Sourcebook Webinar Series:
Post-Grant Considerations: What Startups Need to Know

August 3, 2022

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Meet The Speakers

Chad Shear
Principal

Kenneth Darby
Principal

Overview

- **Housekeeping**
  - CLE
  - Questions
  - Materials
    - http://www.fr.com/webinars

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+ Complimentary CLE Webinar

Post-Grant for Practitioners: 2022 Mid-Year Review

SIGN ME UP

DATE
Thursday
August 11, 2022

TIME
1:30 – 2:30 p.m. ET/
10:30 – 11:30 a.m. PT

Webinar | Post-Grant for Practitioners: 2022 Mid-Year Review

In April 2022, Kathi Vidal assumed office as Director of the United States Patent and Trademark Office, ushering in a new era for the agency. With new guidance concerning *Fintiv* denials, an updated interim process for Director review, and the introduction of major reform legislation, 2022 is shaping up to be a busy year in the post-grant world. If you have missed some of these developments, now is a good time to catch up.

Complimentary Webinar
Thursday, August 11, 2022
1:30 - 2:30 p.m. ET

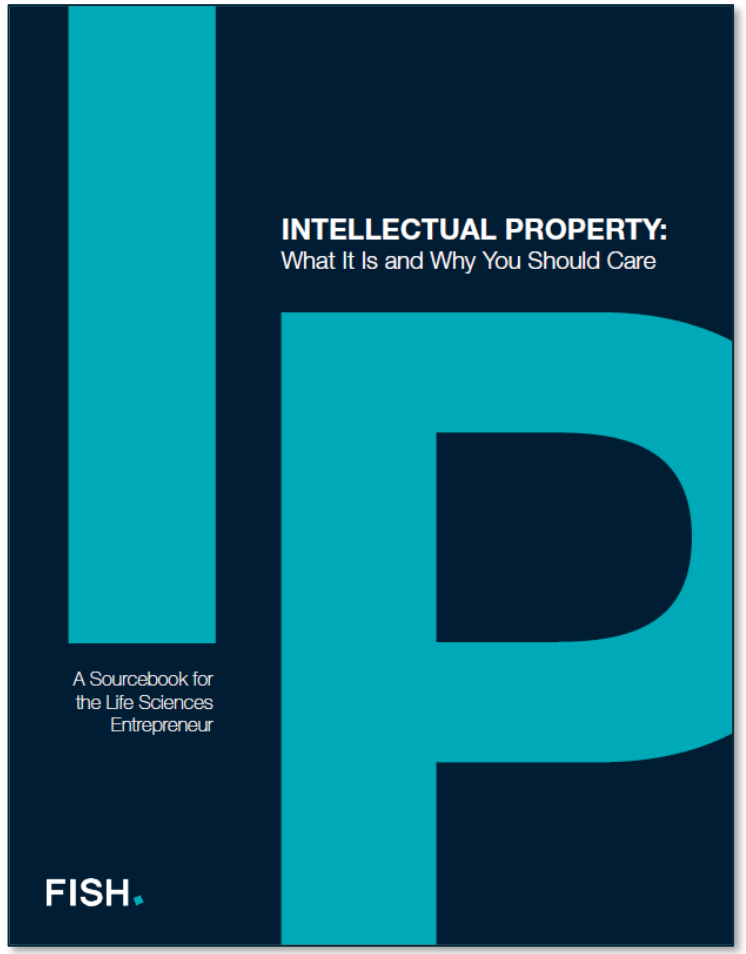
REGISTER

On Thursday, August 11, Fish attorneys Casey Kraning and Nick Stephens will provide a mid-year review of developments in post-grant practice. Our hosts will discuss:

- The USPTO's updated *Fintiv* guidance
- The USPTO's updated applicant admitted prior art guidance
- Proposed PTAB legislation
- Clarification of the scope of IPR estoppel
- An overview of cases selected for Director review

We hope you can join us!

A Shameless Plug . . . The Sourcebook



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Goals

- **Create Lasting Value**
  - Positive review during diligence
  - Survive attack at the Patent Office
  - Able to successfully assert in District Court
- **Create Freedom to Operate**
- **Create Prior Art**

Types of Post Grant Proceedings

PROCEEDING	WHEN DOES IT APPLY?	LEGAL STANDARD	GROUNDS (PRIOR ART)	ESTOPPEL?
PGR — Post-Grant Review (9-month window)	• First available on Sept. 16, 2012 • Applies only to patents having a claim with a priority date on or after March 16, 2013	• More likely than not that at least one claim is unpatentable	• Any invalidity ground	• Raised or reasonably could have raised
IPR — *Inter Partes* Review	• First available on Sept. 16, 2012 • Applies to all patents	• Reasonable likelihood that petitioner would prevail on at least one claim	• Patents • Published patent apps • Printed publications	• Raised or reasonably could have raised

*Covered Business Method Review (CBM) had been a third option for challenging patent validity but is no longer available as of September 2020.

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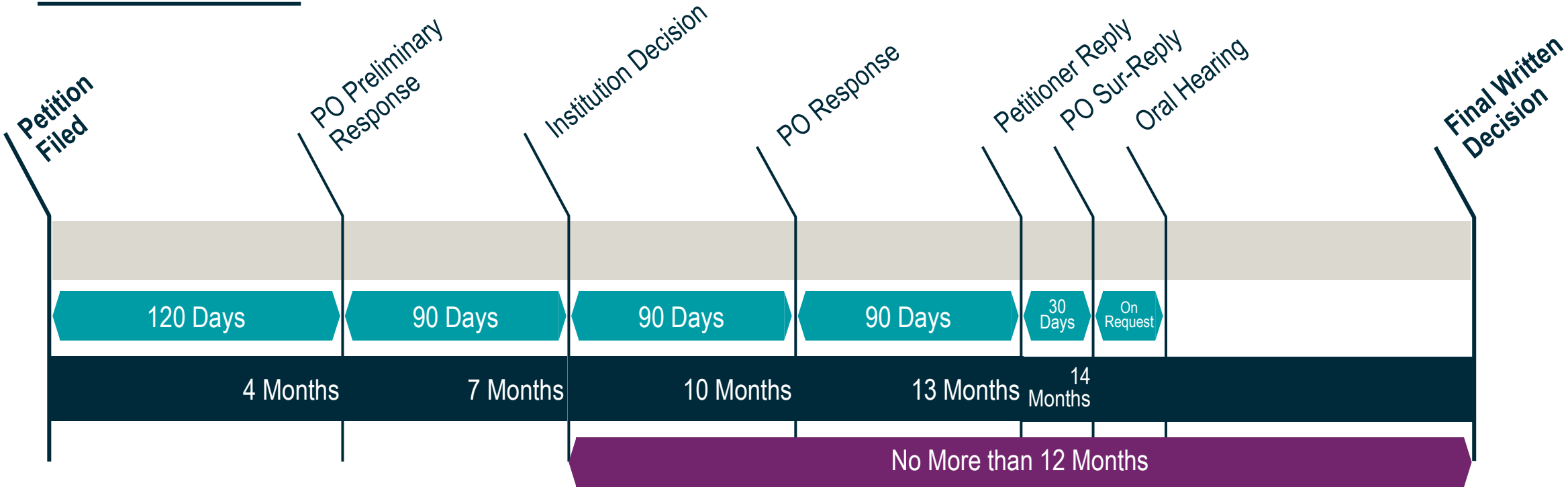
Types of Post Grant Proceedings

IPR Timeline



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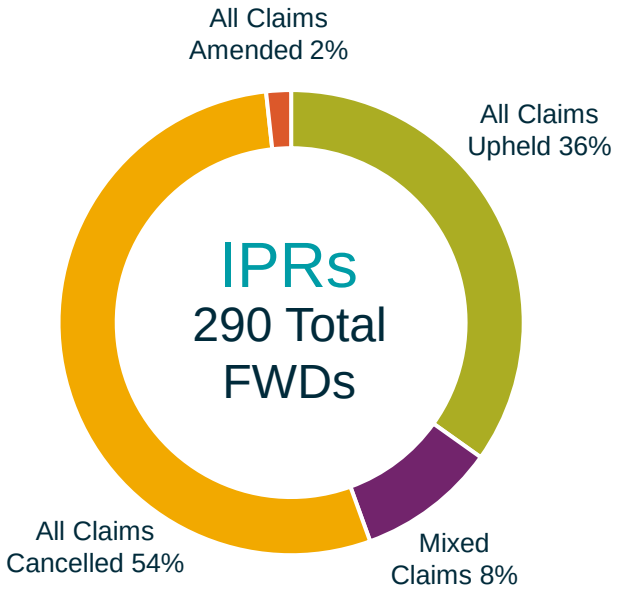
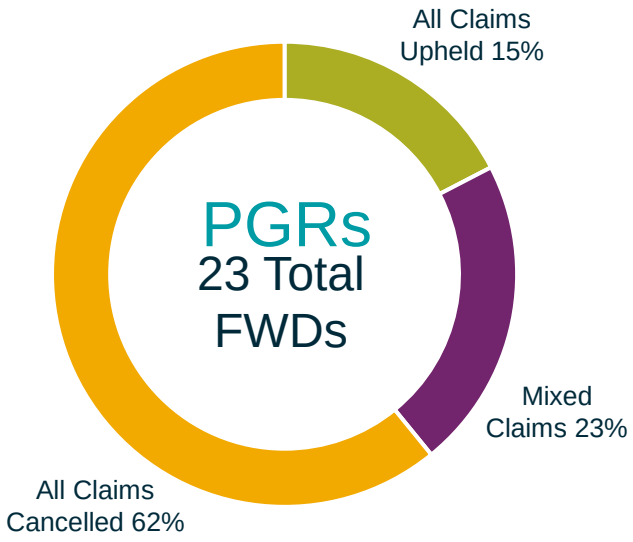
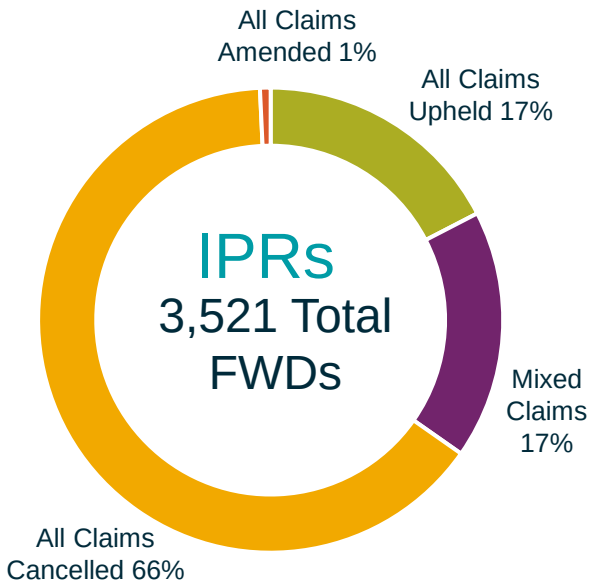
Success at the PTAB for BioPharma vs All Others

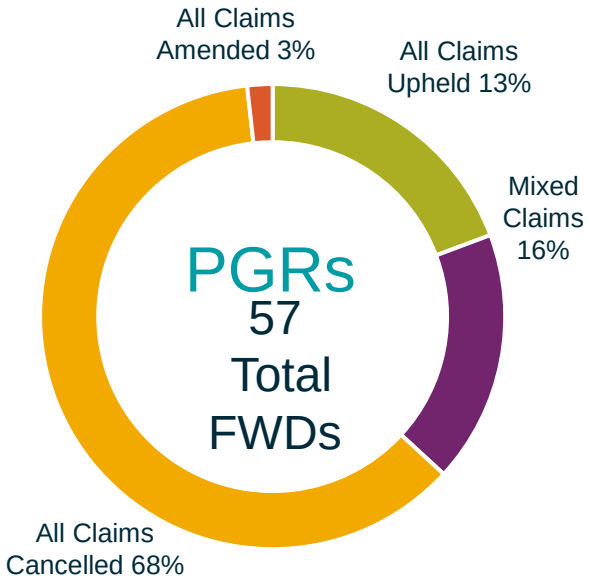
Group 1600





All Other Technologies





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Data taken from Lex Machina on 8/2/2022

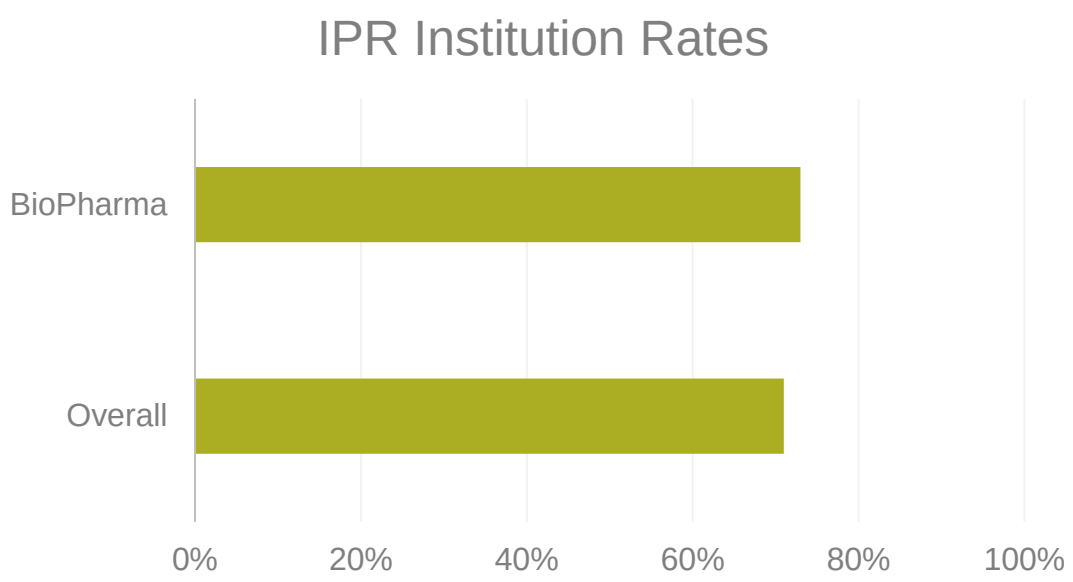
Institution Rates for BioPharma

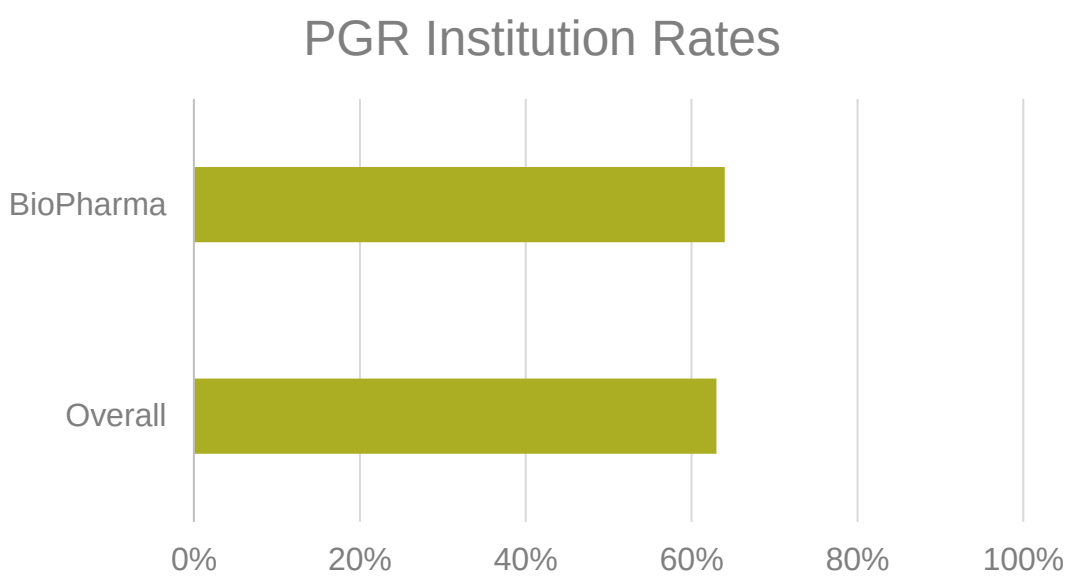
IPRs

- **Filed to Date: 1,199**
- **Reached Institution Decision: 874**
- **Institution Rate: 73%**

PGRs

- **Filed to Date: 104**
- **Reached Institution Decision: 67**
- **Institution Rate: 64%**

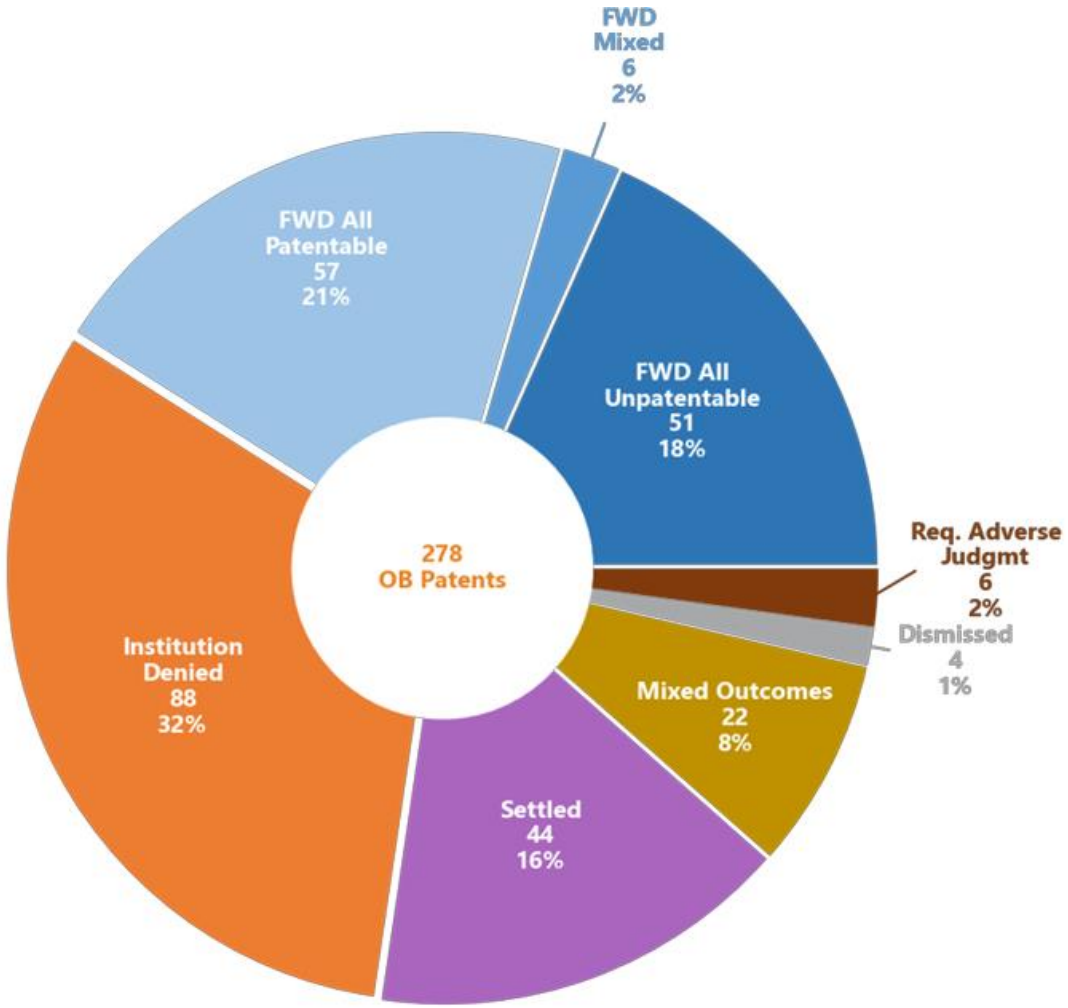




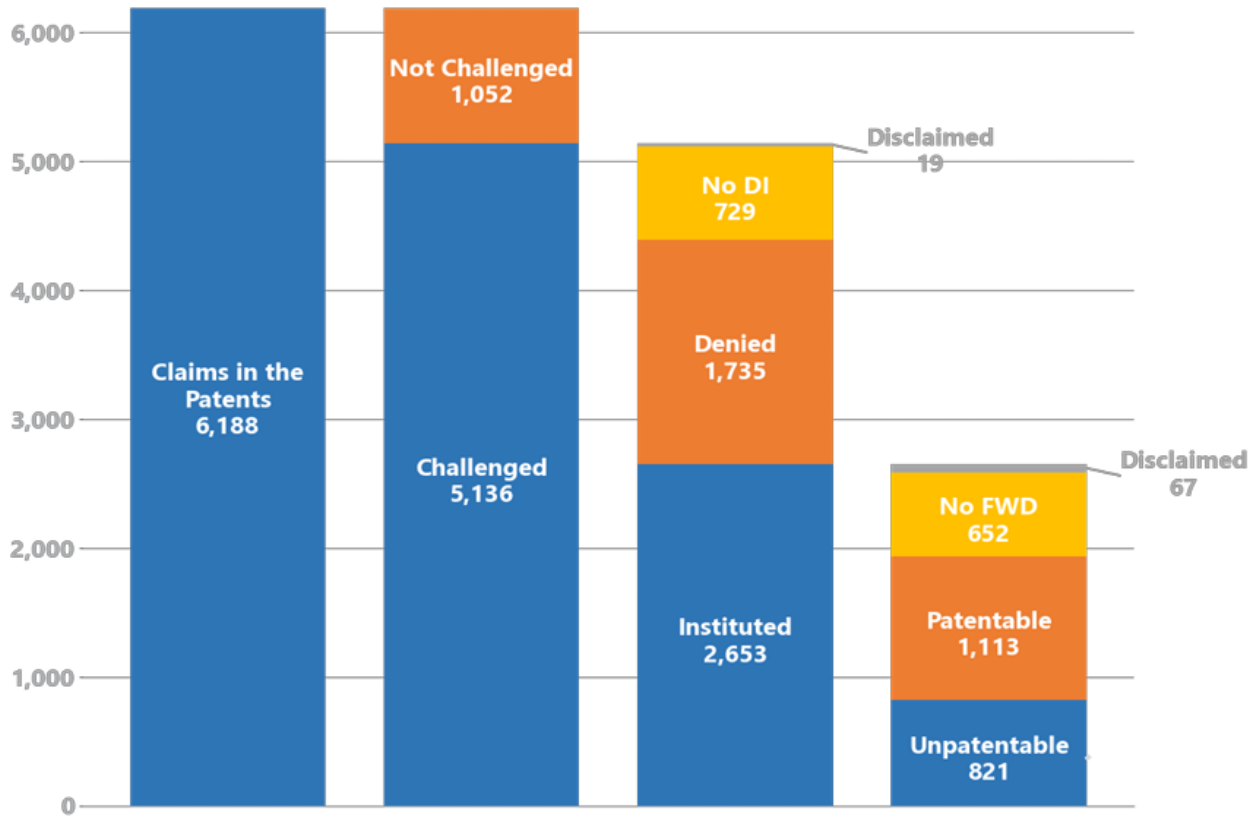
Data taken from Lex Machina on 8/2/2022

PTAB Outcomes for Orange Book Patents

Outcomes Per Patent



Outcomes Per Claim



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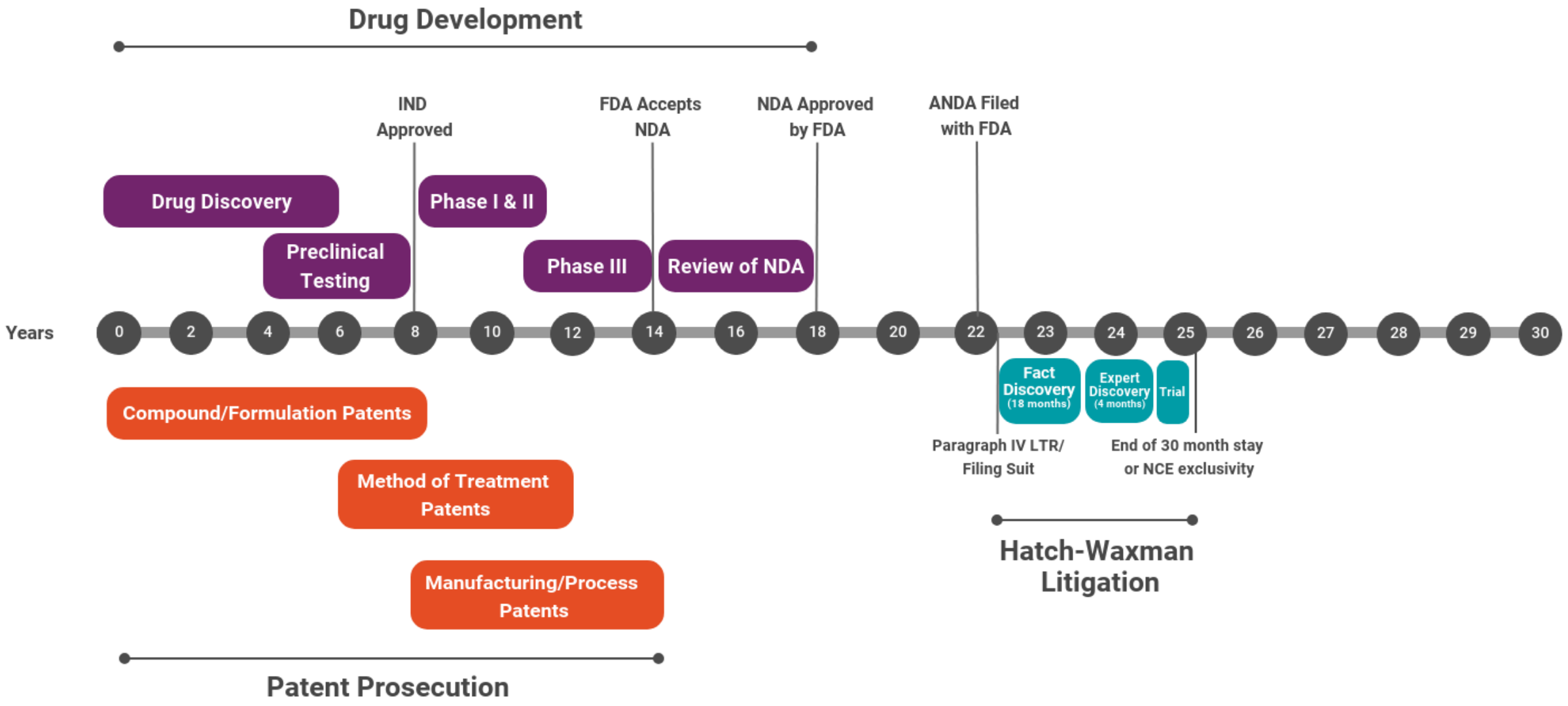
Data and charts taken from United States Patent and Trademark Office, "PTAB Orange Book patent/biologic patent study," FY21 Q3 (June 2021) Update

Claim Drafting To Improve Your Chances of Success

Drug Discovery and Patent Timeline



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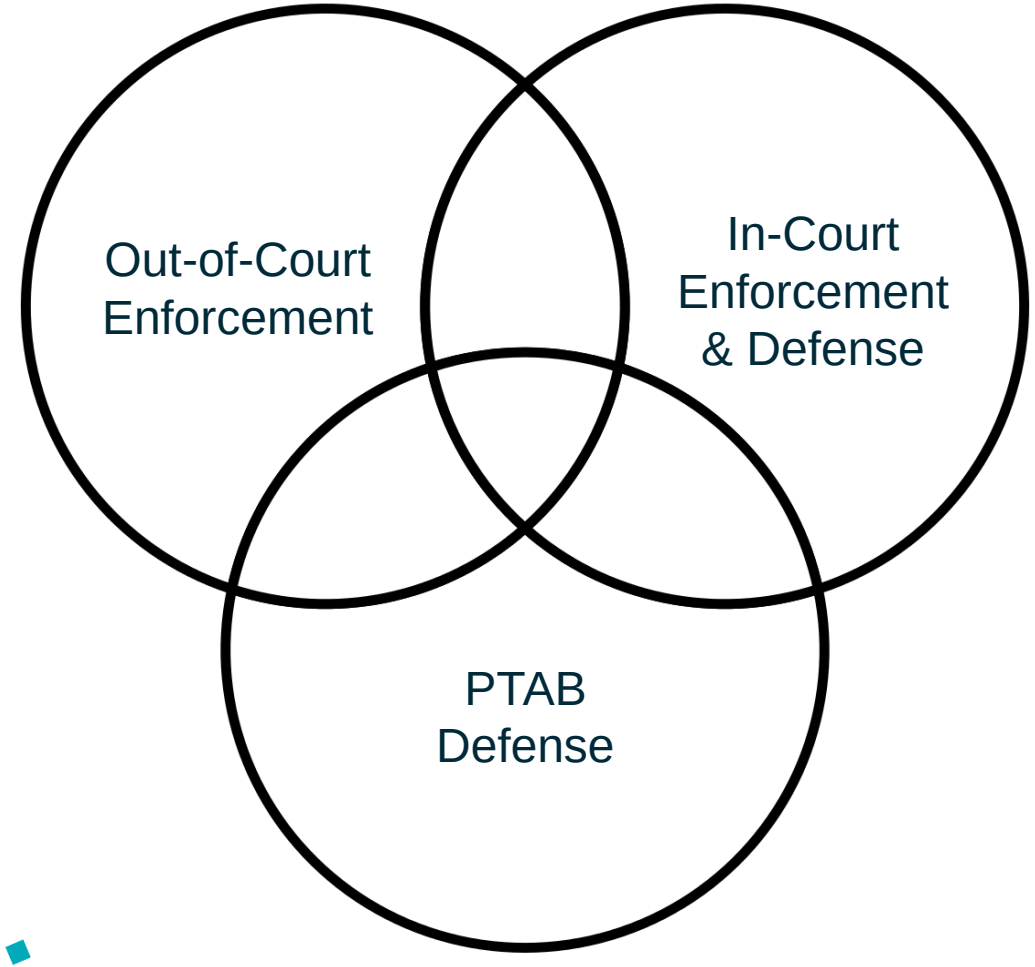
Claim Drafting

Drafting With the PTAB in Mind



Claim Drafting

Drafting With the PTAB in Mind

- **Your Audience:** Patent judges with technical and legal expertise
  - Expect hyper-focus on the claim language
  - Expect scrutiny of the petitioner's mapping and motivation arguments but willingness to accept combinations
- **Your Opponent:** Motivated accused infringer (most likely)
  - Expect better prior art than in prosecution
  - Expect corroborated expert testimony framing the claimed subject matter as "well known"
- **Your Goal:** Save at least the asserted claims
  - Denial of institution is your best bet
  - The patent is only as strong as its broadest claim at institution

Claim Drafting

The Basics

- The ***more*** claims, the better
- Build a ***complex*** claim set
  - Varying scope
  - Diverse language and type
  - Targeted dependent claims
  - Nested dependent claims
  - Means-plus-function claims

Claim Drafting

Recite the Interrelationships

- ***Mix***, don't ***stack***, claim limitations
  - Stacked limitations can be attacked with disparate prior art teachings
  - Mixed limitations demand logically and technically correlated teachings

Claim Drafting

Recite the Interrelationships

Smith & Nephew v. ConforMIS (IPR2017-00372, Paper 7 at 13-14)

- ***Mixing*** the "patient-specific surface" and "guide" limitations supports denial

1. A patient-specific instrument system …comprising:

a patient-specific surface for engaging at least a portion of a substantially uncut joint surface of the diseased or damaged knee joint of the patient…; and

a guide for directing a surgical instrument, ***wherein the guide has a predetermined position relative to <u>the patient-specific surface</u>***…; wherein the guide defines a drilling path through at least a portion of the knee joint…

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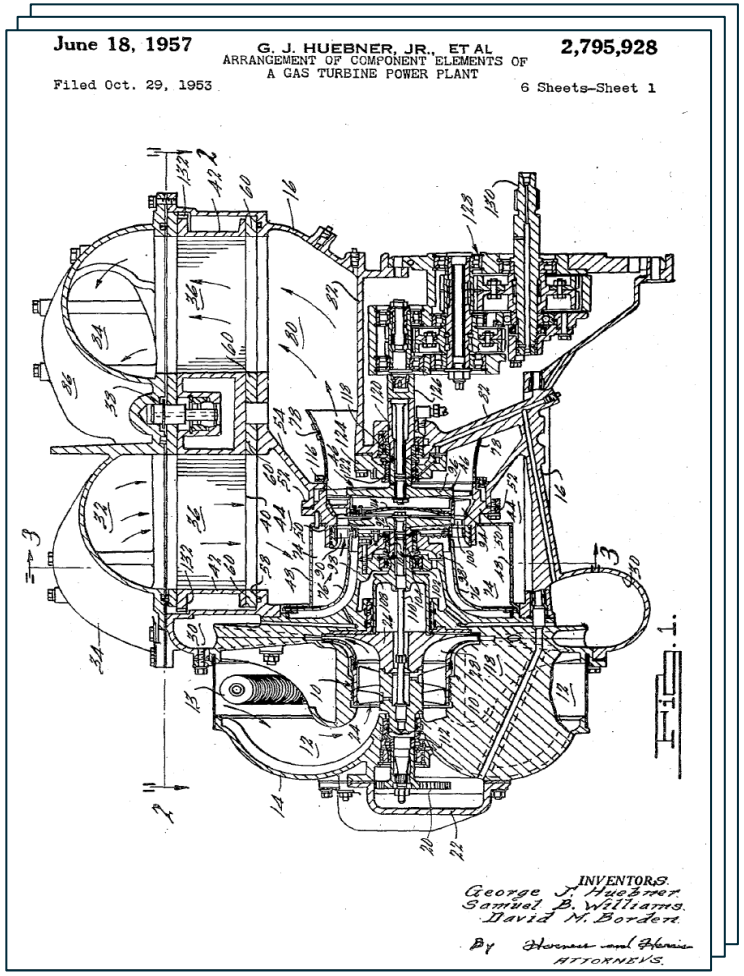
Claim Drafting

Consider Contextual Limitations

- **What?** Limitations placing the point of novelty in a specific setting
- **When?** Novelty relates to the setting, and the setting has value
- **Where?** In the body of the claim (not the preamble)
- **Why?**
  - Distinguish unforeseen prior art
  - Strain potential prior art combinations
  - Support the invention story

Claim Drafting

Consider Contextual Limitations



June 18, 1957 G. J. HUEBNER, JR., ET AL 2,795,928
ARRANGEMENT OF COMPONENT ELEMENTS OF A GAS TURBINE POWER PLANT
Filed Oct. 29, 1953 6 Sheets-Sheet 1

INVENTORS.
George J. Huebner
Samuel B. Williams
David M. Borden
By Harness and Johnson
ATTORNEYS.

Claim Drafting

Strategically Reinforce Structural Limitations With Functional Language

- **When?** Function further defines or clarifies key structure
- **How?**
  - Start with novel structure; add function emphasizing structural novelty
  - Describe the link between structure and function in the specification
- **Why?**
  - The Board will give weight to proper functional language
  - Distinguish unforeseen prior art
  - Support the invention story

Claim Drafting

Strategically Reinforce Structural Limitations With Functional Language

- **Exemplary CAFC Decisions**
  - *Aspex Eyewear v. Marchon Eyewear*, 672 F.3d 1335, 1349 (Fed. Cir. 2012)
  - *In re Giannelli*, 739 F.3d 1375, 1379-81 (Fed. Cir. 2014)
  - *ParkerVision v. Qualcomm*, 903 F.3d 1354, 1361 (Fed. Cir. 2018)

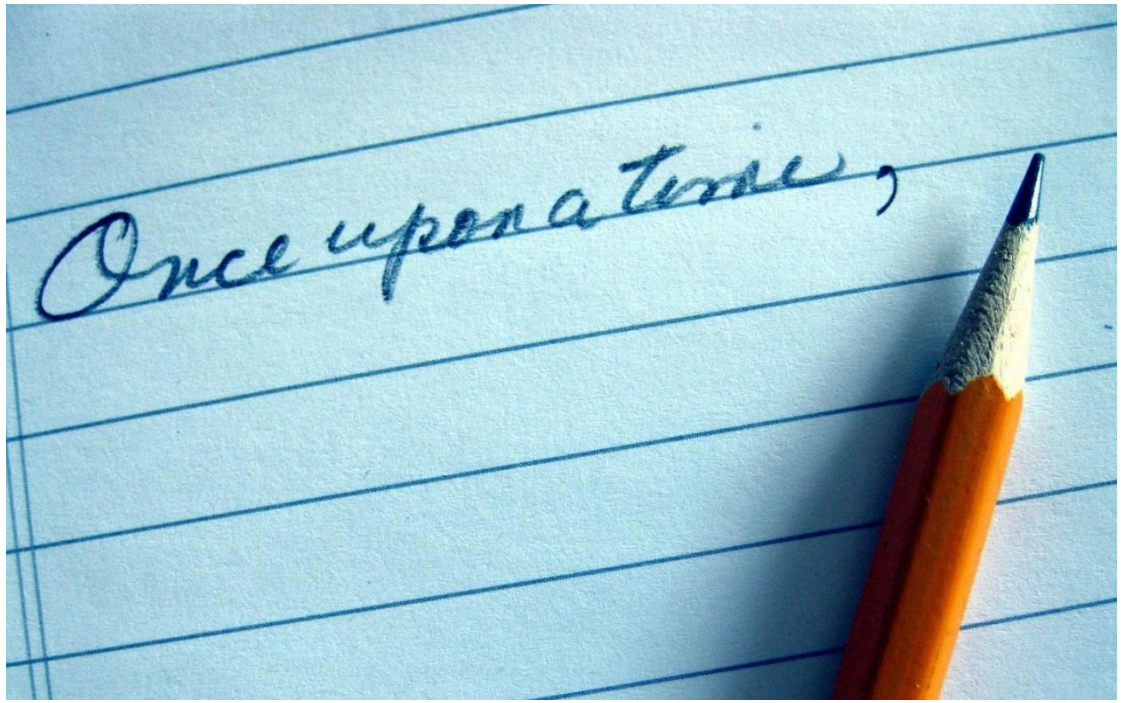
- **Exemplary PTAB Decisions**
  - *Wirtgen America v. Caterpillar Paving Prods*., IPR2018-01199 (Paper 10)
  - *Roland Corp. v. inMusic Brands*, IPR2018-00332 (Paper 12)
  - *Robert Bosch Tool Corp. v. SD3, LLC*, IPR2016-01753 (Paper 15)

Specification Drafting

Why the Invention Story Matters at the PTAB

"In a lawsuit, the first to speak seems right, until…"

- **Counter-balance a one-sided petition**
- **Distinguish your case by highlighting a real-world problem**
- **Bring technical and legal arguments to life**
- **Show the state of the art before the invention**



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Build Out Your Story

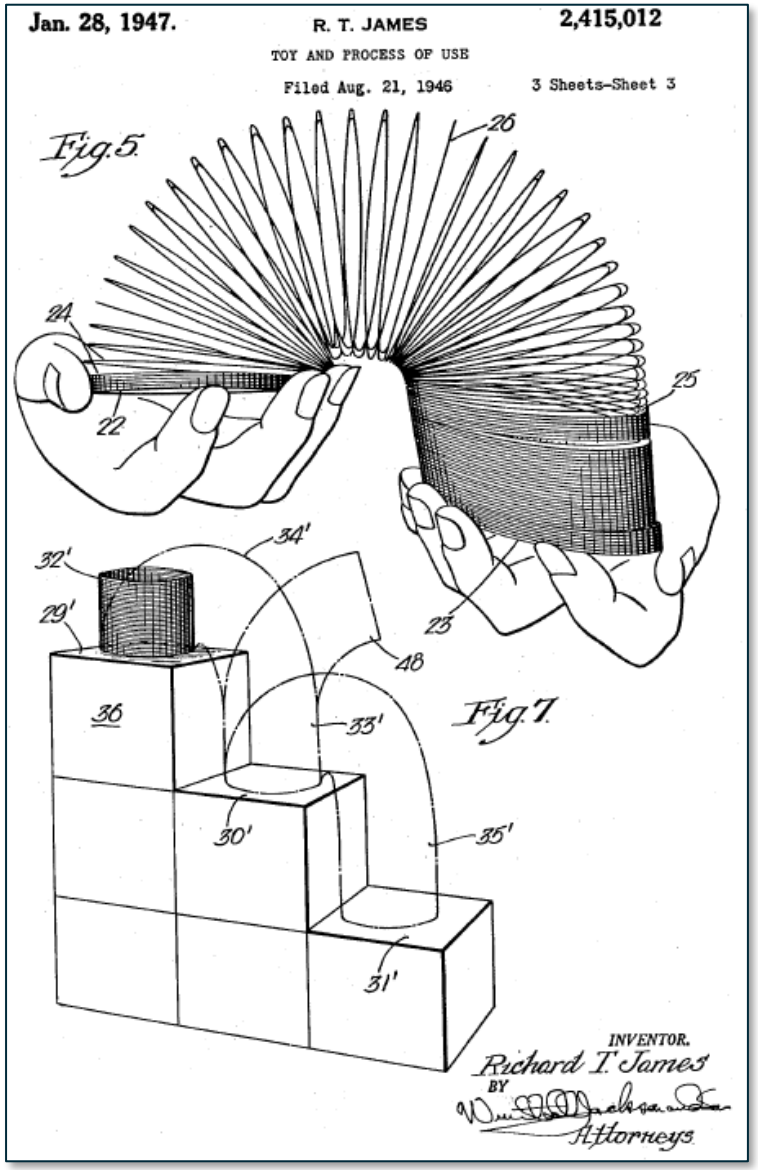
- Talk about the advantages
  - Don’t stop at the overall advantages, but also consider the advantages of individual aspects of the invention
- Not just how, but why?
  - Why were important decisions made?
- Ask inventor(s) about alternative approaches and pros/cons of each
- Don’t be afraid of your own failures

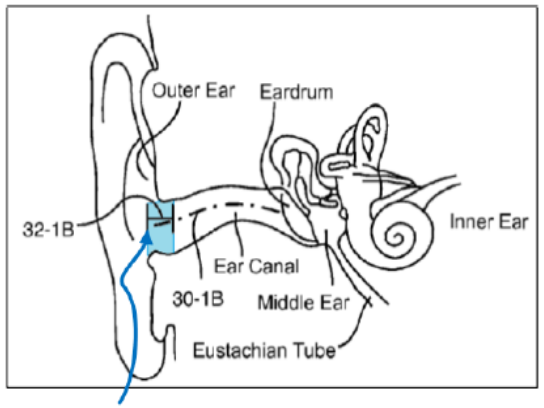
Build Out Your Story

- Think big: Describe the broader context
  - How does the invention interact with and affect the broader system in which it exists?
- Tier your description: describe things at varying levels of granularity

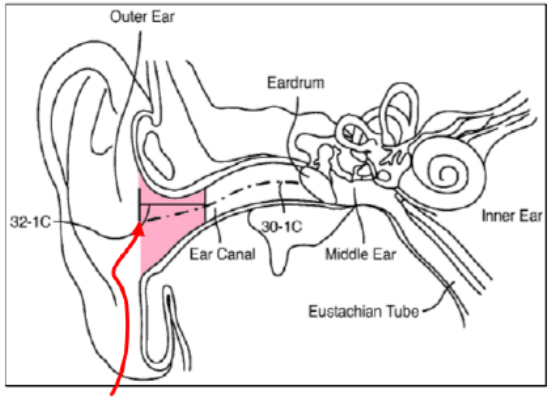
But Don’t Trip Over Your Own Tongue

Figures





"[I]n the cross section of FIG. 1B, there is a relatively sharp transition from ear canal walls that are non-parallel to a centerline 30-1B of the ear canal to walls that are substantially parallel to a centerline of the ear canal, so the entrance 32-1B to the ear canal in relatively short." Ex. 1001, 2:60-65.



"In the cross-second of FIG. 1C, there is a more gradual transition from walls that are non-parallel to a centerline of the ear canal to walls that are substantially parallel to a centerline 30-1C of the ear canal, so the entrance 32-1C to the ear canal is relatively long." Ex. 1001, 2:65-3:2.

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Tracking Secondary Considerations of Non-Obviousness

Tracking Secondary Considerations of Non-Obviousness

"evidence of secondary considerations may often be the most probative and cogent evidence in the record"

- **Solving a long-felt but unsolved need**
- **Failure of others**
- **Unexpected results**
- **Commercial success**
- **Copying**
- **Licensing**
- **Industry praise**
- **Industry skepticism**

Tracking Secondary Considerations of Non-Obviousness

Rewards Outweigh Challenges

- Fact intensive
- Few opportunities
- Short timelines
- Relatively high bar

- Combats obviousness
- Saves claims when there is a close call
- Builds positive narrative
- Complicates petitioner's reply

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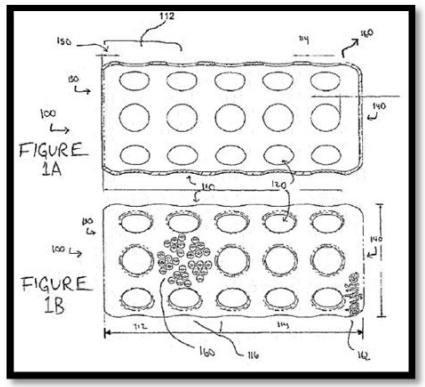
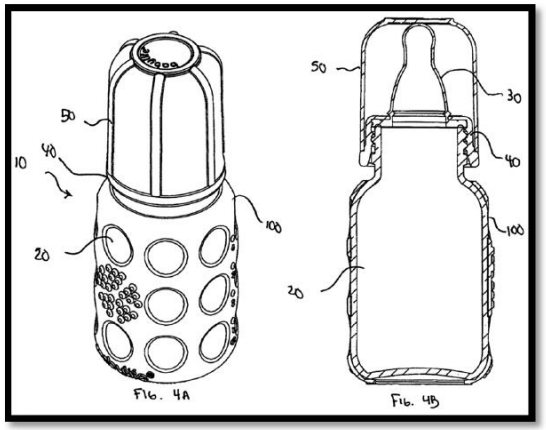
Tracking Secondary Considerations of Non-Obviousness

Saves Claims When There Is a Close Call

extrusion as indicated by Mr. Goldman. For these reasons, we determine that Leapfrog has established by a preponderance of evidence that an ordinarily skilled artisan would have found it obvious to have made Thoreson's casing using a molding process as required in claims 1–5, 7, 9, 10, 12–17, and 19–21.[2]



Based on our review of the record, we determine that Lifefactory has provided strong evidence that the features of claim 20 drove significant commercial success and garnered notable industry praise. We also find Leapfrog's attempts to discount the probative value of Lifefactory's evidence of non-obviousness to be unpersuasive.



Building a Prosecution Record

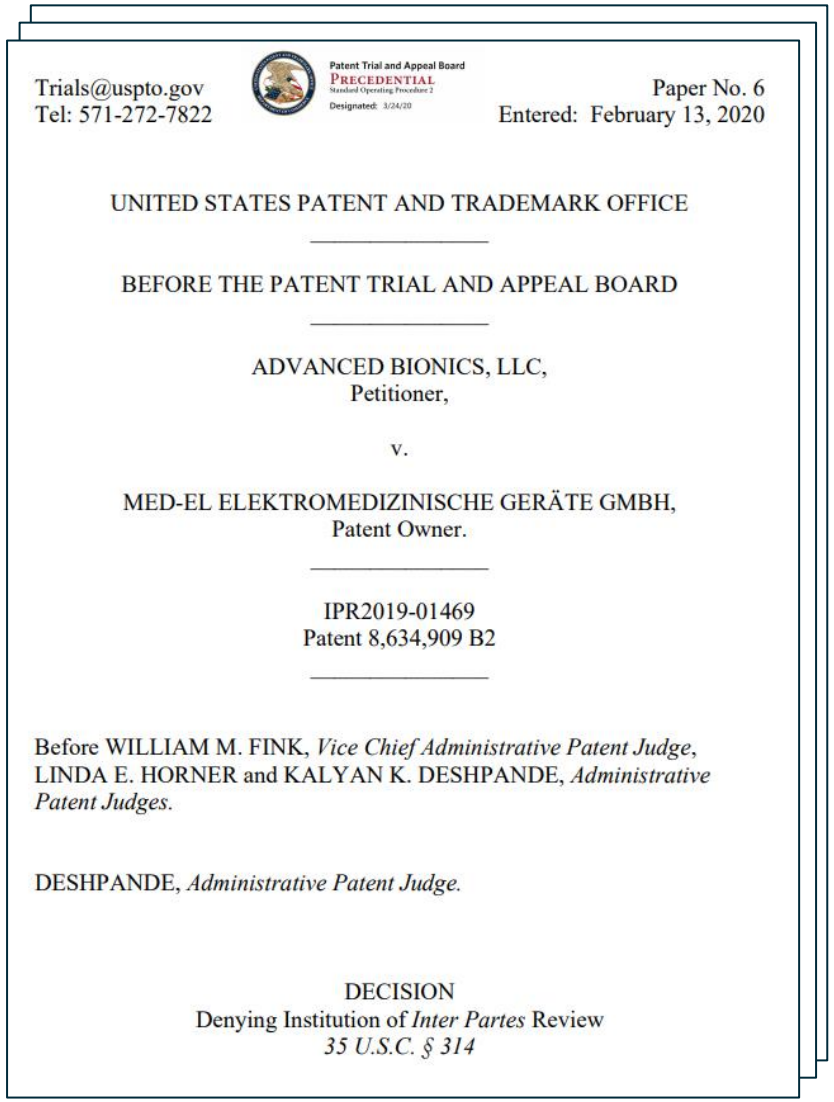
Discretionary Denial – 35 U.S.C. 325(d)

- The Statutory Language:
  - "[T]he Director may … ***reject the petition*** or request because, ***the same or substantially the same prior art or arguments*** previously were presented to the Office."
- The Board's View:
  - "[T]his framework reflects ***a commitment to defer*** to previous Office evaluations of the evidence of record ***unless material error*** is shown."

Building a Prosecution Record

Discretionary Denial – 35 U.S.C. 325(d)

- The ***Advanced Bionics*** Test:
  1. Whether ***the same or substantially the same art*** or ***arguments*** previously were presented to the Office
  2. Whether the petitioner has demonstrated that ***the Office erred*** in a manner material to patentability



Trials@uspto.gov
Tel: 571-272-7822

Patent Trial and Appeal Board
PRECEDENTIAL
Standard Operating Procedure 2
Designated: 3/24/20

Paper No. 6
Entered: February 13, 2020

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ADVANCED BIONICS, LLC,
Petitioner,

v.

MED-EL ELEKTROMEDIZINISCHE GERÄTE GMBH,
Patent Owner.

IPR2019-01469
Patent 8,634,909 B2

Before WILLIAM M. FINK, *Vice Chief Administrative Patent Judge*, LINDA E. HORNER and KALYAN K. DESHPANDE, *Administrative Patent Judges.*

DESHPANDE, *Administrative Patent Judge.*

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

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Building a Prosecution Record

Hallmarks of a Strong 325(d) Record

- The ***best prior art*** was presented to the examiner
- The examiner ***substantively considered*** the art
- Examination progressed ***without material errors***

Building a Prosecution Record

The Continuum of Consideration

Building a Prosecution Record

A few things to consider…

- Perform a novelty search and/or extract prior art from inventors
- Avoid burying references in extensive disclosure statements
- Draft arguments that fully address all standing rejections

Building a Prosecution Record

A few more things…

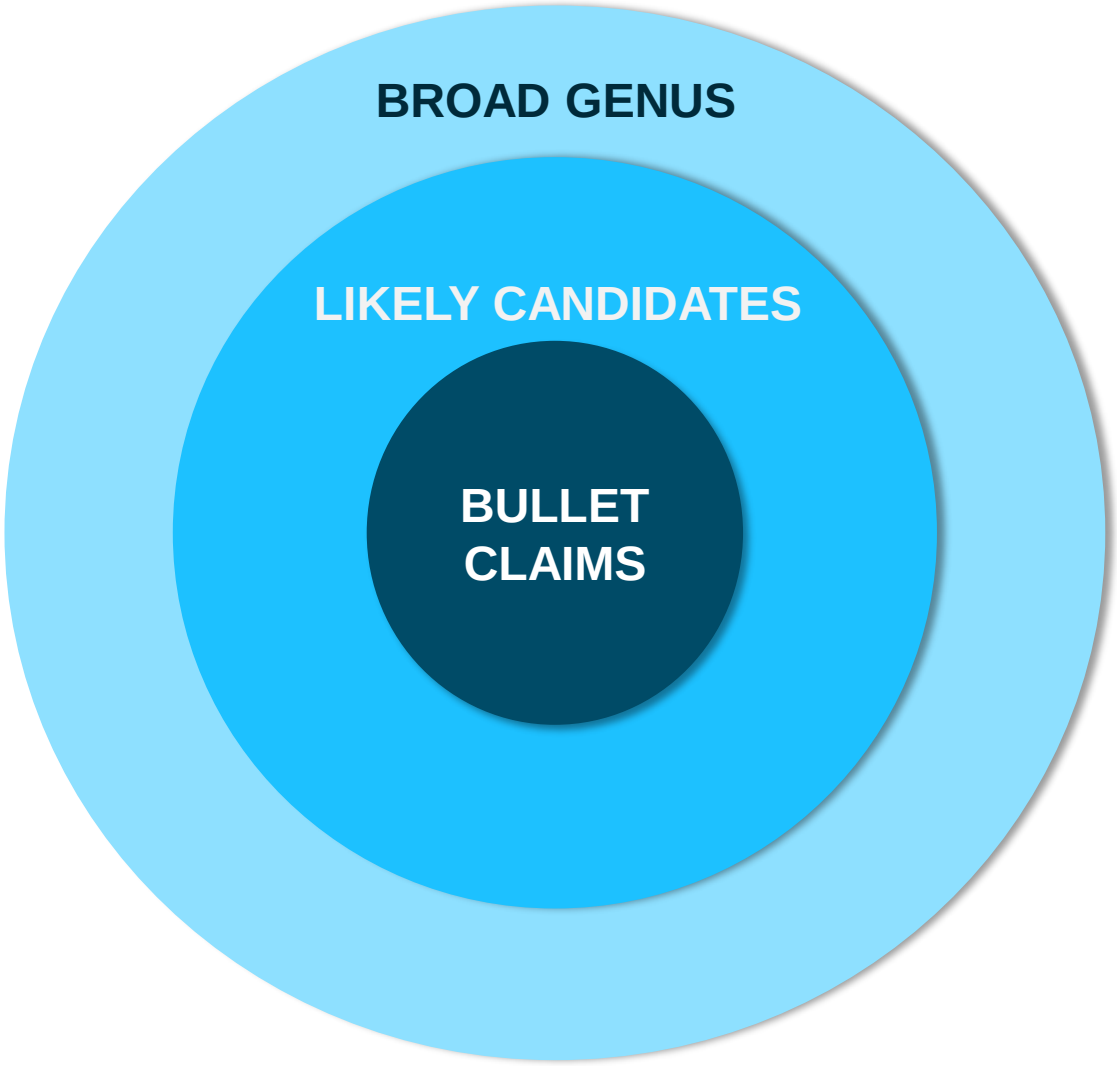
- Discuss more prior art in examiner interviews and note as much in interview summaries
- Scrutinize and clarify the examiner's reasons for allowance
- Avoid overly broad prior art characterizations that can be attacked to show error

Portfolio Building

Variance Across the Family

- Layer your defenses

Layer Your Portfolio



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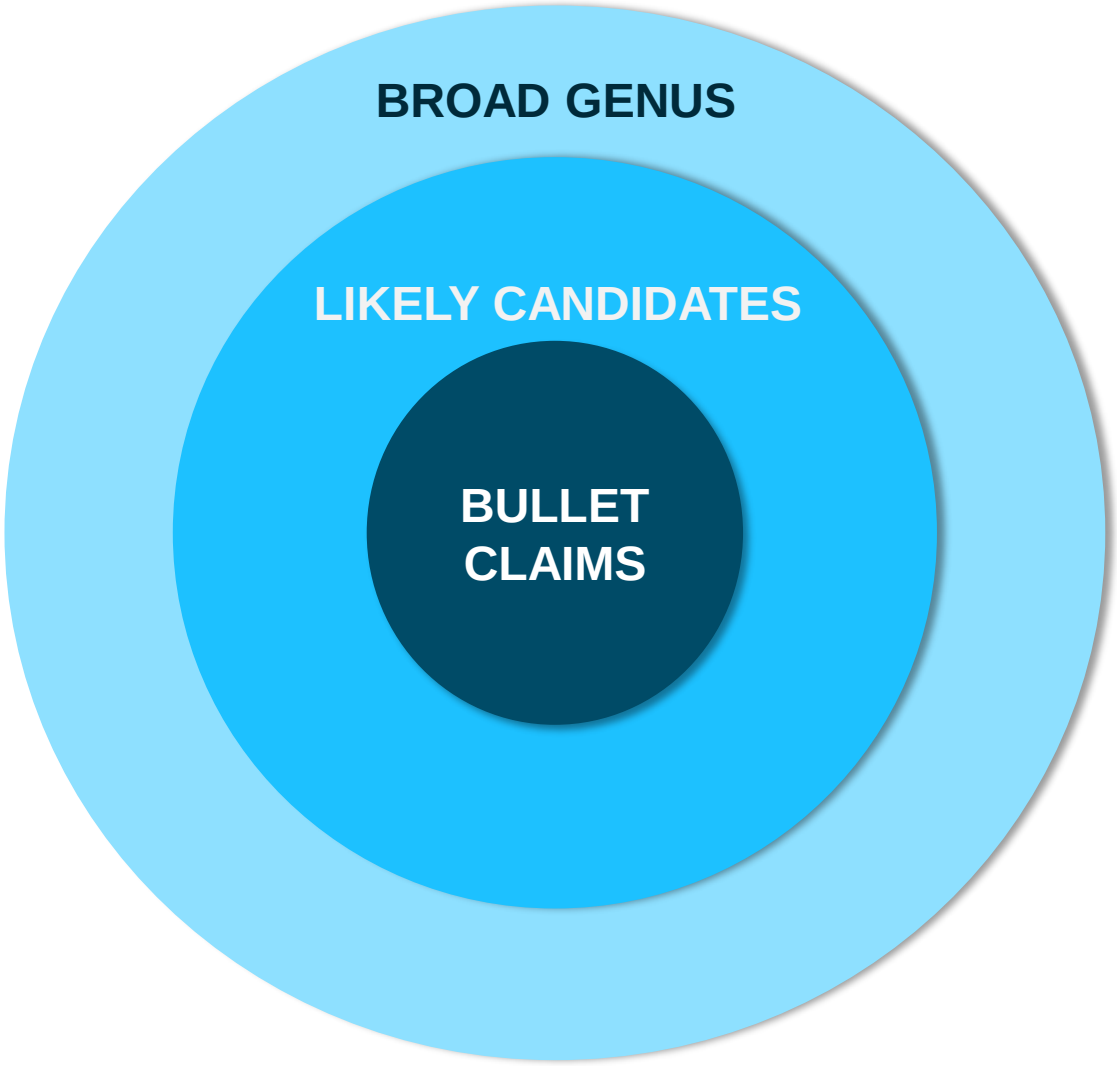
Each Layer Presents its Own Concerns



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Keeping Your Options Open

- Continuations
  - CIPs?
- Reissue
  - Two-year window for broadening: Take a look as you approach deadlines
- Reexamination
  - Narrowing only
  - Deal with prior art
  - Much quicker now, but can still take some time
  - No control over what the examiner might do

Post-Grant Resources

Fish Sites

- **Dedicated Website**: http://fishpostgrant.com/
- **Mobile Application**: http://fishpostgrant.com/app/
- **Case Studies**: http://fishpostgrant.com/case-studies/
- **Webinar Replays**: http://fishpostgrant.com/webinars/
- **Post-Grant Radio**: http://fishpostgrant.com/podcasts/
- **Post-Grant Year-End Reports**: https://fishpostgrant.com/downloads/

USPTO Sites

- **Dedicated Website:** https://www.uspto.gov/patents-application-process/patenttrialandappealboard
- **Post-Grant Trial Practice Guide**: https://www.uspto.gov/sites/default/files/documents/2018_Revised_Trial_Practice_Guide.pdf
- **Standard Operating Procedures:** https://www.uspto.gov/patents-application-process/appealing-patent-decisions/procedures/standard-operating-procedures-0
- **Guidance on *SAS*:** https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/trials/guidance-impact-sas-aia-trial
- **Statistics:** https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/statistics

Thank You!

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Kenneth Darby
Principal
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Please send your NY/NJ CLE forms to mcleteam@fr.com

Any questions about the webinar, contact Emma Horsey at horsey@fr.com

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