Drafting and Prosecuting Patent Applications to Withstand PTAB Scrutiny

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

THURSDAY, MARCH 5, 2015

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

Today’s faculty features:

Thomas L. Irving, Partner, Finnegan Henderson Farabow Garrett & Dunner, Washington, D.C.

Anthony Gutowski, Partner, Finnegan Henderson Farabow Garrett & Dunner, Reston, VA

John Mulcahy, Partner, Finnegan Henderson Farabow Garrett & Dunner, Reston, VA

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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
The Revolution: Inter Partes Review (IPR) Petition Filings Continue To Rise, and Petition Grant Rate is High: Very Likely That Valuable Patents Issuing From Now On Will Be Involved in One!


4 PGRs filed so far; 2 settled prior to institution decision, 2 institution decision pending.
PTAB Rate of Granting Petitions Is High So Far


No PGR institution decisions yet.
Overall, Petitioners Usually Successful

As of Feb. 1, 2015. Source: Finnegan research and Finnegan AIA blog, with thanks to Dan Klodowski, Kai Rajan, Elliot Cook, and Joe Schaffner.

Analysis: 3072 claims at issue; 196 cases.

“mixed outcome” means some instituted claims survived, some did not.
Overall, Petitioners Usually Successful

As of Feb. 1, 2015. Source: Finnegan research and Finnegan AIA blog, with thanks to Dan Klodowski, Kai Rajan, Elliot Cook, and Joe Schaffner. Analysis: 3072 claims at issue; 196 cases.
## Options

<table>
<thead>
<tr>
<th></th>
<th>Ex Parte Reexam</th>
<th>Post-Grant Review</th>
<th>Covered Business Methods PGR</th>
<th>Inter Partes Review</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>When</strong></td>
<td>After grant</td>
<td>Within nine months of grant</td>
<td>After grant, for covered business method patents</td>
<td>After nine months of grant (but one exception)</td>
</tr>
<tr>
<td><strong>Threshold showing</strong></td>
<td>SNQ</td>
<td>More likely than not or novel legal question</td>
<td>More likely than not PLUS sued or charged with infringement</td>
<td>Reasonable likelihood of success</td>
</tr>
<tr>
<td><strong>Grounds</strong></td>
<td>102, 103</td>
<td>101, 102, 103, 112</td>
<td>101, 102, 103, 112</td>
<td>102*, 103</td>
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<tr>
<td><strong>Time at PTO</strong></td>
<td>Years</td>
<td>12-18 months</td>
<td>12-18 months</td>
<td>12-18 months</td>
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<tr>
<td><strong>Anonymity</strong></td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
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<tr>
<td><strong>PTO Fees</strong></td>
<td>$12,000</td>
<td>$12,000 + $18,000</td>
<td>$12,000 + $18,000</td>
<td>$9,000 + $14,000</td>
</tr>
</tbody>
</table>

*§112 issues may arise in context of antedating prior art or contesting claim to priority.*
## Options

<table>
<thead>
<tr>
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<th>Inter Partes Review</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Estoppel</strong></td>
<td>None</td>
<td>Issues raised or reasonably could have been raised</td>
<td>PTO: raised or reasonably could have raised</td>
<td>Issues raised or reasonably could have been raised</td>
</tr>
<tr>
<td><strong>Before whom</strong></td>
<td>CRU</td>
<td>PTAB</td>
<td>PTAB</td>
<td>PTAB</td>
</tr>
<tr>
<td><strong>Discovery/evidence</strong></td>
<td>Declaration</td>
<td>Declaration and discovery</td>
<td>Declaration and discovery</td>
<td>Declaration and discovery</td>
</tr>
<tr>
<td><strong>Appeal</strong></td>
<td>Only patent owner may appeal to PTAB then Federal Circuit</td>
<td>Both parties may appeal to Federal Circuit</td>
<td>Both parties may appeal to Federal Circuit</td>
<td></td>
</tr>
<tr>
<td><strong>Petition grant rate</strong></td>
<td>92% (11013/12016)*</td>
<td>N/A</td>
<td>72% (128/177)*</td>
<td>70% (1030/1478)*</td>
</tr>
<tr>
<td><strong>Final decisions</strong></td>
<td>All claims maintained without change 22%*</td>
<td>All instituted claims survived 100%</td>
<td>All instituted claims survived 13.3% (26/196)**</td>
<td>Claims canceled 85% (23/27)**</td>
</tr>
<tr>
<td></td>
<td>At least one claim amended 66%*</td>
<td>Mixed 15% (4/27)**</td>
<td>Mixed 16.3% (32/196)**</td>
<td>No instituted claims survive 70.4% (138/196)**</td>
</tr>
<tr>
<td></td>
<td>All claims canceled 12%*</td>
<td>Claims canceled 85% (23/27)**</td>
<td>No instituted claims survive 70.4% (138/196)**</td>
<td></td>
</tr>
</tbody>
</table>


**By case. Source: Finnegan research. As of Feb. 1, 2015.**
Petitions Filed as of Feb. 19, 2015

69% petition grant rate (1043/1502); 76% if include joinders (1149/1502).

63% of trials instituted have terminated (settled or final written decision or adverse judgment entered) (725/1149).

Terminated IPRs

- Final Written Decision, 34% 243/725
- Settled, 58% 423/725
- Adverse judgment, 8% 59/725

Note: on a per case basis, substitute claims have been considered in 56 IPRs, and have only been allowed 3 times (5%). Source: Finnegan research, as of Feb. 1, 2015.
Per Claim, 7% of Proposed Substitute Claims Allowed

Note: on a per claim basis, 312 substitute claims have been proposed, only 22 allowed (7%). Source: Finnegan research, as of Feb. 1, 2015.
Thus far ...

*Hundreds of claims,*

*entire patents cancelled*

(in 70% (138/196) of Final Written Decisions, no instituted claims survived)*

26 patents have survived IPR entirely

(13%, 26/196)*

*As of Feb. 1, 2015.  Source: Finnegan research; 196 Final Written Decisions. These statistics do not include settlements, requests for adverse judgment, motions to terminate, still-pending cases, requests for rehearing, and appellate outcomes.*
Stats from IPR Final Written Decisions (FWDs) 
(By Case) (as of Feb. 1, 2015)*

<table>
<thead>
<tr>
<th>TC1600/1700</th>
<th>TC2100</th>
<th>TC2400</th>
<th>TC2600</th>
<th>TC2700</th>
<th>TC2800</th>
<th>TC3600</th>
<th>TC3700</th>
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<td>18</td>
<td>18</td>
<td>18</td>
<td>6</td>
<td>17</td>
<td>16</td>
</tr>
</tbody>
</table>

*Source: Finnegan research. As of Feb. 1, 2015. TC1600 and 1700: 37 FWDs; TC2100: 30 FWDs; TC2400: 7 FWDs; TC2600: 22 FWDs; TC2700: 13 FWDs; TC2800: 41 FWDs; TC3600: 26 FWDs; TC3700: 18 FWDs.
## Reminder of Burdens Unfavorable to Patent Owner

<table>
<thead>
<tr>
<th>ISSUE</th>
<th>PGR/CBM PGR/IPR</th>
<th>DISTRICT COURT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Burden of proof</td>
<td>Preponderance of the evidence</td>
<td>Clear and convincing evidence</td>
</tr>
<tr>
<td>Presumption of Validity?</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Claim construction</td>
<td>Broadest reasonable Interpretation (BRI)</td>
<td>Phillips/Markman framework: analyze claims, specification, and prosecution history to determine how claims would be understood by one of ordinary skill in the art</td>
</tr>
<tr>
<td>Decision maker</td>
<td>Patent Trial and Appeal Board (APJs)</td>
<td>District court judge or jury</td>
</tr>
</tbody>
</table>
Counter-Attack in the Patent Owner’s Preliminary Response (POPR) because Patent Owner Goal is for PTAB to Deny Institution
Irving’s Recollections of Judge Tierney In Dallas on November 12, 2014

• Tell PTAB why patent owner should win.

• Do not make PTAB figure it out.

• PTAB just does not have time.

• PTAB looking for the concise, compelling argument.
Before PTAB, 
Claim Construction Can Be Very Important and Can Even Lead to Denial of Institution
Irving’s Recollections of Judge Tierney in Dallas, November 12, 2014

• Claim construction is critical.
  – 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.
Take-Away

• **Drafting and prosecution**
  – Define terms judiciously, considering dual objectives of patentability and proving infringement.
  – Once defined, 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 your best friend for contradicting Petitioner’s proposed BRI!**
In 187/196 FWDs, PTAB addressed claim construction. Of the 187, 95% used BRI.

84% (157) of the 187, PTAB looked to intrinsic evidence. But Patent Owners are not winning 84% of the time!

Claim Construction Stats By TC  
(as of Feb. 1, 2015)

- Notes:
  - TC1600/1700: in 24 of the 32 claim construction decisions (75%), PTAB relied on intrinsic evidence (7 of these also used dictionaries, 9 also used expert testimony).
  - TC2100: in 27 of the 30 claim construction decisions (90%), PTAB relied on intrinsic evidence.

Federal Circuit Treatment So Far

- *In re Cuozzo Speed Technologies, LLC, --F.3d ___* (Fed. Cir. Feb. 4, 2015)
  - No jurisdiction to review PTAB’s IPR institution decision (See 35 U.S.C. § 314(d)).
  - Affirm PTAB’s Final Written Decision in full (all instituted claims unpatentable as obvious)
    - No error in BRI claim construction;
    - No error in obviousness determination; and
    - No error in denial of Cuozzo’s motion to amend.
      - Lack of written description support;
      - Improper broadening
Federal Circuit Treatment So Far

• *Softview LLC v. Kyocera Corp.*, --F.3d ___ (Fed. Cir. Feb. 9, 2015)

  – Rule 36 affirmance of PTAB’s Final Written Decision in full (all instituted claims unpatentable as obvious)
    • IPR2013-00007 and -00256
    • IPR2013–00004 and –00257
Federal Circuit Treatment So Far

• *Clearlamp, LLC v. LKQ Corp.*, --F.3d ___ (Fed. Cir. Feb. 18, 2015)
  
  – Rule 36 affirmance of PTAB’s Final Written Decision in full
  
  • IPR2013-00020
    
    – 12 claims unpatentable;
    – 12 claims not shown unpatentable
    – Motion to amend denied.
    
    » Did not distinguish over prior art in general.
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.
Legal Advantages Favoring the Challenger

• No presumption of validity (unlike litigation).

• Lower burden of proof (*Baxter v. Fresenius*)
  ➢ “Preponderance of the evidence” vs. “clear and convincing evidence” in litigation

• Claim construction: broadest reasonable interpretation in light of the specification
  ➢ Broader constructions may encompass invalidating art;
  ➢ No attempt to preserve patentability;
  ➢ Not bound to follow district court’s construction, if it exists; and
  ➢ *No Markman* hearing on construction
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 and cannot generate new testimonial evidence prior to institution.
  – Once instituted, Patent Owner can bring in evidence but is already behind the eight-ball.

• Strict limits on discovery.

• No limit on number of IPR petitions by same party, particularly to avoid redundancy.
IPR Procedural Features Favor Petitioners

• Very limited ability to substitute amended claims so far.
  – Motion to amend by canceling claims likely successful.
  – Motion to amend by substituting claims only allowed in
    3 cases so far (IPR2013-00124; IPR2013-00402 and -403)

• PTAB has discretion whether or not to deny institution “the Director
  may take into account whether, and reject the petition or request
  because, the same or substantially the same prior art or arguments
  previously were presented to the Office.” (35 U.S.C. §325(d)).
  – Not denying very often based on prior art already before Examiner during
    prosecution (original, reexam, or reissue).
  – See next slide.
Patent Owners Not Much Success So Far Convincing PTAB to Deny Institution Based on Same Art/Arguments during Prosecution, Better when from Other Petition

Discretion Based on Same Art/Arguments during Prosecution
- PTAB Exercised, 5% (3/55)
- PTAB Did Not Exercise, 95% (52/55)

Discretion Based on Same Art/Arguments in other Petition
- PTAB Did Not Exercise, 42% (14/33)
- PTAB Exercised, 58% (19/33)

Source: Finnegan research analyzing 88 IPRs where 35 U.S.C. §325(d) was raised. As of Feb. 10, 2015.
Practitioner Drafting And Prosecution Tools To Strengthen Potentially Important Patent Applications

- Build up specification and file history during drafting and prosecution.
  - Patent Owners cannot present newly-generated declaration evidence in a Patent Owner's Preliminary Response (POPR);
  - Solidify novelty, non-obviousness, enablement, and written description positions.
  - Consider declarations during prosecution, but be mindful of inequitable conduct attacks in litigation.

- 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).
  – For other technologies, consider at least some very focused claims.
## Patent Profanity: What Is It?

### Words of characterization

<table>
<thead>
<tr>
<th>Chief, Majority</th>
<th>- Vital</th>
<th>Surprising</th>
</tr>
</thead>
<tbody>
<tr>
<td>Critical, Essential, Necessary</td>
<td>- Fundamental</td>
<td>Unexpected (?)</td>
</tr>
<tr>
<td>Solely, Only, Is</td>
<td>- Important</td>
<td>All (?)</td>
</tr>
<tr>
<td>Main</td>
<td>- Principal</td>
<td>Only (?)</td>
</tr>
<tr>
<td>Significant</td>
<td></td>
<td>Each (?)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>“The invention is...” or “This invention...”</th>
</tr>
</thead>
</table>

- 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
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: “unreasonable and unexplained delay.”
Consider Keeping Continuation Application Pending (con’t)

  - 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.
Consider Keeping Continuation Application Pending (con’t)

• Many originally thought a Terminal Disclaimer would lead to the PTAB proceeding being terminated to permit prosecuting a related claim in a continuation, so far TD just held in abeyance until a final decision is rendered.

    • Patent Owner indicated intent to file TD of remaining term of challenged patent and that PTAB should therefore not apply BRI to the claims.

    • “Patent Owner requested authorization, if the terminal disclaimer is filed, to file a motion to terminate the proceeding on the basis that the Board applied the broadest reasonable interpretation standard in the decision to institute this *inter partes* review. Alternatively, Patent Owner requested that the hearing in this proceeding be delayed.

    • Patent Owner filed TD and notified PTAB.

    • Paper 129: PTAB ordered that “terminal disclaimer should be held in abeyance until the instant proceeding terminates or a final written decision is issued, and that the challenged claims should continue to be given their broadest reasonable interpretation in light of the Specification of the ’076 patent.”

    • FWD: 2 claims unpatentable, 14 claims survived.
      • “FURTHER ORDERED that the terminal disclaimer filed by Patent Owner in U.S. Patent Application No. 08/975,590 (issued as the ’076 Patent) on April 11, 2014, shall no longer be held in abeyance.”
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 §103 positions (nonobviousness)

• Consider *Therasense*
  ➢ Careful thought and planning.
Consider Substantive Declarations in Prosecution

Why? Because in the Patent Owner’s Preliminary Response (POPR) before institution of the post-grant proceeding, the Patent Owner cannot file a declaration relying on newly developed evidence and attacking the petitioner’s declaration.

But, the Patent Owner can rely on public records. If there are good declarations in prosecution, those can be submitted by the Patent Owner before institution (Patent Owner’s Preliminary Response) in an effort to persuade PTAB that there is not a substantial likelihood that at least one claim will be unpatentable.

Remember: Patent Owner’s goal is to avoid institution of an IPR/PGR.
“Record” Evidence to Get Petition Denied

  - 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.
Declarations

- Declarations need to be as solid as possible. PTAB has found that defective declarations relied on for patentability during prosecution can form an independent basis for instituting an IPR.


- Board reviewed a § 1.131 declaration from the prosecution, found it deficient, and reapplied the prior art the declaration had antedated, instituting the IPR.

- Case also had live testimony from inventor at oral hearing.
  – One might want declarations from the inventor during prosecution that can then by referred to by the Patent Owner in the optional Preliminary Response to try to ward off institution.
# Federal Circuit: Inequitable Conduct Post-Therasense

<table>
<thead>
<tr>
<th>Case</th>
<th>Judges</th>
<th>Summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aventis Pharma S.A. v. Hospira, Inc., 675 F.3d 1324 (Fed. Cir. 2012)</td>
<td>PROST, Linn, Dyk</td>
<td>Affirmed inequitable conduct; Withheld references material; No credible explanation why disclosed to FDA but not PTO</td>
</tr>
<tr>
<td>Apotex Inc. v. Cephalon, Inc., 2011 WL 6090696 (E.D. Pa. 2011), aff’d without opinion (Fed. Cir. April 8, 2013)</td>
<td>PER CURIAM (Rader, Lourie, O’Malley)</td>
<td>Affirmed inequitable conduct; Concealed supplier’s involvement in claimed invention; No alternative explanation why told PTO it modified Lafon’s modafinil when it did not.</td>
</tr>
<tr>
<td>Intellect Wireless, Inc. v. HTC Corp., 732 F.3d 1339 (Fed. Cir. 2013)</td>
<td>MOORE, Prost, O’Malley</td>
<td>Affirmed inequitable conduct; Submission of false declaration = affirmative egregious misconduct; Pattern of conduct showed intent to deceive: similar false statements in related patents; never notified examiner of error in the declaration or attempted to correct it.</td>
</tr>
<tr>
<td>Ohio Willow Wood Co. v. Alps South, LLC, 735 F.3d 1333 (Fed. Cir. 2013)</td>
<td>REYNA, Bryson, Dyk</td>
<td>Reversed SJ of no inequitable conduct; Failure to disclose material information = submitting a false affidavit; “OWW withheld various pieces of material information and had no reasonable explanation for the several misrepresentations it made to the PTO.”</td>
</tr>
<tr>
<td>Apotex, Inc. v. UCB, Inc., 763 F.3d 1354 (Fed. Cir. 2014)</td>
<td>REYNA, Wallach, and Hughes</td>
<td>Affirmed inequitable conduct; Affirmative misrepresentations of prior art and test results; Pattern of conduct showed intent to deceive.</td>
</tr>
<tr>
<td>American Calcar, Inc. v. American Honda Motor Co., Inc., 768 F.3d 1185 (Fed. Cir. 2014)</td>
<td>PROST, Wallach Dissent - Newman</td>
<td>Affirmed inequitable conduct; Failure to disclose material information; “Mr. Obradovich deliberately decided to withhold the information from the PTO.”</td>
</tr>
</tbody>
</table>
District Court: Inequitable Conduct Post-Therasense

<table>
<thead>
<tr>
<th>Case</th>
<th>Defendant</th>
<th>Misrepresentation</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>Worldwide Home Prods., Inc. v. Time, Inc., --F.Supp.2d___ (S.D.N.Y. February 11, 2015) (on reconsideration in light of Therasense)</td>
<td>Swain</td>
<td>Misrepresentation about prior art was basis for overcoming prior art rejection (“but for” materiality)</td>
<td>Defendants’ counsel alerted applicant of inaccurate description prior to the Notice of Allowance, but applicant did not correct - &gt;specific intent to deceive is single most reasonable inference</td>
</tr>
<tr>
<td>Ohio Willow Wood Co. v. Alps South LLC, 2:04-cv-1223 (S.D.Ohio Sept. 24, 2014)</td>
<td>Frost</td>
<td>Withheld material information and did not correct misrepresentation</td>
<td>“the most reasonable inference to be drawn from the evidence is that OWW acted with deceptive intent in misrepresenting the existence of evidence corroborating the [expert] testimony.”</td>
</tr>
</tbody>
</table>
Expert Declaration of Inventor Used In Support of Written Description

• As seen in the following slides

• Used expert declaration of one of the inventors.

• Used current version of MPEP and its characterization of Wertheim to argue for written description of both claims.

• USPTO rejected written description for the 75 mg.

• USPTO accepted written description for the 60 to 140 mg range.
Expert Declaration Dealing with §112 Issues (redacted)

From that factual evidence, the POSITA would have known to a reasonable certainty to derive the range of 60 to 140 mg recited in claim 27. Declaration, ¶ 22-23. That range is within the general range for active ingredient recited in the ‘731 patent. Declaration, ¶ 19. And the legal authority supporting the POSITA’s application of the facts in the ‘731 patent to derive the 60-140 mg range is ever stronger than that in In re Wertheim, 541 F.2d 257 (CCPA 1976), relied on by the Office in MPEP 2163.05 (III).
Expert Declaration Dealing with §112 Issues (redacted)

And if the Office does not accept expert testimony regarding why the POSITA would conclude that the co-inventors were in possession of the subject matter of claim 27, the Office must provide either an affidavit or detailed reason to explain it non-acceptance as set forth in MPEP 2163 II A:

... and MPEP § 2163.04 (“If applicant amends the claims and points out where and/or how the originally filed disclosure supports the amendment(s), and the examiner finds that the disclosure does not reasonably convey that the inventor had possession of the subject matter of the amendment at the time of the filing of the application, the examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims.”).
These declarations establish that there would have been no reasonable expectation of success of the claimed subject matter by showing:

(1) significant unexpected results in the teeth of strong skepticism by FDA experts and fulfillment of a long-felt need;

(2) the claimed subject matter is reasonably commensurate in scope with commercial success, coupled with a nexus between that commercial success and the merits of the claimed invention;

(3) the claimed subject matter relating to NMR chemical shifts and solvent used is neither necessarily present or inherently anticipated, nor in any way suggested, by the claims of the ‘699 patent relied on for the ODP rejection.
Expert Declaration Dealing with §103 (redacted)

In particular, the declaration supports the patentability of claims as amended, by providing expert opinion establishing significant, unexpected results for the claimed subject matter in the face of skepticism by experts in the field. To do so, the declaration establishes that the drug product capsules comprising achieved results which were significant and unexpected, i.e., they could not have been expected (reasonably predicted), given the previous, but largely inadequate, treatments for the in patients who are refractory to at least one prior systemic therapy.
Expert Declaration Dealing with §103 (redacted)

• More Commercial Success

And that is not all. The declaration of provides factual testimony supporting the patentability of claims by laying a foundation establishing significant commercial success of the capsules comprising 75 mg of such as purchase of rights to those capsules by other pharmaceutical companies, copying of those capsules by generic manufacturers, and significant market share and sales growth for the capsules, even though competing FDA-approved products are available. also lays the predicate for concluding that there is a nexus between the commercial success and the merits of the claimed inventions recited in claims 5 and 18. That is especially because market share has remained stable even though promotional costs have declined. declaration, ¶¶ 9-

And those claims are reasonably commensurate in scope with the commercial success. Independently of both testimony
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).
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 _______ 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 likely requires expert declaration to support assertions of unpatentability, but POR needs to make argument; not enough to just be in expert declaration.
Do Not Depend on Amending Claims!

- Motions to amend by canceling claims granted.
- **So far, 3 motions to amend by substituting claims permitted.**
  - IPR2013-00124; IPR2013-00402 and -403
- Patent Owners get caught requesting cancellation of claims and allowance of substitute claims without arguing patentability of original challenged claims because request to cancel granted and request to allow substitute claims usually denied, leaving Patent Owner with no claims.
  - Petitioner benefits from Patent Owner’s efforts!
  - Even if filing Motion to Amend claims, as Patent Owner, *substantively argue patentability* in POPR and POR.
• Motions to Amend

– Proof of patentability against ALL prior art, not just the references cited by the Petitioner?

– Burden on Patent Owner to show support in original specification and patentability of proposed claims over closest prior art.


– Study *Int’l Flavors*

– *SATA GmbH v. ANEST IWATA Corp.*, IPR2013-00111, FWD: “because there is no examination of the proposed claims, the patent owner must show that the subject matter recited is not taught or suggested by the prior art in general for us to determine if they comply with 35 U.S.C. §§ 102 and 103 and the rest of the patent statutes.”
IPR2013-00124
Int’l Flavors & Fragrances Inc. v. U.S.A., as represented by the Secretary Of Agriculture

• First ever motion to amend granted (not just canceled).

  – No POPR or POR filed.

  – IPR instituted June 27, 2013.

  – Patent Owner filed Motion to Amend on Sept. 30, 2013.
    • cancel all claims (1-26)
    • substitute new claims 27-45.

  – Unopposed; no oral hearing.

  – Granted request to cancel claims 1-26; Granted substitute claims 27-44, denied substitute claim 45 (Paper 12, May 20, 2014).
Old claim 1: A method for repelling arthropods, said method comprising treating an object or area with an arthropod repelling effective amount of at least one isolongifolenone analog and optionally a carrier or carrier material; wherein said at least one isolongifolenone analog has the following formula:

wherein R1 is hydrogen, an oxygen, a C1-10 alcohol, aldehyde, alkyl, ether, or esters of said alcohol with a C1-10 saturated or unsaturated, straight or branched acid and R2 is hydrogen, an oxygen, a C1-10 alcohol, aldehyde, alkyl, ether, or esters of said alcohol with a C1-10 saturated or unsaturated, straight or branched acid; optionally there is a double bond between carbons 5 and 6 and R2 is hydrogen.
Old claim 8: The method according to claim 1, wherein said at least one isolongifolenone analog is selected from the group consisting of

\[\text{and mixtures thereof.}\]
27. A method for repelling arthropods, said method comprising treating an object or area with an arthropod repelling effective amount of at least one isoolongifolenone analog and optionally a carrier or carrier material; wherein said at least one isoolongifolenone analog has the following formula: wherein $R_1$ is hydrogen, an oxygen, a $C_{1-10}$ alcohol, aldehyde, alkyl, ether, or esters of said alcohol with a $C_{1-10}$ saturated or unsaturated, straight or branched acid and $R_2$ is hydrogen, an oxygen, a $C_{1-10}$ alcohol, aldehyde, alkyl, ether, or esters of said alcohol with a $C_{1-10}$ saturated or unsaturated, straight or branched acid; optionally there is a double bond between carbons 5 and 6 and $R_2$ is hydrogen; wherein said at least one isoolongifolenone analog is selected from the group consisting of
Int’l Flavors & Fragrances Inc. v. U.S.A. (Secretary Of Agriculture)
Most Substitute Claims Permitted

• Int’l Flavors (con’t)
  • PTAB:
    • No broadening of scope.
    • Patent Owner showed written description support for amended claims.
      • “We conclude that Patent Owner has made a sufficient showing that each of proposed independent claims 27 and 45, as well as each of proposed dependent claims 28-44, as a whole, has written description support in the application as filed.”

• Patent Owner must overcome prima facie case of obviousness
  • “patent owner bears the burden of proof to demonstrate patentability of the proposed claims over the prior art in general, and thus entitlement to the proposed claims.... the patent owner should discuss, as well as present evidence, if appropriate, as to the level of ordinary skill in the art, and what was known regarding the features being relied upon to demonstrate patentability of the proposed claims.”
“Patent Owner provides several publications, as well as the Declaration of Dr. Aijun Zhang (Ex. 2005; “Zhang Declaration”), to demonstrate the level of ordinary skill in the art, as well as the unobviousness of features being relied upon to demonstrate patentability of the proposed claims. Although Patent Owner’s statement that Behan is the “apparent” closest prior art may appear conclusory, Patent Owner goes beyond that statement to demonstrate the level of ordinary skill in the art, as well as providing evidence regarding what would have been understood by the ordinary artisan as to those features being relied upon to demonstrate patentability of the proposed claim.”
Int’l Flavors & Fragrances Inc. v. U.S.A. (Secretary Of Agriculture)  
Most Substitute Claims Permitted

• **Int’l Flavors (con’t)**
  • **PTAB:**
    • Expert declaration: “the ordinary artisan would not expect that minor structural changes to a known insect, tick, or mite repellent would result in a modified compound having the same repellency as the parent compound. ...According to Dr. Zhang, such activity cannot be predicted based on structure alone, but must be determined by experiment.”

  • “Because the prior art does not provide a reason to modify isolongifolanone to arrive at the modified isolongifolanone compounds of proposed claim 27, nor does it provide a reasonable expectation that such modifications would result in a compound having the desired insect repellent activity, we conclude that the preponderance of the evidence supports the patentability of claim 27. As to dependent claims 28-44, because those claims incorporate all of the limitations of claim 27, they would be patentable for the same reasons.”
Comments

- Use case as guide in ex parte matters
- Way to win on nonobviousness at the PTO in ex parte matters, which of course should be strongly guided by PTAB.
- The claim:
  - “selected from the group consisting of” but better to say “wherein said at least one analog is chosen from…”
  - “and mixtures thereof” is strange in juxtaposition with “at least one” in context of this case
Second motion to amend granted (not just canceled).

June 28, 2013: Petition filed requesting cancellation of claims 1-12 of U.S. Pat. No. 8,312,226 on 2 grounds (anticipation and obviousness).

   ➢ Also did not file POR.

Jan. 2, 2014: IPR instituted on all challenged claims on both grounds.
Claim 1. A source-site appliance of a network memory, comprising:
– a communication interface configured to communicate with a source-site local area network; and
– a processor configured to intercept transmitted data sent from a source-site computer directed over a wide area network to a destination-site computer, to determine whether the transmitted data corresponds to locally accessible data of a destination-site appliance of the network memory coupled to the destination-site computer via a destination-site local area network, to generate an instruction based on the determination in order that the destination-site appliance obtain the transmitted data, and to transfer the instruction over the wide area network to the destination-site appliance.

Claim 4. The source-site appliance of claim 1 wherein the processor is further configured to send a portion of the transmitted data over the wide area network to the destination-site appliance.

- **Motion to amend opposed.**
  - Patent Owner did not show substitute claims patentable.
    - Arguments only based on prior art applied against original claims, not generally and against all art known to Patent Owner.
    - No expert declaration as support or at least to show level of ordinary skill in the art.

- Reply to opposition filed.
  - No requirement for expert declaration and motion informs on level of skill in the art.
  - Motion distinguishes against closest prior art of which Patent Owner is aware.

IPR2013-00402
2 Substitute Claims Permitted

Dec. 30, 2014: PTAB FWD
– Granted request to cancel claims 1–12;
– Granted motion to substitute claims 13 and 15; and
– Denied proposed substitute claims 14 and 16–18.

– No enlargement of scope.
  • “Each claim includes all of the limitations of the corresponding claim for which it is a substitute, and adds additional limitations. No limitations are removed.”

– Written description support.
  • Support in specification identified.
Dec. 30, 2014: PTAB FWD (con’t)

- Express claim construction from institution decision adopted.

- Patentability of substitute claims 13 and 15 shown.
  - Agreed that “Patent Owner addresses the prior art of which it is aware generally”
  - Expert declaration would have been helpful but not a requirement.
  - Motion sufficiently informs about level of skill in the art.
  - “Patent Owner’s explanation as to why the proposed substitute claims are different from pre-existing data de-duplication systems is persuasive and is supported by the evidence of record.”
  - “Patent Owner’s explanations regarding the prior art and why the proposed substitute claims allegedly would not have been obvious are supported by the record and are persuasive.”
  - Noted that Petitioner’s opposition did not “propose any specific combination of references that allegedly would have rendered obvious the proposed substitute claims as a whole.”
Dec. 30, 2014: PTAB FWD (con’t)

• Patentability of substitute claims 14 and 16 not shown.
  - Patent Owner did not show “a special circumstance for making the additional changes in proposed substitute claims 14 and 16, such as a patentable distinction over the parent proposed substitute claims.”
  - “To demonstrate a patentable distinction over parent proposed substitute claims 13 and 15, however, we must assume the parent claims to be prior art. ...Patent Owner’s analysis does not account for the parent claims.”

• Not convinced that substitute claims 17 and 18 recite patentable subject matter.
  - Patent Owner did not address in Motion to Amend.
June 28, 2013: Petition filed requesting cancellation of claims 1-27 of U.S. Pat. No. 8,370,583 on 3 grounds (anticipation and obviousness; same art as IPR2013-00402).

- Also did not file POR.

Jan. 2, 2014: IPR instituted on all challenged claims on 2 of 3 grounds.
IPR2013-00403
Sample Original Claim

• Claim 1. A network memory system comprising:
  – a source-site appliance comprising a first processor and a first memory device, and configured to be coupled to a source-site computer via a source-site local area network; and
  – a destination-site appliance comprising a second processor and a second memory device, and configured to be coupled to a destination-site computer via a destination-site local area network, the source-site computer in communication with the destination-site computer via a wide area network;
  – wherein the source-site appliance is configured to identify locally accessible data of the destination-site appliance, to intercept transmitted data sent from the source-site computer, to perform a determination of whether a portion of the transmitted data corresponds to the locally accessible data of the destination-site appliance, to generate an instruction based on the determination, and to send the instruction to the destination-site appliance over the wide area network;
  – and wherein the destination-site appliance is configured to receive the instruction from the source-site appliance over the wide area network, to process the instruction to obtain the transmitted data locally if the transmitted data corresponds to the locally accessible data of the destination-site appliance, and to transfer the transmitted data to the destination-site computer.
IPR2013-00403

• **Motion to amend opposed.**
  – Patent Owner did not show substitute claims patentable.
    • Arguments only based on prior art applied against original claims, not generally and against all art known to Patent Owner.
    • No expert declaration as support or at least to show level of ordinary skill in the art.

• Reply to opposition filed.
  – No requirement for expert declaration and motion informs on level of skill in the art.
  – Motion distinguishes against closest prior art of which Patent Owner is aware.

• Oral hearing held Sept. 30, 2014.
IPR2013-00403
2 Substitute Claims Permitted

• Dec. 30, 2014: PTAB FWD
  – Granted request to cancel claims 1–27;
  – Granted motion to substitute claims 28 and 30; and
  – Denied proposed substitute claims 29 and 31-33.

  – No enlargement of scope.
    • “Each claim includes all of the limitations of the corresponding claim for which it is a substitute, and adds additional limitations. No limitations are removed.”

  – Written description support.
    • Support in specification identified.
IPR2013-00402
2 Substitute Claims Permitted

• Dec. 30, 2014: PTAB FWD (con’t)
  – Express claim construction from institution decision adopted.
  
  – Patentability of substitute claims 28 and 30 shown.
    • Agreed that “Patent Owner addresses the prior art of which it is aware generally”
    • Expert declaration would have been helpful but not a requirement.
    • Motion sufficiently informs about level of skill in the art.
    • “Patent Owner’s explanation as to why the proposed substitute claims are different from pre-existing data de-duplication systems is persuasive and is supported by the evidence of record.”
    • “Patent Owner’s explanations regarding the prior art and why the proposed substitute claims allegedly would not have been obvious are supported by the record and are persuasive.”
    • Noted that Petitioner’s opposition did not “propose any specific combination of references that allegedly would have rendered obvious the proposed substitute claims as a whole.”

4 Substitute Claims Not Permitted

• Dec. 30, 2014: PTAB FWD (con’t)
  – Patentability of substitute claims 29 and 31 not shown.
  • “Patent Owner has not shown a patentable distinction between proposed substitute claims 29 and 31 and their parent proposed substitute claims 28 and 30, and has not shown any other special circumstance for adding the “another copy” limitation to proposed substitute claims 29 and 31. The “another copy” limitation, therefore, is not responsive to a ground of unpatentability involved in the trial. For the same reasons, proposed substitute claims 29 and 31 amount to a second proposed substitute claim (in addition to the parent proposed substitute claims 28 and 30) for claims 2 and 13, and Patent Owner has not demonstrated a sufficient need for exceeding the presumption that only one substitute claim is needed to replace a challenged claim.”
IPR2013-00402
4 Substitute Claims Not Permitted

• Dec. 30, 2014: PTAB FWD (con’t)
  – Patent Owner did not meet burden to show patentability of proposed substitute claims 32 and 33.

• “Patent Owner has not provided a proposed claim interpretation for certain limitations in the claims expressed in means-plus-function format under 35 U.S.C. § 112, sixth paragraph.”
  – PTAB expressly indicated necessary.
  – No POPR or POR with any proposed claim constructions.

• Patent Owner’s “analysis [in the Motion to Amend] of the two additional means-plus-function limitations in proposed substitute claim 32 is deficient.”
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.”
So Far, Objective Evidence of Nonobviousness Failing

• Objective evidence of nonobviousness must have nexus.

• Patent Owners are not linking the objective evidence of obviousness to the merits of the claimed invention; according to Irving, Tierney agreed in Dallas.

• For example, 29 IPRs relating to bio/pharm/chemical technology where objective evidence of nonobviousness was raised and a Final Written Decision was issued were analyzed (Finnegan, as of Feb. 10, 2015).
  – Of the 29, objective evidence of nonobviousness was not once considered persuasive.
    • In 24, no claims survived (held unpatentable by PTAB or canceled by the Patent Owner).
    • 5 had “mixed results”: some claims held unpatentable, some claims survived. The objective evidence of nonobviousness, however, was not the deciding factor in the surviving claims’ fate.
    • In 1 case, all instituted claims survived. The objective evidence of nonobviousness, however, was not the deciding factor in the surviving claims’ fate.
Though Objective Evidence in “Record” Successfully Used to Get Petition Denied


  - Patent Owner requested PTAB 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.
PGRs
PGRs filed as of Feb. 12, 2015

- **Larose Industries, LLC V. Choon’s Design Inc.,** PGR2014-00008, filed Aug. 5, 2014
  - POPR filed Nov. 5, 2014.
  - Terminated Jan. 5, 2015, following settlement.

  - Terminated Nov. 24, 2014, prior to institution decision.


First Termination of a PGR: All 6 Challenged Claims Survived Unchanged!

  - Second ever filed PGR (at least one patent claim with an effective filing date after March 15, 2013) and the first ever pharma PGR.
    - Patent relates to Helsinn’s Aloxi® drug product for reducing nausea and vomiting in cancer patients.
    - The US’s first ever JMM patent that was actually intended to be a JMM.
    - Tom represented Helsinn.

- Petition attacked all claims under § 112.

- Settled Nov. 24, 2014, before institution decision, and before filing POPR.
Thank You!

Contact Information:

Tom Irving
[mailto:tom.irving@finnegan.com](mailto:tom.irving@finnegan.com)
202.408.4082

Anthony Gutowski
[mailto:tony.gutowski@finnegan.com](mailto:tony.gutowski@finnegan.com)
571.203.2774

John Mulcahy
[mailto:john.mulcahy@finnegan.com](mailto:john.mulcahy@finnegan.com)
571.203.2751