The Impact of IPRs and Other Post-Grant Proceedings on BioPharma

Eldora Ellison, Ph.D. and Eric Steffe

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Introduction to Sterne Kessler

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Director
J.D., Georgetown University
Ph.D., Biochemistry, Molecular and Cell Biology, Cornell University
B.S., Biology, Haverford College
• Extensive experience in inter partes patent matters (55 IPR proceedings), patent interferences, patent reexaminations, patent prosecution, and 22 years of patent law experience.
• Co-chair, SKGF Patent Office Litigation Practice; Editor of Patent Office Litigation treatise

Eric K. Steffe

Director
J.D., George Mason University
M.S., Molecular Genetics, University of Georgia
B.S., Physics, University of Georgia
• Mr. Steffe has extensive expertise in inter partes review proceedings, patent reexaminations, managing complicated multi-family patent portfolios protecting pipeline and FDA-approved biotech products, preserving freedom to operate, interferences, and the IP strategy.
• Chair, SKGF Patent Prosecution Practice; frequent author and speaker.
• The Legal 500 recognized in 2015 Mr. Steffe as a “Leading Lawyer” in the U.S. for his patent prosecution work; a distinction awarded to seven other attorneys in the entire country.
• Who’s Who Legal: Patents 2016
The Rise of PTO Litigation (3/25/16)

- 4,254 IPR petitions
- 428 CBM petitions
- 21 PGR petitions
# PTAB Technology Breakdown

<table>
<thead>
<tr>
<th>Technology</th>
<th># Petitions</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elec./Computer</td>
<td>2800</td>
<td>60%</td>
</tr>
<tr>
<td>Mech./Bus Methods</td>
<td>1192</td>
<td>25%</td>
</tr>
<tr>
<td>Bio/Pharma</td>
<td>401</td>
<td>9%</td>
</tr>
<tr>
<td>Chemical</td>
<td>292</td>
<td>6%</td>
</tr>
<tr>
<td>Design</td>
<td>15</td>
<td>&lt;1%</td>
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37 relate to **biologic products or methods of use**
- 14 appear to involve a biosimilar
- 8 denied institution
- 19 pending
- 4 final written decisions
- 6 settled or otherwise abandoned
PTAB Institution Outcomes (3/25/16)

• Parties reached a settlement prior to a decision on institution in 503 IPRs and 44 CBMs
• The Board institutes trial for ~63% of challenged claims in IPRs.

<table>
<thead>
<tr>
<th>Period</th>
<th>Institution Rate</th>
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<tbody>
<tr>
<td>FY2012-2013</td>
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<tr>
<td>1st Quarter FY2014</td>
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<td>2nd Quarter FY2014</td>
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<tr>
<td>4th Quarter FY2014</td>
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<tr>
<td>1st Quarter FY2015</td>
<td>77.7%</td>
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<tr>
<td>2nd Quarter FY2015</td>
<td>68.8%</td>
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<td>3rd Quarter FY2015</td>
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<tr>
<td>4th Quarter FY2015</td>
<td>62.5%</td>
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<tr>
<td>1st Quarter FY2016</td>
<td>69.1%</td>
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<tr>
<td>2nd Quarter FY2016</td>
<td>64.8%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>71.0%</strong></td>
</tr>
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</table>
TC1600 Compared to All IPRs

• At Institution Decision:
  • TC1600: 65% of proceedings instituted; 60% of claims instituted
  • Overall: 71% of proceedings instituted; 63% of claims instituted

• At Final Written Decision (56 FWDs):
  • TC1600: 56% of instituted claims canceled
  • Overall: 83% of instituted claims canceled

• 28% of IPRs settle
## Top Parties in TC1600 IPRs

<table>
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<tr>
<th>Petitioner</th>
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<tr>
<td>Mylan</td>
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<tr>
<td>Coalition for Affordable Drugs/Kyle Bass</td>
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<tr>
<td>Lupin</td>
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<td>Apotex</td>
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<tr>
<td>Amneal</td>
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<tr>
<td>Dr. Reddy's Laboratories</td>
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<tr>
<td>BioReference Laboratories</td>
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<td>Praxair Distribution</td>
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<table>
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<th>Patent Owner</th>
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<td>Cubist Pharmaceuticals</td>
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<td>Procter &amp; Gamble</td>
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<td>Ino Theapeutics</td>
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<td>Allergan</td>
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<td>DepoMed</td>
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<td>Novartis</td>
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<tr>
<td>Genentech</td>
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<td>Pozen</td>
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New rules finalized April 1st

- Effective May 2, 2016; applies to all petitions filed thereafter, any pending preliminary proceedings, and any ongoing trials.

- Patent owners may submit new testimonial evidence along with the Patent Owner Preliminary Response (POPR)
  - Petitioner may have an opportunity to cross-examine the declarant and, with “good cause,” submit a reply
  - Disputed “material fact[s] created by such testimonial evidence” will be decided in favor of the petitioner pre-institution

- Use the Phillips standard for claims that will expire during a proceeding; use BRI for other claims

- Rule 11-like certifications; word counts
Kyle Bass IPR impact on Acorda stock price
PGRs in the life sciences

• **22** PGR petitions, **10** in TC1600 or 1700

  • Higher percentage of PGR petitions are in TC1600 & 1700 (**46%**) than IPR petitions (**15%**)

• Thus far, higher institution rates than IPR:
  • 10 of 11 PGRs instituted
  • Instituted on 87% of the challenged claims (vs 63% in IPR)
Exemplary PGR decisions

- **Inguran, LLC d/b/a Sexing Technologies v. Premium Genetics (UK) Ltd.,** PGR2015-00017, Paper 8 (December 22, 2015)
  - Analyzed priority benefit to determine PGR eligibility

  - Petitioner bears the burden of establishing PGR eligibility, including when eligibility depends on a priority challenge

- **Front Row Technologies, LLC v. MLB Advanced Media, L.P.,** PGR2015-00023, Paper 8 (February 22, 2016)
  - The relevant date for eligibility is the “effective filing date” of the patent, not whether a later-filed amendment lacks support in the specification
Appeals to the Federal Circuit

- 50% of AIA trials reach a FWD; of those, 50-60% are appealed
- CAFC docket has roughly doubled; ~390 appealed IPRs
- ~80% of appeals are by patent owners

### Cases Submitted to the Federal Circuit

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<tr>
<th>Case Category</th>
<th>Decided</th>
<th>Affirmed</th>
<th>Affirmed Fed. Cir. R. 36</th>
<th>Affirmed Non-Precedential</th>
<th>Affirmed Precedential</th>
<th>Remanded</th>
<th>Reversed</th>
<th>Dismissed</th>
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<td>Affirmed Non-Precedential</td>
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<td>17.3%</td>
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<td>9</td>
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<tr>
<td>Reversed</td>
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<td>6</td>
<td>6.3%</td>
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<td>Dismissed</td>
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<td>12</td>
</tr>
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</table>

Notable Decisions on Reviewability

- **In re Cuozzo Speed Technologies**, LLC, 793 F.3d 1268 (Fed. Cir. 2015)
  - Upheld BRI as appropriate claim construction standard in post-grant proceedings
  - Institution decision is not appealable by statute, even from a final decision
  - SCOTUS argument is 4/25/16
- **St. Jude Med., Inc. v. Volcano Corp.**, 749 F.3d 1373 (Fed. Cir. 2014)
  - The Board’s decision on institution is final and non-appealable by statute
  - There is no interlocutory appeal of an institution decision to the Federal Circuit
- **Versata Dev. Grp., Inc. v. SAP Am., Inc.**, 793 F.3d 1306 (Fed. Cir. 2015)
  - Institution decision *is* reviewable if Board’s “invalidation authority” is implicated
  - Has since been applied in the limited context of covered business method review
- **Achates Reference Publ’g, Inc. v. Apple Inc.**, 803 F.3d 652 (Fed. Cir. 2015)
  - Board’s determination regarding the filing bar of 315(b) is not appealable
  - Even if the 315(b) determination is addressed in the final written decision
Notable Decisions on Amendment

- **Microsoft Corp. v. Proxyconn, Inc.,** 789 F.3d 1292 (Fed. Cir. 2015)
  - The Patent Office’s amendment regulation is reasonable, and so is the Board’s practice of requiring the patent owner to overcome all art in the petition.

- **Prolitec, Inc. v. Scentair Techs., Inc.,** 807 F.3d 1353 (Fed. Cir. 2015)
  - The amendment standard in practice may include a requirement to overcome all art cited in the patent’s file history, as well as all art cited in the petition.

- **Nike, Inc. v. Adidas AG,** 812 F.3d 1326, 1351 (Fed. Cir. 2016)
  - It is not unreasonable to require the patent owner to comply with a “duty of candor” and confirm that it has addressed all art “known to the patent owner.”

As a practical matter, the Board has decided **128 motions** to amend on the merits. Of those decisions, only 1 has been granted in full (that motion was unopposed), and four have been granted in part (two of which are related). At best, that is a **4% success rate.** Many practitioners have commented that they have stopped pursuing such motions as a result.
Other Notable Decisions

  - Rejecting argument that Board imposed an “overly strict nexus requirement” to find that evidence of objective indicia was not sufficiently tied to the “novel features”

  - The estoppel provisions do not reach grounds denied by the Board as “redundant” at the institution stage, so petitioner is not statutorily estopped from raising them again

  - Notwithstanding applicability of the BRI, claim interpretation still “must be reasonable in light of the claims and specification”—reversing Board’s claim construction

Notably, patent owners have been most successful before the Federal Circuit on issues of claim construction, which get de novo review.
Comments from USPTO Officials on Impact on Patent Quality and Prosecution

- On April 11, 2016, Chief APJ Nathan Kelley: hopes that what is going on at the Board directly impacts how new patents are prosecuted going forward.

- He urged prosecutors to adapt accordingly.

- On April 6, 2016, Patent Office Deputy Commissioner for Patent Quality, Valencia Martin-Wallace, stated that the agency is now trying to arm examiners with decisions from AIA trials.

How does this impact strategic portfolio building and patent prosecution?
Strategic Implications for Discussion

- The Board is constructively not permitting amendments during post-grant proceedings
  - What are the new best practices for claim drafting?
  - Does it impact the number of references submitted in IDSs?

- The Board has deferred to claim constructions provided in glossaries
  - *ZTE v. ContentGuard*, IPR2013-00133, Paper 61 (July 1, 2014) ("By setting forth the term in a glossary and using the verb ‘is’ following [the term] in the second sentence, the specification sets forth an explicit definition...")
  - Consider using a glossary to unambiguously define claim terms that are critical
  - Consider claim construction issues *during* prosecution
Strategic Implications for Discussion

- PTAB is strict in considering objective indicia of nonobviousness (requiring strict nexus, comparison to closest prior art and commensurate in scope).
  - Beware basing important patents on “unexpected or superior” results that Board may not deem rigorous
  - Consider impact on obtaining downstream patents (dosing, regimens, pK, manufacturing/process patents, formulations, etc.) arising out of clinical trials
  - Consider expending considerable effort selling to management the need to
    - Strategically perform experiments that may demonstrate “surprising criticalities” to support downstream inventions
    - Coordinate label language with patent efforts
    - Minimize the creation of “self-prior art”
      - publications (including clinicaltrials.gov)
      - unnecessary laundry lists when drafting applications
      - No collaborations or work with investigators absent tight confidentiality agreements
Strategic Implications Discussion

- The Board is analyzing **priority benefit** claims to determine whether intervening art can be applied, and whether patents are eligible for PGR
  - File transition applications with very narrow claims at the outset to increase chance of keeping it out of a PGR
  - Consider whether filing numerous CONs may open the door for an intervening prior art attack
Strategic Implications Discussion

• What are best practices for **raising obstacles** to a would-be IPR/PGR petitioner?

  – Create **patent thicket** to extent possible around product including separate patents only including claims specifically directed to approved product

  • Can serve as an IPR deterrent, e.g., against mid-sized generics and NPEs
  • But beware of creating **ODP** issues (**Gilead**) and truncating important PTA and be aware of the complicated interplay of PTE, PTA and ODP

• Expedited prosecution (e.g., Track One) and judicious use of reissue applications to gain additional patents before being subject to **patent owner estoppel**
IPR Impact on Best Practices

- Should the current best practice of keeping patent file histories as lean as possible due to concerns about discovery in district court litigation be revisited in view of the procedural realities of IPRs?
  - Pros of a developed record
    - Certain evidence much easier to submit during ex parte prosecution than in a contested case -- e.g., Rule 131 “swear behind” evidence, Katz declarations, Rule 130 prior art disqualifications
    - Can significantly increase barrier to entry via IPR/PGR
    - Patent Owner Preliminary Response can refer to evidence already of record
  - Cons of a developed record
    - Increases cost of ex parte prosecution
    - Issues not always evident at ex parte prosecution stage
    - Tension with best practice for district court litigation
IPR impact on Best Practices

• Other considerations for patent owners
  • Consider retaining former employees who are inventors of important company patents as consultants
    – Board has held (e.g., *Redline Detection v. Star Envirotech*) that assignor estoppel does not apply to IPRs
      » Is it better to have on payroll as opposed to possibility of participating in IPR on behalf of competitor?
    – “Consulting experts” need not be disclosed and are not subject to deposition.
Thank You!

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