

**UNITED STATES
PATENT AND TRADEMARK OFFICE**



FY21 Q3 (June 2021) Update

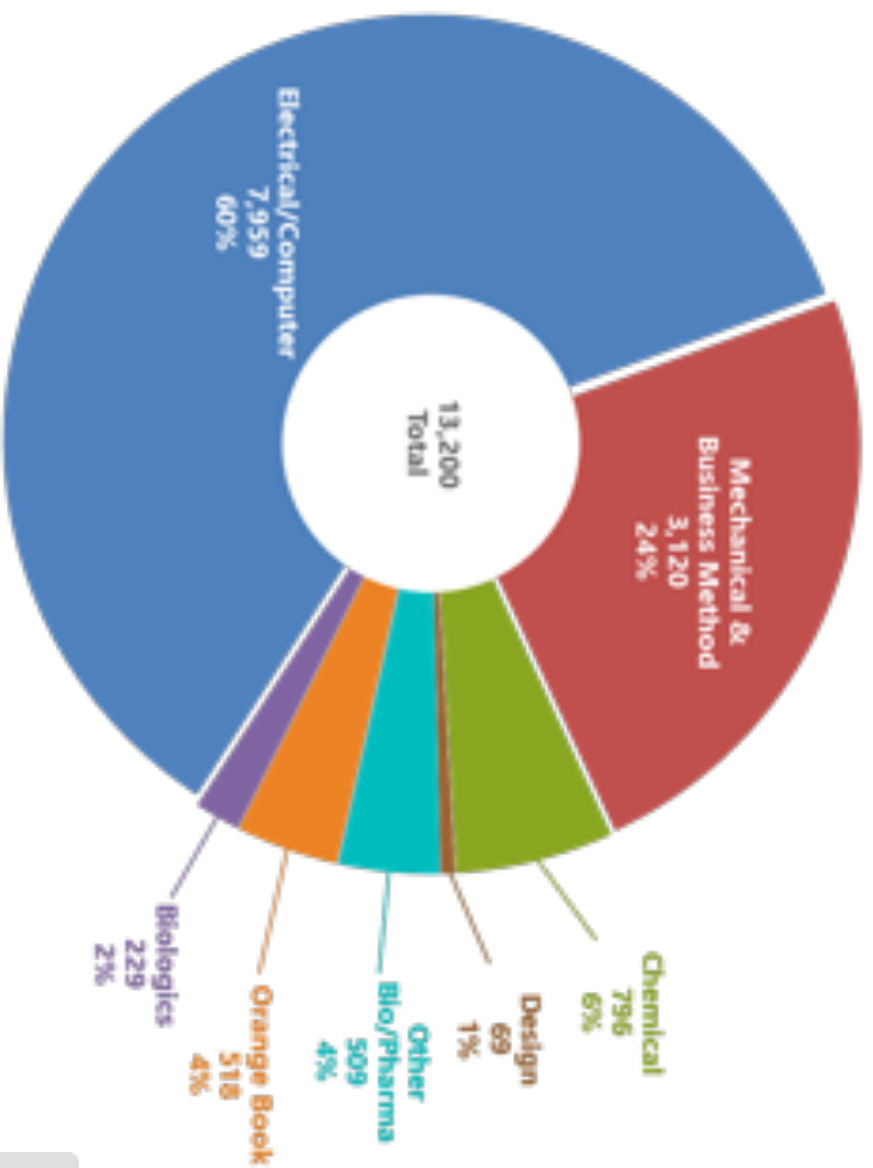
PTAB Orange Book patent/biologic patent study

Overview of findings from AIA proceeding study

- 4% of all AIA petitions challenge Orange Book patents
- 2% of all AIA petitions challenge biologic patents
- Challenges to both Orange Book and biologic patents have decreased over time
- The institution rate for biologic patents (55%) is lower than for Orange Book patents (62%)
- But Orange Book patents have had more claims upheld in a final written decision

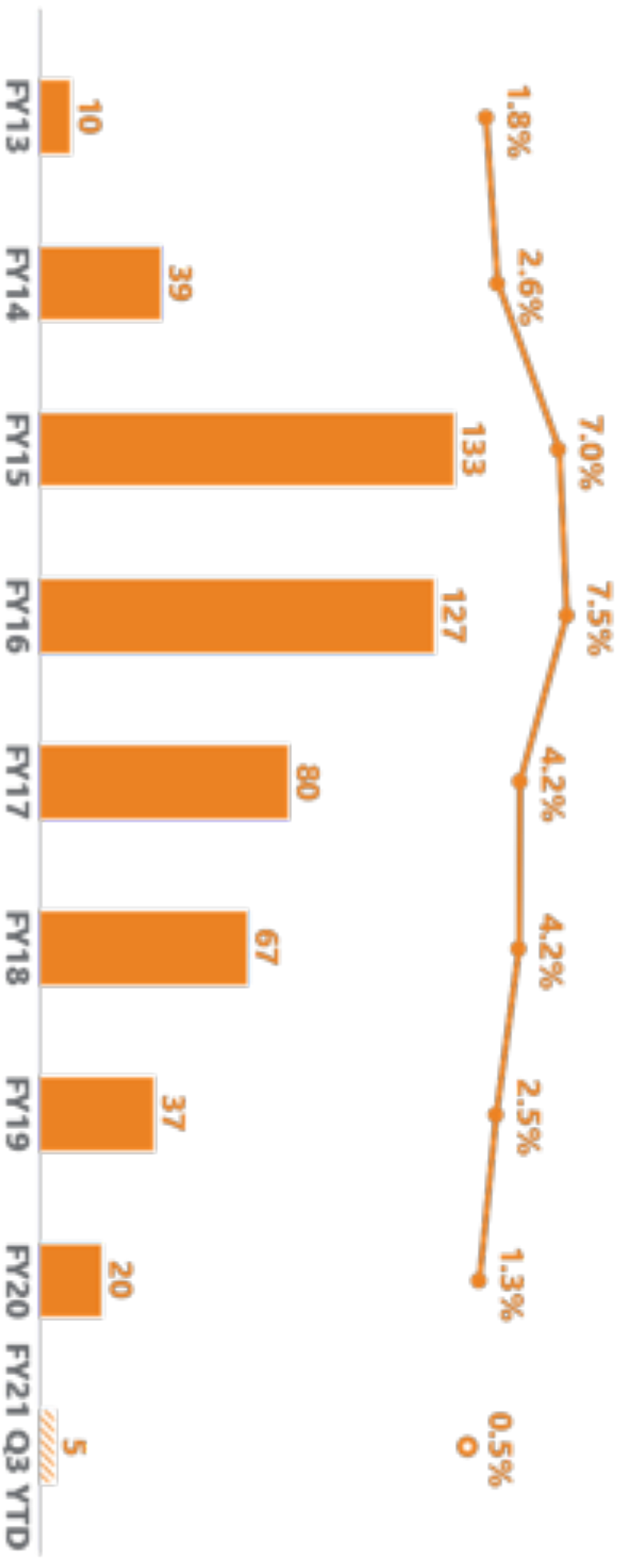
AIA Petitions filed by technology

(Sept. 16, 2012 to June 30, 2021)



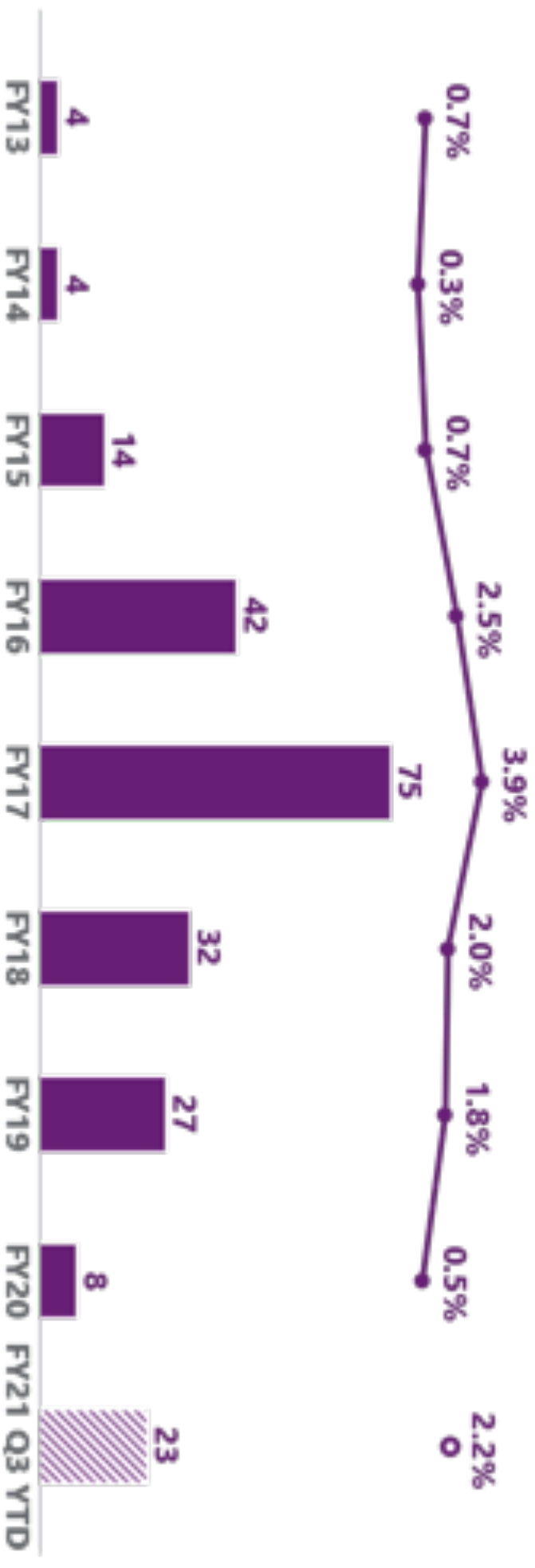
Includes all trial types.

AIA Petitions challenging Orange Book patents (Sept. 16, 2012 to June 30, 2021)



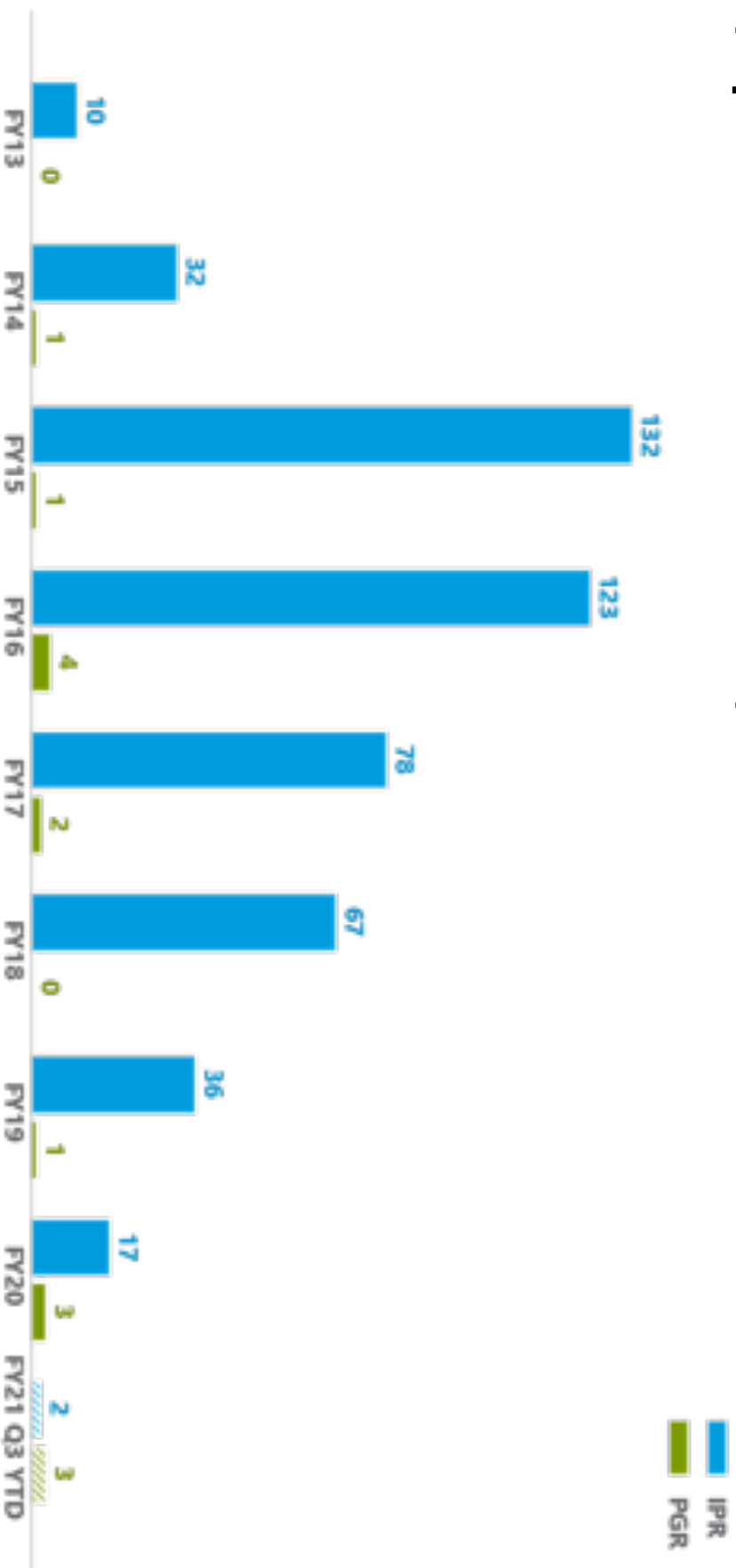
No petitions challenging Orange-Book-listed patents were filed in FY12.

AIA Petitions challenging biologic patents (Sept. 16, 2012 to June 30, 2021)



No petitions challenging biologic patents were filed in FY12.

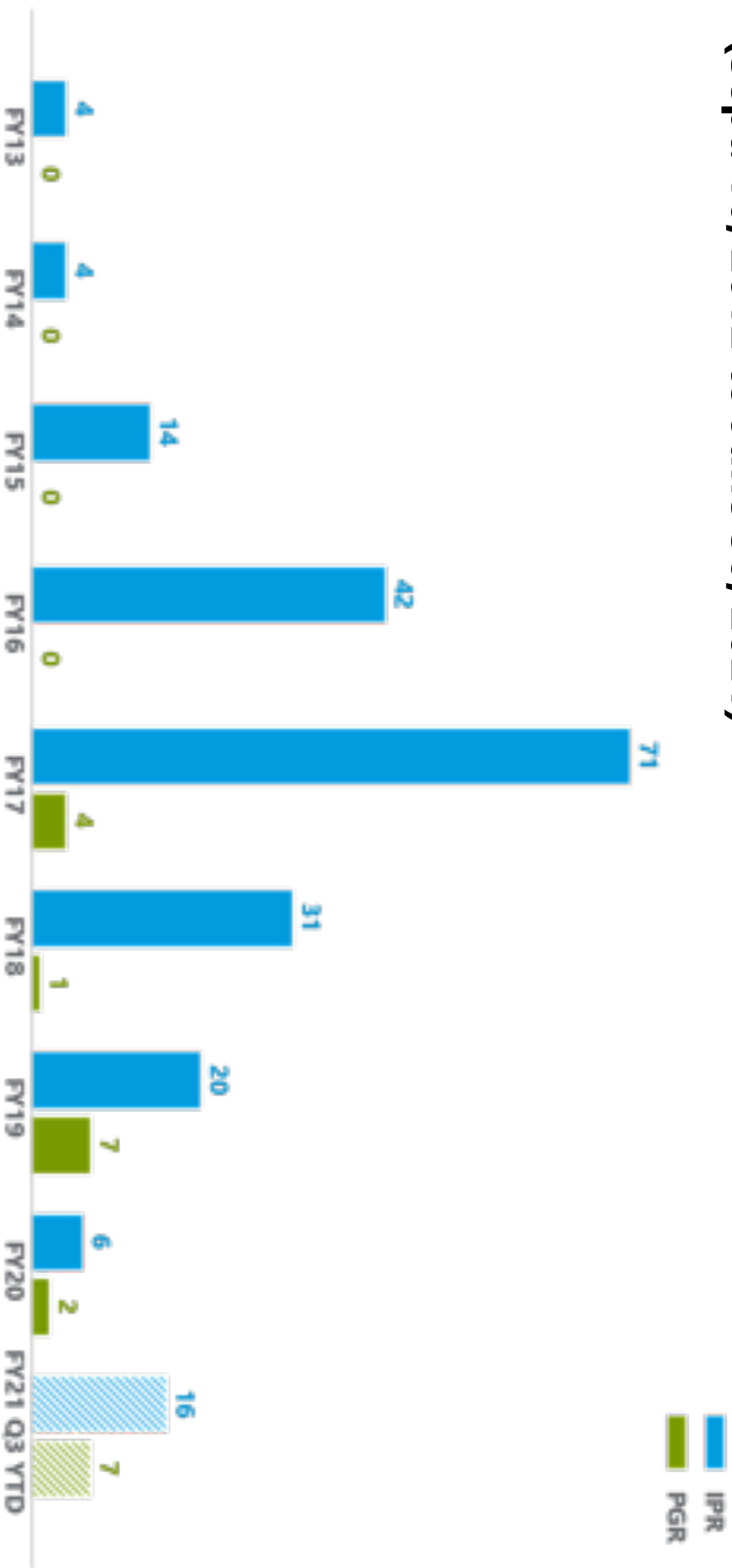
Orange Book petitions filed by trial type (Sept. 16, 2012 to June 30, 2021)



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

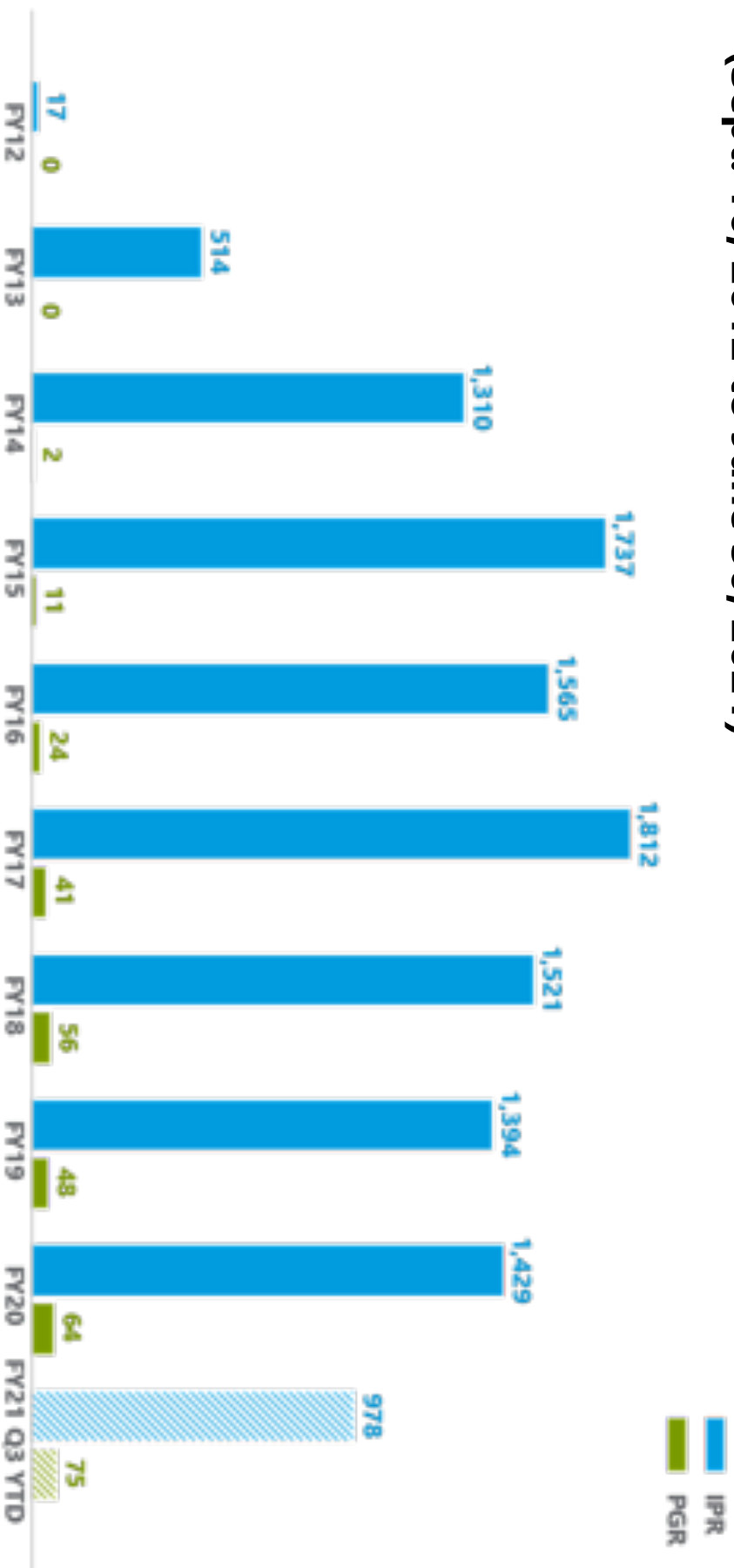
Biologic petitions filed by trial type

(Sept. 16, 2012 to June 30, 2021)



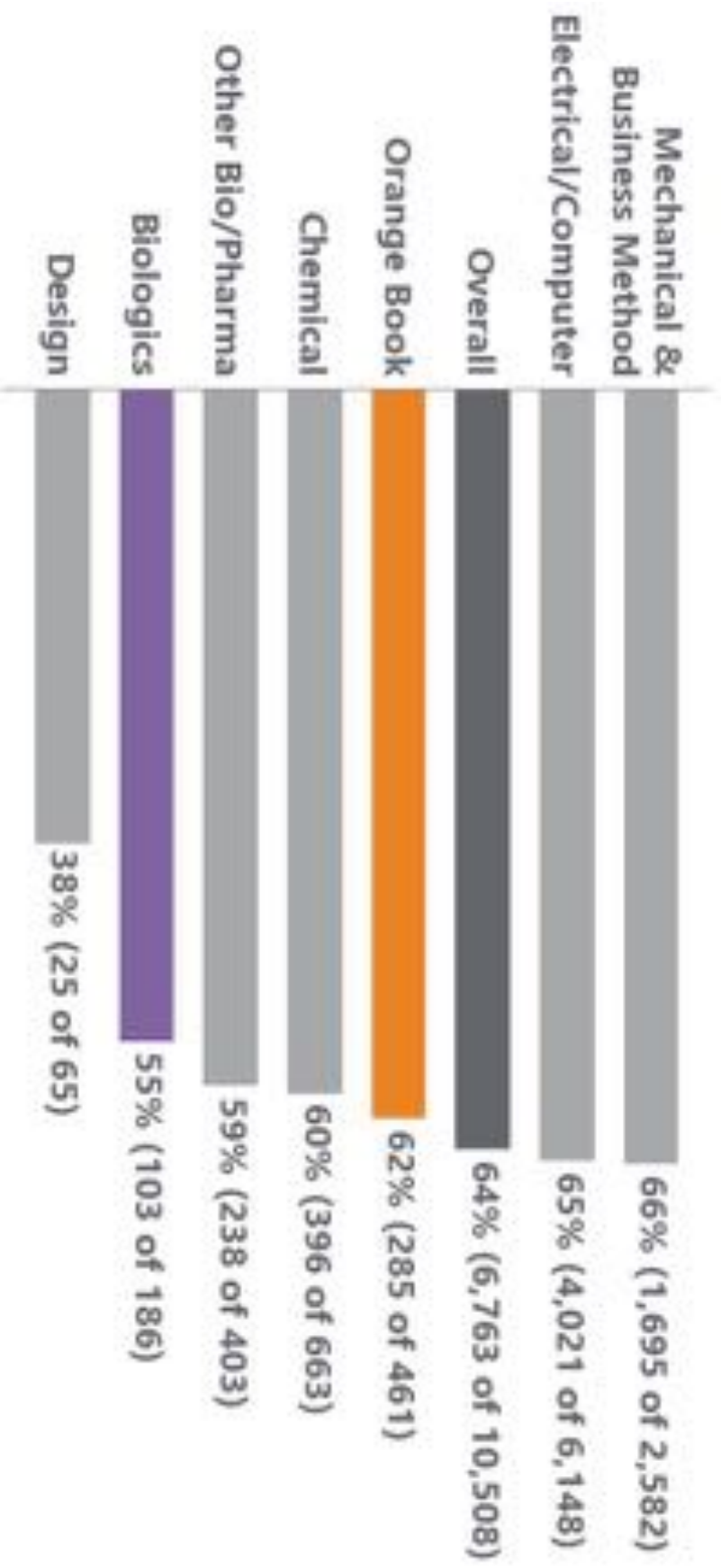
Petitions filed by trial type

(Sept. 16, 2012 to June 30, 2021)



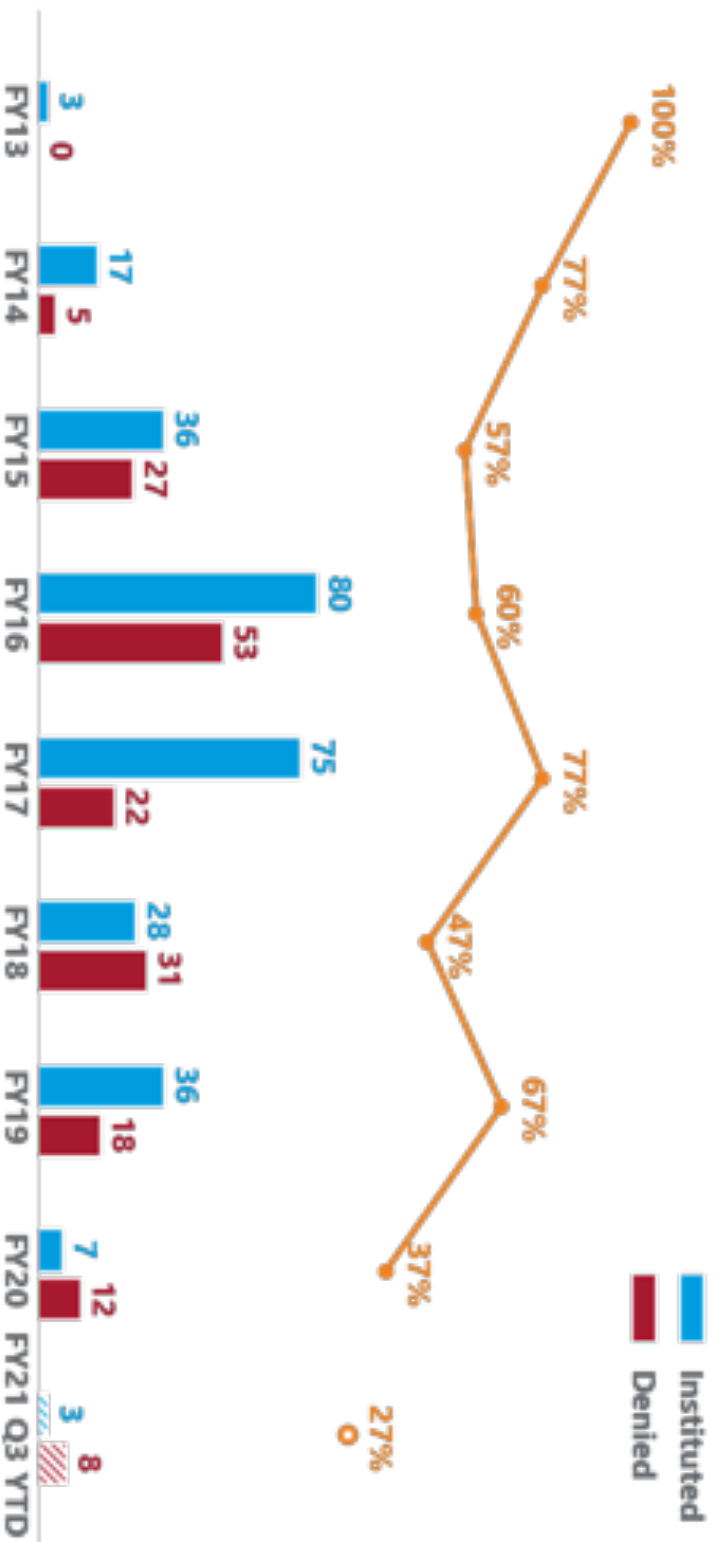
Institution rates by technology

(Sept. 16, 2012 to June 30, 2021)



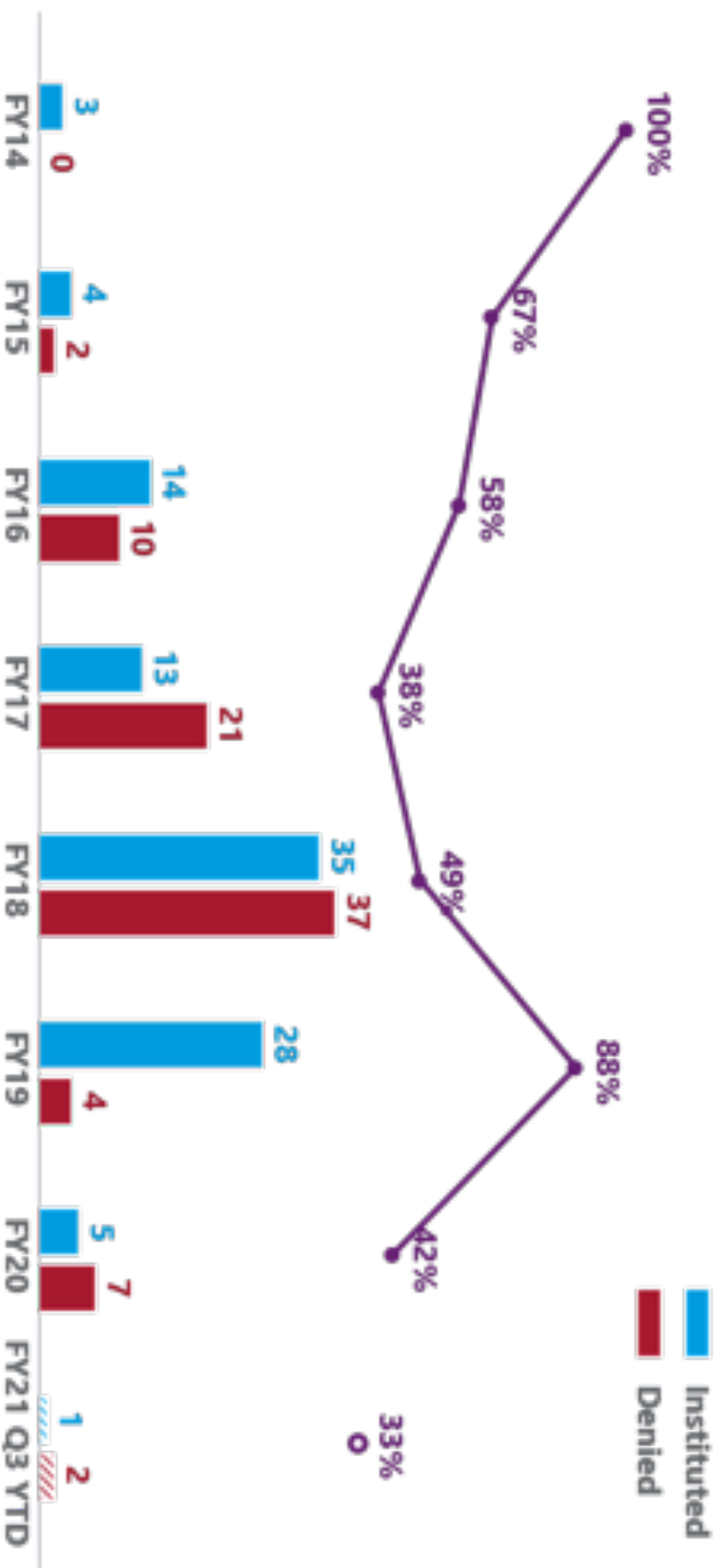
Institution rate for each technology is calculated by dividing petitions instituted by decisions on institution (i.e., petitions instituted plus petitions denied). The outcomes of decisions on institution responsive to requests for rehearing are excluded.

Institution rate Orange Book patents (Sept. 16, 2012 to June 30, 2021)



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 June 30, 2021)

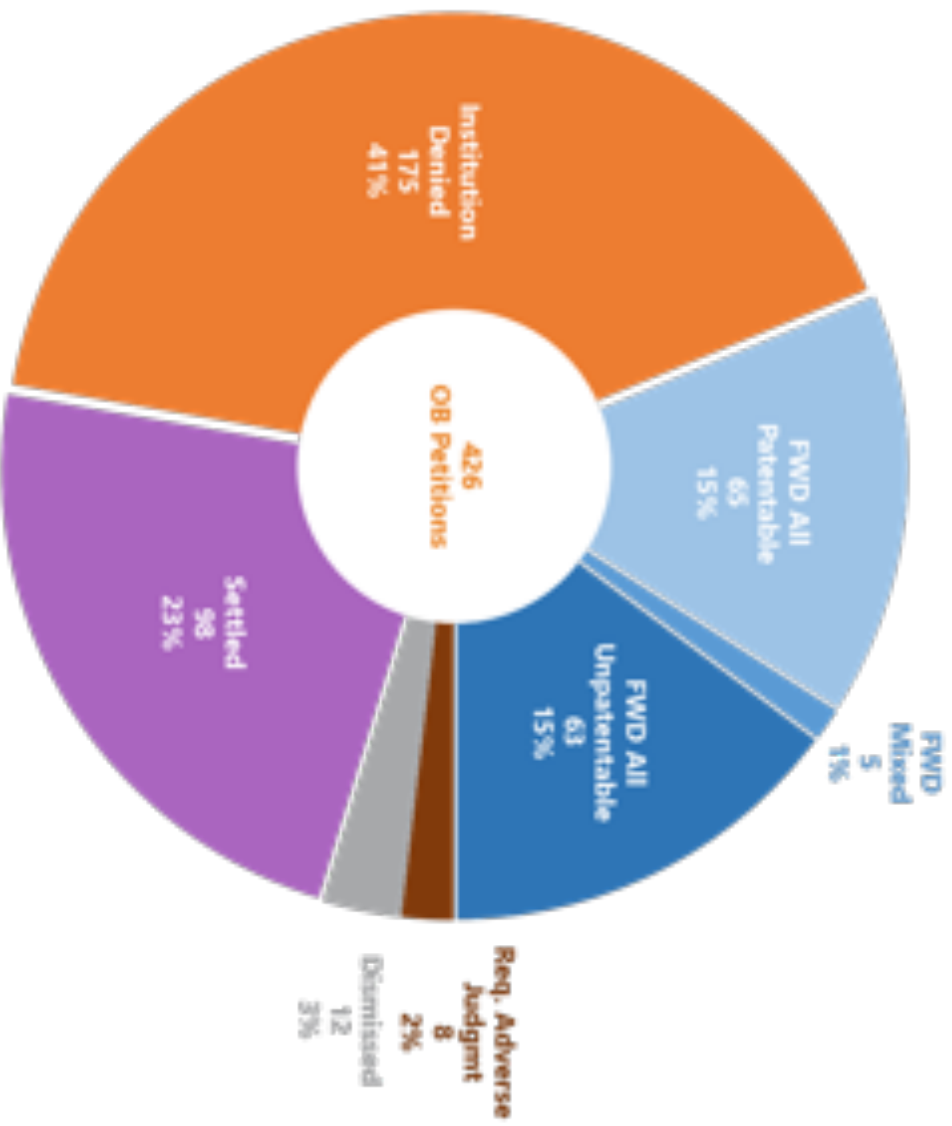


No institution decisions for biologic patents before FY14

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 OB patents

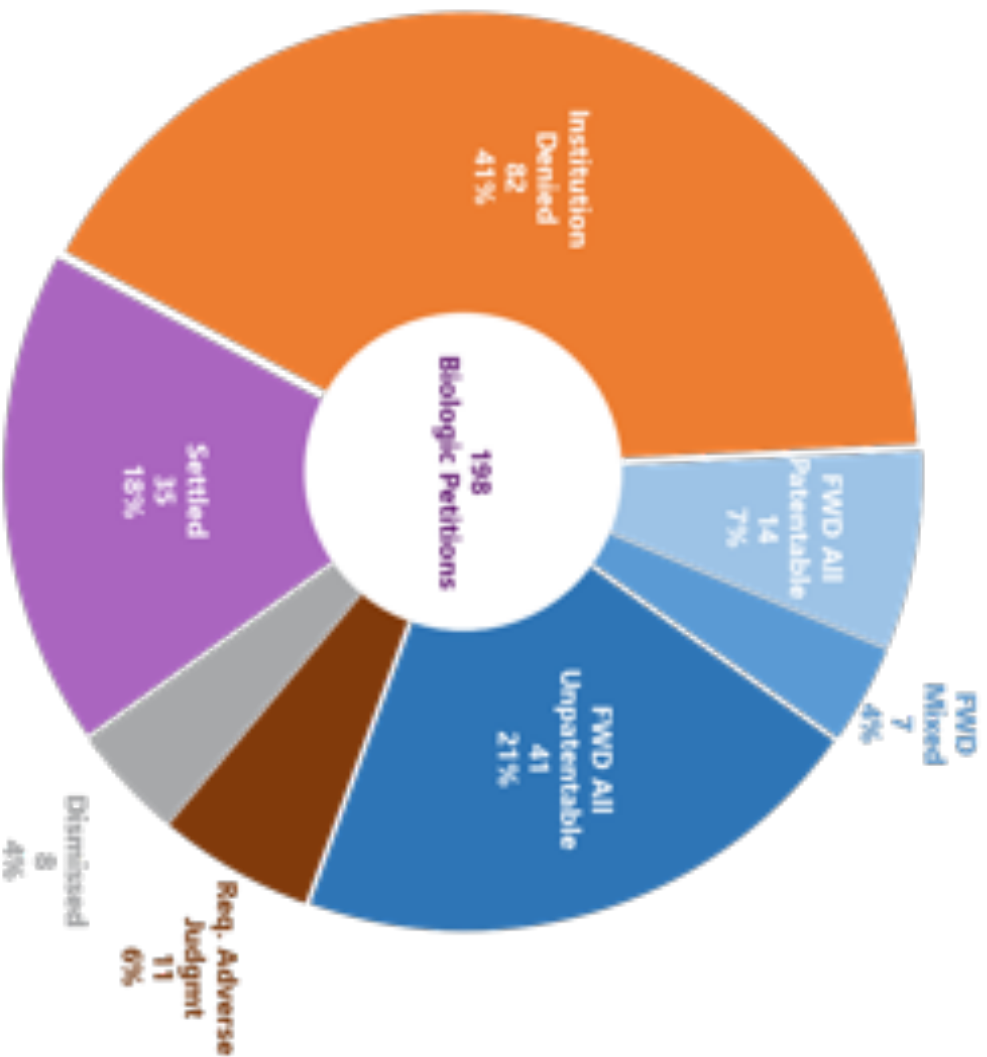
(Sept. 16, 2012 to June 30, 2021)



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 June 30, 2021)

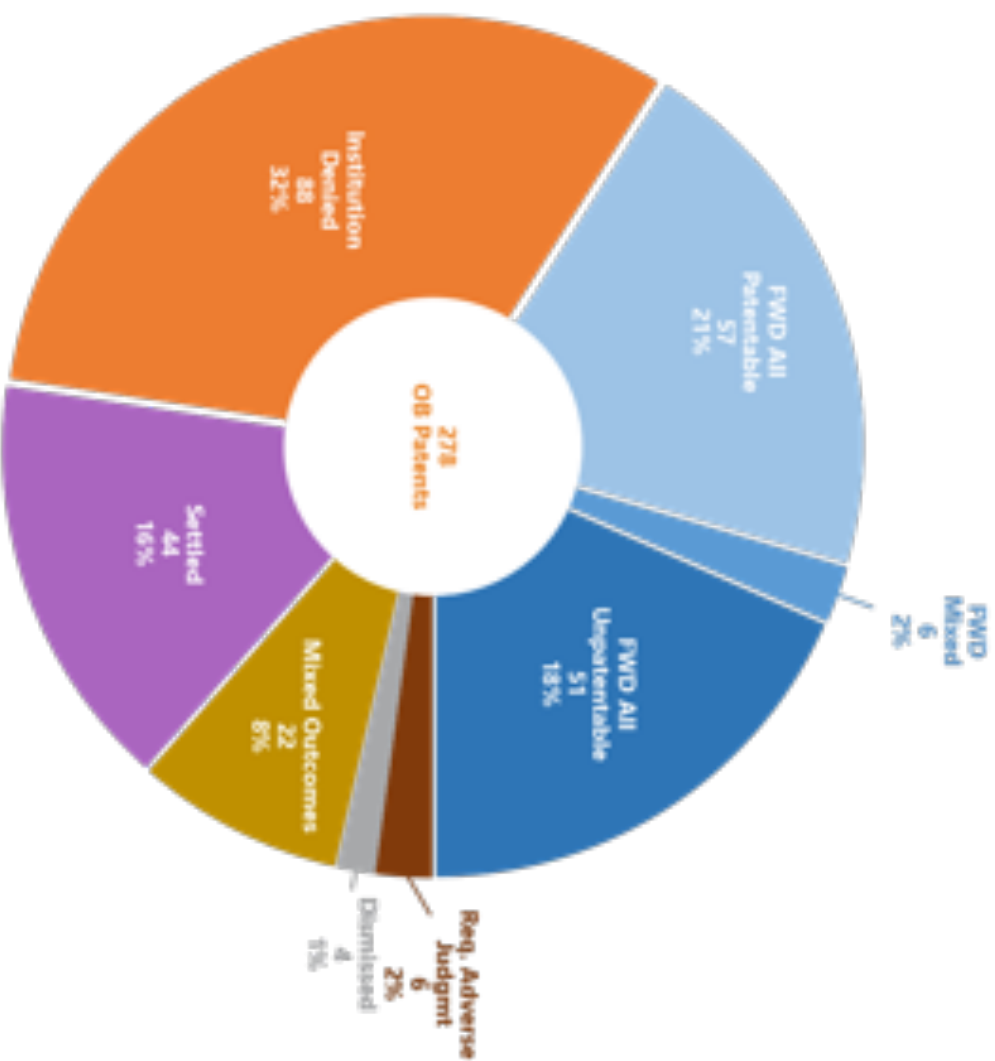


The outcomes of decisions on institution responsive to requests for rehearing are included.

Joined and pending petitions are excluded.

Outcomes by patent for Orange Book patents

(Sept. 16, 2012 to June 30, 2021)



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

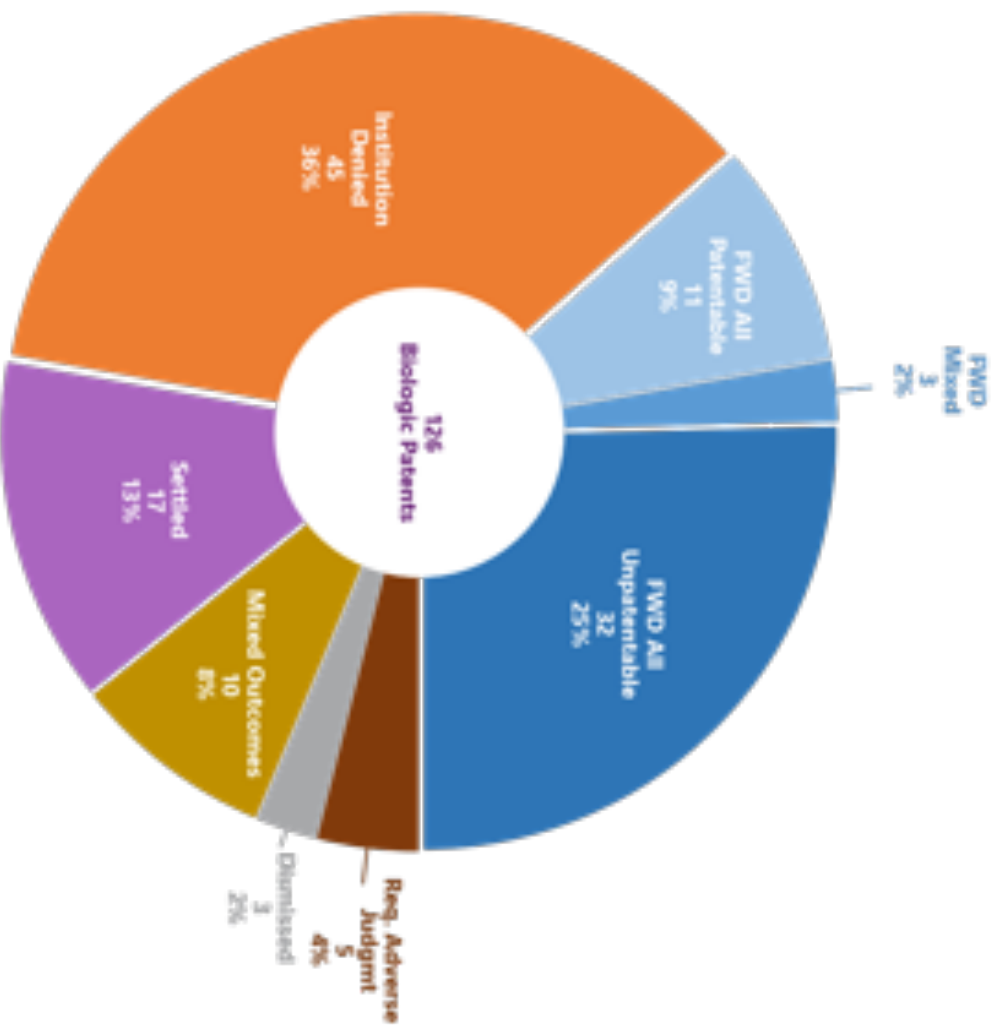
“Mixed Outcome” is shown for patents receiving more than one type of outcome from the list of: denied, settled, dismissed, and/or req. adverse judgement only.

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

4 patents challenged in pending petitions are omitted.

Outcomes by patent for biologic patents

(Sept. 16, 2012 to June 30, 2021)



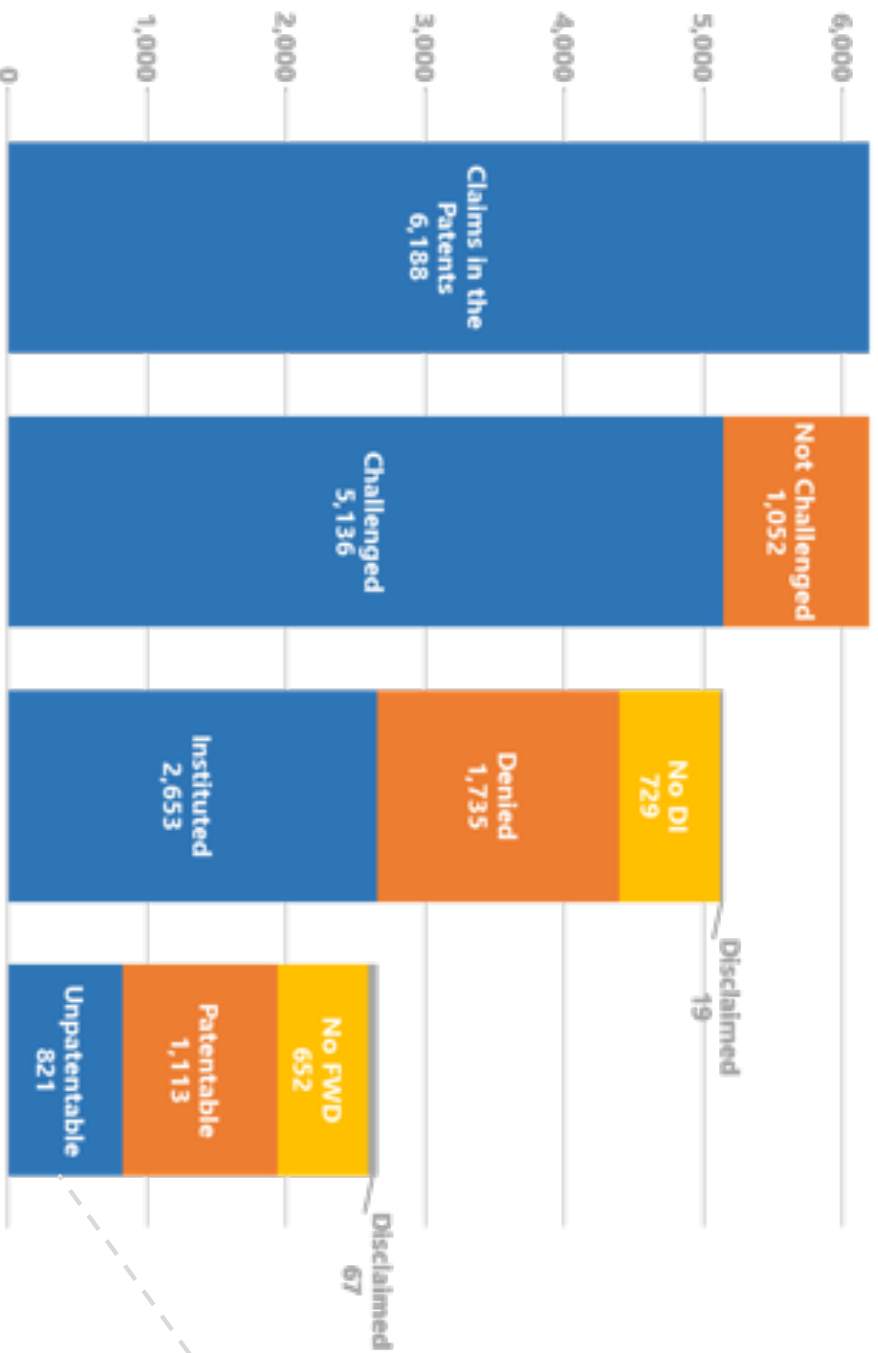
FWD patentability or unpatentability reported with respect to the claims at issue in the FWD.

“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.

19 patents challenged in pending petitions are omitted.

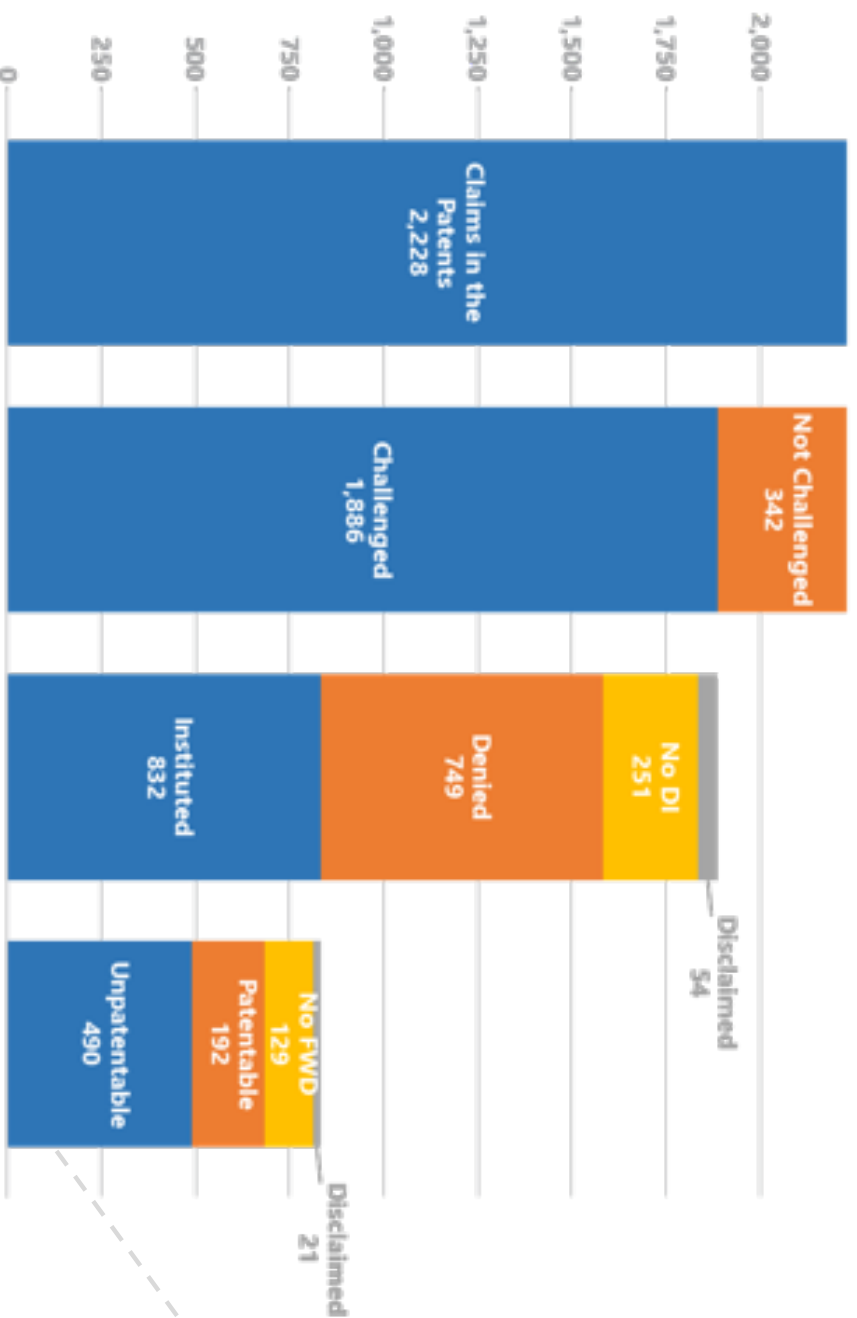
Claim outcomes for Orange Book patents (Sept. 16, 2012 to June 30, 2021)



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

16% of challenged claims and 31% of instituted claims were found unpatentable by a preponderance of the evidence

Claim outcomes for biologic patents (Sept. 16, 2012 to June 30, 2021)



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

26% of challenged claims and 59% of instituted claims were found unpatentable by a preponderance of the evidence

