

## Patent Claim and Specification Drafting and Prosecution

Avoiding Traps That Lead to Royalty Free Licensing of Patented Technology

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# *Royalty-free Licensing of Patents Resulting from Mistakes*



The task of preparing a patent application disclosure is not an easy one:

“There are few, if any, legal documents more difficult to craft, more fraught with pitfalls than patent applications[.]”

Circuit Judge Newman dissenting in Energizer Holdings, Inc. v. International Trade Commission, 2008 WL 1791980, \*10 (Fed. Cir. April 21, 2008)(not published)

Study relating patent prosecution to patent validity found that:

“More than a quarter of the patents held invalid in the data set suffered from drafting problems, which generally reflect a failure to include a specification that adequately describes and enables an invention that is delineated with definiteness in the claims.”

Mann, Ronald J. & Marian Underweiser, *A New Look at Patent Quality: Relating Patent Prosecution to Validity*, 9 J. EMPIRICAL LEGAL STUD. 1 (2012). The Mann Study comprised appeals from the district courts 2003 - 2009.

# *Why Is Careful Attention To Drafting So Important? Disclosure Provides Framework For Claim Construction*

- “The specification is always highly relevant to claim construction and is the single best guide to the meaning of a claim term in dispute.”
  - *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005)(en banc)
  - PTAB relying on dictionary definitions when cannot find guidance in spec.

*Who do you want to decide?*

You?

Or a district court judge or PTAB panel influenced by  
opposing counsel?

**Me! Me! Me!**



# *Specification As Guide To The Meaning Of The Claim Terms*

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*E.I. duPont v. Unifrax*, 921 F.3d 1060 (Fed. Cir. 2019)

- Claim 1. A multilayer laminate...comprising... (iii) an inorganic refractory layer; wherein the inorganic refractory layer of (iii) comprises platelets in an amount of **100% by weight** with a dry areal weight of 15 to 50 gsm and a residual moisture content of greater than 10 percent by weight.
- *Some residual dispersant allowed? or not?*
- DC: Some residual allowed, based on specification (“The refractory layer may comprise some residual dispersant from incomplete drying of the platelet dispersion during manufacture.”)
- FC: Affirmed claim construction based on claims, specification and prosecution history.
  - No carrier material allowed but residual dispersant may be present.
  - Unifrax’s product infringed (vermiculite layer with a dispersant).

# *Specification As Guide To The Meaning Of The Claim Terms*

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- *AstraZeneca AB v. Mylan Pharms. Inc.*, 19 F.4th 1325 (Fed. Cir. 2021)
  - Claim limitation: “the PVP K25 is present at a concentration of 0.001% w/w”
  - AZ: means 0.0005% to 0.0014%
  - Mylan: precisely 0.001% with only “minor variations,” i.e., 0.00095% to 0.00104%.
  - DC: Agreed with AZ; claims valid and infringed.
  - FC: Agreed with Mylan; vacated and remanded.
    - “the ‘ordinary meaning’ of a claim term is not ‘the meaning of the term in the abstract.’ . . . Instead, ‘the ‘ordinary meaning’ of a claim term is its meaning to the ordinary artisan **after reading the entire patent.**” [citations omitted]. **Consistent with Phillips, therefore, we must read the claims in view of both the written description and prosecution history.**”
    - “[T]aken as a whole, the intrinsic record supports a narrower construction of 0.001% to reflect that term’s application to the PVP concentration in particular, and the testing evidence in the written description and prosecution history showing that very minor differences in the concentration of PVP—down to the ten-thousandth of a percentage (fourth decimal place)—impact stability.”

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*Small Words*



**BIG  
PROBLEM**

# “*T<sub>o</sub>*”

- *Chef America, Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371 (Fed. Cir. 2004)
  - Claim process for baking dough by “heating the . . . dough **to** a temperature in the range of about 400 degrees F. to 850 degrees F.”
  - If dough were heated to the temperature specified in the claim, “it would be burned to a crisp.”
  - Expert declaration that one skilled in the art reading the claim would believe temperature range referred to temperature of oven, not dough.
  - Patent gives two examples, each stating that the dough product is placed in a multi-layered convection oven and baked “at temperatures” or “at a temperature” of 680° F to 850° F.
- DC: Construed claim to mean temperature of dough -> no infringement.
- FC: Affirmed. “courts may not redraft claims.”
  - Could have chosen “**at** a temperature”, but didn’t.

*Note: pre-Phillips (2005)*

# “A”

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- *KCJ Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351 (Fed. Cir. 2000) (“a” = one or more unless disclaim plural convention)
  - *Baldwin Graphic Systems, Inc. v. Siebert, Inc.*, 512 F.3d 1338 (Fed. Cir. 2008)(“a” or “an” used with “comprising” in claims means “one or more.”)
  - *Harari v. Lee*, 656 F.3d 1331 (Fed. Cir. 2011)(While “a” generally means “one or more,” the claim language and specification must support construing the claim according to that convention. In this case, “a” means “one.”).
  - *Braintree Laboratories, Inc. v. Novel Laboratories, Inc.*, 749 F.3d 1349 (Fed. Cir. 2014) (“a” construed in the singular).
  - *Globus Tel\*Link Corp. v. Securus Tech., Inc.*, IPR2015-01255, Paper 44 (P.T.A.B. Dec. 14, 2016)(“a” means “one or more”).

# “About”

*Jeneric/Pentron, Inc. v. Dillon Co., Inc.*, 205 F.3d 1377 (Fed. Cir. 2000)

- Jeneric used to modify some component ranges in claim, but not others.
- Claim 1. A two-phase porcelain composition comprising a leucite crystallite phase dispersed in a feldspathic glass matrix, a maturing temperature of from *about* 750° to *about* 1050° C. and a coefficient of thermal expansion of from *about*  $12 \times 10^{-6} / ^\circ\text{C}$ . to *about*  $17.5 \times 10^{-6} / ^\circ\text{C}$ . (room temperature to 450° C.), said porcelain composition comprising:

Component	Amount (wt.%)	Component	Amount (wt.%)
SiO <sub>2</sub>	57-66	Li <sub>2</sub> O	0.5-3
Al <sub>2</sub> O <sub>3</sub>	7-15	CaO	0-3
K <sub>2</sub> O	7-15	MgO	0-7
Na <sub>2</sub> O	7-12	F	0-4
CeO <sub>2</sub>	0-1		

wherein the leucite crystallites possess diameters not exceeding *about* 10 microns and represent from *about* 5 to *about* 65 weight percent of the two-phase porcelain composition..

# “About”

- *Jeneric* (con’t)
  - FC: “Without broadening words that ordinarily receive some leeway, the precise weight ranges of claim 1 do not ‘avoid a strict numerical boundary to the specified parameter.’”
    - Other variables in same claim use qualifying language.
    - Claim had to be written narrowly to avoid prior art.
    - Can’t rely on precise ranges to distinguish prior art during prosecution and then have ranges construed broadly in infringement action.

# ‘Is’

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- *Straight Path v. Sipnet, Inc.*, 806 F.3d 1356 (Fed. Cir. 2015)
    - “It depends on what the meaning of the word 'is' is.”
    - Claim language: “transmitting ... a query as to whether the second [unit] **is** connected to computer network.”
    - FC Majority: PTAB erred by including second units that are registered as being on-line, whether or not they actually are still on-line.
      - Plain meaning of “is” is present tense—“is connected ... at the time the query is sent.”
      - PTAB improperly turned immediately to the specification without directly addressing “the facially clear meaning.”
        - “When claim language has as plain a meaning on an issue as the claim language does here, leaving no genuine uncertainties on interpretive questions ..., it is particularly difficult to conclude that the specification ... reasonably supports a different meaning.”

# “Is”

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- *Straight Path* (con’t)
- Dissent:
  - “John is home.”
  - “How do you know?”
  - “I spoke to him five minutes ago.”
  - “[T]he use of the word ‘is’ does not necessarily imply absolute accuracy or absolute currency.”

# “Or” and “On”

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- “or”
  - *Kustom Signals, Inc. v. Applied Concepts, Inc.*, 264 F.3d 1326 (Fed. Cir. 2001) (“or” = exclusive term)
  - *Brown v. 3M*, 265 F.3d 1349 (Fed. Cir. 2001) (“or” = either/or, not one or the other or both)
  - *Schumer v. Laboratory Computer Systems, Inc.*, 308 F.3d 1304 (Fed. Cir. 2002) (construes “or” as designating alternatives)
  
- “on” and “onto”
  - *Inverness Medical Switzerland GmbH v. Warner Lambert Co.*, 309 F.3d 1373 (Fed. Cir. 2002)(cover impregnation within?)

## “At Least One”

- *Enzo Biochem Inc. v. Applera Corp.*, 780 F.3d 1149 (Fed. Cir. 2015)
  - Claim limitation at issue: “wherein A comprises at least three carbon atoms and represents **at least one** component of a signaling moiety capable of producing a detectable signal;”
  - DC: Infringed.
    - Claim construction - no additional steps required to detect the compound; allowed for both direct and indirect detection of the claimed compound.
  - FC: Reversed claim construction; vacated infringement.
    - “the plain reading of the disputed claim term requires that a signalling moiety be composed of components, of which at least one is ‘A.’”
    - “claim 1 covers only indirect detection”

## “At Least One”

- Claim = “at least one of a W, a X, a Y, and a Z”
- Does the phrase mean at least one W and at least one X and at least one Y and at least one Z?
- Likely, yes
  - “at least one of” modifies each category in the criteria list
  - “and” connotes a conjunctive list
  - see *Superguide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870 (Fed. Cir. 2004)

## *“And/Or”*

- “at least one of a W, a X, a Y, **and/or** a Z”
  - Creates unnecessary ambiguity?
  - Try using “at least one \_\_\_\_\_ (needs to be a noun such as polymer) chosen from a and b,” clearly covers “and/or”.
- What about the phrase “compound and/or salt” ?
  - Try “at least one chemical entity (or “drug substance”) chosen from a compound of formula I and a pharmaceutically acceptable salt thereof” or “at least one chemical entity (or “drug substance”) chosen from compounds of formula I and pharmaceutically acceptable salts thereof.”
- Another approach is present an independent claim to a compound of formula I and another independent claim to a pharmaceutically acceptable salt of the compound of formula I.
  - But if on Track I, that spends two independent claims.

# Post-SuperGuide

- *SIMO Holdings, Inc. v. Hong Kong uCloudlink Network Technology Limited*, 2021 U.S. App. LEXIS 137 (Fed. Cir. Jan. 5, 2021)
  - “a plurality of [a, b, c, d, e and/or f]
  - *Does “a plurality of” apply to each element in a series?*
- DC: No, “a plurality of” requires only ‘at least two’ members selected from the entire list of identified items (memory, processors, etc.)”
- FC: Reversed.
  - “We conclude, along with uCloudlink, that ‘a plurality of’ requires at least two of *each* of the listed items in the phrase at issue in claim 8.” (emphasis in original)
  - Cites *SuperGuide Corporation v. DirecTV Enterprises, Inc.*, 358 F.3d 870 (Fed. Cir. 2004), “a phrase grammatically comparable to ‘a plurality of’ at the start of a list of items joined together by ‘and’ applied to each item in the list, not to the list considered as a whole.”

## “And”

- *Intellectual Ventures II L.L.C. v. JP Morgan Chase & Co.*, 13-cv-03777 (S.D.N.Y July 12, 2017), *aff’d without opinion* (Fed. Cir. 2019)

- Claim 4. A crypto-engine for cryptographic processing of data comprising an arithmetic unit...and an interface controller...the arithmetic unit including: a memory unit...and a sign inversion unit for performing arithmetic operations on said data...

- *Markman* order construed “sign inversion unit” as “[a] unit that changes positive numbers to negative numbers and changes negative numbers to positive numbers.”

- DC: No infringement because JP Morgan’s product does not, and is not capable of, “converting negative numbers into positive ones.”

- JP’s products limit inputs to positive numbers; “the sign inversion unit must be functional in order for the arithmetic unit to be ‘operable as a co-processor for a host processor.’”

- “Claim Four does not mention the ‘capacity’ or ‘capacities’ of the arithmetic unit, but describes only its actual performance.... Neither Claim Four..., nor the construction of Claim Four, describes capability, and therefore alleged capability does not give rise to an issue of fact where there has been no infringement.... Claim Four describes use and function, not capability.”

# “Over”

- *Samsung Electronics Co. Ltd. v. Home Semiconductor Corp.*, IPR2015-00460
  - claim limitation “a step of forming an oxide layer **over** the diffusion region”
  - Patent Owner: “over” means “covering”
  - Petitioner: “over” means “above” (“covering” is too narrow)
  - PTAB: applied Petitioner’s proposed construction -> claims anticipated.
  - FC: Reversed (Case No. 2016-2215 July 25, 2017, non-precedential).
    - “Board’s construction of ‘over’ as meaning ‘above’ is unreasonable in light of the claim language and the specification.
    - “Although ‘over’ and ‘above’ can be interchangeable in certain contexts, they are not coextensive here, and the full scope of ‘above,’ which is not a claim term, cannot be adopted to give meaning to the actual claim term ‘over’ if that adoption would result in an unreasonable interpretation of the claim term in context. This understanding of the claim term ‘over’ is also supported by the specification[.]”
    - Construed claim independently as “forming an oxide layer over the diffusion region in addition to on the sidewalls of the gate electrode.”
    - No anticipation.
      - “the ‘oxide layer’ in Doshi, which teeters above on the outermost edge of the diffusion region, cannot be understood as an oxide layer formed ‘over the diffusion region.’”

# “Of” ≠ “From”

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- *Fluid Energy Group Ltd. v. Green Products and Technologies, LLC*, IPR2021-00357, Paper 48 (P.T.A.B. July 5, 2022)
  - Claim. A method for cleaning a surface **of** a cementitious material comprising:  
providing a composition comprising HCl, urea, complex substituted keto-amine-hydrochloride, an alcohol, an ethoxylate, and a ketone;  
applying the composition to a surface to release a cementitious material therefrom; and  
removing the composition and released cementitious material **from** the surface.
  - Board’s Claim Construction: The preamble’s use of the word “of” inconsistent with the body of the claim and the specification, which “plainly identify the object of the claimed invention as ‘removing cementitious materials **from** surfaces.’”
    - Also, “the body of the claim fully and completely sets forth all of the required method steps of the invention, as well as the components of the required composition.”
    - Preamble was not to be construed as reciting an additional required step.
    - The surface of the material is separate from the cementitious material. There are “two distinctly claimed structures (i.e., ‘a Surface’ and ‘a cementitious material’).”

# *Adjectives and Adverbs, Including Relative Terms*

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*Karsten Mfg. Corp. v. Cleveland Golf Co.*, 242 F.3d 1376 (Fed. Cir. 2001)

- “An **improved correlated** set of iron type golf-clubs, each club...”

*ArcelorMittal France v. AK Steel Corp.*, 700 F.3d 1314 (Fed. Cir. 2012)\*

- “the steel sheet has a **very high** mechanical resistance after thermal treatment.”
- no industry definition of “very high” mechanical resistance;
- DC “relied on the statements in the specification that ‘high’ and ‘substantial’ mechanical resistance ‘may exceed 1500 MPa.’”
- FC: Affirmed construction.
  - **Specification supports district court's construction.**
  - ArcelorMittal argued invention could include a resistance as low as 1000 MPa
    - Specification language: “makes it possible to obtain a mechanical resistance in excess of 1000 MPa.”
    - But specification does not refer to 1000 MPa as “high” or “very high.”

# *Adjectives and Adverbs, Including Relative Terms*

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- *Niazi Licensing Corp. v. St. Jude Med. S.C., Inc.*, 30 F.4th 1339 (Fed. Cir. 2022)
  - DC: Claim terms “resilient” and “pliable” were indefinite.
  - FC: Reversed.
    - the terms “resilient” and “pliable” are broad, but not uncertain.
    - Sufficient explanation and examples in the intrinsic record so a POSITA would have sufficient guidance to understand the terms with reasonable certainty.

# “Essentially Free”

*Sunovion Pharmaceuticals, Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1271 (Fed. Cir. 2013)

- Claim 1. 6-(5-chloro-2-pyridyl)-5-[(4-methyl-1-piperazinyl)carbonyloxy]-7-oxo-6,7-dihydro-5Hpyrrolo[3,4-b]pyrazine, or a pharmaceutically acceptable salt thereof, in the form of its dextrorotatory isomer and **essentially free** of its levorotatory isomer.
- FDA-approved commercial product required that “each tablet ... contain not more than (“NMT”) 0.3% of eszopiclone’s corresponding levorotatory enantiomer, (R)-zopiclone.”
- Reddy’s ANDA sought approval for eszopiclone products restricted to “NMT 0.6%” (i.e., 0.0-0.6%)” of the levorotatory isomer.
- FC: Affirmed summary judgment of noninfringement.
  - Phrase “essentially free” appeared only in the claims, not the specification.
  - Prosecution history shows that the applicants “repeatedly and consistently defined” their invention “as the dextrorotatory isomer of zopiclone containing less than 0.25% of the levorotatory isomer.”

# Words Of Degree

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*Valeo North America, Inc. v. Magna Electronics, Inc.*, IPR2015-00251, Paper 18 (P.T.A.B. May 26, 2016)

- Claim phrase: “**at least about** 200 candelas/sq. meter”
- Asserted reference: “a range of not less than 5 [candelas/sq. meter] and **not more than** 200 [candelas/sq. meter]”
- PTAB FWD: Instituted claims unpatentable as obvious.
  - “not more than” renders obvious “at least about”
  - “Simply stated, ‘not more than’ and ‘at least about’ 200 candelas/sq. meter both include a disclosure of the same value – 200 candelas/sq. meter.”

# *Practice Tip*

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Consider incorporating modifiers into the definitions of the terms rather than in the claims.



# Functional Language

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*Halliburton Energy Services, Inc. v. M-I LLC*, 514 F.3d 1244 (Fed. Cir. 2008)

- Claim: “A method for conducting a drilling operation in a subterranean formation using a fragile gel drilling fluid[.]”
- Specification defined “fragile gel” as:
  - a “gel” that is easily disrupted or thinned, and that liquifies or becomes less gel-like and more liquid-like[.]”
- FC: Halliburton’s claim term “fragile gel” was indefinite - insufficiently defined functionally.
  - “We note that the *patent drafter is in the best position to resolve the ambiguity in the patent claims*, and it is highly desirable that patent examiners demand that applicants do so in appropriate circumstances so that the patent can be amended during prosecution rather than attempting to resolve the ambiguity in litigation.”
  - “A patent drafter could resolve the ambiguities of a functional limitation in a number of ways. For example, the ambiguity might be resolved by using a quantitative metric (e.g., numeric limitation as to a physical property) rather than a qualitative functional feature. The claim term might also be sufficiently definite if the specification provided a formula for calculating a property along with examples that meet the claim limitation and examples that do not.”

# *Functional Claim Construction*

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*Bracco Diagnostics Inc. v. Maia Pharms., Inc.* (Fed. Cir. 2020) (non-precedential)

- Claim 1. A stabilized, physiologically acceptable formulation of sincalide comprising:  
a) an effective amount of sincalide, b) at least one stabilizer, c) a **surfactant/solubilizer**, d) a chelator, e) a bulking agent/tonicity adjuster, and f) a **buffer**.
- Claim 3. The formulation of claim 1, wherein said **buffer** is selected from the group consisting of . . . one or more amino acids . . . and biological buffers.
- Claim 6. The formulation of claim 1, wherein said **surfactant/solubilizer** is selected from the group consisting of . . . amino acids.

# Bracco (con't)

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District court construed “buffer” and “surfactant/solubilizer” to include a list of exemplary agents from specification.

Maia stipulated to infringement.

FC: Affirmed.

- Although district court “technically erred in importing a list of excipients into its definition of buffer” did not invalidate its **functional construction** “that a buffer, for purposes of this invention, is ‘[a]n excipient that: stabilizes the pH of sincalide formulations of the invention, and consequently, reduces the risk of chemical [in]stability at extreme pH values.’”
  - Maia gave up argument that amino acids are not buffers when it stipulated to infringement.
- Although district court “technically erred in importing a list of excipients into its definition of surfactant/solubilizer ” that did not invalidate its essentially correct **functional construction** “that a surfactant/solubilizer ‘may reduce the interfacial tension or aid in solubilization thus preventing or reducing denaturation and/or degradation at air/liquid or liquid/solid interfaces of the product in solution.’”
  - Maia gave up argument that amino acids are not surfactant/solubilizers when it stipulated to infringement.
- District court correctly construed the backslash to mean and/or.

# Does Using “First” and “Second” Mean There are Two Components Required?

*Regents of University of Minnesota v. AGA Medical Corp.*, 717 F.3d 929 (Fed. Cir. 2013)

- **Claim:** a septal defect closure device comprising **first and second** occluding disks...; a central portion of the membrane of the first disk being affixed to a central portion of the membrane of the second disk to define a **conjoint disk** . . . .
- **FC: Yes, there must be two disks that are discrete structures**
  - Specification supports
    - “specification never teaches an embodiment constructed as a single piece. Quite the opposite: ‘every single embodiment disclosed in the ’291 patent’s drawings and its written description is made up of two separate disks.’”
      - “a device formed by attaching two disks together ‘is not just the preferred embodiment of the invention; **it is the only one described.**’”
  - Prosecution history supports
    - Notice of Allowability: “primary reason for the allowance of the [’217 patent’s] claims [wa]s the inclusion, in all the claims, of the limitation that . . . *a first membrane is connected to a central portion of a second membrane to form a conjoint disk.*”

# *Does Order Of Steps Matter?*

*Amgen, Inc. v. Sandoz, Inc.*, 923 F.3d 1023 (Fed. Cir. 2019)

- Amgen’s claim 7. A method of purifying a protein expressed in a non-native limited solubility form in a non-mammalian expression system comprising: 7 steps (a)-(g).
- DC: construed limitations (f) and (g) as separate steps that must occur in order and granted summary judgment of noninfringement.
  - Sandoz’s process only involves one step and one solution.
- Amgen argued that the claims cover any number of solutions or steps as long as the functions of washing and eluting happen in sequence.
- FC: Affirmed.
  - “the claim language logically requires that the process steps, lettered (a) through (g), be performed in sequence”
  - washing and eluting ((f) and (g)) are consistently described in the specification as separate steps performed by different solutions.

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*More Claim Drafting Issues*

# Claim Drafting: Preamble

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## Preamble limiting when:

- Relied upon by the applicant for patentability.
  - See *MBO Laboratories, Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323 (Fed. Cir. 2007).
    - Claim 1. A method of immediately and positively precluding needlestick injury from a contaminated needle comprising the steps of . . . [.]
    - “an essential feature [of the invention is] immediate needle safety upon removal from the patient. It is therefore appropriate to construe the claims so as to ensure that they, too, require that feature.”
- “If the preamble is ‘necessary to give life, meaning and vitality’ to the claim[.]”
  - *Kropa v. Robie*, 187 F.2d 150, 152 (CCPA 1951).

## Preamble not limiting when:

- No reliance upon for patentability.
  - *Marrin v. Griffin*, 599 F.3d 1290 (Fed. Cir. 2010)
    - Claim 1. A scratch-off label for permitting a user to write thereon without the use of a marking implement, comprising: a permanent base having a colored near side which is normally visible to the user and having a far side; and a coating of scratch-off non-transparent material having a color which contrasts with the color of the near side of the permanent base, which coating is applied directly onto the near side of the permanent base with sufficient thickness so as to obscure the color of the permanent base, and which when scratched off reveals the color of the near side of the permanent base.

# Preamble Analysis

*Butamax Advanced Biofuels LLC v. Gevo, Inc.*, IPR2014-00250, Paper 29  
(P.T.A.B. March 13, 2015)

- Claim 1. A process for preparing a **renewable jet fuel** comprising: . . . whereby the product of step (g) meets the requirements of ASTM D1655.
- Claim 18. A **renewable jet fuel or jet fuel precursor** comprising a mixture of aromatic hydrocarbons and C11–C14 aliphatic hydrocarbons.
- PTAB FWD:
  - **Preamble in claim 1 not limiting** - states an intended use; not relied upon to define subject matter of claimed invention because explicitly recited in body of claim.
  - **Preamble in claim 18 is limiting** – “recites a specific characteristic of the source component of the invention.”

Not  
Limiting  
Limiting

*See also Golden Bridge Technology, Inc. v. Apple Inc., 758 F.3d 1362 (Fed. Cir. 2014), for an example of comments about the preamble in an IDS were found to be a disavowal impacting claim construction. Exercise caution when it comes to patentability statements!*

# Preamble Analysis

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*Acceleration Bay, LLC v. Activision Blizzard Inc.*, 908 F.3d 765 (Fed. Cir. 2018)

- Claim 1. A computer network for providing a **game environment** for a plurality of participants, each participant having connections to at least three neighbor participants, ...
- Claim 1. A computer network for providing an **information delivery service** for a plurality of participants, each participant having connections to at least three neighbor participants,
- PTAB did not read “game environment” and “information delivery service” as claim limitations.
- Acceleration: patentable weight because they provide structure, or, alternatively, they are in the body of the claim because there is no transition phrase.

# Preamble Analysis

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## *Acceleration Bay* (con't)

- FC: **Affirmed; phrases are non-limiting preamble phrases.**
  - “[M]erely describe intended uses for what is otherwise a structurally complete invention. They do not impart any structure into or serve as antecedents for the claims at issue.”
  - **“Acceleration’s poor claim drafting will not be an excuse for it to infuse confusion into its claim scope. We conclude that “game environment” and “information delivery service” are part of the preamble of the claims. We see no beneficial purpose to be served by failing to include a transition word in a claim to clearly delineate the claim’s preamble from the body, and we caution patentees against doing so.”**

# Preamble Analysis

- *Bio-Rad Labs. v. 10X Genomics*, 967 F.3d 1353 (Fed. Cir. 2020)
  - Claim: “[a] method for conducting a reaction in plugs in a microfluidic system, comprising the steps of . . . .”
  - District court not limiting; Federal Circuit limiting.
- *Mylan Labs. Ltd. v. Aventis Pharma S.A.*, IPR2016-00712, Paper 112 (P.T.A.B. Oct. 22, 2019), *on remand after Federal Circuit ordered claim construed with preamble as limitation*, *aff’d without opinion* (Fed. Cir. Jan. 15, 2021).
  - “A method of **increasing survival** comprising administering...”
  - Construing preamble as limitation -> claims not obvious and motion to amend proposing substitute claims granted.
- *Stingray IP Sols., LLC v. Legrand*, 2022 U.S. Dist. LEXIS 70339 (E.D.Tex. Apr. 14, 2022)
  - “A mobile ad hoc network comprising” and “A mobile ad-hoc network (MANET) comprising” **NOT limiting**.
  - “An intrusion detection method for a mobile ad-hoc network (MANET) comprising a plurality of nodes, the method comprising” is **limiting**.
    - Antecedent basis for structural limitation and recites the essence of the invention.

## *Claim Drafting Tip*

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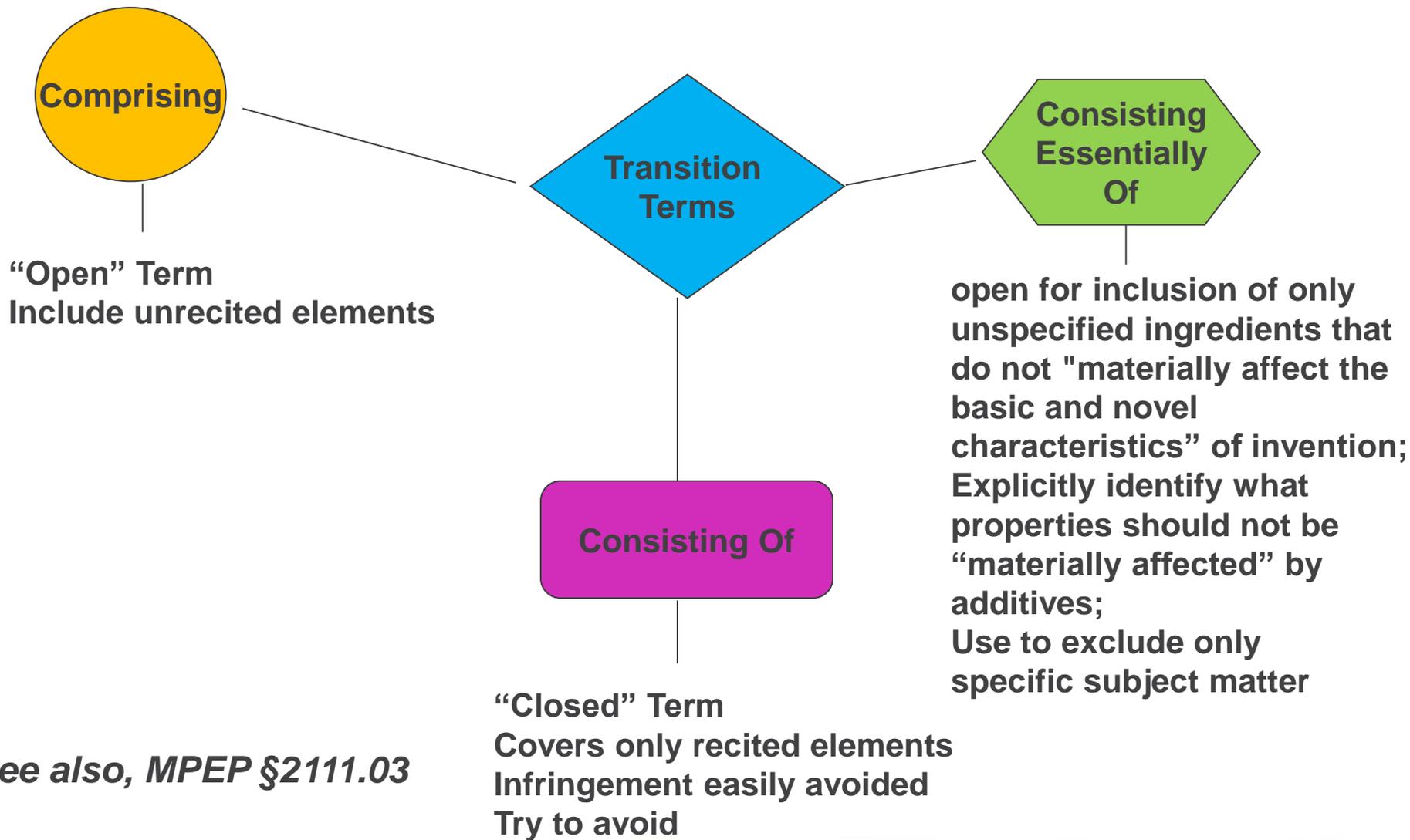
Draft complete, self-contained claims that fully define the intended invention in the body of the claim.

But be prepared to have preamble construed as limitation, so avoid preamble language unless you desire to rely on it.

Again, consider alternative embodiments in which the preamble is definitely a limitation.

***See also, MPEP §2111.02***

# Claim Drafting: Transition Terms



See also, MPEP §2111.03

# *Be Careful About Using Alternative Transition Terms*

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*Argentum Pharms. LLC v. Merck*, IPR2018-00423, Paper 7 (P.T.A.B. July 23, 2018)

- Claim 1. A compound **which is** 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl-benzofuran-5-yl)-piperazine hydrochloride in its crystalline modification, wherein the compound is an anhydrate, hydrate, solvate or dihydrochloride.
- Claim 11. A pharmaceutical composition **comprising** a compound **which is** 1-[4-(5-cyanoindol-3-yl)butyl]-4-(2-carbamoyl- benzofuran-5-yl)-piperazine hydrochloride anhydrate in its crystalline modification IV, and one or more conventional auxiliary substances and/or carriers.
- PTAB: Construed “which is” as “consisting of.”
  - Claim 1 limited to compound which is vilazodone hydrochloride in its crystalline modification or form, wherein the compound is an anhydrate, hydrate, solvate, or dihydrochloride.
  - But claim 11 construed as “a pharmaceutical composition that includes at least a compound which is vilazodone hydrochloride anhydrate in its crystalline modification (or form) IV, “and one or more conventional auxiliary substances and/or carriers,” **but the composition is not limited to those ingredients.**”

# *“Consisting Of” In Markush Groups*

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Members of a Markush group have by definition a common physical or chemical property.

Avoid “selected from the group consisting of A, B, and C.”

Consider “chosen from A, B, and C.”

*See also, MPEP §2173.05(h) [R-08.2017]*

# *Federal Circuit Treatment*

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- *Shire Development LLC v. Watson Pharms., Inc.*, No. 848 F.3d 981 (Fed. Cir. 2017)
- Claims recited the phrase, **“selected from the group consisting of”**
- DC: Watson’s proposed generic product would infringe because the components falling outside the Markush groups were “‘unrelated’ to the invention.”
- FC: Reversed.
  - Watson’s ANDA product “does not satisfy the claim[ed] . . . Markush limitation” because a component it used fell outside the closed Markush group.
  - Use of the phrase “consisting of” “creates a very strong presumption that that claim element is ‘closed’ and therefore ‘exclude[s] any elements, steps, or ingredients not specified in the claim.’”
  - Exception to strong presumption did not apply because the component outside the Markush group “structurally and functionally relates to the invention, and its presence in the outer matrix violates the ‘consisting of’ requirement[.]”
  - Applied “closed” interpretation to the Markush language in Shire’s claims even though the patent examples apparently disclosed the component Watson used.

# Federal Circuit Treatment

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- *Amgen Inc. v. Amneal Pharms. LLC*, 945 F.3d 1368 (Fed. Cir. 2020)
  - Claim 1. A pharmaceutical composition comprising:
    - (a) from about 10% to about 40% by weight of cinacalcet HCl in an amount of from about 20 mg to about 100 mg;
    - (b) from about 45% to about 85% by weight of a diluent selected from the group consisting of microcrystalline cellulose, starch, dicalcium phosphate, lactose, sorbitol, mannitol, sucrose, methyl dextrans, and mixtures thereof,
    - (c) from about 1% to about 5% by weight of at least one binder selected from the group consisting of povidone, hydroxypropyl methylcellulose, hydroxypropyl cellulose, sodium carboxymethylcellulose, and mixtures thereof; and
    - (d) from about 1% to 10% by weight of at least one disintegrant selected from the group consisting of crospovid[o]ne, sodium starch glycolate, croscarmellose sodium, and mixtures thereof, ...
  - DC: Amgen did “not overcome the very strong presumption that the Markush groups for the binder and disintegrant elements are closed to unrecited binders and disintegrants[,]”

# Federal Circuit Treatment

---

- *Amgen* (con't)
  - DC: Amneal and Piramal did not infringe because the binder limitation was not met but Zydus did because starch used as a diluent in the proposed generic product and starch is listed in the Markush group.
  - FC: vacated and remanded the judgment as to Amneal and affirmed with respect to Piramal and Zydus.
    - Amgen’s argument that Piramal’s pregelatinized starch is equivalent to povidone, a listed binder, was rejected based on prosecution history estoppel. The Markush groups were added for patentability and therefore the claims were narrowed to exclude binders other than those listed in the Markush group.
    - “*Multilayer* and *Shire* did not hold broadly that, whenever ‘consisting of’ Markush group language is present in a particular claim limitation, even when the limitation follows a general claim transition phrase of ‘comprising,’ all components of an accused product that perform the general function of the particular limitation must meet the requirements of that limitation, thus precluding components outside the Markush group. No such issue was presented in those cases. ... Those decisions do not apply in this case, where the question is whether the ‘binder’ or ‘disintegrant’ claim limitations are written to preclude other binders and disintegrants in the claimed composition. We conclude that they are not.”

# *Federal Circuit Treatment*

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- *Amgen* (con't)
  - FC:
    - “The issue is whether all binders or disintegrants in the claimed formulation are subject to the specific binder or disintegrant limitations. The answer, we conclude, is no. There is no language in Amgen’s claim indicating that every binder or disintegrant in the claimed formulation must be within the Markush groups. Instead, the claim recites ‘at least one’ binder or disintegrant ‘selected from the group consisting of’ various excipients. And the limitations merely require that those particular binders or disintegrants meet the specified weight-percentage requirements, which is not inconsistent with the overall composition containing other binders or disintegrants. The plain language of this claim requires ‘at least one’ of the Markush members and certainly does not indicate that the only binders and disintegrants in the claimed formulation are those listed in the groups. And we do not see a sufficient basis for a different conclusion in the specification or in the prosecution history we have recited.”
    - Use of “comprising” supported the conclusion that “optional additional binders and disintegrants not recited in the Markush group may be included in the claimed formulation.”
    - Claim amendment adding ranges made for patentability so “Amgen surrendered equivalent but unclaimed binders and disintegrants.”

## *Claim Must Be Complete!*

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*Allen Engineering Corp. v. Bartell Indus.*, 299 F.3d 1336  
(Fed. Cir. 2002)

- Claim 23. The riding trowel as defined in claim 22 wherein said tertiary linkage means comprises crank means driven by said connecting shaft means and coupled to said gearbox means by rigid
- FC: Claim is indefinite because it is impossible to discern the scope of such a truncated limitation.

# *Critical Aspects Of Invention Need To Be Claimed For Objective Evidence To Stick*

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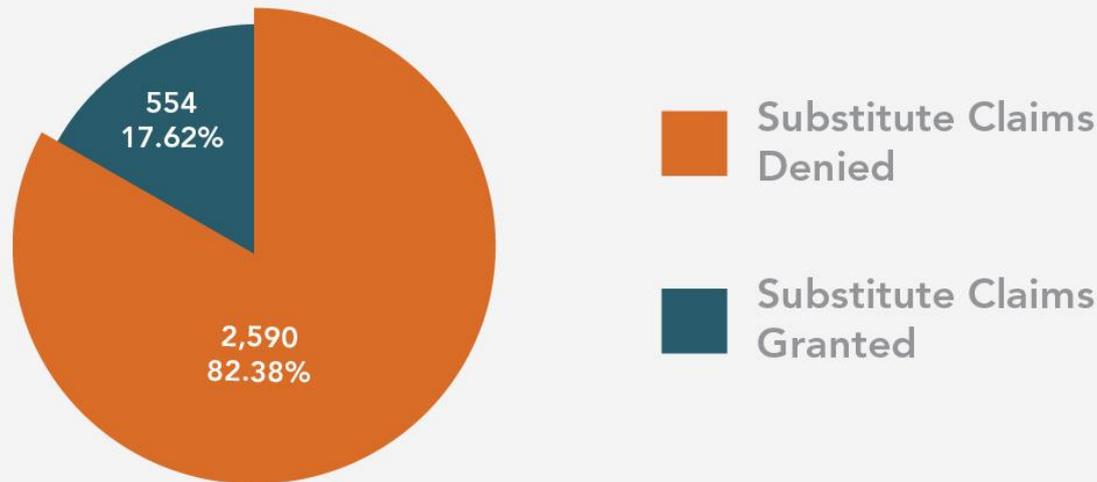
- *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366 (Fed. Cir. 2019)
  - PTAB FWD claims not shown to be obvious; presumed nexus between objective evidence and claims.
    - Presumption of nexus applies when a product is “coextensive” with the claims and “coextensive” means claims must broadly cover the product that is the subject of the objective evidence.
  - FC: Vacate and remand.
    - Specification disclosed features not recited in claims that contributed to “improving chain retention.”
    - “presuming nexus is appropriate ‘when the patentee shows that the asserted objective evidence is tied to a specific product and that product ‘embodies the claimed features, and is coextensive with them.’”
    - “SRAM’s X-Sync chainrings are not coextensive with the independent claims.”
    - “Although we do not require the patentee to prove perfect correspondence to meet the coextensiveness requirement, what we do require is that the patentee demonstrate that the product is essentially the claimed invention.”

# *Patentee Failed To Fix Drafting Error Before Issuance*

- *Bayer Cropscience AG v. Dow Agrosiences, LLC*, 728 F.3d 1324 (Fed. Cir. 2013)
  - Bayer used term monooxygenase in CIP application in 1989.
  - In 1993, Bayer scientists determined “monooxygenase” was incorrect because second oxygen atom did not end up in water; both oxygen atoms were incorporated into non-water products.
  - Patent issued in 2000 using term monooxygenase.
- Dow product is dioxygenase.
- District court: no infringement. Refused to construe claim according to definition other than plain and ordinary meaning to include dioxygenases.
- FC: Affirmed.
  - No indication in intrinsic record that Bayer intended meaning other than “accepted scientific descriptive” meaning of monooxygenase.
  - “it is hardly unknown for a patentee with an invention that could be protected to fail in securing such protection by bad choices in claim drafting. See, e.g., *Chef America...*”.

# *Don't Rely On Being Able To Amend Claims at PTAB*

## IPR Substitute Claim Disposition



(as of February 28, 2022)

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Source: <https://www.finnegan.com/en/america-invents-act/claim-and-case-disposition.html>

# *What If You Forget A Claim?*

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*In re Tanaka*, 640 F.3d 1246 (Fed. Cir. 2011)

- Board held that it is not reissue “error” under 35 U.S.C. §251 to add a subgeneric claim where all existing claims in the patent are maintained, both broader and narrower than the added claim.
- FC: Reversed and remanded.
  - “adding dependent claims as a hedge against possible invalidity of original claims “is a proper reason for asking that a reissue be granted.” *In re Handel*, 50 CCPA 918, 312 F.2d 943, 946 n. 2 (1963).”
  - “the omission of a narrower claim from a patent can render a patent partly inoperative by failing to protect the disclosed invention to the full extent allowed by law.”

*NOTE: AIA removes “without deceptive intention” as requirement of reissue §251; applies to proceedings commenced on or after Sept. 16, 2012.*

# *The Bogeyman of 101!*

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# *Drafting Tips*

## Claims

- Support and claim a variety of invention categories.
- Avoid language indicating a mental step, and instead focus on concrete physical steps and specific claim elements.
- Avoid referring to a technique as “routine” or “conventional” unless that status is undisputed
  - Need to balance § 101 and § 112 requirements.

## Specification

- Disclose practical applications (e.g., implementation beyond “mental step” diagnosis, such as diagnosis + treatment).
- Disclose concrete examples of broadly-claimed methods (e.g., suitable technologies for carrying out the method).
- Disclose why recited elements (e.g., compositions, steps in a method) are non-routine.
- \*Disclose why the invention is an improvement over the prior art.
- \*Disclose why one of skill in the art would not have reasonably expected success in making the invention.

# *To Consider*

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## ***35 U.S.C. 112(f): Means Plus Function Claiming***

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.*

# *Means Plus Function Claim 3-prong Analysis*

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1—Claim limitation uses terms: “means” or “step” or equivalent terms

2—Such term is modified with **functional language**, typically linked to transitional language, such as “for” or “such that”

3—Such term is *not* modified by sufficient structure, material or acts for performing the claimed function—*this is important to avoid having the claim classified as something other than MPF.*

# *Means Plus Function Claiming: How?*

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Claim *combination* of substances OR a *combination* of steps in a process (including method of use) AND meet the 3-prong analysis.

# *Means Plus Function Claiming*

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Example—effective against **ANDA** applicant and could be used in biologics:

1. A composition comprising:

component A and

**means**

**for**

**[achieving some desirable outcome].**

Example—effective against **505(b)(2)** applicant and could be used in biologics:

1. A composition comprising:

**means**

**for**

**[achieving some desirable outcome];** and

a pharmaceutically acceptable carrier.

# Linking Examples

Claim limitation	Specification
<p>“means for making said formulation stable at 24 months when stored at room temperature”</p>	<p>“there . . . exists a need for an appropriate range of concentrations for both the 5-HT3 receptor antagonist and its pharmaceutically acceptable carriers that would facilitate making a formulation with . . . increased stability.” <b>give chapter and verse</b></p>
	<p>“[t]he inventors have . . . discovered that by adjusting the formulation’s pH and/or excipient concentrations it is possible to increase the stability of palonosetron formulations.” <b>give chapter and verse</b></p>
	<p>“exemplary embodiments that demonstrate what means (i.e., structure and/or materials and/or acts) could be used to increase the stability of palonosetron formulations” <b>give chapter and verse</b></p>

# *Other Possibilities for Drafting or Amending Method Claims to Avoid/Overcome a § 101 Rejection*

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- Recite a practical application and/or tangible result.
- Recite at least one concrete/physical step.
- If possible, recite a *series* of steps.
- If possible, recite at least one non-routine element.
- Model claims off claims held eligible by courts.
  
- Choose a clear preamble, and continue with language consistent with that preamble:
  - A method of treatment . . .
  - A method of preventing . . .
  - A method of [achieving X tangible/measurable result] . . .
  
- If claiming a method of diagnosis, include a non-routine element or a treatment step.

## *Other Possibilities for Drafting or Amending Kit Claims to Avoid/Overcome a § 101 Rejection*

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- Distinguish kits as more than rephrased method claims.
- Similar to tips for method claims (practical application, tangible result, concrete elements, non-routine elements).

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*More Specification Drafting Issues*

# Drafting Specification

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- Focus on objective of literal infringement (by single actor).
- Minimize background.
  - Avoid admission that the need (motivation) was in the art, in favor of using recognition of problem as part of the invention story.
  - Avoid characterizing prior art.
- Specification is the roadmap.
  - Disclose broadly to claim broadly.
  - If broad meaning for a term intended, set forth a broad definition in the specification.
  - Consider other embodiments with narrower definitions.
  - Consider crafting definitions to address concerns about related prior art.
  - Use specification to eliminate uncertainty.
    - *Athletic Alternatives, Inc. v. Prince Manufacturing, Inc.*, 73 F.3d 1573, 1581 (Fed. Cir. 1996): when there is an equal choice between a broad and a narrow meaning of a claim, the public notice function is better served by interpreting the claim more narrowly.
  - Use specification to describe how claims will be infringed.

# *Define And Consistently Use Terms*

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Examples of where failure to define and consistently use terms cost the patentee the desired claim construction.

- *Union Pacific Resources Co. v. Chesapeake Energy Corp.*, 236 F.3d 684 (Fed. Cir. 2001)
  - Patentee's failure to define claim terms “comparing” and “rescaling” resulted in the claims being held invalid.
- *Aqua-Aerobic Systems, Inc. v. Aerators Inc.*, 211 F.3d 1241 (Fed. Cir. 2000)
  - Phrases “prevent flow of air” and “prevent passage of air,” were interpreted differently, even though the patentee argued for them to be construed the same and expert testimony indicated that one of ordinary skill in the art would understand them to be the same.
- *Ortho-McNeil v. Caraco*, 476 F.3d 1321 (Fed. Cir. 2007)
  - Drafter did not use the term “about” every time a range was recited, so the court interpreted ranges with “about” differently than those without.

# *How Consistent Use Saved The Day*

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*In re Abbott Diabetes Care Inc.*, 696 F.3d 1142 (Fed. Cir. 2012)

- Background of Invention section discussed prior art systems using external wires and cables that restricted movement of user.
- No examples in specification included external cables or wires.
- Board construed claim term “electrochemical sensor” to include external cables and wires because no explicit disclaimer in specification.
- FC: Vacate and remand because rejection based on unreasonable claim construction.
  - “specification contains only disparaging remarks [about] external cables and wires of the prior-art sensors”
  - patents “repeatedly, consistently, and exclusively” depict an electrochemical sensor without external cables or wires while simultaneously disparaging sensors with external cables or wires.”

# ‘Patent Profanity’

- PTAB and courts now both use *Phillips* standard.
- PTO ex parte uses broadest reasonable interpretation (BRI).
- Patent owners may face situation where a broad construction is good for an infringement position in litigation while a narrow construction is good for patentability in an IPR.
  - Profanity describing some embodiments could be useful.
    - See, e.g., *Conopco, Inc. v. Procter & Gamble Co.*, IPR2013-00510, where Petitioner argued “no evidence in the '155 patent or its file history of the criticality of the recited ranges in the compositions as claimed[.]”
    - See, e.g., *BASF Corp. v. Enthone, Inc.*, IPR2016-00697, Paper 31 (P.T.A.B. Sept. 11, 2017), FWD all instituted claims unpatentable: “there is insufficient evidence on this record demonstrating that the claimed range is critical or achieves unexpected results relative to the range disclosed by [the prior art]. Accordingly, we are not persuaded by Enthone’s arguments in this regard.”

# Examples Where Profanity Hurt Patent Owner

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- “Very important”
  - *Inpro II Licensing, S.A.R.L. v. T-Mobile USA, Inc.*, 450 F.3d 1350 (Fed. Cir. 2006)
- “Critical,” “Special,” “Peculiar,” “Superior”
  - *Bayer AG v. Elan Pharmaceuticals Research Corp.*, 212 F.3d 1241 (Fed. Cir. 2000)
- “Critical,” “Essential,” “Key”
  - *Pharmacia & Upjohn Co. v. Mylan Pharmaceuticals, Inc.*, 170 F.3d 1373 (Fed. Cir. 1999)
- “Necessary”
  - *Atofina v. Great Lakes Chemical Corp.*, 441 F.3d 991 (Fed. Cir. 2006)
    - “it is ***necessary*** to have a catalyst containing ***solely*** chromium.”
    - Shows how patentability argument can cause problems later.

# *Profanity in the Specification: “The Invention Is...”*

- *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858 (Fed. Cir. 2004)
  - Claimed plug for hernias, but no claim language about plug surface.
  - **Specification “consistently described as having pleats”**
  - **Summary of Invention, Abstract**
  - DC: No infringement.
    - Claim construed to require pleated plug.
  - FC: Affirmed -> no infringement by plugs without pleats.
    - **“because the patent globally defined the plug as having a pleated surface, the term ‘pleated’ need not be repeated each time a term describing some other aspect of the plug is used.”**
    - **Statements of general applicability clearly define the claimed plug as “having” or “includ[ing] a pleated surface.”**

# “The Invention”

- *Forest Laboratories, LLC v. Sigmapharm Laboratories, LLC*, 918 F.3d 928 (Fed. Cir. 2019)
  - Composition claim 1. A pharmaceutical composition comprising as a medicinally active compound: [asenapine] or a pharmaceutically acceptable salt thereof; wherein the composition is a solid composition and disintegrates within 30 seconds in water at 37° C.
  - MOT claim 4. A method for treating tension, excitation, anxiety, and psychotic and schizophrenic disorders, comprising **administering sublingually or buccally** an effective amount of a pharmaceutical composition comprising [asenapine or a pharmaceutically acceptable salt thereof].
  - Forest sells Saphris, a sublingual formation containing asenapine maleate.
    - Asenapine was originally developed as a conventional oral tablet that is swallowed.

# “The Invention”

- *Forest Labs.* (con’t)
  - DC: Claims valid but not infringed.
    - District court “construed claim 1 to be limited to buccal and sublingual formulations” even though no limitation in claim.
  - FC: Affirmed construction of claim 1 but vacated and remanded to reconsider non-obviousness and non-infringement findings under the corrected construction of claim 4.
    - District court claim construction correct because **the specification indicated “[t]he invention relates to a sublingual or buccal pharmaceutical composition,”**
      - Also looked at title and other disclosure: **“The specification, ... repeatedly uses ‘sublingual or buccal’ to modify ‘composition,’ indicating that these are properties of the composition itself.”**

# *Disavowal of Claim Scope*

*Techtronic Indus. Co. v. ITC*, 944 F.3d 901 (Fed. Cir. 2019)

- Claim limitation: “wall console”
- ITC: infringement.
  - Claim scope covered wall-mounted console with and without passive infrared detectors.
- FC: Reversed-in-part, vacated-in-part
  - Disavowal of wall consoles lacking a passive infrared detector.
  - Sole embodiment described wall console with passive infrared detector.
  - Specification disparaged prior art with detector in head unit.
  - **Consistently describing as containing feature means claim construed as such, even without express claim limitation.**
  - **“A disavowal must be clear, but it need not be explicit.”**
  - “the entire specification focuses on enabling placement of the passive infrared detector in the wall console, which is both responsive to the prior art deficiency the '319 patent identifies and repeatedly set forth as the objective of the invention. Thus, the '319 patent disavows locating the detector elsewhere, even without an express concession to that effect.”

# How Many “Features” Required?

---

*Pacing Tec v. Garmin*, 778 F.3d 1021 (Fed. Cir. 2015):

- DC: Summary judgment of noninfringement.
- FC: Affirmed.
  - “the specification similarly contains a clear and unmistakable statement of disavowal or disclaimer. In a section entitled “Summary and Objects of the Invention,” the ‘843 patent states that ‘it is a principal object of the present invention to . . . .’ ... It then lists 18 additional features, each time preceding the feature with the phrase ‘[i]t is another object of the present invention’ or ‘[i]t is still another object of the present invention.’ .....[M]any of the different ‘objects of the present invention’ disclosed in the ‘843 patent are recited as features in one or more independent or dependent claims.”
  - “In this case, where the patent includes a long list of different ‘objects of the present invention’ that correspond to features positively recited in one or more claims, it seems unlikely that the inventor intended for each claim to be limited to all of the many objects of the invention. However, the ‘843 patent goes further, and includes additional language that constitutes unmistakable disclaimer when considered in the context of the patent as a whole. Immediately following the enumeration of the different objects of the present invention, the ‘843 patent states that ‘[t]hose [listed 19 objects] and other objects and features of the present invention are accomplished, as embodied and fully described herein, by a repetitive motion pacing system that includes . . . a data storage and playback device adapted to producing the sensible tempo.’”

# *How Many “Features” Required?*

---

## *Pacing Tec v. Garmin (con’t)*

- FC:
  - “With these words, the patentee does not describe yet another object of the invention—he alerts the reader that the invention accomplishes all of its objects and features (the enumerated 19 and all others) with a repetitive motion pacing system that includes a data storage and playback device adapted to produce a sensible tempo. In the context of this patent, this clearly and unmistakably limits ‘the present invention’ to a repetitive motion pacing system having a data storage and playback device that is adapted to producing a sensible tempo.”

*Narrow Construction Of Claim Based On Specification:  
Killed By A Profanity And A Comma*

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**Cultor Corp. v. A.E. Staley Mfg. Co., 224 F.3d 1328 (Fed. Cir. 2000)**

- Claim: “polydextrose composition substantially free of bitter-tasting residual compounds made by the process consisting essentially of” 3 steps, but did not specify **in the claims** a citric acid catalyst.
- Specifications read: the expression "**water-soluble polydextrose**" (also known as polyglucose or poly-D-glucose) **specifically refers to** the water-soluble polydextrose prepared by melting and heating dextrose (also known as glucose or D-glucose), **preferably with about 5-15% by weight of sorbitol present, in the presence of a catalytic amount (about 0.5 to 3.0 mol %) of citric acid.**
- Yikes: compare with no comma: **preferably with about 5-15% by weight of sorbitol present in the presence of a catalytic amount (about 0.5 to 3.0 mol %) of citric acid**

# *Narrow Construction Of Claim Based On Comma*

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## *Cultor (con't)*

- Cultor: "polydextrose" in its ordinary meaning, to persons of skill in the art, is not encumbered by the nature of the catalyst, and thus is not limited to the specific acid catalyst actually used in its production.
- FC: Construed "water-soluble polydextrose" as limited to polydextrose produced with citric acid as a catalyst, both for literal infringement and for infringement under the doctrine of equivalents. **Clearly, that was based on the unfortunate "comma": noted on the previous slide.**

# *Principles In Tension*

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“[A] court may not read into a claim a limitation from a preferred embodiment, if that limitation is not present in the claim itself.” *Bayer AG v. Biovail Corp.*, 279 F.3d 1340, 1348 (Fed. Cir. 2002)

"When the preferred embodiment is described in the specification as the invention itself, the claims are not necessarily entitled to a scope broader than that embodiment." *SciMed Life Sys. v. Advanced Cardiovascular Sys.*, 242 F.3d 1337 (Fed. Cir. 2001), quoting *Modine Mfg. Co. v. United States Int'l Trade Comm'n*, 75 F.3d 1545, 1551 (Fed. Cir. 1996).

# *Describing In Only One Way May Mean Limited To One Embodiment*

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*Honeywell Int'l, Inc. v. ITT Industrials, Inc.*, 452 F.3d 1312 (Fed. Cir. 2006)

- Limitation: “fuel system component.”
- DC: SJ of noninfringement
  - Claim scope limited to a fuel filter only because the written description expressly refers to the filter as “this invention.”
- FC: Affirmed
  - Cited Phillips.
  - Construction based on language in specification: “the written description uses language that leads us to the conclusion that a fuel filter is the only ‘fuel injection system component’ that the claims cover, and that a fuel filter was not merely discussed as a preferred embodiment. On at least four occasions, the written description refers to the fuel filter as ‘this invention’ or ‘the present invention’”
  - “No other fuel injection system component with the claimed limitations is disclosed or suggested.”

# *Compare These Cases*

- catheter
- *ACS, Inc. v. Medtronic, Inc.* (Fed. Cir. 2001)
  - Specification: “although the present invention has been described principally in conjunction with catheters having coaxial lumens, it should be appreciated that the invention is as applicable, if not more applicable, to catheters having side-by-side lumens.”
    - Medtronic: claims limited to coaxial. Medtronic product is side-by-side. Broad construction based on specification.
- *SciMed Life Systems, Inc. v. ACS, Inc.* (Fed. Cir. 2001)
  - Specification: “[the coaxial lumen structure is] the ‘basic sleeve structure for all embodiments of the present invention contemplated and disclosed herein.’”
    - Narrow construction based on specification.

# *Different Scopes*

## ACS's claim scope: covered coaxial and side-by-side configurations

- Preferred embodiment = coaxial design
- Accused device = side-by-side design
- Claim language did not restrict to coaxial design
  - Claim limitations can be met by either design
- No PHE (related applications not relevant b/c no common limitation)
- Infringed

## SciMed's claim scope: covered coaxial configurations only

- Coaxial and dual (adjacent) known in the art
- Preferred embodiment = coaxial design
- Accused device = dual design
- No specific design mentioned in claim
- No relevant prosecution history
- No infringement

# *How Scimed's Spec Caused Problem*

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FC:

- “That language,,, ‘leaves no doubt that a person skilled in the art would conclude that the inventor envisioned only one design for the catheters taught in SciMed's patents--an intermediate sleeve section containing two . . . lumens arranged coaxially.’”
- “This language defines SciMed's invention in a way that excludes the dual, or side-by-side, lumen arrangement. SciMed argues that the references to the annular inflation lumen are meant only to refer to the preferred embodiment of the invention, and not to indicate that the claims should be construed as limited to a structure employing coaxial lumens. That argument, however, flies in the face of the many statements in the written description that define "the invention" as employing a coaxial lumen structure and distinguish the prior art in part on the ground that it used a dual lumen structure ...”

# *Application of SciMed*

*Indivior Inc. v. Dr. Reddy's labs.*, 752 Fed. Appx. 1024 (Fed. Cir. 2018)(non-preced)

- DC: granted preliminary injunction.
  - In the “Delaware Decision,” the patentee disavowed solely using conventional air drying, so “dried” construed to exclude that method.
    - No infringement.
  - In current case, claim terms “dried” and “drying” changed to “continuously” and “continuously cast.”
  - DC held current claims did not include drying limitation, so specification disclaimer from other case did not apply.
- FC: Vacated.
  - Err in conclusion Indivior likely to succeed on the merits.
  - Cites *SciMed* for using specification to determine correct claim scope.
  - Current patent “’rife with remarks that disparage, and therefore, disclaim’ solely using conventional top air drying to form films.”
  - Claims exclude conventional top air drying.

# *Boilerplate Paragraphs*

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- For example: “Although the invention has been described with reference to a particular embodiment, this description is not meant to be construed in a limiting sense. Various modifications of the disclosed embodiments as well as alternative embodiments of the invention will become apparent to persons skilled in the art . . . . It is therefore contemplated that the appended claims will cover any such modifications or embodiments that fall within the scope of the invention.”
- *Will not override if specification indicates narrow construction is appropriate.*

# Disclosure-Dedication

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Subject matter disclosed but not claimed establishes dedication to the public.

- *PSC Computer Products Inc. v. Foxconn Int'l Inc.*, 355 F.3d 1353 (Fed. Cir. 2004)
  - “If one of ordinary skill in the art can understand the unclaimed disclosed teaching upon reading the written description, the alternative matter disclosed has been dedicated to the public. This ‘disclosure-dedication’ rule does not mean that any generic reference in a written description necessarily dedicates all members of that particular genus to the public. **The disclosure must be of such specificity that one of ordinary skill in the art could identify the subject matter that had been disclosed and not claimed.**”



# Dedication-Disclosure

- *Eagle Pharms. Inc. v. Slayback Pharma Inc.*, 958 F.3d 1171 (Fed. Cir. 2020)
  - Claim 1: A non-aqueous liquid composition comprising: bendamustine, or a pharmaceutically acceptable salt thereof; a *pharmaceutically acceptable fluid* comprising a mixture of *polyethylene glycol and propylene glycol*, wherein the ratio of polyethylene glycol to propylene glycol in the pharmaceutically acceptable fluid is from about 95:5 to about 50:50; and a stabilizing amount of an antioxidant . . . .
  - Slayback’s proposed product included polyethylene glycol and ethanol instead of propylene glycol.
  - Ethanol was identified in specification as alternative to propylene glycol:
  - Federal Circuit affirmed no DOE based on disclosure-dedication rule.
    - “[W]hen a patent drafter discloses but declines to claim subject matter, . . . this action dedicates the unclaimed subject matter to the public.”
    - “To determine whether the disclosure-dedication doctrine applies in a given case, we ask whether the specification discloses unclaimed subject matter with ‘such specificity that one of ordinary skill in the art could identify the subject matter that had been disclosed and not claimed.’”



## *Admissions Of Prior Art*

- *In re Nomiya*, 509 F.2d 566, 571 (CCPA 1975): admission of prior art is binding prior art on applicant even if not prior art against anyone else in the world
- AIA:
  - May still be the case that *Nomiya* admissions are still admissions of prior art against the applicant.
    - USPTO says “yes”! (See *Examination Guidelines pp. 11064 and 11075*)
  - Avoid such admissions.

## *Admissions Of Prior Art*

- Merely listing reference in IDS may not be treated as an admission of prior art.
- *Abbott Laboratories v. Baxter Pharmaceutical Products Inc.*, 334 F.3d 1274 (Fed. Cir. 2003): listing of references in an IDS only indicates that references in the disclosure may be material to prosecution of the pending claims.
- See 37 C.F.R. §1.97(h).

# *Drafting Specification: Drawings And Examples*

- §112 support for full range of claims.
  - Possession and enablement.
  - Drawings and charts.
  - Actual and hypothetical examples. A cautionary tale: Hoffmann-LaRoche, Inc. v. Promega Corp., 323 F.3d 1354 (Fed. Cir. 2003).
  - Method of using.

# Drafting Specification: Numerical Ranges

- Don't necessarily use as the main statement of your invention or to recite the broadest, claimed invention.
- Define functionally (by objective purpose).
- Consider using “about” at each end of range if appropriate. See *Jeneric/Pentron, Inc. v. Dillon Co., Inc.*, 205 F.3d 1377 (Fed. Cir. 2000)



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# *§112 Considerations*

# Recent 112a Cases in Life Sciences

Failed to fulfill requirements of §112(a)

Fulfilled requirements of §112(a)

*Enzo Life Scis., Inc. v. Roche Molecular Sys.*, 928 F.3d 1340 (Fed. Cir. 2019)

*Amgen Inc. v. Sanofi*, 987 F.3d 1080 (Fed. Cir. 2021)

*Purdue Pharma L.P. v. Iancu*, 767 Fed. Appx. 918 (Fed. Cir. 2019)

*Idenix Pharms. v. Gilead Sciences Inc.*, 941 F.3d 1149 (Fed. Cir. 2019)

*Madame LP Ltd. v. Reddy's Labs. S.A.*, 18 F.4th 1323 (Fed. Cir. 2021)

*Biogen Int'l GmbH v. Mylan Pharms., Inc.*, 2021 U.S. App. LEXIS 35254 (Fed. Cir. 2021)

*Pac. Biosciences of Cal., Inc. v. Oxford Nanopore Techs., Inc.*, 996 F.3d 1342 (Fed. Cir. 2021)

*Bristol-Myers Squibb Co. v. Sigmapharm Labs. LLC*, 858 Fed. Appx. 359 (Fed. Cir. Sept. 3, 2021)

*Fleming v. Cirrus Design Corp.*, 28 F.4th 1214 (Fed. Cir. 2022)

*Juno Therapeutics, Inc. v. Kite Pharma, Inc.*, 10 F.4th 1330 (Fed. Cir. 2021)

*Novartis Pharms. Corp. v. Accord Healthcare, Inc.*, 21 F.4th 1362 (Fed. Cir. 2022), *reh'g*, No. 21-1070 (Fed. Cir. June 21, 2022)

*Bayer HealthCare LLC v. Baxalta Inc.*, 989 F.3d 964 (Fed. Cir. 2021)

*BASF Plant Sci., LP v. Commonwealth Sci. & Indus. Research Organisation*, 28 F.4th 1247 (Fed. Cir. 2022)

*Immunex Corp. v. Sandoz Inc.*, 964 F.3d 1049 (Fed. Cir. 2020)

*Verinata Health v. Ariosa Diagnostics*, 809 Fed. Appx. 965 (Fed. Cir. April 24, 2020)

Just switched sides!

# *Make Sure §112 Chain Tight*

- §112(a) attacks on priority date (of challenged claims or of asserted reference) can even be used in IPR, even though IPR grounds are limited to patents and printed publications.



- See *Butamax<sup>TM</sup> Advanced Biofuels LLC v. Gevo, Inc.*, IPR2013-00539
  - Paper 9 (P.T.A.B. March 14, 2014): Petitioner successfully challenged patent's priority claim and therefore 102(e) reference was anticipating prior art.
    - “On this uncontested record, Butamax has made a sufficient showing that the '952 and '209 provisionals would not convey, with reasonable clarity, to one of ordinary skill that the inventors had invented or were in possession of [the subject matter of the challenged claims].”
  - Paper 33 (P.T.A.B. March 3, 2015): all instituted claims unpatentable as anticipated by the 102(e) reference.

# *Indefiniteness: Multiple Ways To Measure Without Guidance Which One to Use Is Still Causing Issues*



- *Pacific Coast v CertainTeed Gypsum*, 2020 U.S. App. LEXIS 20421 (Fed. Cir. 2020)
  - 21. A laminated, sound-attenuating structure which comprises: ...
    - a scored flexural strength of the laminated structure is about 22 pounds per 1/2 inch thickness of the structure;
    - the scored flexural strength being the flexural strength of the laminated structure after the outer, paper-clad surface of one of the first and second gypsum boards has been scored.
  - DC: Indefinite.
    - “Scored flexural strength” is patentee term, not an industry term and the “specification did not specifically explain how to measure” it.
  - FC: Affirmed.
    - “there are multiple ways to measure ‘scored flexural strength’ and that the specification's lack of guidance for choosing which measurement to use renders claim 21 indefinite.”
    - POSITA would not know that term or how to measure it.

# *Note: USPTO Memo Jan. 6, 2021*

- Approach to Indefiniteness Under 35 U.S.C. §112 in AIA Post-Grant Proceedings
- USPTO approach: *In re Packard*, 751 F.3d 1307 (Fed. Cir. 2014) (per curiam): “unclear.”
- Supreme Court: *Nautilus v. Biosig Instr., Inc.*, 572 U.S. 898 (2014): “fails to inform, with reasonable certainty.”
- 2018: PTAB changed to *Phillips* standard for claim construction.
- Going forward, “the Board shall follow *Nautilus* in AIA post-grant proceedings.”

# *Examples May Provide §112 Support, But Caution: Verb Tense For Actual Vs. Prophetic Examples*

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*Hoffmann-LaRoche, Inc. v. Promega Corp.*, 323 F.3d 1354 (Fed. Cir. 2003)

- Example 6 written in past tense but not performed as written.
  - Originated from Preps 3 and 4; contained all steps but not same order as Example 6.
- Conducting Example 6 as written would give a different result than that obtained with Preps 3 and 4.
- Materiality: threshold level met
  - Response to office action: asserted that claimed product was more pure than prior art product.
  - Reasonable examiner would want to know no experimental results to support purity.
- Intent: threshold level met
  - Inventor knew past tense = actual work done.
  - Roche provided no reason why past tense used for an experiment not performed.
  - No evidence of oversight in use of past tense.
  - No clear error in concluding use of past tense was knowingly false.
- FC: Remanded to determine if CAFC's findings of inequitable conduct justify sanction of unenforceability.

# More Prophetic Examples

- *Novo Nordisk Pharmaceuticals, Inc. v. Bio-Technology General Corp.*, 424 F.3d 1347 (Fed. Cir. 2005)

- Novo's Example 1 written in the past tense in the priority applications (1983 PCT application claiming priority to 1982 Danish national application).

- “[t]he fusion product was purified from this extract,”
- “[t]he purified fusion protein was evaluated to be more than 98% pure,”
- “[t]his ... product was then treated with leucine aminopeptidase,”

- Undisputed that when 1983 PCT application filed, inventors had not successfully prepared hGH with LAP using recombinant DNA.

- DC: BTG established by clear and convincing evidence that Novo committed inequitable conduct.

- Example 1 was material in deciding whether the 1983 PCT application enabled the invention of the '856 application, and therefore grounded the priority claim that allowed Novo to antedate the prior art reference.
- **Novo, nine years after it first submitted Example 1 to the PTO, knew or should have known that the examiner would have considered the fact that Example 1 was prophetic, not actual.**
- Novo never disclosed that it had not successfully produced ripe hGH using the methodology described in Example 1 -> affirmative intent to deceive the examiner.

- FC: Affirmed.

- Inventor was aware that Example 1 was prophetic, and “knowledge of the law is chargeable to the inventor.”

# *Drafting Takeaway*

- Using phrases such as “the present invention is” or “an essential element of the invention is ” risks disclaiming any subject matter that does not fall within the description.
  - If a narrow claim construction is desired, that language can be accentuated in claim construction arguments.
  - If a broad claim construction is desired, that language will have to be addressed and minimized.

# *Drafting Takeaways*

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Be cautious about leaving information out of the specification.

Be diligent about trying to draft the patent application so that the claim terms will be construed as desired, whether broadly or narrowly.

To the maxim of patent law that “claims are construed in light of the specification, and are not limited to a designated ‘preferred embodiment’,” the practitioner should be cautioned, “**unless that embodiment is in fact the entire invention presented.**” (*Vulcan Eng'g Co. v. Fata Aluminum, Inc.*, 278 F.3d 1366 (Fed. Cir. 2002)).

# *Careful Drafting: Summary*

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Test by analyzing “design around” possibilities from viewpoint of infringer.

Determine necessity of each term.

Identify where each term is defined in specification.

Identify ambiguity and eliminate it!

- Ascertain whether an infringer could “misconstrue” the applicant’s intended meaning of any term.

Is every term used consistently?

The mantra:

- Necessary
- Clearly defined
- Consistently used

# *Polling Question #1*

- The claims say a blue widget is heated to 400 F.
- The spec, including the examples, teaches blue widget must be heated to 400 F for 15 minutes and points out the blue widgets will melt if left longer.
- At trial, experts on both sides declared that the blue widget must be heated at 400 F, for 15 minutes, not to 400F.
- The claim is to be construed as requiring heat to 400 F:
- *Yes or No?*

## *Polling question #2*

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- An independent claim recites: a machine comprising a blue widget and a yellow widget.
- Another independent claim recites a machine comprising a blue widget and at least one red widget.
- Is each independent claim to be construed to allow more than one blue widget?
- **Yes or No**

## *Polling question #3*

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- An independent claim recites: a machine comprising a blue widget and a yellow widget.
- The specification recites another machine comprising a blue widget and at least one yellow widget.
- Is the independent claim to be construed to allow only one blue widget?
- **Yes or No**

## *Polling Question #4*

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- Claim is directed to a machine comprising blue widget or yellow widget.
- Alleged infringer uses a machine with both a blue and yellow widget.
- Is there infringement?
- **Yes or No**

## *Polling Question #5*

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In a patent claim reciting alternative species A, B, and C, which of the following claim expressions would provide a relatively broader claim scope?

- a. “at least one of A, B, and C”
- b. “selected from the group consisting of A, B, and C”
- c. “chosen from A, B, and C”
- d. “at least one of A, B, or C”
- e. All of the above expressions (a) – (d), which have essentially the same scope
- f. Expressions (a), (c), and (d), which have essentially the same scope
- g. Expressions (c) and (d), which have essentially the same scope

# Thank You!



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