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### Drafting and Prosecuting Patent Applications to Withstand PTAB Scrutiny

Building Reasonable Claim Construction to Avoid Unpatentability and Using Declarations to Survive Post-Grant Proceedings

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THURSDAY, DECEMBER 21, 2017

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific
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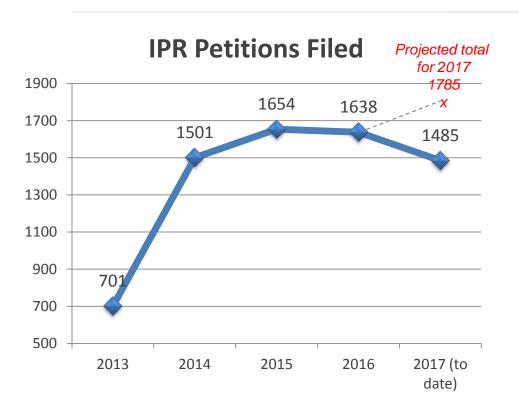
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### Outline

- I. Claim drafting strategies across various fields of technology
- II. Specification drafting strategies, including judicious use of patent profanity to limit reasonability of broadest claim construction, at least in certain embodiments
- III. Prosecution strategies
  - A. Continuation applications
  - B. Carefully prepared declarations
    - 1. To shore up claims against inherency attacks
    - 2. To support written description and enablement
    - 3. To support nonobviousness
    - 4. To avoid inequitable conduct attacks in litigation

# Why Should You Be Concerned about PTAB When Drafting and Prosecuting Patent Applications?

### Inter Partes Review (IPR) Petition Filings Continue To Be High, and Petition Grant Rate Remains High



#### **Institution Decisions**



Source: http://www.managingip.com/Article/3765192/PTAB-round-up-steady-filing-Aqua-Products-fall-out-precedential-and-informative-decisions-and-more.html as of Oct. 31, 2017.

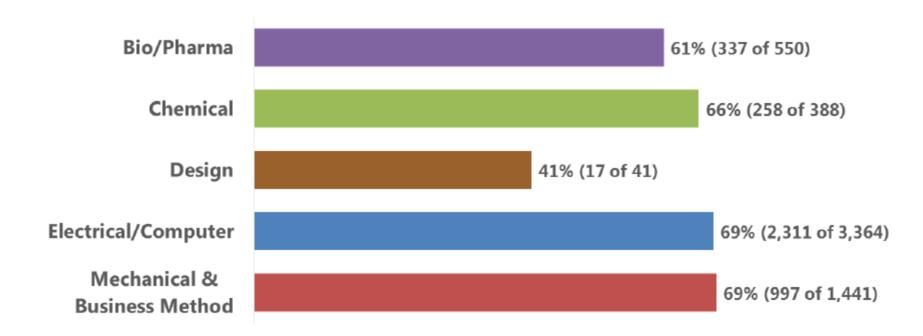
Source:

https://www.uspto.gov/sites/default/files/documents/trial\_statistics\_october\_2017.pdf; slide 7, (FY13toFY17:10/1/12to9/30/17)

### No Industry Is Immune, Though Some Seem More Vulnerable Than Others

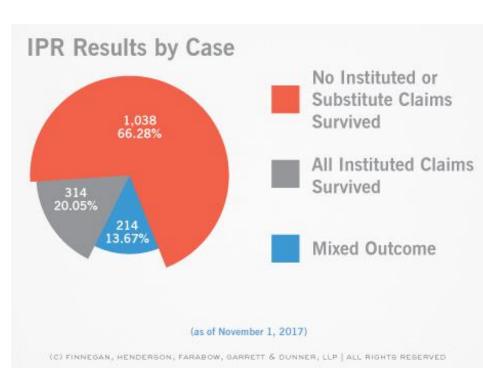
### **Institution Rates by Technology**

(All Time: 9/16/12 to 10/31/17)



Source: https://www.uspto.gov/sites/default/files/documents/trial\_statistics\_october\_2017.pdf; as of Oct. 31, 2017

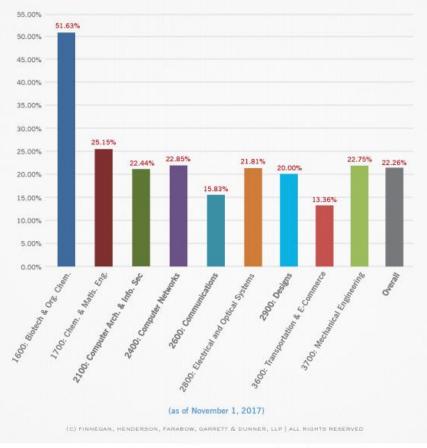
### Overall, Petitioners Usually Successful, Though Again, Variation Among Technologies



<sup>&</sup>quot;mixed outcome" means some instituted claims survived, some did not.

As of Nov. 1, 2017. Source: Finnegan research, http://www.aiablog.com/claim-and-case-disposition/

### IPR AND CBM INSTITUTED CLAIM SURVIVAL RATE BY TECHNOLOGY CENTER



### Reminder of Differences

ISSUE	PGR/CBM PGR/IPR	DISTRICT COURT
Burden of proof	Preponderance of the evidence	Clear and convincing evidence
Presumption of Validity?	No	Yes
Claim construction	Broadest reasonable Interpretation (BRI)	Phillips/Markman framework: analyze claims, specification, and prosecution history to determine how claims would be understood by one of ordinary skill in the art
Decision maker	Patent Trial and Appeal Board (APJs)	District court judge or jury

# Tactical Advantages Favoring the Challenger

- Challenger has unlimited time to plan attack, secure experts, and prepare detailed and compelling expert written reports.
  - Patent Owner has only three months to file POPR.
- Strict limits on discovery.
- Many think that the Supreme Court will find the AIA post-grant proceedings to be constitutional, but we should know by no later than June 30, 2018, the end of the current term of the Supreme Court.
- No limit on number of IPR petitions by same party, particularly to avoid redundancy.
  - Though USPTO recently looked into alleged abuse and designated a case as precedential for guidance, *General Plastic Industrial Co. v. Canon Kabushiki Kaisha*IPRs: 2016-01357, 2016-01358, 2016-01359, 2016-01360, 2016-01361; and
  - 3 informative decisions on §325(d): *Unified Patents, Inc. v. Berman*, IPR2016-01571; *Hospira, Inc. v. Genentech*, IPR2017-00739; *Cultec, Inc. v. Stormtech LLC*; IPR2017-00777.

# Gen. Plastics Indus. v. Canon Kabushiki Kaisha, IPR2016-01357, Paper 19 (Sept. 6, 2017) (expanded panel).

- A non-exhaustive list of factors the Board may weigh when exercising its discretion with respect to serial petitions:
  - 1. whether petitioner previously filed a petition on the same claims of the same patent;
  - 2. whether at the time of filing of the first petition the petitioner knew or should have known of the prior art asserted in the second petition;
  - 3. whether at the time of filing of the second petition the petitioner already received the patent owner's preliminary response or the Board's institution decision in the first petition;
  - 4. the length of time between when petitioner learned of the prior art asserted in the second petition and the filing of the second petition;
  - 5. whether the petitioner provided adequate explanation for the time elapsed between the multiple petitions directed to the same claims of the same patent;
  - 6. the finite resources of the Board; and
  - 7. the requirement under § 316(a)(11) for the Board to issue a final determination not later than 1 year after the date of institution.

### So Far, Granted Motions to Amend Substituting Claims Are The Exception



Source: Finnegan, http://www.aiablog.com/claim-and-case-disposition/, as of Nov. 1, 2017.

# Unclear Yet Whether Federal Circuit en banc decision in Aqua Products Will Lead to More Granted Motions to Amend

- Aqua Products, Inc. v. Matal, en banc rehearing,
   872 F.3d 1290 (Fed Cir. Oct. 4, 2017)
  - In a plurality opinion, with 7/11 judges,
     O'MALLEY, joined by NEWMAN, LOURIE, MOORE,
     and WALLACH; DYK and REYNA concurring:
    - The USPTO may not place the burden of persuasion regarding the patentability of proposed amended claims on the patent owner.

### Denial of Petition is First Objective of Patent Owner

- All claims survive without change.
- Possibly a basis for §325(d) denial for any subsequentlyfiled petitions.
- Surviving post-grant proceedings begins with claim/specification drafting and prosecution.

### Claim and Specification Drafting Strategies

### Understanding The Prior Art When Preparing/Prosecuting Patent Application

Prior art which will likely be cited in an IPR petition when preparing and prosecuting a patent application;

- Consider conducting a pre-filing search of the prior art;
- Consider studying and understanding prior art cited in any Office
   Action or in any counterpart PCT and foreign prosecution; and
- Cite all prior art that is known to be relevant.
- Consider whether to cite any PCT/foreign search reports and office actions, and/or any office actions from US applications that may be related.

### Practitioner Drafting And Prosecution Tools To Strengthen Potentially Important Patent Applications

- Build up specification and file history during drafting and prosecution.
  - > 3-month deadline makes hard to generate solid declaration evidence in a Patent Owner's Preliminary Response (POPR);
  - Solidify novelty, non-obviousness, enablement, and written description positions.
  - If preparing declarations during prosecution, but be mindful of inequitable conduct attacks in litigation.

### Practitioner Drafting And Prosecution Tools To Strengthen Potentially Important Patent Applications

### Draft and prosecute claims to seek desired claim construction.

- Broadest reasonable claim interpretation for infringement purposes;
- ➤ But BRI needs to avoid unpatentability before the PTAB, based on any relevant statutory provision, such as, in an IPR, prior art under 35 USC §§ 102 and 103 or, in a PGR, nonenablement and lack of written description under 35 USC § 112.

### Considerations for Drafting and Prosecuting Claims that will Withstand Attack

- Claim scope: broad enough to cover close competitors but narrow enough to avoid art.
  - In pharma, obtain claims directed to the FDA-approved drug substance/product and bioequivalents thereof.
    - At least assuring literal infringement (strongest position).
    - Claims reflecting label may provide basis for induced infringement too (see Sanofi v. Watson, --F.3d\_\_\_ (Fed. Cir. Nov. 9, 2017)
  - For other technologies, consider at least some very focused claims.

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### Patent Profanity: What Is It?

### Words of characterization

Chief, Majority

Critical, Essential, Necessary

• Solely, Only, Is

Main

Significant

- Vital

- Fundamental

- Important

- Principal

Surprising

Unexpected (?)

▶ All (?)

• Only (?)

Each (?)

"The invention is..." or "This invention..."

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### Would Patent Drafter Want To Consider Alternative Use Of "Patent Profanity"?

- PTAB and PTO ex parte: broadest reasonable claim construction and interpretation (BRI).
  - Profanity could put limits on BRI and could be advantageous to the patent owner.
  - See, e.g., Conopco, Inc. v. Procter & Gamble Co., IPR2013-00510, where Petitioner argued "no evidence in the '155 patent or its file history of the criticality of the recited ranges in the compositions as claimed[.]"

# Drafting Claims And Specification To Withstand Challenges In District Court Litigation And PTAB Proceedings

- Profanity for some embodiments
  - Narrow claim scope
  - ➤ Keep out of IPR/PGR
- No profanity for other embodiments
  - Broad (fully-supported) claim scope
  - Catch design-arounds

### Drafting Specification: Focus On Objective Of Literal Infringement

Specification acts as a definition for the claim terminology.

- If broad meaning for a term intended, set forth a broad definition in the specification.
- Alternatively, consider embodiments with narrower definitions.
- Consider crafting definitions to address concerns about related prior art.
- Use specification to eliminate uncertainty.
  - Athletic Alternatives, Inc. v. Prince Manufacturing, Inc., 73 F.3d 1573, 1581 (Fed. Cir. 1996): when there is an equal choice between a broad and a narrow meaning of a claim, the public notice function is better served by interpreting the claim more narrowly.
- Use specification to describe how claims will be infringed.

## Choose Claim Terms Carefully: Summary

Test by analyzing "design around" possibilities from viewpoint of infringer.

Determine necessity of each term.

Identify where each term is defined in specification.

Identify ambiguity and eliminate it!

Ascertain whether an infringer could "misconstrue" the applicant's intended meaning of any term.

Is every term used consistently?

The mantra: Necessary

Clearly defined Consistently used

### How Claims Will be Construed Is Priority to Consider When Drafting and Prosecuting Claims

- If the Patent Owner has not made it clear in specification and claims, it could be a tough go for the Patent Owner.
- Lack of specification definition/claim clarity could force PTAB to rely on dictionary definitions.
- Before PTAB, claim construction can be very important and can even lead to denial of institution

### Petition Denied Based Upon PTAB's Acceptance of Patent Owner's Proposed Claim Construction

Lenroc Co. v. Enviro Tech. Chemical Services, Inc., IPR2014-00382

- POPR
  - Proposed claim construction.
  - Reference does not anticipate because does not disclose every limitation.
  - Combination of references does not render invention obvious.
- PTAB: Petition denied.
  - "Based on our review of the Specification and related prior art, we agree with Patent Owner['s proposed claim construction]."
  - "We do not adopt Declarant's proposed construction ... because Declarant's testimony is at odds with the intrinsic evidence,"
  - Based on claim construction, no anticipation or obviousness.
    - "We agree with Patent Owner that Stephan's disclosure is directed to formation of a dry, free-flowing powder, not a wet solid, of monoalkali metal cyanurate....A "wetcake," as we interpret this claim term, does not encompass a free-flowing powder, and does not necessarily encompass material in the form of a hydrate."

# Petition Denied Based Upon PTAB's Acceptance of Patent Owner's Proposed Claim Construction

Polygroup Ltd. v. Willis Electric Co., Ltd., IPR2014-01264, Paper 12 (PTAB Jan. 30, 2015)

- PTAB concluded only one claim term required construction, "a first light string."
  - Petitioner did not propose construction for that claim term (but proposed constructions for other terms).
  - Patent Owner did.
- PTAB: Petition denied.
  - Agreed with Patent Owner's proposed construction.
    - Based on intrinsic and extrinsic evidence.
    - "light string," means "a string of lights that can be positioned over a plurality of branches."
    - The asserted references do not show "'light strings' as we have construed the term. Therefore, Petitioner has not shown, on this record, that [the asserted references] describe "light strings" as required by independent claims 1 and 7."

### Claim Limitation As Construed Not Present

### BioDelivery Sciences Int'l, Inc. v. MonoSol Rx, LLC, IPR2014-00794

- PTAB: Petition denied.
  - Agreed with Patent Owner's claim constructions; based on specification.
    - "the claim language, read in view of the Specification, dictates that the polymer matrix during film casting must be a shear-thinning pseudoplastic fluid throughout the entire shear rate range of 10-10<sup>5</sup> sec<sup>-1</sup>"
  - Petitioner did "not point to any disclosure [of] polymer matrix during film casting is a shear-thinning pseudoplastic fluid when exposed to shear rates of 10-10<sup>5</sup> sec<sup>-1</sup>"
  - Petitioner relied on inherency arguments for both anticipation and obviousness assertions, but failed "to establish a reasonable likelihood that the polymer matrix formed according to prior art is a shear-thinning pseudoplastic fluid when exposed to shear rates above 10<sup>3</sup> sec<sup>-1</sup>, specifically, in the range of 10<sup>3</sup>-10<sup>5</sup> sec<sup>-1</sup>."

### Make Sure §112 Chain Tight

§112(a) attacks on priority date (of challenged claims or of asserted reference) can even be used in IPR, even though IPR grounds are limited to patents and printed publications.



- See Butamax<sup>TM</sup> Advanced Biofuels LLC v. Gevo, Inc., IPR2013-00539
  - No POPR filed
  - Paper 9 (P.T.A.B. March 14, 2014): Petitioner successfully challenged patent's priority claim and therefore 102(e) reference was anticipating prior art.
    - "On this uncontested record, Butamax has made a sufficient showing that the '952 and '209 provisionals would not convey, with reasonable clarity, to one of ordinary skill that the inventors had invented or were in possession of [the subject matter of the challenged claims]."
  - Paper 33 (P.T.A.B. March 3, 2015): all instituted claims unpatentable as anticipated by the 102(e) reference.

### Asserted References Not Shown To Antedate Patent

Baxter Healthcare Corp. v. Millenium Biologix, LLC, IPR2013-00591, Paper 8 (P.T.A.B. March 21, 2014) and IPR2013-00583, Paper 9 (P.T.A.B. March 21, 2014)

- Petitioners tried to break priority chain of challenged claims; not entitled to Aug. 30, 1996 priority filing date, only entitled to March 1998 date.
- Prior art reference publications date is 1997.
- PTAB: Petitions denied.
  - "Petitioners' argument and evidence do not persuade us that it is likely to prevail in showing that claims ...are not entitled to the benefit of Pugh's filing date"
    - "Because the claims were entitled to date benefit, the reference could not be prior art under §102 or §103."
  - "inconsistency of Petitioners' argument here with their argument in IPR2013-00590, and do not see the logic of how Pugh could be an anticipatory reference disclosing each and every claim limitation in claims 1, 9, and 11, if Pugh fails to disclose the substitution limitation required by independent claim 1."

### Indefiniteness: A Trending Issue

Nautilus, Inc. v. Biosig Instruments, Inc., 134 S.Ct. 2120 (U.S. June 2, 2014)

- Vacate and remand.
  - 35 U. S. C. §112, ¶2: —The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention."
  - Federal Circuit (715 F.3d 891): §112, ¶2 met if claim is "amenable to construction," and the claim, as construed, is not "insolubly ambiguous."
  - Supreme Court:
    - this "does not satisfy the statute's definiteness requirement."
    - standard: "a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention."

### Indefiniteness (con't)

#### *Nautilus* (con't)

- Supreme Court:
  - "To determine the proper office of the definiteness command, therefore, we must reconcile concerns that tug in opposite directions. Cognizant of the competing concerns, we read §112, ¶2 to require that a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty. The definiteness requirement, so understood, mandates clarity, while recognizing that absolute precision is unattainable. The standard we adopt accords with opinions of this Court stating that 'the certainty which the law requires in patents is not greater than is reasonable, having regard to their subject-matter.'"

### "Insolubly Ambiguous": "Breeds Confusion"

#### *Nautilus* (con't)

- Supreme Court:
  - Federal Circuit's standard of "amenable to construction" or "insolubly ambiguous" "can leave courts and the patent bar at sea without a reliable compass" and "breed lower court confusion, for they lack the precision §112, ¶2 demands. It cannot be sufficient that a court can ascribe some meaning to a patent's claims; the definiteness inquiry trains on the understanding of a skilled artisan at the time of the patent application, not that of a court viewing matters post hoc. To tolerate imprecision just short of that rendering a claim 'insolubly ambiguous' would diminish the definiteness requirement's publicnotice function and foster the innovation-discouraging 'zone of uncertainty,' ...against which this Court has warned."

# Federal Circuit Didn't Wait For Supreme Court In Nautilus

*In re Packard*, 751 F.3d 1307 (Fed. Cir. 2014)

- Federal Circuit upheld USPTO decision rejecting "pre-issuance" claims in Packard's patent application as indefinite applying MPEP standard, "unclear."
  - § 2173.05(e):
    - "A claim is indefinite when it contains words or phrases whose meaning is unclear."
    - "If the scope of a claim would be reasonably ascertainable by those skilled in the art, then the claim is not indefinite."

# Federal Circuit Didn't Wait For Supreme Court In Nautilus

#### Packard (con't)

- Different standards for issued patents and applications.
  - MPEP § 2173.02:
    - "Patented claims enjoy a presumption of validity and are not given the broadest reasonable interpretation during court proceedings involving infringement and validity, and can be interpreted based on a fully developed prosecution record. Accordingly, when possible, courts construe patented claims in favor of finding a valid interpretation. A court will not find a patented claim indefinite unless it is 'insolubly ambiguous.'"
    - "In contrast, no presumption of validity attaches before the issuance of a patent. ... In deciding whether a pending claim particularly points out and distinctly claims the subject matter, a lower threshold of ambiguity is applied during prosecution. ... applicant has the ability to provide explanation and/or amend the claims to ensure that the meaning of the language is clear and definite prior to issuance."

## Nautilus On Remand

Biosig Instruments, Inc. v. Nautilus, Inc., 783 F.3d 1374 (Fed. Cir. 2015), cert. denied (Nov. 30, 2015)

- On remand from Supreme Court, Federal Circuit maintained reversal of the district court's determination that Biosig's patent claims are indefinite.
- Claim limitation at issue: "a first live electrode and a first common electrode mounted on said first half in spaced relationship with each other"
- Based on the intrinsic evidence, "a skilled artisan would understand with reasonable certainty the scope of the invention."

### USPTO Standard For Indefiniteness

Ex parte McAward, Appeal 2015-006416 (P.T.A.B. Aug. 25, 2017), precedential

- Claim 1. A water detector comprising:
  - a housing;
  - flow connectors...;
  - an electically actuatable valve...; and
  - control circuits...wherein the water detector is configured to be reliably installed by an untrained installer or a homeowner and to not require the services of a plumber or electrician to perform installation, thereby permitting widespread and cost effective adoption.
- Examiner rejected as indefinite.
  - No "structure provided to the apparatus or system that would allow it to be 'configured' to function as described in the claims."
- PTAB: Affirmed.

### USPTO Standard For Indefiniteness

### McAward (con't)

 Appellants: limitation "would be understood to mean capable of being installed without special knowledge or tools" and "[g]arden hose connectors or electrical plugs for home wall outlets would be understood as examples of such configuration."

#### PTAB:

- Indefiniteness analysis: construe claims according to BRI, then establish prima facie case of indefiniteness explaining how the "metes and bounds" of a claim are not clear.
- Footnote 3: The Board's precedential decision in Miyazaki [89 USPQ2d 1207 (BPAI 2008)(precedential)], which remains Board precedent, provides an example in which the Board affirmed an indefiniteness rejection of a claim containing words or phrases whose meanings were unclear, i.e., the approach approved in Packard. The instant decision reaffirms, after the Supreme Court's decision in Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S.\_, 134 S. Ct. 2120 (2014), the USPTO's long-standing approach to indefiniteness and the reasons for this approach.

### Courts And PTAB Have Different Approaches To §112 Because Of Different Roles In Patent System

- PTAB:
- BRI "ensures that claims, once fixed and issued, are as 'precise, clear, correct, and unambiguous' as possible."
- "The Office's application of the broadest reasonable interpretation for pending claims and its employment of an interactive process for resolving ambiguities during prosecution naturally results in an approach to resolving questions of compliance with §112 that fundamentally differs from a court's approach to indefiniteness. To that end, the Office's approach effectively results in a lower threshold for ambiguity than a court's. .... The different approaches to indefiniteness before the Office and the courts stem not from divergent interpretations of §112, but from the distinct roles that the Office and the courts play in the patent system. The lower threshold makes good sense during patent examination because the patent record is in development and not fixed, the Office construes claims broadly during that period, and an applicant may freely amend claims. See, e.g., Packard, 751 F.3d at 1325 .... By contrast, once a patent has been issued and is under review by a court, simple amendments are impossible, the full prosecution record is available, and courts endeavor to adopt saving constructions."

# Nautilus Did Not Mandate Change In PTO Approach Outlined In Packard

- PTAB:
  - "We recognize that after the Packard decision, the Supreme Court in Nautilus, Inc. v. Biosig Instruments, Inc., 572 U.S.\_, 134 S. Ct. 2120, 2129 (2014), explained that the 'definiteness command' of § 112, ¶12 'require[s] that a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty.' The Court stated that '[t] he definiteness requirement, so understood, mandates clarity, while recognizing that absolute precision is unattainable.' Id. We do not understand Nautilus, however, to mandate a change in the Office's approach to indefiniteness in patent-examination matters in which, as discussed above, the claims are interpreted under the broadest reasonable interpretation standard and an opportunity to amend the claims is afforded. See Packard, 751 F.3d at 1323-24[.]"

### Claim Language In This Case "Unclear"

- PTAB: "the claimed 'configured' limitation, under the broadest reasonable interpretation when read in light of the Specification, is vague and unclear, and a person having ordinary skill in the art would not be able to discern the metes and bounds of the claimed invention in light of this claim language."
  - The claim "language fails to provide adequate clarity to the required structure because the skill level of 'an untrained installer or a homeowner' is ambiguous and vague, and thus, the meaning of a structure configured to be 'reliably installed' by such an installer is unclear."
  - "[T]he Specification contains no description of, for example, the knowledge or tools required for installation of the claimed water detector, nor does the Specification define the skill level of an 'untrained installer' or a 'homeowner.'"
  - Also, "the claim language of the 'configured' limitation, when read in light of the Specification, fails to further clearly define the structure encompassed by the limitation."
  - Preferred embodiment describing connector elements as "standard hose connectors used with flexible hose[]s" and providing an example of such a connector, but "neither the language of claim 1 nor anything in Appellants' Specification delineates how a person of ordinary skill would determine whether a water detector that includes each of the structural limitations of claim 1 further satisfies the 'configured' limitation."

### But Note Footnote 4!

- PTAB:
  - Footnote 4: "We do not address, in this decision, the approach to indefiniteness that the Office follows in post-grant trial proceedings under the America Invents Act."

### PGR Petition Denied Because Claims Not Eligible For PGR (Claims Supported In Priority Document)

- Mylan Pharms. Inc. v. Yeda Research & Development Co. Ltd., 2016-00010, Paper 9 (P.T.A.B. Aug. 16, 2016)
  - Petitioner: claims PGR-eligible because not entitled to benefit of priority claim to August 20, 2009 (priority applications do not provide written description support for all claim limitations); effective filing date is actual filing date of May 22, 2015.
  - PTAB: Claims not eligible for PGR.
    - Examiner specifically addressed that pre-AIA applied to claims.
    - Examiner found claims supported by priority document.
    - Petitioner did not show break in priority chain; "Petitioner has not demonstrated that it is more likely than not that the '776 patent has at least one claim having an effective filing date on or after March 16, 2013."

### PTO BRI Standard in Rules

### § 42.100 Procedure; pendency.

- (a) An <u>inter partes</u> review is a trial subject to the procedures set forth in subpart A of this part.
- (b) A claim in an unexpired patent that will not expire before a final written decision is issued shall be given its broadest reasonable construction in light of the specification of the patent in which it appears. A party may request a district court-type claim construction approach to be applied if a party certifies that the involved patent will expire within 18 months from the entry of the Notice of Filing Date Accorded to Petition. The request, accompanied by a party's certification, must be made in the form of a motion under § 42.20, within 30 days from the filing of the petition.

### § 42.200 parallel rule for PGR's.

### USSC

- Cuozzo Speed Techs., LLC v. Lee, 136 S.Ct. 2131 (U.S., June 20, 2016).
  - Held:
    - -Federal Circuit decision not allowing attack of the decision to institute affirmed.
      - In this case, §314(d) bars judicial review of whether PTAB wrongly instituted an IPR on grounds not specifically mentioned in a third party's review request.
    - -Federal Circuit decision affirmed (unanimous, 8-0), as to the BRI standard.
      - USPTO has authority under §316(a)(4) to enact 37 CFR
         §42.100(b) (BRI is the claim construction standard in IPRs).

## Maintaining <u>Reasonableness</u> In BRI

In re Smith International, Inc., 871 F.3d 1375 (Fed. Cir. 2017):

"Even when giving claim terms their broadest reasonable interpretation, the Board cannot construe the claims 'so broadly that its constructions are unreasonable under general claim construction principles.' ...'[T]he protocol of giving claims their broadest reasonable interpretation ... does not include giving claims a legally incorrect interpretation' 'divorced from the specification and the record evidence.'"

## Take-Away

- Drafting and prosecution
  - Define terms judiciously and with definiteness, considering dual objectives of patentability and proving infringement.
  - Once defined with definiteness, use terms consistently.
  - Lay basis for Patent Owner's desired claim construction, both at PTAB and in district court litigation.
  - Probably want range of claims from broad to narrow, but consider what limits you want on broad claims so that the broadest reasonable interpretation (BRI) is not unreasonable.

 Such a specification can be Patent Owner's best friend for contradicting Petitioner's proposed BRI!

## Prosecution Strategies

## Build Record in Specification and Prosecution That Will Be Helpful (and Not Hurtful) If Patents Challenged

### PGR Petitions Denied

- PGR2016-00008, Paper 11 (P.T.A.B. Aug. 17, 2016)
  - PTAB: Petition denied.
  - Patent Owner laid the groundwork for defending against the §112 attacks during prosecution.
  - PTAB:
    - "Here, it is undisputed that the specification describes formulations comprising the same ingredients, in the same amounts, concentrations, and combinations required by the challenged claims. Given this disclosure, one of ordinary skill in the art could hardly fail to recognize a description of the claimed formulations in the specification, whether or not the claims recite that the formulations are stable."

### PGR Petitions Denied

- PGR2016-00007, Paper 12 (P.T.A.B. Aug. 17, 2016)
  - PTAB: Petition denied.
  - Patent Owner laid the groundwork for defending against the §103 attacks during prosecution.
    - At least one of the asserted references was before the examiner during prosecution.
      - "We agree with Patent Owner that a person of ordinary skill in the art would have considered Tang to be relevant to a "palonosetron development project." ... We need not determine whether Tang actually teaches away from the claimed formulations—it is enough that we agree with Patent Owner that Tang would not have led a person of ordinary skill in the art to expect that a solution of palonosetron at a concentration of 0.05 mg/mL would be effective in treating emesis.
        Id. at 39 (citing Ex. 1008, 466). If anything, Tang would have suggested amounts and concentrations still higher than the highest dose and concentration evaluated by Tang."

### PGR Petitions Denied

- PGR2016-00007, Paper 12 (P.T.A.B. Aug. 17, 2016)
  - PTAB:
    - "We agree with Patent Owner that Petitioner has not established that one of ordinary skill in the art would have had a reason to formulate a pharmaceutical sterile intravenous solution comprising "palonosetron hydrochloride . . . at a concentration of 0.05 mg/mL," as required by all the challenged claims.."

# Consider Keeping Continuation Application Pending

*Tafas v. Doll*, 559 F.3d 1345 (Fed. Cir. 2009)

*In re Bogese*, 303 F.3d 1362 (Fed. Cir. 2002)

Symbol Tech., Inc. v. Lemelson Medical, Educ. & Research Foundation, 422 F.3d 1378 (Fed. Cir. 2005)

Take into account those cases and avoid: "unreasonable and unexplained delay."

## Consider Keeping Continuation Application Pending (con't)

AC Dispensing Equipment, Inc. v. Prince Castle, LLC, IPR2014-00511, Paper (PTAB Oct. 17, 2014)

- Petitioner requested permission to file a motion to stay the prosecution of the continuation patent application.
- PTAB: Denied.
  - "Patent Owner will not be permitted to obtain in a patent any claims that are not patentably distinct from any claim that is canceled as a result of this proceeding. But whether any of the claims in the '497 patent will be canceled is an issue that is not yet decided and will not necessarily be decided until a final written decision is entered in this case and appeals from it are exhausted. To bar Patent Owner from prosecuting claims now that may be patentably indistinct from the claims under review thus would be premature. It is sufficient, under the current circumstances, for Patent Owner to continue to take reasonable steps to apprise the Examiner of the status of this proceeding."

## Consider Keeping Continuation Application Pending (con't)

Estoppel impact of a patent owner receiving an adverse written decision and how it would likely preclude seeking patentability of a claim in the continuation that is not patentably distinct from the claim determined to be unpatentable in the written decision.

- 37 C.F.R. §42.73(d)(3): "(3) Patent applicant or owner. A patent applicant or owner is precluded from taking action inconsistent with the adverse judgment, including obtaining in any patent:
  - (i) A claim that is not patentably distinct from a finally refused or canceled claim; or
  - (ii) An amendment of a specification or of a drawing that was denied during the trial proceeding, but this provision does not apply to an application or patent that has a different written description.

## Considerations for Drafting and Prosecuting Claims that will Withstand Attack

- Strong patentability positions during drafting and prosecution.
  - Consider declarations supporting §112 positions (written description and enablement) and even, if desired, definiteness, and §103 positions (nonobviousness)
- Consider Therasense
  - Careful thought and planning to avoid meritorious allegations of inequitable conduct.

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## Use Record Evidence to Get Petition Denied

Omron Oilfield & Marine, Inc. v. Md/Totco, A Division Of Varco, L.P., IPR2013-00265, Paper 11 (PTAB Oct. 21, 2013)

- Patent Owner requested PTAB to exercise its discretion to deny the petition because of the same art/arguments before the Office during reexamination.
  - Patent Owner was able to rely on evidence of the record.
- PTAB reviewed the objective evidence of nonobviousness provided to the examiner during a reexamination, and agreed that it was persuasive.

## For Declarations: Commensurate in Scope

As explained at the interview, Federal Circuit case law binding on the USPTO establishes that commercial success establishes the patentability of a claim broader in scope than the single embodiment of commercial success shown within the claim. See *In re Glatt*, 630 F.3d 1026, 1030 (Fed. Cir. 2011) and *Applied Materials, Inc. v. Adv. Semiconductor Materials Am., Inc.*, 98 F.3d 1563, 1570 (Fed. Cir. 1996).<sup>7</sup>

### Commensurate in Scope (con't)

In addition, In re Hollingsworth, 253 F.2d 238 (CCPA 1958),° cited in MPEP 716.03(a)(II), also shows that one embodiment having commercial success within the scope of new claims 27 and 28 can be sufficient to show non-obviousness over the claims of the '699 patent:

If a particular range is claimed, applicant does not need to show commercial success at every point in the range. "Where, as here, the claims are directed to a combination of ranges and procedures not shown by the prior art, and

where substantial commercial success is achieved at an apparently typical point within those ranges, and the affidavits definitely indicate that operation throughout the claimed ranges approximates that at the particular points involved in the commercial operation, we think the evidence as to commercial success is persuasive." In re Hollingsworth . . . .

## Reissue Corrective Action to get Ready for IPR: Use of Tanaka

- Reissue Declaration (redacted)
  - 14. The patent attorneys have explained to us that in view of a recent court case called In re Tanaka, which they explain in the Reissue Preliminary Amendment, the failure in the patent to present claims such as , as amended, and new claim failed to protect the disclosed invention to the full extent allowed by law. The patent attorneys have explained that the patent claimed fewer claims than we could have properly made, and that the issued claims thus were too narrow. As we understand it, therefore, the patent claimed less than we had a right to claim, those issued claims were too narrow, the I patent failed to protect the disclosed invention to the full extent allowed by law, and those were errors, as explained above, that rendered the patent partly inoperative.



### Lessons Learned

### Tell PTAB clearly why you should win!

 USP Labs, LLC v. Harcol Research, IPR2013-00399: "It is not exactly clear from the Petition what reasoning USPlabs is relying upon to challenge claims 1, 5, and 7[.]"

### Lessons Learned

POR may require expert declaration to support assertions of patentability, but <u>POR</u> needs to make argument; not enough to just be in expert declaration.

### Use POR

If trial instituted, file Patent Owner Response (POR) and identify why facts or reasoning of Institution is faulty.

- Especially if Institution claim construction unhelpful.
- Illumina v. Columbia, IPR2012-00006, FWD: "Columbia did not in their [Patent Owner] response ...identify a defect in the factual findings or reasoning which led to the institution of the patentability challenge. We therefore adopt the findings and reasoning set forth in the Decision on Petition."

## Load Up on Your Evidence During Prosecution!

The "objective evidence of nonobviousness" (also known as "secondary considerations," as the term was coined in *Graham v. John Deere*) can, for example, includes:

- Long-felt but unsolved need,
- Failure of others,
- Commercial success,
- Unexpected results created by the claimed invention, and
- Skepticism of skilled artisans before the invention.

See In re Rouffet, 149 F.3d 1350, 1355 (Fed. Cir. 1998).

These objective considerations, when present, are important evidence, as they protect against the prejudice of hindsight bias, which frequently overlooks the fact that "[t]he genius of invention is often a combination of known elements which in hindsight seems preordained."

McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1351 (Fed. Cir. 2001).

## Load Up on Your Evidence During Prosecution!

Indeed, secondary consideration evidence "may be the most probative and cogent evidence in the record." *Apple Inc. v. ITC*, 725 F.3d 1356, 1366 (Fed. Cir. 2013) (internal quotation marks and citations omitted). Objective evidence of these secondary considerations can establish that "an invention appearing to have been obvious in light of the prior art was not." *Stratoflex*, *Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983).

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### So Far, Some POs Struggling to Find Success with Objective Evidence of Nonobviousness

Objective evidence of nonobviousness must have nexus.

Patent Owners are not linking the objective evidence of obviousness to the merits of the claimed invention.

# Nexus Required For Objective Evidence Of Nonobviousness Is Not A New Concept

- CCPA, Federal Circuit, PTAB case law and MPEP:
  - All rely on *Graham v. John Deere Co.*, 383 U.S. 1 (1966):
    - (1) the scope and content of the prior art;
    - (2) differences between the prior art and the claims at issue;
    - (3) the level of ordinary skill in the pertinent art; and
    - (4) evaluation of any relevant secondary considerations.

# "Nexus" Between Evidence and Claimed Invention

- Manual of Patent Examining Procedure §716.01(b)
  - "The term "nexus" designates a factually and legally sufficient connection between the objective evidence of nonobviousness and the claimed invention so that the evidence is of probative value in the determination of nonobviousness. Demaco Corp. v. F. Von Langsdorff Licensing Ltd., 851 F.2d 1387, 7 USPQ2d 1222 (Fed. Cir.), cert. denied, 488 U.S. 956 (1988)."

## PTAB Requires Nexus

- Gnosis S.p.A. v. Merck & Cie, IPR2013-00117, Paper 71 (P.T.A.B. June 20, 2014)
  - PTAB: Instituted claims held unpatentable (or canceled by Patent Owner)
    - "Merck argues, and Gnosis does not dispute, that administration of each of the above Pamlab products to a patient falls within the scope of the claims under review. ...It is not sufficient, however, that a product or its use merely falls within the scope of a claim in order for objective evidence of nonobviousness tied to that product to be given substantial weight. There must also be a causal relationship, termed a "nexus," between the evidence and the claimed invention. . . . A showing of sufficient nexus is required in order to establish that the evidence relied upon traces its basis to a novel element in the claim, not to something in the prior art. . . . Objective evidence that results from something that is not 'both claimed and novel in the claim' lacks a nexus to the merits of the invention." [citations omitted]

## PTAB Requires Nexus (con't)

- Gnosis (con't)
  - PTAB rejected objective evidence
    - "Nexus must exist in relation to all types of objective evidence of nonobviousness. GPAC, 57 F.3d at 1580 (generally); In re Huang, 100 F.3d 135, 140 (Fed. Cir. 1996) (commercial success); In re Antor Media Corp., 689 F.3d 1282, 1293 (Fed. Cir. 2012) (licensing); Wm. Wrigley Jr. Co. v. Cadbury Adams USA LLC, 683 F.3d 1356, 1364 (Fed. Cir. 2012) (copying); Ormco Corp. v. Align Tech., Inc., 463 F.3d 1299, 1313 (Fed. Cir. 2006) (failure of others); Rambus Inc. v. Rea, 731 F.3d 1248, 1256 (Fed. Cir. 2013) (long-felt need); Kao, 639 F.3d at 1069 (unexpected results); Stamps.com Inc. v. Endicia, Inc., 437 F. App'x 897, 905 (Fed. Cir. 2011) (skepticism); Muniauction, Inc. v. Thomson Corp., 532 F.3d 1318, 1328 (Fed. Cir. 2008) (praise)."

## PTAB Requires Nexus (con't)

- Gnosis (con't)
  - PTAB rejected objective evidence
    - "Thus, for objective evidence to be accorded substantial weight, the record 'must establish a nexus between the evidence and the merits of the claimed invention.' . . . . Moreover, establishing nexus involves a showing that novel elements in the claim, not prior-art elements, account for the objective evidence of nonobviousness. . . . As the Federal Circuit explains, '[t]o the extent that the patentee demonstrates the required nexus, his objective evidence of nonobviousness will be accorded more or less weight.' . . . Thus, the stronger the showing of nexus, the greater the weight accorded the objective evidence of nonobviousness." [citations omitted]

### What Would Be Sufficient Nexus?

PTAB looking for causation of the objective evidence by the merits of the claimed invention; mere correlation may not be enough.

Need to analyze and/or explain why the objective evidence was driven by the merits of the claimed invention.

Phigenix, Inc. v. Immunogen, Inc., IPR2014-00676

- Petition challenged 8 claims; 8 asserted grounds.
  - Submitted prosecution declarations as exhibits.
  - Argued that the declarations submitted to overcome examiner's rejection did not in fact prove unexpected results and lack of reasonable expectation of success.

Phigenix, Inc. v. Immunogen, Inc., IPR2014-00676

- POPR:
  - Petitioner failed to establish a reason to combine the prior art with a reasonable expectation of success
  - Petitioner failed to properly account for objective indicia of nonobviousness as discussed in prosecution declarations.
    - Unexpected results from clinical trials
    - Praise in the industry
    - long-felt need
    - commercial success
    - Cited Omron Oilfield & Marine, Inc. v. MD/Totco, to support denial because petition fails to "challenge the merits of Patent Owner's secondary consideration evidence" of record.

#### Phigenix, Inc. v. Immunogen, Inc., IPR2014-00676

- PTAB instituted IPR on all challenged claims on one asserted ground.
  - "Petitioner has established a reasonable likelihood that it would prevail in showing prima facie obviousness, i.e., that an ordinary artisan would have had reason to make immunoconjugates as described in Chari 1992 using huMAB4D5-8 disclosed in the HERCEPTIN® Label, with a reasonable expectation of success in making them."
  - Considered objective evidence, but decided that Petitioner had made sufficient showing for institution.
    - The prosecution declarations addressed "a rejection during prosecution based on different references than those cited in asserted grounds in the Petition."
    - "In addition, Patent Owner evidence of record at this time do not address adequately considerations such as whether evidence of objective indicia are reasonably commensurate with the scope of the challenged claims, whether a sufficient nexus exists between such evidence and the merits of the claimed invention, or whether evidence of unexpected results establishes a difference between the results obtained and those of the closest prior art."

Maybe could have obtained denial

Phigenix, Inc. v. Immunogen, Inc., IPR2014-00676, Paper 39 (PTAB Oct. 27, 2015)

- PTAB FWD: All claims survived (not shown to be unpatentable).
  - "viewing the record as a whole, Petitioner does not persuade us that a preponderance of the evidence establishes that a skilled artisan would have had a reasonable expectation of success in 2000 that a Herceptin®- maytansinoid immunoconjugate would be useful in the treatment of breast tumors in humans[.]"
  - "Petitioner has not established by a preponderance of the evidence that a skilled artisan would have had reason to combine the teaching of the cited references to make the immunoconjugates of claim 6 and 8."
  - "Although failure to establish a reason to combine the cited teachings is sufficient, by itself, to conclude non-obviousness, Patent Owner cites substantial evidence of objective indicia of non-obviousness in relation to claim 8, which is directed to the T-DM1/Kadcyla® commercial product."

Phigenix, Inc. v. Immunogen, Inc., IPR2014-00676, Paper 39 (PTAB Oct. 27, 2015)

- PTAB FWD: (con't)
  - Objective evidence
    - unexpected superior results as compared to closest prior art compositions
    - fulfilling a long-felt and unmet need for an immunoconjugate capable of targeting a solid tumor in patients without excessive toxicity.
    - praise in the field
    - commercial success: sales and prescription data, marketing and promotional efforts.
  - "we are persuaded that Patent Owner establishes a sufficient nexus in relation to the cited objective evidence of nonobviousness."
  - "The specification of the 856 patent discloses, and claim 8 recites, the very components that led to the unexpected results, praise and commercial success. . . . Patent Owner sufficiently establishes that it is the exact combination of those components recited in claim 8, rather than different components previously combined in the prior art, that provided the unexpected results at issue, and led to praise and commercial success."

### Another Successful Example

- Innopharma Licensing, Inc. v. Senju Pharmaceutical Co., Ltd., IPR2015-00902, Paper 90 (P.T.A.B. July 28, 2016) and IPR2015-00903, FWD, Paper 82 (P.T.A.B. July 28, 2016)
  - Patent Owner submitted objective evidence of nonobviousness in POR (after trial instituted), supported by expert declarations.
    - Evidence of unexpected results against closest prior art (also identified as such by Petitioner's expert), found to be commensurate in scope with claimed invention.
    - Evidence of commercial success, including evidence of how the commercial product falls within the scope of the claims; sufficient to trigger presumption that commercial product embodied the invention. Petitioner did not overcome.
      - From IPR2015-00903 FWD: "Patent Owner ...presents persuasive declaration testimony, which we credit, that Prolensa has, in fact, achieved substantial marketplace success—which Petitioner tacitly acknowledges by seeking to replicate that success by copying exactly the claimed invention."

- Innopharma Licensing, Inc. v. Senju Pharmaceutical Co., Ltd.,
   IPR2015-00903, FWD, Paper 82 (P.T.A.B. July 28, 2016)
  - Patent Owner submitted objective evidence of nonobviousness in POR (after trial instituted), supported by expert declarations (con't)
    - Evidence of industry acclaim (not addressed by Petitioner).
    - "We hold that the objective evidence of non-obviousness outweighs Petitioner's evidence of obviousness based on the prior art."

 Innopharma Licensing, Inc. v. Senju Pharmaceutical Co., Ltd., IPR2015-00903, FWD, Paper 82 (P.T.A.B. July 28, 2016)

#### PTAB:

 "Taking account of the objective indicia of non-obviousness, including Patent Owner's significant evidence of unexpected results, we are not persuaded that Petitioner demonstrates sufficiently that the combined disclosures of Ogawa and Sallmann, when considered in light of the teachings of the asserted background prior art references, establish the obviousness of the claimed invention. Petitioner's proposed substitution of tyloxapol for polysorbate 80 produced a surprising and unexpected stabilizing effect on bromfenac. The other objective indicia of non-obviousness flow from that surprising result. Accordingly, we hold that Petitioner fails to establish that it would have been obvious at the time of the invention to prepare a bromfenac formulation comprising tyloxapol in the manner claimed

#### Another Successful Example

- Google Inc. v. At Home Bondholders' Liquidating Trust, IPR2015-00657 and IPR2015-00660
  - PTAB found that the Patent Owner showed sufficient nexus and provided an extensive discussion en route to holding instituted claims were not shown to be unpatentable.
  - In the POR, the Patent Owner presented objective evidence of nonobviousness, including long-felt need, industry praise, copying, and commercial success, along with expert testimony as to how the commercial method embodied the challenged claims.
  - Petitioner argued no nexus to the challenged claims.

- Google Inc. v. At Home Bondholders' Liquidating Trust, IPR2015-00657 and IPR2015-00660 (con't)
  - PTAB concluded that the Patent Owner had shown sufficiently through the expert testimony that the method embodied the claims:
    - "[W]e find that Mr. Griffiths provides a reasonable and credible walk-though of how the TrueCount service worked that is tied to the recited features of the challenged independent claims."
    - "[W]e credit Mr.Griffiths's testimony as evidence that establishes the operation of TrueCount and, in combination with Dr. Almeroth's testimony, a nexus between Patent Owner's evidence regarding TrueCount and the challenged independent claims."

- Google Inc. v. At Home Bondholders' Liquidating Trust, IPR2015-00657 and IPR2015-00660 (con't)
  - As such, the PTAB found that the Patent Owner was entitled to a presumption of nexus, and that the Petitioner had failed to rebut that presumption.
  - The PTAB then proceeded to analyze the objective evidence of nonobviousness, finding it sufficiently persuasive that, in addition to the substantive arguments of nonobviousness presented, on balance the Petitioner had not shown that the challenged claims were unpatenable.
  - The Patent Owner clearly benefited from the time and effort spent establishing nexus.

### Take Aways

- Best case scenario for a Patent Owner is to have the petition denied and avoid an IPR, particularly since denial cannot be judicially reviewed.
- Even if this is not achieved, the POPR may lead to the trial being instituted on fewer grounds and/or fewer claims than challenged in the petition -> still a positive development for a Patent Owner now faced with a trial narrower in scope. But we will see how the Supreme Court decides the SAS case.
- Patent Owner consider loading evidence into her prosecution, along with crisp and compelling arguments to show no prima facie case of obviousness, at least in applications likely to end up in litigation or a post-grant proceedings.

### Take Aways

- Solid evidentiary showings and/or possibly declarations, in addition to on-point legal arguments, may help to develop strong patentability records.
- Prudently establishing such records during prosecution could support Patent Owner's efforts to persuade the PTAB that Petitioner does not have a "reasonable likelihood" of success and thus achieve denial of institution.

### Take Aways

- The PTAB desires to have cases front-loaded to make the most efficient use of the its resources by allowing it to make the institution decision based on the most information possible.
- If Patent Owner has relevant and compelling information in the prosecution history, or in related proceedings, such as reexamination or litigation, that could well help Patent Owner convince the PTAB to deny the petition. In particular, in the POPR, Patent Owner can tell the PTAB in a concise, compelling argument why the petition should be denied.
- Such concise and compelling arguments can help the PTAB achieve both the policy objective that post-grant proceedings be "just, speedy, and inexpensive" and the statutory objective of resolution 12-18 months from institution.

#### **Thank You!**





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