January 11, 2017

Post-Grant for Practitioners: 2016 Year in Review

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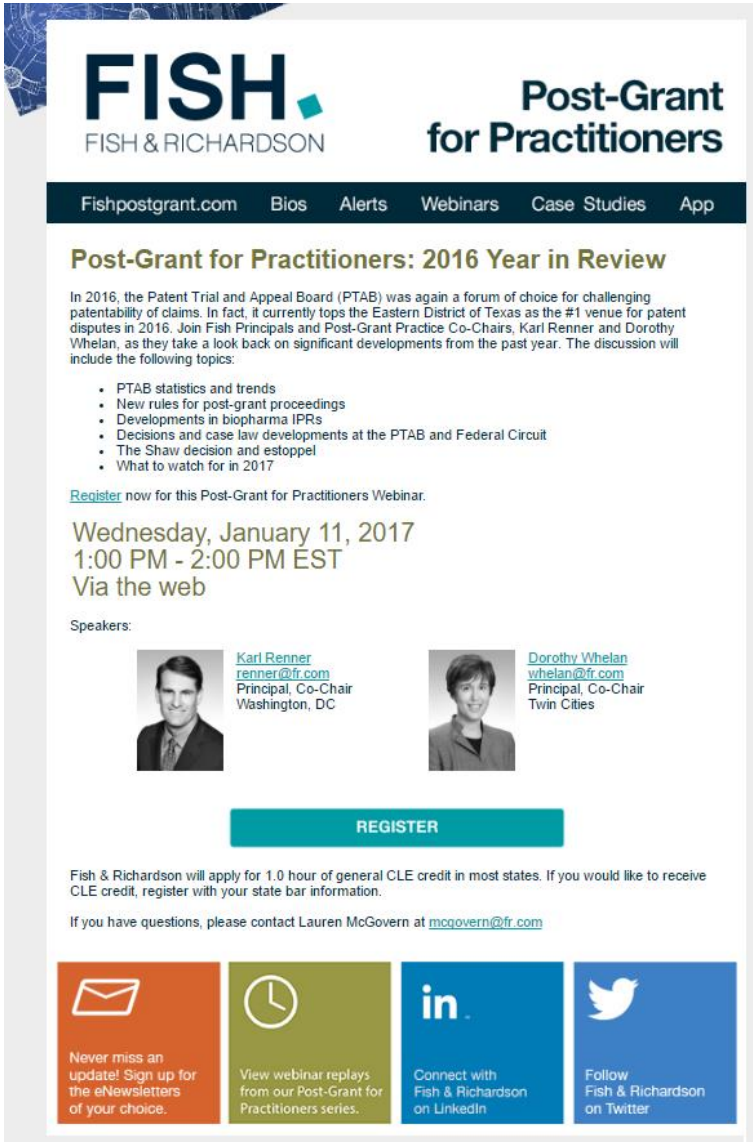
Overview

- How often? … bi-monthly
- When? … 2nd Wednesday
- Topics? …
  - Important decisions
  - Developments
  - Practice tips
- Housekeeping
  - CLE
  - Questions
  - Materials
    - http://fishpostgrant.com/webinars/



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Post-Grant for Practitioners

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Post-Grant for Practitioners: 2016 Year in Review

In 2016, the Patent Trial and Appeal Board (PTAB) was again a forum of choice for challenging patentability of claims. In fact, it currently tops the Eastern District of Texas as the #1 venue for patent disputes in 2016. Join Fish Principals and Post-Grant Practice Co-Chairs, Karl Renner and Dorothy Whelan, as they take a look back on significant developments from the past year. The discussion will include the following topics:

- PTAB statistics and trends
- New rules for post-grant proceedings
- Developments in biopharma IPRs
- Decisions and case law developments at the PTAB and Federal Circuit
- The Shaw decision and estoppel
- What to watch for in 2017

Register now for this Post-Grant for Practitioners Webinar.

Wednesday, January 11, 2017
1:00 PM - 2:00 PM EST
Via the web

Speakers:

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Fish & Richardson will apply for 1.0 hour of general CLE credit in most states. If you would like to receive CLE credit, register with your state bar information.

If you have questions, please contact Lauren McGovern at mcgovern@fr.com

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Agenda

- Statistics
- New Rules for Post-Grant Proceedings
- Developments in Biopharma IPRs
- Decisions and Case Law Developments
- What To Watch For in 2017

USPTO Statistics on Adversarial Post-Grant Proceedings

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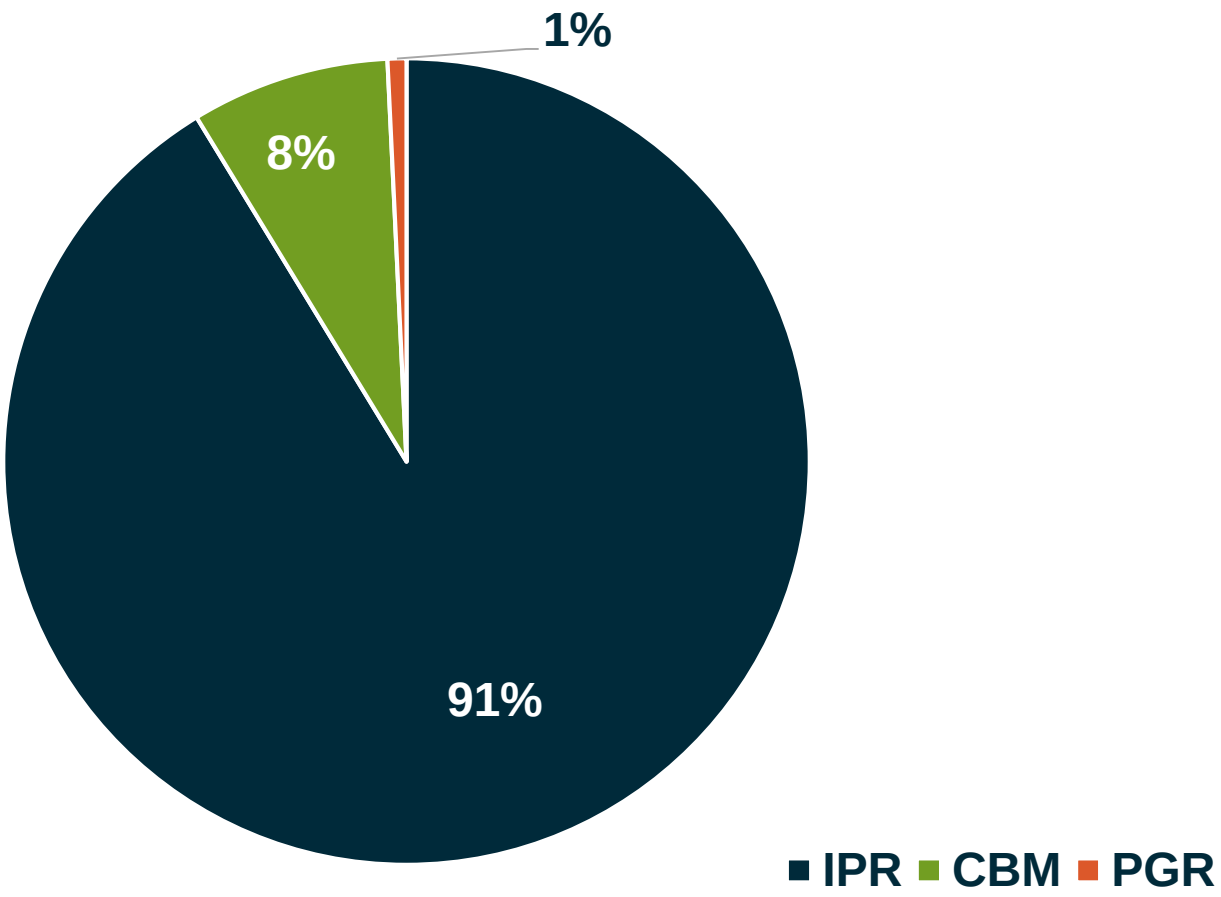
PTAB – Most Active Forum

In 2014 and 2016, the PTAB was the most active forum for US patent validity challenges, and in 2015 the PTAB had a **record** year for filings.

Most active courts by number of cases	2011	2012	2013	2014	2015	2016	2017 YTD
PTAB	**-**	**112**	**792**	**1,677**	**1,800**	**1,758**	**52**
TXED	580	1,252	1,498	1,428	2,548	1,678	17
DED	486	1,001	1,335	942	544	458	10
CACD	329	506	411	320	277	287	2

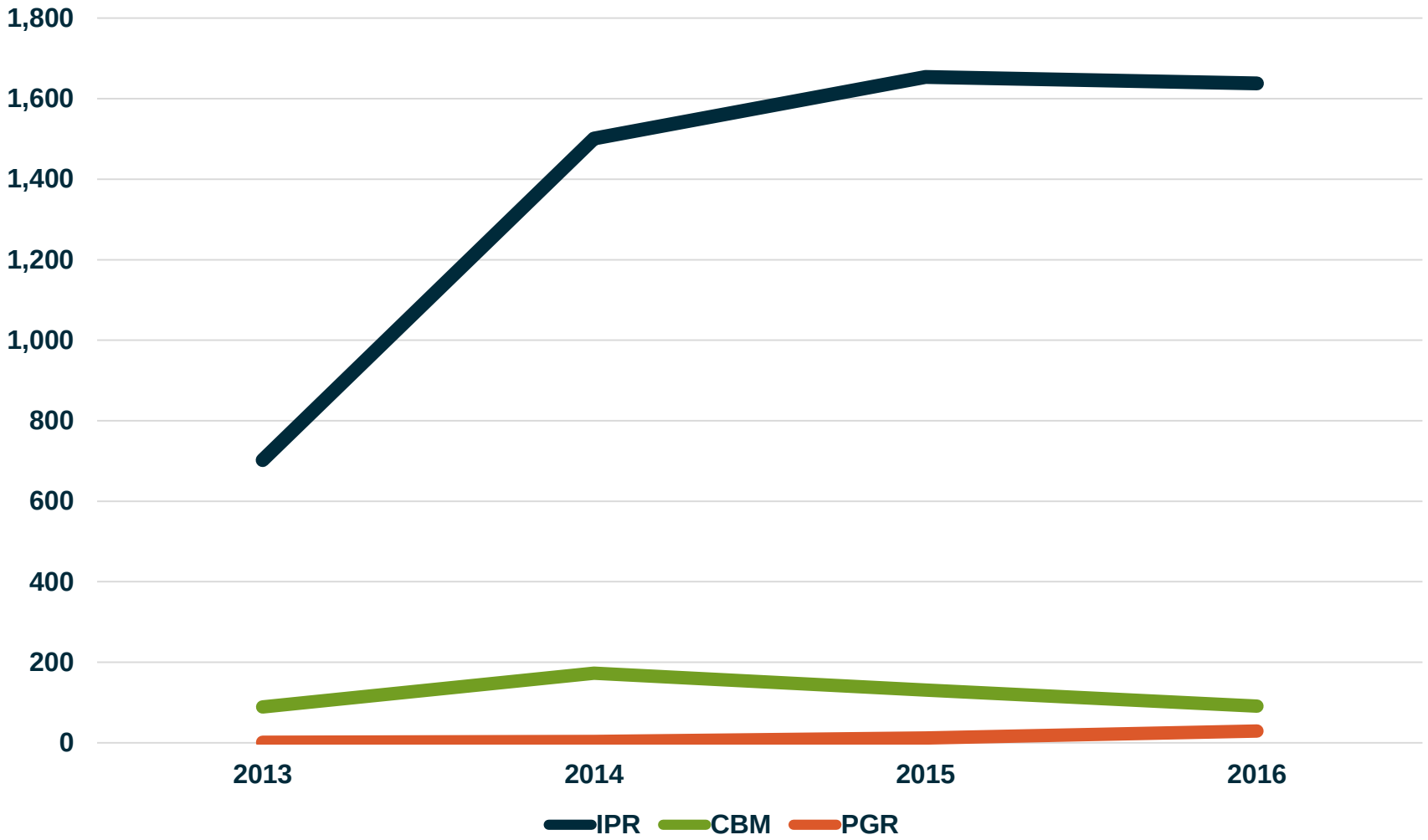
AIA Petitions Have Exceeded Expectations . .

6,095 AIA Petitions Filed Since 2013



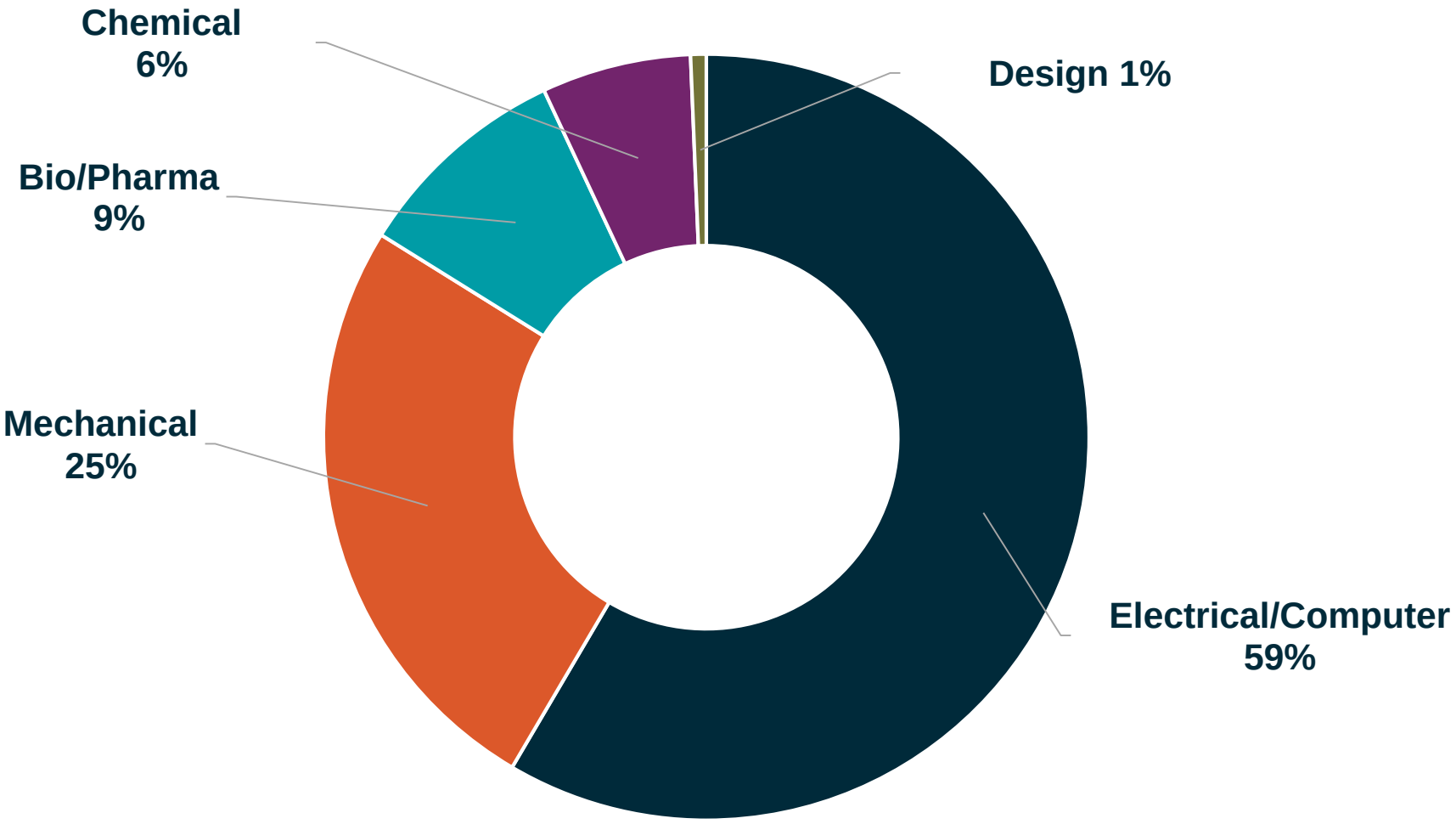
Source: LexMachina, data current as of 1/9/2017

. . . And They Continue to be Favored . . .



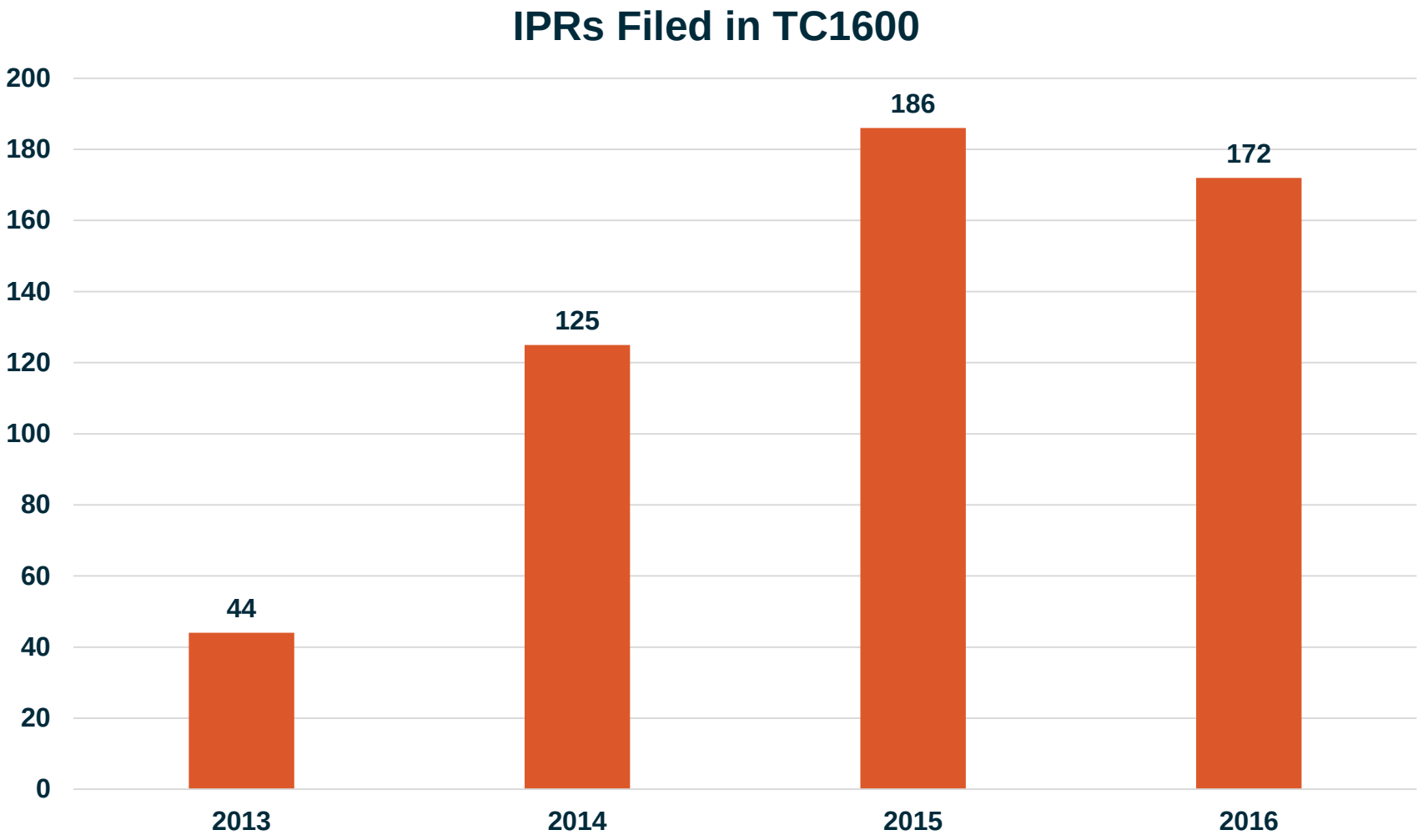
Source: LexMachina, data current as of 1/8/2017

Technology Breakdown by USPTO Tech Center (2013-Present)



Source: LexMachina, data current as of 1/8/2017

BioPharma IPR Filings



Source: LexMachina, data current as of 1/8/2017

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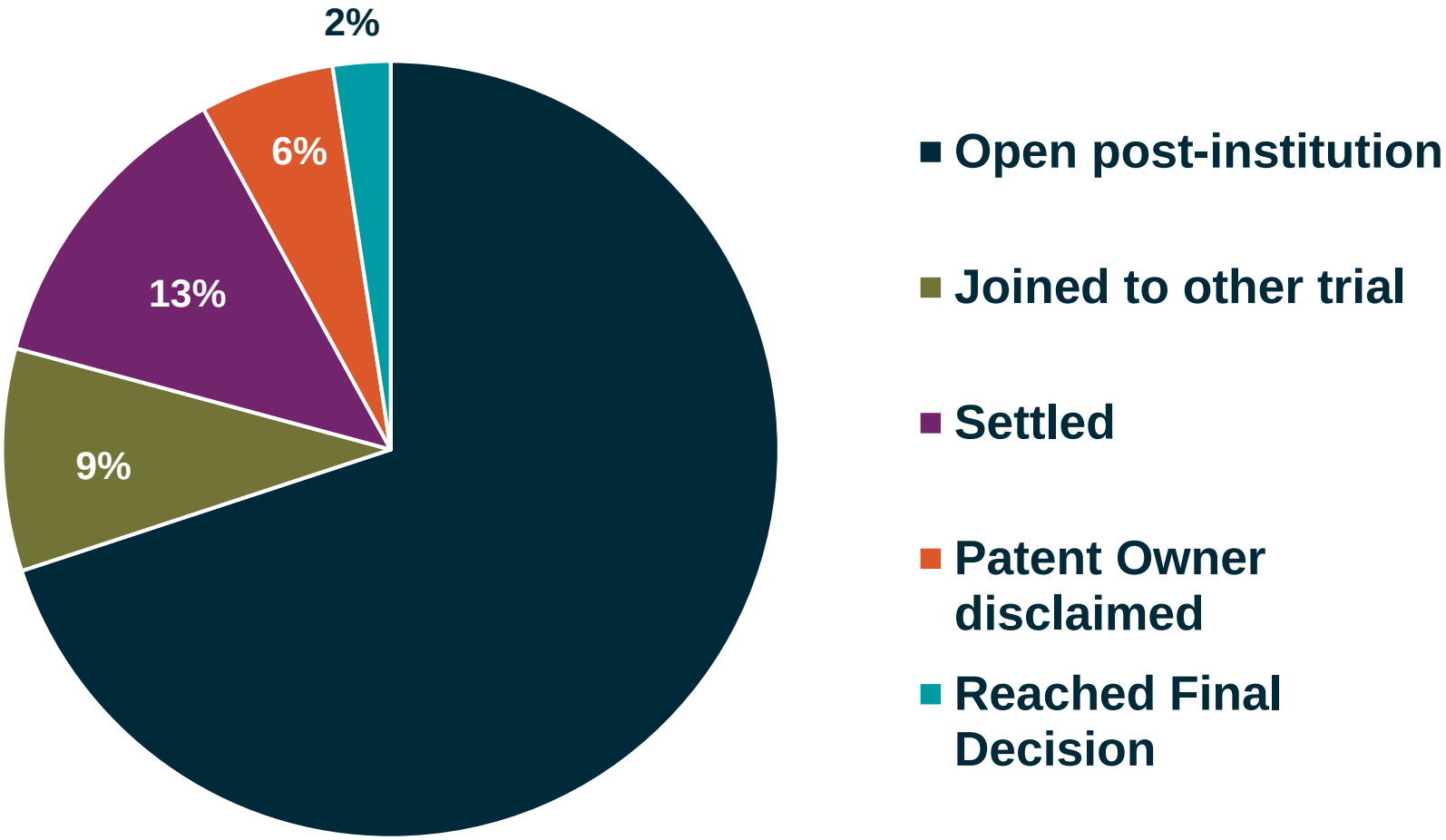
2016 By the Numbers – IPR Petitions

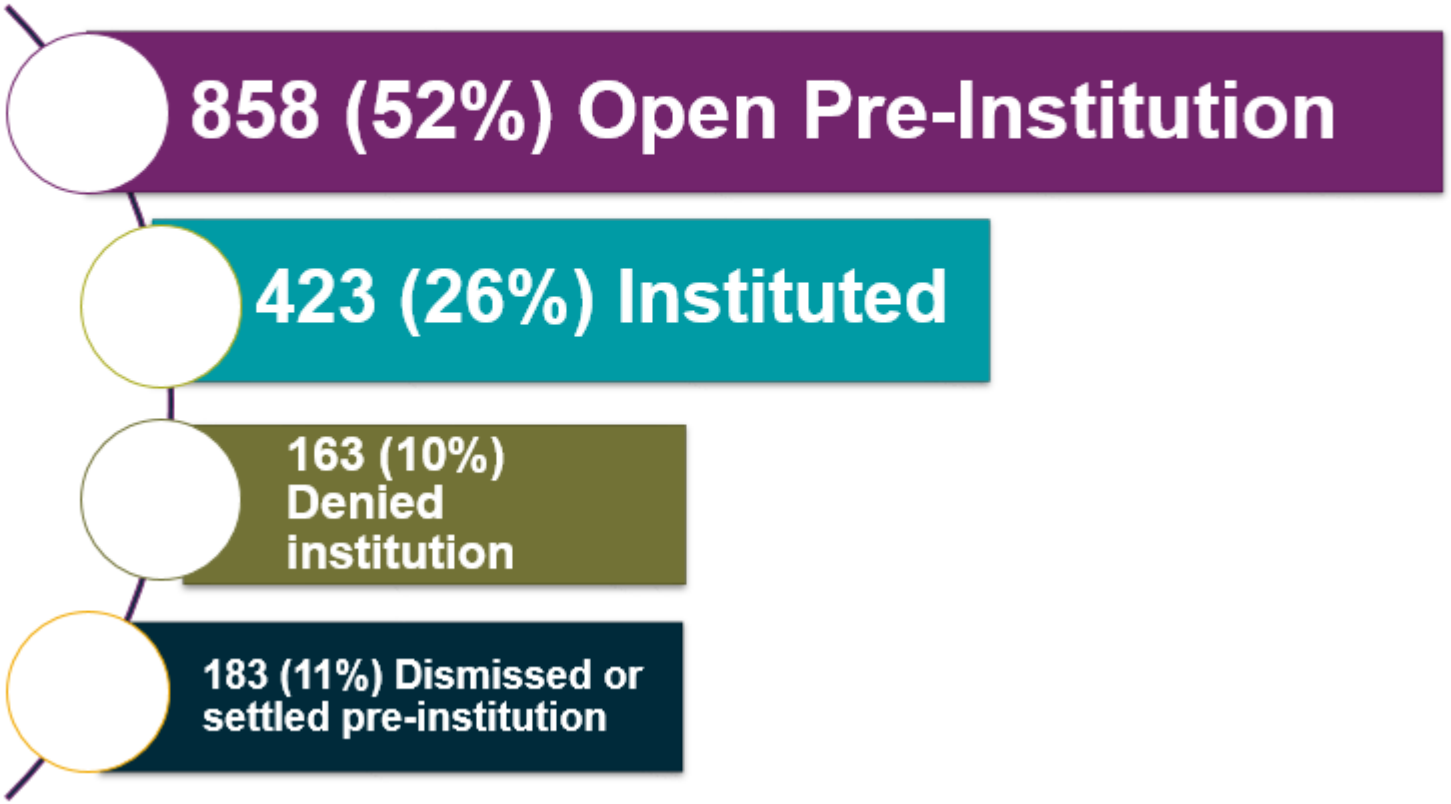
878 IPR petitions were instituted in 2016



Source: LexMachina, petitions instituted between 1/1/2016 and 12/31/2016
<.01% (1) case dismissed post-institution

2016 By the Numbers

- **1,638 petitions filed 1/1/2016-12/31/2016**

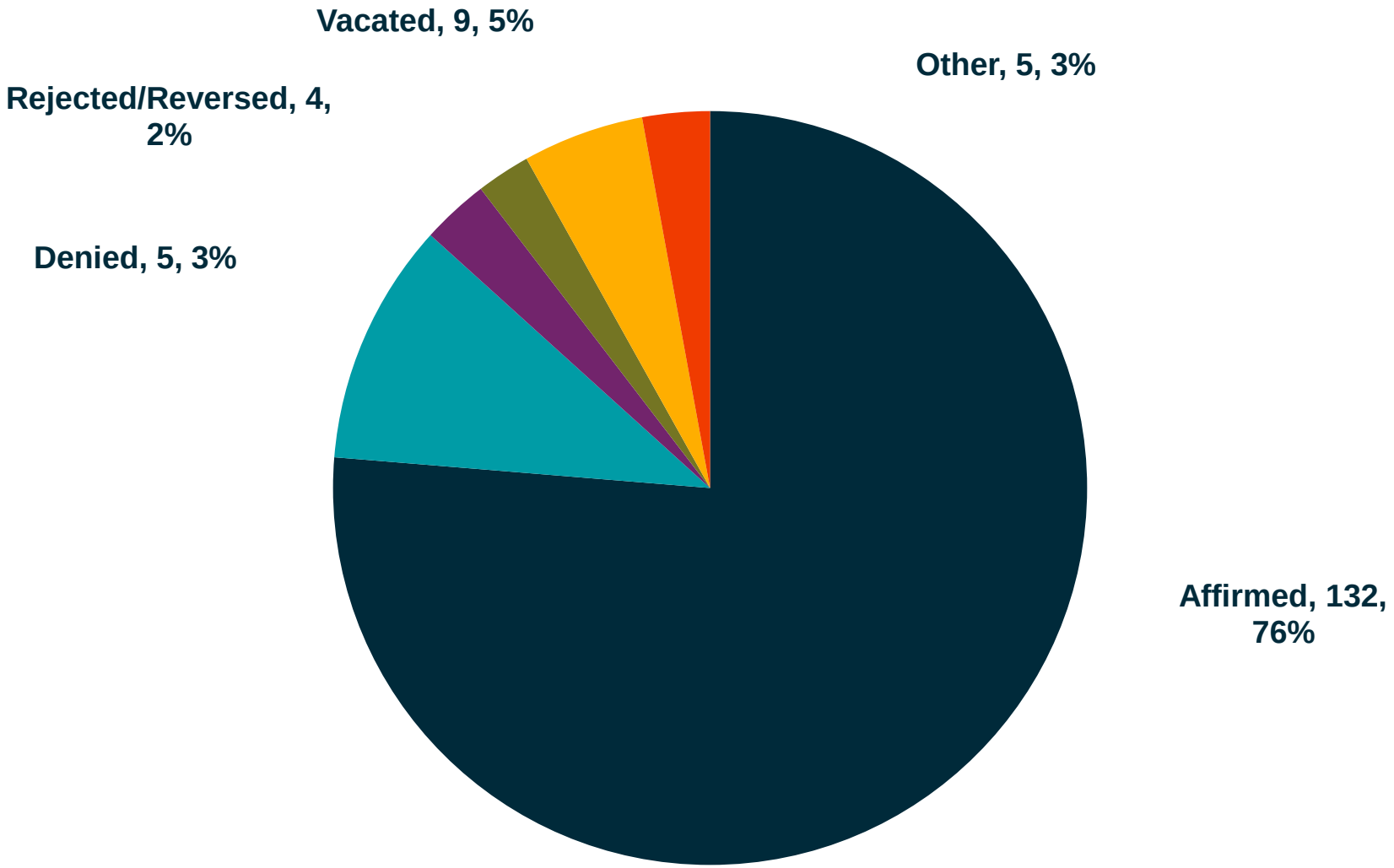


2016 By the Numbers – IPR Petitions

565 IPR petitions reached Final Written Decision in 2016

Source: LexMachina, petitions with Final Written Decision between 1/1/2016 and 12/31/2016

IPR Federal Circuit Decisions



Source: DocketNavigator, as of 1/10/2017

New Rules for Post-Grant Proceedings

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PTAB's New Rules

- "Quick Fixes" (effective May 19, 2015)
  - Increased size for some briefing;
  - Objections are filed, not just served
- "Second Round" of New Rules (effective May 2, 2016)
  - Testimonial evidence allowed with preliminary responses
  - Word limits instead of page limits
- Revised Trial Practice Guide (TBD)

"*Second Round*" of New Rules (effective May 2, 2016)

- Testimonial Evidence with a Preliminary Response
- Revised Document Size Limits (Word Count)
- PTAB Has Sanction Authority & Procedure
- Claim Construction for Expiring Patents
- No Change to Claim Amendments

Developments in Biopharma IPRs

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IPR Activity Related to Biologics

- Avastin (bevacizumab)
  - Pending
- Herceptin (trastuzumab)
  - Pending
- Neulasta (pegfilgrastim)
  - Pending
- Rituxan (rituximab)
  - Pending
- Humira (adalimumab)
  - Trial instituted on RA dosing patents, no FWD
- Tysabri (natalizumab)
  - Denied institution
- Orencia (abatacept)
  - FWD: challenged claims not unpatentable

Decisions and Case Law Developments

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APA – Parties Must Be Afforded an Opportunity to Respond

SAS Institute, Inc. v. ComplementSoft, LLC, Nos. 2015-1346 & 1347, slip op. (Fed. Cir. June 10, 2016)

- The Federal Circuit vacated on procedural grounds the PTAB's final written decision confirming the patentability of one claim.
- Term X was construed in the ID, and it was not challenged by the patent owner in its response.
- Term X was otherwise construed by the Board in the FWD, however, in a manner that significantly differed from the institution decision, to the demise of the petitioner's grounds.
- As a consequence of this process, Petitioner was not afforded notice that a different construction was even being considered, and thus could not have imagined the need to address the new construction in its reply.

APA – Parties Must Be Afforded an Opportunity to Respond

SAS Institute, Inc. v. ComplementSoft, LLC, Nos. 2015-1346 & 1347, slip op. (Fed. Cir. June 10, 2016)

- The Federal Circuit held that the PTAB's actions deprived petitioner of its APA right to respond to an agency's change in legal theory:

  "It is difficult to imagine either party anticipating that already-interpreted terms were actually moving targets, and it is thus unreasonable to expect that they would have briefed or argued, in the alternative, hypothetical constructions not asserted by their opponent." slip op. at 17-18.

- On remand, the Federal Circuit instructed the PTAB to re-evaluate the patentability of the claim after hearing from both parties.

APA Right to Respond – Parties Must Take Action

***Genzyme Therapeutic Products Ltd. v. Biomarin Pharmaceutical Inc.,* Nos. 2015-1720 & 1721, slip op. (Fed. Cir. June 14, 2016)**

- Federal Circuit upheld PTAB, despite reliance by the final written decision on references not offered in the petition or earlier relied upon in the institution decision.

- Setup:
  - In its reply, petitioner cited two references (Kikuchi and van der Ploeg '91) to show the state of the art at the time of the invention.
  - Neither reference formed the basis of a proposed ground of unpatentability, nor did the PTAB discuss either reference substantively in the institution decision or rely in the grounds on which it granted the petition.
  - During oral argument, the parties disputed what use the PTAB could make of the two references.
  - In its final written decision, the PTAB referred to both references as support for its findings regarding the state of the art. However, the grounds themselves on which the PTAB found the claims unpatentable were the grounds identified in the institution decision.

APA Right to Respond – Parties Must Take Action

***Genzyme Therapeutic Products Ltd. v. Biomarin Pharmaceutical Inc.*, Nos. 2015-1720 & 1721, slip op. (Fed. Cir. June 14, 2016)**

- Patent owner appeal:
  Genzyme argued that the PTAB abridged its procedural rights under the APA by changing its theory of the cases between institution and final written decision when it referred to the Kikuchi and van der Ploeg '91 references.

- The Federal Circuit rejected patent owner's argument:
  "[T]he introduction of new evidence in the course of the trial is to be expected in *inter partes* review trial proceedings and, as long as the opposing party is given notice of the evidence and an opportunity to respond to it, the introduction of such evidence is perfectly permissible under the APA …. There is no requirement, either in the Board's regulations, in the APA, or as a matter of due process, for the institution decision to anticipate and set forth every legal or factual issue that might arise in the course of the trial." slip op. at 9.

APA Right to Respond – Parties Must Take Action

***Genzyme Therapeutic Products Ltd. v. Biomarin Pharmaceutical Inc.*, Nos. 2015-1720 & 1721, slip op. (Fed. Cir. June 14, 2016)**

- The Federal Circuit held that patent owner had received adequate notice of the two references:

  "Genzyme cannot plausibly argue that it lacked notice that the Board might cite Kikuchi and van der Ploeg '91 in its final written decisions. Genzyme itself raised the issue of the *in vivo* studies in its patent owner responses when it argued that Kikuchi and other *in vivo* studies that the petitioner had cited in its petitions should not be considered as rebuttal evidence …. Biomarin then addressed both of the *in vivo* references in its replies, arguing that the in vivo references were relevant to show the state of the art at the time of the inventions." slip op. at 10.

APA Right to Respond – Parties Must Take Action

***Genzyme Therapeutic Products Ltd. v. Biomarin Pharmaceutical Inc.*, Nos. 2015-1720 & 1721, slip op. (Fed. Cir. June 14, 2016)**

- The Federal Circuit stated that patent owner could have sought to exclude the references or could have sought leave to file a surreply:
  "If Genzyme had wanted the Board to disregard those references, it could have filed a motion to exclude them …. If it had wished to submit a further substantive response to those references, it could have asked for leave to file a surreply, as longstanding Board practice allows …. But despite having actual notice that Biomarin was relying on the *in vivo* references to rebut Genzyme's arguments, Genzyme failed to take advantage of its procedural options to seek to exclude that evidence or to respond to Biomarin's arguments." slip op. at 12-13.

APA Right To Respond – New Combinations

***In re NuVasive, Inc*., 841 F.3d 966 (Fed. Cir. 2016)**

- The Petition relied on art having many different embodiments, but only argued invalidity based on certain embodiments. For the first time in the Reply, the Petitioner proposed relying on a new embodiment.
- The PTAB ultimately invalidated based on the new embodiment.
- The CAFC vacated and remanded, stating that "NuVasive was entitled to an adequate opportunity to respond" to the new arguments.

  "Despite requests from NuVasive, the Board refused to permit NuVasive to file a surreply or even to address the matter during oral argument."

“Substantial Evidence” Standard Not Upended

***Merck & Cie v. Gnosis SpA*, 808 F.3d 829, 832 (Fed. Cir. 2015), cert. denied, 137 S. Ct. 297, 196 L. Ed. 2d 238 (2016)**

- Merck argued that CAFC should review PTAB findings using the stricter “clear error” standard used for district court decisions, not the “substantial evidence” standard”
- The CAFC disagreed, holding that the law requires the use of the “substantial evidence” standard of review, giving deference to the PTAB’s findings
- Based on this standard, the CAFC is less likely to overturn factual findings by the PTAB
- A request for *en banc* review was denied, with a concurrence agreeing that a change in standards was a question for congress but adding the “substantial evidence” standard is inappropriate

Burden of Proof After Institution

***In re: Magnum Oil Tools International Ltd.*, 829 F.3d 1364, 1368 (Fed. Cir. 2016)**

- PTAB took the position that when it institutes review of a patent, it necessarily finds the petitioner has demonstrated a reasonable likelihood of success. Therefore, the burden shifts to the patent owner to prove its patent is not invalid after institution.
- CAFC overturned, holding that burden of proof remains with the challenger
- CAFC said that shifting the burden was "directly at odds with our precedent" and would "introduce unnecessary confusion" to proceedings

BRI Is the Proper Standard at the PTAB

***Cuozzo Speed Technologies, LLC v. Lee*, 579 U.S. __ (2016)**

- The US Supreme Court considered issues regarding claim construction and appealability of institution decisions
- Is "broadest reasonable interpretation" (BRI) the proper claim construction standard?
  - Supreme Court decided that the PTAB may apply the BRI standard, explaining that the standard was within a "reasonable exercise of its rulemaking authority"
  - The Court, however, did not explain *how* that standard is to be applied
- Are institution decision appealable?
  - PTAB decisions made at institution are, for the most part, unreviewable on appeal
  - However…the Federal Circuit might have review in extreme cases, such as when a constitutional right is implicated

CBM Eligibility – *Financial in Nature* Not Unbounded

***Unwired Planet, LLC v. Google Inc.*, __ F.3d __ (Fed. Cir. Nov. 21, 2016)**

- Unwired Planet LLC's patent covered a system for restricting access to a wireless device's location information, e.g. by enforcing a user's privacy preferences
- PTAB had found that the patent was subject to CBM review because *sales could result from* advertising related to use of the patent
- The Federal Circuit found the PTAB erred in using an overly broad interpretation of which patents are subject to the CBM review, as methods "incidental or complementary to" sales are not necessarily CBM eligible

> "[I]t cannot be the case that a patent covering a method and corresponding apparatuses becomes a CBM patent because its practice could involve a potential sale of a good or service. All patents, at some level, relate to potential sale of a good or service." Slip op. at 12.

Considering Redundant Grounds at FWD

***Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356 (Fed. Cir. 2016)**

- The PTAB instituted IPR based on one obvious combination, but not four other grounds, calling them "redundant."
- In the Final Written Decision, the PTAB found that the claims were not obvious over the instituted ground after-all.
- Petitioner argued that the PTAB was compelled to revisit the allegedly redundant grounds in light of the conclusion that the instituted ground was insufficient.
- The CAFC disagreed, finding "no statutory requirement that the Board address every claim raised in an IPR petition" even when a claim is ultimately found patentable over an instituted ground.
- "[I]t is clear that the Board may choose to institute some grounds and not institute others as part of its comprehensive institution decision."

Estoppel (*Shaw* and *HP v. MPHJ)*

- ***Shaw Industries Group, Inc. v Automated Creel Systems, Inc.*, 817 F.3d 1293 (Fed. Cir. 2016)**
  - Obviousness grounds instituted, anticipation grounds denied as redundant
  - Instituted ground distinguished on non-combinability, however
  - *Shaw* sought a writ of mandamus, pointing out that the Board erred was evident in denial of anticipation grounds as redundant of obviousness grounds, given combination issue, and seeking relief to avoid preclusion of anticipation grounds on estoppel
  - In denying, Fed. Cir. held:

    "Both parts of § 315(e) create estoppel for arguments 'on any ground that the petitioner raised or reasonably could have raised *during* that inter partes review.' Shaw raised its Payne-based ground in its petition for IPR. the PTO denied the petition as to that ground, thus no IPR was instituted on that ground. The IPR does not begin until it is instituted. . . . Thus, Shaw did not raise—nor could it have reasonably raised—the Payne-based ground during the IPR. The plain language of the statute prohibits the application of estoppel under these circumstances." *Shaw*, 817 F. 3d at 1300 (emphasis added).

- ***HP Inc. V. MPHJ Technology Inv., LLC*, 817 F.3d 1339 (Fed. Cir. 2016)**
  - "As we explained *supra*, however, the noninstituted grounds do not become a part of the IPR. Accordingly, the noninstituted grounds were not raised and, as review was denied, could not be raised in the IPR. Therefore, the estoppel provisions of § 315(e)(1) do not apply." 817 F. 3d at 1347.

Statutory Framework

"(e) ESTOPPEL.—

"(1) PROCEEDINGS BEFORE THE OFFICE.—The petitioner in an inter partes review of a claim in a patent under this chapter that results in a final written decision under section 318(a), or the real party in interest or privy of the petitioner, may not request or maintain a proceeding before the Office with respect to that claim on any ground that the petitioner raised or reasonably could have raised during that inter partes review.

"(2) CIVIL ACTIONS AND OTHER PROCEEDINGS.—The petitioner in an inter partes review of a claim in a patent under this chapter that results in a final written decision under section 318(a), or the real party in interest or privy of the petitioner, may not assert either in a civil action arising in whole or in part under section 1338 of title 28 or in a proceeding before the International Trade Commission under section 337 of the Tariff Act of 1930 that the claim is invalid on any ground that the petitioner raised or reasonably could have raised during that inter partes review.

- According to Senator Kyl, "[a]dding the modifier 'reasonably' ensures that could-have-raised estoppel extends only to that prior art which a skilled searcher conducting a diligent search reasonably could have been expected to discover." 157 Cong. Rec. S1375 (daily ed. Mar. 8, 2011) (statement of Sen. Kyl) (emphasis added).

Ultimate Implications Unclear

- In a recent decision out of the District of Delaware, a trial judge read *Shaw* to necessarily mean that estoppel under section 315(e) can only apply to the grounds instituted in an IPR and no other grounds—raised or not in the petition:

> Although [plaintiff's] argument in this regard is perfectly plausible, in the sense that [defendant] certainly could have raised these additional obviousness grounds based on public documents at the outset of their IPR petition, the Federal Circuit has construed the above language quite literally. . . . Although extending the above logic to prior art references that were never presented to the PTAB at all (despite their public nature) confounds the very purpose of this parallel administrative proceeding, the court cannot divine a reasoned way around the Federal Circuit's interpretation in *Shaw*. Defendant] may not raise obviousness based on [3 references raised during IPR] against the relevant claims of the [patent] in the case at bar. However, [defendant] may present the additional invalidity grounds at trial.

Intellectual Ventures I LLC et al v. Toshiba Corporation et al, 1-13-cv-00453 (DED December 19, 2016, Order) (Robinson, USDJ).

Same Panel Decides Institution and Merits

***Ethicon Endo-Surgery, Inc. v. Covidien LP*, 812 F.3d 1023 (Fed. Cir. 2016)**

- The PTAB, through a panel of judges, granted the petition. On the merits, the same PTAB panel found all challenged claims invalid as obvious over the prior art.
- Patent Owner argued that having the same panel make the decision to institute and the later decision on the merits raises "serious due process concerns."
- The CAFC disagreed, finding no due process concerns with using the same panel of judges to institute a post-grant proceeding and to make the final decision on the merits

What To Watch For in 2017

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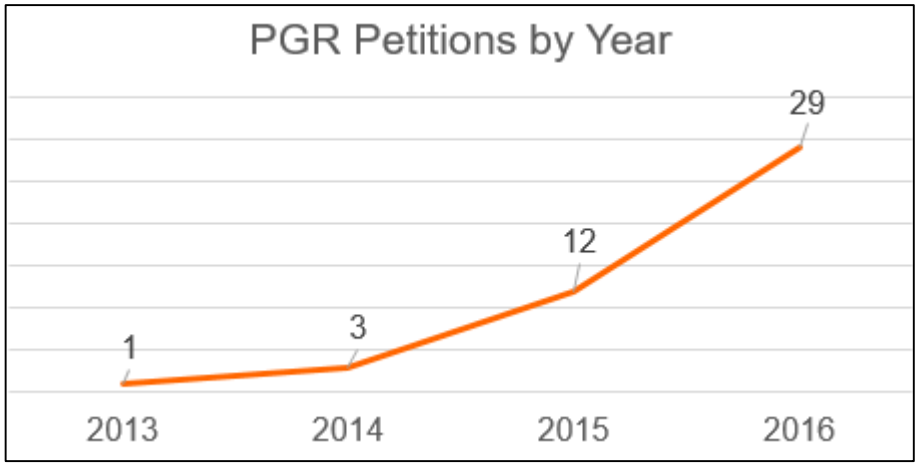
PGR Increasing

- Majority of 2016 PGR filings have been against biotech, pharmaceutical and chemical technology patents (mechanical technology patents a far second)
- Will PGR Filings continue to increase?
- What technologies will be involved?



Consistency of Decisions at the PTAB

- The PTAB now has exactly 8 precedential post-grant decisions and thousands of non-precedential decisions
  - https://www.uspto.gov/patents-application-process/appealing-patent-decisions/decisions-and-opinions/precedential

- Several decisions were deferred, and still others are pending
  - ***In re Aqua Prod., Inc*., 823 F.3d 1369, 1372 (Fed. Cir.), *reh'g en banc granted, opinion vacated*, 833 F.3d 1335 (Fed. Cir. 2016)**
  - ***Wi-Fi One, LLC v. Broadcom Corp.*, 837 F.3d 1329 (Fed. Cir. 2016)**

Open Question – Burden of Proof for Substitute Claims

***In re Aqua Prod., Inc*., 823 F.3d 1369, 1372 (Fed. Cir.), *reh'g en banc granted, opinion vacated*, 833 F.3d 1335 (Fed. Cir. 2016)**

- PTAB denied motion to amend claims finding that Patent Owner failed to prove they are patentable over the prior art.
- The CAFC panel found no abuse of discretion in giving the burden of proof to Patent Owner
- The panel decision was vacated and is currently being heard *en banc* (oral argument was December 9)
  - "(a) When the patent owner moves to amend its claims under 35 U.S.C. § 316(d), 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?"

Appealability of Institution Decision

***Wi-Fi One, LLC v. Broadcom Corp.*, 837 F.3d 1329 (Fed. Cir. 2016)**

- Wi-Fi argued that PTAB institution decisions finding that a petition is not time-barred should be reviewable, under the narrow exception provided by the Supreme Court in *Cuozzo*
- Citing precedent, the CAFC held that it cannot review such decisions, and that *Cuozzo* did not overrule earlier precedent
- The CAFC recently agreed to take this case *en banc* in 2017, with the question:
  - "Should this court overrule *Achates Reference Publishing, Inc. v. Apple Inc.*, 803 F.3d 652 (Fed. Cir. 2015), and hold that judicial review is available for a patent owner to challenge the PTO's determination that the petitioner satisfied the timeliness requirement of 35 U.S.C. § 315(b) governing the filing of petitions for inter partes review?"

Post-Grant Resources

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Resources

- Fish websites:
  - Post-Grant for Practitioners: http://fishpostgrant.com/webinars/
  - General: http://fishpostgrant.com/
  - IPR: http://fishpostgrant.com/inter-partes-review/
  - PGR: http://fishpostgrant.com/post-grant-review/
  - Rules governing post-grant: http://fishpostgrant.com/
  - Post-Grant App: http://fishpostgrant.com/app/
  - Post-Grant Radio: http://fishpostgrant.com/podcasts/
- USPTO sites:
  - AIA Main: http://www.uspto.gov/aia_implementation/index.jsp
  - Inter Partes: http://www.uspto.gov/aia_implementation/bpai.jsp

Thank You!

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