FOR FURTHER INFORMATION CONTACT: Dr. Subhas G. Malghan, FQA Program Manager, Building 820, Room 306, NIST, Gaithersburg, MD 20899; telephone (301) 975–5120, fax (301) 975–5414, E-mail: malghan@nist.gov.

SUPPLEMENTARY INFORMATION: On June 1, 1998, NIST announced in the **Federal Register**, (63 FR 29702), that it would be holding a public meeting on June 16, 1998, to provide details and interpretations on the regulations related to the Quality Assurance System (QAS) of fastener manufacturing contained in the April 14, 1998, final regulation under the Fastener Quality Act. NIST is postponing that meeting and will issue a future notice announcing a new date for the meeting.

Dated: June 10, 1998.

Robert E. Hebner,

Acting Deputy Director, National Institute of Standards and Technology.

[FR Doc. 98–15935 Filed 6–12–98; 8:45 am]

BILLING CODE 3510–13–M

DEPARTMENT OF COMMERCE

Patent and Trademark Office

[Docket No. 980605148–8148–01]

Request for Comments on Interim Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112 ¶ 1 ''Written Description'' Requirement

AGENCY: Patent and Trademark Office, Commerce.

ACTION: Notice and request for public comments.

SUMMARY: The Patent and Trademark Office (PTO) requests comments from any interested member of the public on the following interim guidelines. These guidelines will be used by PTO personnel in their review of biotechnological patent applications for compliance with the ''written description'' requirement of 35 U.S.C. 112 ¶ 1. Although the guidelines are directed primarily to written descriptions of biotechnological inventions, they reflect the current understanding of the PTO and apply across the board to all relevant technologies.

DATES: Written comments on the interim guidelines will be accepted by the PTO until September 14, 1998.

ADDRESSES: Written comments should be addressed to Box 8, Commissioner of Patents and Trademarks, Washington, D.C. 20231, marked to the attention of Scott A. Chambers, Associate Solicitor or to Box Comments, Assistant Commissioner for Patents, Washington, D.C. 20231 marked to the attention of Linda S. Therkorn. Alternatively, comments may be submitted to Scott Chambers via facsimile at (703) 305–9373 or by electronic mail addressed to ''scott.chambers@uspto.gov'' or to Linda Therkorn via facsimile at (703) 305–8825 or by electronic mail addressed at ''linda.therkorn@uspto.gov.''

FOR FURTHER INFORMATION CONTACT: Scott Chambers by telephone at (703) 305–9035, by facsimile at (703) 305–9373, by mail to his attention addressed to Box 8, Commissioner of Patents and Trademarks, Washington, D.C. 20231, or by electronic mail at ''scott.chambers@uspto.gov'; or Linda Therkorn by telephone at (703) 305–8800, by facsimile at (703) 305–8825, by mail addressed to Box Comments, Assistant Commissioner for Patents, Washington, D.C. 20231, or by electronic mail at ''linda.therkorn@uspto.gov.''

SUPPLEMENTARY INFORMATION: The PTO requests comments from any interested member of the public on the following interim guidelines. These guidelines will be used by PTO personnel in their review of biotechnological patent applications for compliance with the ''written description'' requirement of 35 U.S.C. 112 ¶ 1. Although the guidelines are directed primarily to written descriptions of biotechnological inventions, they reflect the current understanding of the PTO and apply across the board to all relevant technologies. Because these guidelines govern internal practices, they are exempt from notice and comment rulemaking under 5 U.S.C. 553(b)(A).

Written comments should include the following information: (1) name and affiliation of the individual responding; and (2) an indication of whether the comments offered represent views of the respondent's organization or are they respondent's personal views. The PTO is particularly interested in comments relating to: (1) the accuracy of the methodology; (2) relevant factors to consider in determining whether the written description requirement of 35 U.S.C. 112 ¶ 1 is satisfied; (3) whether the scope of these guidelines should be limited to certain technologies, such as biotechnology, or even a particular area of biotechnology such as nucleic acids, or encompass all technologies generally; (4) whether the scope of these guidelines should be expanded to include processes and/or product-by-process claims; and (5) the impact these guidelines may have on currently pending applications as well as future applications.

Parties presenting written comments are requested, where possible, to provide their comments in machine-readable format in addition to a paper copy. Such submissions may be provided by electronic mail messages sent over the Internet, or on a 3.5″ floppy disk formatted for use in either a Macintosh, Windows, Windows for Workgroups, Windows 95, Windows NT, or MS-DOS based computer.

Written comments will be available for public inspection on or about September 14, 1998, in Suite 918, Crystal Park 2, 2121 Crystal Drive, Arlington, Virginia. In addition, comments provided in machine-readable format will be available through anonymous file transfer protocol (ftp) via the Internet (address: comments.uspto.gov) and through the World Wide Web (address: www.uspto.gov).

Interim 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, in view of *University of California* v. *Eli Lilly* [1] and the earlier cases *Fiers* v. *Revel* [2] and *Amgen, Inc.* v. *Chugai Pharmaceutical Co.* [3] These Interim Guidelines are directed primarily to determining whether there is written description support for product claims and are not intended to specifically address the description necessary to support process or product-by-process claims. Similarly, these Guidelines are not intended to directly address the question of new matter, which is currently addressed in the Manual of Patent Examining Procedure §§ 2163.06–.07. The Final Guidelines may address these additional issues if public comment suggests they should be addressed. These guidelines are based on the Office's current understanding of the law and are believed to be fully consistent with binding precedent of the Supreme Court, the Federal Circuit, and the Federal Circuit's predecessor courts.

These guidelines do not constitute substantive rulemaking and hence do not have the force and effect of law. They are 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 failure by Office personnel to follow the 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 these 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. Although these guidelines address examples principally drawn from the biotechnological arts, they are intended to be equally applicable to all fields of invention.

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.[4] This 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.''[5] Another objective is to put the public in possession of what the applicant claims as the invention. The written description requirement prevents an applicant from claiming subject matter that was not described in the specification as filed, and the proscription against the introduction of new matter in a patent application[6] serves to prevent an applicant from adding information that goes beyond the subject matter originally filed.

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.[7] This requirement of the Patent Act promotes the progress of the useful arts by ensuring that patentees adequately describe their inventions in their patent specifications for the benefit of the public in exchange for the right to exclude others from practicing the invention for the duration of the patent's term.[8]

II. Evaluate Whether The Application Complies With the ''Written Description'' Requirement

The inquiry into whether the description requirement is met must be determined on a case-by-case basis and is a question of fact.[9] The examiner has the initial burden of presenting evidence or reasons why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims.[10] 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.

A. Review the Entire Application To Determine What Applicant has Invented, the Field of the Invention and the Level of Predictability in the Art

Prior to determining whether the claims satisfy the written description requirement, Office personnel should review the entire specification, including the specific embodiments, figures, sequence listings, and the claims, to understand what applicant has invented and the correspondence between what applicant has described, i.e., has possession of, and what applicant is claiming. Such a review should be conducted from the standpoint of one of skill in the art at the time the application was filed and should include a determination of the field of the invention and, thus, the level of predictability in the art. Predictability of the structure of a species can be premised upon:

(1) Whether the level of skill in the art leads to a predictability of structure; and/or

(2) Whether teachings in the application or prior art lead to a predictability of structure.

There is an inverse correlation between the level of predictability in the art and the amount of disclosure necessary to satisfy the written description requirement. For example, if there is a well-established correlation between structure and function in the art, one skilled in the art will be able to reasonably predict the complete structure of the claimed invention from its function. Thus, in some factual situations, the written description requirement may be satisfied through disclosure of function alone when there is a well-established correlation between structure and function. In contrast, without such a correlation, prediction of structure from function is highly unlikely. In this latter case, disclosure of function alone will not satisfy the written description requirement.[11]

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

Each claim must be separately analyzed and given its broadest reasonable interpretation.[12] The entire claim, including its preamble language and transitional phrase, must be considered. ''Preamble language'' is that language in a claim appearing before a transitional phase, e.g., before ''comprising,'' ''consisting essentially of,'' or ''consisting of''. The transitional term ''comprising'' (and other comparable terms, e.g., ''containing'' and ''including'') is ''open-ended''—it covers the expressly recited subject matter alone or in combination with other unstated subject matter.[13] There must be adequate written description to support the claimed invention *including* the preamble.[14] The claim as a whole, including all limitations found in the preamble, the transitional phrase, and the body of the claim, must be described sufficiently to satisfy the written description requirement.[15] For claims of the form ''A [structure] comprising SEQ ID NO: 1'' there may be a written description problem if the claim as a whole, including its preamble and transitional phrase, is directed to an invention of unpredictable structure that is not fully described.

For example, when the term ''gene,'' ''mRNA,'' or ''cDNA'' is recited in the preamble, it implies a specific structure (or a small genus of specific structures) when used in the traditional sense, i.e., to mean the structure having the naturally occurring sequence. Thus, ''A gene comprising SEQ ID NO: 1''; ''A mRNA comprising SEQ ID NO: 1''; and ''A cDNA comprising SEQ ID NO: 1'' implicitly recite specific structures such as promoters, enhancers, coding regions, and other regulatory elements in the preamble which must be sufficiently described in the specification so as to show the applicant was in possession of the claimed inventions.

In contrast, use of less specific, generic preamble language, such as ''composition,'' ''nucleic acid,'' ''DNA,'' and ''RNA,'' does not typically present a written description problem. These terms are sufficiently general that one skilled in the art can readily envision a sufficient number of members of the claimed genus to provide written description support for the genus.

A claim such as ''A gene comprising SEQ ID NO: 1,'' can be viewed as a species claim in which the preamble recites a combination and the body of the claim recites a subcombination: The ''gene'' is the combination and ''SEQ ID

NO: 1'' (which is a fragment of the gene) is the subcombination. Written description of only the subcombination (in this example the fragment SEQ ID NO: 1) normally does not put one in possession of the combination (in this example the gene).

Likewise, generic claims to sequences can be viewed as a genus of such combination-subcombination claims. For example, a claim such as ''A nucleic acid comprising SEQ ID NO: 1'' can be viewed as a genus claim in which each member of the genus (each species) is itself a combination-subcombination: Each member of the genus ''nucleic acid'' is a combination containing the subcombination ''SEQ ID NO: 1'' (which is a fragment of the nucleic acid). Again, the generic term ''nucleic acid'' does not typically present a written description problem because one skilled in the art can readily envision a sufficient number of members of the claimed genus to provide written description support for the genus. [16]

C. For Each Claimed Species, Determine Whether There is Sufficient Written Description To Inform a Skilled Artisan That Applicant was in Possession of the Claimed Invention at the Time the Application was Filed

Written description may be satisfied through disclosure of relevant identifying characteristics, i.e., structure, other physical and/or chemical characteristics, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. What is well known to one skilled in the art need not be disclosed. 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.

For each claimed species:

(1) Determine whether a complete structure is disclosed. The complete structure of a species 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. If a complete structure is disclosed, the written description requirement is satisfied for that species, and a rejection under 35 U.S.C. 112 ¶ 1 for lack of written description must not be made.

For example, consider the following claim:

A probe for use in detecting nucleic acid sequences coding for enzyme Q from the genus Bacillus consisting of SEQ ID NO: 16.

Considering the claim as a whole, it is a species claim covering the probe SEQ ID NO: 16. The specification discloses the complete sequence for SEQ ID NO: 16. Thus, this claim falls into the ''safe harbor'' described under C(1).

(2) If the complete structure is not disclosed, determine whether the specification discloses other relevant identifying characteristics, i.e., physical and/or chemical characteristics and/or functional characteristics coupled with a known or disclosed correlation between function and structure, 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. Disclosure of any combination of such identifying characteristics that would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. In such a case, a rejection for lack of written description under 35 U.S.C. 112 ¶ 1 must not be made.

For example, consider the following claim:

An isolated double-stranded DNA consisting of (1) a single-stranded DNA which has a molecular size of 2.57 Kb and is derived from golden mosaic virus, and (2) a DNA complementary to said single-stranded DNA, giving the restriction endonuclease cleavage map shown in FIG.2(a) and having no Mbo I restriction endonuclease site.

Although the specification does not disclose the complete structure for the claimed DNA, it does disclose sufficient identifying characteristics, i.e., size, cleavage map, and source from which the DNA is derived. Thus, while this claim does not meet the C(1) criteria because the complete sequence is not disclosed, it does meet the C(2) criteria because one skilled in the art would recognize from the characteristics, e.g., size, map, source, that applicant was in possession of the claimed material at the time of filing.

The following protein claim also falls within the C(2) criteria:

An isolated alginate lyase enzyme wherein said enzyme lyses alginate in the mucous substance produced in a patient with cystic fibrosis and wherein said enzyme has the N-terminal amino acid sequence SEQ ID No. 1, obtained from Flavobacterium pepermentium and has the following physicochemical properties: (1) Activity: lyses alginate to saccharides having a non-reducing end C_4–C_5 double bond and ultimately to 4-deoxy-5-ketouronic acid; (2) Molecular weight: 60,000 daltons; (3) Optimal pH: 8.0; (4) Stable pH: 6.0–8.0; (5) Optimal temperature: 70 degrees C; and (6) Substrate specificity: alginate.

In this example, the specification discloses the molecular weight, origin, activity, and specificity but does not disclose the complete structure for the claimed enzyme. Thus, this claim would not meet the C(1) criteria because the complete sequence is not disclosed. However, the claim meets the C(2) criteria because, although the complete structure is not disclosed, one skilled in the art would recognize from the disclosed physical characteristics—e.g., molecular weight, origin, activity, and specificity—that applicant was in possession of the claimed material at the time of filing.

In contrast, consider the following claim:

An isolated nucleotide sequence consisting of the sequence of the reverse transcript of a human mRNA, which mRNA encodes insulin.

The specification in this example provides the coding sequence for rat insulin but not that for human insulin. The description for the reverse transcript of human mRNA is limited to its function, encoding human insulin, and to a method for isolating the claimed sequence from its natural source. A sequence described only by a *purely* 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 species. In this case, even though a genetic code table would correlate a known insulin amino acid sequence with a genus of coding nucleic acids, the same table cannot predict the native, naturally occurring nucleic acid sequence of human mRNA or its corresponding cDNA. Thus, the specification in this example does not provide adequate written description, either under the C(1) or C(2) criteria.

Any claim to a species that does not meet the test described under C(1) or C(2)must be rejected as lacking adequate written description under 35 U.S.C. 112 ¶ 1.

D. For Each Claimed Genus, Determine Whether There is Sufficient Written Description to Inform a Skilled Artisan That Applicant was in Possession of the Claimed Genus at the Time the Application was Filed

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by relevant identifying characteristics, i.e., structure or other physical and/or chemical characteristics, 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. A ''representative number of species'' requires that the species which are expressly described be representative of the entire genus. Thus, when there is substantial variation within the genus, it may require a description of the various species which reflect the variation within the genus. For example, a broadly drawn claim to a specific gene from ruminant mammals may require a representative species from cattle, buffalo, bison, goat, deer, antelope, camel, giraffe and llama.

What constitutes a ''representative number'' is an inverse function of the predictability of the art, as determined in IIA above. The number must be sufficient to reasonably identify the other members of genus. In an unpredictable art, adequate written description of a genus *cannot* be achieved by disclosing only one species within the genus. In fact, if the members of the genus are expected to vary widely in their identifying characteristics, such as structure and activity, written description for each member within the genus may be necessary.

Generalized descriptions alone, such as ''vertebrate insulin cDNA'' or ''mammalian insulin cDNA,'' fail to satisfy the written description requirement because they do not describe any members of the genus except by function without any known or disclosed correlation between function and structure.[24] If the correlation between structure and function in the art would not have been known to one skilled in the art and the specification does not describe the correlation, the written descriptive support cannot depend on that correlation.

For each claim to a genus:

(1) Determine whether a representative number of species have been described by complete structure as in C(1) above. If a representative number have been so described, then the applicant has written description support for the claimed genus and a rejection under 112 ¶ 1 for lack of written description must not be made.

For example, consider the following claim to a genus:

> An isolated DNA probe for detecting HIV–X, wherein said DNA probe hybridizes to the nucleotide sequence set forth in SEQ ID NO:1 under the following conditions: hybridization in 7% sodium dodecyl sulfate (SDS), 0.5M $NaPO_4$ pH 7.0, 1mM EDTA at 50° C.; and washing with 1% SDS at 42° C.

In this case, the specification discloses the sequence of the isolated DNA molecule consisting of SEQ ID NO: 1 and discloses several sequences that hybridize to SEQ ID NO: 1. Hybridization under the stringent conditions specified here requires that the claimed nucleic acid probes be structurally similar to the complement of the nucleic acid sequence disclosed as SEQ ID NO: 1. In this case, the description as a whole is sufficient to evidence possession of the claimed genus because the genus is defined by relation to the structure of the sequence provided as SEQ ID NO: 1, and because several species are disclosed that possess the hybridization property which further defines the genus. Thus, this claim to a genus meets the D(1) criteria.

(2) For each claim to a genus not supported as described under D(1), determine whether there is a representative number of adequately described species, as analyzed under C(2). The representative number must permit one skilled in the art to reasonably identify the remaining members of the genus. If a representative number are so described, then the written description requirement is satisfied and, again, a rejection under 112 ¶ 1 for lack of written description must not be made.

For example, consider the following claim to a genus:

> A monoclonal antibody which specifically binds to the novel cancer associated TAG–31 antigen but which does not substantially bind normal adult human tissues, wherein said monoclonal antibody has a binding affinity of greater than 3 times 10^9 M^{-1} for TAG–31.

Considering the claim as a whole, it is drawn to a genus of monoclonal antibodies. Although the specification does not disclose the complete structure of a representative number of species to support the claimed genus of antibodies, it does disclose multiple monoclonal antibodies which have the isotype claimed as well as the binding specificity and binding affinity characteristics recited in the claims. In this well-developed art, additional identifying characteristics for a substantial portion of the genus are well-known (e.g., number of chains, disulfide bonds, constant and variable regions, etc.). Thus, applicant's disclosure combined with what was known in the art are sufficient to describe the claimed genus of monoclonal antibodies in such full, clear, concise and exact terms to show applicant was in possession of the claimed antibodies. Thus, the claim meets the D(2) criteria.

As another example, consider the following claim to a genus:

> An isolated mutanase enzyme produced by Bacillus having the following physicochemical properties (1) to (9): (1) action: an ability to cleave alpha-1,3-glucosidic links of mutan; (2) substrate specificity: an ability to effectively decompose mutan; (3) optimum pH: pH 4 to 4.5 when reacting on a mutan substrate at 35 degrees C for 10 minutes; (4) pH range for stability: pH 4 to 10 when kept at 25 degrees C for 24 hours; (5) optimum temperature: 50 degrees to 65 degrees C when reacted at pH 5 with mutan as a substrate; (6) thermal stability: enzyme activity remains stable below 50 degrees C after incubation at pH 5 for 10 minutes; (7) effect of metal ions: mercury and silver show inhibitory effect on a mutan substrate; (8) effect of inhibitors: p-chloromercurybenzoic acid shows inhibitory effect on a mutan substrate; and (9) molecular weight: about 140,000 to about 160,000 as determined by SDS-polyacrylamide gel electrophoresis.

Considering the claim as a whole, it covers a genus of mutanase enzymes. Although the specification does not disclose the complete structure of a representative number of species to support the claimed genus of enzyme compositions, it does disclose 3 mutanase species produced by different strains of Bacillus (mutanases A, B and C) which are identified by multiple relevant identifying characteristics, i.e., molecular weight, substrate specificity, optimum and ranges of temperature and pH for mutan cleavage activity, etc. In this well-developed art, these identifying characteristics are sufficient for a skilled artisan to recognize applicant had possession of the species from the identifying characteristics of the three mutanase species, to reasonably predict sufficient identifying characteristics of the other members of the genus and, thus, establish possession of the genus. Thus, the claim meets the D(2) criteria.

As another example, consider the following claim to a genus:

A DNA comprising a novel DF3 enhancer and DNA encoding a heterologous gene but not encoding DF3 wherein said DF3 enhancer consists of SEQ ID NO: 1.

Considering the claim as a whole, it covers a genus of DNA. The specification does not describe a representative number of members of the genus by complete structure. Thus, the claim does not meet the D(1) criteria. However, there is sufficient disclosure of identifying characteristics common to the members of the genus, i.e., DF3 enhancer, to meet the D(2) criteria. Because of the nature of the generic term ''DNA,'' one skilled in the art could envision a sufficient number of the members of the genus to describe the invention in such full, clear and concise terms as to show possession of the invention at the time of filing.

In contrast, consider the claim:

An isolated nucleic acid comprising the structure of the reverse transcript of a mammalian mRNA, which mRNA encodes insulin.

Considering the claim as a whole, the claim covers the genus of nucleotide sequences encoding mammalian insulin. The specification only provides the coding sequence for rat insulin cDNA and a method to isolate the coding sequence from its natural source.[25] This description does not meet the criteria of D(1) or D(2) and thus does not satisfy the written description requirement.

Also contrast the claim ''A gene comprising SEQ ID NO: 1.'' Although all genes encompassed by this claim share the characteristic of comprising SEQ ID NO: 1, and as such might appear to meet the D(2) criteria, there is insufficient description of the characteristics (e.g., promoters, enhancers, coding regions, and other regulatory elements) which identify the genes, as opposed to any DNA comprising SEQ ID NO: 1.

If sufficient identifying characteristics are not disclosed for a given genus, as described in D(1) or D(2), the claim to that genus must be rejected as lacking adequate written description under 35 U.S.C. 112 ¶ 1.

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 the Patent Act.

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.

Specific to these guidelines:

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

In rejecting a claim, 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 not described; and

(2) provide reasons why a person skilled in the art at the time the application was filed would not have recognized the description of this limitation in view of the disclosure of the application as filed.

When appropriate, suggest amendments to the claims which would bring the claims into compliance with the written description in the specification, bearing in mind the prohibition against new matter in the claims and corresponding description set forth in 35 U.S.C. 112 and 132.

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

Upon reply by applicant, before repeating any rejection under Section 112 ¶ 1 for lack of written descriptive basis, 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 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. Any affidavits, including those relevant to the 112 ¶ 1 written description requirement, must be thoroughly analyzed and discussed in the Office action.

Endnotes

1. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997).
2. 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993).
3. 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991).
4. *E.g., Vas-Cath, Inc.* v. *Mahurkar,* 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1115 (Fed. Cir. 1991).
5. *In re Barker,* 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977).
6. 35 U.S.C. §§ 132 & 251.
7. *E.g., Vas-Cath, Inc.* v. *Mahurkar,* 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991). 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. *E.g., see Martin* v. *Mayer,* 823 F.2d 500, 502, 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); *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 can be mined from 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.

8. *See Eli Lilly,* 119 F.3d at 1566, 43 USPQ2d at 1404.
9. *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 a case-by-case development.''); *In re Wertheim,* 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976) (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).
10. *Wertheim,* 541 F.2d at 262, 191 USPQ at 96.
11. *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'').

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

13. *See, e.g., Ex parte Davis*, 80 USPQ 448, 450 (1948) (''comprising'' leaves the ''claim open for the inclusion of unspecified ingredients even in major amounts''.), *quoted with approval in Moleculon Research Corp* v. *CBS, Inc.*, 793 F.2d 1261, 1271, 229 USPQ 805, 812 (Fed. Cir. 1986).

14. *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).

15. An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations. *Lockwood* v. *American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997).

16. *E.g., Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1405–06.

17. A ''relevant identifying characteristic'' is one that would provide evidence that applicant was in possession of what is claimed. 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 could determine whether the gene disclosed was the same as or different than 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.

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 can 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* v. *American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997) (''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'').

However, 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.3 at 1568, 43 USPQ2d at 1406. *See also Fiers*, 984 F.2d at 1169–71, 25 USPQ2d at 1605–06 (discussing Amgen).

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

19. *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 to be sufficient'').

20. 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).

21. The examples contained within these guidelines are not intended to represent the minimum requirements necessary to comply with 35 U.S.C. § 112 ¶ 1.

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

23. *See id.* at 1568, 43 USPQ2d at 1406.

24. *Cf. Eli Lilly*, 119 F.3d at 1567, 43 USPQ2d at 1405 (stating that ''The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning itself.'').

25. *See id.* 1568, 43 USPQ2d at 1406.

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Bruce A. Lehman,

Assistant Secretary of Commerce and Commissioner of Patents and Trademarks.

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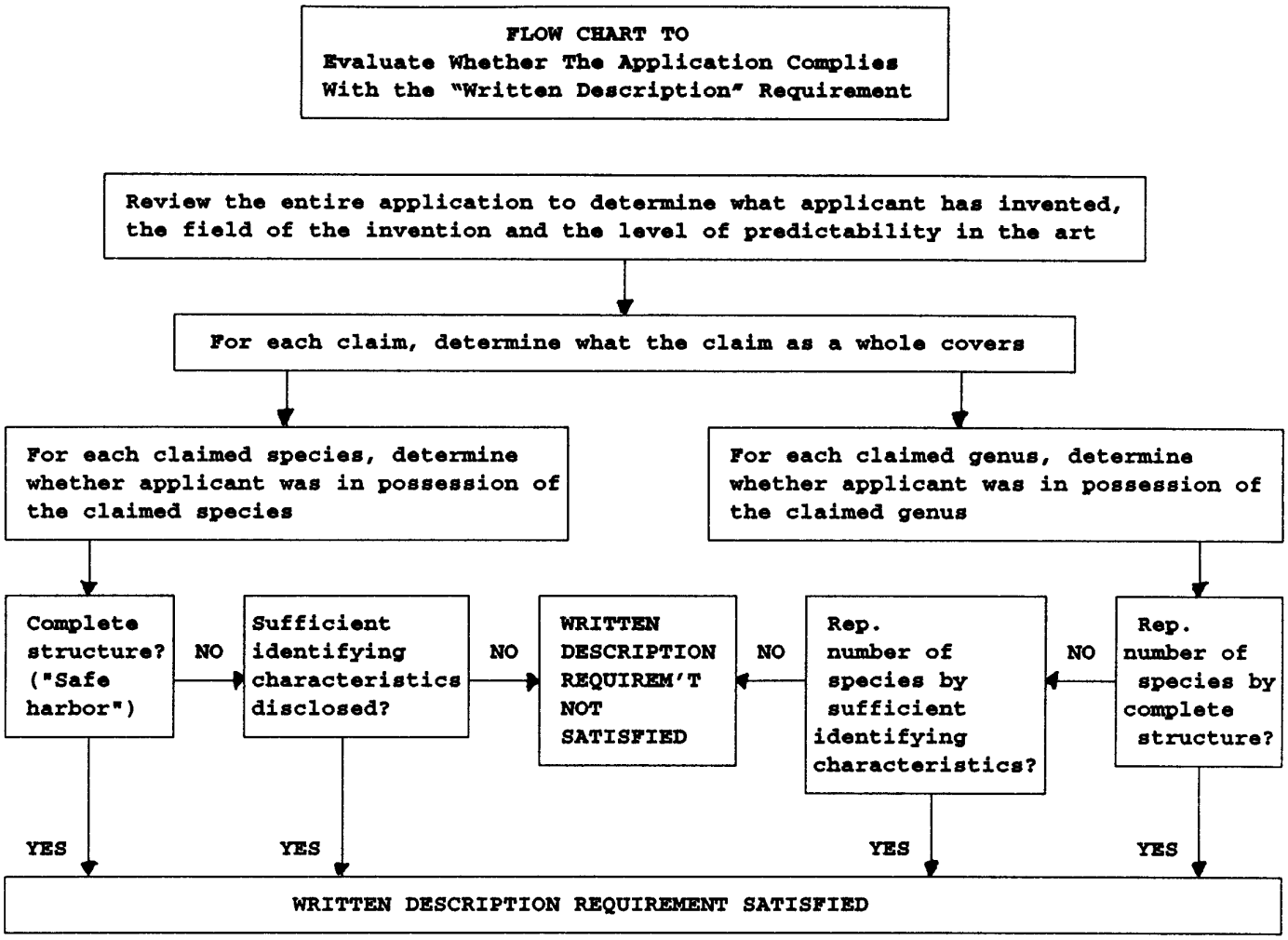

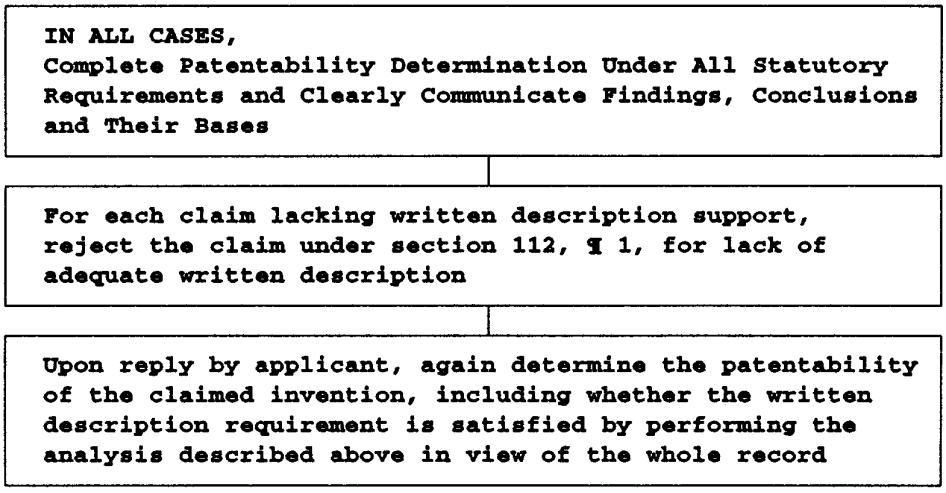

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