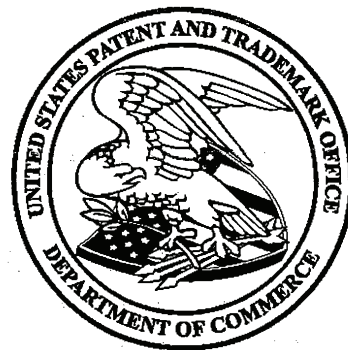


Manual of PATENT EXAMINING PROCEDURE

Original Ninth Edition, March 2014

U.S. DEPARTMENT OF
COMMERCE
United States Patent and
Trademark Office



AVAILABILITY

The paperbound format of the Manual was discontinued by the government printing office effective December 13, 2012. The Manual is available electronically in html and PDF renderings on the USPTO Web site at <http://www.uspto.gov/web/offices/pac/mpep/index/htm>. The Office also provides a search engine for searching the full text of the Manual at <http://mpep.uspto.gov/RDMS>.

Most hyperlinks from the Manual to internal and external Web sites are active. For particularly long Web site addresses (URLs), an extra space has been added to the rendered text for readability (especially in the PDF rendering). Clicking on a hyperlink will direct the user to the referenced Web site because the reference link data in the source document includes the URL without the extra space; however, copying text that includes the extra space and thereafter pasting it in a browser will result in an error.

Previous editions and revisions of the Manual are available from the MPEP Archives page on the USPTO Web site at <http://www.uspto.gov/web/offices/pac/mpep/old/index.htm>.

EXPLANATION OF NOTATIONS

Revision Date Indicator. Each section within an MPEP Chapter includes a revision date indicator, e.g., [R-11.2013]. The numbers within the bracket indicate the date the revision cycle for that section was completed, which would be November 2013 in the example above. Note that the publication date of the Manual as indicated on the title page and on the bottom of the PDF renderings may be later than the date the revision cycle was completed because of the time required for clearance processes.

Express Mail. Effective July 28, 2013, the United States Postal Service (USPS) changed the name of “Express Mail” to “Priority Mail Express.” All characteristics of the “Priority Mail Express” service are the same as those of the former “Express Mail” service (although the mailing labels differ). References to “Express Mail” or “Express Mail from the USPS in accordance with [37 CFR 1.10](#) throughout this Manual should be construed as applicable to the “Priority Mail Express” service of the USPS on or after July 28, 2013.

"Pre-AIA." Where the phrase "pre-AIA" is associated with a law or rule, it means that version which was in force before the date of the change necessitated by the AIA.

Five Asterisks. The use of five asterisks in the body of the laws, rules, treaties, and administrative instructions indicates a portion of the law, rule, treaty, or administrative instruction which was not reproduced.

First Edition, November 1949

Second Edition, November 1953

Third Edition, November 1961

Fourth Edition, June 1979

Fifth Edition, August 1983

Sixth Edition, January 1995

Seventh Edition, July 1998

Eighth Edition, August 2001

Ninth Edition, March 2014[R-11.2013]

Foreword

This Manual is published to provide U.S. Patent and Trademark Office (USPTO) patent examiners, applicants, attorneys, agents, and representatives of applicants with a reference work on the practices and procedures relative to the prosecution of patent applications before the USPTO. It contains instructions to examiners, as well as other material in the nature of information and interpretation, and outlines the current procedures which the examiners are required or authorized to follow in appropriate cases in the normal examination of a patent application. The Manual does not have the force of law or the force of the rules in Title 37 of the Code of Federal Regulations.

A separate manual entitled “Trademark Manual of Examining Procedure” is published by the USPTO as a reference work for trademark cases.

Examiners will be governed by the applicable statutes, rules, decisions, and orders and instructions issued by the Director of the USPTO and other officials authorized by the Director of the USPTO.

Subsequent changes in practice and other revisions will be incorporated in the form of revisions to sections of chapters and/or to appendices of the Manual.

Suggestions for improving the form and content of the Manual are always welcome. They should be addressed to:

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Commissioner for Patents
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Alexandria, Virginia 22313-1450

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the novel aspect of an invention must be enabled in the patent.”). The Federal Circuit has stated that “[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.” *Auto. Technologies*, 501 F.3d at 1283, 84 USPQ2d at 1115 (quoting *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997)). The rule that a specification need not disclose what is well known in the art is “merely a rule of supplementation, not a substitute for a basic enabling disclosure.”

Genentech, 108 F.3d at 1366, 42 USPQ2d 1005; see also *ALZA Corp.*, 603 F.3d at 940-41, 94 USPQ2d at 1827. Therefore, the specification must contain the information necessary to enable the novel aspects of the claimed invention. *Id.* at 941, 94 USPQ2d at 1827; *Auto. Technologies*, 501 F.3d at 1283-84, 84 USPQ2d at 1115 (“[T]he ‘omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required.’”) (quoting *Genentech*, 108 F.3d at 1366, 42 USPQ2d at 1005). For instance, in *Auto. Technologies*, the claim limitation “means responsive to the motion of said mass” was construed to include both mechanical side impact sensors and electronic side impact sensors for performing the function of initiating an occupant protection apparatus. *Auto. Technologies*, 501 F.3d at 1282, 84 USPQ2d at 1114. The specification did not disclose any discussion of the details or circuitry involved in the electronic side impact sensor, and thus, it failed to apprise one of ordinary skill how to make and use the electronic sensor. Since the novel aspect of the invention was side impact sensors, the patentee could not rely on the knowledge of one skilled in the art to supply the missing information. *Auto. Technologies*, 501 F.3d at 1283, 84 USPQ2d at 1114.

A rejection under [35 U.S.C. 112\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), first paragraph for lack of enablement must be made when the specification does not enable the full scope of the claim. USPTO personnel should establish a reasonable basis to question the enablement provided for the claimed invention and provide reasons for the uncertainty of the enablement. For more information regarding the

enablement requirement, see [MPEP § 2164.01\(a\)](#) - [MPEP § 2164.08\(c\)](#), e.g., [MPEP § 2164.06\(c\)](#) on examples of computer programming cases.

2162 Policy Underlying 35 U.S.C. 112(a) or Pre-AIA 35 U.S.C. 112, First Paragraph [R-11.2013]

To obtain a valid patent, a patent application must be filed that contains a full and clear disclosure of the invention in the manner prescribed by [35 U.S.C. 112\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), first paragraph. The requirement for an adequate disclosure ensures that the public receives something in return for the exclusionary rights that are granted to the inventor by a patent. The grant of a patent helps to foster and enhance the development and disclosure of new ideas and the advancement of scientific knowledge. Upon the grant of a patent in the U.S., information contained in the patent becomes a part of the information available to the public for further research and development, subject only to the patentee’s right to exclude others during the life of the patent.

In exchange for the patent rights granted, [35 U.S.C. 112\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), first paragraph, sets forth the minimum requirements for the quality and quantity of information that must be contained in the patent to justify the grant. As discussed in more detail below, the patentee must disclose in the patent sufficient information to put the public in possession of the invention and to enable those skilled in the art to make and use the invention. The applicant must not conceal from the public the best way of practicing the invention that was known to the patentee at the time of filing the patent application. Failure to fully comply with the disclosure requirements could result in the denial of a patent, or in a holding of invalidity of an issued patent.

2163 Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112(a) or Pre-AIA 35 U.S.C. 112, para. 1,

“Written Description” Requirement [R-11.2013]

The following Guidelines establish the policies and procedures to be followed by Office personnel in the evaluation of any patent application for compliance with the written description requirement of [35 U.S.C. 112](#). 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 U.S. Supreme Court, as well as the U.S. Court of Appeals for the Federal Circuit and its predecessor courts.

The 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 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.

I. GENERAL PRINCIPLES GOVERNING COMPLIANCE WITH THE “WRITTEN DESCRIPTION” REQUIREMENT FOR APPLICATIONS

[35 U.S.C. 112\(a\)](#) and the first paragraph of [pre-AIA 35 U.S.C. 112](#) require that the “specification shall contain a written description of the invention” This requirement is separate and distinct from the enablement requirement. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560, 19 USPQ2d 1111, 1114 (Fed. Cir. 1991). See also *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 920-23, 69 USPQ2d 1886, 1890-93 (Fed. Cir. 2004) (discussing history and purpose of the written

description requirement); *In re Curtis*, 354 F.3d 1347, 1357, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004) (“conclusive evidence of a claim’s enablement is not equally conclusive of that claim’s satisfactory written description”). 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.” *In re Barker*, 559 F.2d 588, 592 n.4, 194 USPQ 470, 473 n.4 (CCPA 1977). Another objective is to put the public in possession of what the applicant claims as the invention. See *Regents of the Univ. of Cal. v. Eli Lilly*, 119 F.3d 1559, 1566, 43 USPQ2d 1398, 1404 (Fed. Cir. 1997), *cert. denied*, 523 U.S. 1089 (1998). “The ‘written description’ requirement implements the principle that a patent must describe the technology that is sought to be patented; the requirement serves both to satisfy the inventor’s obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed.” *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1084 (Fed. Cir. 2005). Further, the written description requirement 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. See, e.g., *Moba, B.V. v. Diamond Automation, Inc.*, 325 F.3d 1306, 1319, 66 USPQ2d 1429, 1438 (Fed. Cir. 2003); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116. However, a showing of possession alone does not cure the lack of a written description. *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 323 F.3d 956, 969-70, 63 USPQ2d 1609, 1617 (Fed. Cir. 2002). 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 these 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). 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.

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. *Lockwood v. Amer. Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, 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, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., 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; *Amgen, Inc. v. Chugai Pharm.*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by “whatever characteristics sufficiently distinguish it”). “Compliance with the written description requirement is essentially a fact-based inquiry that will ‘necessarily vary depending on the

nature of the invention claimed.” *Enzo Biochem*, 323 F.3d at 963, 63 USPQ2d at 1613. An application specification may show actual reduction to practice by describing testing of the claimed invention or, in the case of certain biological materials, by specifically describing a deposit made in accordance with [37 CFR 1.801](#) *et seq.* See *Enzo Biochem*, 323 F.3d at 965, 63 USPQ2d at 1614 (“reference in the specification to a deposit may also satisfy the written description requirement with respect to a claimed material”); see also Deposit of Biological Materials for Patent Purposes, Final Rule, 54 Fed. Reg. 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 Fed. Reg. 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.”).

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 (see, e.g., *LizardTech, Inc. v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1345, 76 USPQ2d 1724, 1733 (Fed. Cir. 2005); *Enzo Biochem*, 323 F.3d at 968, 63 USPQ2d at 1616 (Fed. Cir. 2002); *Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398), 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\(c\)](#). 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., *New Railhead Mfg. L.L.C. v. Vermeer Mfg. Co.*, 298 F.3d 1290, 63 USPQ2d 1843 (Fed. Cir. 2002); *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 47 USPQ2d 1829 (Fed. Cir. 1998); *Fiers 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)). Compliance with the written description requirement is a question of fact which must be resolved on a case-by-case basis. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d at 1563, 19 USPQ2d at 1116 (Fed. Cir. 1991).

A. Original Claims

There is a strong presumption that an adequate written description of the claimed invention is present when the application is filed. *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”). However, as discussed in subsection I., *supra*, 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. 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. 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.

The claimed invention as a whole may not be adequately described 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. 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. Gen. Elec. 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.”).

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. 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 necessarily 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”).

B. New or Amended Claims

The proscription against the introduction of new matter in a patent application ([35 U.S.C. 132](#) and [251](#)) serves to prevent an applicant from adding information that goes beyond the subject matter originally filed. See *In re Rasmussen*, 650 F.2d 1212, 1214, 211 USPQ 323, 326 (CCPA 1981). See [MPEP § 2163.06](#) through [§ 2163.07](#) for a more detailed discussion of the written description requirement and its relationship to new matter. 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). 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. 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).

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. *In re Oda*, 443 F.2d 1200, 170 USPQ 268 (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. Deposits made after the application filing date cannot be relied upon to support additions to or correction of information in the application as filed. 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.

Under certain circumstances, omission of a limitation can raise an issue regarding whether the inventor had possession of a broader, more generic invention. See, e.g., *PIN/NIP, Inc. v. Platte Chem. Co.*, 304 F.3d 1235, 1248, 64 USPQ2d 1344, 1353 (Fed. Cir. 2002) (Claim for a method of inhibiting sprout growth on tubers by treating them with spaced, sequential application of two chemicals was held invalid for lack of adequate written description where the specification indicated that invention was a method of applying a “composition,” or mixture, of the two chemicals.); *Gentry Gallery, Inc. v. Berkline 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 Assoc. 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.). 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. 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\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), para. 1, as not enabling, or under [35 U.S.C. 112\(b\)](#) or [pre-AIA 35 U.S.C. 112](#), para. 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](#).

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

II. METHODOLOGY FOR DETERMINING ADEQUACY OF WRITTEN DESCRIPTION

A. Read and Analyze the Specification for Compliance with 35 U.S.C. 112(a) or Pre-AIA 35 U.S.C. 112, para. 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\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), para. 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, *Wertheim*, 541 F.2d at 262, 191 USPQ at 96; however, with respect to newly added or amended claims, applicant should show support in the original disclosure for the new or amended claims. 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.”). 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. 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 Sec. 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).

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. See, e.g., *In re Morris*, 127 F.3d 1048, 1053-54, 44 USPQ2d 1023, 1027 (Fed. Cir. 1997). The entire claim must be considered, including the preamble language and the transitional phrase. “Preamble language” is that language in a claim appearing before the transitional phrase, 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 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”). See also

[MPEP § 2111.03](#). “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 Indus. v. Guardian Indus.*, 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 *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1239-1240, 68 USPQ2d 1280, 1283-84 (Fed. Cir. 2003); *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). See also [MPEP § 2111.03](#). The claim as a whole, including all limitations found in the preamble (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)), the transitional phrase, and the body of the claim, must be sufficiently supported to satisfy the written description requirement. 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.

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. 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.”). 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\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), para. 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. 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 Pharm. 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”). 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 filed (see, e.g., *Wang Labs. v. Toshiba Corp.*, 993 F.2d 858, 865, 26 USPQ2d 1767, 1774 (Fed. Cir. 1993)) 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. See, e.g., *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986).

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 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. See, e.g., *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1323, 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 Elect., 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.”).

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. *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). 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.* See especially [37 CFR 1.804](#) and [1.809](#). See also subsection I., *supra*.

An applicant may show possession of an invention by disclosure of drawings or structural chemical formulas that are sufficiently detailed to show that applicant was in possession of the claimed invention as a whole. See, e.g., *Vas-Cath*, 935 F.2d at 1565, 19 USPQ2d at 1118 (“drawings alone may provide a ‘written description’ of an invention as required by [Sec. 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 Am. 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.”); *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.”). The description need only describe in detail that which is new or not conventional. See *Hybritech v. Monoclonal Antibodies*, 802 F.2d at 1384, 231 USPQ at 94; *Fonar Corp. v. Gen. Elec. Co.*, 107 F.3d at 1549, 41 USPQ2d at 1805 (source code description not required). 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 characteristics which provide evidence that applicant was in possession of the claimed invention, 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. *Enzo Biochem*, 323 F.3d at 964, 63 USPQ2d at 1613. 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 whether the gene disclosed is the same as or different from a gene isolated by another by comparing the restriction enzyme maps. 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. As explained by the Federal Circuit, “(1) examples are not necessary to support the adequacy of a written description; (2) the written description standard may be met ... even where

actual reduction to practice of an invention is absent; and (3) there is no per se rule that an adequate written description of an invention that involves a biological macromolecule must contain a recitation of known structure.” *Falkner v. Inglis*, 448 F.3d 1357, 1366, 79 USPQ2d 1001, 1007 (Fed. Cir. 2006). See also *Capon v. Eshhar*, 418 F.3d at 1358, 76 USPQ2d at 1084 (“The Board erred in holding that the specifications do not meet the written description requirement because they do not reiterate the structure or formula or chemical name for the nucleotide sequences of the claimed chimeric genes” where the genes were novel combinations of known DNA segments.). For example, disclosure of an antigen fully characterized by its structure, formula, chemical name, physical properties, or deposit in a public depository provides an adequate written description of an antibody claimed by its binding affinity to that antigen. *Noelle v. Lederman*, 355 F.3d 1343, 1349, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (holding there is a lack of written descriptive support for an antibody defined by its binding affinity to an antigen that itself was not adequately described). Additionally, 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”). 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 Pharm. Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991)). An adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. See, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004) (The patent at issue claimed a method of selectively inhibiting PGHS-2 activity by

administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product, however the patent did not disclose any compounds that can be used in the claimed methods. While there was a description of assays for screening compounds to identify those that inhibit the expression or activity of the PGHS-2 gene product, there was no disclosure of which peptides, polynucleotides, and small organic molecules selectively inhibit PGHS-2. The court held that “[w]ithout such disclosure, the claimed methods cannot be said to have been described.”).

If a claim limitation invokes [35 U.S.C. 112\(f\)](#) or [pre-AIA 35 U.S.C. 112](#), para. 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\(f\)](#) or [pre-AIA 35 U.S.C. 112](#), para. 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\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), para. 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\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), para. 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\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), para. 2, “cannot stand where there is adequate description in the specification to satisfy [35 U.S.C. 112\(a\)](#) or [pre-AIA 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](#), para. 6,” 65 Fed. Reg. 38510, June 21, 2000. See also [MPEP § 2181](#).

What is conventional or well known to one of ordinary skill in the art need not be disclosed in detail. See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d at 1384, 231 USPQ at 94. See also *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1085 (Fed. Cir. 2005) (“The ‘written description’ requirement must be applied in the context of the particular invention and the state of the knowledge.... As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution.”). 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. 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”).

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\(e\)](#).

i) For Each Claim Drawn to a Single Embodiment or Species:

(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.

(1) 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. [35 U.S.C. 112\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), para. 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). 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\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), para. 1, for lack of written description must not be made.

(2) 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. 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).

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. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406. The description needed to satisfy the requirements of [35 U.S.C. 112](#) “varies with the nature and scope of the invention at issue, and with the scientific and technologic knowledge already in existence.” *Capon v. Eshhar*, 418 F.3d at 1357, 76 USPQ2d at 1084. 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 claims present in the application when originally filed, even if the specification discloses only a method of making the invention and the function of the invention. See, e.g.,

In re Hayes Microcomputer Prod., 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 [35 U.S.C. 112\(a\)](#) or [pre-AIA section 112](#), first paragraph, when one skilled in the relevant art would understand what is intended and know how to carry it out.”).

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. 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. Furthermore, disclosure of a partial structure without additional characterization of the product may not be sufficient to evidence possession of the claimed invention. 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 Lab.*

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.*

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\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), para. 1.

ii) 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 i)(A), above), reduction to drawings (see i)(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 i)(C), above). See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

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. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure “indicates that the patentee has invented species sufficient to constitute the gen[us].” See *Enzo Biochem*, 323 F.3d at 966, 63 USPQ2d at 1615; *Noelle v. Lederman*, 355 F.3d 1343, 1350, 69 USPQ2d 1508, 1514 (Fed. Cir. 2004) (Fed. Cir. 2004) (“[A] patentee of a biotechnological invention cannot necessarily claim a genus after only describing a limited number of species because there may be unpredictability in the results obtained from species other than those specifically enumerated.”). “A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when ... the evidence indicates ordinary artisans could not predict the operability in the invention of any species other

than the one disclosed.” *In re Curtis*, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004) (Claims directed to PTFE dental floss with a friction-enhancing coating were not supported by a disclosure of a microcrystalline wax coating where there was no evidence in the disclosure or anywhere else in the record showing applicant conveyed that any other coating was suitable for a PTFE dental floss.) On the other hand, there may be situations where one species adequately supports a genus. See, e.g., *Rasmussen*, 650 F.2d at 1214, 211 USPQ at 326-27 (disclosure of a single method of adheringly applying 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.).

The Federal Circuit has explained that a specification cannot always support expansive claim language and satisfy the requirements of [35 U.S.C. 112](#) “merely by clearly describing one embodiment of the thing claimed.” *LizardTech v. Earth Resource Mapping, Inc.*, 424 F.3d 1336, 1346, 76 USPQ2d 1731, 1733 (Fed. Cir. 2005). The issue is whether a person skilled in the art would understand applicant to have invented, and been in possession of, the invention as broadly claimed. In *LizardTech*, claims to a generic method of making a seamless discrete wavelet transformation (DWT) were held invalid

under [35 U.S.C. 112](#), first paragraph, because the specification taught only one particular method for making a seamless DWT and there was no evidence that the specification contemplated a more generic method. See also *Tronzo v. Biomet*, 156 F.3d at 1159, 47 USPQ2d at 1833 (Fed. Cir. 1998), wherein the disclosure of a species in the parent application did not suffice to provide written description support for the genus in the child application where the specification taught against other species.

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 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. See, e.g., *Eli Lilly*. 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. 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). 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\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), para. 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. 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.”). However, when filing an amendment an applicant should show support in the original disclosure for new or amended claims. See [MPEP § 714.02](#) and [§ 2163.06](#) (“Applicant should ... specifically point out the support for any amendments made to the disclosure.”).

To comply with the written description requirement of [35 U.S.C. 112\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), para. 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, implicitly, or inherently supported in the originally filed disclosure. 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). See also *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.](#)); *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); *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). Furthermore, each claim must include all elements which applicant has described as essential. See, e.g., *Johnson Worldwide Assoc. 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.

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\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), para. 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\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), para. 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 35 U.S.C. 112(a) or Pre-AIA 35 U.S.C. 112, para. 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. See, e.g., *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). 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. *Wertheim*, 541 F.2d at 263, 191 USPQ at 97. 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:

- (A) Identify the claim limitation at issue; and
- (B) 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. See *Rasmussen*, 650 F.2d at 1214, 211 USPQ at 326.

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\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), para. 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\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), para. 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 [35 U.S.C. 112\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), para. 1, written description requirement, must be thoroughly analyzed and discussed in the next Office action. See *In re Alton*, 76 F.3d 1168, 1176, 37 USPQ2d 1578, 1584 (Fed. Cir. 1996).

2163.01 Support for the Claimed Subject Matter in Disclosure [R-11.2013]

A written description requirement issue generally involves the question of whether the subject matter of a claim is supported by [conforms to] the disclosure of an application as filed. If the examiner concludes that the claimed subject matter is not supported [described] in an application as filed, this would result in a rejection of the claim on the ground of a lack of written description under [35 U.S.C. 112\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), first paragraph, or denial of the benefit of the filing date of a previously filed application. The claim should not be rejected or objected to on the ground of new matter. As framed by the court in *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981), the concept of new matter is properly employed as a basis for objection to amendments to the abstract, specification or drawings attempting to add new disclosure to that originally presented. While the test or analysis of description requirement and new matter issues is the same, the examining procedure

and statutory basis for addressing these issues differ. See [MPEP § 2163.06](#).

2163.02 Standard for Determining Compliance With the Written Description Requirement [R-11.2013]

The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, “does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.” *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon “reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.” *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)).

Whenever the issue arises, 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. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). 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. *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, 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, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Regents of the Univ. of Cal. v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); *Amgen, Inc. v. Chugai Pharm.*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by “whatever characteristics sufficiently distinguish it”).

The subject matter of the claim need not be described literally (i.e., using the same terms or *in haec verba*) in order for the disclosure to satisfy the description requirement. If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application. This conclusion will result in the rejection of the claims affected under [35 U.S.C. 112\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), first paragraph - description requirement, or denial of the benefit of the filing date of a previously filed application, as appropriate.

See [MPEP § 2163](#) for examination guidelines pertaining to the written description requirement.

2163.03 Typical Circumstances Where Adequate Written Description Issue Arises [R-11.2013]

A description requirement issue can arise in a number of different circumstances where it must be determined whether the subject matter of a claim is supported in an application as filed. See [MPEP § 2163](#) for examination guidelines pertaining to the written description requirement. While 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 (see, e.g., *Regents of the Univ. of Cal. v. Eli Lilly*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997)), there is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed. *In re Wertheim*, 541 F.2d 257,

262, 191 USPQ 90, 96 (CCPA 1976). Consequently, rejection of an original claim for lack of written description should be rare. Most typically, the issue will arise in the following circumstances:

I. AMENDMENT AFFECTING A CLAIM

An amendment to the claims or the addition of a new claim must be supported by the description of the invention in the application as filed. *In re Wright*, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989). An amendment to the specification (e.g., a change in the definition of a term used both in the specification and claim) may indirectly affect a claim even though no actual amendment is made to the claim.

II. RELIANCE ON FILING DATE OF PARENT APPLICATION UNDER 35 U.S.C. 120

Under [35 U.S.C. 120](#), the claims in a U.S. application are entitled to the benefit of the filing date of an earlier filed U.S. application if the subject matter of the claim is disclosed in the manner provided by [35 U.S.C. 112\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), first paragraph in the earlier filed application. See, e.g., *Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 47 USPQ2d 1829 (Fed. Cir. 1998); *In re Scheiber*, 587 F.2d 59, 199 USPQ 782 (CCPA 1978).

III. RELIANCE ON PRIORITY UNDER 35 U.S.C. 119

Under [35 U.S.C. 119\(a\) or \(e\)](#), the claims in a U.S. application are entitled to the benefit of a foreign priority date or the filing date of a provisional application if the corresponding foreign application or provisional application supports the claims in the manner required by [35 U.S.C. 112\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), first paragraph. *In re Ziegler*, 992 F.2d 1197, 1200, 26 USPQ2d 1600, 1603 (Fed. Cir. 1993); *Kawai v. Metlesics*, 480 F.2d 880, 178 USPQ 158 (CCPA 1973); *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989).

IV. SUPPORT FOR A CLAIM CORRESPONDING TO A COUNT IN AN INTERFERENCE

In an interference proceeding, the claim corresponding to a count must be supported by the

specification in the manner provided by [35 U.S.C. 112\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), first paragraph.

Fields v. Conover, 443 F.2d 1386, 170 USPQ 276 (CCPA 1971) (A broad generic disclosure to a class of compounds was not a sufficient written description of a specific compound within the class.). Furthermore, when a party to an interference seeks the benefit of an earlier-filed U.S. patent application, the earlier application must meet the requirements of [35 U.S.C. 112\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), first paragraph for the subject matter of the count. *Hyatt v. Boone*, 146 F.3d 1348, 1352, 47 USPQ2d 1128, 1130 (Fed. Cir. 1998).

2163.04 Burden on the Examiner with Regard to the Written Description Requirement [R-11.2013]

The inquiry into whether the description requirement is met must be determined on a case-by-case basis and is a question of fact. *In re Wertheim*, 541 F.2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). 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. See, e.g., *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971). 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. *Wertheim*, 541 F.2d at 263, 191 USPQ at 97.

I. STATEMENT OF REJECTION REQUIREMENTS

In rejecting a claim, the examiner must set forth express findings of fact which support the lack of written description conclusion (see [MPEP § 2163](#) for examination guidelines pertaining to the written description requirement). These findings should:

- (A) Identify the claim limitation(s) at issue; and
- (B) 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. A simple statement such as “Applicant has not pointed out where the new (or amended) claim is supported, nor does there appear to be a written description of the claim limitation ‘_____’ in the application as filed.” may be sufficient where the claim is a new or amended claim, the support for the limitation is not apparent, and applicant has not pointed out where the limitation is supported. See *Hyatt v. Dudas*, 492 F.3d 1365, 1370, 83 USPQ2d 1373, 1376 (Fed. Cir. 2007) (holding that “[[MPEP § 2163.04](#) [subsection] (I)(B) as written is a lawful formulation of the *prima facie* standard for a lack of written description rejection.”).

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

II. RESPONSE TO APPLICANT'S REPLY

Upon reply by applicant, before repeating any rejection under [35 U.S.C. 112\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), para. 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\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), para. 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 [35 U.S.C. 112\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), para. 1, written description requirement, must be thoroughly analyzed and discussed in the next Office

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

2163.05 Changes to the Scope of Claims [R-11.2013]

The failure to meet the written description requirement of [35 U.S.C. 112\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), first paragraph, commonly arises when the claims are changed after filing to either broaden or narrow the breadth of the claim limitations, or to alter a numerical range limitation or to use claim language which is not synonymous with the terminology used in the original disclosure. To comply with the written description requirement of [35 U.S.C. 112\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), para. 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, implicitly, or inherently supported in the originally filed disclosure. See [MPEP § 2163](#) for examination guidelines pertaining to the written description requirement.

I. BROADENING CLAIM

A. Omission of a Limitation

Under certain circumstances, omission of a limitation can raise an issue regarding whether the inventor had possession of a broader, more generic invention. See, e.g., *Gentry Gallery, Inc. v. Berkline 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 Assoc. 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.); *In re Wilder*, 736 F.2d 1516, 222 USPQ 369 (Fed. Cir. 1984) (reissue claim omitting “in synchronism” limitation with respect to scanning means and indexing means was not supported by the original patent’s disclosure in such a way as to indicate possession, as of the original filing date, of that generic invention.).

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. 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). Compare *In re Peters*, 723 F.2d 891, 221 USPQ 952 (Fed. Cir. 1983) (In a reissue application, a claim to a display device was broadened by removing the limitations directed to the specific tapered shape of the tips without violating the written description requirement. The shape limitation was considered to be unnecessary since the specification, as filed, did not describe the tapered shape as essential or critical to the operation or patentability of the claim.). 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\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), para. 1, as not enabling, or under [35 U.S.C. 112\(b\)](#) or [pre-AIA 35 U.S.C. 112](#), para. 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](#).

B. Addition of Generic Claim

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species. 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. The disclosure of only one species encompassed within a genus adequately describes a claim directed to that genus only if the disclosure “indicates that the patentee has invented species sufficient to constitute the gen[us].” See *Enzo Biochem*, 323 F.3d at 966, 63 USPQ2d at 1615. “A patentee will not be deemed to have invented species sufficient to constitute the genus by virtue of having disclosed a single species when ... the evidence indicates ordinary artisans could not predict the operability in the invention of any species other than the one disclosed.” *In re Curtis*, 354 F.3d 1347, 1358, 69 USPQ2d 1274, 1282 (Fed. Cir. 2004) (Claims directed to PTFE dental floss with a friction-enhancing coating were not supported by a disclosure of a microcrystalline wax coating where there was no evidence in the disclosure or anywhere else in the record showing applicant conveyed that any other coating was suitable for a PTFE dental floss.) On the other hand, there may be situations where one species adequately supports a genus. See, e.g., *In re Rasmussen*, 650 F.2d 1212, 1214, 211 USPQ 323, 326-27 (CCPA 1981) (disclosure of a single method of adheringly applying 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 1154, 1159, 47 USPQ2d 1829, 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 where the specification taught against other species. See also *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989) (generic and subgeneric claims in the U.S. application were not entitled to the benefit of foreign priority where the foreign application disclosed only two of the species encompassed by the broad generic claim and the subgeneric Markush claim that encompassed 21 compounds).

II. NARROWING OR SUBGENERIC CLAIM

The introduction of claim changes which involve narrowing the claims by introducing elements or limitations which are not supported by the as-filed disclosure is a violation of the written description requirement of [35 U.S.C. 112\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), first paragraph. 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). In *Ex parte Ohshiro*, 14 USPQ2d 1750 (Bd. Pat. App. & Inter. 1989), the Board affirmed the rejection under [35 U.S.C. 112](#),

first paragraph, of claims to an internal combustion engine which recited “at least one of said piston and said cylinder (head) having a recessed channel.” The Board held that the application which disclosed a cylinder head with a recessed channel and a piston without a recessed channel did not specifically disclose the “species” of a channeled piston.

While these and other cases find that recitation of an undisclosed species may violate the description requirement, a change involving subgeneric terminology may or may not be acceptable. Applicant was not entitled to the benefit of a parent filing date when the claim was directed to a subgenus (a specified range of molecular weight ratios) where the parent application contained a generic disclosure and a specific example that fell within the recited range because the court held that subgenus range was not described in the parent application. *In re Lukach*, 442 F.2d 967, 169 USPQ 795 (CCPA 1971). On the other hand, in *Ex parte Sorenson*, 3 USPQ2d 1462 (Bd. Pat. App. & Inter. 1987), the subgeneric language of “aliphatic carboxylic acid” and “aryl carboxylic acid” did not violate the written description requirement because species falling within each subgenus were disclosed as well as the generic carboxylic acid. See also *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) (“Whatever may be the viability of an inductive-deductive approach to arriving at a claimed subgenus, it cannot be said that such a subgenus is necessarily described by a genus encompassing it and a species upon which it reads.” (emphasis added)). Each case must be decided on its own facts in terms of what is reasonably communicated to those skilled in the art. *In re Wilder*, 736 F.2d 1516, 1520, 222 USPQ 369, 372 (Fed. Cir. 1984).

III. RANGE LIMITATIONS

With respect to changing numerical range limitations, the analysis must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure. In the decision in *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), the ranges described in the original specification included a range of “25%- 60%” and specific examples of “36%” and “50%.” A corresponding new claim limitation to “at least 35%” did not meet the

description requirement because the phrase “at least” had no upper limit and caused the claim to read literally on embodiments outside the “25% to 60%” range, however a limitation to “between 35% and 60%” did meet the description requirement.

See also *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1328, 56 USPQ2d 1481, 1487 (Fed. Cir. 2000) (“[T]he 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”). Compare *Union Oil of Cal. v. Atl. Richfield Co.*, 208 F.3d 989, 997, 54 USPQ2d 1227, 1232-33 (Fed. Cir. 2000) (Description in terms of ranges of chemical properties which work in combination with ranges of other chemical properties to produce an automotive gasoline that reduces emissions was found to provide an adequate written description even though the exact chemical components of each combination were not disclosed and the specification did not disclose any distinct embodiments corresponding to any claim at issue. “[T]he Patent Act and this court’s case law require only sufficient description to show one of skill in the . . . art that the inventor possessed the claimed invention at the time of filing.”).

2163.06 Relationship of Written Description Requirement to New Matter [R-11.2013]

Lack of written description is an issue that generally arises with respect to the subject matter of a claim. If an applicant amends or attempts to amend the abstract, specification or drawings of an application, an issue of new matter will arise if the content of the amendment is not described in the application as filed. Stated another way, information contained in any one of the specification, claims or drawings of the application as filed may be added to any other part of the application without introducing new matter.

There are two statutory provisions that prohibit the introduction of new matter. The first provision is [35 U.S.C. 132](#), which provides that no amendment shall

introduce new matter into the disclosure of the invention. The second provision is [35 U.S.C. 251](#), which provides that no new matter shall be introduced into the application for reissue.

I. TREATMENT OF NEW MATTER

If new subject matter is added to the disclosure, whether it be in the abstract, the specification, or the drawings, the examiner should object to the introduction of new matter under [35 U.S.C. 132](#) or [251](#) as appropriate, and require applicant to cancel the new matter. If new matter is added to the claims, the examiner should reject the claims under [35 U.S.C. 112\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), first paragraph - written description requirement. *In re Rasmussen*, 650 F.2d 1212, 211 USPQ 323 (CCPA 1981). The examiner should still consider the subject matter added to the claim in making rejections based on prior art since the new matter rejection may be overcome by applicant.

When the claims have not been amended, *per se*, but the specification has been amended to add new matter, a rejection of the claims under [35 U.S.C. 112\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), first paragraph, should be made whenever any of the claim limitations are affected by the added material.

When an amendment is filed in reply to an objection or rejection based on [35 U.S.C. 112\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), first paragraph, a study of the entire application is often necessary to determine whether or not “new matter” is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure.

II. REVIEW OF NEW MATTER OBJECTIONS AND/OR REJECTIONS

A rejection of claims is reviewable by the Patent Trial and Appeal Board, whereas an objection and requirement to delete new matter is subject to supervisory review by petition under [37 CFR 1.181](#). If both the claims and specification contain new matter either directly or indirectly, and there has been both a rejection and objection by the examiner, the issue becomes appealable and should not be decided by petition.

III. CLAIMED SUBJECT MATTER NOT DISCLOSED IN REMAINDER OF SPECIFICATION

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 disclosed 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). Form paragraph 7.44 may be used where originally claimed subject matter lacks proper antecedent basis in the specification. See [MPEP § 608.01\(o\)](#).

2163.07 Amendments to Application Which Are Supported in the Original Description [R-08.2012]

Amendments to an application which are supported in the original description are NOT new matter.

I. REPHRASING

Mere rephrasing of a passage does not constitute new matter. Accordingly, a rewording of a passage where the same meaning remains intact is permissible. *In re Anderson*, 471 F.2d 1237, 176 USPQ 331 (CCPA 1973). The mere inclusion of dictionary or art recognized definitions known at the time of filing an application may not be considered new matter. If there are multiple definitions for a term and a definition is added to the application, it must be clear from the application as filed that applicant intended a particular definition, in order to avoid an issue of new matter and/or lack of written description. See, e.g., *Scarring Corp. v. Megan, Inc.*, 222 F.3d 1347, 1352-53, 55 USPQ2d 1650, 1654 (Fed. Cir. 2000). In *Scarring*, the original disclosure was drawn to recombinant DNA molecules and used the term “leukocyte interferon.” Shortly after the filing date, a scientific committee abolished the term in favor of “IFN-(a),” since the latter term more specifically identified a particular polypeptide and since the committee found that leukocytes also produced other types of interferon. The court held that the subsequent amendment to the specification and claims substituting the term “IFN-(a)” for “leukocyte interferon” merely renamed

the invention and did not constitute new matter. The claims were limited to cover only the interferon subtype coded for by the inventor's original deposits.

II. OBVIOUS ERRORS

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 error in the specification, but also the appropriate correction.

In re Odd, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971).

Where a foreign priority document under [35 U.S.C. 119](#) is of record in the U.S. application file, applicant may not rely on the disclosure of that document to support correction of an error in the pending U.S. application. *Ex parte Bondiou*, 132 USPQ 356 (Bd. App. 1961). This prohibition applies regardless of the language of the foreign priority documents because a claim for priority is simply a claim for the benefit of an earlier filing date for subject matter that is common to two or more applications, and does not serve to incorporate the content of the priority document in the application in which the claim for priority is made. This prohibition does not apply where the U.S. application explicitly incorporates the foreign priority document by reference. For applications filed on or after September 21, 2004, where all or a portion of the specification or drawing(s) is inadvertently omitted from the U.S. application, a claim under [37 CFR 1.55](#) for priority of a prior-filed foreign application that is present on the filing date of the application is considered an incorporation by reference of the prior-filed foreign application as to the inadvertently omitted portion of the specification or drawing(s), subject to the conditions and requirements of [37 CFR 1.57\(a\)](#). See [37 CFR 1.57\(a\)](#) and [MPEP § 217](#).

Where a U.S. application as originally filed was in a non-English language and an English translation thereof was subsequently submitted pursuant to [37 CFR 1.52\(d\)](#), if there is an error in the English translation, applicant may rely on the disclosure of the originally filed non-English language U.S.

application to support correction of an error in the English translation document.

2163.07(a) Inherent Function, Theory, or Advantage [R-08.2012]

By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter. *In re Reynolds*, 443 F.2d 384, 170 USPQ 94 (CCPA 1971); *In re Smythe*, 480 F.2d 1376, 178 USPQ 279 (CCPA 1973). "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.'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted).

2163.07(b) Incorporation by Reference [R-11.2013]

Instead of repeating some information contained in another document, an application may attempt to incorporate the content of another document or part thereof by reference to the document in the text of the specification. The information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed. Replacing the identified material incorporated by reference with the actual text is not new matter. See [37 CFR 1.57](#) and [MPEP § 608.01\(p\)](#) for Office policy regarding incorporation by reference. See [MPEP § 2181](#) for the impact of incorporation by reference on the determination of whether applicant has complied with the requirements of [35 U.S.C. 112\(b\)](#) or [pre-AIA 35 U.S.C. 112](#), second paragraph

when [35 U.S.C. 112\(f\)](#) or [pre-AIA 35 U.S.C. 112](#), sixth paragraph is invoked.

2164 The Enablement Requirement [R-11.2013]

The enablement requirement refers to the requirement of [35 U.S.C. 112\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), first paragraph that the specification describe how to make and how to use the invention. The invention that one skilled in the art must be enabled to make and use is that defined by the claim(s) of the particular application or patent.

The purpose of the requirement that the specification describe the invention in such terms that one skilled in the art can make and use the claimed invention is to ensure that the invention is communicated to the interested public in a meaningful way. The information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention. However, to comply with [35 U.S.C. 112\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), first paragraph, it is not necessary to “enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect.” *CFMT, Inc. v. Yieldup Int’l Corp.*, 349 F.3d 1333, 1338, 68 USPQ2d 1940, 1944 (Fed. Cir. 2003) (an invention directed to a general system to improve the cleaning process for semiconductor wafers was enabled by a disclosure showing improvements in the overall system). Detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention. A patent claim is invalid if it is not supported by an enabling disclosure.

The enablement requirement of [35 U.S.C. 112\(a\)](#) or [pre-AIA 35 U.S.C. 112](#), first paragraph, is separate and distinct from the written description requirement. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116-17 (Fed. Cir. 1991) (“the purpose of the ‘written description’ requirement is broader than to merely explain how to ‘make and use’”). See also [MPEP § 2161](#). Therefore, the fact that an additional limitation to a claim may lack descriptive support in the disclosure as originally

filed does not necessarily mean that the limitation is also not enabled. In other words, even if a new limitation is not described in the original disclosure, the addition of a new limitation in and of itself may not create an enablement problem provided that one skilled in the art could make and use the claimed invention with the new limitation. Consequently, such limitations must be analyzed for both enablement and description using their separate and distinct criteria.

Furthermore, when the limitation is not described in the specification portion of the application as filed but is in the claims, the limitation in and of itself may enable one skilled in the art to make and use the claimed invention. When claimed subject matter is only presented in the claims and not in the specification portion of the application, the specification should be objected to for lacking the requisite support for the claimed subject matter using form paragraph 7.44. See [MPEP § 2163.06](#). This is an objection to the specification only and enablement issues should be treated separately.

2164.01 Test of Enablement [R-08.2012]

Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term “undue experimentation,” it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also *United States v. Teletronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) (“The test of enablement is whether one