Recent Developments In Biomedical IP Law Part II: Patent Applications From Claim Construction To The Doctrine Of Equivalents.

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About the Presenter

ADRIENNE B. NAUMANN

Adrienne B. Naumann established her own practice in 1996 which is exclusively intellectual property law. Ms. Naumann's practice includes individual entrepreneurs and start-up companies, as well as small and medium sized businesses. Her issued patents include a broad range of technologies including: a razor handle, board game, agricultural method, pneumatically driven trench shoring device, floral containers, electromechanical lock, laminar flow nozzle, portable exercise devices, mechanical bag holder and shelving. She has also filed successful patent application appeals in the Patent & Trademark Office on behalf of clients.

Ms. Naumann has obtained trademarks, copyrights and design patents on behalf of artists, writers and companies. In addition to obtaining intellectual property protection through government agencies, Ms. Naumann advises and drafts documents on matters of ownership, shop rights, work for hire, transfers of rights, licenses, permissions, rescission, consents, non-disclosure agreements, releases, trade secrets, proprietary information and web sites.

Ms. Naumann judges the Illinois Institute of Technology Interprofessional Projects Program in Chicago. Ms. Naumann also serves on the Board of the University of Chicago, Chicago Women's Alliance and on the e-Discovery committee for the Seventh Circuit Court of Appeals

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Course Description

Course Presentation

This course is an in-depth review of Biomedical Intellectual Property Law and review of cases from the Federal Circuit and Appellate Courts. The course reviews ongoing litigation between higher learning institutions. Intellectual Property law deals with laws to protect and enforce rights of the creators and owners of inventions, writing, music, designs and other works, known as the "intellectual property." The course examines intellectual property case law regarding Biomedical Devices, Pharmaceuticals and Genetic Engineering.

The course reviews Intellectual Property Law claim construction; written description requirements; possession of the specific subject matter claimed in the patent; and the patent application filing date. The patent must describe the technology that is sought to be patented. The written description requirement satisfies 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.

The course provides a fundamental overview of written description and indefiniteness, obviousness, patentable subject matter eligibility (and in particular several of the above categories for antibodies and pharmaceuticals) and a working understanding on significant intellectual property case law.

The course reviews Intellectual Property Law regarding Indefiniteness; Written Description And Enablement; Amendments Affecting A Claim and Original Claim Not Sufficiently Described

The course reviews Intellectual Property Law Statement Of Rejection Requirements; Broadening a Claim; Treatment Of New Matter; Patent Subject Matter Eligibility and the Doctrine Of Equivalents.

This course provides an intellectual foundation and introduces a set of learning skills essential for success in the legal profession and for life beyond. The course will provide opportunities for careful reading, for creative and critical thinking, for oral and written communication, and for engaging with others in a shared conversation about stimulating material.

Course Material

This material is intended to be a guide in general and is not legal advice. If you have any specific question regarding the state of the law in any particular jurisdiction, we recommend that you seek legal guidance relating to your particular fact situation.

The course materials will provide the attendee with the knowledge and tools necessary to identify the current legal trends with respect to these issues. The course materials are designed to provide the attendee with current law, impending issues and future trends that can be applied in practical situations.

Course Learning Objectives and Outcomes

This course is designed to provide the following goals, learning objectives and outcomes:

- Participants will develop a working understanding on significant Intellectual Property case law.
- Participants will learn how to analyze the protection afforded by Intellectual Property Law and how to steer a business's IP strategies and objectives.
- Participants will gain the ability to recognize and describe Biomedical Intellectual Property Law and cases from the Federal Circuit and appellate Courts.
- Participants will gain the ability to recognize and describe how Intellectual Property Law protects and enforces the rights of the creators and owners of inventions.
- Participants will develop an understanding of Intellectual Property case law regarding Biomedical Devices, Pharmaceuticals and Genetic Engineering.
- Participants will develop an understanding of the written description requirement in a patent applicant and the specific subject matter claimed in the patent as of the patent application filing date.
- Participants will learn to critically evaluate and analyze how the written description requirement satisfies 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.

- Participants will learn to critically evaluate and analyze the written description and indefiniteness, obviousness, patentable subject matter eligibility in Intellectual Property Law.
- Participants will develop an understanding of Intellectual Property Law Amendments Affecting A Claim; Statement Of Rejection Requirements and the Narrowing Or Subgeneric Claim.
- Participants will develop an understanding of Intellectual Property Law Reviewing New Matter Objections And Rejections; Rephrasing and Obvious Errors.
- Participants will develop an understanding of Intellectual Property Law Patent Subject Matter Eligibility and the Doctrine Of Equivalents.
- Upon completion of the course, participants should be able to apply the course material; improve their ability to research, plan, synthesize a variety of sources from authentic materials, draw conclusions; and demonstrate an understanding of the theme and concepts of the course by applying them in their professional lives.

Timed Agenda:

Presenter Name: Adrienne B. Naumann

CLE Course Title: Recent Developments In Biomedical IP Law Part II: Patent Applications From Claim Construction To The Doctrine Of Equivalents

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Recent Developments In Biomedical IP Law Part II: Patent Applications From Claim Construction To The Doctrine Of Equivalents

Course Material

Claim Construction

V. Claim Construction:

AstraZeneca AB et al. v. Mylan Pharmaceuticals, Inc. et al.,19 F.4th 1325 (Fed. Cir. 2021)

A. *Outcome*: The Federal Circuit

1. Affirmed the judgment of non-obviousness, but

2. Vacated the judgment of infringement to be re-evaluated under the proper claim construction

B. *Background*

a. AstraZenca's claims are directed to a spray composition for treating asthma, and

b. containing 0.001% weight per weight (w/w) of a stabilizer ingredient.

c. AstraZeneca sued Mylan for patent infringement

d. the district court concluded that

(1) the standard scientific range for a claimed 0.001% w/w of a stabilizer ingredient would encompass 0.0005% w/w through .0014% w/w

(2) for the claimed concentration of the stabilizer ingredient, and

(3) under this construction of the claimed 0.001%,

(4) AstraZenica's patent (i) was not invalid for obviousness, but (ii) was infringed.

d. upon appeal, Mylan maintained that

(1) the district court improperly construed the claimed 0.001% w/w range for the claimed stabilizer ingredient, because

(2) the court improperly relied upon an extrinsic general scientific standard for determining a numerical range, but

(3) the correct standard depends upon the patent specification and prosecution history as interpreted by an ordinary skilled artisan

3. *Federal Circuit analysis*

a. the correct standard under U.S. patent law is

(1) the understanding of the ordinary skilled artisan based upon a patent's written description and prosecution history

b. here a much narrower range of a 0.001% w/w with a 0.00095% to .0014 % w/w margin for experimental error is correct, because

(1) the testing data within the written description clearly demonstrates that very small variations from 0.001% w/w result in dramatically different stabilities, and

(2) the prosecution history reveals that the inventors progressively cancelled or narrowed claims of other stabilizer concentrations

Indefiniteness

VI. Indefiniteness, 35 U.S.C. section 112

A. University of Massachusetts et al. v. L'Oreal S. A. et al., 2022 U.S. Lexis 16147 (Fed. Cir. June 13, 2022) [hereinafter 'UMass' and 'L'Oreal']

1. *Outcome:* Reversed the district court's claim construction, vacated the summary judgment, and remanded

2. *Background*

a. UMass owned two patents disclosing a method for using a topical skin formulation.

(1) the topical skin formulation included a range of adenosine concentrations, and where skin comprised

(2) an upper layer/epidermis and a lowerlayer/dermis.

b. an independent claim read in relevant part:

A method…the method comprising topically applying…a composition comprising a concentration of adenosine…wherein the adenosine concentration applied to the dermal cells is…. (Series of adenosine concentrations) [emphasis added]

c. UMass contended that the concentration of adenosine in the above claim was measured within the volume of dermal cells, and

(1) not within the adenosine solution prior to application to skin

d. the district court concluded that the concentration refers to the total dermal cells' volume, and

(1) that the claim is indefinite and invalid

e. upon appeal UMass challenged the court's determination that this claim is indefinite

3. Federal Circuit analysis

a. the claim language is not clear, so the next step is to review the specification

b. the specification describes multiple embodiments, but

(1) none of the embodiments address concentration after seepage into the dermis,

(2) much less a quantified concentration per unit volume of dermal cells

c. moreover, during the prosecution history the amendment "wherein the concentration applied to the dermal cells is 10-4 to 10-6 M" was added to the independent claim to achieve allowance of the application

(1) with this amendment, UMass overcame two prior art references which disclosed adenosine concentration prior to skin application

d. therefore, the correct construction of the wherein clause is the measurement of adenosine concentration prior to application to the skin

e. St. Jude asserted that these terms did not provide a sufficiently objective definite claim scope, and

f. upon appeal, Niazi challenged the district court's conclusion that the terms 'pliable' and 'resilient' resulted in indefinite claims

3. *Federal Circuit analysis*

a. a claim is only indefinite when the remaining claim language, patent specification, prosecution history and/or any relevant extrinsic evidence do not

(1) provide reasonable certainty of the claim's scope to an ordinary skilled artisan

b. such certainty existed for the term "resilient," because

(1) the claims designate an outer resilient catheter

(i) with "… shape memory and sufficient stiffness."

(2) the dependent claims designate exemplary resilient materials such as braided silastic

(3) the written description discloses an outer catheter with

(i) sufficient shape memory to return to its original shape when undistorted, and

(ii) sufficient “torque control” and “stiffness”

c. the term “pliable” for the inner catheter claims

(1) there are numerous examples of exemplary materials in the written description

(2) the written description also discloses that (i) material characteristics of the inner catheter (ii) are relative to material characteristics of the resilient outer catheter, and

(3) the inner catheter comprises a material such as silicone, and without longitudinal braiding

(4) the written description also discloses that the interior catheter materials are “… extremely flexible and able to conform to various shapes.”

d. dictionary definitions are consistent with intrinsic terms, i.e., “returning to the original form or position after being bent, compressed or stretched”

e. based upon the written description, the inner catheter, and the outer catheter

(1) clearly comprise differing flexibilities relative to each other

Written Description And Enablement

The following section is from the USPTO.gov website
https://www.uspto.gov/web/offices/pac/mpep/s2163.html#:~:text=%22The%20'written%20description'%20requirement,that%20the%20patentee%20was%20in
last reviewed 2/10/2023

USPTO Guidelines

2163 Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112(a) or Pre-AIA 35 U.S.C. 112, first paragraph, "Written Description" Requirement [R-10.2019]

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 that 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 that 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. Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1340, 94 USPQ2d 1161, 1167 (Fed. Cir. 2010) (en banc); 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 the 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 convey to the public 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). For example, it is now well accepted that a satisfactory description may be found in originally-filed claims or any other portion of the originally-filed specification. See In re Koller, 613 F.2d 819, 204 USPQ 702 (CCPA 1980); In re Gardner, 475 F.2d 1389, 177 USPQ 396 (CCPA 1973); In re Wertheim, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). However, that does not mean that all originally-filed claims have adequate written support. The specification must still be examined to assess whether an originally-filed claim has adequate support in the written disclosure and/or the drawings.

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 1612. 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 1.801et 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 determining whether an original claim is 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)), 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, 365, or 386 (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., Martin v. Mayer, 823 F.2d 500, 503, 3 USPQ2d 1333, 1335 (Fed. Cir. 1987); 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 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) ("[W]e 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, issues of adequate written description may arise even for original claims, for example, 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 at the time of filing. 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 or known in the art. Consider the claim "A gene comprising SEQ ID NO:1." The claim may be construed to include specific structures in addition to SEQ ID NO:1, such as a promoter, a coding region, or other elements. Although SEQ ID NO:1 is fully disclosed, there may be insufficient description of other structures embraced by the claim (e.g., promoters, enhancers, coding regions, and other regulatory elements). For guidance on subject matter eligibility of such claims, see MPEP § 2106.

An invention described solely in terms of a method of making and/or its function may lack written descriptive support where there is no described or art-recognized correlation between the disclosed function and the structure(s) responsible for the function. For example, the amino acid sequence of a protein along with knowledge of the genetic code might put an inventor in possession of the genus of nucleic acids capable of encoding the protein, but the same information would not place the inventor in possession of the naturally-occurring DNA or mRNA encoding the protein. See In re Bell, 991 F.2d 781, 26 USPQ2d 1529 (Fed. Cir. 1993); 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). (For guidance on subject matter eligibility of claims to naturally-occurring compositions, see MPEP § 2106.) The Federal Circuit has pointed out that, under United States law, a description that merely renders a claimed invention obvious may not sufficiently describe the

invention for the purposes of the written description requirement of 35 U.S.C. 112. See 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.").

Written description issues may also arise if the knowledge and level of skill in the art would not have permitted the ordinary artisan to immediately envisage the claimed product arising 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) ("[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").

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 also 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 that 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) (an adequate description of a genus may not support claims to a subgenus or species within the genus).

While there is no in haec verba requirement, newly added claims or 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 the ordinary artisan 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., David Laehnemann et al., Denoising DNA deep sequencing data—high-throughput sequencing errors and their correction, 17 Briefings in Bioinformatics 154–1791 (2016); Peter Richterich, Estimation of Errors in 'Raw' DNA Sequences: A Validation Study, 8 Genome Research 251-59 (1998). For example, if an application as filed includes incorrect nucleic acid sequence information and references a deposit of the sequenced material made in accordance with the requirements of 37 CFR 1.801et seq., an amendment to correct the nucleic acid sequence may be permissible where the amendment conforms the sequence information to the compound described in the specification and covered by the claims. See Cubist Pharm., Inc. v. Hospira, Inc., 805 F.3d 1112, 1118, 117 USPQ2d 1054, 1059 (Fed. Cir. 2015)("The fact that the inventors were mistaken as to one aspect of the structure of daptomycin at the time the application [ ] was filed does not render the specification inadequate to satisfy the written description requirement. It was enough that the specification disclosed relevant identifying characteristics that distinguished daptomycin from other compounds and thus showed that the inventors had possession of daptomycin, even though they may not have had an accurate picture of the entire chemical structure of that compound." Id. at 1120, 117 USPQ2d at 1060.) Deposits made after the filing date may be relied upon to provide support for the correction of sequence information only if applicant

submits a statement in compliance with 37 CFR 1.804 stating that the biological material which is deposited is the 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" containing 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) (stating that, 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, 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.'"); see also 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 that 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, first paragraph, as not enabling, or under 35 U.S.C. 112(b) or pre-AIA 35 U.S.C. 112, second paragraph. 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, first paragraph

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, first paragraph. There is a 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, thus 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 the written description of the invention as providing adequate support for the claimed invention. To make a prima facie case, it is necessary to identify the claim limitations that are not adequately supported, and explain why the claim is not fully supported by the disclosure. For example, in Hyatt v. Dudas, 492 F.3d 1365, 1371, 83 USPQ2d 1373, 1376-1377 (Fed. Cir. 2007), the examiner made a prima facie case by clearly and specifically explaining why applicant's specification did not support the particular claimed combination of elements, even though applicant's specification listed each and every element in the claimed combination. The court found the "examiner was explicit that while each element may be individually described in the specification, the deficiency was lack of adequate description of their combination" and, thus, "[t]he burden was then properly shifted to [inventor] to cite to the examiner where adequate written description could be found or to make an amendment to address the deficiency." Id.; see also Stored Value Solutions, Inc. v. Card Activation Techs., 499 Fed.App'x 5, 13-14 (Fed. Cir. 2012) (non-precedential) (Finding inadequate written support for claims drawn to a method of processing debit purchase transactions requiring three separate authorization codes because "the written description [did] not contain a method that include[d] all three codes" and "[e]ach authorization code

is an important claim limitation, and the presence of multiple authorization codes in [the claim] was essential".).

With respect to newly added or amended claims, applicant should show support in the original disclosure for the new or amended claims. See, e.g., Hyatt v. Dudas, 492 F.3d 1365, 1370, n.4 (Fed. Cir. 2007) (citing MPEP § 2163.04 which provides that 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 also 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."). The inquiry into whether the description requirement is met is a question of fact that must be determined on a case-by-case basis. AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc., 759 F.3d 1285, 1297, 111 USPQ2d 1780, 1788 (Fed. Cir. 2014) ("Whether a patent claim is supported by an adequate written description is a question of fact."); 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 Katz Interactive Call Processing Patent Litigation, 639 F.3d 1303, 1319-1320, 97 USPQ2d 1737, 1750 (Fed. Cir. 2011) (stating that "[t]he construction of the claims [is] important to the written description analysis" and patent holder's failure "to point to a genuine factual dispute over whether the specification

disclosed" the claimed subject matter made summary judgment proper on that issue.); 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 phase, e.g., before "comprising," "consisting essentially of," or "consisting of." The transitional term "comprising" (and other comparable terms, e.g., "containing," and "including") is "open-ended" in that 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 F3.d 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, first paragraph, 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 provides adequate written description 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. The disclosure of an element may be critical where those of ordinary skill in the art would require it to understand 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 ordinary

skill in the art at the time the application was filed (see, e.g., Wang Labs., Inc. 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. For some arts, 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). However, sufficient information must be provided to show that the inventor had possession of the invention as claimed.

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 Elec., 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 1.801et seq., 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. 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 (quoting the Written Description Guidelines, 66 Fed. Reg. at 1106, n. 49, stating that "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." Id.

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.). However, the claimed invention itself must be adequately described in the written disclosure and/or the drawings. For example, disclosure of an antigen fully characterized by its structure, formula, chemical name, physical properties, or deposit in a public depository does not, without more, provide an adequate written description of an antibody claimed by its binding affinity to that antigen, even when preparation of such an antibody is routine and conventional. See Amgen Inc. v. Sanofi, 872 F.3d 1367, 1378, 124 USPQ2d 1354, 1361 (Fed. Cir. 2017)("knowledge of the chemical structure of an antigen [does not give] the required kind of structure-identifying information about the corresponding antibodies"); see also Centocor Ortho Biotech, Inc. v. Abbott Labs., 636 F.3d 1341, 1351-52, 97 USPQ2d 1870, 1877 (Fed. Cir. 2011)(patent disclosed the antigen the claimed antibody was supposed to bind, but did not disclose any antibodies with the specific claimed properties).

Other ways of establishing possession of a claimed invention may include unique cleavage by particular enzymes, isoelectric points of fragments, detailed

restriction enzyme maps, a comparison of enzymatic activities, or antibody cross-reactivity. See Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966 (Stating that the 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."). Conversely, describing a composition by its function alone typically will not suffice to sufficiently describe the composition. See Eli Lilly, 119 F.3 at 1568, 43 USPQ2d at 1406 (Holding that description of a gene's function will not enable claims to the gene "because it is only an indication of what the gene does, rather than what it is."); 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, sixth paragraph, 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, sixth paragraph. See also B. Braun Medical, Inc. v. Abbott Labs., 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, first paragraph, 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, first paragraph, if: (1) The written description adequately links or associates adequately described particular structure, material, or acts to perform 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 disclosed in the

specification perform the function recited in a means- (or step-) plus- function limitation. See Aristocrat Techs. Australia PTY Ltd. v. Int'l Game Tech., 521 F.3d 1328, 1336-37, 86 USPQ2d 1235, 1242 (Fed. Cir. 2008) ("'consideration of the understanding of one skilled in the art in no way relieves the patentee of adequately disclosing sufficient structure in the specification.' It is not enough for the patentee simply to state or later argue that persons of ordinary skill in the art would know what structures to use to accomplish the claimed function."), quoting Atmel Corp. v. Information Storage Devices, Inc., 198 F.3d 1374, 1380, 53 USPQ2d 1225, 1229 (Fed. Cir. 1999); Biomedino, LLC v. Waters Technologies Corp., 490 F.3d 946, 953, 83 USPQ2d 1118, 1123 (Fed. Cir. 2007) ("The inquiry is whether one of skill in the art would understand the specification itself to disclose a structure, not simply whether that person would be capable of implementing a structure."). Note also that a rejection under 35 U.S.C. 112(b) or pre-AIA 35 U.S.C. 112, second paragraph, "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. However, when a means- (or step-) plus-function claim limitation is found to be indefinite based on failure of the specification to disclose sufficient corresponding structure, materials, or acts that perform the entire claimed function, then the claim limitation necessarily lacks an adequate written description. Thus, when a claim is rejected as indefinite under 35 U.S.C. 112(b) or pre-AIA 35 U.S.C. 112, second paragraph because there is no corresponding structure, materials, or acts, or an inadequate disclosure of corresponding structure, materials, or acts, for a means- (or step-) plus-function claim limitation, then the claim must also be rejected under 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph, for lack of an adequate written description.

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, first paragraph; 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, first paragraph, 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, in the biotech art, if a strong correlation has been

established 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").

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.

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 Labs. 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, first paragraph.

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. See AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc., 759 F.3d 1285, 1300, 111 USPQ2d 1780, 1790 (Fed. Cir. 2014) (Claims directed to a functionally defined genus of antibodies were not supported by a disclosure that "only describe[d] one type of structurally similar antibodies" that "are not representative of the full variety or scope of 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. Id.; see also Tronzo v. Biomet, 156 F.3d at 1159, 47 USPQ2d at 1833 (Fed. Cir. 1998)(holding that the disclosure of a species in a parent application did not provide adequate written description support for claims to a genus in a child application where the specification taught against other species).

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, 119 F.3d at 1568, 43 USPQ2d at 1406. Instead, the disclosure must adequately reflect the structural diversity of the claimed genus, either through the disclosure of sufficient species that are "representative of the full variety or scope of the genus," or by the establishment of "a reasonable structure-function correlation." Such correlations may be established "by the inventor as described in the specification," or they may be "known in the art at the time of the filing date." See AbbVie, 759 F.3d at 1300-01, 111 USPQ2d 1780, 1790-91 (Fed. Cir. 2014) (Holding that claims to all human antibodies that bind IL-12 with a

particular binding affinity rate constant (i.e., koff) were not adequately supported by a specification describing only a single type of human antibody having the claimed features because the disclosed antibody was not representative of other types of antibodies in the claimed genus, as demonstrated by the fact that other disclosed antibodies had different types of heavy and light chains, and shared only a 50% sequence similarity in their variable regions with the disclosed antibodies.). 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, first paragraph.

(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, 365, or 386

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, first paragraph, or to be entitled to an earlier priority date or filing date under 35 U.S.C. 119, 120, 365, or 386, 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)); Yeda Research and Dev. Co. v. Abbott GMBH & Co., 837 F.3d 1341, 120 USPQ2d 1299 (Fed. Cir. 2016) ("Under the doctrine of inherent disclosure, when a specification describes an invention that has certain undisclosed yet inherent properties, that specification serves as adequate written description to support a subsequent patent application that explicitly recites the invention’s inherent properties.") (citing Kennecott Corp. v. Kyocera Int’l, Inc., 835 F.2d 1419, 1423 (Fed. Cir. 1987)). 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, first paragraph, as lacking adequate written

description, or in the case of a priority or benefit claim under 35 U.S.C. 119, 120, 365, or 386, the priority or benefit claim 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, first paragraph, 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, first paragraph, 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, first paragraph, 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, first paragraph, 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, first paragraph, 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 reGosteli, 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 reKaslow, 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-10.2019]

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. 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 reWright, 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 reScheiber, 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 reZiegler, 992 F.2d 1197, 1200, 26 USPQ2d 1600, 1603 (Fed. Cir. 1993); Kawaiv.Metlesics, 480 F.2d 880, 178 USPQ 158 (CCPA 1973); In reGosteli, 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).

V. Original Claim Not Sufficiently Described

While there is a 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), a question as to whether a specification provides an adequate written description may arise in the context of an original claim. An original claim may lack written description support when (1) the claim defines the invention in functional language specifying a desired result but the disclosure fails to sufficiently identify how the function is performed or the result is achieved or (2) a broad genus claim is presented but the disclosure only describes a narrow species with no evidence that the genus is contemplated. See Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1349-50 (Fed. Cir. 2010) (en banc). The written description requirement is not necessarily met when the claim language appears in ipsis verbis in the specification. "Even if a claim is supported by the specification, the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is claimed. The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement."Enzo Biochem, Inc. v. Gen-Probe, Inc., 323 F.3d 956, 968, 63 USPQ2d 1609, 1616 (Fed. Cir. 2002).

VI. Indefiniteness Rejection Of A Means- (Or Step-) Plus-Function Limitation

A claim limitation expressed in means- (or step-) plus-function language "shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof." 35 U.S.C. 112(f) or pre-AIA 35 U.S.C. 112, sixth paragraph. If the specification fails to disclose sufficient corresponding structure, materials, or acts that perform the entire claimed function, then the claim limitation is indefinite because the applicant has in effect failed to particularly point out and distinctly claim the invention as required by 35 U.S.C. 112(b) or pre-AIA 35 U.S.C. 112, second paragraph. In re Donaldson Co., 16 F.3d 1189, 1195, 29 USPQ2d 1845, 1850 (Fed. Cir. 1994) (en banc). Such a limitation also lacks an adequate written description as required by 35 U.S.C. 112(a) or pre-AIA 35 U.S.C. 112, first paragraph, because an indefinite, unbounded functional limitation would cover all ways of performing a function and indicate that the inventor has not provided sufficient disclosure to show possession of the invention. See also MPEP § 2181.

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 reWertheim, 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-07.2015]

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. See AbbVie Deutschland GmbH & Co., KG v. Janssen Biotech, Inc., 759 F.3d 1285, 1300, 111 USPQ2d 1780, 1790 (Fed. Cir. 2014) (Claims directed to a functionally defined genus of antibodies were not supported by a disclosure that "only describe[d] one type of structurally similar antibodies" that "are not representative of the full variety or scope of 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 corticosteriod 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); Rozbicki v. Chiang, 590 Fed.App'x 990, 996 (Fed. Cir. 2014) (non-precedential) (The court found that patentee, "while attempting to obtain the broadest claim language possible during prosecution, cannot now improperly narrow its language by importing limitations not supported by the claim language or written description."). In Ex parteOhshiro, 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 reLukach, 442 F.2d 967, 169 USPQ 795 (CCPA 1971). On the other hand, in Ex parteSorenson, 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 reSmith, 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 reWilder, 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 reWertheim, 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 reBenno, 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-08.2017]

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., Schering Corp. v. Amgen, Inc., 222 F.3d 1347, 1352-53, 55 USPQ2d 1650, 1654 (Fed. Cir. 2000). In Schering, 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 reOda, 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, applicants may not rely on the disclosure of that document to support correction of an error in the pending U.S. application. Ex parteBondiou, 132 USPQ 356 (Bd. Pat. App. & Int. 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-08.2017]

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 reReynolds, 443 F.2d 384, 170 USPQ 94 (CCPA 1971); In reSmythe, 480 F. 2d 1376, 178 USPQ 279 (CCPA 1973); Yeda Research and Dev. Co. v. Abbott GMBH & Co., 837 F.3d 1341, 120 USPQ2d 1299 (Fed. Cir. 2016) ("Under the doctrine of inherent disclosure, when a specification describes an invention that has certain undisclosed yet inherent properties, that specification serves as adequate written description to support a subsequent patent application that explicitly recites the invention's inherent properties." (citing Kennecott Corp. v. Kyocera Int'l, Inc., 835 F.2d 1419, 1423 (Fed. Cir. 1987))). "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.

END of USPTO Guidelines

https://www.uspto.gov/web/offices/pac/mpep/s2163.html#:~:text=%22The%20'written%20description'%20requirement,that%20the%20patentee%20was%20in

VII. Written description and enablement, 35 U.S.C. section 112

A. Indivior UK Limited v. Dr. Reddy's Laboratory et al.,18 F.4th 1323 (Fed. Cir. 2021)

1. *Outcome*: Affirmed P.T.A.B.'s finding of anticipation based upon insufficient written description within of an earlier application

2. *Background*

a. Indivior's patent was directed to orally dissolvable films containing therapeutic agents, and

(1) claiming ranges for the concentration of a specific polymer ingredient.

b. Dr. Reddy's instituted an inter partes review to cancel numerous claims,

(1) based upon anticipation by a specific reference

c. the only manner in which to remove this reference was to rely upon the earlier filing date (priority date) of Indivior's related patent application

d. the P.T.A.B. concluded that Indivior's earlier patent application did not comprise a sufficient disclosure of these later claimed numerical ranges, and

(1) therefore, Indivior could not rely upon its priority date patent application to remove this anticipating reference, except for

(2) one claim designating a single value for which there was sufficient written description within Indivior's earlier filed application.

3. *Federal Circuit analysis*

a. issue on appeal: Was there sufficient written description in Indivior's priority application to support the challenged claims of the subsequent related patent?

b. a patent must disclose the subject matter of the claim with some clarity, and

(1) this subject matter should be reasonably discernable within the patent

c. here the claimed numerical ranges were not expressly disclosed in the earlier application, because

(1) two tables disclosed by Indivior's earlier application provided specific numerical entries, but not the claimed ranges, and

(2) the values in these tables are merely individual examples

d. furthermore, one paragraph in the earlier application stated that the film may contain any level of this particular polymer

e. however, the court affirmed that the claim limitation for a single numerical value was sufficiently disclosed, because

(1) the ordinary skilled artisan need only combine the disclosed amounts of the selected components

(2) in a straightforward and foreseeable manner to those of ordinary skill in this technology.

B. Amgen et al. v. Sanofi et al., 987 F.3d 1080 (Fed. Cir 2021), petition for certiorari filed November 16, 2021

1. *Outcome*: Affirmed judgement as a matter of law for claims being invalid based upon insufficient enablement

2. *Background*

a. Amgen owns two patents directed to bioengineered antibodies that bind to a specific naturally occurring enzyme

(1) this enzyme in excess impairs regulation of LDL cholesterol, by natural receptors upon cell surfaces, because

(2) individual enzymes attach to an excessive number of these receptors

(i) so the receptors are no longer available to bind LDL cholesterol

b. the claims characterized the bioengineered antibodies exclusively by functional binding of the antibody to the enzyme

(1) rather than structurally by protein sequences, or

(2) other characteristics which all the qualifying antibodies share in common

c. according to the specifications there are two functions for each claimed antibody:

(1) binding to the enzyme, and

(2) preventing the enzyme from attaching to an LDL cholesterol receptor

d. Amgen's issue upon appeal: Whether the claims are sufficiently enabled if the antibodies are exclusively defined by

(1) their function

(2) instead of their chemical composition or other shared characteristics

3. *Federal Circuit analysis*

a. enablement requires that the ordinary skilled artisan can

(1) make and use the invention exclusively from (i) the patent(s) and (ii) the ordinary artisan's own knowledge and skills in this technology

(2) without undue experimentation for the entire scope of the claim

b. here the claims are not enabled because they require undue experimentation, because

(1) the claims are far broader in functional diversity than the disclosed examples

c. this invention exists within an unpredictable science, so

(1) substitution of one amino acid may affect function in an unforeseen manner, and

d. there must be trial and error testing for each antibody within the millions of antibodies encompassed by the claim

(1) to ensure that an antibody exhibits the claimed binding and blocking functions, and

e. only a small subset of antibodies are predictably created based upon the limited number of disclosed examples

C. Pacific Biosciences of California, Inc. v. Oxford Nanopore Technologies, Inc. et al. [herein after 'Pacific'and 'Oxford'], 996 F.3d 1324 (Fed. Cir. 2021)

1. *Outcome:* Affirmed denial of judgment notwithstanding the verdict because of non-enablement

2. *Background*

a. two of Pacific's patents disclose sequencing of nucleic acids using nanopore technology

b. this technology measures the electric current generated by nucleotides passing through each nanopore, and

c. the method included the number of nucleotides affecting this current measurement, and this number was designated as 'N'

(1) however, there was no disclosure for how to quantify or otherwise identify N

d. both of Pacific's patents claimed a priority date of April 12, 2009, from an earlier application.

e. Pacific sued Oxford for infringement of these two patents

f. the jury found the disputed claims invalid based upon insufficient enablement

g. among other issues, Pacific appealed the denial of its motion for judgment notwithstanding the verdict based upon non-enablement

3. *Federal Circuit analysis*

a. sufficient enablement requires that an ordinary skilled artisan could rely exclusively upon a patent's disclosure and his/her own industry knowledge, and

(1) without undue experimentation to create the invention

b. the disputed claims was not sufficiently enabled, because only a few examples were disclosed to represent a very broad claim scope

(1) substantial evidence indicated that the first successful physical nanopore DNA sequencing did not occur until 2011, and

(i) at that time was achieved by Oxford

(2) there was no evidence that Oxford's 2011 achievement was based upon the disputed patents

c. Pacific presented no evidence it physically achieved the claimed methods when it submitted its 2009 application to the U. S. patent office, and

d. there was no manner to determine the value of N based upon the patents, priority application or knowledge of the relevant ordinary skilled artisan

D. BASF Plant Science LP v. Commonwealth Scientific and Industrial Research Organization, 28 F.4th 1247 (Fed. Cir. 2022)

1. *Outcome*

a. affirmed the jury verdict finding sufficient written description for species claims, but

b. reversed the jury verdict because of insufficient written description for broader generic claims.

2. *Background*

a. Commonwealth's patents claimed genetically engineered canola plants which produce a particular oil for feeding fish, and

(1) based exclusively upon results in genetically engineered non-canola plants which produce this same oil, although

(2) the patents' written description did not describe a canola plant embodiment

b. Commonwealth also claimed all similarly genetically engineered plants that could produce this same oil

c. for this particular oil no canola plant had yet been physically achieved as of the patents' priority date

d. BASF commenced a declaratory judgment lawsuit for non-infringement of Commonwealth's patents, and

(1) Commonwealth counterclaimed for patent infringement

(2) among other issues BASF contended that there was insufficient written description

e. BASF appealed the jury verdict finding of an adequate written description of all similarly bioengineered plant claims as well canola plant claims

3. *Federal Circuit analysis*

a. whether a patent satisfies the written description requirement depends upon (i) the perspective of an ordinary skilled artisan in the industry (ii) as of the relevant filing date

b. actually physically achieving the invention is not part of the written description requirement

c. here there was sufficient evidence that

(1) skilled artisans as of the priority date understood that this specific oil production in this specific genetically engineered laboratory plant

(2) was highly predictive of similar results in genetically engineered canola plants

d. although testimony addressing predicted results in canola plants was disputed,

(1) the jury could have properly credited Commonwealth's testimony addressing similarly bioengineered canola plants

e. however, the jury verdict approving claims encompassing all bioengineered plants was reversed, because

(1) there was insufficient written description within the patents to support these much broader and inclusive claims

E. University of California et al. v. The Broad Institute et al., Interference No. 106,115 (P.T.A.B. February 22, 2022), appeal filed April 15, 2022

1. *In this second interference*, and on preliminary motions the P.T.A.B. addressed whether U.C. or Broad achieved the first/earliest constructive reduction to practice

a. that is, which patent application

(1) was the earliest filed, and

(2) included a sufficient written description of CRISPR-Cas9 in eukaryotes

2. *The P.T.A.B. concluded* there was insufficient written description of CRISPR-Cas9 operable within eukaryotic cells in U.C.'s earliest applications

a. in U.C.'s two earliest filed applications, there was no disclosure of successful experiments or other information

(1) that explicitly disclosed achievement of CRISPR-Cas9 operation within eukaryotic cells

3. *In contrast*, Broad's earliest priority application included a sufficient disclosure of experiments to specifically achieve an operable eukaryotic CRISPR-Cas9

a. Broad's priority filing date (i.e., the date of submitting the earliest application with these disclosed experiments in eukaryotes),

(1) was prior to the filing date of the U.C. applications which subsequently sufficiently disclosed operable eukaryotic CRISPR-Cas9

b. consequently, Broad became the presumptive first party to invent

(1) but U.C. could still establish that it actually physically created and/or conceived ('thought of') the CRISPR-Cas9 in eukaryotic cells earlier than Broad, and

(2) within the same interference proceeding

F. Juno Therapeutics, Inc. et al. v. Kite Pharma, Inc., 10 F.4th 1330 (Fed. Cir. 2021)

1. *Outcome:* Reversed the final judgment, because

a. the jury incorrectly concluded that there was sufficient written description

2. *Background*

a. the invention addresses bioengineered genetic information for reprogramming certain white blood cells [T-cells]

(1) to create T-cell surface receptors that attach to and thereby attack specific 'target cells' such as cancer cells

(2) for this attachment, each reprogrammed receptor binds to a particular antigen (foreign substance) upon a specific kind of cancer cell or other 'target' cell "of clinical interest"

(3) each reprogrammed T-cell receptor comprises a component (variable binding fragment, i.e., ---scFv) that attaches to an antigen upon a particular target cell

b. the patent exclusively discloses two examples of variable binding fragments that each exclusively attach to one of two corresponding kinds of cancer cells, although

(1) there are no disclosed amino acid sequences for the two examples of variable fragments, but

(2) Juno's broadest claims designate any and all target cells for this T-cell receptor binding response

c. Juno sued Kite for patent infringement and prevailed at the district court,

(1) although Kite maintained that the patent was invalid because there was no adequate written description

3. *Federal Circuit's analysis*

a. Juno's independent claim reads in relevant part:

A nucleic acid polymer encoding a T-cell receptor … binding element that specifically interacts with a selected target… [emphasis added]

b. for sufficient written description, Juno must disclose either

(1) sufficient species, that is, engineered antibodies with appropriate binding regions (variable fragments)upon the receptors, to support this very broad functional claim, OR

(i) features common to the genus/universe of these particular antibodies such as, but not exclusively, structure, formula or chemical designation/description

(2) these features should also distinguish non-binding bioengineered receptors from binding bioengineered receptors

c. here the ordinary skilled artisan cannot determine which receptor binds to which target cell from the patent

(1) within a numerically large genus/universe of possible bioengineered antibodies variable fragments

(2) the same analysis is true for the species claims, because

(3) the two disclosed examples of prostate and lymphoma receptor variable fragments

(i) do not represent the entire scope of the claimed possible known and unknown variable binding fragments for these two target cells

d. there is also unpredictability, because

(1) antibody components of the T-cell receptors exhibiting the same general common structure

(2) may nevertheless comprise different amino acid sequences, and

(i) as a consequence, recognize a different antigen upon a target cell

e. that other T-cell receptors outside the claims' scope were already known is insufficient for the written description requirement when

(1) there is a functionally claimed genus without any guidance for

(i) selection of reprogrammed receptors comprising variable fragments for corresponding target cells, and

(ii) which variable fragments upon receptors bind or do not bind to an undetermined and undesignated number of corresponding antigens

G. Biogen International GmbH et al. v. Mylan Pharmaceuticals, Inc., 18 F.4th 1333 (Fed. Cir. 2021), panel rehearing and en banc rehearing denied March 16, 2022.

1. *Outcome*: In patent infringement lawsuit, the judgment of patent invalidity based upon insufficient written description was affirmed.

2. *Background*

a. Biogen's patent addresses a multiple sclerosis pharmaceutical treatment, and

b. as of its February 8, 2007, priority date, this patent disclosed several dosage ranges with the claimed dosage of 480 mg. at one end of a particular range.

(1) a single paragraph including this particular range, and with the 480 mg. dose at one end, was the only disclosure of the claimed dosage as of the priority date, and

(2) this claimed dose was not specifically and explicitly correlated to treatment of multiple sclerosis

c. Biogen sued Mylan for patent infringement after Mylan requested the FDA to approve a generic version of Biogen's product.

d. on appeal Mylan contended that Biogen's earlier priority February 8, 2007, provisional patent application

(1) did not comprise sufficient written description for this claimed dosage

3. *Federal Circuit analysis*

a. the patent specification should disclose the invention with all its features/limitations by using descriptive means such as, although not exclusively,

(1) words, structures, figures, diagrams, and formulas

b. in sum, a sufficient written description requires a precise specific definition of the claimed invention.

c. in this case the claimed dosage was not sufficiently linked to an effective dose for multiple sclerosis treatment,

(1) because other neurological diseases are disclosed within the specification

d. moreover, the claim

(1) was not otherwise identified as a critical and optimal dosage.

H. Novartis Pharmaceuticals Corp., Inc. v. HEC Pharmaceutical Co. Ltd., et al., 21 F.4th 1362 (Fed. Cir. 2021)

1. *Outcome:* Upon HEC's petition for panel rehearing, the Federal Circuit vacated its prior decision, and

a. reversed the district court's judgment that Novartis's claims were not invalid for inadequate written description

2. *Background*

a. Novartis patented a method of treating relapsing multiple sclerosis with

(1) a claimed quantified dosage of a specific pharmaceutical formulation, and

(2) which eliminated the administration of a dose known as a loading dose to a patient

b. HEC requested approval from the FDA to market a generic version of Novartis' formulation

(1) for treating relapsing multiple sclerosis, and

(2) thereafter Novartis sued HEC and other entities for patent infringement.

c. both the priority date provisional application and disputed subsequent patent describe

(1) prophetic human clinical trials, as well as

(2) completed dosage experiments in laboratory rats.

d. the laboratory experiment disclosed the most effective dosages in rats, but

(1) loading doses were not explicitly disclosed as absent from the patented treatment for humans or rats, although

(2) loading doses were used in earlier multiple sclerosis treatments which were not the subject of these patents

e. in the subsequent patent infringement lawsuit, HEC contended there was insufficient written description for

(1) the claimed dose of 0.5 milligrams/kilogram/day, and

(2) the negative claim limitation of no loading dose of the claimed formulation

3. *Federal Circuit analysis of negative limitations*

a. to support a negative limitation by written description, such as absence of a loading dose,

(1) the specification must describe a reason to exclude the relevant element comprising the claimed limitation

b. the written description requirement is not met by

(1) silence in the specification regarding presence or absence of a claimed limitation

c. moreover, when a specification is silent expert testimony is insufficient, because

(1) otherwise, expert testimony could effectively eliminate the written description requirement

d. here the specification does not describe either or (i) administering a loading dose or (ii) elimination of a loading dose

e. the prosecution history reveals that the explicit no-loading dose limitation was added to allow the claim of which it was part

(1) this explicit additional limitation strongly implies that

(i) if 'daily dosage' without explicitly claiming a loading dose necessarily excluded a loading dose,

(ii) then there was no reason to add the explicit loading dose limitation for allowance

f. in sum, there is sufficient intrinsic evidence that

(1) an ordinary skilled artisan would not conclude that there was an absence of a loading dose

(2) merely because there is a recited daily dosage without mentioning a loading dose

g. there may be circumstances in which an ordinary skilled artisan would understand a negative limitation to necessarily be present in a patent disclosure, but

(1) this was not such a case

Patent Subject Matter Eligibility

VIII. Patentable subject matter eligibility, 35 U.S.C. section 101

A. In re Board of Trustees of the Leland Stanford Junior University, 989 F.3d 1367 (Fed. Cir. 2021)

1. *Outcome:* The Federal Circuit affirmed the P.T.A.B.'s affirmance of the examiner's final rejection based upon patent ineligible subject matter

2. *Background*

a. Stanford's patent application claimed improved methods and computing systems

(1) for predicting the parent from whom a gene variant is inherited.

b. the asserted improvement comprised

(1) an increase in the accuracy of human genetic predictors, and

(2) by implementing a specific pedigree and specific genotype data as well as improved statistical tools, and whereby

(3) chromosome regions are accessed where there was previously no possible prediction of genetic transfer for a particular inherited trait

3. *Federal Circuit analysis*

a. relied upon the analysis detailed in Alice Corporation Pty. Ltd. v. CLS Bank International et al., 573 U. S. 208 (2014) for evaluating patentable subject matter

b. Alice Step 1

(1) Stanford's claims were directed to a new abstract idea, because

(2) an improved statistical genetic analysis implementing additional data, nevertheless, remains an abstract idea, and where

(3) there is no disclosed improved technological process

c. Alice Step 2

(1) the claims do not designate or result in an improvement to a computer such as

(2) a specialized memory or processor

B. In re Board of Trustees of the Leland Stanford Junior University, 991 F.3d 1245 (Fed. Cir. 2021)

1. *Outcome*: The Federal Circuit affirmed the P.T.A.B.'s affirmance of the examiner's final rejection based upon patent ineligible subject matter.

2. *Background*

a. Stanford's second related patent also disclosed statistical modeling whereby

b. the improvement is directed to more accurately predicting a genetic trait,

(1) based upon genotype data obtained through sequencing an individual's genome, and

(2) obtaining analogous data from unrelated persons, a

(3) by implementing enhanced statistical methods

3. *Federal Circuit analysis*

a. Alice Corporation Pty. Ltd. v. CLS Bank International et al., 573 U.S. 208 (2014)

b. Alice Step 1

(1) the claims designate mathematical calculations, assortment of data and statistical modeling

(2) this statistical model ---- implemented with a conventional computer---- does not transform the mathematics into patent eligible subject matter.

c. Alice Step 2

(1) the claimed steps exclusively designate receiving, extracting, and storing data which are well known, routine and conventional steps.

(2) moreover, these claims do not designate specialized memory or processors

(3) that a combination of mathematical steps provides a more accurate genetics prediction

(i) does not transform the abstract idea into patentable subject matter

C. CardioNet, LLC v et al. v. InfoBionic, Inc., 2021 U.S. App. Lexis 32392 (Fed. Cir. October 29, 2021) (non-precedential)

1. *Outcome*: Summary judgment was vacated and remanded for entry of judgment of no infringement, where

a. the district court should have granted InfoBionic's motion for judgment on the pleadings, because

(1) there was no patent eligible subject matter

2. *Background*

a. CardioNet's patent was directed to an improved heart monitoring device with a specialized component known as a T-wave filter

b. CardioNet alleged that Infobionic's device included CardioNet's patented T-wave filter and commenced a patent infringement lawsuit.

c. the court denied InfoBionic's motion for judgment on the pleadings based upon patent subject matter ineligibility, and

d. InfoBionic appealed the denial of judgment on the pleadings

3. *Federal Circuit analysis*

a. Alice step 1

(1) the claims are directed to the abstract mathematical idea of filtering patient heartbeat signals to increase accuracy, and

(i) filtering data only requires abstract ideas

(2) the invention used a general- purpose computer to filter data, and

(3) required a doctor's mental process to activate this filter

b. Alice step 2

(1) there is no inventive concept, because even an improved mathematical idea remains an abstract idea, and

(2) the machine or transformation test is not dispositive

(3) here there are only conventional computer components performing conventional functions

Doctrine Of Equivalents

IX. Doctrine of Equivalents:

A. Jennewein Biotechnologie GmbH v. International Trade Commission, Glycosyn LLC (Intervenor), 2021 U. S. App. Lexis 28200 (Fed. Cir. September 17, 2021) [hereinafter "Jennewein,""Glycosyn" and "ITC"]

1. *Outcome*: The Federal Circuit affirmed the ITC's limited exclusion order for Jennewein's products, and

a. The ITC's claim construction under the doctrine of equivalents.

2. *Background*

a. Gycosyn's patented methods comprise the use of a gene which is inserted within certain bacteria

(1). this inserted gene produces an enzyme used for commercial production of a naturally occurring substance found in human milk

(2) Glycosyn's inserted gene includes genetic material which did not originate from within these particular bacteria

b. Gycosyn filed a complaint with the ITC

(1) alleging that Jennewein's imported product and process infringed its patented process comprising this inserted gene

c. Jennewein's method comprised two gene fragments which

(1) together expressed the same enzyme as Glycosyn's inserted single gene

d. the ITC concluded that the two gene fragments infringed Glycogen's single gene under the doctrine of equivalents

(1) Glycosyn's independent claim reads in relevant par

(ii) an exogenous functional beta-galactosidase gene….," [emphasis added]

e. Jennewein appealed and contended that the two gene fragments were not equivalent to Glycosyn's patented single gene, because

(1) Jennewein's two gene fragments were not of exogenous origin

3. *Federal Circuit analysis*

a. the doctrine of equivalents is a judicially created analysis to determine

(1) whether an accused device or method infringes patented subject matter, and

(2) even if each and every element of the claimed patented invention is not identically present in a potentially infringing device or method

(3) for this doctrine to apply, the accused product or process should contain elements equivalent to each claimed limitation

b. here the combined two gene fragments in Jennewein's bacteria are equivalent to Glycosyn's exogenous gene limitation, because

(1) the term 'exogenous' is defined in this context as:

(2) genetic materials originating from outside the bacterium into which the genetic material is introduced

c. substantial evidence supported the finding that

(1) the relevant enzyme activity in both parties' bacteria exclusively resulted from

(2) the inserted genetic material which did not naturally occur within the receiving bacterium, and

(3) where together these fragments comprised the same genetic material as the claimed gene, and

(i) result in the same function within the recipient bacteria.

d. even if one fragment was not exogenous, (and which the Federal Circuit disputed)

(1) the COMBINATION of the two fragments, and where at least one fragment was originally exogenous, together results in exogenous genetic material

Conception/Reduction To Practice

IX. Conception and reduction to practice:

University of California et al. v. The Broad Institute et al., Interference No. 106,115 (P.T.A.B. February 22, 2022), appeal filed April 15, 2022

A. *After resolving constructive reduction to practice,*

1. The P.T.A.B. resolved whether U.C. or Broad was first to actually create operable CRISPR-Cas9,

a. with certain structural features and functional capabilities, and within eukaryotic cells and

b. which cleaves eukaryotic DNA in an improved manner

2. Why do we need to know reduction to practice and conception after the America Invents Act?

a. licensing agreements and, but not exclusively,

b. best mode, derivation proceedings and prior user rights

B. *Two major inquiries for resolving* first to invent under U.S patent interference law are (i) first person to actually reduce to practice, and (ii) first person to conceive the invention

a. the person(s) who actually physically creates (reduces to practice) the invention is the first to invent, unless

b. another person(s) conceived ('thought of') the invention earlier and then physically reduced it to practice

(1) within a reasonable time thereafter

c. conception requires possessing a specific concrete idea encompassing the invention, and without numerous and major modifications

(1) prior to successful physical actual reduction to practice

C. *The P.T.A.B. concluded* that U.C. was not the first to invent CRISPR-Cas9 operable in eukaryotic cells for two reasons:

1. There was no actual reduction to practice by U.C. prior to October 2012

a. although U.C.'s collaborating European scientist contended that he may have achieved CRISPR-Cas9 operability with zebra fish embryos

b. however, there no documents evidencing that in 2012 these zebra fish embryo experiments

(1) were recognized as a successful reduction to practice, and

(2) it also appears that although one among fifty zebra fish embryos displayed the appropriate mutation, this scientist was unsure whether CRISPR-Cas9 was the causation

c. moreover, no zebra fish embryo experimental results appeared in U.C.'s October 19, 2012 application or January 28, 2013 application, and

d. the European investigator abandoned these zebra fish embryo experiments which evidences that he did not regard them as successful

2. U.C. and its European colleagues were also not first to conceive CRISPR-Cas9 in eukaryotic cells

a. although U.C. alleged conception based upon a March 1, 2012 proposed experiment for creating CRISPR-Cas9 operable in eukaryotes,

b. U.C. experienced a prolonged period of experimental failures for this project throughout 2012

3. The P.T.A.B. concluded that Broad was first to actually reduce to practice an operable CRISPR-Cas9 within eukaryotic cells

a. Broad's scientist reported the results of July 2012 mouse cell experiments in an October 5, 2012 manuscript submitted to a professional journal

b. this manuscript described all the features of the claimed CRISPR-Cas9 in eukaryotic cells

c. based upon this manuscript, Broad sufficiently evidenced actual reduction to practice by October 5, 2012, and so

d. Broad was first to invent CRISPR-Cas9 operable in eukaryotes, and

(1) U.C.' lost its asserted claims for this same invention

Resources

Resources Specific to this Course

In addition, please see the resources cited within the material.

Resources for the Legal Professional

ABA Center for Professional Responsibility - www.abanet.org/cpr

Chicago Bar Association - www.chicagobar.org

Commission on Professionalism - www.2civility.org

Judicial Inquiry Board - http://www.illinois.gov/jib

Illinois Board of Admissions to the Bar - www.ilbaradmissions.org

Illinois Department of Financial and Professional Regulation - www.idfpr.com/default.asp

Illinois Lawyers' Assistance Program, Inc - www.illinoislap.org

Illinois State Bar Association - www.isba.org

Illinois Supreme Court - www.state.il.us/court

Lawyers Trust Fund of Illinois - www.ltf.org

MCLE Program - www.mcleboard.org