

# Protecting Biopharmaceutical Innovation—Litigation and Patent Office Procedures

Janet Gongola, Senior Advisor  
Office of the Under Secretary and Director

[Janet.gongola@uspto.gov](mailto:Janet.gongola@uspto.gov)

Direct dial: 571-272-8734

UNITED STATES  
PATENT AND TRADEMARK OFFICE

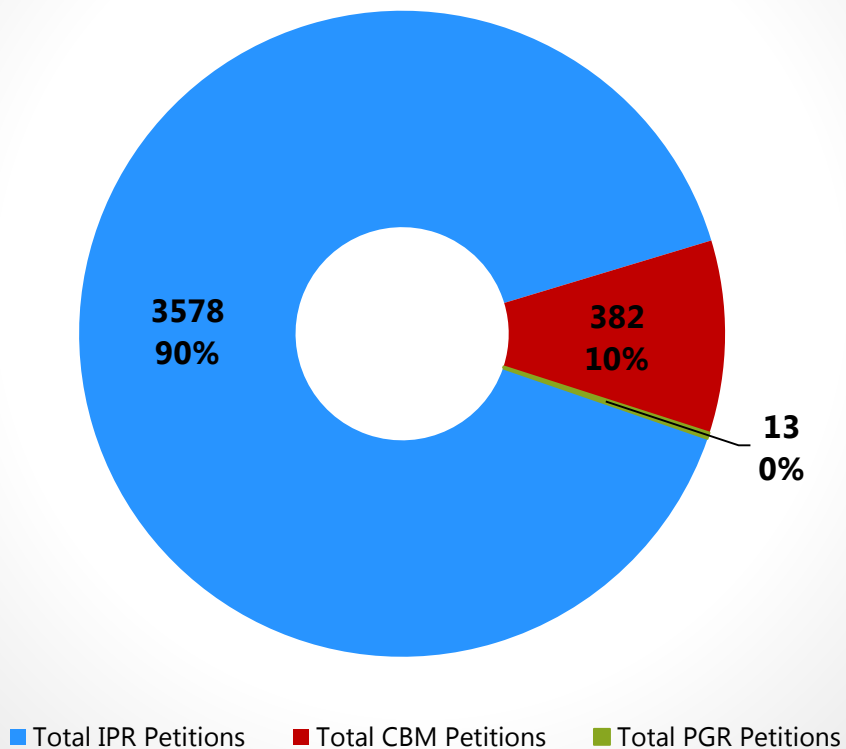


# Overview

- AIA Trial Statistics
- Tips from the Judges
- Proposed Rulemaking

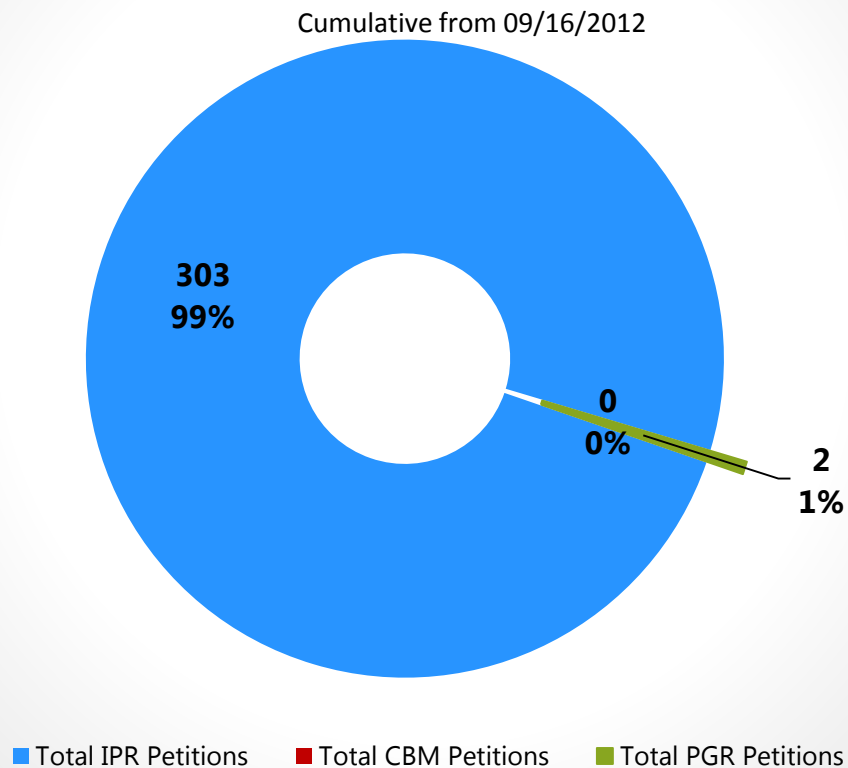
## 3973 Total AIA Petitions\*

Cumulative from 09/16/2012



\*Data current as of: 9/30/2015

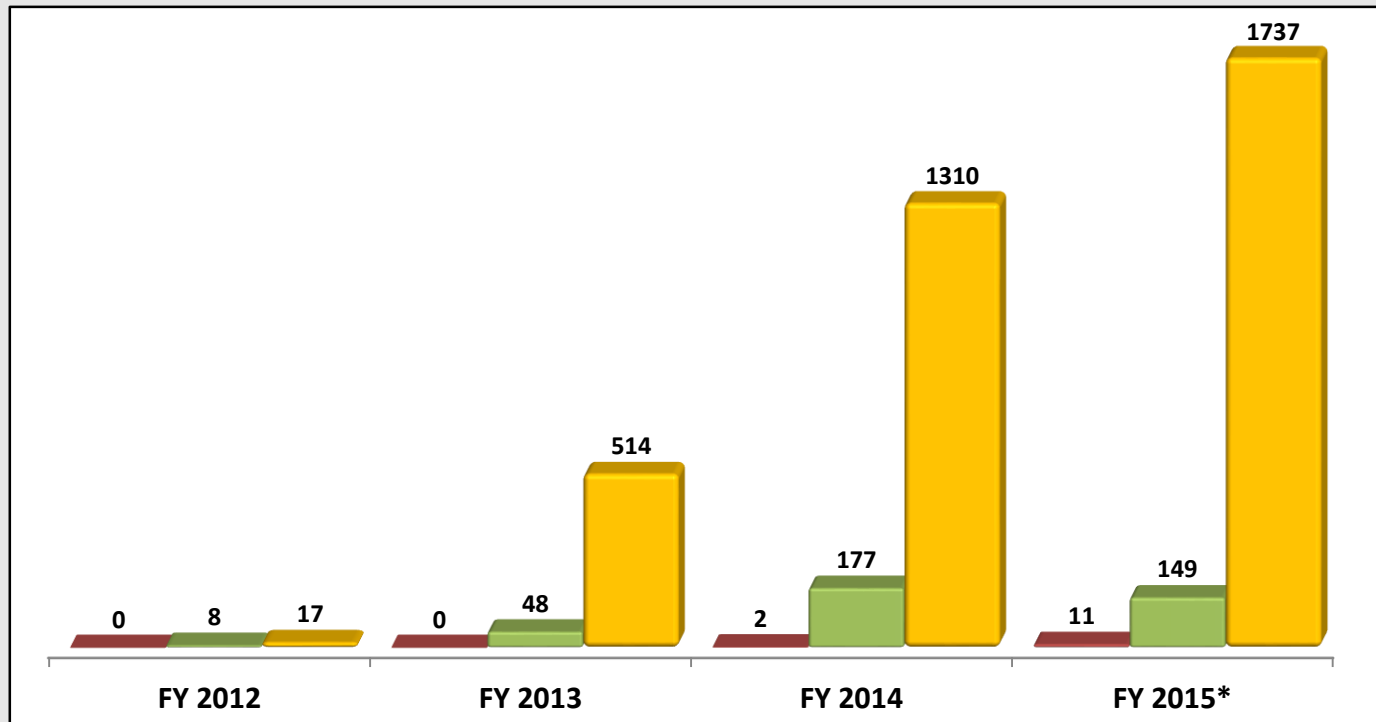
## 305 Total AIA Petitions from TC1600\*



\*Data current as of: 9/30/2015

## AIA Petitions Filed by Fiscal Year by Type

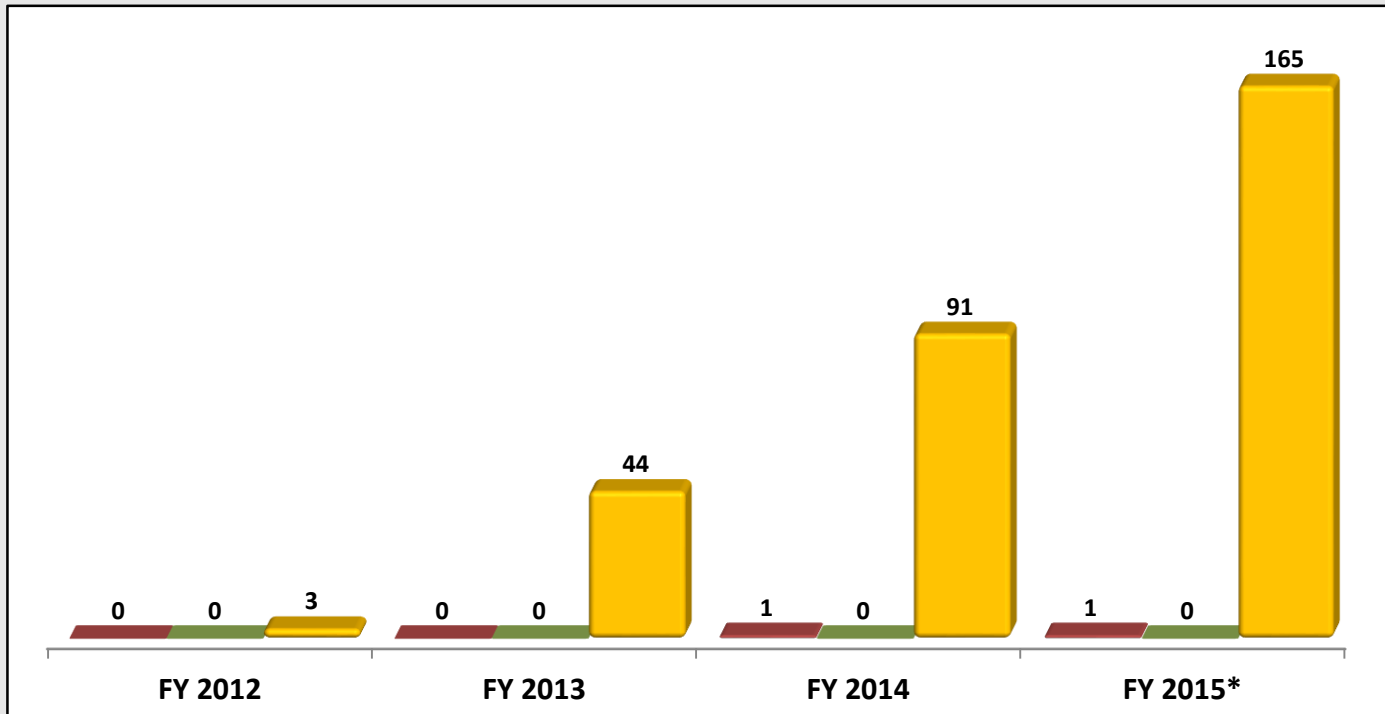
■ PGR   ■ CBM   ■ IPR



\*Data current as of: 9/30/2015

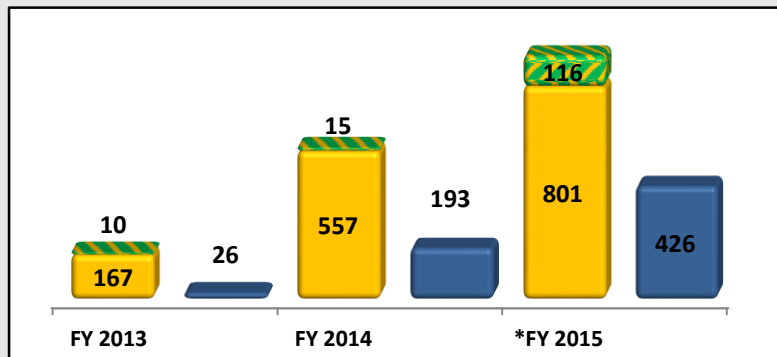
## AIA Petitions Filed by Fiscal Year by Type from TC1600

■ PGR    ■ CBM    ■ IPR



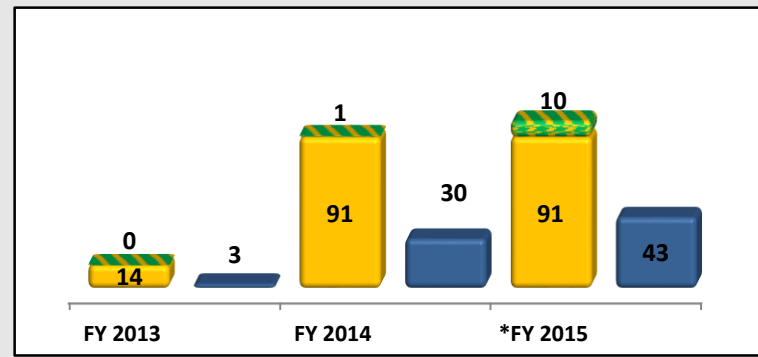
\*Data current as of: 9/30/2015

**IPR - Decisions On Institution Per Fiscal Year by Outcome**



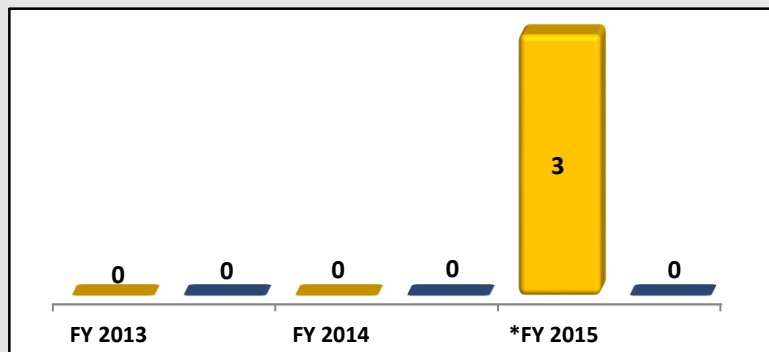
■ Instituted ■ Joiners ■ Denials

**CBM - Decisions On Institution Per Fiscal Year by Outcome**



■ Instituted ■ Joiners ■ Denials

**PGR - Decisions On Institution Per Fiscal Year by Outcome**

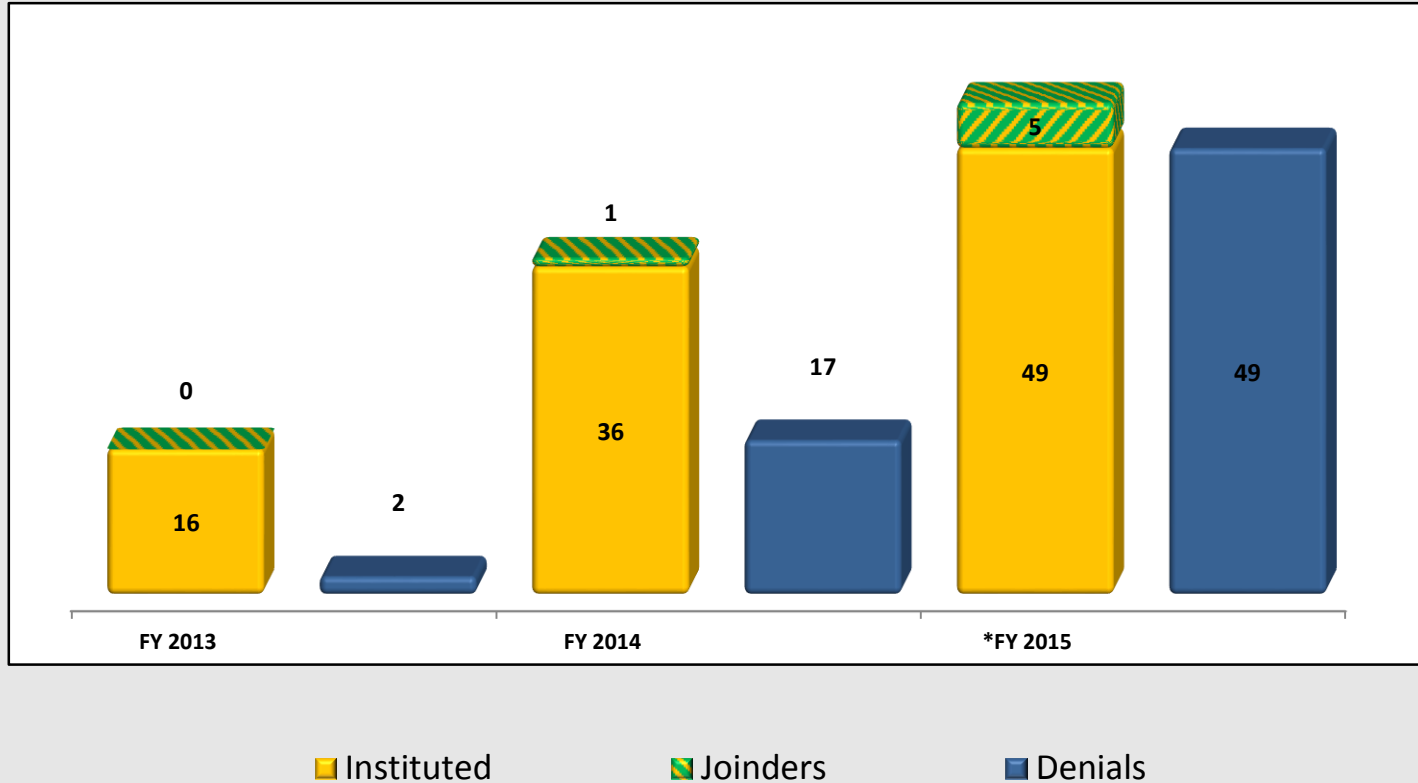


■ Instituted ■ Joiners ■ Denials

**\*Data current as of: 9/30/2015**



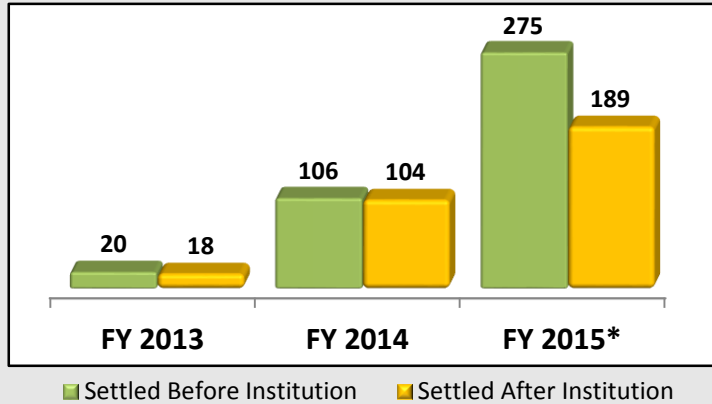
## IPR - Decisions On Institution Per Fiscal Year by Outcome for TC1600



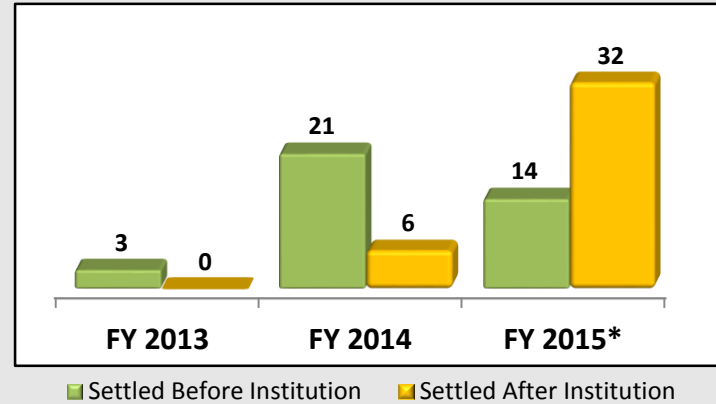
\*Data current as of: 9/30/2015



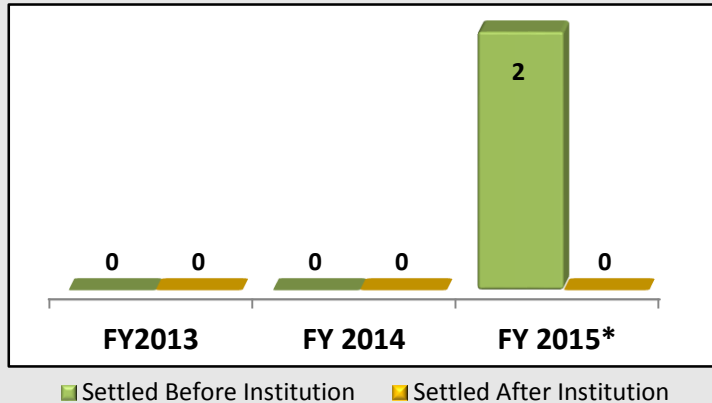
### IPR - Settlements



### CBM - Settlements

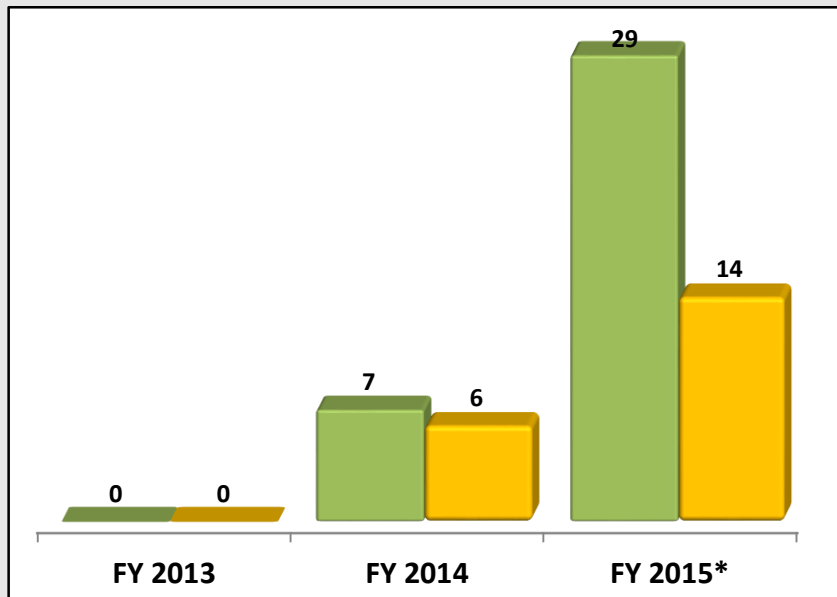


### PGR - Settlements



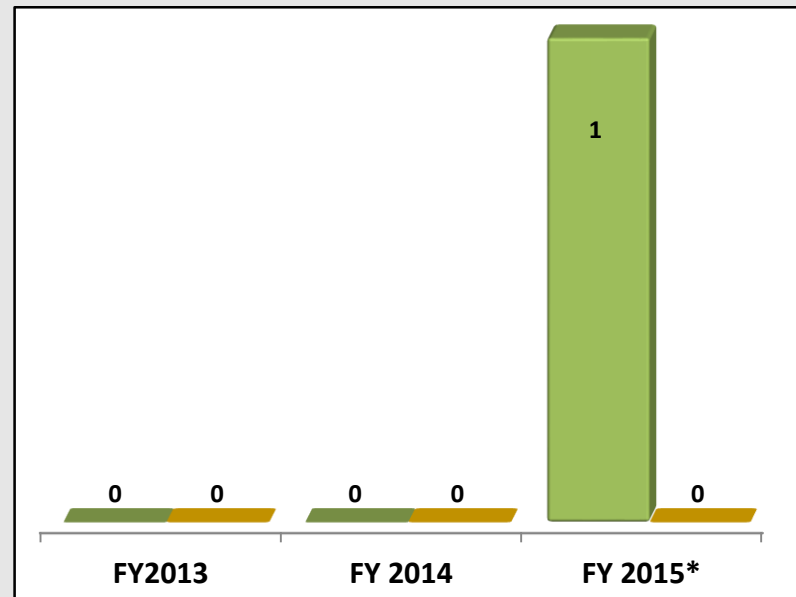
\*Data current as of: 9/30/2015

## IPR – Settlements for TC1600



■ Settled Before Institution   ■ Settled After Institution

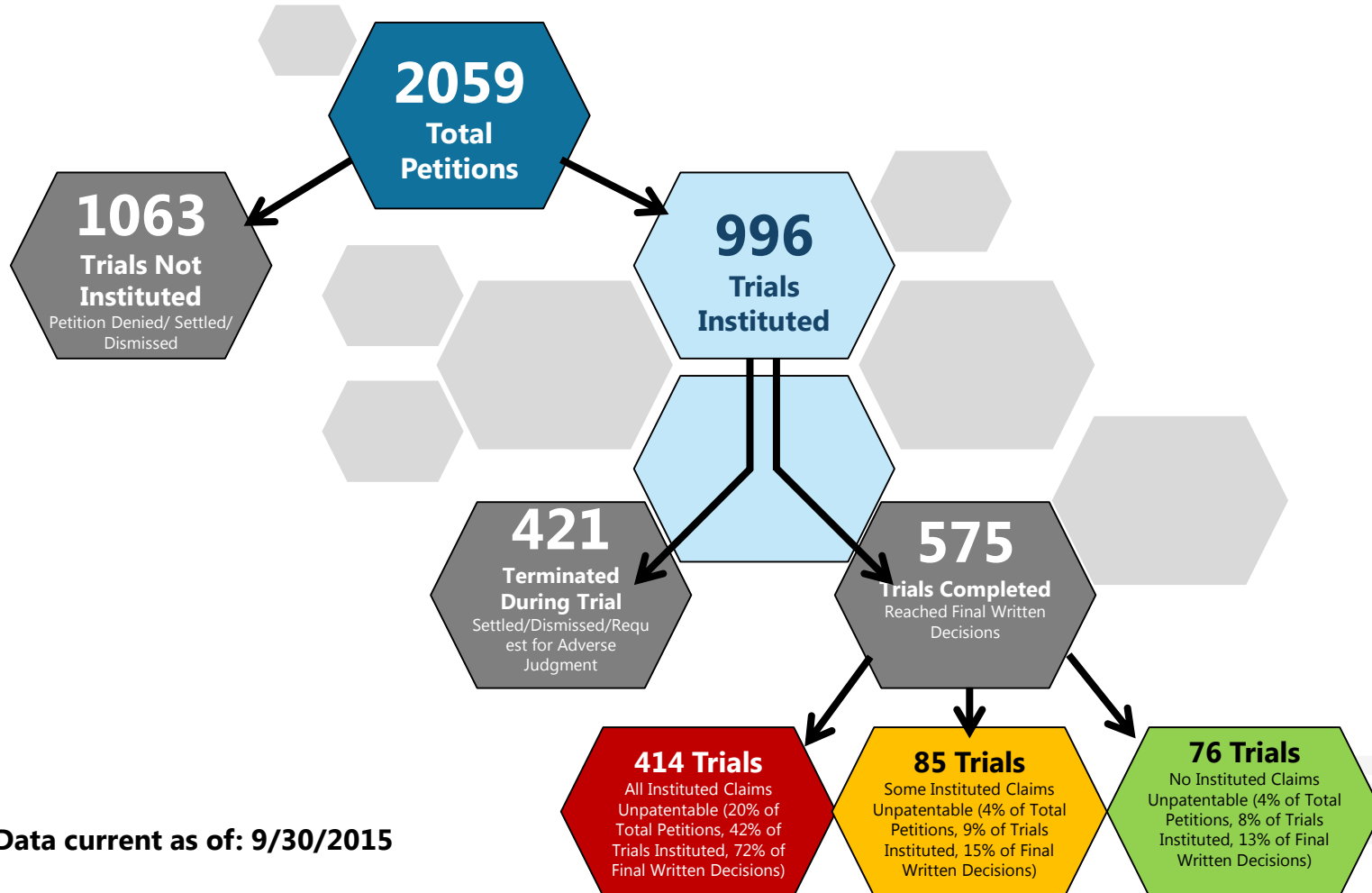
## PGR – Settlements for TC1600



■ Settled Before Institution   ■ Settled After Institution

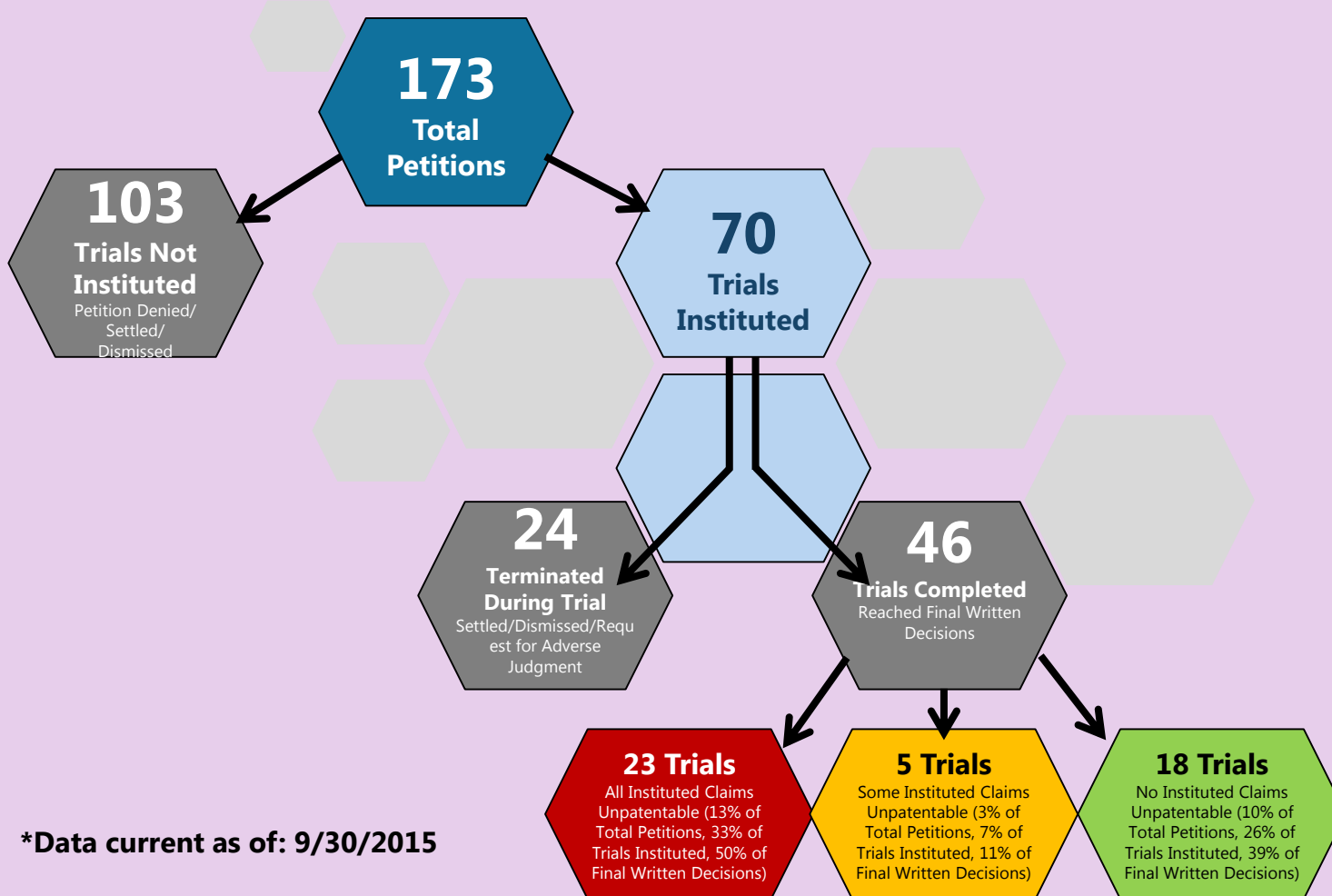
**\*Data current as of: 9/30/2015**

## Disposition of IPR Petitions Completed to Date\*



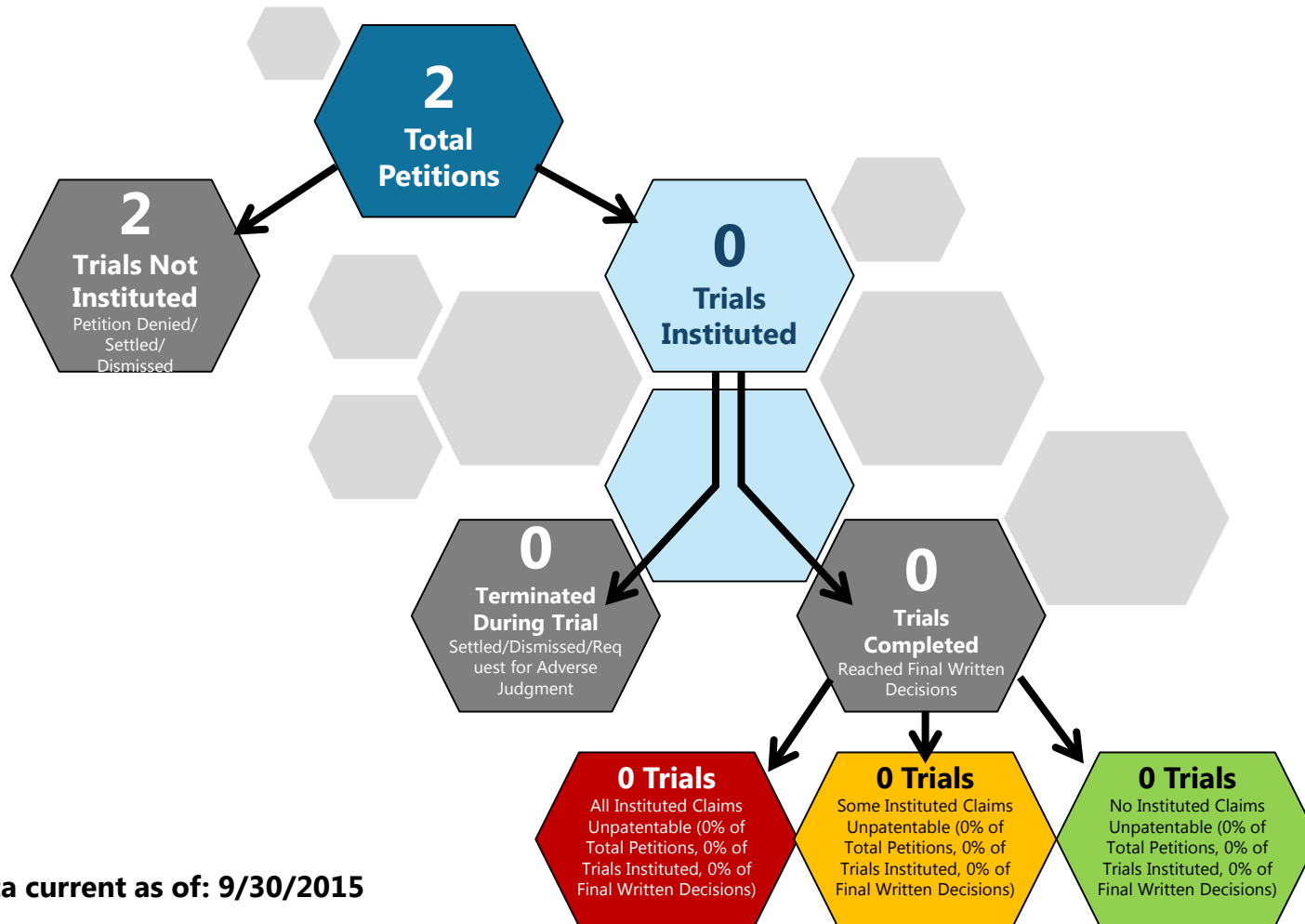
\*Data current as of: 9/30/2015

# Disposition of IPR Petitions Completed to Date for TC1600\*



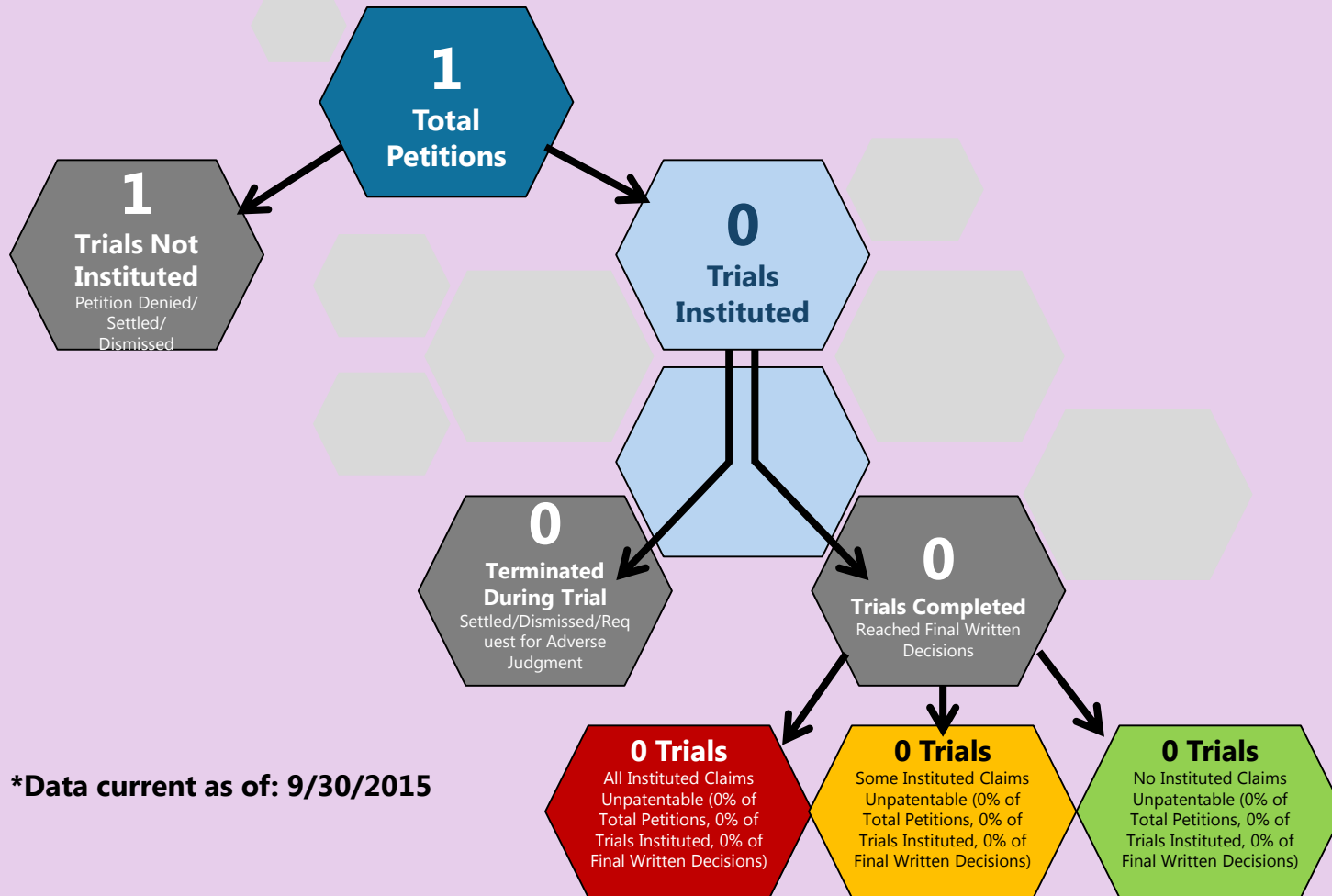
\*Data current as of: 9/30/2015

## Disposition of PGR Petitions Completed to Date\*



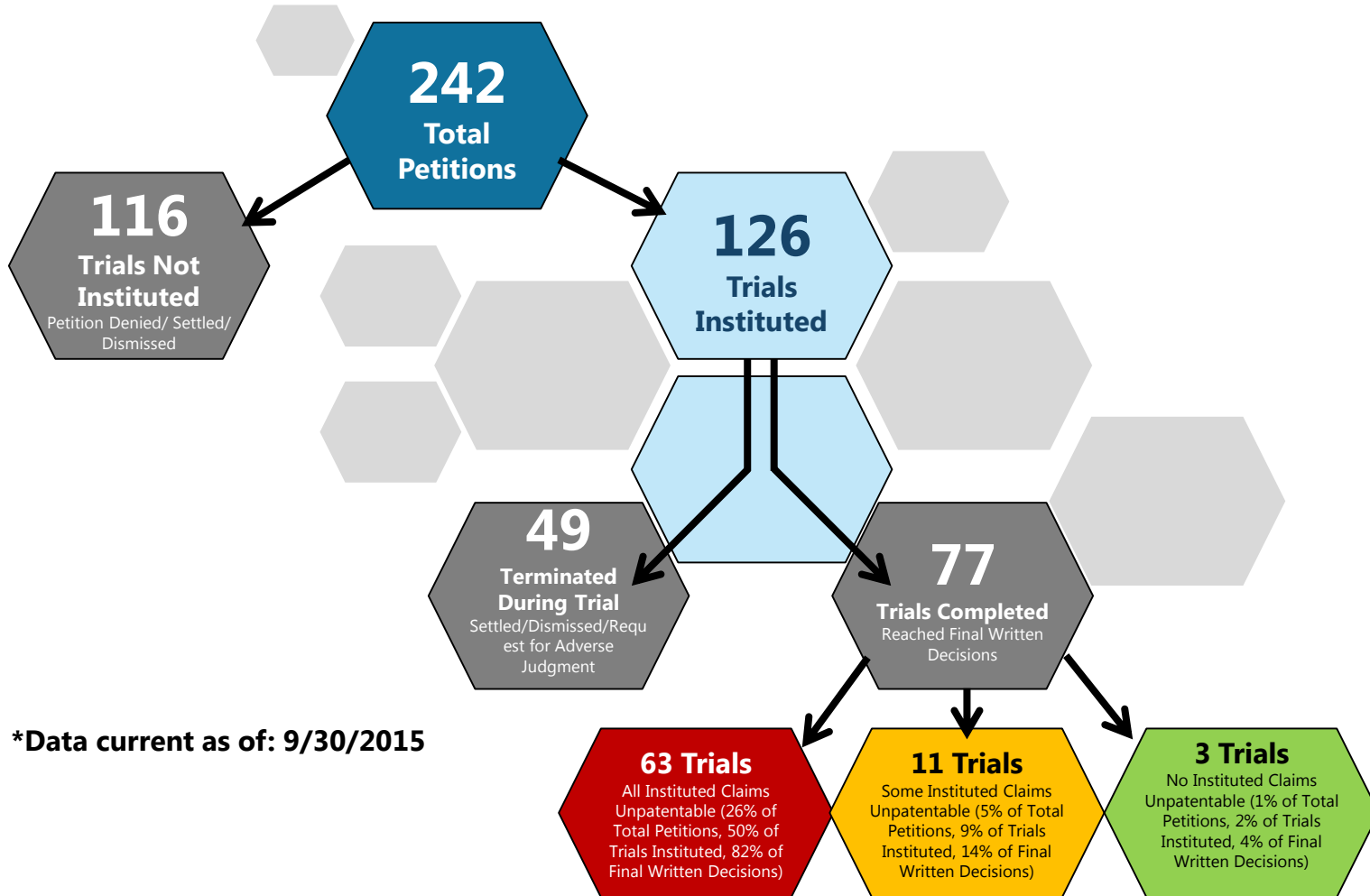
\*Data current as of: 9/30/2015

# Disposition of PGR Petitions Completed to Date for TC1600\*



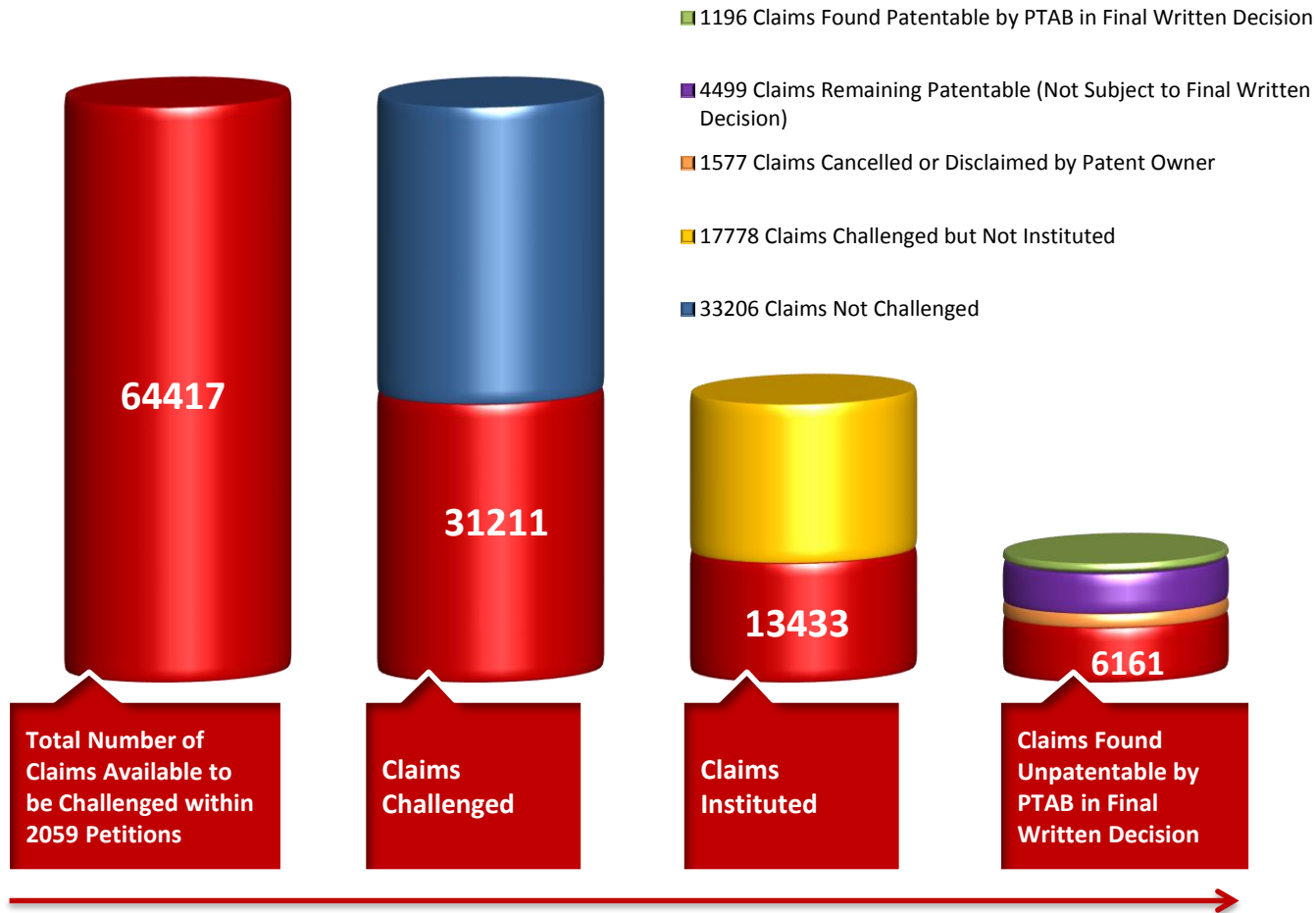
\*Data current as of: 9/30/2015

## Disposition of CBM Petitions Completed to Date\*



\*Data current as of: 9/30/2015

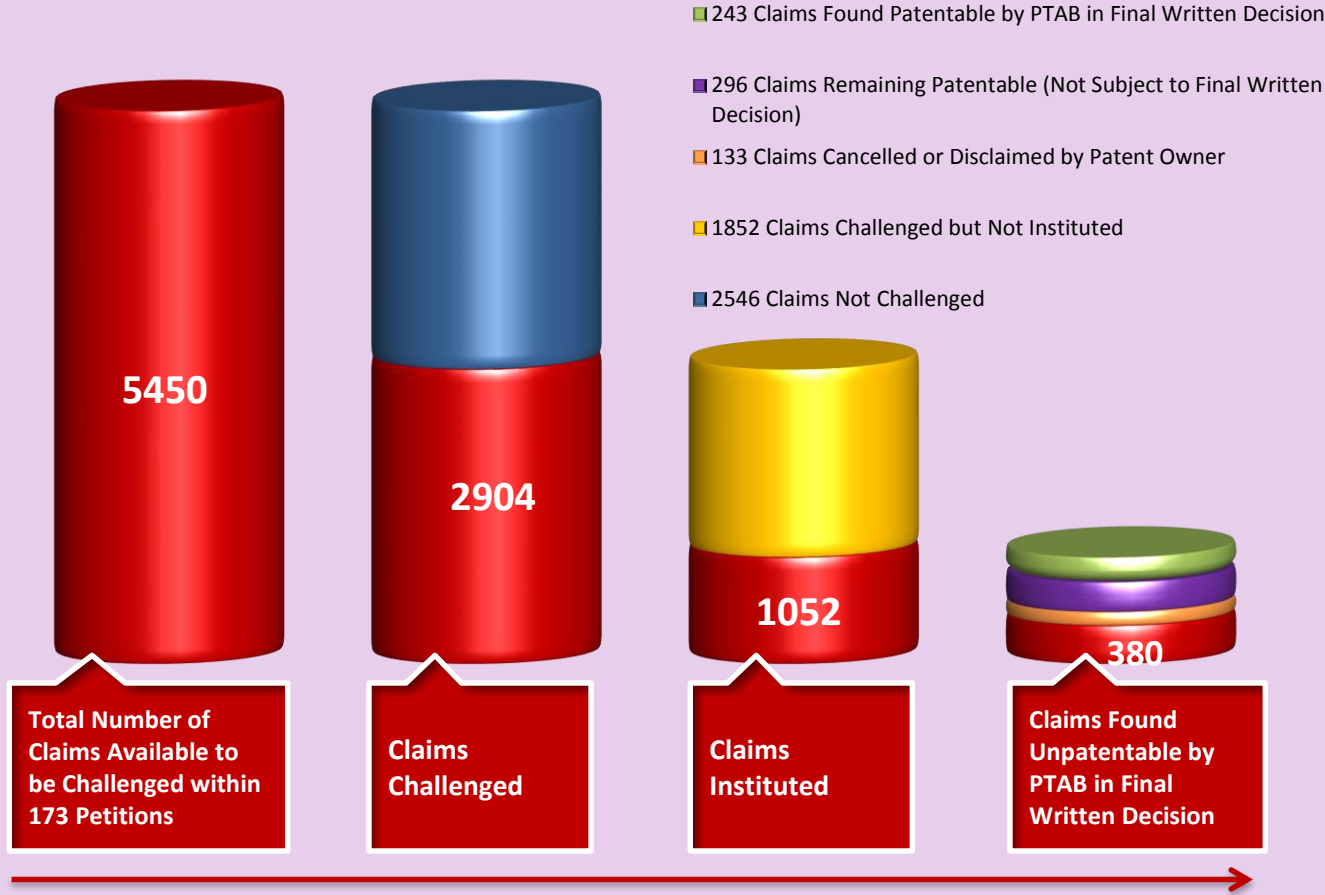
## IPR Petitions Terminated to Date\*



\*Data current as of: 9/30/2015

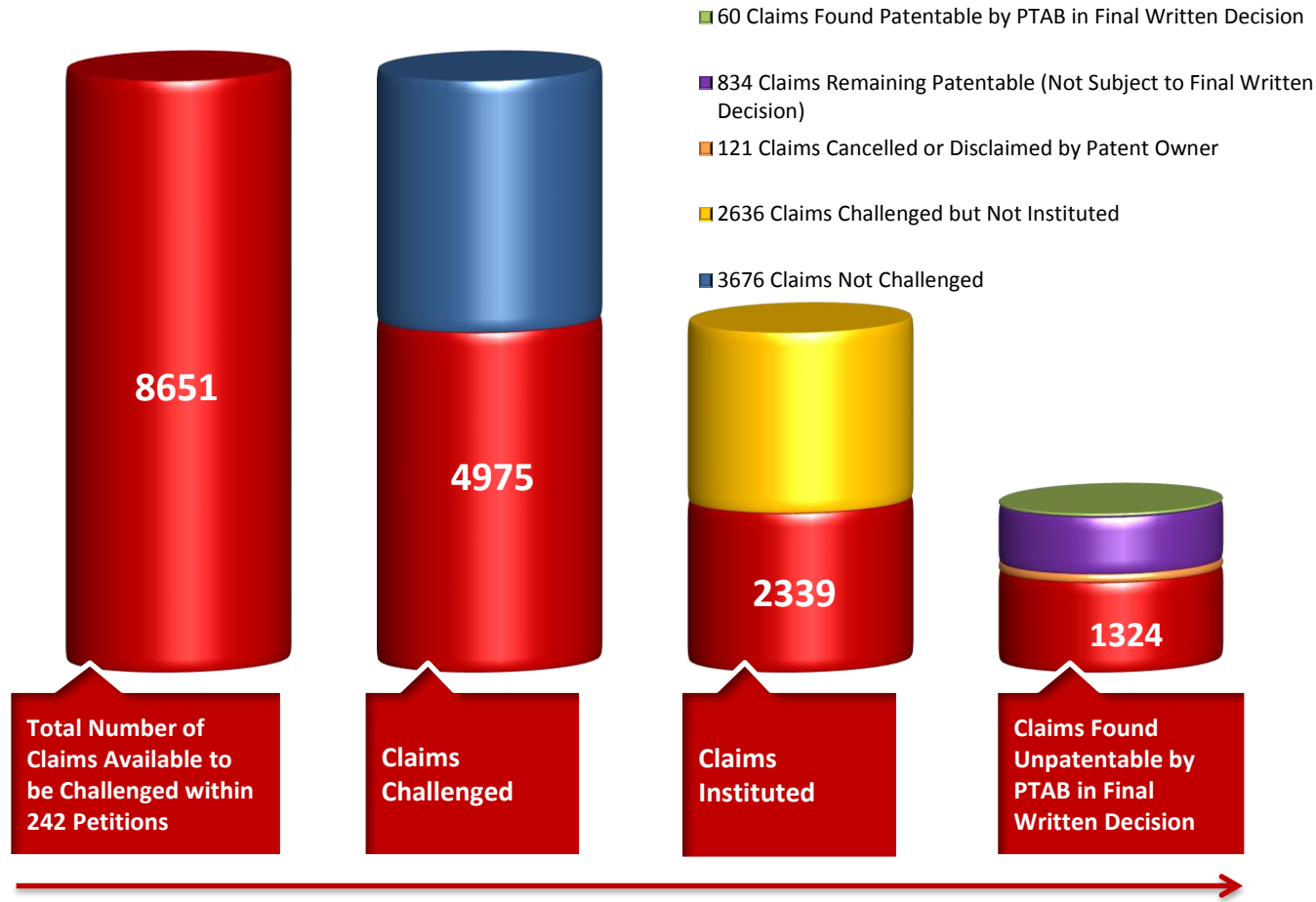


## IPR Petitions Terminated to Date for TC1600\*



\*Data current as of: 9/30/2015

## CBM Petitions Terminated to Date\*



\*Data current as of: 9/30/2015

# Tips from the Judges: Ways Bio-Pharma Patent Owners (PO) Could Strengthen their Filings

- Point out any issues regarding:
  - § 315(b): whether the Petitioner was served with compliant alleging infringement more than 1 year before petition filing
  - § 325(d): whether the same or substantially the same prior art or arguments previously were presented
  - real parties-in-interest
  - claim construction, especially if any differs from those proposed by Petitioner

# Tips from the Judges: Ways Bio-Pharma Patent Owners (PO) Could Strengthen their Filings

- Point out:
  - if asserted prior art is not prior art or PO can swear behind § 102(a) art
  - if a ground fails to address a limitation of a claim
  - if a ground fails to articulate a reason to combine references
  - if there may not be a reasonable expectation of success in combining the references because bio-pharma is an unpredictable art
    - But must provide evidence that art is unpredictable, not just make the argument
    - Preferring a declaration merely stating art is unpredictable is not sufficient

# Tips from the Judges: Ways Bio-Pharma Patent Owners (PO) Could Strengthen their Filings

- Consider doing due diligence on your relevant patent portfolio, in view of commercial products and regulatory approval, before filing a patent infringement suit
- Make sure you have narrowest to broadest claims covering relevant commercial products (yours and competitors) to help ensure that if broad claims get knocked out later, you still have claim coverage
- Consider reexam or reissue before anyone thinks to file an IPR, especially to obtain less broad but viable claims

# Tips from the Judges: Common PO Mistakes

- Claim construction:
  - Support with citation to intrinsic evidence; and
  - Be careful about proposing a construction that contradicts a construction previously proposed or adopted by a court
- Inherency: Explain and cite evidence as to why a limitation at issue would not necessarily exist or be “natural result”
- Expert declarations: Make sure they cite evidence

# Tips from the Judges: Common PO Mistakes

- Obviousness: Explain why things would not have been obvious to try and cite evidence why something would not have been routine optimization
- Secondary considerations: provide evidence, including evidence of nexus between the different considerations and what's patentable in the claims (vs. already known in the art)

# Proposed AIA Trial Rulemaking

- Allow patent owners to include, with their opposition to a petition to institute a proceeding, new testimonial evidence such as expert declaration
- New requirement on practitioners before the PTAB, akin to the Rule 11 requirements in federal courts, that would give the USPTO a more robust means with which to police misconduct
- Clarifies that the PTAB will use the claim construction standard used by district courts for patents that will expire during proceedings and therefore cannot be amended, while confirms the use of broadest reasonable interpretation (BRI) for all other cases
  - Notes the PTAB's development of motions-to-amend practice through its own body of decisions
- Uses a word count for major briefing



# Motions-to-Amend

- *MasterImage 3D, Inc. v. RealD Inc.*, Case IPR2015-00040 (PTAB July 15, 2015) (Paper 42) (representative)
  - Clarified earlier *Idle Free* decision
  - Patent Owner must show patentable distinction over prior art of record (in the proceeding; in the prosecution history; in any other proceeding involving the same patent)
  - Duty of candor and good faith in the Office may lead to additional prior art made of record by the Patent Owner when moving to amend

# Possible Single Judge Institution Pilot

- Single APJ would decide whether to institute an IPR trial,
- If instituted, two additional APJs would be assigned to conduct trial

# Public Feedback

- Proposed AIA Trial Rules
  - Comments due by November 18, 2015
  - [trialrules2015@uspto.gov](mailto:trialrules2015@uspto.gov)
- Possible Single Judge Institution Pilot
  - Comments due by October 26, 2015
  - [ptabtrialpilot@uspto.gov](mailto:ptabtrialpilot@uspto.gov)

# Questions?

Janet Gongola, Senior Advisor  
Office of the Under Secretary and Director

[Janet.gongola@uspto.gov](mailto:Janet.gongola@uspto.gov)

Direct dial: 571-272-8734

UNITED STATES  
PATENT AND TRADEMARK OFFICE



