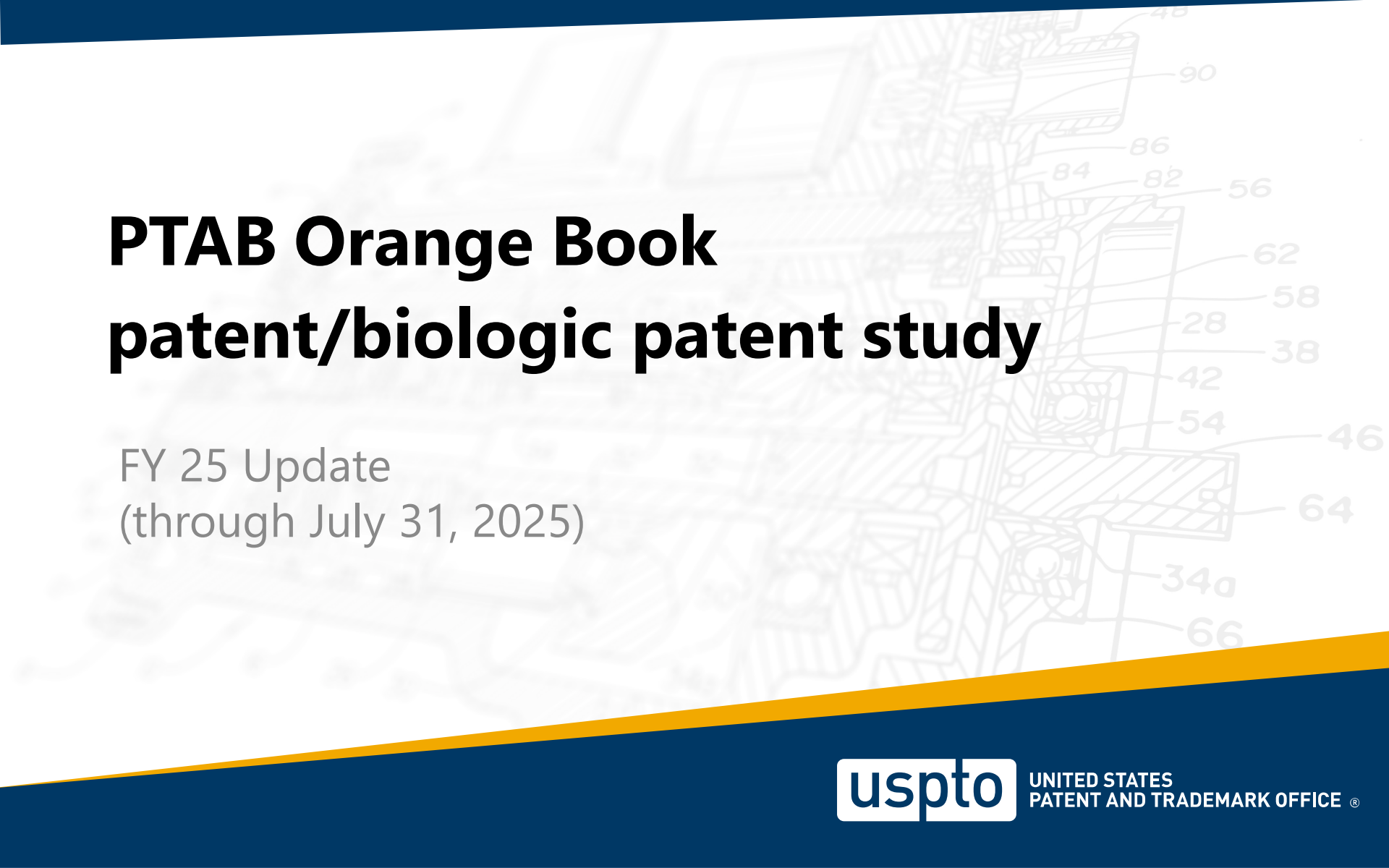


UNITED STATES
PATENT AND TRADEMARK OFFICE





PTAB Orange Book

patent/biologic patent study

FY 25 Update
(through July 31, 2025)



UNITED STATES
PATENT AND TRADEMARK OFFICE ®

Overview of findings from Orange Book/biologic patent study (1/2)

- 3% of all AIA Trials 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 1.4% of all petitions filed this FY
- Challenges to biologic patents have been more steady, but fewer since FY 2017

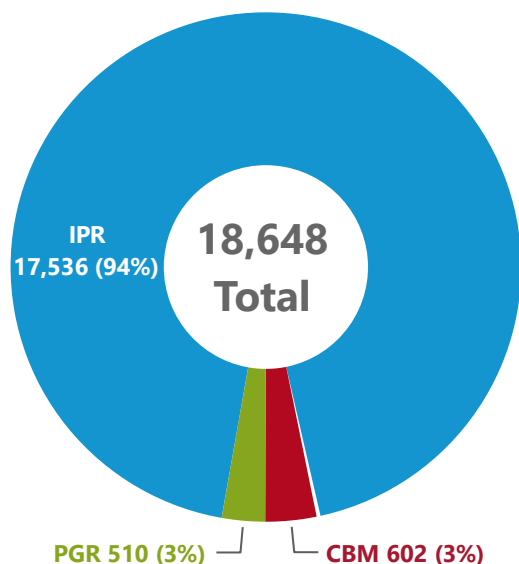
Overview of findings from Orange Book/biologic patent study (2/2)

- 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 (61%) is similar to the institution rate for Orange Book-listed patents (62%)
- Orange Book-listed patents have had a greater percentage of claims upheld in a final written decision than biologic patents

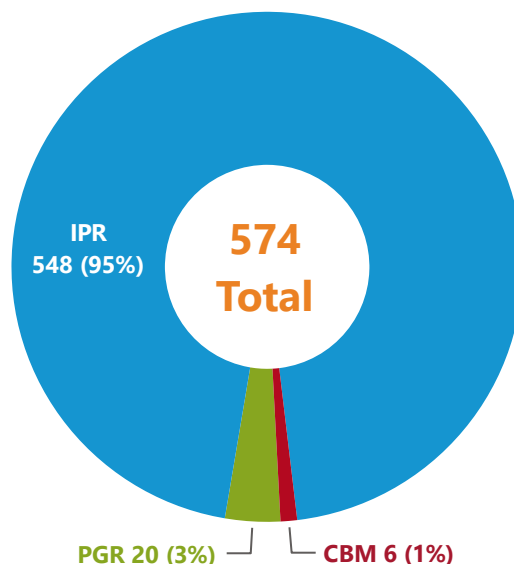
Petitions filed by trial type

(September 16, 2012 to July 31, 2025)

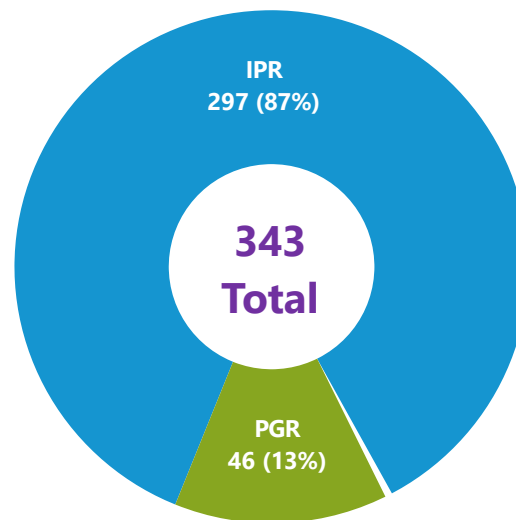
All Technology Categories



Orange Book



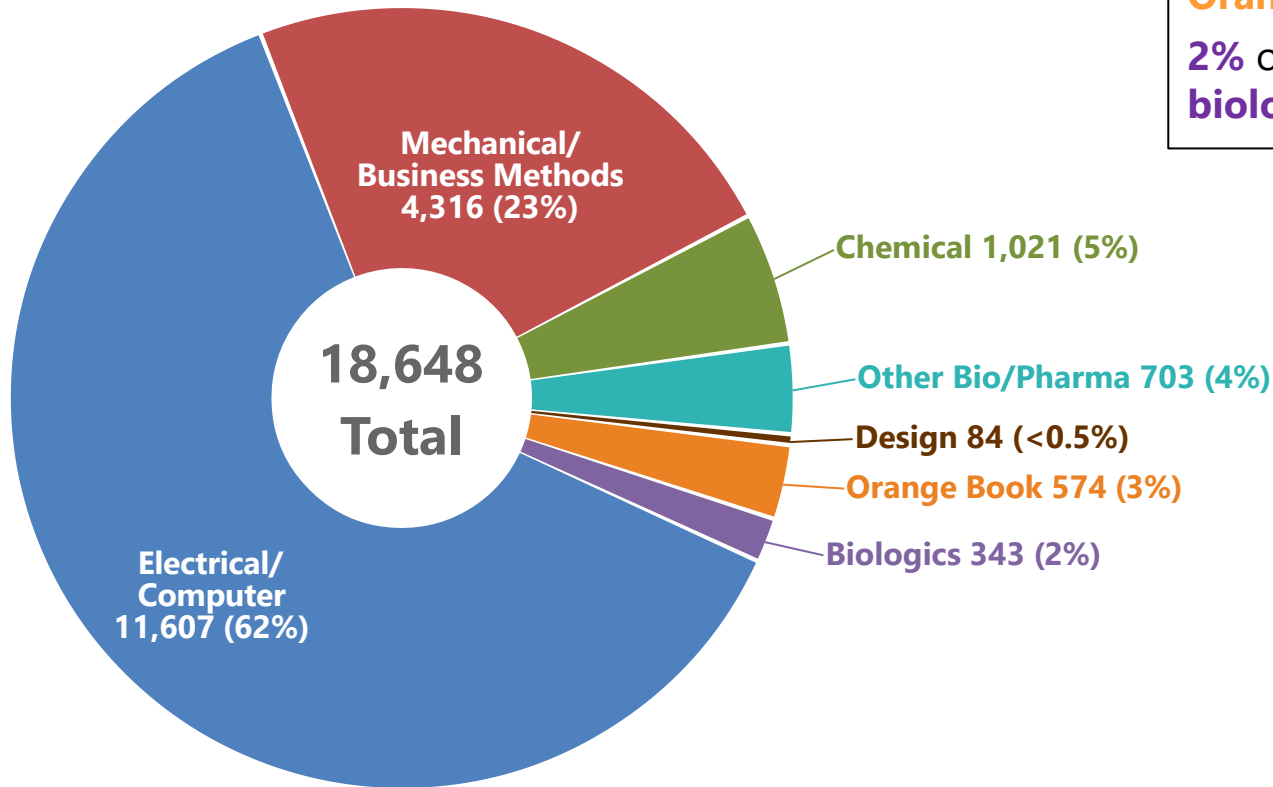
Biologics



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

Petitions filed by technology

(September 16, 2012 to July 31, 2025)

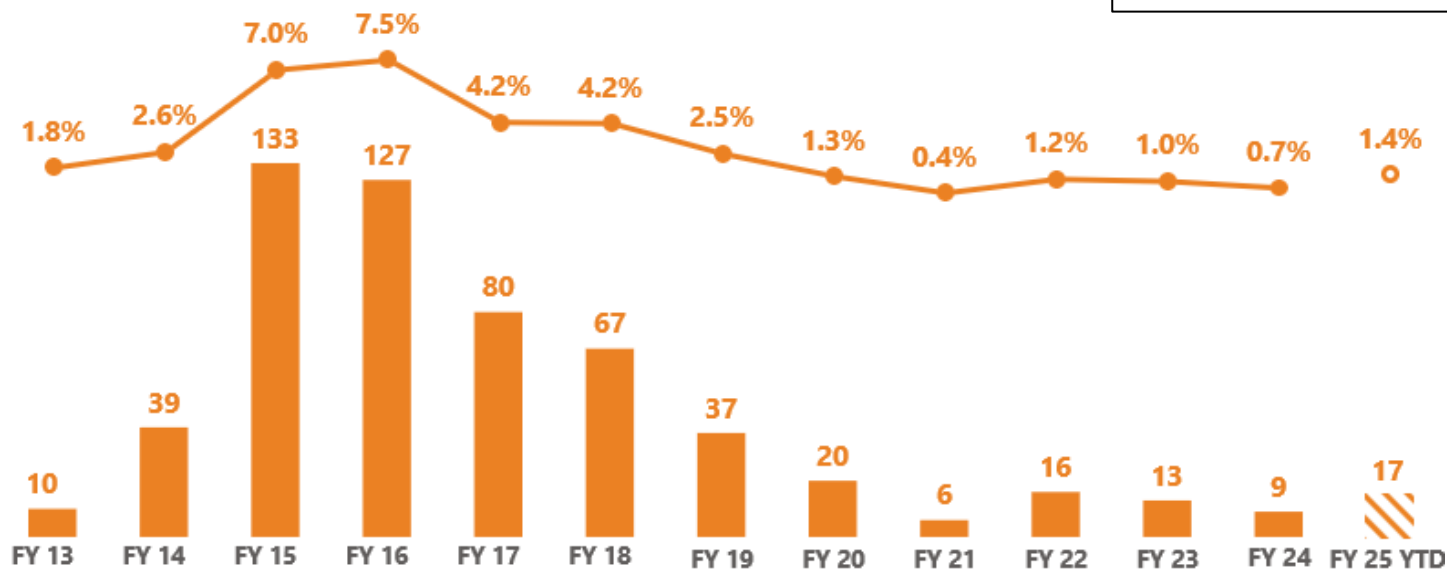


3% of all AIA petitions challenge
Orange Book patents
2% of all AIA petitions challenge
biologic patents

Petitions challenging Orange Book patents

(October 1, 2012 to July 31, 2025)

Challenges to **Orange Book patents** have fallen from a peak of 7.5% of all petitions filed in FY 2016 to less than 1.4% of all petitions filed this FY

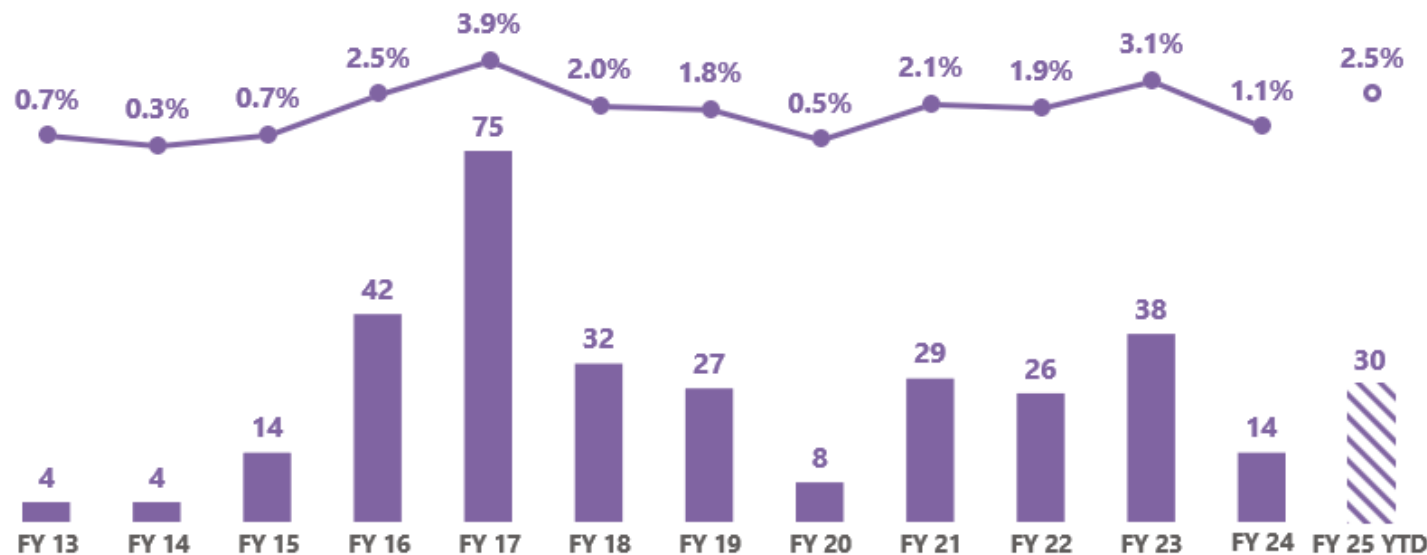


No petitions challenging Orange-Book-listed patents were filed in FY12.

Petitions challenging biologic patents

(October 1, 2012 to July 31, 2025)

Challenges to **biologic patents** have been more steady, but fewer since FY 2017

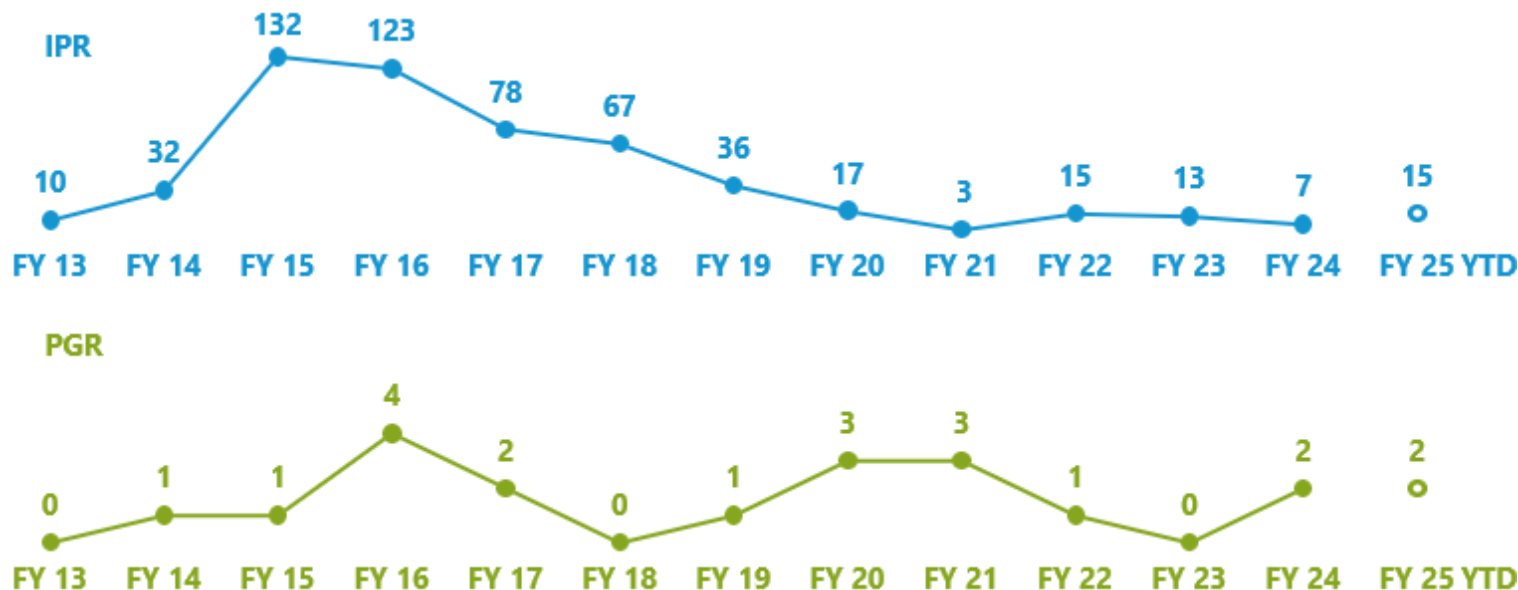


No petitions challenging biologic patents were filed in FY12.

Orange Book petitions filed by trial type

(October 1, 2012 to July 31, 2025)

Petitioners most often use IPR petitions to challenge
Orange Book patents

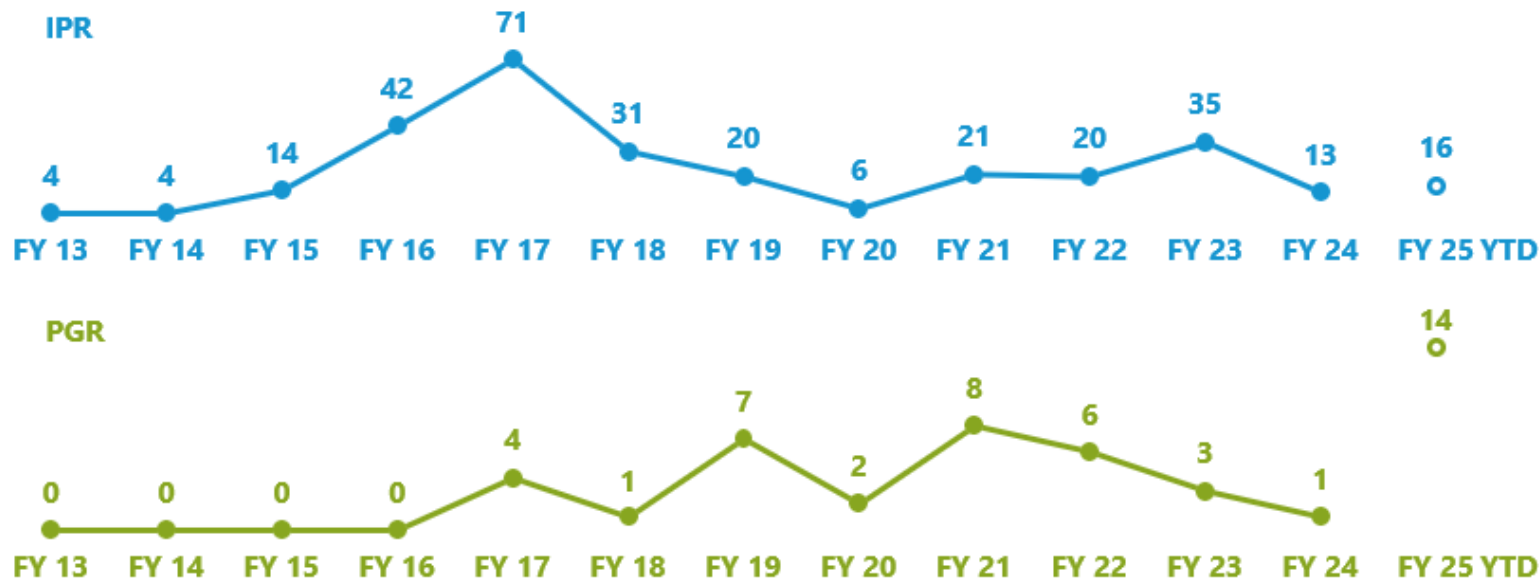


Not shown: 6 CBMs challenging OB-listed patents were filed in 2014.

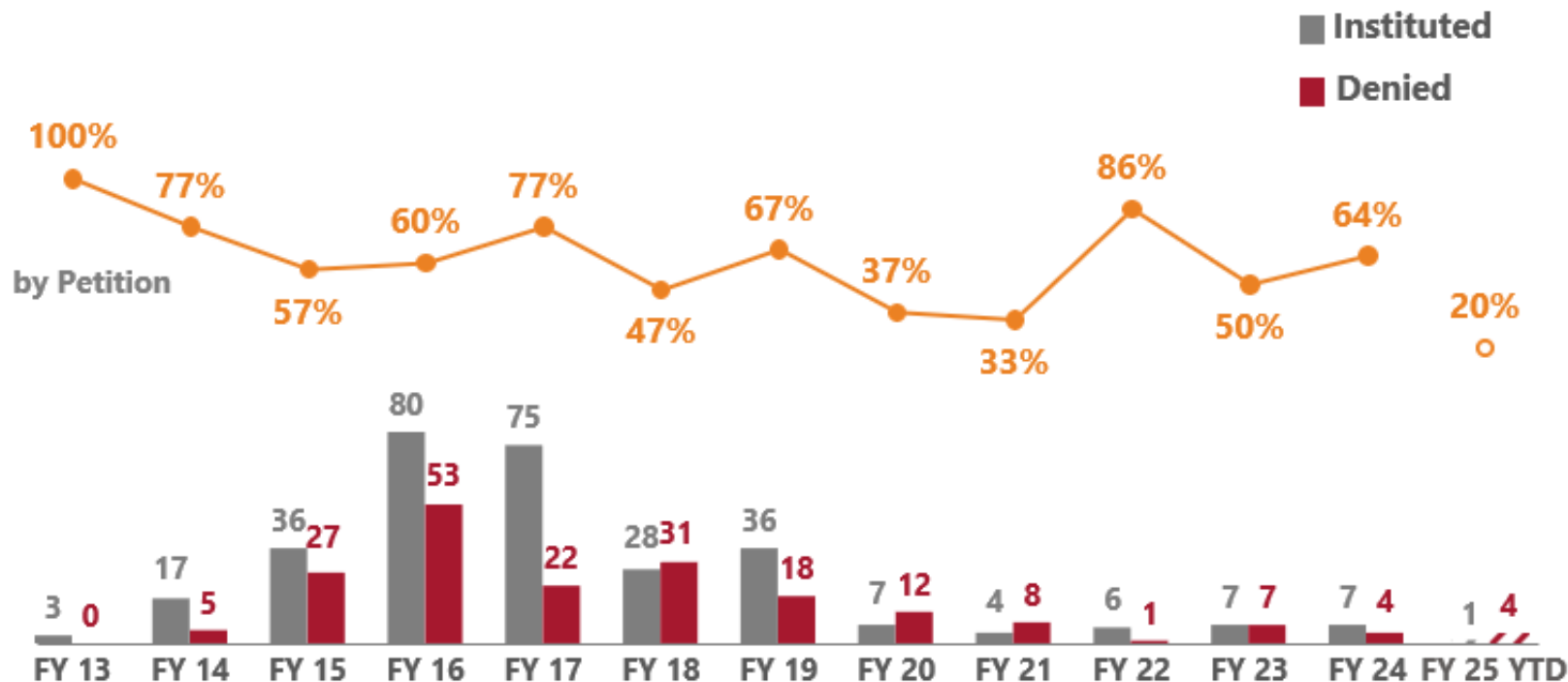
Biologic petitions filed by trial type

(October 1, 2012 to July 31, 2025)

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

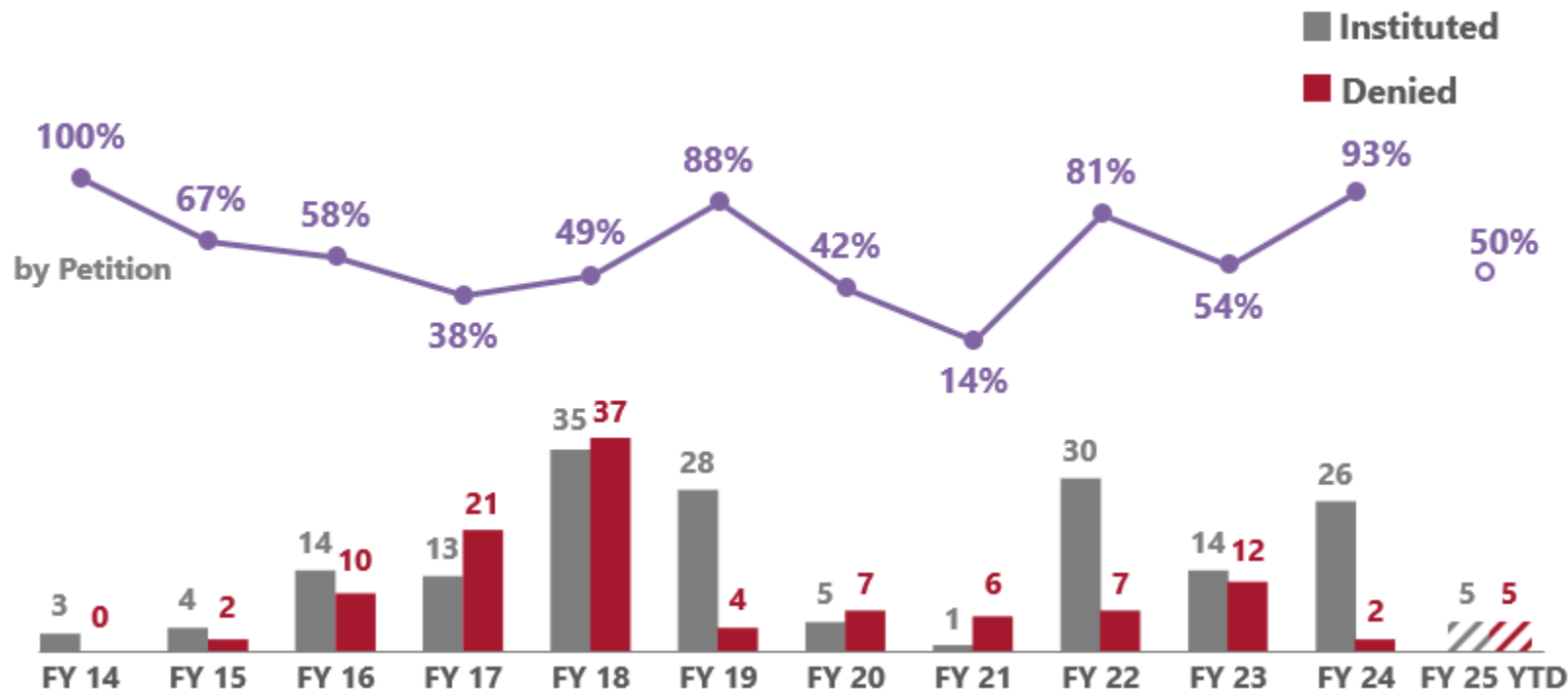


Institution rates by petition for Orange Book patents (October 1, 2012 to July 31, 2025)



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 rates by petition for biologic patents (October 1, 2013 to July 31, 2025)

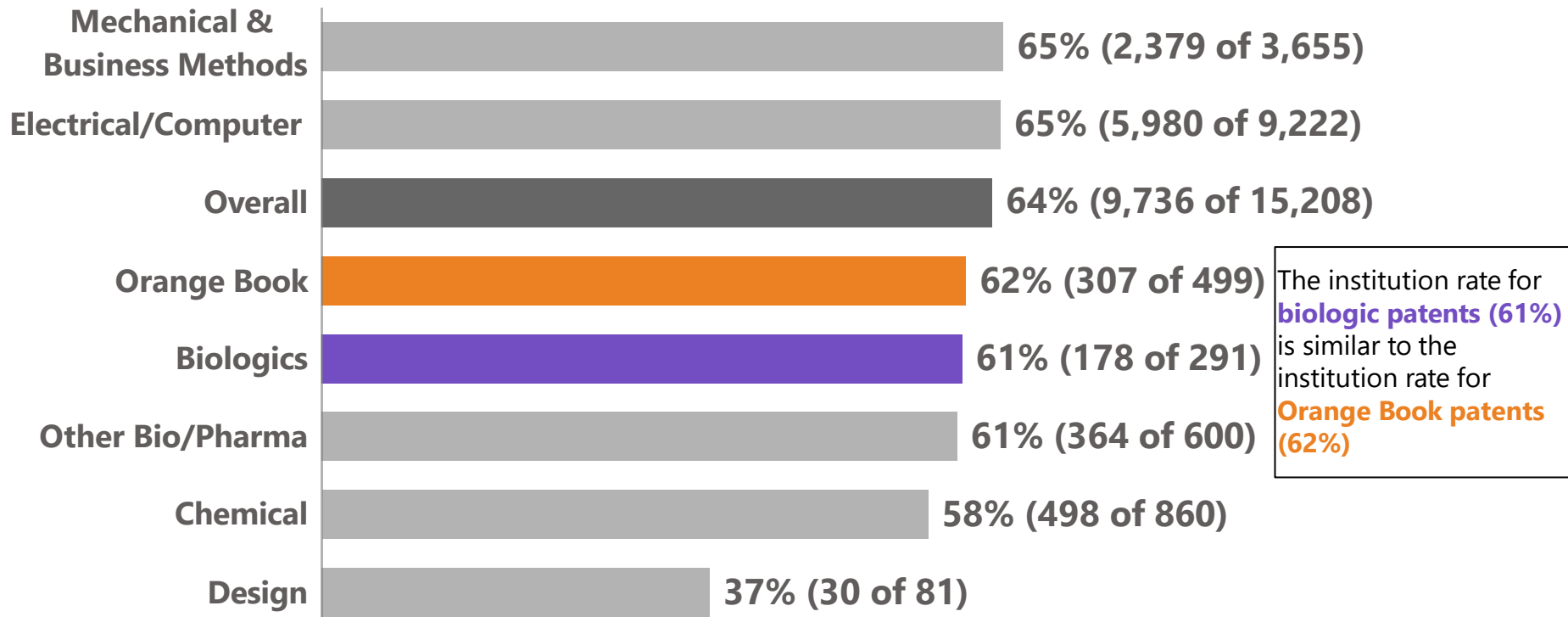


No institution decisions for biologic patents before FY14

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.

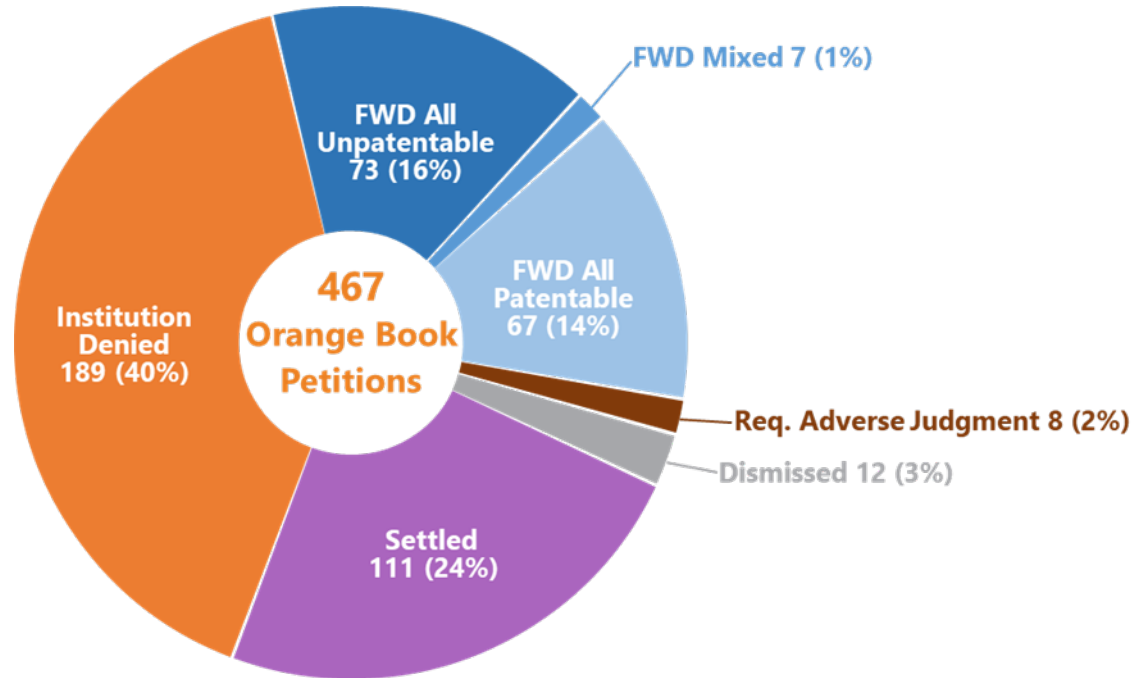
Institution rates by technology

(September 16, 2012 to July 31, 2025)



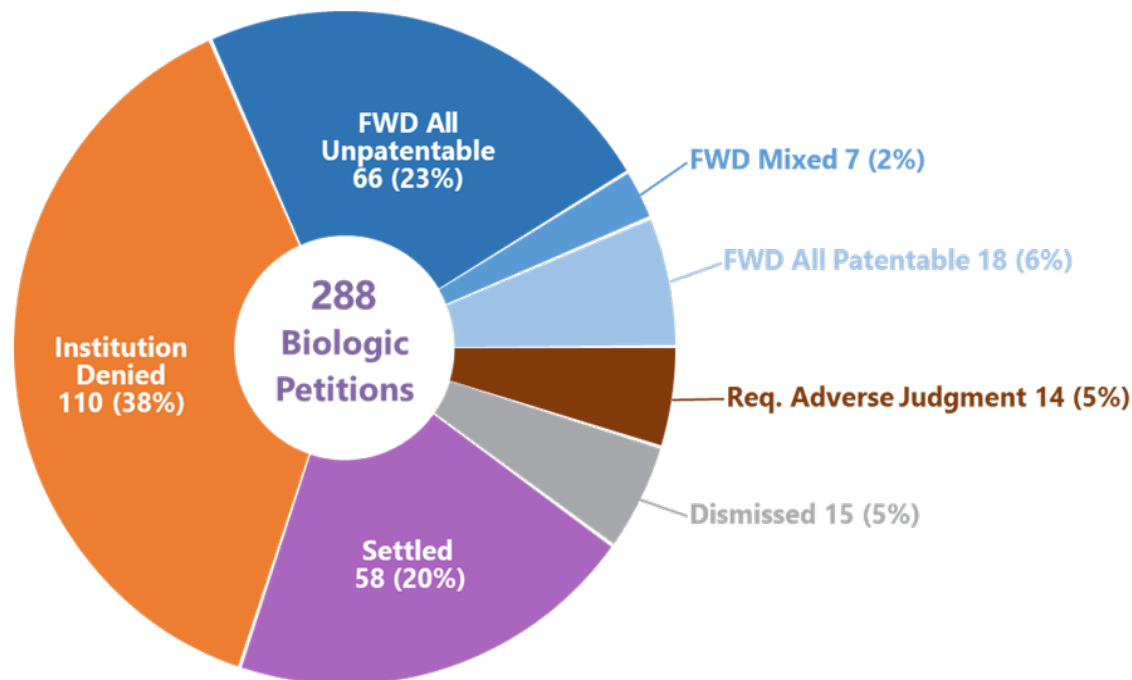
Institution rate for each technology is calculated by dividing petitions instituted by decisions on institution (i.e., petitions instituted plus petitions denied). The outcomes of decisions on institution responsive to requests for rehearing are excluded.

Outcomes of petitions challenging Orange Book patents (September 16, 2012 to July 31, 2025)



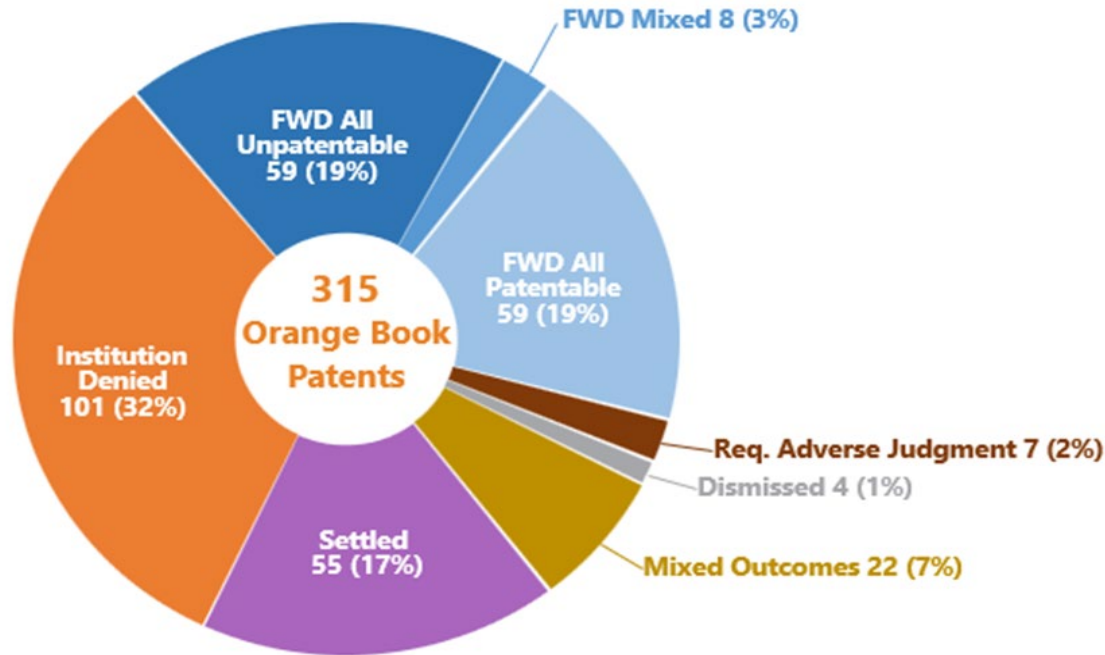
FWD patentability or unpatentability reported with respect to the claims at issue in the FWD.
Joined cases are excluded. The outcomes of decisions on institution responsive to requests for rehearing are included.

Outcomes of petitions challenging biologic patents (September 16, 2012 to July 31, 2025)



FWD patentability or unpatentability reported with respect to the claims at issue in the FWD.
Joined cases are excluded. The outcomes of decisions on institution responsive to requests for rehearing are included.

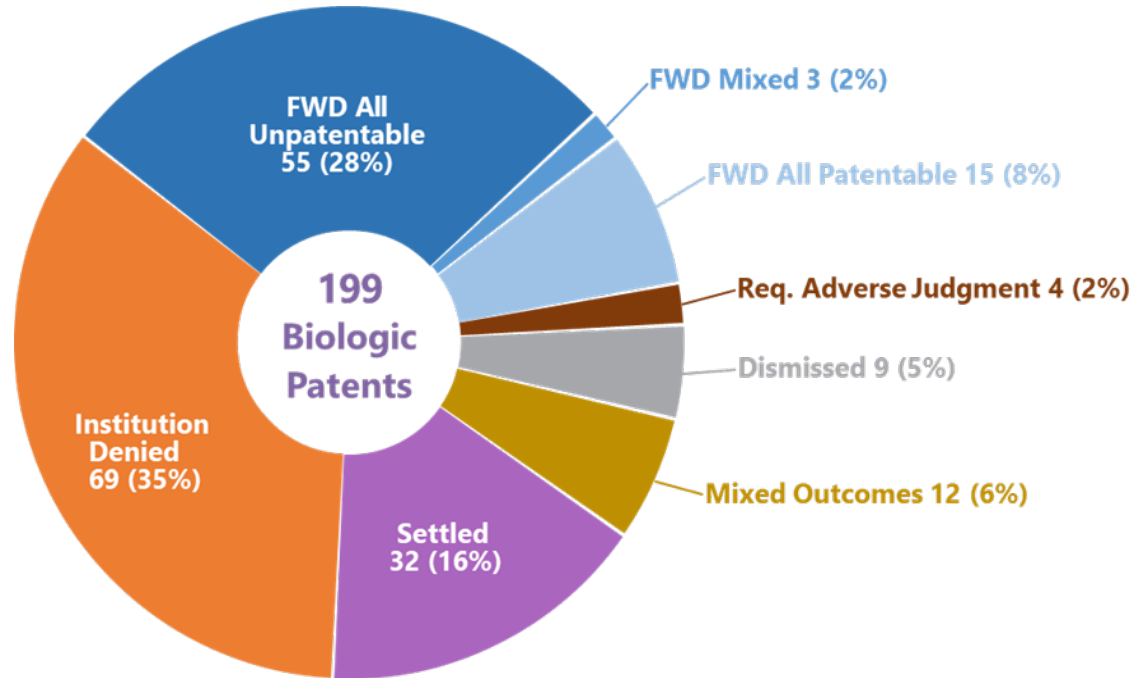
Outcomes by patent for Orange Book patents (September 16, 2012 to July 31, 2025)



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.

Outcomes by patent for biologic patents

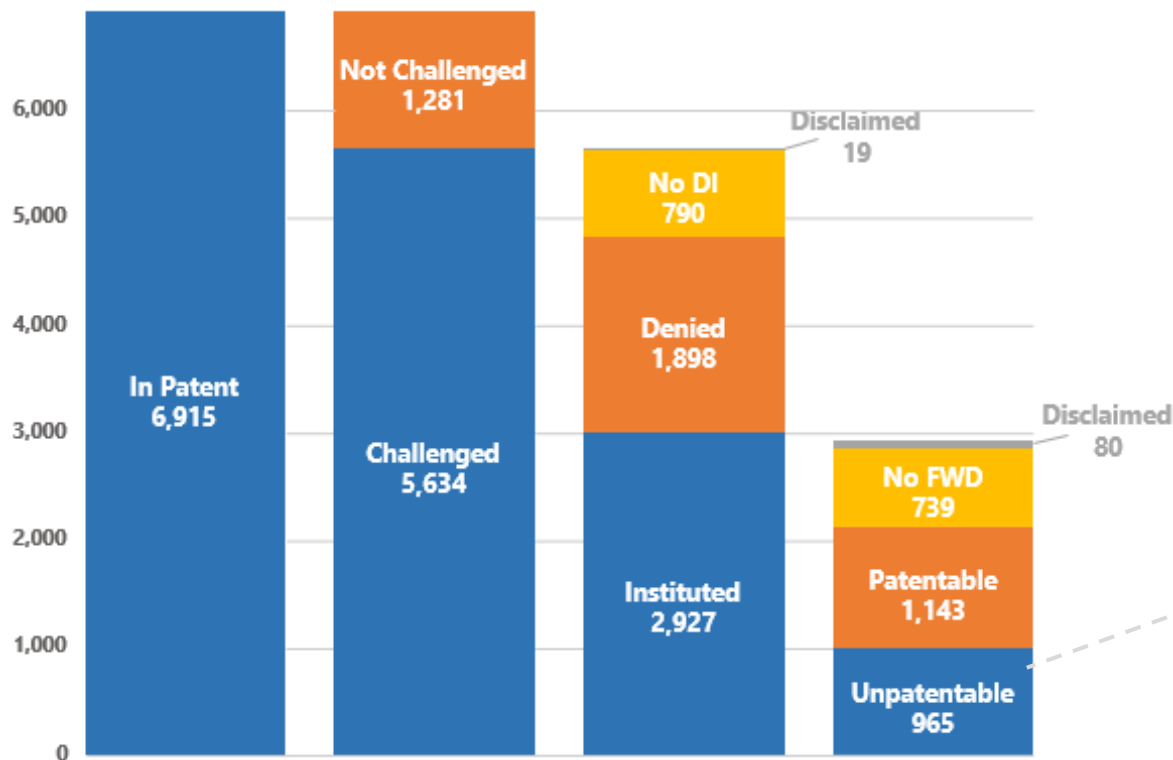
(September 16, 2012 to July 31, 2025)



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.

Claim outcomes for Orange Book patents

(Sep. 16, 2012 to Jul. 31, 2025)



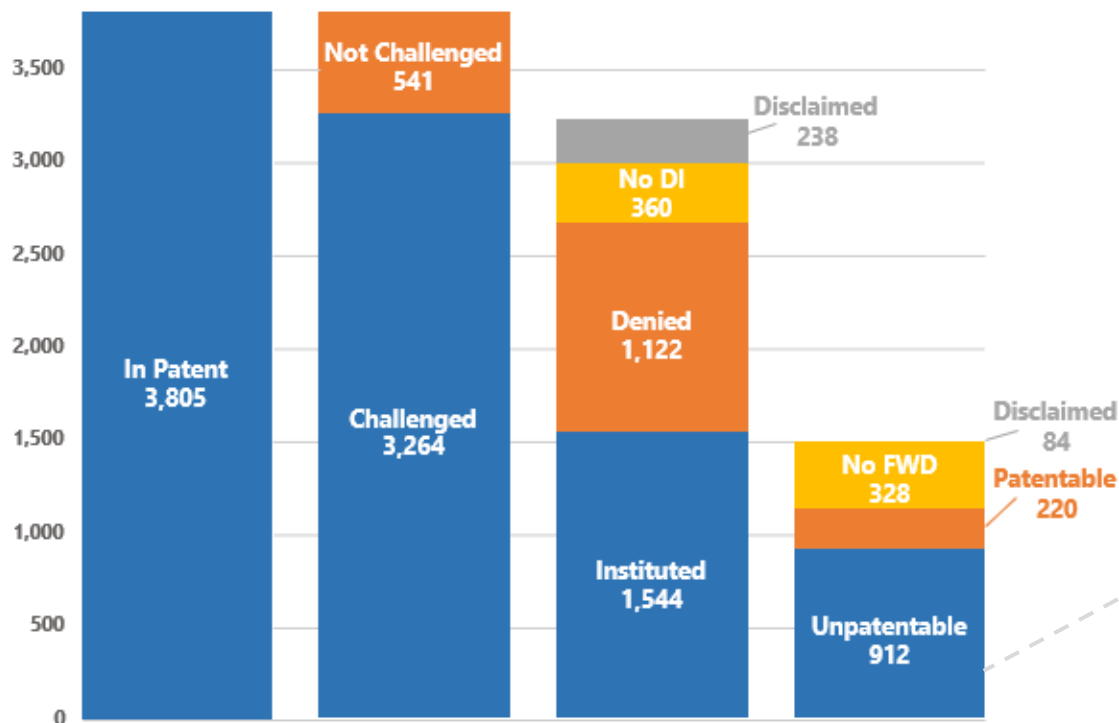
"No DI" and "No FWD" means the claim was challenged but not addressed in a DI/FWD, e.g., due to settlement.

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

(September 16, 2012 to July 31, 2025)



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

Biologic patents:

27% of challenged claims and 59% of instituted claims were found unpatentable by a preponderance of the evidence

