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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Outline

I. Understanding 35 U.S.C. §112(b) (“indefiniteness”)
II. Post-Nautilus case law
III. Post-Packard/McAward case law
IV. Best practices for preparing strong patent claims that will hold up in litigation and before PTAB under any of the definiteness standards

Questions:

– How do the decisions distinguish the USPTO's standard and the court's standard for indefiniteness?
– What are the implications of the post-Nautilus and post-Packard/McAward cases for patent counsel in drafting applications?
– What steps can counsel take to increase the likelihood that patent claims will survive in litigation and under PTAB review?
Understanding 35 U.S.C. § 112(b) (“indefiniteness”)

(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.
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 - §112(b) Definiteness Requirement


  – “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).”


  – “[d]efiniteness is measured from the viewpoint of a person skilled in [the] art at the time the patent was filed.’ …See generally E. Manzo, Patent Claim Construction in the Federal Circuit §0.2, p. 9 2014)[.]”
Proper Perspective For Assessing Compliance - §112(b) Definiteness Requirement (con’t)

• 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

  • there 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) Definiteness Requirement: 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.__, 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.
Second Part of §112(b)

• “distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.”

• Subjective inquiry based on opinion of inventor(s).

• Rejection requires evidence that the inventor(s) considers invention different from what is defined by the claims.
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 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. While ‘absolute precision is unattainable’ in patented claims, the definiteness requirement ‘mandates clarity.’ Nautilus, Inc. v. Biosig Instruments, Inc., 527 U.S. ____, 134 S. Ct. 2120, 2129, 110 USPQ2d 1688, 1693 (2014). A court will not find a patented claim indefinite unless the claim interpreted in light of the specification and the prosecution history fails to ‘inform those skilled in the art about the scope of the invention with reasonable certainty.’ Id. at 1689.”

• “The Office does not interpret claims when examining patent applications in the same manner as the courts. In re Packard, 751 F.3d 1307, 1312, 110 USPQ2d 1785, 1788 (Fed. Cir. 2014); ...The Office construes claims by giving them their broadest reasonable interpretation during prosecution in an effort to establish a clear record of what the applicant intends to claim. Such claim construction during prosecution may effectively result in a lower threshold for ambiguity than a court's determination. Packard, 751 F.3d at 1323-24, 110 USPQ2d at 1796-97 (Plager, J., concurring). However, applicant has the ability to amend the claims during prosecution to ensure that the meaning of the language is clear and definite prior to issuance or provide a persuasive explanation (with evidence as necessary) that a person of ordinary skill in the art would not consider the claim language unclear.” ... The lower threshold is also applied because the patent record is in development and not fixed during examination, and the agency does not rely on it for interpreting claims. Packard, 751 F.3d at 1325 (Plager, J., concurring).”
Indefiniteness

  - 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.’”

“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.’”
Indefiniteness (cont.)

• *Nautilus* (cont.)

– Supreme Court:

  • “To determine the proper office of the definiteness command, therefore, we must reconcile concerns that tug in opposite directions. Cognizant of the competing concerns, we read §112, ¶2 to require that a patent’s claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty. The definiteness requirement, so understood, mandates clarity, while recognizing that absolute precision is unattainable. 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.’”
“Insolubly Ambiguous”
“Breeds Confusion”

• *Nautilus* (cont.)

– Supreme Court:

• Federal Circuit’s standard of “amenable to construction” or “insolubly ambiguous” “can leave courts and the patent bar at sea without a reliable compass” and “breed lower court confusion, for they lack the precision §112, ¶2 demands. It cannot be sufficient that a court can ascribe *some* meaning to a patent’s claims; the definiteness inquiry trains on the understanding of a skilled artisan at the time of the patent application, not that of a court viewing matters post hoc. To tolerate imprecision just short of that rendering a claim ‘insolubly ambiguous’ would diminish the definiteness requirement’s public-notice function and foster the innovation-discouraging ‘zone of uncertainty,’ ... against which this Court has warned.”
On Remand

• *Biosig Instruments, Inc. v. Nautilus, Inc.*, 783 F.3d 1374 (Fed. Cir. 2015), *cert. denied* (Nov. 30, 2015)

  – On remand from Supreme Court, Federal Circuit maintained reversal of the district court's determination that Biosig's patent claims are indefinite.

  – Based on the intrinsic evidence, “a skilled artisan would understand with reasonable certainty the scope of the invention.”

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.”

- Provided expert testimony that a POSITA would understand “vitamin B12” to mean cyanocobalamin in the context of the patent and in the medical field.
Post-Nautilus Case Law

• *Eli Lilly v. Teva* (cont.)
  
  – DC: Claims not invalid.
  
  – FC: Affirmed.

  • “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 (in contrast to the facts in *Teva*).
• *Eli Lilly v. Teva* (cont.)

  – FC: Affirmed (cont.)

• Claim language informs POSITA that supplementation form of vitamin B12 (cyanocobalamin) is being used.

• Markush group listing redundancy not an “inflexible” rule.

• Prosecution history supports.
Post-Nautilus Case Law

• 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 NOx, 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 NH3 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 NOx; 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* (cont.)
  - 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 use functional language with no boundaries on amount of effectiveness required or how to measure effectiveness.
Post-*Nautilus* Case Law

• *BASF Corp. v. Johnson Matthey* (cont.)
  
  — 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.’”
• **BASF Corp. v. Johnson Matthey** (cont.)
  
  – FC: Reversed and remanded (cont.)

  • “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.’”
Query

• Does functional claiming provide a path for life science claims struggling with §112 indefiniteness (and §101 subject matter eligibility)?
Post-*Nautilus* Case Law


  - 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 Tmax 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* (cont.)
  
  - 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-\textit{Nautilus} Case Law

\begin{itemize}
  \item \textit{Forest Labs. v. Teva} (cont.)
    \begin{itemize}
    \item FC: Affirmed.
      \begin{itemize}
      \item “\textit{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.”
      \item “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.”
      \item 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.”
      \item “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.”
      \end{itemize}
    \end{itemize}
\end{itemize}
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/α-olefin interpolymer having: . . . and (vi) a slope of strain hardening coefficient greater than or equal to 1.3 . . . .

  - 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-\textit{Nautilus} Case Law

\begin{itemize}
\item \textit{Dow Chemical Co.} (cont.)
\end{itemize}

\begin{itemize}
\item FC: Reversed supplemental damage award.
\item Claims indefinite: did \textbf{not} provide one skilled in the art with the scope of the invention.
\begin{itemize}
\item Different methods existed to determine the maximum slope providing different results.
\item Patent did not provide any guidance as to which method should be used, let alone the possible universe of methods that could be used.
\item No guidance in prosecution or testimony that a POSITA would choose one method over another.
\item “Before \textit{Nautilus}, a claim was not indefinite if someone skilled in the art could arrive at a method and practice that method. ... Under \textit{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 \textit{Nautilus}.”
\end{itemize}
\end{itemize}
Post-\textit{Nautilus} Case Law

- \textit{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...\textit{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 to which steps in the claimed process it applied rendered claim indefinite.
Post-\textit{Nautilus} Case Law

- \textbf{Akzo Nobel Coatings, Inc. v. Dow Chemical Co.} (cont.)

  - 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.”
      - “we are...construing the claims to require the heightened temperature range to apply to the elevated temperature phases in accordance with the specification.”
Post-Nautilus Case Law


  - Claim limitation at issue: “the topical formulation produces less than 0.1% impurity A after 6 months at 25°C and 60% humidity”

  - Horizon’s proposed construction: Less than 0.1% of Impurity A (USP Diclofenac Related Compound A RS) present in the formulation sample after the sample was maintained at 25°C and 60% humidity for 6 months.
    - No reference to USP Compound A in intrinsic evidence, but a POSITA would know.

  - Actavis’ proposed construction: Indefinite because does not inform POSITA with reasonable certainty what is claimed.

  - DC: “indefinite as to the identity of ‘impurity A’”
    - “specification provides no guidance as to which of the proposed pharmacopoeia chromatographic systems a POSA could use to evaluate the identity of ‘impurity A.’”
    - “The identity of ‘impurity A’ as claimed in claim 4 of the ’913 Patent is unknowable to a reasonable certainty to a POSA. Accordingly, ‘impurity A’ is indefinite.”
Post-*Nautilus* Case Law

- *Horizon* (cont.)
  - Claim limitation at issue: “the formulation degrades by less than 1% over 6 months”
  - Horizon’s proposed construction: Less than 0.1% of Impurity A (USP Diclofenac Related Compound A RS) present in the formulation sample after the sample was maintained at 25°C and 60% humidity for 6 months.
  - Actavis’ proposed construction: Indefinite because does not inform POSITA with reasonable certainty what is claimed.
  - DC: Indefinite.
    - “No ... explanation for how to identify the means of degradation is provided.”
    - “Either degradation is equated with ‘impurity A’, which has already been deemed indefinite, or the Court is presented with multiple methods for how to evaluate stability -- and accordingly how to evaluate degradation -- without further guidance, rendering the term indefinite.”
Post-\textit{Nautilus} Case Law

• \textit{Horizon} (cont.)

• Claim limitation at issue: “consisting essentially of”

• Horizon’s proposed construction: no construction needed in \textit{Markman} phase.

• Actavis’ proposed construction: “comprising” or indefinite.

• DC: “indefinite due to indefiniteness of the basic and novel properties of the invention.”

• Construing according to well-established meaning of “consisting essentially of”

• \textit{Nautilus} standard of indefiniteness applies: “the basic and novel properties are part of the scope of the claim, and as such are part and parcel of the claims”

• “a court’s assessment of the basic and novel properties may be performed at the claim construction phase because under certain circumstances the basic and novel properties of an invention are part of the construction of a claim containing the phrase ‘consisting essentially of.’”
Post-Nautilus Case Law

- **Horizon** (cont.)

  - Claim limitation at issue: “consisting essentially of” (cont.)

  - Horizon identified five basic and novel properties for the claimed invention.

  - DC: “indefinite due to indefiniteness of the basic and novel properties of the invention.”

    - “the specification describes two different methods for evaluating [one of the five] and the two methods do not provide consistent results at consistent times.”

    - “once one of them is indefinite, they all become problematic…. Once one property does not have ‘reasonable certainty,’ it follows that the group of properties itself does not have the requisite ‘reasonable certainty.’ Consequently, the term ‘consisting essentially of’ must be construed as indefinite due to the inability for a POSA to have ‘reasonable certainty’ about what the basic and novel properties of the invention are, and thus the POSA would lack ‘reasonable certainty’ about whether an additional ingredient would materially alter the basic and novel properties of the claimed invention.”
Post-Nautilus Case Law


• Claim 1. A topical formulation comprising: diclofenac sodium present at 2% w/w; DMSO present at 25% to 60% w/w; and a viscosity of 500-5000 centipoise, *wherein the formulation is administered twice daily*, to thereby effectively treat pain.

• Horizon’s proposed construction: may be administered twice daily.

• Actavis’ proposed construction: must be administered twice daily.

• DC: agreed with Horizon.
  • “The term ‘is administered twice daily’ simply describes the nature of formulation.”
  • Actavis’ construction “would improperly turn all formulations that require the action of the user into method claims.”
Post-Nautilus Case Law

- *Horizon* (cont.)

- Claim limitation at issue: “improved absorption”

- Horizon: the absorption of compositions of the claimed invention compared to the “comparative liquid composition.”

- Actavis: cannot tell what parameters to use.

- DC: Not indefinite.

  - Adopted Horizon’s proposed construction.

  - The claim language is silent, but the “specification shows that Cmax and AUC are the parameters by which the gel formulation compares with the liquid formulation.”

  - “the specification and Example 7 as a whole would inform a POSA that in order to evaluate whether a formulation has ‘improved absorption’ relative to the comparative liquid formulation, the POSA should compare Cmax and AUC using scaled clinical doses.”
Post-*Nautilus* Case Law

- *Horizon* (cont.)

  - Claim 1. A topical formulation comprising: diclofenac sodium present at 2% w/w; DMSO present at 25% to 60% w/w; and a viscosity of 500-5000 centipoise, wherein the formulation is administered twice daily, to thereby *effectively treat pain*.

- Horizon: “effectively treat pain as measured by the WOMAC scale”

- Actavis: inherently subjective and therefore indefinite.

- DC: Not indefinite.
  - Adopted Horizon’s proposed construction.
  - Not indefinite “simply because the claim describes how the formulation is used.”
  - A POSITA, “when considering Claim 1 in the patent in tandem with Example 8, a POSA would understand that the efficacy of the formulation in treating pain is a reduction of pain or physical function on the WOMAC scale of at least 1 Likert scale unit over a 12 week period.”
Post-*Nautilus* Case Law

• Not chemical or biotech, but see also:

    • Reversed a district court holding of indefiniteness because “the claims merely use permissible functional language to describe the capabilities of the claimed system.”

    • Affirmed holding of no indefiniteness because the claimed measurement “was within the skill of a skilled artisan based on an established method.”
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, which requires that claims 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.”
Federal Circuit Didn’t Wait For Supreme Court In *Nautilus*

- *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.”
Standard for Pre-Issuance Claims

• *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.
Standard for Pre-Issuance Claims

• Packard (con’t)
  – 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).”
Standard for Pre-Issuance Claims

• *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.”
Standard for Pre-Issuance Claims

• 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.’”
Standard for Pre-Issuance Claims

• *Packard* (con’t)

  – Federal Circuit:

  • PTO can apply a different standard for indefiniteness than would be applied by the courts.

  • Did not need to wait for the Nautilus Supreme Court decision because that relates to definiteness of an issued patent claim.
Federal Circuit Didn’t Wait For Supreme Court In Nautilus

• Packard (con’t)

  – 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.”
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 actuatuble 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 precedent 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.
Courts And PTAB Have Different Approaches To §112 Because Of Different Roles In Patent System

- **McAward** (con’t)

  - **PTAB:**
    
    - BRI “ensures that claims, once fixed and issued, are as ‘precise, clear, correct, and unambiguous’ as possible.”
    
    - “The Office's application of the broadest reasonable interpretation for pending claims and its employment of an interactive process for resolving ambiguities during prosecution naturally results in an approach to resolving questions of compliance with §112 that fundamentally differs from a court's approach to indefiniteness. To that end, the Office's approach effectively results in a lower threshold for ambiguity than a court's. .... The different approaches to indefiniteness before the Office and the courts stem not from divergent interpretations of §112, but from the distinct roles that the Office and the courts play in the patent system. The lower threshold makes good sense during patent examination because the patent record is in development and not fixed, the Office construes claims broadly during that period, and an applicant may freely amend claims. See, e.g., Packard, 751 F.3d at 1325 .... By contrast, once a patent has been issued and is under review by a court, simple amendments are impossible, the full prosecution record is available, and courts endeavor to adopt saving constructions.”
**Nautilus** Did Not Mandate Change In PTO Approach Outlined In *Packard*

- *McAward* (con’t)

  - **PTAB:**

    - “We recognize that after the Packard decision, the Supreme Court in *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S._, 134 S. Ct. 2120, 2129 (2014), explained that the ‘definiteness command’ of § 112, ¶12 ‘require[s] that a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty.’ The Court stated that ‘[t]he definiteness requirement, so understood, mandates clarity, while recognizing that absolute precision is unattainable.’ Id. We do not understand *Nautilus*, however, to mandate a change in the Office's approach to indefiniteness in patent-examination matters in which, as discussed above, the claims are interpreted under the broadest reasonable interpretation standard and an opportunity to amend the claims is afforded. See Packard, 751 F.3d at 1323-24[.]”
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.”
But Note Footnote 4!

• *McAward* (con’t)

  – PTAB:

    • Footnote 4: “We do not address, in this decision, the approach to indefiniteness that the Office follows in post-grant trial proceedings under the America Invents Act.”
Then What Happened?

• Applicant filed an RCE Oct. 25, 2017 and a Reply to Decision on Appeal listing replacement claim 1:

  1. A water detector comprising:
     • a housing;
     • a first flow connector carried at an inflow end of the housing;
     • a second flow connector carried at an outflow end of the housing;
     • water presence sensor carried by the housing;
     • an electrically actuatable valve carried by the housing and having a first state and a second state;
     • control circuits carried by the housing and coupled to the water presence sensor and the electrically actuatable value; and
     • a communications port coupled to the control circuits,
     • wherein, responsive to the leakage indicating signal from the water presence sensor, the control circuits actuate the electrically actuatable valve to cause the electrically actuatable valve to change from the first state to the second state, and
     • wherein the communications port is directly coupled to another water detector for receiving an alarm indicating signal therefore to actuate the electrically actuatable valve for transmitting the leakage indicating signal thereto to actuate a local water shutoff valve.
Then What Happened?

• Interview on Dec. 18, 2017:

In a telephonic interview with attorney Hammer, the examiner remarked that the application was in condition for allowance pending several 112b issues with claims 1, 8, 10 related to the "local water shutoff valve". The examiner proposed amendments to fix these issues (please see the Examiner's Amendment for more details). Attorney Hammer agreed to the examiner's amendment thus placing the application in condition for allowance by way of Examiner's Amendment.

• Amendment to claim 1 is in the last line:
  “wherein the communications port is directly coupled to another water detector for receiving an alarm indicating signal therefore to actuate the electrically actuable valve for transmitting the leakage indicating signal thereto to actuate a local water shutoff valve [of the another water detector].

**Examiner's note:** the claim was amended to clarify that the "local shutoff valve" is a part of the another water detector as opposed to a different shut off valve such a water main shutoff valve (which is not supported by the disclosure).**

• Notice of allowance Jan. 8, 2018.
Indefiniteness at PTAB

Source: Finnegan research, as of Jan. 31, 2018; 90 PGR petitions filed.
A Closer Look at the 11 Bio/Pharm/Chem PGR Petitions Raising 112b

- Denied, 3, 27%
- Granted on at least one claim, 6, 55%
- Pending, 1, 9%
- Settled, 1, 9%

Reasons for denials:
- not-PGR eligible
- statutory disclaimer
- failed to show indefinite (or lack of WD support or enablement)

Grant rate 67% (6/9)

Source: Finnegan research, as of Jan. 31, 2018; 90 PGR petitions filed.
Denial for Failure to Show Indefiniteness


  - Claim 1. A method for bleaching hair comprising:
    - (a) mixing a formulation comprising an active agent with a bleaching formulation, wherein the active agent has the formula:
      - or salts thereof;
    - and
    - (b) applying the mixture to the hair;
    - wherein the active agent in the mixture is at a concentration ranging from about 0.1% by weight to about 50% by weight;
    - and
    - wherein the mixture does not contain a hair coloring agent.

- L’Oréal: claims simultaneously require “a bleaching formulation” and exclude “a hair coloring agent,” “which under a proper interpretation includes bleaching agents.”
Denial for Failure to Show Indefiniteness

- **L’Oréal USA, Inc. v. Liqwd, Inc.,** PGR2017-00011 (con’t)

  - But PTAB construed “hair coloring agent” to not include a bleaching agent.

  - PTAB: “We have not been directed to evidence of record that a person of ordinary skill in the art would have considered a bleaching agent to be ‘a colorant or pigment.’...Accordingly, on the present record, we are not persuaded that Petitioner has shown that it is more likely than not that claims 1–10 of the ’419 patent are indefinite.”
Claims 4 and 5 each recite “[t]he method of claim 1, wherein the active agent is present in an amount ranging from about [a minimum weight percentage] to [a maximum weight percentage] of the formulation.”

But Claim 1 recites two formulations: “a formulation comprising an active agent” and “a bleaching formulation”

L’Oréal: “the recitation of ‘the formulation’ in claims 4 and 5 to refer to an unspecified one of the two ‘formulation[s]’ recited in claim 1 renders claims 4 and 5 indefinite.”
Denial for Failure to Show Indefiniteness

• *L’Oréal USA, Inc. v. Liqwd, Inc.*, PGR2017-00011 (con’t)

  – PTAB: “We are not persuaded that Petitioner has shown it is more likely than not that claims 4 and 5 of the ’419 patent are indefinite.”

  • “a person of ordinary skill in the art would understand “the formulation” in claims 4 and 5, given the specific reference in those claims to the amount of active agent in the formulation, as referring to the “formulation comprising an active agent” in claim 1.

  • “Petitioner does not explain why a person of ordinary skill in the art could not reasonably determine the scope of those claims given their express language.”
Indefiniteness At PTAB


  - 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 (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
Types of Claims Attacked in the 11 Bio/Pharm/Chem PGR Petitions Raising 112b

<table>
<thead>
<tr>
<th>Type of claim</th>
<th>Grant rate (granted/denied)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Composition/formulation</td>
<td>67% (2/3)</td>
</tr>
<tr>
<td>Method of treatment</td>
<td>75% (3/4)</td>
</tr>
<tr>
<td>Apparatus</td>
<td>100% (1/1)</td>
</tr>
<tr>
<td>Method of making</td>
<td>100% (1/1)</td>
</tr>
<tr>
<td>Method of use</td>
<td>50% (1/2)</td>
</tr>
<tr>
<td>Product-by-process</td>
<td>100% (1/1)</td>
</tr>
</tbody>
</table>

Source: Finnegan research, as of Jan. 31, 2018; 11 Bio/Pharm/Chem PGR Petitions Raising 112b. More than one type of claim may be raised per petition.
A Closer Look at the 6 Bio/Pharm/Chem Instituted PGRs Raising 112b

- Of the 6 instituted PGRs in which 112b was asserted, 4 were instituted on other grounds.
  - PGR2015-00011, instituted on 103 (FWD all instituted claims survived);
  - PGR2015-00017, instituted on 102 and 103 (FWD all instituted claims unpatentable);
  - PGR2016-00012, instituted on 102, 103, 112a (FWD all instituted claims unpatentable);
  - PGR2017-00022, instituted on 102, 103, 102a, pending.

- 2 were instituted on, inter alia, 112b.
  - PGR2017-00033, pending.
  - PGR2016-00018, settled.

Source: Finnegan research, as of Jan. 31, 2018; 6 Bio/Pharm/Chem PGR Petitions Raising 112b Granted on at least one claim. More than one type of claim may be raised per petition.
Instituted on Indefiniteness


  – Claim 11. The process of claim 1, wherein after step (b) the amount of free fatty acids in the marine oil composition is from about 0.5% by weight to about 5% by weight, preferably 1-3% by weight, most preferably about 2% by weight.

  – Nippon: claims are indefinite because they recite both broad and narrow limitations.
Instituted on Indefiniteness

- *Nippon Suisan Kaisha Ltd. v. Pronova Biopharma Norge, AS, PGR2017-00033 (con’t)*

  - PTAB: Instituted (on this and other grounds)
    
    - “it is not clear from a plain reading of this language whether the claim covers only the most preferred range (“about 2% by weight”) or the substantially broader range of “from about 0.5% by weight to about 5% by weight.”

    - Petitioner’s expert testified a POSITA would not know.

    - cited *Packard*, “a claim is indefinite when it contains words or phrases whose meaning is unclear.”

    - “we determine that it is more likely than not that claim 11 is indefinite[.]”
Indefiniteness At PTAB

• §112b 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

    – 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.”
Sample Claims

  - Ortho’s patent claims topiramate (TOPOMAX®) as a compound with “and” linking a number of components.
    - R2, R3, R4 and R5 are independently hydrogen or lower alkyl and R2 and R3 and/or R4 and R5 together may be a group of the following formula ...wherein R6 and R7 are the same or different and are hydrogen, lower alkyl or are alkyl and are joined to form a ... ring.
  - **Blue** and **green** have to be met to infringe?
  - Mylan’s compound met the **green** component, but did not meet the **blue** component.

- DC: permanent injunction against Mylan and reset effective approval date for Mylan's ANDA.
- FC: Affirmed - claim 1 covers Mylan’s compound
  - “the claim language depicts two subsets of compounds, but does not require their simultaneous existence.”
  - “as used in this claim, and conjoins mutually exclusive possibilities.”
Sample Claims

- **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.”
    - “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.”
    - “Proof of indefiniteness ...is met where an accused infringer shows by clear and convincing evidence that a skilled artisan *could not discern the boundaries of the claim* based on the claim language, the specification, and the prosecution history, as well as her knowledge of the relevant art area.”
Sample Claims


  - Claim: 4. A process of substantially preventing the formation of at least one nitrosamine ..., the process comprising: drying...*in a controlled environment* and for a time sufficient to substantially prevent the formation of said at least one nitrosamine;...; and wherein *said controlled environment* is provided by controlling at least one of humidity, temperature, and airflow.

  - FC: Claim not indefinite.

    - “record repeatedly shows that a person of skill in the art of tobacco curing would possess adequate understanding to manipulate these variables to create a controlled environment” even though numerical values for variables not recited.

    - “the term ‘controlled environment’ falls well within the bounds of ordinary skill in the art. Thus, this term is not insolubly ambiguous and is not indefinite.”
Sample Claims

- **Amgen, Inc. v. Hoechst Marion Roussel, Inc.,** 314 F.3d 1313 (Fed. Cir. 2003)
  - Claim: glycoprotein having “glycosylation which differs from that of human urinary erythropoietin.”
  - Specification taught three measurement methods, but failed to limit "glycosylation which differs" to particular method.

  - DC: patent failed to identify a single standard by which the “difference” could be measured, so no infringement and patent invalid for failure to satisfy §112.

  - FC: Affirmed because claims indefinite. “One cannot logically determine whether an accused product comes within the bounds of a claim of unascertainable scope.”
Sample Claims

  
  - FC: claim ending in the middle of a limitation (“coupled to said gearbox means by rigid...”) is indefinite because it is impossible to discern the scope of such a truncated limitation.
Sample Claims

• *Enzo Biochem, Inc. v. Applera Corp.*, 599 F.3d 1325 (Fed. Cir. 2010)
  
  – Linkage group “not interfering substantially”
  
  – DC: SJ of invalidity based on indefiniteness
  
  – FC: Reversed – not indefinite

  – Req. rehearing denied; Judge Plager, dissenting:
    • “Despite the varying formulations that this court has used over the years in describing its ‘indefiniteness’ jurisprudence ..., the general conclusion from our law seems to be this: if a person of ordinary skill in the art can come up with a plausible meaning for a disputed claim term in a patent, that term, and therefore the claim, is not indefinite.” (emphasis added)
Sample Claims

• *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367 (Fed. Cir. 1986)
  – Claim limitation: “affinity for the antigenic substance of at least about $10^8$ liters/mole”

  – DC: claims are indefinite because antibody affinity cannot be estimated with any consistency; was no standard set of experimental conditions used to estimate affinities.

  – FC: claims are NOT indefinite
    • “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.**”
Ensuring Compliance - §112(b) Definiteness Requirement

• Avoid issue by including definitions in specification!
  – Put yourself in shoes of a judge who is ignorant of the relevant technology and of patent law.
  – Just remember that definitions can be a double edged sword

• Words of degree can be risky and may require special attention.
  – Substantially
  – Essentially
  – Faster
  – Stronger
  – More stable
Patent Profanity: Claims Too Definite to Prevent Design-Around?

- “Very important”

- “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.
More Words of Characterization

- Chief, Majority - Vital
- Critical, Essential, Necessary - Fundamental
- Solely, Only, Is - Important
- Main - Principal
- Significant
Words That Make Other Words Profanity

- Surprising
- Unexpected (?)
- All (?)
- Only (?)
- Each (?)
- “The invention is...” or “This invention...”
Connection to Claim Construction Debate

- Broadest Reasonable Interpretation (BRI) in PTAB (IPRs, PGRs, CBMs) and USPTO (examination and reexamination).

- *Philips* in courts.

- Definiteness also applies different rules in the USPTO than in the courts (*Nautilus/Packard*).

- But do those different standards make a difference?
BRI in PTAB: amending/adding claims to be more precise?

• In IPR/PGR, BRI (in light of the specification) applies to issued claims
  – frequently means that more potentially invalidating prior art may be used.
  – historically considered appropriate standard because patent owner has an ability to amend claims.

  – But query how real is ability to amend in IPR?
BRI in PTAB?

• Does PTAB never have to defer to the examiner’s determination on indefiniteness?

• Is PTAB always going to be applying a completely different (post-issuance) standard than the examiners?

• In general, do BRI and Phillips lead to different conclusions?
Do Packard and Nautilus Mean More Indefiniteness Challenges?
In PTAB? Maybe

% of filed PGR petitions including 112b grounds

Source: Finnegan research, as of Jan. 31, 2018; 90 PGR petitions filed.
FY13 and FY 14 not included because only 3 PGR petitions filed in those two years.
Two Audiences – PTAB and Courts
Indefiniteness at Court


- U.S. Pat. No. 9,051,066 Claim 1:
  - 1. An apparatus comprising:
    - a housing comprising an opening at a first end, and a plurality of holes extending through a common face of the housing at a second end;
    - a plurality of flexible hollow tubes, …;
    - a plurality of containers, …; and
    - a plurality of elastic fasteners, …*each elastic fastener configured to provide a connecting force that is not less than a weight of one of the containers when substantially filled with water, …, such that shaking the hollow tubes in a state in which the containers are substantially filled with water overcomes the connecting force and causes the containers to detach from the hollow tubes* thereby causing the elastic fasteners to automatically seal the containers, wherein the apparatus is configured to fill the containers substantially simultaneously with a fluid.
• *Tinnus* (con’t)

  – *Tinnus*: “‘substantially filled’ was indefinite because it required subjectivity in determining when the container had become substantially filled.”

  – Judge: “identified ‘specific parameters’ in the claims describing how to determine whether a container is substantially filled—for example, ‘when the ‘water overcomes the connecting force and causes the containers to detach from the hollow tubes.’”

  – Granted motion for preliminary injunction.
Federal Circuit Decision

• *Tinnus* (con’t)

  – FC: Affirmed.
    - Noted presumption of validity of issued patent.
    - DC determination reviewed for clear error.
    - Cited *Nautilus*.
    - Level of ordinary skill important: “We find it difficult to believe that a person with an associate’s degree in a science or engineering discipline who had read the specification and relevant prosecution history would be unable to determine with reasonable certainty when a water balloon is ‘substantially filled.’”

• FN: “We are aware that the PTAB issued a Final Written Decision on December 30, 2016, concluding that the claims of the '066 patent are indefinite. The PTAB's decision is not binding on this court, and based on the record before us and the applicable standard of review, it does not persuade us that the district court abused its discretion in granting the preliminary injunction. The parties are, of course, free to ask the district court to reconsider its preliminary injunction in light of the PTAB's Decision.”
Parallel Proceeding on Same Patent – Different Outcome


  – PTAB: Instituted trial on most challenged claims.

  • “We have analyzed the claim language in light of: (1) the ’066 Patent disclosure; (2) the teachings of the prior art; and (3) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. See MPEP § 2173.02(II). On the current record, we are not persuaded that the Specification or prior art provides any objective standard for measuring the scope of ‘filled’ or ‘substantially filled.’”

  • “a POSA could not interpret the metes and bounds of the shake-to-detach feature so as to understand how to avoid infringement.”
Parallel Proceeding on Same Patent – Different Outcome


  - FWD: Claims indefinite.

  - “[T]he phrase ‘...substantially filled with water’ is unclear and indefinite. A person of ordinary skill in the art could not interpret the metes and bounds of the phrase so as to understand how to avoid infringement because neither claim 1 nor the Specification provides any objective standard for measuring the scope of the term ‘filled.’”

  - “the claims are unclear and indefinite for the additional reason that there is no standard by which one of ordinary skill in the art can measure ‘substantially’ so as to understand what is claimed when the claims are read in light of the Specification.”
Parallel Proceeding on Same Patent – Different Outcome

• *Telebrands v. Tinnus*, PGR2015-00018 (con’t)

  – “In this post-grant review AIA proceeding, we apply the test for indefiniteness approved by the Federal Circuit in Packard, i.e., ‘a claim is indefinite when it contains words or phrases whose meaning is unclear.’”

  – “We recognize that Packard involved a USPTO patent-examination matter. We also recognize that subsequent to the Packard decision, the Supreme Court in Nautilus enunciated a differently worded definiteness requirement in the context of patent infringement litigation. We do not understand Nautilus, however, to mandate the Board’s approach to indefiniteness in patent examination or reexamination matters or in AIA proceedings, in which the claims are interpreted under the broadest reasonable interpretation standard, and an opportunity to amend the claims is afforded. The test for indefiniteness approved in Packard, which is applied by the USPTO in patent examination, sets a threshold for indefiniteness that demands at least as much clarity, and potentially more clarity, than the Nautilus definiteness requirement.” (footnotes excluded)
Parallel Proceeding on Same Patent – Different Outcome

• *Telebrands v. Tinnus*, PGR2015-00018 (con’t)

  – “The different approaches to indefiniteness before the PTO and the courts stem from the distinct roles that the PTO and the courts play in the patent system.”

  – “[A]mong the reasons supporting application of the Packard-approved indefiniteness test in this AIA proceeding are those recognized by the Supreme Court in Cuozzo as supporting use of the broadest reasonable interpretation standard in inter partes review AIA proceedings. ...Of these, the most important is the opportunity to amend the claims to correct any ambiguity.”.
• **Telebrands v. Tinnus**, PGR2015-00018 (con’t)
  
  – “[A]pplying the Packard indefiniteness test, that claim 1 is indefinite on several levels.”

  • “Patent Owner’s argument that “filled” means holding as much as can be contained—and no less ...is inconsistent with the Specification and the weight of the evidence.”
  • Instead, “the Specification consistently teaches that whether a container is ‘filled’ depends, subjectively, on whether a desired size or volume has been reached.”
  • “Patent Owner has not persuaded us that a person of ordinary skill in the art would disregard the broad meaning attributed to the word ‘filled’ in the Specification[.]”
  • “[T]he Specification does not supply an objective standard for measuring the scope of the term ‘filled’ or ‘substantially filled.’”
Parallel Proceeding on Same Patent – Different Outcome

• *Telebrands v. Tinnus*, PGR2015-00018 (con’t)
  
  – Patent Owner’s expert’s testimony “conclusory and unpersuasive.”
  
  – “the level of water in a ‘substantially filled’ container is not ascertainable or measurable by reference to any objective standard.”

  – The term “substantially” is not per se indefinite.

  • “Although a claim that encompasses a wide scope of subject matter or includes functional language may not be indefinite for that reason alone, a claim that ‘lacks the requisite minimum clarity to define the boundaries of the claims’ is indefinite. See Packard[.]”

  • “the case law requires some sort of standard by which one of ordinary skill in the art can measure a term of degree such as ‘substantially’ so as to understand what is claimed.” Ex parte Lazzara, Appeal No. 2007-0192, slip op. at 3 (BPAI Nov. 13, 2007) (informative).
Parallel Proceeding on Same Patent – Different Outcome

• *Telebrands v. Tinnus*, PGR2015-00018 (con’t)

  – The PTAB noted that it warned the patent owner “of the significance of the absence of an objective standard, but Patent Owner did not identify persuasively any such standard in the Patent Owner Response. ...Patent Owner also did not move to amend the claims to avoid any of the ambiguities that we identified in our Institution Decision.”
Appeal of PGR

- **Tinnus Enterprises v. Telebrands Corp., Case No. 17-1726**
  - USPTO intervened to argue in favor of Packard standard.
    - “The Packard approach to indefiniteness demands at least as much, and sometimes more, clarity than the Nautilus standard. It is the appropriate legal standard to be applied in this context.”

- No decision yet.
Preparing Strong Patent Claims

• What if the language is in a granted claim and then the patentee adds a dependent claim in a continuation.

• Does the dependent claim potentially become indefinite based on the PTO standard even though under Phillips, the language could be considered definite in the parent claim?

• Can anyone say “Jedi Master Mixer”....
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.
Take-Away for Drafting and Prosecution

• Use claims definite under any of the standards, as well as clear under the BRI of PTAB!!!

• Accurate translation is important, where poor choice in English can result in lack of clarity of the English-language claim.

• Consider what would be clear to one skilled in the art “at the time the patent was filed”
  
  – Challenge arises when words take on meaning after the patent filing that may not have been known to those skilled in the art at the time of filing.

  – Should that timing matter?
Thank you.

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