#### UNITED STATES PATENT AND TRADEMARK OFFICE



#### **Chat with the Chief**

#### New PTAB Studies in AIA Proceedings: Expanded Panels and Trial Outcomes for Orange Book-listed Patents

David P. Ruschke Chief Administrative Patent Judge

Michelle N. Ankenbrand Lead Administrative Patent Judge

Jason Repko Administrative Patent Judge

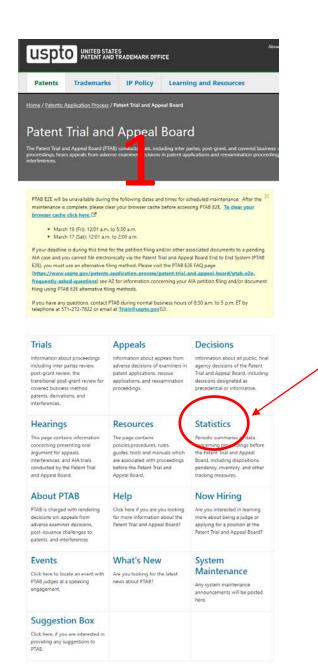
March 13, 2018

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# Agenda

- Expanded Panel Study (Chief and Lead Judge Ankenbrand)
  - Questions
- Orange Book-Listed Patent Study (Chief and Judge Repko)
  - Questions





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### **Expanded Panel Study**



#### **SOP 1: Reasons for Panel Expansion**

- Chief has discretion to expand a panel per authority delegated from Director
- Expanded panel is **rare** and **"ordinarily will not be used"**
- Reasons for expanding a panel:
  - Issue of exceptional importance (Guidance)
  - Maintain uniformity of Board decisions (Consistency)
  - Written request from Commissioner for Patents or the Commissioner's delegate identifying an issue:
    - o Of first impression; or
    - Governed by a prior Board decision where Commissioner has determined it would not be in the public interest to follow the prior Board decision

### **SOP 1: Suggestion for Panel Expansion**

- Who may suggest the need for the designation of an expanded panel?
  - Judge
  - Merits panel
  - Interlocutory panel
  - Applicant or patent owner in an *ex parte* appeal
  - Party in an *inter partes* reexam, interference, or AIA trial
- Suggestion must be in writing with reasons and basis for expansion



#### **Current Expanded Panel Practice**

- Current panel expansion practice ensures:
  - Predictable and uniform application of agency policy
  - Similarly situated parties, under the same facts, are treated the same
  - Notice to the public
- Current preferred panel expansion practice (*see General Plastic*):
  - All expanded panel decisions include Chief Judge and Deputy Chief Judge
  - All expanded panel decisions explain the **basis** for expansion
  - Panel expanded **without changing** the underlying result
    - Emphasizes the underlying result or reasoning to provide guidance
  - Potential designation of decision as informative, and
  - May consider the decision for precedential designation
- Early AIA practice expanded panels in families for case resource management
  - Now discontinued

#### What Did PTAB Study?

- **Question 1**: How common are expanded panels?
- **Question 2**: When were panels expanded?
- **Question 3**: Why were panels expanded?
- **Question 4**: What was the result of the expansion?

#### Methodology

- Reviewed IPR, PGR, and CBM proceedings filed on or before 12/31/2017, which covers 7,930 Petitions and their associated:
  - 6,033 Decisions on Institution
  - 1,912 Final Written Decisions
  - Thousands of Interlocutory Orders
- Used a manual process to identify expanded panel decisions
- Excluded families in which the panel was expanded for case resource management
  - Example: Apple Inc. v. Smartflash LLC 14 individual cases all administered by a 4-or 5-judge panel (see Case CBM2014-00102, et al.)

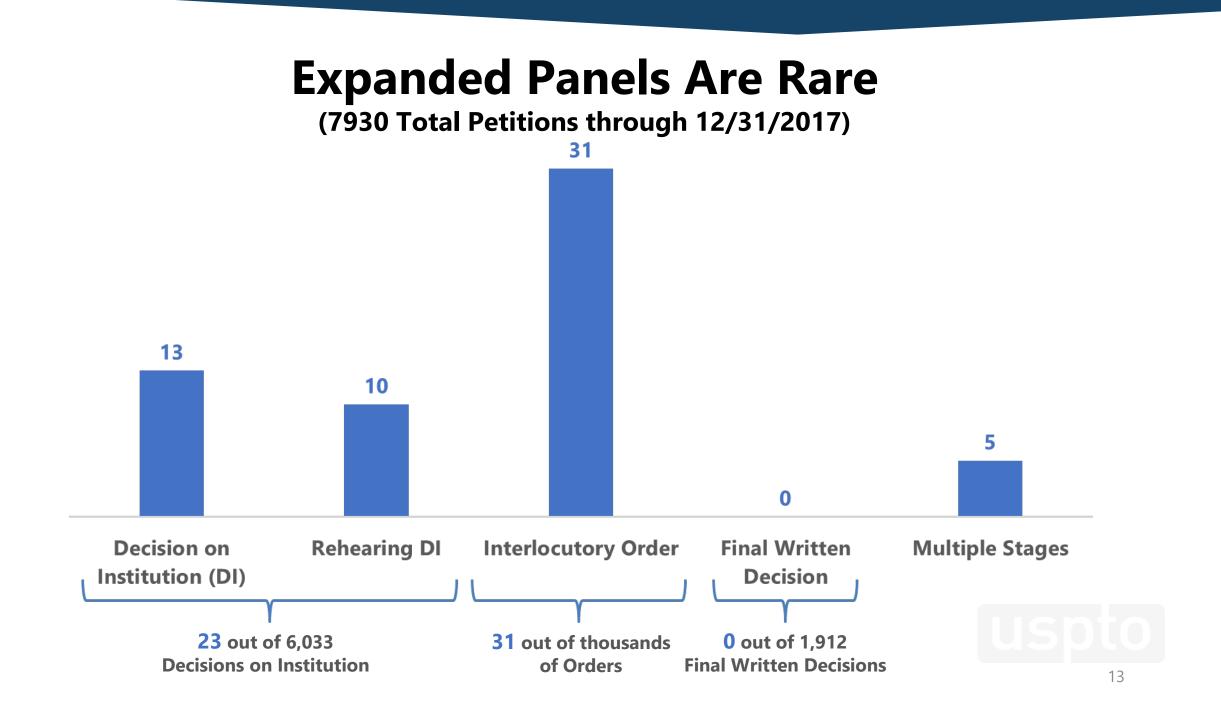
### Highlights

- Expanded panels are very **rare**
- Most expanded panel decisions issued as original decisions, not decisions on rehearing
- Panels were expanded for **guidance** and **consistency**:
  - to provide forward-looking guidance on reoccurring issues; and/or
  - to treat similarly situated parties the same
- Underlying result remained the **same** after panel expansion on rehearing, except for *Target* and *Nidec*, both of which address same-party joinder

### **Question 1**:

#### **How Common Are Expanded Panels?**

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### **Question 2**:

#### When Were Panels Expanded?

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#### Majority of Panels Were Expanded In Original Decision

• About 80% of panels expanded in original decision

• About 20% of panels expanded on request for rehearing

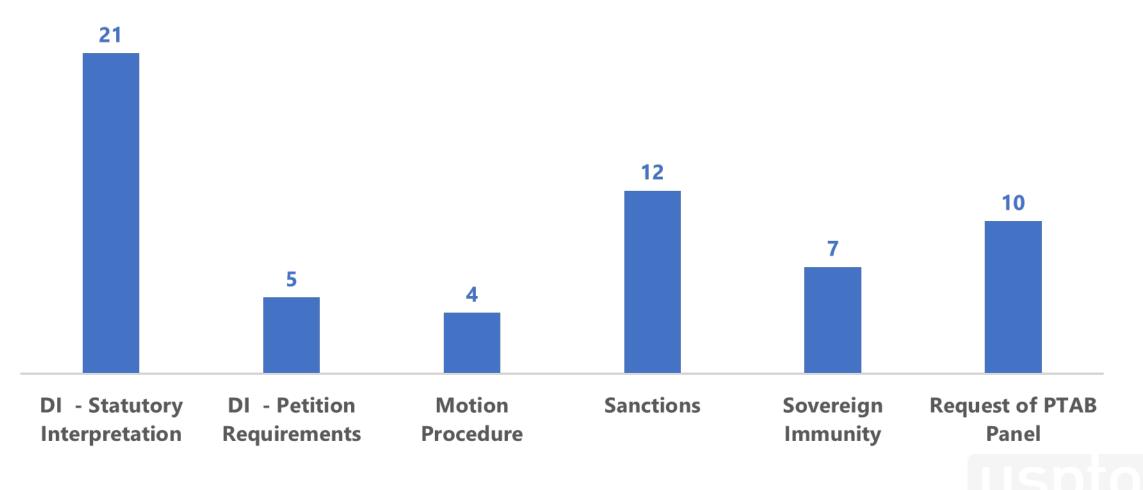


### **Question 3**:

#### Why Were Panels Expanded?

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#### Panels Were Expanded For Guidance and Consistency (Individual Cases)



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#### **Reason 1: DI Procedure – Statutory Interpretation Issues**

Specific Issue Addressed	Number of Individual Cases	Lines of Cases
35 U.S.C. § 314(a) multiple petitions	5	1
35 U.S.C. § 315(b) time bar	3	2
35 U.S.C. § 315(b) and real party in interest	5	1
35 U.S.C. § 315(c) same-party joinder	6	2
35 U.S.C. § 325(d) same art or arguments	1	1
AIA § 18 CBM pre-institution disclaimer	1	1
Total	21	8

#### **Reason 1: Recent Example Expanded Panel Decisions**

- <u>314(a) Multiple Petitions</u>: General Plastic v. Canon, Case IPR2016-01357, -01358, -01359, -01360, -01361 (PTAB Sept. 6, 2017) (Paper 19) (precedential) (vote from 3-0 to 7-0 with expansion on rehearing)
  - Emphasizes the factors that the Board considers in deciding whether to exercise its discretion to deny a followon Petition in an AIA proceeding under 35 U.S.C. § 314(a).
- <u>325(d) Similar Art/Arguments</u>: *Neil Ziegmann v. Carlis G. Stephens*, Case IPR2015-01860 (PTAB Sept. 6, 2017) (Paper 13) (vote from 3-0 to 5-0 with expansion on rehearing)
  - Emphasizes that prior art or arguments may be considered "substantially the same" under 35 U.S.C. § 325(d) if they are "cumulative to or substantially overlap with issues previously considered by the Office with respect to the patent."
- <u>CBM Pre-Institution Disclaimer</u>: *Facebook v. Skky*, Case CBM2016-00091 (PTAB Sept. 28, 2017) (Paper 12) (precedential) (vote from 3-0 to 5-0 with expansion on rehearing)
  - Emphasizes that CBM patent review eligibility is determined based on the claims of the challenged patent as they exist at the time of the decision to institute, and that statutorily disclaimed claims must be treated as if they never existed for the purpose of institution.

#### **Reason 2: DI Procedure – Petition Requirements**

Specific Issue Addressed	Number of Individual Cases	Lines of Cases
Corrected Petition untimely, no excuse	2	1
Petition insufficient under 37 C.F.R. § 42.104	2	2
Petition sets forth redundant grounds	1	1
Total	5	4



#### **Reason 3: Motion Procedure**

Specific Issue Addressed	Number of Individual Cases	Lines of Cases
Motion to amend requirements	2	2
Motion for pro hac vice requirements	2	2
Total	4	4



#### **Reason 4: Sanctions**

Specific Issue Addressed	Number of Individual Cases	Lines of Cases
PTAB may impose sanctions for continued course of conduct	7	2
Denying motion for sanctions alleging abuse of process	5	1
Total	12	3



#### **Reason 4: Recent Example Expanded Panel Decisions**

- <u>PTAB May Impose Sanctions for Continued Course of Conduct</u>: *GEA Process Engineering, Inc. v. Steuben Foods, Inc.*, Case IPR2014-00041 (Paper 147), -00043 (Paper 125), -00051 (Paper 123), -00054 (Paper 144), -00055 (Paper 116) (PTAB Nov. 28, 2016) (5-0 decision)
  - Parties were not authorized to request a teleconference or file papers on the merits of the cases, which had been terminated with all appeals exhausted.



#### **Reason 5: Constitutional Issue**

- Sovereign immunity (7 individual cases, 2 lines of cases)
- Recent Example Expanded Panel Decisions
  - LSI Corporation v. Regents of the University of Minnesota, Case IPR2017-01068 (PTAB Dec. 19, 2017) (Paper 19) (6-1 decision)
  - Ericsson, Inc. v. Regents of the University of Minnesota, Case IPR2017-01186, -01197, -01200, -01213, -01214, -01219 (PTAB Dec. 19, 2017) (Paper 14) (6-1 expanded panel decision)
    - Panels expanded in all 7 proceedings to address whether a patent owner can invoke and waive sovereign immunity in an AIA proceeding, and to ensure uniformity in decision as to the same patent owner.

#### **Reason 6: Request of PTAB Panel**

- Ensure consistent application of 35 U.S.C. § 112(f) (10 individual cases, 1 line of cases)
- Recent Example Expanded Panel Decision
  - HTC America v. Virginia Innovation Sciences, Case IPR2017-00870, -00871, -00872, -00873, -00874, -00875, -00876, -00877, -00878, -00879 (PTAB Sept. 13, 2017) (Paper 11) (3-2 decision)
  - Original panel suggested expansion to maintain uniformity due to substantial difference of opinion among the judges on a group of 10 related cases regarding an issue arising under 35 U.S.C. § 112(f).



### Question 4: What Was The Result of the Expansion If On Rehearing?

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#### **Expanded Panels Reach Same Underlying Result**

- Exception: *Target* and *Nidec*
- Both addressed same-party joinder
- Both were decided more than 3 years ago
- Both were expanded to ensure consistency
  - All decisions pre-*Target* permitted same-party joinder
  - All decisions post-*Nidec* have permitted same-party joinder

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#### Recap

- Expanded panels are very **rare**
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### **Questions?**



### **Orange Book-listed Patent Study**



#### What Are Orange Book-listed Patents?

 Short-hand for patents covering FDA-approved drug products that are listed in the publication Approved Drug Products With Therapeutic Equivalence Evaluations (commonly known as the Orange Book)

 Orange Book-listed patents are governed under the provisions of the Hatch-Waxman Act, which created an abbreviated regulatory approval pathway for generic drug products



#### What Is the Hatch-Waxman Act?

- Allows a generic company to secure quicker FDA approval without repeating expensive and lengthy clinical trials that were conducted on brand drug
- In exchange, a generic company must certify to FDA that:
  - Generic version of approved drug will not interfere with any patents that branded pharmaceutical company has listed in the Orange Book; or
  - Patents that branded pharmaceutical company has listed in the Orange Book are not infringed and/or invalid

### Highlights

- 83% of all petitions challenging Orange Book-listed patents result in patent being unchanged by PTAB
- The cumulative institution rate for Orange Book petitions (66%) is essentially the same as the cumulative overall institution rate (68%)
- Just over half of all final written decisions for petitions challenging Orange Booklisted patents find all claims patentable
- 80% of all challenged Orange Book-listed patents have 1 or 2 <u>petitions</u>, compared to 87% of all challenged patents
- 85% of all challenged Orange Book-listed patents have 1 or 2 petitioners, compared to 94% of all challenged patents

### Methodology

- PTAB classified a petition as challenging an Orange Book-listed patent by comparing the petition's filing date with data from the FDA's electronic Orange Book indicating when the patent was listed
- Statistics depict data through the end of FY 2017
- Unless otherwise noted, statistics were calculated the same way as the monthly trial statistics published on PTAB's website: <u>https://www.uspto.gov/patents-application-process/appealing-patent-decisions/statistics/aia-trial-statistics</u>

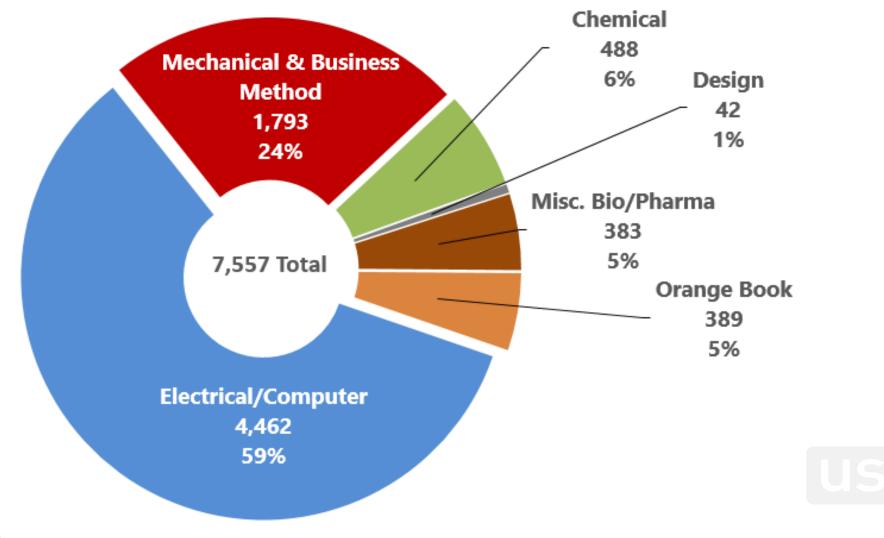
#### What Did PTAB Study?

- <u>Question 1</u>: What are the filing trends for petitions challenging Orange Booklisted patents?
- <u>Question 2</u>: How does the institution rate on petitions challenging Orange Book-listed patents compare to those of other technologies?
- <u>Question 3</u>: What are the outcomes of challenges to Orange Book-listed patents?
- <u>Question 4</u>: What is the status of every petition ever filed that challenged an Orange Book-listed patent?
- <u>Question 5</u>: What is the status of each challenged Orange Book-listed patent when the results of multiple challenges are combined?

# Question 1: What are the filing trends for petitions challenging Orange Book-listed patents?

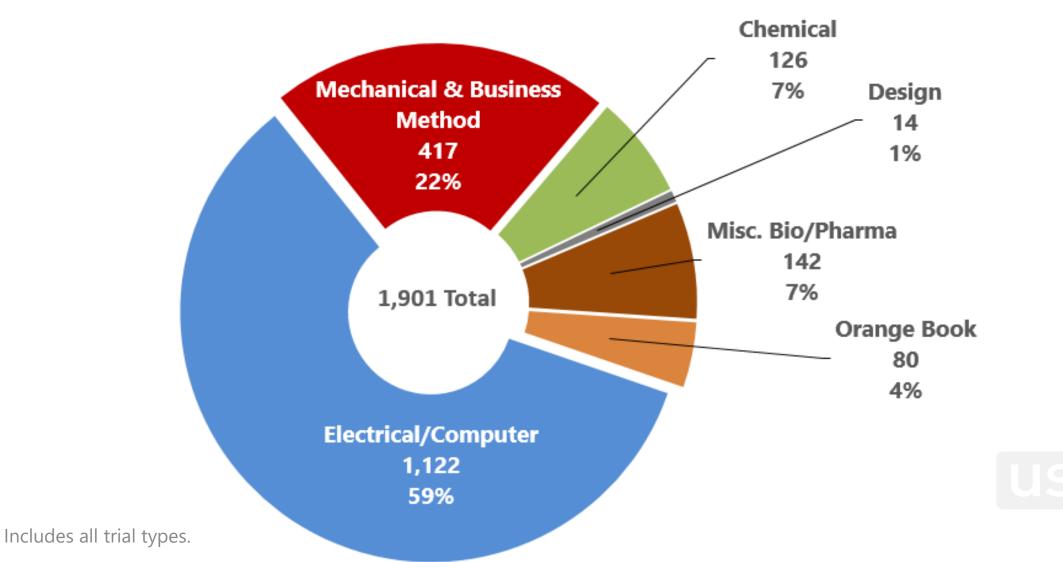


# Petitions Filed by Technology (as of End FY17: 9/16/12 to 9/30/17)



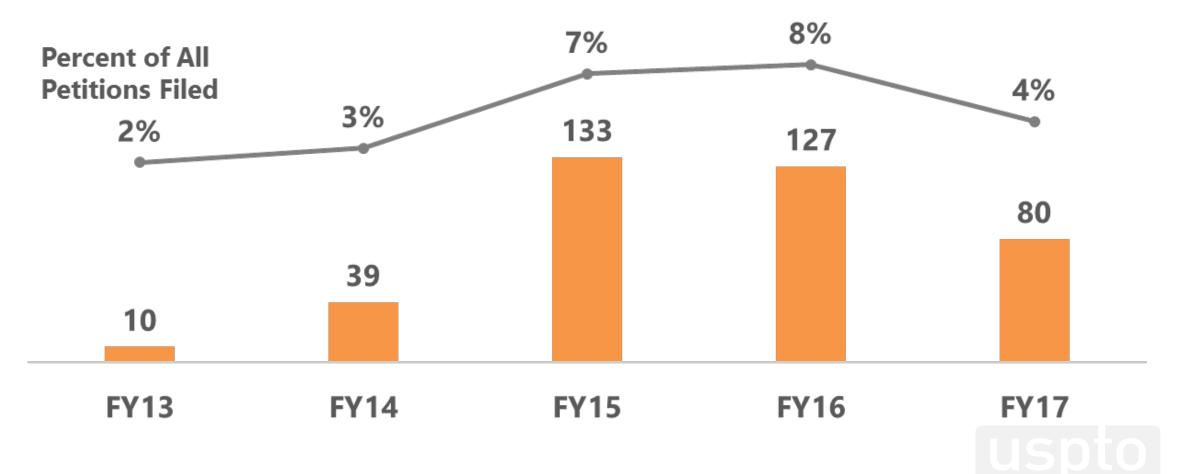
Includes all trial types.

# Petitions Filed by Technology in FY17 Only (FY17: 10/1/16 to 9/30/17)



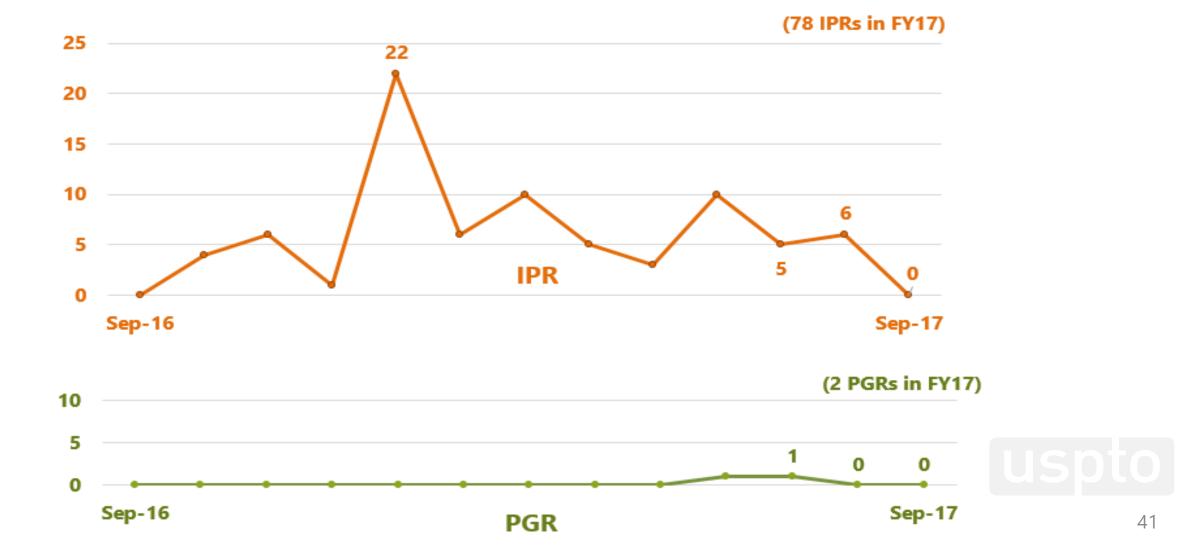
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# Petitions Challenging Orange Book-listed Patents (as of End FY17: 9/16/12 to 9/30/17)



No petitions challenging Orange Book-listed patents were filed in FY12

# Petitions Challenging Orange Book-listed Patents Filed by Month (September 2017 and Previous 12 Months: 9/1/16 to 9/30/17)



# **Question 2:** How does the institution rate on petitions challenging **Orange Book-listed patents** compare to those of other technologies?



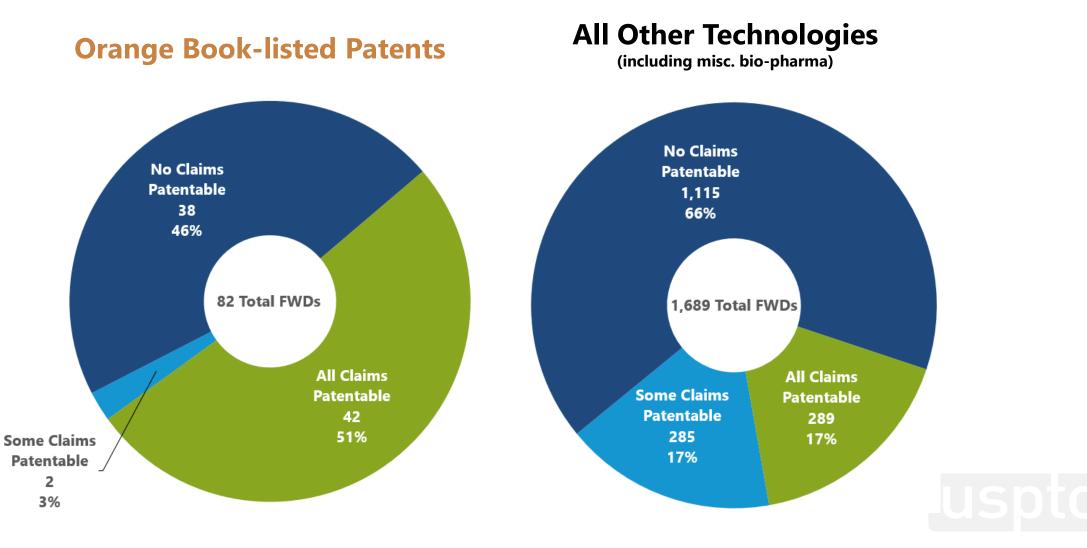
## Institution Rates by Technology (As of End FY17: 9/16/12 to 9/30/17)

Mechancial & BM	70% (958 of 1,376)	
Electrical/Computer	69% (2,256 of 3,270)	
Chemical	68% (251 of 369)	
Overall	68% (3,833 of 5,607)	
Orange Book	66% (211 of 318)	
Misc. Bio/Pharma	60% (141 of 234)	
Design	40% (16 of 40)	

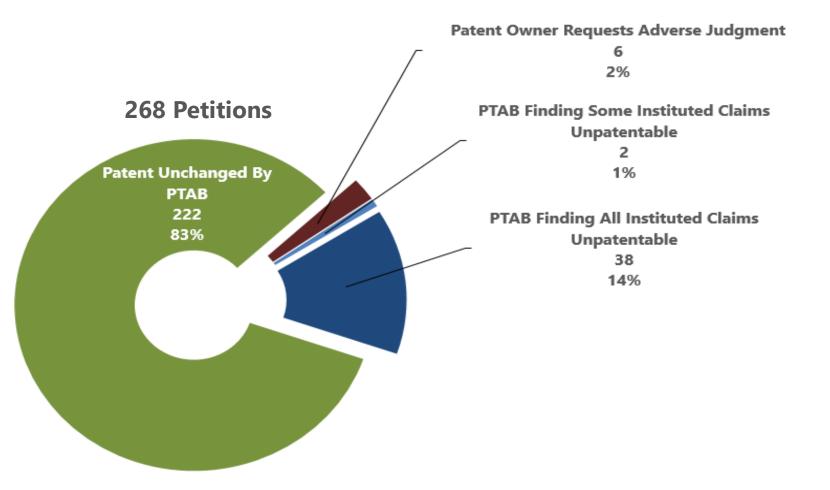
# Question 3: What are the outcomes of challenges to Orange Book-listed patents?



#### Status of Instituted Claims in Final Written Decisions (As of End FY17: 9/16/12 to 9/30/17)



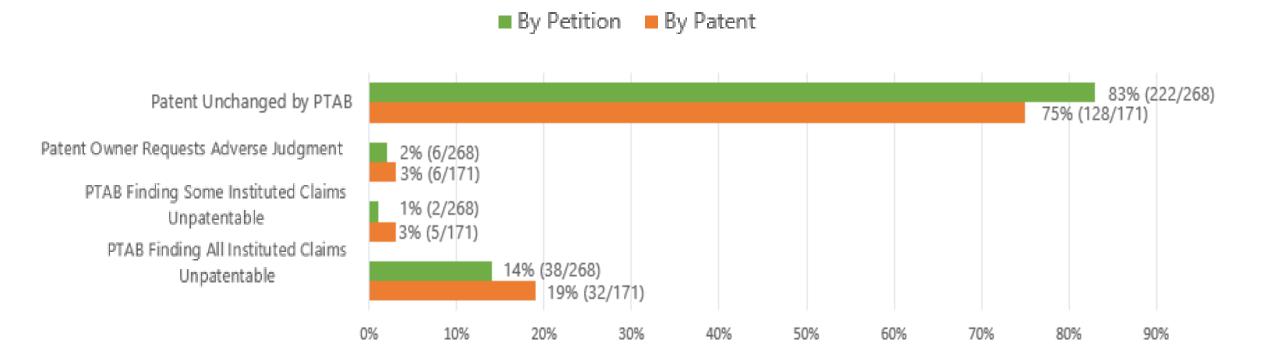
#### Outcomes for Petitions Challenging Orange Book-listed Patents (as of End FY17: 9/16/12 to 9/30/17)



The patent being unchanged by PTAB includes final written decisions with all claims patentable, settlements, dismissals, and petitions denied institution.

## **Outcomes for Petitions Challenging Orange Book-listed Patents**

(As of End FY17: 9/16/12 to 9/30/17)



**"By petition"** accounts for whether a particular petition results in any unpatentable claims **"By patent"** accounts for whether any one petition against a particular patent results in any unpatentable claims

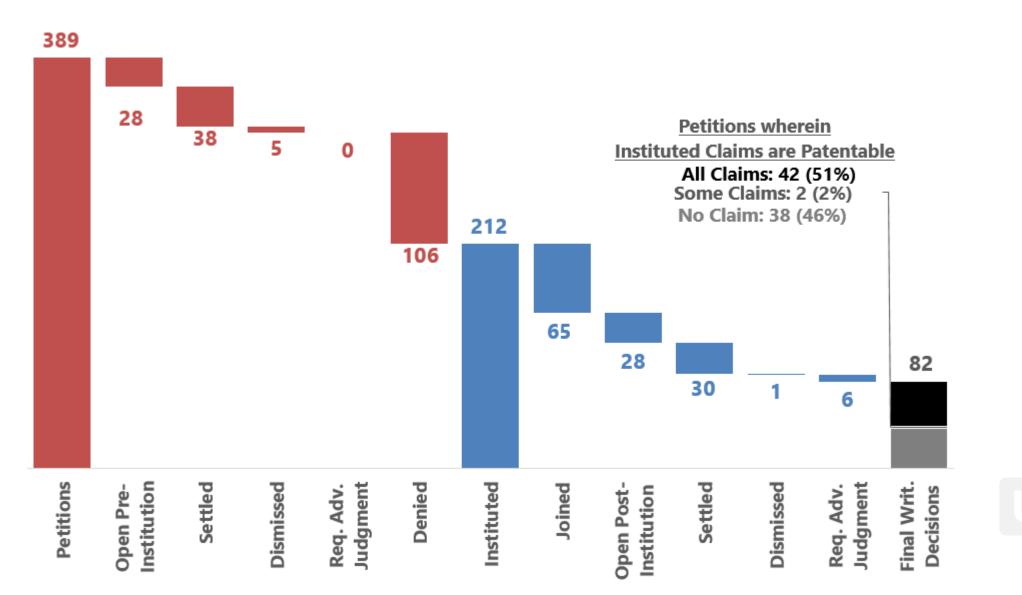
# Question 4: What is the status of every petition ever filed that challenged an Orange Book-listed patent?



#### Status of Petitions Challenging Orange Book-listed Patents (as of End FY17: 9/16/12 to 9/30/17)

Petition Status	Orange Book	All Other Technologies
Reached Final Written Decision	21% (82)	24% (1,689)
Settled	17% (68)	22% (1,585)
Denied Institution	27% (106)	23% (1,651)
Dismissed	2% (6)	1% (103)
Joined	17% (65)	4% (289)
Open	14% (56)	22% (1,587)
Request for Adverse Judgment	2% (6)	4% (264)
Total Petitions	100% (389)	100% (7,168)

#### Status of Petitions Challenging Orange Book-listed Patents (As of End FY17: 9/16/12 to 9/30/17)



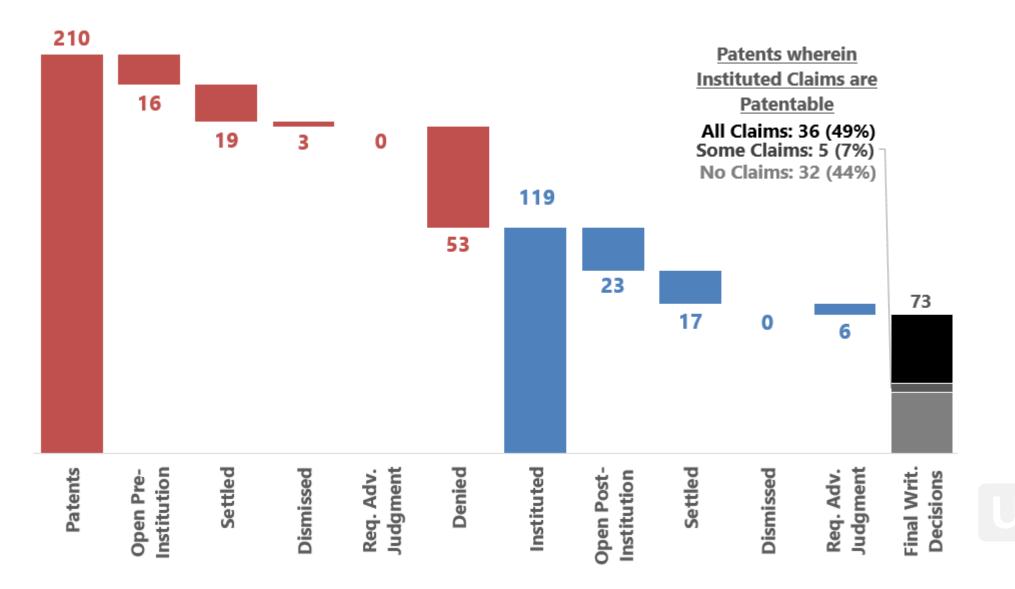
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# Question 5: What is the status of each challenged Orange Book-listed patent when the results of multiple challenges are combined?

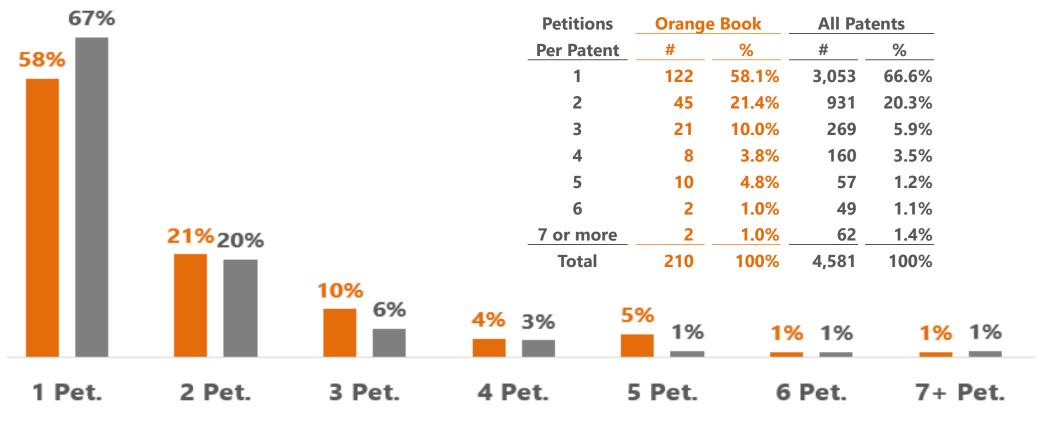
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#### Status of Orange Book-listed Patents Considering Multiple Challenges (as of End FY17: 9/16/12 to 9/30/17)



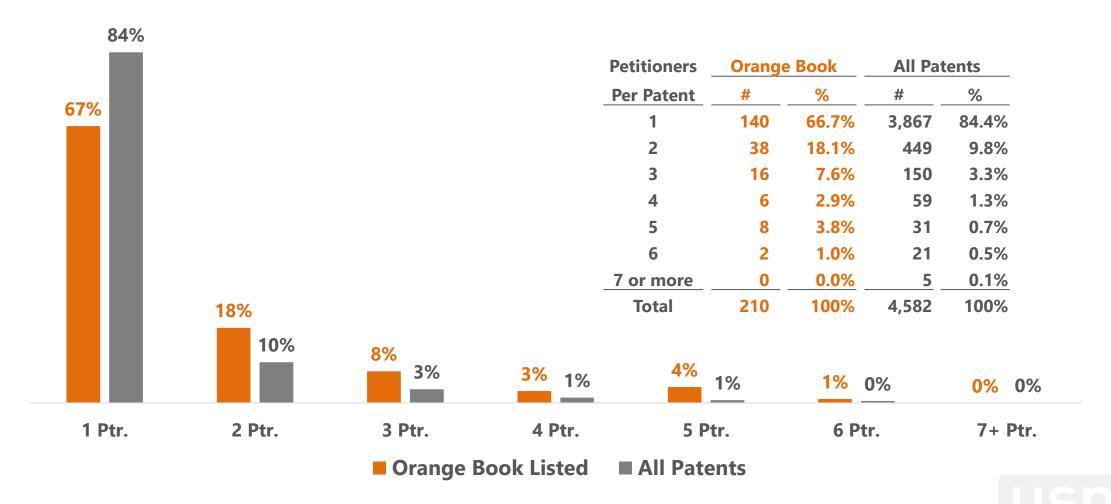
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## Percent of Challenged Patents by Number of Petitions (as of End FY17: 9/16/12 to 9/30/17)



Orange Book Listed All Patents

## Percent of Challenged Patents by Number of Petitioners (as of End FY17: 9/16/12 to 9/30/17)



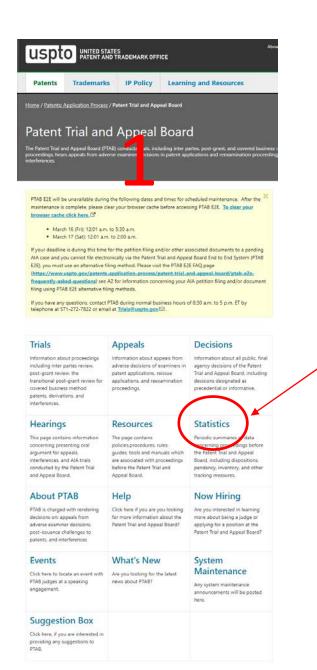
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# Recap

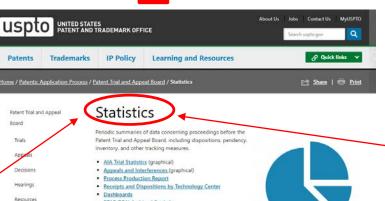
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# **Questions?**





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Motion to Amend Study (update through September 30, 2017)

Data for 275 Completed Trials (MTA Study)

#### **AIA Trial Statistics** Patent Trial and Appeal Board Trials FY 2018 Appeals October 2017 November 2017 Decisions December 2017 Hearings FY 2017 **Resources** October 2016 Statistics November 2016 December 2016 Performance Measures January 2017 February 2017 About PTAB March 2017 April 2017 PTAS Help May 2017 June 2017 · July 2017 August 2017 September 2017 Multiple Petitions Study Motion to Amend Study (update through May 31, 2017) Data for 254 Completed Trials (MTA Study)

# uspto

# Mark Your Calendars for Free PTAB Events

- Thursday, April 5, noon to 1 pm: Boardside Chat webinar on AIA Motion Practice
- Thursday, June 7, noon to 1 pm: Boardside Chat webinar on Motions to Exclude and Motions to Strike
- Thursday, June 28, 9 to 5 pm: Judicial Conference

# **Thank You**

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# **Appendix of Expanded Panel Cases**



## Expanded Panel Decisions Breakdown Forward-Looking Guidance

#### **1. DI Procedure Involving Statutory Interpretation**

#### • 35 U.S.C. § 314(a) multiple petitions

- General Plastic Industrial Co. v. Canon Kabushiki Kaisha, Case IPR2016-01357 (Paper 19), -01358, -01359, -1360, -01361 (PTAB Sept. 6, 2017) (Paper 15) (precedential)
  - Emphasizes the factors that the Board considers in deciding whether to exercise its discretion to deny a follow-on Petition in an AIA proceeding under 35 U.S.C. § 314(a).

#### • 35 U.S.C. § 315(b) time bar

- Apple Inc. v. Rensselaer Polytechnic Institute, Case IPR2014-00319, -00320 (PTAB Dec. 12, 2014) (Paper 20)
  - Expanded panel reaffirmed original panel's decision that Petition was untimely under 35 U.S.C. § 315(b), even though prior infringement action had been dismissed.
- St. Jude Medical, Cardiology Division, Inc. v. Volcano Corp., Case IPR2013-00258 (PTAB Oct. 16, 2013) (Paper 29)
  - Denied Petition under 35 U.S.C. § 315(b) that was not filed within one year of service of counterclaim alleging infringement of patent.

#### • 35 U.S.C. § 315(b) and real party in interest

- TRW Automotive US LLC v. Magna Electronics, Inc., Case IPR2014-00293, -00294, -00298 (Paper 18), -00296, -00297 (Paper 14) (PTAB June 27, 2014) (informative)
  - Service of amended complaint attached as an exhibit to a motion for leave to file the amended complaint did not trigger one-year time period under 35 U.S.C. § 315(b);
  - Petitioner's identification of two entities as being "related to Petitioner" did not contradict Petitioner's certification as to a different real party in interest.

#### • 35 U.S.C. § 315(c) same-party joinder\*

- Target Corp. v. Destination Maternity Corp., Case IPR2014-00508 (Paper 28), -00509 (Paper 29) (PTAB Feb. 12, 2015) (see also Case IPR2013-00531 (Paper 86) -00533 (Paper 82) (PTAB May 8, 2015))
  - Original majority decision of 5-judge panel denied institution and motion for joinder of same party to already-instituted proceeding; dissenting opinion would have granted institution and joinder motion;
  - Expanded panel to 7 judges and majority instituted review and granted joinder motion.
- Zhongshan Broad Ocean Motor Co. v. Nidec Motor Corp., Case IPR2015-00762 (PTAB Oct. 5, 2015) (Paper 16) (see also Case IPR2014-01121 (Paper 67) (PTAB Oct. 5, 2015), (Paper 86) (PTAB May 9, 2016))
  - Original majority decision denied institution and motion for joinder of same party to already-instituted proceeding; dissenting opinion would have granted institution and joinder motion;
  - Expanded majority instituted review and granted joinder motion.

\* The cases to which Petitioners were joined are included in the total of individual cases with expanded panel 62 decisions

- 35 U.S.C. § 325(d) substantially same prior art during examination
  - Ziegmann v. Stephens, Case IPR2015-01860 (PTAB Sept. 6, 2017) (Paper 13)
    - Emphasizes that prior art or arguments may be considered "substantially the same" under 35 U.S.C. § 325(d) if they are "cumulative to or substantially overlap with issues previously considered by the Office with respect to the patent."

#### • AIA § 18 CBM pre-institution disclaimer

- Facebook, Inc. v. Skky, LLC, Case CBM2016-00091 (PTAB Sept. 28, 2017) (Paper 12) (precedential)
  - Emphasizes that CBM patent review eligibility is determined based on the claims of the challenged patent as they exist at the time of the decision to institute, and that statutorily disclaimed claims must be treated as if they never existed for the purpose of institution.

#### **2.** Decisions Involving Petition Requirements

- Untimely response to deficiency notice
  - DealerSocket, Inc. v. AutoAlert LLC, Case CBM2014-00142 (Paper 10), -00147 (Paper 8) (PTAB Sept. 8, 2014)
    - Dismissed Petitions where the Petitioner was 74 days and 64 days late in correcting defects in the Petitions, and did not take prompt remedial action after recognizing the missed deadlines.

#### • Petition insufficient under 37 C.F.R. § 42.104

- Zetec, Inc. v. Westinghouse Electric Co., Case IPR2014-00384 (PTAB July 23, 2014) (Paper 10)
  - Denied institution on Petition that presented 127 grounds of unpatentability relying on one or more of 14 references, underdeveloped unpatentability arguments, and proposed claim constructions unsupported by evidence.
- Cisco Systems, Inc. v. C-Cation Techs., LLC, Case IPR2014-00454 (PTAB Aug. 29, 2014) (Paper 12) (informative)
  - Declined to consider arguments not made in the Petition and incorporated by reference from expert declaration;
  - Denied institution where the Petition did not specify sufficiently where each claim element was found in the applied references, did not explain in detail the significance of the quotations and citations from the applied references, and provided conclusory obviousness assertions.

#### • Redundant grounds in petition

- Liberty Mutual Insurance Co. v. Progressive Casualty Insurance Co., Case CBM2012-00003 (Paper 7) (PTAB Oct. 25, 2102) (representative), (Paper 11) (PTAB Nov. 26, 2012)
  - Ordered the Petitioner to select subsets of 422 asserted grounds to maintain in the proceeding, where the grounds were redundant.

#### 3. Motion Procedure

#### • Motion to amend requirements

- Idle Free Systems, Inc. v. Bergstrom, Inc., Case IPR2012-00027 (PTAB June 11, 2013) (Paper 26) (informative)
  - Emphasizes requirements under 35 U.S.C. § 316(d) and 37 C.F.R. §§ 42.20(c), 42.121 for a patent owner's motion to amend claims, as well as the need to show patentable distinction over the prior art of record and prior art known to the patent owner.
- MasterImage 3D, Inc. v. RealD Inc., Case IPR2015-00040 (PTAB July 15, 2015) (Paper 42) (precedential)
  - Clarifies *Idle Free* references to "prior art of record" and "prior art known to the patent owner" to include no more than the material prior art made of record in the proceeding, prosecution history, and any other proceeding before the Office involving the patent.

#### • *Pro hac vice* motion requirements

- Unified Patents, Inc. v. Parallel Iron, LLC, Case IPR2013-00639 (PTAB Oct. 15, 2013) (Paper 7) (representative)
  - Sets forth requirements for filing motions for *pro hac vice* admission under rule 37 C.F.R. § 42.10(c).
- Motorola Mobility LLC v. Arnouse, Case IPR2013-00010 (PTAB Oct. 15, 2012) (Paper 6) (informative)
  - Sets forth requirements for filing motions for *pro hac vice* admission under rule 37 C.F.R. § 42.10(c).

#### 4. Sanctions issues

- PTAB may impose sanctions for continued course of conduct
  - Samsung Electronics Co. v. Black Hills Media, LLC, Case IPR2014-00717 (Papers 6, 7), -00735 (Papers 8, 9) (PTAB July 10, 2014)
    - E-mail from counsel attaching evidence and reiterating arguments from teleconference with panel, and e-mail from
      opposing counsel providing substantive response were unauthorized and inappropriate.
  - *GEA Process Engineering, Inc. v. Steuben Foods, Inc.,* Case IPR2014-00041 (Paper 147), -00043 (Paper 125), -00051 (Paper 123), -00054 (Paper 144), -00055 (Paper 116) (PTAB Nov. 28, 2016)
    - Parties were not authorized to request a teleconference or file papers on the merits of the cases, which had been terminated with all appeals exhausted.
- Denying motion for sanctions alleging abuse of process
  - Coalition for Affordable Drugs VI, LLC v. Celgene Corp., Case IPR2015-01092 (Paper 19), -01096, -01102 (Paper 20), -01103, -01169 (Paper 21) (PTAB Sept. 25, 2015)
    - Economic motive for challenging a patent does not itself raise abuse of process issues, and *inter partes* reviews not limited to parties having a competitive interest in the challenged patent.

## Forward-Looking Guidance and Treat Similarly Situated Parties the Same

#### 5. Constitutional issue

#### • Sovereign immunity

- LSI Corp. v. Regents of the University of Minnesota, Case IPR2017-01068 (PTAB Dec. 19, 2017) (Paper 19)
- Ericsson Inc. v. Regents of the University of Minnesota, Case IPR2017-01186, -01197, -01213, -01214 (Paper 14), -01200 (Paper 16), -01219 (Paper 15) (PTAB Dec. 19, 2017)
  - Panels expanded in all 7 proceedings to emphasize that a patent owner that is an arm of the state can invoke and waive sovereign immunity in an *inter partes* review; concurring opinions that sovereign immunity does not apply to *inter partes* review.



## **Expanded Panel Decisions Breakdown: Treat Similarly Situated Parties the Same**

- HTC America, Inc. v. Virginia Innovation Sciences, Inc., Case IPR2017-00870, -00872, -00873, -00874, -00876, -00877, -00879 (Paper 11), -00871 (Paper 14), -00875 (Paper 13), -00878 (Paper 12) (PTAB Sept. 13, 2017)
  - Original panel suggested expansion to maintain uniformity in Decision on Institution due to substantial difference of opinion among the judges regarding claim interpretation under 35 U.S.C. § 112, sixth paragraph.



#### UNITED STATES PATENT AND TRADEMARK OFFICE

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