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Challenging and Defending Patents in the Country's Largest Venue – the PTAB

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MIND + MUSCLE

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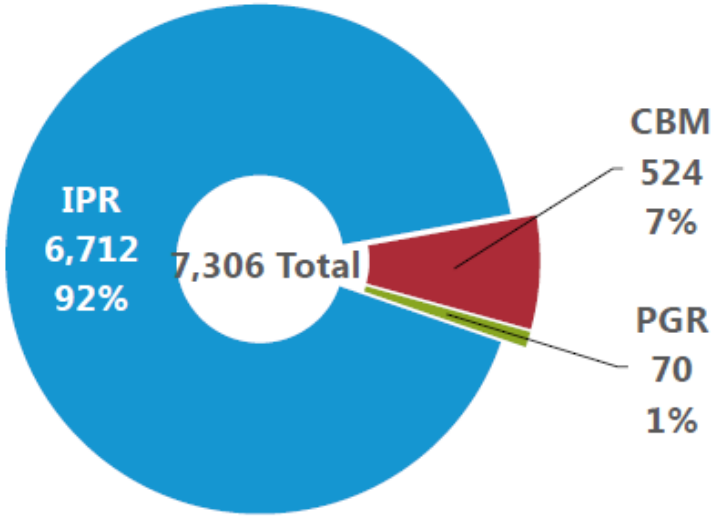
Petitions by Trial Type
(All Time: 9/16/12 to 7/31/17)



Trial types include Inter Partes Review (IPR), Post Grant Review (PGR), and Covered Business Method (CBM).

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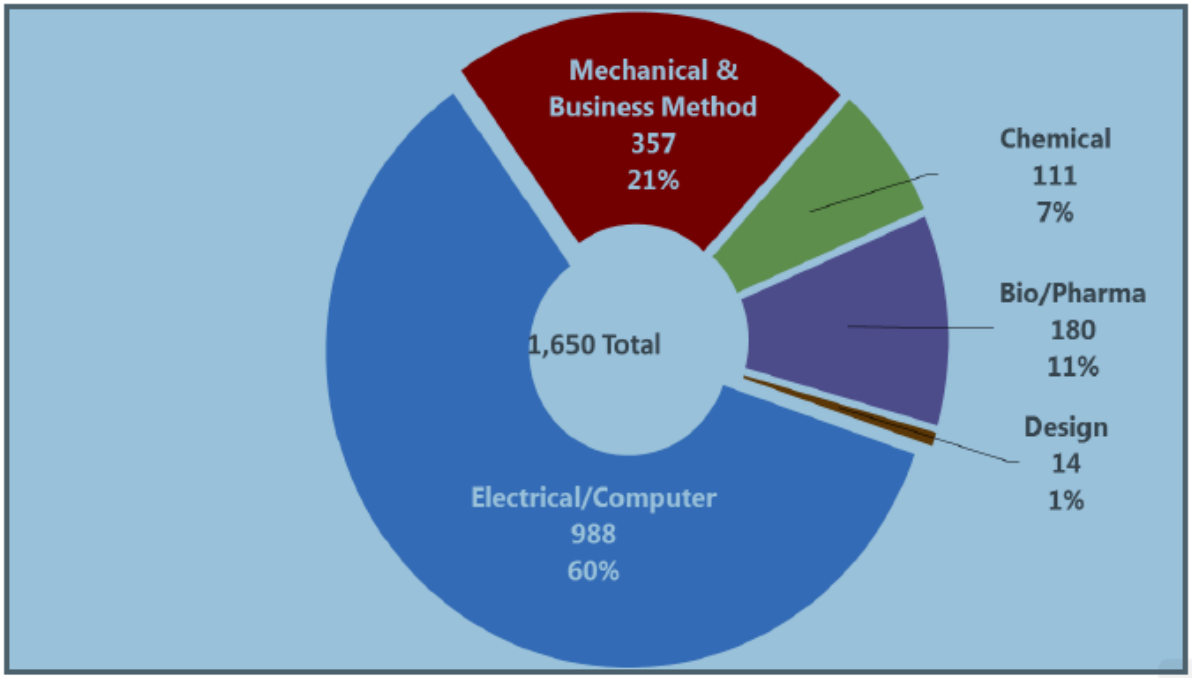
Petitions Filed by Technology in FY17

(FY17 to date: 10/1/16 to 7/31/17)



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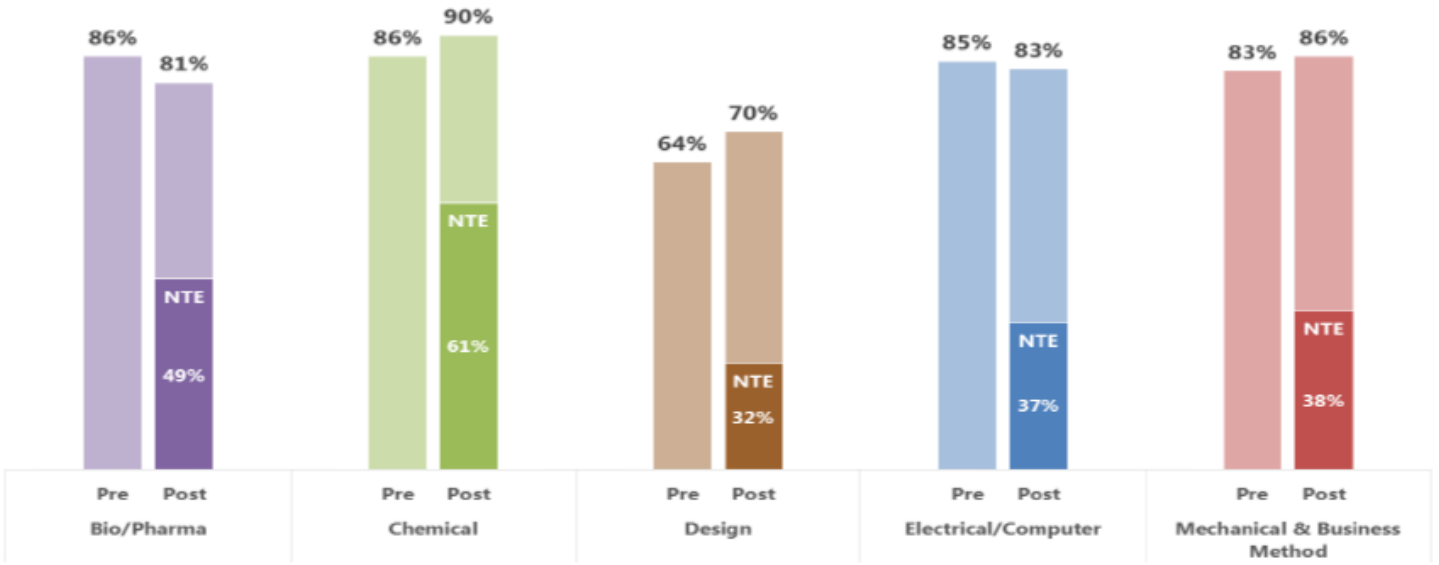
Preliminary Response Filing Rates

Pre- and Post-Rule To Allow New Testimonial Evidence (NTE) (All Time: 9/16/12 to 7/31/17)



The rule to allow new testimonial evidence was effective May 2, 2016.

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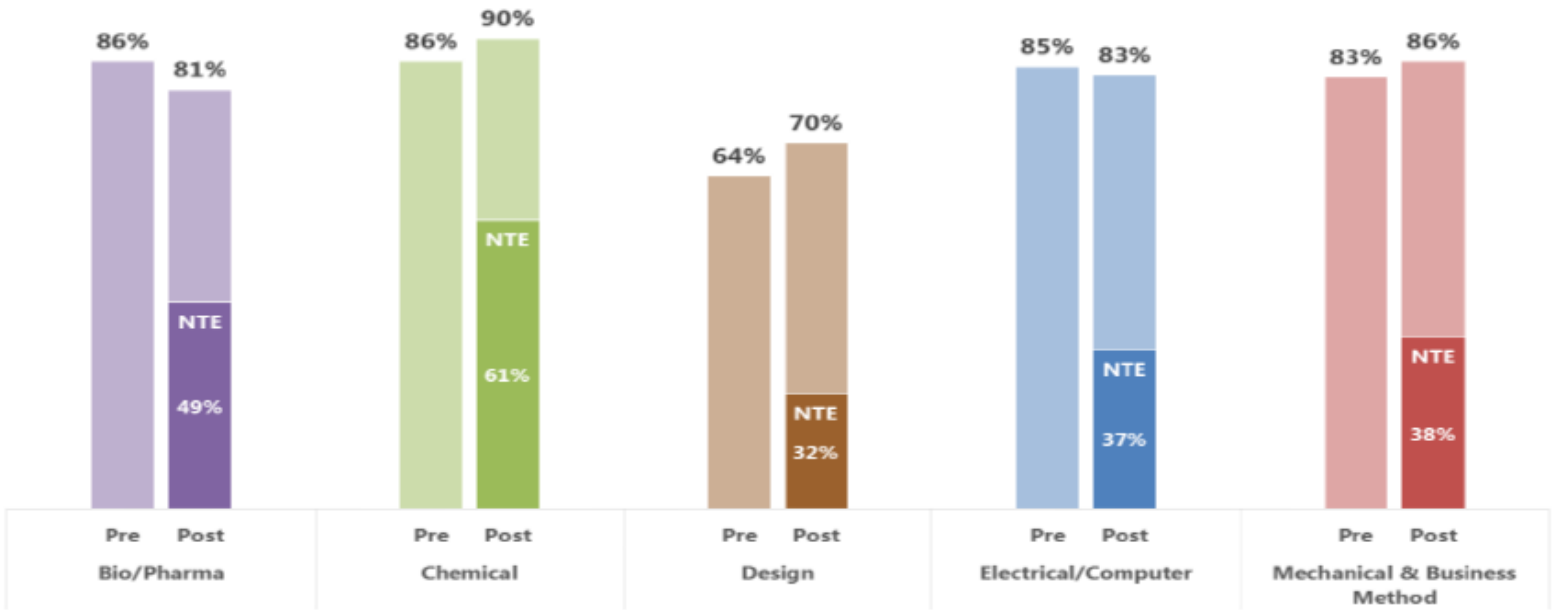

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Oil States Energy Services, LLC v. Greene's Energy Group, LLC

- **Issue**: Whether *inter partes* review, an adversarial process used by the Patent and Trademark Office (PTO) to analyze the validity of existing patents, violates the Constitution by extinguishing **private property rights** through a **non-Article III forum** without a jury.

- 32 amicus briefs

Evidentiary Burden in IPRs

Novartis AG v. Noven Pharm. 2016-1678, -1679 (Fed. Cir. April 4, 2017)

- **CAFC affirmed PTAB's invalidation** of claims to Novartis's "rivastigmine" composition for treating Alzheimer's disease.
- Novartis argued **"fundamental legal error"** because the PTAB reached **different conclusions** from the prior litigation.
- Citing *Cuozzo,* CAFC disagreed because the **PTAB record differed** from that in the prior litigation. **And** Novartis's argument fails as a matter of law due to the **different burdens** in district court litigation versus IPR proceedings.

Discretion to Institute Trial

Apotex Inc. v. OSI Pharmaceuticals, IPR 2016-01284, Paper 8 (Jan. 9, 2017)

- **"Schnur was explicitly considered by the Office during examination**"
- "Thus, balancing the competing interests involved and taking full account of the facts and equities involved in this particular matter, **we exercise our discretion, under 35 U.S.C. § 325(d), to deny the Petition** and decline to institute inter partes review based on anticipation by Schnur."

- *Compare:* "**We are not persuaded … that a citation to prior art in an IDS**, without substantive discussion of the reference by the Examiner, **is sufficient** reason to exercise our discretion under 35 U.S.C. § 325(d)…. IPR2017-00249.

GENERAL PLASTIC v. CANON IPR2016-01357 (9/6/17)

- Trial denied on 1st set of IPRs; follow-on IPRs denied under 35 U.S.C. **§ 314(a)** and 37 C.F.R. **§ 42.108(a).**
- **Expanded panel** denied rehearing.
- **Factors:**
  1. previous petition on same patent
  2. knew or should have known of the prior art
  3. already received POPR or Decision on Institution
  4. time between learning of art in 2nd petition and filing of the 2nd petition
  5. explanation for the time between petitions directed to the same claims
  6. the finite resources of the Board
  7. the requirement to issue a FWD in $\leq$ 1 year

FACEBOOK v. SOUND VIEW INNOV.
IPR2017-00998 and IPR2017-01002 (9/5/17)

- "With regard to the construction of **means-plus-function** limitations ..., the **same construction applies** under both the broadest reasonable interpretation and district court-type standards."
- "Perhaps even more troubling, **Petitioner chose not to inform us** in its Petitions that it simultaneously was arguing a different treatment of the terms of claim 19 before the district court."
- "[I]n view of the district court's determination that the sole challenged claim is **indefinite** and Petitioner's failure to inform us of its **seemingly inconsistent** claim construction positions or to provide us with means-plus-function constructions as required by our Rules, we deny [trial under **§ 314(a)** and rule **§ 42.108(a)**]."
- "At the very least, Petitioner's failure to inform us of its differing claim construction arguments before the district court raises the **specter of lack of candor**."

Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co., (Fed. Cir. Aug. 22, 2017)

- Expanded PTAB panel held "§ 315(c) encompasses both **party joinder and issue joinder**...."
- Dyk + Wallach concurrence:
  - "The issue … is whether the time bar provision allows a time-barred petitioner to add new issues, rather than simply belatedly joining a proceeding.... **Section 315(c) does not explicitly allow this practice**."
  - "[W]e question … the practice of **expanding panels** where the PTO is dissatisfied with a panel's earlier decision…."

Rituxan

- Multiple patents & multiple challenges per patent
  - Boehringer
  - Celltrion
  - Pfizer
- May obtain different results, even based on same art

- Motions for joinder
  - May create risks for second petitioner
  - May delay ultimate resolution

Amendments

In Re Aqua Products, 2015-1177; appeal from IPR2013-00159; argued *en banc* Dec. 9, 2016

- (a) May the PTO require the patent owner to bear the burden of persuasion, or a burden of production, regarding patentability of the amended claims as a condition of allowing them? **Which burdens are permitted** under 35 U.S.C. § 316(e)?

- (b) When the petitioner does not challenge the patentability of a proposed amended claim, or the Board thinks the challenge is inadequate, **may the Board sua sponte raise patentability challenges** to such a claim? If so, where would the burden of persuasion, or a burden of production, lie?

Objective Indicia

Novartis AG v. Torrent Pharm. 2016-1352 (Fed. Cir., April 12, 2017)

- PTAB found obviousness. Novartis argued that long-felt need, industry praise, and commercial success "due to Gilenya being the **first commercially available** solid oral treatment for multiple sclerosis."
- PTAB and CAFC rejected Novartis' arguments: "The fact that Gilenya was the first to receive FDA approval for commercial marketing does not overcome the fact that solid multiple sclerosis compositions were **already known**."

Sovereign Immunity

- *Covidien LP v. Univ. Florida Research Foundation, Inc.* IPRs 2016-01274

  "On the whole, considering the nature of *inter partes* review and civil litigation, we conclude that the considerable resemblance between the two is sufficient to implicate the **immunity** afforded to the States by the **Eleventh Amendment**."

- *Neochord, Inc. v. University of Maryland, Baltimore*
- *Reactive Surfaces v. Toyota* — dismissed Univ. Minn. but not Toyota
- *Mylan & Teva v Allergan* – Restasis® IPRs

  Allergan: "Under the terms of the agreement, the Tribe will receive **$13.75 million** upon execution of the agreement. Additionally, the Tribe will be eligible to receive **$15 million in annual royalties**."

  "The agreement with the Tribe has no impact on the pending abbreviated new drug application (ANDA) patent litigations…."

Standing to Appeal

Phigenix v. ImmunoGen, 2016-1544 (Fed. Cir., Jan. 9, 2017)

- "[A]lthough **Article III standing** is not necessarily a requirement to appear before an administrative agency," **an appellant must nevertheless supply the requisite proof of an injury in fact** when it seeks review of an agency's final action in a federal court

Momenta v. BMS, No. 17-1694, appeal from IPR2015-01537

- BMS: "Momenta's Hypothetical Future Biosimilar Drug Application Does Not Provide An Injury-In-Fact"

Estoppel

35 USC § 315(e)(2):

- On "any ground that the petitioner raised or reasonably could have raised **during that *inter partes* review."**

Shaw Industries Group, Inc. v. Automated Creel Systems, Inc., 817 F.3d 1293, (Fed. Cir. 2016)

- PTAB denied grounds based on the "Payne" reference as redundant.
- CAFC rejected Shaw's estoppel arguments, stating: **"The IPR does not begin until it is instituted…. The plain language of the statute prohibits the application of estoppel under these circumstances."**

Verinata Health (Illumina) v. Ariosa Diagnostics

N.D. Cal. Jan. 19, 2017; Fed. Cir. Mar. 9, 2017

- **IPR trial proceeded over references A + B + C**
- **Court later found estoppel on references A + B ("subset").**
- **No estoppel on grounds D + E which were raised in the petition, but on which trial was not instituted.**
- BIO and PhRMA filed amicus briefs supporting Verinata
- Denying a writ of mandamus, CAFC stated Petitioners have failed to show why they cannot raise their arguments regarding § 315(e)(2) with an appeal from the district court's final judgment….

Biscotti Inc. v. Microsoft

2-13-cv-01015 (TXED May 11, 2017)

- "Th[e] broad reading of *Shaw* and *HP* has prompted **increasing concern in the trial courts**."
- The Court recommends adopting the **narrow view** of *Shaw* and *HP*, consistent with *Douglas Dynamics….* Namely, the Court reads *Shaw* and *HP* to exempt an IPR petitioner from § 315(e)'s estoppel provision **only if the PTAB precludes the petitioner from raising a ground during the IPR proceeding for purely procedural reasons, such as redundancy**.
- See also, *Douglas Dynamics LLC v. Meyer Products LLC,* 2017 WL 1382556v. (WD Wis. April 18, 2017)

Remands

Los Angeles Biomed. v. Eli Lilly & Co. 2016-01518 (Fed. Cir., Feb. 28, 2017)

- "Because the Board's obviousness determination was predicated on an **erroneous claim construction** …, and because the **Board did not make factual findings as to whether there was an apparent reason to combine the prior art references** …. and whether a person of skill in the art would have had a **reasonable expectation of success** from such a combination, we **remand** this case to the Board."

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Thank you!

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