LATHAM & WATKINS LLP

June 11, 2020

IP Strategic Considerations

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Agenda

- Patentable Subject Matter
- Written Description and Enablement for Biopharmaceuticals
- *Inter Partes* Review (IPR)

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Patentable Subject Matter

Patentable Subject Matter – 35 U.S.C. § 101

Whoever invents or discovers any **new and useful** process, machine, manufacture, or composition of matter, or any **new and useful improvement** thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. § 101

Exceptions: laws of nature, natural phenomena, and abstract ideas.

Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576, 589 (2013)

Two-Part Test for Patentable Subject Matter

(1) Are the claims at issue directed to one of those patent-ineligible concepts?

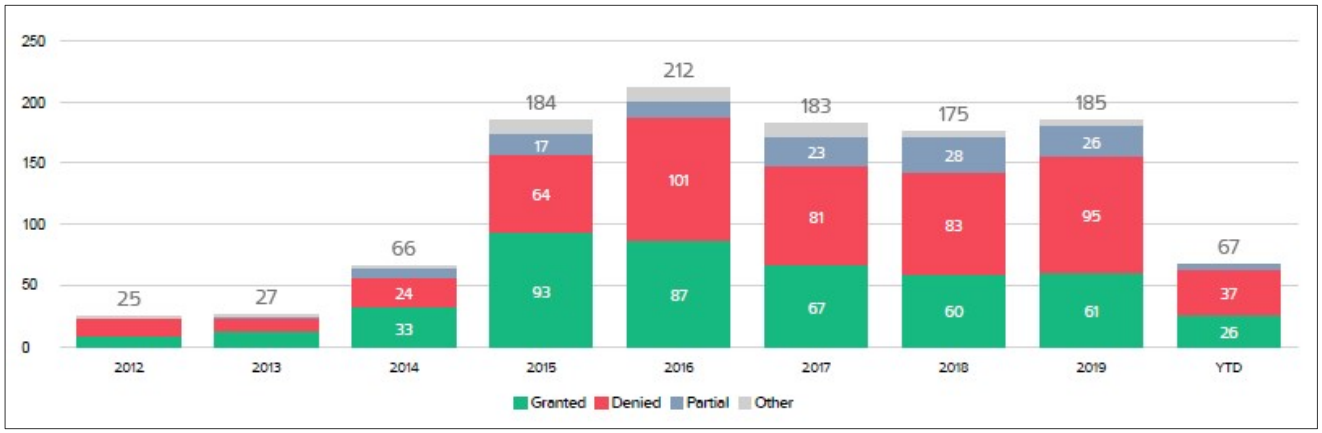
(2) If so, do the elements of each claim transform the nature of the claim into a patent-eligible application (is there an "**inventive concept**")?

Alice Corp. Pty. Ltd. v. CLS Bank Int'l., 569 U.S. 208, 217 (2014)

Examples – Patent-Ineligible Matter

	Abstract Idea	Natural Phenomenon / Law of Nature
Patent-Eligible?	***No*** – Intermediated settlement (use of third party to mitigate settlement risk)	***No*** – Correlations between thiopurine metabolite levels and the toxicity and efficacy of thiopurine drug dosages
Inventive Concept?	***No*** – Generic computer implementation "fail[s] to transform that abstract idea into a patent-eligible invention."	***No*** – Claim "amounts to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients."
	Alice Corp., 573 U.S. at 218, 221	*Mayo Collaborative Servs. v. Prometheus Labs. Inc.*, 566 U.S. 66, 76-77, 80 (2012)

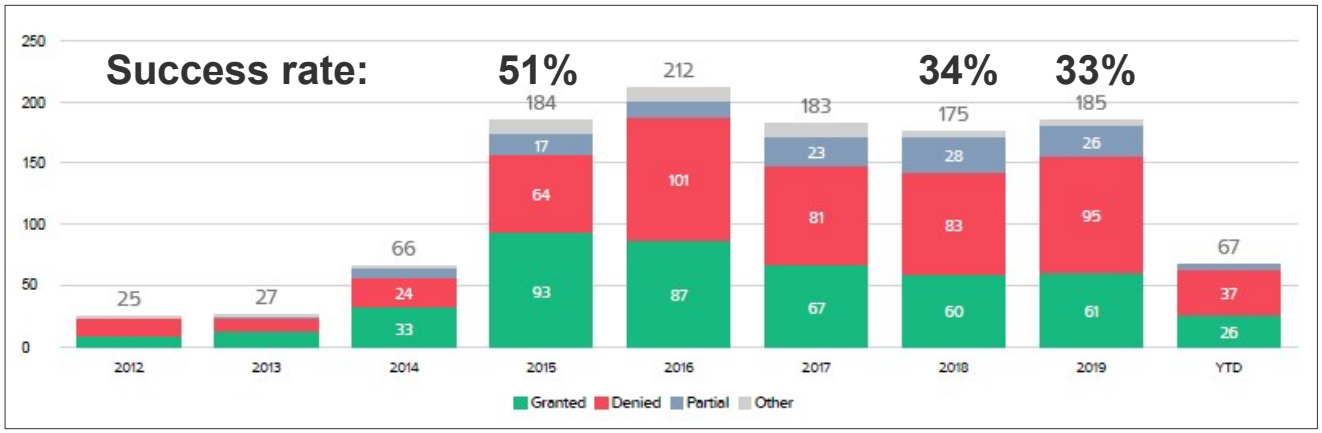
Motions Based on 35 U.S.C. § 101



Source: Docket Navigator

Alice

Motions Based on 35 U.S.C. § 101



Source: Docket Navigator

Federal Circuit: *Berkheimer*

Berkheimer v. HP Inc., 881 F.3d 1360 (Fed. Cir. 2018)

- Whether a claim recites patent-eligible subject matter is a **question of law** which may contain **underlying facts**.
- The question of whether a claim element or combination of elements is **well-understood, routine, and conventional** to a skilled artisan in the relevant field is a **question of fact** that must be proven by clear and convincing evidence.
- Eligible subject matter must be "captured in the claims."

Diagnostics: **Vulnerable to Challenge?**

> "Under *Mayo*, we have consistently held diagnostic claims unpatentable as directed to ineligible subject matter."

Illumina, Inc. v. Ariosa Diagnostics, Inc., 592 F.3d 1367, 1371 (Fed. Cir. 2020)

Examples:

- Methods for performing a prenatal diagnosis
  Ariosa Diagnostics, Inc. v. Sequenom, Inc., 788 F.3d 1371, 1374 (Fed. Cir. 2015)
- Methods for testing for myeloperoxidase and correlating to cardiovascular risk
  Cleveland Clinic Found. v. True Health Diagnostics LLC, 859 F.3d 1352, 1363 (Fed. Cir. 2017)
- Methods for diagnosing neurological disorders by detecting autoantibodies to muscle-specific tyrosine kinase
  Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC, 915 F.3d 743, 746 (Fed. Cir. 2019)

- ***But***, methods of preparation are patent-eligible
  E.g., Illumina, 952 F.3d at 1374

Methods of Treatment: **Patent-Eligible**

> "[W]e have held that method of treatment claims are patent-eligible."

Illumina, 592 F.3d at 1371

Examples:

- Method of treating schizophrenia using iloperidone

  Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd., 887 F.3d 1117 (Fed. Cir. 2018)

- Method of treating type 2 diabetes using DPP-IV inhibitors (linagliptin)

  Boehringer Ingelheim Pharms. Inc. v. Mylan Pharms. Inc., 803 F. App'x 397 (Mar. 16, 2020) (nonprecedential)

Software: **Sometimes Patent-Eligible**

> Software claims "are eligible as long as they are directed to non-abstract improvements to the functionality of a computer or network platform itself."

Uniloc USA, Inc. v. LG Elecs. USA, Inc., 957 F.3d 1303, 1309 (Fed. Cir. 2020)

Examples:

- Patent eligible: improvement to computer communication functionality

  Uniloc, 957 F.3d at 1309

- Patent ineligible: method for routing information using "result-based functional language" (e.g. "converting," "routing," "controlling," "monitoring")

  Two-Way Media Ltd. v. Comcast Cable Commcn's, LLC, 874 F.3d 1329, 1337 (Fed. Cir. 2017)

Mechanical Arts: **Not Patent-Eligible?**

- Driveshaft propeller
  - The claims "are directed to the utilization of a **natural law** (here, Hooke's law and possibly other natural laws) in a particular context."

    Am. Axle & Mfg., Inc. v. Neapco Holdings LLC, 939 F.3d 1355, 1366 (Fed. Cir. 2019)

- Wireless garage-door opener
  - The claims "are drawn to the **abstract idea** of wirelessly communicating status information about a system."

    Chamberlain Grp, Inc. v. Techtronic Indus. Co. Ltd., 935 F.3d 1341, 1348 (Fed. Cir. 2019)

- Electric vehicle charging station
  - Communication over a network is a "building block of the modern economy" and is an "'**abstract idea**' beyond the scope of § 101."

    Chargepoint, Inc. v. SemaConnect, Inc., 920 F.3d 759, 773 (Fed. Cir. 2019)

PTO Patent-Eligibility Guidance – Abstract Ideas

- **Mathematical concepts**, such as formulas, equations and calculations
- Methods of **organizing human activity**, including economic practices, commercial or legal interactions like contracts or advertising, or managing personal behavior such as social activities or teaching
- **Mental processes** that can be performed by the human mind, like observation, evaluation, and judgment

Congressional Reform – Removes Judicial Exceptions

Whoever invents or discovers any ~~new and~~ **useful** process, machine, manufacture, or composition of matter, or any ~~new and~~ **useful** improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The term "**useful**" means any invention or discovery that provides **specific and practical utility** in any field of technology through human intervention.

Strategies for Approaching Patent Eligibility

Patent Owners:

- Focus on fact issues (complaint, expert declarations, claim construction)
- Highlight practical improvements over the prior art
- Distinguish between known and well-known
- Leverage discovery for factual disputes on inventiveness

Defendants:

- Focus on core abstract concept in patent disclosure and claims
- Highlight admissions of conventionality in intrinsic record
- Show any alleged inventiveness is not claimed

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Written Description & Enablement for Biopharmaceuticals

Written Description & Enablement

In biopharmaceutical cases, we see patent claims often directed to:

- A whole group (or "genus") of compounds, *instead of* a single compound
- Functional attributes of a compound, *instead of* structural attributes

These claims must be enabled and adequately described

Common issues in pharmaceutical patent claims:

- Is the size of the claimed genus too broad?
- Does the patent teach a structure-function relationship?
- Does the patent teach how to determine claimed functions (affinity, epitope, etc.)?

Section 112 Requirements: Written Description

Written Description – Question of *Fact*

- The specification must describe that "the inventor actually invented the invention claimed."
  Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc)

- Requires a "precise definition . . . sufficient to distinguish the genus from other materials" and can describe either **representative species** or **common structural features** of members of the genus.
  Ariad, 598 F.3d at 1349-50

- Working examples and actual reduction to practice are not required.
  Ariad, 598 F.3d at 1352;
  Alcon Res. Ltd. v. Barr Labs., Inc., 745 F.3d 1180, 1190-92 (Fed. Cir. 2014);
  Falko-Gunter Falkner v. Inglis, 448 F.3d 1357, 1366-67 (Fed. Cir. 2006)

- "There is no per se rule that whenever a claim limitation is directed to a biological macromolecule, the specification must contain a recitation of known structure."
  Falko-Gunter Falkner, 448 F.3d at 1366 (allowing poxvirus claims when examples only used herpes virus)

Enablement – Question of *Law* Based on Underlying Factual Issues

- Specification must teach skilled artisans "how to make and use the **full scope** of the invention without undue experimentation."

  MagSil Corp. v. Hitachi Glob. Storage Techs. Inc., 687 F.3d 1377, 1380 (Fed. Cir. 2012)

- "The scope of the claims must be less than or equal to the scope of the enablement"

  MagSil, 687 F.3d at 1381

- "After the challenger has put forward evidence that **some experimentation is needed** to practice the patented claim," the *Wands* factors are considered to determine whether experimentation is "'undue' or sufficiently routine."

  Alcon Res. Ltd. v. Barr Labs., Inc., 745 F.3d 1180, 1188 (Fed. Cir. 2014)

Different Approaches to 112 Defenses

	Written Description	Enablement
Narrow	Do embodiments actually **possess** the claimed characteristics?	Are **disclosed embodiments** or characteristics feasible to make and use?
Broad	Do embodiments adequately **represent** claimed characteristics?	Is there guidance to make **other compounds** with those characteristics?

Example: *MorphoSys v. Janssen Biotech*

morphosys

Ad hoc: MorphoSys Sues Janssen Biotech and Genmab for Patent Infringement

HOME > MEDIA AND INVESTORS > INVESTOR & MEDIA INFORMATION > AD HOC: MORPHOSYS SUES JANSSEN BIOTECH AND...

April 04, 2016 / 5:37 pm, CEST

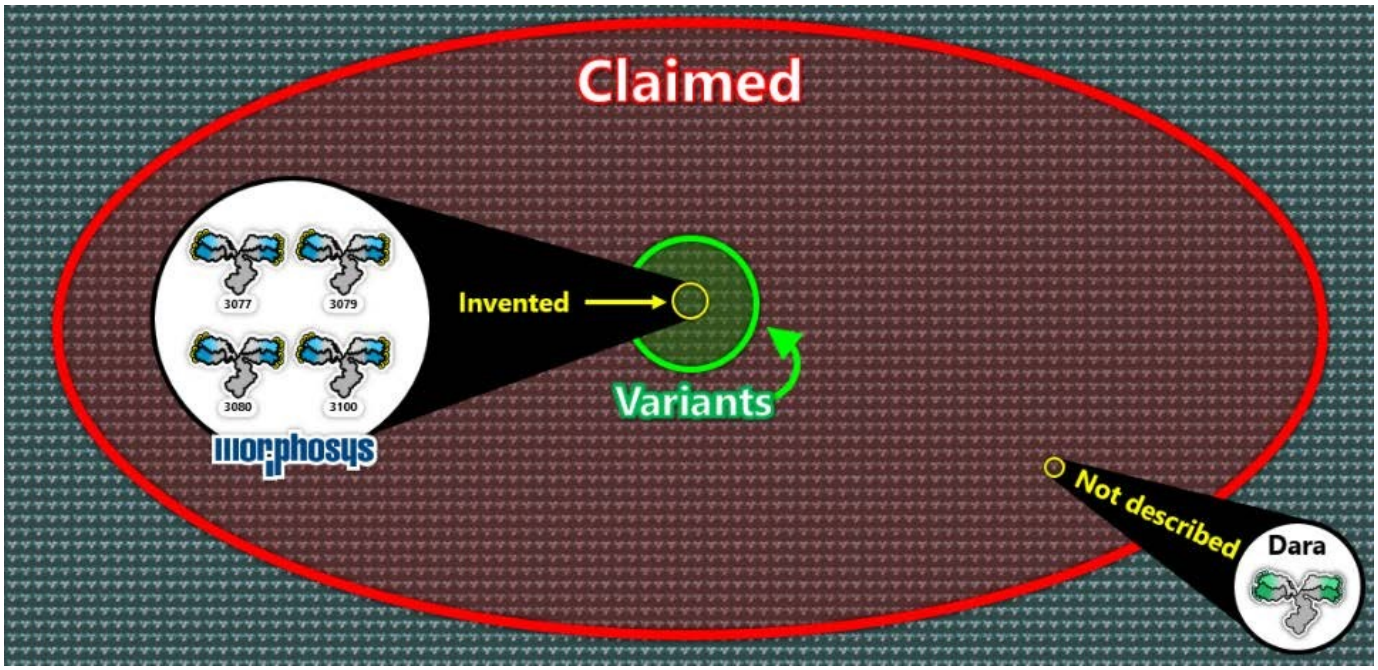
MorphoSys AG (FSE: MOR; Prime Standard Segment, TecDAX; OTC: MPSYY) today announced that it filed a lawsuit in the United States (U.S.) District Court of Delaware against Janssen Biotech, and Genmab, A/S for patent infringement of U.S. Patent Number 8,263,746. This patent, which is owned by MorphoSys, describes and claims antibodies with particular features that bind to CD38.

MorphoSys v. Janssen Biotech

morphosys

Claims Covered Trillions of Antibodies…	But Taught Only 1 to 4
14. An isolated human or humanized antibody or antibody fragment thereof containing an antigen-binding region which specifically binds within amino acids 44 to 206 of CD38 (SEQ ID NO: 22).	***Four Antibodies*** • MOR 3077 • MOR 3080 • MOR 3079 • MOR 3100
18. An isolated antibody or antibody fragment thereof containing an antigen-binding region of claim **15**, which specifically binds within amino acids 192-206 of CD38 (SEQ ID NO: 22).	***One Antibody*** • MOR 3079

MorphoSys: Janssen Demonstrated Broad Scope



MorphoSys v. Janssen Biotech et al.,
358 F. Supp. 3d 354 (D. Del. 2019)

MorphoSys: Key Undisputed Facts on Summary Judgment

1) "MorphoSys does not genuinely dispute that the accurate number [of claimed antibodies] is **very large**," including "**millions**" or "**billions**"

2) "[I]t is undisputed that even small changes to an antibody's sequence, particularly in the antibody's [CDR], can have **dramatic and unpredictable effects** on function."

3) Alleged "unique structural motif" is not properly considered because it relies on **knowledge unavailable to POSA**—i.e., sequence and binding of accused product

4) Obtaining antibodies within claims "would require **substantial time**," be "**extremely laborious**," and require "trial-and-error", and take "**months**" or "longer"

MorphoSys: Summary Judgment Outcome

Enablement	Written Description
The full scope is not enabled when there is ***an embodiment*** within the claim's scope that a person of ordinary skill, reading the specification, would be unable to practice without undue experimentation. * * * Based on the record evidence, the only reasonable conclusion is that these steps would take a substantial amount of time and effort. For example, three of MorphoSys' experts characterized screening techniques as "extremely laborious [and] involving trial-and-error experimentation"….	**Representative species:** For example, a reasonable factfinder could find that the four disclosed antibodies ***are representative of*** all known members of the claimed genera, including daratumumab. **Common structural features:** Given the undisputed lack of a known relationship between antibody's structure (its sequence) and its function (its binding properties), … the specification ***does not sufficiently disclose*** structural features common to the members of the genus.

Summary: *MorphoSys v. Janssen Biotech*

- Latham represented Janssen Biotech.
- Won on summary judgment
- Case decided on **enablement** grounds
- Recently, District Courts seem to prefer to decide based on **enablement** approach (question of law) rather than **written description** (fact) – though Federal Circuit continues to support written description defense (see *Idenix*)
- *Amgen v. Sanofi* (D. Del.) relied heavily on *MorphoSys*

Litigation Strategies for Enablement Challenges

Defending Against Enablement Challenge:

- **Narrow claim construction** as much as possible
- **High level of skill in the art;** POSAs bring own knowledge to bear in identifying compounds
- Develop **structure-function relationship**
- Focus on **low threshold** to establish function
- Use **embodiments or examples** in the specification

Litigation Strategies for Enablement Challenges

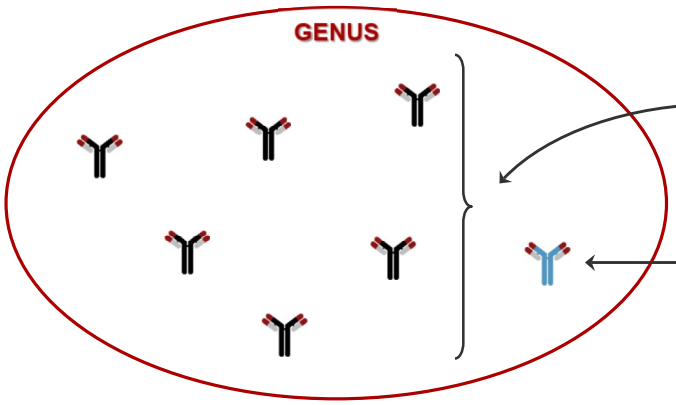
Attacking Claims for Non-Enablement:

- Emphasize **breadth of claims** and **number of compounds** falling within genus
- **Highlight unpredictability** of field
- Undermine predictability of **structure-function relationship**
- Emphasize **amount, time, cost of experimentation required**
- Emphasize lack of disclosure or **guidance** in the specification

Enablement vs. Obviousness

Reconciling **obviousness** with **lack of enablement** for broad claims

- Arguing obviousness assumes predictability and high skill in art
- Arguing lack of enablement assumes unpredictable art



Lack of Enablement: it would have been difficult to make and use the ***full scope*** of the claimed genus

Obviousness: it would have been obvious to make ***at least one*** compound within the scope of the claimed genus

Enablement vs. Obviousness

Tension in positions re: predictability and level of skill in the art

Patentee strategy

- Patent specification is usually more on-point than prior art
- Tie predictability to teachings in the patent specification
- Conflicting positions have potential to undermine both obviousness and enablement positions and create fact disputes on summary judgment

Defendant strategy

- Put patentee in squeeze – but have an end-game
- Streamline trial strategy and reconcile defenses

Lessons Learned for § 112 Defenses

Summary judgment

- **Written description** has a simple standard and limited record (four corners of the specification) but is a question of **fact**
- **Enablement** has multiple *Wands* factors but is a question of **law**

Trial

- Both are technical defenses that are not intuitive to a jury
- Trial theme & compelling product development story are critical

Post-trial motions and appeal

- Historically, lower reversal rates for enablement and written description
- Need to ensure record is adequately developed for appeal

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Inter Partes Review

Patent Trial & Appeal Board (PTAB)

- Highest authority in the US Patent and Trademark Office (USPTO)

- Composed of Administrative Patent Judges (APJs)
  - Technical expertise
  - Three judge panel

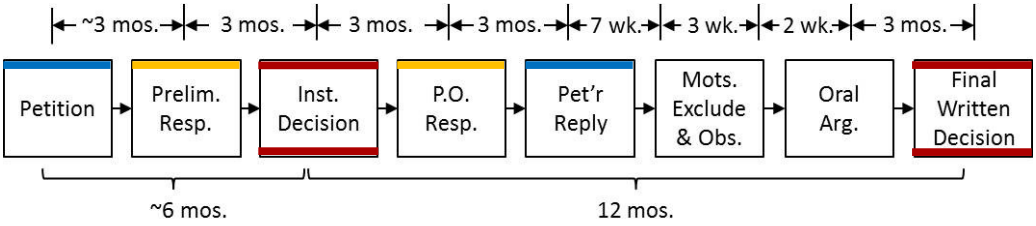
PTAB Proceedings

- *Inter Partes* Review (IPR)
  - Pre- and post-AIA patents, nine months after issue or later
  - Must file within a year of being served with infringement complaint
  - Bases: 35 U.S.C. § 102, 103 (anticipation, obviousness) challenges only

- Post Grant Review (PGR)
  - Post-AIA patents within first nine months after issue
  - Bases: Patent eligible subject matter, anticipation, obviousness, and § 112 challenges

- Covered Business Method Review (CBM)
  - Patents related to “financial services”; method or apparatus for performing data processing, but no “technological inventions”
  - Bases: Patent eligible subject matter, anticipation, obviousness, and § 112 challenges
  - Note: Slated to end Sept. 16, 2020 (unless Congress extends)

PTAB Process



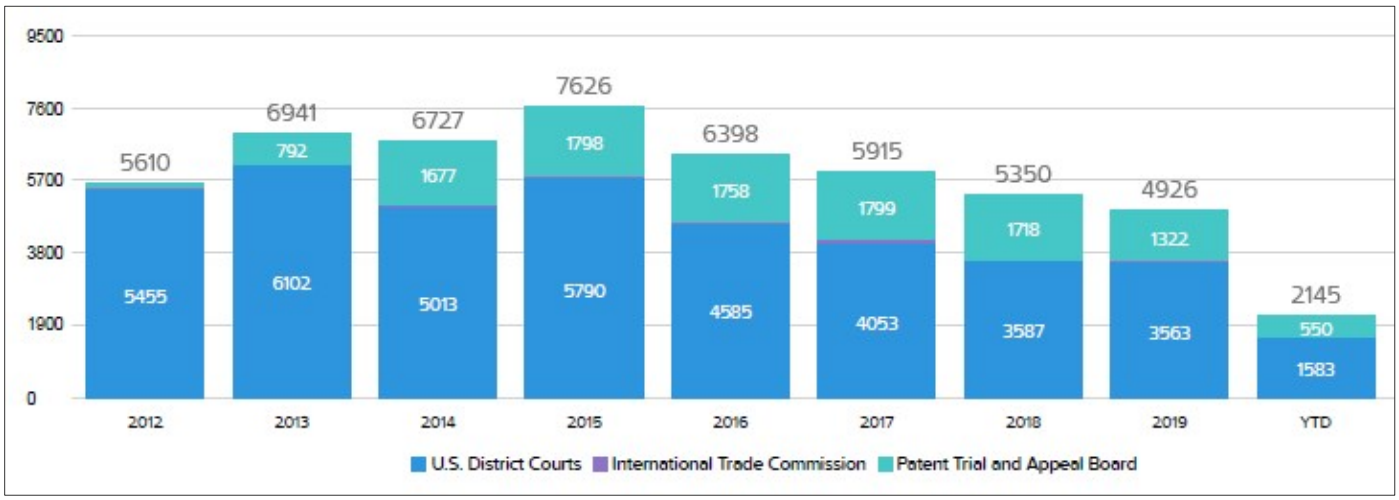
- Briefs
  - Petitioner: Petition and Reply
  - Patent Owner (P.O.): Preliminary Response and Response
  - Motions to exclude, observations
- No live testimony
  - Parties submit declarations as direct testimony (typically expert witnesses)
  - Later deposition serves as cross-examination
- Generally, no other discovery

Should We File an IPR?

- Offensive Strategies
  - Resolve invalidity issues quickly & before technically sophisticated judges
  - Clear a path to market (but not too early: no appeal without Article III standing)
  - File early to potentially stay litigation
  - Settlement leverage
  - Draw out favorable opponent positions on § 112
  - Risks:
    - Potential estoppel
    - “Gold-plated” patents
    - Squandering best prior art
- Defensive Strategies
  - Varied coverage
  - Amend claims
  - Keep a live continuation patent
  - Printed publication evidence

PTAB or District Court?

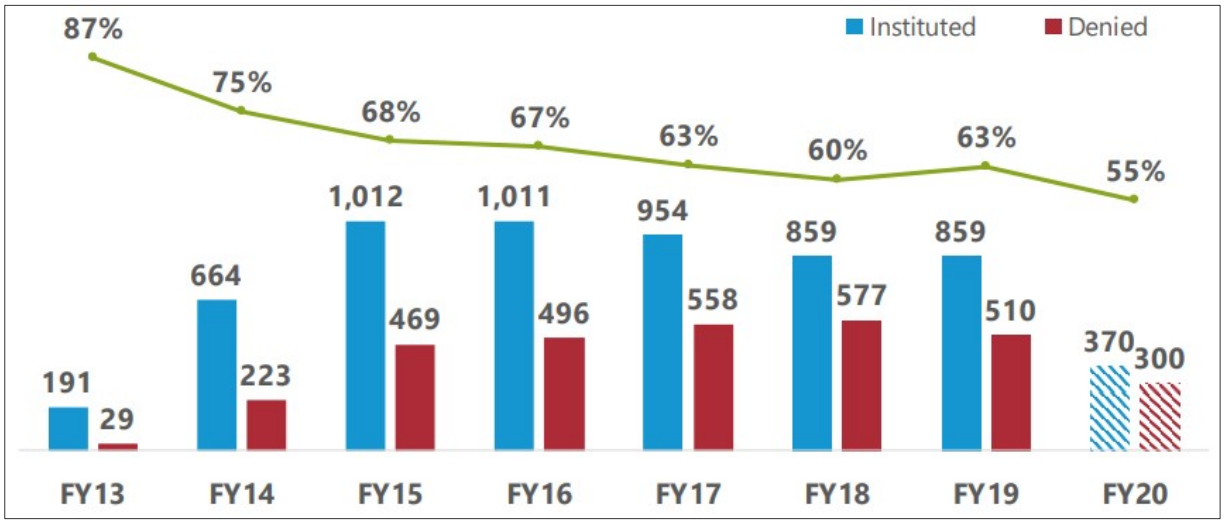
New Cases by Year



Source: Docket Navigator

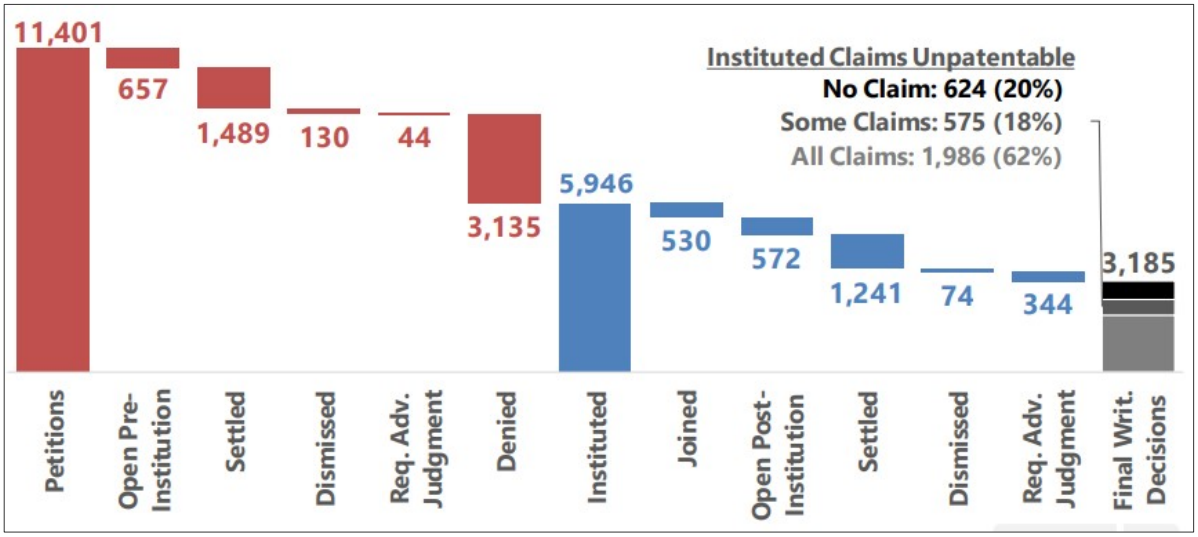
PTAB Institution Rates Declining

Institution Rates



Source: https://www.uspto.gov/sites/default/files/documents/trial_statistics_20200430.pdf

Instituted Claims Unpatentable



Source: https://www.uspto.gov/sites/default/files/documents/trial_statistics_20200430.pdf

Discretionary Denial

- Institution of IPR is discretionary
  - § 325(d): "same or substantially the same prior art or arguments" previously presented to the Patent Office
  - § 314(a): advanced state of a parallel proceeding

- Factors for § 314(a) discretionary denial:
  - Whether the court granted a **stay** or may grant a stay if IPR is instituted
  - Proximity of **court's trial date** to date for Board's final written decision
  - **Investment** in parallel proceeding by court and parties
  - **Overlap of issues**
  - Same **parties**
  - **Other circumstances** (including **merits**)

NHK Spring Co., Ltd. v. Intri-Plex Techs., Inc., IPR2018-00752, Paper No. 8 at 20 (Sept. 12, 2018);
Apple Inc. v. Fintiv, Inc., IPR2020-00019, Paper No. 15 at 7-8 (May 13, 2020)

PTAB Strategic Considerations

Patent Challengers: Prove diligence

- Don't wait - file IPR early
- Provide reasons and evidence of no undue delay
- Consider seeking pre-institution stay at district court
- Provide evidence why IPR is still warranted in view of case schedule

Patent Owners: Prove inefficiency

- Consider filing in "rocket docket" jurisdiction
- Seek discretionary denial to avoid two bites at the apple
- Provide evidence of court's and parties' investment in the case
- Provide evidence of challenger's undue delay

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