

UNITED STATES
PATENT AND TRADEMARK OFFICE



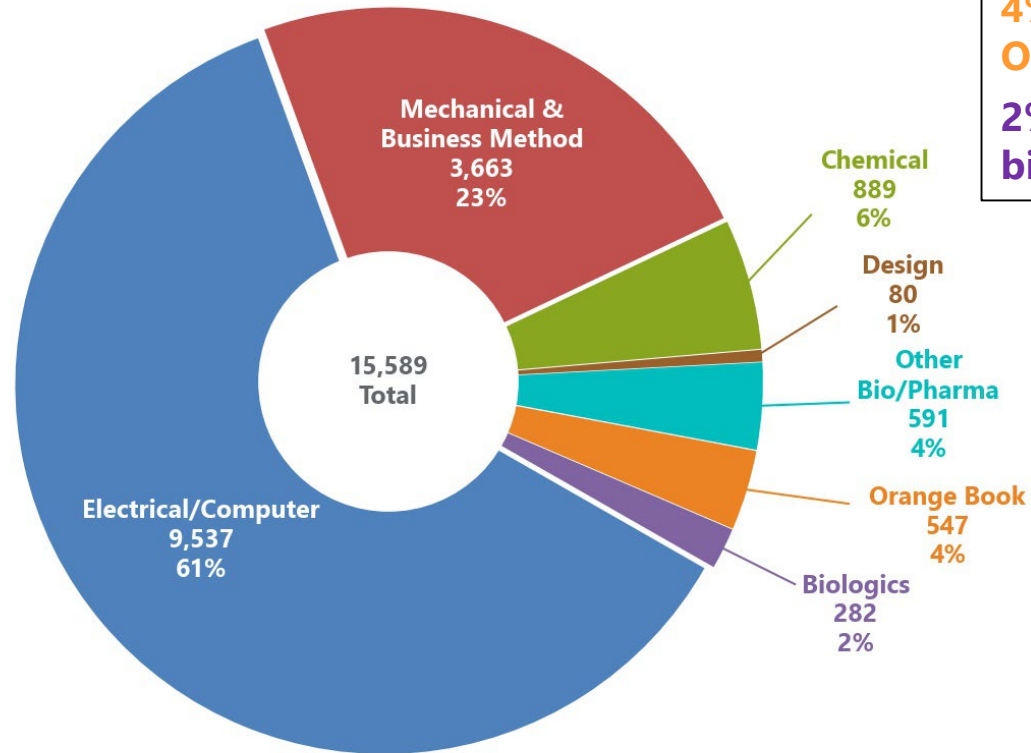
PTAB Orange Book patent/biologic patent study
FY23 Q2 Update (through March 31, 2023)

Overview of findings from Orange Book/biologic patent study

- 4% of all AIA petitions challenge Orange Book-listed patents
- 2% of all AIA petitions challenge biologic patents
- Challenges to Orange Book-listed patents have fallen from a peak of 7.5% of all petitions filed in FY 2016 to less than 2% of all petitions filed this FY
- Challenges to biologic patents have been more steady, but fewer since FY 2017
- PGR petitions are used more often when challenging biologic patents, compared to Orange Book-listed patents and other technologies
- The institution rate for biologic patents (59%) is lower than for Orange Book-listed patents (62%)
- But Orange Book-listed patents have had a greater percentage of claims upheld in a final written decision

AIA Petitions filed by technology

(Sept. 16, 2012 to Mar. 31, 2023)



4% of all AIA petitions challenge **Orange Book patents**

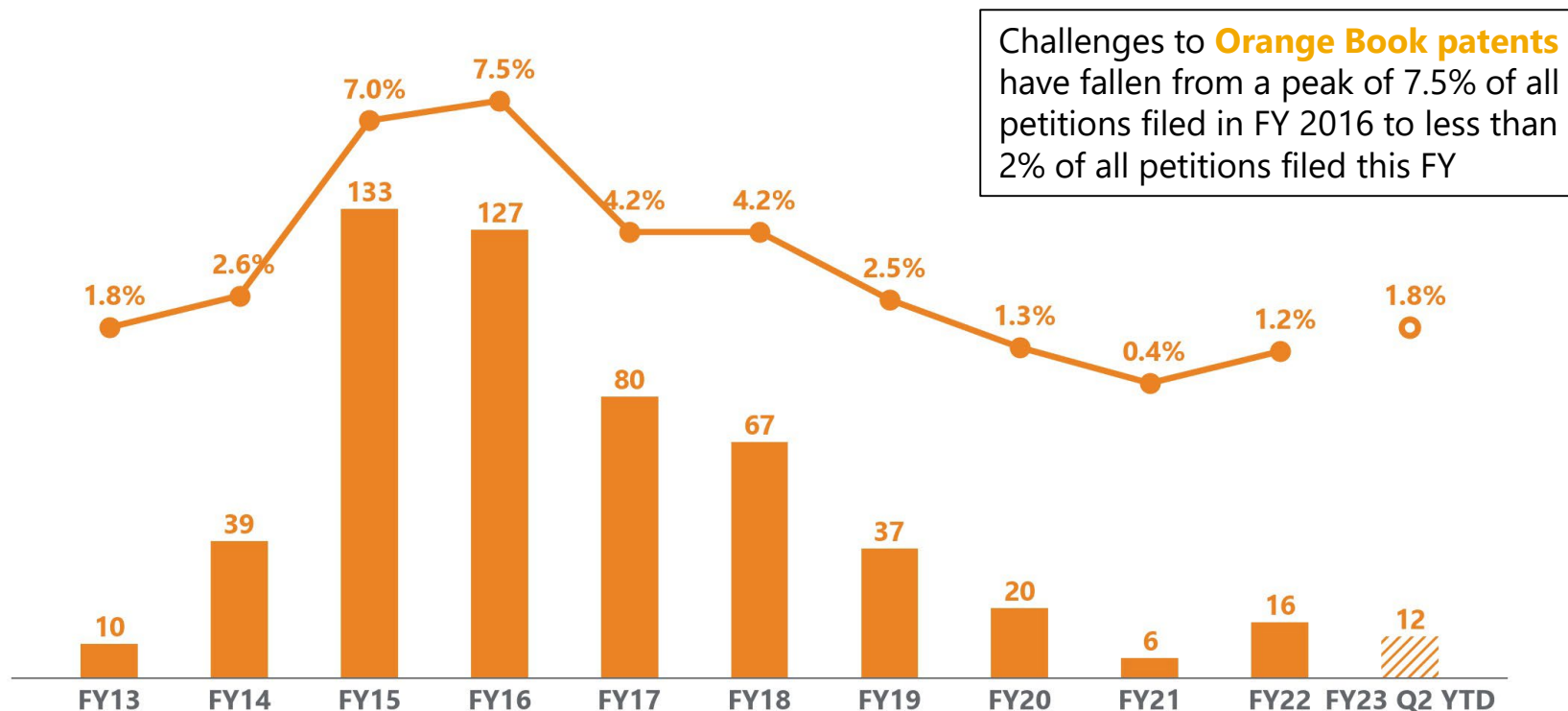
2% of all AIA petitions challenge **biologic patents**

Includes all trial types.



AIA Petitions challenging Orange Book patents

(Sept. 16, 2012 to Mar. 31, 2023)



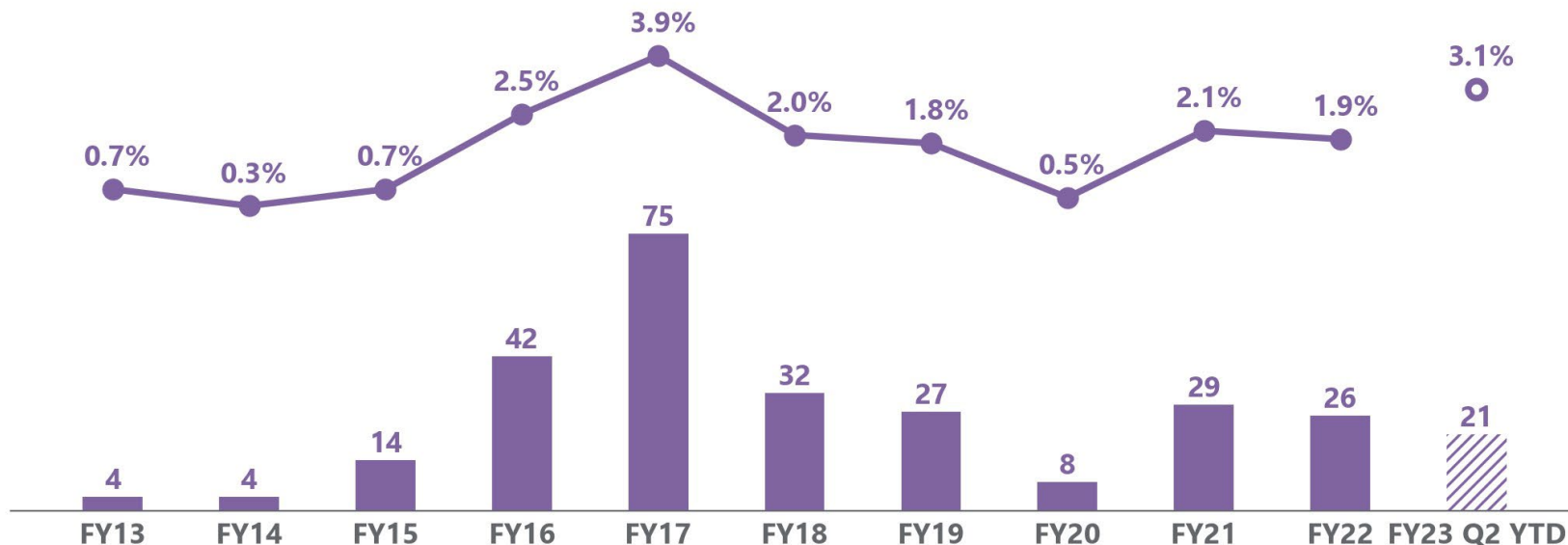
No petitions challenging Orange-Book-listed patents were filed in FY12.



AIA Petitions challenging biologic patents

(Sept. 16, 2012 to Mar. 31, 2023)

Challenges to **biologic patents** have been more steady, but fewer since FY2017

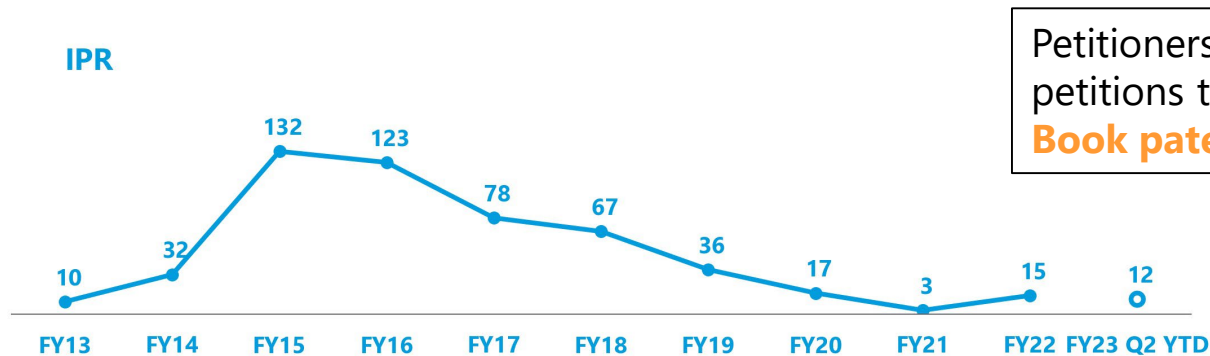


No petitions challenging biologic patents were filed in FY12.



Orange Book petitions filed by trial type

(Sept. 16, 2012 to Mar. 31, 2023)



Petitioners most often use IPR petitions to challenge **Orange Book** patents

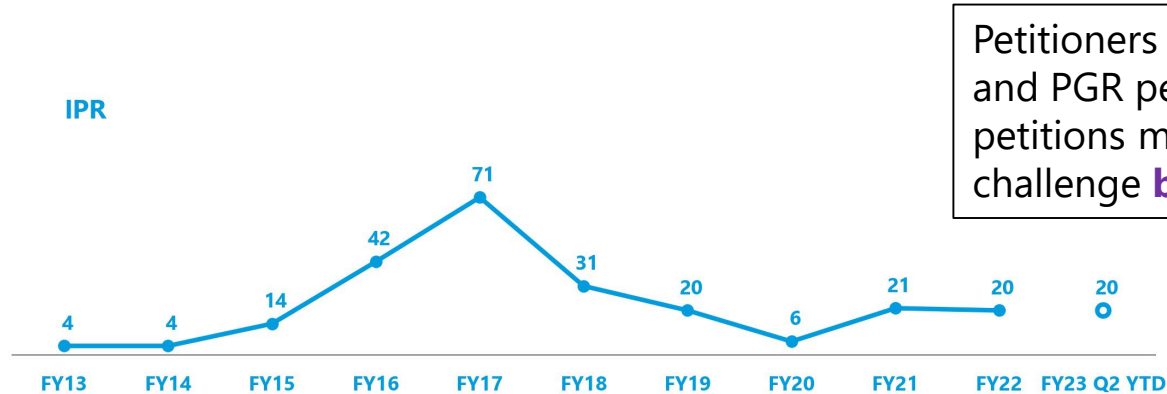


Not shown: 6 CBMs challenging OB-listed patents were filed in 2014.



Biologic petitions filed by trial type

(Sept. 16, 2012 to Mar. 31, 2023)



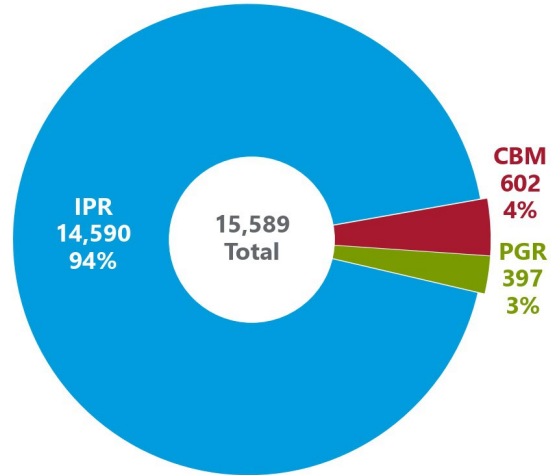
Petitioners generally use IPR and PGR petitions, but IPR petitions more frequently, to challenge **biologic patents**



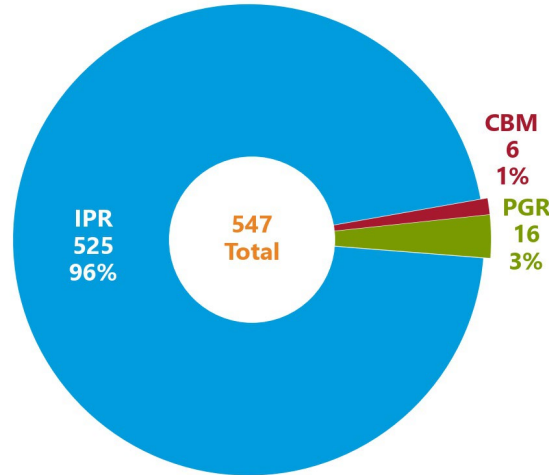
Petitions filed by trial type

(Sept. 16, 2012 to Mar. 31, 2023)

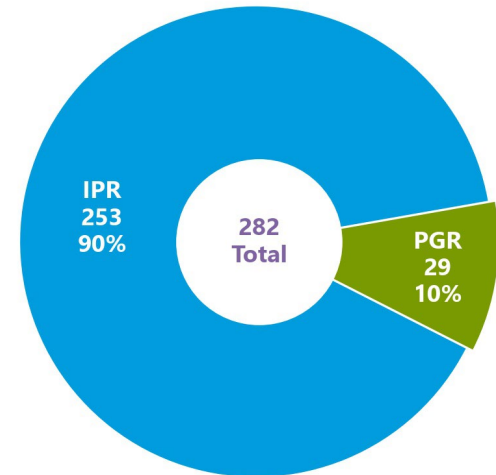
All Technology Categories



Orange Book



Biologics



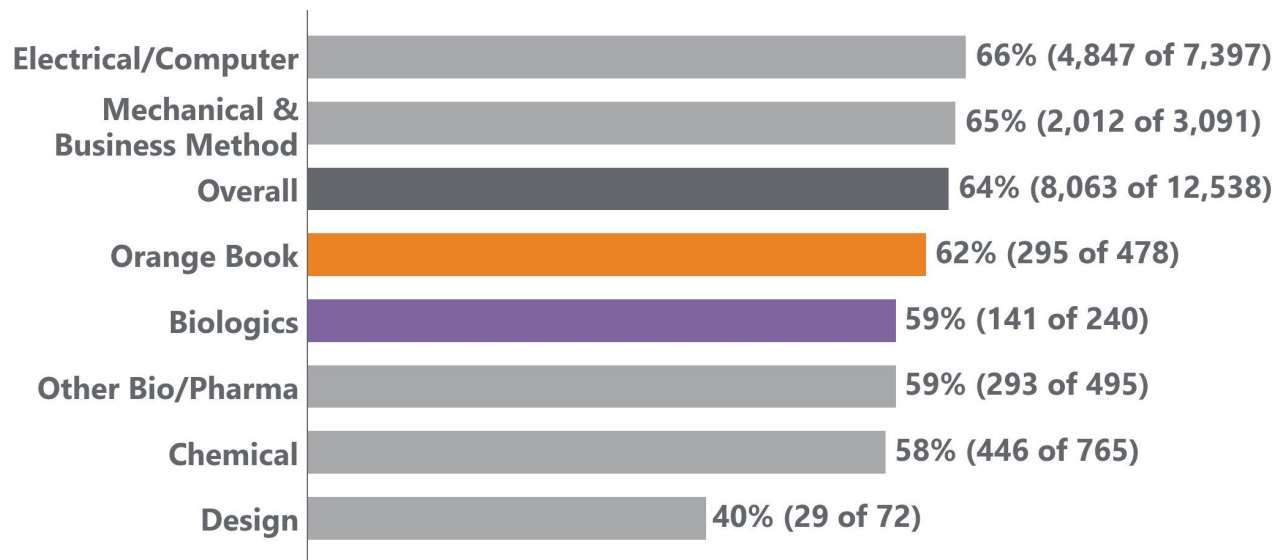
PGR petitions are used more often when challenging **biologic patents**, compared to **Orange Book patents** and other technologies



Institution rates by technology

(Sept. 16, 2012 to Mar. 31, 2023)

The institution rate for **biologic patents (59%)** is lower than for **Orange Book patents (62%)**

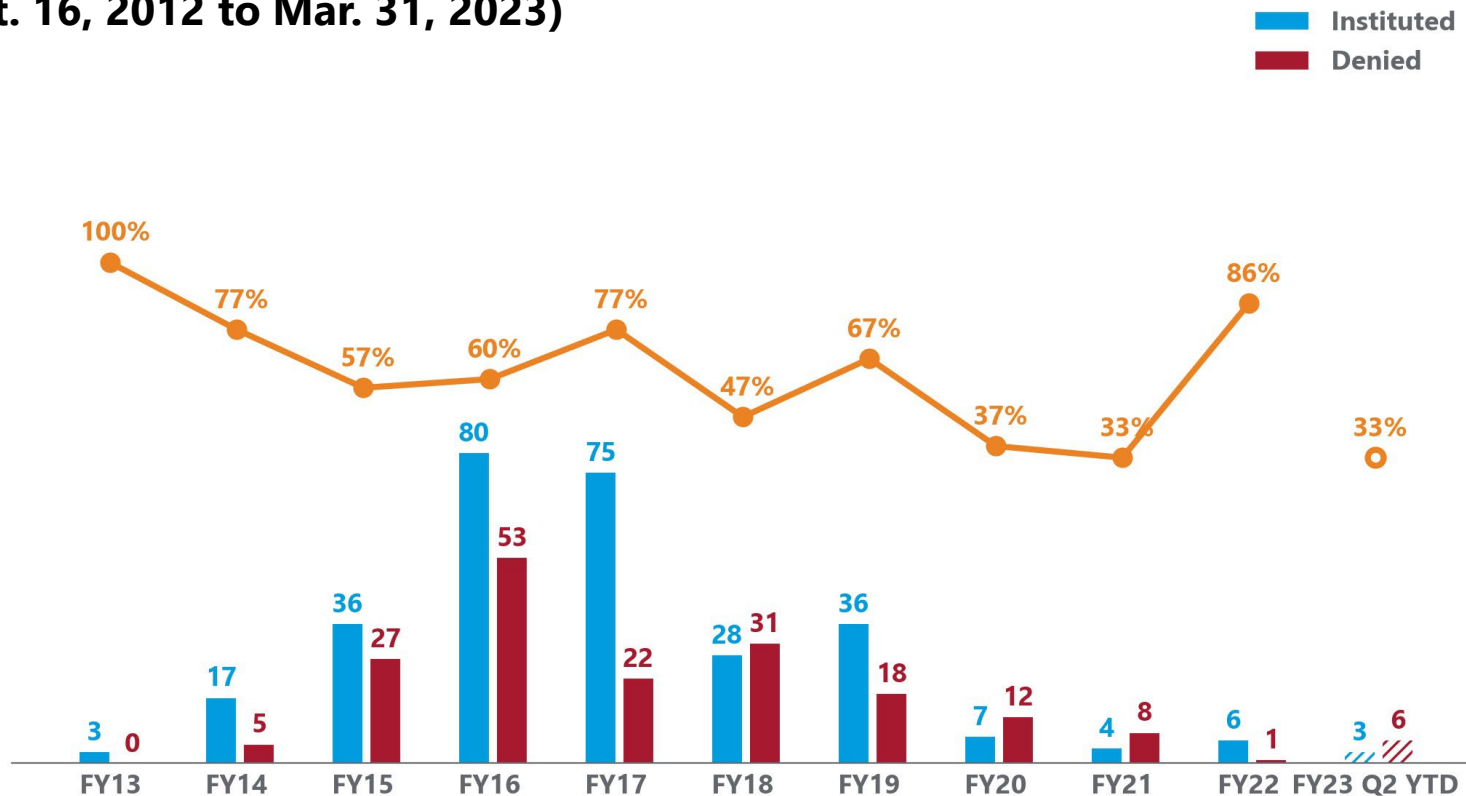


Institution rate for each technology is calculated by dividing petitions instituted by decisions on institution (i.e., petitions instituted plus petitions denied). The outcomes of decisions on institution responsive to requests for rehearing are excluded.



Institution rate Orange Book patents

(Sept. 16, 2012 to Mar. 31, 2023)

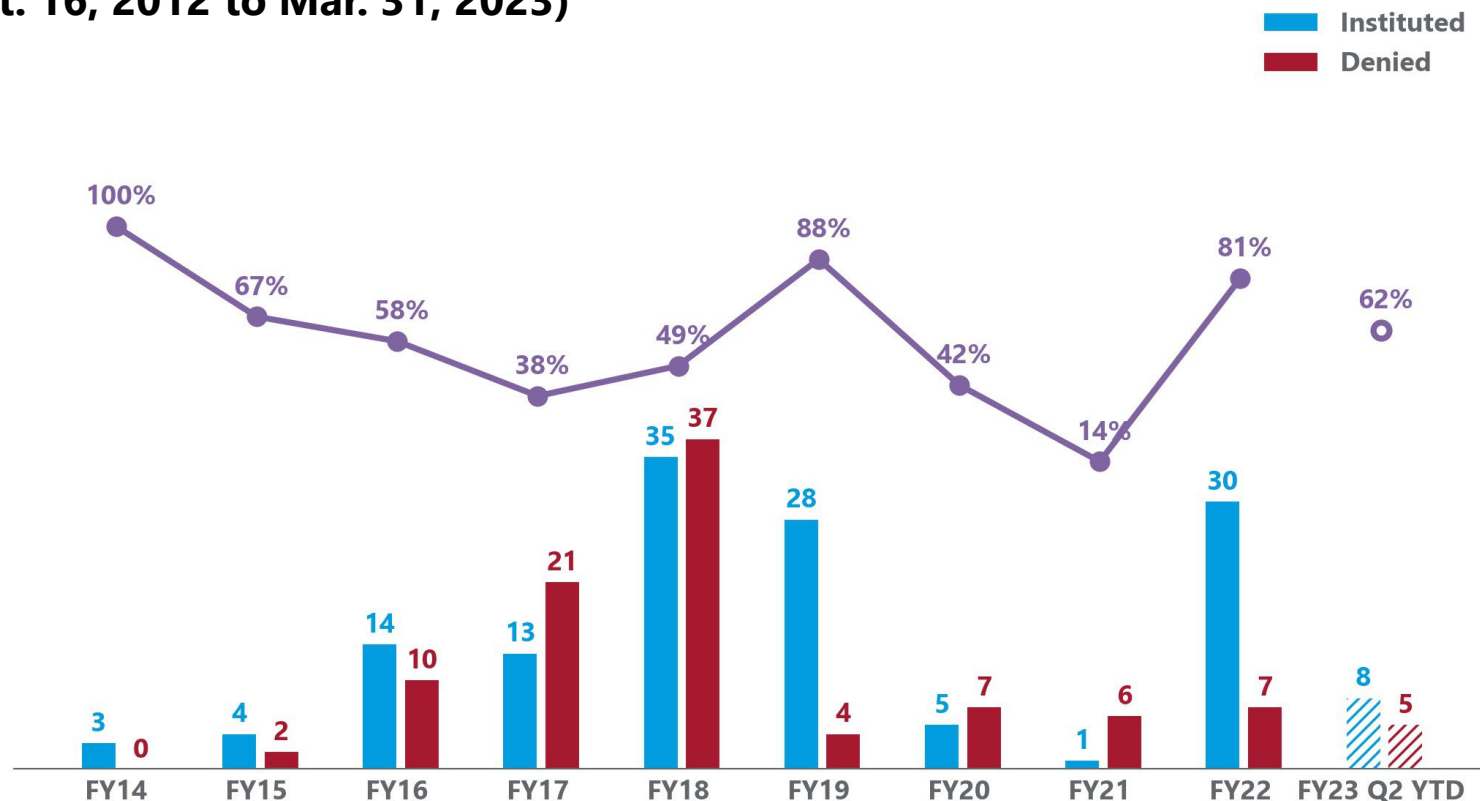


Institution rate for each technology is calculated by dividing petitions instituted by decisions on institution (i.e., petitions instituted plus petitions denied). The outcomes of decisions on institution responsive to requests for rehearing are excluded.



Institution rate biologic patents

(Sept. 16, 2012 to Mar. 31, 2023)



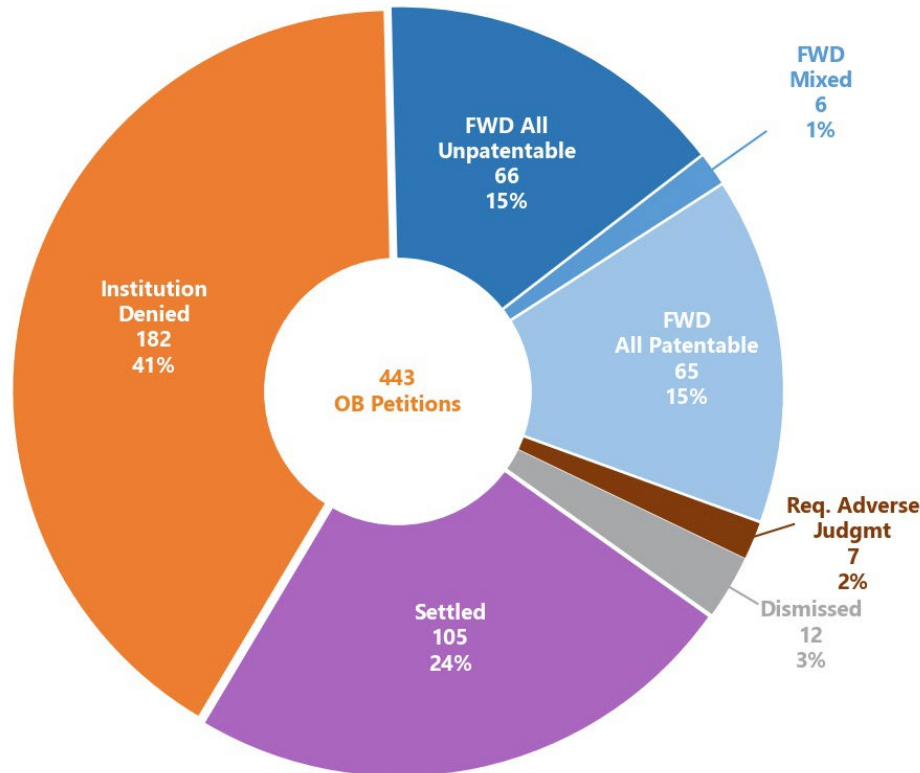
No institution decisions for biologic patents before FY14

Institution rate for each technology is calculated by dividing petitions instituted by decisions on institution (i.e., petitions instituted plus petitions denied). The outcomes of decisions on institution responsive to requests for rehearing are excluded.



Outcomes of AIA petitions challenging Orange Book patents

(Sept. 16, 2012 to Mar. 31, 2023)

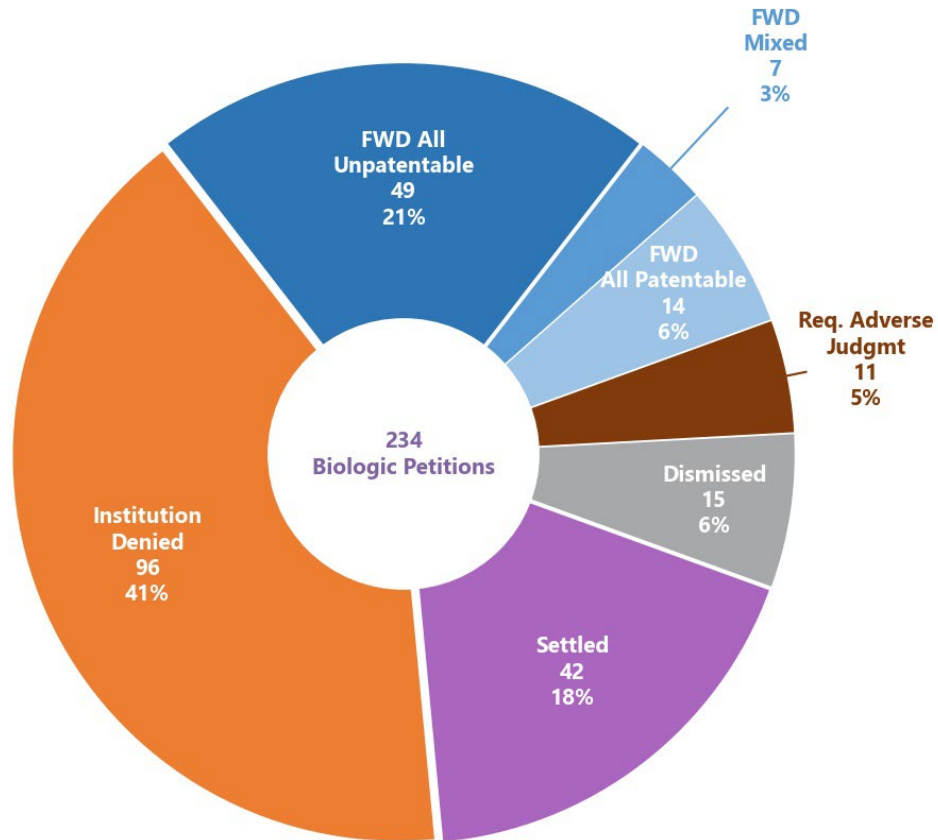


The outcomes of decisions on institution responsive to requests for rehearing are included.

Joined and pending petitions are excluded.



Outcomes of AIA petitions challenging biologic patents (Sept. 16, 2012 to Mar. 31, 2023)

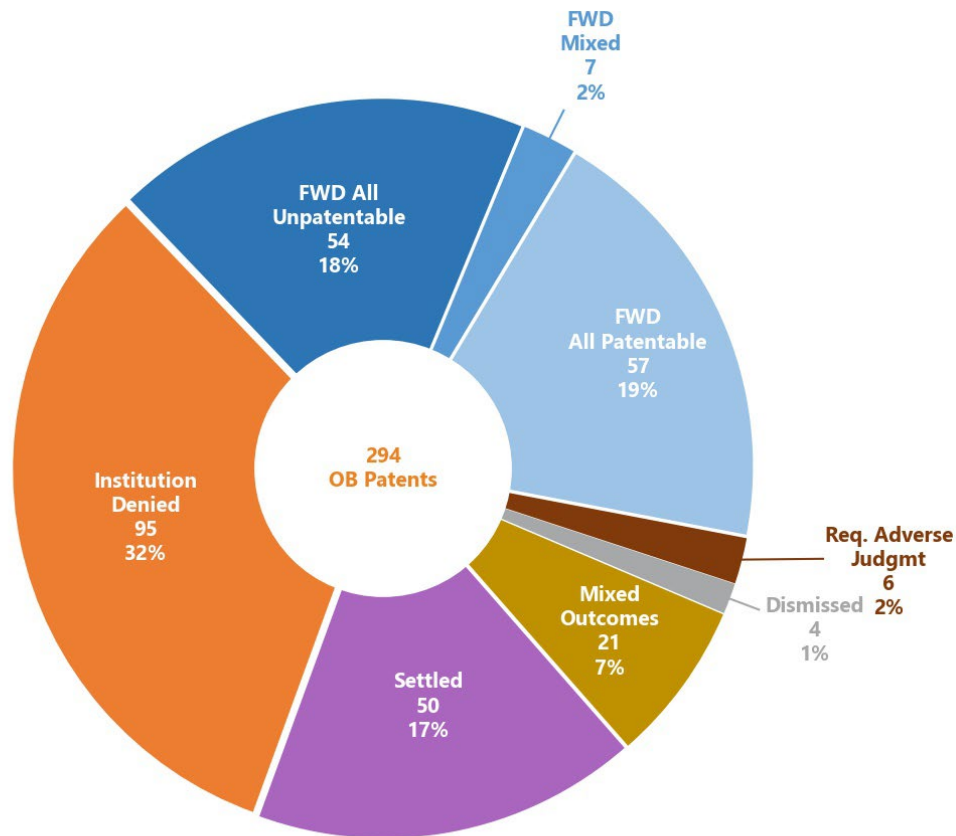


The outcomes of decisions on institution responsive to requests for rehearing are included.

Joined and pending petitions are excluded.

Outcomes by patent for Orange Book patents

(Sept. 16, 2012 to Mar. 31, 2023)



FWD patentability or unpatentability reported with respect to the claims at issue in the FWD.

“Mixed Outcome” is shown for patents receiving more than one type of outcome from the list of: denied, settled, dismissed, and/or req. adverse judgement only.

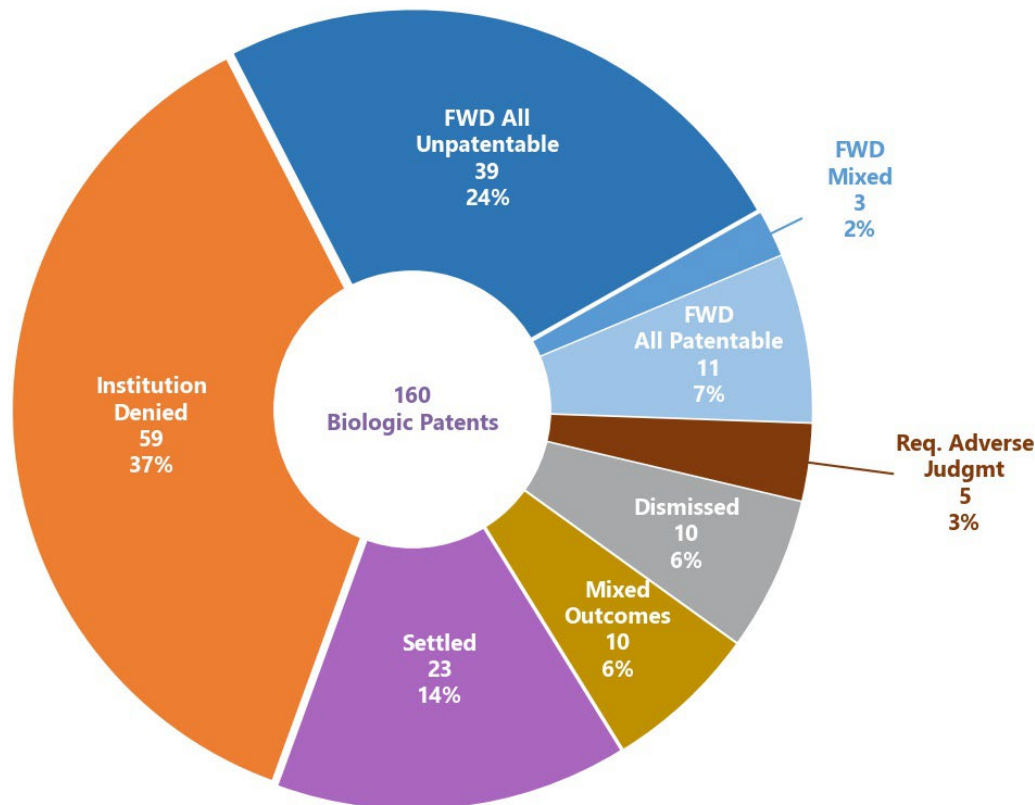
A patent is listed in a FWD category if it ever received a FWD, regardless of other outcomes.

Challenged patents having only pending petitions are omitted.



Outcomes by patent for biologic patents

(Sept. 16, 2012 to Mar. 31, 2023)



FWD patentability or unpatentability reported with respect to the claims at issue in the FWD.

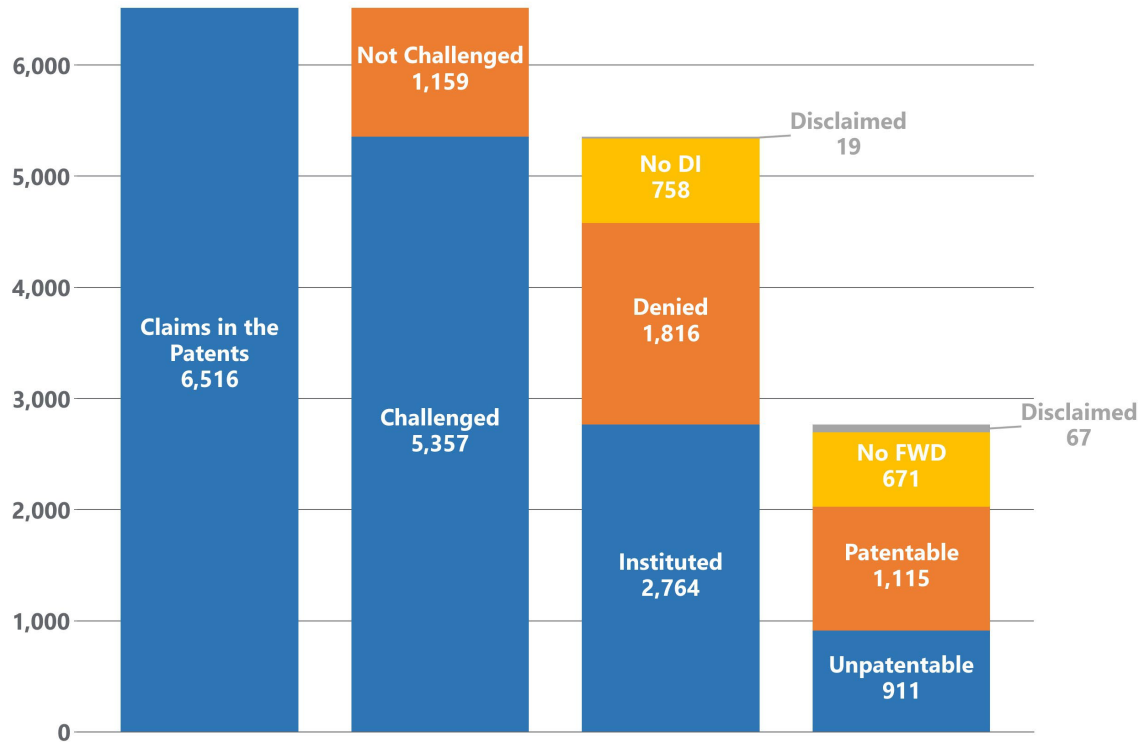
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A patent is listed in a FWD category if it ever received a FWD, regardless of other outcomes.

Challenged patents having only pending petitions are omitted



Claim outcomes for Orange Book patents (Sept. 16, 2012 to Mar. 31, 2023)



*"No DI" and "No FWD" means the claim was challenged but not addressed in a DI/FWD, e.g., due to settlement.

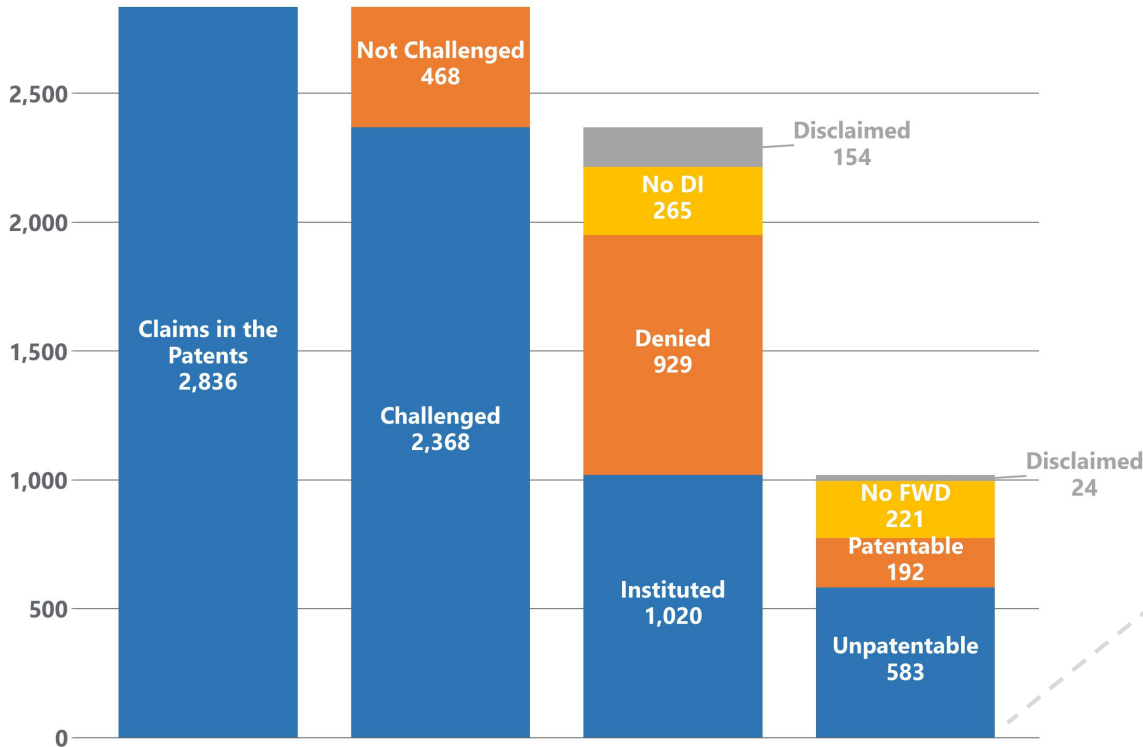
Orange Book patents:

17% of challenged claims and 33% of instituted claims were found unpatentable by a preponderance of the evidence



Claim outcomes for biologic patents

(Sept. 16, 2012 to Mar. 31, 2023)



**"No DI" and "No FWD" means the claim was challenged but not addressed in a DI/FWD, e.g., due to settlement.

Biologic patents:
 25% of challenged claims and 57% of instituted claims were found unpatentable by a preponderance of the evidence



