Trends in Post-Grant Proceedings

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Attorney Advertising
Empirical Evidence on IPRs Against Orange Book-Listed Patents
IPRs Filed Through September 4, 2015

Total: 3,467

OB-Listed IPRs
168 (4.85%)

Non-OB Listed IPRs
3,299 (95.15%)
OB IPRs by Petitioner Type

Total: 168

128 (76.19%) Generic Manufacturers

32 (19.05%) Investment Firms

7 (4.16%) Brand Manufacturers

1 (0.60%) Public Interest Org.
OB IPRs by Petitioner

- Amneal: 12
- Apotex: 15
- ADROCA: 31
- Wockhardt Bio: 6
- Praxair: 10
- Mylan: 12
- Lupin: 9
- Dr. Reddy's: 9
- Others: 11
- Endo: 6
- Prescience: 6
OB IPRs by Patent Owner

- Others: 104
- Cubist: 13
- Celgene: 5
- Alcon: 5
- DepoMed: 9
- INO: 10
- Jazz: 9
- Novartis: 7
- Senju: 6

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OB IPRs by Patent Status

- Pending: 84 (50.00%)
- Instituted: 48 (28.57%)
- Not Instituted: 36 (21.43%)

Total: 168
Instituted OB IPRs by Status

- **Awaiting Trial**: 25
- **FWD: Claims Patentable**: 11
- **FWD: Claims Canceled**: 1
- **Settled**: 11

**Total**: 48
Time to Institution Decision

Days to Institution Decision

Date of Filing (Oct. 2012 - May 2015)
Rate of Petitions

Number of Petitions Per Month (Sept. 2012 - Aug. 2015)
Extrapolation/Conclusions

- Lack of past success
- Small number of repeat petitioners
  - Mainly generics and ADROCA
- Diverse patent holders
- OB IPRs on the rise
  - ~20 IPRs/mo.
Impact of *Amgen v. Sandoz* on Biosimilar IPRs
BPCIA Act

• Signed into law in 2010
• Implemented a rubric for biosimilar approval
• Shares similarities with ANDA approval process
• Created a “patent dance” for resolving patent disputes
BPCIA – Patent Dance

- 351(k) application (aBLA) is accepted by FDA
- 20 days later applicant provides aBLA to Reference Product Sponsor (RPS)
- 60 days later exchange of patent lists begins
- Culminates in a patent infringement action filed against the aBLA applicant
BPCIA – Why Bother?

Exclusivity

- RPS and Applicant both get periods of exclusivity for engaging in the process
- It is different from the small molecule world
BPCIA – Name Brand Exclusivity

Exclusivity periods for name brand:

• No aBLA can be filed until 4 years after Reference Product Approval

• No approval of aBLA for 12 years after RP Approval
BPCIA – Biosimilar Exclusivity

• More complicated
• The earlier of:
  • 1 year after first sale of first biosimilar, or
  • 18 months after final decision or dismissal of litigation as part of “patent dance”
• 42 months after approval if “patent dance” case is still pending after 42 months
• 18 months after approval if not sued under “patent dance” rules
Amgen v. Sandoz

- Sandoz filed an ABLA for Neupogen® (filgrastim) and notified Amgen of the filing in what it believed to be its 180 day marketing notice
  - However, it did not disclose the aBLA to Amgen
- Amgen sued Sandoz on claims it violated the BPCIA and for patent infringement
Amgen v. Sandoz

Federal Circuit was presented with two issues related to interpretation of BPCIA

• Is the disclosure of the aBLA mandatory
• Whether an applicant can give the 180-day notice to market in advance of FDA approval of its application
• Short answer: no to both
What Happens Now?

- Biosimilar applicants can choose not to dance
- RPS is given 180 days of exclusivity post biosimilar approval
Strategies for Success in Defending IPRs for Life Sciences Companies
Strategies for Patent Owner

Before Post-Grant Petitions are filed – consider:

- Scope of claims during prosecution
- Is there better/closer prior art that could be found
- What claim strategies can be employed
- Claim construction issues
- Keeping applications pending
Strategies for Patent Owner

Before Post-Grant Petitions are filed – consider:

• Evaluation priority date of claims
  • Disclosure
  • Inventorship
• For high value portfolios – consider informal ranking
• Are there available experts I can retain
• Internal education – very important
Strategies for Patent Owner

When Post-Grant Petitions are filed – first steps:

- Mandatory notices – 21 days after service
- Ownership evaluation
- Determination of who should be listed as RPI and Privies
Strategies for Patent Owner

When Post-Grant Petitions are filed – consider:

• Engage expert (if not already engaged)
• Sober review of the prior art cited
• Claim constructions by petitioner
• Commercial considerations of claims and positions
Strategies for Patent Owner

When Post-Grant Petitions are filed – consider:

- Strategic review of challenged claims
- Considerations of Real Party of Interest and Privity Issues for Petitioner
- Consideration of potential settlement
Strategies for Patent Owner

Considerations on Preliminary Responses

- To file or not to file
- Declaration evidence (proposed rules)
- Request Discovery for RPI or Privity Issues?
- What to argue in Preliminary Response
  - Choose arguments that matter
  - Identify procedural deficiencies not factual disputes
Strategies for Patent Owner

Considerations on Depositing Petitioner’s Declarant

• Depose? Almost certainly yes
• Nature of Cross Examination
• Narrow, focused questions
• Have outline of Response before deposition
• Be mindful of (but not limited to) the declaration testimony
Strategies for Patent Owner

Preparing PO Response

- Consider if the burden of production has shifted (e.g., need to antedate a reference)
- Address claim construction of Board and petitioner as needed
- Focus on positions taken by petitioner as addressed in the DI
- Consider missing limitations and combinability
- Are the secondary considerations to be presented
- Develop a credible approach toward patentability
- Focus on technical merits
Strategies for Patent Owner

Considerations on Defending PO Declarant

• Prepare the expert on the full range of issues
• Ensure that the Expert understands
  • The objectives of the PO
  • That the deposition is cross examination
• Frame issues positively, not defensively
• Consider using multiple declarations as needed
• Don’t file a declaration for someone who cannot be deposed*
Strategies for Patent Owner

Considerations on Observations on Cross Examinations

• Fewer observations that are focused is more powerful than more that are diffuse
• If the significant isn’t apparent in a few words consider not included
• Consider the whole quote in context – not the sound bit

Considerations on Motions to Exclude

• Really evaluate whether one should be filed
• What purpose it could serve
• Observations on reading the denials to MTE
Strategies for Patent Owner

Strategies for Oral Hearing

• Prepare, prepare, prepare
• Work on sequencing and structure in your slides
• Don’t get too tied to slides
• Answer questions completely
• Acknowledge what is in the prior art – don’t pretend it doesn’t exist
• State your case affirmatively – avoid seeming to rely on the burden of proof
• Have fun, you’re the Patent Owner
Questions?