

# ASPI-GRAPI Oct. 4&6, 2022

Philippe Signore – Nicolas Seckel

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- 1) Introduction: actualités de l'USPTO
- 2) « Written Description Requirement » : l'autre face de la suffisance de description
- 3) « Definiteness » : la clarté, question de fait, questions de droit

\*\*\* Pause \*\*\*

- 4) Introduction : actualités du PTAB
  - 5) Clauses de sélection de forum dans les licences et accords de confidentialité
  - 6) « On sale » : panorama (anticipation, contrefaçon)
  - 7) Morceaux choisis
-

ASPI-GRAPI Oct. 4&6, 2022

## Written description updates

Nicolas E. Seckel  
Seckel IP, *PLLC*  
Washington, DC

Intellectual Property Law

# Written description

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- 1) Experimental values
    - Biogen v. Mylan
  - 2) Value ranges
    - Indivior v. Dr. Reddy
  - 3) Negative limitation (disclaimer)
    - Novartis v. Accord
-

# Basics

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- 35 USC 112(a): The specification shall contain a [1] written description of the invention, and of the manner and process of making and using it...
    - [in such full, clear, concise, and exact terms as to [2] enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same,
    - and shall set forth the [3] best mode contemplated by the inventor or joint inventor of carrying out the invention].
  - Case law on written description: reasonably convey to those skilled in the art that the inventor had **possession** of the claimed subject matter as of the filing date
    - “[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion”. (Brenner v. Manson, S.Ct. 1966)
  - Question of fact
-

# Written description

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- 1) **Experimental values**
    - **Biogen v. Mylan**
  - 2) Value ranges
    - Indivior v. Dr. Reddy
  - 3) Negative limitation (disclaimer)
    - Novartis v. Accord
-

# Biogen v. Mylan

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- Biogen patent claim: method of treating a subject in need of treatment for **multiple sclerosis** comprising orally administering to the subject in need thereof a pharmaceutical composition consisting essentially of (a) a therapeutically effective amount of dimethyl fumarate, monomethyl fumarate, or a combination thereof, and (b) one or more pharmaceutically acceptable excipients, wherein the **therapeutically effective amount** of dimethyl fumarate, monomethyl fumarate, or a combination thereof is **about 480 [milligrams] per day**.
-

# Biogen patent description

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- Effective doses will also vary, as recognized by those skilled in the art, dependent on route of administration, excipient usage, and the possibility of co-usage with other therapeutic treatments including use of other therapeutic agents. For example, an **effective dose** of DMF or MM[F] to be administered to a subject orally can be from about 0.1 g to 1 g per day, 200 mg to about 800 mg per day (e.g., from about 240 mg to about 720 mg per day; or **from about 480 mg to about 720 mg per day**; or about 720 mg per day). For example, the 720 mg per day may be administered in separate administrations of 2, 3, 4, or 6 equal doses.
-

# District Court

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- Description of dosage is generic to neurodegenerative diseases
  - Description does not show “possession” by the inventors of a method to treat MS with 480 mg/day dose
-



# Federal Circuit

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- **Affirmed**
  - Effective dose is described in neurodegenerative therapy context, but not in MS therapy context
  - POSA would not have recognized that the inventors disclosed 480 mg/day dose as treatment for MS
  - 480-720 range links 480 to known effective 720 dose, but 240-720 range links to known ineffective 240 dose
-

# Written description

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    - **Indivior v. Dr. Reddy**
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-

# Indivior v. Dr. Reddy

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- Indivior patent's main claim:
    - 1. An oral, self-supporting, mucoadhesive film comprising (a) **about 40 wt% to about 60 wt%** of a water-soluble polymeric matrix...
  - Dependent claims:
    - 7. The film of claim 1, wherein the film comprises **about 48.2 wt % to about 58.6 wt %** of the water soluble polymeric matrix.
    - 8. The film of claim 7, wherein the film comprises **about 48.2 wt %** of the water soluble polymeric matrix.
  - Description:
    - Discloses **“any desired level”, “at least 25%”, “at least 50%”**
    - Tables 1 and 5: formulations correspond to total polymer weight of **48.2 wt%** and **58.6 wt%** (can be calculated by POSA)
-

# IPR

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- Dr. Reddy petitioned for IPR
  - Why was written description an issue in IPR?
    - Effective filing date: Indivior needs descriptive support in parent application to avoid prior art
  - PTAB: claims 1 and 7 unpatentable
    - **Insufficient** descriptive support for 40-60 wt% **and** 48.2-58.6 wt% ranges in the parent application
    - Intervening prior art
  - => Patentee Indivior appeals
-

# Federal Circuit

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- In re Wertheim (CCPA 1976): broadly articulated rules are particularly inappropriate in this area
  - No case, with necessarily varied facts, controls the resolution of the written description issue in this case
  - **Affirmed**
-

# Dissent

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- Too strict
  - Patent claim sufficiently described in *In re Wertheim* (CCPA 1976):
    - Claim: between **35%** and **60%** solid contents
    - Description: 25-**60%** solid contents, with examples at **36%** and 50%
  - Patent claim sufficiently described in *Nalpropion v. Actavis* (Fed. Cir. 2019):
    - One-hour release **39-70%**, two-hour release **62-90%**
    - Description: less than about 80% or less than about **70%** at one-hour, less than about **90%** or less than about 80% at two-hour, examples at **39%**, 67% at one-hour, **62%**, 85% at two-hour
-

# Written description

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    - **Novartis v. Accord**
-

### 3) Disclaimer: Novartis v. Accord

---

- Patent claim: method of treating multiple sclerosis comprising:
    - Administering fingolimod “at a daily dosage of 0.5 mg, absent an immediately preceding loading dose regimen.”
  - Description: only administration at regular intervals
    - No mention of loading dose
    - No mention of absence of loading dose
-



# Case law on negative limitation

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- Silence does not support reading the claims to exclude the limitation
    - Something in the specification that conveys to a skilled artisan that the inventor intended the exclusion
  - But a negative limitation need not be recited identically in the specification
    - If POSA would understand the specification as inherently disclosing the negative limitation
      - **Inherency**: 1) **necessarily** present and 2) recognized by POSA
      - Not just making the negative limitation obvious
-

# District Court

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- District Court: **not invalid** for lack of written description
    - Description of regular dosage without description of loading dose = description of no loading dose
    - Prophetic example describes “**initially**” regular daily dosage
-

# Federal Circuit (x1)

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- Jan 3, 2021: affirmed (2 judges)
  - 1 dissent

# Federal Circuit (x2)

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- Mar 11, 2022: Judge who wrote decision **retires**
  - Jun 21, 2022 (**on request for rehearing**):  
**reversed (2 judges)**
    - “**Initially**” refers to length of treatment, not dosage
    - Expert testimony is insufficient
      - Only establishes possibility of no loading dose, not necessity
    - 1 dissent (remaining judge from previous majority)
      - Question of fact, no clear error by the District Court
-

# On the [descriptive] fence

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- Compare:
  - “Initially, patients receive treatment for two to six months”
    - Insufficient description of the negative limitation  
“absence of loading dose”
  - “Sulfacrate... is known to have occasional adverse effects”
    - Sufficient description of the negative limitation  
“absence of sulfacrate” (Santarus v. Par, Fed. Cir. 2012)
-

# Breaking news

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- Sep 29, 2022: Supreme Court has stayed the Federal Circuit's reversal mandate
  - Possible preliminary step to a petition for certiorari
-

# Conclusion

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- Practice tip: describe, expand options
    - Be explicit
  - Key words:
    - “for example”
    - “preferably”
    - “advantageously”
    - “either... or... or both...”
    - “in one aspect... in another aspect...”
-

# Questions, comments?

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## Indefiniteness updates

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# Indefiniteness standard

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- 35 U.S.C. 112(b): The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention
  - Nautilus v. Biosig (S. Ct. 2014): “reasonable certainty” in defining what is patented
    - Stricter than pre-2014 “amenable to construction” or “not insolubly ambiguous”
  - Question of law
    - Based on claim language, specification, prosecution history
    - Disclaimer in specification or prosecution history (if unmistakable)
    - But can involve questions of facts if extrinsic evidence
-

# Typical case

- Claim: an ethylene polymer having... a slope of hardening coefficient [SHC]
- Specification:  $\text{SHC} = (\text{slope of strain hardening}) * (l_2)^{0.25}$
- Trial record: four methods
  - ❑ 10% secant
  - ❑ final slope
  - ❑ most linear
  - ❑ 50-point linear regression
- Fed. Cir. pre-Nautilus: definite
  - ❑ Patentee's expert method
- Fed. Cir. post-Nautilus: indefinite

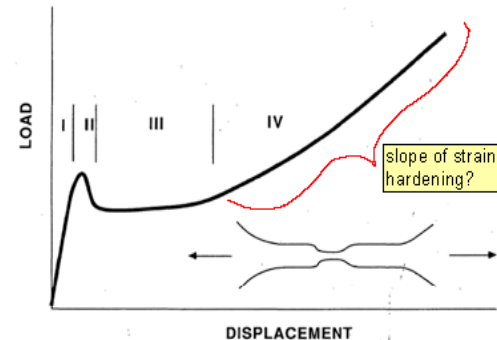


Figure 8. A typical load-displacement curve.

# Update 1: U. Mass v. L'Oreal USA (Fed. Cir., June 13, 2022)

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- Claim:
  - Topically **applying to the skin** a composition comprising a concentration of adenosine in an amount effective...
  - ... wherein the adenosine concentration **applied to the dermal cells** is  $10^{-4}$  M to  $10^{-7}$  M.
-

# Epidermis v. Dermis

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# Timeline

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- 2017: District Court, infringement complaint
  - 2018: PTAB, IPR not instituted
    - PTAB claim interpretation: concentration applied to dermal cells, not concentration in the composition applied topically on the epidermis
  - 2021: District Court, summary judgment of invalidity
    - U Mass: concentration is the molar amount of adenosine per volume of dermal cells
    - District Court: indefinite, the concentrations in the composition and in dermal cells are different
-

# Federal Circuit: claim language

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- Claim language is unclear on its face
    - “Application **to the skin**” includes direct (epidermis) and indirect (dermis)
    - Specification: “**preferably**” topical means directly to epidermis and indirectly to dermis
    - But “**a concentration**” in the composition is before application, contradicts “**the concentration**” in the dermal layer
-



# Federal Circuit: specification

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- Specification does not resolve ambiguity
    - ❑ Mentions M ranges in the composition **before application**
    - ❑ Explains that **not all the adenosine reaches the dermal layer**
    - ❑ Reports experiments **without indicating** that adenosine concentration is after permeating into the dermal layer
-

# Federal Circuit: prosecution history (1)

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- Original claims
    - Main claim only recited “a concentration”
    - Dependent claim only recited “the adenosine concentration” and the range
  - Applicant’s amendment:
    - Incorporated dependent claim into main claim
    - Added “applied to dermal cells”
-

# Federal Circuit: prosecution history (2)

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- Applicant's remarks to amendment:
    - Distinguished two documents based on concentration measured **in the composition before application**
  - Examiner's comment in notice of allowance:
    - "The instant claims are directed to a method... administering adenosine at a concentration of 10-4M to 10-7M **to the skin**"
  - Applicant's comments to notice of allowance:
    - Examiner's reason for allowance "not the only reason"
    - "Claimed concentration is **applied to the dermal cells**"
-

# Federal Circuit: conclusion

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- No contradiction
  - No indefiniteness: **reversed**, remanded
    - Note 1: Nautilus is not even cited
    - Note 2 (digression): also remanded for jurisdictional discovery against L'Oréal France
-

## Update 2: Dyfan v. Target (Fed. Cir. Mar 24, 2022)

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- 35 U.S.C. 112(f): An element in a claim for a combination may be expressed as a **means or step for performing a specified function** without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the **corresponding structure, material, or acts described in the specification and equivalents thereof**.
-

# Dyfan claim

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- 15. A **system**, comprising:
  - a building... including:
    - a first broadcast short-range communication unit...
    - a second broadcast short-range communication unit...
    - **code** configured to be executed by at least one of the plurality of mobile devices, **the code, when executed, configured to:**
      - cause display...
      - receive an indication of a receipt...
      - in response to the indication of the receipt... cause to be sent... at least one first message...
    - said code, when executed, further configured to:
      - receive... the first response message...
      - in response to the receipt... cause to be output... the first visual information..
      - receive... the second response message...
      - after the first visual information... cause to be output... the second visual information
  - wherein **the system is configured such that** the first visual information is automatically caused to be output... and the second visual information is automatically cause to be output
-

## District Court: **indefinite**

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- “Code” defines a “special-purpose computer function” under 35 U.S.C. 112f
    - **No algorithm** as corresponding structure in the specification
  - “System” also indefinite
    - No explanation of which components perform which functions in the specification
-

# Federal Circuit: “code” definite

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- Presumption that 112(f) applies if the word “means” is used
    - “Code” does not raise 112(f) presumption
  - Presumption rebuttable if “nonce” word (reflects nothing more than verbal construct)
    - “Code” is not a “nonce word” (has a reasonably well understood meaning in the art)
    - Expert testimony that “off-the-shelf” code (“software modules”) were available to display info and generate messages as claimed
-



# Federal Circuit: “system” definite

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- In absolute, could be a “nonce” word
  - Here, includes structure (“building”, “communication unit”, “code”)
-

# Federal Circuit: conclusion

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- “We recognize that the asserted claims are not models of clarity...”

# Note: possible nonce words for “means”

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- Mechanism for
- Module for
- Unit for
- Component for
- Element for
- Member for
- Apparatus for
- Machine for
- System for
- Etc.
- Other “black box” terminology

# Update 3: Nature Simulation v. Autodesk (Fed. Cir. Jan 27, 2022)

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- Patent claims a method of triangulation
  - Examiner's amendment in the notice of allowance
  - Accused infringer's expert raised a list of “unanswered questions” about how the triangulation is defined after the examiner's amendment
  - District Court decision: indefinite
-

# Prosecution history

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- Original claim: triangulation method “using modified Watson method”
  - Examiner’s indefiniteness rejection:
    - “The nexus between ‘extending the intersection lines’ and ‘searching neighboring triangles’ is also not clearly set forth. The examiner is not able to ascertain the scope of the claimed invention”
-

# Examiner's amendment

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[3] splitting each triangle through which an intersection line passes using modified Watson method, wherein the modified Watson method includes removing duplicate intersection points, identifying positions of end intersection points, and splitting portion of each triangle including an upper portion, a lower portion, and a middle portion;

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# Federal Circuit

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- PTO examiners are “assumed to have some expertise in interpreting the references and to be familiar from their work with the level of skill in the art and whose duty it is to issue only valid patents.”
  - Claims **not indefinite: reversed** and remanded
  - Dissent: “modified Watson method” is not a term of the art, description does not explain
-

# Conclusion

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- Practice tip: pay attention to descriptive support and clarity of amendments proposed by Examiners
    - Interviews, end-of-production-quarter phone calls from Examiners...
-



# Questions, comments?

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## PTAB updates

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# PTAB, PGP Updates

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- 1) Discretionary denial of institution
  - 2) Director review
  - 3) Patent owner estoppel
-

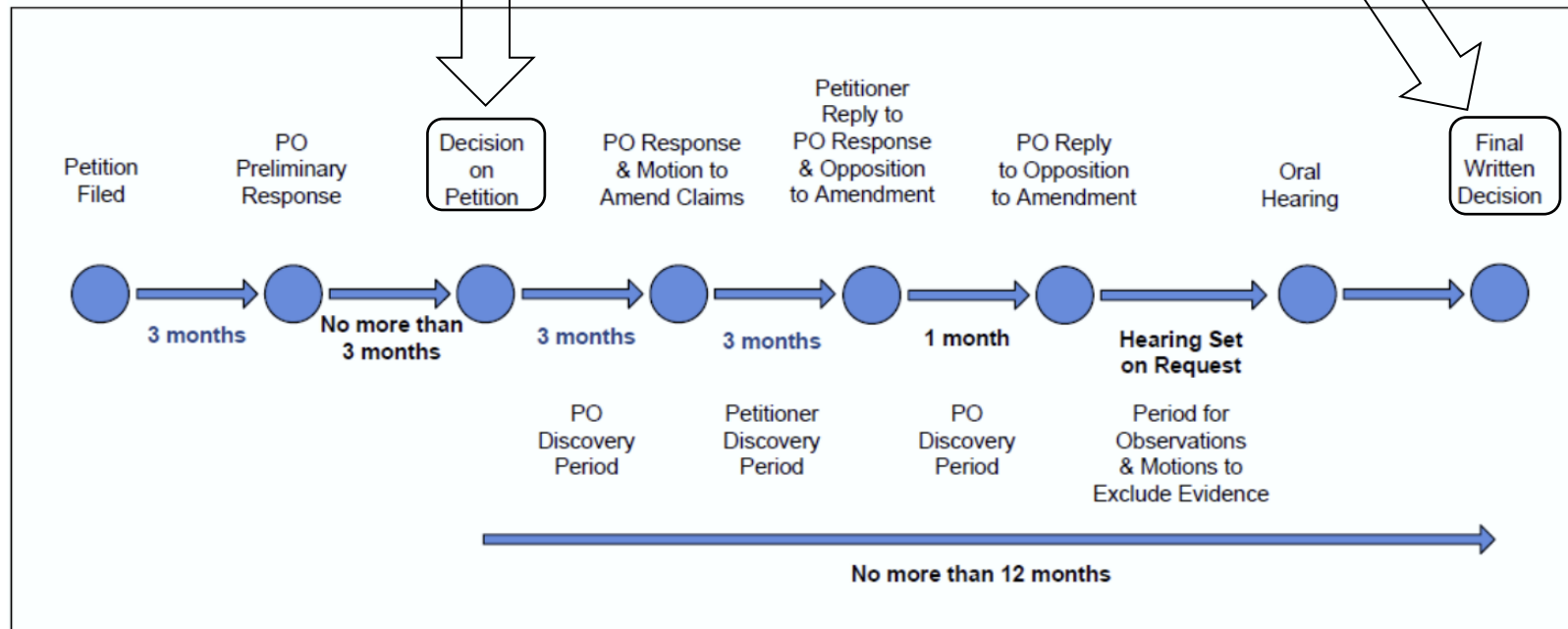
# PTAB, PGP Updates

## Standard timeline for AIA trials

1) Discretionary denial

2) Director review

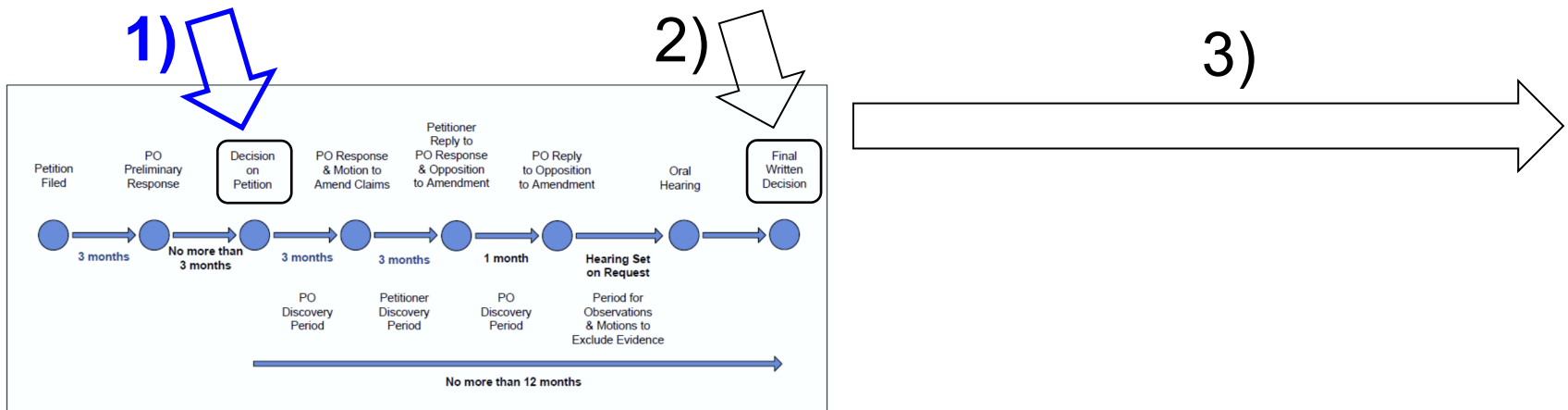
3) Estoppel



# PTAB, PGP Updates

- **1) Discretionary denial of institution**
- 2) Director review
- 3) Patent owner estoppel

## Standard timeline for AIA trials



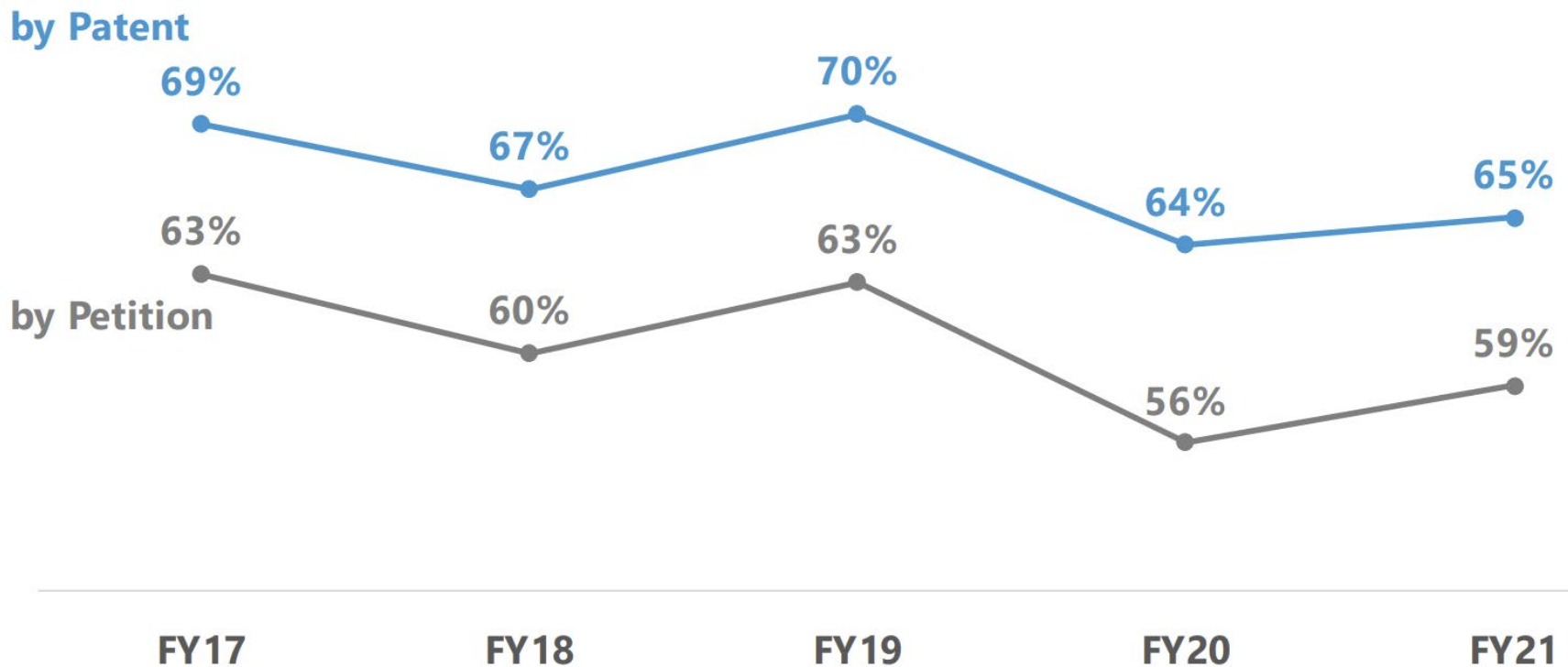
# 1) Discretionary denials of institution

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- Parallel track litigation:
    - About 80% of IPRs are of a patent involved in litigation
    - About 50% of patent infringement defendants file an IPR
    - Accused infringer can raise the same grounds of invalidity/unpatentability in court and at the PTAB
  - Court has discretion to stay during PTAB review
  - PTAB has discretion to refuse to institute a review (not appealable)
    - “Fintiv” factors (Apple v. Fintiv, PTAB 2020)
    - Director Memo of June 21, 2022
-

# Institutions statistics (1)

## Institution rates by patent and by petition (FY17 to FY21: Oct. 1, 2016 to Sept. 30, 2021)

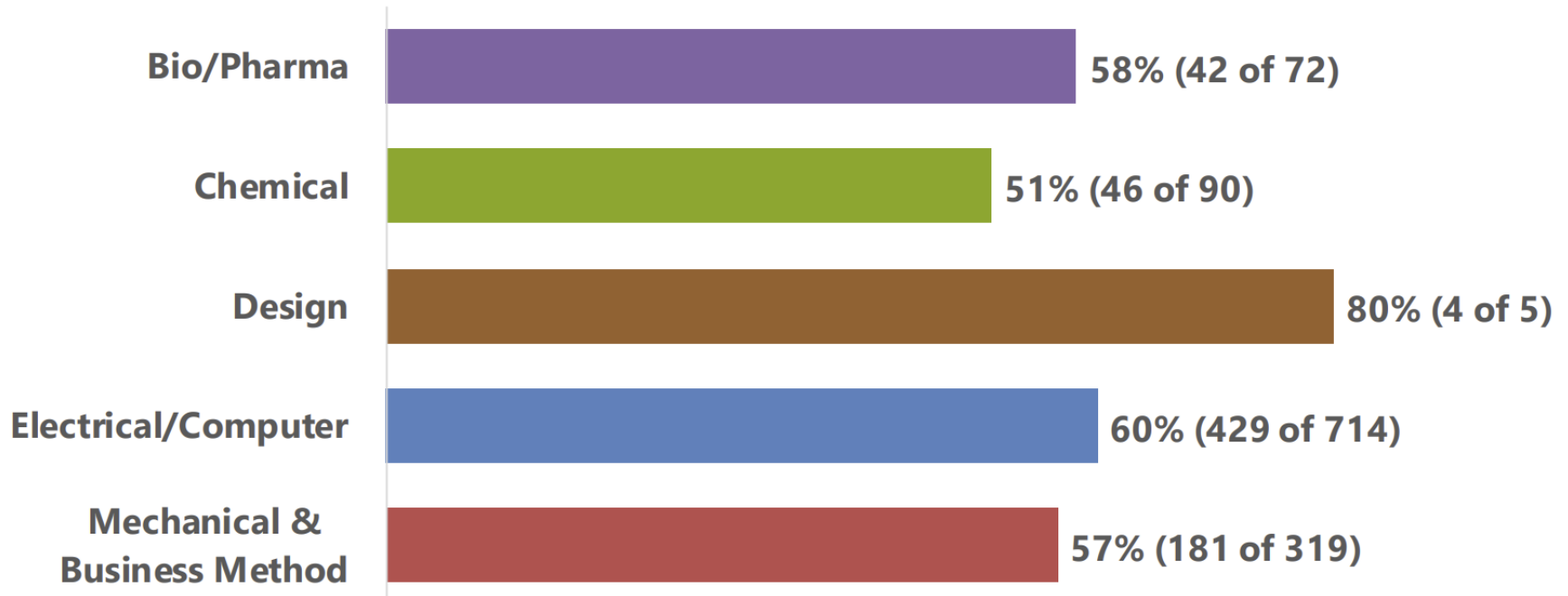




# Institutions statistics (2)

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## Institution rates by technology (FY21: Oct. 1, 2020 to Sept. 30, 2021)



# “Fintiv” factors of discretionary denial when parallel infringement lawsuit

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- 1) Did the court grant a stay or indicated it would?
  - 2) Proximity of court’s trial date?
    - Some judges issue ambitious schedules to trial
  - 3) Investment in the court proceeding?
  - 4) Overlap of issues in court and in the petition?
    - Petitioners have improved their odds of institution with stipulation (will not raise the same grounds in court, or even any grounds that reasonably could have been raised before the PTAB)
  - 5) Petitioner is defendant in court?
  - 6) Other circumstances, e.g., merit of petition?
-

# Director Memo of June 21, 2022

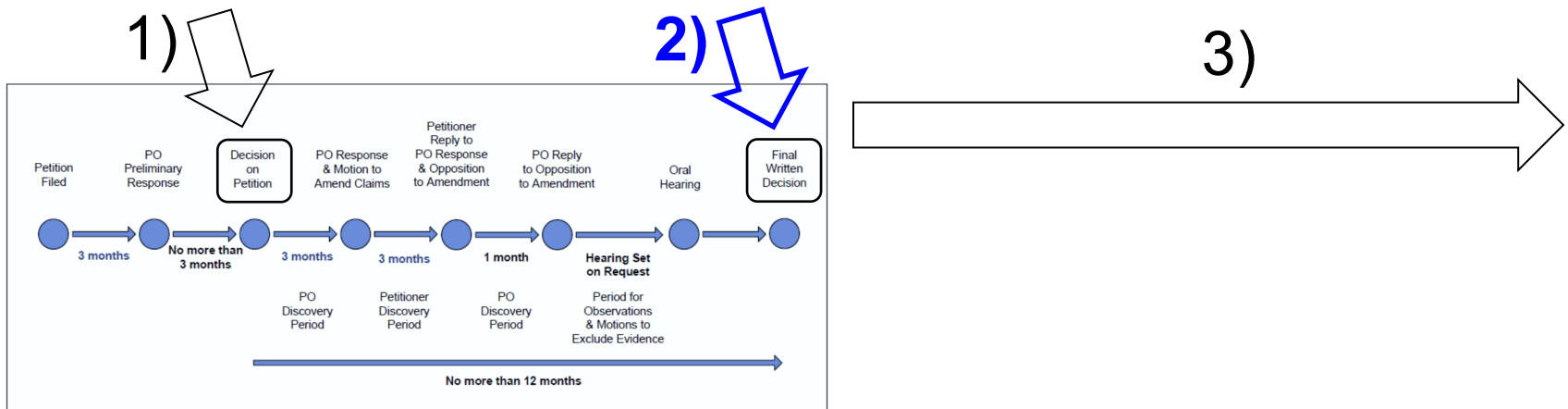
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- 2) Proximity of court's trial date?
    - PTAB will consider **median time to trial** in the district
    - **No denial of institution** for parallel **ITC proceeding**
  - 4) Overlap of issues in court and in the petition?
    - **No denial of institution** if the petitioner files a **broad ("Sotera") stipulation** (petitioner will not pursue in court the same grounds or any grounds that reasonably could have been raised before the PTAB)
  - 6) Other circumstances, e.g., merit of petition?
    - **No denial of institution** if the petition presents a **compelling unpatentability challenge**
    - Compare with the statutory standard for institution (IPR: **more likely than not** that at least one claim is unpatentable, PGR: **reasonable likelihood** that at least one claim is unpatentable)
-

# PTAB, PGP Updates

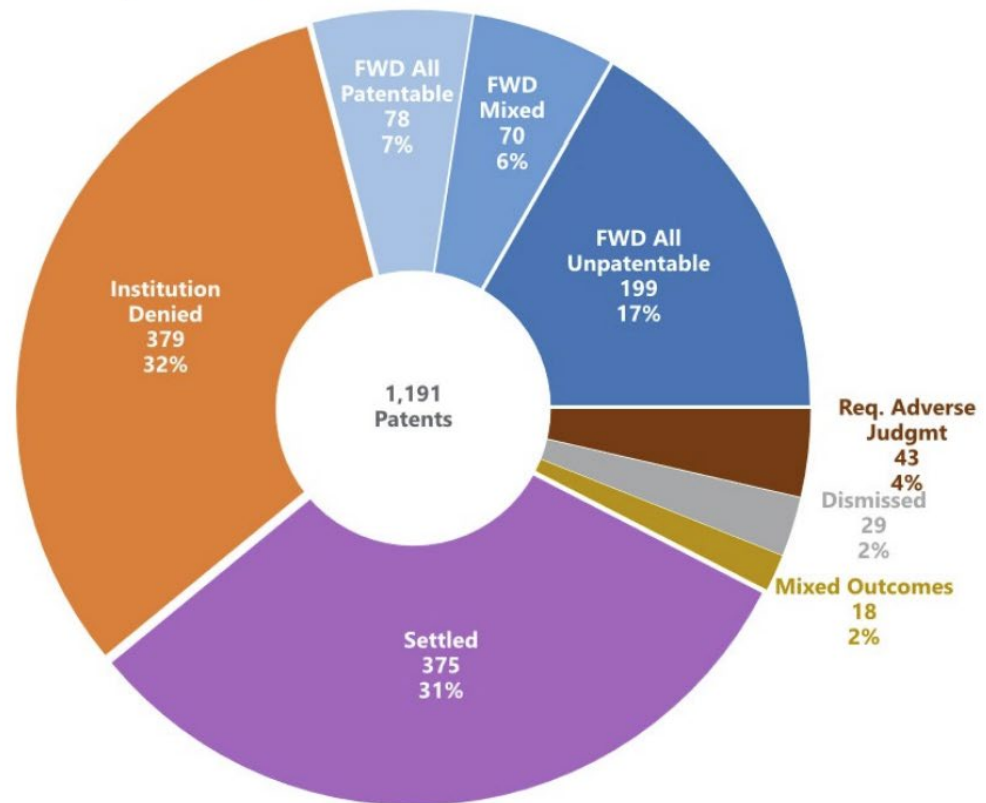
- 1) Discretionary denial of institution
- **2) Director review**
- 3) Patent owner estoppel

## Standard timeline for AIA trials



# Final Written Decisions statistics

## Outcomes by patent (FY21: Oct. 1, 2020 to Sept. 30, 2021)

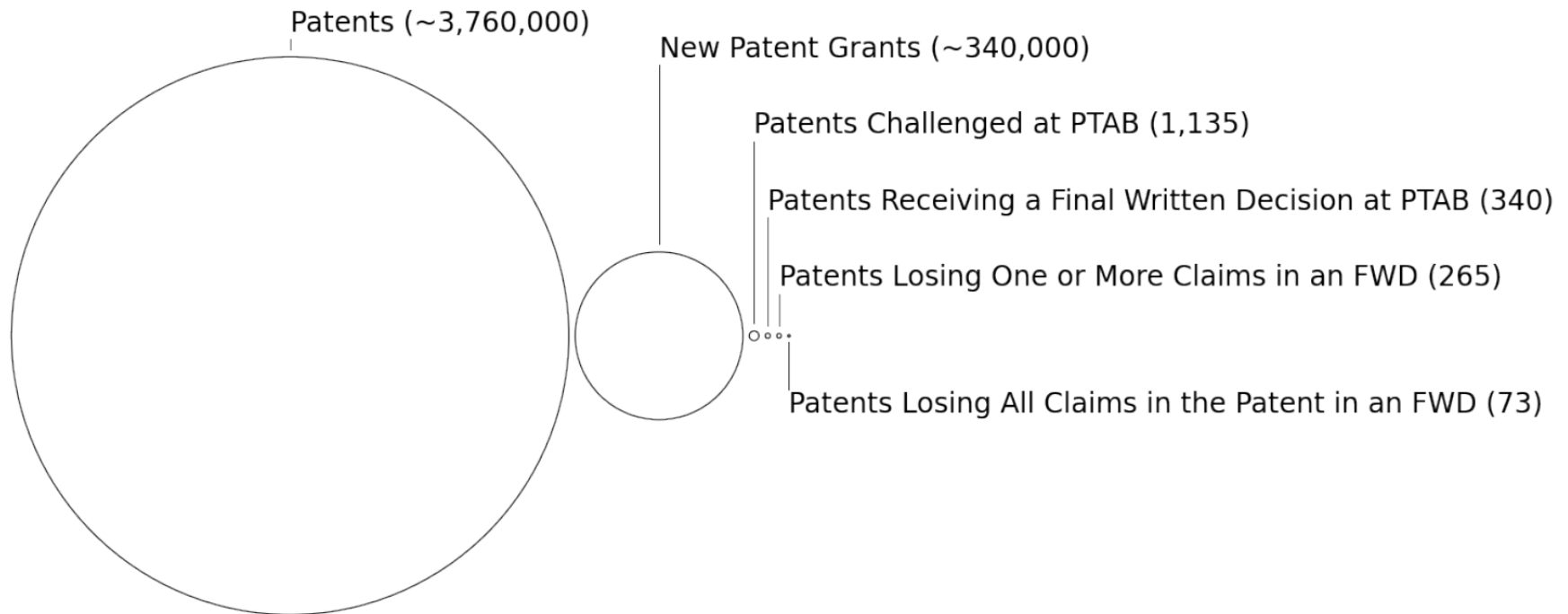


# Final Written Decisions in context

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## All patents

(FY21: Oct. 1, 2020 to Sept. 30, 2021)



## 2) Director review

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- June 21, 2021: U.S. v. Arthrex (S. Ct. 2021): PTAB review without director supervision is unconstitutional
    - PTAB judges are “inferior officers” of the executive
  - Jun 29, 2021: interim **director rehearing** procedure
    - Alternative to PTAB **panel rehearing** (not limited to arguments “misapprehended or overlooked”)
-

# Director review updates (June 2022)

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- No director rehearing of decisions on institution
    - But general authority to do so on petition
  - Not precedential unless designated
    - Like PTAB decisions
  - Directly appealable to Federal Circuit
    - Like PTAB decisions
-



# Director review statistics (Jul 6, 2022)

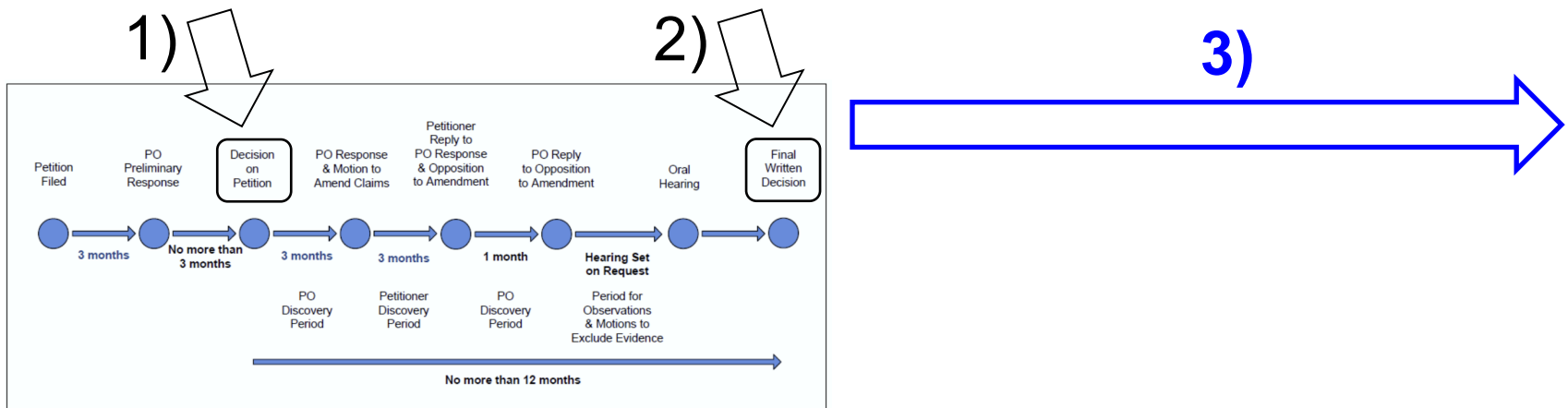
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- 204 request, 198 decisions
    - 5 granted
    - 1 withdrawn
    - 192 denied
  - Compare: PTAB rehearing grants (about 4%)
-

# PTAB, PGP Updates

- 1) Discretionary denial of institution
- 2) Director review
- **3) Patent owner estoppel**

## Standard timeline for AIA trials



### 3) Patent owner estoppel

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- 35 U.S.C. 315(e): upon review final decision, petitioner is estopped from asserting grounds **raised in the review or that reasonably could have been raised in the review**
  - Before 2018, PTAB did partial institution, so it was unclear if the estoppel was narrow (grounds decided only?) or broad (grounds decided? not presented? not instituted?)
-

# CalTech v. Broadcom

## (Fed. Cir., Feb. 4, 2022)

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- Estoppel is broad
    - “Claims and grounds asserted in the petition”
    - “All grounds not in the IPR but which reasonably could have been included in the petition”
  - But estoppel does not extend to
    - Claims not challenged in the petition
-

# Note: District Court estoppel trends

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- Reasonably could have been raised?
    - Prior art document was discovered in later search
    - District court trend: “skilled searcher” or “diligent search” test
  - Estoppel on real product as prior art?
    - Actual product cannot be used in petition (not a “printed publication” like a catalog or manual)
    - District Court trend: is the real product substantially different from the catalog or manual?
-

# Questions, comments?

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“On sale”, “offers to sell, or sells” updates

Intellectual Property Law



# “On sale” updates

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- 1) “On sale bar” as prior art
- 2) “offers to sell, or sells... within the United States” as infringing act

# “On sale” updates

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- 1) “On sale bar” as prior art
- 2) “offers to sell, or sells... within the United States” as infringing act

# On sale bar: basics

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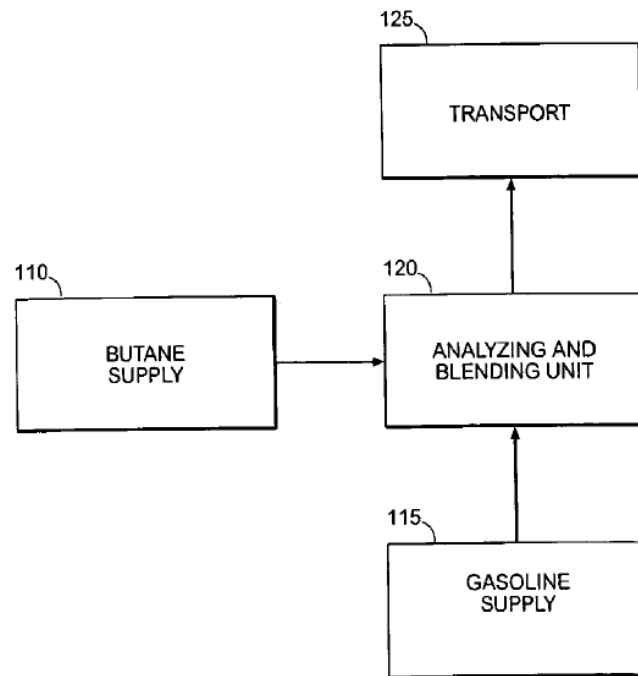
- 35 U.S.C. 102:
    - A person shall be entitled to a patent unless—
    - (1) the claimed invention was patented, described in a printed publication, or in public use, **on sale**, or otherwise available to the public before the effective filing date of the claimed invention; or...
  - Public or private sale
    - *Helsinn v. Teva* (S. Ct. 2019)
  - Not limited to the U.S.
    - Unlike pre-AIA 35 U.S.C. 102 “in this country”
-

# Sunoco v. US Venture (Fed. Cir. Apr 29, 2022)

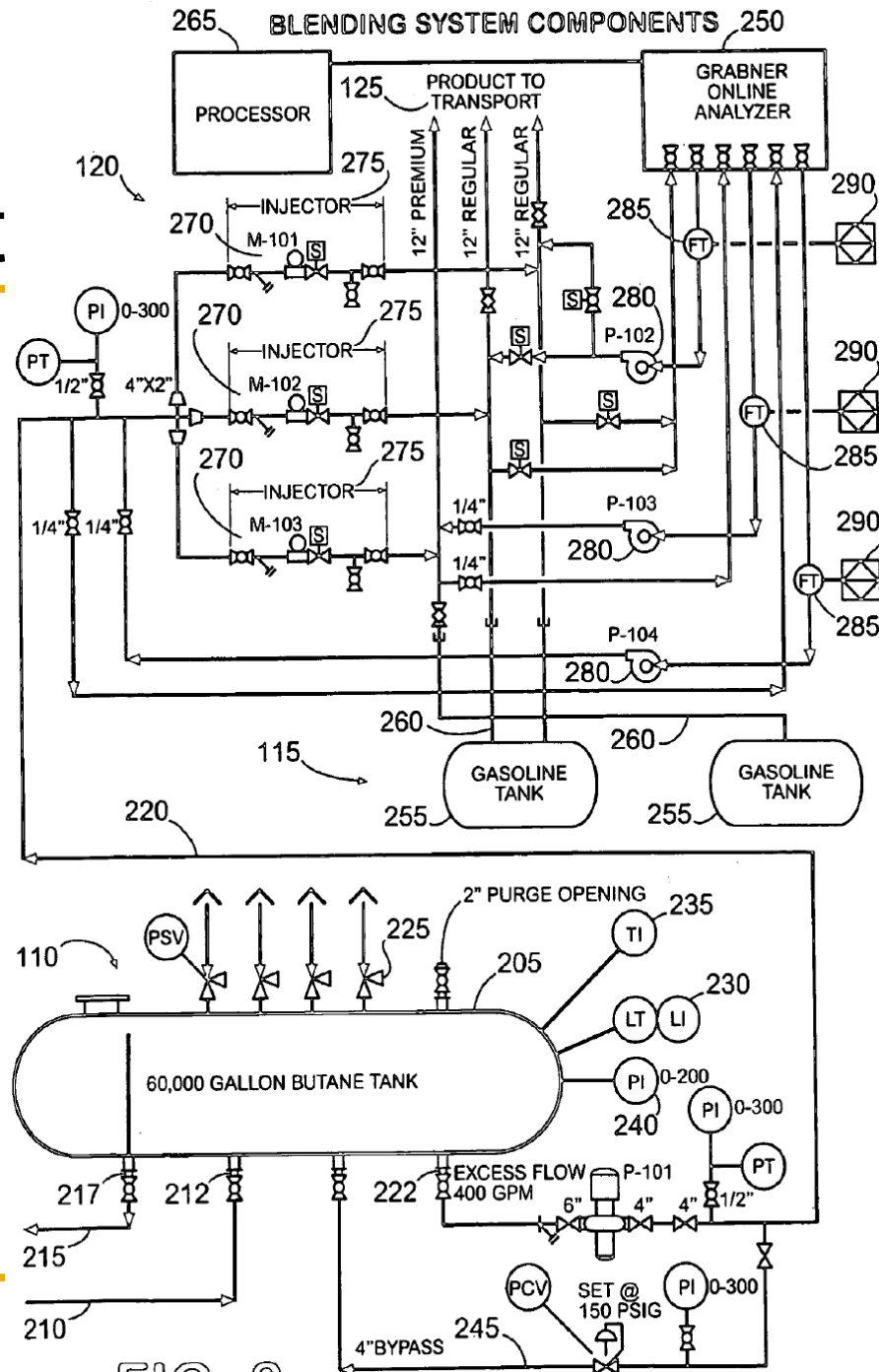
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- Sunoco patents are directed to an installation for blending gasoline and butane

BLENDING ARCHITECTURE OVERVIEW



# Sunoco '629 patent



# Sunoco v. US Venture (Fed. Cir. Apr 29, 2022)

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- Feb. 7, 2000: inventors' company MCE contracted with third party Equilon:
    - MCE provides a butane-blending system
    - Equilon commits to buy 500,000 barrels of butane over 5 years
  - Feb. 9, 2001: patent application filed
  - => Question: was the MCE-Equilon contract a “**sale**”?
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# District Court

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- Contract was for **purchase of butane**, not the system
  - No “on sale” bar
-

# Federal Circuit

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- “On sale bar” test:
    - 1) A commercial “offer” to sell
    - 2) The invention was “ready for patenting”
      - “Experimental” exception (confirming that the invention works for its intended purpose)
  - Apply “law of contracts as generally understood”
    - Here, signed contract, so was it a “sale”? (contract uses the word “sale”)
    - Does experimental exception apply? (contract includes “testing” clauses)
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# Federal Circuit

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- Contract is commercial and transfers title
    - Describes “sale” (of the Equipment)
    - Describes “consideration” (purchase of butane)
    - Similar to the contract in *Helsinn v. Teva* (S. Ct. 2019)
  - Testing clauses are for acceptance, not to experiment
    - “Equipment testing” clause (to “minimum operating standards established by MCE”)
    - “Post-installation testing” clause (“to determine whether the Equipment is properly blending butane”)
  - Holding of no “on sale” bar is **reversed**
    - Remanded to evaluate “ready for patenting”
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# Note: “experimental use” factors

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- (1) “the **necessity for public testing**,”
  - (2) “the amount of control over the experiment retained by the inventor,”
  - (3) “the nature of the invention,”
  - (4) “the length of the test period,”
  - (5) “whether payment was made,”
  - (6) “whether there was a secrecy obligation,”
  - (7) “whether records of the experiment were kept,”
  - (8) “who conducted the experiment,”
  - (9) “the **degree of commercial exploitation during testing**,”
  - (10) “whether the invention reasonably requires evaluation under actual conditions of use,”
  - (11) “whether testing was systematically performed,”
  - (12) “whether the inventor continually monitored the invention during testing,” and
  - (13) “the nature of the contacts made with potential customers.”
- GM v. GE (Fed. Cir. 2005)
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# Other note:

## question of fact v. question of law

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- Anticipation is a question of fact (jury)
  - On sale is a question of law (judge)
    - Legal interpretation
    - Can be based on questions of facts
-

# Side note: duty to disclose “on sale” events

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- Inventors did not disclose a sale before the critical date
- Patent unenforceable for inequitable conduct
- But no litigation misconduct
- => Question: **attorney fees?**
- District Court: **yes**
- Federal Circuit: **affirmed**
  - No weighing of “good” litigation conduct vs. “bad” examination conduct

Energy Heating v. Heat on-the-fly (Fed. Cir., Oct. 14, 2021)

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# “On sale” updates

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- 1) “On sale bar” as prior art
- **2) “offers to sell, or sells... within the United States” as infringing act**

# “offers to sell or sells” infringement basics

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- 35 U.S.C. 271:
    - (a) Except as otherwise provided in this title, whoever without authority makes, uses, **offers to sell, or sells** any patented invention, **within the United States** or imports into the United States any patented invention during the term of the patent therefor, infringes the patent.
  - Question: how is the “location” of a contract determined?
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# CalTech v. Broadcom, Apple (Fed. Cir., Feb. 4, 2022)

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- Many issues (**infringement**, validity, IPR estoppel, etc.)
  - District Court: reasonable royalty on **extraterritorial sales** (products manufactured and delivered outside the US)
  - => Appeal: jury verdict supported by “substantial evidence”?
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# Federal Circuit

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- Factors
    - Pricing
    - Negotiation
    - Substantial activities of the transaction
  - Here, jury determined that the “**sales cycle leading to design wins**” was in the US
    - Supported by substantial evidence
  - This portion of the decision affirmed
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# Domestic transaction factors

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- “**sell**” needs more than just pricing and contracting negotiations in the US
    - Halo v. Pulse (Fed. Cir. 2016): when **substantial activities** of a sales transaction, including the **final formation of a contract for sale encompassing all essential terms** as well as the delivery and performance under that sales contract, occur entirely outside the United States, **pricing and contracting negotiations in the United States alone** do not constitute or transform those extraterritorial activities into a sale within the United States
  - Here, **final contract signed in the US + other activities**
    - + Jury decision that it’s a domestic sale
  - Also, beware “**offer to sell**”
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# Note: 8 steps of sales

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- Preparation
- Prospect
- Research
- Approach
- Pitch
- Handle objections
- Close the sale
- Follow-up

# Note (of caution): 8 steps of sales

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- Preparation
- Prospect
- Research
- Approach
- Pitch  
and/or
- Handle objections  
and/or
- Close the sale
- Follow-up

# Other note: calculation of damages

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- Jury relied on CalTech's two-tier hypothetical negotiation (depending on position in supply chain)
    - High royalty for Apple consumer products
    - Residual lower royalty for OEM components
  - District Court: acceptable
  - Federal Circuit: reversed, remanded for new trial on damages
    - No evidence that two-tier negotiation model was accepted practice
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# Questions, comments?

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This presentation is not legal advice

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# ASPI-GRAPI Oct. 4&6, 2022

Philippe Signore – Nicolas Seckel

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- 1) Introduction: actualités de l'USPTO
- 2) « Written Description Requirement » : l'autre face de la suffisance de description
- 3) « Definiteness » : la clarté, question de fait, questions de droit

\*\*\* Pause \*\*\*

- 4) Introduction : actualités du PTAB
  - 5) Clauses de sélection de forum dans les licences et accords de confidentialité
  - 6) « On sale » : panorama (anticipation, contrefaçon)
  - 7) Morceaux choisis
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ASPI-GRAPI Oct. 4&6, 2022

## Short topic: Moderna v. Pfizer

Nicolas E. Seckel  
Seckel IP, *PLLC*  
Washington, DC

Intellectual Property Law

# Moderna v. Pfizer

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- Dec 2020: Pfizer's mRNA vaccine authorized by FDA
  - Jan 2021: Moderna 's mRNA vaccine authorized by FDA
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# Moderna v. Pfizer

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- Oct 2020: Moderna promised not to sue competitors during the pandemic
  - Mar 2022: Moderna modified its promise
  - Aug 26, 2022: Moderna sued Pfizer
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# Moderna patents

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- '574 patent: mRNA vaccine platform based on modified U (uridine)
  - '600 patent: coronavirus S (spike) protein vaccine
  - '127 patent: S protein vaccine nanoparticle formulation
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# '574 patent issued Jan. 26, 2021

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(21) Appl. No.: **15/927,730**

(22) Filed: **Mar. 21, 2018**

(65) **Prior Publication Data**

US 2019/0060458 A1 Feb. 28, 2019

## **Related U.S. Application Data**

(60) Continuation of application No. 15/379,284, filed on Dec. 14, 2016, now Pat. No. 9,950,068, which is a division of application No. 14/337,513, filed on Jul. 22, 2014, now Pat. No. 9,533,047, which is a continuation of application No. 13/897,362, filed on May 18, 2013, now abandoned, which is a continuation of application No. 13/437,034, filed on Apr. 2, 2012, now Pat. No. 8,710,200.

(60) Provisional application No. 61/470,451, filed on Mar. 31, 2011.

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# '600 issued Jul. 7, 2020

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(21) Appl. No.: **16/805,587**

(22) Filed: **Feb. 28, 2020**

## **Related U.S. Application Data**

- (63) Continuation of application No. 16/368,270, filed on Mar. 28, 2019, which is a continuation of application No. 16/040,981, filed on Jul. 20, 2018, now Pat. No. 10,272,150, which is a continuation of application No. 15/674,599, filed on Aug. 11, 2017, now Pat. No. 10,064,934, which is a continuation of application No. PCT/US2016/058327, filed on Oct. 21, 2016.
- (60) Provisional application No. 62/247,362, filed on Oct. 28, 2015, provisional application No. 62/247,394, filed on Oct. 28, 2015, provisional application No. 62/247,483, filed on Oct. 28, 2015, provisional application No. 62/247,297, filed on Oct. 28, 2015, provisional application No. 62/244,802, filed on Oct. 22, 2015, provisional application No. 62/244,946, filed on Oct. 22, 2015, provisional application No. 62/244,813, filed on Oct. 22, 2015, provisional application No. 62/244,837, filed on Oct. 22, 2015, provisional application No. 62/245,031, filed on Oct. 22, 2015.
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# ‘127 issued Mar. 2, 2021`

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(21) Appl. No.: 16/880,829

(22) Filed: May 21, 2020

(65) **Prior Publication Data**

US 2020/0282046 A1 Sep. 10, 2020

## **Related U.S. Application Data**

(60) Division of application No. 16/805,587, filed on Feb. 28, 2020, now Pat. No. 10,702,600, which is a continuation of application No. 16/368,270, filed on Mar. 28, 2019, now Pat. No. 10,702,599, which is a continuation of application No. 16/040,981, filed on Jul. 20, 2018, now Pat. No. 10,272,150, which is a continuation of application No. 15/674,599, filed on Aug. 11, 2017, now Pat. No. 10,064,934, which is a continuation of application No. PCT/US2016/058327, filed on Oct. 21, 2016.

(60) Provisional application No. 62/247,394, filed on Oct. 28, 2015, provisional application No. 62/247,362, filed on Oct. 28, 2015, provisional application No. 62/247,297, filed on Oct. 28, 2015, provisional application No. 62/247,483, filed on Oct. 28, 2015, provisional application No. 62/244,802, filed on Oct. 22, 2015, provisional application No. 62/245,031, filed on Oct. 22, 2015, provisional application No. 62/244,946, filed on Oct. 22, 2015, provisional application No. 62/244,813, filed on Oct. 22, 2015, provisional application No. 62/244,837, filed on Oct. 22, 2015.

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# Questions, comments?

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