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Finnegan Europe LLP

WIPO Conference on IP Dispute Resolution in Life Sciences 2016

Amanda K. Murphy, Ph.D.

U.S. Judicial System

U.S. Supreme Court

Federal Circuit

94 District Courts (at least 1 in each state)

Court of Federal Claims

Quasi-Judicial Federal Agencies

International Trade Commission

Patent Trial & Appeals Board

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 Abbreviated New Drug Application (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 not later than 20 days after receipt of FDA Paragraph IV acknowledgment letter.
  - 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.

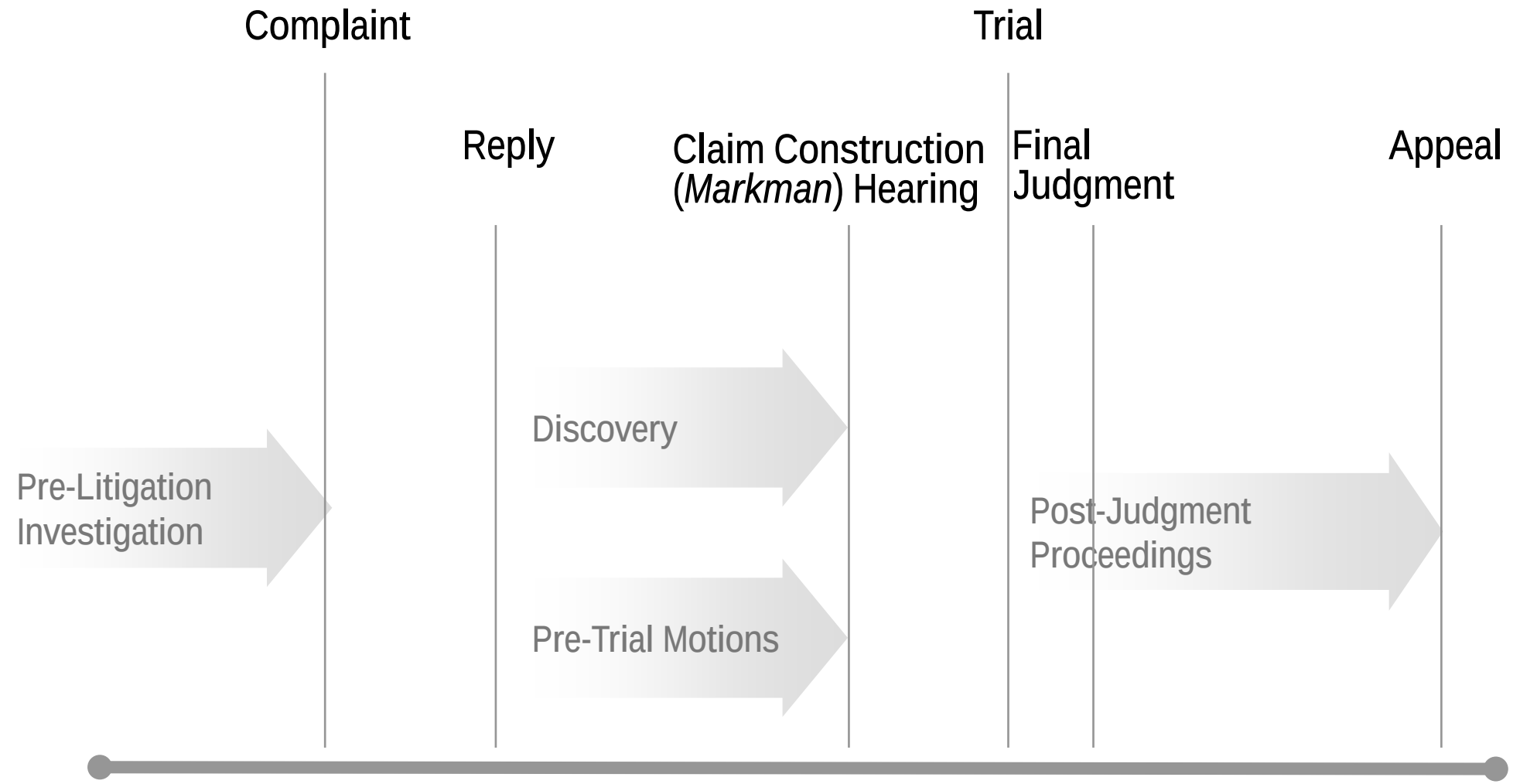
Statutory Stay of ANDA Approval

- 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 the later of the date of receipt of notice of paragraph IV certification by any owner of the listed patent or by the NDA holder.
  - 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.

Typical Stages of A U.S. Patent Litigation

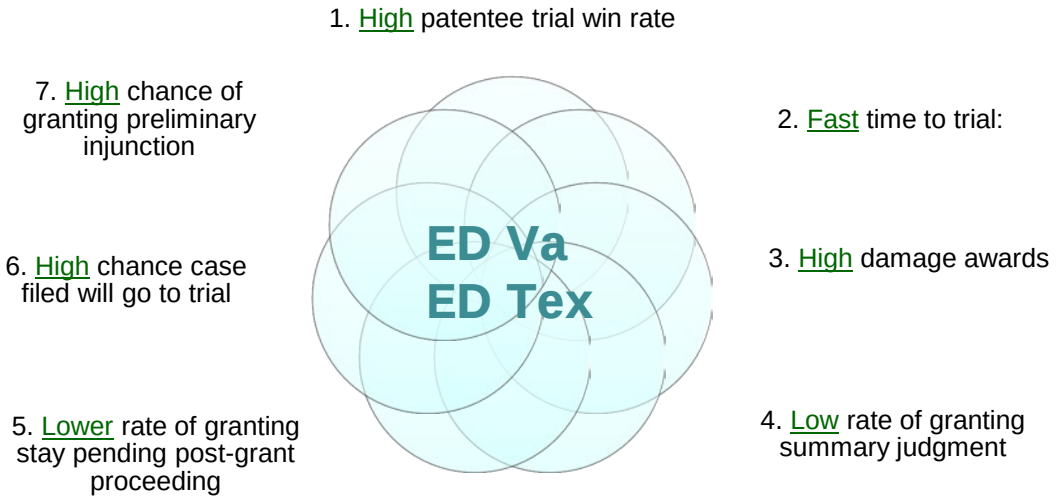


Where to File Suit?

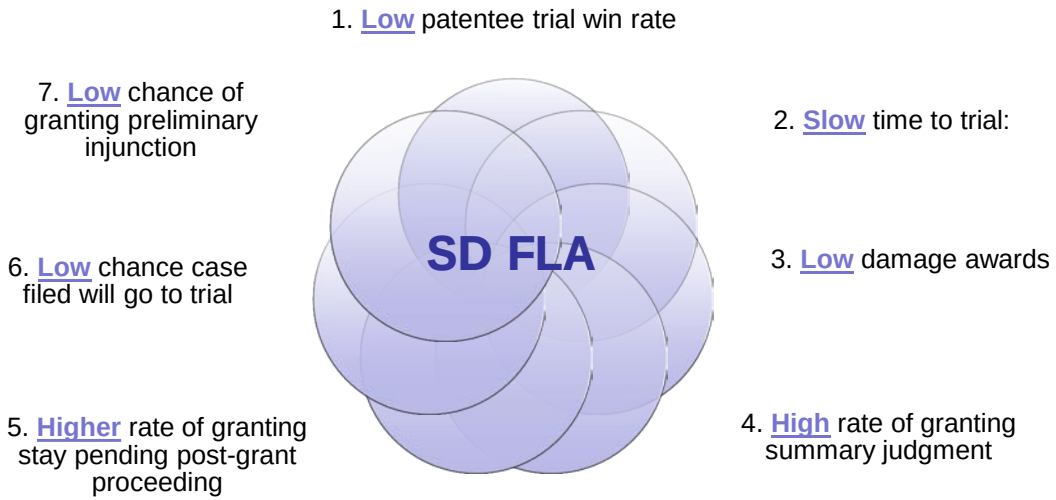
- Speed to trial
- Jury pool
- Avoid transfer
- Judges' track record
- Witness availability
- Avoid defendant's backyard

U.S. District Court Forum-Shopping: 7 Data Metrics

- Factors for patent owners deciding in which district court to initiate patent litigation



- Factors for alleged infringers deciding in which district court to initiate patent litigation:



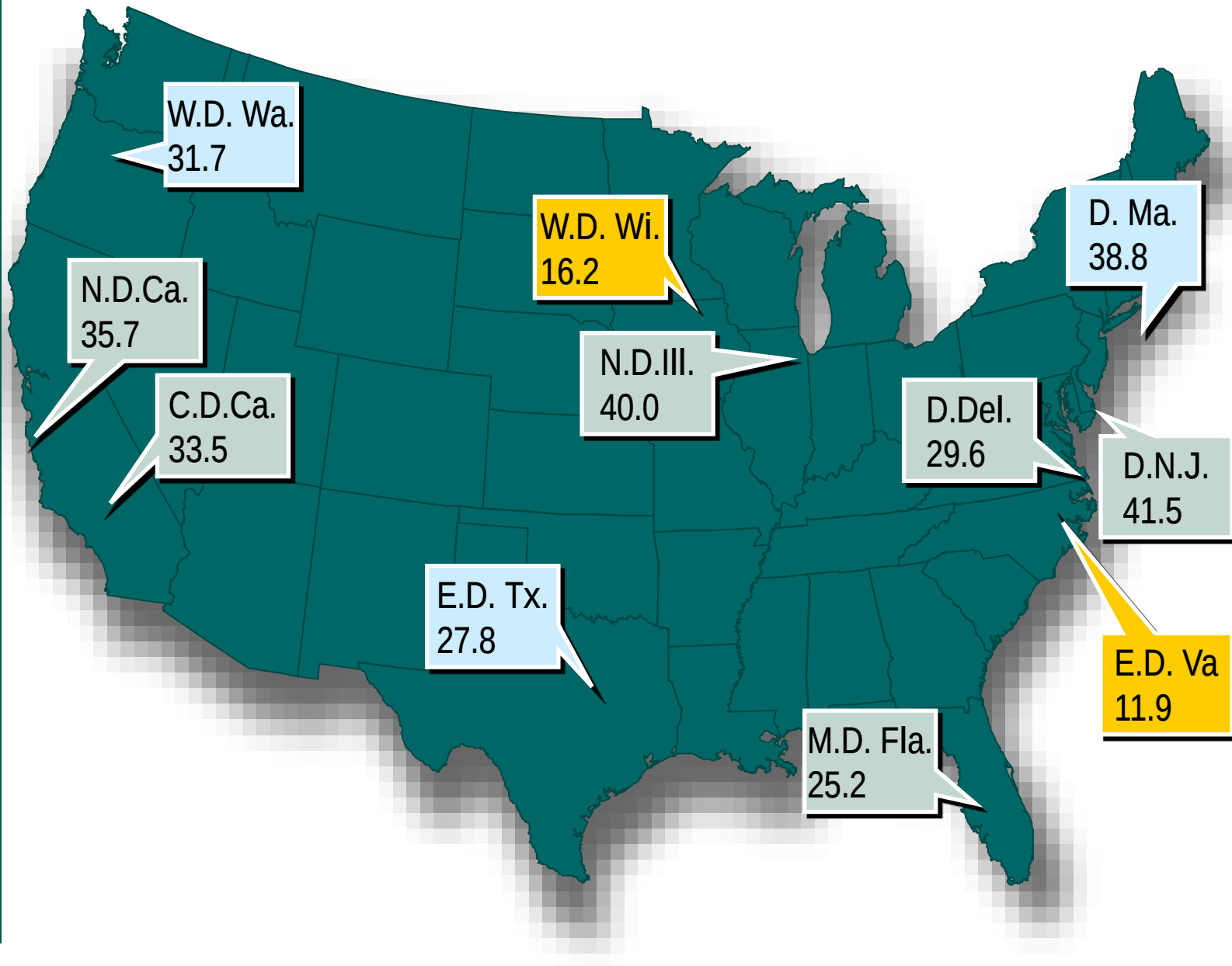
**Source: PriceWaterhouseCooper 2015 Patent Litigation Study, Fig. 16, based only on factors 1, 2, and 3, weighted equally.*

Time to Trial is Unpredictable and Can Be Lengthy.

The average time to trial nationally is 33 months, but varies widely by district.

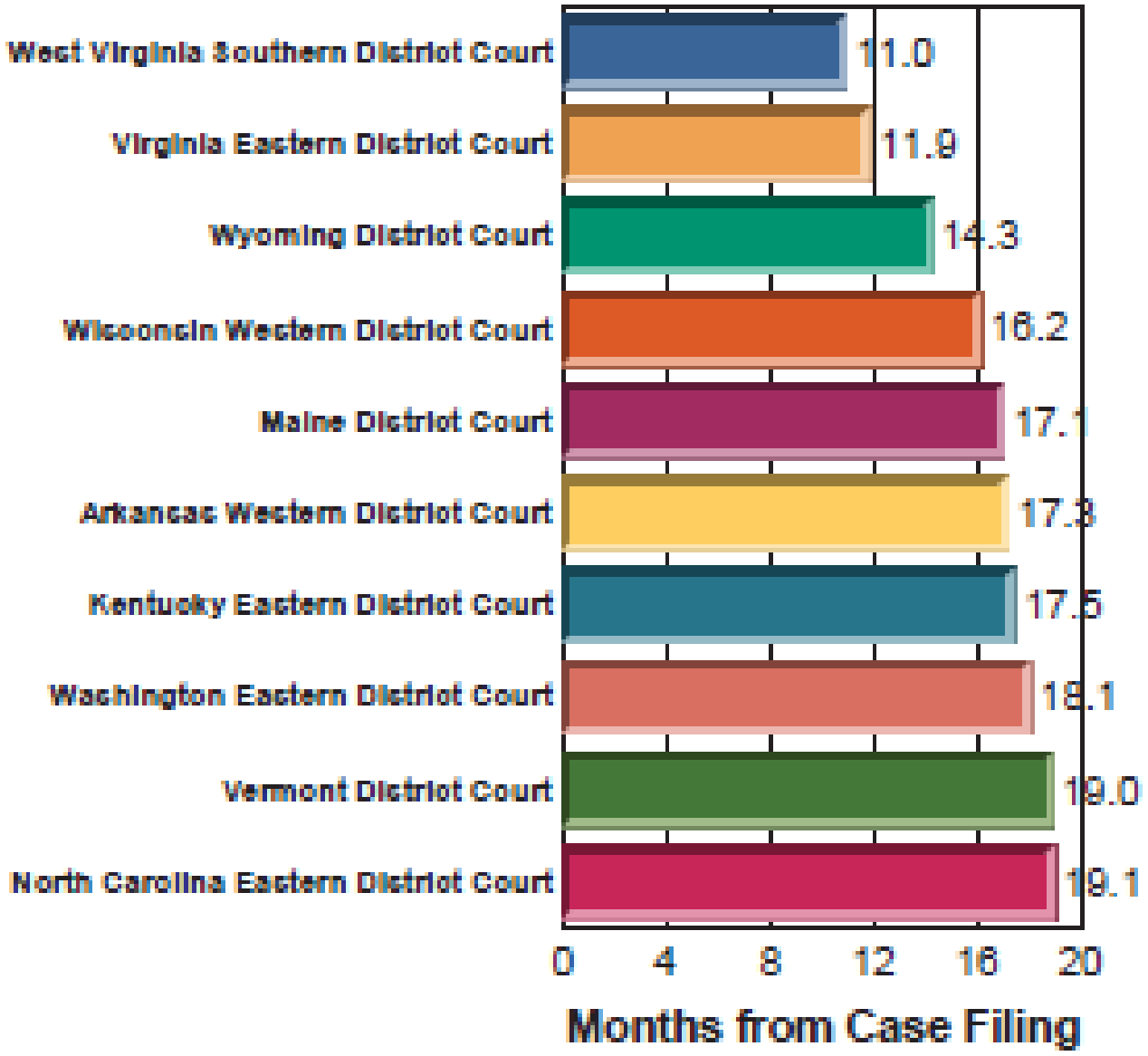
Slowest: 98.4 months (MD LA).

Fastest: 11 months (SD WVa).



LegalMetric Nationwide Time to Trial Report Patent Cases January 1991 to December 2015

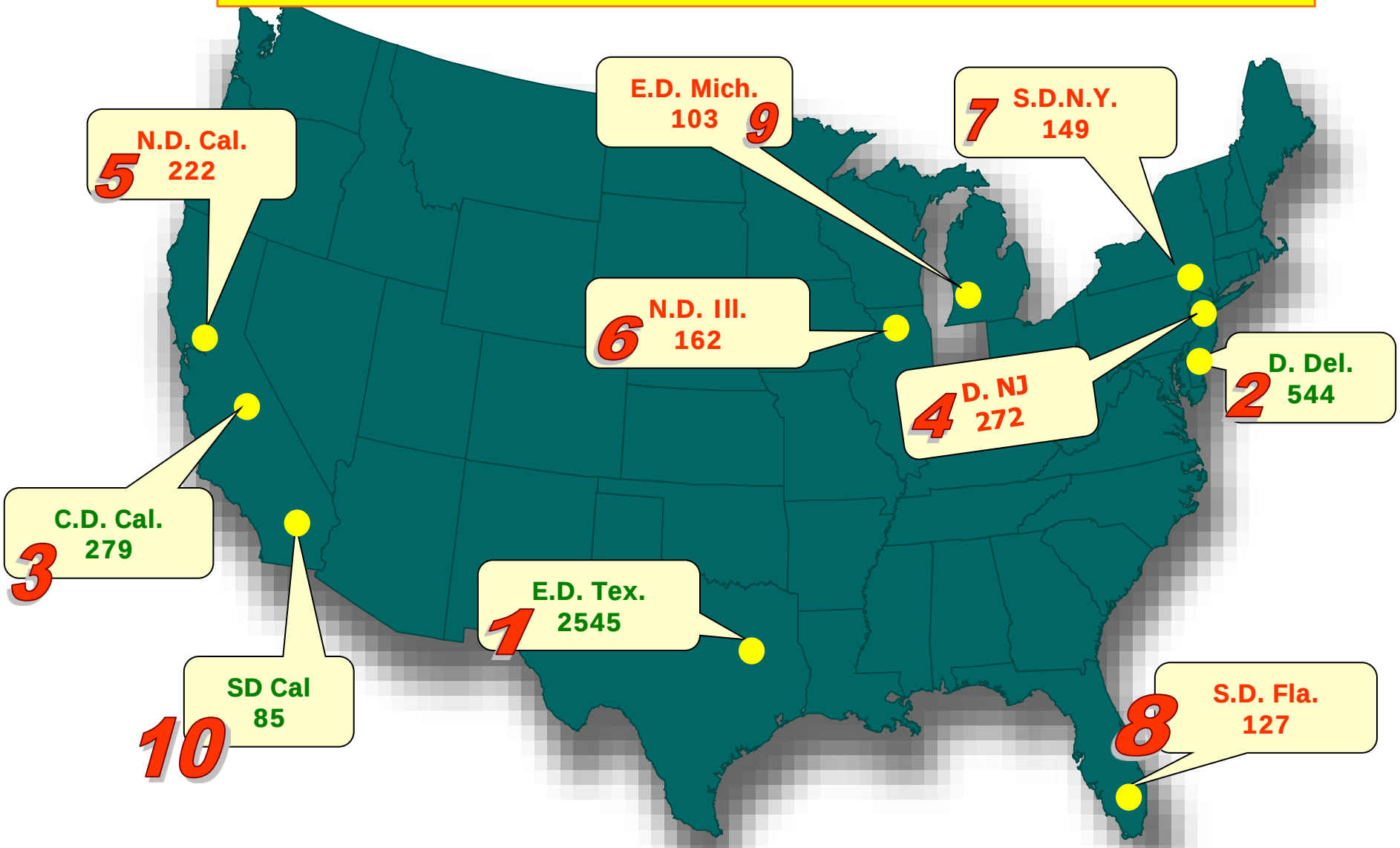
Fastest Time to Trial Districts



LegalMetric Nationwide Time to Trial Report Patent Cases January 1991 to December 2015.

2015 Patent Infringement Litigation Filings

E.D. Tex. went from 33 in 2001 to 2545 in 2015.



These 10 districts represent >2/3 of all patent litigation filings.

Bench and Jury Patent Owner Win Rates in 10 Most Active Patent Infringement Litigation District Courts (By Filings)

District Court	Bench Win Rate	Jury Win Rate
Eastern District of Texas	100%	55.0%
District of Delaware	46.1%	58.3%
Central District of California	60.0%	40.0%
District of New Jersey	67.7%	100.0%
Northern District of California	83.8%	44.4%
Northern District of Illinois	66.7%	71.4%
Southern District of New York	33.3%	100%
Southern District of Florida	60.0%	66.7%
Northern District of Texas	N/A	100%
Southern District of California	100%	62.5%

LegalMetric District Reports, January 2010 – Aug. 2015.

Figure 21. Most active district court judges: 1995–2014

Rank	Judge last name	Judge first name	District	Identified decisions	Identified trial decisions	Median damages award	Overall success rate	Median time-to-trial (in years)
1	Robinson	Sue	Delaware	72	42	$21,900,503	38%	1.9
2	Sleet	Gregory	Delaware	33	29	$21,624,925	58%	1.9
3	Davis	Leonard	Texas Eastern	30	22	$8,895,467	63%	2.4
4	Stark	Leonard	Delaware	23	11	$16,001,822	48%	2.1
5	Clark	Ron	Texas Eastern	15	13	$6,950,660	73%	1.8
6	Huff	Marilyn	California Southern	12	7	$42,854,609	42%	2.1
7	Young	William	Massachusetts	12	4	$236,890	17%	1.7
8	Darrah	John	Illinois Northern	11	3	$10,301,716	9%	3.5
9	Alsup	William	California Northern	11	4	$19,394,779	9%	1.6
10	Gilstrap	Rodney	Texas Eastern	11	9	$8,241,792	64%	3.0

2015 Patent Litigation Study PWC

Median Patent Infringement Litigation Costs

All Patent Infringement Lit.	2015
< $ 1 mill at risk	$600,000
$1 to $10 mill at risk	$2,000,000
$10 to $25 mill at risk	$3,100,000
> $25 mill at risk	$5,000,000

ANDA Lit.	2015
< $ 1 mill at risk	$650,000
$1 to $10 mill at risk	$1,500,000
$10 to $25 mill at risk	$3,000,000
> $25 mill at risk	$5,000,000

Source: AIPLA Report of the Economic Survey 2015

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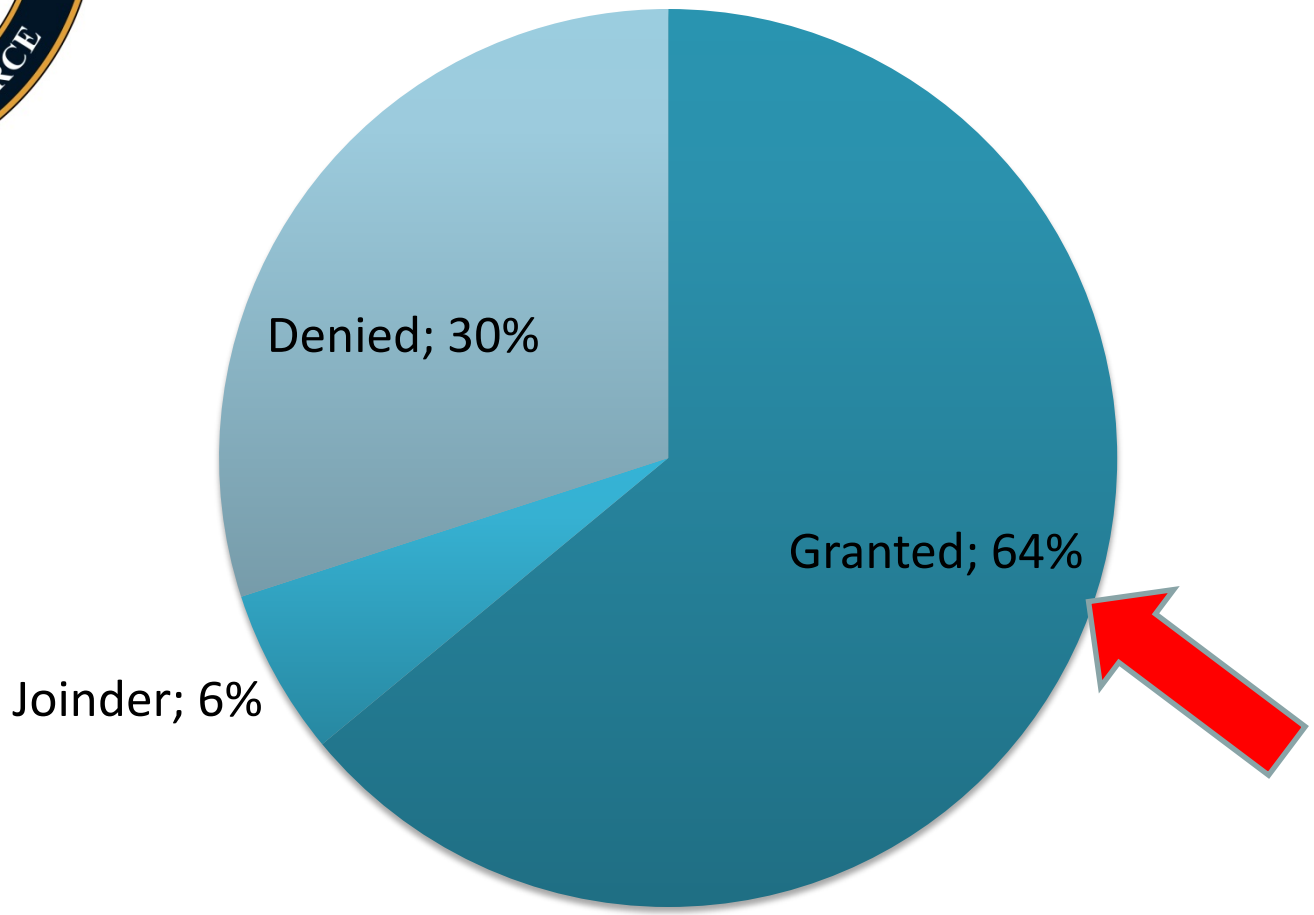
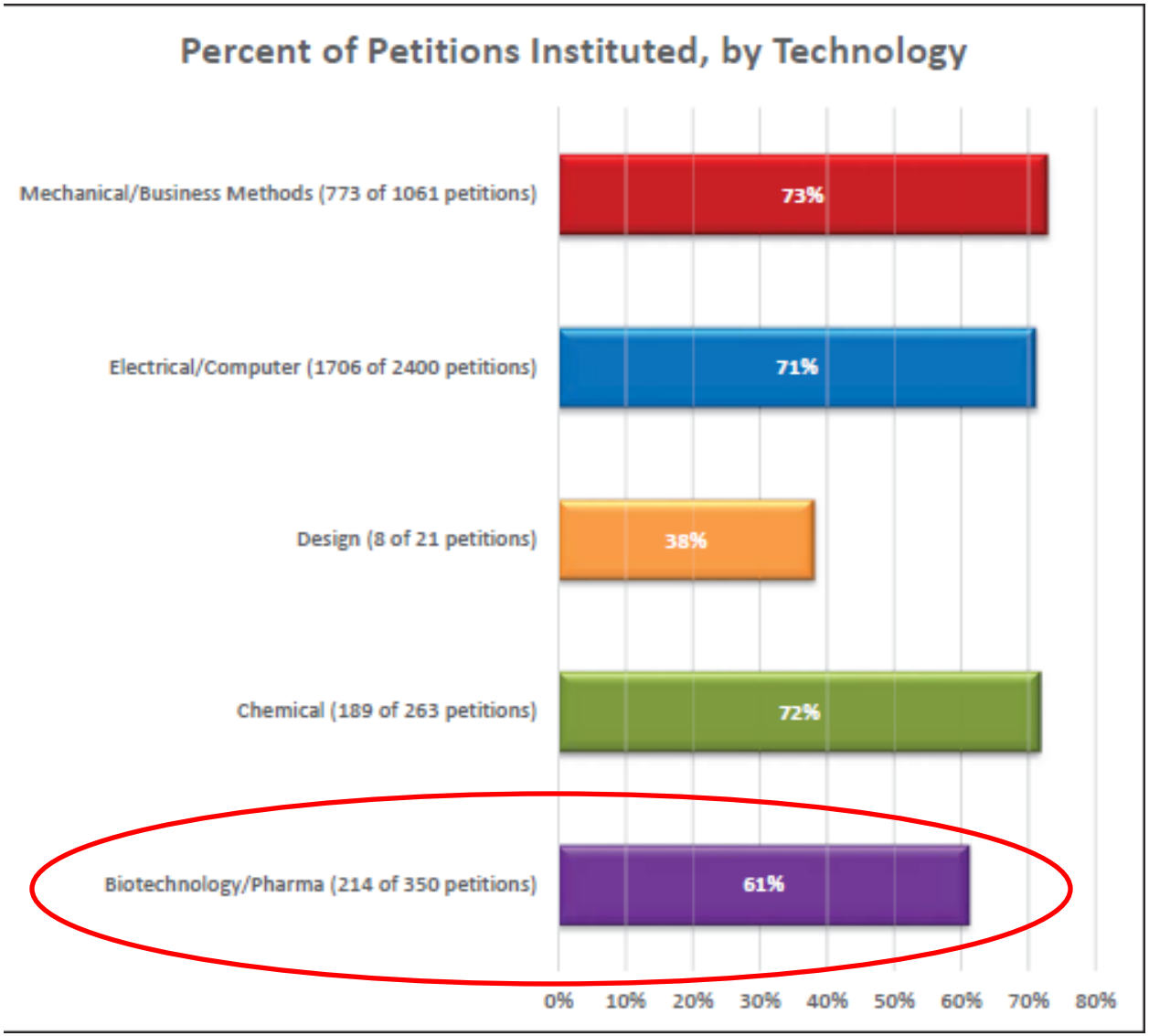
ENTER THE PTAB
Petition Grant Rate is High!



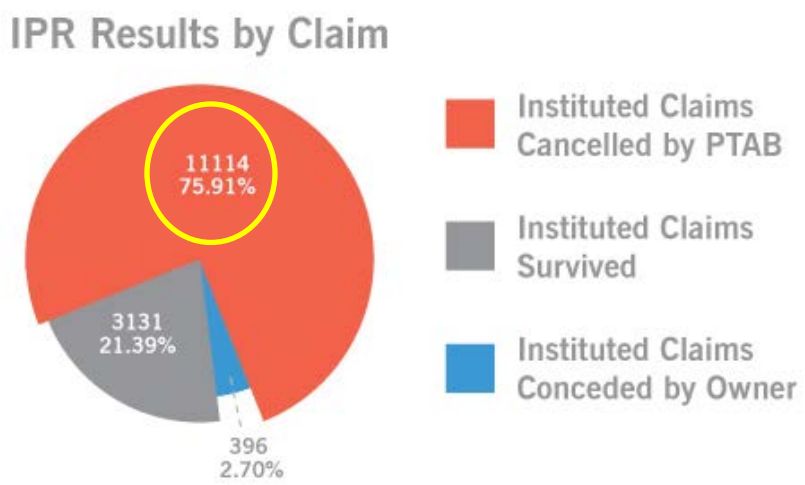
FY2014-FY2016 to Sept. 30, 2016. Source: https://www.uspto.gov/sites/default/files/documents/aia_statistics_september2016A.pdf

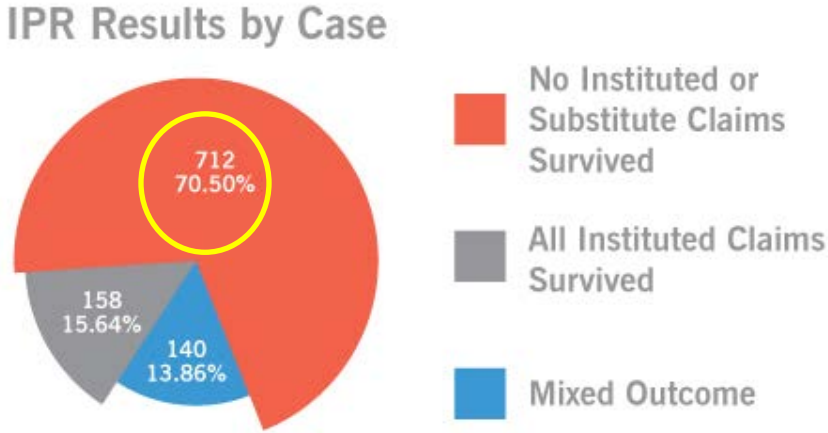
Petition Grant Rates by Technology

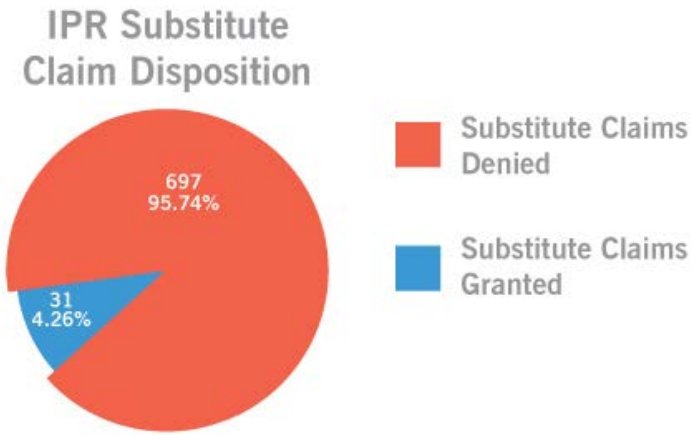


As of Sept. 30, 2016. Source: https://www.uspto.gov/sites/default/files/documents/aia_statistics_september2016A.pdf

AND IF INSTITUTED, CLAIM CANCELLATION RATE IS HIGH

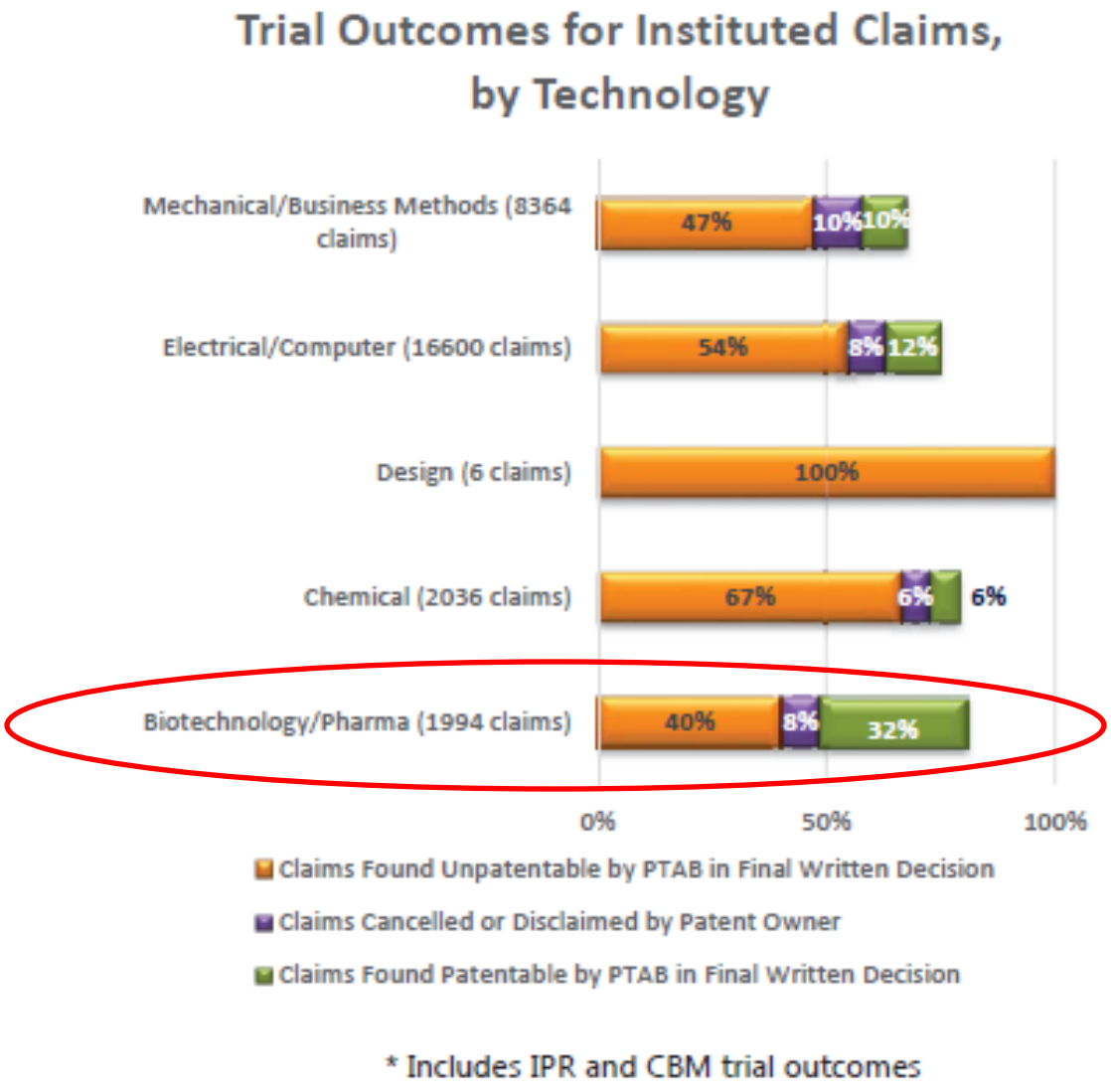






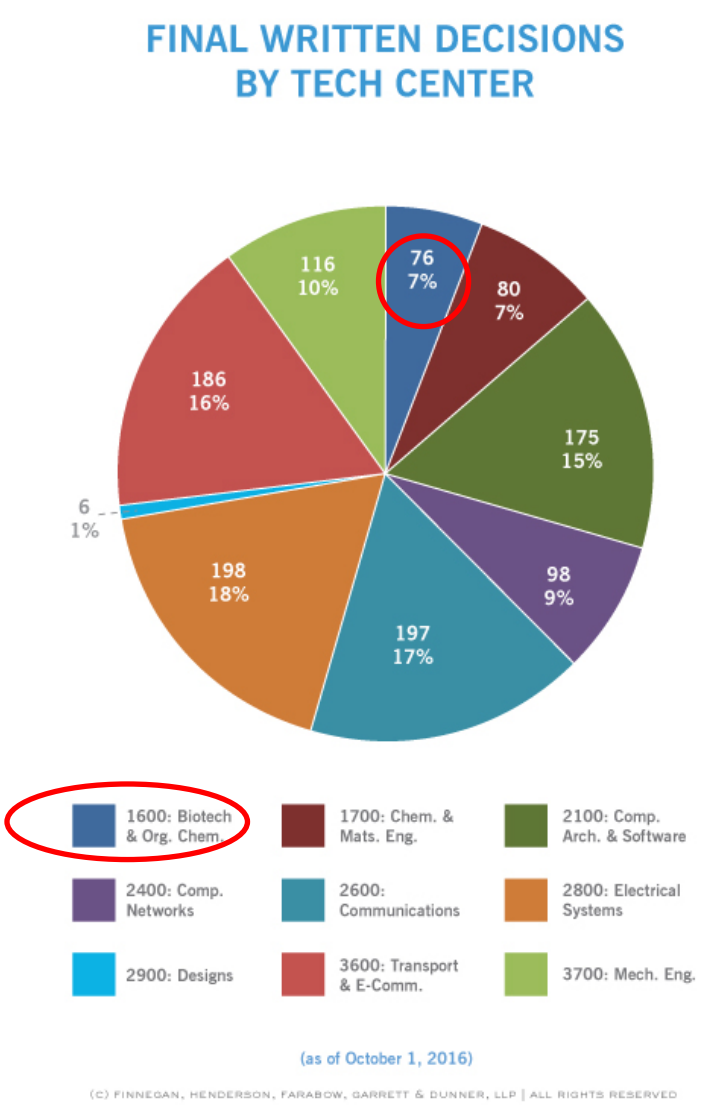
"Mixed outcome": at least one instituted claims survived and at least one instituted claim was canceled.
As of Oct. 1, 2016. *Source*: Finnegan research, http://www.aiablog.com/claim-and-case-disposition/

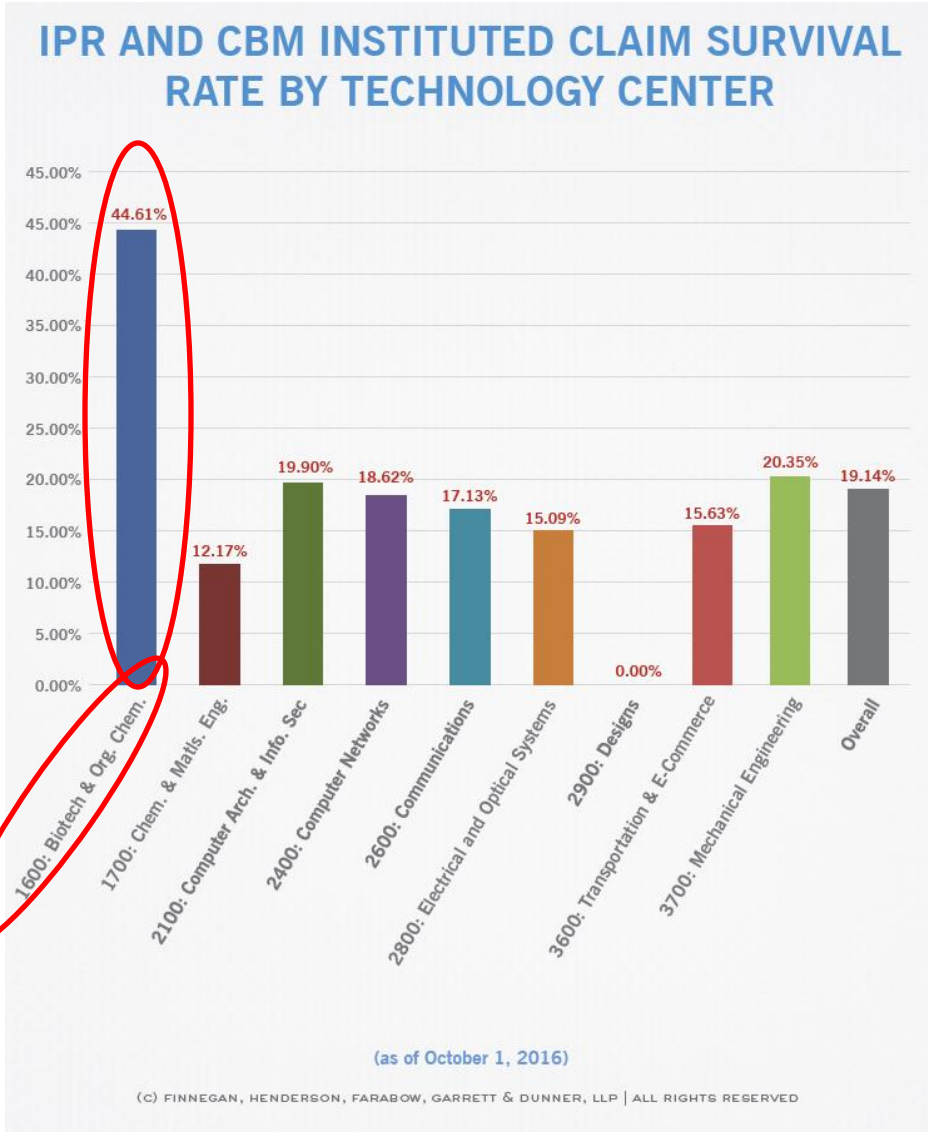
BIOPHARM CLAIM SURVIVAL RATE A LITTLE BETTER THAN OVERALL AVERAGE



As of Sept. 30, 2016. Source: https://www.uspto.gov/sites/default/files/documents/aia_statistics_september2016A.pdf

INSTITUTION RATE/SURVIVAL RATE BY TECHNOLOGY





As of Oct. 1, 2016
http://www.aiablog.com/technology-breakdown/

Notable IPR Cases with Corresponding ANDA Litigation

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	FWD: All instituted claims survive
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 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)	FWD: All instituted claims survived in '00654 and 00656; all instituted claims unpatentable in 00652
IPR2014-01126	Actavis	Research Corp. Tech.	Vimpat® (lacosamide)	N (threshold not met)	
IPR2014-00559	Torrent Pharms.	Merck Canada	Daliresp® (roflumilast)	N (threshold not met)	

Questions?

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- Experience in all aspects of U.S. patent law including prosecution, post-grant proceedings, and litigation.
- Practice focuses on strategic client counseling, portfolio management, and patent prosecution in the pharmaceutical and biotechnological arts.
- Frequent lecturer on various aspects of patent law issues affecting the chemical, pharmaceutical, and biotech industries.

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