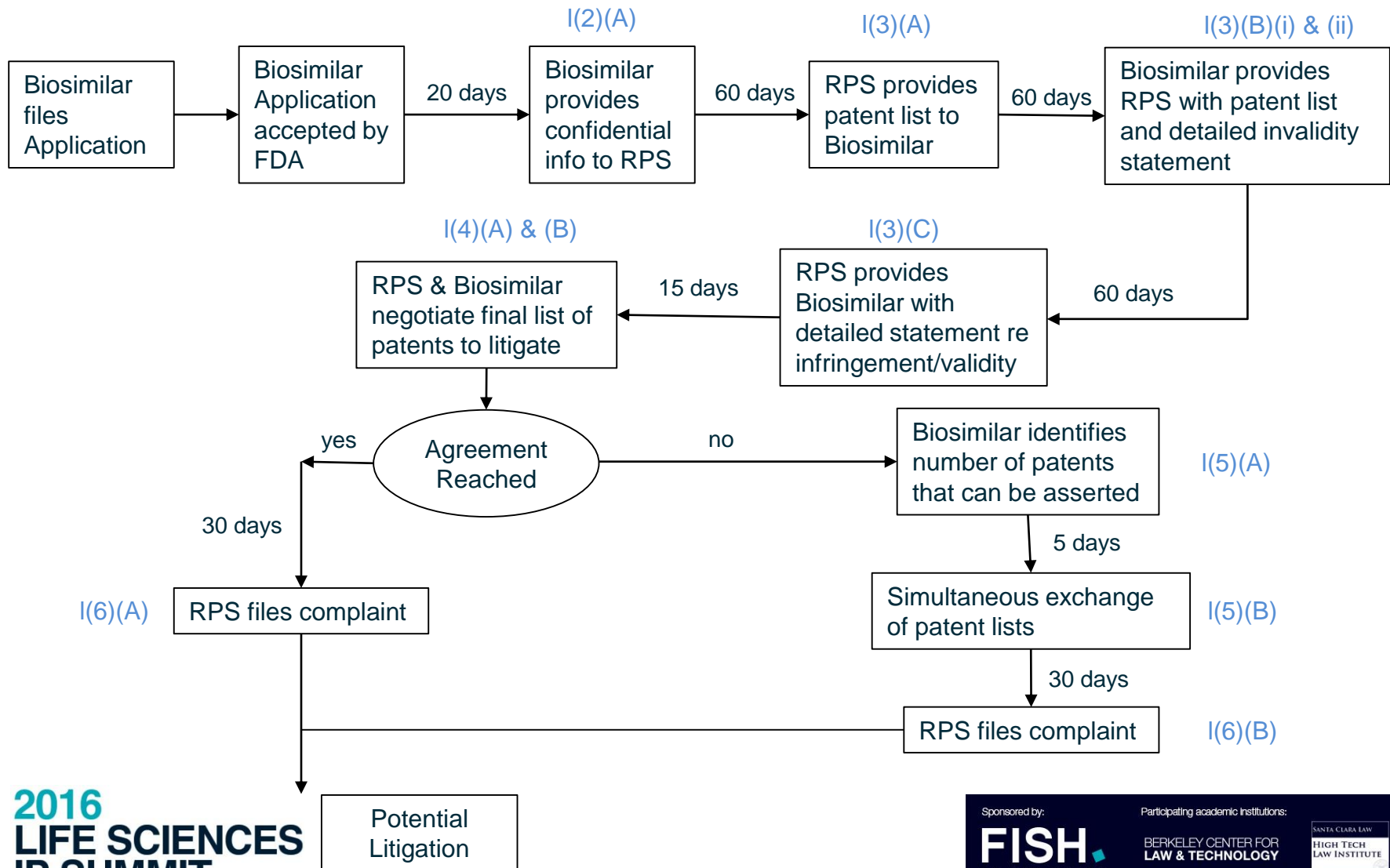


# Strategic Considerations in Asserting or Challenging Patents in the Biologic/Biosimilar Space

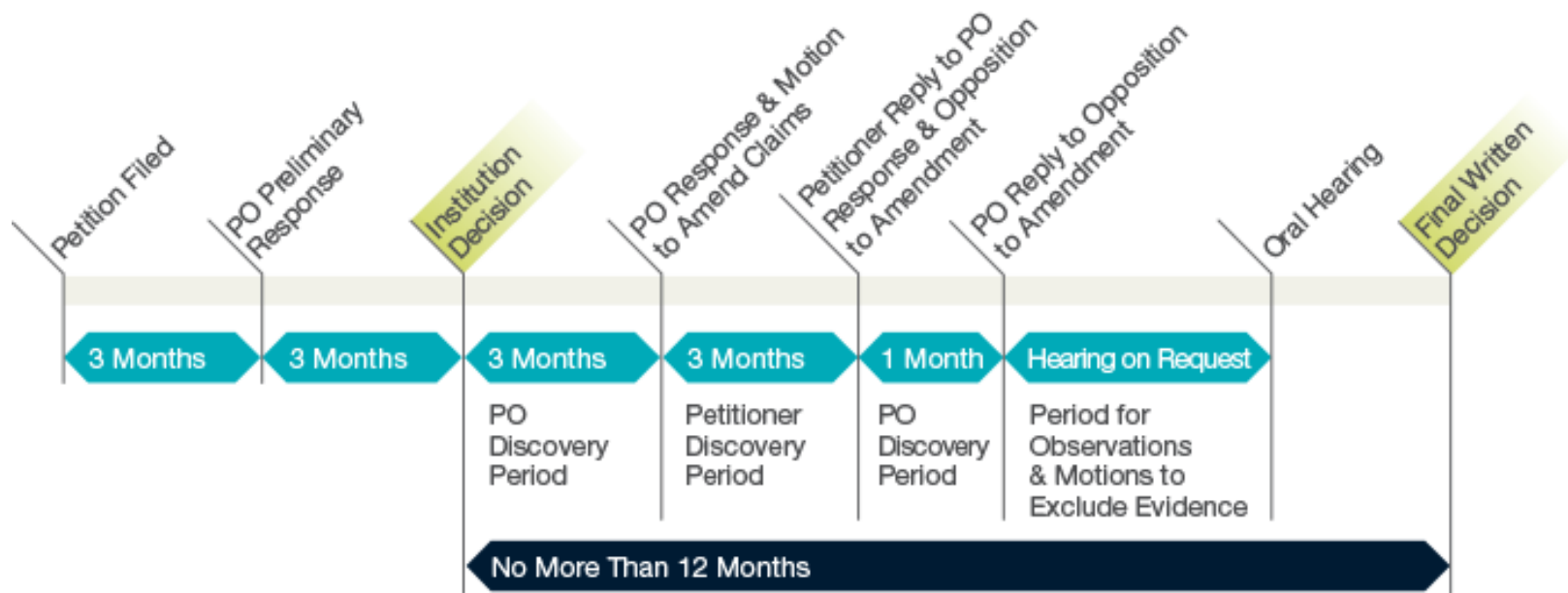
# A. The BPCIA Statute and What it Amends

- Public Health Service Act 42 U.S.C. § 262
  - “351(k)” – biosimilar application requirement
  - “351(l)” – patent exchanges procedures
- Patent Statutes 35 U.S.C. § 271
  - 271(e)(2)(c) – new artificial act of infringement

# The BPCIA Patent Dance

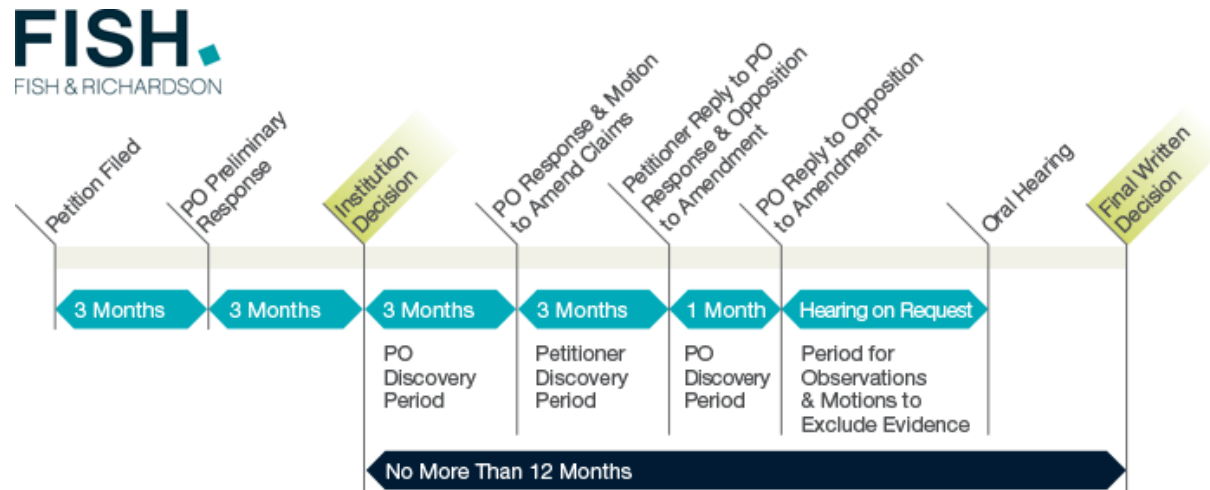


# IPR Overview

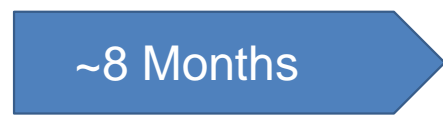


# IPR vs. Patent Dance

IPR

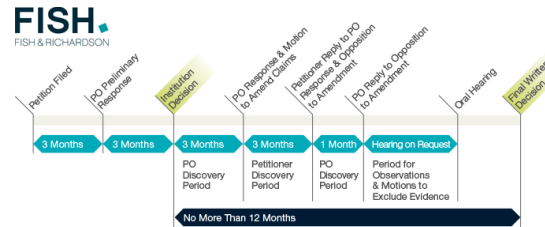


Patent Dance



# IPR vs. Patent Dance vs District Court Litigation

IPR



Patent Dance



District Court Litigation



# Biologics patents challenged in IPR

**HUMIRA**<sup>®</sup>  
adalimumab

**Rituxan**<sup>®</sup>  
*Rituximab*

 **Herceptin**<sup>®</sup>  
trastuzumab

 **Enbrel**<sup>®</sup>  
etanercept

 **AVASTIN**<sup>®</sup>  
bevacizumab

 **TYSABRI**<sup>®</sup>  
(natalizumab)



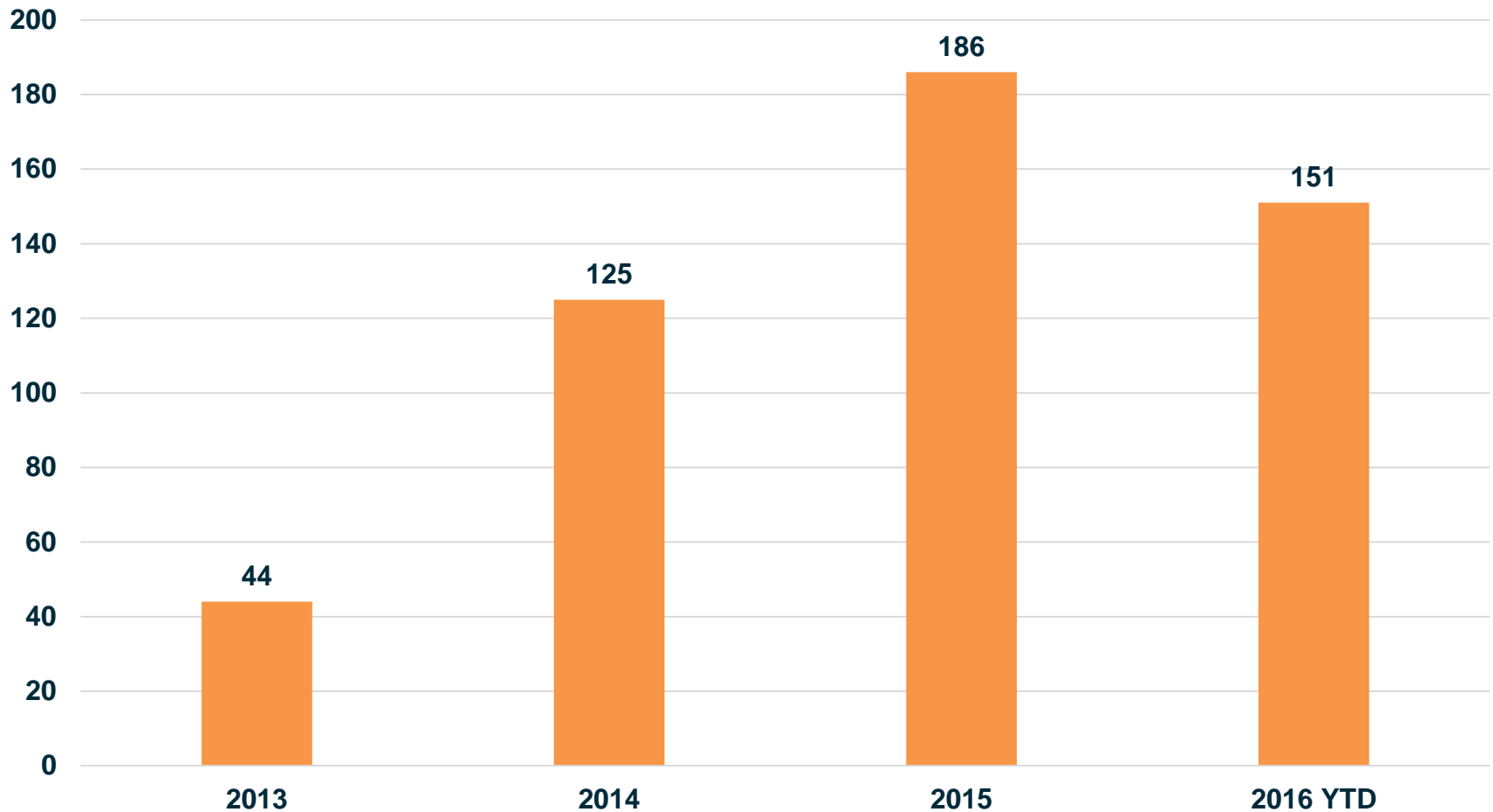
 **Neulasta**<sup>®</sup>  
(pegfilgrastim)

 **ORENCIA**<sup>®</sup>  
(abatacept)

**2016**  
**LIFE SCIENCES**  
**IP SUMMIT**

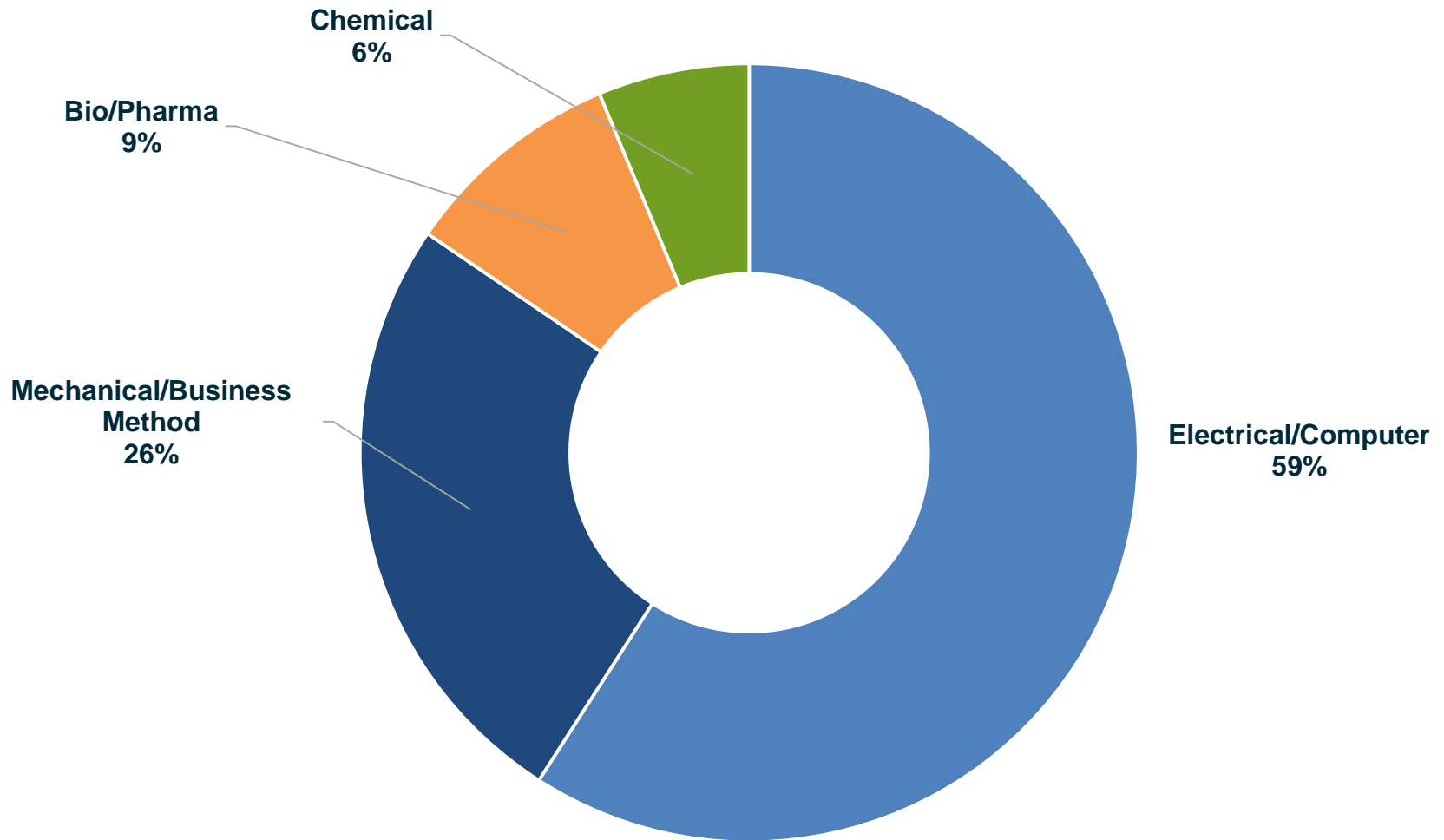
# BioPharma IPR Filings Steadily Increase

## IPRs Filed in TC1600



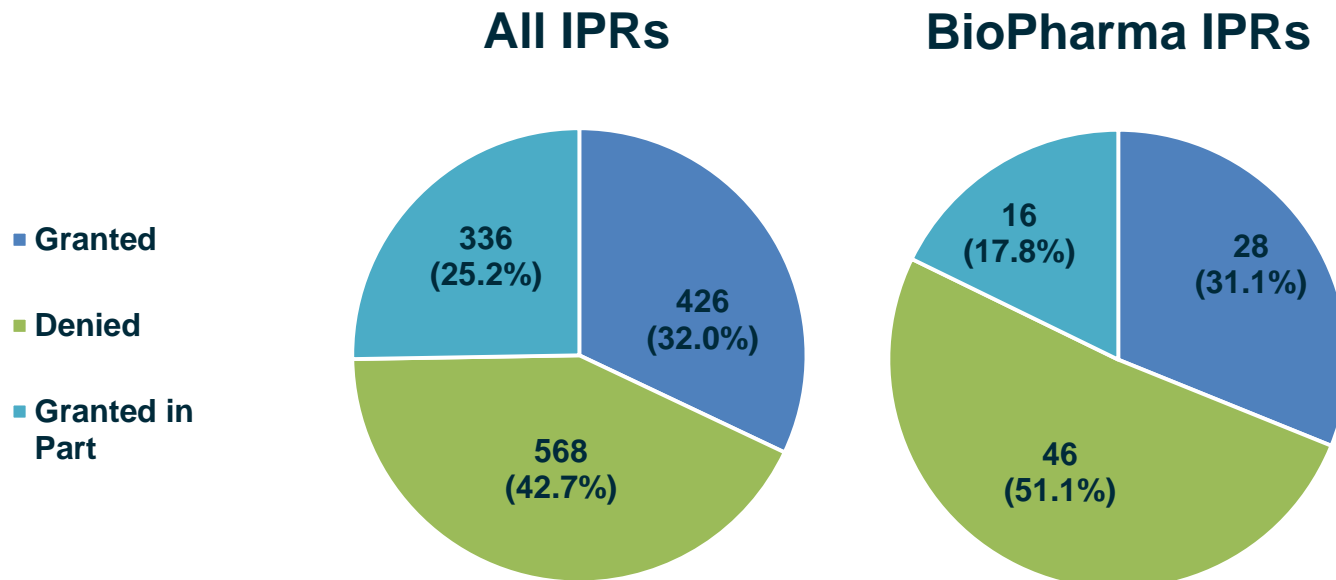


# Technology Breakdown by USPTO Tech Center (2013-Present)



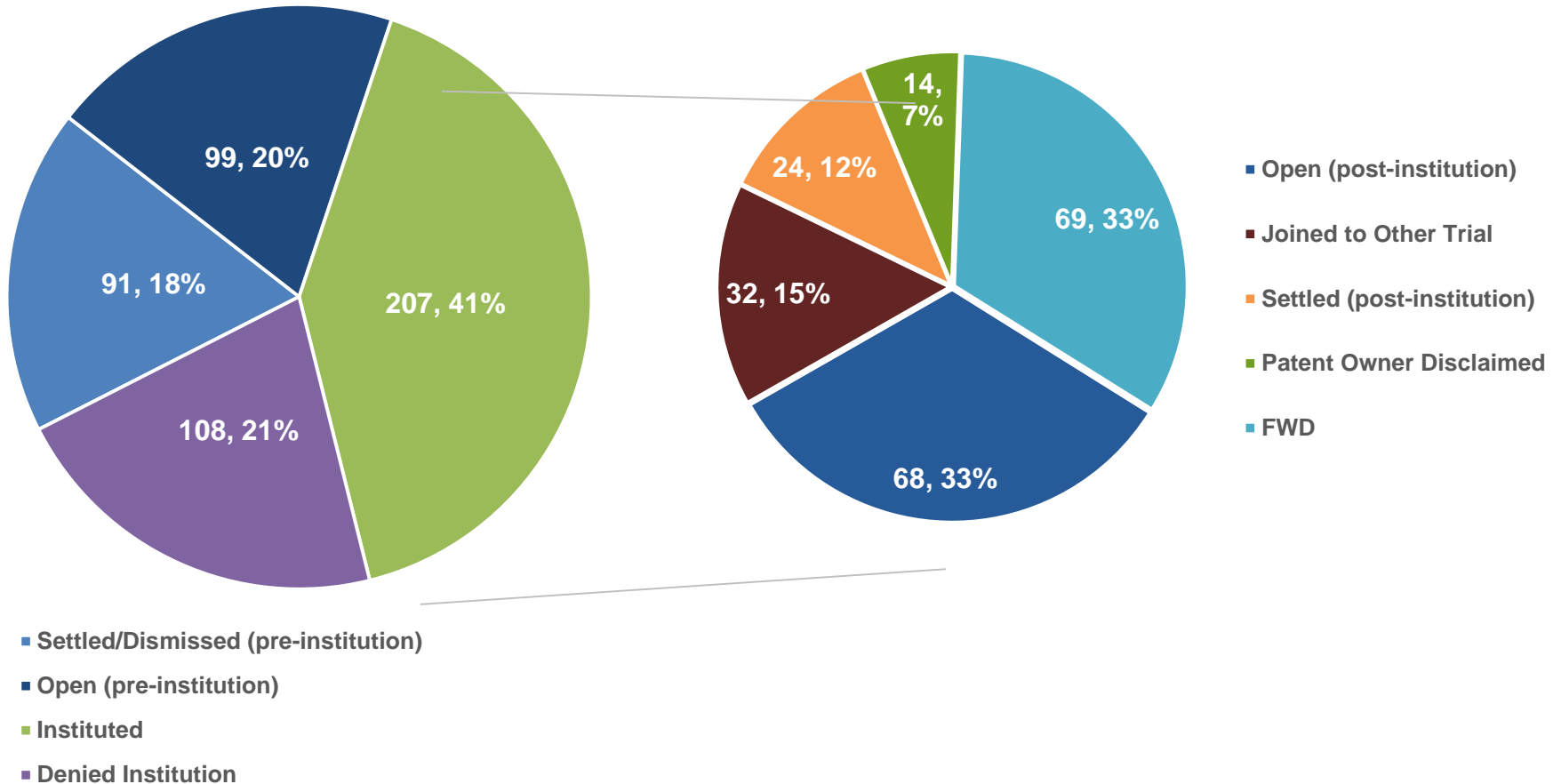
# BioPharma by the Numbers

- 60% of biopharma AIA petitions instituted
  - The other 40% were either denied or settled before institution
- Settlement rate of about 30%
- 15% settled before PTAB issued a decision on institution
- FY2015 institution rates for IPR (all tech centers v. biopharma)



# BioPharma IPR Status

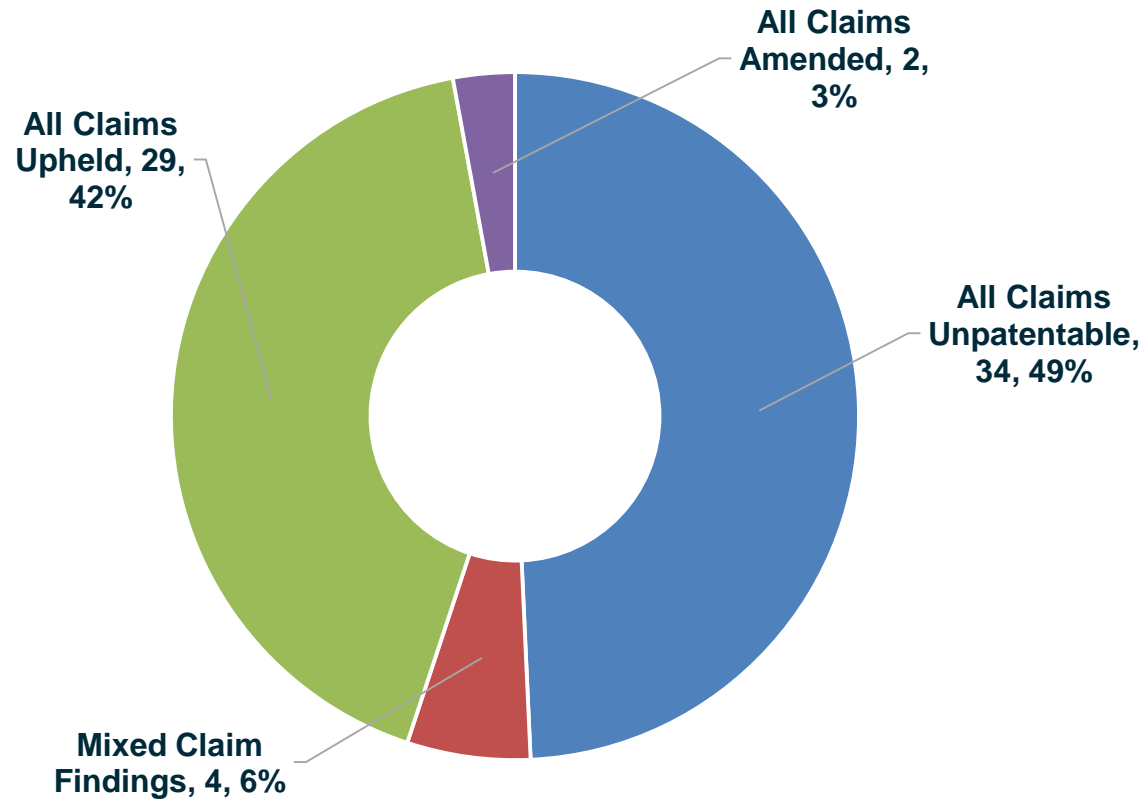
- 506 total biopharma IPR petitions filed since 2013\*



Source: LexMachina, data current as of 10/25/2016;  
 \*1 petition in which patent owner disclaimed pre-institution

# FWD Outcomes – BioPharma IPRs (2013-2016)

- 69 petitions filed since 2013 have reached a Final Written Decision



# Contact Fish & Richardson

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Contact us with your questions and comments.



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