

Trends in Post-Grant Proceedings

David Cavanaugh, Partner, Chair, Post-Grant Proceedings, WilmerHale

Jacob Oyloe, Corporate Counsel, IP, MedImmune

Jacob Sherkow, Associate Professor, Innovation Center for Law and Technology, New York Law School

Colleen Superko, Partner, WilmerHale

Attorney Advertising

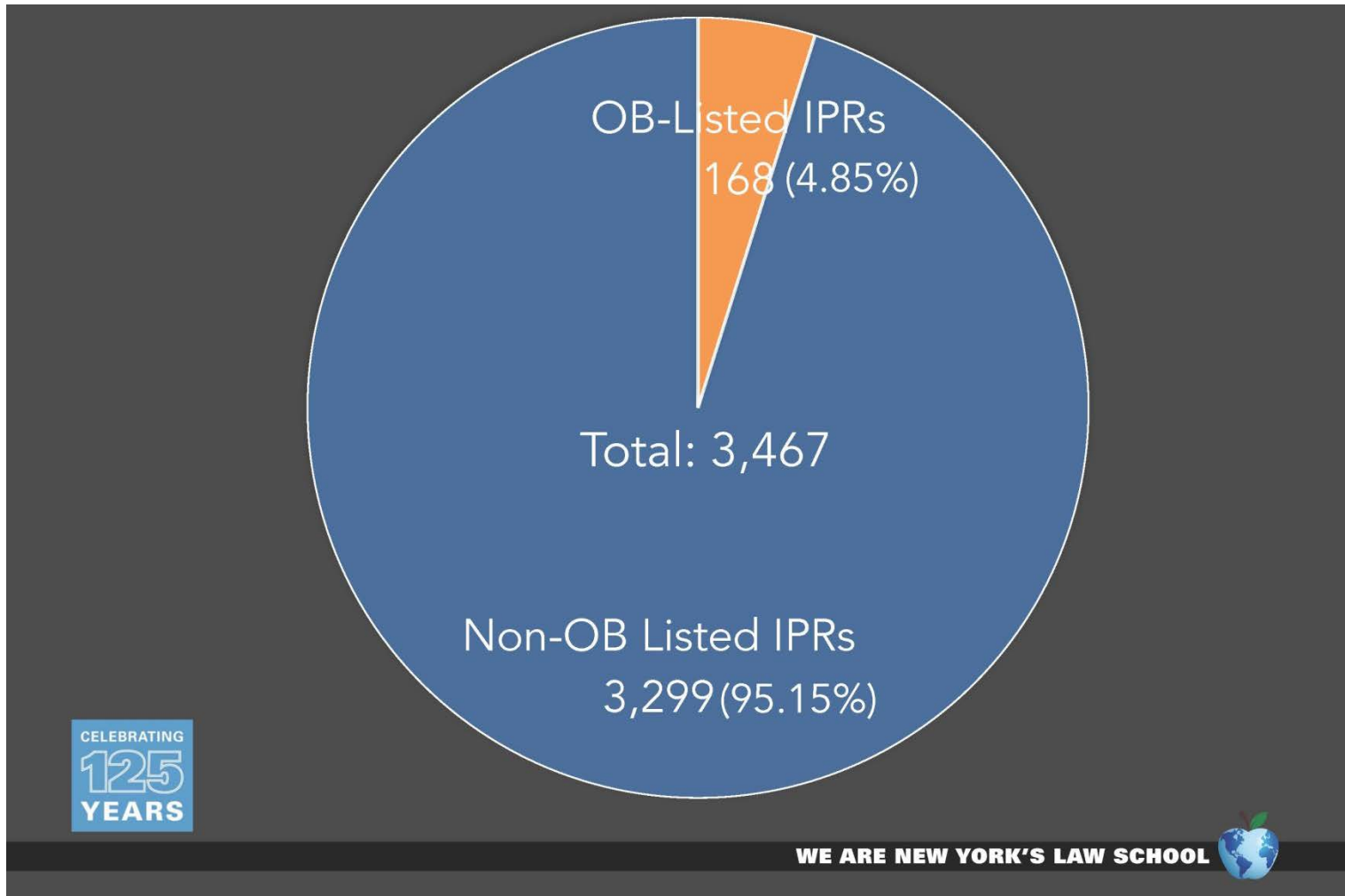


WILMER CUTLER PICKERING HALE AND DORR LLP®



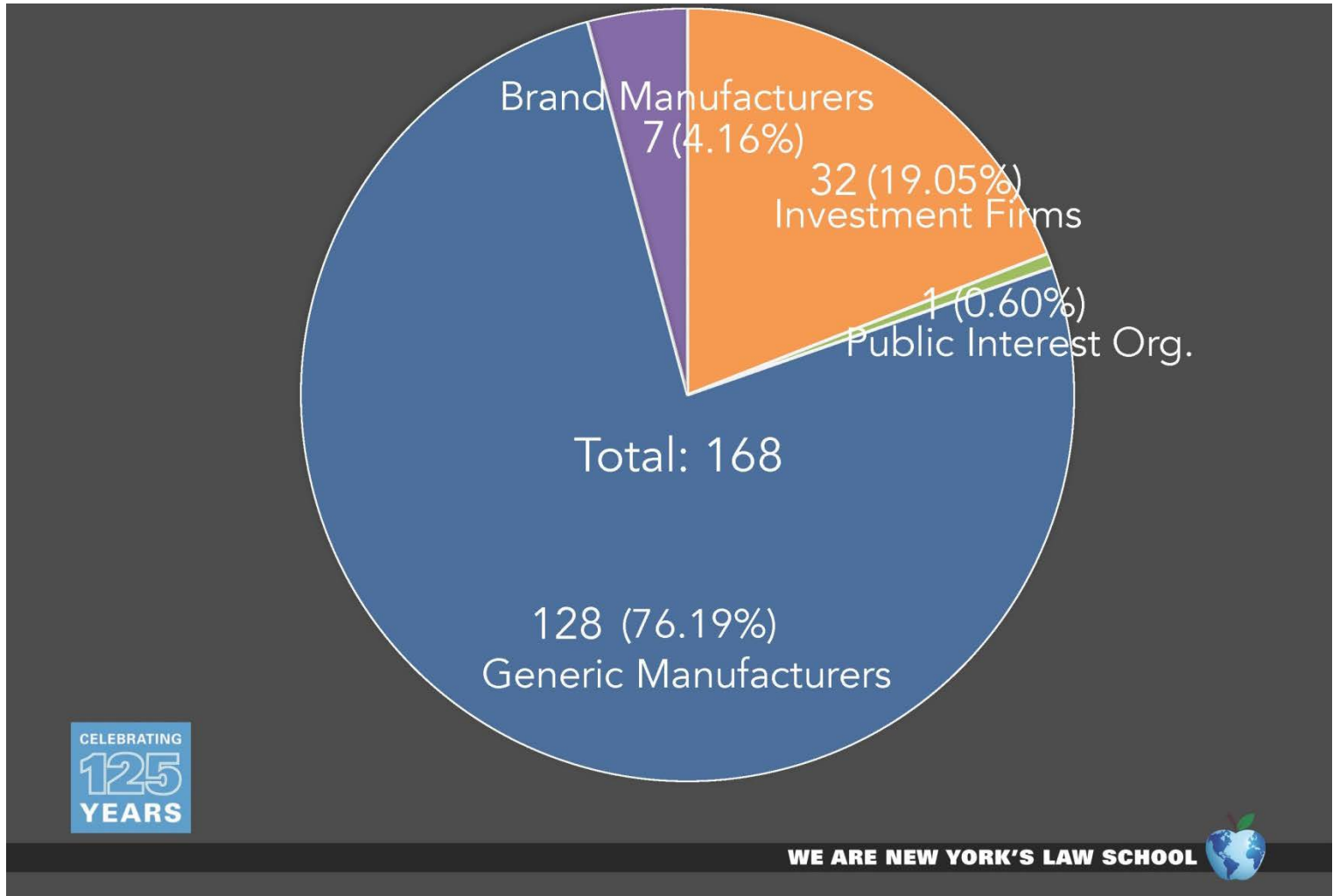
Empirical Evidence on IPRs Against Orange Book-Listed Patents

IPRs Filed Through September 4, 2015



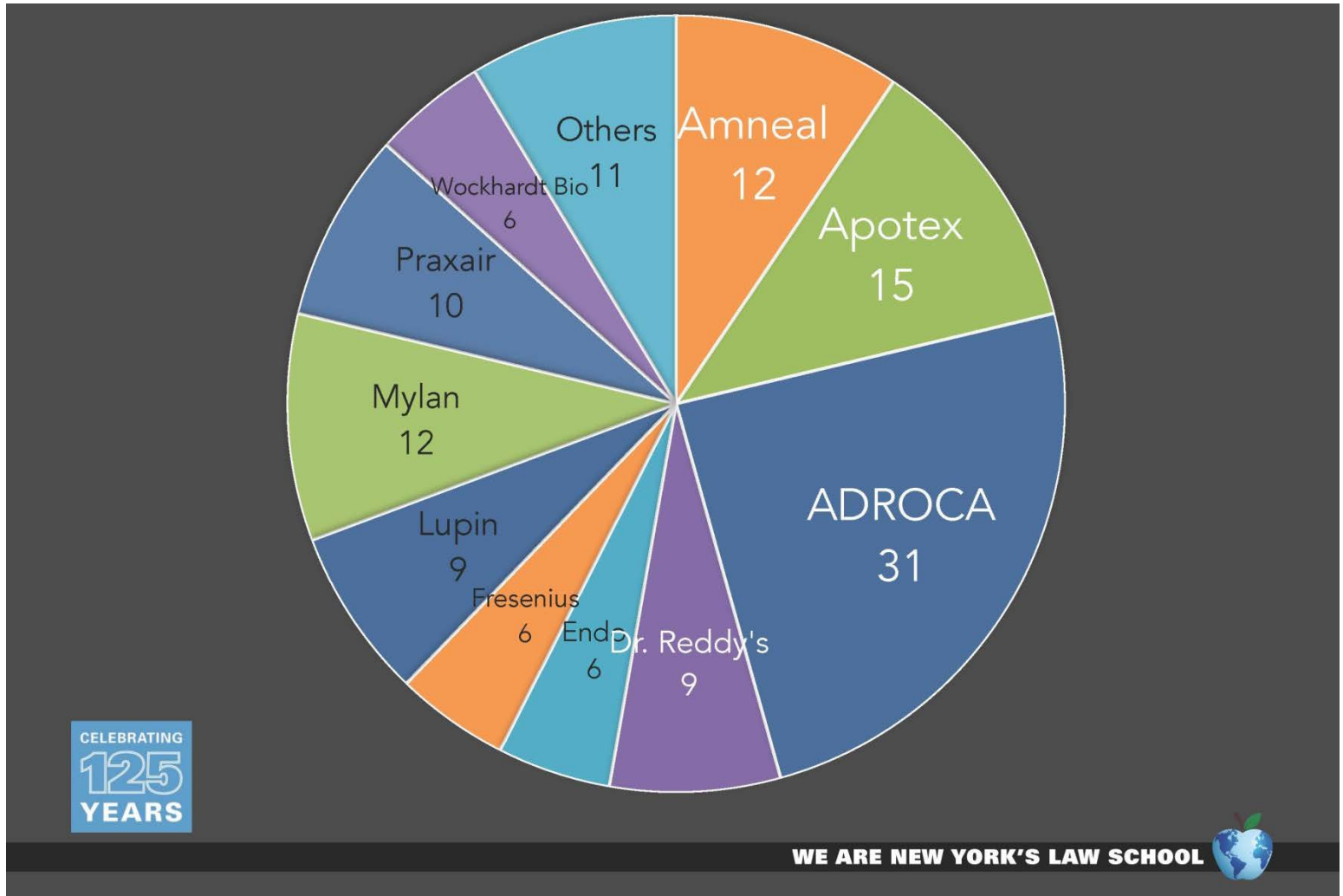


OB IPRs by Petitioner Type



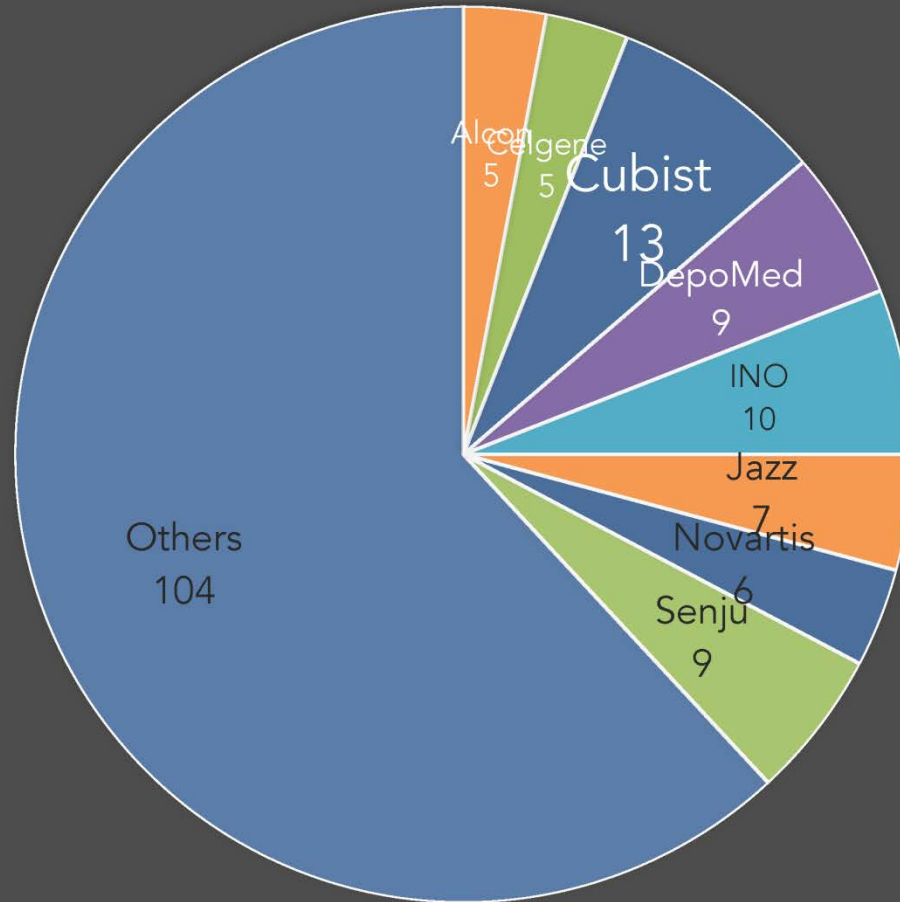


OB IPRs by Petitioner





OB IPRs by Patent Owner

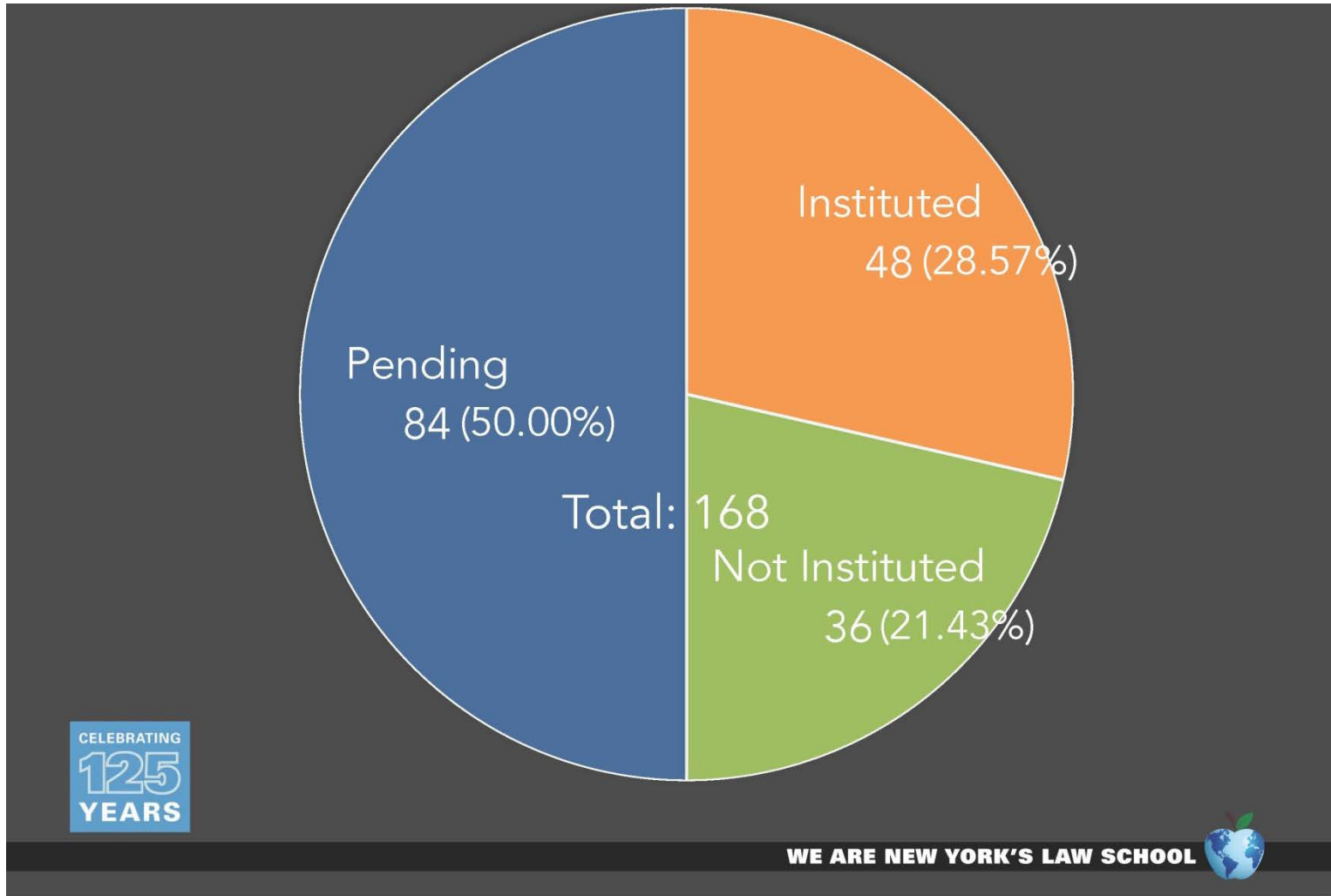


WE ARE NEW YORK'S LAW SCHOOL



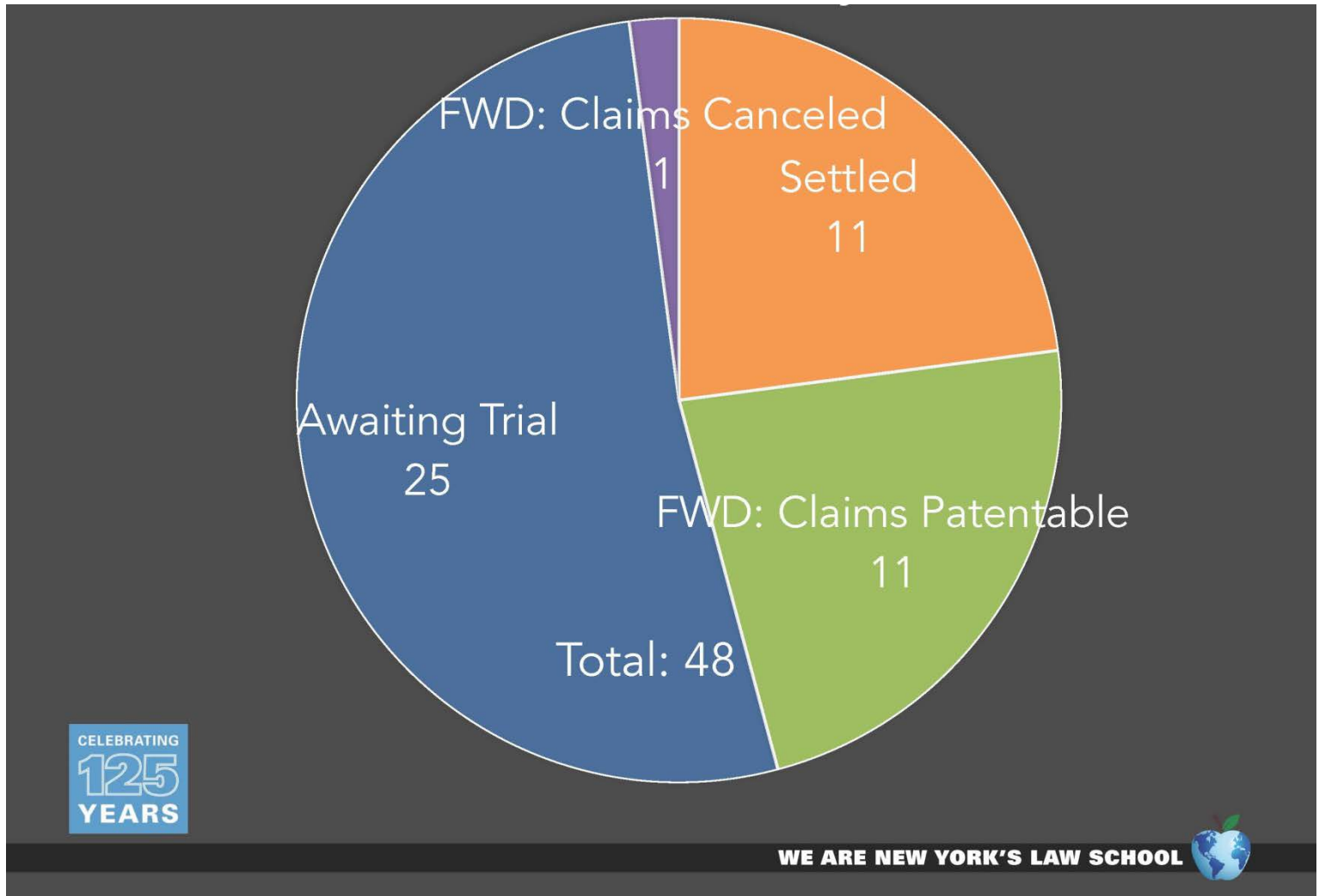


OB IPRs by Patent Status



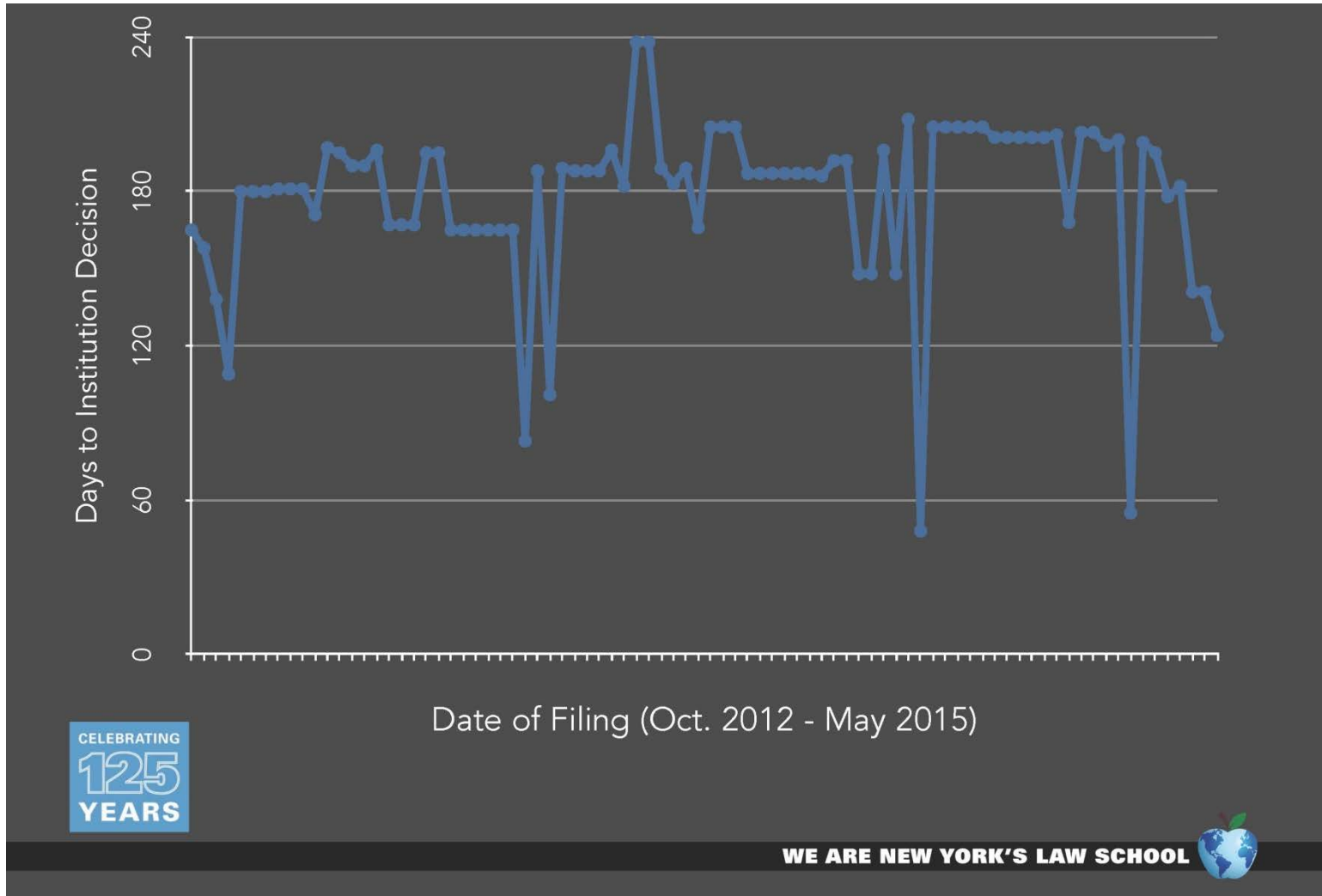


Instituted OB IPRs by Status



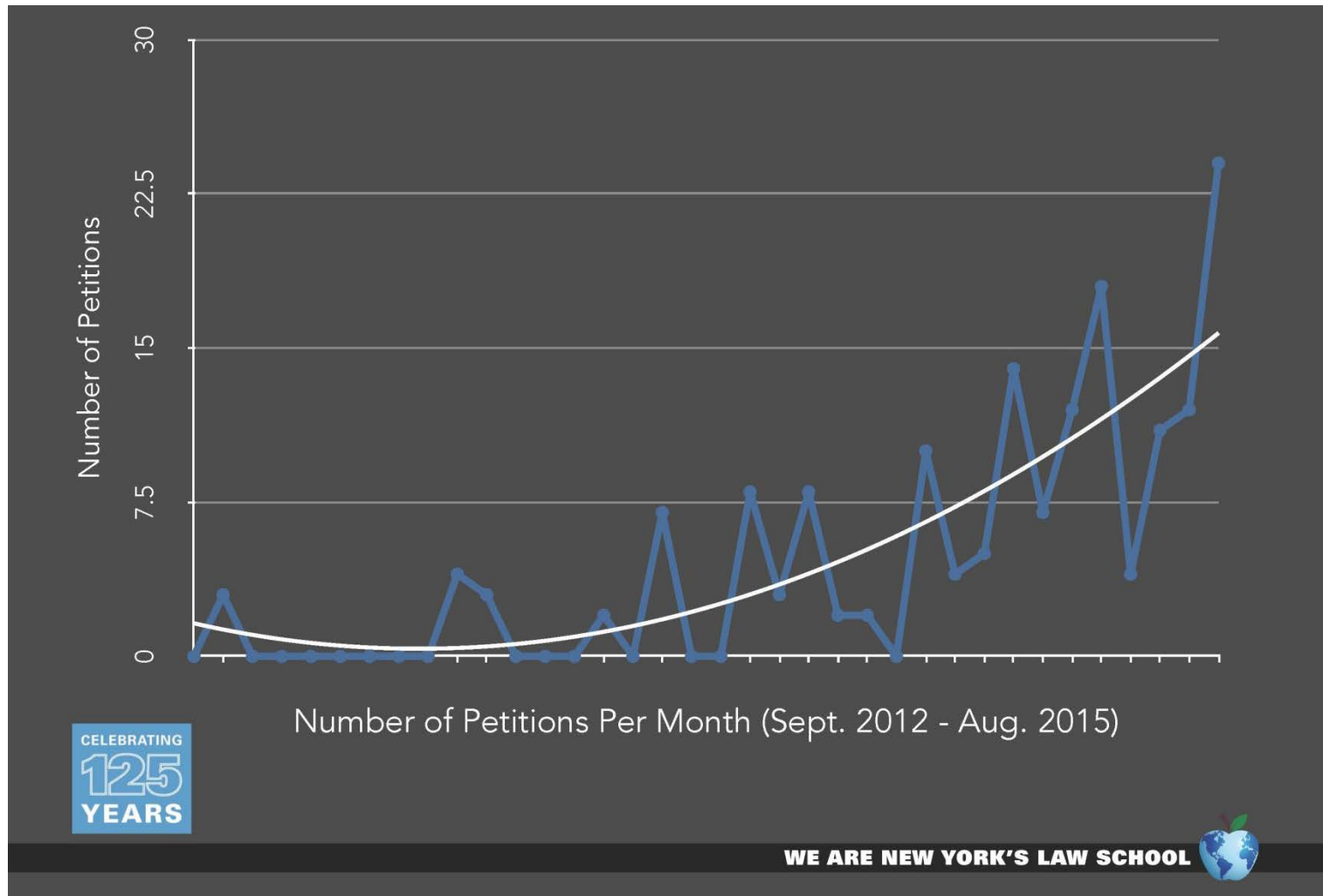


Time to Institution Decision





Rate of Petitions





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?

Wilmer Cutler Pickering Hale and Dorr LLP is a Delaware limited liability partnership. WilmerHale principal law offices: 60 State Street, Boston, Massachusetts 02109, +1 617 526 6000; 1875 Pennsylvania Avenue, NW, Washington, DC 20006, +1 202 663 6000. Our United Kingdom offices are operated under a separate Delaware limited liability partnership of solicitors and registered foreign lawyers authorized and regulated by the Solicitors Regulation Authority (SRA No. 287488). Our professional rules can be found at www.sra.org.uk/solicitors/code-of-conduct.page. A list of partners and their professional qualifications is available for inspection at our UK offices. In Beijing, we are registered to operate as a Foreign Law Firm Representative Office. This material is for general informational purposes only and does not represent our advice as to any particular set of facts; nor does it represent any undertaking to keep recipients advised of all legal developments. Prior results do not guarantee a similar outcome. © 2015 Wilmer Cutler Pickering Hale and Dorr LLP