

# Hatch-Waxman and IPR Strategy

March 27, 2019



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# Overview

- **Topics**

- Important Decisions
- Developments
- Practice Tips

- **Housekeeping**

- CLE
- Questions
- Materials

- <http://fishpostgrant.com/webinars/>



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## Hatch-Waxman and IPR Strategy

Wednesday, March 27  
1:00-2:00pm EDT

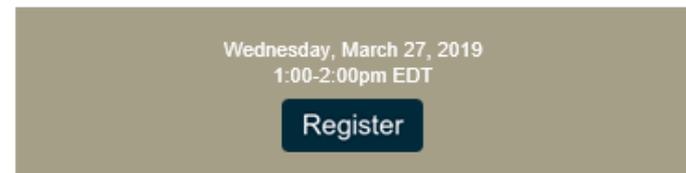
Register

*Inter partes* review (IPR) proceedings have become an attractive option for generic drug manufacturers wishing to utilize the PTAB's streamlined patent validity decision process while also reaping the benefits of the Hatch-Waxman Act. However, many believe that allowing generics to apply both of these strategies disrupts the balance between encouraging pharmaceutical innovation and lowering drug prices that the Hatch-Waxman Act intended to preserve. This debate has escalated since the [Hatch-Waxman Integrity Act of 2018](#), which seeks to force generics to choose between the Hatch-Waxman framework and IPR.

In our latest webinar, Principal and Post-Grant Practice Co-Chair [Dorothy Whelan](#) and Principal [Chad Shear](#) will address these complex issues and more, including:

- IPR basics and how they apply to Hatch-Waxman cases
- The "who, when, and where" of IPR filings and the decisions that go into filing
- Recent decisions and arguments impacting Hatch-Waxman and IPR strategy

Reserve your place today!



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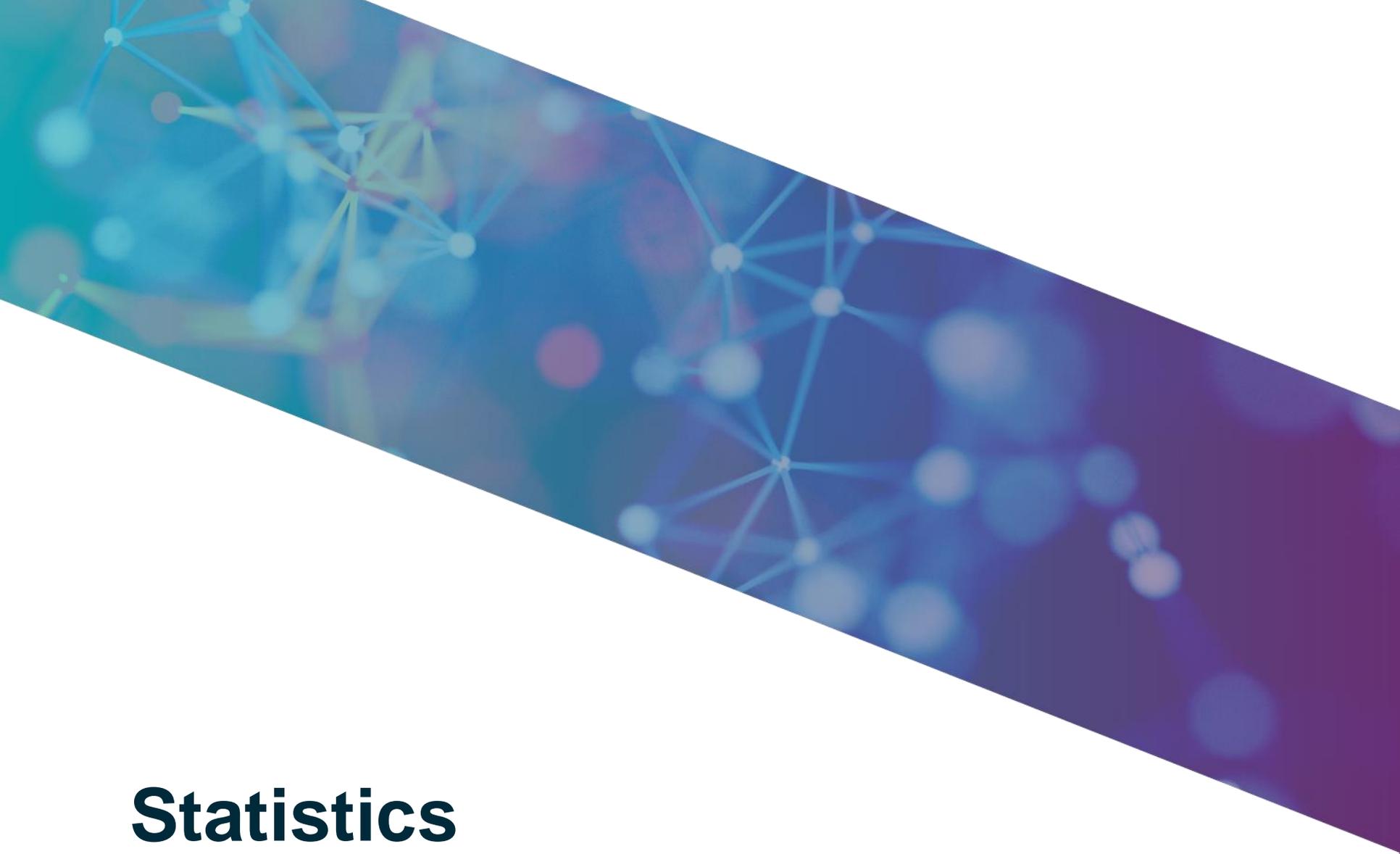
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If you have questions, please contact [Angela Park](#).

# Agenda

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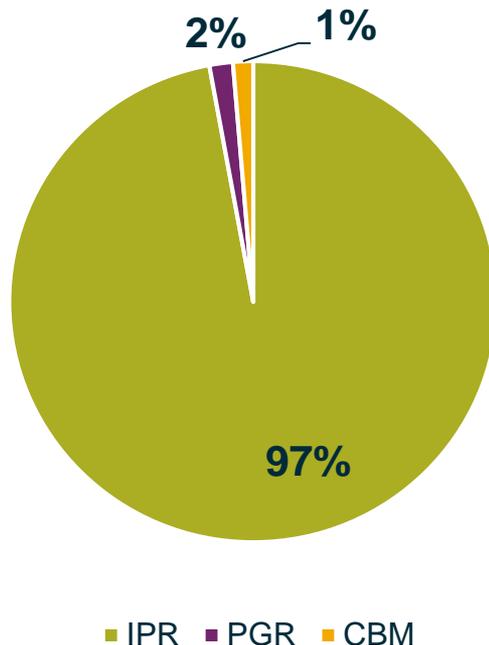
- **Statistics**
- **IPR basics and how they apply to Hatch-Waxman cases**
- **The PTAB vs District Court**



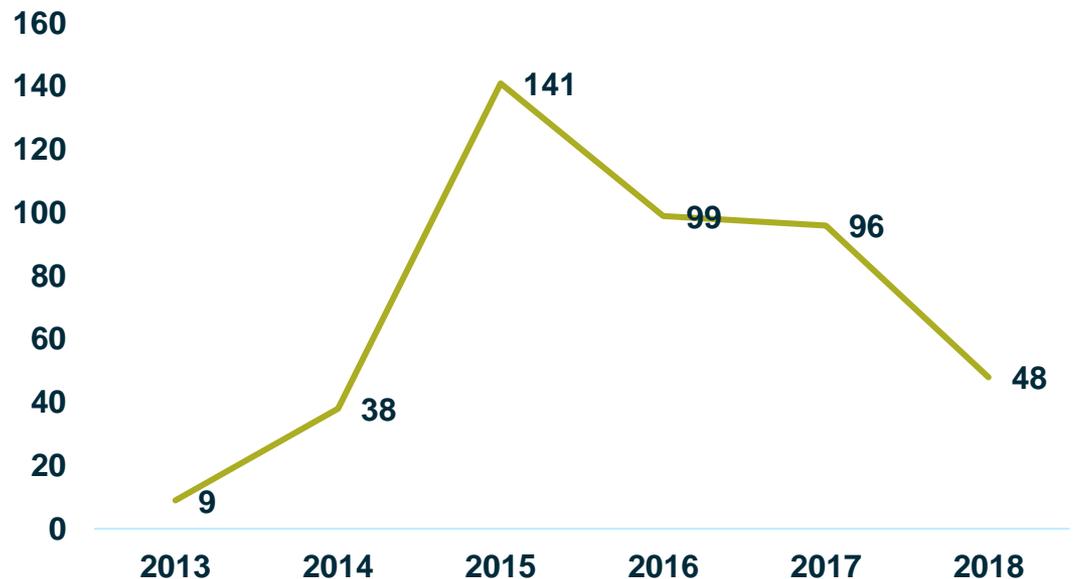
# Statistics

# Orange Book Patents - PTAB

Since inception, 450 petitions (IPR, PGR, CBM) have been filed at the PTAB related to Orange Book listed patents (4.5% of all petitions filed):



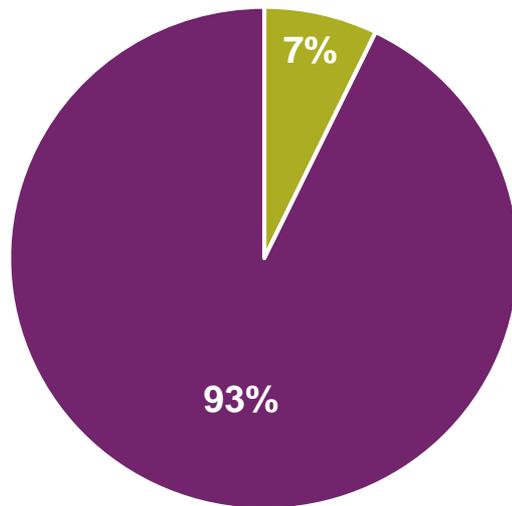
IPR Petitions Filed, By Year



# Hatch-Waxman Cases – USDC

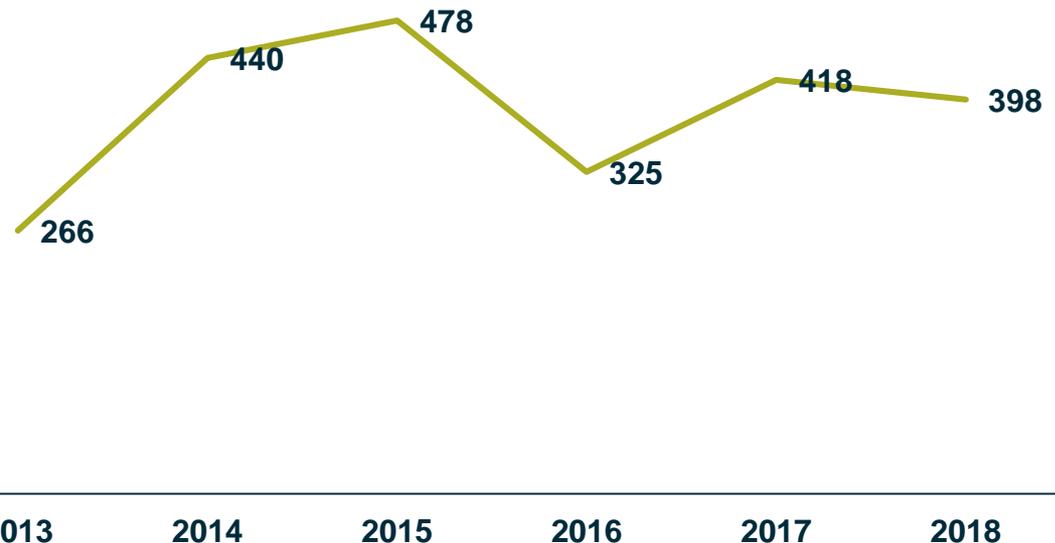
- Since September 2012, 2,490 ANDA-related patents have been asserted in USDC.
  - 93% of Orange Book-listed patents filed at the PTAB were also challenged in USDC.

## Cases Filed



■ ANDA ■ All Cases

## Cases Filed, By Year



# Top Filers

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## Top Filers at the PTAB

1. Mylan Pharmaceuticals
2. Amneal Pharmaceuticals
3. Apotex
4. Teva Pharmaceuticals
5. Par Pharmaceutical
6. Wockhardt Bio AG
7. Dr. Reddy's
8. Fresenius Kabi
9. Jazz Pharmaceuticals
10. Lupin

## Top Filers at USDC

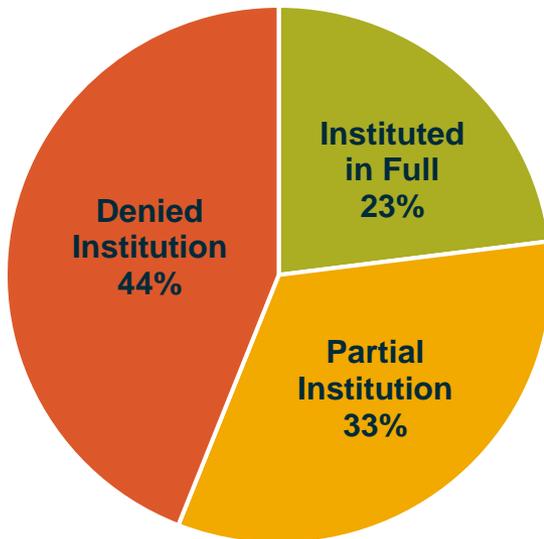
1. Eli Lilly and Company
2. Pfizer Inc.
3. AstraZeneca AB
4. Novartis Pharmaceuticals Corporation
5. UCB Pharma GmbH
6. Novartis AG
7. Cephalon, Inc.
8. Biogen MA Inc.
9. Sanofi-Aventis US LLC
10. ICOS Corporation

# Success at the PTAB

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450 Petitions Filed at the PTAB:

Institution

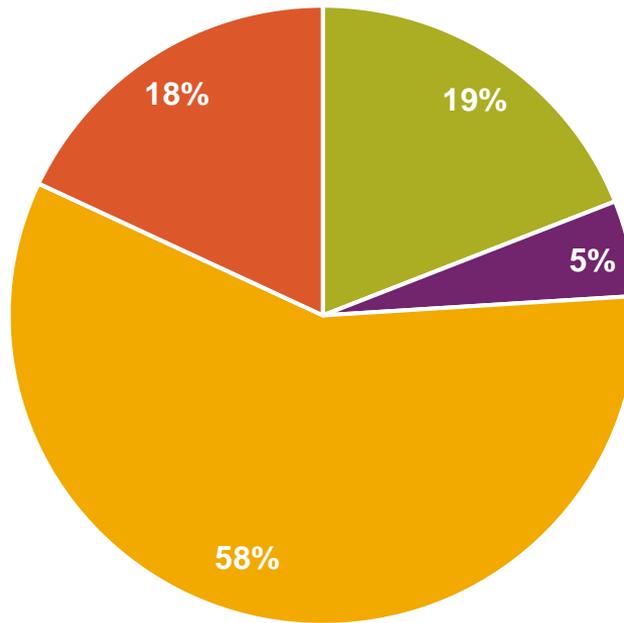


Final Written Decision



# Success at USDC

1,923 cases have reached a decision:



■ Plaintiff Win ■ Defendant Win ■ Settled ■ Procedural Resolution\*

\*Procedural Resolution: Consolidation, Dismissal, Contested Dismissal, Interdistrict Transfer, Stay

- 15% of cases had claimant win at consent judgment vs. 2% claim defendant win at consent judgment.
- 3% of cases were won by the claimant at trial and only 1% won at trial by claim defendant.



# **IPR Basics and How they Apply to Hatch-Waxman Cases**

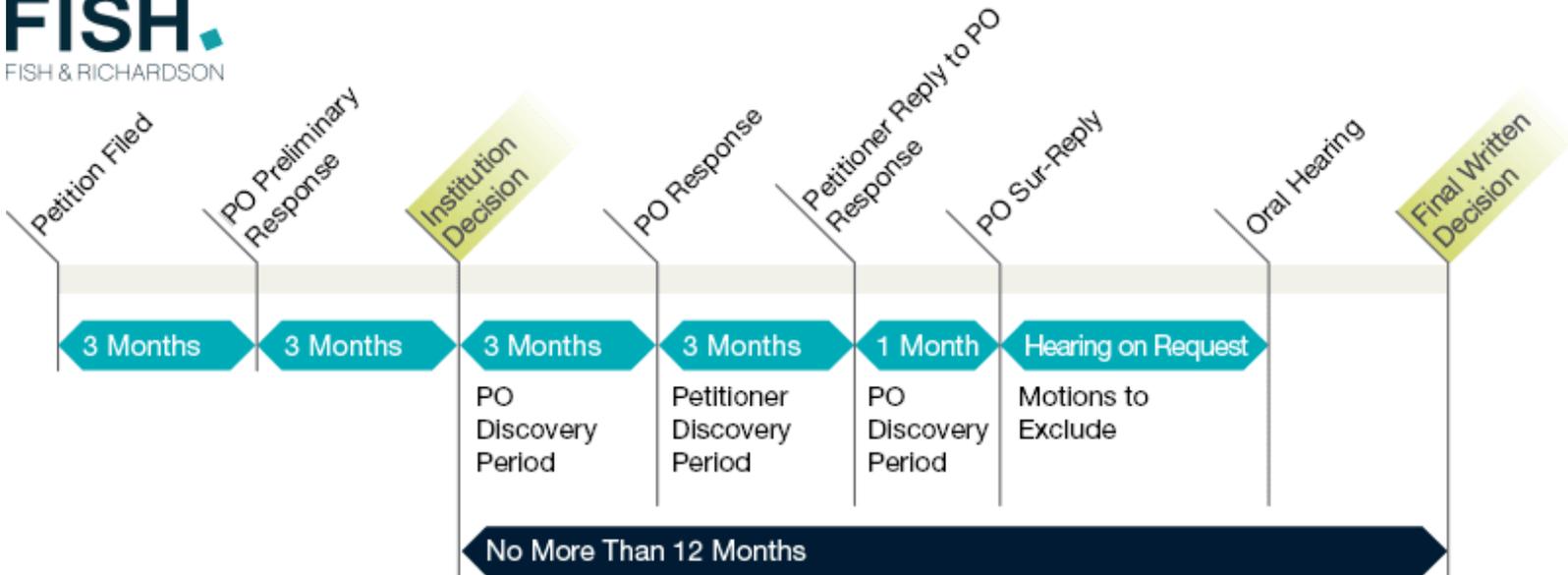
# Types of Post Grant Proceedings

Proceeding	When Does It Apply?	Legal standard	Grounds (Prior Art)	Estoppel?
<b>PGR: Post-grant review (9 month window)</b>	<ul style="list-style-type: none"> <li>-First available on Sept. 16, 2012</li> <li>-Applies only to patents having a claim with a priority date on or after March 16, 2013</li> </ul>	More likely than not that at least 1 claim is unpatentable	Any invalidity ground	Raised or reasonably could have raised
<b>IPR: <i>Inter partes</i> review (after PGR)</b>	<ul style="list-style-type: none"> <li>-First available on Sept. 16, 2012</li> <li>-Applies to all patents</li> <li>-Must file within 1 year of being served with infringement complaint</li> </ul>	Reasonable likelihood that petitioner would prevail on at least 1 claim	<ul style="list-style-type: none"> <li>Patents</li> <li>Published patent apps</li> <li>Printed publications</li> </ul>	Raised or reasonably could have raised
<b>CBM: Covered Business Method</b>	<ul style="list-style-type: none"> <li>-First available on Sept. 16, 2012</li> <li>-Applies to all patents related to “financial services” but excludes “technological inventions”</li> </ul>	<ul style="list-style-type: none"> <li>-More likely than not that at least 1 claim is unpatentable</li> <li>-Petitioner sued or “charged with infringement”</li> </ul>	Any invalidity ground	Narrow: Raised (Civil) or reasonably could have raised (USPTO)

# IPR Timeline

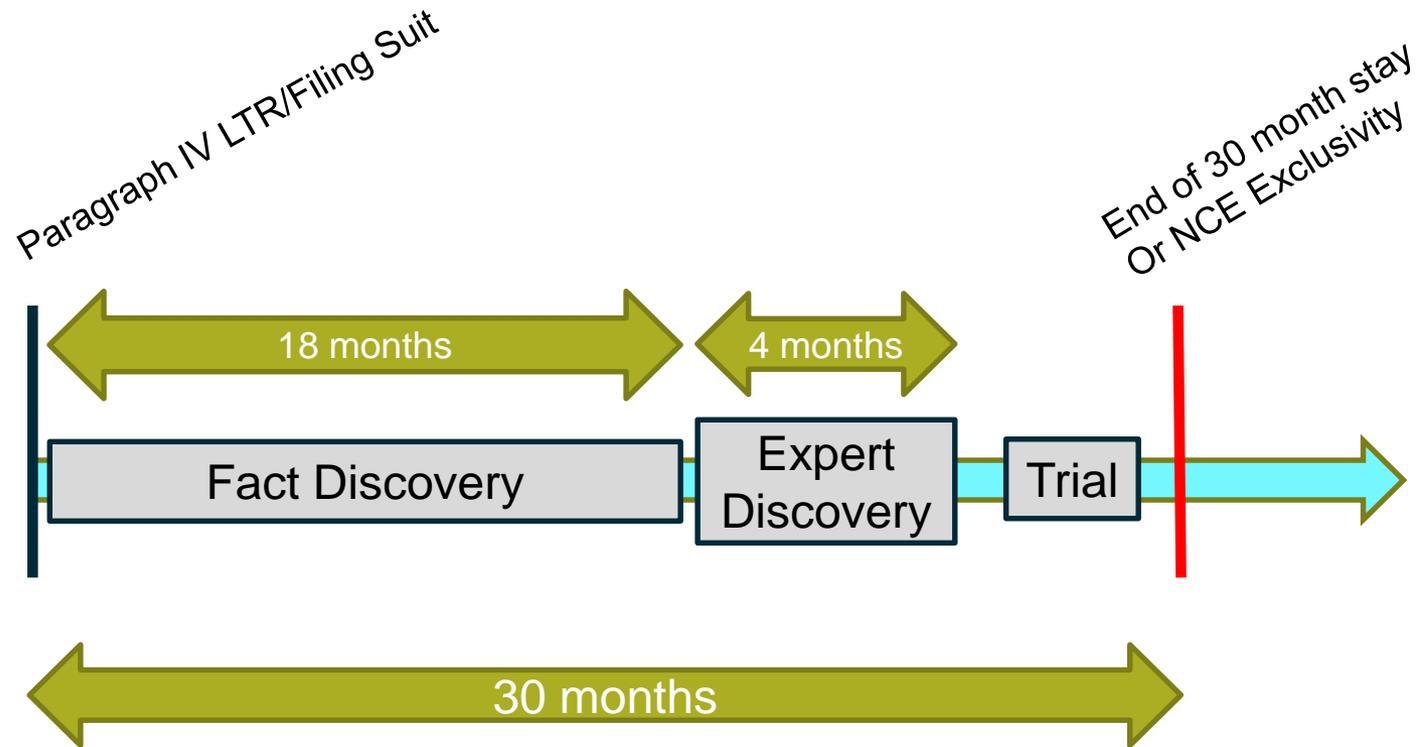


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# District Court – Background – Timeline

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# IPR vs. District Court

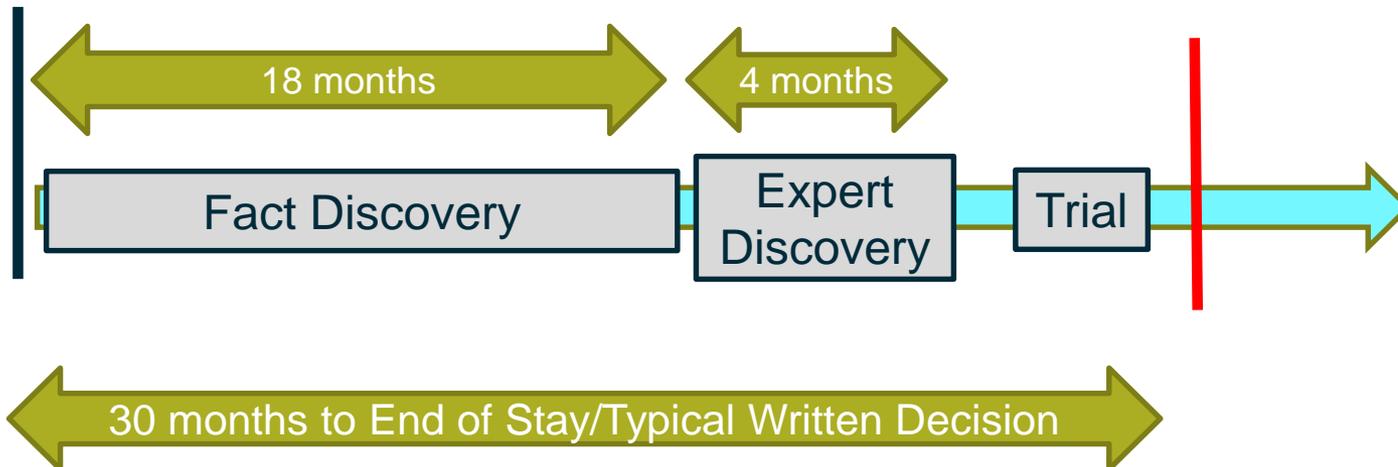
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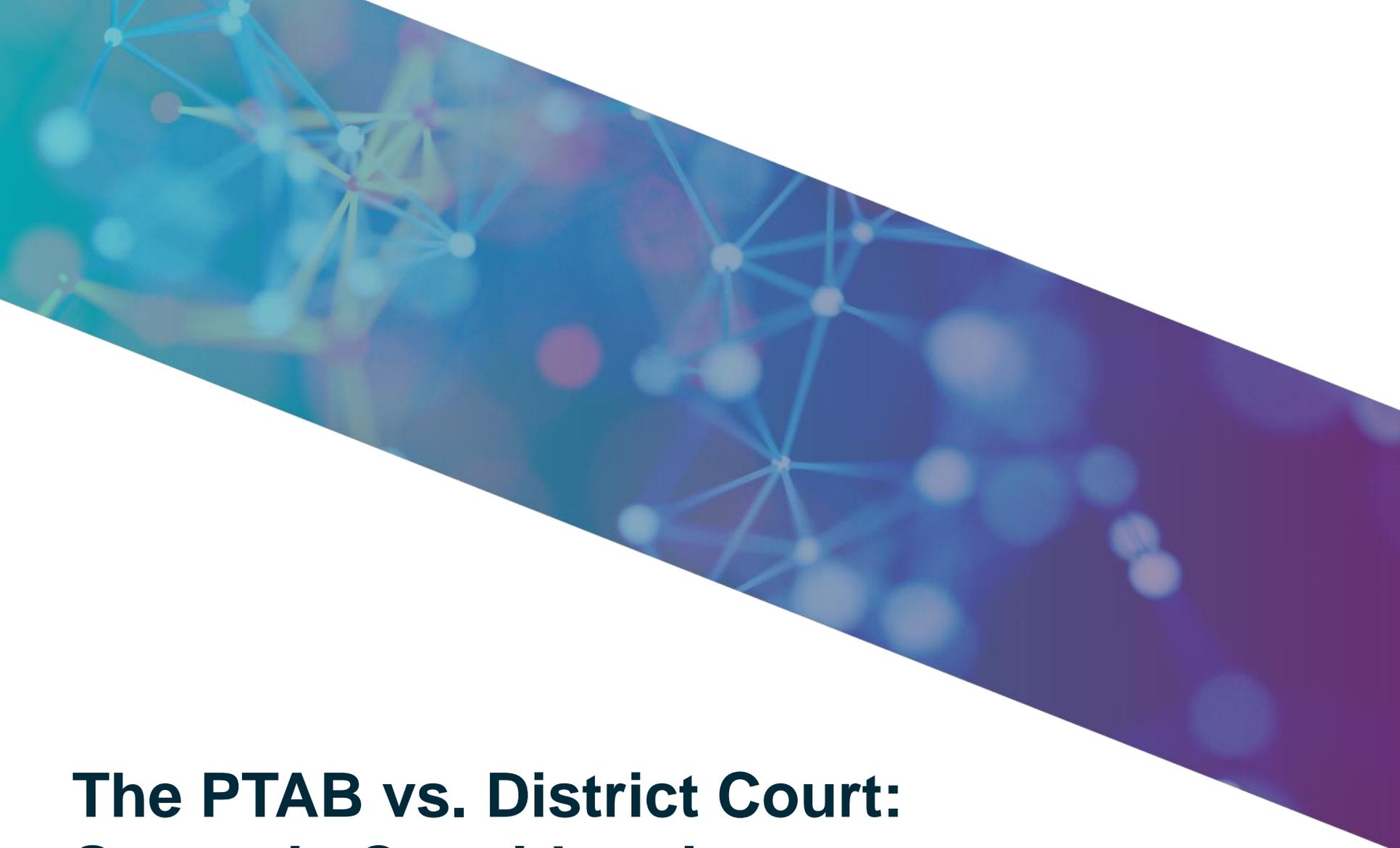
## IPR Timing



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## DCT Timing





# **The PTAB vs. District Court: Strategic Considerations**

# IPR vs. District Court

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## Issues to consider:

- Timing of settlement (IPRs are often used to gain settlement leverage).
- Ability to defeat a motion for preliminary injunction
- Critical dates in the IPR timeline:
  - Filing of petition.
  - Institution deadline (3 mos. after filing).
  - Patent Owner Response (3 mos. after institution).
  - Final Written Decision (1 year after institution).

# Timing

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- The PTAB is much faster than a district court litigation.
- Decision on petition within 6 months of filing.
- Final written decision within 1 year of institution.
- Direct appeal to Federal Circuit from final written decision.

# Patent Owner Strengths and Weaknesses

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- **Factors tending to favor District Court:**
  - Story to tell.
  - Live fact witnesses (may be a strength and a weakness).
  - “Secondary” indicia of non-obviousness.
  - Emotional appeal.
  - Presumption of validity.
  - Lay Judge as opposed to Panel of Judges with technical backgrounds (could go either way).

# Challenger Strengths and Weaknesses

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- **Factors favoring PTAB:**
  - Simple presentation.
  - Only rely on expert witnesses.
  - No emotional appeal.
  - Lower burden of proof (preponderance vs. clear and convincing) and broader claim construction.
  - Panel of Judges with technical backgrounds (could go either way).

# Board Has Discretion

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- Board has discretion to deny petition if a rehash of previously considered arguments.
  - “Show me something new”
  - 325(d)
- Timing issues and multiple petitions .
  - Rubber meets road when your talking about second and third filers.
  - Board has discretion under *General Plastics* factors.
  - Allows Board to kick later filed petitions where the first was denied.
- By and large, Institution decisions are not appealable.
- SAS – Institution is now all or nothing.

# Stays

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## Unique Hatch-Waxman Issues

- Under 21 U.S.C. § 355(j), once a branded company sues a generic ANDA filer, the FDA will not grant the generic final approval for 30 months absent a court decision holding the patent not infringed, invalid, and/or not enforceable.
- Purpose of stay is to give court time to resolve patent issues
- If generic files an IPR petition before or after being sued by branded company, and then moves to stay litigation, will this affect the 30 month stay?
- 21 U.S.C. § 355(j)(5)(B)(iii): FDA approval “shall be made effective upon expiration of the thirty month [stay] ... or such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action.”

# Estoppel

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What happens to the loser?

## **Petitioner:**

- IPR/PGR: Any ground raised or reasonably could have been raised.
- CBM: Limited to grounds actually raised for civil actions.
- All:
  - Attaches at the time the final written decision issues.
  - Applies to district court, ITC, and PTO proceedings.
  - Applies to petitioner and its privies.

# Estoppel

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## What happens to the winner?

*BTG Int'l Ltd. et al. v. Amneal Pharm. LLC et al.*, Case No. 19-1147 (Fed. Cir.) (pending)

- Appeal from IPR in which Petitioner won (i.e. challenged claims found unpatentable).
- In co-pending district court litigation, Petitioner raised the same basis for invalidity.
- Patent Owner argued that Petitioner was estopped from raising the same arguments in the district court because the statute did not distinguish between successful and unsuccessful petitioners. District court rejected the argument and Patent Owner appealed.
- USPTO filed an amicus brief in which it agreed with Patent Owner.
- Consequences for generic filers?

# Joinder

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- PTAB has the discretion to join multiple petitions. 35 U.S.C. § 314.
  - Multiple petitions by a single party.
  - Multiple petitions by multiple parties.
- Motion for joinder must be filed no later than one month after the institution date of the first IPR petition. 37 CFR § 42.122(b).
- Joinder is an exception to the one year from service filing bar for IPR petitions.

## Hatch-Waxman Framework at Odds with AIA Post-Grant Framework

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- 180-day exclusivity is created by and vests at time of Para. IV filing.
- Para. IV filing automatically triggers a cause of action in ***District Court***.
- Failure to Market provision is only triggered by ***court*** decision in an infringement action (*i.e.* PTAB decision affirmed by CAFC does not count until adopted by district court).
- Only a decision by a ***district court*** in a Paragraph IV litigation will lift the statutory 30 month stay. 21 USC §355(j)(5)(B)(iii)(I).
- No impediment to generic filing IPR.

# Post-Grant Resources

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## 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](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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