

July 13, 2016

# Post-Grant for Practitioners

## Midyear Review of Decisions and Developments at the PTAB



**Dorothy Whelan**  
*Principal*

**Stuart Nelson**  
*Associate*

- Where? ... see invitation
- How often? ... monthly
- When? ... 2<sup>nd</sup> Wednesday
- Topics? ...
  - Important decisions
  - Developments
  - Practice tips
- Housekeeping
  - CLE
  - Questions
  - Materials
    - <http://fishpostgrant.com/webinars/>

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for Practitioners**

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### Midyear Review of Decisions and Developments at the PTAB

Join us for a midyear review and discussion of the latest Patent Trial and Appeal Board decisions in 2016. Fish attorneys [Dorothy Whelan](#) and [Stuart Nelson](#) will offer insights and best practices based on their experience, and project what's ahead for the second half of 2016. Topics include:

- Recent cases the PTAB identified as precedential
- Latest developments in biopharma IPRs

[Register](#) now for this Post-Grant for Practitioners Webinar.

Wednesday, July 13, 2016  
1:00 PM - 2:00 PM EST  
Via the web

Speakers:



[Dorothy Whelan](#)  
[whelan@fr.com](mailto:whelan@fr.com)  
Principal, Co-Chair  
Twin Cities



[Stuart Nelson](#)  
[snelson@fr.com](mailto:snelson@fr.com)  
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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 [mogovern@fr.com](mailto:mogovern@fr.com)



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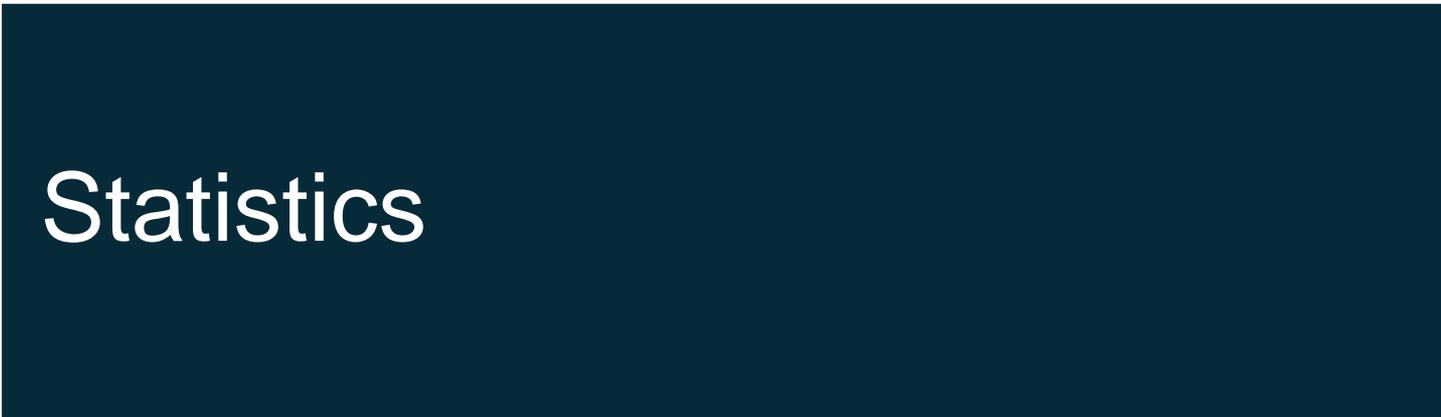


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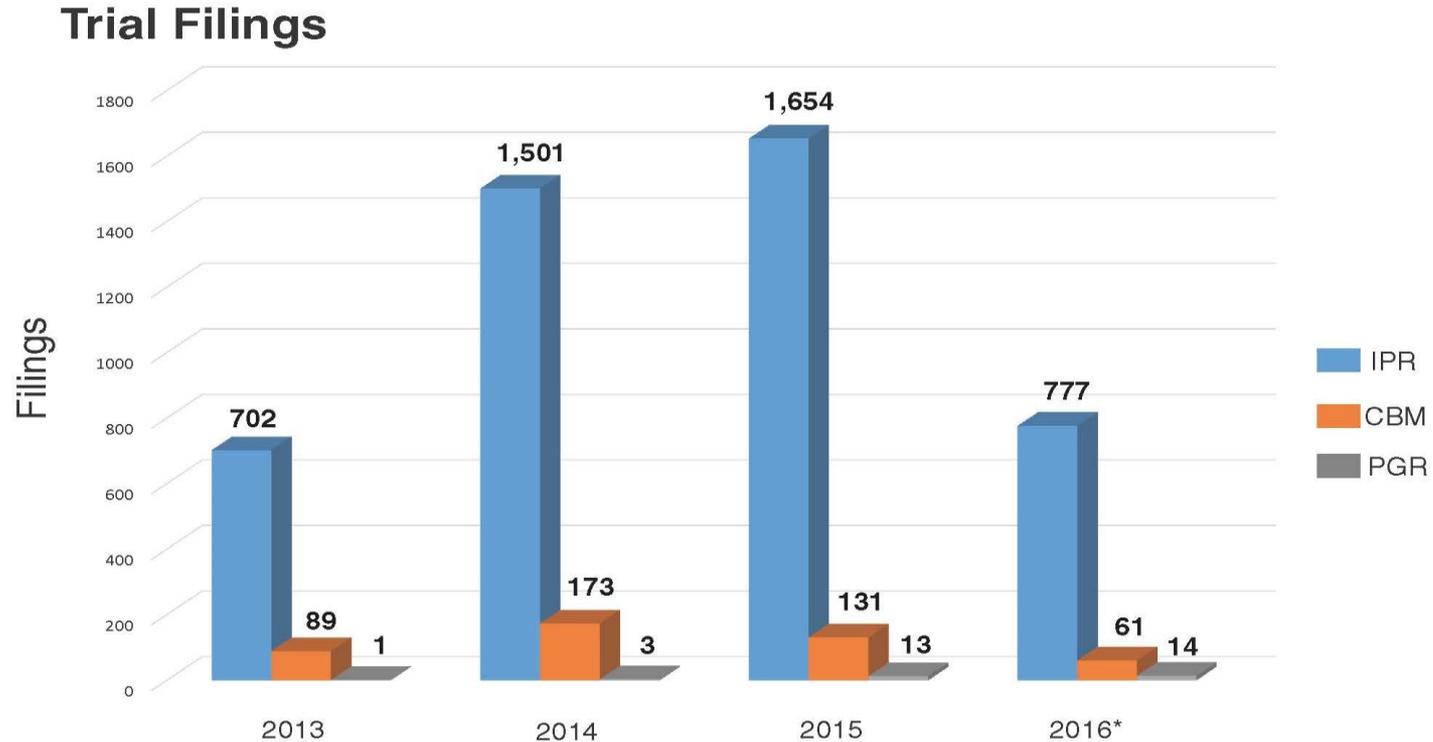
- I. Overview of Webinar Series
- II. Statistics
- III. Recent Cases and Decisions:
  - I. New evidence/arguments in reply brief: *Biomarin* and *SAS*
  - II. Late filings: *Teva* and *Samsung*
- IV. Other Developments
  - I. New Rules
  - II. Motion to Amend Study
- V. Upcoming Post-Grant Webinar
- VI. Post Grant Resources



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# PTAB Statistics and Trends

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\*2016 numbers are year-to-date. Numbers are through July 8, 2016.

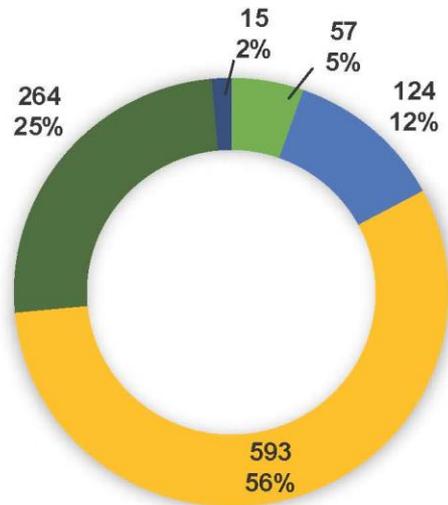
### Trial Status



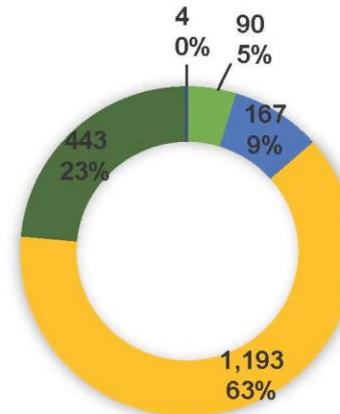
Source: LexMachina PTAB Trial Data, filed between 2013 and July 8, 2016.

# PTAB Statistics and Trends

918 Total AIA Petitions in FY 16\*  
(Technology Breakdown)

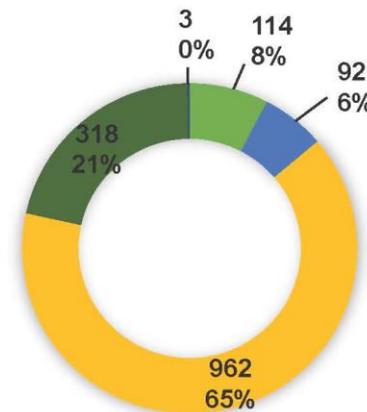


1897 Total AIA Petitions in FY 15\*  
(Technology Breakdown)



**Narrative:** The pie chart shows the total number of AIA petitions filed in the current fiscal year to date as well as the number and percentage of these petitions broken down by technology.

1489 Total AIA Petitions in FY 14\*  
(Technology Breakdown)



- Electrical/Computer - TCs 2100, 2400, 2600, 2800
- Mechanical/Business Method - TCs 3600, 3700
- Chemical - TC 1700
- Bio/Pharma - TC 1600
- Design - TC 2900

\*Data current as of 5/31/2016

Source: USPTO Patent Trial and Appeal Board Statistics, 5/31/2016



# Recent Cases and Decisions

# New Evidence/Arguments in Reply Briefs

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- 37 C.F.R. § 42.23(b): “A reply may only respond to arguments raised in the corresponding opposition, patent owner preliminary response, or patent owner response.”
- After petitioner files its reply, patent owner cannot file a surreply as a matter of right. Patent owner’s only recourse is to file a motion for observation regarding cross-examination of a reply witness IF petitioner submits a declaration with its reply and patent owner deposes the witness.
- Motions to exclude are designed to address evidentiary issues for which an objection was previously raised. Motions to exclude are not appropriate for addressing whether petitioner’s reply exceeds the scope of patent owner’s response.

# New Evidence/Arguments in Reply Briefs

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

- Federal Circuit affirms PTAB's determination that claims were unpatentable.
- 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. Although petitioner included both references in its petition, neither reference formed the basis of a proposed ground of unpatentability.
- In its institution decision, the PTAB did not include either reference in the grounds on which it granted the petition, nor did it discuss either reference substantively.
- 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.

# New Evidence/Arguments in Reply Briefs

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

- Patent owner 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.

# New Evidence/Arguments in Reply Briefs

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*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.

# New Evidence/Arguments in Reply Briefs

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*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 two 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.

# New Evidence/Arguments in Reply Briefs

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*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.
- The patentability determination was based on a claim construction that, though correct, significantly differed from the claim construction given by the PTAB in its institution decision.
- Patent owner did not challenge the Board's construction in its owner's response. Therefore, petitioner had no way of knowing that PTAB was contemplating a different construction and thus could not have addressed the new construction in its reply.

# New Evidence/Arguments in Reply Briefs

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*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.

# New Evidence/Arguments in Reply Briefs

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## Take-aways

- In *Biomarin*, both references were mentioned in the petition, although not used in a proposed ground.
  - Different result if petitioner had relied on references not of record?
  - Different result if references not mentioned in the petition but used to cross-examine expert during deposition?

# New Evidence/Arguments in Reply Briefs

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## Take-aways

- In *Biomarin*, the Federal Circuit stated that the patent owner could have filed a motion to exclude or sought leave to file a surreply.
- Is either a viable option?
- What should patent owners do if they suspect petitioner is relying on new evidence/arguments in its reply brief?
  - Request telephone conference with PTAB for guidance?
  - File a motion to exclude, even though the PTAB has stated in numerous decisions that this is not the purpose of motions to exclude?
  - See leave to file a surreply?

# Missed Filing Deadlines

*Teva Pharmaceuticals USA Inc. v. MonoSol RX LLC*, IPR2016-00281 and 00282 (PTAB May 23, 2016)

- Petitioner attempted to file two IPR petitions exactly one year after it was sued for patent infringement.
- 35 USC § 315(b) bars IPR if filed more than 1 year after a complaint alleging infringement was filed.
- In order to receive a filing date, petition must be filed and served before midnight EST.
- In Teva, petitioner began the filing process at 9:45 PM EST. However, due to technical issues with the PTAB's e-filing system, including rejections of payment, filing was not completed until shortly after midnight. The petitions were not served until after 3 AM.

# Missed Filing Deadlines

*Teva Pharmaceuticals USA Inc. v. MonoSol RX LLC*, IPR2016-00281 and 00282 (PTAB May 23, 2016)

- The PTAB held that the petitions were time-barred. The PTAB stated it was not aware of any technical with the processing system and that petitioner failed to present “objective evidence” to back its claim. As to the payment rejections, the PTAB noted that in one instance the credit card exceeded its daily limit and in another the deposit account had insufficient funds.
- The PTAB further stated:  
“Waiting until the last minute—without explanation—is ill advised and had petitioner not done so, any alleged delays caused by ‘technical issues’ would have been moot.”

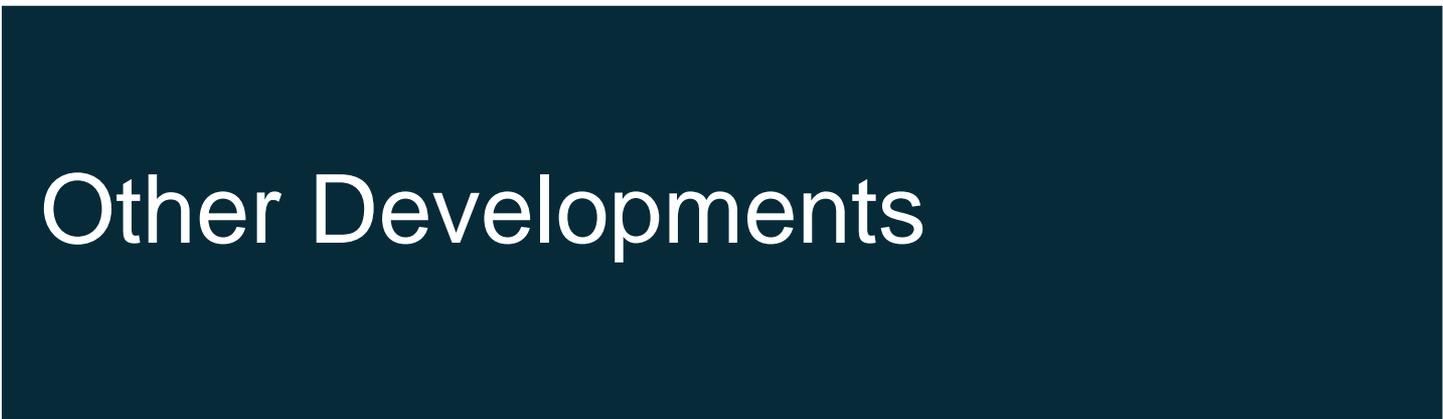
*Teva Pharmaceuticals USA Inc. v. MonoSol RX LLC*, IPR2016-00281 and 00282 (PTAB May 23, 2016)

- Would there have been a different result if petitioner had been able to demonstrate, with objective evidence, that problems with the PTAB's filing system caused the delay?
- As the party filing the papers, do you want to take that risk?
  - Filing takes a lot longer than you might think, particularly if you are uploading a large number of exhibits.
  - Note that in order to get a filing date, you must file AND serve.

# Missed Filing Deadlines

*Samsung Electronics Co., Ltd. et al. v. Elm 3DS Innovations LLC*, IPR2016-00386, 00388, and 00390 (PTAB June 30, 2016)

- Petitioner also filed petitions more than one year after being sued for infringement.
- PTAB held that petitions were not time-barred. One year date was December 24, 2015. However, due to a massive power outage at the USPTO on December 22, 2015, the PTO stated that 12/22/15 to 12/24/15 would be regarded as federal holidays. This meant that any filings normally due during that period would be due on the next business day (12/28/15).
- Samsung filed its petitions on 12/28/15.



Other Developments

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- “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)
  - Word limits instead of page limits;
  - Declarations allowed with preliminary response
- Revised Trial Practice Guide (TBD)

# Does Your Webpage Have The Latest Rules?

[www.bitlaw.com](http://www.bitlaw.com)



## 42.24 PAGE LIMITS FOR PETITIONS, MOTIONS, OPPOSITIONS, AND REPLIES.

(a) Petitions and motions.

(1) The following page limits for petitions and motions apply and include any statement of material facts to be admitted or denied in support of the petition or motion. The page limit does not include a table of contents, a table of authorities, a certificate of service, or appendix of exhibits or claim listing.

(i) Petition requesting inter partes review: 60 pages.

- Still lists old rules on page limits

# Does Your Webpage Have The Latest Rules?

[www.federalregister.gov](http://www.federalregister.gov)



4. Section 42.24 is revised to read as follows:

 § 42.24 Type-volume or page-limits for petitions, motions, oppositions, and replies.

(a) *Petitions and motions.* (i) The following word counts or page limits for petitions and motions apply and include any statement of material facts to be admitted or denied in support of the petition or motion. The word count or page limit does not include a table of contents, a table of authorities, grounds for standing under § 42.104, § 42.204, or § 42.304, mandatory notices under § 42.8, a certificate of service or word count, or appendix of exhibits or claim listing.

(i) Petition requesting *inter partes* review: 14,000 words.

- Included the new rules, but with an error that was corrected before the effective date

# Does Your Webpage Have The Latest Rules?

[www.ecfr.gov](http://www.ecfr.gov)



## §42.24 Type-volume or page-limits for petitions, motions, oppositions, and replies.

(a) *Petitions and motions.* (1) The following word counts or page limits for petitions and motions apply and include any statement of material facts to be admitted or denied in support of the petition or motion. The word count or page limit does not include a table of contents, a table of authorities, mandatory notices under §42.8, a certificate of service or word count, or appendix of exhibits or claim listing.

(i) Petition requesting *inter partes* review: 14,000 words.

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**e-CFR data is current as of July 7, 2016**

[Title 37](#) → [Chapter I](#) → [Part 42](#)

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[www.law.cornell.edu](http://www.law.cornell.edu)



**§ 42.24 Type-volume or page-limits for petitions, motions, oppositions, and replies.**

**(a) *Petitions and motions.***

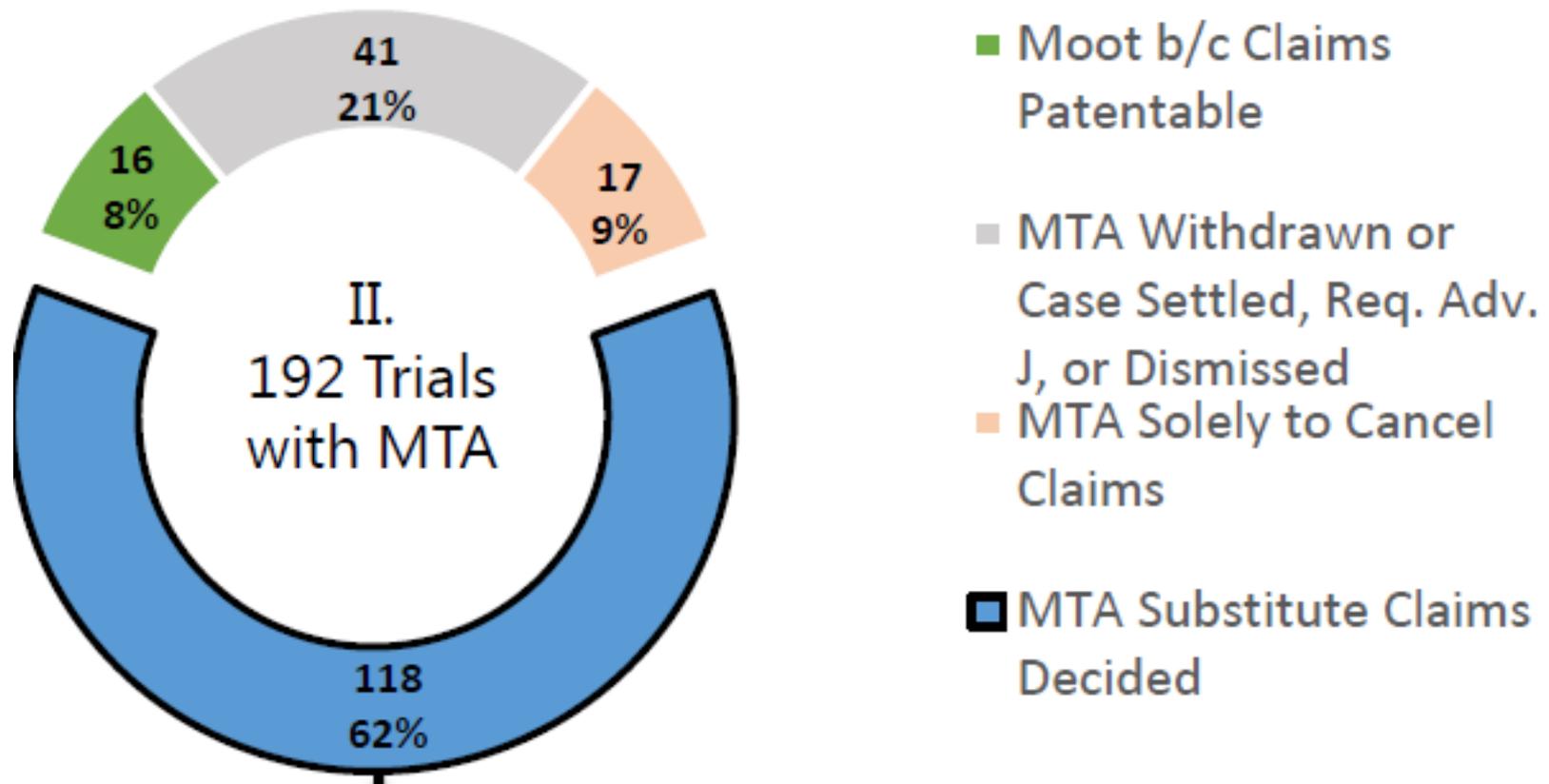
**(1)** The following word counts or page limits for petitions and motions apply and include any statement of material facts to be admitted or denied in support of the petition or motion. The word count or page limit does not include a table of contents, a table of authorities, mandatory notices under § 42.8, a certificate of service or word count, or appendix of exhibits or claim listing.

**(i)** Petition requesting *inter partes* review: 14,000 words.

- Cornell has it correct *now*
- But erroneously had “grounds for standing” still in the exceptions for a time

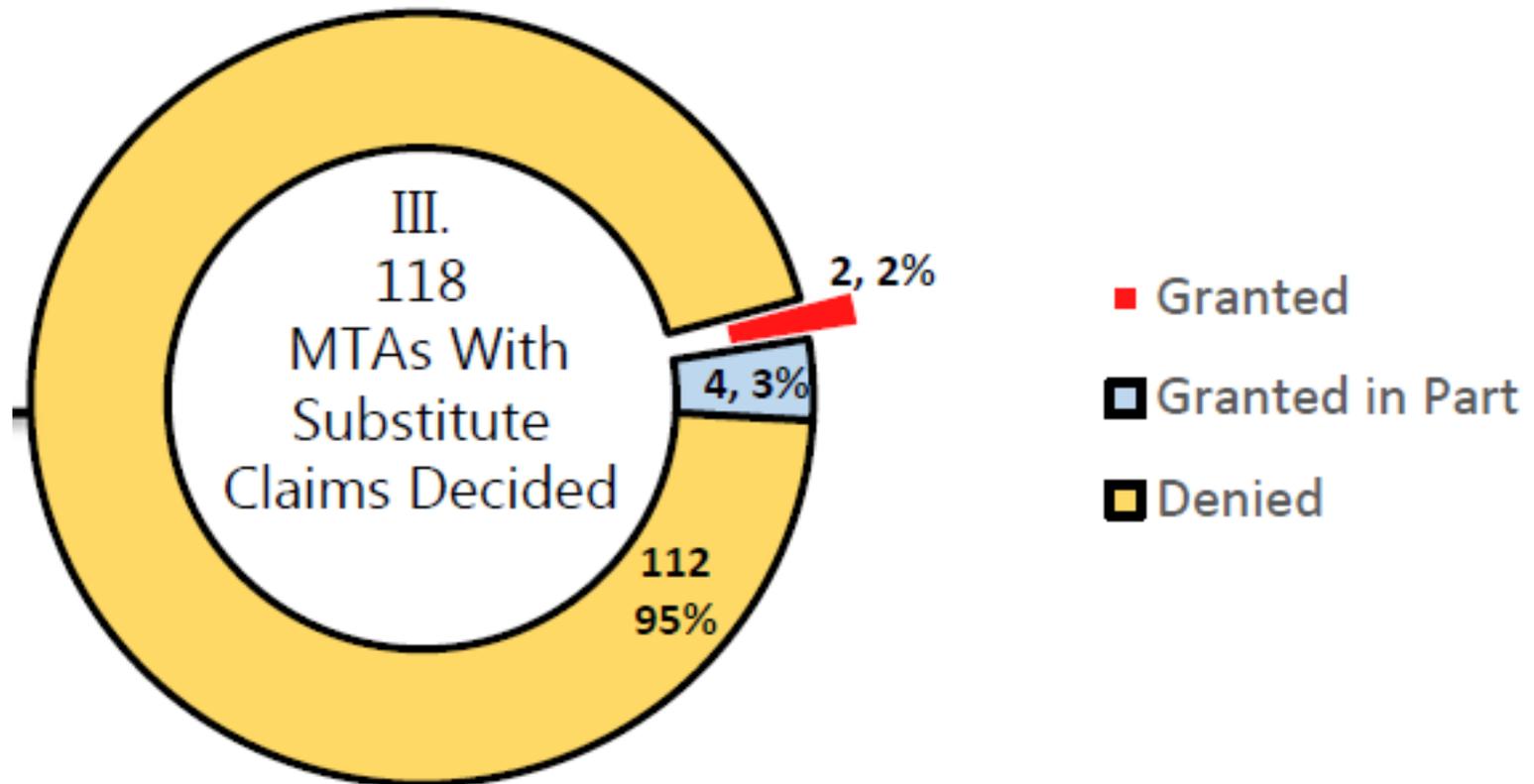
# Motion to Amend Study

## Subsequent Developments of the Motions to Amend



# Motion to Amend Study

## How Many Motions to Amend Substituting Claims Are Granted?



# Motion to Amend Study

## Reasons Provided for Denying Entry of Substitute Claims\*

<i>Reason Given</i>	<i># of Cases</i>	<i>Pct</i>
<b><i>Reasons Based in Whole or Part on 35 U.S.C.:</i></b>		
101 Non-Statutory Subject Matter	7	6%
112(a) Written Description	9	8%
112(b) Definiteness	1	1%
102/103 Anticipated/Obvious Over Art of Record	41	35%
316(d)(3) Claims Enlarge Scope of Patent	6	5%
316(d)(1)(B) Unreasonable # Substitute Claims	3	3%
Multiple Statutory Reasons Given**	27	23%
<b><i>Reasons Based Solely on Procedure:</i></b>		
Cases Where Only Procedural Reasons Given	22	19%
<b><i>Totals:</i></b>	<b>116</b>	<b>100%</b>

\* 116 MTAs requesting entry of substitute claims have been denied in whole or in part.

\*\* Of the "Multiple Statutory Reasons Given" trials, 24 of the 27 trials included "Anticipated/Obvious" as a reason.

# Motion to Amend Study

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Fish Post-Grant Radio: A monthly series of podcasts dedicated to the discussion of developments in post-grant proceedings before the Patent Trial and Appeal Board and related practice tips.

Our host [Stuart Nelson](#), an attorney in our Twin Cities office, will talk with practitioners and thought leaders across the country to discuss a wide range of post-grant topics. Be sure to visit [fishpostgrant.com](#) to listen to all of our past episodes and to subscribe to this podcast! To listen on-the-go, please download [our app](#). You can also follow us on Twitter [@fishpostgrant](#) or subscribe by choosing one of the methods below.

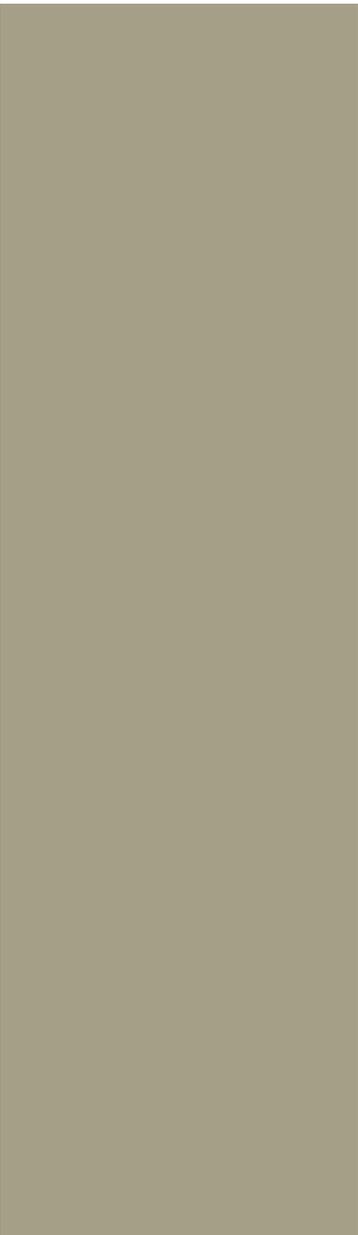


- Podcast available at:
- [fishpostgrant.com/podcasts/](#)
  - iTunes

## Fish Post-Grant Radio: Episode #3: Tom Rozylowicz

This episode of Fish Post-Grant Radio features Tom Rozylowicz, Fish Principal and a member of our Post-Grant Practice, who talks about the Patent Trial and Appeal Board's recent "Motion to Amend" Study.

A screenshot of a SoundCloud player interface. On the left is a portrait of Tom Rozylowicz with a "FISH. Post-Grant (RADIO)" logo and a "Cookie policy" link below. To the right is a play button icon, the text "Fish &amp; Richardson" and "Fish Post-Grant Radio | Episode #3: Tom Rozyl...", and a "Share" button. Below the text is a waveform visualization and a "20:15" duration indicator. At the bottom right is a play button and the number "21".

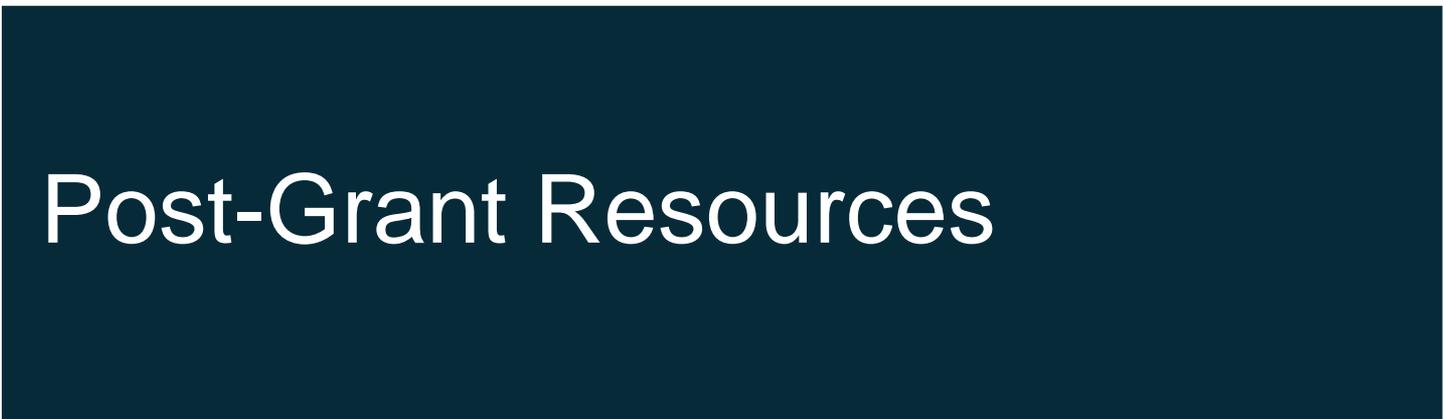


# Post-Grant for Practitioners Webinar Series

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## Mark your Calendar!

Our next Post-Grant for Practitioners webinar will be on  
**August 10, 2016 (1:00pm-2:00pm EDT)**



# Post-Grant Resources

- Fish web sites:
  - 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](http://www.uspto.gov/aia_implementation/index.jsp)
  - Inter Partes: [http://www.uspto.gov/aia\\_implementation/bpai.jsp](http://www.uspto.gov/aia_implementation/bpai.jsp)

# Thank You!

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