

## **Sect. 112 Indefiniteness in Chemical and Biotech Patent Claims**

Drafting and Prosecuting Patent Claims That Will Hold Up Under Any Definiteness Standard

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1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

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# Understanding 35 U.S.C. §112(b)

(a) IN GENERAL.—The specification shall contain a 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 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 best mode contemplated by the inventor or joint inventor of carrying out the invention.

(b) CONCLUSION.—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.

Definiteness of claim scope: one skilled in the art must be able to determine with a reasonable degree of certainty the meets and bounds of the claim.

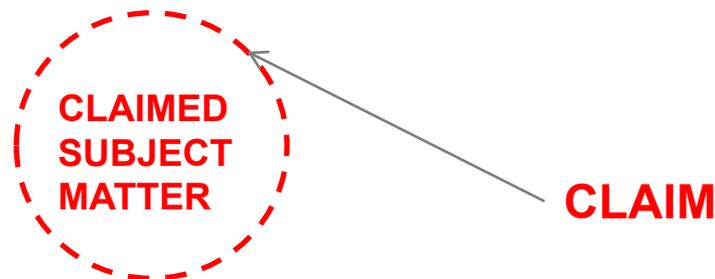
Subject matter claimed must be what the inventor(s) believe(s) is the invention

# *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.”

# *Satisfying §112(b) Definiteness Requirement*

- **Distinguish between §112 (a) and (b):**
  - USPTO rejections can confuse first and second paragraphs of §112
    - **Breadth ≠ indefiniteness** → broad claim with clear scope satisfies para. (b)
      - *In re Miller*, 441 F.2d 690 (CCPA 1971); MPEP § 2173.04
    - Often see rejections as “**vague and indefinite**” based on requirement for “**particularly pointing out and distinctly claiming.**”
- **Definiteness** → clear claim scope, boundaries of claimed subject matter



## *Assessing Compliance With §112(b)*

- *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898 (2014):
  - “definiteness is to be evaluated from the perspective of someone skilled in the relevant art. See, e.g., *General Elec. Co. v. Wabash Appliance Corp.*, 304 U. S. 364, 371 (1938).”
  - “in assessing definiteness, claims are to be read in light of the patent’s specification and prosecution history. See, e.g., *United States v. Adams*, 383 U. S. 39, 48–49...(1966) (specification); *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U. S. 722, 741...(2002).”
  - “[d]efiniteness is measured from the viewpoint of a person skilled in [the] art *at the time the patent was filed*.’...See generally Sarnoff & Manzo,...Patent Claim Construction in the Federal Circuit 9 2014)[.]”

# Indefiniteness

- *Nautilus, Inc. v. Biosig Instruments, Inc.* (con't)
  - **Vacate and remand.**
    - 35 U. S. C. §112, ¶2: —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.
    - Federal Circuit (715 F.3d 891): §112, ¶2 met if claim is “amenable to construction,” and the claim, as construed, is not “insolubly ambiguous.”
    - Supreme Court:
      - this “does not satisfy the statute’s definiteness requirement.”
      - **standard: “a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.”**

# *“Delicate Balance”*

“On the one hand, the definiteness requirement must take into account the inherent limitations of language. ... Some modicum of uncertainty, the Court has recognized, is the “price of ensuring the appropriate incentives for innovation.”

“recognizing that absolute precision is unattainable.”



“At the same time, a patent must be precise enough to afford clear notice of what is claimed, thereby ‘appris[ing] the public of what is still open to them.’”

“The definiteness requirement, so understood, mandates clarity.”

## *Assessing Compliance With §112(b)*

- *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1555 (Fed. Cir. 1983)
  - “stretch rate”
    - *no formula in specification* for calculating stretch rate
    - was uncontradicted evidence in the record that, **at the time the application was filed, “stretch rate” meant to those skilled in the art** the percent of stretch divided by the time of stretching, and that the latter was measurable, for example, with a stopwatch.
    - the **post-filing date development** of varying formulae, including inventor’s later addition of a formula in his corresponding Japanese patent, is **irrelevant**.
    - Not indefinite.
- Claim language in prior art can evidence definiteness if one skilled in art could understand terms in context of invention.

# *Satisfying §112(b): Can Depend on Nature of Subject Matter*

- Definiteness requirement does not require greater precision than the subject matter permits.
  - *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S.898\_, 134 S. Ct. 2120 (2014): “The standard we adopt accords with opinions of this Court stating that ‘the certainty which the law requires in patents is not greater than is reasonable, having regard to their subject-matter.’ [citations omitted]”
  - See also, *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385 (Fed. Cir. 1986)(“**the claims, read in light of the specification, reasonably apprise those skilled in the art and are as precise as the subject matter permits. As a matter of law, no court can demand more.**”).
- If precision is challenged during prosecution, consider **Rule 132 declaration** of expert explaining the degree of precision available (or lack thereof) in the relevant art at the relevant time.
- **Interview** – ask what Examiner wants.

# Recital Of Hybritech Principle

- *Guangdong Alison Hi-Tech Co. v. ITC*, 936 F.3d 1353 (Fed. Cir. 2019)
  - Claim: 1. A composite article to serve as a flexible, durable, light-weight insulation product, said article comprising a *lofty* fibrous *batting* sheet and a continuous aerogel through said batting.
  - Specification: ““lofty batting” is “a fibrous material that shows the properties of bulk and some resilience (with or without full bulk recovery).”
  - Alison argument: “patent fails to disclose precisely how much resilience is enough to satisfy the claim.”
  - ITC: Term not indefinite.
    - Bulk and resilience further explained in spec.

# Recital Of Hybritech Principle

- *Guangdong* (con't)
  - FC: Affirmed.
    - Written description (description, functional characteristics, several examples) “informs the meaning of ‘lofty...batting’ with reasonable certainty.”
    - “[t]he degree of precision necessary for adequate claims is a function of the nature of the subject matter.”
    - “While we agree that ‘lofty . . . batting’ is a term of degree, Alison seeks a level of ‘mathematical precision’ beyond what the law requires.”
    - “written description provided sufficient guidance and points of comparison to render claim terms not indefinite.”
    - Rejected “multiple ways to measure” argument: “Because ‘lofty . . . batting’ is expressly defined by the ’359 patent based on two properties, bulk and resilience, we find it unremarkable that the specification discloses two methods of measuring loftiness.”



## Post-Nautilus Case Law



- *Eli Lilly and Company v. Teva Parenteral Medicines, Inc.*, 845 F.3d 1357 (Fed. Cir. 2017)
  - Claim 1. A method of administering pemetrexed disodium to a patient in need thereof comprising administering an effective amount of folic acid and an effective amount of a methylmalonic acid lowering agent followed by administering an effective amount of pemetrexed disodium, wherein the methylmalonic acid lowering agent is selected from the group consisting of *vitamin B12*, hydroxycobalamin, cyano-10-chlorocobalamin, aquocobalamin perchlorate, aquo-10-cobalamin perchlorate, azidocobalamin, cobalamin, cyanocobalamin, or chlorocobalamin.
  - Parties agreed that, “depending on the context, ‘vitamin B12’ can be used in the art to refer either to cyanocobalamin specifically or, more broadly, to a class of compounds including pharmaceutical derivatives of cyanocobalamin.”
  - Specification used the term both ways.
  - Teva: “because ‘vitamin B12’ is used in two different ways in the intrinsic record, ‘it is impossible to determine’ which meaning applies to the claims ‘with any reasonable certainty,’ as required by *Nautilus*.”
  - Lilly: “the claims of the ’209 patent ‘involve administering a vitamin B supplement to a patient,’ and in that context, ‘the one and only meaning’ of vitamin B to a person of ordinary skill is cyanocobalamin.”
    - Expert testified that a POSITA would understand that “although ‘vitamin B12’ can refer to a class of compounds in other contexts, it refers specifically to cyanocobalamin when ‘vitamin B12’ is prescribed in the medical field.

# *Post-Nautilus Case Law*

- *Eli Lilly v. Teva* (con't)
  - FC: Affirmed claims not invalid.
    - We therefore hold that a person of ordinary skill in the art would understand the scope of the claim term ‘vitamin B12’ with reasonable certainty. Applying *Nautilus* in this case does not lead us to a different result from the district court’s conclusion on the question of indefiniteness.”
    - No clear error in district court’s reliance on expert testimony about a POSITA’s understanding, which meant the disputed term had a plain meaning that could be determined from context.
    - Claim language informs POSITA that form of vitamin B12 (cyanocobalamin) is being used.
    - Markush group listing redundancy not an “inflexible” rule (claim listed both B12 and cyanocobalamin).

# Post-Nautilus Case Law

- *Forest Labs., Inc. v. Teva Pharms. USA, Inc.*, 2017 WL 6311688 (Fed. Cir. Dec. 11, 2017) (unpublished)
  - Claim 1. A solid pharmaceutical composition in a unit dosage form for once daily oral administration comprising an extended release formulation of 5 to 40 mg memantine or pharmaceutically acceptable salt thereof, wherein administration of a dose of the composition to a human subject provides a plasma memantine concentration profile, as measured in a single-dose human PK [pharmacokinetic] study, characterized by a *change in memantine concentration as a function of time (dC/dT) that is less than 50% that of an immediate release dosage form comprising the same dose of memantine as the composition*, wherein the dC/dT is measured between the time period of 0 to T<sub>max</sub> of the immediate release form of memantine.
  - Forest: means a “change in plasma memantine concentration of the extended [sustained] release dosage form as a function of time (dC/dT) that is less than 50% that of an immediate release dosage form comprising the same dose of memantine as the extended [sustained] release dosage form.”
  - Teva: Indefinite because requires “comparison of a concentration profile of an immediate-release formulation and a concentration profile of an extended-release formulation, as measured in human pharmacokinetic studies. But, ...neither the claim language nor the specification adequately describes how to conduct the studies to obtain those concentration profiles, and differences in study design lead to variable results in the claim-required comparison.”
    - Or alternative construction: “both the immediate-release and extended-release profiles to be measured in the same human study.”

# *Post-Nautilus Case Law*

- *Forest Labs. v. Teva* (con't)
  - DC: Claims invalid for indefiniteness.
    - “construed the claim to require that the concentration profile of the extended-release formulation and the concentration profile of the immediate release formulation be measured in human pharmacokinetic studies.”
    - “the intrinsic evidence does not disclose a specific human-study design or provide guidance as to how to design a human study.”
    - Extrinsic evidence showed wide variety in profiles generated by human pharmacokinetic studies.
    - Therefore, a POSITA would not know with reasonable certainty “which ‘human [pharmacokinetic] study’ on which to rely when considering whether a formulation of memantine might infringe[.]”

# Post-Nautilus Case Law

- *Forest Labs. v. Teva* (con't)
  - FC: Affirmed.
    - “review de novo a district court’s determination of indefiniteness, but we review for clear error any of the district court’s underlying findings of fact based on extrinsic evidence.”
    - “While it is grammatically possible to read that phrase as referring to only the profile of the extended-release formulation, such a reading is unreasonable in the context of the intrinsic evidence.”
    - Forest argued two figures showed the immediate-release profile in the claims, but “[t]he descriptions of the figures are no more than what they purport to be: descriptions of the figures. They do not constitute a definition and are not even directed to the meaning of the claim terms.”
    - “the district court’s indefiniteness ruling is supported by precedents that hold claims indefinite in particular circumstances where the claims require measured quantities (absolute or relative), different techniques for such measurements are known in the art and some produce infringing results and others not, the intrinsic evidence does not adequately specify the technique or techniques to use, and extrinsic evidence does not show that a relevant skilled artisan would know what technique or techniques to use.”

# Post-Nautilus Case Law



Johnson Matthey

- *BASF Corp. v. Johnson Matthey Inc.*, 875 F.3d 1360 (Fed. Cir. 2017)
  - Claim 1. A catalyst system for treating an exhaust gas stream containing NO<sub>x</sub>, the system comprising:
    - at least one monolithic catalyst substrate having an inlet end and an outlet end; an undercoat washcoat layer coated on one the outlet end of the monolithic substrate and which covers less than 100% of the total length of the monolithic substrate, and containing a material composition A *effective for catalyzing* NH<sub>3</sub> oxidation;
    - an overcoat washcoat layer coated over a total length of the monolithic substrate from the inlet end to the outlet end sufficient to overlay the undercoat washcoat layer, and containing a material composition B *effective to catalyze* selective catalytic reduction (SCR) of NO<sub>x</sub>; and
    - wherein material composition A and material composition B are maintained as physically separate catalytic compositions.
  - DC: Claim invalid for indefiniteness.
    - Materials not specified; “claims recite a performance property...rather than its actual composition.”
    - No minimum level or way to measure if meet “effective” limitation

# *Post-Nautilus Case Law*

- *BASF Corp. v. Johnson Matthey* (con't)
  - BASF: phrases have plain and ordinary meaning as used “in the art of exhaust systems.”
    - Specification describes examples and testing conditions.
    - Expert: “effective to catalyze” understood as “capable of catalyzing.”
  - JM: phrases indefinite because is functional language with no boundaries on amount of effectiveness required or how to measure effectiveness.

# *Post-Nautilus Case Law*

- *BASF Corp. v. Johnson Matthey* (con't)
  - FC: Reversed and remanded.
    - “Under *Nautilus*, the question presented here is this: would the ‘composition ... effective to catalyze’ language, understood in light of the rest of the patent and the knowledge of the ordinary skilled artisan, have given a person of ordinary skill in the art a reasonably certain understanding of what compositions are covered?”
    - *Nautilus* does not prohibit identifying product by what it does.
      - “we have long held that nothing in the law precludes, for indefiniteness, ‘defining a particular claim term by its function.’”

# Post-*Nautilus* Case Law

- *BASF Corp. v. Johnson Matthey* (con't)
  - FC: Reversed and remanded (con't)
    - “The district court’s analysis in the present case lacks such support for its conclusion about what a relevant skilled artisan could determine without more information than the patent here provides.”
    - “What is needed is a context-specific inquiry into whether particular functional language actually provides the required reasonable certainty.”
      - “the specification makes clear that it is the arrangement of the SCR and AMOx catalysts, rather than the selection of particular catalysts, that purportedly renders the inventions claimed in the ’185 patent a patentable advance over the prior art. As a result, the claims and specification let the public know that any known SCR and AMOx catalysts can be used as long as they play their claimed role in the claimed architecture.”
    - “the relevant skilled artisan would be informed by the specification’s numerous examples of qualifying compositions A and B, disclosure of the stoichiometric reactions, and equating of the ‘composition ... effective to catalyze’ phrases with familiar terms such as ‘SCR catalyst’ and ‘AMOx catalyst.’”

# *Post-Nautilus Case Law*

- *Dow Chemical Co. v. Nova Chemicals Corp.*, 803 F.3d 620 (Fed. Cir. 2015), *reh'g denied*, 809 F.3d 1223 (Dec. 2015), *cert. denied* (U.S., May 23, 2016)
  - Claim: An ethylene polymer composition comprising: at least one homogeneously branched linear ethylene/ $\alpha$ -olefin interpolymer having: . . . and (vi) **a slope of strain hardening coefficient greater than or equal to 1.3**; and . . .
  - FC: “We hold that the intervening change in the law of indefiniteness resulting from *Nautilus* provides an exception to the doctrine of law of the case or issue preclusion. ...In reviewing the supplemental damages award under the *Nautilus* standard, we hold that the claims are indefinite and reverse the award of supplemental damages.”

# *Post-Nautilus Case Law*

- *Dow Chemical Co. (con't)*
  - FC: Reversed supplemental damage award.
  - Claims indefinite: did not provide one skilled in the art with the scope of the invention.
    - Different methods existed to determine the maximum slope providing different results.
    - Patent did not provide any guidance as to which method should be used or even whether the possible universe of methods is limited to these four methods.
    - No guidance in prosecution or testimony that a POSITA would choose one method over the others.
    - “Before Nautilus, a claim was not indefinite if someone skilled in the art could arrive at a method and practice that method. ...Under Nautilus this is no longer sufficient. ...Here the required guidance is not provided by the claims, specification, and prosecution history...Therefore, the claims were indefinite under Nautilus.”

# Post-Nautilus Case Law

- *Akzo Nobel Coatings, Inc. v. Dow Chemical Co.*, 811 F.3d 1334 (Fed. Cir. 2016)
  - Claim 1. A process for producing a dispersion of a polymer in an aqueous medium... *to have an aqueous dispersion with a viscosity below 10 Pa.s.*
    - Dow argued that failure to require temperature for viscosity test rendered claim indefinite.
  - Claim 2. “[a] process according to claim 1 which is *carried out at a temperature of from about 5 to 150° C above the melting point of the polymer.*”
    - Dow argued that failure to specify which steps in the claimed process occur at those elevated temperatures rendered claim indefinite.

# *Post-Nautilus Case Law*

- *Akzo Nobel Coatings, Inc. v. Dow Chemical Co.* (con't)
  - DC: claims not indefinite.
    - “in context [a POSITA] would know with reasonable certainty that viscosity is to be measured at room temperature.”
    - “Dow has provided no evidence to show that a [POSITA] would not know with reasonable certainty the steps to which the limitation in claim 2 applies.”
  - FC: Affirmed.
    - No clear error in fact finding and does not conflict with intrinsic record.
      - “room temperature is the only temperature mentioned at all in the ‘956 patent in connection with a viscosity measurement.”
      - The specification teaches that the dispersing step occurs before the dispersion is extruded, and it is during that step that the temperature limitation applies.
      - “Dow has provided no evidence to show that a person of ordinary skill in the art would not know with reasonable certainty the steps to which the limitation in claim 2 applies.”

# *Post-Nautilus Case Law*

- *HZNP Meds. LLC v. Actavis Labs.*, 2019 U.S. App. LEXIS 30332 (Fed. Cir. 2019), *cert. denied*, (U.S., Nov. 2, 2020)
  - Horizon method of use patents.
    - Claim 10. A method for applying topical agents to a knee of a patient with pain, said method comprising:
      - applying a first medication consisting of a topical diclofenac preparation ... ;
      - waiting for the treated area to dry;
      - subsequently applying a sunscreen, or an insect repellent to said treated area after said treated area is dry, ....
  - Horizon formulation patents.
    - Claim 49. A topical formulation **consisting essentially of**:
      - 1-2% w/w diclofenac sodium; 40-50% w/w DMSO; 23-29% w/w ethanol; 10-12% w/w propylene glycol; hydroxypropyl cellulose; and water to make 100% w/w, wherein the topical formulation has a viscosity of 500-5000 centipoise.

# Post-Nautilus Case Law

- HZNP (con't)
  - DC claim construction:
    - “the topical formulation produces less than 0.1% impurity A after 6 months at 25°C and 60% humidity” indefinite because the identity of “impurity A” is unknowable to a POSITA.
    - “the formulation degrades by less than 1% over 6 months” indefinite because neither the claims nor the specification disclose the means to evaluate degradation.
    - “consisting essentially of” indefinite.
      - DC found 5 “basic and novel properties” in specification: (1) better drying time; (2) higher viscosity; (3) increased transdermal flux; (4) greater pharmacokinetic absorption; and (5) favorable stability.
      - “better drying time” indefinite.
        - Specification described two different methods for evaluating “better drying time” which gave different results.
        - “a POSITA would not know under which standard to evaluate the drying rate of the claimed invention.”
        - A POSITA would not have “reasonable certainty” about the scope of the basic and novel properties of the invention.
        - On rehearing, found “favorable stability” indefinite too.

# *Federal Circuit: Affirmed Indefinite*

- HZNP (con't)
  - Affirmed indefiniteness holding.
    - The claims do not make clear that “impurity A” refers to an impurity of diclofenac sodium.
    - None of the specification, the claims, or the prosecution history defines or directly connects “impurity A” to USP Compound A. Nor does the extrinsic evidence.
    - “Having used the phrase ‘consisting essentially of,’ and thereby incorporated unlisted ingredients or steps that do not materially affect the basic and novel properties of the invention, a drafter cannot later escape the definiteness requirement by arguing that the basic and novel properties of the invention are in the specification, not the claims. Indeed, this contravenes the legal meaning associated with the phrase ‘consisting essentially of.’”
    - “To determine if an unlisted ingredient materially alters the basic and novel properties of an invention, the *Nautilus* definiteness standard requires that the basic and novel properties be known and definite. Accordingly, in this case, the district court did not err in considering the definiteness of the basic and novel properties during claim construction.”
    - The district court did not err in determining that the basic and novel property of ‘better drying time’ was indefinite.
      - the two different methods disclosed in the specification for evaluating ‘better drying time’ do not provide consistent results at consistent times.

# Post-Nautilus Case Law

- *IBSA Institut Biochimique, S.A. v. Teva Pharms. USA, Inc.*, 966 F.3d 1374 (Fed. Cir. 2020)
  - Claim 1, reads: A pharmaceutical composition comprising thyroid hormones or their sodium salts in the form of either:
    - a) a soft elastic capsule consisting of a shell of gelatin material containing a **liquid or half-liquid** inner phase ..., said **liquid or half-liquid** inner phase being in direct contact with said shell without any interposed layers, or
    - b) a swallowable uniform soft-gel matrix .... (emphasis added.)
  - IBSA: “half-liquid” should be construed as “semi-liquid, i.e., having a thick consistency between solid and liquid.”
    - Italian priority application used the term “semiliquido” wherever the U.S. patent used “half-liquid,” and its certified translation, which used “semi-liquid” for “semiliquido.”
    - Specification cited internally to pharmaceutical references which used the term “semi-liquid.”
  - Teva: expert’s testimony that the term “half-liquid” was not a well-known term in the art.
  - DC: Claim term indefinite.
    - Many differences between the priority application and the U.S. application, suggesting those differences were intentional.
    - Citations merely established that the applicant knew of the term “semi-liquid” and chose not to use it.
    - A POSITA would understand from the specification that a “half-liquid” was *not* a gel or paste, which directly contradicts IBSA’s proposed construction of a substance “having a thick consistency between solid and liquid.”
    - At one point there was a pending claim using “half-liquid” and another claim, depending from that claim, using the term “semi liquid.” The dependent claim was removed before the patent issued - “evidence that the applicant did not mean ‘semi-liquid’ when he used the term ‘half-liquid.’”

# Post-Nautilus Case Law

- IBSA (con't)
  - FC: Affirmed.
    - Claims - “the claim language clarifies only that a ‘half-liquid’ differs from a ‘liquid,” but does not make the meaning of “half-liquid” reasonably clear.
    - Specification - disjunctive lists “designate that a ‘half-liquid’ is an alternative to the other members of the list, including pastes and gels.” However, because “[p]astes and gels...have a thick consistency between a liquid and a solid and would be included in IBSA’s proposed construction[, s]uch inclusion is at odds with the above passages and creates uncertainty as to the boundaries of a ‘half-liquid.’”
    - Prosecution history - differences between the Italian priority application and the patent application would indicate to a POSITA that the differences were intentional. Also, removing dependent claim reciting “semi-liquid” corroborated an intentional difference between using that term and “half-liquid.”
    - Extrinsic evidence - No scientific dictionary in the record contained the term “half-liquid” and IBSA’s expert could not explain how a POSITA would know what constitutes a “half-liquid.”

# Post-Nautilus Case Law

- Not chemical or biotech, but see *Presidio Components, Inc. v. American Technical Ceramics Corp.*, 875 F.3d 1369, 1377 (Fed. Cir. 2017), for example of showing definiteness based on knowledge in the art:
  - Claim limitation: “in an edge to edge relationship in such proximity as to form a first fringe-effect capacitance with the first contact that is capable of being determined by measurement in terms of a standard unit.”
  - Patent disclosed insertion loss testing as method of measuring; insertion loss testing well-known in the art; and expert testimony that a POSITA would know how to measure fringe-effect capacitance by using insertion loss measurements and be able to determine the capacitance in terms of the standard unit of Farads.
  - Affirmed holding of **no indefiniteness because the claimed measurement required “was within the skill of a skilled artisan based on an established method.”**
  - “the general approach was sufficiently well established in the art and referenced in the patent to render the claims not indefinite.”
  - Distinguished *Teva* and *Dow* where competing existing methods reached different results and patent failed to describe which method to use.

# TIP

- Try to avoid claim language that could raise questions about “reasonable certainty” under 35 U.S.C. §112(b).
- Undefined terms that do not have well-established meanings in the art, such as “half-liquid,” are the types of claim language that could raise questions regarding indefiniteness.
- Carefully review translations and discuss any uncommon or unusual terminology with the inventors before filing an application with the USPTO.



# *Multiple Ways to Measure*

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- *Teva Pharms. v. Sandoz*, on remand from Supreme Court after clarifying standard of review for claim construction, 789 F.3d 1335 (Fed. Cir. 2015)
  - Group I claims
    - Copolymer–1 having a molecular weight of about 5 to 9 kilodaltons, made by a process comprising the steps of:
      - reacting protected copolymer–1 ...; and purifying said copolymer–1, to result in copolymer1 having a molecular weight of about 5 to 9 kilodaltons.
  - Group II claims
    - Copolymer–1 having over 75% of its mole fraction within the molecular weight range from about 2 kDa to about 20 kDa....”
- “molecular weight” insolubly ambiguous because it could refer to M<sub>p</sub>, M<sub>n</sub>, M<sub>w</sub>, or yet another average molecular weight measure?

# *Multiple Ways to Measure*

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- *Teva Pharms. v. Sandoz* (con't)
  - DC: construed “molecular weight” as Mp and held that the Group I and Group II claims are not indefinite.
  - FC: Affirm Group II claims not invalid; reverse for Group I claims - invalid for indefiniteness.
    - Group I claims do not indicate which average molecular weight measure is intended. Two prosecution statements directly contradict each other (one says M p, one says M w) and render the ambiguity insoluble.
    - Group II claims recite the percentage of copolymer–1 molecules in a sample falling between precise points on the “Molecular Weight” axis - scope of Group II claims is thus readily ascertainable.
  - **FC on remand: Reversed district court.**
    - **Claims invalid for indefiniteness with respect to which of three possible ways of measuring molecular weight.**
      - **“patentee has failed to inform with reasonable certainty those skilled in the art about the scope of the invention. On this record, there is not reasonable certainty that molecular weight should be measured using Mp.**

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

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- *Pac. Coast Bldg. Prods. v. CertainTeed Gypsum, Inc.*, 816 Fed. Appx. 454 (Fed. Cir. 2020)
  - Claim 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.

# *But Need To Show Method Of Measure Outcome-Determinative*

- *Takeda Pharmaceutical Co. v. Zydus Pharms. USA, Inc.*, 743 F.3d 1359 (Fed. Cir. 2014), cert. denied
  - Claim limitation: “fine granules having an average particle diameter of 400  $\mu\text{m}$  or less.”
  - Takeda: “average particle diameter should be determined by measuring each individual core, regardless of whether they had fused together into a hard agglomerate.” (Zydus's ANDA product would infringe)
  - Zydus: since “specification describes measuring particle size after the coating process and says nothing about deagglomeration, it by definition includes hard agglomerates in the measurement of average particle diameter.” (Zydus's ANDA product would not infringe).

# *But Need To Show Method Of Measure Outcome-Determinative*

- *Takeda* (con't)
  - ZyduS:
    - “patent is indefinite because it does not specify the method of measurement that should be used to determine average particle diameter. ...the skilled artisan has no way to determine whether his or her product infringes the ' 994 patent based on the information provided in the specification.”
  - FC: Did not show indefinite.
    - several possible ways to measure average particle diameter.
    - “However, we do not believe that the mere possibility of different results from different measurement techniques renders claim 1 indefinite. ...Moreover...there is a ‘high degree of correlation for the results’ between the two techniques[.]”
    - “ZyduS did not present clear and convincing evidence that the method of measurement is in fact outcome-determinative in the infringement analysis.”

# *But Need To Show Method Of Measure Outcome-Determinative*

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*FloodBreak, LLC v. Art Metal Indus., LLC*, 2020 U.S. Dist. LEXIS 140554 (D. Conn. Aug. 6, 2020)

- “stops...not obstructing said passage...”
- DC: “The assertion of indefiniteness simply fails.”
  - Figures
  - Descriptions of embodiments
  - Definition of “unobstructively”
  - Claims establish that purpose of invention is to permit ventilation.
  - No need to provide precise numbers regarding how much a component may impact a passage’s ventilation because will vary with embodiments.
  - Do not need to know precise method for calculating air flow to understand the limitation

# *Multiple Ways To Measure Only Issue if Results in Materially Different Outcomes*

- *Ball Metal Bev. Container Corp. v. Crown Packaging Tech., Inc.*, 2020 U.S. App. LEXIS 40849 (Fed. Cir. 2020) (non-precedential)
  - Claim terms at issue: “second point” and “transition”
  - DC: Indefinite.
    - “the patents failed to reference any test for locating the second point and Crown's expert had inconsistently presented at least three different tests for locating the second point.”
  - FC: Vacated.
    - “Under our case law, then, a claim may be invalid as indefinite when
      - 1) different known methods exist for calculating a claimed parameter,
      - 2) nothing in the record suggests using one method in particular, and
      - 3) application of the different methods result in materially different outcomes for the claim's scope such that a product or method may infringe the claim under one method but not infringe when employing another method.”
    - “[O]n remand the district court should review Mr. Higham's methodologies and analyze whether the methods lead to materially different results for the angle.”

# Relative Terms

- *One-E-Way, Inc. v. ITC*, 859 F.3d 1059 (Fed. Cir. 2017)
  - Claim term: “virtually free” (from interference)
  - ITC: Indefinite.
    - Term not defined in the patents and does not “have an understood meaning in the relevant art.”
    - POSITA “had ‘no guidepost in the intrinsic or extrinsic evidence from which [she] could discern the scope of the limitation.’”
  - FC: Reversed.
    - “As long as claim terms satisfy [the Nautilus test: viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty], relative terms and words of degree do not render patent claims invalid.”
    - “the applicant used the term ‘interference’ in a non-technical manner to simply mean that the wireless headphone user is able to listen without eavesdropping. This interpretation is consistent with the specification and prosecution history and provides a clear line such that it informs those skilled in the art about the scope of the invention with reasonable certainty. For the purposes of definiteness, the term is not required to have a technical measure of the amount of interference.”

# *Assessing Compliance With §112(b): Prosecution*

- MPEP § 2173.05(e)
- “A claim is indefinite when it contains words or phrases whose meaning is **unclear**.”
- “If the scope of a claim would be **reasonably ascertainable** by those skilled in the art, then the claim is not indefinite.”

## *MPEP § 2173.02*

- “Patented claims enjoy a presumption of validity and are not given the broadest reasonable interpretation during court proceedings involving infringement and validity, and can be interpreted based on a fully developed prosecution record. Accordingly, when possible, courts construe patented claims in favor of finding a valid interpretation. A court will not find a patented claim indefinite unless it is ‘insolubly ambiguous.’”
- “In contrast, no presumption of validity attaches before the issuance of a patent. ... In deciding whether a pending claim particularly points out and distinctly claims the subject matter, a lower threshold of ambiguity is applied during prosecution. ... applicant has the ability to provide explanation and/or amend the claims to ensure that the meaning of the language is clear and definite prior to issuance.”

# Relative Terms

- **2173.05(b) Relative Terminology [R-08.2017]**

- The use of relative terminology in claim language, including terms of degree, does not automatically render the claim indefinite under 35 U.S.C. 112(b) or pre-AIA 35 U.S.C. 112, second paragraph. *Seattle Box Co., Inc. v. Industrial Crating & Packing, Inc.*, 731 F.2d 818, 221 USPQ 568 (Fed. Cir. 1984). Acceptability of the claim language depends on whether one of ordinary skill in the art would understand what is claimed, in light of the specification.

- **I. TERMS OF DEGREE**

- Terms of degree are not necessarily indefinite. ... Thus, when a term of degree is used in the claim, the examiner should determine whether the specification provides some standard for measuring that degree. ... If the specification does not provide some standard for measuring that degree, a determination must be made as to whether one of ordinary skill in the art could nevertheless ascertain the scope of the claim (e.g., a standard that is recognized in the art for measuring the meaning of the term of degree).
- The claim is not indefinite if the specification provides examples or teachings that can be used to measure a degree even without a precise numerical measurement (e.g., a figure that provides a standard for measuring the meaning of the term of degree). ...
- During prosecution, an applicant may also overcome an indefiniteness rejection by providing evidence that the meaning of the term of degree can be ascertained by one of ordinary skill in the art when reading the disclosure. ...

# Subjective Terms

- **2173.05(b) Relative Terminology [R-08.2017]**
  - IV. SUBJECTIVE TERMS
    - When a subjective term is used in the claim, the examiner should determine whether the specification supplies some standard for measuring the scope of the term, similar to the analysis for a term of degree. **Some objective standard must be provided in order to allow the public to determine the scope of the claim. A claim that requires the exercise of subjective judgment without restriction may render the claim indefinite. ...**
    - During prosecution, the applicant may overcome a rejection by amending the claim to remove the subjective term, or by providing evidence that the meaning of the term can be ascertained by one of ordinary skill in the art when reading the disclosure. However, “[f]or some facially subjective terms, the definiteness requirement is not satisfied by merely offering examples that satisfy the term within the specification.” *DDR Holdings, LLC v. Hotels.com, L.P.*, 773 F.3d 1245, 1261, 113 USPQ2d 1097, 1108 (Fed. Cir. 2014).

## *USPTO Standard*

- *In re Packard*, 751 F.3d 1307 (Fed. Cir. 2014) (per curiam) (decided before *Nautilus*)
  - Federal Circuit upheld USPTO decision rejecting “pre-issuance” claims in Packard's patent application as indefinite applying MPEP standard, “unclear.”
    - § 2173.05(e):
      - “A claim is indefinite when it contains words or phrases whose meaning is **unclear**.”
      - “If the scope of a claim would be **reasonably ascertainable** by those skilled in the art, then the claim is not indefinite.”

# USPTO Standard

- *Packard* (con't)
  - Packard argued that Board should have applied “insolubly ambiguous” standard to his claims.
    - “not indefinite if a court can give **any** meaning to the disputed term in the context of the claim”
    - “insolubly ambiguous” applies to both pre- and post-issuance claims.
  - Federal Circuit:
    - Affirmed rejection.
      - “indefiniteness under the MPEP standard properly applied by the USPTO”
    - de novo review as question of law (claim construction)
    - Resolved without addressing the broad issues raised by Packard, including standard for post-issuance indefiniteness.
    - “when the USPTO has initially issued a well-grounded rejection that identifies ways in which language in a claim is ambiguous, vague, incoherent, opaque, or otherwise unclear in describing and defining the claimed invention, and thereafter the applicant fails to provide a satisfactory response, the USPTO can properly reject the claim as failing to meet the statutory requirements of § 112(b).”

# *USPTO Standard*

- *Packard* (con't)
  - Federal Circuit:
    - “indefiniteness rejections by the USPTO arise in a different posture from that of indefiniteness challenges to an issued patent.”
      - examiner’s initial rejection
      - applicant has chance to respond to that prima facie case
      - if inadequate, examiner confirm rejection on the substantive basis of having failed to meet the requirements of § 112(b).
    - “statutory language of ‘particular[ity]’ and ‘distinct[ness]’ indicates, claims are required to be cast in clear—as opposed to ambiguous, vague, indefinite— terms. It is the claims that notify the public of what is within the protections of the patent, and what is not.”
    - “At the same time, this requirement is not a demand for unreasonable precision. ...Rather, how much clarity is required necessarily invokes some standard of reasonable precision in the use of language in the context of the circumstances.”

# *USPTO Standard*

- *Packard* (con't)
  - Federal Circuit:
    - “reasonable implementation of the examination responsibility, as applied to § 112(b), for the USPTO, upon providing the applicant a well-grounded identification of clarity problems, to demand persuasive responses on pain of rejection. That approach decides this case, because Mr. Packard did not offer a satisfactory response to well-grounded indefiniteness rejections in this case.”
    - “[Packard] did not focus on the claim language difficulties, nor did he propose clarifying changes or show why, on close scrutiny, the existing claim language really was as reasonably precise as the circumstances permitted.”
    - “crucial distinction between what Mr. Packard argued and what is required to address an indefiniteness problem: Mr. Packard’s ‘arguments focus on what is contained in the disclosure, whereas the indefiniteness to which [§ 112(b)] is applied is in the language of the claims.’”

# USPTO Standard

- *Packard* (con't)
  - Federal Circuit:
    - PTO can apply a different standard for indefiniteness than would be applied by the courts.
    - Different standards for issued patents and applications.
      - MPEP § 2173.02:
        - “Patented claims enjoy a presumption of validity and are not given the broadest reasonable interpretation during court proceedings involving infringement and validity, and can be interpreted based on a fully developed prosecution record. Accordingly, when possible, courts construe patented claims in favor of finding a valid interpretation. A court will not find a patented claim indefinite unless it is ‘insolubly ambiguous.’”
        - “In contrast, no presumption of validity attaches before the issuance of a patent. ... In deciding whether a pending claim particularly points out and distinctly claims the subject matter, a lower threshold of ambiguity is applied during prosecution. ... applicant has the ability to provide explanation and/or amend the claims to ensure that the meaning of the language is clear and definite prior to issuance.”
    - Did not need to wait for the *Nautilus* Supreme Court decision because that relates to definiteness of an issued patent claim.

# *USPTO Standard For Indefiniteness*

- *Ex parte McAward*, Appeal 2015-006416 (P.T.A.B. Aug. 25, 2017), **precedential**
  - Claim 1. A water detector comprising:
    - a housing;
    - flow connectors...;
    - an electrically actuatable valve...; and
    - control circuits...wherein the water detector is *configured to be reliably installed by an untrained installer or a homeowner and to not require the services of a plumber or electrician to perform installation, thereby permitting widespread and cost effective adoption.*
  - Examiner rejected as indefinite.
    - No “structure provided to the apparatus or system that would allow it to be ‘configured’ to function as described in the claims.”
  - PTAB: Affirmed.

# USPTO Standard For Indefiniteness

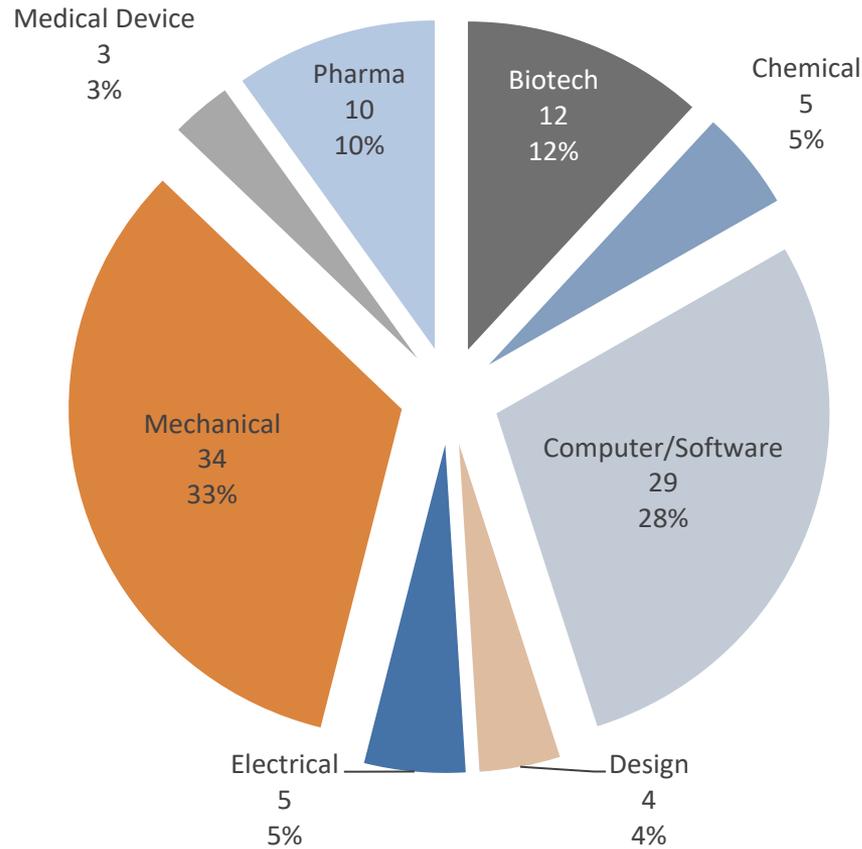
- *McAward* (con't)
  - Appellants: limitation “would be understood to mean capable of being installed without special knowledge or tools” and “[g]arden hose connectors or electrical plugs for home wall outlets would be understood as examples of such configuration.”
  - PTAB:
    - Indefiniteness analysis: construe claims according to BRI, then establish prima facie case of indefiniteness explaining how the “metes and bounds” of a claim are not clear.
    - Footnote 3: The Board's precedential decision in *Miyazaki* [89 USPQ2d 1207 (BPAI 2008)(precedential)], which remains Board precedent, provides an example in which the Board affirmed an indefiniteness rejection of a claim containing words or phrases whose meanings were unclear, *i.e.*, the approach approved in *Packard*. **The instant decision reaffirms, after the Supreme Court's decision in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. \_\_\_, 134 S. Ct. 2120 (2014), the USPTO's long-standing approach to indefiniteness and the reasons for this approach.**

# *Claim Language In This Case “Unclear”*

- *McAward* (con’t)
  - PTAB: “the claimed ‘configured’ limitation, under the broadest reasonable interpretation when read in light of the Specification, is vague and unclear, and a person having ordinary skill in the art would not be able to discern the metes and bounds of the claimed invention in light of this claim language.”
    - The claim “language fails to provide adequate clarity to the required structure because the skill level of ‘an untrained installer or a homeowner’ is ambiguous and vague, and thus, the meaning of a structure configured to be ‘reliably installed’ by such an installer is unclear.”
    - “[T]he Specification contains no description of, for example, the knowledge or tools required for installation of the claimed water detector, nor does the Specification define the skill level of an ‘untrained installer’ or a ‘homeowner.’”
    - Also, “the claim language of the ‘configured’ limitation, when read in light of the Specification, fails to further clearly define the structure encompassed by the limitation.”
    - Preferred embodiment describing connector elements as “standard hose connectors used with flexible hose[.]s” and providing an example of such a connector, but “neither the language of claim 1 nor anything in Appellants’ Specification delineates how a person of ordinary skill would determine whether a water detector that includes each of the structural limitations of claim 1 further satisfies the ‘configured’ limitation.”

# Indefiniteness At PTAB

112b Raised in PGR Petitions



Source: Finnegan research, as of June 9, 2021.

# *Indefiniteness At PTAB*

- *B.R.A.H.M.S. GmbH v. Becton, Dickinson and Co.*, PGR2016-00018, Paper 8 (P.T.A.B. Nov. 2, 2016)
  - Claim 1. A method for the advanced detection of sepsis in a SIRS-positive subject, comprising the steps of:
    - a) measuring at a plurality of time points, prior to laboratory confirmation of a clinically significant infection causative of sepsis, an amount of procalcitonin in fluid or tissue of the subject; and
    - (b) measuring at a plurality of time points, prior to laboratory confirmation of a clinically significant infection causative of sepsis, **one or more clinical markers of the subject, to detect sepsis in the subject;**
  - wherein an **increase in the amount of procalcitonin** from a previous amount over a 24 hour interval **detects sepsis in the subject.**
  - Petitioner: claims indefinite – “no clear recitation of how clinical markers are used to detect sepsis.”
  - Patent Owner: clinical markers not required because claim recites only an increase in the amount PCT detects sepsis.

# *Indefiniteness At PTAB*

- PGR2016-00018 (con't)
  - PTAB: Instituted IPR (on this and other grounds); Petitioner established more likely than not that claim 1 is indefinite
    - “We are persuaded by Petitioner’s argument and evidence that claim 1 is drafted in such a way as to be internally inconsistent and indefinite, because it is unclear how the recited measurement of ‘one or more clinical markers’ is used ‘to detect sepsis in the subject.’”
    - Step 1(b) “to detect sepsis in the subject” is based on the measurement of “one or more clinical markers.”
    - “Wherein” clause “to detect sepsis in the subject” is based on the measured increase in PCT levels over a 24-hour interval[.]”
    - “If we were to read claim 1 as a method that requires only increased PCT levels over a 24-hour interval to detect sepsis in the subject, then we would be reading out measuring step 1(b)[.]”

*Case settled Mar. 17, 2017*

# *Indefiniteness At PTAB*

- *Grunenthal GmbH v. Antecip Bioventures II LLC*, PGR2019-00028, Paper 25 (P.T.A.B. July 28, 2020)
  - Claim 17. A method of treating autonomic motor change associated with complex regional pain syndrome, comprising administering neridronic acid in a salt form or an acid form to a human being suffering from **autonomic motor change associated with complex regional pain syndrome**.
  - PTAB: Claims not shown to be indefinite under either *Nautilus* or *Packard*.
    - Based on the record, a POSITA would understand the meaning of “autonomic motor change.”
      - “Specifically, we conclude that a person of ordinary skill in the art would have understood this phrase to mean ‘changes in the autonomic motor system, such as changes in skin blood flow, changes in temperature, such as temperature asymmetry, and sweating changes.’”

# *Indefiniteness At PTAB*

- *Progenics Pharms. Inc. v. Max-Planck*, PGR2019-00052, Paper 10 (P.T.A.B. Apr. 27, 2020)
  - Compound claim.
  - Petitioner: Variable p appears at multiple locations on the recited compounds and it is unclear whether p is the same at each instance or is independently selected each time it appears.
  - PTAB: Claims not shown to be indefinite under either *Nautilus* or *Packard*.
    - “[T]he context provided by the surrounding claim language and well-established claim construction principles support interpreting ‘p’ to be the same integer each time it appears in the claim.”
    - “[T]he fact that claim 1 recites four different variables (i.e., p, n, n1, and n2) with the same definition [(“an integer selected from 0 to 10”)] cuts against interpreting p to be independently selected each time it appears in the recited formula because such an interpretation would render the other identically-defined variables redundant.
    - Also, claim defines other variables with the term “independently” (“wherein . . . X, Y, W, and Z represent independently of each other . . .”) showing that “independent selection is not within the plain meaning of ‘p’ and must be separately recited.”
    - General claim construction principle of a “presumption that the same terms appearing in different portions of the claims should be given the same meaning unless it is clear from the specification and prosecution history that the terms have different meanings at different portions of the claims. . . there is nothing in the Specification or prosecution history that provides the clear evidence typically necessary to depart from the presumption that ‘p’ has the same meaning each time it appears in Patent Owner’s claims.”
    - “p” is the same integer selected from 0 to 10 each time it appears.

# *Indefiniteness At PTAB*

- *Nippon Suisan Kaisha Ltd. v. Pronova BioPharma Norge AS*, PGR2017-00033, Paper 37 (P.T.A.B. Jan. 16, 2019)
  - Claim 6. ... in the range of at least 50% [] by weight of the crude oil composition..... in the range of at least [] 60%, 70%, 80% or 90% by weight of the crude oil composition...
  - Petitioner: Indefinite because broad and narrow limitations relating to same element.
  - Patent Owner: BRI is the broadest range -> definite.
  - PTAB: Claims shown to be indefinite under either *Nautilus* or *Packard*.
    - “By reciting both broader and narrower limitations for the same components, the scope of coverage for these claims is unclear.”
    - Patent Owner “conflate[s] claim construction and indefiniteness.”
    - “[T] that approach is a backward ‘fixing’ of the claim insofar as it would require rewriting the claims to take out the narrower limitations, which we will not do.”

# *Indefiniteness At PTAB*

- §112(b) may be ground for attack in PGR (35 U.S.C. §321(b)), but also may arise in IPRs in context of:
  - claim construction/indefiniteness
    - *Medshape, Inc. v. Cayenne Medical, Inc.*, IPR2015-00848, Paper 9 (P.T.A.B. Sept. 14, 2015)
      - PTAB denied the IPR on some of the asserted claims that it held were indefinite because of phrase, ““said second member being of a *substantially different* construction than said first member.”
        - “In the absence of any sufficient demonstration that claim 6 indicates the scope of the claimed invention, we do not attempt to apply claim 6 to the asserted prior art.”

# What If Claim Cannot Be Construed by PTAB Because Indefinite?

- There was debate over whether PTAB had authority in that case to cancel the claims as unpatentable, even though 112(b) cannot be a ground asserted in an IPR.
- Before *Samsung* case in Feb. 2020:

Stage of Proceeding	Does Indefiniteness Prevent Comparison to Prior Art?	Board's Various Approaches to Addressing Indefinite Claims
Institution	Yes	<ul style="list-style-type: none"> <li>• Partial denial of institution (pre-SAS)</li> <li>• Full institution, including indefinite claims (post-SAS)</li> </ul>
Trial	Yes	<ul style="list-style-type: none"> <li>• Determine that claims are indefinite and terminate proceedings prior to final written decision.</li> <li>• Determine that claims are indefinite but provide no subsequent decision on patentability.</li> <li>• Determine that claims are indefinite and conclude Petitioner failed to meet its burden of showing unpatentability</li> </ul>
Trial	No	<ul style="list-style-type: none"> <li>• Determine that claims are indefinite and compare challenged claims to prior art.</li> </ul>

From: Tucker, et al, "Indefiniteness in Inter Partes Review: The Existing Quagmire and a Path Forward," Chicago-Kent Journal of Intellectual Property, June 2019; <https://www.finnegan.com/en/insights/articles/indefiniteness-in-inter-partes-review-the-existing-quagmire-and-a-path-forward.html>.

# *Prior Art Based Invalidity Analysis May Be Possible For Indefinite Claim*

- *Samsung Elecs. Am., Inc. v. Prisia Eng'g Corp.*, 948 F.3d 1342 (Fed. Cir. 2020)
  - Samsung petitioned for IPR of claims 1-4, 8 and 11.
  - PTAB initially declined to review claims 1-4 and 8 on any ground because could not determine scope of claims.
  - Post-SAS, instituted on all claims.
  - PTAB: FWD certain claims unpatentable but did not analyze claims 1-4 or 8 because were indefinite.
  - On appeal, Samsung argued that PTAB should have canceled claims 1-4 and 8 for indefiniteness.

# *Prior Art Based Invalidity Analysis May Be Possible For Indefinite Claim*

- *Samsung* (con't)
  - FC:
    - “We reject Samsung's contention that the IPR statute authorizes the Board to cancel challenged claims for indefiniteness.”
    - “the proper course for the Board to follow, if it cannot ascertain the scope of a claim with reasonable certainty for purposes of assessing patentability, is to decline to institute the IPR or, if the indefiniteness issue affects only certain claims, to conclude that it could not reach a decision on the merits with respect to whether petitioner had established the unpatentability of those claims under sections 102 or 103. It would not be proper for the Board to cancel claims on a ground that is unavailable in an IPR.”
    - “In essence, Samsung's argument is that there is no limit to the Board's authority to make unpatentability determinations at the conclusion of an IPR proceeding. That position is at odds with both the statutory language and the case law, and we reject it.”
    - “Even though the validity of the challenged claims may be subject to question for IPXL-type indefiniteness, that is simply another ground on which the claims might be challenged in an appropriate forum (other than the Board). ... It does not necessarily preclude the Board from addressing the patentability of the claims on section 102 and 103 grounds. In the remand proceedings, the Board should determine whether claim 1 and its dependent claims are unpatentable as anticipated or obvious based on the instituted grounds.”

# *Prior Art Based Invalidity Analysis May Be Possible For Indefinite Claim*

- *Cochlear Bone Anchored Sols. AB v. Oticon Med. AB*, 958 F.3d 1348 (Fed. Cir. 2020)
  - Appeal of IPR2017-01018 and IPR2017-01019.
  - PTAB: claims 4-6 and 11-12 unpatentable but claims 7-10 survived.
    - Initially did not institute on claims 7-10 because MPF claims with no identified corresponding structure in the specification but after *SAS*, ordered supplemental briefing on claim construction and instituted.
    - But in FWD, held “means-plus-function limitations of [claims 7-10] have no corresponding structure disclosed in the specification,” so could not “ascertain the differences between the claimed invention and the asserted prior art” for those claims.
  - Claim 10. The hearing aid apparatus according to claim 6, further comprising: directivity means comprising at least one directivity dependent microphone **and/or** signal processing means in the electronic circuitry.

# *Prior Art Based Invalidity Analysis May Be Possible For Indefinite Claim*

- *Cochlear* (con't)
  - FC: Affirmed except claim 10.
    - Claims 7-9: “contains at least one required means-plus-function claim element for which the specification provides no corresponding structure.”
      - “Such a claim logically cannot be compared to prior art, because an essential claim element has no discernible meaning. Such a claim is indefinite[.] ... In this situation, the Board should ‘conclude that it could not reach a decision on the merits with respect to whether petitioner had established the unpatentability of those claims under sections 102 or 103.’ ... The Board here properly did just that for claims 7-9.”
      - Note: “Such a necessary rejection of the petitioner's prior-art challenge rests on a deficiency of the patentee's making, not the petitioner's. We have accordingly held, and here reiterate, that ‘in cases in which the Board cannot reach a final decision as to the patentability of certain claims because it cannot ascertain the scope of those claims with reasonable certainty, the petitioner would not be estopped by 35 U.S.C. § 315(e) from challenging those claims under sections 102 or 103 in other proceedings.’”

# *Prior Art Based Invalidity Analysis May Be Possible For Indefinite Claim*

- *Cochlear* (con't)
  - FC: Vacate and remand claim 10.
    - “Claim 10 is different in a crucial respect. It does not contain a required claim element in means-plus-function form. ...The use of the disjunctive creates three alternative subsets of claim coverage[.]”
    - “[C]laim 10, unlike the other means-plus-function claims, also describes a stand-alone alternative to the signal processing means: a directivity dependent microphone, which is a clear structure for performing the claimed directivity means. The Board ...relied entirely on the presence of the signal-processing-means alternatives in the claim to deem a prior-art analysis impossible. ...**That was error.**”
    - “**Samsung establishes that indefiniteness of a claim does not always imply inability to conduct a prior-art analysis needed for an inter partes review.** ...Here, even if claim 10 is indefinite, such a conclusion would not imply that it is incapable of being compared to prior art to determine if one of its alternatives is anticipated or would have been obvious on the grounds asserted.”
    - “The Board should consider on remand whether the directivity-dependent-microphone alternative is outside the scope of § 112, ¶16, because it recites a structure (the directivity dependent microphone) that sufficiently corresponds to the claimed directivity means. ...The Board also should consider whether any asserted prior-art challenges render the directivity-dependent-microphone alternative within claim 10 unpatentable, if considered on its own, and whether, if so, claim 10 as a whole is unpatentable on that ground.”
    - “**We emphasize that we go no farther in vacating and remanding with respect to claim 10 than to hold that a prior-art analysis is not made impossible, in the context of the ‘and/or’ claim at issue, by the impossibility of such an analysis as to other alternatives in such a disjunctive formulation.**”

# *Does Functional Claiming Language Provide a Path for Life Science Claims Struggling With §112 Indefiniteness ?*

- *Nevro Corp. v. Boston Scientific*, 955 F.3d 35 (Fed. Cir. 2020)
  - Claim limitation at issue: “paresthesia-free”
  - DC: granted summary judgment system and device claims indefinite but not method claims.
    - System and device claims “depended upon the effect of the system on a patient, and not a parameter of the system or device itself and therefore, ‘a skilled artisan cannot identify the bounds of these claims with reasonable certainty.’”

# *Does Functional Claiming Language Provide a Path for Life Science Claims Struggling With §112 Indefiniteness ?*

- *Nevro* (con't)
  - FC: Vacate and remand.
    - “It is undisputed that ‘paresthesia,’ as used in the asserted patents, means ‘a sensation usually described as tingling, pins and needles, and numbness...It is also undisputed that ‘a skilled artisan would be able to quickly determine whether a signal creates paresthesia for any given patient.’ ...In nonetheless holding indefinite the asserted ‘paresthesia-free’ system and device claims, the district court applied the wrong legal standard. **The test for indefiniteness is not whether infringement of the claim must be determined on a case-by-case basis. Instead, it is simply whether a claim ‘inform[s] those skilled in the art about the scope of the invention with reasonable certainty.’ *Nautilus*, 572 U.S. at 910. We conclude that both the ‘paresthesia-free’ method claims and the ‘paresthesia-free’ system and device claims satisfy this standard.”**

# Does Functional Claiming Language Provide a Path for Life Science Claims Struggling With §112 Indefiniteness ?

- *Nevro* (con't)
  - FC: Vacate and remand.
    - “‘Paresthesia-free’ is a functional term, defined by what it does rather than what it is. But that does not inherently render it indefinite. ...In fact, we have held that functional language can ‘promote[] definiteness because it helps bound the scope of the claims by specifying the operations that the [claimed invention] must undertake.’ ... When a claim limitation is defined in ‘purely functional terms,’ a determination of whether the limitation is sufficiently definite is ‘highly dependent on context (e.g., the disclosure in the specification and the knowledge of a person of ordinary skill in the relevant art area).’ ...We have held that the ambiguity inherent in functional terms may be resolved where the patent ‘provides a general guideline and examples sufficient to enable a person of ordinary skill in the art to determine the scope of the claims.’ *Enzo Biochem. Inc. v. Applera Corp.*, 599 F.3d 1325, 1335 (Fed. Cir. 2010).”
    - “[T]he patents provide reasonable certainty about the claimed inventions’ scope by giving detailed guidance and examples of systems and devices that generate and deliver paresthesia-free signals with high frequency, low amplitude, and other parameters. .... That a given signal will eliminate paresthesia in some patients, but not others, does not render the claims indefinite.”
    - “Definiteness does not require that a potential infringer be able to determine ex ante if a particular act infringes the claims. ...Our decisions in *Halliburton* and *Geneva* do not hold otherwise. In *Halliburton*, we held claims reciting the term ‘fragile gel’ indefinite not because infringement could only be determined after use, but because infringement could not be determined at any time. 514 F.3d at 1254-56. That is not the case here, as ‘a skilled artisan would be able to quickly determine whether a signal creates paresthesia for any given patient.’ ...And in *Geneva*, we held that ‘[t]he fact that the same dosage amount does not yield synergy under other circumstances is irrelevant” and does not alone render the term “synergistically effective amount’ indefinite. 349 F.3d at 1384.”

# *Does Functional Claiming Language Provide a Path for Life Science Claims Struggling With §112 Indefiniteness ?*

- *Galderma S.A. v. Medy-Tox, Inc.*, PGR2019-00062, Paper 14 (March 19, 2020)
  - Claim 1. A method for treating a condition in a patient in need thereof, comprising:
    - locally administering a therapeutically effective amount of a botulinum toxin composition that does not comprise an animal-derived product or recombinant human albumin;
    - whereby the botulinum toxin composition exhibits **a longer lasting effect** in the patient when compared to treatment of the same condition with a botulinum toxin composition that contains an animal-derived product or recombinant human albumin dosed at a comparable amount and administered in the same manner and to the same location(s) as that of the botulinum toxin composition that does not comprise an animal-derived product or recombinant human albumin,
    - wherein the condition is selected from the group consisting of glabellar lines, marionette lines, brow furrows, lateral canthal lines, and any combination thereof.

# *Does Functional Claiming Language Provide a Path for Life Science Claims Struggling With §112 Indefiniteness ?*

- *Galderma* (con't)
  - PTAB: IPR instituted. (Note: also example of one ground pulling in others post-SAS).
    - “Although the claims define ‘longer lasting effect’ to require a comparison of compositions having the same toxin with and without animal protein for ‘treatment of the same condition . . . dosed at a comparable amount and administered in the same manner and to the same location(s),’ **the methodology for making such a comparison is not clear from either the claim language or the specification.**”
    - “We find that it is appropriate to take into account the ’728 patent’s and Patent Owner’s own acknowledgement that some of the assessment techniques described in the specification caused the administration of MT10109 and MT10109L to fall within the claim scope, while other assessment techniques resulted in those same compositions falling outside the claim scope. This is a hallmark of indefiniteness.”

# *Preparing Strong Patent Claims*

- **Consider including definitions in specification!**
  - Put yourself in shoes of a judge who is ignorant of the relevant technology and of patent law.
- **Words of degree and relative terms** can be risky and require special attention.
  - Substantially
  - Essentially
  - Virtually
  - Faster
  - Stronger
  - More stable
- Beware of ranges without end points at both ends.
- What if the language is in a granted claim and then the patentee adds a dependent claim – does the dependent claim potentially become indefinite based on language that would be considered definite in the parent claim?

# *Preparing Strong Patent Claims*

- Define and consistently use claim terms.
- Test by analyzing “design around” possibilities from viewpoint of a single 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.
- Consider what would be clear to one skilled in the art “at the time the patent was filed”
- Watch out for multiple ways to measure (also for enforcement!)

# *Strategies For Avoiding/Overcoming §112(b) Rejections*



- Focus arguments on clarity and “reasonable certainty” under 35 U.S.C. §112(b).
- Push back - breadth alone is not indefiniteness.
  - Consider expert declaration.

## *Polling Question No. 1*

You disclose and claim an “improved” widget. There is no definition of “improved” in the specification or the prior art. And nothing in the specification compares an improved widget to a non-improved widget. And you can’t find an expert to opine solidly on what “improved” means. Will a U.S. court or a PTAB panel likely find that the metes and bounds of such a claim are unclear and thus indefinite under 35 U.S.C. §112 (b)?

- Yes
- No

## *Polling Question No. 2*

You disclose and claim a mascara. The disclosure and claims recite a viscosity of 26,000 millipascal seconds (mPa s) for the mascara. Will a U.S. court or a PTAB panel likely find that the metes and bounds of such a claim are unclear and thus indefinite under 35 U.S.C. §112 (b)?

- Yes
- No

## *Polling Question No. 3*

You disclose and claim a stable rubber material for use in wallboard. Will a U.S. court or a PTAB panel likely find that the metes and bounds of such a claim are unclear and thus indefinite under 35 U.S.C. §112 (b)?

- Yes
- No

## *Polling Question No. 4*

In claiming a gearbox, a friend of yours presents a claim ending in the middle of a limitation (“coupled to said gearbox means by rigid...”) Will a U.S. court or a PTAB panel likely find that the metes and bounds of such a claim are unclear and thus indefinite under 35 U.S.C. §112 (b)?

- Yes
- No

# Thank you.

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