceptions

- Supreme Court has long held that § 101 *excludes* certain subject matter from patent eligibility:
  - Abstract Ideas
  - Laws of Nature/Natural Principles
  - Natural Phenomena (including Products of Nature)
- High level of judicial activity in this area since 2010
  - Four Supreme Court cases (*Bilski*, *Mayo*, *Myriad*, *Alice Corp*.)
  - Many Federal Circuit decisions

Iterative Guidance Process



Interim Eligibility Guidance (IEG)
December 16, 2014

- Explains the USPTO's interpretation of subject matter eligibility requirements in view of case law
  - Sets forth uniform procedure for examination implementing the two-part analysis from *Alice Corp./Mayo* (called Steps 2A & 2B in the IEG)
  - Included discussion of case law precedent, and examples illustrating application of eligibility analysis to various types of claims
- Requested comments and feedback from public

Guidance Explains How To Identify "Products of Nature" in Step 2A

- The **Markedly Different Characteristics (MDC)** analysis is used to determine if a nature-based product is a "product of nature" exception in Step 2A
- MDC analysis considers characteristics of the nature-based product including function, structure, phenotype, and chemical and physical properties
  - If nature-based product exhibits MDC from any naturally occurring counterpart, it is not an exception
  - If nature-based product (i) is naturally occurring or (ii) lacks MDC from a naturally occurring counterpart, it is a "**product of nature**" exception

Guidance Explains How To Analyze Claim For Significantly More In Step 2B

Considerations that assist in determining whether claim elements provide significantly more than a judicial exception:

May provide "significantly more"

- Improvements to another technology or technical field
- Improvements to the functioning of the computer itself
- Applying the judicial exception with, or by use of, a particular machine
- Effecting a transformation or reduction of a particular article to a different state or thing
- Adding a specific limitation other than what is well-understood, routine and conventional in the field
- Adding unconventional steps that confine the claim to a particular useful application
- Other meaningful limitations beyond generally linking the use of the judicial exception to a particular technological environment

May <u>not</u> provide

- Generic computer performing generic computer function
- Words equivalent to "apply the exception"
- Mere instructions to implement a judicial exception on a computer
- Insignificant extra-solution activity, such as mere data gathering
- Generally linking the use of the judicial exception to a particular technological environment or field of use
- Merely appending well understood, routine, conventional activities previously known to the industry, specified at a high level of generality

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July 2015 Update
July 30, 2015

- Provides clarifications on the IEG and responds to feedback
  - Addresses questions regarding how the markedly different characteristics (MDC) analysis fits into the *Alice*/*Mayo* framework and explains benefits of applying the MDC analysis in Step 2A
  - Also includes additional abstract idea examples based on cases and hypotheticals (Appendix 1) and responds to other concerns, such as prima facie case and preemption
- Again requested comments and feedback from public

May 2016 Update
May 4, 2016

- Provides clarifications on examination practice under the IEG and responds to feedback
  - Directs examiners on best practices in formulating a subject matter eligibility rejection, *i.e.*, providing reasoned rationale when identifying an exception in Step 2A and explaining why additional elements do not add significantly more in Step 2B
  - Emphasizes the importance of considering applicant's arguments and challenges to an eligibility rejection
  - New set of Life Science Examples, including six examples drawn from case law and hypotheticals intended to show various ways to draft claims for eligibility
- Again requested comments and feedback from public

Rapid Litigation Mgmt. v. CellzDirect (July 2016)

- Claims were **eligible** because they were not directed to a judicial exception (Step 2A inquiry in Office guidance)
  - The inventors discovered hepatocyte's ability to survive multiple freeze-thaw cycles, "but that is not where they stopped, nor is it what they patented"
  - End result of claims was more than observation or detection of this ability, because claims recite a number of process steps (*e.g.*, fractionating, recovering, and cryopreserving) that manipulate hepatocytes in accordance with their ability to survive multiple freeze-thaw cycles, to achieve a desired outcome (a preparation of multi-cryopreserved viable hepatocytes)
- Federal Circuit made two other points:
  - Eligibility does not turn on ease of execution or obviousness of application
  - Pre-emption is not the test for determining patent eligibility – it is a concern that undergirds § 101 jurisprudence

Ariosa v. Sequenom (Federal Circuit June 2015)

- Claims to methods of detecting and performing non-invasive prenatal diagnosis found ineligible, because directed to the naturally occurring phenomena of cffDNA in maternal plasma or serum and the additional steps relating to preparation and detecting are well-understood, routine, conventional activities performed by doctors at the time of the application
- Rehearing *en banc* denied; Petition for certiorari denied June 2016

Written Description for Claims Directed to Antibodies

Excerpts from 2016 training delivered in Workgroup 1640

UNITED STATES PATENT AND TRADEMARK OFFICE

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The Written Description Guidelines

- MPEP 2163: W.D. guidelines for complying with the written description requirement of 35 U.S.C. 112(a) that the "specification shall contain a written description of the invention. … ".

- This requirement is separate and distinct from the enablement requirement (*Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1355 (Fed. Cir. 2010)).

2008 Written Description Training Materials

- Example 13: Antibodies to a Single Protein
  - Claim 1. An isolated antibody capable of binding to antigen X
  - Disclosure limited to characterization of antigen X; no reduction to practice of an antibody

2008 Written Description Training Materials

- Example 13 (cont.)
  - Considering the facts, including the routine art-recognized method of making antigen specific antibodies, the adequate description of antigen X, the well-defined structural characteristics for the classes, subclasses and isotypes of antibody, the functional characteristics of antibody binding, and the fact that antibody technology was well developed and mature, one of skill in the art would have recognized that the disclosure of the adequately described antigen X put the applicant in possession of antibodies which bind to antigen X.

2008 Written Description Training Materials

- EXAMPLE 14: Antibodies to a Genus of Proteins

  - Claim 1. A monoclonal antibody that binds Protein X.
  - Claim 2. The antibody of claim 1 which binds murine Protein X.
  - Claim 3. The antibody of claim 1 which binds human Protein X.
  - Disclosure limited to characterization of murine Protein X.

2008 Written Description Training Materials

- Claim 2: Meets the WD requirement by disclosure of murine Protein X.
- Claim 3: Fails under WD because there is no disclosure of the human Protein X.
- Claim 1: Fails under WD because it encompasses protein X from non-murine species.

Centocor Ortho Biotech, Inc. v. Abbott Laboratories, 636 F.3d 1341, 1351-52, 97 USPQ2d 1870, 1877 (Fed. Cir. 2011)

- "In *Centocor,* the patent at issue claimed antibodies with specific properties including high affinity to a particular antigen, which was characterized in the prior art. The patent did disclose the antigen, but did not disclose any antibodies with the specific claimed properties. The court held that the claimed antibodies were not adequately described, because as of the priority date of the patent, the generation of such antibodies was not possible using conventional, routine or well-developed technology." (MPEP 2163)

***AbbVie Deutschland GmbH v. Janssen Biotechnology, Ltd.*, 759 F.3d 1285 (Fed. Cir. 2014)**

Abbvie v. Janssen (2014)

- Human antibody against human IL-12

- AbbVie patents US 7,504,485 and US 6,914,128, shared specification with claims directed to **fully human anti-IL-12** antibodies

- Centocor produced Stelara® (ustekinumab) indicated for the treatment of adults with moderate-to-severe plaque psoriasis

- From AbbVie '128, claim 29:

A neutralizing isolated human antibody, or antigen-binding portion thereof that binds to human IL-12 and disassociates from human IL-12 with a K_{off} rate constant of $1x10^{-2}$ s^{-1} or less, as determined by surface plasmon resonance.

Written Description support is raised

- AbbVie's '128 and '485 taught ~300 fully human antibodies that bind and neutralize IL-12

- All disclosed AbbVie antibodies were derived from 1st Gen antibody "Joe-9." Joe-09 CDR3 (VH/VL) mutated to increase affinity & neutralizing activities

- All disclosed AbbVie antibodies have:

1. VH3 heavy chains
2. Lambda light chains
3. At least **90% similarity** with Joe-9 in variable regions
4. More than 200 of the abs differ from the 2nd gen ab (Y61) at a single amino acid residue (**99.5% similarity** in variable regions)

Written Description support is raised (Cont.)

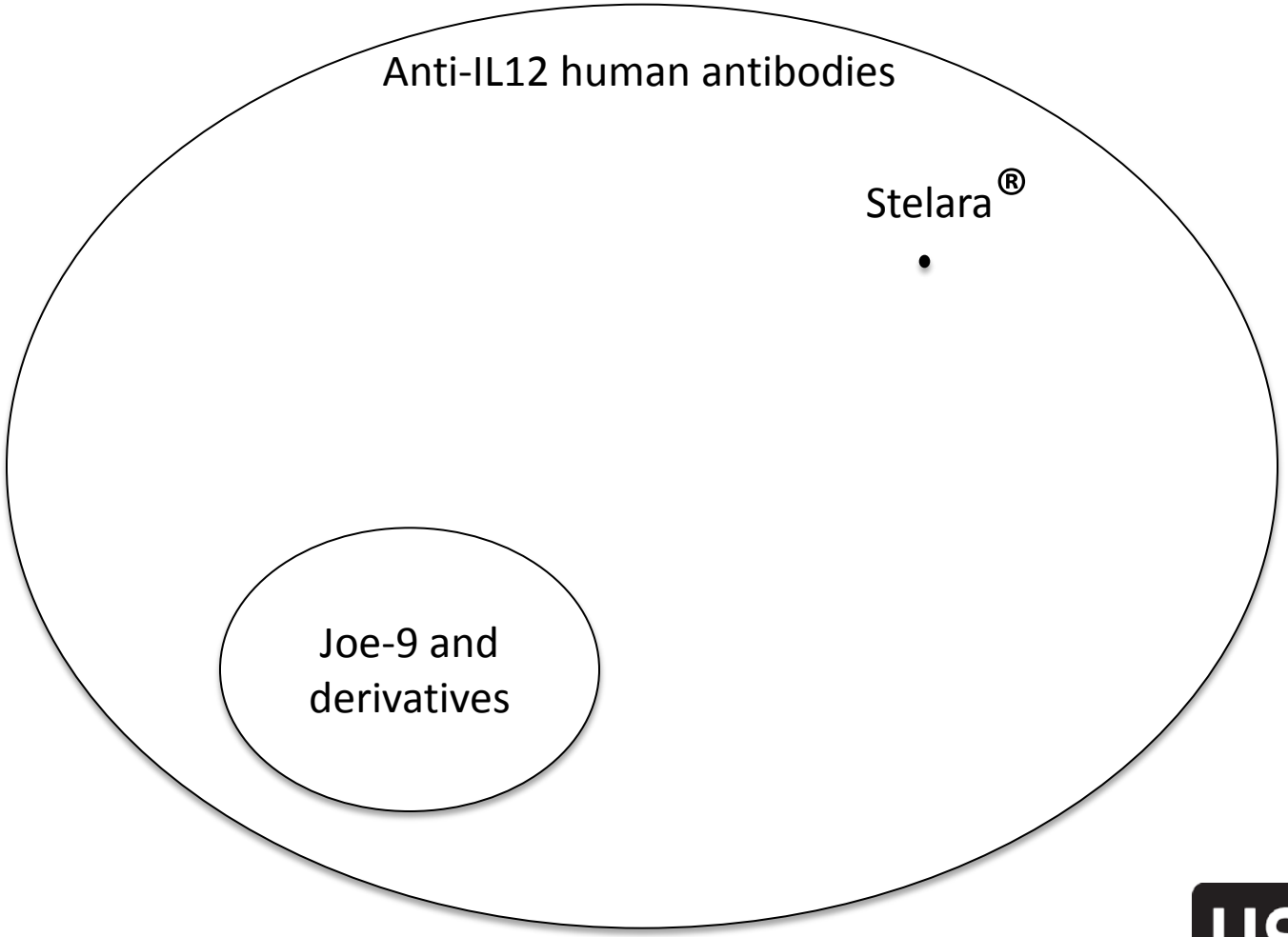
- Stelara® met the functional claim limitations:

1. Fully human
2. Anti-IL-12
3. Neutralize activity of IL-12

- But is structurally distinct from Joe and Joe-derived abs.

	Stelara®	J695	Joe-9
Sequence Similarity	50%	90%	90%
CDR Length	Different	Identical	Identical
Epitope Binding Site	Side Binder	Bottom Binder	Bottom Binder
V_H Family	V_H5	V_H3	V_H3
Light Chain Type	Kappa	Lambda	Lambda

Stelera® is not encompassed by Joe-9 and its derivatives



Written Description support is raised (Cont.)

Representative Number and/or Common Structural Features

•"When a patent claims a genus using functional language to ***define a desired result***, the specification must demonstrate that the applicant has ***made a generic invention*** **that achieves the claimed result** and do so by showing that the applicant has ***invented species sufficient to support*** a claim to the functionally-defined ***genus"*** (*Capon v. Eshhar*, 418 F.3d 1349 (Fed. Cir. 2005)) (emphasis added).

•"***[A] sufficient description*** of a genus . . . requires the disclosure of ***either*** a ***representative number**** of species falling within the scope of the genus or ***structural features common*** to the members of the genus so that one of skill in the art can ***'visualize or recognize'*** the members of the genus" (*AbbVie,* 759 F.3d at 1297, reiterating *Eli Lilly*, 119 F.3d at 1568-69)(emphasis added).

*author's comment: representative number of examples that vary greatly from each other

Written Description support is raised (cont.)

Functional limitations are not strictly prohibited.

•"It is true that functionally defined claims can meet the written description requirement if a ***reasonable structure-function correlation*** is established, whether by the inventor as ***described in the specification or known in the art at the time of the filing date***" (*AbbVie*, 759 F.3d at 1298, reiterating *Enzo Biochem, Inc.,* 323 F.3d at 964)(emphasis added).

But, genus claims need core structure or representative examples

•"The asserted claims attempt to claim ***every fully human IL-12*** antibody that would ***achieve a desired result***, i.e., high binding affinity and neutralizing activity, and cover an antibody as ***different as Stelara®***, whereas the patents do not describe representative examples to support the full scope of the claims." Jury's decision of invalidly for lack of adequate written description for the claimed genus affirmed (*AbbVie*, 759 F.3d at 1298)(emphasis added).

Genus-Species guidance in MPEP 2163. MPEP includes citations of *Noelle v. Lederman*, 355 F.3d 1343 (Fed. Cir. 2004), *Enzo Biochem, Inc*. v. *Gen-Probe Inc*., 323 F.3d 956 (Fed. Cir. 2002), and *Regents of the University of California* v. *Eli Lilly Co.* 119 F.3d 1559 (Fed. Cir. 1997)

101 & 112
WHAT DID THE INVENTOR INVENT?

101 Reading

- Nothing is Patentable - http://papers.ssrn.com/abstract=2642361
- America's First Patents - http://papers.ssrn.com/abstract=2017275
- A Surprisingly Useful Requirement - http://papers.ssrn.com/abstract=1790463
- Life after Bilski - http://papers.ssrn.com/abstract=1725009
- Forward to the Past - http://papers.ssrn.com/abstract=1678163
- Everything is Patentable - http://papers.ssrn.com/abstract=1085871

Prong one (step 2A) drives the discussion

- This is a level of abstractions problem
- Level of abstractions problems are difficult to solve
- There is no clear rationale to determine when something is “abstract” or “natural”
  - PTO guidelines seem to follow from court decisions as they come in
  - But court decisions are not exactly clear

X001

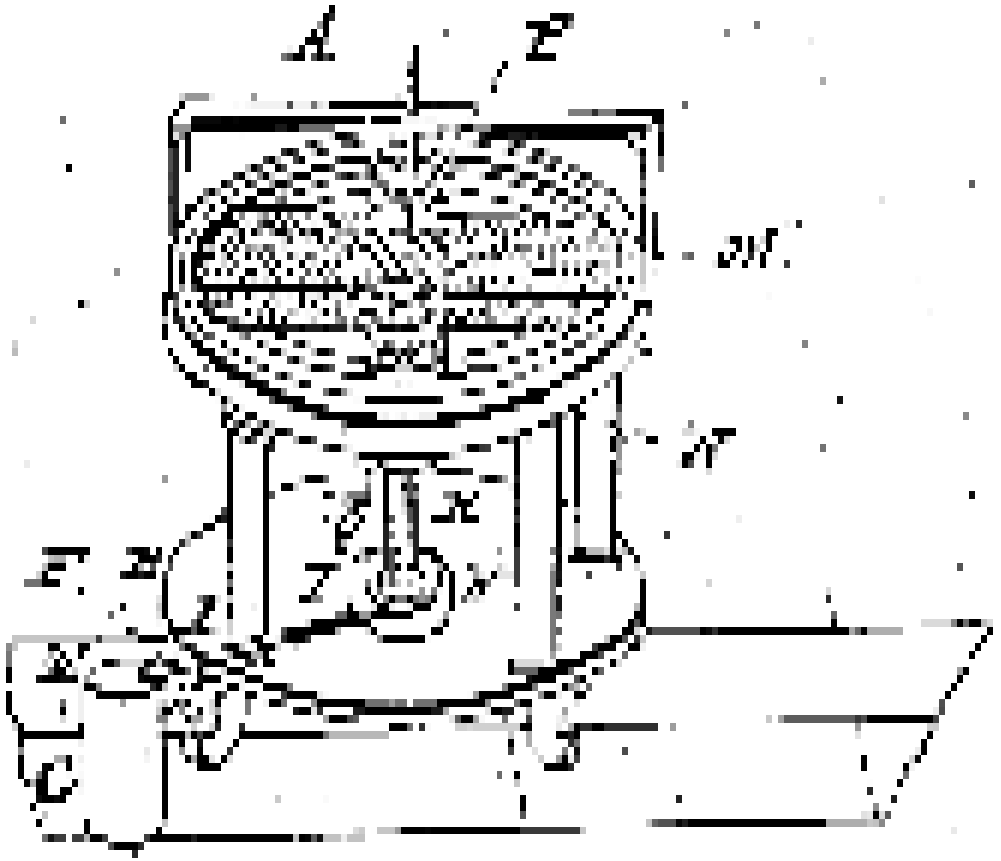
X000001
July 31, 1790

The United States.

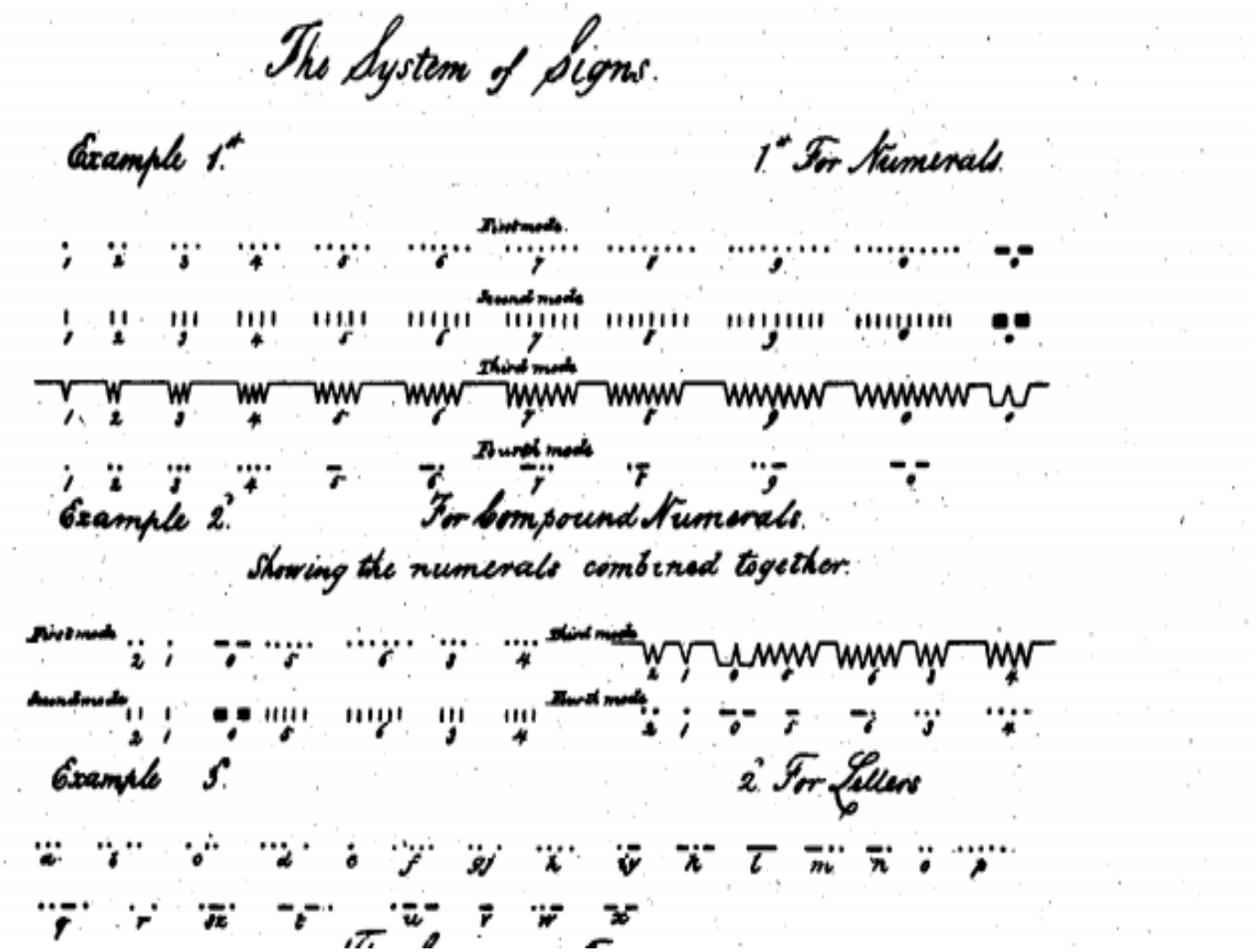
To all to whom these Presents shall come. Greeting.

Whereas Samuel Hopkins of the City of Philadelphia and State of Pensylvania hath discovered an Improvement, not known or used before such Discovery, in the making of Pot ash and Pearl ash by a new Apparatus and Process; that is to say, in the making of Pearl ash 1st. by burning the raw Ashes in a Furnace, 2d. by dissolving and boiling them when so burnt in Water, 3rd. by drawing off and settling the Ley, and 4th. by boiling the ley into Salts which then are the true Pearl ash; and also in the making of Pot ash by fluxing the Pearl ash so made as aforesaid; which Operation of burning the raw Ashes in a Furnace, preparatory to their Dissolution and boiling in Water, is new, leaves little Residuum; and produces a much greater Quantity of Salt: These are therefore in pursuance of the Act, entituled "An Act to promote the Progress of useful Arts", to grant to the said Samuel Hopkins, his Heirs, Administrators and Assigns, for the Term of fourteen Years, the sole and exclusive Right and Liberty of using, and vending to others the said Discovery, of burning the raw Ashes previous to their being dissolved and boiled in Water, according to the true Intent and Meaning of the Act aforesaid. In Testimony whereof I have caused these Letters to be made patent, and the Seal of the United States to be hereunto affixed. Given under my Hand at the City of New York this thirty first Day of July in the Year of our Lord one thousand seven hundred & Ninety.

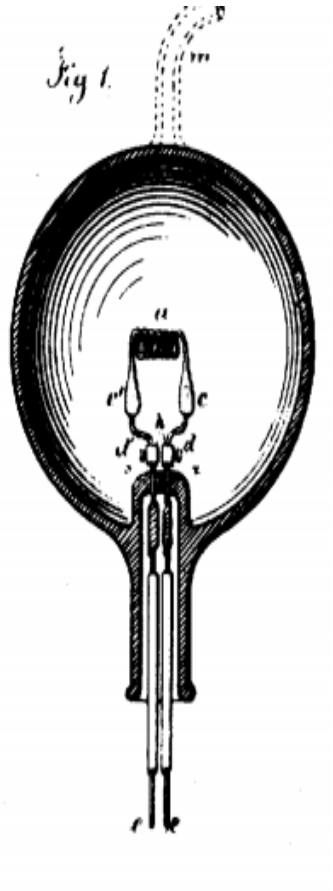
Davenport's Electric Motor (No. 1322)



Morse Code (RE117)



Edison's Light Bulb (223,898)

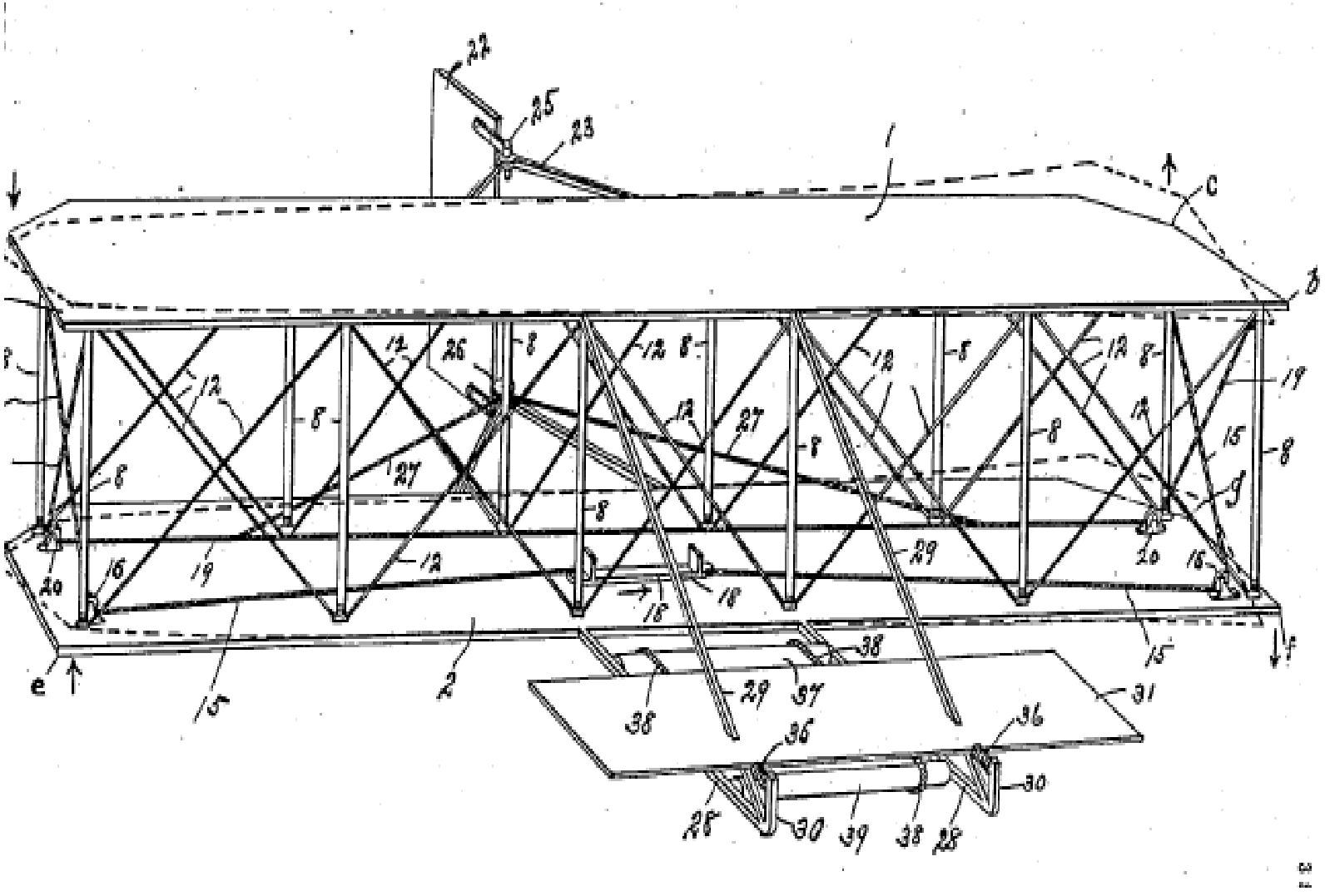


An electric lamp for giving light by incandescence, consisting of a filament of carbon of high resistance, made as described, and secured to metallic wires, as set forth

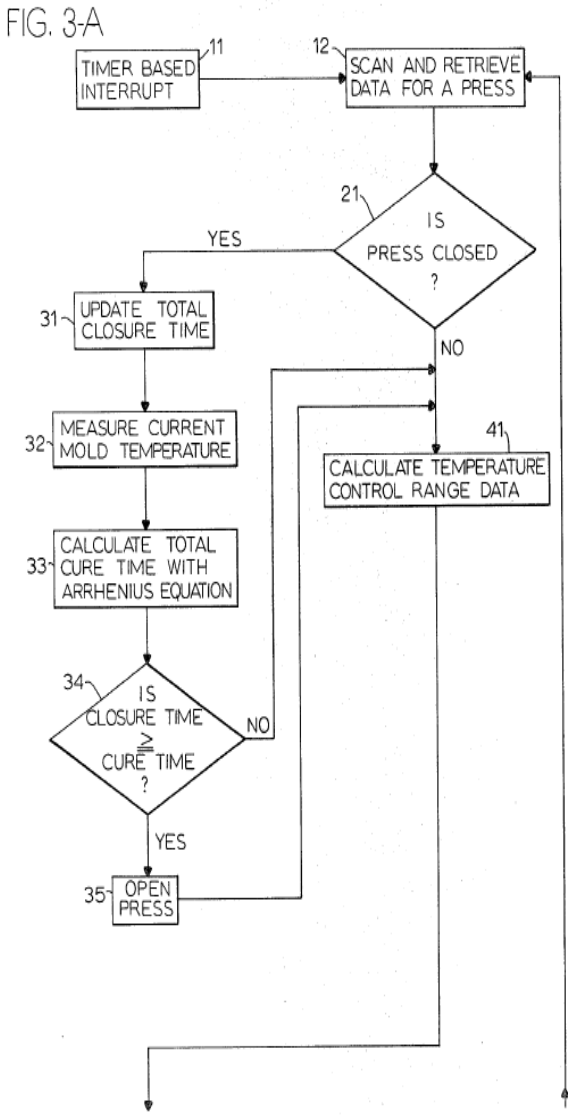
The Telephone (186,787)

In a system of electric telegraphy or telephony, consisting of transmitting and receiving instruments united upon an electric circuit, the production, in the armature of each receiving instrument, of any given motion, by subjecting said armature to an attraction varying in intensity, however such variation may be produced in the magnet, and hence I claim the production of any given sound or sounds from the armature of the receiving-instrument, by subjecting said armature to an attraction varying in intensity, in such manner as to throw the armature into that form of vibration that characterizes the given sound or sounds.

Wright (821393)



Diehr (4344142)



Modern day applications

- New software
- New hardware
- Diagnostics
- Treatment methods
- New uses for old
  - Machines
  - Medicines

112 Reading

- A Brief Defense of the Written Description Requirement
  http://papers.ssrn.com/abstract=1504631
- Response to PTO on Functional Claiming and Software Patents
  http://www.uspto.gov/sites/default/files/patents/law/comments/sw-f_risch_20130312.pdf
- A Surprisingly Useful Requirement
  http://papers.ssrn.com/abstract=1790463
- The Failure of Public Notice in Patent Prosecution
  http://papers.ssrn.com/abstract=931543

Why have Written Description?

- One word: conception
- More words: has the inventor actually invented the full scope of the claim?
- Historical basis: before claims, it was all 112
  - See Journal of the Franklin Institute

Description/Enablement

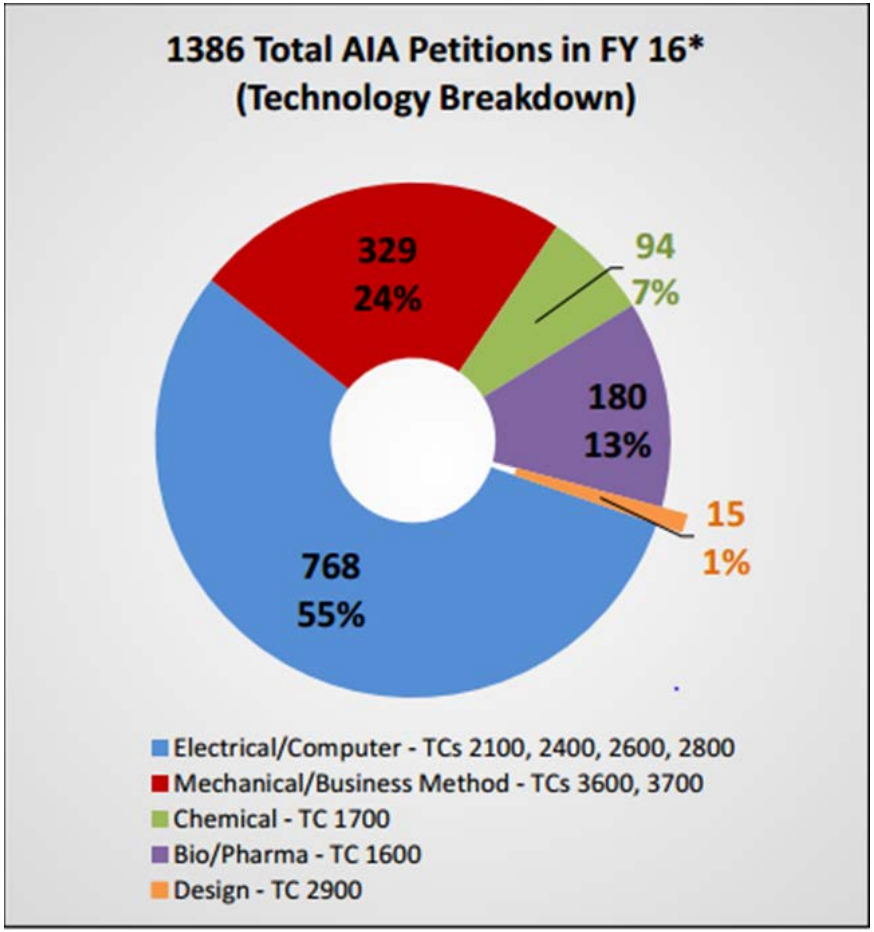
- Different goals that don't always align
  - Rochester case
- Misconstrued throughout history
  - Incandescent lamp
  - Bell's telephone
- Not a "heightened" requirement for bio
  - Like utility, bio just may be more susceptible to issues

A Middle Ground

- Preferred v. All Embodiments
- Prophetic Inventions
- Key question: does the specification show conception of the broader principle?
  - Common threads (e.g. type of fibers in lights)
  - Broad principles (e.g. Bell telephone)
  - Identifiable differences in species (e.g. Lilly, Rochester)
  - Sufficient examples (Ariad?)

RECENT DEVELOPMENTS IN IPRS

Percentage of Bio/Pharma Patents in AIA Proceedings



Data through July 31, 2006. From Patent Trial and Appeal Board Statistics, *available at* http://www.uspto.gov/sites/default/files/documents/2016-07-31%20PTAB.pdf

Number of AIA Proceedings Involving Pharmaceutical Patents

Type of AIA Proceeding	Number of Proceedings Involving an Orange Book Patent
Covered Business Method Review	5
Post-Grant Review	6
Inter Partes Review	297

Data Current as of August 24, 2016

Status of AIA Proceedings Involving Pharmaceutical Patents

Status of Proceeding	Number of Proceedings Involving an Orange Book Patent
Awaiting Institution Decision	73
Denied Institution by the PTAB	76
Instituted by the PTAB	132
Proceeded to a Final Written Decision	55

Data current as of August 27, 2016 with Final Written Decision data current as of September 19, 2016

Final Written Decisions in IPRs Involving Orange Book Patents

Outcome in Final Written Decision	Number of IPRs Involving Orange Book Patents
All Claims Addressed in the Final Written Decision Found Unpatentable	**28**
Some Claims Addressed in the Final Written Decision Found Unpatentable	**1**
All Claims Addressed in the Final Written Decision Found Not Unpatentable	**26**

Data current as of September 19, 2016

IPR Proceedings Filed by Hedge Funds

- Kyle Bass has filed 35 IPR petitions related to patents that are listed in the Orange Book
  - The PTAB denied institution in 15 and instituted review in 20 of these IPR's. The first PTAB final written decision should come out in October
- Other hedge fund entities have also filed IPR petitions related to patents listed in the Orange Book
  - GKC General Partner II, LLC; GKC Partners II, LP; Gerchen Keller Capital, LLC; and Niagara Funding Co, LLC
  - Rosellini Scientific, LLC and nXn Partners, LLC
  - Flat Line Capital LLC
  - Foxhill Opportunity Fund, L.P. and Foxhill Capital Partners, LLC; and Foxhill Capital, LLC

Federal Circuit Developments

- Recent Federal Circuit opinions have limited the PTAB's reach in AIA proceedings. These cases have addressed:
  - Denials of motions to amend,
  - Findings of unpatentability,
  - Claim constructions that were unreasonable under the BRI standard, and
  - Inadequate notice to the Patent Owner

Motions to Amend in IPR Proceedings

- The AIA provides that the Patent Owner may file one motion to amend in an IPR proceeding
- The PTAB rarely grants motions to amend and places the burden on the Patent Owner to show that the proposed amended claims would make the claims patentable over the known prior art
- The Federal Circuit has upheld the PTAB's placement of the burden of proof for proposed amendments on the Patent Owner
- However, two recent Federal Circuit cases signal that there may be push back on the PTAB's denial of motions to amend

In re: Aqua Products Inc., 2015-1177

- The Federal Circuit panel affirmed the PTAB's denial of Aqua's motion to amend on May 25, 2016.
- The Federal Circuit ordered a rehearing *en banc* regarding two questions on August 12, 2016:
  - "When the patent owner moves to amend its claims under 35 U.S.C. § 316(d), may the PTO require the patent owner to bear the burden of persuasion, or a burden of production, regarding patentability of the amended claims as a condition of allowing them? Which burdens are permitted under 35 U.S.C. § 316(e)?"
  - "When the petitioner does not challenge the patentability of a proposed amended claim, or the Board thinks the challenge is inadequate, may the Board sua sponte raise patentability challenges to such a claim? If so, where would the burden of persuasion, or a burden of production, lie?"
- Oral Argument is scheduled for December 9, 2016.

Veritas Technologies LLC v. Veeam Software Corporation, 2015-1894

- On August 30, 2016, the Federal Circuit affirmed the PTAB's obviousness findings but vacated the PTAB's denial of Patent Owner's motion to amend as "arbitrary and capricious"
  - The Court explained, "The Board denied the motion based on its insistence that the patent owner discuss whether each newly added feature was separately known in the prior art. . . . The Board concluded that the motion and the declaration of Veritas's expert, Dr. Levy, do not discuss the features separately but discuss only 'the newly added feature in combination with other known features. . . . '"
  - According to the Federal Circuit panel, "[t]hat conclusion, the sole basis for denying the motion to amend, is unreasonable and hence must be set aside as arbitrary and capricious."
- The panel explained that the PTAB's finding was "erroneous" independent from the Federal Circuit's resolution of *In re Aqua Products* en banc

In re Magnum Oil Tools International, Ltd., 2015-1300 (Fed. Cir. July 25, 2016)

- The Federal Circuit reversed the PTAB's obviousness finding. The Court found that the Petitioner failed to establish obviousness by a preponderance of the evidence and the PTAB improperly shifted the burden to the Patent Owner to disprove obviousness.
- The Court rejected the PTO's argument on appeal that the PTAB can adopt arguments on behalf of the Petitioner that could have been raised during the IPR proceeding.

Arendi S.A.R.L. v. Apple Inc., 2015-2073 (Fed. Cir. Aug. 10, 2016)

- The Federal Circuit found that the PTAB's conclusion that the addition of a limitation missing from a prior art reference would be common sense was "conclusory and unsupported by substantial evidence"
- The Federal Circuit explained that there are at least three caveats in applying a common sense analysis:
  - "First, common sense is typically invoked to provide a known *motivation to combine*, not to supply a missing claim limitation." (emphasis in original).
  - Second, in a case where common sense was used to supply a limitation missing from the prior art, that limitation was "unusually simple and the technology particularly straightforward."
  - Third, "references to 'common sense' [in Federal Circuit cases]—whether to supply a motivation to combine or a missing limitation—cannot be used as a wholesale substitute for reasoned analysis and evidentiary support, especially when dealing with a limitation missing from the prior art references specified."
- The Court reversed the PTAB's finding of unpatentability

Claim Construction Under the Broadest Reasonable Interpretation Standard

- The Supreme Court upheld the PTAB's use of the broadest reasonable interpretation standard in *Cuozzo Speed Techs., LLC v. Lee*, 15-446 (June 20, 2016).
- The Federal Circuit has held that the PTAB improperly applied this standard in a number of cases:
  - Microsoft v. Proxyconn, 2014-1542 (Fed. Cir. June 16, 2015)
  - Straight Path IP Group Inc. v. Sipnet EU S.R.O., 2015-1212 (Fed. Cir. Nov. 25, 2015)
  - Cutsforth, Inc. v. MotivePower, Inc., 2015-1314 (Fed. Cir. Apr. 6, 2016)

Notice to Patent Owner in IPR Proceedings

- The Federal Circuit has vacated Final Written Decisions where the Court found that the Patent Owner was not provided with sufficient notice. *See, e.g.*, *Dell Inc. v. Acceleron, LLC,* 2015-1513 (Fed. Cir. Mar. 15, 2016).
- However, the Federal Circuit has also upheld the PTAB's reliance in Final Written Decisions on references not included in the PTAB's institution decision when the opposing party is given notice and an opportunity to respond. *See Genzyme Therapeutic Products Ltd. v. BioMarin Pharmaceutical Inc.,* 2015-01720 (Fed. Cir. June 14, 2016)

Questions?

WilmerHale has been accredited by the New York State and California State Continuing Legal Education Boards as a provider of continuing legal education. This program is being planned with the intention to offer CLE credit in California and non-transitional CLE credit in New York. This program, therefore, is being planned with the intention to offer CLE credit for experienced New York attorneys only. Attendees of this program will be able to claim England & Wales CPD for this program. WilmerHale is not an accredited provider of Virginia CLE, but we will apply for Virginia CLE credit if requested. The type and amount of credit awarded will be determined solely by the Virginia CLE Board. Attendees requesting CLE credit must attend the entire program.

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