

# **Biotech/Chem/Pharm Customer Partnership Meeting**

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November 6, 2017

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# The Definiteness Requirement

- **Pre-AIA Section 112, Second Paragraph:** The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
- **Post-AIA Section 112(b):** The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.

# Indefiniteness in the Courts

- *Nautilus v. Biosig*, 134 S. Ct. 2120 (Jun. 2, 2014)
  - Overruled “insolubly ambiguous” and “amenable to construction” standard.
  - Held: “[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.”

# Indefiniteness in the Courts

- New test may produce different results – it demands more than the ability to ascribe some meaning to patent’s claims.
- The “Delicate Balance”:
  - The definiteness requirement must take into account the inherent limitations of language, BUT
  - A patent must be precise enough to afford clear notice of what is claimed.

# Indefiniteness in the Courts

- Other Aspects of Indefiniteness Confirmed in *Nautilus*:
  - Evaluated from the perspective of someone skilled in the relevant art.
  - Claims are to be read in light of the patent's specification and prosecution history.
  - Measured from the viewpoint of a person skilled in [the] art *at the time the patent was filed*.

# PTO Approach to Indefiniteness

- PTO applies a lower threshold of ambiguity (*Ex parte Miyazaki*)
  - Practice (which differs from court) stems from distinct roles of PTO and dcts
  - “[a] claim is indefinite when it contains words or phrases whose meaning is unclear” (*In re Packard*; *Ex parte McAward*)
- Per PTO, *Nautilus* did not mandate a change in PTO’s approach to indefiniteness in patent examination (*Ex parte McAward*)

# PTO Approach to Indefiniteness

- Supplementary Guidelines published in 2011
- General test: under BRI, are the metes and bounds clear?
  - Can one draw a boundary between what is covered by the claim and what is not?
  - A boundary cannot be drawn if there is more than one reasonable interpretation of what is covered
- Breadth should not be confused with indefiniteness
  - Ex. A genus may be broad but if one cannot ascertain the species within the genus, then it may be indefinite
- Identifies key areas in which indefiniteness issues may arise and ways in which an applicant can overcome a rejection

# Subjective Terms

- Examples of Subjective Terms: comparable, superior, aesthetically pleasing
- Claim scope cannot depend solely on the unrestrained, subjective opinion of a particular individual purported to be practicing the invention. *Datamize LLC v. Plumtree Software, Inc.*, 417 F.3d 1342 (Fed. Cir. 2005).
- A claim that requires the exercise of subjective judgment without restriction may render the claim indefinite. *In re Musgrave*, 431 F.2d 882, 893 (CCPA 1970).
- Must look at the rest of the claim and the specification.
- Does the specification provide some standard for determining the “objective boundaries” of the claim?

# Subjective Terms Ex. 1

- *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1373 (Fed. Cir. 2014):
  - **Subjective term:** providing to the content display system a set of instructions for enabling the content display system to selectively display, in an **unobtrusive manner** that does not distract a user of the display device or an apparatus associated with the display device from a primary interaction with the display device or apparatus, an image or images generated from a set of content data; and
  - **Held:** Indefinite – The “unobtrusive manner that does not distract a user” phrase, when viewed in light of the specification and prosecution history, fails to “inform those skilled in the art about the scope of the invention with reasonable certainty.”

# Subjective Terms Ex. 1

- *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1373 (Fed. Cir. 2014):
  - **The Term:**
    - “The patents’ ‘unobtrusive manner’ phrase is highly subjective and, on its face, provides little guidance to one of skill in the art.”
  - **The Claims:**
    - “[T]he claim language offers no objective indication of the manner in which content images are to be displayed to the user.”
  - **The Specification:**
    - Interval argued that “unobtrusive manner” was tied to a particular embodiment, and therefore, only had a spatial meaning.
    - Federal Circuit: “We do not agree with Interval that it is reasonably clear that the “unobtrusive manner” language is tied to a specific type of display.”
      - “The **hazy relationship** between the claims and the written description fails to provide the clarity that the subjective claim language needs.”
      - The PTAB determined the claim term includes multiple embodiments.

# Subjective Terms Ex. 2

- *AstraZeneca LP v. Sigmapharm Labs., LLC*, 2017 WL 679854 (D. Del. Feb. 17, 2017)
  - **Subjective term:** “specific peaks of high intensity”
  - **Held:** Not Indefinite – “[T]he term is not isolated when used in the asserted claims; rather, the rest of the claim provides context for what is meant.”
  - Claim 1 of the '124 patent reads, in part, “a compound of formula (I) characterized by an X-ray powder diffraction pattern containing specific peaks of high intensity at  $5.3^\circ (\pm 0.1^\circ)$ ,  $20.1^\circ (\pm 0.1^\circ)$ ,  $20.7^\circ (\pm 0.1^\circ)$ ,  $21.0^\circ (\pm 0.1^\circ)$  and  $21.3^\circ (\pm 0.1^\circ)$   $2\theta$ .” In other words, the claim specifies which peaks must be present in the diffraction pattern.
  - The specification refers to this compound as Polymorph I and lists the same “specific peaks of high intensity” as those listed in the claims.
  - The specification also includes a longer list of “specific peaks” that the diffraction pattern “[m]ore preferably” contains.

# Terms of Degree

- Examples of terms of degree: “relatively,” “substantial,” “the order of about”
- Terms of degree do not necessarily render a claim indefinite
- The examiner should determine whether the specification provides some standard for measuring that degree, and if it does not, then the examiner should ascertain whether OOSKA could nevertheless ascertain the scope
- Claim should not be indefinite if specification provides teachings that can be used to measure a degree, even if it does not provide a precise numerical measurement

# Terms of Degree – Ex. 1

- *Bayer Intellectual Property GmbH v. Warner Chilcott Company, LLC*, 2015 WL 1849015 (D. Del. 2015)
- 1. A pharmaceutical combination preparation with two hormone components that are manufactured physically separately in a packaging unit and that are intended for time-sequential oral administration, comprising a number of daily dosage units of a first and a second hormone component ... said first hormone component comprises, in combination, an estrogen preparation and a dosage effective to inhibit ovulation of a gestagen preparation ...; and said second hormone component consisting essentially of an estrogen preparation ... whereby the low effective estrogen content and low total hormone content provides high contraceptive reliability, low incidence of follicular development, and satisfactory cycle control with reliable avoidance of intracyclic menstrual bleeding and undesirable side-effects.

# Terms of Degree Ex. 1

- Terms “high,” “low,” “satisfactory,” and “reliable” are terms of degree
  - No standards against which to draw comparisons
  - Patent offered no suggestion for how to measure
- Patentee offered extrinsic evidence and expert testimony
  - Asserted that terms of degree mean claimed regimen performs comparably to other products on market
  - Court rejected as inconsistent with spec and fh statements
- Court explained that “comparable” is subjective, and no data for comparison was provided. Claim held invalid as indefinite.

# Terms of Degree Ex. 2

- *Ex parte Burton*, 2017 WL 1279451 (PTAB Mar. 24, 2017)
- 1. A method of killing a cell that is resistant to anti-CD74 antibody comprising
  - a) exposing the anti-CD74 resistant cell to interferon- $\gamma$ ;
  - b) increasing expression of CD74 on the cell surface by exposing the cell to interferon- $\gamma$ ; and
  - c) exposing the cell to an anti-CD74 antibody or antigen-binding fragment thereof after the cell has been exposed to interferon- $\gamma$ ,  
wherein exposing the cell that is resistant to anti-CD74 antibody to interferon- $\gamma$  results in an increase in the percent growth inhibition or percent apoptosis of the cell exposed to anti-CD74 antibody that is two fold higher or more.

# Terms of Degree Ex. 2

- Degree to which cells must be resistant to anti-CD74 antibody was not clear
- Figures in specification showed that cells could be sensitive to anti-CD74 antibody to some extent even without interferon- $\gamma$
- Claim limitation requiring functional characteristic of resistance plus increased expression of CD74 failed to apprise OOSKA of claim scope
- Argument that resistant meant “shows a substantial inhibition of cell proliferation” did not provide clear scope for term
- PTAB affirms indefiniteness rejection, noting that claims are amendable to “two or more plausible claim constructions”

# Multiple Methods of Measure Ex. 1

- *Teva Pharm. v. Sandoz, Inc.*, 789 F.3d 1335 (Fed. Cir. 2015)
- 1. A method of manufacturing copolymer-1, comprising reacting protected copolymer-1 with hydro-bromic acid to form trifluoroacetyl copolymer-1, treating said trifluoroacetyl copolymer-1 with aqueous piperidine solution to form copolymer-1, and purifying said copolymer-1, to result in copolymer-1 having a molecular weight of about 5 to 9 kilodaltons.

U.S. Patent 5,800,808

# Multiple Methods of Measure Ex. 1

- Three different measures of molecular weight known in art:  $M_p$ ,  $M_n$ ,  $M_w$
- All three measures calculated in different manner and yield different result
- Rejected argument that Ex. 1 and Fig. 1 indicated  $M_p$  as correct measure
  - Data mismatch created doubt that Fig. 1 reflected  $M_p$
  - Rejected argument that fh indicated  $M_p$  to be the correct measure because statement in fh of related patent indicated  $M_w$
  - Did not matter that explanation of  $M_w$  contained scientific error
- Claims held indefinite because there is not reasonable certainty that  $M_p$  is the correct measure of molecular weight

# Multiple Methods of Measure Ex. 2

- *Dow Chemical Co. v. Nova Chemicals Corp.*, 803 F.3d 620 (Fed. Cir. 2015)
- 6. An ethylene polymer composition comprising
  - (A) from about 10 percent . . . to about 95 percent . . . of at least one homogeneously branched linear ethylene/ $\alpha$ -olefin interpolymer having:
    - (i) a density from about 0.89 grams/cubic centimeter ( $\text{g}/\text{cm}^3$ ) to about 0.935  $\text{g}/\text{cm}^3$ ,
    - (ii) a molecular weight distribution ( $M_w/M_n$ ) from about 1.8 to about 2.8,
    - (iii) a melt index ( $I_2$ ) from about 0.001 grams/10 minutes ( $\text{g}/10\text{ min}$ ) to about 10  $\text{g}/10\text{ min}$ ,
    - (iv) no high density fraction,
    - (v) a single melting peak as measured using differential scanning calorimetry, and
    - (vi) a slope of strain hardening coefficient greater than or equal to 1.3; and
  - (B) from about 5 percent . . . to about 90 percent . . . of at least one heterogeneously branched linear ethylene polymer having a density from about 0.93  $\text{g}/\text{cm}^3$  to about 0.965  $\text{g}/\text{cm}^3$ .

# Multiple Methods of Measure Ex. 2

- Where different approaches to measurement are involved, must have:
  - disclosure of single known approach OR
  - established that OOSKA would know which of multiple approaches to select
- Slope of strain hardening coefficient =  $(\text{slope of strain hardening})(I_2)^{0.25}$
- SH has more than 1 slope
- $\geq 4$  methods to measure max. slope; all may yield different max. slope

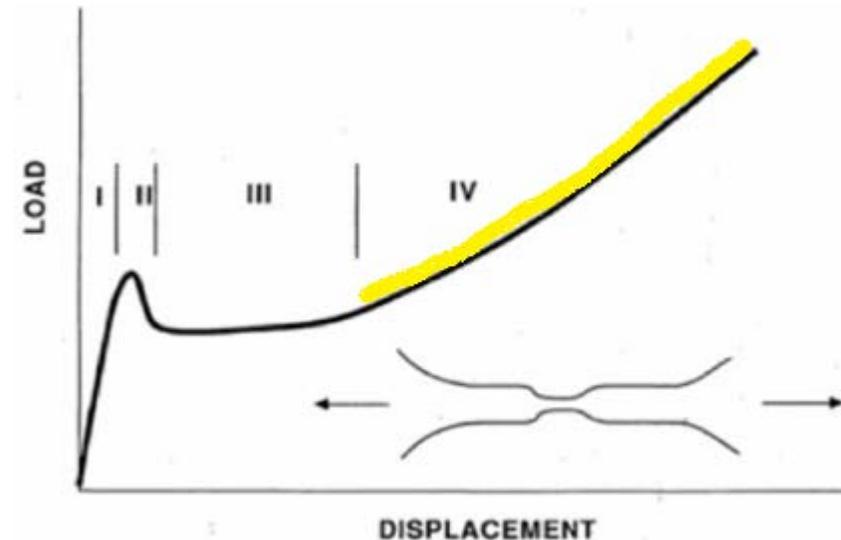


Figure 8. A typical load-displacement curve.

# Multiple Methods of Measure Ex. 2

- CAFC finds indefinite under *Nautilus*
- Neither patent nor fh gave guidance on which method should be used
  - During prosecution, SHC limitation added in preliminary amendment
  - 112, 2 rejections (“greater than about”) but not to the SHC limitation
  - But SHC limitation was the subject of a 102/103 rejection – PTO stated it did not have means to conduct analytical tests related to SHC
  - 102/103 rejection overcome on other grounds
- Indicates that claim likely would have been definite pre-*Nautilus* because OOSKA could arrived at a method and practiced the claim
- “a claim term is indefinite if it ‘leave[s] the skilled artisan to consult the unpredictable vagaries of any one person's opinion.’”

# Use of the Specification

- **MPEP 2173.03:**

- The specification should ideally serve as a glossary to the claim terms so that the examiner and the public can clearly ascertain the meaning of the claim terms. Correspondence between the specification and claims is required by 37 CFR 1.75(d)(1), which provides that claim terms must find clear support or antecedent basis in the specification so that the meaning of the terms may be ascertainable by reference to the specification.
- A claim, although clear on its face, may also be indefinite when a conflict or inconsistency between the claimed subject matter and the specification disclosure renders the scope of the claim uncertain as inconsistency with the specification disclosure or prior art teachings may make an otherwise definite claim take on an unreasonable degree of uncertainty.

# Use of the Specification Ex. 1

- *Supernus Pharms., Inc. v. Twi Pharms., Inc.*, -- F. Supp. 3d – (D.N.J. 2017)
  - 1. A pharmaceutical formulation for once-a-day administration of oxcarbazepine comprising **a homogeneous matrix** comprising....
  - TWi argued that the Patents-in-Suit are invalid as indefinite because the specification and prosecution history contain no guidance on how to determine whether a matrix is homogeneous.
  - Twi expert – “homogenous matrix” is not a term of art and the Patents-in-Suit provide no test for homogeneity or uniformity.

# Use of the Specification Ex. 1

- *Supernus Pharms., Inc. v. Twi Pharms., Inc.*, -- F. Supp. 3d – (D.N.J. 2017)
  - **Held:** It is clear from the prosecution history that “one of ordinary skill in the art would appreciate that the formulations derived according to the protocol set forth in the Examples would necessarily comprise a homogeneous matrix.”
    - Perfect and absolute homogeneity is not achievable in this context.
    - A person skilled in the art would understand that homogeneity and the uniform dispersion of constituents in this context is measured by lack of localization.
    - Example 4 discloses the manufacturing step-by-step process the inventors used to produce a homogeneous matrix tablet.
    - The PTO never issued a rejection based on indefiniteness for the term “homogeneous matrix.”

# Use of the Specification Ex. 2

- *Otsuka Pharm. Co., Ltd. v. Torrent Pharms. Ltd., Inc.*, 151 F. Supp. 3d 525 (D.N.J. 2015)
  - **Representative Claim**: A pharmaceutical solid oral preparation comprising Anhydrous Aripiprazole Crystals B having low hygroscopicity and one or more pharmaceutically acceptable carriers, wherein said low hygroscopicity is a moisture content of [0.40%/0.10%] or less after placing said Crystals for 24 hours in a desiccator maintained at a temperature of 60°C and a humidity level of 100% wherein said crystals...exhibit an endothermic peak near about 140.7°C in differential scanning calorimetry (heating rate 5°C/min); and **have a mean particle size** of 50 µm or less, wherein said pharmaceutical solid oral preparation has at least one dissolution rate selected from the group consisting 60% or more at pH 4.5 after 30 minutes, 70% or more at pH 4.5 after 60 minutes, and 55% or more at pH 5.0 after 60 minutes.

# Use of the Specification Ex. 2

- *Otsuka Pharm. Co., Ltd. v. Torrent Pharms. Ltd., Inc.*, 151 F. Supp. 3d 525 (D.N.J. 2015)
  - **Held:** Indefinite – the intrinsic record fails to provide guidance regarding the meaning of the term.
    - The *presumptive* method disclosed in the specification for measuring “mean particle size” generates two “mean” measures – a volume measure and a surface area measure.
    - The submissions by the parties demonstrate a lack of uniform understanding in the art regarding which of the two measures is more frequently accepted, i.e., the default meaning.
    - The specification makes no connection between “mean particle size” and volumetric measures.
    - The specification provides no indication of how particle size should be characterized, even though there are multiple ways to define size based on different points of reference.

# Approximate Terms & Ranges

- Example terms of approximation: “about,” “essentially,” “similar,” “substantially,” “type”
- Examples in MPEP 2173 suggest that if the specification contains general guidelines on what the applicant intended to cover, then the claim may not be indefinite
- Example terms invoking ranges: “at least 20%,” “an effective amount”
- Generally, no indefiniteness issue if the claim recites a specific numerical range, or if OOSKA can determine specific values for the amount covered
- May need to compare to dependent claims to ascertain whether limitation is indefinite

# Approximate Terms & Ranges Ex. 1

- *Cayenne Medical, Inc. v. Medshape, Inc.*, 2016 WL 2606983 (D. Ariz. 2016)
- 6. A material fixation system, comprising an implant . . . said implant comprising:
  - a body having a longitudinal axis, a distal end, and proximal end;
  - a first member on said body which is movably expandable outwardly;
  - a second member on said body which is disposed axially from said first member and is also movably expandable outwardly, said second member being of a **substantially different construction** than said first member;
  - a distal end of said body comprising a space for receiving soft tissue therethrough, . . .; and
  - a deployment device which is movable in a generally axial direction to deploy at least one of said first and second members.

# Approximate Terms & Ranges Ex. 1

- Distinction between “substantially different” and “substantially the same” (MPEP 2173.05(b))?
- “Substantially different construction” added during prosecution to overcome § 103 rejection where primary reference disclosed expandable members having substantially identical construction
- “Some” standard is not enough, “must provide objective boundaries for those of skill in the art”
- Finds “compelling” PTAB’s decision not to institute an IPR on these challenged claims, because PTAB considered them “highly subjective” and therefore indefinite

# Approximate Terms & Ranges Ex. 2

- *Ex parte Kreutzer*, 2016 WL 7097694 (PTAB Nov. 29, 2016)
- 1. An isolated double stranded RNA (dsRNA) comprising two complementary oligoribonucleotide strands wherein the dsRNA is 15 to 49 base pairs in length, wherein one strand of the dsRNA is complementary to an RNA transcript of at least part of a mammalian target gene and the other strand of the dsRNA is complementary to the first strand, wherein the dsRNA is enclosed by a micellar structure, and wherein said dsRNA is capable of specifically inhibiting the expression of the mammalian target gene.
- 32. The dsRNA of claim 1, wherein the dsRNA is in an amount, and wherein the amount of the dsRNA introduced into a mammalian cell is less than an amount of RNA transcript of the mammalian target gene in the mammalian cell.

# Approximate Terms & Ranges Ex. 2

- PTAB affirms rejection under § 112(b)
- Amount to be used is relative, and applicants did not identify in specification or record evidence to support meaning of claim language
- “at an amount” as determined by “an amount” of RNA transcript is indefinite
- Rejects applicants’ reliance on CAFC precedent relating to patent validity in district litigation
  - Indefiniteness rejections arise in different posture from examination than from validity challenge to issued patent
  - Cites to *In re Packard*

# Chemical Compounds

- Heavy reliance on terms of art.
- Examples may be necessary to understand how the compositions are made.
- Functional claim language may create uncertainty regarding the scope of the invention.
- Structural components may be virtually limitless.

# Chemical Compounds Ex. 1

- *Senju Pharm. Co., Ltd. v. Lupin Ltd.*, 162 F. Supp. 3d 405 (D.N.J. 2015)
  - **Representative Claim**: A stable aqueous liquid preparation comprising (a) a first component; and (b) a second component, ... the first component is the sole pharmaceutical active ingredient contained in the preparation; the second component is tyloxapol and is present in said liquid preparation **in an amount sufficient to stabilize** said first component; and wherein said **stable** liquid preparation is formulated for ophthalmic administration.
  - **Defendants' Argument**:
    - The terms “stable” and “stabilized” can refer to many different attributes in the context of an ophthalmic preparation, such as chemical stability or physical stability.
    - The experimental examples in the specification do not define the boundary between “stable” and unstable, and there is no way to know what does or does not fall within the meaning of the terms “stable” or “stabilize.”

# Chemical Compounds Ex. 1

- *Senju Pharm. Co., Ltd. v. Lupin Ltd.*, 162 F. Supp. 3d 405 (D.N.J. 2015)
  - **Held:** Not Indefinite – Particularly with the benefit of Experimental Examples that illustrate the exact testing conditions and results at which the solution would be acceptable for ophthalmic use, the Court finds that the terms “stable” and “in an amount sufficient to stabilize said first component” are not indefinite.
    - A skilled person would know from reading the specification that a solution containing tyloxapol would be considered chemically stable when it shows a remaining rate of bromfenac of over 90% under the conditions indicated.
    - The fact that the patent does not identify a particular stability range or attribute (e.g., chemical stability versus physical stability) does not render the terms indefinite.
    - The specification identifies, with detailed experimental illustrations, a particular method for determining resistance to chemical degradation and preservative efficacy; describes how the testing was carried out; and provides a precise numerical measurement or standard that serves as a benchmark for what would be considered acceptable for pharmaceutical use for eye drops.

# Chemical Compounds Ex. 2

- *BASF Corp. v. Johnson Matthey, Inc.*, 2016 WL 661407 (D. Del. Feb. 9, 2016):
  - **Representative Claim Term:** an undercoat washcoat layer containing a “material composition A effective for catalyzing NH<sub>3</sub> oxidation” and an overcoat washcoat layer containing “a material composition B effective to catalyze selective catalytic reduction (SCR) of NO<sub>x</sub>.”
  - **Held:** Indefinite – The disputed limitations are not “precise enough to afford clear notice of what is claimed” and do not provide reasonable certainty as to the scope of the invention.
    - The claims utilize functional language, specifically “effective,” to purportedly define them.
    - In other words, the claims recite a performance property the composition must display, rather than its actual composition.
    - None of the claims recite a minimum level of function needed to meet this “effective” limitation nor a particular measurement method to determine whether a composition is “effective” enough to fall within the claims.

# Recommendations

- When an applicant introduces a new claim term in order to overcome a § 102 or 103 rejection, consider whether a § 112(b) issue arises and ask for clarification on the record or note clarification in an interview summary.
- When an applicant files a continuation or continuation-in-part application, consider whether new terms are introduced into the claims that are not found in the specification.
- If a term raises a potential § 112(b) question, consult related fhs or encourage applicant to identify whether the issue is addressed in such fhs.
- Introduce post-*Nautilus* guidance, and address particular areas which may require more specificity (e.g., multiple methods of measure).