

WRITTEN DESCRIPTION TRAINING MATERIALS



In 1999, the United States Patent and Trademark Office (“USPTO”) published training materials regarding the examination of patent applications under the written description requirement of 35 U.S.C. § 112, first paragraph. (See <http://www.uspto.gov/web/offices/pac/writtendesc.pdf>). Since that time, the case law and technology have developed in such a way as to necessitate a revision of the 1999 training materials. Consequently, this revision was created to supercede and replace the 1999 training materials. To the extent that any conflict exists between the 1999 training materials and the present materials, the present materials control.

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APPLYING THE WRITTEN DESCRIPTION REQUIREMENT

As discussed in the Guidelines for Examination of Patent Applications under the 35 U.S.C. 112, paragraph 1, "Written Description" Requirement (attached as Appendix A - Fed. Reg. 66(4):1103), the examination of patent claims for compliance with the Written Description Requirement should include:

1. A determination as to what the claim as a whole covers.
In making this determination, the examiner should consider and discuss the full scope of the claim.
2. A full review of the application to understand how the applicant provides support for the claimed invention including each element and/or step. This review includes comparing the claim scope with the scope of the description.
3. A determination as to whether one skilled in the art would recognize that the applicant was in possession of the claimed invention as a whole at the time of filing. This determination should include the following considerations:
 - a. Actual reduction to practice
 - b. Disclosure of drawings or structural chemical formulas
 - c. Sufficient relevant identifying characteristics, such as:
 - i. Complete structure
 - ii. Partial structure
 - iii. Physical and/or chemical properties
 - iv. Functional characteristics when coupled with a known or disclosed correlation between function and structure
 - d. Method of making the claimed invention
 - e. Level of skill and knowledge in the art
 - f. Predictability in the art
4. For each claim drawn to a single embodiment or species, consider the above factors in regard to that embodiment or species to determine whether one of ordinary skill in the art would recognize that the applicant was in possession of the species or embodiment at the time of filing.
5. For each claim drawn to a genus, consider each of the above factors to determine whether there is disclosure of a representative number of species which would lead one skilled in the art to conclude that the applicant was in possession of the claimed invention. The number of species required to represent a genus will vary, depending

on the level of skill and knowledge in the art and the variability among the claimed genus. For instance, fewer species will be required where the skill and knowledge in the art is high, and more species will be required where the claimed genus is highly variable.

EXAMPLE 1: PRIORITY, ORIGINAL AND AMENDED CLAIMS

1A: 35 U.S.C. 120 BENEFIT

Specification:

The specification is directed to an artificial hip socket that includes cup implants adapted to replace the acetabulum (the cup-shaped socket of the hip bone). The specification discloses that the shape of the cup is not important, so long as the implant can effectively function as an artificial hip socket. The application is a continuation-in-part (CIP). The parent application describes an acetabular cup prosthesis wherein the cup is a trapezoid, a truncated cone, or of conical shape. All of these terms describe a conical-shaped cup. In contrast to the CIP specification, the parent specification touts the criticality of a conical cup over all other shaped cups.

A reference disclosing the claimed invention was published between the filing date of the parent application and the instant application. Applicant asserts entitlement to the filing date of the parent application.

Claims:

Claim 1. An acetabular cup prosthesis comprising:

a body extending generally longitudinally and terminating into front and rear surfaces,

the front surface extending substantially transversely toward the body; and
at least one fin for securing the cup to a prepared acetabulum cavity,

the fin having a length extending generally longitudinally from the front surface continuously along the body toward the rear surface thereby engaging the body with the cavity and securing the cup.

Claim 2. The prosthesis of claim 1, wherein the body has a generally conical outer surface.

Analysis:

Claim 1

Claim 1 is broadly drawn to an acetabular cup prosthesis that is generic as to shape. (Compare claim 1 to claim 2.)

CASE NOTE

This example is based, in part, on the fact pattern in Tronzo v. BioMet, Inc., 156 F.3d 1154, 47 U.S.P.Q.2d 1829 (Fed. Cir. 1998).

EXAMPLE 1: PRIORITY, ORIGINAL AND AMENDED CLAIMS

The parent application more narrowly describes acetabular cup prostheses. For example, the parent application discloses only conical shaped cups, and discloses that a conical shape is critical to cup function compared with other cup shapes.

For a claim in a later-filed application to be entitled to the filing date of an earlier application, the earlier application must describe the subject matter of the claim in a way that satisfies the written description requirement of 35 U.S.C. 112, first paragraph.

To do so, the disclosure of the earlier application must convey to one of ordinary skill in the art that the inventor had possession of the later-claimed subject matter at the time the parent application was filed. Here, there is nothing in the earlier-filed application to suggest that shapes other than conical are part of the disclosure. In fact, the earlier-filed application teaches the advantages of conical cups versus other shapes of cups. Accordingly, a person of ordinary skill in the art would not view the applicant to have been in possession of the generic subject matter claimed based on the single species disclosed in the earlier-filed application.

Conclusion:

The parent application fails to adequately describe the full scope of the genus of claim 1. Thus, claim 1 is not entitled to the benefit of the parent application filing date. Accordingly, a rejection should be made under the appropriate section(s) of 35 U.S.C. 102 over the intervening prior art.

Claim 2

Claim 2 is narrowly drawn to an acetabular cup prosthesis that has a conical outer surface.

Because the parent application likewise describes acetabular cup prostheses that have conical shapes, a person of ordinary skill in the art would view the applicant to have been in possession of the narrow subject matter claimed based on the single species disclosed the earlier-filed application.

Conclusion:

The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to the full scope of claim 2.

A notation should be made in the file that claim 2 is entitled the benefit of the parent application filing date. Claim 2 would not be rejected for anticipation.

PRACTICE NOTE

This example deals only with the written description analysis of the claimed prosthesis. Other issues, such as enablement, are not addressed here, but should be considered during examination.

EXAMPLE 1: PRIORITY, ORIGINAL AND AMENDED CLAIMS

1B: CRITICAL FEATURE MISSING FROM ORIGINAL, GENERIC CLAIM

The fact pattern is similar to the fact pattern of Example 1A, except that in this example there is no continuation-in-part (CIP) application.

Specification:

The specification is directed to an artificial hip socket that includes cup implants adapted to replace the acetabulum (the cup-shaped socket of the hip bone). The specification discloses that a conical-shaped cup is critical to the prosthesis effectively functioning as an artificial hip socket. The specification describes an acetabular cup prosthesis wherein the cup is a trapezoid, a truncated cone, or of conical shape. All of these terms describe a conical cup. The specification also touts the criticality of a conical-shaped cup over all other shaped cups.

Claims:

Claim 1. An acetabular cup prosthesis comprising:

a body extending generally longitudinally and terminating into front and rear surfaces,

the front surface extending substantially transversely toward the body; and

at least one fin for securing the cup to a prepared acetabulum cavity,

the fin having a length extending generally longitudinally from the front surface continuously along the body toward the rear surface thereby engaging the body with the cavity and securing the cup.

Claim 2. The prosthesis of claim 1, wherein the body has a generally conical outer surface.

Analysis:

Claim 1

Claim 1 is broadly drawn to an acetabular cup prosthesis that is generic as to shape. (Compare claim 1 to claim 2.)

The specification discloses only conical shaped cups. There is no reduction to practice or disclosure of shapes other than conical. The specification discloses that prosthesis shape is critical to the proper functioning of the claimed invention, and that the device will not work without the proper shape. However, the specification does not disclose what other shapes might function as claimed. Further, no information is provided from which a person of ordi-

PRACTICE NOTE

If applicant amended the parent by adding claims to the subject matter of claim 1, the amendment would have been new matter and the amended claims would have been rejected for lack of written description.

EXAMPLE 1: PRIORITY, ORIGINAL AND AMENDED CLAIMS

nary skill in the art could predict which shapes would function properly, *i.e.*, there is no known or disclosed structure-function correlation. Because a conical shape is the only contemplated shape of the invention, a person of ordinary skill in the art would not view the applicant to have been in possession of the generic subject matter claimed based on the single species disclosed in the specification.

Conclusion:

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.

Claim 2

Claim 2 is narrowly drawn to an acetabular cup prosthesis that has a conical outer surface. Because the specification likewise discloses acetabular cup prostheses that have only conical shapes, a person of ordinary skill in the art would view the applicant to have been in possession of the narrow subject matter claimed based on the specification.

Conclusion:

The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to the full scope of claim 2.

1C: A PREFERRED FEATURE MISSING FROM ORIGINAL CLAIM

The fact pattern is similar to the fact pattern of Example 1B, except that in this example the shape of the conical cup is disclosed as being preferred.

Specification:

The specification is directed to an artificial hip socket that includes cup implants adapted to replace the acetabulum (the cup-shaped socket of the hip bone). The specification discloses that the shape of the cup must allow the prosthesis to effectively function as an artificial hip socket, but does not define which shapes will or will not effectively function. The application describes and has figures of an acetabular cup prosthesis wherein the shape of the cup is trapezoid, a truncated cone, or of conical shape. All of these terms describe a conical cup. The specification emphasizes that a conical cup is preferred over all other shaped cups.

EXAMPLE 1: PRIORITY, ORIGINAL AND AMENDED CLAIMS

Claims:

Claim 1. An acetabular cup prosthesis comprising:

a body extending generally longitudinally and terminating into front and rear surfaces,

the front surface extending substantially transversely toward the body; and at least one fin for securing the cup to a prepared acetabulum cavity,

the fin having a length extending generally longitudinally from the front surface continuously along the body toward the rear surface thereby engaging the body with the cavity and securing the cup.

Claim 2. The prosthesis of claim 1, wherein the body has a generally conical outer surface.

Analysis:

Claim 1

Claim 1 is broadly drawn to an acetabular cup prosthesis that is generic as to shape. (Compare claim 1 to claim 2.)

The specification does not show the reduction to practice of any acetabular cup prostheses. The specification includes drawings of only acetabular cup prostheses that have conical shapes. The specification does not disclose what shapes other than conical might function as claimed. Although the application states that conical shaped cups are preferred, the specification does not indicate that a conical shape is critical to cup function compared with other cup shapes. Thus, the shape of the cup is not a critical feature. Accordingly, a person of ordinary skill in the art would view the applicant to have been in possession of the generic subject matter claimed based on the single species disclosed in the specification because the invention as claimed will function in its intended manner even without the specific disclosed conical shape.

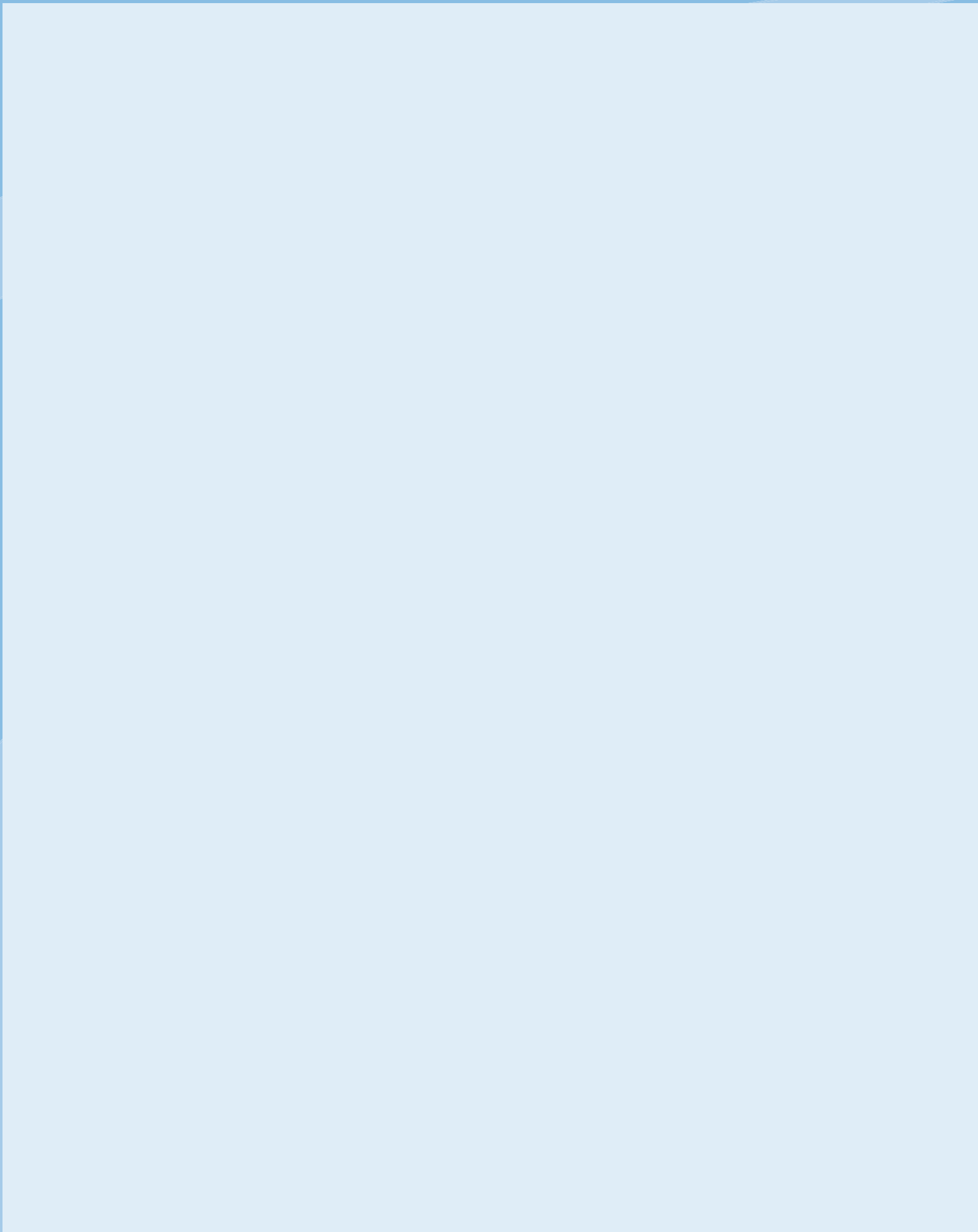
Conclusion:

The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to the full scope of claim 1.

Claim 2

Claim 2 is narrowly drawn to an acetabular cup prosthesis that has a conical outer surface.

Because the specification describes acetabular cup prostheses that have conical shapes as a preferred embodiment, a person of ordinary skill in the art would view the applicant to have been in possession of the narrow subject matter claimed based on in the specification.



EXAMPLE 2: AMENDED CLAIM

CASE NOTE

This example is based on the fact pattern in Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473, 45 U.S.P.Q.2d 1498 (Fed. Cir. 1998).

Specification:

The specification is directed to a unit of a sectional sofa with a console between two reclining chairs, wherein the control means for the reclining chairs are mounted on the console. The specification clearly identifies the console as the only possible location for the controls, and provides for only the most minor variation in the location of the controls; *i.e.*, the controls may be mounted on the top, front, or side surfaces of the console. Additionally, the specification states that the purpose of the console is to house the controls. The original claims required the controls to be on the console. The applicant subsequently amends the claims to remove this limitation.

Claim:

Claim 1. (Amended) A sectional sofa comprising:
a pair of reclining seats disposed in parallel relationship with one another in a double reclining seat sofa section,
each of said reclining seats having a backrest and seat cushions and being movable between upright and reclined positions,
a fixed console disposed in the double reclining seat sofa section between the pair of reclining seats, and
a pair of control means mounted on the double reclining seat sofa section to enable each of the pair of reclining seats to move separately between the reclined and upright positions.

Analysis:

The facts indicate that the claim has been amended. Therefore, the examiner should follow Appendix B: “Decision Tree: Where No Benefit Claimed” in these training materials. Following that decision tree, the examiner should first compare the scope of the amended claim to the scope of the original claim(s) and the disclosure in the specification.

Here, the amended claim is directed to a sectional sofa comprising, *inter alia*, a pair of control means mounted anywhere on the double reclining seat sofa sectional unit. The original claim required that the pair of control means was located on the center console. Thus, the amended claim is broader than the original claim, because it is missing an element (limitation) that was recited in the original claim.

The decision tree directs the examiner to consider next whether the missing element is described in the specification as being a critical feature of the invention. Here, the specification

EXAMPLE 2: AMENDED CLAIM

makes clear that the disclosed invention is a unit of a sectional sofa comprising control means located on a console that separates the seats in the double reclining seat sofa section. The disclosure provides no description or support for controls located anywhere other than on the console. The disclosure unambiguously limits the location of the controls to the console. Thus, the claim is broader than the description of the invention in the specification.

Because the specification supports only a narrow understanding of the location of the controls, the specification does not support a broader claim that omits this limitation. Accordingly, the specification does not adequately describe the genus recited in claim 1.

Conclusion:

The specification fails to satisfy the written description requirement of 35 U.S.C. 112, first paragraph, with respect to claim 1.

EXAMPLE 3: FLOW DIAGRAMS

Specification:

The specification is directed to a mechanism for controlling the mode of operation of a modem. A modem is used for modulating and demodulating signals, both analog and digital, over telephone lines. It has two modes: (1) a transparent mode, in which the modem performs the modulation-demodulation function, and (2) a command mode, in which the modem responds to predetermined commands and performs operations by executing a set of instructions stored in Read-Only-Memory (ROM) or firmware. An escape command tells the modem when to switch between transparent and command modes.

The application claims an improved mechanism for detecting an escape command by a modem. The decision making capability and timing means preferably reside in a microprocessor, preferably a Z-8 type microprocessor. The specification discloses logic flow diagrams and provides a detailed functional recitation that describes how to program computers to detect an escape command, but the specification does not provide a computer program listing with source code. The specification describes the escape sequence as one full second of no data, followed by the predetermined escape command, followed by another full second of no data.

Claim:

Claim 1. In a modem including data input port for connecting said modem to a utilization device, and a telephone port for connecting said modem to a telephone line, said modem being of the type having two distinct modes of operation;

a transparent mode of operation for which said modem provides modulated signals to said telephone port in response to data signals provided to said data input port; and

a command mode of operation for which said modem responds to said data signals provided to said data input port as instructions to said modem;

said modem including means defining a predetermined sequence of said data signals as an escape character, the improvement comprising:

timing means for detecting each occurrence of a passage of a predetermined period of time after provision of one of said data signals to said data input port; and

means, operative when said modem is in said transparent mode of operation, for detecting provision of said predetermined sequence of said data signals, and for causing said modem to switch to said command mode of operation, if and only if said predetermined sequence of data signals occurs contiguous in time with at least

EXAMPLE 3: FLOW DIAGRAMS

one said occurrence of said passage of said predetermined period of time during which none of said data signals are provided to said data input port.

Analysis:

Claim 1

Claim 1 is drawn to a genus of modems having two modes of operation (transparent and command), a timing means, and a means for detecting an escape sequence and causing the modem to switch from the transparent to the command mode.

The specification does not describe a reduction to practice of modems having two modes of operation (transparent and command) with any particular timing means or means for detecting the escape command and switching to the command mode.

The specification provides drawings of the modems as claimed in the form of detailed functional flow diagrams. However, aside from the detailed drawings, the specification does not disclose the complete or partial structures of a modem, nor the physical properties of timing means or means for detecting the escape command and switching to the command mode. The specification does not disclose a method for making the claimed modems.

Nonetheless, a search of the prior art indicates that the hardware required to construct the claimed modems is conventional, and that one skilled in the art would know how to program a microprocessor to perform the necessary steps described in the specification and detailed drawings. A review of the prior art also indicates that there would be no substantial variation expected among the species of modem within the claimed genus.

Because the claimed invention is supported by conventional hardware structure and because there is a detailed description, including drawings, of what the software does to operate the computer, there is sufficient description of the claimed invention. Disclosing a microprocessor capable of performing certain functions is sufficient to satisfy the written description requirement, when one skilled in the relevant art would understand what is being described and recognize that the applicant was in possession of the invention claimed.

Conclusion:

The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to claim 1.

EXAMPLE 4: EXPRESSED SEQUENCE TAGS (ESTs)

4A: EFFECT OF OPEN TRANSITIONAL LANGUAGE

Specification:

The specification discloses SEQ ID NO: 16, which is an EST, *i.e.*, a cDNA that corresponds to only part of a protein-encoding open reading frame (ORF). The specification does not address whether the cDNA crosses an exon/intron splice junction. The specification provides a working example in which the cDNA of SEQ ID NO: 16 was isolated from a yeast cDNA library and sequenced. The specification discloses that SEQ ID NO: 16 will hybridize to its complement in yeast genomic DNA and that the cDNA is useful for identifying yeast infections.

Claim:

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

Analysis:

Claim 1

Claim 1 is directed to the genus of DNAs comprising the cDNA sequence described in the specification as SEQ ID NO: 16; the claimed DNAs may also include additional DNA sequences attached to either end of the sequence shown in SEQ ID NO: 16. The claimed genus therefore includes the full-length open reading frame (ORF) that includes SEQ ID NO: 16, as well as fusion constructs and vectors comprising SEQ ID NO: 16. (The genus might include the full-length genomic gene. More specifically, if SEQ ID NO: 16 is derived from a single exon, the genomic sequence would comprise SEQ ID NO: 16; if SEQ ID NO: 16 is derived from more than one exon, the genomic sequence would not comprise SEQ ID NO: 16.)

There may be substantial variability among the species of DNAs encompassed by the scope of the claim because SEQ ID NO: 16 may be combined with other DNA sequences, how-

PRACTICE NOTE

ESTs are recognized in the art as small pieces of DNA sequence (usually 200 to 500 nucleotides long) that are generated by sequencing either one or both ends of an expressed gene. The idea is to sequence bits of DNA that represent genes expressed in certain cells, tissues, or organs. These "tags" are used to "fish out" a gene from a portion of chromosomal DNA by matching base pairs. See, e.g., www.ncbi.nlm.nih.gov/About/primer/est.html, "Just the Facts: A Basic Introduction to the Science Underlying NCBI Resources, ESTs: GENE DISCOVERY MADE EASIER."

EXAMPLE 4: EXPRESSION SEQUENCE TAGS

ever the scope of the genus is defined by the presence of the structure shown in SEQ ID NO: 16. Thus, all members of the genus will predictably include SEQ ID NO: 16.

The specification provides an actual reduction to practice and the complete structure of one species within the genus; *i.e.*, the cDNA consisting of the sequence shown in SEQ ID NO: 16. SEQ ID NO: 16 also represents a partial structure of each DNA encompassed by the claimed genus: each member of the claimed genus must include SEQ ID NO: 16 as part of its structure because the presence of SEQ ID NO: 16 defines the scope of the claimed genus. It is within the level of skill and knowledge to add any desired DNA sequence to either end of SEQ ID NO: 16 with no more than routine experimentation.

Because SEQ ID NO: 16 is a structural feature common to all members of the genus and the specification describes the complete structure (sequence) of SEQ ID NO: 16, one skilled in the art would recognize that the applicant was in possession of a common structural feature of members of the genus. The species shown in the specification; *i.e.*, SEQ ID NO: 16, is therefore representative of the species within the claimed genus.

Conclusion:

The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to the claimed DNAs.

4B: EFFECT OF CLOSED TRANSITIONAL LANGUAGE **Specification:**

The specification discloses a working example in which ESTs were isolated from certain metastatic cancers. Example 1 describes a process for isolating and quantifying three ESTs from bladder and kidney tumors, as well as from normal healthy bladder and kidney tissue. The ESTs are named BKC1, BKC2, and BKC3, and their nucleic acid sequences are disclosed as SEQ ID NOS: 1-3, respectively. The sequences are each 300 nucleotides in length.

Example 2 provides data from over 300 patients showing that these three ESTs are found in 10- to 50-fold higher concentrations on average in the tumors of adults having bladder and kidney cancer compared with the corresponding tissues in normal healthy adults. The data also indicate that tumors having 30-fold and higher concentrations of BKC2 are three times less likely to respond to chemotherapies using cisplatin. Prophetic examples are also provided for

PRACTICE NOTE

This example deals only with the written description analysis of the claimed product. Claims to ESTs often raise other issues, particularly whether the application discloses a patentable utility for the claimed EST(s), whether the claims are enabled throughout their scope, and whether the claims are so broad that they read on products disclosed in the prior art. These other issues are not addressed here, but should be considered during examination. Other rejections should be made when appropriate.

EXAMPLE 4: EXPRESSION SEQUENCE TAGS

making a library of cDNAs encoding full length proteins using random primers in combination with primers based on the nucleic acid sequences of the three disclosed ESTs.

Claims:

Claim 1. An isolated nucleic acid comprising SEQ ID NO: 1.

Claim 2. An isolated nucleic acid consisting of SEQ ID NO: 1.

Analysis:

Claim 2

Because claim 2 uses the “closed” transitional term “consisting of” it encompasses a single species of isolated nucleic acid, *i.e.*, BKC1. The specification discloses the complete structure of BKC1, *i.e.*, SEQ ID NO: 1. The specification also describes a method of isolating BKC1 from bladder and kidney cells. Because the specification discloses the complete structure of the claimed species, as well as a method of making it, those of ordinary skill in the EST art would recognize the inventor to have been in possession of the claimed nucleic acid at the time of filing.

Conclusion:

The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to the full scope of claim 2.

Claim 1

Claim 1 encompasses a genus of isolated nucleic acids each having as part of its structure SEQ ID NO: 1. Because the claim uses the open transitional phrase “comprising,” the claimed nucleic acids may also include additional DNA sequences at either end of the sequence shown in SEQ ID NO: 1. The genus, therefore, includes the full-length open reading frame that includes SEQ ID NO: 1, as well as fusion constructs and vectors comprising SEQ ID NO: 1. (The genus might include the full-length genomic gene. More specifically, if SEQ ID NO: 1 is derived from a single exon, the genomic sequence would comprise SEQ ID NO: 1; if SEQ ID NO: 1 is derived from more than one exon, the genomic sequence would not comprise SEQ ID NO: 1.)

There may be substantial variability among the species of DNAs encompassed by the scope of the claim because SEQ ID NO: 1 may be combined with other DNA sequences, but the scope of the genus is defined by the presence of the structure shown in SEQ ID NO: 1. Thus, all members of the genus will predictably include SEQ ID NO: 1.

The specification provides an actual reduction to practice and disclosure of one species within the genus; *i.e.*, the cDNA consisting of the sequence shown in SEQ ID NO: 1. That sequence also represents a partial structure of each DNA encompassed by the claimed genus: each member of the claimed genus must include SEQ ID NO: 1 as part of its structure because the presence of SEQ ID NO: 1 defines the scope of the claimed genus.

EXAMPLE 4: EXPRESSION SEQUENCE TAGS

It is within the level of skill and knowledge in the art to add any desired DNA sequence to either end of SEQ ID NO: 1 with no more than routine experimentation. Because SEQ ID NO: 1 is a structural feature common to members of the claimed genus and the specification describes the complete structure (sequence) of SEQ ID NO: 1, one skilled in the art would recognize that the applicant was in possession of a structural feature shared by members of the claimed genus. The species shown in the specification; *i.e.*, SEQ ID NO: 1, is, therefore, representative of the species within the claimed genus.

Conclusion:

The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to the full scope of claim 1.

PRACTICE NOTE

This example deals only with the written description analysis of the claimed product. Claims to ESTs often raise other issues, particularly whether the application discloses a patentable utility for the claimed EST(s), whether the claims are enabled throughout their scope, and whether the claims are so broad that they read on products disclosed in the prior art. These other issues are not addressed here but should be considered during examination. Other rejections should be made when appropriate.

EXAMPLE 5: PARTIAL PROTEIN STRUCTURE

CASE NOTE

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

Specification:

The specification discloses a working example in which Protein A was isolated from human urine. Protein A is a 22 kDa protein that binds to and activates Protein X. Example 1 describes a process for isolating Protein A 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 high pressure liquid chromatography (HPLC), wherein the purity of Protein A is confirmed by SDS-PAGE under reducing conditions. The example provides data showing that Protein A so isolated binds to and activates Protein X. The specification also discloses a 10 amino acid sequence from the N-terminus of Protein A (identified as SEQ ID NO: 1).

Prophetic examples are also provided for making a library of cDNAs encoding Protein A using random primers in combination with primers based on nucleic acid sequences predicted from the disclosed 10 amino acid sequence of the N-terminus of Protein A.

Claims:

- 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, and 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.
- 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, and 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

EXAMPLE 5: PARTIAL PROTEIN STRUCTURE

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.

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 to and activate Protein X as Protein A from human urine. The claim is generic because it recites the “open” transitional term “comprising.” The specification fails to disclose the complete structure of Protein A. The specification also fails to disclose any art-recognized correlation between the structure of the claimed protein and its function of binding and activating Protein X. However, the specification discloses a partial structure of Protein A (*i.e.*, the 10 amino acid N-terminal sequence of SEQ ID NO: 1), and other relevant identifying characteristics of the protein (e.g., its ability to bind and activate Protein X, its approximate molecular weight, and the 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 in which Protein A is successfully isolated using the disclosed method. Thus, those of ordinary skill in the art of isolating proteins would recognize the inventor to have been in possession of the claimed protein at the time of filing based on these identifying characteristics and the disclosed isolation method.

Conclusion:

The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to the full scope of claim 1.

Claim 2

Claim 2 encompasses DNAs encoding Protein A that have an N-terminal amino acid sequence of SEQ ID NO: 1, and the same ability to bind to and activate Protein X as Protein A isolated from human urine. The claim is generic because it recites the “open” transitional term “comprising.” The specification fails to disclose the complete structure of any DNA encoding Protein A, or 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. The specification also fails to disclose any art-recognized correlation between structure and the disclosed function of the claimed DNAs (*i.e.*, encoding Protein A) and/or the disclosed function of Protein A (*i.e.*, binding

TECHNICAL NOTE

Because the average amino acid weighs ~110 Da, a 22 kDa protein (like Protein A) can be predicted to be about 200 amino acids in length. Because three nucleotides are needed to code for one amino acid, a cDNA encoding Protein A would be about 600 nucleotides in length.

EXAMPLE 5: PARTIAL PROTEIN STRUCTURE

and activating Protein X). The specification does not disclose the isolation or cloning of any DNA that encodes Protein A and/or refer to any deposited DNA capable of coding for Protein A. Although the specification discloses relevant identifying characteristics of Protein A (e.g., its ability to bind and activate Protein X, its approximate molecular weight, and the concentration of acetonitrile at which Protein A will elute from a reverse phase HPLC column), only Protein A's molecular weight provides any information about the claimed DNAs (*i.e.*, a rough approximation of the size of a cDNA encoding Protein A).

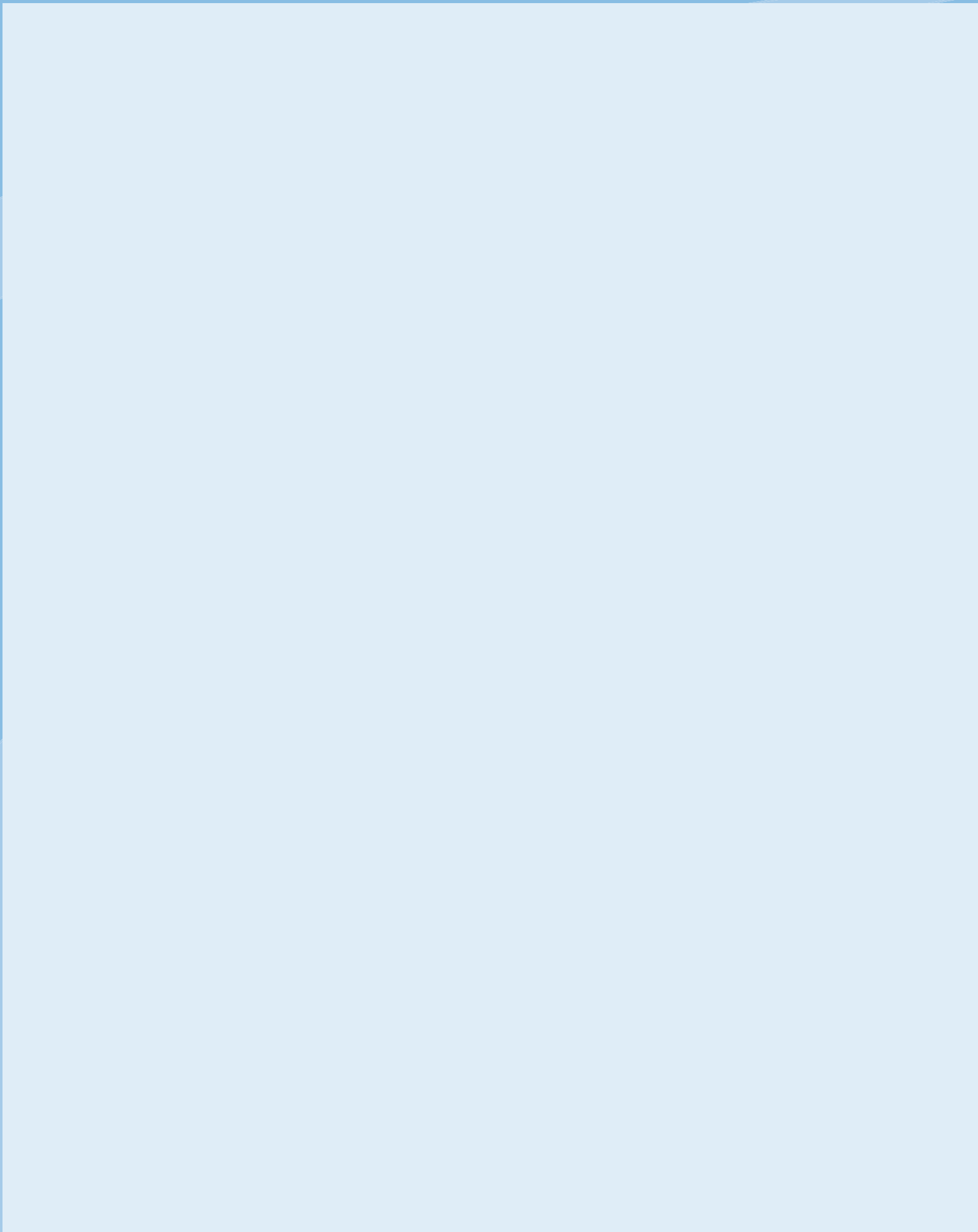
However, the size of a DNA alone will not distinguish it from other DNAs. Thus, the specification fails to disclose sufficient relevant identifying characteristics of the claimed DNAs.

The specification discloses 10 amino acids of Protein A's approximately 200 total amino acids, and a prophetic example for making a library of DNAs encoding Protein A using random primers and primers based on this amino acid sequence. Using the genetic code, those of ordinary skill in the art could predict all of the nucleic acid sequences able to encode the disclosed 10 amino acids of SEQ ID NO: 1. Thus, those of ordinary skill in the art would recognize the inventor to have been in possession of 5% of the structure of the claimed DNAs. However, the specification fails to disclose any information about the structure of the remaining 95% of the claimed DNAs. Although the prophetic example showing how to isolate the claimed DNAs might eventually lead to an actual reduction to practice, because of unpredictability in the art, those of ordinary skill in the art would not consider the inventor to have been in possession of even one species of the claimed DNAs at the time of filing.

Because the specification fails to support even one species of DNA in the claimed genus, it is apparent that a representative number of species is not disclosed.

Conclusion:

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 6: DNA HYBRIDIZATION

Specification:

The specification discloses a novel cDNA (SEQ ID NO: 1) which encodes a protein that binds to a newly-discovered growth factor (NDG) receptor and stimulates tyrosine kinase activity. The specification includes an example demonstrating that the protein encoded by SEQ ID NO: 1 binds to the NDG receptor and stimulates tyrosine kinase activity. SEQ ID NO: 1 was not placed into a public depository. The specification expressly defines highly stringent hybridization conditions as: at least about 6X SSC and 1% SDS at 65°C, with a first wash for 10 minutes at about 42°C with about 20% (v/v) formamide in 0.1X SSC, and with a subsequent wash with 0.2 X SSC and 0.1% SDS at 65°C. It is known in the art that hybridization techniques using a known nucleic acid as a probe under highly stringent conditions, such as those set forth in the specification, will identify structurally similar nucleic acids.

Claims:

Claim 1. An isolated nucleic acid that encodes a protein that binds to the NDG receptor and stimulates tyrosine kinase activity.

Claim 2. An isolated nucleic acid that encodes a protein that binds to the NDG receptor and stimulates tyrosine kinase activity, and consists of the sequence set forth in SEQ ID NO: 1.

Claim 3. An isolated nucleic acid that encodes a protein that binds to the NDG receptor and stimulates tyrosine kinase activity, wherein the nucleic acid hybridizes under highly stringent conditions to the complement of the sequence set forth in SEQ ID NO: 1.

Analysis:

Claim 2

Claim 2 encompasses a single nucleic acid that has the sequence set forth in SEQ ID NO: 1, and encodes a protein that binds to the NDG receptor and stimulates tyrosine kinase activity.

The specification discloses an actual reduction to practice of the claimed nucleic acid, as well as the complete chemical structure of the claimed nucleic acid (*i.e.*, SEQ ID NO: 1) and method of making the claimed nucleic acid. The specification fails to disclose any art-recognized correlation between the disclosed function of the claimed nucleic acid (*i.e.*, that it encodes a protein that binds to the NDG receptor and stimulates tyrosine kinase activity) and structure. Further, the specification does not indicate that the claimed nucleic acid (*i.e.*,

EXAMPLE 6: DNA HYBRIDIZATION

SEQ ID NO: 1) has been placed into a public depository. However, based on the breadth of the disclosure and narrowness of the claim, those of ordinary skill in the art would recognize the applicant to be in possession of the claimed nucleic acid.

Conclusion:

The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to the full scope of claim 2.

Claim 3

Claim 3 encompasses a genus of isolated nucleic acids that (1) hybridize under highly stringent conditions to a nucleic acid having a sequence that is complementary to that set forth in SEQ ID NO: 1, and (2) encode a protein that binds to the NDG receptor and stimulates tyrosine kinase activity.

The specification discloses an actual reduction to practice and the complete chemical structure of only one species of the claimed genus of nucleic acids (*i.e.*, SEQ ID NO: 1). The specification does not indicate that any nucleic acids that both hybridize to the complement of SEQ ID NO: 1 and encode a protein that binds to the NDG receptor under highly stringent conditions have been placed into a public depository.

Because hybridization under highly stringent conditions requires a high degree of structural complementarity, nucleic acids that hybridize to the complement of SEQ ID NO: 1 must share many nucleotides in common with SEQ ID NO: 1. Thus, the claimed genus necessarily includes partial structures of SEQ ID NO: 1. The disclosure of SEQ ID NO: 1 combined with the knowledge in the art regarding hybridization would put one in possession of the genus of nucleic acids that would hybridize under stringent conditions to SEQ ID NO: 1. However, without a recognized correlation between structure and function, those of ordinary skill in the art would not be able to identify without further testing which of those nucleic acids that hybridize to SEQ ID NO: 1 would also encode a polypeptide that binds to NDG receptor and stimulates tyrosine kinase activity. Thus, those of ordinary skill in the art would not consider the applicant to have been in possession of the claimed genus of nucleic acids based on the single species disclosed.

Conclusion:

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.

Claim 1

Claim 1 encompasses the broad genus of all isolated nucleic acids that encode a protein that binds to the NDG receptor and stimulates tyrosine kinase activity, and is not limited to those having complementarity to SEQ ID NO: 1, but also includes nucleic acids having little structural similarity with SEQ ID NO: 1.

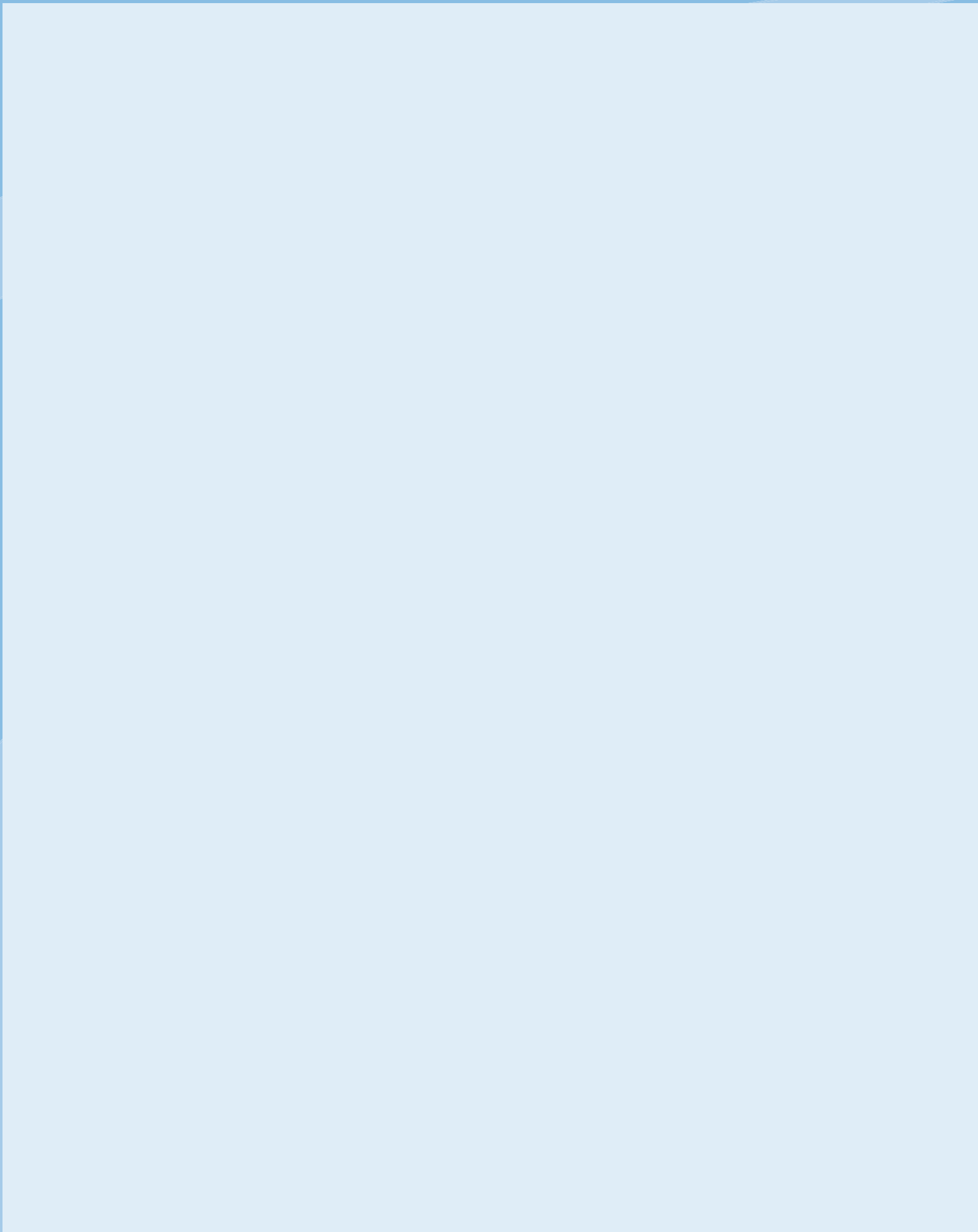
EXAMPLE 6: DNA HYBRIDIZATION

It is known in the art that many receptor-binding proteins share a common receptor-binding domain(s). Thus, some of the proteins encoded by the claimed nucleic acids (*i.e.*, functional NDG receptor agonist(s)) may share a common or similar NDG receptor-binding domain(s). Given the degeneracy of the genetic code, many nucleic acids that encode the NDG receptor-binding domain(s) would be expected to have a common or highly similar coding region for at least that domain(s). However, the specification fails to disclose any information about whether such a domain(s) exists or, if it exists, the structure and/or location of the NDG receptor-binding domain(s) in the protein encoded by SEQ ID NO: 1, or that of the corresponding nucleic acid sequence. Importantly, the claimed nucleic acids are not limited to such a domain(s).

Further, it is known within the art that receptor agonists can vary substantially outside of their receptor-binding domains. Importantly, the claims are not limited to nucleic acids encoding receptor agonists having such a binding domain, but may include nucleic acids encoding agonists with non-canonical binding domains. Given the high degree of variability that may be found in receptor agonists, and that the number of species required to form a representative number varies proportionally with the degree of variability within the claimed genus, those of ordinary skill in the art would not consider the applicant to have been in possession of the entire breadth of the claimed genus of nucleic acids based on the single species disclosed.

Conclusion:

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 7: ALLELIC VARIANTS

Specification:

The specification discloses a DNA, SEQ ID NO: 1, said to encode a cell surface receptor for adenovirus. The cell surface receptor is designated protein X and its sequence is given as SEQ ID NO: 2. No allelic sequence information is disclosed, but the specification states that allelic variants of SEQ ID NO: 1 can be obtained, e.g., by hybridizing SEQ ID NO: 1 to a DNA library made from the same species that yielded SEQ ID NO: 1

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.

Claim 3. An isolated allele of SEQ ID NO: 1.

Analysis:

Claim 1

Claim 1 is drawn to the genus of DNAs that encode the amino acid sequence SEQ ID NO: 2, *i.e.*, all sequences degenerately related by the genetic code to SEQ ID NO: 1.

The specification describes the complete structure of only one species in the claimed genus. The specification does not describe other members of the genus by complete or partial structure, or physical and/or chemical characteristics.

Those skilled in the art are aware of a known correlation between nucleic acid structure and coding function. According to the genetic code, each amino acid in a protein can be encoded by one of a small number of possible triplet codons in a nucleic acid. That is, those skilled in the art are aware that only a limited number of codons can encode a specific amino acid, and that the genetic code provides a known correlation between the codon function (encoding a specific amino acid) and each codon structure. Thus, one skilled in the art would be able to readily envision all the DNAs capable of encoding SEQ ID NO: 2. One of skill in the art would conclude that the applicant would have been in possession of the genus based on the specification and the general knowledge in the art concerning the genetic code table. The facts are sufficient to support an overall finding that the disclosure, coupled with knowledge in the art about the genetic code, provides an adequate written description of the claimed genus of DNAs encoding a protein having SEQ ID NO: 2.

EXAMPLE 7: ALLELIC VARIANTS

Conclusion:

The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to the full scope of claim 1.

Claim 2

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

The specification does not provide any particular definition for the term “allele.” In this circumstance, the meaning of the term is the ordinary usage in the art. The ordinary meaning

PRACTICE NOTE

Because the Office has the burden of supporting its position, see MPEP 2163.04, a reference should be relied on as authority for the Office’s interpretation of the claim term “allele.”

of the term “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 at one or more mutational sites. See, e.g., R. Rieger et al., GLOSSARY OF GENETICS, 5th Ed. (Springer-Verlag, Berlin 1991), p. 16.

The alleles in claim 2 are “strictly neutral” because they encode identical proteins, and make no difference to phenotype. See Rieger et al., p. 17.

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 claimed in claim 1.

The specification discloses the complete structure of only one species within the scope of the claimed genus: SEQ ID NO: 1. The specification does not describe other members of the genus by structure, or physical and/or chemical characteristics. Common structural attributes of the species in the genus are not described. All members of the genus have the same function, *i.e.*, they all encode Protein X, but no correlation between naturally occurring allelic structures and their common coding function is disclosed. The question is whether one of skill in the art would be able to distinguish members of the subgenus (native DNAs) from other members of the genus encoding a protein having SEQ ID NO: 2.

The specification proposes to discover other species in the genus by using a hybridization procedure. The proposal to search by hybridization is not a practical way to describe the full extent of the claimed subgenus because finding a naturally-occurring allele could be successful only empirically. There is no description of the mutational sites that exist in nature, and there is no description of how the structure of SEQ ID NO: 1 relates to the structure of any other strictly neutral alleles. 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.

EXAMPLE 7: ALLELIC VARIANTS

The nature of alleles is that they are variant structures, and in the present state of the art, the structure of one allele does not provide guidance to the existence or structure of other alleles. In other words, the existence and structure of other alleles are not predictable from the one species of allele described. The description given is not adequate to allow one of skill in the art to distinguish members of the claimed subgenus from other members of the genus of claim 1. One of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only one member of this genus is not representative of the species in the genus and is insufficient to support the claim.

Conclusion:

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.

Claim 3

Claim 3 is drawn to the genus including all DNA alleles of SEQ ID NO: 1. The specification does not provide any particular definition for the term “allele.” See the discussion above referring to Rieger et al. Rieger discloses that there are at least seven different kinds of allele in addition to the “strictly neutral” type discussed above for Claim 2. See Rieger et al., pp. 16-17 (amorphs, hypomorphs, hypermorphs, antimorphs, neomorphs, isoalleles, and unstable alleles). The alleles are distinguished by the effect their different structures have on phenotype. According to Rieger, alleles may differ functionally according to their distinct structures. For example, they may differ in the amount of biological activity the protein product may have, may differ in the amount of protein produced, and may even differ in the kind of activity the protein product will have.

The specification discloses only one allele within the scope of the genus: SEQ ID NO: 1. The specification describes the complete structure of only one species in the claimed genus. The specification does not describe other species in the genus by structure, or physical and/or chemical characteristics. The functions of the other species in the genus are not disclosed, and there is no known or disclosed correlation between the unknown structures and the unknown functions (*i.e.*, phenotypes), or between the unknown structures and the structure of the single species disclosed.

The specification proposes to discover other members of the genus by using a hybridization procedure. There is no description of the mutational sites that exist in nature, and there is no description of how the structure of SEQ ID NO: 1 relates to the structure of different alleles. The general knowledge in the art concerning alleles does not provide any indication of how the structure of one allele is representative of other unknown alleles having concordant or discordant functions. The common attributes of the genus are not described and the identifying attributes of individual alleles, other than SEQ ID NO: 1, are not described. The nature of al-

EXAMPLE 7: ALLELIC VARIANTS

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. In other words, the existence of other alleles is unpredictable and the structure of other alleles, if they exist, is also unpredictable. In addition, according to the standard definition, the genus might include members that have widely divergent functional properties. One of skill in the art would conclude that the applicant was not in possession of the claimed genus because a description of only one member of this genus is not representative of the variants of the genus and is insufficient to support the claim.

Conclusion:

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 8: BIOINFORMATICS

Specification:

The specification discloses a process for identifying and selecting biological compounds that are present in a biological system in a tissue specific manner. In the disclosed process, the expression level of a set of compounds (selected from DNA, RNA, proteins, and metabolites) is quantitatively determined in multiple tissues within an organism. The expression level data are then graphically displayed in such a manner that compounds that are differentially expressed are easily identified. One skilled in the art could select compounds that are expressed at a high level in one tissue and at a different level in a second tissue based on the displayed information. The specification does not provide any particular examples, but discloses that the expression levels can be determined by any analytical method consistent with the class of compounds being detected. This type of measurement requires actual physical steps.

Claim:

Claim 1. A computer-implemented method of selecting tissue specific compounds, said method comprising the steps of:

- (a) analyzing the expression level of at least two compounds in a first and second tissue sample and obtaining expression level data for each of said compounds;
- (b) inputting the expression level data obtained in step a) into a computer;
- (c) displaying a first axis corresponding to the expression level of each of said compounds in said first tissue;
- (d) displaying a second axis substantially perpendicular to said first axis, said second axis corresponding to the expression level data of each of said compounds in said second sample;
- (e) displaying a mark at a position, wherein said position is selected relative to said first axis in accordance with an expression level of said compound in said first sample and relative to said second axis in accordance with the expression of said compound in said second sample; and
- (f) selecting a compound of interest based on the position of the mark.

Analysis:

Claim 1

Claim 1 is drawn to a method of identifying compounds that are differentially expressed across tissue types. The claim does not limit the compounds that may be used in the method.

The specification does not describe the complete structure, partial structures, physical properties, or chemical properties of any compound that is differentially expressed. However,

EXAMPLE 8: BIOINFORMATICS

knowledge of the structures and properties of a compound that may be differentially expressed is not needed to practice the claimed method. The claimed invention is drawn to a generic method for selecting compounds identified in a screening process, not the compounds screened.

Practicing the steps of the claimed method requires obtaining, inputting, and displaying the expression level of compounds in different tissues. The specification does not provide an actual reduction to practice of any species, or identify any specific method of obtaining expression level data, any specific algorithm for processing the data, or any data display device. The level of skill and knowledge in the art is such that those skilled in the art know (1) how to analyze expression levels, (2) that numerous compounds are differentially expressed, (3) how to program a computer to accept and display comparative data, and (4) how to obtain suitable display devices.

In this fact situation, the art is sufficiently developed so as to put one of skill in the art in possession of the complete steps of the process.

Based on these factors, those of ordinary skill in the art of differential expression of compounds would recognize the inventor to have been in possession of the claimed method at the time of filing.

Conclusion:

The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to claim 1.

CASE NOTE

See In re Hayes Microcomputer Products Inc. Patent Litigation, 982 F.2d 1527, 1534-35, 25 USPQ2d 1241, 1246 (Fed. Cir. 1992), where the court stated: One skilled in the art would know how to program a microprocessor to perform the necessary steps described in the specification. Thus, an inventor is not required to describe every detail of his invention. An applicant's disclosure obligation varies according to the art to which the invention pertains.

EXAMPLE 9: PROTEIN VARIANTS

Specification:

The specification describes a protein isolated from liver. A working example shows that the isolated protein was sequenced and determined to have the amino acid sequence shown in SEQ ID NO: 3. The isolated protein was additionally characterized as being 65 kD in molecular weight and having tumor necrosis activity. The specification states that the invention provides variants of SEQ ID NO: 3 having one or more amino acid substitutions, deletions, insertions and/or additions. No further description of the variants is provided. The specification indicates that procedures for making proteins with amino acid substitutions, deletions, insertions and/or additions are routine in the art. The specification does not define when a protein ceases to be a variant of SEQ ID NO: 3.

Claims:

Claim 1. An isolated protein comprising the amino acid sequence shown in SEQ ID NO: 3.

Claim 2. An isolated variant of the protein of claim 1.

Analysis:

Claim 1

Claim 1 is directed to a protein comprising the sequence shown in SEQ ID NO: 3 and the specification describes the complete structure (sequence) of SEQ ID NO: 3. The claimed genus is defined by the presence of this structure. Therefore, one skilled in the art would recognize that the applicant was in possession of a structural feature shared by all members of the genus. The specification does not describe other members of the genus by complete structure. However, given the existing knowledge in the art concerning fusion proteins, which are an example of additions that could be made to SEQ ID NO: 3, those of skill in the art would conclude that the applicant would have been in possession of the claimed genus at the time of filing.

Conclusion:

The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to the full scope of claim 1.

Claim 2

Claim 2 is a genus claim. According to the specification, the term “variant” means a protein having one or more amino acid substitutions, deletions, insertions and/or additions made to SEQ ID NO: 3. The specification and claim do not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to SEQ ID NO: 3.

EXAMPLE 9: PROTEIN VARIANTS

Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted.

The specification does not describe any members of the claimed genus by complete structure. However, the pre-existing general knowledge in the art supplements the description: additions to the end of known or disclosed proteins resulting in fusion proteins have been described and are generally known. However, the specification does not describe the structure for substitution variants, deletion variants or insertion variants of SEQ ID NO: 3. The specification does not describe the physical or chemical characteristics for substitution variants, deletion variants or insertion variants of SEQ ID NO: 3. The specification does not disclose any correlation(s) between the structure of the variants and SEQ ID NO: 3, or any correlation(s) of structure with variant function.

Although the specification states that these types of amino acid changes are routinely made in the art, the specification and claim do not describe any specific changes to be made. No common structural attributes identify the members of the substitution, deletion and insertion variant genus. Because the disclosure fails to describe the common attributes or characteristics that identify substitution, deletion and insertion variant members of the genus, and because the genus is highly variant, SEQ ID NO: 3 is insufficient to describe the genus, even when considered in light of the general knowledge in the art concerning fusion proteins. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus, and thus, that the applicant was not in possession of the claimed genus. The claimed subject matter is not supported by an adequate written description because a representative number of species has not been described. A rejection under the written description requirement, relying on the analysis set out above, should be entered against the claim to the extent it covers substitution, deletion and insertion variants.

Conclusion:

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 10: PRODUCT CLAIMED BY ITS FUNCTION

Specification:

The specification discloses a protein isolated from mouse liver that catalyzes the reaction A->B. The isolated protein was sequenced and its sequence was set forth in the specification as SEQ ID NO: 3. The specification also contemplates, but does not exemplify variants of the protein wherein the variant can have any or all of the following: substitutions, deletions, insertions and additions. The specification indicates that procedures for making proteins with substitutions, deletions, insertions and additions are routine in the art and provides an assay for detecting the catalytic activity of the protein or its variants.

Claims:

Claim 1. An isolated protein comprising the amino acid sequence shown in SEQ ID NO: 3.

Claim 2. An isolated variant of a protein comprising the amino acid sequence shown in SEQ ID NO: 3, wherein the variant comprises an amino acid sequence that is at least 95% identical to SEQ ID NO: 3.

Claim 3. The isolated variant of claim 2, wherein the variant catalyzes the reaction A->B.

Analysis:

Claim 1

Claim 1 is directed to a protein comprising the sequence shown in SEQ ID NO: 3. Because it uses open claim language (“comprising”), the claim is generic; *i.e.*, it encompasses proteins that include the sequence of SEQ ID NO: 3 together with other amino acids added to either end of that sequence.

The specification provides an actual reduction to practice of a protein comprising SEQ ID NO: 3 and describes the complete structure (sequence) of SEQ ID NO: 3. The specification describes a method of making a protein comprising SEQ ID NO: 3. The specification describes the function of the described protein (catalyzing the reaction of A->B), although no correlation between this function and the protein’s structure is disclosed (e.g., by identifying which amino acids are involved in the active site, substrate binding, etc.). Those skilled in the art would expect that most species within the genus would retain the function of the protein consisting of SEQ ID NO: 3 because each species must include SEQ ID NO: 3 as part of its structure. Thus, predictability of species within the genus is high.

EXAMPLE 10: PRODUCT CLAIMED BY ITS FUNCTION

The claimed genus of proteins is defined by the presence of the structure represented by SEQ ID NO: 3. Therefore, one skilled in the art would recognize that the applicant was in possession of a structural feature shared by each of the members of the claimed genus at the time of filing. The species shown in the specification's SEQ ID NO: 3 is, therefore, representative of the species within the claimed genus.

Conclusion:

The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to claim 1.

Claim 2

Claim 2 is directed to a variant of the protein defined by claim 1 (a protein comprising SEQ ID NO: 3), where the amino acid sequence of the variant is at least 95% identical to SEQ ID NO: 3. The claim is not limited to variants of the protein of SEQ ID NO: 3 having the function of catalyzing the reaction A->B.

The specification adequately describes proteins comprising the amino acid sequence of SEQ ID NO: 3 (see the analysis of claim 1). All of the proteins within the scope of claim 2 share at least 95% of the amino acid sequence of SEQ ID NO: 3; therefore, the specification describes 95% of the structure that defines the proteins within the claimed genus. All of the species within the genus share a significant degree of partial structure (*i.e.*, at least 95% of SEQ ID NO: 3).

The claimed variants can have amino acid substitutions, deletions, insertions, or additions, as compared to SEQ ID NO: 3. The specification does not provide an actual reduction to practice of any variants of the protein of SEQ ID NO: 3. The specification does not describe the complete structure or physical or chemical properties of any variants of SEQ ID NO: 3, although those skilled in the art would expect members of the genus to have properties similar to those of SEQ ID NO: 3, because of the high degree of structural similarity.

In view of the disclosure of SEQ ID NO: 3, those skilled in the art could readily envision all of the amino acid sequences that are 95% identical to SEQ ID NO: 3. Those skilled in the art could recognize amino acid sequences that are 95% identical to SEQ ID NO: 3 by comparing a given sequence to SEQ ID NO: 3. The presence of an amino acid sequence that is at least 95% identical to SEQ ID NO: 3 is a structural feature of each of the proteins within the claimed genus.

PRACTICE NOTE

This example deals only with the written description analysis of the claimed product. Enablement issues that may be raised by the recited facts are not addressed here but should be considered during examination. A separate rejection for nonenablement should be made when appropriate.

EXAMPLE 10: PRODUCT CLAIMED BY ITS FUNCTION

The level of skill and knowledge in the art is such that one of ordinary skill would be able to make and identify variants having 95% identity to SEQ ID NO: 3 routinely.

Thus, those skilled in the art would have recognized the disclosure as showing that the applicant was in possession of the claimed genus of protein variants at the time of filing.

Conclusion:

The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to claim 2.

Claim 3

Claim 3 is directed to the genus of variants of SEQ ID NO: 3 that comprise an amino acid sequence at least 95% identical to SEQ ID NO: 3 and catalyze the reaction A->B.

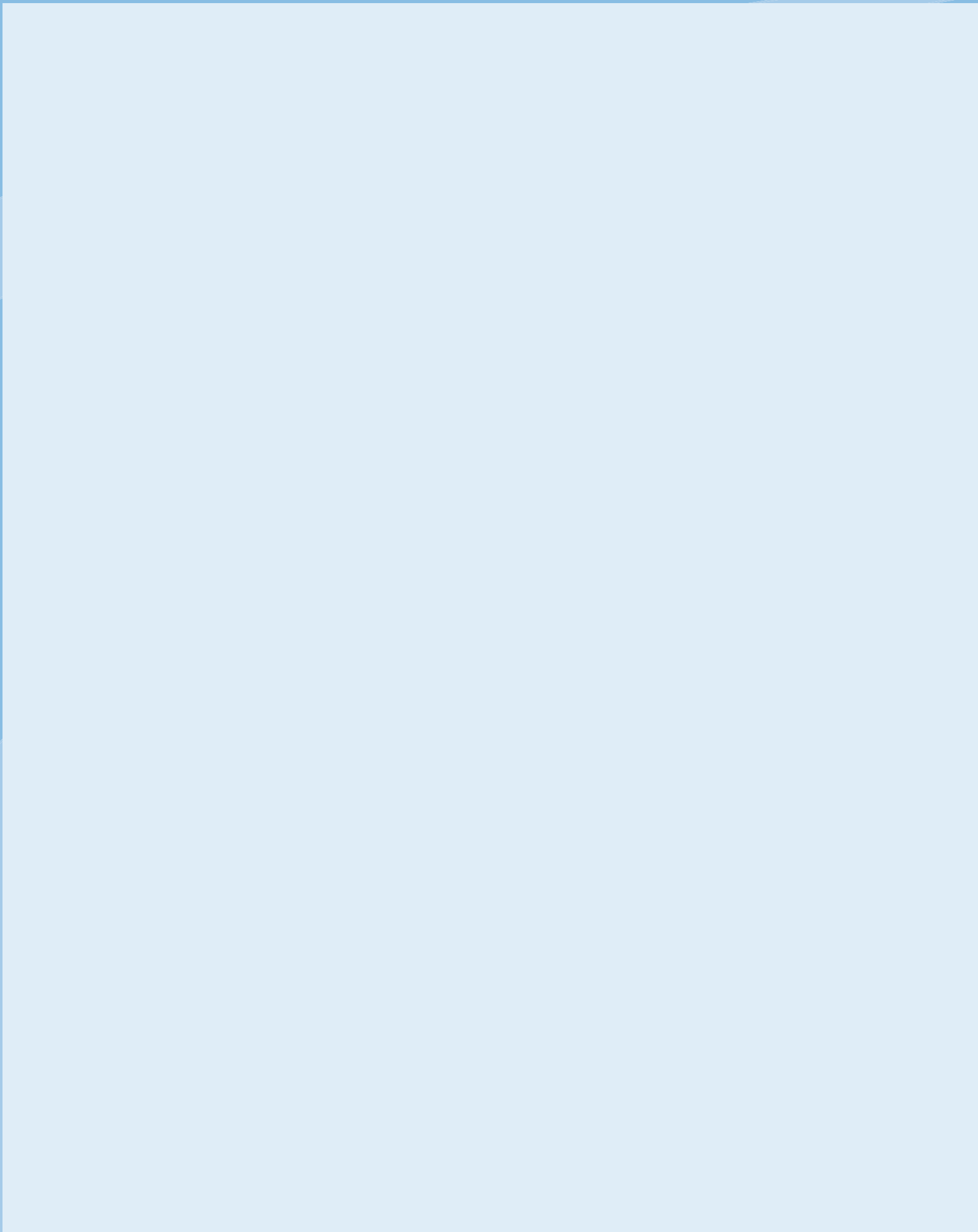
The specification discloses the reduction to practice of one species within the claimed genus; specifically, the protein having the amino acid sequence of SEQ ID NO: 3. There are no drawings or structural formulas disclosed of any other proteins that catalyze the reaction A->B.

The recitation of a polypeptide with at least 95% amino acid sequence identity to SEQ ID NO: 3 represents a partial structure. That is, the claimed proteins share at least 95% of the structure of SEQ ID NO: 3, while 5% of the structure can vary. There is no teaching in the specification regarding which 5% of the structure can be varied while retaining the ability of the protein to catalyze the reaction A->B. Further, there is no art-recognized correlation between any structure (other than SEQ ID NO: 3) and the activity of catalyzing A->B, based on which those of ordinary skill in the art could predict which amino acids can vary from SEQ ID NO: 3 without losing the catalytic activity. Consequently, there is no information about which amino acids can vary from SEQ ID NO: 3 in the claimed genus of proteins and still retain the catalytic activity.

Although the disclosure of SEQ ID NO: 3 combined with the knowledge in the art, would put one in possession of proteins that are at least 95% identical to SEQ ID NO: 3, the level of skill and knowledge in the art is such that one of ordinary skill would not be able to identify without further testing which of those proteins having at least 95% identity to SEQ ID NO: 3 (if any) have the activity of catalyzing the reaction A->B. Based on the lack of knowledge and predictability in the art, those of ordinary skill in the art would not conclude that the applicant was in possession of the claimed genus of proteins based on disclosure of the single species of SEQ ID NO: 3.

Conclusion:

The specification fails to satisfy the written description requirement of 35 U.S.C. 112, first paragraph, with respect to claim 3.



EXAMPLE 11: PERCENT IDENTITY

11A: ART-RECOGNIZED STRUCTURE-FUNCTION CORRELATION NOT PRESENT

Specification:

The 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, and 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.

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 SEQ ID NO: 2; wherein the polypeptide has activity X.

Analysis:

Claim 1

Claim 1 encompasses nucleic acids that encode the polypeptide of SEQ ID NO: 2, as well as those that encode any polypeptide having 85% structural identity to SEQ ID NO: 2. However, 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.

The recitation of a polypeptide with at least 85% identity represents a partial structure, that is, at least 85% percent of the amino acids in the polypeptide will match those in SEQ ID NO: 2, and up to 15% of them may vary from those in SEQ ID NO: 2. However, there is no teaching regarding which 15% of the amino acids may vary from SEQ ID NO: 2. Consequently, there is also no information given about which nucleotides will vary from SEQ ID NO: 1 in the claimed genus of nucleic acids.

There is no functional limitation on the nucleic acids of claim 1 other than that they encode the polypeptide of SEQ ID NO: 2 or any polypeptide having 85% structural identity to SEQ ID NO: 2. The genetic code and its redundancies were known in the art before the application was filed.

The disclosure of SEQ ID NO: 2 combined with the pre-existing knowledge in the art regarding the genetic code and its redundancies would have put one in possession of the ge-

EXAMPLE 11: PERCENT IDENTITY

nus 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 of the nucleic acids that encode a polypeptide with at least 85% sequence identity with SEQ ID NO: 2. Thus, one of ordinary skill in the art would conclude that the applicant was in possession of the claimed genus at the time the application was filed.

Conclusion:

The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to the scope of claim 1.

Claim 2

Claim 2 encompasses nucleic acids that encode the polypeptide of SEQ ID NO: 2, and nucleic acids that encode a polypeptide having 85% sequence identity to SEQ ID NO: 2 and have activity X. The specification discloses the reduction to practice of only a single species that encodes SEQ ID NO: 2 and has activity X; *i.e.*, SEQ ID NO: 1. There are no other drawings or structural formulas disclosed of a nucleic acid that encodes either SEQ ID NO: 2 or a polypeptide having 85% sequence identity to SEQ ID NO: 2 and activity X.

The claim includes a genus that can be analyzed at several levels sequentially for the purpose of focusing the issue.

First, the disclosure of SEQ ID NO: 2 combined with pre-existing knowledge in the art regarding 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 identify all of the nucleic acid sequences that encode a polypeptide with at least 85% sequence identity with SEQ ID NO: 2. However, there is no teaching regarding which 15% of the amino acids can vary from SEQ ID NO: 2 and still result in a protein that retains activity X. Further, there is no disclosed or art-recognized correlation between any structure other than SEQ ID NO: 2 and novel activity X.

An important consideration is that structure is not necessarily a reliable indicator of function. In this example, there is no disclosure relating similarity of structure to conservation of function. General knowledge in the art included the knowledge that some amino acid varia-

TECHNICAL NOTE

For information on amino acid substitution exchange groups and empirical similarities between amino acid residues, see a standard text such as Schulz et al., PRINCIPLES OF PROTEIN STRUCTURE, pp. 14-16, Springer-Verlag (New York 1979). There is a limit to how much substitution can be tolerated before the original tertiary structure is lost. Generally, tertiary structure conservation would be lost when the amino acid sequence varies by more than 50%. See, e.g., Cyrus Chothia and Arthur M. Lesk, "The relation between the divergence of sequence and structure in proteins," 5 THE EMBO JOURNAL 823-26 (1986).

EXAMPLE 11: PERCENT IDENTITY

tions are tolerated without losing a protein's tertiary structure. The results of amino acid substitutions have been studied so extensively that amino acids are grouped in so-called "exchange groups" of similar properties because substituting within the exchange group is expected to conserve the overall structure. For example, the expectation from replacing leucine with isoleucine would be that the protein would likely retain its tertiary structure. On the other hand, when non-exchange group members are substituted, e.g., proline for tryptophan, the expectation would be that the substitution would not likely conserve the protein's tertiary structure. Given what is known in the art about the likely outcome of substitutions on structure, those in the art would have likely expected the applicant to have been in possession of a genus of proteins having a tertiary structure similar to SEQ ID NO: 2 although the claim is not so limited.

However, conservation of structure is not necessarily a surrogate for conservation of function. In this case, there is no disclosed correlation between structure and function. The need for correlating information can vary. More specifically, those of skill in the art might require more or less correlating information depending on the kind of protein activity. If activity X is simply structural, e.g., a member of the collagen class, correlating information might not be a critical factor. However, if activity X is enzymatic, and there is no disclosure of the active site amino acid residues responsible for the catalytic activity, lack of that kind of correlating information may be a problem. Similarly, if activity X is as a ligand, and there is no disclosure of the domain(s) responsible for the ligand activity, the absence of information may be persuasive that those of skill in the art would not take the disclosure as generic.

Summarizing, there are no known or disclosed proteins having activity X other than SEQ ID NO: 2. As of the filing date, there was no known or disclosed correlation between a structure other than SEQ ID NO: 2 and activity X. While general knowledge in the art may have allowed one of skill in the art to identify other proteins expected to have the same or similar tertiary structure, in this example there is no general knowledge in the art about activity X to suggest that general similarity of structure confers the activity. Accordingly, one of skill in the art would not accept the disclosure of SEQ ID NO: 2 as representative of other proteins having activity X.

Conclusion:

The specification, taken with the pre-existing knowledge in the art of amino acid substitution and the genetic code, fails to satisfy the written description requirement of 35 U.S.C. 112, first paragraph, with respect to the scope of claim 2.

11B: ART-RECOGNIZED STRUCTURE-FUNCTION CORRELATION PRESENT

Specification:

The 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

EXAMPLE 11: PERCENT IDENTITY

has a novel activity Y, and 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 Y other than SEQ ID NO: 1. However, the specification discloses data from deletion studies that identify two domains as critical to activity Y, *i.e.*, a binding domain and a catalytic domain. The specification proposes that conservative mutations in these domains (e.g., one basic amino acid substituted for another basic amino acid) will still result in a protein having activity Y, whereas most non-conservative mutations in these domains will not result in a polypeptide having the recited activity. The specification also proposes that most mutations, conservative or non-conservative, outside the two domains will not affect activity Y to any great extent.

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 SEQ ID NO: 2; wherein the polypeptide has activity Y.

Analysis:

Claim 1

(This analysis proceeds the same as the analysis for claim 1 in Example 11A (Art-Recognized Structure-Function Correlation Not Present))

Claim 1 encompasses a vast genus of nucleic acids that encode the polypeptide of SEQ ID NO: 2, as well as those that encode any polypeptide having 85% structural identity to SEQ ID NO: 2.

The specification, however, discloses the reduction to practice of 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.

Although the recitation of a polypeptide with at least 85% identity represents a partial structure -- in that 85% percent of the polypeptide is known, while 15% of the structure may vary -- there is no teaching regarding which 15% of the amino acids will vary from SEQ ID NO: 2. Consequently, there is also no information about which nucleotides will vary from SEQ ID NO: 1 in the claimed genus of nucleic acids.

There are no functional characteristics disclosed for 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. Further, the specification fails to disclose a method of making nucleic acids encoding polypeptides having 85% identity to SEQ ID NO: 2.

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Nonetheless, the disclosure of SEQ ID NO: 2 combined with the knowledge in the art regarding the genetic code would put one in possession of the genus of nucleic acids that encode SEQ ID NO: 2. Further, with the aid of a computer, one could list all of the nucleic acid sequences that encode a polypeptide with at least 85% sequence identity with SEQ ID NO: 2. Additionally, the level of skill and knowledge in the art is such that one of ordinary skill would be able to use conventional sequencing and nucleic acid synthesis techniques to routinely generate and identify nucleic acids that encode the polypeptide of SEQ ID NO: 2, as well as those that encode any polypeptide having 85% structural identity to SEQ ID NO: 2. Thus, one of ordinary skill in the art conclude that the applicant would have been in possession of the claimed genus at the time of filing.

Conclusion:

The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to the scope of claim 1.

Claim 2

Claim 2 encompasses a genus of nucleic acids that encode the polypeptide of SEQ ID NO: 2 and those that encode any polypeptide having 85% structural identity to SEQ ID NO: 2, wherein the polypeptide additionally has activity Y.

The specification, however, discloses the reduction to practice of only a single species that encodes SEQ ID NO: 2 and has activity Y, *i.e.*, SEQ ID NO: 1. There are no other drawings or structural formulas disclosed of a nucleic acid that encodes either (i) SEQ ID NO: 2 or (ii) a polypeptide with 85% sequence identity to SEQ ID NO: 2 wherein the polypeptide also has activity Y.

The disclosure of SEQ ID NO: 2 combined with the knowledge in the art regarding the genetic code would have put one in possession of the genus of nucleic acids that encode SEQ ID NO: 2. Further, with the aid of a computer, one could list all of the nucleic acid sequences

that encode a polypeptide with at least 85% sequence identity to SEQ ID NO: 2. However, the specification fails to teach 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.

Nonetheless, the specification identifies two domains responsible for activity Y, *i.e.*, a binding domain and catalytic domain. The specification also predicts that conservative mutations in these domains will result in a protein having activity Y. Although all conservative amino acid substitutions in these domains will not nec-

PRACTICE NOTE

This example deals only with the written description analysis of the claimed nucleic acids. Enablement issues that may be raised by the recited facts are not addressed here, but should be considered during examination. A separate rejection for nonenablement should be made when appropriate.

EXAMPLE 11: PERCENT IDENTITY

essarily result in a protein having activity Y, those of ordinary skill in the art would expect that many of these conservative substitutions would result in a protein having the required activity. Further, amino acid substitutions outside of the two identified functional domains are unlikely to greatly affect activity Y. Thus, a correlation exists between the function of the claimed protein and the structure of the disclosed binding and catalytic domains. Consequently, there is information about which nucleic acids can vary from SEQ ID NO: 1 in the claimed genus of nucleic acids and still encode a polypeptide having activity Y. Based on the applicant's disclosure and the knowledge within the art, those of ordinary skill in the art would conclude that the 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.

Conclusion:

The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to the scope of claim 2.

EXAMPLE 12: ANTISENSE OLIGONUCLEOTIDES

Specification:

The specification discloses a messenger RNA (mRNA) sequence that encodes newly discovered growth factor (NDG): SEQ ID NO: 1. The specification states that the invention includes antisense oligonucleotides that inhibit the production of NDG, but does not disclose the sequences of any antisense oligonucleotides. The specification describes several art-recognized methods of screening for antisense oligonucleotides, including using computer-based models of RNA structure, “gene walking” with numerous antisense oligonucleotides, randomized oligonucleotide libraries, and DNA arrays. Gene walking involves obtaining antisense oligonucleotides that are complementary to the target sequence, and is disclosed as the preferred method of screening for antisense oligonucleotides. The specification also discloses the use of modified nucleotides to avoid degradation by nucleases in biological fluids.

Claim:

Claim 1. An antisense oligonucleotide complementary to all or a portion of a messenger RNA having SEQ ID NO: 1 and encoding NDG, wherein said antisense oligonucleotide inhibits the production of NDG.

Analysis:

Claim 1

Claim 1 is drawn to a genus of antisense oligonucleotides that are complementary to all or a portion of NDG mRNA (SEQ ID NO: 1) and that, when bound to NDG mRNA, inhibit NDG protein production.

The specification does not disclose the actual reduction to practice of any antisense oligonucleotides falling into the scope of claim 1. However, it is generally accepted in the art that oligonucleotides that are complementary to an mRNA will have antisense activity if and when they hybridize to accessible regions on the target mRNA. Generally, the closer in size an antisense oligonucleotide is to a full length mRNA of interest, the greater the likelihood the oligonucleotide will have antisense activity for that mRNA. Because the general knowledge in the art is that the binding of any full-length complement of a target mRNA to that target mRNA will inhibit its expression, the specification discloses the complete structure of one species within the genus of claim 1, *i.e.*, the full-length complement of SEQ ID NO: 1.

The specification does not disclose the full or partial structures of any other species within the genus of claim 1. However, the structure of all possible antisense oligonucleotides that are complementary to NDG mRNA can be predicted from the full-length complement of SEQ ID NO: 1. Even though all of the oligonucleotides that are complementary to NDG mRNA

EXAMPLE 12: ANTISENSE OLIGONUCLEOTIDES

PRACTICE NOTE

The difference between the outcomes in this example and in claim 2 of Example 7 (Allelic Variants) is due to the subject matter being claimed and knowledge in the art. Claim 2 in Example 7 is directed to the genus of alleles encoding protein X having SEQ ID NO: 2. Although those of ordinary skill in the art could predict all of the DNAs encoding protein X having SEQ ID NO: 2, there is no way to know which of those DNAs would be alleles without testing all of the DNAs in existence. In this example, those of ordinary skill in the art could predict all of the oligonucleotides that are complementary to NDG mRNA, but would not be able to predict with 100% accuracy which of those oligonucleotides would have antisense activity. However, those of ordinary skill in the art have algorithms to aid in predicting which oligonucleotides will have the required function, and can readily make and test those oligonucleotides for antisense activity.

will not have antisense function, there are certain art-recognized correlations between the antisense oligonucleotide's function and the structure of the target mRNA that would aid the selection of those fragments having antisense activity. For example, oligonucleotides that retain complementarity to the Shine-Delgarno sequence typically have antisense activity. As previously mentioned, the closer in size and structure an oligonucleotide is to its target mRNA, the more antisense activity. In contrast, regions having high G-C content are usually inaccessible and, therefore, not good candidates for antisense oligonucleotides. Several mRNA computer modeling software packages exist that incorporate these structure-function correlations, and can be used to predict those oligonucleotides having antisense activity. Although these programs do not operate with 100% accuracy, because SEQ ID NO: 1 defines and limits the structure of any effective antisense oligonucleotides, and because there are art-recognized correlations between antisense oligonucleotide's function and target mRNA structure, those skilled in the art would conclude that the applicant would have been in possession of several representative species of the antisense oligonucleotides of claim 1.

Given the high level of skill in the antisense oligonucleotides art, and that the number of species required to form a representative number varies inversely with the level of skill in the art, those of ordinary skill in the art would consider the applicant to have been in possession of the entire breadth of the claimed genus of antisense oligonucleotides based on the single species that could be predicted from the disclosure (*i.e.*, the complement of SEQ ID NO: 1).

Conclusion:

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 13: ANTIBODIES TO A SINGLE PROTEIN

Specification:

The specification discloses that a protein designated antigen X has been isolated from HIV and is useful for detection of HIV infections. The specification describes purifying antigen X by gel filtration and discloses its amino acid sequence. Antigen X is further characterized as a 55 kD monomer having no disulfide bonds, with a slightly acidic pI. The specification discusses antibodies which specifically bind to antigen X and asserts that these antibodies can be used in immunoassays to detect HIV. However, there is no working or detailed prophetic example of an antibody that binds to antigen X.

Claim:

Claim 1. An isolated antibody capable of binding to antigen X.

Analysis:

The specification does not describe an actual reduction to practice of an antibody that binds to antigen X by reference to a deposit (e.g., deposit of a hybridoma) or by describing an antibody in structural terms sufficient to show possession. The specification also does not describe the complete structure of an antibody capable of binding antigen X in detailed drawings or through a structural chemical formula. The specification does not describe a partial structure of the claimed antibody. The specification does not describe any physical or chemical properties of the claimed antibody (e.g., molecular weight, association constant).

TECHNICAL NOTE

As evidence, see, e.g., Elvin A. Kabat, STRUCTURAL CONCEPTS IN IMMUNOLOGY AND IMMUNOCHEMISTRY, 2nd Ed. (Holt, Rinehart and Winston 1976), p. 17:

Early studies empirically established that proteins were good antigens when injected into a species other than the one from which they originated. . . . Indeed, it was shown very early in this [20th] century that rabbit serum proteins injected into even as closely related a species as hare would yield antibody (and vice versa). No difficulties were encountered in preparing antibodies to protein antigens from remotely related sources such as bacteria, viruses, and egg, milk, and plant proteins. In most of these studies it sufficed to immunize the animal (an animal receiving injections of an antigen is being immunized) with a solution of the antigen, or preferably, with the protein antigen adsorbed on floccules of aluminum hydroxide (alum precipitate), since the use of antigens in particulate form had been shown to give a better antibody response.

EXAMPLE 13: ANTIBODIES TO A SINGLE PROTEIN

The specification does not disclose a correlation between the function of binding to antigen X and the structure of the claimed antibody. Finally, the specification does not describe a method of making an antibody that binds antigen X.

However, the level of skill and knowledge in the art of antibodies at the time of filing was such that production of antibodies against a well-characterized antigen was conventional.

Antibodies were known to be of five general types; each of the five types had been characterized as having substantial common structural, chemical and biological features.

The antigen-specific variable regions of antibodies vary.

It does not appear that persons of skill in the art consider knowledge of the amino acid sequence of the variable regions critical for purposes of assessing possession of an antibody.

Considering the facts, including the routine art-recognized method of making antigen-specific antibodies, the adequate description of antigen X, the well-defined structural characteristics for the classes, subclasses and isotypes of antibody, the functional characteristics of anti-

TECHNICAL NOTE

For an example discussion of the variable and hypervariable region sequence variation, see Kabat at pp. 286-300.

body binding, and the fact that antibody technology was well developed and mature, one of skill in the art would have recognized that the disclosure of the adequately described antigen X put the applicant in possession of antibodies which bind to antigen X.

Conclusion:

The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect

to the full scope of claim 1.

TECHNICAL NOTE

For example, Kabat shows the shared physical, chemical and biological properties of IgG, IgA, IgM, IgD and IgE in tabular form at pp. 227-29.

EXAMPLE 14: ANTIBODIES TO A GENUS OF PROTEINS

CASE NOTE

This example is based on the fact pattern in Noelle v. Lederman, 355 F.3d 1343, 69 U.S.P.Q.2d 1508 (Fed. Cir. 2004).

Specification:

The specification describes a monoclonal antibody that specifically binds to Protein X isolated from murine tissues. Protein X is said to be located on the surface of certain immune cells. Protocols for producing anti-Protein X antibodies are disclosed. The specification explains that an antibody that specifically binds Protein X can be used to repress cell-to-cell signaling interaction between certain cells in the immune system. Thus, the antibody is said to be useful for treating certain immune disorders involving cell-to-cell signaling.

The specification discloses a method of isolating and purifying murine Protein X. The specification discloses several physical and chemical properties of isolated murine Protein X, including its amino acid sequence. The specification does not disclose a physical or chemical property for Protein X isolated from another species. For example, there is no disclosure of molecular weight, or cross-reactivity by human Protein X with anti-murine Protein X antibodies, and there is no sequence information given for human Protein X or for Protein X from any species other than mouse. However, the specification discloses that human Protein X is expected to have the same in vivo function that murine Protein X has, and discloses that antibodies to human Protein X will be useful for treating immune disorders involving cell-to-cell signaling.

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.

Analysis:

Claim 2

Claim 2 is directed to a monoclonal antibody that specifically binds murine Protein X.

The specification characterizes murine Protein X sufficiently so that those of skill in the art would accept the applicant to have been in possession of murine Protein X at the time the application was filed. As explained in Example 13 (Antibodies To A Single Protein), those of skill in the art of immunology would accept that an adequate description of a purified antigen would have put an inventor in possession of antibodies which bind to the purified antigen. Given the information in this specification, those of skill in the art would accept that the applicant would

EXAMPLE 14: ANTIBODIES TO A GENUS OF PROTEINS

have been in possession of monoclonal antibodies specifically binding murine Protein X at the time the application was filed.

Conclusion:

The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to the full scope of claim 2.

Claim 3

Claim 3 is directed to a monoclonal antibody that specifically binds human Protein X.

The specification does not describe an actual reduction to practice of a monoclonal antibody that binds to human Protein X by either reference to a deposit (e.g., deposit of a hybridoma) or by description of an antibody in structural terms sufficient to show possession. The specification also does not describe a complete or partial structure of an antibody capable of binding human Protein X in detailed drawings or through a structural chemical formula. Further, the specification does not disclose a correlation between human Protein X and the described murine Protein X, or between antibodies that specifically bind murine Protein X and antibodies that specifically bind human Protein X. Finally, the specification does not describe a method of making an antibody that binds human Protein X that can be performed without first having human Protein X.

Even though an adequate description of an antigen may be accepted by those of skill in the art as sufficient to put an inventor in possession of antibodies against the antigen, see Example 13 (Antibodies To A Single Protein), the specification does not provide a description of human Protein X.

In the absence of direct descriptive information for human Protein X, a question for consideration concerning Claim 3 is whether the description of murine Protein X supports a claim to antibodies specifically binding human Protein X. A review of the specification, including the drawings and original claims, as well as prior art, finds no evidence that the disclosed properties of murine Protein X are predictive of corresponding properties for human Protein X. The disclosure of human Protein X is simply functional, and there is no correlation(s) to its physical or chemical properties. There is no evidence that those of skill in the art would accept a disclosure of murine Protein X and its cognate antibodies as evidence that the inventor had been in possession of human Protein X or its cognate antibodies. Thus, Claim 3 is directed to an unknown that is identified only by reference to another unknown.

Conclusion:

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

Claim 1

Claim 1 is directed to a monoclonal antibody that specifically binds Protein X. The claim is generic in two ways. First, it is generic in the sense that it includes many species of monoclonal antibody that specifically bind Protein X. Second, the term Protein X is generic because it includes Protein X from multiple species.

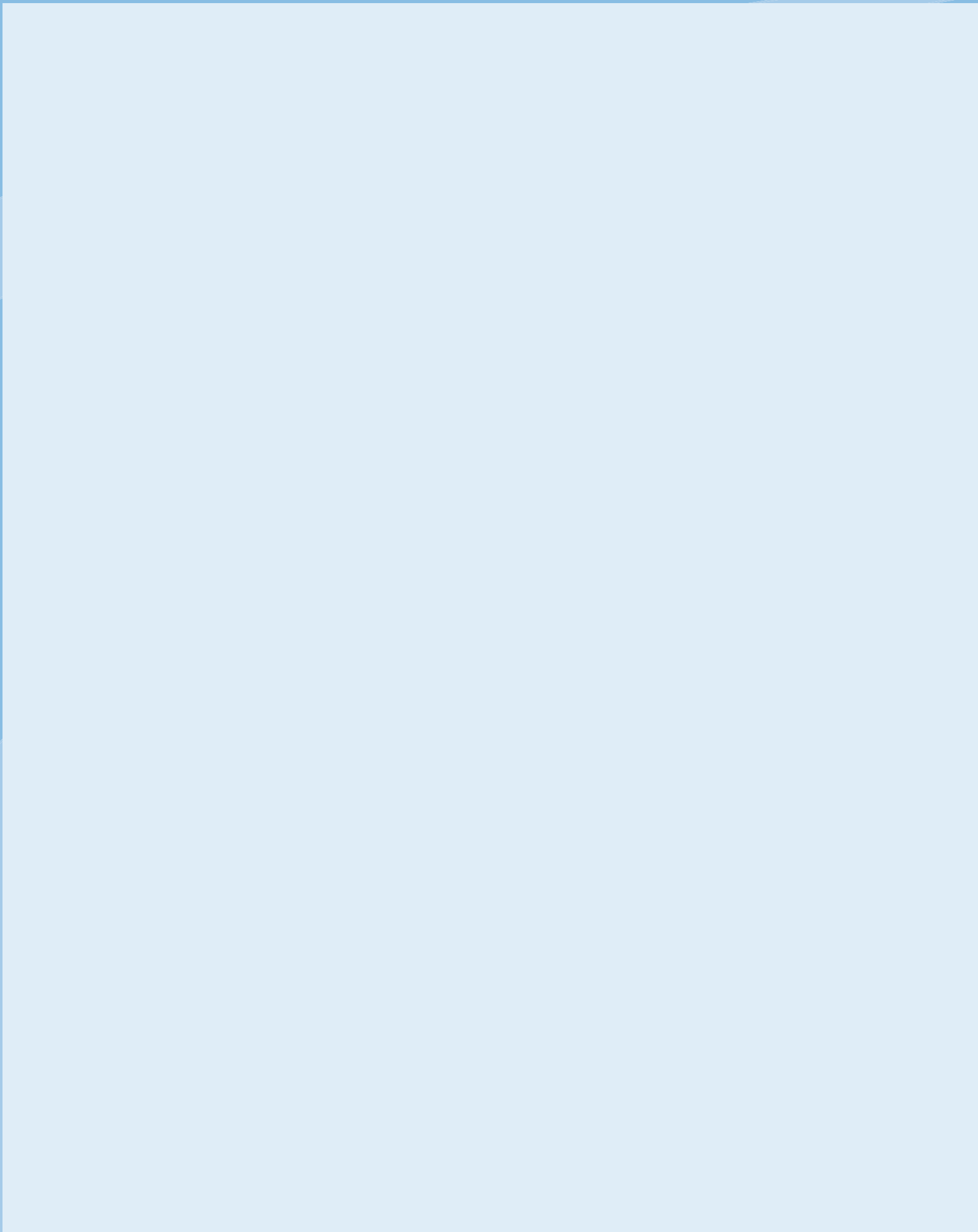
The disclosure is sufficient to describe an antibody that specifically binds murine Protein X. However, the specification does not describe an actual reduction to practice of an antibody that specifically binds to Protein X from other (non-murine) species either by reference to a deposit (e.g., deposit of a hybridoma) or by description of an antibody in structural terms sufficient to show possession. The specification also does not describe a complete or partial structure of an antibody capable of binding a non-murine Protein X in detailed drawings or through a structural chemical formula. Further, the specification does not disclose a correlation between murine and non-murine Protein X and the structure of the claimed antibody. Finally, the specification does not describe a method of making an antibody that binds non-murine Protein X that can be performed without first having the specific non-murine Protein X.

Even though an adequate description of an antigen may be accepted by those of skill in the art as sufficient to put an inventor in possession of antibodies against the antigen, see Example 13 (Antibodies To A Single Protein), the specification does not provide a description of Protein X from species other than mouse.

Claim 1 is generic because it includes antibodies to Protein X from any species. If murine Protein X is representative of the genus Protein X, Claim 1 might be described. However, there is no description of structural features shared by murine Protein X and Protein X from other species, nor is there a disclosure of a correlation between structure and function that would allow those of skill in the art to recognize other members of the claimed genus from the disclosure of murine Protein X. There is no evidence that murine Protein X is representative of the genus of Protein X molecules from other species. There is no evidence that those of skill in the art would accept a disclosure of murine Protein X and its cognate antibodies as evidence that the inventor would have been in possession of a genus of Protein X molecules or cognate antibodies at the time of filing.

Conclusion:

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 15: GENUS WITH WIDELY VARYING SPECIES

Specification:

The specification discloses a working example in which a full-length cDNA was isolated from a mouse cDNA library. The complete cDNA sequence (SEQ ID NO: 1) and predicted amino acid sequence (SEQ ID NO: 2) are disclosed. The specification states that the cDNA encodes a novel protein that the specification refers to as the murine “Squeaker” protein. The specification discloses a method for isolating human and other mammalian Squeaker cDNA sequences. However, the specification does not disclose any working examples showing isolation of other Squeaker cDNAs, and does not disclose any cDNA sequences other than the mouse sequence. There is no evidence in the record of allelic variants of the mouse Squeaker protein or gene. However, the art recognized that homologous genes in different species tend to differ in sequence, and that the amount and type of sequence variation is unpredictable.

Claims:

Claim 1. An isolated nucleic acid comprising a nucleic acid sequence encoding a mammalian Squeaker protein.

Claim 2. The isolated nucleic acid of claim 1 wherein said nucleic acid sequence encodes mouse Squeaker protein.

Claim 3. The isolated nucleic acid of claim 1 wherein said nucleic acid sequence encodes the amino acid sequence of SEQ ID NO: 2.

Claim 4. The isolated nucleic acid of claim 1 wherein said nucleic acid sequence comprises the sequence of SEQ ID NO: 1.

Claim 5. The isolated nucleic acid of claim 1 wherein said nucleic acid sequence encodes human Squeaker protein.

Analysis:

All of the claims are genus claims in that they use the transitional phrase “comprising” and, therefore, allow for the presence of nucleic acid sequences in addition to those specified in the claim. Claims 2-5 are each directed to a subgenus of claim 1. The examiner should, therefore, begin with claims 2-5.

Claim 2

Claim 2 is directed to a nucleic acid comprising a sequence that encodes mouse Squeaker protein.

The specification describes the structure (SEQ ID NO: 2) of mouse Squeaker protein, and the record contains no evidence of variability among mouse Squeaker proteins. The level of knowledge and skill in the art is such that skilled artisans are aware of the genetic code. In the

EXAMPLE 15: GENUS WITH WIDELY VARYING SPECIES

genetic code, each amino acid in a protein can be encoded by one of only a small number of possible codons (*i.e.*, three-nucleotide-long sequences) in a nucleic acid. Thus, those of ordinary skill in the art know that only a limited number of possible nucleic acid structures can encode a specific amino acid, and those nucleic acid structures can be predicted by applying the genetic code. The genetic code, therefore, provides a known correlation between function (encoding a specific amino acid) and structure (triplet codons). Thus, one skilled in the art would be able to readily envisage many nucleic acid sequences that could encode SEQ ID NO: 2. Based on the knowledge in the art and the correlation between structure and function provided by the genetic code, those skilled in the art would have recognized that the description of the mouse Squeaker amino acid sequence would have put the applicant in possession of the nucleic acid sequences encoding that sequence at the time of filing.

Conclusion:

The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to claim 2.

Claim 3

Claim 3 is directed to a nucleic acid comprising a sequence that encodes the amino acid sequence of SEQ ID NO: 2.

The specification provides an actual reduction to practice and the full structure of one nucleic acid sequence (SEQ ID NO: 1) that encodes SEQ ID NO: 2. The specification discloses that the function of the cDNA of SEQ ID NO: 1 is to encode SEQ ID NO: 2. Therefore, the analysis of claim 2 (above) applies equally to claim 3: those of ordinary skill in the art could readily envisage, by applying the genetic code, a variety of nucleic acids that encode mouse Squeaker protein (SEQ ID NO: 2). Methods of making nucleic acid sequences of any desired sequence are routine in the art. Based on the level of knowledge in the art and the correlation between structure and function provided by the genetic code, those skilled in the art would have recognized that the description of SEQ ID NO: 2 would have put the applicant in possession of the nucleic acid sequences encoding SEQ ID NO: 2 at the time of filing.

Conclusion:

The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to claim 3.

Claim 4

Claim 4 is directed to a nucleic acid comprising the sequence shown in SEQ ID NO: 1.

The specification provides an actual reduction to practice of a cDNA comprising SEQ ID NO: 1 and describes the complete structure (sequence) of SEQ ID NO: 1. The specification describes a method of isolating the cDNA comprising SEQ ID NO: 1. The specification describes the function of the described cDNA (encoding SEQ ID NO: 2), which is correlated to

EXAMPLE 15: GENUS WITH WIDELY VARYING SPECIES

its structure (shown in SEQ ID NO: 1) via the genetic code. Predictability of species within the genus is high because each species must comprise SEQ ID NO: 1 as part of its structure.

The claimed genus of nucleic acids is defined by the presence of the structure represented by SEQ ID NO: 1. Therefore, one skilled in the art would recognize that the applicant would have been in possession of a common distinguishing feature of members of the genus. The species shown in the specification's SEQ ID NO: 1 is, therefore, representative of the species within the claimed genus.

Conclusion:

The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to claim 4.

Claim 5

Claim 5 is directed to a nucleic acid comprising a sequence that encodes human Squeaker protein.

The specification describes a method of isolating the claimed nucleic acids, but does not provide an actual reduction to practice of the claimed nucleic acid or the protein encoded by it. The specification does not describe the complete structure of the claimed nucleic acid or the encoded protein in drawings or by chemical formula. The specification does not describe any partial structure of the claimed nucleic acid (e.g., by nucleotide sequence or restriction sites) or of the encoded protein. The specification does not describe any physical or chemical properties of the claimed nucleic acid (e.g., length, molecular weight, or hybridization to DNAs of known structure), nor are any such properties taught in the prior art. The specification does not describe the function of the claimed nucleic acid in terms of encoding a specified amino acid sequence, such that its function could be correlated to specific structure by operation of the genetic code.

The level of knowledge and skill in the art does not allow those skilled in the art to structurally envisage or recognize a nucleic acid encoding human Squeaker protein because it is known that a gene in one species will tend to differ unpredictably from the corresponding gene in other species (e.g., the human insulin gene will differ in unpredictable ways from the rat insulin gene). Therefore, those skilled in the art would have recognized that the specification's description of the mouse Squeaker cDNA and protein would not have put the applicant in possession of nucleic acids encoding the human Squeaker protein at the time of filing. Thus, the specification does not describe sufficiently detailed, relevant characteristics to show that the applicant was in possession of the claimed nucleic acid encoding human Squeaker protein.

Conclusion:

The specification fails to satisfy the written description requirement of 35 U.S.C. 112, first paragraph, with respect to claim 5.

EXAMPLE 15: GENUS WITH WIDELY VARYING SPECIES

Claim 1

Claim 1 is directed to a nucleic acid comprising a sequence encoding a mammalian Squeaker protein.

The specification adequately describes one subgenus within the claimed genus (i.e., nucleic acids encoding mouse Squeaker protein) but does not describe any other species or subgenera within the genus sufficiently to show possession of those species or subgenera.

The specification describes a method of isolating other mammalian Squeaker-encoding cDNAs. The specification does not describe any structural features of the mouse Squeaker nucleic acid sequence that would have been expected to be shared by members of the claimed genus. The specification does not describe any structural features of the Squeaker protein that would have been expected to be shared by other mammalian Squeaker proteins and could be correlated to structural features of the claimed nucleic acids via the genetic code. The specification does not describe any physical or chemical properties of either the Squeaker protein or Squeaker-encoding cDNAs that would be expected to be shared by members of the claimed genus. The level of knowledge and skill in the art does not allow those skilled in the art to structurally envisage or recognize a nucleic acid encoding a non-murine mammalian Squeaker protein because it is known that corresponding genes in different species tend to differ in sequence and the amount and type of sequence variation is unpredictable. Because the structure of the species within the claimed genus would be expected to vary unpredictably from the structure of the single, described subgenus, the disclosed mouse Squeaker-encoding cDNA is not a “representative number” of species within the claimed genus.

Because the single, described subgenus is not representative of the entire claimed genus, and the specification does not disclose structural features shared by members of the genus, the description of the mouse cDNA would not have put the applicant in possession of common structural attributes or features shared by members of the genus that structurally distinguish the members of the genus from other materials at the time of filing. Thus, the description of the mouse Squeaker-encoding cDNA is not sufficient to describe the claimed genus of mammalian Squeaker-encoding cDNAs. Accordingly, the specification does not provide a representative number of species or sufficient common structural features to show that the applicant would have been in possession of the claimed genus as a whole at the time of filing.

Conclusion:

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 16: PROCESS CLAIM WHERE NOVELTY RESIDES IN THE PROCESS STEPS

Specification:

The specification discloses a method for transforming mitochondria within mammalian cells. In the disclosed method, DNA is complexed with a specified, known chemical compound (compound X, which is defined by structure in the specification), and the DNA/compound X complex is entrapped in liposomes. The specification discloses that when mammalian cells are contacted with liposomes containing the DNA/compound X complex under particular conditions, the DNA/compound X complex will be taken up into both the cell's cytoplasm and its mitochondria. All of the chemicals used in the disclosed method, as well as the use of liposomes to transform cells (but not mitochondria), were known in the art. The method is disclosed to be useful for treating diseases caused by mutations in mitochondrial DNA and the specification discloses specific mutations of mitochondrial DNA that are recognized in the art as associated with diseases. The specification provides a working example showing transformation of mitochondria in mouse cells in vitro with the E. coli β -galactosidase gene using the disclosed method.

Claim:

Claim 1. A method of introducing a nucleic acid into the mitochondria of mammalian cells, comprising:

- (a) contacting a nucleic acid with compound X to form a complex of said nucleic acid and compound X;
- (b) contacting mammalian cells with said complex; and
- (c) incubating said cells and said complex under the following conditions [here the claim recites the specific, novel conditions of culture medium, temperature, time, etc. that are disclosed in the specification to result in transformation of mitochondria].

Analysis:

Claim 1

Claim 1 is directed to a method of introducing a variety of nucleic acids into mitochondria of mammalian cells. Claim 1, therefore, is generic.

Practicing the method of claim 1 requires a defined chemical compound, a nucleic acid, and mammalian cells. The specification describes the structure of compound X and one nucleic acid (the β -galactosidase gene) used to transform mitochondria. The specification also provides an actual reduction to practice of one species within the claimed genus; *i.e.*, transformation of

EXAMPLE 16: PROCESS CLAIM WHERE NOVELTY RESIDES IN THE PROCESS STEPS

mitochondria with DNA encoding β -galactosidase. The level of skill and knowledge in the art is such that those skilled in the art know of numerous nucleic acids that could potentially be complexed with compound X (itself a known compound) to be used in the claimed method to transform the mitochondria of numerous mammalian cells. (Although the sequences of these nucleic acids are not disclosed in the specification, a patent application is not required to reproduce knowledge that is available in the art.)

The degree of predictability within the claimed genus is high, because introduction of a nucleic acid into mitochondria is disclosed to depend on complexing with compound X and contacting the complex with mammalian cells under specified conditions. According to the specification, those conditions would be expected to result in transformation regardless of which nucleic acid is complexed and contacted with cells. Based on these factors, those of ordinary skill in the art of mammalian cell transformation would recognize the inventor to have been in possession of the claimed method at the time of filing.

Conclusion:

The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to claim 1.

PRACTICE NOTE

This example deals only with the written description analysis of the claimed method. Enablement issues that may be raised by the recited facts are not addressed here, but should be considered during examination. A separate rejection for nonenablement should be made when appropriate.

EXAMPLE 17: METHODS USING COMPOUNDS CLAIMED BY FUNCTIONAL LIMITATIONS, METHODS OF IDENTIFYING COMPOUNDS, AND COMPOUNDS SO IDENTIFIED

Specification:

The specification discloses the nucleotide sequences of the coding and promoter regions of two genes that encode the human enzymes POPKIN-1 and POPKIN-2, and a comparison of those sequences. The specification characterizes the enzymatic activity of POPKIN-1 and POPKIN-2 as the same activity. The specification also describes how to make cells that express either POPKIN-1 or POPKIN-2, but not both. The specification describes assays using these cells to screen for compounds which selectively inhibit the expression or activity of POPKIN-2 but not POPKIN-1. “Selective inhibition” is defined as the ability to inhibit POPKIN-2 activity but not POPKIN-1 activity. The specification describes methods of treating specified diseases characterized by aberrant POPKIN-2 activity, using compounds to be identified in screening assays to selectively inhibit POPKIN-2. There are no known compounds that selectively inhibit POPKIN-2 and none are disclosed in the specification.

CASE NOTE

This example is partially based on the fact pattern in Univ. of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 69 USPQ2d 1886 (Fed. Cir. 2004).

EXAMPLE 17: COMPOUNDS CLAIMED BY FUNCTION

Claims:

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.

Claim 2: A method for identifying a compound that selectively inhibits POPKIN-2 activity comprising

(a) contacting a test compound with a cell expressing POPKIN-2 but not POPKIN-1 and measuring POPKIN-2 activity,

(b) comparing the measured activity from step a to the activity of POPKIN-2 in a non-contacted control cell,

and if the measured activity of step a is less than the measured activity of POPKIN-2 in the control cell then,

(c) contacting the compound with a cell expressing POPKIN-1, but not POPKIN-2 and measuring POPKIN-1 activity, and

(d) comparing the measured POPKIN-1 activity from step c to the activity of POPKIN-1 in a non-contacted control cell,

wherein, if the measured POPKIN-1 activity of contacted and control cells is the same, a compound that selectively inhibits POPKIN-2 is identified.

Claim 3: A compound identified by the method of claim 2.

Analysis:

Claim 1

A selective POPKIN-2 inhibitor is required to practice the invention.

The specification does not describe an actual reduction to practice of a method of selectively inhibiting POPKIN-2 using a compound that selectively inhibits POPKIN-2 activity. The specification also does not describe the complete structure of a compound that selectively inhibits POPKIN-2 activity. Further, the specification does not describe the partial structures, or physical properties, or chemical properties of a compound that selectively inhibits POPKIN-2 activity.

While the specification describes the amino acid sequences of POPKIN-1 and POPKIN-2, the specification does not describe any correlation between the sequences 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; however, there is no information regarding what structural features would likely be associated with such selective, inhibitory activity. Thus, the specification does not disclose a correlation between selective inhibitory activity and the structure of a putative inhibitor.

EXAMPLE 17: COMPOUNDS CLAIMED BY FUNCTION

The level of skill and knowledge in the art is that there are no known compounds that selectively inhibit POPKIN-2 and no known correlation between any structural component and the ability to selectively inhibit POPKIN-2. Thus, the disclosure does not allow one of skill in the art to visualize or recognize the structure of any compound required to practice the claimed method. Accordingly, one of ordinary skill in the art would conclude that the applicant would not have been in possession of the claimed method of selectively inhibiting POPKIN-2 activity because a compound possessing the desired activity required to practice the method is not adequately described and was not known in the art.

Conclusion:

The specification fails to satisfy the written description requirement of 35 U.S.C. 112, first paragraph, with respect to claim 1.

Claim 2

The claim is drawn to a screening assay for identifying compounds that selectively inhibit the activity of POPKIN-2, but not POPKIN-1. The claim does not limit the compounds that may be used in the assay.

The specification does not describe the complete structure, partial structures, physical properties, or chemical properties of a compound that selectively inhibits POPKIN-2 activity, nor does the specification describe any correlation between the sequences of POPKIN-1 and POPKIN-2 and the structure of any compounds that would selectively inhibit POPKIN-2 activity. The specification does describe the claimed method of screening compounds for selective inhibition of POPKIN-2 activity, reciting the instant steps for identifying a compound with the desired activity.

The level of skill and knowledge in the art is such that one would be able to follow the detailed steps of the claimed method. The practice of the method requires no knowledge of the structures and properties of a compound that would predictably result in the desired activity; rather the claimed invention is the screening process, not the compounds screened or the compounds identified via the claimed process. Thus, one of ordinary skill in the art would conclude that the applicant would have been in possession of the claimed method for identifying compounds that selectively inhibit POPKIN-2 activity at the time of filing.

Conclusion:

The specification satisfies the written description requirement of 35 U.S.C. 112, first paragraph, with respect to claim 2.

Claim 3

The claim is drawn to a selective POPKIN-2 inhibitor. The claim encompasses a genus, in which all potential members share a functional activity, *i.e.*, selective inhibition of POPKIN-2.

EXAMPLE 17: COMPOUNDS CLAIMED BY FUNCTION

The number of structures encompassed by the claim may be vast or conversely there may be no structures that possess the claimed function.

The specification does not describe the complete structure of a compound that selectively inhibits POPKIN-2 activity. The specification also does not describe the partial structures, or physical properties, or chemical properties of a compound that selectively inhibits POPKIN-2 activity.

While the specification describes the amino acid sequences of POPKIN-1 and POPKIN-2, the specification does not describe any correlation between the sequences 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; however, there is no information regarding what structural features would likely be associated with such selective, inhibitory activity. Thus, the specification does not disclose a correlation between selective inhibitory activity and the structure of a putative inhibitor.

The level of skill and knowledge in the art is such that one would be able to follow the detailed steps of the disclosed method, however, claim 3 is drawn to a product, not a method. The claim extends beyond what is disclosed (*i.e.*, is a so-called “reach through” claim). Given that there is no known correlation between any structural component and the ability to selectively inhibit POPKIN-2, the specification’s description of a screening method does not correlate to a structural description of the resulting products. Thus, while one of ordinary skill in the art would conclude that the applicant would have been in possession of the claimed method for identifying compounds that selectively inhibit POPKIN-2 activity, one of ordinary skill in the art would not conclude that the applicant would have been in possession of any compounds having the desired activity at the time of filing.

Conclusion:

The specification fails to satisfy the written description requirement of 35 U.S.C. 112, first paragraph, with respect to claim 3.

an asserted utility, unless countervailing evidence can be provided that shows that one of ordinary skill in the art would have a legitimate basis to doubt the credibility of such a statement. Similarly, Office personnel must accept an opinion from a qualified expert that is based upon relevant facts whose accuracy is not being questioned; it is improper to disregard the opinion solely because of a disagreement over the significance or meaning of the facts offered.

Once a *prima facie* showing of no specific and substantial credible utility has been properly established, the applicant bears the burden of rebutting it. The applicant can do this by amending the claims, by providing reasoning or arguments, or by providing evidence in the form of a declaration under 37 CFR 1.132 or a patent or a printed publication that rebuts the basis or logic of the *prima facie* showing. If the applicant responds to the *prima facie* rejection, the Office personnel should review the original disclosure, any evidence relied upon in establishing the *prima facie* showing, any claim amendments, and any new reasoning or evidence provided by the applicant in support of an asserted specific and substantial credible utility. It is essential for Office personnel to recognize, fully consider and respond to each substantive element of any response to a rejection based on lack of utility. Only where the totality of the record continues to show that the asserted utility is not specific, substantial, and credible should a rejection based on lack of utility be maintained.

If the applicant satisfactorily rebuts a *prima facie* rejection based on lack of utility under § 101, withdraw the § 101 rejection and the corresponding rejection imposed under § 112, first paragraph.

Dated: December 29, 2000.

Q. Todd Dickinson,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

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DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

[Docket No. 991027288-0264-02]

RIN 0651-AB10

Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement

AGENCY: United States Patent and Trademark Office, Commerce.

ACTION: Notice.

SUMMARY: These Guidelines will be used by USPTO personnel in their review of patent applications for compliance with the "written description" requirement of 35 U.S.C. 112, ¶ 1. These Guidelines supersede the "Revised Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 'Written Description' Requirement" that were published in the **Federal Register** at 64 FR 71427, Dec. 21, 1999, and in the Official Gazette at 1231 O.G. 123, Feb. 29, 2000. These Guidelines reflect the current understanding of the USPTO regarding the written description requirement of 35 U.S.C. 112, ¶ 1, and are applicable to all technologies.

DATES: The Guidelines are effective as of January 5, 2001.

FOR FURTHER INFORMATION CONTACT: Stephen Walsh by telephone at (703) 305-9035, by facsimile at (703) 305-9373, by mail to his attention addressed to United States Patent and Trademark Office, Box 8, Washington, DC 20231, or by electronic mail at "stephen.walsh@uspto.gov"; or Linda Therkorn by telephone at (703) 305-8800, by facsimile at (703) 305-8825, by mail addressed to Box Comments, Commissioner for Patents, Washington, DC 20231, or by electronic mail at "linda.therkorn@uspto.gov."

SUPPLEMENTARY INFORMATION: As of the publication date of this notice, these Guidelines will be used by USPTO personnel in their review of patent applications for compliance with the "written description" requirement of 35 U.S.C. 112, ¶ 1. Because these Guidelines only govern internal practices, they are exempt from notice and comment rulemaking under 5 U.S.C. 553(b)(A).

Discussion of Public Comments

Comments were received from 48 individuals and 18 organizations in response to the request for comments on the "Revised Interim Guidelines for Examination of Patent Applications

Under the 35 U.S.C. 112, ¶ 1 'Written Description' Requirement" published in the **Federal Register** at 64 FR 71427, Dec. 21, 1999, and in the Official Gazette at 1231 O.G. 123, Feb. 29, 2000. The written comments have been carefully considered.

Overview of Comments

The majority of comments favored issuance of final written description guidelines with minor revisions. Comments pertaining to the written description guidelines are addressed in detail below. A few comments addressed particular concerns with respect to the associated examiner training materials that are available for public inspection at the USPTO web site (www.uspto.gov). Such comments will be taken under advisement in the revision of the training materials; consequently, these comments are not specifically addressed below as they do not impact the content of the Guidelines. Several comments raised issues pertaining to the patentability of ESTs, genes, or genomic inventions with respect to subject matter eligibility (35 U.S.C. 101), novelty (35 U.S.C. 102), or obviousness (35 U.S.C. 103). As these comments do not pertain to the written description requirement under 35 U.S.C. 112, they have not been addressed. However, the aforementioned comments are fully addressed in the "Discussion of Public Comments" in the "Utility Examination Guidelines" Final Notice, which will be published at or about the same time as the present Guidelines.

Responses to Specific Comments

(1) *Comment:* One comment stated that the Guidelines instruct the patent examiner to determine the correspondence between what applicant has described as the essential identifying characteristic features of the invention and what applicant has claimed, and that such analysis will lead to error. According to the comment, the examiner may decide what applicant should have claimed and reject the claim for failure to claim what the examiner considers to be the invention. Another comment suggested that the Guidelines should clarify what is meant by "essential features of the invention." Another comment suggested that what applicant has identified as the "essential distinguishing characteristics" of the invention should be understood in terms of *Fiers v. Revel*, 984 F.2d 1164, 1169, 25 USPQ2d 1601, 1605 (Fed. Cir. 1993) ("Conception of a substance claimed *per se* without reference to a process requires conception of its structure, name,

formula, or definitive chemical or physical properties.”).

Response: The suggestions have been adopted in part. The purpose of the written description analysis is to confirm that applicant had possession of what is claimed. The Guidelines have been modified to instruct the examiners to compare the scope of the invention claimed with the scope of what applicant has defined in the description of the invention. That is, the Guidelines instruct the examiner to look for consistency between a claim and what provides adequate factual support for the claim as judged by one of ordinary skill in the art from reading the corresponding written description.

(2) *Comment:* Two comments urge that *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), is bad law and should not be followed by the USPTO because it conflicts with binding precedent, such as *Vas-Cath v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991). *Response:* The final Guidelines are based on the Office's current understanding of the law and are believed to be fully consistent with binding precedent of the U.S. Supreme Court and the U.S. Court of Appeals for the Federal Circuit. *Eli Lilly* is a precedential decision by the Court that has exclusive jurisdiction over appeals involving patent law. Accordingly, the USPTO must follow *Eli Lilly*. Furthermore, the USPTO does not view *Eli Lilly* as conflicting with *Vas-Cath*. *Vas-Cath* explains that the purpose of the written description requirement is to ensure that the applicant has conveyed to those of skill in the art that he or she was in possession of the claimed invention at the time of filing. *Vas-Cath*, 935 F.2d at 1563-64, 19 USPQ2d at 1117. *Eli Lilly* explains that a chemical compound's name does not necessarily convey a written description of the named chemical compound, particularly when a genus of compounds is claimed. *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1405. The name, if it does no more than distinguish the claimed genus from all others by function, does not satisfy the written description requirement because “it does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus.” *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. Thus, *Eli Lilly* identified a set of circumstances in which the words of the claim did not, without more, adequately convey to

others that applicants had possession of what they claimed.

(3) *Comment:* Several comments urged that the Guidelines do not recognize the inconsistency between the original claim doctrine and the written description requirement as set out in *Fiers* and *Eli Lilly*. On the other hand, another comment asserts that there is no strong presumption that an originally filed claim constitutes an adequate written description of the claimed subject matter. Several comments indicate that *in haec verba* support should be sufficient to comply with the written description requirement. Two comments urge that the concept of constructive reduction to practice upon filing of an application has been ignored. *Response:* As noted above, the USPTO does not find *Fiers* and *Eli Lilly* to be in conflict with binding precedent. An original claim may provide written description for itself, but it still must be an adequate written description which establishes that the inventor was in possession of the invention. The “original claim doctrine” is founded on cases which stand for the proposition that originally filed claims are part of the written description of an application as filed, and thus subject matter which is present only in originally filed claims need not find independent support in the specification. *See, e.g., In re Koller*, 613 F.2d 819, 824, 204 USPQ 702, 706 (CCPA 1980) (later added claims of similar scope and wording were adequately described by original claims); *In re Gardner*, 480 F.2d 879, 880, 178 USPQ 149, 149 (CCPA 1973) (“Under these circumstances, we consider the original claim in itself adequate ‘written description’ of the claimed invention. It was equally a ‘written description’ * * * whether located among the original claims or in the descriptive part of the specification.”). However, as noted in the preceding comment, *Eli Lilly* identified a set of circumstances in which the words of the claim did not, without more, adequately convey to others that applicants had possession of what they claimed. When the name of a novel chemical compound does not convey sufficient structural information about the compound to identify the compound, merely reciting the name is not enough to show that the inventor had possession of the compound at the time the name was written. The Guidelines indicate that there is a “strong presumption” that an adequate written description of the claimed invention is present when the application is filed, consistent with *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ

90, 97 (CCPA 1976) (“we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims.”). In most cases, the statement that “an originally filed claim is its own written description,” is borne out because the claim language conveys to others of skill in the art that the applicant was “in possession” of what is claimed. The Guidelines emphasize that the burden of proof is on the examiner to establish that a description as filed is not adequate and require the examiner to introduce sufficient evidence or technical reasoning to shift the burden of going forward with contrary evidence to the applicant.

(4) *Comment:* One comment stated that the Guidelines change the substance of the written description requirement to require some level of enablement. The comment stated that the *Eli Lilly* case should not be followed because its change in the quality of the description required is in conflict with precedent. Another comment suggested that to comply with the written description requirement, the description must both (i) demonstrate possession of the claimed invention by the applicant; and (ii) put the public in possession of the claimed invention. *Response:* As noted in the comment above, the USPTO is bound by the Federal Circuit's decision in *Eli Lilly*. The Guidelines have been revised to clarify that an applicant must provide a description of the claimed invention which shows that applicant was in possession of the claimed invention. The suggestion to emphasize that the written description requirement must put the public in possession of the invention has not been adopted because it removes much of the distinction between the written description requirement and the enablement requirement. Although the two concepts are entwined, they are distinct and each is evaluated under separate legal criteria. The written description requirement, a question of fact, ensures that the inventor conveys to others that he or she had possession of the claimed invention; whereas, the enablement requirement, a question of law, ensures that the inventor conveys to others how to make and use the claimed invention.

(5) *Comment:* One comment suggested that the Guidelines should provide examples of situations in which the written description requirement was met but the enablement requirement was not, and vice versa. Another comment stated that examiners often use enablement language in making

written description rejections.

Response: The enablement and written description requirements are not coextensive and, therefore, situations will arise in which one requirement is met but the other is not. Federal Circuit case law demonstrates many circumstances where enablement or written description issues, but not both, were before the Court. These Guidelines are intended to clarify for the examining corps the criteria needed to satisfy the written description requirement. For examples applying these Guidelines to hypothetical fact situations, see the "Synopsis of Application of Written Description Guidelines" (examiner training materials available on-line at <http://www.uspto.gov/web/menu/written.pdf>). These examples, as well as the examination form paragraphs and instructions on their proper use, provide the appropriate language examiners should use in making written description rejections.

(6) *Comment:* One comment disagreed with the statement in an endnote that "the fact that a great deal more than just a process is necessary to render a product invention obvious means that a great deal more than just a process is necessary to provide written description for a product invention." The comment indicated that the statement is overly broad and inconsistent with the "strong presumption that an adequate written description of the claimed invention is present when the application is filed." As an extreme case, for example, for product-by-process claims, nothing else would be needed to provide the written description of the product. *Response:* The endnote has been clarified and is now more narrowly drawn. However, there is no *per se* rule that disclosure of a process is sufficient to adequately describe the products produced by the process. In fact, *Fiers v. Revel* and *Eli Lilly* involved special circumstances where the disclosure of a process of making and the function of the product alone did not provide an adequate written description for product claims. Even when a product is claimed in a product-by-process format, the adequacy of the written description of the process to support product claims must be evaluated on a case-by-case basis.

(7) *Comment:* Several comments urge that actual reduction to practice, as a method of satisfying the written description requirement by demonstrating possession, has been over-emphasized. *Response:* The Guidelines have been clarified to state that describing an actual reduction to practice is one of a number of ways to show possession of the invention.

Description of an actual reduction to practice offers an important "safe haven" that applies to all applications and is just one of several ways by which an applicant may demonstrate possession of the claimed invention. Actual reduction to practice may be crucial in the relatively rare instances where the level of knowledge and level of skill are such that those of skill in the art cannot describe a composition structurally, or specify a process of making a composition by naming components and combining steps, in such a way as to distinguish the composition with particularity from all others. Thus, the emphasis on actual reduction to practice is appropriate in those cases where the inventor cannot provide an adequate description of what the composition is, and a definition by function is insufficient to define a composition "because it is only an indication of what the [composition] does, rather than what it is." *Eli Lilly*, 119 F.3d at 1568, 43 USPQ at 1406. See also *Amgen Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991).

(8) *Comment:* One comment asserts that the citation to *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 48 USPQ2d 1641 (1998) is inappropriate and should be deleted because *Pfaff* is concerned with § 102(b) on-sale bar, not written description. Another comment suggested that the Guidelines should provide an explanation of how the "ready for patenting" concept of *Pfaff* should be used in determining compliance with the written description requirement. *Response:* The Guidelines state the general principle that actual reduction to practice is not required to show possession of, or to adequately describe, a claimed invention (although, as noted in the previous comment, an actual reduction to practice is crucial in relatively rare instances). An alternative is to show that the invention described was "ready for patenting" as set out in *Pfaff*. For example, a *description* of activities that demonstrates the invention was "ready for patenting" satisfies the written description requirement. As *Wertheim* indicates, "how the specification accomplishes this is not material." 541 F.2d at 262, 191 USPQ at 96.

(9) *Comment:* One comment stated that the written description of a claimed DNA should be required to include the complete sequence of the DNA and claims should be limited to the DNA sequence disclosed. *Response:* Describing the complete chemical structure, *i.e.*, the DNA sequence, of a claimed DNA is one method of

satisfying the written description requirement, but it is not the only method. See *Eli Lilly*, 119 F.3d at 1566, 43 USPQ2d at 1404 ("An adequate written description of a DNA * * * requires a precise definition, *such as* by structure, formula, chemical name, or physical properties." (emphasis added, internal quote omitted)). Therefore, there is no basis for a *per se* rule requiring disclosure of complete DNA sequences or limiting DNA claims to only the sequence disclosed.

(10) *Comment:* One comment stated that it is difficult to envision how one could provide a description of sufficient identifying characteristics of the invention without physical possession of a species of the invention, and thus this manner of showing possession should be considered as a way to show actual reduction to practice. *Response:* This suggestion has not been adopted. The three ways of demonstrating possession as set forth in the Guidelines are merely exemplary and are not mutually exclusive. While there are some cases where a description of sufficient relevant identifying characteristics will evidence an actual reduction to practice, there are other cases where it will not. See, *e.g.*, *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1576, 227 USPQ 177, 180 (Fed. Cir. 1985) (disclosure taken with the knowledge of those skilled in the art may be sufficient support for claims).

(11) *Comment:* One comment stated that the Guidelines should be revised to indicate that the test of disclosure of sufficiently detailed drawings should be expanded to include structural claiming of chemical entities. *Response:* The suggestion has been adopted.

(12) *Comment:* One comment stated that the Guidelines should reflect that an inventor is in possession of the invention when the inventor demonstrably has at least a complete conception thereof, and that factors and attributes which provide proof of written description should include evidence typically provided to prove a complete conception. *Response:* The suggestion has not been adopted because the conception analysis typically involves documentary evidence in addition to the description of the invention in the application as filed. However, it is acknowledged that if evidence typically provided to prove a complete conception is present in the specification as filed, it would be sufficient to show possession. The Federal Circuit has stated "[t]he conception analysis necessarily turns on the inventor's ability to describe his invention with particularity. Until he can do so, he cannot prove possession

of the complete mental picture of the invention.” *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1228, 32 USPQ2d 1915, 1919 (Fed. Cir. 1994). As further noted by the Federal Circuit, in order to prove conception, “a party must show possession of every feature recited in the count, and that every limitation of the count must have been known to the inventor at the time of the alleged conception.” *Coleman v. Dines*, 754 F.2d 353, 359, 224 USPQ 857, 862 (Fed. Cir. 1985).

(13) *Comment*: One comment indicated that a “possession” test does not appear in Title 35 of the U.S. Code and is not clearly stated by the Federal Circuit. Therefore, it is recommended that patent examiners be directed to use existing judicial precedent to make rejections of claims unsupported by a statutory written description requirement. *Response*: While the Federal Circuit has not specifically laid out a “possession” test, the Court has clearly indicated that possession is a cornerstone of the written description inquiry. *See, e.g., Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991); *see also Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000) (“[o]ne skilled in the art, reading the disclosure, must immediately discern the limitation at issue in the claims”) (internal quote omitted). The possession test as set forth in the Guidelines is extrapolated from case law in a wide variety of technologies and is not intended to be limiting. Any rejections made by examiners will be made under 35 U.S.C. 112, ¶1, with supporting rationale. Final rejections are appealable if applicant disagrees and follows the required procedures to appeal.

(14) *Comment*: Two comments indicated that if the amino acid sequence for a polypeptide whose utility has been identified is described, then the question of possession of a class of nucleotides encoding that polypeptide can be addressed as a relatively routine matter using the understanding of the genetic code, and that the endnote addressing this issue should be revised. *Response*: The suggestion of these comments has been incorporated in the Guidelines and will be reflected in the training materials. However, based upon *In re Bell*, 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994), this does not mean that applicant was in possession of any particular species of the broad genus.

(15) *Comment*: One comment disagreed with an endnote which stated

that a laundry list disclosure of moieties does not constitute a written description of every species in a genus. Specifically, the comment indicates that if the existence of a functional genus is adequately described in the specification, a laundry list of the species within that genus must satisfy the written description requirement.

Response: The suggestion to revise the endnote will not be adopted. A lack of adequate written description problem arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosure. This was aptly demonstrated in *In re Bell* and *In re Baird* where possession of a large genus did not put a person of ordinary skill in the art in possession of any particular species. *See also Purdue Pharma*, 230 F.3d at 1328, 56 USPQ2d at 1487 (because the original specification did not disclose the later claimed concentration ratio was a part of the invention, the inventors cannot argue that they are merely narrowing a broad invention).

(16) *Comment*: One comment suggested that in the majority of cases, a single species will support a generic claim, and that the Guidelines should emphasize this point. *Response*: The suggestion has been adopted to a limited degree. The Guidelines now indicate that a single species may, in some instances, provide an adequate written description of a generic claim when the description of the species would evidence to one of ordinary skill in the art that the invention includes the genus. Note, however, *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 47 USPQ2d 1829 (Fed. Cir. 1998), where the species in the parent application was held not to provide written description support for the genus in the child application.

(17) *Comment*: One comment asserted that the Guidelines should focus on the compliance of the claims, not the specification, with the written description requirement. *Response*: This suggestion will not be adopted. “The specification shall contain a written description of the invention.” 35 U.S.C. 112. The claims are part of the specification. *Id.*, ¶ 2. If an adequate description is provided, it will suffice “whether located among the original claims or in the descriptive part of the specification.” *In re Gardner*, 480 F.2d 879, 880, 178 USPQ 149 (CCPA 1973). The entire disclosure, including the specification, drawings, and claims, must be considered.

(18) *Comment*: One comment asserted that the Guidelines confuse “new matter,” 35 U.S.C. 132, with the written description requirement, and that the

same standard for written description should be applied to both original claims and new or amended claims.

Response: The Guidelines indicate that for both original and amended claims, the inquiry is whether one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention at the time the application was filed.

(19) *Comment*: One comment suggested that the second paragraph of the section pertaining to determining what the claim as a whole covers should be deleted because it relates more to compliance with § 112, second paragraph, than with the written description requirement. *Response*: This suggestion will not be adopted. The claims must be construed and all issues as to the scope and meaning of the claim must be explored during the inquiry into whether the written description requirement has been met. The concept of treating the claim as a whole is applicable to all criteria for patentability.

(20) *Comment*: One comment suggested a different order for the general analysis for determining compliance with the written description requirement, starting with reading the claim, then the specification, and then determining whether the disclosure demonstrates possession by the applicant. *Response*: This suggestion will not be adopted. The claims must be construed as broadly as reasonable in light of the specification and the knowledge in the art. *See In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). Then the disclosure must be evaluated to determine whether it adequately describes the claimed invention, i.e., whether it conveys to a person having ordinary skill in the art that the applicant had possession of what he or she now claims.

(21) *Comment*: Several comments suggested that the Guidelines are unclear with regard to how the examiner should treat the transitional phrase “consisting essentially of.” The comments also suggested that the endnote that explains “consisting essentially of” does not make clear how the use of this intermediate transitional language affects the scope of the claim. Several comments stated that the USPTO does not have legal authority to treat claims reciting this language as open (equivalent to “comprising”). Another comment suggested that the phrase “clear indication in the specification” be replaced with “explicit or implicit indication.” *Response*: The transitional phrase “consisting essentially of” “excludes

ingredients that would 'materially affect the basic and novel characteristics' of the claimed composition." *Atlas Powder Co. v. E.I. DuPont de Nemours & Co.*, 750 F.2d 1569, 1574, 224 USPQ 409, 412 (Fed. Cir. 1984). The basic and novel characteristics of the claimed invention are limited by the balance of the claim. *In re Janakirama-Rao*, 317 F.2d 951, 954, 137 USPQ 893, 896 (CCPA 1963). However, during prosecution claims must be read broadly, consistent with the specification. *In re Morris*, 127 F.3d 1048, 1054, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). Thus, for purposes of searching for and applying prior art in a rejection under 35 U.S.C. 102 or 103, if the specification or the claims do not define the "basic and novel" properties of the claimed subject matter (or if such properties are in dispute), the broadest reasonable interpretation consistent with the specification is that the basic and novel characteristics are merely the presence of the recited limitations. See, e.g., *Janakirama-Rao*, 317 F.2d at 954, 137 USPQ at 895-96. This does not indicate that the intermediate transitional language is never given weight. Applicants may amend the claims to avoid the rejections or seek to establish that the specification provides definitions of terms in the claims that define the basic and novel characteristics of the claimed invention which distinguish the claimed invention from the prior art. When an applicant contends that additional steps or materials in the prior art are excluded by the recitation of 'consisting essentially of,' applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). The language used in the Guidelines is consistent with *PPG Industries Inc. v. Guardian Industries Corp.*, 156 F.3d 1351, 1355, 48 USPQ2d 1351, 1355 (Fed. Cir. 1998) ("PPG could have defined the scope of the phrase 'consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics.").

(22) *Comment*: One comment stated that the written description should "disclose the invention," including why the invention works and how it was developed. *Response*: This suggestion has not been adopted. An inventor does not need to know how or why the invention works in order to obtain a patent. *Newman v. Quigg*, 877 F.2d 1575, 1581, 11 USPQ2d 1340, 1345

(Fed. Cir. 1989). To satisfy the enablement requirement of 35 U.S.C. 112, ¶1, an application must disclose the claimed invention in sufficient detail to enable a person of ordinary skill in the art to make and use the claimed invention. To satisfy the written description requirement of 35 U.S.C. 112, ¶1, the description must show that the applicant was in possession of the claimed invention at the time of filing. There is no statutory basis to require disclosure of why an invention works or how it was developed. "Patentability shall not be negated by the manner in which the invention was made." 35 U.S.C. 103(a).

(23) *Comment*: One comment recommended that the phrases "emerging and unpredictable technologies" and "unpredictable art" be replaced with the phrase—inventions characterized by factors which are not reasonably predictable in terms of the ordinary skill in the art—. *Response*: The suggestion is adopted in part and the recommended phrase has been added as an alternative.

(24) *Comment*: One comment recommended that the phrase "conventional in the art" be replaced with—part of the knowledge of one of ordinary skill in the art—. *Response*: The suggestion is adopted in part and the recommended phrase has been added as an alternative. The standard of "conventional in the art" is supported by case law holding that a patent specification "need not teach, and preferably omits, what is well known in the art." See *Spectra-Physics, Inc. v. Coherent, Inc.*, 827 F.2d 1524, 1534, 3 USPQ2d 1737, 1743 (Fed. Cir. 1987); *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986). See also *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 1382, 53 USPQ2d 1225, 1231 (Fed. Cir. 1999).

(25) *Comment*: One comment recommended that the Guidelines be amended to state that the appropriate skill level for determining possession of the claimed invention is that of a person of ordinary skill in the art. *Response*: The comment has not been adopted. The statutory language itself indicates that compliance with the requirements of 35 U.S.C. 112, ¶1, is judged from the standard of "any person skilled in the art." It is noted, however, that the phrases "one of skill in the art" and "one of ordinary skill in the art" appear to be synonymous. See, e.g., *Union Oil Co. v. Atlantic Richfield Co.*, 208 F.3d 989, 997, 54 USPQ2d 1227, 1232 (Fed. Cir. 2000) ("The written description requirement does not require the applicant 'to describe exactly the subject

matter claimed, [instead] the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.' Thus, § 112, ¶ 1, ensures that, as of the filing date, the inventor conveyed with reasonable clarity to those of skill in the art that he was in possession of the subject matter of the claims." (citations omitted, emphasis added)).

(26) *Comment*: One comment stated that an endnote misstates the relevant law in stating that, to show inherent written descriptive support for a claim limitation, the inherent disclosure must be such as would be recognized by a person of ordinary skill in the art. The comment recommended that the endnote be amended to delete the reference to recognition by persons of ordinary skill and to cite *Pingree v. Hull*, 518 F.2d 624, 186 USPQ 248 (CCPA 1975), rather than *In re Robertson*, 169 F.3d 743, 49 USPQ2d 1949 (Fed. Cir. 1999). *Response*: The comment has not been adopted. Federal Circuit precedent makes clear that an inherent disclosure must be recognized by those of ordinary skill in the art. See, e.g., *Hyatt v. Boone*, 146 F.3d 1348, 1354-55, 47 USPQ2d 1128, 1132 (Fed. Cir. 1998) ("[T]he purpose of the description requirement is 'to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him.' * * * Thus, the written description must include all of the limitations of the interference count, or the applicant must show that any absent text is necessarily comprehended in the description provided and would have been so understood at the time the patent application was filed." (emphasis added)). See also *Reiffin v. Microsoft Corp.*, 214 F.3d 1342, 1346, 54 USPQ2d 1915, 1917 (Fed. Cir. 2000) (The "application considered as a whole must convey to one of ordinary skill in the art, either explicitly or inherently, that [the inventor] invented the subject matter claimed * * * . See * * * *Continental Can Co. USA v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 USPQ2d 1746, 1749 (Fed. Cir. 1991) (descriptive matter may be inherently present in a specification if one skilled in the art would necessarily recognize such a disclosure)").

(27) *Comment*: Several comments pointed out an inconsistency in the **Federal Register** Notice re: the Revised Interim Written Description Guidelines. The inconsistency concerned the treatment of claims directed to an isolated DNA comprising SEQ ID NO:1 wherein SEQ ID NO:1 is an expressed sequence tag. The comments contrasted paragraphs 34 and 35 of the Response to

Public Comments with the statement in the text of the Guidelines that a genus must be supported by a representative number of species (as analyzed in Example 7 of the training materials). *Response:* The USPTO acknowledges that there was an inconsistency. The Office notes that a claim reciting a nucleic acid comprising SEQ ID NO:1 may be subject to a rejection for lack of an adequate written description where particular identifiable species within the scope of the claim lack an adequate written description. The training materials as amended exemplify an appropriate analysis.

(28) *Comment:* One comment stated that the USPTO should respond to the issue of whether the U.S. is meeting its TRIPs obligations. This comment noted that the USPTO did not address an earlier comment regarding the "Interim Guidelines for the Examination of Patent Applications under the 35 U.S.C. 112, ¶ 1, 'Written Description' Requirement," 63 FR 32,639, June 15, 1998, which questioned whether the written description requirement is truly different from the enablement requirement, and indicated that such a requirement may be contrary to the TRIPs provisions of the World Trade Organization (Article 27.1). Article 27.1 requires WTO Members to, *inter alia*, make patents available, with limited exceptions, for products and processes in all fields of technology so long as those products and processes are new, involve an inventive step, and are capable of industrial application. The comment further suggested a response. *Response:* TRIPs Article 27 does not address what must be included in a patent application to allow WTO Member officials to determine whether particular inventions meet the standards for patentability established in that Article. TRIPs Article 29, which is more relevant to this comment, states that Members "shall require" patent applicants to disclose their invention "in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art." If the written description is not clear and complete, the applicant may not have been in possession of the invention. This may support both written description and enablement standards. In addition, Article 29 expressly authorizes Members to require patent applicants to disclose the best method the inventor knows at the time of filing an application for carrying out the invention.

(29) *Comment:* Two comments commended the USPTO for eliminating the Biotechnology Specific Examples in the Revised Interim Written Description

Guidelines and providing separate training materials. One comment indicated a need to reconfirm the examples set forth in the Interim Written Description Guidelines published in 1998. *Response:* The current training materials reflect the manner in which the USPTO interprets the Written Description Guidelines.

(30) *Comment:* Several comments addressed specific concerns about the examiner training materials. *Response:* The comments received with respect to the training materials will be taken under advisement as the Office revises the training materials in view of the revisions to the Guidelines. The specific comments will not be addressed herein as they do not impact the language of the Guidelines.

Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1, "Written Description" Requirement

These "Written Description Guidelines" are intended to assist Office personnel in the examination of patent applications for compliance with the written description requirement of 35 U.S.C. 112, ¶ 1. This revision is based on the Office's current understanding of the law and public comments received in response to the USPTO's previous request for public comments on its Revised Interim Written Description Guidelines and is believed to be fully consistent with binding precedent of the U.S. Supreme Court, as well as the U.S. Court of Appeals for the Federal Circuit and its predecessor courts.

This revision does not constitute substantive rulemaking and hence does not have the force and effect of law. It is designed to assist Office personnel in analyzing claimed subject matter for compliance with substantive law. Rejections will be based upon the substantive law, and it is these rejections which are appealable. Consequently, any perceived failure by Office personnel to follow these Guidelines is neither appealable nor petitionable.

These Guidelines are intended to form part of the normal examination process. Thus, where Office personnel establish a *prima facie* case of lack of written description for a claim, a thorough review of the prior art and examination on the merits for compliance with the other statutory requirements, including those of 35 U.S.C. 101, 102, 103, and 112, is to be conducted prior to completing an Office action which includes a rejection for lack of written description. Office personnel are to rely on this revision of the Guidelines in the event of any inconsistent treatment of

issues involving the written description requirement between these Guidelines and any earlier guidance provided from the Office.

I. General Principles Governing Compliance With the "Written Description" Requirement for Applications

The first paragraph of 35 U.S.C. 112 requires that the "specification shall contain a written description of the invention * * *." This requirement is separate and distinct from the enablement requirement.¹ The written description requirement has several policy objectives. "[T]he 'essential goal' of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed."² Another objective is to put the public in possession of what the applicant claims as the invention.³ The written description requirement of the Patent Act promotes the progress of the useful arts by ensuring that patentees adequately describe their inventions in their patent specifications in exchange for the right to exclude others from practicing the invention for the duration of the patent's term.

To satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention.⁴ An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention.⁵ Possession may be shown in a variety of ways including description of an actual reduction to practice,⁶ or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete,⁷ or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention.⁸ A question as to whether a specification provides an adequate written description may arise in the context of an original claim which is not described sufficiently, a new or amended claim wherein a claim limitation has been added or removed, or a claim to entitlement of an earlier priority date or effective filing date under 35 U.S.C. 119, 120, or 365(c).⁹ Compliance with the written description requirement is a question of

fact which must be resolved on a case-by-case basis.¹⁰

A. Original Claims

There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed.¹¹ However, the issue of a lack of adequate written description may arise even for an original claim when an aspect of the claimed invention has not been described with sufficient particularity such that one skilled in the art would recognize that the applicant had possession of the claimed invention.¹² The claimed invention as a whole may not be adequately described if the claims require an essential or critical feature which is not adequately described in the specification and which is not conventional in the art or known to one of ordinary skill in the art.¹³ This problem may arise where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function.¹⁴ A lack of adequate written description issue also arises if the knowledge and level of skill in the art would not permit one skilled in the art to immediately envisage the product claimed from the disclosed process.¹⁵

B. New or Amended Claims

The proscription against the introduction of new matter in a patent application¹⁶ serves to prevent an applicant from adding information that goes beyond the subject matter originally filed.¹⁷ Thus, the written description requirement prevents an applicant from claiming subject matter that was not adequately described in the specification as filed. New or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement.¹⁸ While there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure. An amendment to correct an obvious error does not constitute new matter where one skilled in the art would not only recognize the existence of the error in the specification, but also recognize the appropriate correction.¹⁹ Deposits made after the application filing date cannot be relied upon to support additions to or correction of information in the application as filed.²⁰

Under certain circumstances, omission of a limitation can raise an

issue regarding whether the inventor had possession of a broader, more generic invention.²¹ A claim that omits an element which applicant describes as an essential or critical feature of the invention originally disclosed does not comply with the written description requirement.²²

The fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed.²³

II. Methodology for Determining Adequacy of Written Description

A. Read and Analyze the Specification for Compliance With 35 U.S.C. 112, ¶1

Office personnel should adhere to the following procedures when reviewing patent applications for compliance with the written description requirement of 35 U.S.C. 112, ¶1. The examiner has the initial burden, after a thorough reading and evaluation of the content of the application, of presenting evidence or reasons why a person skilled in the art would not recognize that the written description of the invention provides support for the claims. There is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed;²⁴ however, with respect to newly added or amended claims, applicant should show support in the original disclosure for the new or amended claims.²⁵ Consequently, rejection of an original claim for lack of written description should be rare. The inquiry into whether the description requirement is met is a question of fact that must be determined on a case-by-case basis.²⁶

1. For Each Claim, Determine What the Claim as a Whole Covers

Claim construction is an essential part of the examination process. Each claim must be separately analyzed and given its broadest reasonable interpretation in light of and consistent with the written description.²⁷ The entire claim must be considered, including the preamble language²⁸ and the transitional phrase.²⁹ The claim as a whole, including all limitations found in the preamble,³⁰ the transitional phrase, and the body of the claim, must be sufficiently supported to satisfy the written description requirement.³¹

The examiner should evaluate each claim to determine if sufficient structures, acts, or functions are recited to make clear the scope and meaning of the claim, including the weight to be given the preamble.³² The absence of definitions or details for well-

established terms or procedures should not be the basis of a rejection under 35 U.S.C. 112, ¶1, for lack of adequate written description. Limitations may not, however, be imported into the claims from the specification.

2. Review the Entire Application to Understand How Applicant Provides Support for the Claimed Invention Including Each Element and/or Step

Prior to determining whether the disclosure satisfies the written description requirement for the claimed subject matter, the examiner should review the claims and the entire specification, including the specific embodiments, figures, and sequence listings, to understand how applicant provides support for the various features of the claimed invention.³³ The analysis of whether the specification complies with the written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention. Such a review is conducted from the standpoint of one of skill in the art at the time the application was filed³⁴ and should include a determination of the field of the invention and the level of skill and knowledge in the art. Generally, there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement. Information which is well known in the art need not be described in detail in the specification.³⁵

3. Determine Whether There is Sufficient Written Description to Inform a Skilled Artisan That Applicant was in Possession of the Claimed Invention as a Whole at the Time the Application Was Filed

a. Original claims. Possession may be shown in many ways. For example, possession may be shown, *inter alia*, by describing an actual reduction to practice of the claimed invention. Possession may also be shown by a clear depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that applicant had possession of the claimed invention. An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention.³⁶

A specification may describe an actual reduction to practice by showing

that the inventor constructed an embodiment or performed a process that met all the limitations of the claim and determined that the invention would work for its intended purpose.³⁷ Description of an actual reduction to practice of a biological material may be shown by specifically describing a deposit made in accordance with the requirements of 37 CFR 1.801 *et seq.*³⁸

An applicant may show possession of an invention by disclosure of drawings³⁹ or structural chemical formulas⁴⁰ that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. The description need only describe in detail that which is new or not conventional.⁴¹ This is equally true whether the claimed invention is directed to a product or a process.

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics⁴² which provide evidence that applicant was in possession of the claimed invention,⁴³ *i.e.*, complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.⁴⁴ What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail.⁴⁵ If a skilled artisan would have understood the inventor to be in possession of the claimed invention at the time of filing, even if every nuance of the claims is not explicitly described in the specification, then the adequate description requirement is met.⁴⁶

(1) For each claim drawn to a single embodiment or species:⁴⁷

(a) Determine whether the application describes an actual reduction to practice of the claimed invention.

(b) If the application does not describe an actual reduction to practice, determine whether the invention is complete as evidenced by a reduction to drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole.

(c) If the application does not describe an actual reduction to practice or reduction to drawings or structural chemical formula as discussed above, determine whether the invention has been set forth in terms of distinguishing identifying characteristics as evidenced by other descriptions of the invention that are sufficiently detailed to show that applicant was in possession of the claimed invention.

(i) Determine whether the application as filed describes the complete structure

(or acts of a process) of the claimed invention as a whole. The complete structure of a species or embodiment typically satisfies the requirement that the description be set forth "in such full, clear, concise, and exact terms" to show possession of the claimed invention.⁴⁸ If a complete structure is disclosed, the written description requirement is satisfied for that species or embodiment, and a rejection under 35 U.S.C. 112, ¶ 1, for lack of written description must not be made.

(ii) If the application as filed does not disclose the complete structure (or acts of a process) of the claimed invention as a whole, determine whether the specification discloses other relevant identifying characteristics sufficient to describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention.⁴⁹

Whether the specification shows that applicant was in possession of the claimed invention is not a single, simple determination, but rather is a factual determination reached by considering a number of factors. Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient.⁵⁰ Patents and printed publications in the art should be relied upon to determine whether an art is mature and what the level of knowledge and skill is in the art. In most technologies which are mature, and wherein the knowledge and level of skill in the art is high, a written description question should not be raised for original claims even if the specification discloses only a method of making the invention and the function of the invention.⁵¹ In contrast, for inventions in emerging and unpredictable technologies, or for inventions characterized by factors not reasonably predictable which are known to one of ordinary skill in the art, more evidence is required to show possession. For example, disclosure of only a method of making the invention and the function may not be sufficient to support a product claim other than a

product-by-process claim.⁵² Furthermore, disclosure of a partial structure without additional characterization of the product may not be sufficient to evidence possession of the claimed invention.⁵³

Any claim to a species that does not meet the test described under at least one of (a), (b), or (c) must be rejected as lacking adequate written description under 35 U.S.C. 112, ¶ 1.

(2) For each claim drawn to a genus:

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice (see (1)(a), above), reduction to drawings (see (1)(b), above), or by disclosure of relevant, identifying characteristics, *i.e.*, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see (1)(c), above).⁵⁴

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. On the other hand, there may be situations where one species adequately supports a genus.⁵⁵ What constitutes a "representative number" is an inverse function of the skill and knowledge in the art. Satisfactory disclosure of a "representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed. For inventions 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.⁵⁶ Description of a representative number of species does not require the description to be of such specificity that it would provide individual support for each species that the genus embraces.⁵⁷ If a representative number of adequately described species are not disclosed for a genus, the claim to that genus must be rejected as lacking adequate written description under 35 U.S.C. 112, ¶ 1.

b. New claims, amended claims, or claims asserting entitlement to the benefit of an earlier priority date or filing date under 35 U.S.C. 119, 120, or

365(c). The examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the original disclosure a description of the invention defined by the claims.⁵⁸ However, when filing an amendment an applicant should show support in the original disclosure for new or amended claims.⁵⁹ To comply with the written description requirement of 35 U.S.C. 112, ¶ 1, or to be entitled to an earlier priority date or filing date under 35 U.S.C. 119, 120, or 365(c), each claim limitation must be expressly,⁶⁰ implicitly,⁶¹ or inherently⁶² supported in the originally filed disclosure.⁶³ Furthermore, each claim must include all elements which applicant has described as essential.⁶⁴

If the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, ¶ 1, as lacking adequate written description, or in the case of a claim for priority under 35 U.S.C. 119, 120, or 365(c), the claim for priority must be denied.

III. Complete Patentability Determination Under All Statutory Requirements and Clearly Communicate Findings, Conclusions, and Their Bases

The above only describes how to determine whether the written description requirement of 35 U.S.C. 112, ¶ 1, is satisfied. Regardless of the outcome of that determination, Office personnel must complete the patentability determination under all the relevant statutory provisions of title 35 of the U.S. Code.

Once Office personnel have concluded analysis of the claimed invention under all the statutory provisions, including 35 U.S.C. 101, 112, 102, and 103, they should review all the proposed rejections and their bases to confirm their correctness. Only then should any rejection be imposed in an Office action. The Office action should clearly communicate the findings, conclusions, and reasons which support them. When possible, the Office action should offer helpful suggestions on how to overcome rejections.

A. For Each Claim Lacking Written Description Support, Reject the Claim Under Section 112, ¶ 1, for Lack of Adequate Written Description

A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary

has been presented by the examiner to rebut the presumption.⁶⁵ The examiner, therefore, must have a reasonable basis to challenge the adequacy of the written description. The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims.⁶⁶ In rejecting a claim, the examiner must set forth express findings of fact regarding the above analysis which support the lack of written description conclusion. These findings should:

- (1) Identify the claim limitation at issue; and
- (2) Establish a *prima facie* case by providing reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in possession of the invention as claimed in view of the disclosure of the application as filed. A general allegation of "unpredictability in the art" is not a sufficient reason to support a rejection for lack of adequate written description.

When appropriate, suggest amendments to the claims which can be supported by the application's written description, being mindful of the prohibition against the addition of new matter in the claims or description.⁶⁷

B. Upon Reply by Applicant, Again Determine the Patentability of the Claimed Invention, Including Whether the Written Description Requirement Is Satisfied by Reperforming the Analysis Described Above in View of the Whole Record

Upon reply by applicant, before repeating any rejection under 35 U.S.C. 112, ¶ 1, for lack of written description, review the basis for the rejection in view of the record as a whole, including amendments, arguments, and any evidence submitted by applicant. If the whole record now demonstrates that the written description requirement is satisfied, do *not* repeat the rejection in the next Office action. If the record still does not demonstrate that the written description is adequate to support the claim(s), repeat the rejection under 35 U.S.C. 112, ¶ 1, fully respond to applicant's rebuttal arguments, and properly treat any further showings submitted by applicant in the reply. When a rejection is maintained, any affidavits relevant to the 112, ¶ 1, written description requirement,⁶⁸ must be thoroughly analyzed and discussed in the next Office action.

Dated: December 29, 2000.

Q. Todd Dickinson,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

Endnotes

¹ See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991).

² *In re Barker*, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977).

³ See *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1566, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998).

⁴ See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. Much of the written description case law addresses whether the specification as originally filed supports claims not originally in the application. The issue raised in the cases is most often phrased as whether the original application provides "adequate support" for the claims at issue or whether the material added to the specification incorporates "new matter" in violation of 35 U.S.C. 132. The "written description" question similarly arises in the interference context, where the issue is whether the specification of one party to the interference can support the newly added claims corresponding to the count at issue, *i.e.*, whether that party can "make the claim" corresponding to the interference count. See, e.g., *Martin v. Mayer*, 823 F.2d 500, 503, 3 USPQ2d 1333, 1335 (Fed. Cir. 1987).

In addition, early opinions suggest the Patent and Trademark Office was unwilling to find written descriptive support when the only description was found in the claims; however, this viewpoint was rejected. See *In re Koller*, 613 F.2d 819, 204 USPQ 702 (CCPA 1980) (original claims constitute their own description); *accord In re Gardner*, 475 F.2d 1389, 177 USPQ 396 (CCPA 1973); *accord In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976) (*accord*). It is now well accepted that a satisfactory description may be in the claims or any other portion of the originally filed specification. These early opinions did not address the quality or specificity of particularity that was required in the description, *i.e.*, how much description is enough.

⁵ *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

⁶ An application specification may show actual reduction to practice by describing testing of the claimed invention or, in the case of biological materials, by specifically describing a deposit made in accordance with 37 CFR 1.801 *et seq.* See also *Deposit of Biological Materials for Patent Purposes, Final Rule*, 54 FR 34,864 (August 22, 1989) ("The requirement for a specific identification is consistent with the description requirement of the first paragraph of 35 U.S.C. 112, and to provide an antecedent basis for the biological material which either has been or will be deposited before the patent is granted." *Id.* at 34,876. "The description must be sufficient to permit verification that the deposited biological material is in fact that disclosed. Once the

patent issues, the description must be sufficient to aid in the resolution of questions of infringement.” *Id.* at 34,880.) Such a deposit is not a substitute for a written description of the claimed invention. The written description of the deposited material needs to be as complete as possible because the examination for patentability proceeds solely on the basis of the written description. *See, e.g., In re Lundak*, 773 F.2d 1216, 227 USPQ 90 (Fed. Cir. 1985). *See also* 54 FR at 34,880 (“As a general rule, the more information that is provided about a particular deposited biological material, the better the examiner will be able to compare the identity and characteristics of the deposited biological material with the prior art.”).

⁷ *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

⁸ *See Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by “whatever characteristics sufficiently distinguish it”).

⁹ A description requirement issue can arise for original claims (*see, e.g., Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398) as well as new or amended claims. Most typically, the issue will arise in the context of determining whether new or amended claims are supported by the description of the invention in the application as filed (*see, e.g., In re Wright*, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989)), whether a claimed invention is entitled to the benefit of an earlier priority date or effective filing date under 35 U.S.C. 119, 120, or 365(c) (*see, e.g., Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 47 USPQ2d 1829 (Fed. Cir. 1998); *Fiens v. Revel*, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993); *In re Ziegler*, 992 F.2d 1197, 1200, 26 USPQ2d 1600, 1603 (Fed. Cir. 1993)), or whether a specification provides support for a claim corresponding to a count in an interference (*see, e.g., Fields v. Conover*, 443 F.2d 1386, 170 USPQ 276 (CCPA 1971)).

¹⁰ *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116 (Fed. Cir. 1991).

¹¹ *In re Wertheim*, 541 F.2d 257, 263, 191 USPQ 90, 97 (CCPA 1976) (“we are of the opinion that the PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims”).

¹² See endnote 4.

¹³ For example, consider the claim “A gene comprising SEQ ID NO:1.” A determination of what the claim as a whole covers may result in a conclusion that specific structures such as a promoter, a coding region, or other elements are included. Although all genes encompassed by this claim share the characteristic of comprising SEQ ID NO:1, there may be insufficient description of those specific structures (*e.g.*, promoters, enhancers, coding regions, and other regulatory elements) which are also included.

¹⁴ A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying

characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence. For example, even though a genetic code table would correlate a known amino acid sequence with a genus of coding nucleic acids, the same table cannot predict the native, naturally occurring nucleic acid sequence of a naturally occurring mRNA or its corresponding cDNA. *Cf. In re Bell*, 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993), and *In re Deuel*, 51 F.3d 1552, 34 USPQ2d 1210 (Fed. Cir. 1995) (holding that a process could not render the product of that process obvious under 35 U.S.C. 103). The Federal Circuit has pointed out that under United States law, a description that does not render a claimed invention obvious cannot sufficiently describe the invention for the purposes of the written description requirement of 35 U.S.C. 112. *Eli Lilly*, 119 F.3d at 1567, 43 USPQ2d at 1405.

Compare Fonar Corp. v. General Electric Co., 107 F.3d 1543, 1549, 41 USPQ2d 1801, 1805 (Fed. Cir. 1997) (“As a general rule, where software constitutes part of a best mode of carrying out an invention, description of such a best mode is satisfied by a disclosure of the functions of the software. This is because, normally, writing code for such software is within the skill of the art, not requiring undue experimentation, once its functions have been disclosed. * * * Thus, flow charts or source code listings are not a requirement for adequately disclosing the functions of software.”).

¹⁵ *See, e.g., Fujikawa v. Wattanasin*, 93 F.3d 1559, 1571, 39 USPQ2d 1895, 1905 (Fed. Cir. 1996) (a “laundry list” disclosure of every possible moiety does not constitute a written description of every species in a genus because it would not “reasonably lead” those skilled in the art to any particular species); *In re Ruschig*, 379 F.2d 990, 995, 154 USPQ 118, 123 (CCPA 1967) (“If n-propylamine had been used in making the compound instead of n-butylamine, the compound of claim 13 would have resulted. Appellants submit to us, as they did to the board, an imaginary specific example patterned on specific example 6 by which the above butyl compound is made so that we can see what a simple change would have resulted in a specific supporting disclosure being present in the present specification. The trouble is that there is no such disclosure, easy though it is to imagine it.”) (emphasis in original); *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000) (“the specification does not clearly disclose to the skilled artisan that the inventors * * * considered the [] ratio to be part of their invention * * *. There is therefore no force to Purdue’s argument that the written description requirement was satisfied because the disclosure revealed a broad invention from which the [later-filed] claims carved out a patentable portion”).

¹⁶ 35 U.S.C. §§ 132 and 251. *See also In re Rasmussen*, 650 F.2d 1212, 1214, 211 USPQ 323, 326 (CCPA 1981). *See Manual of Patent Examining Procedure (MPEP)* §§ 2163.06–2163.07 (7th Ed., Rev. 1, Feb. 2000) for a more detailed discussion of the written description requirement and its relationship to new matter.

¹⁷ The claims as filed in the original specification are part of the disclosure and, therefore, if an application as originally filed contains a claim disclosing material not found in the remainder of the specification, the applicant may amend the specification to include the claimed subject matter. *In re Benno*, 768 F.2d 1340, 226 USPQ 683 (Fed. Cir. 1985).

¹⁸ *See, e.g., In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971) (subgenus range was not supported by generic disclosure and specific example within the subgenus range); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily described by a genus encompassing it and a species upon which it reads).

¹⁹ *In re Oda*, 443 F.2d 1200, 170 USPQ 260 (CCPA 1971). With respect to the correction of sequencing errors in applications disclosing nucleic acid and/or amino acid sequences, it is well known that sequencing errors are a common problem in molecular biology. *See, e.g., Peter Richterich, Estimation of Errors in ‘Raw’ DNA Sequences: A Validation Study*, 8 Genome Research 251–59 (1998). If an application as filed includes sequence information and references a deposit of the sequenced material made in accordance with the requirements of 37 CFR § 1.801 et seq., amendment may be permissible.

²⁰ Corrections of minor errors in the sequence may be possible based on the argument that one of skill in the art would have resequenced the deposited material and would have immediately recognized the minor error. Deposits made after the filing date can only be relied upon to provide support for the correction of sequence information if applicant submits a statement in compliance with 37 CFR § 1.804 stating that the biological material which is deposited is a biological material specifically defined in the application as filed.

²¹ *See, e.g., Gentry Gallery, Inc. v. Berklene Corp.*, 134 F.3d 1473, 45 USPQ2d 1498 (Fed. Cir. 1998) (claims to a sectional sofa comprising, *inter alia*, a console and a control means were held invalid for failing to satisfy the written description requirement where the claims were broadened by removing the location of the control means.); *Johnson Worldwide Associates v. Zebco Corp.*, 175 F.3d 985, 993, 50 USPQ2d 1607, 1613 (Fed. Cir. 1999) (In *Gentry Gallery*, the “court’s determination that the patent disclosure did not support a broad meaning for the disputed claim terms was premised on clear statements in the written description that described the location of a claim element—the ‘control means’—as ‘the only possible location’ and that variations were ‘outside the stated purpose of the invention.’ *Gentry Gallery*, 134 F.3d at 1479, 45 USPQ2d at 1503. *Gentry Gallery*, then, considers the situation where the patent’s disclosure makes crystal clear that a particular (*i.e.*, narrow) understanding of a claim term is an ‘essential element of [the inventor’s] invention.’”); *Tronzo v. Biomet*, 156 F.3d at 1158–59, 47 USPQ2d at 1833 (Fed. Cir. 1998) (claims to generic cup shape were not entitled to filing date of parent application which disclosed “conical cup” in view of the disclosure of the

parent application stating the advantages and importance of the conical shape.)

²² See *Gentry Gallery*, 134 F.3d at 1480, 45 USPQ2d at 1503; *In re Sus*, 306 F.2d 494, 504, 134 USPQ 301, 309 (CCPA 1962) (“[O]ne skilled in this art would not be taught by the written description of the invention in the specification that any ‘aryl or substituted aryl radical’ would be suitable for the purposes of the invention but rather that only certain aryl radicals and certain specifically substituted aryl radicals [i.e., aryl azides] would be suitable for such purposes.”) (emphasis in original). A claim which omits matter disclosed to be essential to the invention as described in the specification or in other statements of record may also be subject to rejection under 35 U.S.C. 112, ¶ 1, as not enabling, or under 35 U.S.C. 112, ¶ 2. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976); *In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976); and *In re Collier*, 397 F.2d 1003, 158 USPQ 266 (CCPA 1968). See also MPEP § 2172.01.

²³ See, e.g., *Vas-Cath, Inc.*, 935 F.2d at 1563–64, 19 USPQ2d at 1117.

²⁴ *Wertheim*, 541 F.2d at 262, 191 USPQ at 96.

²⁵ See MPEP §§ 714.02 and 2163.06 (“Applicant should * * * specifically point out the support for any amendments made to the disclosure.”); and MPEP § 2163.04 (“If applicant amends the claims and points out where and/or how the originally filed disclosure supports the amendment(s), and the examiner finds that the disclosure does not reasonably convey that the inventor had possession of the subject matter of the amendment at the time of the filing of the application, the examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims.”).

²⁶ See *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (“Precisely how close [to the claimed invention] the description must come to comply with § 112 must be left to case-by-case development.”); *In re Wertheim*, 541 F.2d at 262, 191 USPQ at 96 (inquiry is primarily factual and depends on the nature of the invention and the amount of knowledge imparted to those skilled in the art by the disclosure).

²⁷ See, e.g., *In re Morris*, 127 F.3d 1048, 1053–54, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997).

²⁸ “Preamble language” is that language in a claim appearing before the transitional phrase, e.g., before “comprising,” “consisting essentially of,” or “consisting of.”

²⁹ The transitional term “comprising” (and other comparable terms, e.g., “containing,” “including,” and “having”) is “open-ended—it covers the expressly recited subject matter, alone or in combination with unrecited subject matter. See, e.g., *Genentech, Inc. v. Chiron Corp.*, 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) (“‘Comprising’ is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.”); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948) (“comprising” leaves the

“claim open for the inclusion of unspecified ingredients even in major amounts”). “By using the term ‘consisting essentially of,’ the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially affect the basic and novel properties of the invention. A ‘consisting essentially of’ claim occupies a middle ground between closed claims that are written in a ‘consisting of’ format and fully open claims that are drafted in a ‘comprising’ format.” *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353–54 (Fed. Cir. 1998). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, “consisting essentially of” will be construed as equivalent to “comprising.” See, e.g., *PPG*, 156 F.3d at 1355, 48 USPQ2d at 1355 (“PPG could have defined the scope of the phrase ‘consisting essentially of’ for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention.”). See also *In re Janakirama-Rao*, 317 F.2d 951, 954, 137 USPQ 893, 895–96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of “consisting essentially of,” applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant’s invention. *In re De LaJarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964).

³⁰ See *Pac-Tec Inc. v. Amerace Corp.*, 903 F.2d 796, 801, 14 USPQ2d 1871, 1876 (Fed. Cir. 1990) (determining that preamble language that constitutes a structural limitation is actually part of the claimed invention).

³¹ An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations. *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

³² See, e.g., *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995) (“[A] claim preamble has the import that the claim as a whole suggests for it.”); *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989) (“The determination of whether preamble recitations are structural limitations can be resolved only on review of the entirety of the application “to gain an understanding of what the inventors actually invented and intended to encompass by the claim.”).

³³ An element may be critical where those of skill in the art would require it to determine that applicant was in possession of the invention. *Compare Rasmussen*, 650 F.2d at 1215, 211 USPQ at 327 (“one skilled in the art who read Rasmussen’s specification would understand that it is unimportant how the layers are adhered, so long as they are adhered”) (emphasis in original), with *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (“it is well established in our law that conception of a chemical

compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it”).

³⁴ See, e.g., *Wang Labs. v. Toshiba Corp.*, 993 F.2d 858, 865, 26 USPQ2d 1767, 1774 (Fed. Cir. 1993).

³⁵ See, e.g., *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379–80, 231 USPQ 81, 90 (Fed. Cir. 1986).

³⁶ See, e.g., *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, ___, 56 USPQ2d 1481, 1483 (Fed. Cir. 2000) (the written description “inquiry is a factual one and must be assessed on a case-by-case basis”); see also *Pfaff v. Wells Electronics, Inc.*, 55 U.S. at 66, 119 S.Ct. at 311, 48 USPQ2d at 1646 (“The word ‘invention’ must refer to a concept that is complete, rather than merely one that is ‘substantially complete.’ It is true that reduction to practice ordinarily provides the best evidence that an invention is complete. But just because reduction to practice is sufficient evidence of completion, it does not follow that proof of reduction to practice is necessary in every case. Indeed, both the facts of the *Telephone Cases* and the facts of this case demonstrate that one can prove that an invention is complete and ready for patenting before it has actually been reduced to practice.”).

³⁷ *Cooper v. Goldfarb*, 154 F.3d 1321, 1327, 47 USPQ2d 1896, 1901 (Fed. Cir. 1998). See also *UMC Elecs. Co. v. United States*, 816 F.2d 647, 652, 2 USPQ2d 1465, 1468 (Fed. Cir. 1987) (“[T]here cannot be a reduction to practice of the invention * * * without a physical embodiment which includes all limitations of the claim.”); *Estee Lauder Inc. v. L’Oreal, S.A.*, 129 F.3d 588, 593, 44 USPQ2d 1610, 1614 (Fed. Cir. 1997) (“[A] reduction to practice does not occur until the inventor has determined that the invention will work for its intended purpose.”); *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1578, 38 USPQ2d 1288, 1291 (Fed. Cir. 1996) (determining that the invention will work for its intended purpose may require testing depending on the character of the invention and the problem it solves).

³⁸ 37 CFR 1.804, 1.809. See also endnote 6.

³⁹ See, e.g., *Vas-Cath*, 935 F.2d at 1565, 19 USPQ2d at 1118 (“drawings alone may provide a ‘written description’ of an invention as required by § 112”); *In re Wolfensperger*, 302 F.2d 950, 133 USPQ 537 (CCPA 1962) (the drawings of applicant’s specification provided sufficient written descriptive support for the claim limitation at issue); *Autogiro Co. of America v. United States*, 384 F.2d 391, 398, 155 USPQ 697, 703 (Ct. Cl. 1967) (“In those instances where a visual representation can flesh out words, drawings may be used in the same manner and with the same limitations as the specification.”).

⁴⁰ See, e.g., *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406 (“In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus.”).

APPENDIX A

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⁴¹ See *Hybritech v. Monoclonal Antibodies*, 802 F.2d at 1384, 231 USPQ at 94; *Fonar Corp. v. General Electric Co.*, 107 F.3d at 1549, 41 USPQ2d at 1805 (source code description not required).

⁴² For example, the presence of a restriction enzyme map of a gene may be relevant to a statement that the gene has been isolated. One skilled in the art may be able to determine when the gene disclosed is the same as or different from a gene isolated by another by comparing the restriction enzyme map. In contrast, evidence that the gene could be digested with a nuclease would not normally represent a relevant characteristic since any gene would be digested with a nuclease. Similarly, isolation of an mRNA and its expression to produce the protein of interest is strong evidence of possession of an mRNA for the protein.

For some biomolecules, examples of identifying characteristics include a sequence, structure, binding affinity, binding specificity, molecular weight, and length. Although structural formulas provide a convenient method of demonstrating possession of specific molecules, other identifying characteristics or combinations of characteristics may demonstrate the requisite possession. For example, unique cleavage by particular enzymes, isoelectric points of fragments, detailed restriction enzyme maps, a comparison of enzymatic activities, or antibody cross-reactivity may be sufficient to show possession of the claimed invention to one of skill in the art. See *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966 ("written description" requirement may be satisfied by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention").

⁴³ A definition by function alone "does not suffice" to sufficiently describe a coding sequence "because it is only an indication of what the gene does, rather than what it is." *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. See also *Fiers*, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing *Amgen Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991)).

⁴⁴ If a claim limitation invokes 35 U.S.C. 112, ¶ 6, it must be interpreted to cover the corresponding structure, materials, or acts in the specification and "equivalents thereof." See 35 U.S.C. 112, ¶ 6. See also *B. Braun Medical, Inc. v. Abbott Lab.*, 124 F.3d 1419, 1424, 43 USPQ2d 1896, 1899 (Fed. Cir. 1997). In considering whether there is 35 U.S.C. 112, ¶ 1, support for a means- (or step-) plus-function claim limitation, the examiner must consider not only the original disclosure contained in the summary and detailed description of the invention portions of the specification, but also the original claims, abstract, and drawings. A means- (or step-) plus-function claim limitation is adequately described under 35 U.S.C. 112, ¶ 1, if: (1) The written description adequately links or associates adequately described particular structure, material, or acts to the function recited in a means- (or step-) plus-function claim limitation; or (2) it is clear based on the facts of the application that one skilled in the art would have known what structure, material, or acts perform the function recited in a means- (or step-) plus-

function limitation. Note also: A rejection under 35 U.S.C. 112, ¶ 2, "cannot stand where there is adequate description in the specification to satisfy 35 U.S.C. 112, first paragraph, regarding means-plus-function recitations that are not, per se, challenged for being unclear." *In re Noll*, 545 F.2d 141, 149, 191 USPQ 721, 727 (CCPA 1976). See *Supplemental Examination Guidelines for Determining the Applicability of 35 U.S.C. 112*, ¶ 6, 65 FR 38510, June 21, 2000.

⁴⁵ See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94.

⁴⁶ See, e.g., *Vas-Cath*, 935 F.2d at 1563, 19 USPQ2d at 1116; *Martin v. Johnson*, 454 F.2d 746, 751, 172 USPQ 391, 395 (CCPA 1972) (stating "the description need not be in *ipsis verbis* [i.e., "in the same words"] to be sufficient").

⁴⁷ A claim which is limited to a single disclosed embodiment or species is analyzed as a claim drawn to a single embodiment or species, whereas a claim which encompasses two or more embodiments or species within the scope of the claim is analyzed as a claim drawn to a genus. See also MPEP § 806.04(e).

⁴⁸ 35 U.S.C. 112, ¶ 1. Cf. *Fields v. Conover*, 443 F.2d 1386, 1392, 170 USPQ 276, 280 (CCPA 1971) (finding a lack of written description because the specification lacked the "full, clear, concise, and exact written description" which is necessary to support the claimed invention).

⁴⁹ For example, if the art has established a strong correlation between structure and function, one skilled in the art would be able to predict with a reasonable degree of confidence the structure of the claimed invention from a recitation of its function. Thus, the written description requirement may be satisfied through disclosure of function and minimal structure when there is a well-established correlation between structure and function. In contrast, without such a correlation, the capability to recognize or understand the structure from the mere recitation of function and minimal structure is highly unlikely. In this latter case, disclosure of function alone is little more than a wish for possession; it does not satisfy the written description requirement. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406 (written description requirement not satisfied by merely providing "a result that one might achieve if one made that invention"); *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming a rejection for lack of written description because the specification does "little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate"). Compare *Fonar*, 107 F.3d at 1549, 41 USPQ2d at 1805 (disclosure of software function adequate in that art).

⁵⁰ See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

⁵¹ See, e.g., *In re Hayes Microcomputer Products, Inc. Patent Litigation*, 982 F.2d 1527, 1534-35, 25 USPQ2d 1241, 1246 (Fed. Cir. 1992) ("One skilled in the art would know how to program a microprocessor to perform the necessary steps described in the specification. Thus, an inventor is not required to describe every detail of his invention. An applicant's disclosure

obligation varies according to the art to which the invention pertains. Disclosing a microprocessor capable of performing certain functions is sufficient to satisfy the requirement of section 112, first paragraph, when one skilled in the relevant art would understand what is intended and know how to carry it out.")

⁵² See, e.g., *Fiers v. Revel*, 984 F.2d at 1169, 25 USPQ2d at 1605; *Amgen*, 927 F.2d at 1206, 18 USPQ2d at 1021. Where the process has actually been used to produce the product, the written description requirement for a product-by-process claim is clearly satisfied; however, the requirement may not be satisfied where it is not clear that the acts set forth in the specification can be performed, or that the product is produced by that process.

⁵³ See, e.g., *Amgen*, 927 F.2d at 1206, 18 USPQ2d at 1021 ("A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it. Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. We hold that when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, *i.e.*, until after the gene has been isolated.") (citations omitted). In such instances the alleged conception fails not merely because the field is unpredictable or because of the general uncertainty surrounding experimental sciences, but because the conception is incomplete due to factual uncertainty that undermines the specificity of the inventor's idea of the invention. *Burroughs Wellcome Co. v. Barr Laboratories Inc.*, 40 F.3d 1223, 1229, 32 USPQ2d 1915, 1920 (Fed. Cir. 1994). Reduction to practice in effect provides the only evidence to corroborate conception (and therefore possession) of the invention. *Id.*

⁵⁴ See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

⁵⁵ See, e.g., *Rasmussen*, 650 F.2d at 1214, 211 USPQ at 326-27 (disclosure of a single method of adhering one layer to another was sufficient to support a generic claim to "adheringly applying" because one skilled in the art reading the specification would understand that it is unimportant how the layers are adhered, so long as they are adhered); *In re Herschler*, 591 F.2d 693, 697, 200 USPQ 711, 714 (CCPA 1979) (disclosure of corticosteroid in DMSO sufficient to support claims drawn to a method of using a mixture of a "physiologically active steroid" and DMSO because "use of known chemical compounds in a manner auxiliary

to the invention must have a corresponding written description only so specific as to lead one having ordinary skill in the art to that class of compounds. Occasionally, a functional recitation of those known compounds in the specification may be sufficient as that description.”); *In re Smythe*, 480 F.2d 1376, 1383, 178 USPQ 279, 285 (CCPA 1973) (the phrase “air or other gas which is inert to the liquid” was sufficient to support a claim to “inert fluid media” because the description of the properties and functions of the air or other gas segmentizing medium would suggest to a person skilled in the art that appellant’s invention includes the use of “inert fluid” broadly.). However, in *Tronzo v. Biomet*, 156 F.3d at 1159, 47 USPQ2d at 1833 (Fed. Cir. 1998), the disclosure of a species in the parent application did not suffice to provide written description support for the genus in the child application.

⁵⁶ See, e.g., *Eli Lilly*.

⁵⁷ For example, in the molecular biology arts, if an applicant disclosed an amino acid sequence, it would be unnecessary to provide an explicit disclosure of nucleic acid sequences that encoded the amino acid sequence. Since the genetic code is widely known, a disclosure of an amino acid sequence would provide sufficient information such that one would accept that an applicant was in possession of the full genus of nucleic acids encoding a given amino acid sequence, but not necessarily any particular species. Cf. *In re Bell*, 991 F.2d 781, 785, 26 USPQ2d 1529, 1532 (Fed. Cir. 1993) and *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994).

⁵⁸ See *Wertheim*, 541 F.2d at 263, 191 USPQ at 97 (“[T]he PTO has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims.”).

⁵⁹ See MPEP §§ 714.02 and 2163.06 (“Applicant should * * * specifically point out the support for any amendments made to the disclosure.”).

⁶⁰ See, e.g., *In re Wright*, 866 F.2d 422, 425, 9 USPQ2d 1649, 1651 (Fed. Cir. 1989) (Original specification for method of forming images using photosensitive microcapsules which describes removal of microcapsules from surface and warns that capsules not be disturbed prior to formation of image, unequivocally teaches absence of permanently fixed microcapsules and supports amended language of claims requiring that microcapsules be “not permanently fixed” to underlying surface, and therefore meets description requirement of 35 U.S.C. 112.).

⁶¹ See, e.g., *In re Robins*, 429 F.2d 452, 456–57, 166 USPQ 552, 555 (CCPA 1970) (“[W]here no explicit description of a generic invention is to be found in the specification * * * mention of representative compounds may provide an implicit description upon which to base generic claim language.”); *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (a subgenus is not necessarily implicitly described by a genus encompassing it and a species upon which it reads).

⁶² See, e.g., *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950–51 (Fed. Cir.

1999) (“To establish inherency, the extrinsic evidence “must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.””) (citations omitted).

⁶³ When an explicit limitation in a claim “is not present in the written description whose benefit is sought it must be shown that a person of ordinary skill would have understood, at the time the patent application was filed, that the description requires that limitation.” *Hyatt v. Boone*, 146 F.3d 1348, 1353, 47 USPQ2d 1128, 1131 (Fed. Cir. 1998).

⁶⁴ See, e.g., *Johnson Worldwide Associates Inc. v. Zebco Corp.*, 175 F.3d at 993, 50 USPQ2d at 1613; *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d at 1479, 45 USPQ2d at 1503; *Tronzo v. Biomet*, 156 F.3d at 1159, 47 USPQ2d at 1833.

⁶⁵ See, e.g., *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971).

⁶⁶ *Wertheim*, 541 F.2d at 263, 191 USPQ at 97.

⁶⁷ See *Rasmussen*, 650 F.2d at 1214, 211 USPQ at 326.

⁶⁸ See *In re Alton*, 76 F.3d 1168, 1176, 37 USPQ2d 1578, 1584 (Fed. Cir. 1996).

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BILLING CODE 3510–16–U

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Revision of Currently Approved Information Collection; Comment Request

AGENCY: Corporation for National and Community Service

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (hereinafter “Corporation”), as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirement on respondents can be properly assessed.

Currently, the Corporation is soliciting comments concerning the proposed revision of its Voucher and

Payment Request Form (OMB #3045–0014).

Copies of the forms can be obtained by contacting the office listed below in the address section of this notice.

DATES: Written comments must be submitted to the office listed in the **ADDRESSES** section by March 6, 2001.

ADDRESSES: Send comments to Levon Buller, National Service Trust, Corporation for National and Community Service, 1201 New York Ave., NW., Washington, DC 20525.

FOR FURTHER INFORMATION CONTACT: Levon Buller, (202) 606–5000, ext. 383.

SUPPLEMENTARY INFORMATION: The Corporation is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Corporation, including whether the information will have practical utility;

- Evaluate the accuracy of the agency’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

- Enhance the quality, utility and clarity of the information to be collected; and

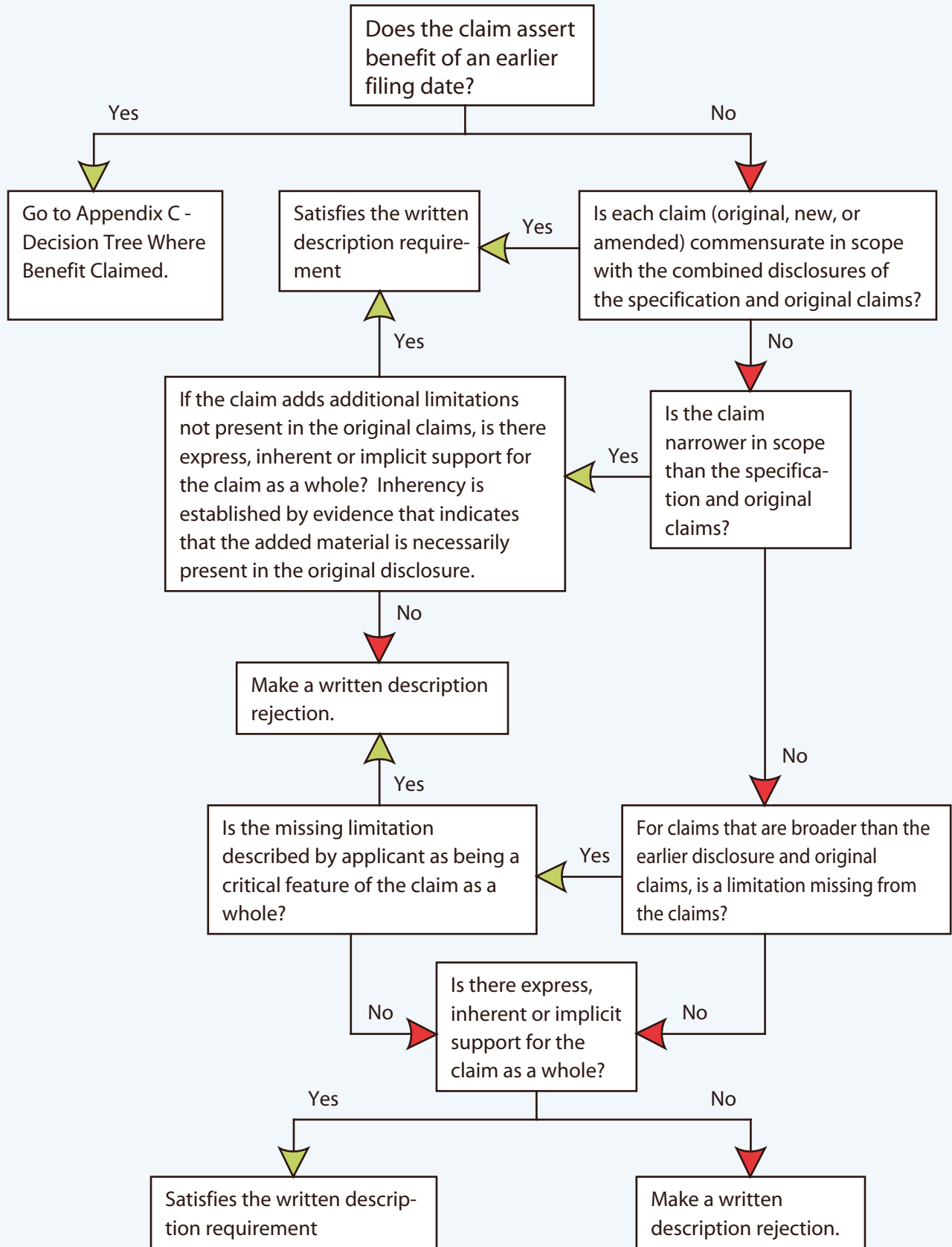
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

Background

The Corporation supports programs that provide opportunities for individuals who want to become involved in national service. The service opportunities cover a wide range of activities over varying periods of time. Upon successfully completing an agreed-upon term of service in an approved AmeriCorps program, a national service participant—an AmeriCorps member—receives an “education award”. This award is an amount of money set aside in the member’s name in the National Service Trust Fund. This education award can be used to make payments towards qualified student loan or pay for educational expenses at qualified post-secondary institutions and approved school-to-work opportunities programs. Members have seven years in which to draw against any unused balance.

The National Service Trust is the office within the Corporation that administers the education award

APPENDIX B - DECISION TREE WHERE NO BENEFIT CLAIMED



APPENDIX C - DECISION TREE WHERE BENEFIT CLAIMED

