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Finnegan Europe LLP

**WIPO Conference on IP Dispute
Resolution in Life Sciences
22 May 2015**

Anthony C. Tridico, Ph.D.



Overview of Hatch-Waxman Act

- Enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984
- Struck balance between competing interests
 - Supporting pioneer research and development vs.
 - Enabling competitors to market low-cost generic copies of drugs
- Generics allowed a “safe harbor” from patent infringement for testing “reasonably related” to obtaining FDA approval of ANDA
 - Overruled Federal Circuit’s decision in *Roche v. Bolar*
- Submission of ANDA for a drug claimed by an unexpired patent is an act of infringement

ANDA Paragraph IV Certifications

- ANDA filer submitting Paragraph IV Certification must give notice to patent owner and NDA holder within 20 days after FDA acceptance of ANDA
 - Must include a detailed statement of the factual and legal bases for the ANDA filer's opinion that the patent is unenforceable and/or that its claims are invalid and/or will not be infringed
- Patent owner has 45 days to file suit for infringement
 - During this 45-day period, the ANDA filer is barred from bringing a declaratory judgment action
 - If the patent owner fails to bring suit within 45 days, the FDA may approve the ANDA and/or the ANDA filer may attempt to bring a declaratory judgment action for invalidity, unenforceability and/or noninfringement

Statutory Stay of ANDA Approval

- If patent owner files suit within 45 days after receiving a Paragraph IV notice letter, automatic stay of ANDA approval becomes effective
 - Generally 30 months from date on which notice letter was received
 - Extended to 7.5 years from date of NDA approval for new chemical entity
- Purpose of statutory stay
 - Allow court to adjudicate patent suit and prevent ANDA filer from accruing huge damages for infringement
- Generally, only one statutory stay is permitted per ANDA, regardless of the number of patents covering the drug

U.S. Judicial System



U.S. Supreme Court



Federal Circuit

Quasi-Judicial Federal Agencies

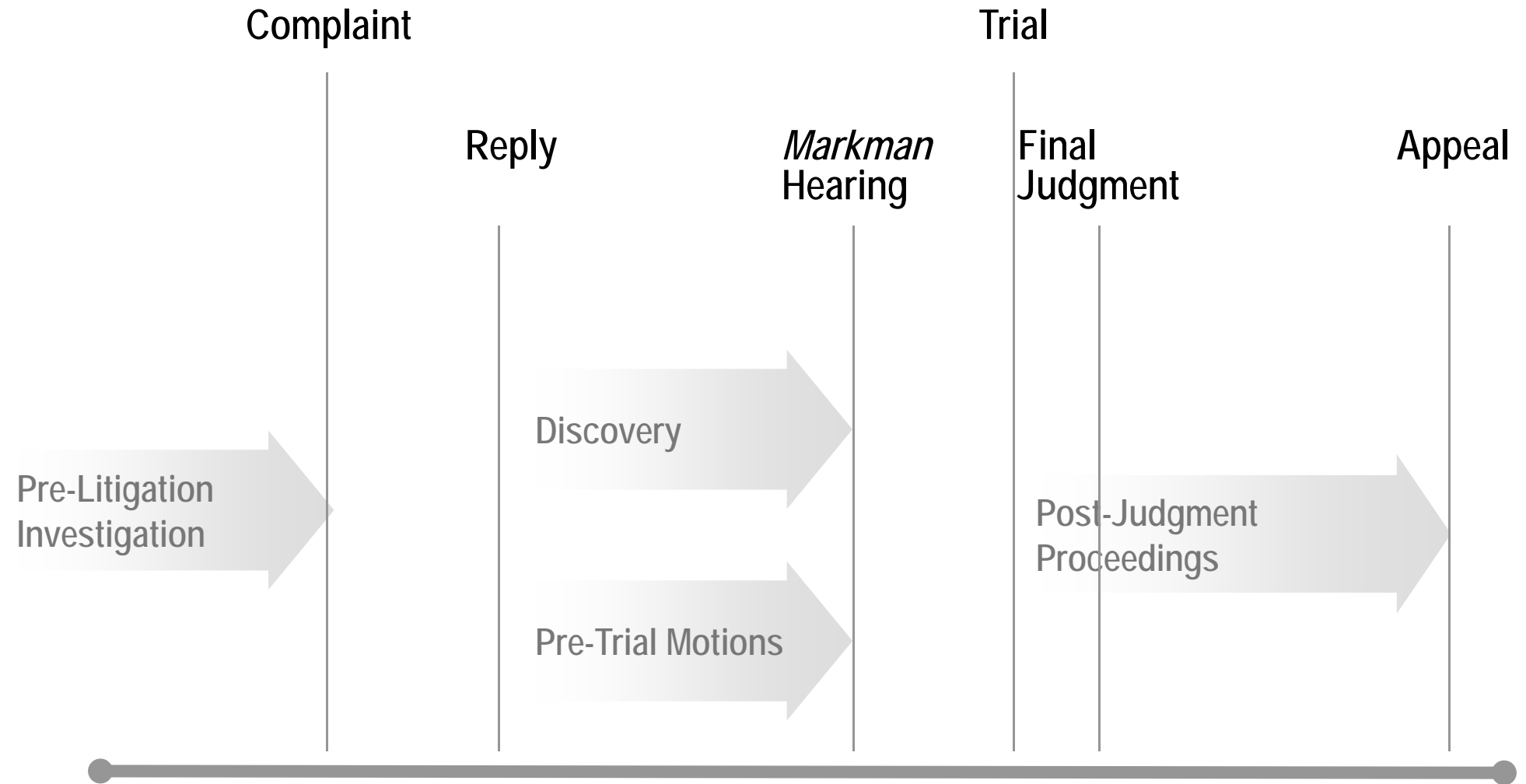
International Trade Commission

Patent Trial & Appeals Board

94 District Courts
(at least 1 in each state)

Court of Federal Claims

Typical Stages of A U.S. Patent Litigation

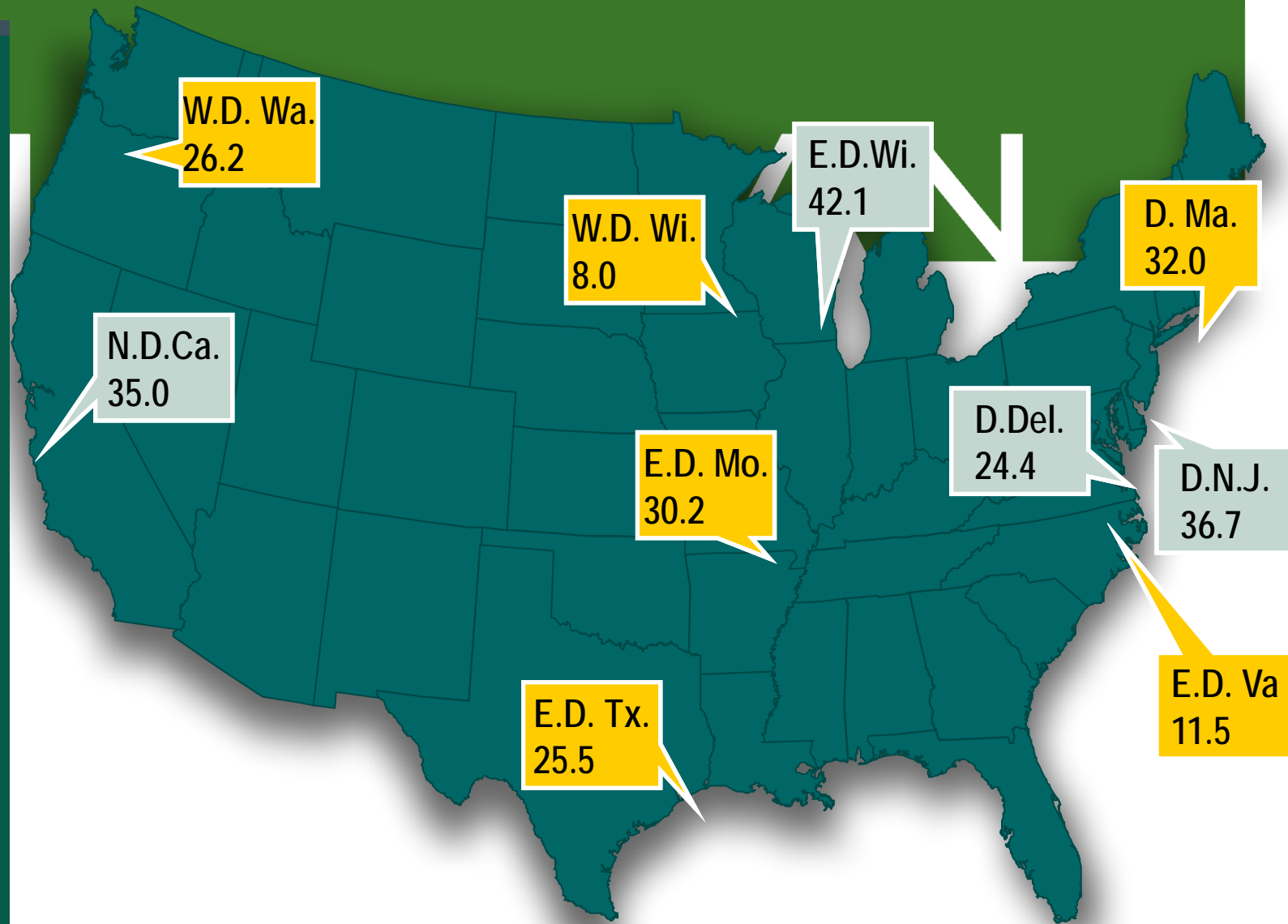


Where to File Suit?

- Speed to trial
- Jury pool
- Avoid transfer
- Judges' track record
- Witness availability
- Avoid defendant's backyard

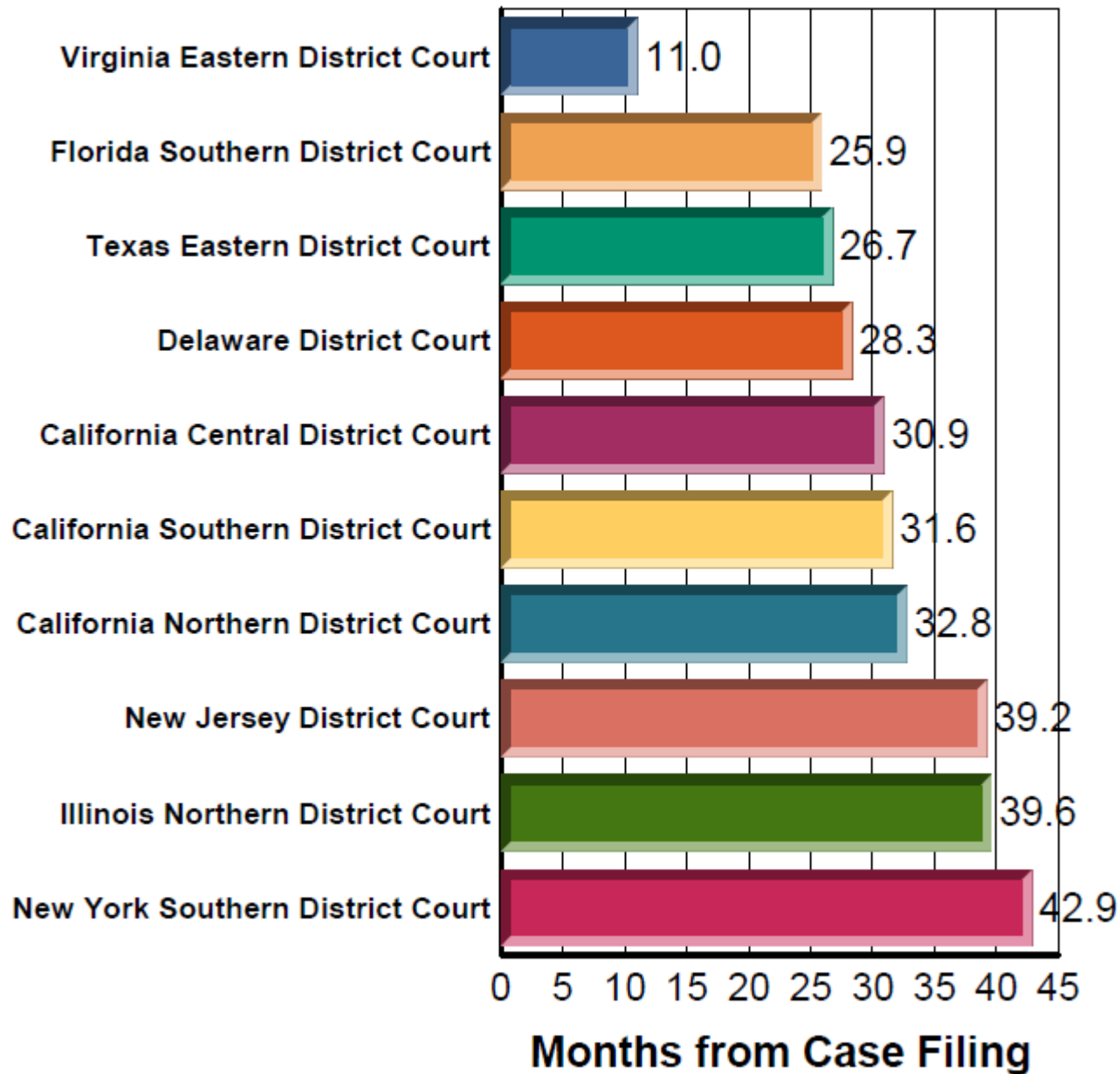
... So Time to Trial is Unpredictable and Can Be Lengthy.

The average time to trial in 2010 ranged from 30 months to 42 months.



Lemley, M. , "Where to File your Patent Case," 38 AIPLA Q.J. 1 (Fall 2010)

Fastest Time to Trial Districts



Legalmetric report from Jan 1991-Nov 2014.

Where to File Suit?

Highest Patent Owner Win Rates (In Courts Hearing 25 Patents Cases or More per Year)

- Northern District of Texas (55.1%)
- Middle District of Florida (46.3%)
- District of Nevada (46.2%)
- District of Delaware (45.3%)
- District of Oregon (45.2%)
- Eastern District of Texas (40.3%)

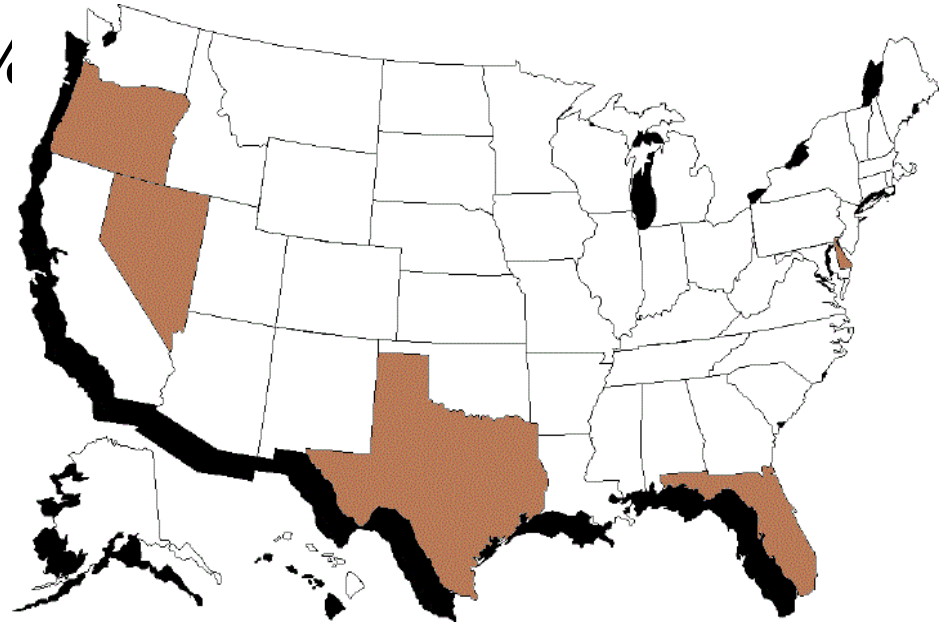


Chart 13. Top ten most active district court judges: 1995–2013

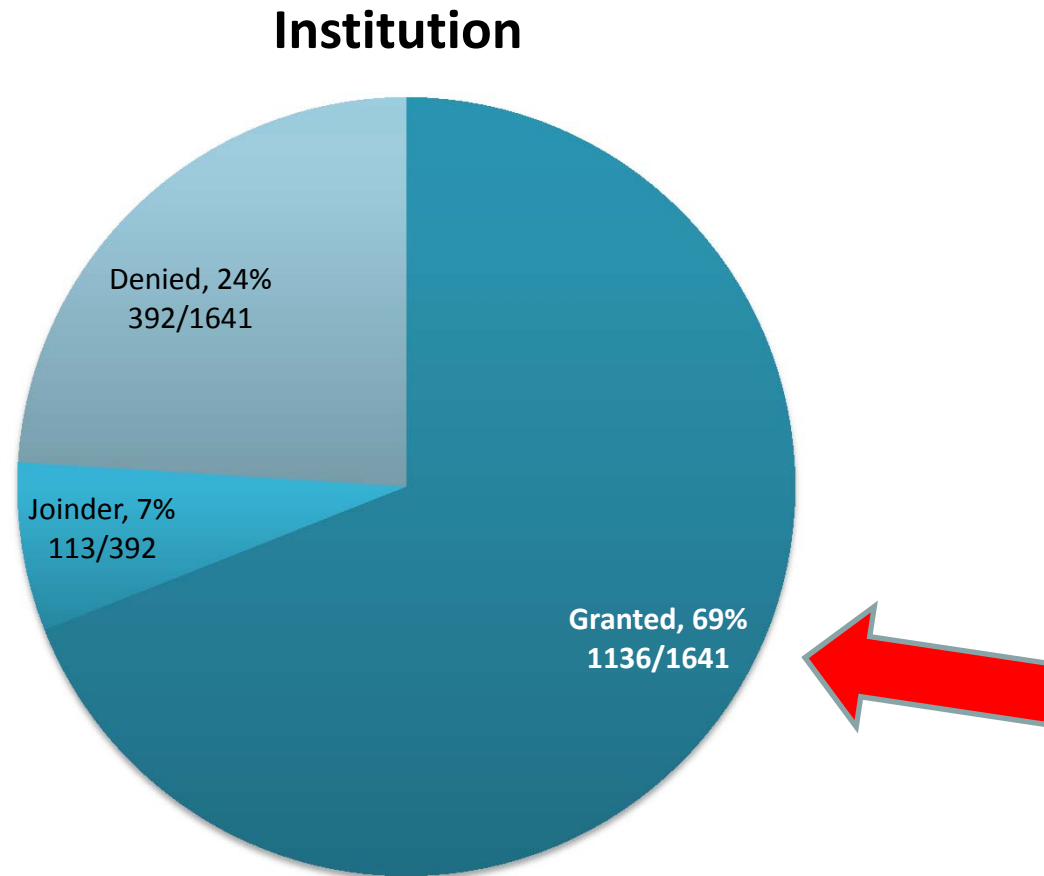
Rank	Judge last name	Judge first name	District court	Identified decisions	Identified trial decisions	Median damages	Overall success rate	Time to trial	Percent of decisions that are SJs
1	Robinson	Sue	Delaware	65	41	\$21,555,613	38%	1.88	37%
2	Sleet	Gregory	Delaware	29	25	\$21,284,375	55%	1.88	10%
3	Davis	Leonard	Texas Eastern	27	20	\$9,752,865	63%	2.29	26%
4	Stark	Leonard	Delaware	17	7	\$13,083,385	41%	2.12	41%
5	Wilken	Claudia	California Northern	16	7	\$9,675,832	38%	2.20	56%
6	Clark	Ron	Texas Eastern	15	13	\$6,841,200	73%	1.79	13%
7	Huff	Marilyn	California Southern	11	6	\$25,419,854	36%	2.07	45%
8	Young	William	Massachusetts	11	4	\$233,159	18%	1.72	64%
9	Darrah	John	Illinois Northern	11	3	\$10,139,484	9%	3.50	73%
10	Alsup	William	California Northern	10	4	\$18,807,241	10%	1.61	60%

Median Patent Infringement Litigation Costs

All Varieties	2013
< \$ 1 mill at risk	\$700,000
\$1 to \$10 mill at risk	\$2,000,000
\$10 to \$25 mill at risk	\$3,325,000
> \$25 mill at risk	\$5,500,000

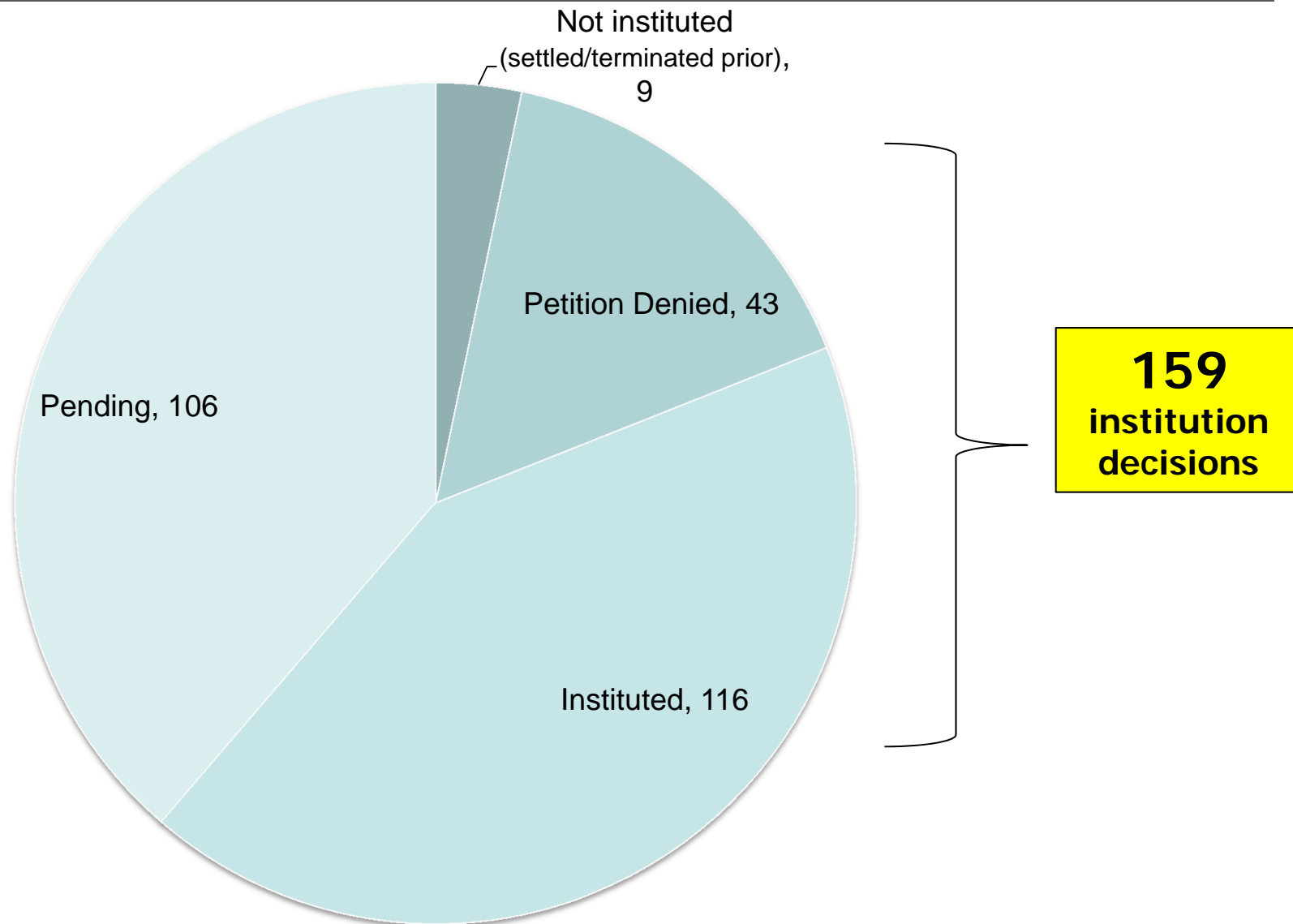
ANDA Litigation	2013
< \$ 1 mill at risk	\$513,000
\$1 to \$10 mill at risk	\$1,800,000
\$10 to \$25 mill at risk	\$4,000,000
> \$25 mill at risk	\$6,000,000

ENTER THE PTAB Petition Grant Rate is High!



As of March 26, 2015. Source: http://www.uspto.gov/sites/default/files/documents/032615_aia_stat_graph.pdf

Even Higher for Pharma/Chem/Bio Petitions

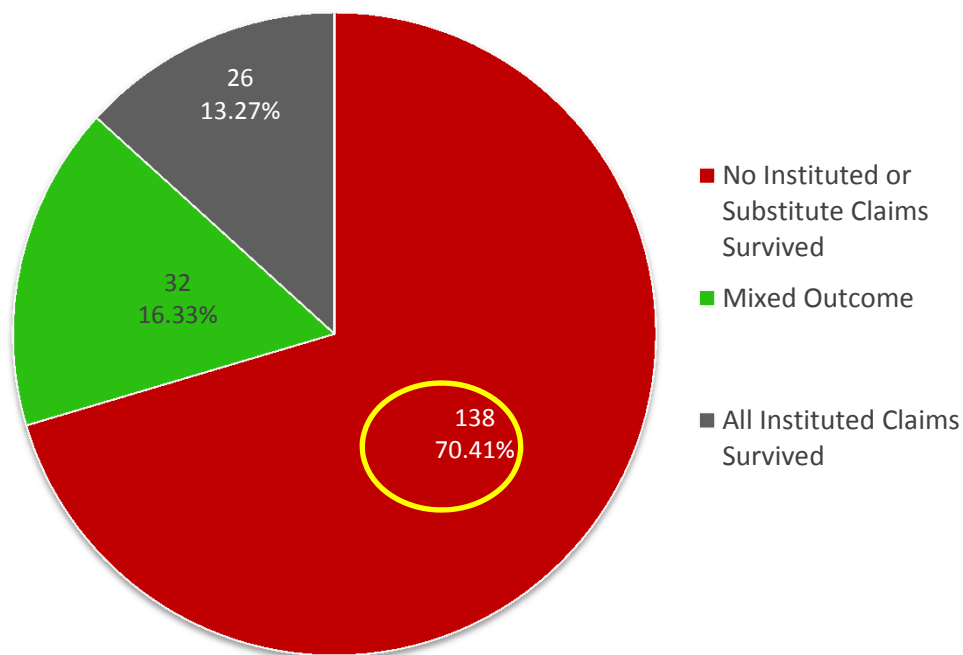


As of April 5, 2015. Source: Finnegan research.

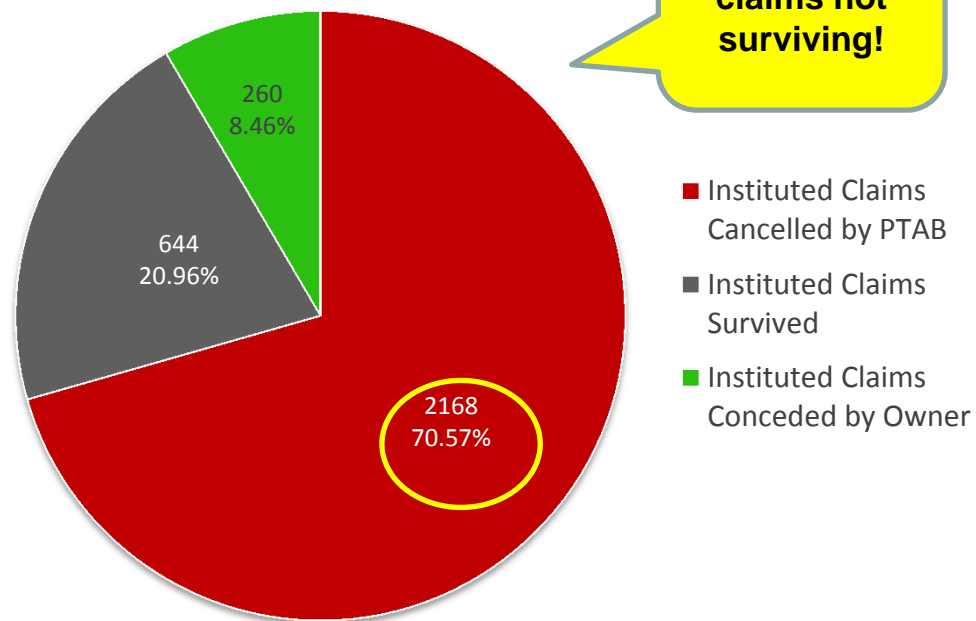
Grant rate 73% (116/159)

And When IPR Instituted, Cancellation Rate is High!

IPR Results by Case



IPR Results by Claim



“mixed outcome” means some instituted claims survived, some did not.

As of Feb. 1, 2015. Source: Finnegan research, with thanks to Dan Klodowski, Kai Rajan, Elliot Cook, and Joe Schaffner. Analysis: 3072 claims at issue; 196 cases.

Notable IPR/ANDA Cases

IPR	Petitioner	Patent Owner	Product	Instituted?	Status
IPR2013-00012; -00015	Apotex	Alcon Pharms.	Vigamox® (moxifloxacin hydrochloride)	Y	Settled/terminated
IPR2013-00024	Ranbaxy Labs.	Vertex Pharms.	Lexiva® (fosamprenavir calcium)	Y	Settled/terminated
IPR2013-00428; -00429; -00430	Apotex	Alcon Research Ltd.	Travatan Z® (travoprost)	Y	Settled/terminated
IPR2013-00368; -00371; -00372	Amneal Pharms.	Supernus Pharm.	Oracea® (doxycycline)	Y	FWD: All instituted claims survived
IPR2014-00115	Apotex	Wyeth	Tygacil® (tigecycline for injection)	Y	Oral hearing
IPR2013-00582; -00590	Baxter Healthcare	Millenium Biologix	Actifuse®	Y	FWD: All instituted claims unpatentable
IPR2013-00583; -00591	Baxter Healthcare	Millenium Biologix	Actifuse®	N (claims entitled to priority date so art not anticipating)	

Notable IPR/ANDA Cases (con't)

IPR	Petitioner	Patent Owner	Product	Instituted?	Status
IPR2014-00651; -00653; -00655	Endo Pharms.	Depomed	Acuform®; Gralise®; Glumetza®; Janumet®; NUCYNTA®	N (threshold not met for anticipation grounds)	
IPR2014-00652; -00654, -00656	Endo Pharms.	Depomed	Acuform®; Gralise®; Glumetza®; Janumet®; NUCYNTA®	Y (threshold met for obviousness grounds)	Reply to Patent Owner Response
IPR2014-01126	Actavis	Research Corp. Tech.	Vimpat® (lacosamide)	N (threshold not met)	
IPR2014-00559	Torrent Pharms.	Merck Canada	Daliresp® (roflumilast)	N (threshold not met)	

Anthony C. Tridico, Ph.D.

(anthony.tridico@finnegan.com/+44 7500 864 501)

- Managing Partner of the firm's European office in London
- Experience in all aspects of U.S. and European patent law including prosecution, post-grant proceedings, and litigation
- Practice focuses on client counseling, IP portfolio management and patent office procedures (appeals, post-grant proceedings) in the chemical (organic, polymer), pharmaceutical, and biotechnological arts
- Frequent lecturer on various aspects of on patent law issues affecting the chemical, pharmaceutical, and biotech industries

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