



Training Academy Session # 42

Update on Hatch-Waxman/Paragraph IV Disputes

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Session Overview

1. Skinny Label Update (Slides 3-10)
2. ANDA Trends Across the United States (Slides 11-21)
3. 180-Day Exclusivity Forfeiture (Slides 22-26)
4. Update on Patent Listing and De-Listing (Slides 27-31)
5. Bond Requirements under Rule 65(c) – *Otsuka v. Hetero* (Slides 32-35)
6. Tax Implications of Hatch-Waxman Litigations (Slide 36)

1. SKINNY LABEL UPDATE

- ***Hikma Pharmaceuticals USA Inc. v. Amarin Pharma, Inc.*, __ U.S. __, 146 S. Ct. 1391 (2026)**
 - The lede: On June 4, 2026, a unanimous Supreme Court agreed with Hikma and the district court that a motion to dismiss should have been granted where the complaint asserted that, even with the proposed “skinny label,” Amarin alleged only a possible inducing effect rather active steps to induce infringement by third party doctors.
- **Active Inducement Infringement under 35 U.S.C. § 271(b):**
 - “Whoever **actively induces** infringement of a patent shall be liable as an infringer.”
- **How did we get here?**
- **Where will this lead?**

1. SKINNY LABEL UPDATE

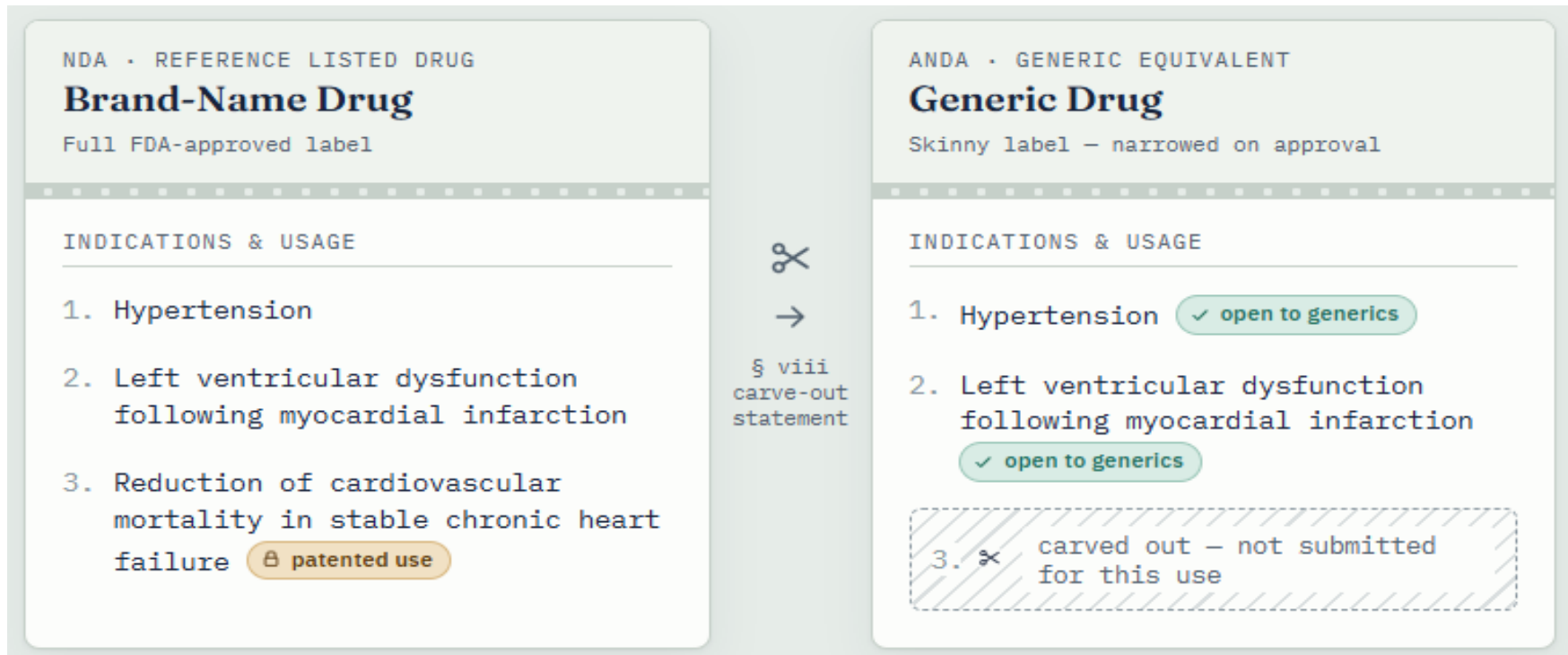
- **21 U.S.C. § 355(j)(2)(A)(viii) [Section viii Carve-Out or Skinny Label]**
 - An abbreviated application for a new drug shall contain –
 - (viii) if with respect to the listed drug referred to in clause (i) information was filed under subsection (b) or (c) for a **method of use patent** which does not claim a use for which the applicant is seeking approval under this subsection, a statement that the method of use patent does not claim such a use.
 - (i) information to show that the conditions of use prescribed, recommended, or suggested in the labeling proposed for the new drug have been previously approved for a drug listed under paragraph (7) (hereinafter in this subsection referred to as a “listed drug”);

1. SKINNY LABEL UPDATE

- The Skinny Label allows a generic manufacturer (an ANDA filer) to carve out methods of use that it chooses not to pursue
- Prior to *Hikma*, the Federal Circuit wrestled with *Glaxo SmithKline LLC v. Teva Pharmaceuticals USA, Inc.*, 7 F.4th 1320 (Fed. Cir. 2021)
 - Procedural posture: Appeal after trial finding infringement and substantial damages
 - Teva asserted that its skinny label for carvedilol (Coreg®) carved out the patented use and left two unpatented uses for FDA approval
 - GSK asserted that Teva took active steps to induce doctors to prescribe carvedilol for the carved-out use
 - Federal Circuit overturned a JMOL, finding that substantial evidence demonstrated Teva failed to carve out the method of use at issue from its label

1. SKINNY LABEL UPDATE

- Teva carved out the newly patented method of use (represented in AI generated diagram below):



1. SKINNY LABEL UPDATE

- Judge Prost dissented, finding that the opinion of the majority (written by Chief Judge Moore) failed to properly assess whether substantial evidence supported a finding of intentional inducement
 - In the dissent, Judge Prost opined: “I write in this case because far from being a disagreement among reasonable minds about the individual facts, this case signals that our law on this issue has gone awry.”
 - Specifically, “the majority further weakens the intentional-encouragement prong of inducement by effectively eliminating the demarcation between describing an infringing use and encouraging that use in a label.”
- **When GSK issued, not once but twice, the generic community questioned whether and to what extent the skinny label provisions had real force**

1. SKINNY LABEL UPDATE

- In *Hikma*, the Supreme Court put these fears to rest using a motion to dismiss vehicle to demonstrate that **active** inducement means just that, intentional inducement with evidence of intent, not simply a label with the patented method extant
- What does **active inducement** require (says *Hikma*, 146 S. Ct. at 1398)?
 - Direct infringement by a third party (citing *Limelight Networks, Inc. v. Akamai Techs., Inc.*, 572 U.S. 915, 920-21 (2014))
 - Knowledge by the inducer that the induced acts constitute patent infringement (citing *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 766 (2011)); and
 - “Active steps” by the inducer “to encourage direct infringement (citing *Metro-Goldwyn-Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913, 936 (2005)).

1. SKINNY LABEL UPDATE

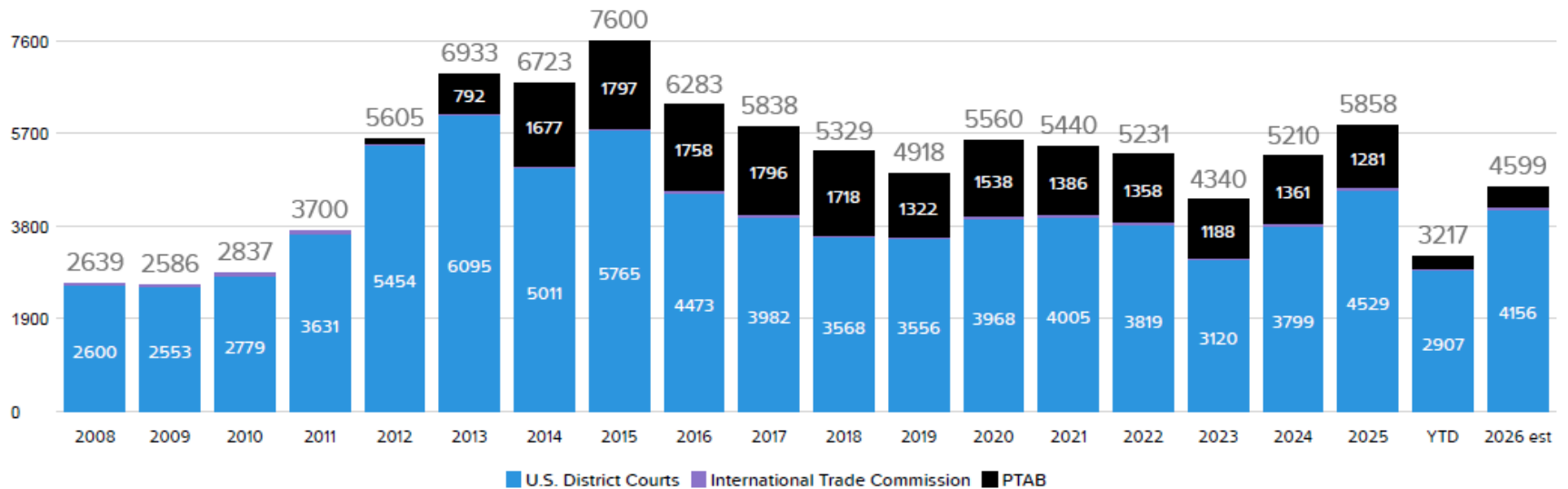
- Was the evidence in *Hikma* sufficiently pled to avoid a motion to dismiss? No!
- The Court held that Amarin fails to allege more than a sheer possibility that Hikma actively induced infringement and no active steps to induce
 - The label's inclusion of a study related to the carved-out use was statutorily mandated, not an "active" step to induce
 - Amarin alleged no evidence of an affirmative statement or representation that the generic drug should be used for the carved-out use even though a medical provider could piece that together
 - And guesswork on how medical providers may act does not suffice to demonstrate the type of active inducement necessary to plead induced infringement

1. SKINNY LABEL UPDATE

- Where does this lead?
 - A clearer statement of the active part of active inducement flows from the opinion
 - The balance Congress chose with the skinny label amendments is maintained
 - True active inducement still possible
- The case has been cited eight times – most for the refinement to the motion to dismiss standard, the factors for induced infringement, or for its general statements on Hatch-Waxman law
- Likely, the fear generics had regarding the possible loss of utility of the skinny label has been eased and will not be a subject of repeated litigation

2. ANDA TRENDS ACROSS THE UNITED STATES

- Overall Court Activity – District Courts, ITC, PTAB

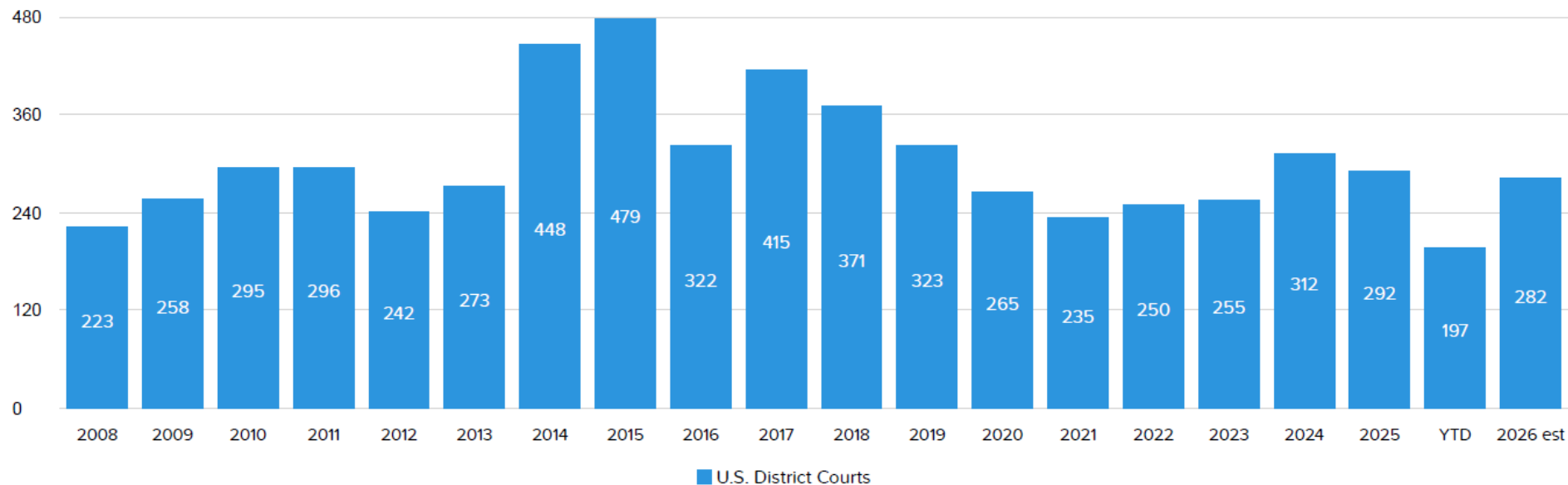


	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	YTD	2026 est
U.S. District Courts	2600	2553	2779	3631	5454	6095	5011	5765	4473	3982	3568	3556	3968	4005	3819	3120	3799	4529	2907	4156
International Trade Commission	39	33	58	69	40	46	35	38	52	60	43	40	54	49	54	32	50	48	40	57
PTAB	0	0	0	0	111	792	1677	1797	1758	1796	1718	1322	1538	1386	1358	1188	1361	1281	270	386
Total	2639	2586	2837	3700	5605	6933	6723	7600	6283	5838	5329	4918	5560	5440	5231	4340	5210	5858	3217	4599

Source: Docket Navigator

2. ANDA TRENDS ACROSS THE UNITED STATES

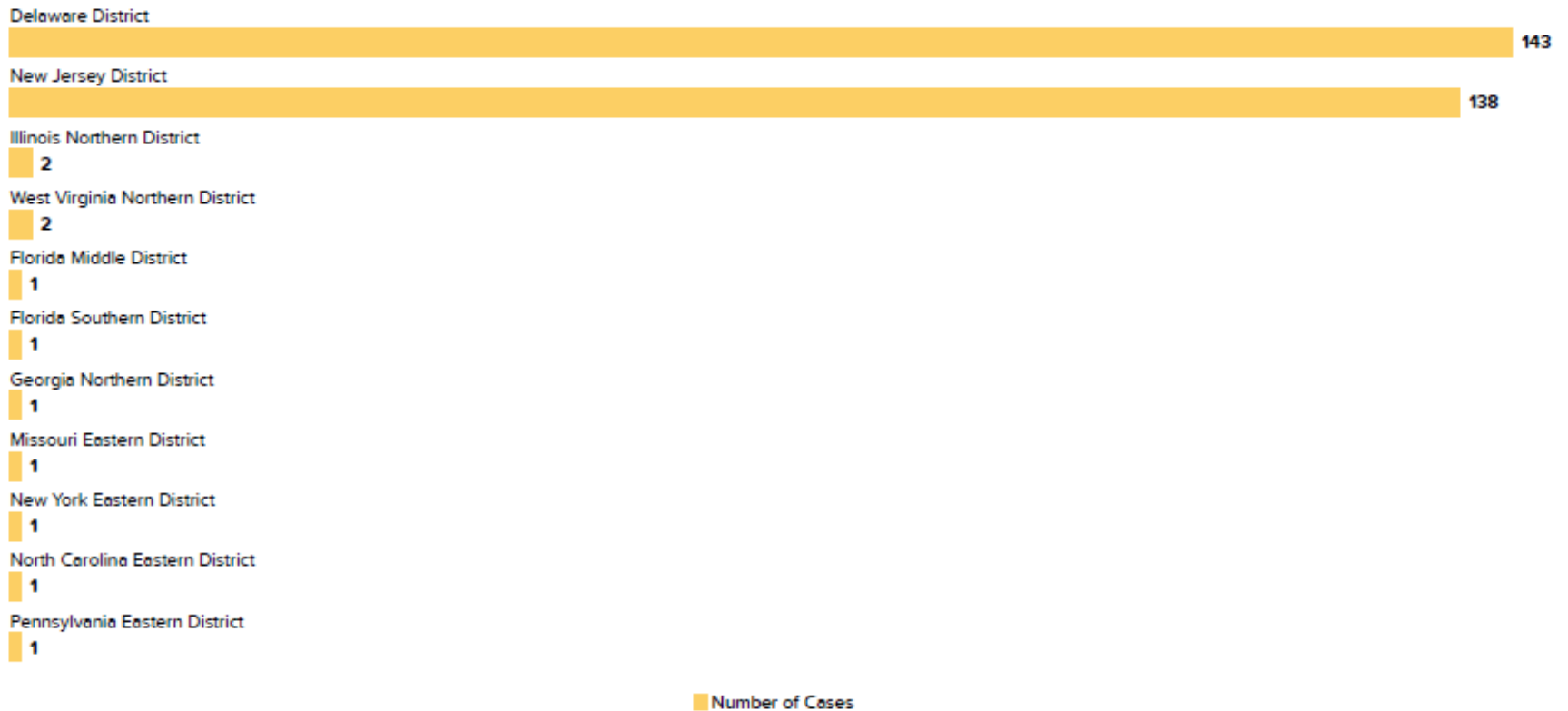
- ANDA Cases



Source: Docket Navigator

2. ANDA TRENDS ACROSS THE UNITED STATES

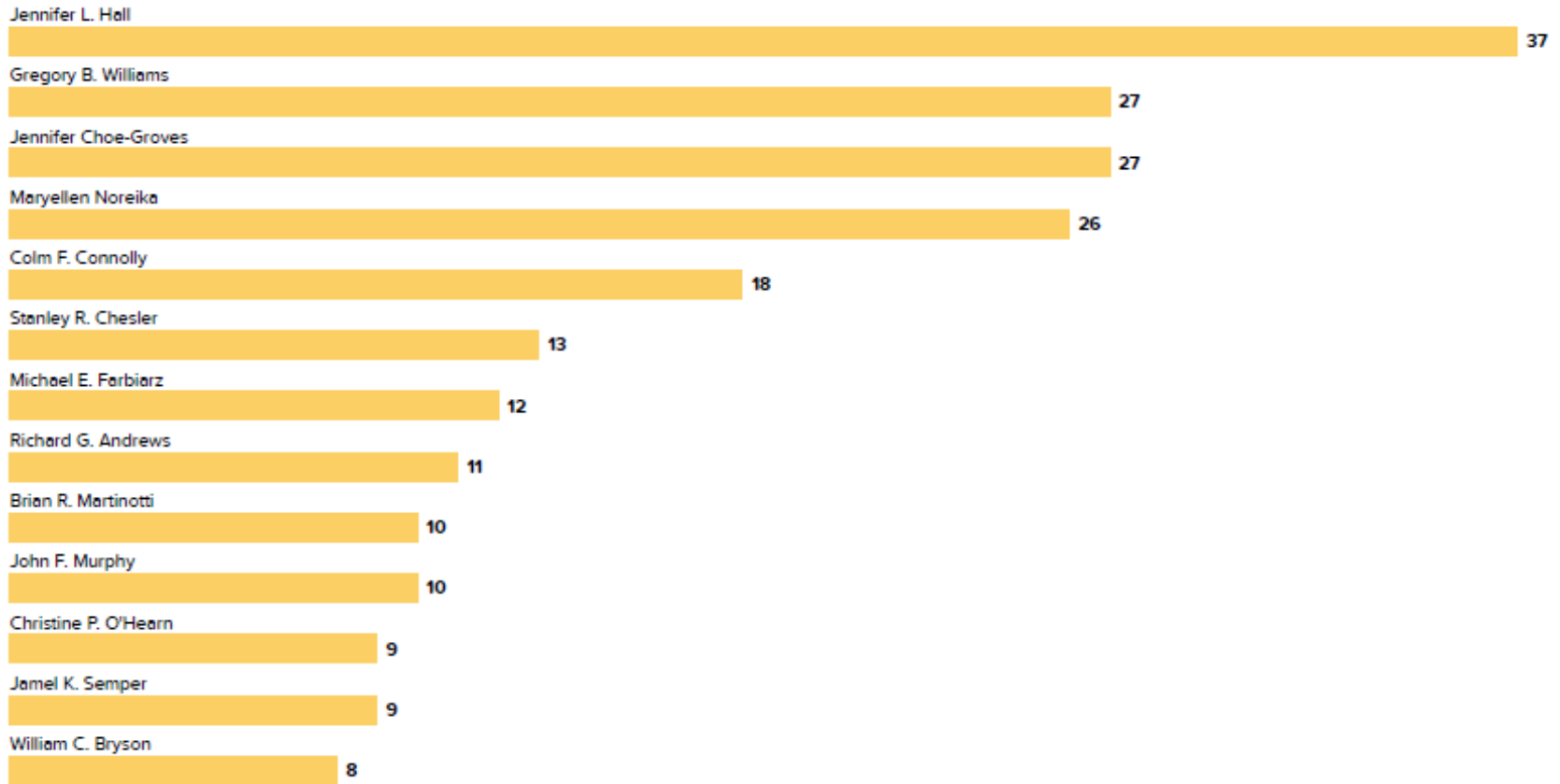
- Most Active ANDA Courts



Source: Docket Navigator

2. ANDA TRENDS ACROSS THE UNITED STATES

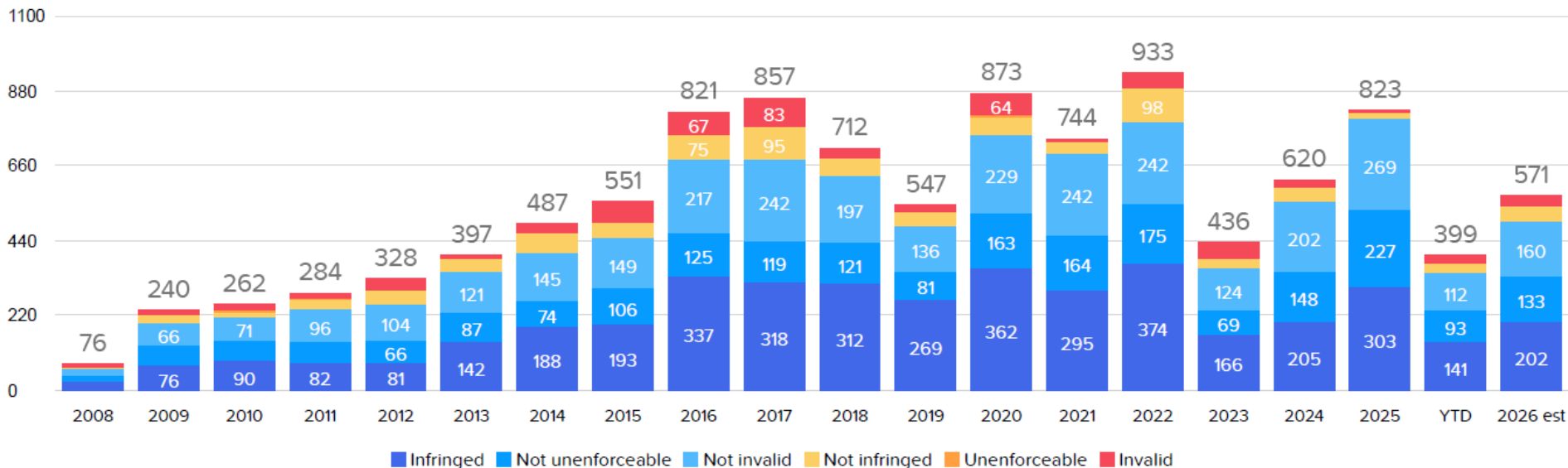
- Most Active ANDA Judges



Source: Docket Navigator

2. ANDA TRENDS ACROSS THE UNITED STATES

- ANDA Determinations

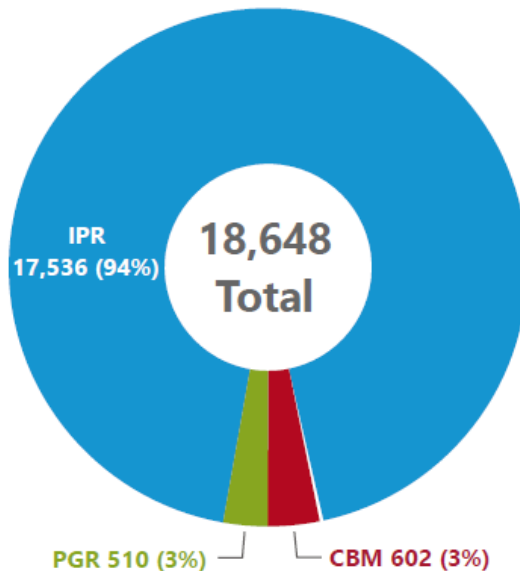


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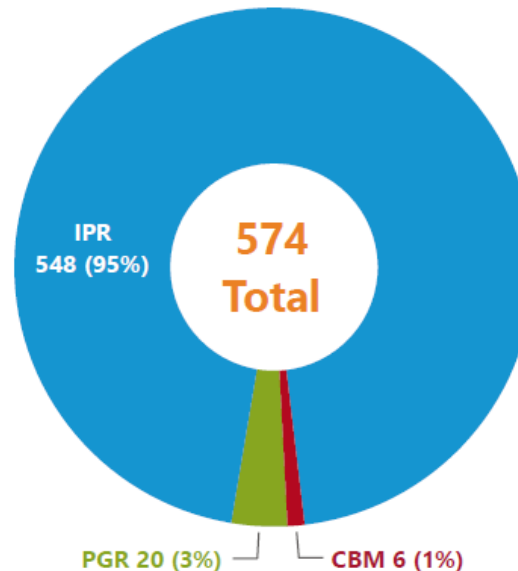
2. ANDA TRENDS ACROSS THE UNITED STATES

- PTAB Orange Book Patent/Biologic Patent Study as of July 31, 2025

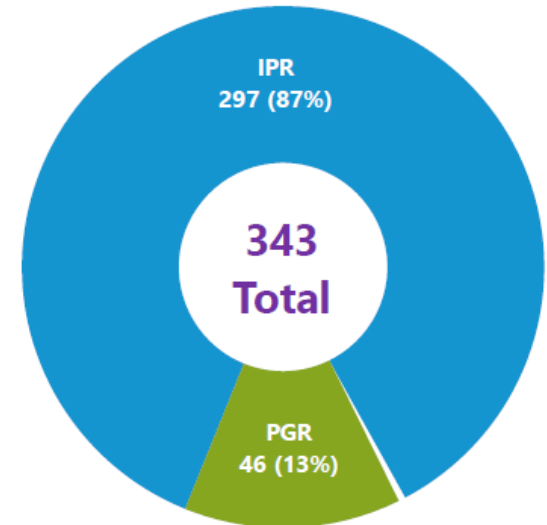
All Technology Categories



Orange Book



Biologics



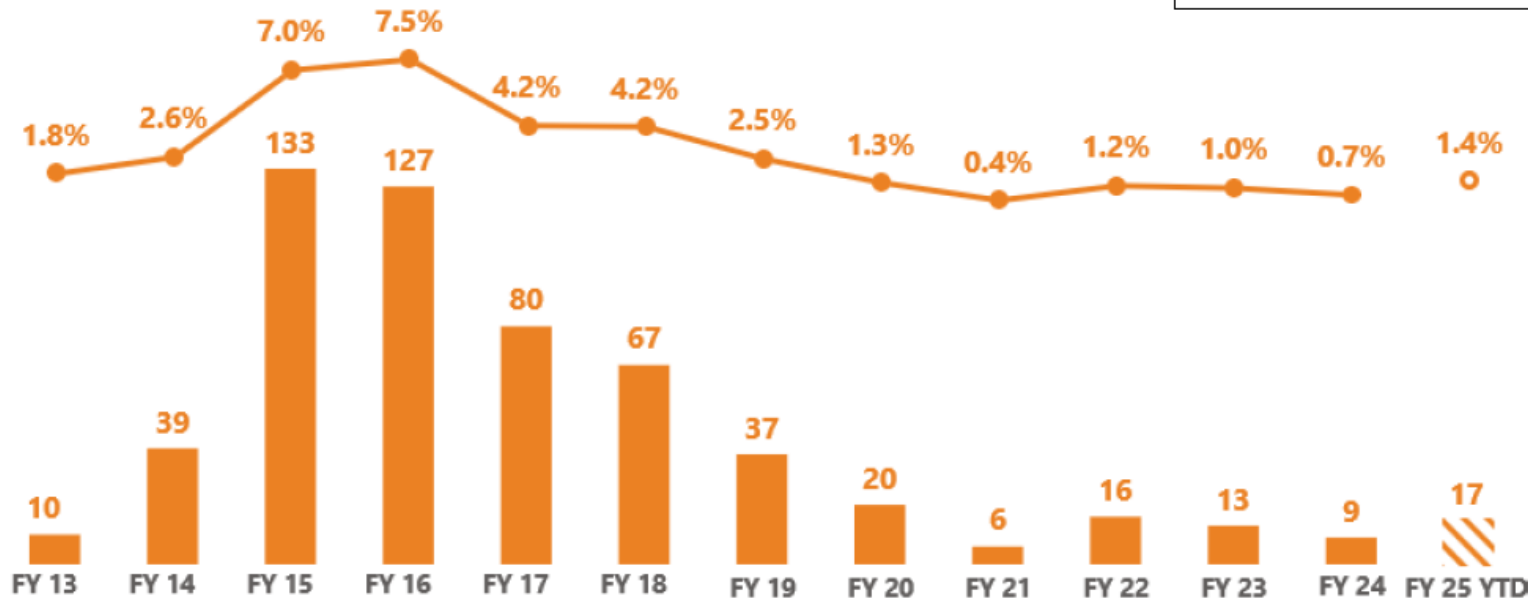
PGR petitions are used more often when challenging **biologic patents**, compared to **Orange Book patents** and other technologies

Source: USPTO

2. ANDA TRENDS ACROSS THE UNITED STATES

- PTAB Orange Book Patent/Biologic Patent Study as of 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

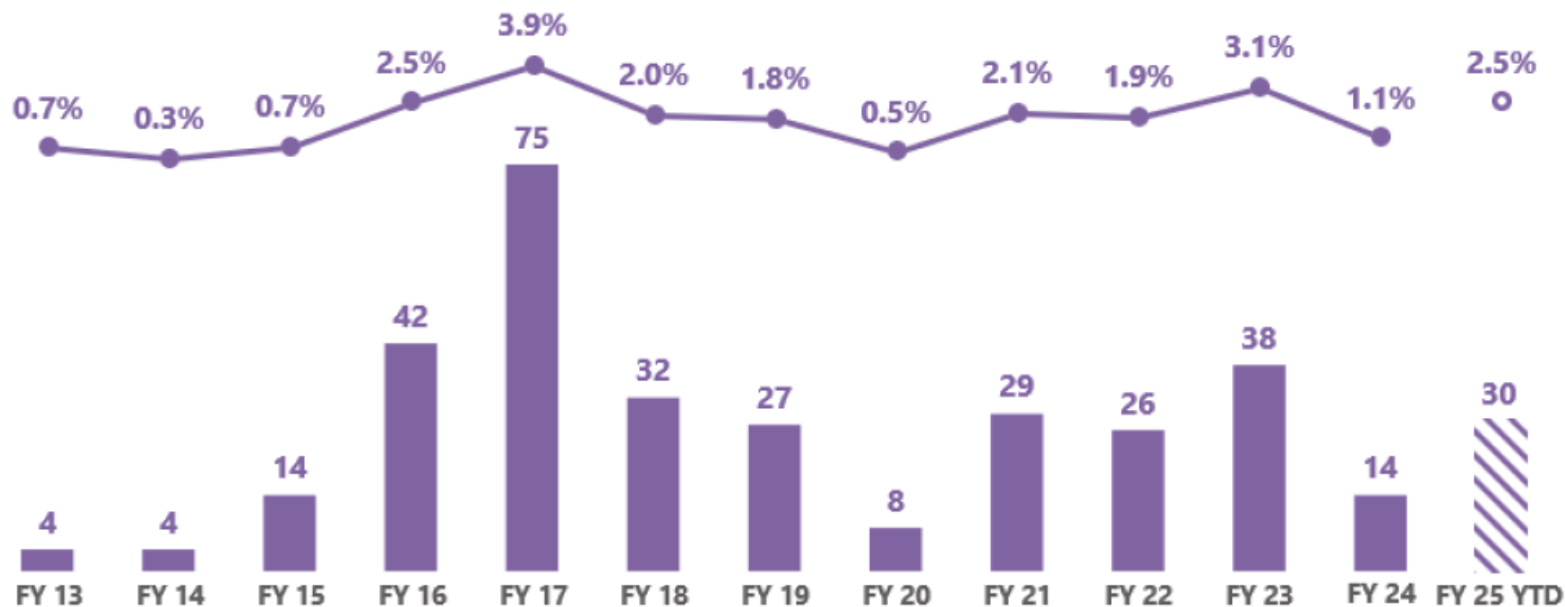


Source: USPTO

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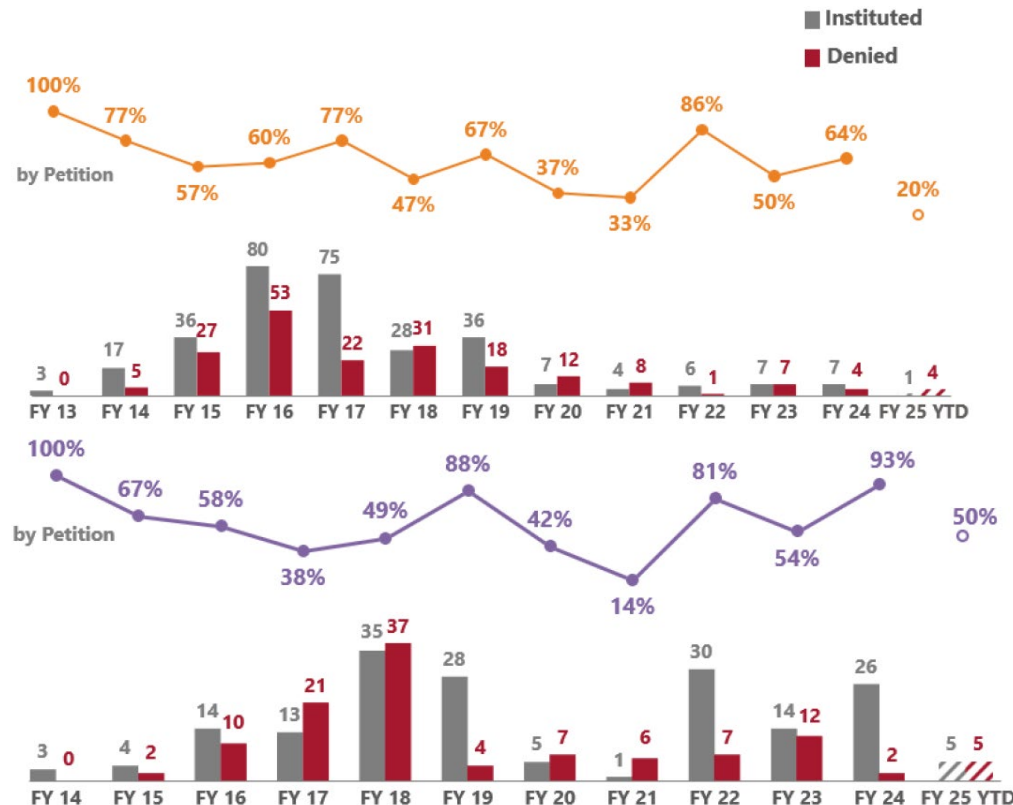
Challenges to **biologic patents** have been more steady, but fewer since FY 2017



Source: USPTO

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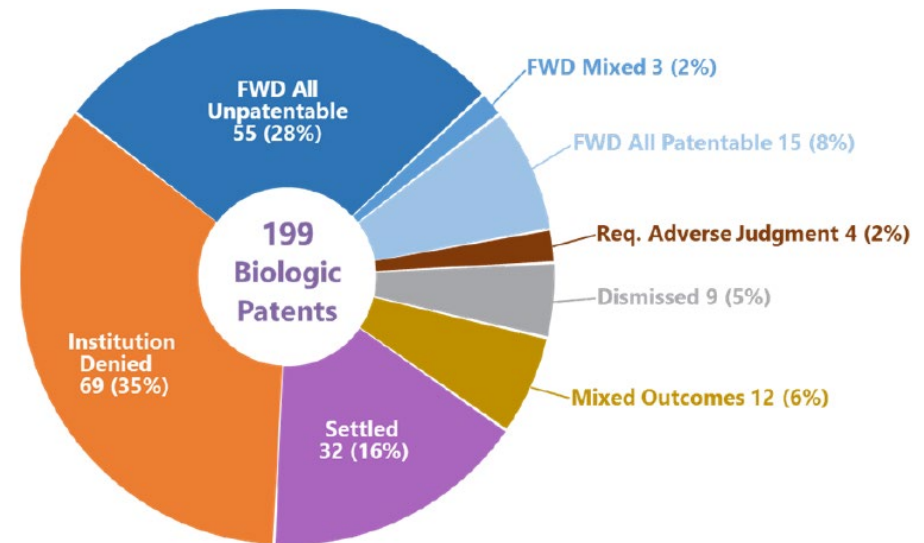
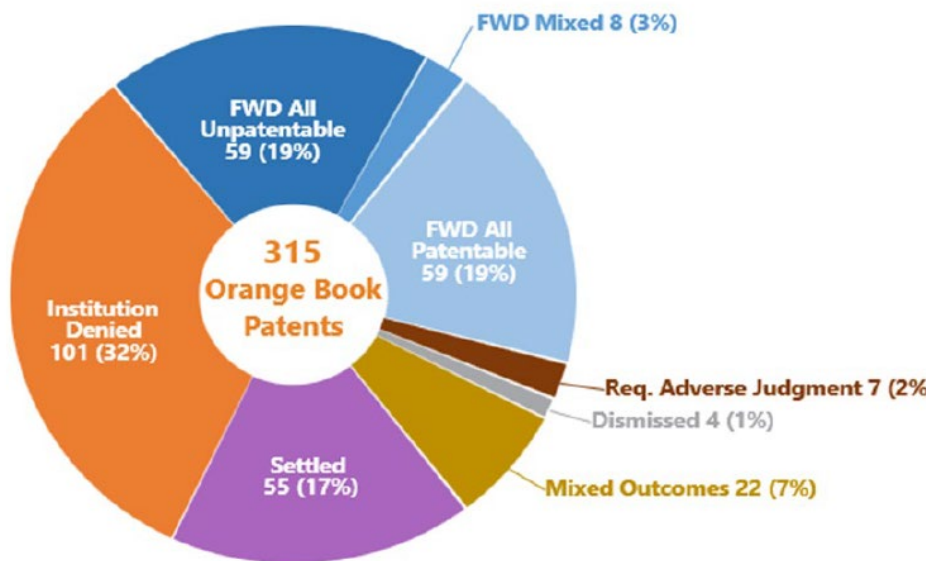


The institution rate for **biologic patents (61%)** is similar to the institution rate for **Orange Book patents (62%)**

Source: USPTO

2. ANDA TRENDS ACROSS THE UNITED STATES

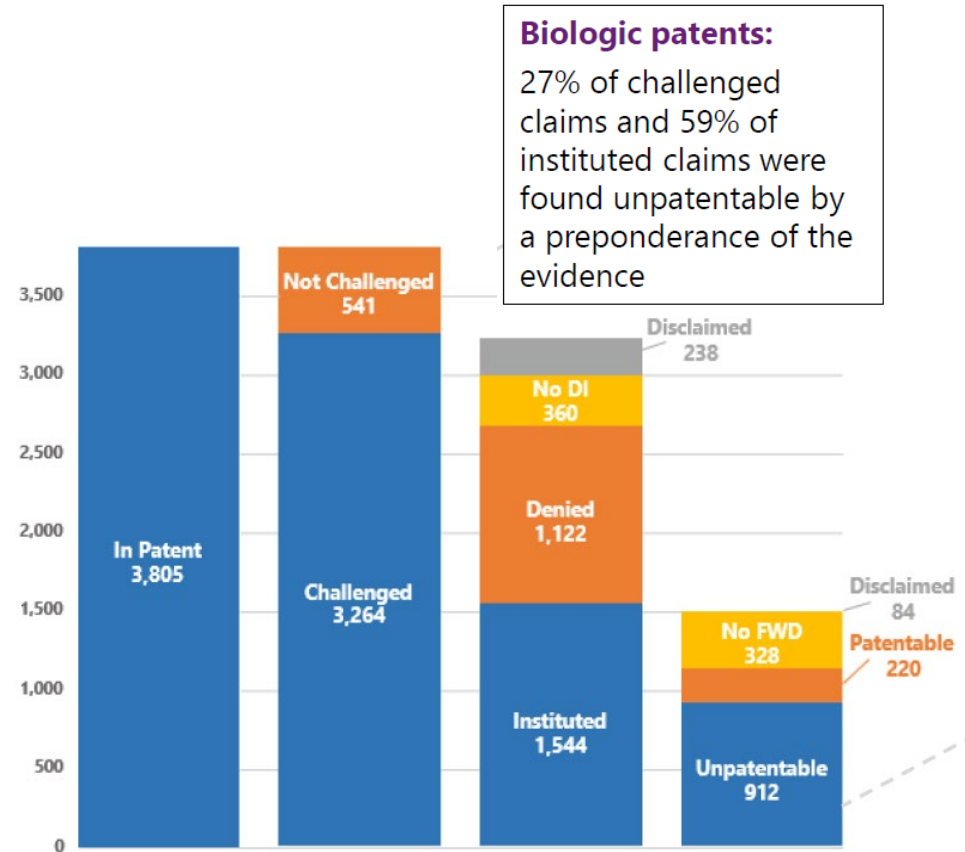
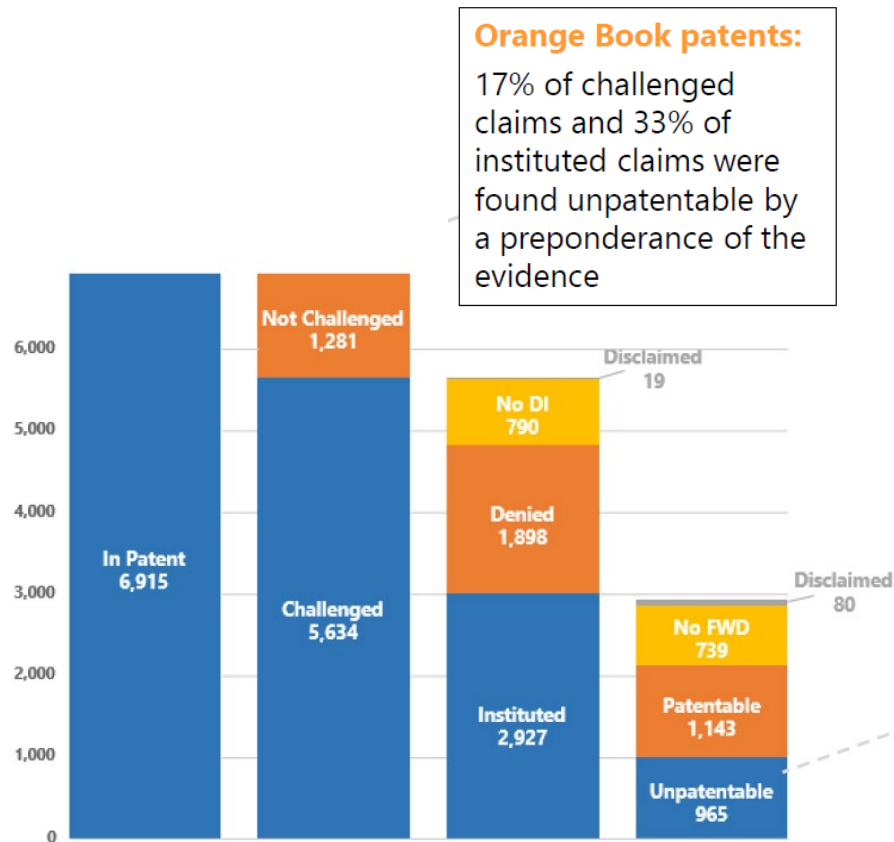
- PTAB Orange Book Patent/Biologic Patent Study as of July 31, 2025



Source: USPTO

2. ANDA TRENDS ACROSS THE UNITED STATES

- PTAB Orange Book Patent/Biologic Patent Study as of July 31, 2025



Source: USPTO



3. 180-DAY EXCLUSIVITY FORFEITURE

- Typically, successful first applicants or first filers of ANDAs obtain a 180-day period of exclusivity to see their FDA-approved ANDA products against only the brand
 - Incentive to maintain the challenge
 - Provides first filers with compensation through sales for taking the risk of the challenge
- In 2003, Congress enacted the Medicare Prescription Drug, Improvement and Modernization Act and included six provisions describing when a first applicant could forfeit its exclusivity [21 U.S.C. § 335(j)(5)(D)(i)(I-VI)]
 - (I) failure to market
 - (II) withdrawal of ANDA
 - (III) amendment of PIV certification
 - (IV) failure to obtain tentative approval within 30 months of filing
 - (V) unlawful collusion
 - (VI) expiration of all patents
 - A “forfeiture event” occurs if *any* of the conditions exist.



3. 180-DAY EXCLUSIVITY FORFEITURE

- ***Norwich Pharms., Inc. v. Kennedy***, __ F. 4th __, 2026 U.S. App. LEXIS 25648 (D.C. Cir. Aug. 25, 2026) addresses two forfeiture provisions: (I) failure to market and (IV) failure to obtain tentative approval
 - Actavis is a first applicant
 - Norwich is a later applicant
 - If, as the FDA found, Actavis maintained its exclusivity, Norwich is blocked from FDA final approval for its generic rifaximin (used for IBS-D and hepatic encephalopathy (“HE”))
 - FDA blocked Norwich from final approval due to Actavis’s exclusivity
 - Norwich argued that Actavis forfeited its exclusivity
 - Actavis received FDA final approval on March 19, 2026, but has not entered the market under the terms of its settlement agreement with Salix

3. 180-DAY EXCLUSIVITY FORFEITURE

- **Did Actavis Fail to market?**

- A first applicant will forfeit its exclusivity if more than 30 months have elapsed since filing and the first applicant does not market within 75 days of a “triggering event” – a final court decision of invalidity or noninfringement; a settlement or consent decree finding that the patent is invalid or not infringed; or the withdrawal of patent information by the patent holder
- Actavis has not launched and it is more than 30 months from ANDA filing and more than 75 days from final approval
- The key language requires that the triggering event must apply to “each of the patents with respect to which the first applicant submitted and lawfully maintained a certification qualifying the first applicant for the 180-day exclusivity period”
- Actavis and Norwich had common certifications except for the HE patent – Norwich opted for a section viii carve out – Actavis did not and challenged

3. 180-DAY EXCLUSIVITY FORFEITURE

- **D.C. Circuit Panel holds:**
 - First, that the certifications need not be “common,” *i.e.*, Norwich’s section viii carve out did not free FDA to approve Norwich’s ANDA because the triggering event had not occurred.
 - The Court stated: “And a first applicant forfeits exclusivity under that [failure to market] provision only if a triggering event occurs ‘**as to each**’ of those qualifying certifications.
 - Result: Affirmance of no failure to market forfeiture
- **Failure to obtain tentative approval**
 - A first applicant forfeits exclusivity if it fails to obtain tentative approval of the application within 30 months of filing “unless the failure is caused by a change or a review of the requirements for approval of the application imposed after the date on which the application is filed .”

3. 180-DAY EXCLUSIVITY FORFEITURE

- **Failure to obtain tentative approval (cont'd)**
 - Actavis filed its ANDA on December 18, 2015
 - FDA publishes a revised draft product guidance for rifaximin requiring additional studies
 - By June 18, 2018, Actavis had not obtained tentative approval
 - Actavis obtained final approval on March 19, 2026
 - Norwich asserts the delay caused by FDA was not the but-for cause for failing to obtain approval and, therefore, Actavis forfeited
 - Actavis argues that any delay is sufficient to offset the failure to obtain approval provisions
 - FDA agreed with Actavis that but-for causation is not required
- **Held: But-for causation is required, and FDA applied the wrong standard**
 - But-for causation is the norm and “[a]pplying a but-for causation standard ensures that an applicant is excused from that failure **only** if that applicant would have timely secured approval absent some relevant FDA ‘change in or ... review of the requirements.’”
 - **Remand to FDA**



4. PATENT LISTING AND DE-LISTING

- Historically, the FDA is very “hands off” and does not police listings
- In *Mylan v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001), the Federal Circuit held that Mylan’s declaratory judgment action to delist an Orange Book patent was not authorized by the Act or recognizable as a defense to infringement
- In 2003, Congress authorized generic applicants to assert counterclaims requiring the ANDA holder to correct or delete patent information if the patent did not cover the approved drug product or approved method of use (21 U.S.C. § 355(j)(5)(C)(ii)(I))
- In 2012, the Supreme Court clarified that such a counterclaim (a “delisting counterclaim”) was also available to correct overbroad use codes (*Caraco Pharm. Labs. Ltd. v. Novo Nordisk A/S*, 566 U.S. 399 (2012))
- **Practical Problem with delisting counterclaims:** not resolved quickly enough to benefit the generic
 - Rule 12(b) motion to dismiss
 - Rule 12(c) motion for judgment on the pleadings
 - Summary Judgment motion

4. PATENT LISTING AND DE-LISTING

- 21 U.S.C. § 355(b)(1)(A)(viii) [as amended by 2021 FDCA Omnibus reform] requires NDA holder to submit patent information
 - Listable:
 - drug substance (active ingredient)
 - drug product (formulation or composition)
 - method-of-use (if it covers an approved therapeutic indication)
 - Not-Listable
 - manufacturing process
 - packaging
 - drug delivery device when it does not incorporate the active ingredient in the claims
 - distribution system
 - risk management system



4. PATENT LISTING AND DE-LISTING

- From 2005-2015, Orange Book listings per drug increased 53%, driven by secondary formulation, device, and method-of-use patents
- The FTC set out to address that
- September 14, 2023 – FTC issued a Policy Statement declaring that improper Orange Book patent listings may constitute an unfair method of competition in violation of Section 5 of the FTC Act
- FTC warning letters started in November of 2023
- FTC-initiated listing challenges via 21 C.F.R. § 314.53(f)(1)
 - FTC files the dispute
 - FDA notifies NDA holder, who has 30 days to withdraw or amend the listing or certify that the listing complies with the requirements
- From September of 2023 to May of 2025, the FTC challenged more than 600 patent listings in the Orange Book
- Teva paid \$35 million to settle a class-action antitrust lawsuit tied to improper listings; in December of 2025, Teva removed more than 200 patents from the registry covering more than 30 branded products



4. PATENT LISTING AND DE-LISTING

Teva Branded Pharm. Prods. R&D, Inc. v. Amneal Pharms. of N.Y., LLC, 124 F.4th 898 (Fed. Cir. 2024)

- Amneal argued that Teva improperly listed patents in the Orange Book and delayed entry of generic products onto the market
- District Court (D.N.J.) agreed: the patents contained no claim for the active ingredient at issue (albuterol sulfate), but instead were directed to components of a metered inhaler device
- Federal Circuit affirmed the delisting order
 - Noted that the 2021 amendment “sets both a floor and a ceiling for what patents an NDA holder must list”
 - “None of the claims in the five asserted patents explicitly require the presence of an active drug, let alone any specific active drug”
 - “To summarize, our analysis of the numerous relevant statutory provisions and the relevant case law leads us to only one conclusion: To list a patent in the Orange Book, that patent must, among other things, claim the drug for which the applicant submitted the application and for which the application was approved. And to claim that drug, the patent must claim at least the active ingredient. Thus, patents claiming just the device components of the product approved in an NDA do not meet the listing requirement of claiming the drug for which the applicant submitted the application.”

4. PATENT LISTING AND DE-LISTING

- FDA issued new Orange Book guidance in June of 2026: “Forms FDA 3542a and FDA 3542: Questions and Answers (available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/forms-fda-3542a-and-fda-3542-questions-and-answers>)
- Orange Book – only listable patents
 - Drug substance
 - Drug product
 - Method-of-use
- Things to watch out for with Forms 3542:
 - Identify any applicable U.S. agent for the patent owner or NDA holder
 - Describe and clearly explain changes by the NDA holder to use code
 - Identify the specific subsections of the approved product labeling that describe the approved method of use
 - Ensure the use code description matches the use code description in the Orange Book when the sponsor intends to use a use code identical to one already published in the Orange Book



5. BOND REQUIREMENTS – OTSUKA

- ***Otsuka Am. Pharm., Inc. v. Hetero Labs Ltd.***, 179 F.4th 1352 (Fed. Cir. 2026)
 - District Court (Delaware, Judge Williams) granted preliminary injunction that enjoined Hetero from introducing a generic drug to compete with Nuedexta (neurological disorders)
 - Hetero appealed: (1) claim construction, and (2) whether district court permissibly waived the requirement of Fed. R. Civ. P. 65(c) that Otsuka post a bond pending appeal
 - Federal Circuit vacated the district court's order waiving the bond
 - Bond requirement of Rule 65(c) is not specific to patent law, so regional circuit law applied (Third Circuit)
 - Requirement to impose a bond is “strictly interpreted” and waiver is appropriate only under certain limited exceptions



5. BOND REQUIREMENTS – OTSUKA

- ***Otsuka Am. Pharm., Inc. v. Hetero Labs Ltd.***, 179 F.4th 1352 (Fed. Cir. 2026)
 - Rule 65 – Injunctions and Restraining Orders
 - (c) Security. The court may issue a preliminary injunction or a temporary restraining order only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained.
 - Third Circuit *rarely* waives the requirement
 - If there is no risk of monetary loss to the defendant
 - In non-commercial cases upon considering possible loss to enjoined party together with hardship that the requirement imposes on the applicant (citing *Temple University v. White*, 941 F.2d 201, 219-220 (3d Cir. 1991))
 - In suits to enforce important federal rights or public interests, arising out of comprehensive federal health and welfare statutes
 - District Court applied first *Temple* exception, finding the financial harm to Hetero speculative at best and expressed concern over a “chilling effect on access to justice” if multi-million dollar bond were required



5. BOND REQUIREMENTS – OTSUKA

- ***Otsuka Am. Pharm., Inc. v. Hetero Labs Ltd.***, 179 F.4th 1352 (Fed. Cir. 2026)
 - “We are bound to follow the Third Circuit’s narrow exceptions to Rule 65(c). And the Third Circuit has ‘never excused a district court from requiring a bond where an injunction prevents commercial, money-making activities.’ Hetero’s attempt to enter the market with its generic pharmaceutical product is clearly a commercial, money-making activity.”
 - Vacated the waiver and remanded to the district court for reconsideration
 - On remand, district court may exercise its discretion in determining an appropriate amount to require as a security in light of the limited time remaining before the patent-in-suit expires (about 4 months)
 - Regarding the concern about a large expense on the plaintiffs, noted the Local Rules for the District of Delaware, where the reasonable premiums or expenses paid on bonds or security stipulations shall be allowed as taxable costs when those amounts are furnished by requirements of the law or rule of Court or where required to enable a party to receive or preserve some right

5. BOND REQUIREMENTS – OTSUKA

- ***Otsuka Am. Pharm., Inc. v. Hetero Labs Ltd.***, 2026 U.S. Dist. LEXIS 197920, No. 25-647 (D. Del Aug. 26, 2026)
 - Otsuka argued \$5 million was appropriate
 - Hetero argued \$80 million was appropriate
 - Court set it at \$5 million
 - Lots of back and forth
 - Reiterated the \$5 million bond requirement to be paid within 7 days of the Court's Order



6. Tax Implications of Hatch-Waxman Litigations

- ***Actavis Labs. FL, Inc. v. United States*, 131 F.4th 1345 (Fed. Cir. 2025)**
 - Question: Are litigation expenses of ANDA filer “ordinary business expenses” that may be deducted in the year in which they are incurred?
 - Answer: Yes!
 - As Judge Stark noted in the opinion for the Court: “While some background explanation of pharmaceutical patent litigation is necessary to understand this appeal, this is not actually a patent case. It is, instead, a tax case.”
- Tax deductions allowed or not allowed based on whether the litigation expenses are the costs of doing business during the year or whether they are capital expenditures which may only be deducted over the useful life of the subject matter
 - Suffice it to say, without too much tax law, the Federal Circuit held that these expenses which are generated without a guarantee of success are ordinary business expenses
 - Under the “origin of the claim” test, the Court (and Actavis) agreed that the origin of the claim is patent infringement
 - Under the “significant future benefit” standard, because Hatch-Waxman litigation is separate from the ANDA approval process, it is not a pursuit of an asset, but rather litigation with no asset at its end

Speakers



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