

**UNITED STATES  
PATENT AND TRADEMARK OFFICE**

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# Orange Book patent/biologic patent study and district court pharma litigation study

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UNITED STATES  
PATENT AND TRADEMARK OFFICE



# Question/Comment Submission

To send in questions or comments during the webinar, please email:

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# What are Orange Book patents?

- Short-hand for patents covering FDA-approved drug products that are listed in the publication *Approved Drug Products With Therapeutic Equivalence Evaluations* (commonly known as the Orange Book)
- These patents are governed under the provisions of the Hatch-Waxman Act, which created an abbreviated regulatory approval pathway for generic drug products

# What is the Hatch-Waxman Act?

- Allows a generic company to secure quicker FDA approval without repeating expensive and lengthy clinical trials that were conducted on the brand drug
- In exchange, the generic company must certify to the FDA that:
  - The generic version of the approved drug will not infringe with any patents that the branded pharmaceutical company has listed in the Orange Book; or
  - That the patents the branded pharmaceutical company has listed in the Orange Book are not infringed and/or invalid

# What are biologic patents?

- Biologic patents are different than Orange Book drug patents
  - Biologics are large, complex molecules, such as vaccines, made from natural sources
  - Drugs typically are small molecules made through chemical synthesis
- Due to the difference, biologics are governed under a different statutory scheme than drugs—The Biologics Price Competition and Innovation Act of 2009 (BPCIA)
- The BPCIA created an abbreviated regulatory approval pathway for biological products shown to be “biosimilar” or interchangeable with an FDA-approved biological product

# What is the BPCIA?

- A company producing a biosimilar product can secure FDA approval without repeating all the studies and clinical trials that were conducted on the biologic product
- Provides a statutory scheme for resolving patent disputes related to biosimilar products, that can include an information exchange regarding patents with which the biosimilar product may infringe
- The information exchange may result in litigation after the biosimilar applicant provides notice that it will commercially market the biosimilar product
- Patents covering FDA-approved biologic products are not listed in a publication; however, FDA produces a "Purple Book," which lists FDA-licensed biological products (including biosimilar products)

# Methodology

- PTAB classified an AIA petition as challenging an Orange Book-listed patent by comparing the petition's filing date with data from the FDA's electronic Orange Book indicating when the patent was listed
- PTAB manually identified biologic patents as any patent potentially covering a Purple Book-listed product and any non-Orange Book-listed patent directed to treating a disease or condition
- The litigation referenced in this study is limited to litigation that the parties to a particular AIA proceeding identified in their papers and in the notice of a district court patent suit filed with the office under 35 U.S.C. § 290
- Statistics depict data through November 30, 2018



# Overview of findings from AIA proceeding study

- 2% of all AIA petitions challenge biologic patents
- 5% of all AIA petitions challenge Orange Book patents
- The institution rate for biologic patents (50%) is lower than for Orange Book patents (64%)
- But Orange Book patents have a greater chance of claims being upheld in a final written decision

# Overview of findings from litigation study

## Biologics:

- Most biologic AIA petitions (65%) were filed before any litigation started
- Most challenged biologic patents (53%) were not asserted in district court litigation
- Most of those patents did not have litigation between patent owner and petitioner (71%)

# Overview of findings from litigation study

Orange Book:

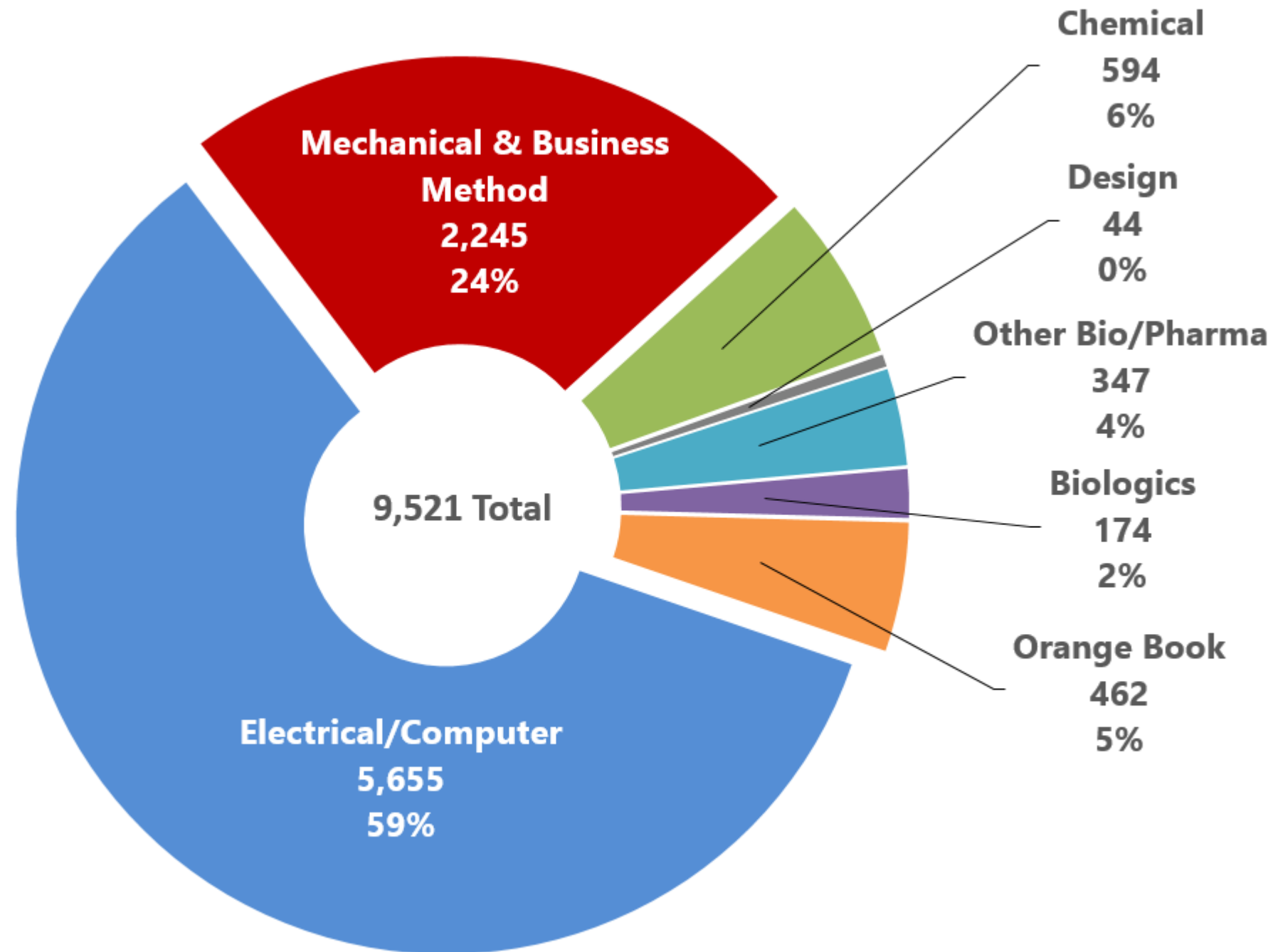
- Most Orange Book AIA petitions (95%) were filed after litigation started
- Most challenged Orange Book patents (91%) were asserted in district court litigation
- Most of those patents had litigation between patent owner and petitioner (66%)
- Most of those patents had an AIA petition filed during that litigation (96%)

# AIA proceedings

**What are the filing rates for AIA petitions challenging Orange Book-listed and biologic patents?**

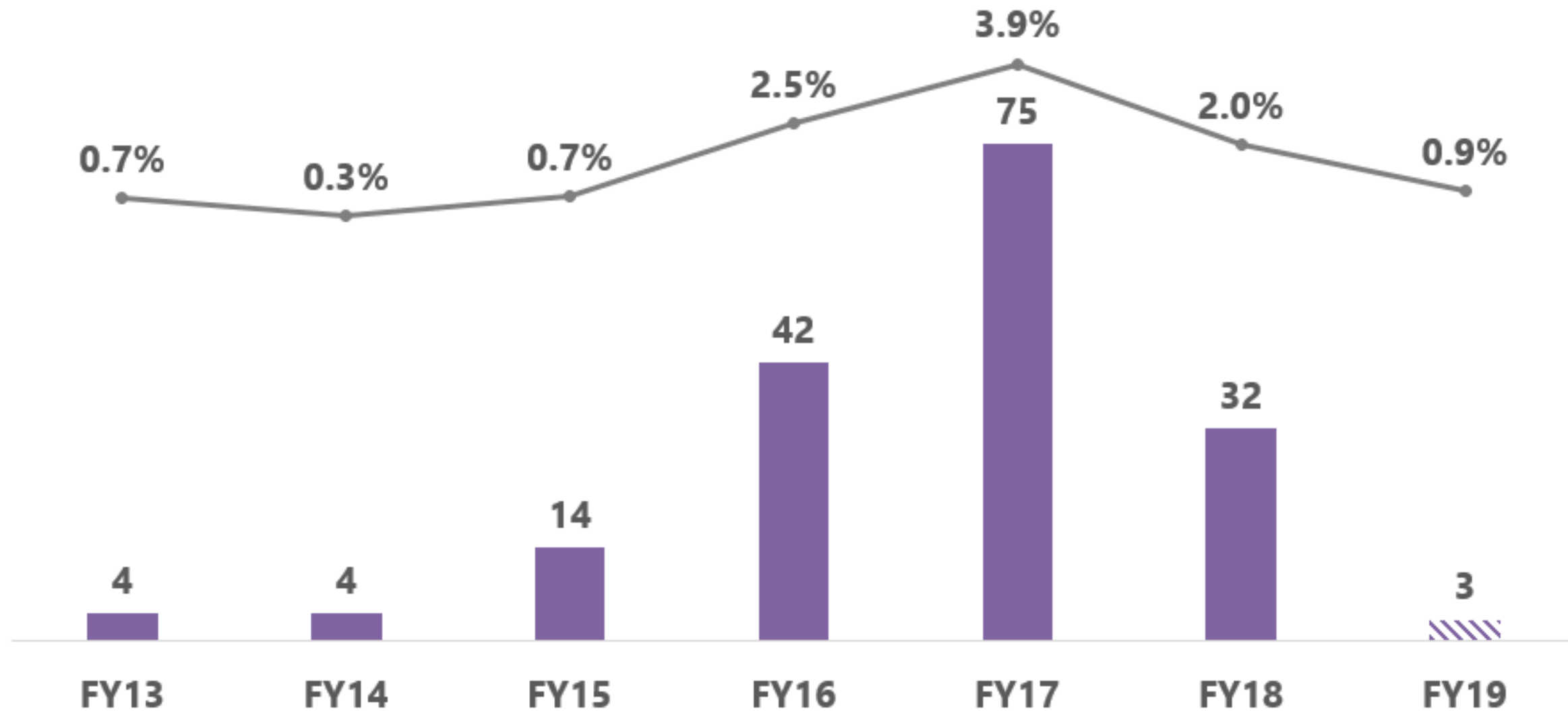
# AIA Petitions filed by technology

(Sept. 16, 2012 to Nov. 30, 2018)



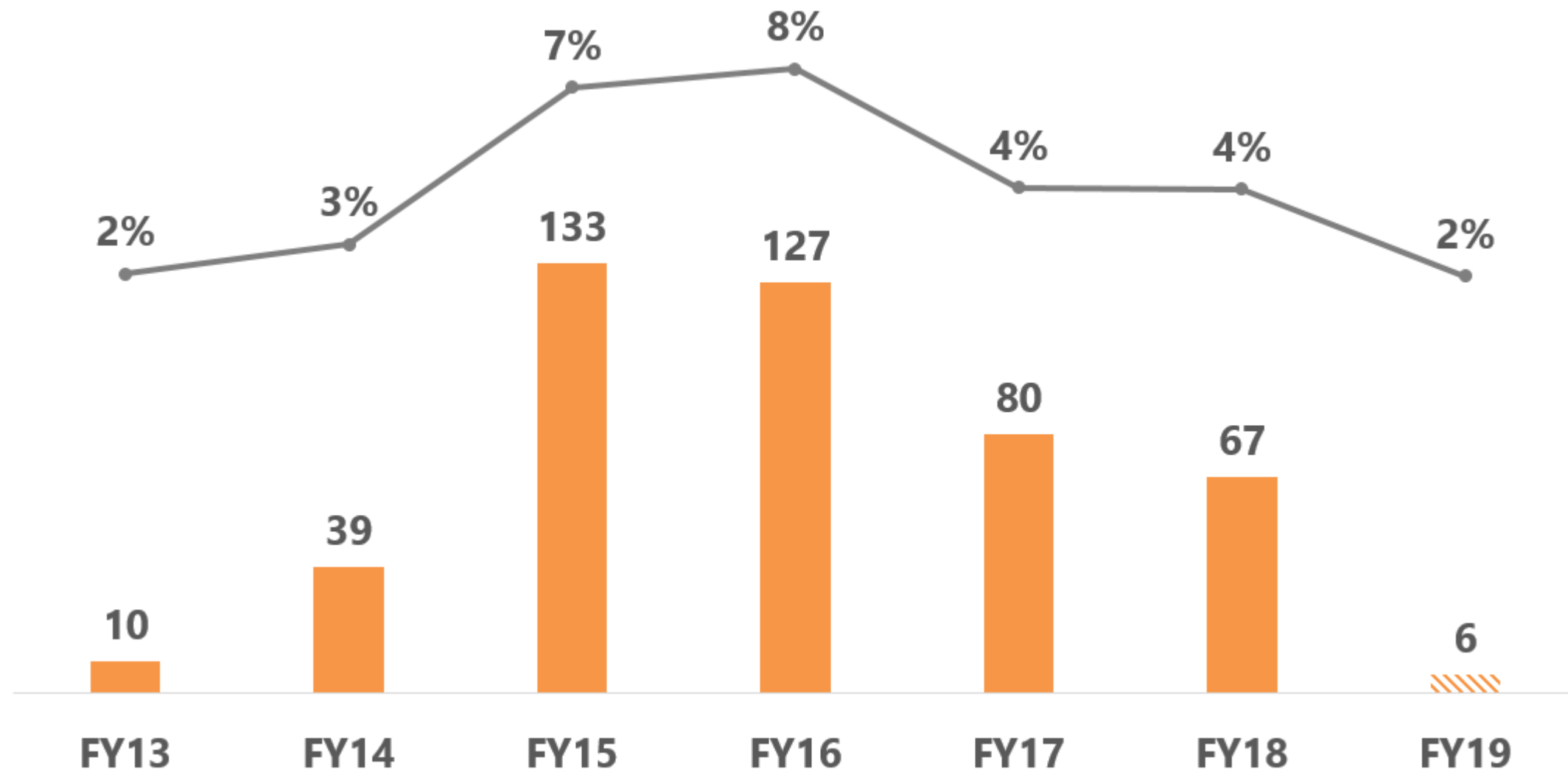
Includes all trial type

# AIA Petitions challenging biologic patents (Sept. 16, 2012 to Nov. 30, 2018)



No petitions challenging biologic patents were filed in FY12.

# AIA Petitions challenging Orange Book patents (Sept. 16, 2012 to Nov. 30, 2018)



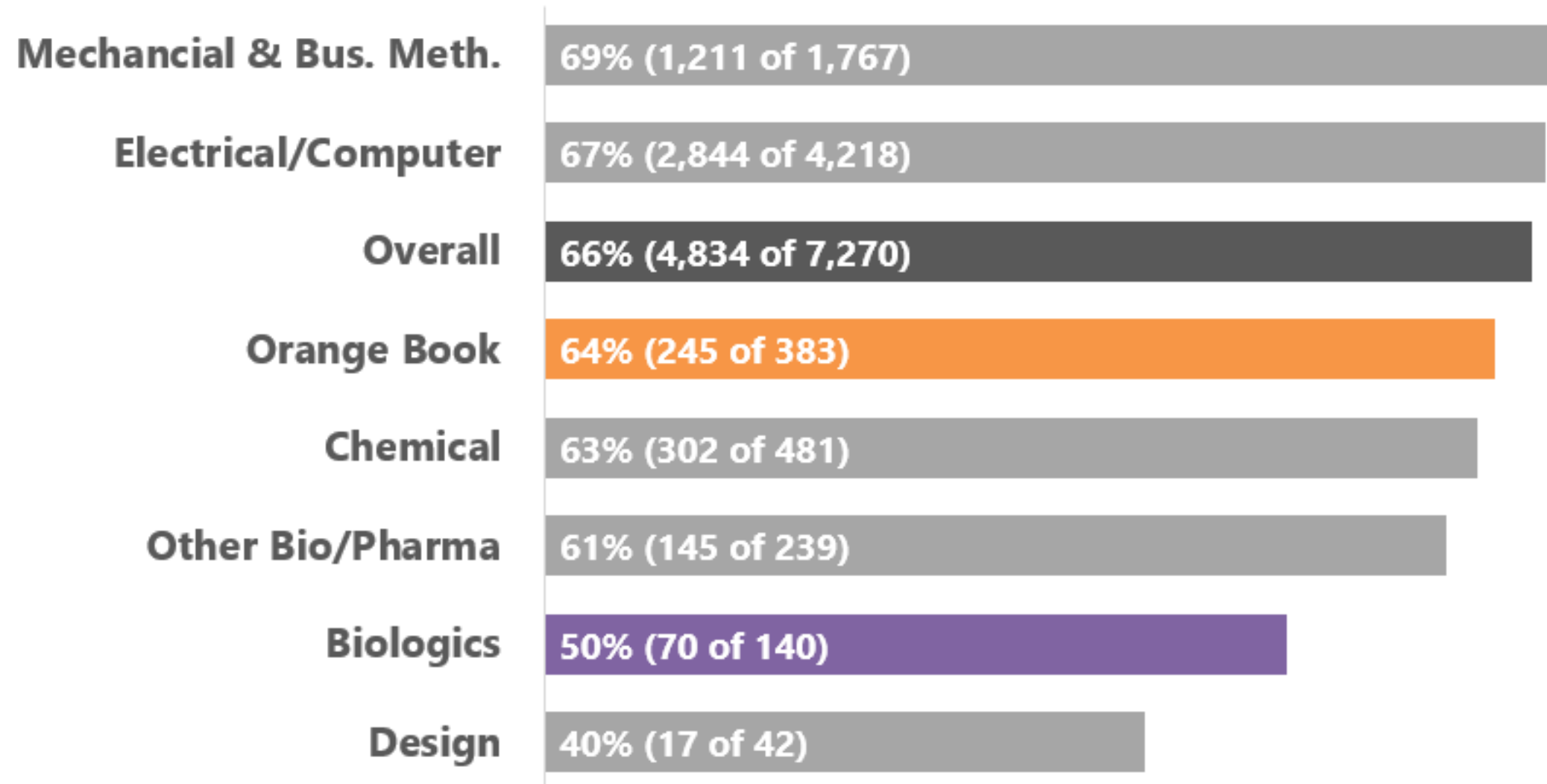
No petitions challenging Orange-Book-listed patents were filed in FY12.



**How does the institution rate for  
AIA petitions challenging  
Orange Book-listed or biologic  
patents compare to other  
technologies?**

# Institution rates by technology

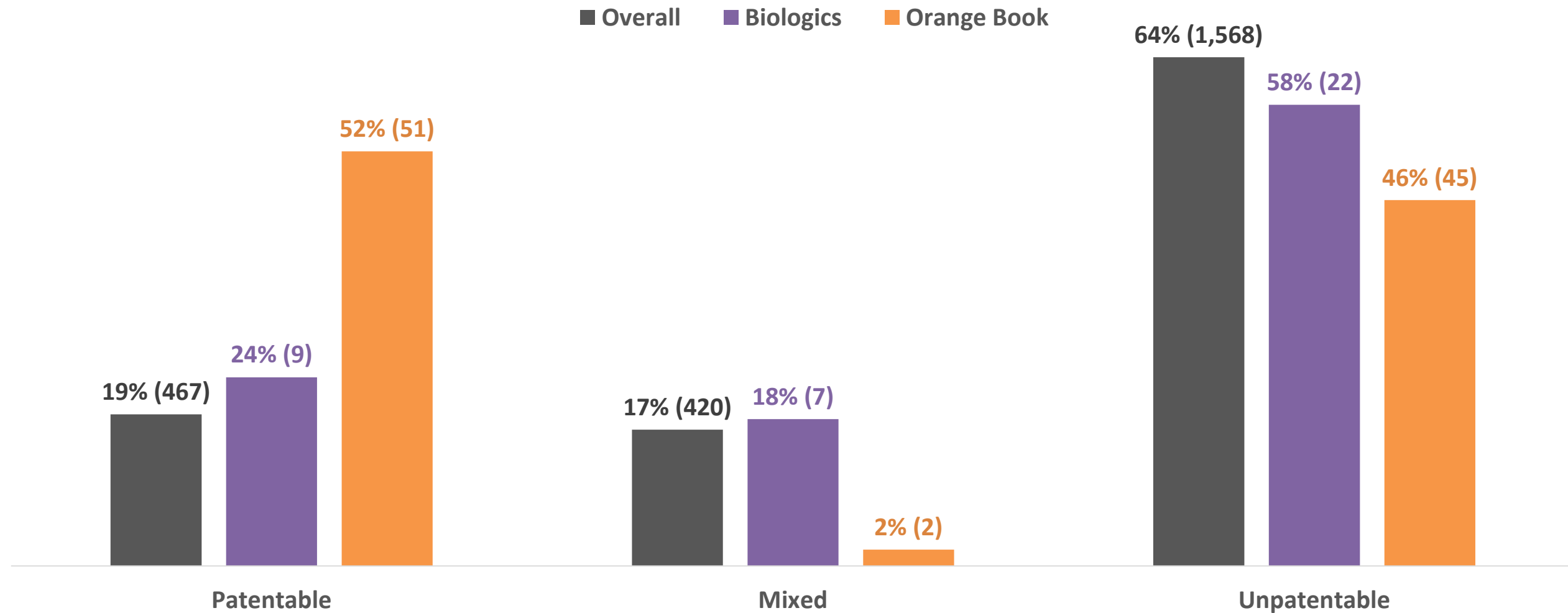
(Sept. 16, 2012 to Nov. 30, 2018)



**What are the outcomes to instituted  
Orange Book-listed or biologic  
patents?**

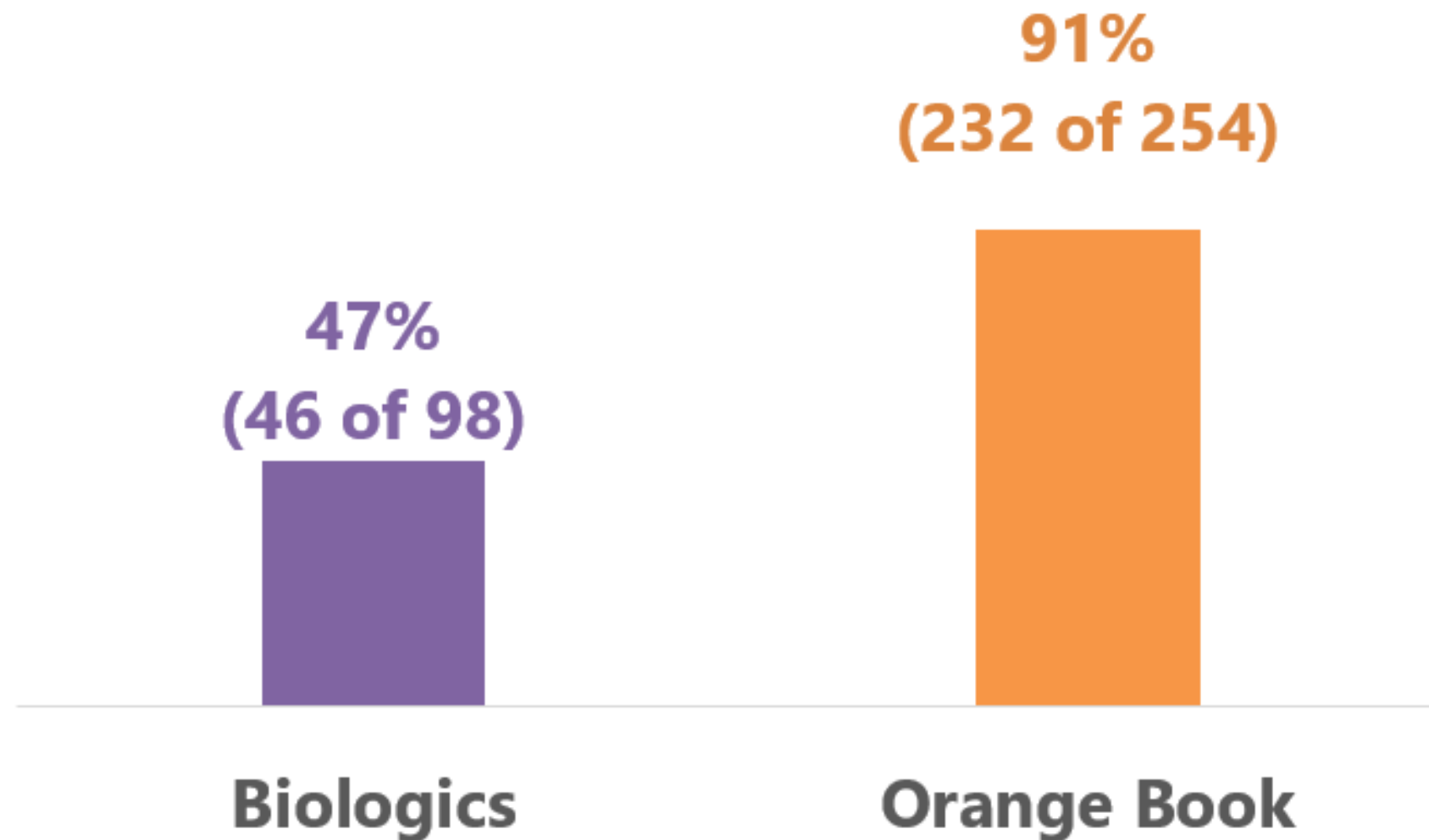
# Status of instituted claims in final written decisions

(Sept. 16, 2012 to Nov. 30, 2018)



# Litigation study

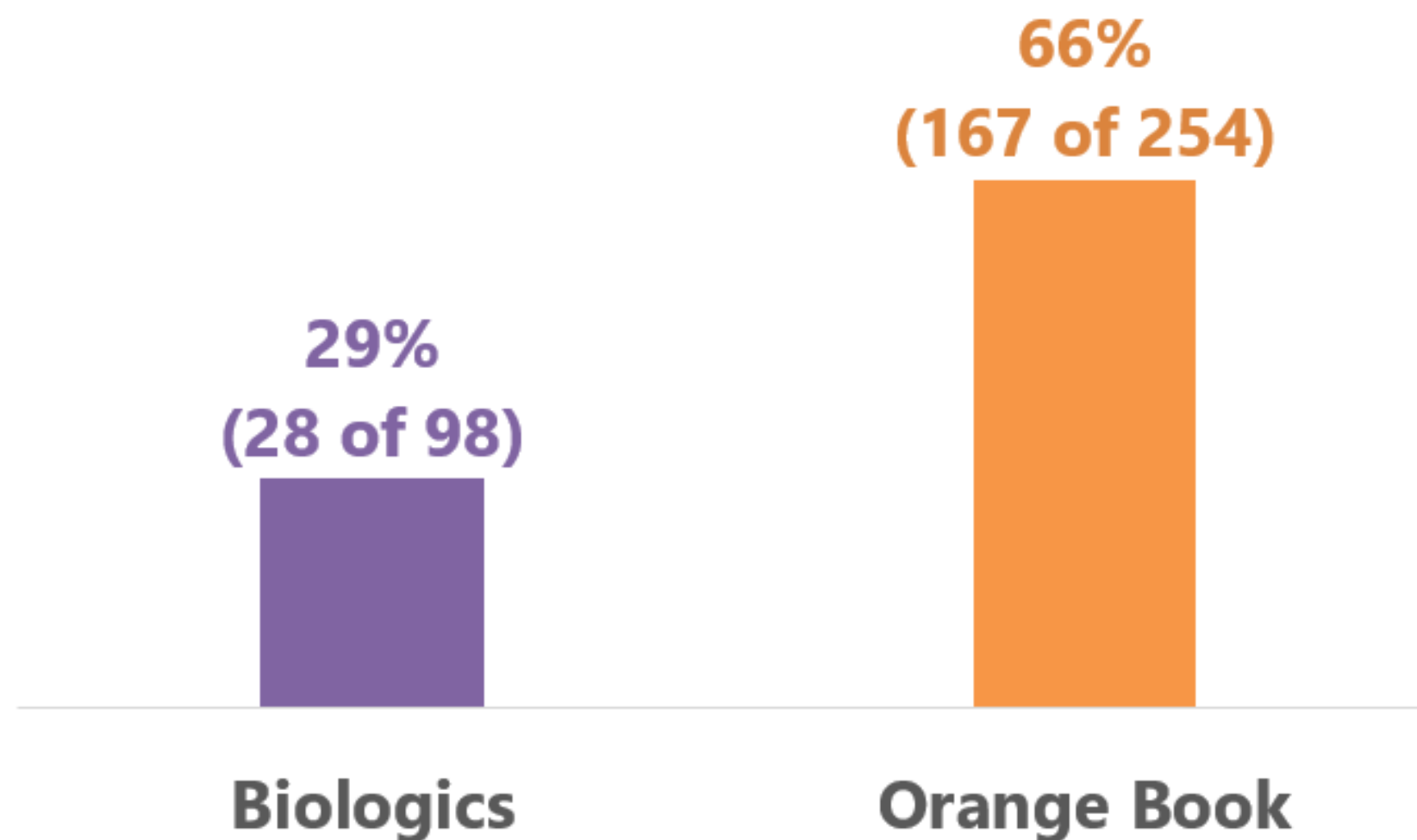
# What percent of patents challenged in AIA proceedings have been involved in any district court litigation? (Sept. 16, 2012 to Nov. 30, 2018)



The litigation in this part of the study is limited to litigation that the parties to a particular AIA proceeding identified in their papers and in the notice of patent suit filed with the office under 35 U.S.C. § 290

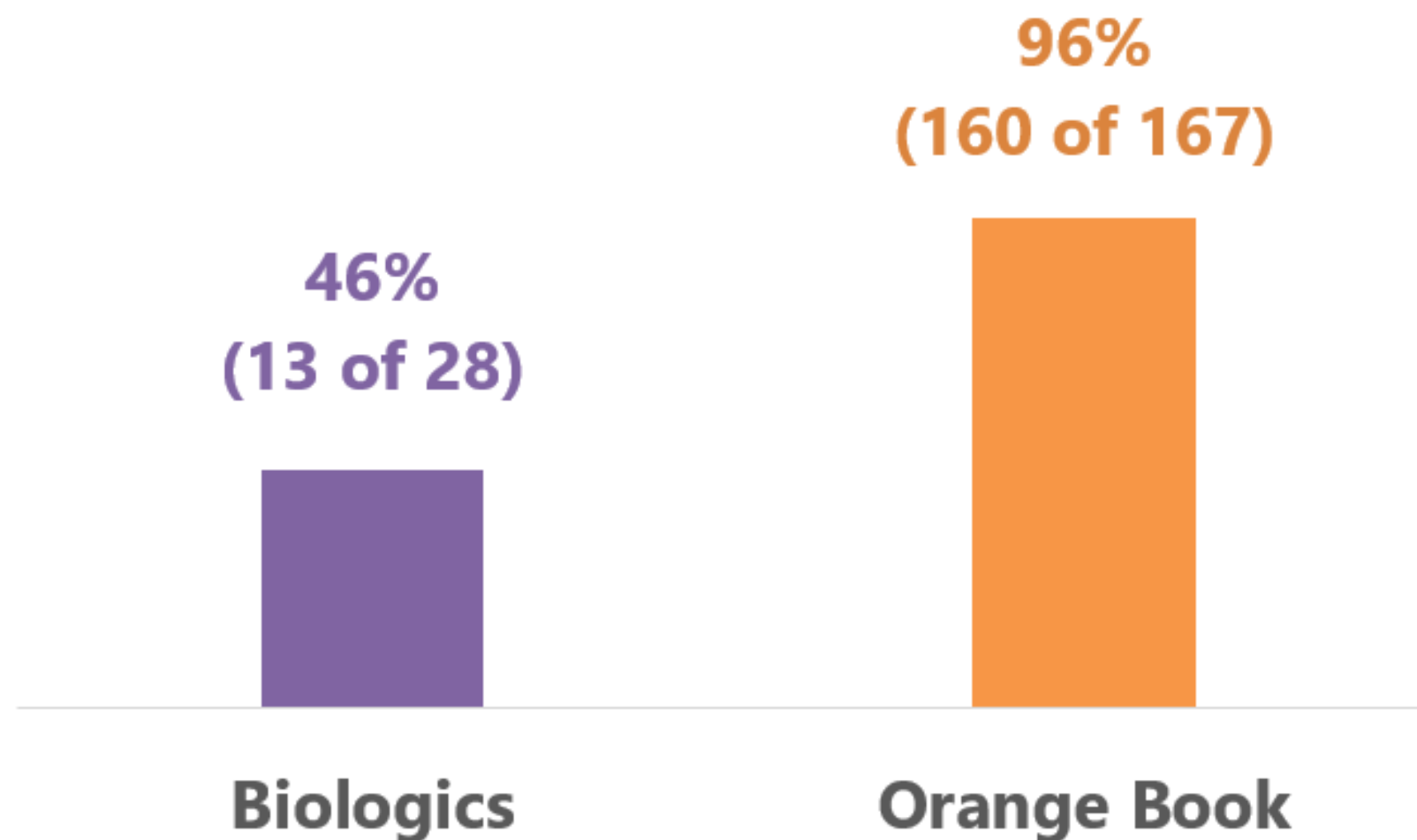
# What percent of patents challenged in AIA proceedings had district court litigation between the petitioner and patent owner?

(Sept. 16, 2012 to Nov. 30, 2018)



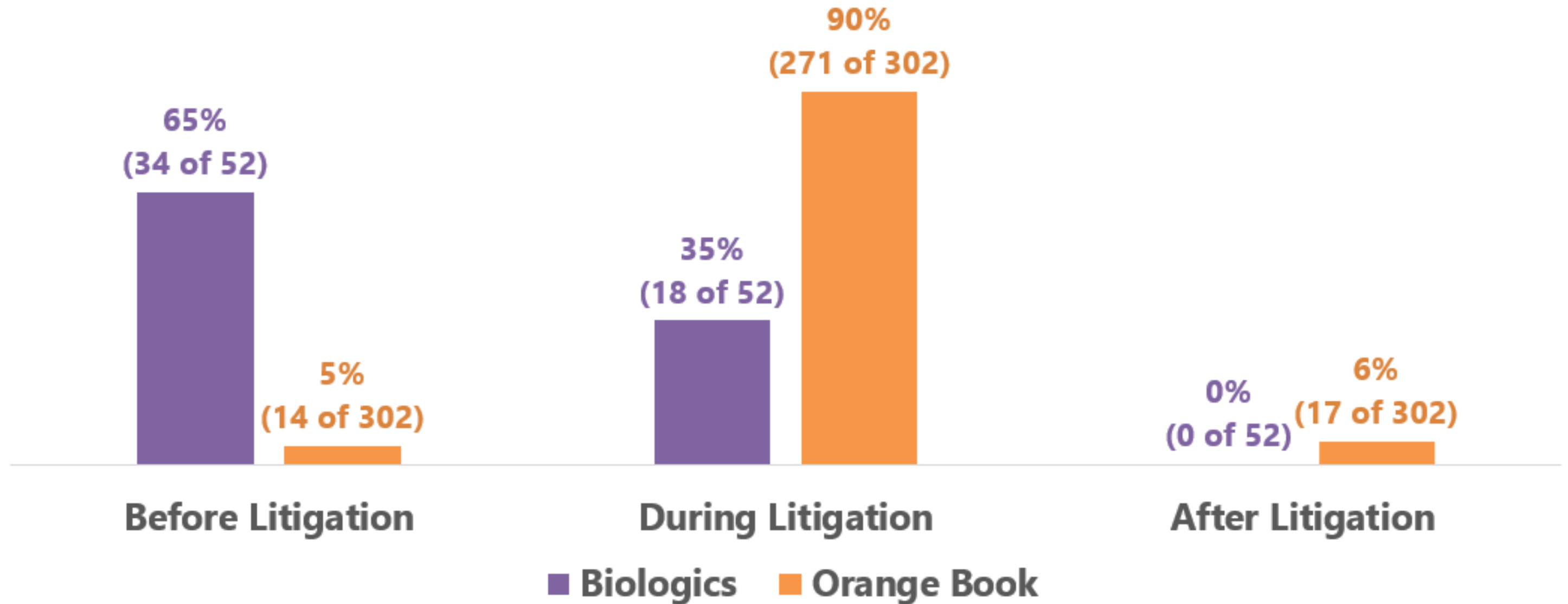
# What percent of those patents had an AIA petition filed during district court litigation between the petitioner and patent owner?

(Sept. 16, 2012 to Nov. 30, 2018)





# When were AIA petitions filed relative to corresponding district court litigation? (Sept. 16, 2012 to Nov. 30, 2018)



The litigation in this part of the study is limited to litigation that the parties to a particular AIA proceeding identified in their papers

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**Thank you**

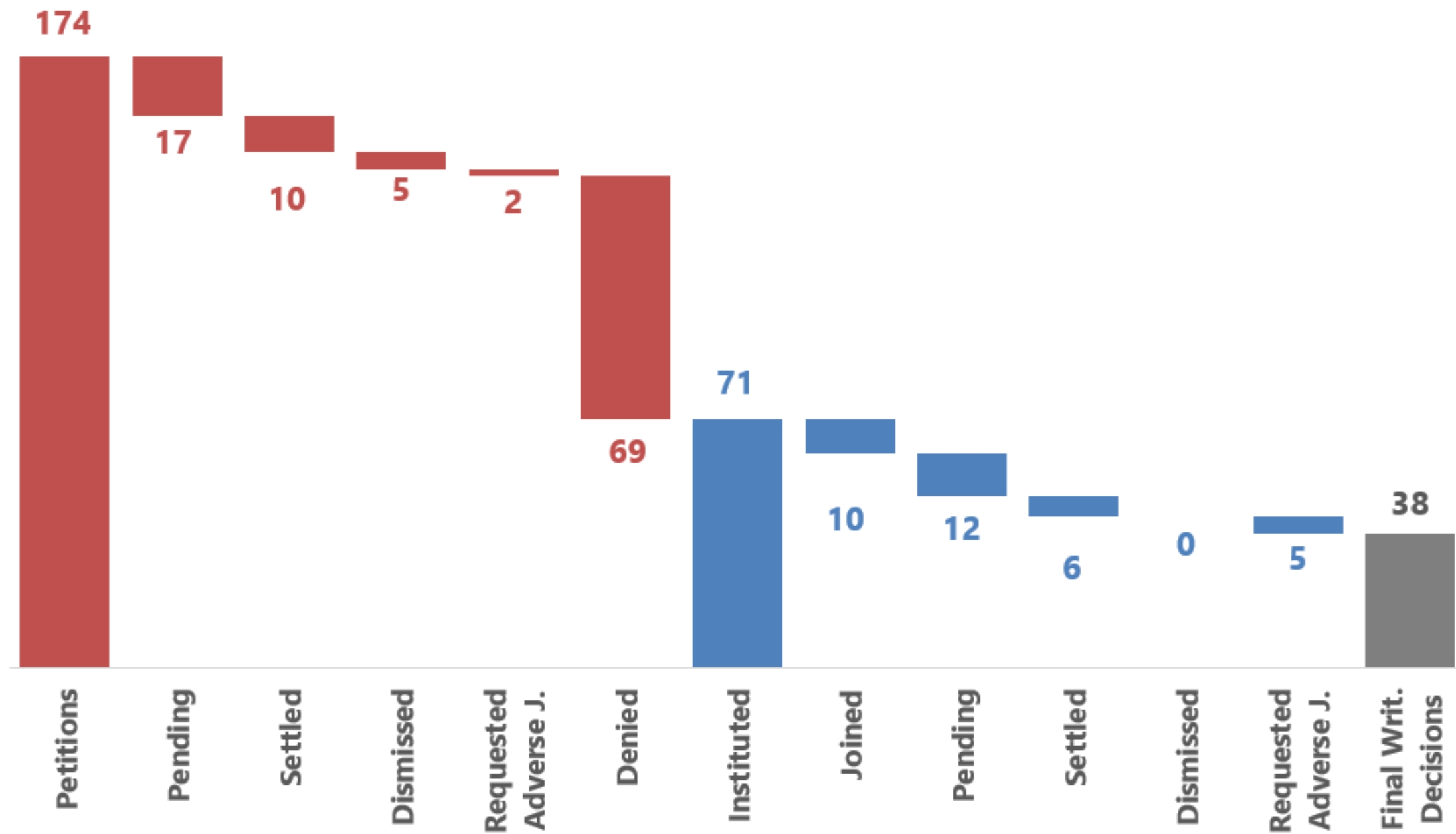
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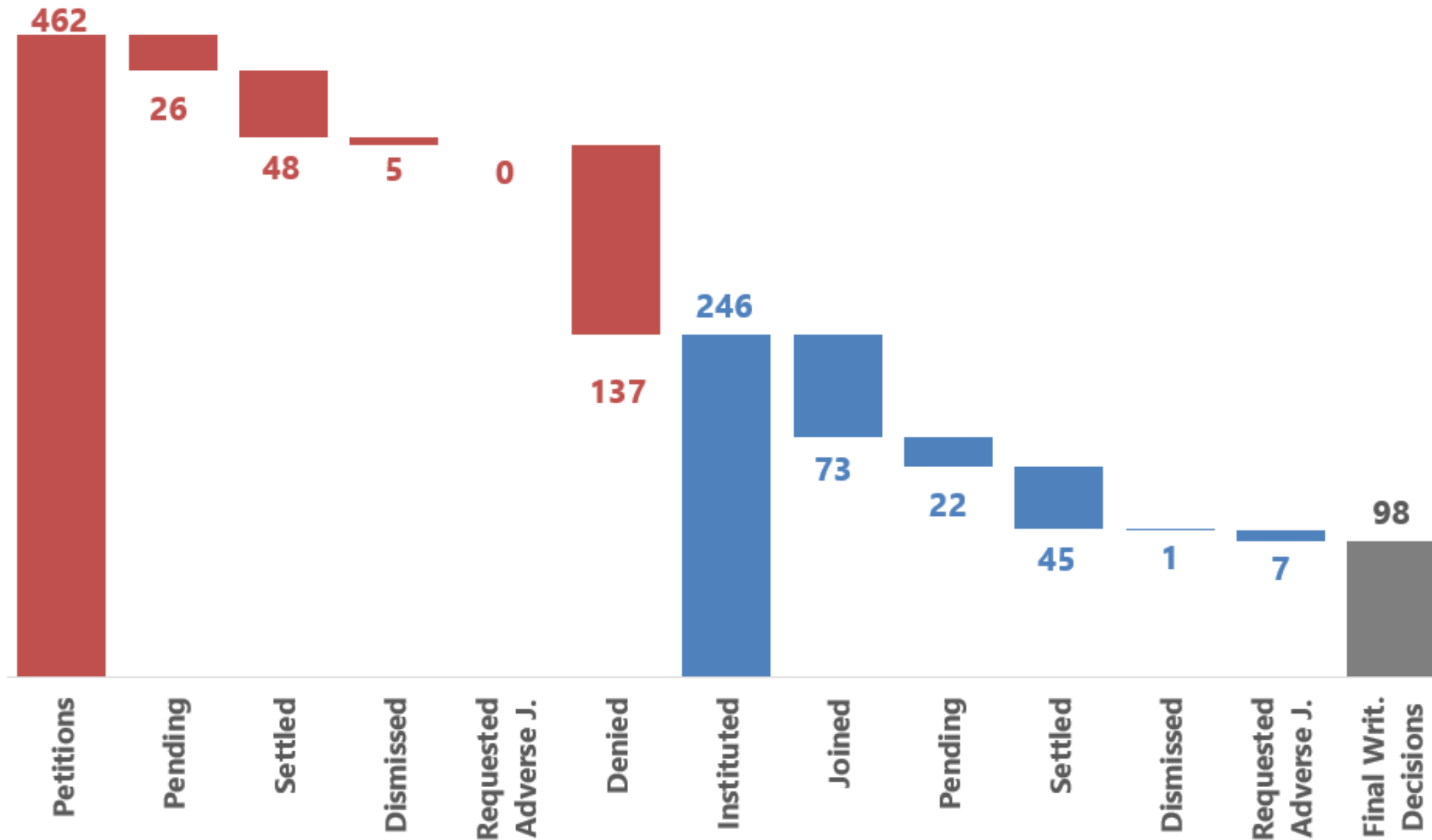
# Appendix

# Status of AIA petitions challenging Biologic patents

(Sept. 16, 2012 to Nov. 30, 2018)



# Status of AIA petitions challenging Orange Book patents (Sept. 16, 2012 to Nov. 30, 2018)



# Status of AIA petitions challenging any patent (Sept. 16, 2012 to Nov. 30, 2018)

