The Written Description Requirement of 35 U.S.C. 112, first paragraph

TC1600 Training

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35 U.S.C. 112, first paragraph

- 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 of carrying out his invention.

USPTO Written Description Guidelines, Examples, and Notices

- Written Description Guidelines (66 FR 1099 (Jan. 5, 2001); 1242 O.G. 168 (Jan. 30, 2001)
  - http://www.uspto.gov/web/menu/current.html#register
  - First posted December 27, 1999
- Training Materials
  - Revised Interim training materials first posted Dec. 27, 1999
  - Revision I of the Written Description Training materials, posed 4/11/08: http://www.uspto.gov/web/menu/written.pdf
  - MPEP 2163

Type of Claims Subject to Written Description

All claims are subject to the written description requirement, including:

- Products, Processes, Products by process
- Original claims
- New claims and amended claims
- Claims asserting benefit of an earlier priority or filing date

Written Description - General Principles

- Basic inquiry: Would one skilled in the art reasonably conclude that the inventor had **possession** of the claimed invention at the time the application was filed?
  - *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 1566-67, 43 USPQ2d 1398, 1404-05 (Fed. Cir. 1997); *Hyatt v. Boone*, 146 F.3d 1348, 1354, 47 USPQ2d 1128, 1132 (Fed. Cir. 1998); MPEP 2106.

- Written description requirement is separate and distinct from the enablement requirement.
  - *See, e.g., Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991). See also Univ. of Rochester v. G.D. Searle & Co., 358 F.3d 916, 920-23, 69 USPQ2d 1886, 1890-93 (Fed. Cir. 2004) (discussing history and purpose of the written description requirement); In re Curtis, 354 F.3d 1347, 1357, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004) ("conclusive evidence of a claim's enablement is not equally conclusive of that claim's satisfactory written description"); MPEP 2163.*

Written Description – Basics of Examiner's Analysis

- Determine the scope of each claim as a whole
  - Broadest reasonable interpretation in light of and consistent with written description
    - *In re Morris*, 127 F.3d 1048, 44 USPQ2d 1023 (Fed. Cir. 1997); and MPEP 2163.
  - Consider the full scope of the claim

Written Description –Basics of Examiner's Analysis (cont.)

- Review entire application to understand how the applicant provides support for the claimed invention
  - Review includes consideration for each element and/or step claimed.
  - Review includes comparing the claim scope with the scope of the disclosure.

Written Description – Basics of Examiner's Analysis (cont.)

- **Factors to consider when analyzing claims for compliance with the written description requirement** :
  a. Actual reduction to practice
  b. Disclosure of drawings or structural chemical formulas
  c. Sufficient relevant identifying characteristics
  d. Method of making the claimed invention
  e. Level of skill and knowledge in the art
  f. Predictability in the art

Written Description – Basics of Examiner's Analysis (cont.)

a. Actual reduction to practice
   - Does the specification show any embodiments that meet all the limitations of the claim reduced to practice?
   - *Reduction to practice not required to meet written description cf.: Amgen Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991)*

b. Disclosure of drawings or structural chemical formulas
   - An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole.
     - *See, e.g., Vas-Cath, 935 F.2d at 1565, 19 USPQ2d at 1118; In re Wolfensperger, 302 F.2d 950, 133 USPQ 537 (CCPA 1962); Autogiro Co. of America v. United States, 384 F.2d 391, 398, 155 USPQ 697, 703 (Ct. Cl. 1967); Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406; MPEP 2163.*

Written Description –Basics of Examiner's Analysis (cont.)

c. Sufficient relevant identifying characteristics:

   i. Complete structure

   ii. Partial structure

   iii. Physical and/or chemical properties

   iv. Functional characteristics when coupled with correlation between structure and function

Enzo Biochem, 323 F.3d at 964, 63 USPQ2d at 1613; MPEP 2163

Written Description – Basics of Examiner's Analysis (cont.)

d. Method of making the claimed invention

e. Level of skill and knowledge in the art

- What is conventional or well known to one skilled in the art need not be disclosed in detail *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991)

f. Predictability in the art

Written Description – Basics of Examiner's Analysis (cont.)

Written Description Determination for Genus Claims:

- Possession is analyzed for each claim drawn to a single embodiment or species first, and

- Then for each claim drawn to a genus

Written Description – Basics of Examiner's Analysis (cont.)

Written Description Determination for Genus Claims:

- Written description for claimed genus may be satisfied through sufficient description of a representative number of species
  - inverse function of the skill and knowledge in the art.
  - depends on whether one of skill in the art would recognize necessary common attributes or features possessed by the members of the genus
  - in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus.
  - *See Enzo Biochem, 323 F.3d at 966, 63 USPQ2d at 1615; Noelle v. Lederman, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004); Eli Lilly, 119 F.3d at 1568, 43 USPQ2d at 1406.*

New or Amended Claims, or Claims Asserting Entitlement to Earlier Filing Date

- Each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure
- Each claim must include all elements which applicant has described as essential or critical

Burden on the Examiner with Regard to the Written Description Requirement

- Description as filed presumed adequate
- No *per se* rules
- Unsupported allegation of unpredictability in the art is insufficient
- Need reasonable basis to challenge
  - Evidence
  - Technical reasoning
- *MPEP 2163.04*

Example 4A-Expressed Sequence Tags (ESTs): Effect of Open Transitional Language

- Specification:
  - Discloses SEQ ID NO: 16, which is an EST
  - A working example in which the cDNA of SEQ ID NO: 16 was isolated from a yeast cDNA library.
  - Discloses that SEQ ID NO: 16 will hybridize to its complement in yeast genomic DNA and can be used to identify yeast infections.

Example 4A-Expressed Sequence Tags (ESTs): Effect of Open Transitional Language

- Claim:
  - Claim 1. An isolated DNA comprising SEQ ID NO: 16.

Example 4A-Expressed Sequence Tags (ESTs): Effect of Open Transitional Language

- Analysis:
  - Claim 1 is directed to a genus of DNAs comprising SEQ ID NO: 16.
    - The claimed DNAs may include additional DNA sequences attached to either end of the sequence shown in SEQ ID NO: 16.
    - The claimed genus includes the full-length open reading frame (ORF) as well as fusion constructs and vectors comprising SEQ ID NO: 16.
    - There may be substantial variability among the species.
    - All members of the claimed genus include SEQ ID NO: 16.

Example 4A-Expressed Sequence Tags (ESTs): Effect of Open Transitional Language

- Analysis *cont.*:
  - Actual reduction to practice and the complete structure of one species within the genus, SEQ ID NO: 16.
  - SEQ ID NO: 16 represents a partial structure.
    - Each member must include SEQ ID NO: 16 as part of its structure.
  - It is routine and within the level of skill and knowledge in the art to add any desired DNA sequence to either end of SEQ ID NO: 16.

Example 4A-Expressed Sequence Tags (ESTs): Effect of Open Transitional Language

- Conclusion:
  - SEQ ID NO: 16 is a common structural feature of members of the genus.
  - The species shown, SEQ ID NO: 16 is representative of the species within the claimed genus which all have to include SEQ ID NO: 16.
  - The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph.

**Claims to ESTs often raise other examination issues such as utility, enablement, and anticipation/obviousness that must be addressed accordingly if applicable.*

Example 5-Partial Protein Structure

Based on the fact pattern in In re Wallach, 378 F.3d 1330, 71 U.S.P.Q.2d 1939 (Fed. Cir. 2004)

- Specification:
  - Example 1 describes a process by which Protein A was isolated from human urine.
    - The process includes dialyzing human urine to form a crude protein concentrate, loading the protein concentrate onto an affinity column of immobilized Protein X and eluting Protein A from the column as a single peak in a fraction corresponding to about 31% acetonitrile using reversed-phase HPLC.
  - Isolated protein A is 22kDa when measured by SDS-PAGE under reducing conditions
  - Isolated protein A binds to and activates Protein X.
  - Discloses a 10 amino acid sequence from the N-terminus of Protein A (SEQ ID NO: 1).

Example 5-Partial Protein Structure

- Claim:
  - Claim 1. An isolated protein comprising Protein A, wherein said Protein A
    - includes the amino acid sequence of SEQ ID NO: 1 in the N-terminal portion of the protein,
    - has the same ability to bind to and activate Protein X as Protein A from human urine,
    - and wherein said Protein A is purified by subjecting a crude protein recovered from a dialyzed concentrate of human urine to affinity chromatography on a column of immobilized Protein X, and elutes from a reversed-phase HPLC column as a single peak in a fraction corresponding to about 31% acetonitrile and shows a molecular weight of about 22 kDa when measured by SDS-PAGE under reducing conditions.

Example 5-Partial Protein Structure

- Claim *cont*:
  - Claim 2. An isolated DNA comprising a DNA that encodes Protein A,
    - wherein said Protein A includes the amino acid sequence of SEQ ID NO: 1 in the N-terminal portion of the protein,
    - has the same ability to bind to and activate Protein X as Protein A from human urine,
    - and wherein said Protein A is purified by subjecting a crude protein recovered from a dialyzed concentrate of human urine to affinity chromatography on a column of immobilized Protein X, and elutes from a reversed-phase HPLC column as a single peak in a fraction corresponding to about 31% acetonitrile and shows a molecular weight of about 22 kDa when measured by SDS-PAGE under reducing conditions.

Example 5-Partial Protein Structure

- Analysis (Claim 1):
  - Claim 1 encompasses proteins having an N-terminal amino acid sequence of SEQ ID NO: 1 and the same ability to bind and activate Protein X as Protein A from human urine.
  - The claim is generic because it recites the "open" transitional term "comprising."

Example 5-Partial Protein Structure

- Analysis (Claim 1) *cont.*:
  - The specification fails to disclose the complete structure of Protein A
  - The specification fails to disclose and there is no art-recognized correlation between the structure of the claimed protein and its function of binding and activating Protein X

Example 5-Partial Protein Structure

- Analysis (Claim 1) *cont.*:
  - The specification discloses partial structure, i.e., SEQ ID NO: 1.
  - Other relevant identifying characteristics are disclosed
    - ability to bind and activate Protein X,
    - molecular weight and
    - concentration of acetonitrile at which Protein A will elute from a reverse phase HPLC column.
  - The specification also discloses a method for isolating Protein A from human urine and a working example demonstrating successful isolation.

Example 5-Partial Protein Structure

- Conclusion (Claim 1):
  - Those of skill in the art of isolating proteins would recognize the inventor to be in possession of the claimed protein at time of filing based on
    - the identifying characteristics and
    - disclosed method of isolating.
  - The specification satisfies the written description requirement of 35 U.S.C 112, first paragraph with respect to the full scope of claim 1.

Example 5-Partial Protein Structure

- Analysis (Claim 2):
  - Claim 2 encompasses DNAs encoding proteins having an N-terminal amino acid sequence of SEQ ID NO: 1 and the same ability to bind and activate Protein X as Protein A from human urine.
  - The claim is generic because it recites the "open" transitional term "comprising."

Example 5-Partial Protein Structure

- Analysis (Claim 2) *cont.*:
  - No DNAs are reduced to practice
  - Relevant identifying characteristics
    - of Protein A are disclosed,
    - only molecular weight provides any information about the claimed DNAs, i.e., a rough approximation of the size of the cDNA encoding Protein A.
  - There is a prophetic example of making a library of DNAs encoding Protein A.
  - Using the genetic code, one could predict nucleic acid sequences that encode the 10 amino acids of SEQ ID NO: 1.

Example 5-Partial Protein Structure

- Analysis (Claim 2) *cont.*:
  - The specification fails to disclose:
    - the complete structure of any DNA encoding Protein A
    - the complete structure of Protein A from which the structures of the claimed DNAs might be predicted based on knowledge in the art of the genetic code.
  - There is no art-recognized correlation between structure and the disclosed function of the claimed DNAs and/or the disclosed function of Protein A.

Example 5-Partial Protein Structure

- Conclusion (Claim 2):
  - Those of skill in the art would recognize the inventor to have been in possession of 5% of the structure of claimed DNAs based on SEQ ID NO: 1.
  - There is no information about the structure of the remaining 95%
  - A representative number of species is not disclosed.
  - The written description requirement of 35 U.S.C. 112, first paragraph is not satisfied with respect to the full scope of claim 2.

Example 7- Allelic Variants

- Specification:
  - Discloses a DNA, SEQ ID NO: 1
    - encodes Protein X (SEQ ID NO: 2) which is a cell surface receptor for adenovirus.
  - No allelic sequence information is disclosed.
  - States that allelic variants of SEQ ID NO: 1 can be obtained by hybridizing SEQ ID NO: 1 to a DNA library made form the same species that yielded SEQ ID NO: 1.

Example 7- Allelic Variants

- Claims:
  - Claim 1. An isolated DNA that encodes Protein X having the amino acid sequence SEQ ID NO: 2.
  - Claim 2. An isolated allele of the DNA according to claim 1, which allele encodes Protein X having the amino acid SEQ ID NO: 2.

Example 7- Allelic Variants

- Analysis (Claim 1):
  - Claim 1 is drawn to the genus of DNAs that encode the amino acid sequence SEQ ID NO: 2, i.e., degenerates.

Example 7- Allelic Variants

- Analysis (Claim 1):
  - The specification describes the complete structure of only one species in the claimed genus (SEQ ID NO: 1).
  - The specification does not describe other members of the genus by complete or partial structure, physical and/or chemical characteristics.

Example 7- Allelic Variants

- Analysis (Claim 1):
  - Only a limited number of codons can encode a specific amino acid
  - The genetic code provides a known correlation between the codon function and each codon structure.

Example 7- Allelic Variants

- Conclusion (Claim 1):
  - One skilled in the art would be able to readily envision all the DNAs capable of encoding SEQ ID NO: 2.
  - The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to the full scope of claim 1.

Example 7- Allelic Variants

- Analysis (Claim 2):
  - Claim 2 is drawn to a genus of allelic DNAs that encode the amino acid sequence SEQ ID NO: 2.

Example 7- Allelic Variants

- Analysis (Claim 2):
  - The specification does not provide any definition for the term “allele.”
  - Ordinary meaning in the art* for allele is
    - one of two or more alternate forms of a gene
    - occupying the same locus in a particular chromosome or linkage structure and
    - differing from other alleles of the locus by one or more mutational sites.

**reference should be cited in office action*

Example 7- Allelic Variants

- Analysis *cont.* (Claim 2):
  - The alleles in claim 2 are “strictly neutral”
    - they encode identical proteins and make no difference in phenotype.
  - In view of the ordinary meaning for “allele,” claim 2 is drawn to native DNAs that encode protein X.
  - Claim 2 thus represents a subgenus of the DNAs of claim 1.

Example 7- Allelic Variants

- Analysis *cont.* (Claim 2):
  - Reduction to practice of only one species, SEQ ID NO: 1.
  - No other members of the genus disclosed by
    - complete or partial structure,
    - physical and/or chemical characteristics.
  - All members of the genus have the same function i.e., the encode Protein X,
  - No correlation between naturally occurring allelic structures and their common coding function is disclosed.

Example 7- Allelic Variants

- Analysis *cont.* (Claim 2):
  - The specification proposes to discover other species in the genus by using a hybridization procedure.
  - No description of the mutational sites that exist in nature.
  - There is no description of how the structure of SEQ ID NO: 1 relates to the structure of any other strictly neutral alleles.

Example 7- Allelic Variants

- Analysis *cont.*(Claim 2):
  - The general knowledge in the art concerning alleles does not provide any indication of how the structure of one allele is representative of unknown alleles.
  - The nature of alleles is that they are variant structures where the structure and function of one does not provide guidance to the structure and function of others.

Example 7- Allelic Variants

- Conclusion (Claim 2):
  - The existence of other alleles is unpredictable.
  - The structure of one allele does not provide guidance to the existence or structure of other alleles.
  - The description of only one member of this genus is not representative of the variants of the genus.
  - The specification fails to satisfy the written description requirement of 35 U.S.C. 112, first paragraph with respect to the full scope of claim 2.

Example 11A- Percent Identity

- Specification:
  - Discloses a polynucleotide having the nucleic acid sequence of SEQ ID NO: 1, which encodes the polypeptide of SEQ ID NO: 2.
  - The polypeptide of SEQ ID NO: 2 has the novel activity X
  - SEQ ID NO: 2 does not share significant sequence identity with any known polypeptide or polypeptide family.
  - The specification does not disclose any nucleic acid sequences that encode a polypeptide with novel activity X other than SEQ ID NO: 1.

Example 11A- Percent Identity

- Claims:
  - Claim 1. An isolated nucleic acid that encodes a polypeptide with at least 85% amino acid sequence identity to SEQ ID NO: 2.
  - Claim 2. An isolated nucleic acid that encodes a polypeptide with at least 85% amino acid sequence identity to a SEQ ID NO: 2; wherein the polypeptide has activity X.

Example 11A- Percent Identity

- Analysis (Claim 1):
  - Claim 1 encompasses nucleic acids
    - that encode the polypeptide of SEQ ID NO: 2
    - that encode any polypeptide having 85% structural identity to SEQ ID NO: 2.

Example 11A- Percent Identity

- Analysis (Claim 1):
  - Actual reduction of only a single species that encodes SEQ ID NO: 2; i.e., SEQ ID NO: 1.
  - No other drawings or structural formulas disclosed that encode either SEQ ID NO: 2 or a sequence with 85% identity to SEQ ID NO: 2.

Example 11A- Percent Identity

- Analysis (Claim 1):
  - The recitation of a polypeptide with at least 85% identity represents a partial structure.
    - Up to 15% of the amino acids may vary from those in SEQ ID NO: 2.
    - No information about which 15% may vary from SEQ ID NO: 2.
  - There is no functional limitation on the nucleic acids of claim 1 other than they encode the polypeptide of SEQ ID NO: 2 or any polypeptide having 85% structural identity to SEQ ID NO: 2.

Example 11A- Percent Identity

- Analysis (Claim 1):
  - The genetic code and its redundancies were known in the art before the application was filed.

Example 11A- Percent Identity

- Conclusion (Claim 1):
  - SEQ ID NO: 2 combined with the genetic code would have put one in possession of the genus of nucleic acids that encode SEQ ID NO: 2.
  - With the aid of a computer, one of skill in the art could have identified all the nucleic acids that encode a polypeptide with at least 85% sequence identity with SEQ ID NO: 2.
  - One of skill in the art would conclude that applicant was in possession of the claimed genus at the time of filing and the specification satisfied the requirements of 35 U.S.C. 112 first paragraph.

**This example deals only with the written description analysis. Enablement issues that may be raised are not addressed.*

Example 11A- Percent Identity

- Analysis (Claim 2):
  - Claim 2 encompasses nucleic acids
    - that encode the polypeptide of SEQ ID NO: 2
    - that encode a polypeptide having 85% sequence identity to SEQ ID NO: 2 and have activity X.

Example 11A- Percent Identity

- Analysis (Claim 2):
  - The specification discloses only a single species that encodes SEQ ID NO: 2; i.e., SEQ ID NO: 1.
  - There are no other drawings or structural formulas disclosed that encode either SEQ ID NO: 2 or a sequence with 85% identity to SEQ ID NO: 2.

Example 11A- Percent Identity

- Analysis (Claim 2):
  - The disclosure of SEQ ID NO: 2 combined with the genetic code would have put one in possession of the genus of nucleic acids that encode SEQ ID NO: 2.
  - With the aid of a computer, one of skill in the art could have identified all the nucleic acids that encode a polypeptide with at least 85% sequence identity with SEQ ID NO: 2.

Example 11A- Percent Identity

- Analysis (Claim 2):
  - There is no teaching
    - of which 15% of the amino acids can vary from SEQ ID NO: 2 and still result in a protein that retains activity X.
    - of art-recognized correlation between any structure other than SEQ ID NO: 2 and novel activity X.
    - of which nucleic acids that encode a polypeptide with at least 85% sequence identity to SEQ ID NO: 2 encode a polypeptide having the required activity X.

Example 11A- Percent Identity

- Analysis (Claim 2):
  - General knowledge in the art is that some amino acid variations are tolerated without losing a protein's tertiary structure.
  - Conservation of structure is not necessarily a surrogate for conservation of function.

Example 11A- Percent Identity

- Conclusion (Claim 2):
  - There was no known or disclosed correlation between a structure other than SEQ ID NO: 2 and activity X.
  - There is no general knowledge in the art about activity X to suggest that general similarity of structure confers the activity.

Example 11A- Percent Identity

- Conclusion *cont,* (Claim 2):
  - One of skill in the art would not accept the disclosure of SEQ ID NO: 2 as representative of other proteins having activity X.
  - The specification, taken with the knowledge in the prior art, fails to satisfy the written description requirement of 35 U.S.C. 112, first paragraph.

Example 11B- Percent Identity

- Specification:
  - Discloses a polynucleotide having the nucleic acid sequence of SEQ ID NO: 1, which encodes the polypeptide of SEQ ID NO: 2.
  - The polypeptide of SEQ ID NO: 2 has the novel activity Y.
  - SEQ ID NO: 2 not share significant sequence identity with any known polypeptide or polypeptide family.
  - No nucleic acid sequences that encode a polypeptide with novel activity Y other than SEQ ID NO: 1 are disclosed.

Example 11B- Percent Identity

- Specification *cont*:
  - Discloses data from deletion studies that identify two domains critical to activity Y.
  - proposes that conservative mutations within the domains will retain activity while non-conservative substitution will not.
  - proposes that most mutations outside of the domains will not affect activity Y.

Example 11B- Percent Identity

- Claims:
  - Claim 1. An isolated nucleic acid that encodes a polypeptide with at least 85% amino acid sequence identity to SEQ ID NO: 2.
  - Claim 2. An isolated nucleic acid that encodes a polypeptide with at least 85% amino acid sequence identity to a SEQ ID NO: 2; wherein the polypeptide has activity Y.

Example 11B- Percent Identity

- Analysis (Claim 2):
  - Claim 2 encompasses nucleic acids
    - that encode the polypeptide of SEQ ID NO: 2
    - that encode a polypeptide having 85% sequence identity to SEQ ID NO: 2 and have activity Y.

Example 11B- Percent Identity

- Analysis (Claim 2):
  - Actual reduction of only a single species that encodes SEQ ID NO: 2; i.e., SEQ ID NO: 1.
  - No other drawings or structural formulas disclosed that encode either SEQ ID NO: 2 or a sequence with 85% identity to SEQ ID NO: 2.

Example 11B- Percent Identity

- Analysis (Claim 2):
  - The disclosure of SEQ ID NO: 2 combined with the genetic code and its redundancies would have put one in possession of the genus of nucleic acids that encode SEQ ID NO: 2.
  - With the aid of a computer, one of skill in the art could have identified all the nucleic acids that encode a polypeptide with at least 85% sequence identity with SEQ ID NO: 2.

Example 11B- Percent Identity

- Analysis (Claim 2):
  - No teaching of which of the nucleic acid sequences that encode a polypeptide with at least 85% sequence identity to SEQ ID NO: 2 encode a polypeptide having the required activity Y.

Example 11B- Percent Identity

- Analysis (Claim 2):
  - The specification identifies two domains responsible for activity Y.

Example 11B- Percent Identity

- Analysis (Claim 2):
  - Conservative substitutions would likely result in a protein having the required activity.
  - Amino acid substitutions outside of the two identified domains are unlikely to greatly affect activity Y.
  - Correlation exists between function of the claimed protein and the structure of the identified domains.

Example 11B- Percent Identity

- Conclusion (Claim 2):
  - Based on applicant's disclosure and knowledge within the art, those of skill in the art would conclude that applicant would have been in possession of the claimed genus of nucleic acids based on the disclosure of the single species of SEQ ID NO: 1 and relevant identifying characteristics.
  - The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph.

Example 14- Antibodies to a Genus of Proteins

- Specification discloses:
  - A monoclonal antibody that binds to Protein X isolated from murine tissues.
  - Protocols for producing anti-Protein X antibodies
  - A method of isolating and purifying murine Protein X.
  - Several physical and chemical properties of murine Protein X, including amino acid sequence.
  - Human Protein X is expected to have the same *in vivo* function as murine Protein X.

Example 14- Antibodies to a Genus of Proteins

- Specification:
  - No disclosure of physical or chemical properties of Protein X isolated from another species.
  - No disclosure of cross-reactivity by human Protein X with anti-murine Protein X antibodies.
  - No sequence information given for human Protein X or Protein X from any other species.

Example 14- Antibodies to a Genus of Proteins

- Claims:
  - Claim 1. A monoclonal antibody that binds Protein X.
  - Claim 2. The antibody of claim 1 which binds murine Protein X.
  - Claim 3. The antibody of claim 1 which binds human Protein X.

Example 14- Antibodies to a Genus of Proteins

- Analysis (Claim 2):
  - Claim 2 is directed to a monoclonal antibody that binds murine Protein X.

Example 14- Antibodies to a Genus of Proteins

- Analysis and conclusion (Claim 2):
  - The applicant was in possession of murine Protein X at the time of filing.
  - Production of antibodies against well-characterized antigens was conventional at the time of filing.
  - The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph with respect to the full scope of claim 2.

Example 14- Antibodies to a Genus of Proteins

- Analysis: (Claim 3):
  - Claim 3 is directed to a monoclonal antibody that binds human Protein X.

Example 14- Antibodies to a Genus of Proteins

- Analysis: (Claim 3)
  - No actual reduction to practice of a monoclonal antibody that binds human Protein X.
  - No Complete or partial structure of an antibody capable of binding human Protein X in detailed drawings or through a structural chemical formula.
  - No correlation between human Protein X and the described murine Protein X
  - No correlation between antibodies that bind murine Protein X and antibodies that bind human Protein X.

Example 14- Antibodies to a Genus of Proteins

- Analysis *cont.*: (Claim 3)
  - The specification discloses that human Protein X is expected to have the same *in vivo* function as murine Protein X.
  - No evidence that the disclosed chemical and physical properties of murine Protein X are predictive of corresponding properties for human Protein X.

Example 14- Antibodies to a Genus of Proteins

- Conclusion: (Claim 3)
  - Claim 3 is directed to an unknown that is identified only be reference to another unknown.
  - The specification fails to satisfy the written description requirement of 35 U.S.C. 112, first paragraph with respect to the full scope of claim 3.

Example 14- Antibodies to a Genus of Proteins

- Analysis: (Claim 1):
  - Claim 1 is directed to
    - a monoclonal antibody that binds Protein X.
    - includes many species of monoclonal antibody that specifically bind Protein X.
  - The term Protein X is generic because it includes Protein X from multiple species.

Example 14- Antibodies to a Genus of Proteins

- Analysis: (Claim 1):
  - Actual reduction of an antibody that binds murine Protein X.
  - No actual reduction to practice of an antibody that binds Protein X from other species.
  - No complete or partial structure of an antibody capable of binding a non-murine Protein X in detailed drawings or through a structural chemical formula.

Example 14- Antibodies to a Genus of Proteins

- Analysis: (Claim 1):
  - No correlation between murine and non-murine Protein X and the structure of the claimed antibody.
  - No method of making an antibody that binds non-murine Protein X that can be performed without first having the non-murine Protein X.

Example 14- Antibodies to a Genus of Proteins

- Analysis *cont.*: (Claim 1)
  - No description of structural features shared by murine Protein X and Protein X from other species.
  - No correlation between structure and function that would allow those of skill in the art to recognize other members of the claimed genus from disclosure of murine Protein X.

Example 14- Antibodies to a Genus of Proteins

- Conclusion: (Claim 1)
  - No evidence that murine Protein X is representative of the genus of Protein X molecules from other species.
  - The specification fails to satisfy the written description requirement of 35 U.S.C. 112, first paragraph with respect to the full scope of claim 1.

Example 17- Methods Using Compounds Claim by Functional Limitations, Methods of Identifying Compounds, and Compounds.

Based on Univ. of Rochester v G.D. Searle & Co., Inc., 358 F.3d 916, 69 USPQ2d 1886 (Fed. Cir. 2004)

- Specification:
  - Discloses the nucleotide sequences that encode the human enzymes POPKIN-1 and POPKIN-2
  - Describes how to make cells that express either POPKIN-1 or POPKIN-2, but not both.
  - Describes assays using these cells to screen for compounds which selectively inhibit the expression or activity of POPKIN-2 but not POPKIN-1.

Example 17- Methods Using Compounds Claim by Functional Limitations, Methods of Identifying Compounds, and Compounds.

- Claim:
  - Claim 1. A method for selectively inhibiting POPKIN-2 activity in a patient, comprising administering a compound that selectively inhibits activity of the POPKIN-2 enzyme.

Example 17- Methods Using Compounds Claim by Functional Limitations, Methods of Identifying Compounds, and Compounds.

- Analysis: (Claim 1)
  - A selective POPKIN-2 inhibitor is required to practice the invention.
  - No actual reduction to practice of a compound that selectively inhibits POPKIN-2 activity.
  - No actual reduction to practice of a method of selectively inhibiting POPKIN-2 using a compound
  - No partial structures, physical properties, or chemical properties of a compound that selectively inhibits POPKIN-2 activity.

Example 17- Methods Using Compounds Claim by Functional Limitations, Methods of Identifying Compounds, and Compounds.

- Analysis: (Claim 1)
  - No correlation between the sequences of POPKIN-1 and 2 and the structure of any compounds that would selectively inhibit POPKIN-2 activity.
  - The specification describes a method of screening compounds for selective inhibition of POPKIN-2 activity.
  - No information regarding what structural features would likely be associated with selective, inhibitory activity.

Example 17- Methods Using Compounds Claim by Functional Limitations, Methods of Identifying Compounds, and Compounds.

- Analysis: (Claim 1)
  - No known compounds in the art that selectively inhibit POPKIN-2
  - No known structural component associated with the ability to selectively inhibit POPKIN-2 activity.

Example 17- Methods Using Compounds Claim by Functional Limitations, Methods of Identifying Compounds, and Compounds.

- Conclusion: (Claim 1)
  - One of skill in the art would conclude that the applicant wound not have been in possession of the claimed method of selectively inhibiting POPKIN-2 activity.
    - a compound possessing the desired activity required to practice the method is not adequately described and was not known in the art.
  - The specification fails to satisfy the written description requirement of 35 U.S.C. 112, first paragraph, with respect to claim 1.

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- List of Case Law Cited in the Examples
  - Tronzo v. BioMet, Inc. 156 F.3d 1154, 47 USPQ 2d 1829 (Fed Cir 1998)
    - Example 1, page 3
  - Gentry Gallery, Inc v. Berkline Corp., 134 F.3d 1473, 45 USPQ2.d 1498 (Fed Cir 1998)
    - Example 2, page 9
  - In re Wallach, 378 F.3d 1330, 71 USPQ.2d 1939 (Fed Cir 2004)
    - Example 5, page 17
  - In re Hayes Microcomputer Products, Inc Patent Litigation 982 F.2d 1527, 1534-35, 25 UPQ2d 1241, 1246 (Fed Cir 1992)
    - Example 8, page 30
  - Noelle v Lederman 355 F.3d 1343, 69 USPQ.2d 1508 (Fed Cir 2004)
    - Example 14, page 47
  - Univ of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 69 USPQ2d 1886 (Fed Cir 2004)
    - Example 17, page 57