

# Freedom to Operate and the Use of AIA Review

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**IP Life Sciences Exchange, Munich Germany**

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# Firm Profile

## Five Decades. One Focus: IP

### **Eight offices nationwide**

California (Five Offices)

New York, NY – opening in 2017

Washington, D.C.

Seattle, WA

### **Broad Technical Expertise**

Over 300 lawyers and scientists

Over 95% of attorneys hold technical degrees

Over 50 PhDs

# Firm Profile

- Attorney staffing according to customer technology and needs
  - Effective delegation leads to lower ultimate costs, defined budgets, and cost-effectiveness
- Compact prosecution with emphasis on interviewing
- Global Network - strong relationship with attorneys from other countries
- Diverse client base: Amazon, Amgen, BASF, Illumina, Qualcomm, Smith & Nephew, Starbucks, etc.
- [www.knobbe.com](http://www.knobbe.com)

# Recognitions

- IP Law Firm of the Year - USA (2016) – *Lawyer Monthly Magazine*
- Top IP Boutique Law Firm (2016) – *Vault*
- Ranked among “Best Law Firms” (2016) for National Patent Litigation – *U.S. News & World Report* and *Best Lawyers*
- Top 5 in “Largest IP Practice Group” (2015) – *Law360*
- Top 10 for Overall Diversity (2015) – *The American Lawyer*

# Firm Philosophy

## **A Culture of Collaboration**

Compensation structure cultivates a collegial atmosphere focused on high quality of service

Attorneys motivated to match clients with an attorney/scientist team custom built to deliver success

## **The Importance of Team Continuity**

Continuous team throughout lifecycle of a patent from development to litigation

Increased efficiency

# Freedom to Operate

- Identifying infringement risk
- Third party patent (infringement) – claim searching
  - Timing
    - Discrete, continuous
  - Searching
    - In-house, search agency
  - Screening/analyzing
    - Ranking systems
  - Narrow down to potential infringement risk(s)

# Questions on Identifying?

- Search results
  - Too many hits?
  - Not happy with results?
- Monitoring 3<sup>rd</sup> party patents
  - Pending applications
- Possible tools and processes

# Freedom to Operate – What next?

- What to do with infringement risk?
  - Acquire/license
  - Design-around
  - Establish FTO position (non-infringement and/or invalidity)
    - Willfulness damages (treble damages)
    - Opinions of counsel post-*Halo* (June 2016) decision?
      - No objective recklessness
      - Clear and convincing reduced to preponderance
  - Challenge patent validity (more certainty)
    - Declaratory judgment
    - Post-grant America Invents Act (AIA) review



# Post-Grant Proceedings After the AIA

- **Before AIA**

- *Inter Partes* Re-exam
- *Ex Parte* Re-exam

- **After AIA**

- ~~– *Inter Partes* Reexam~~
- *Ex Parte* Re-exam
- **Post-Grant Review (PGR)**
- **Transitional Program for Covered Business Method Patents (CBM)**
- ***Inter Partes* Review (IPR)**

# IPR v. PGR v. CBM

	IPR	PGR	CBM
Patents Eligible	Any patent	First-to-File patents only	Financial product or service
Timing	<ul style="list-style-type: none"> <li>1 year of being sued for infringement</li> <li>after PGR eligibility</li> </ul>	<ul style="list-style-type: none"> <li>within 9 months of issue</li> </ul>	<ul style="list-style-type: none"> <li>sued for infringement</li> </ul>
Grounds	<ul style="list-style-type: none"> <li>102 (novelty)</li> <li>103 (obviousness)</li> </ul>	<ul style="list-style-type: none"> <li>101 (utility, statutory subject matter)</li> <li>102 (novelty)</li> <li>103 (obviousness)</li> <li>112 (written description, enablement, indefiniteness)</li> </ul>	<ul style="list-style-type: none"> <li>101 (utility, statutory subject matter)</li> <li>102 (novelty)</li> <li>103 (obviousness)</li> <li>112 (written description, enablement, indefiniteness)</li> </ul>
Evidence	patents and printed publications	any evidence	any evidence
Estoppel	102, 103	101, 102, 103, 112	101, 102, 103, 112

# Why Are IPRs So Popular?

## **Litigation**

**Average Cost:** ~\$2.5M-\$3.5M

**Average Time to Trial:** 2.5 years

**Standard of Proof:** Clear and convincing evidence

**Claim Construction:** Plain and ordinary meaning

**Judge/Jury**

## **IPRs**

**Average Cost:** \$400k - \$1M

**Time to Decision:** 18 mos.

**Standard of Proof:** Preponderance of the evidence

**Claim Construction:** Broadest reasonable interpretation

**Panel of Three APJs**

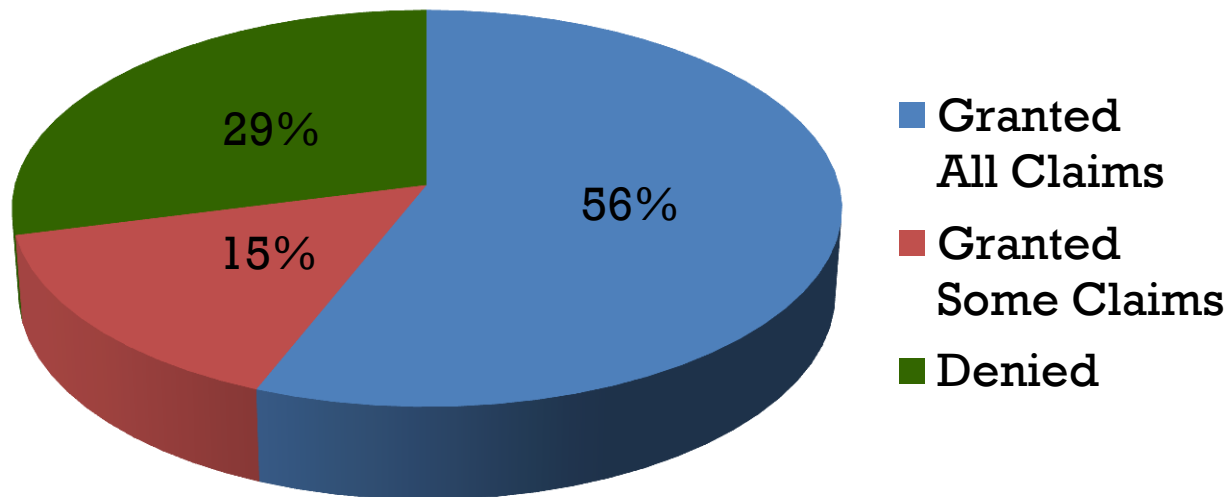
**Also:**

- Potential to stay litigation
- Gain settlement leverage upon institution
- Estoppel

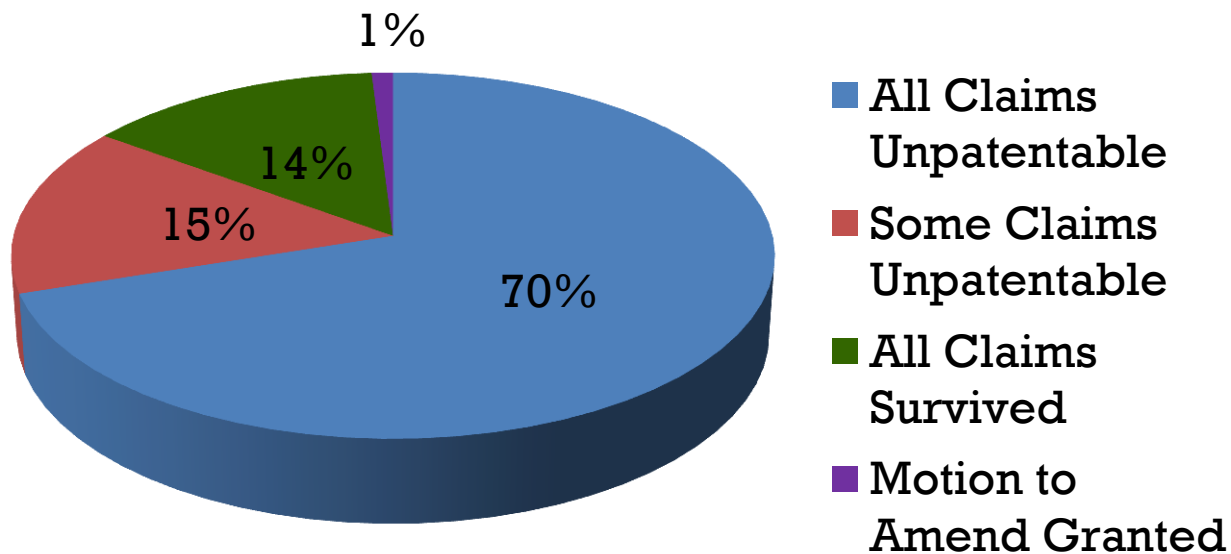
# Offensive and Defensive IPR Strategies

- **Defensive Use**
  - Response to lawsuit
- **Offensive Uses**
  - Eliminate FTO hits
    - Avoid design-around time/expense
  - Leverage in settlement negotiations / litigation
  - Financial sector - short selling

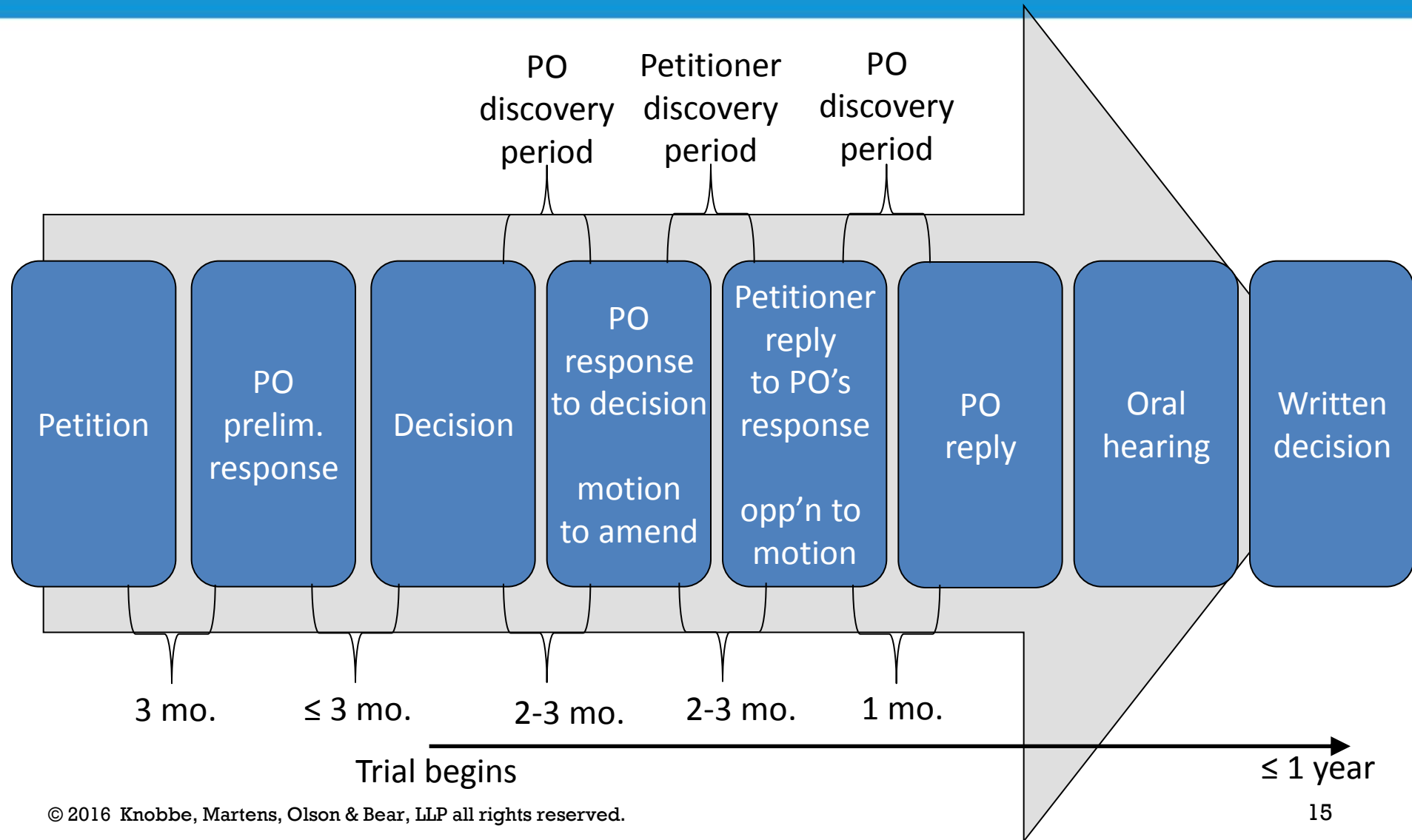
# Trial Institutions Overall



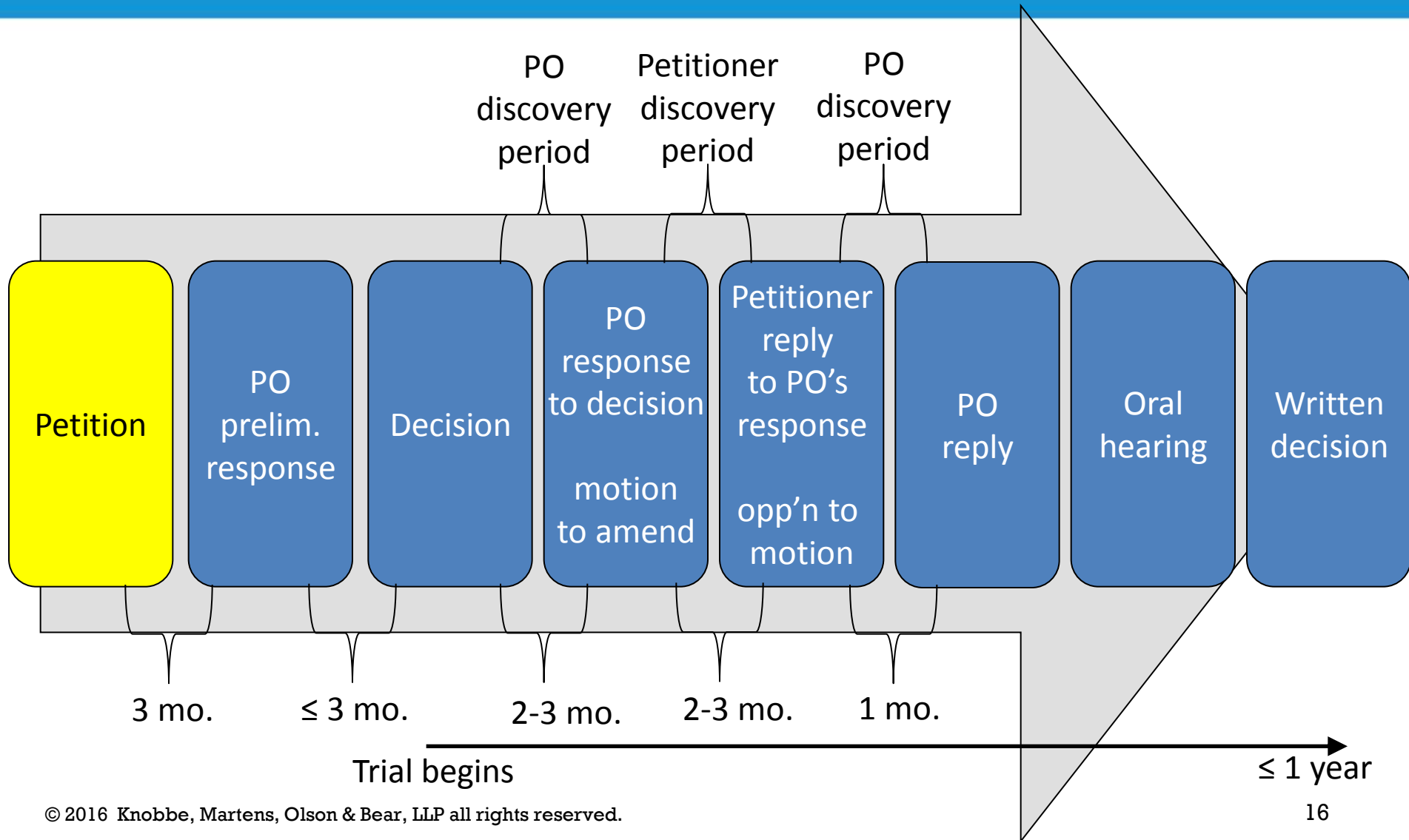
# Final Written Decisions



# Trial Proceedings Timeline

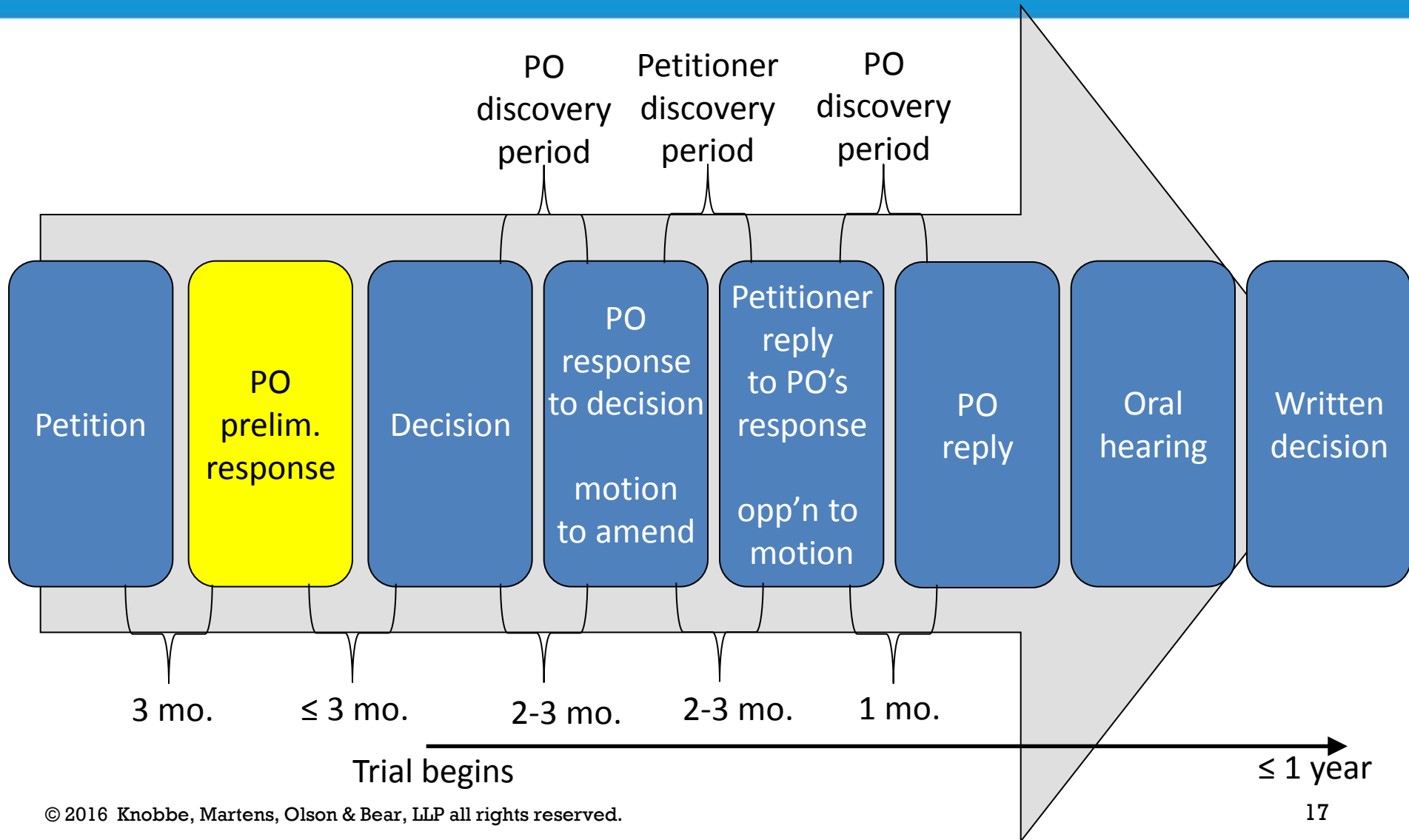


# Trial Proceedings Timeline

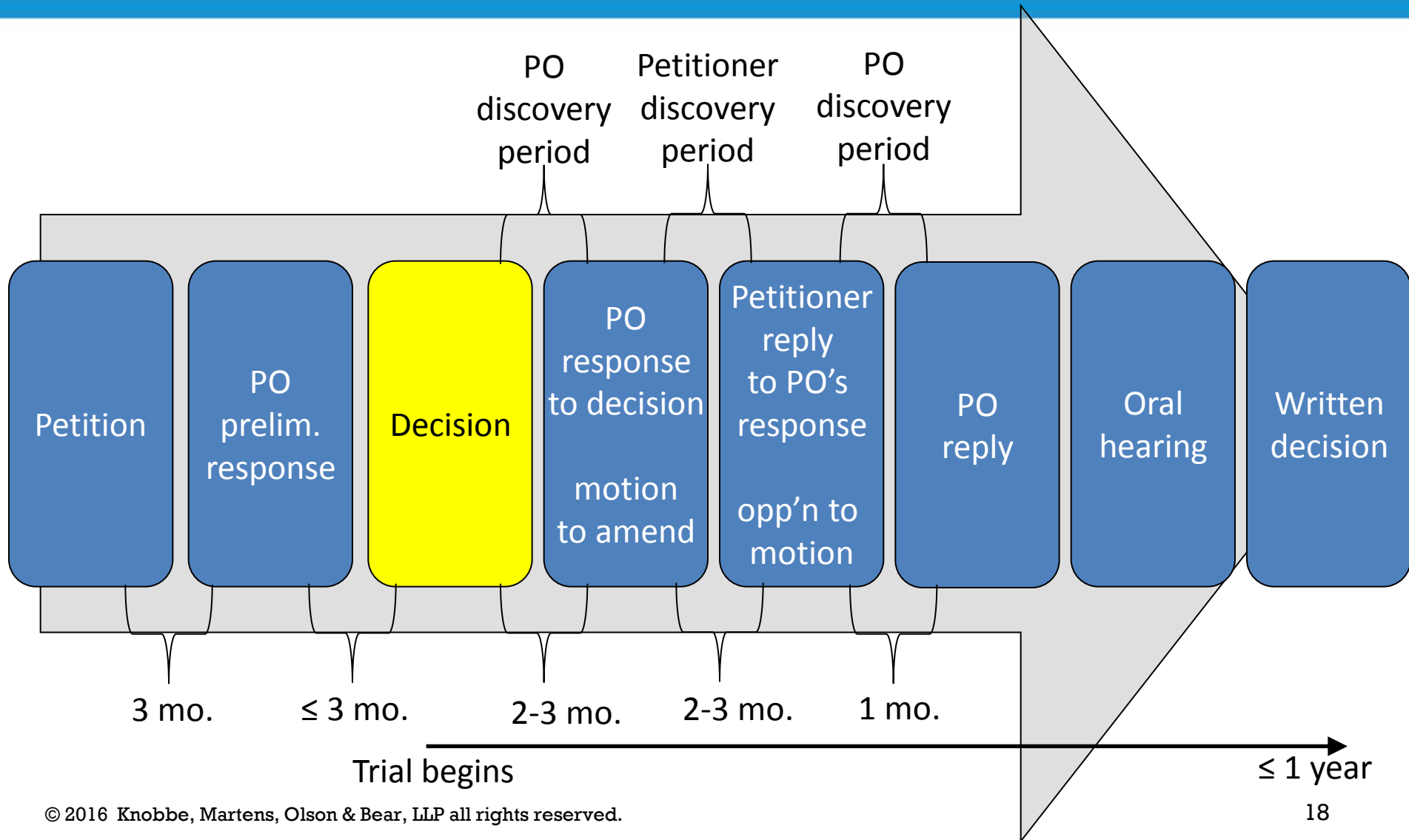




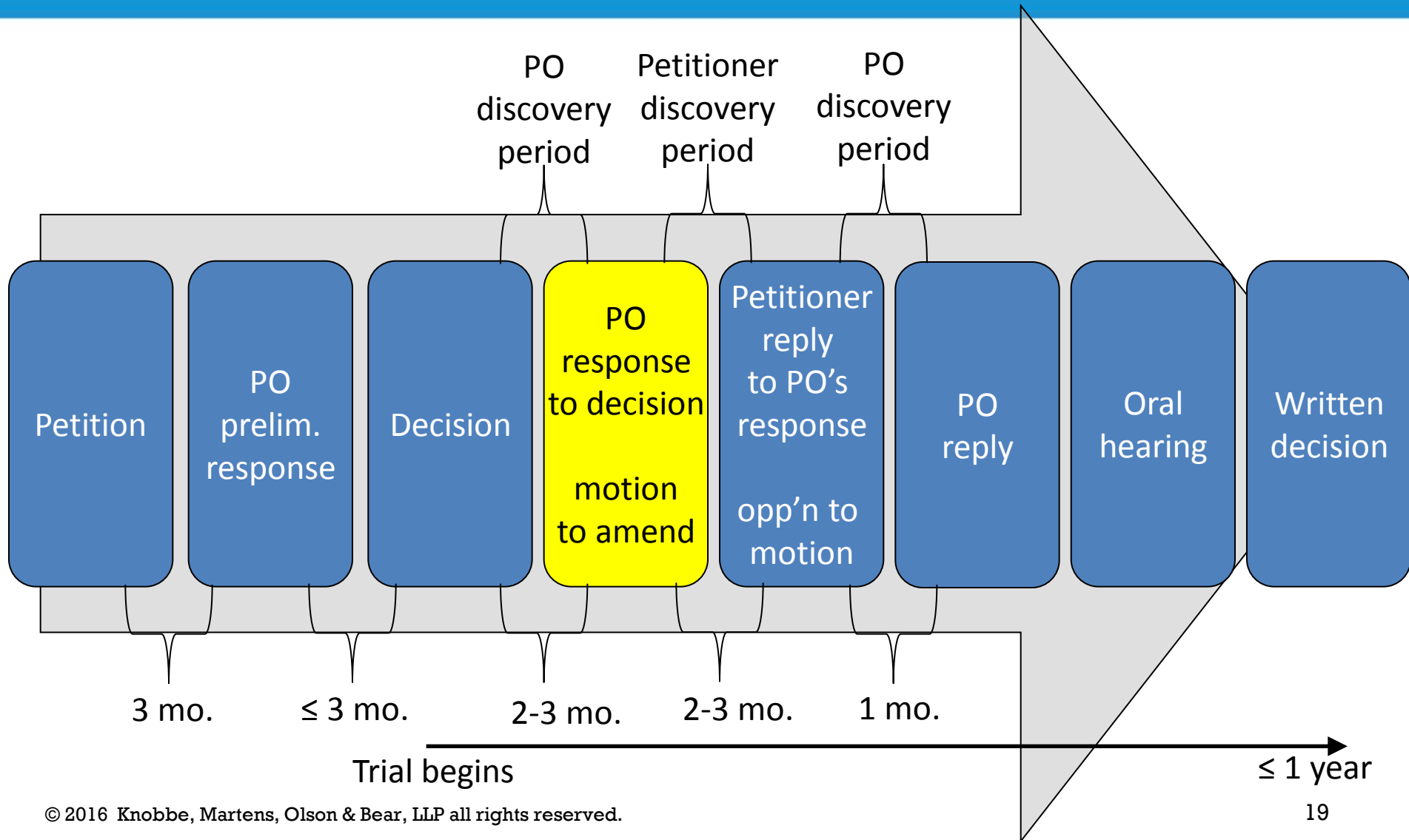
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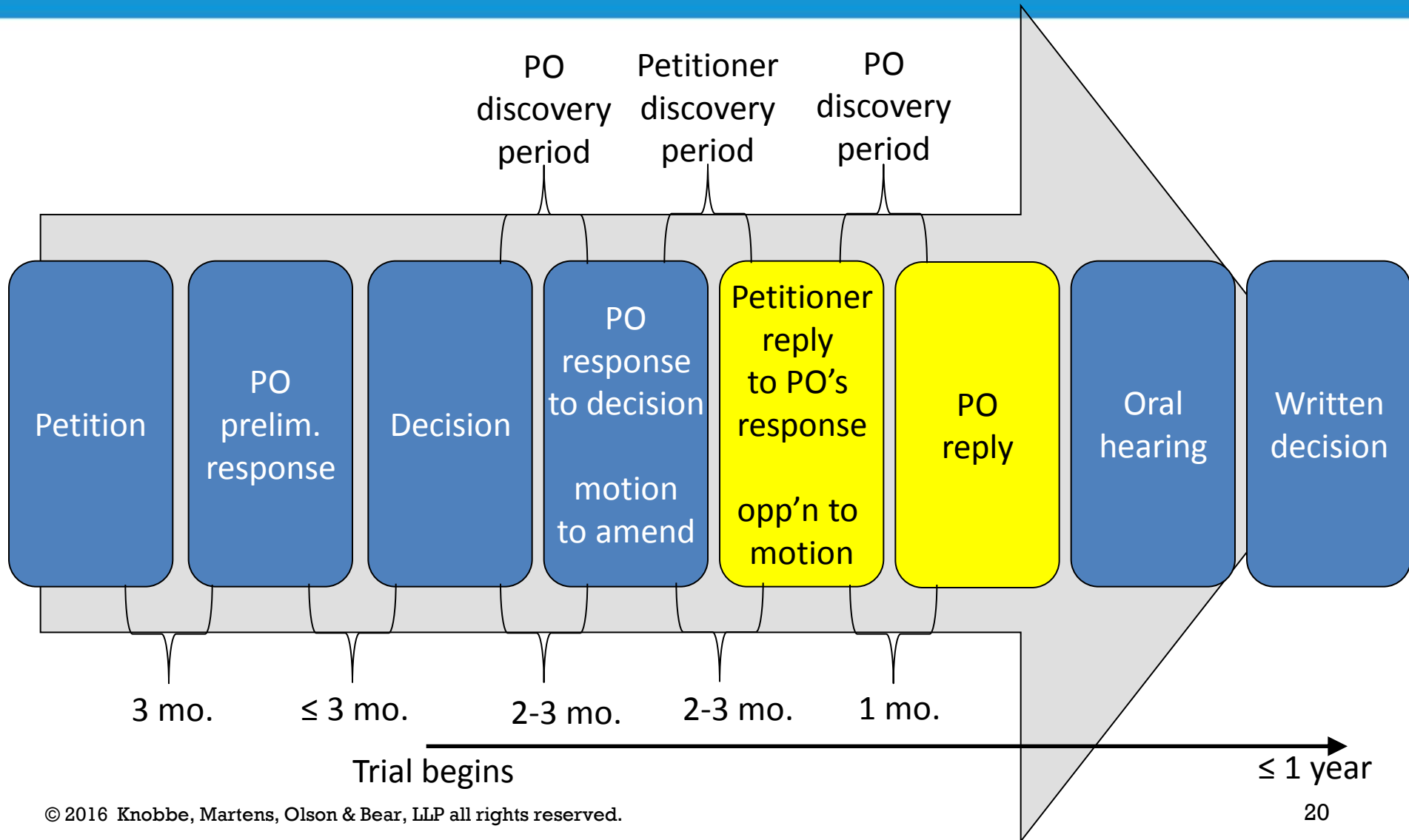
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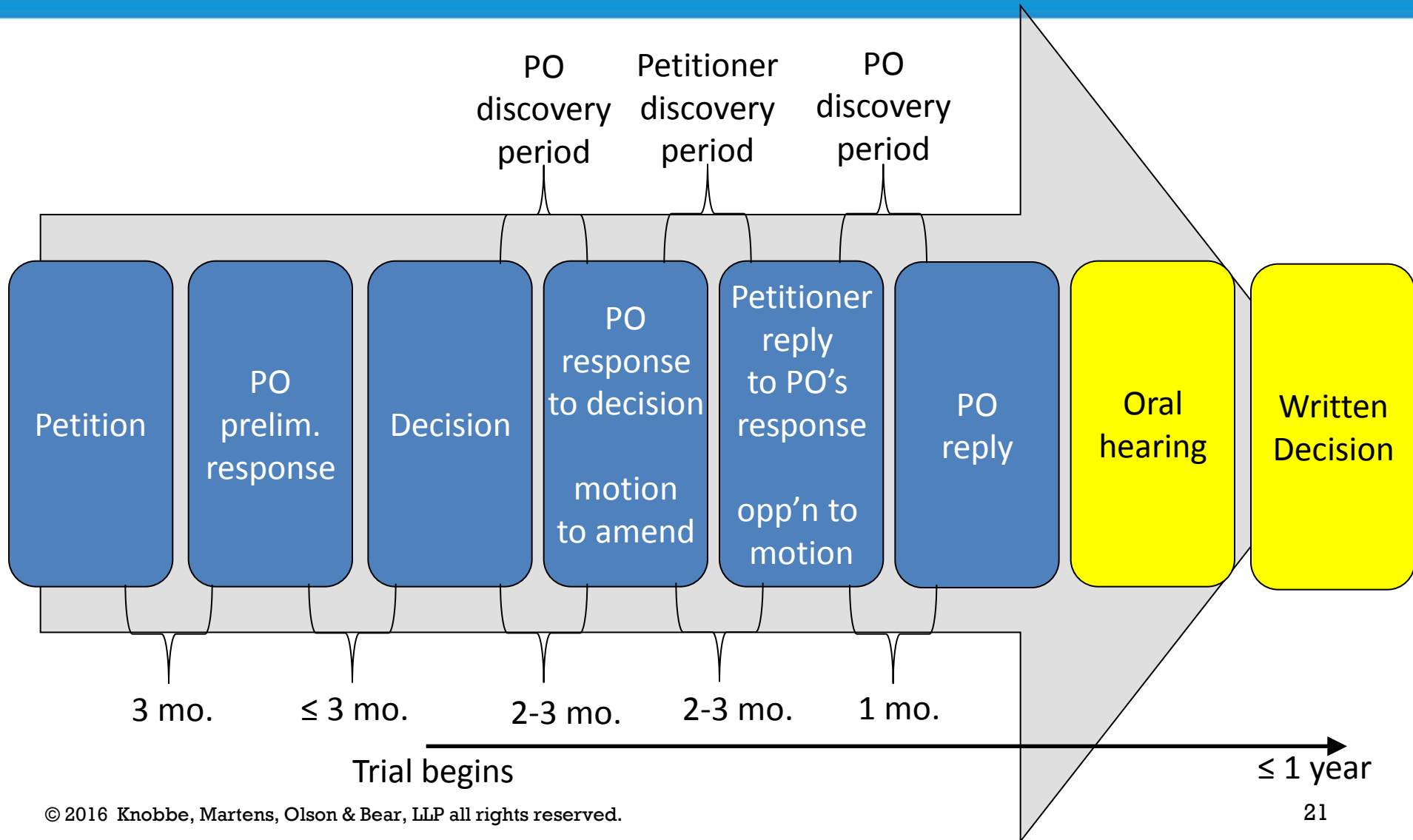
# Trial Proceedings Timeline



# Trial Proceedings Timeline



# Trial Proceedings Timeline



# Discovery in IPR

- Discovery:
  - Phased discovery by period; unlike district court litigation
  - Typically extremely limited
    - Document discovery rare
    - Only via motion practice
  - Depositions of declarants
    - Choice of declarants
    - Strategy for depositions
  - Additional if in the “interests of justice”

# Trial Preparation

- Early case development and strategy
  - Knowledge of phases and use of each phase
- Each filing is important
- Oral hearing demonstratives must be exchanged in advance
  - Content
  - Number
  - Strategy
  - “Old-school” approach

# Oral Hearing Approach

- Mock hearing(s)
- Identify weakest points and response
- Knowledge of the complete record
  - Organize by topic
  - Key questions and answers
  - Transition map to get back on message
- Team approach; know your target audience



# Settlement in IPR

- Settlement:
  - Parties avoid estoppel
  - Typically terminates trial, but not always
    - Petitioner required by statute to terminate
    - Board may opt to continue proceeding
      - If settlement is late in proceeding
      - If patent still involved in litigation or other IPRs

# Estoppel in IPR

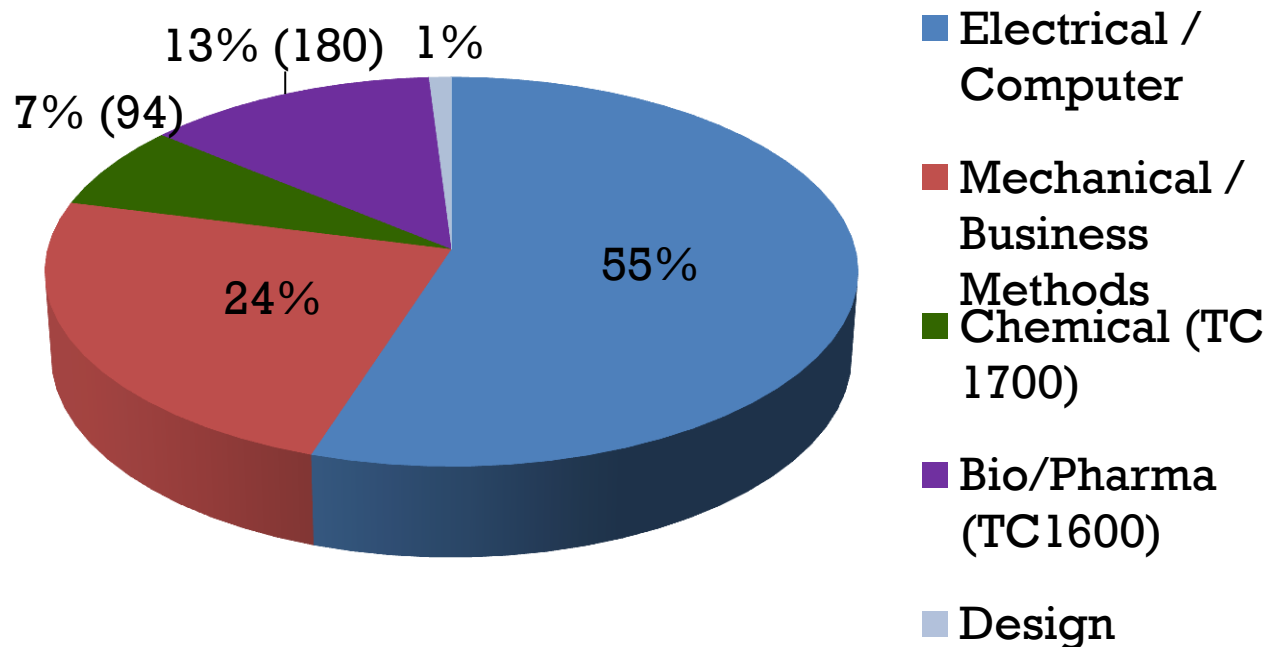
- Estoppel:
  - Claim-by-claim basis for issues raised or reasonably could have been raised
  - Grounds denied as redundant not subject to estoppel
  - Still in a state of flux and development

# IPR Statistics

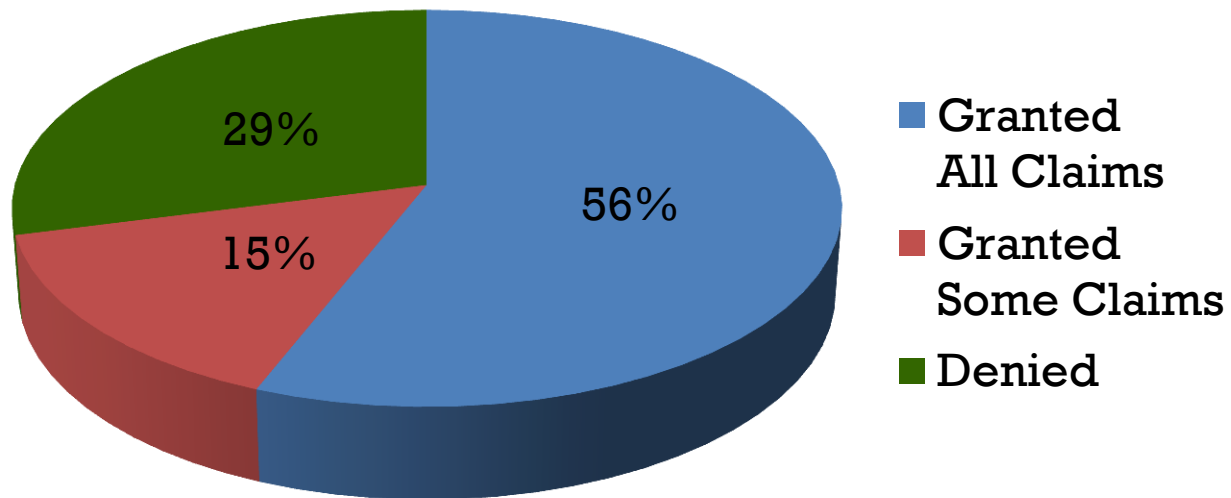
## NUMBER OF IPR PETITIONS

• 2012	17
• 2013	514
• 2014	1,310
• 2015	1,737
• 2016	1,281 (through September)
• Cumulative	4,859

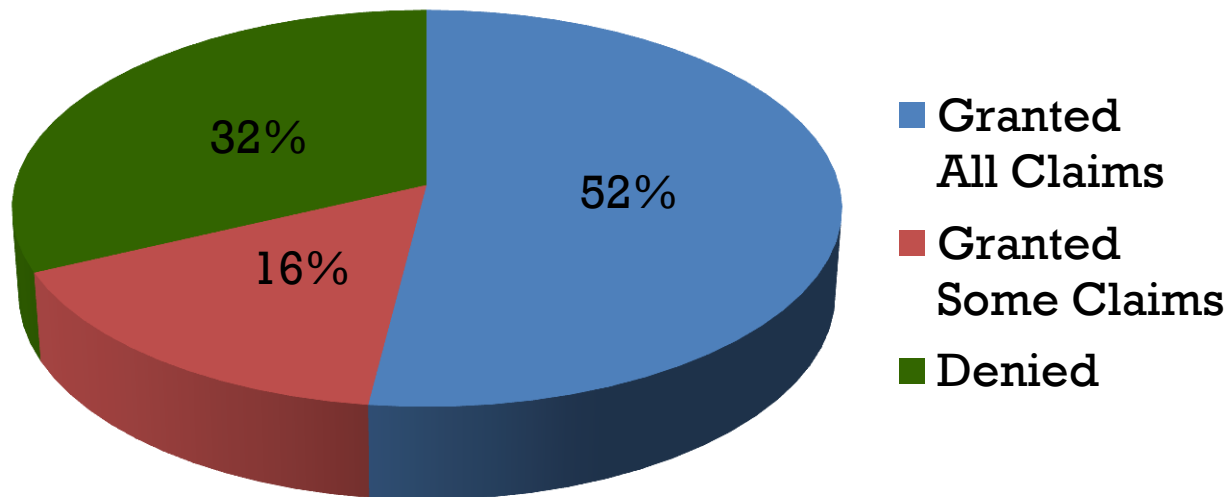
# Technology Breakdown FY2016 for All Petitions



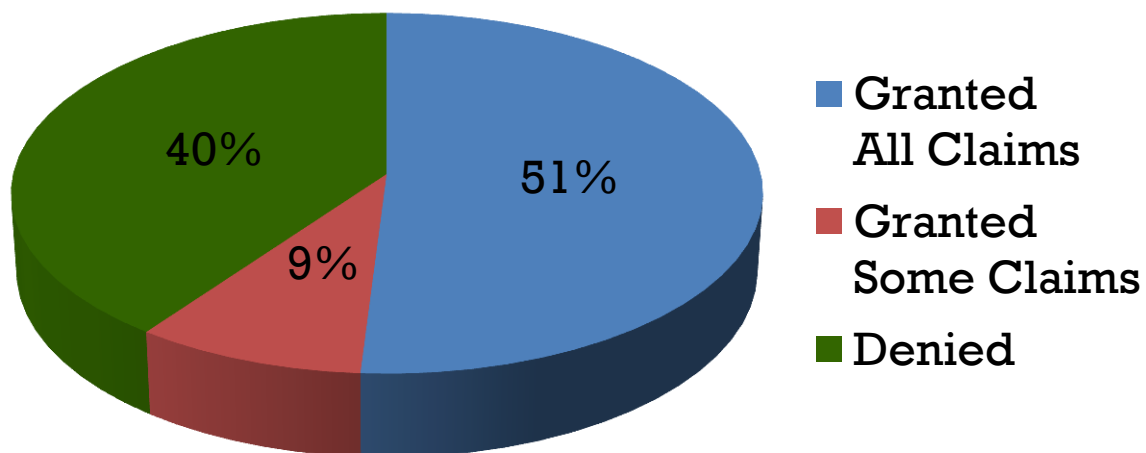
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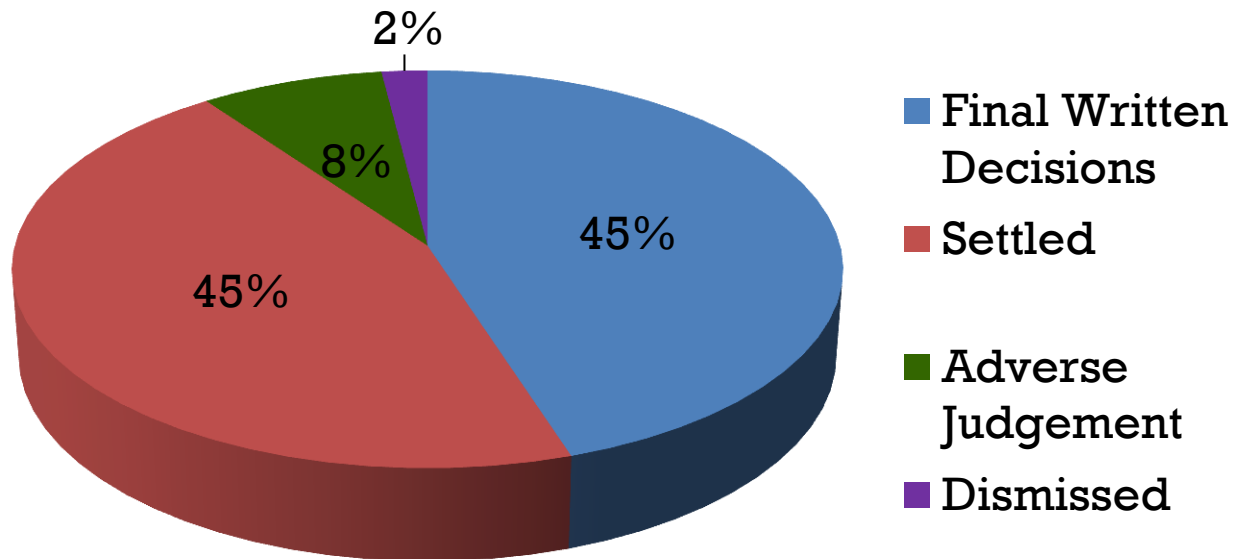
# Institution Rate for FY2016



# Life Sciences Institution Rate for FY2016

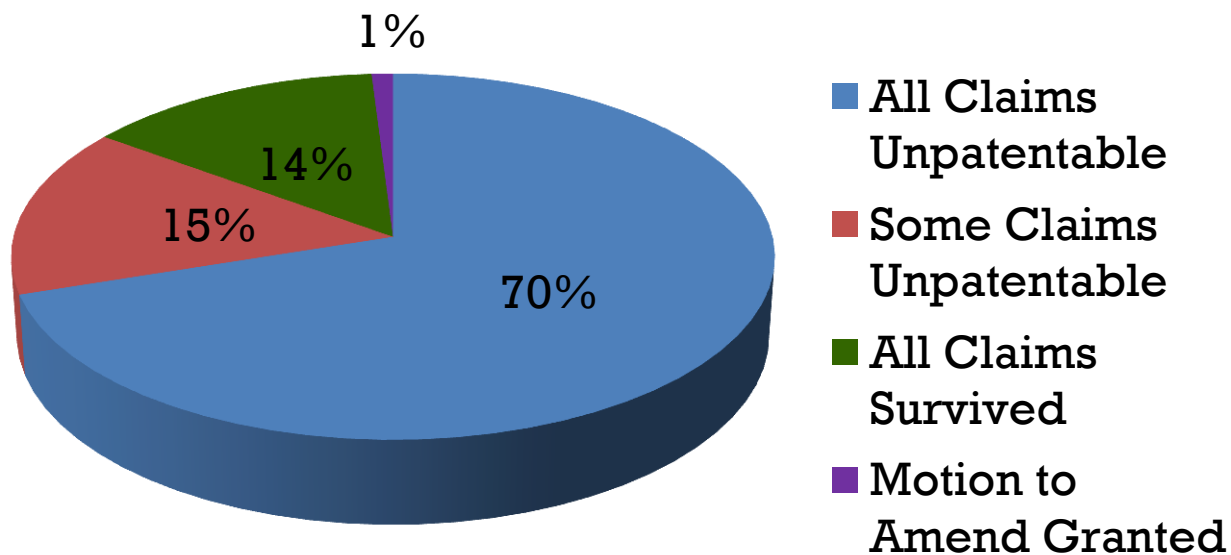


# “Disposals”

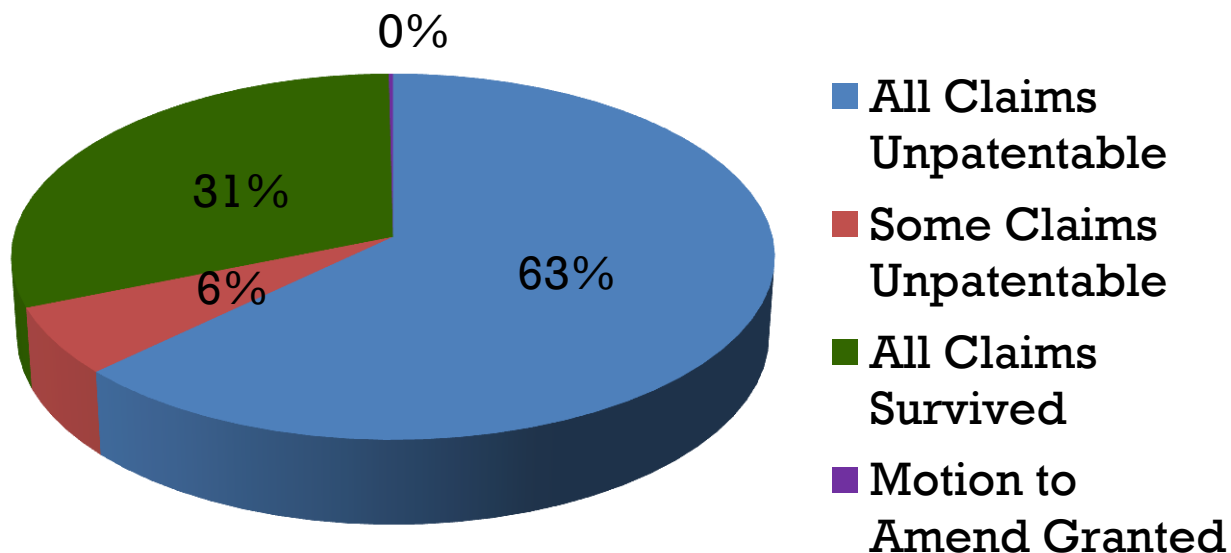




# Final Written Decisions



# Life Sciences Final Written Decisions



# MORE IPR QUESTIONS?

## Thank You

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Orange County



San Diego



San Francisco



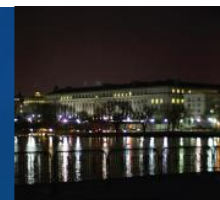
Silicon Valley



Los Angeles



Seattle



Washington DC

# Mark R. Benedict, Ph.D., J.D.

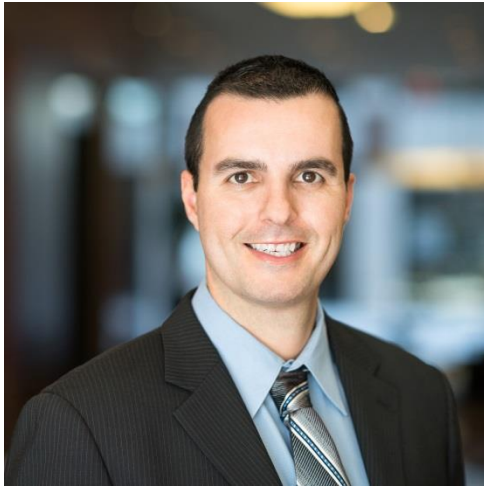


## Education

- J.D. Syracuse University, College of Law (*Magna Cum Laude*, Order of Coif)
- Ph.D. Biochemistry, Syracuse University

- Joined Knobbe Martens in 1997 and became a partner in the Orange County Office in 2002
- Member of the firm's executive committee since 2012
- Practice includes patent prosecution, strategic portfolio management, licensing and other IP transactions, infringement and validity analyses, IP due diligence, and related client counseling
- Represents large and small corporations, universities and non-profit research institutions worldwide in various technologies, including pharmaceuticals, biotechnology, medical devices and other life sciences
- Recognized by the IAM 1000 for the fifth consecutive year as one of the World's Leading Patent Practitioners
- Prior to joining Knobbe, he conducted basic and clinical research as a faculty member at SUNY Upstate Medical Center on the molecular mechanisms of growth factor regulation of cell proliferation and aging
- More information on Mark Benedict can be found at <http://www.knobbe.com/attorneys/mark-benedict>

# David Schmidt, Ph.D., Associate



- J.D., University of Notre Dame
- Ph.D., M.S., B.S., Biomedical Engineering, University of Wisconsin - Madison
- M.S. Pharmaceutical Sciences, University of Wisconsin - Madison
- Focused on biotech, medical device, and pharmaceuticals patent prosecution and IP strategy
- IP experience in stem cells, drug delivery, orthopedics, cardiovascular devices, endoscopy, biomaterials, wound care, neurovascular devices, and other areas
- Extensive research experience in the fields of biomaterials, tissue engineering, and drug delivery
- Multiple publications and conference presentations
- Taught graduate-level course in biomaterials titled “Biological interactions with Biomaterials”
- More information on David can be found at [www.knobbe.com/david.schmidt](http://www.knobbe.com/david.schmidt)

# Traditional Patent Proceeding v. IPR

District Court	IPR
Single judge or jury	Panel of three administrative patent judges
<ul style="list-style-type: none"> <li>• Presumption of validity</li> <li>• Clear and convincing evidence</li> </ul>	<ul style="list-style-type: none"> <li>• No presumption of validity</li> <li>• Preponderance of the evidence</li> </ul>
<ul style="list-style-type: none"> <li>• live witness testimony/cross-examination</li> <li>• unpredictable evidence/events</li> <li>• large evidentiary record</li> </ul>	<ul style="list-style-type: none"> <li>• rarely live witness testimony/cross-examination</li> <li>• closed record</li> <li>• pre-disclosed demonstratives</li> </ul>
<p>Full discovery (many months to years)</p> <ul style="list-style-type: none"> <li>• document requests</li> <li>• interrogatories/admissions</li> <li>• depositions</li> </ul> <p>any requests reasonably calculated to lead to admissible evidence</p>	<p>Limited discovery (within one year)</p> <ul style="list-style-type: none"> <li>• exhibits cited in a paper</li> <li>• information inconsistent with position advanced</li> <li>• cross-examination of declarants</li> </ul> <p>additional discovery only in the interests of justice</p>
Trial lasts for several days to weeks	Oral argument limited to 30-45 minutes per side
<ul style="list-style-type: none"> <li>• appeal to Federal Circuit</li> <li>• facts reviewed for <u>clear error</u></li> <li>• legal issues reviewed <i>de novo</i></li> </ul>	<ul style="list-style-type: none"> <li>• appeal to Federal Circuit</li> <li>• facts reviewed for <u>substantial evidence</u></li> <li>• legal issues reviewed <i>de novo</i></li> </ul>