Freedom to Operate and the Use of AIA Review

Mark R. Benedict
Dave Schmidt

IP Life Sciences Exchange, Munich Germany
November 15, 2016

The recipient may only view this work. No other right or license is granted.
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
Recognitions

• IP Law Firm of the Year - USA (2016) – Lawyer Monthly Magazine

• Top IP Boutique Law Firm (2016) – Vault


• 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 3rd 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-\textit{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

<table>
<thead>
<tr>
<th></th>
<th>IPR</th>
<th>PGR</th>
<th>CBM</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patents Eligible</strong></td>
<td>Any patent</td>
<td>First-to-File patents only</td>
<td>Financial product or service</td>
</tr>
<tr>
<td><strong>Timing</strong></td>
<td>• 1 year of being sued for infringement</td>
<td>• within 9 months of issue</td>
<td>• sued for infringement</td>
</tr>
<tr>
<td></td>
<td>• after PGR eligibility</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Grounds</strong></td>
<td>• 102 (novelty)</td>
<td>• 101 (utility, statutory subject matter)</td>
<td>• 101 (utility, statutory subject matter)</td>
</tr>
<tr>
<td></td>
<td>• 103 (obviousness)</td>
<td>• 102 (novelty)</td>
<td>• 102 (novelty)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 103 (obviousness)</td>
<td>• 103 (obviousness)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 112 (written description, enablement,</td>
<td>• 112 (written description, enablement,</td>
</tr>
<tr>
<td></td>
<td></td>
<td>indefiniteness)</td>
<td>indefiniteness)</td>
</tr>
<tr>
<td><strong>Evidence</strong></td>
<td>patents and printed publications</td>
<td>any evidence</td>
<td>any evidence</td>
</tr>
<tr>
<td><strong>Estoppel</strong></td>
<td>102, 103</td>
<td>101, 102, 103, 112</td>
<td>101, 102, 103, 112</td>
</tr>
</tbody>
</table>
## Why Are IPRs So Popular?

<table>
<thead>
<tr>
<th><strong>Litigation</strong></th>
<th><strong>IPRs</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Average Cost:</strong> ~$2.5M-$3.5M</td>
<td><strong>Average Cost:</strong> $400k - $1M</td>
</tr>
<tr>
<td><strong>Average Time to Trial:</strong> 2.5 years</td>
<td><strong>Time to Decision:</strong> 18 mos.</td>
</tr>
<tr>
<td><strong>Standard of Proof:</strong> Clear and convincing evidence</td>
<td><strong>Standard of Proof:</strong> Preponderance of the evidence</td>
</tr>
<tr>
<td><strong>Claim Construction:</strong> Plain and ordinary meaning</td>
<td><strong>Claim Construction:</strong> Broadest reasonable interpretation</td>
</tr>
</tbody>
</table>

**Judge/Jury**

- 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

- 56% Granted All Claims
- 29% Granted Some Claims
- 15% Denied
Final Written Decisions

- 70% All Claims Survived
- 15% Some Claims Unpatentable
- 14% All Claims Unpatentable
- 1% Motion to Amend Granted
Trial Proceedings Timeline

- Petition
- PO prelim. response
- Decision
- PO response to decision motion to amend
- Petitioner reply to PO’s response opp’n to motion
- PO reply
- Oral hearing
- Written decision

- 3 mo.
- ≤ 3 mo.
- 2-3 mo.
- 2-3 mo.
- 1 mo.

Trial begins ≤ 1 year
Trial Proceedings Timeline

- **Petition**
  - Petitioner's response
  - PO discovery period

- **Decision**
  - Petitioner's response to decision
  - PO response to decision
  - Motion to amend

- **PO reply**
  - Petitioner's reply to PO's motion
  - Opp'n to motion

- **Oral hearing**
- **Written decision**

Timeline:
- **Trial begins**
  - ≤ 3 mo.
- PO discovery period
  - ≤ 3 mo.
- Decision
  - 2-3 mo.
- Motion to amend
  - 2-3 mo.
- Petitioner's reply
  - 1 mo.
- Oral hearing
- Written decision

Total ≤ 1 year
Trial Proceedings Timeline

- Petition: 3 mo.
- PO prelim. response: ≤ 3 mo.
- Decision: 2-3 mo.
- PO response to decision motion to amend: 2-3 mo.
- Petitioner reply to PO’s response opp’n to motion: 1 mo.
- PO reply: 1 mo.
- Oral hearing: ≤ 1 year
- Written decision

© 2016 Knobbe, Martens, Olson & Bear, LLP all rights reserved.
Trial Proceedings Timeline

- **Petition**
  - 3 mo.

- **PO prelim. response**
  - ≤ 3 mo.

- **Decision**
  - 2-3 mo.

- **PO response to decision**
  - 2-3 mo.

- **Petitioner reply to PO’s response**
  - opp’n to motion

- **PO reply**
  - 1 mo.

- **Oral hearing**

- **Written decision**

**Trial begins**

≤ 1 year
Trial Proceedings Timeline

- Petition
- PO prelim. response
- Decision
- PO response to decision motion to amend
- Petitioner discovery period
- Petitioner discovery period
- PO discovery period
- PO reply
- Oral hearing
- Written decision

- 3 mo.
- ≤ 3 mo.
- 2-3 mo.
- 2-3 mo.
- 1 mo.
- ≤ 1 year

Trial begins

© 2016 Knobbe, Martens, Olson & Bear, LLP all rights reserved.
Trial Proceedings Timeline

- Petition
- PO prelim. response
- Decision
- PO response to decision motion to amend
- Petitioner reply to PO’s response opp’n to motion
- PO reply
- Oral hearing
- Written decision

- 3 mo.
- ≤ 3 mo.
- 2-3 mo.
- 2-3 mo.
- 1 mo.

Trial begins ≤ 1 year
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

- **Electrical / Computer**: 55%
- **Mechanical / Business Methods**: 13% (180)
- **Chemical (TC 1700)**: 24%
- **Bio/Pharma (TC1600)**: 7% (94)
- **Design**: 1%
Trial Institutions Overall

- 56% Granted All Claims
- 29% Granted Some Claims
- 15% Denied

© 2016 Knobbe, Martens, Olson & Bear, LLP all rights reserved.
Institution Rate for FY2016

- 52% Granted All Claims
- 32% Granted Some Claims
- 16% Denied
Life Sciences Institution Rate for FY2016

- Granted All Claims: 51%
- Granted Some Claims: 9%
- Denied: 40%
“Disposals”

- Final Written Decisions: 45%
- Settled: 45%
- Adverse Judgement: 8%
- Dismissed: 2%
Final Written Decisions

- All Claims Survived: 70%
- Some Claims Unpatentable: 15%
- All Claims Unpatentable: 14%
- Motion to Amend Granted: 1%

© 2016 Knobbe, Martens, Olson & Bear, LLP all rights reserved.
Life Sciences Final Written Decisions

- 63% All Claims Survived
- 31% Some Claims Unpatentable
- 6% All Claims Unpatentable
- 0% Motion to Amend Granted
Thank You

Mark R. Benedict, Ph.D., J.D.
2040 Main Street
Irvine, CA 92614
mark.benedict@knobbe.com

David Schmidt, Ph.D., J.D.
2040 Main Street
Irvine, CA 92614
david.schmidt@knobbe.com
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](http://www.knobbe.com/attorneys/mark-benedict)

© 2016 Knobbe, Martens, Olson & Bear, LLP all rights reserved.
David Schmidt, Ph.D., Associate

- 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

- 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
# Traditional Patent Proceeding v. IPR

<table>
<thead>
<tr>
<th>District Court</th>
<th>IPR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single judge or jury</td>
<td>Panel of three administrative patent judges</td>
</tr>
<tr>
<td>• Presumption of validity</td>
<td>• No presumption of validity</td>
</tr>
<tr>
<td>• Clear and convincing evidence</td>
<td>• Preponderance of the evidence</td>
</tr>
<tr>
<td>• live witness testimony/cross-examination</td>
<td>• rarely live witness testimony/cross-examination</td>
</tr>
<tr>
<td>• unpredictable evidence/events</td>
<td>• closed record</td>
</tr>
<tr>
<td>• large evidentiary record</td>
<td>• pre-disclosed demonstratives</td>
</tr>
<tr>
<td><strong>Full discovery (many months to years)</strong></td>
<td><strong>Limited discovery (within one year)</strong></td>
</tr>
<tr>
<td>• document requests</td>
<td>• exhibits cited in a paper</td>
</tr>
<tr>
<td>• interrogatories/admissions</td>
<td>• information inconsistent with position advanced</td>
</tr>
<tr>
<td>• depositions</td>
<td>• cross-examination of declarants</td>
</tr>
<tr>
<td>any requests reasonably calculated to lead to</td>
<td>additional discovery only in the interests of justice</td>
</tr>
<tr>
<td>admissible evidence</td>
<td></td>
</tr>
<tr>
<td><strong>Trial lasts for several days to weeks</strong></td>
<td><strong>Oral argument limited to 30-45 minutes per side</strong></td>
</tr>
<tr>
<td>• appeal to Federal Circuit</td>
<td>• appeal to Federal Circuit</td>
</tr>
<tr>
<td>• facts reviewed for clear error</td>
<td>• facts reviewed for substantial evidence</td>
</tr>
<tr>
<td>• legal issues reviewed <em>de novo</em></td>
<td>• legal issues reviewed <em>de novo</em></td>
</tr>
</tbody>
</table>