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TC1600 New Matter Training

Deborah Reynolds

Quality Assurance Specialist,

TC1600

571-272-0734



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- Statutes That Govern New Matter
 - 35 USC 112, First Paragraph
 - ◆ The specification shall contain a written description of the invention...
 - ◆ The purpose is to ensure that applicant provides enough information in the original disclosure such that it is clear that applicant invented that which is claimed.



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- Statutes That Govern New Matter
 - 35 USC 132 – prohibits the amendment of the specification to include matter that was not described in the original disclosure
 - 35 USC 251 prohibits the introduction of new matter into an application for reissue patent
 - 35 USC 305 requires reexamination of a patent to be conducted according to procedures established for initial examination under 35 USC 132



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- Questions to ask:
 - Did the original description reasonably allow persons of skill in the art to recognize that applicant invented the invention what is now claimed?
 - Did the description convey with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention, and that the invention, in that context, is whatever is now claimed?
 - Did the disclosure reasonably convey to the artisan that the inventor had possession at that time of the later claimed subject matter?



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- Conclusions:
 - Must be resolved based on the facts of each specific application
 - Requires one to look at the description in the original disclosure to determine whether the new or amended claim was literally or implicitly described with reasonable clarity



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- Amendments to an application which are supported in the original description are NOT new matter.
MPEP 2163.07
 - 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.
 - Literal support is not necessary-the claims do not have to use the exact wording of the specification in order to satisfy the description requirement.



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- Disclosure in an application that merely renders the later-claimed (by amendment) invention obvious is not sufficient to meet the written description requirement of 35 USC112, first paragraph. Lockwood, v. American Airlines, Inc. 41 USPQ .2d 1961 at 1966 (CAFC, 3/4/97)



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Typical Circumstances Under Which New Matter May Arise

- Amendment affecting a claim
 - Amendment of a claim to include a limitation that was not described in the original disclosure as being part of the invention
 - Addition of a new claim that includes a limitation that was not described in the original disclosure as being part of the invention



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Typical Circumstances Under Which New Matter May Arise

- Amendment affecting a claim:
 - Amendment to the claims that omit limitations
 - Amendments to the specification that change the definition of a word, where the word appears in the claims
 - (Note: in this instance the specification should be objected to under 35 USC 132 and the claims should be rejected under 35 USC 112, first paragraph)



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Typical Circumstances Under Which New Matter May Arise

- Amendments affecting the disclosure:
 - Addition of material to the specification or drawings
 - Deletion of original material from the specification or drawings



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- Benefit Claims under 35 USC 120
 - Entitles applicant to benefit of an earlier filing date for claims in a later filed application based on an earlier filed U.S. application under certain conditions, including:
 - ◆ Subject matter claimed is disclosed in the earlier filed US application in the manner provided by 35 USC 112, first paragraph
 - If a claim in an application that claims benefit to an earlier filed US application lacks written description in that earlier filed US application, the benefit is not accorded to the claim



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- Priority Claim under 35 USC 119
 - 35 USC 119(a) entitles an applicant to the benefit of a foreign priority date for claims in a later-filed US application based on a corresponding foreign-filed application if certain conditions are met.
 - 35 USC 119(e) entitles applicant to the benefit of an earlier filing date for claims in a later filed application based on an earlier filed US provisional application if certain conditions are met.
 - If a claim in an application that claims priority under 35 USC 119(a) or (e) lacks written description in the earlier application, then the benefit under USC 119(a) or (e) is not accorded to the claim.



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- Support for an Interference Count
 - A claim copied to provoke an interference proceeding or which corresponds to a count in an interference proceeding, which was amended or newly added to the application, must find written description in the original disclosure.
 - If the claim does not find written description in the original disclosure the claim should be rejected accordingly.
 - ◆ This may take the application out of the interference proceeding or prevent it from getting in to that proceeding until the written description issue is resolved.
 - If a party to the interference is relying upon an earlier filing date under 35 U.S.C. 120 or 35 U.S.C. 119(e), then the claims corresponding to the interference count must find written description in the earlier filed U.S. application or provisional application.



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- Things To Look For:
 - Amendments to claims or new claims that change the scope relative to originally filed claims (broaden/narrow)
 - Changes in range limitations (may broaden or narrow)
 - Rewording of claims where the rewording does not retain the same meaning as the original language
 - Incorporation by reference
 - Negative Limitations
 - Correction of errors
 - Inherent function, theory or advantage



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- Broadening Amendment
 - Amendments that render the claims broader than the original disclosure may raise the issue of lack of written description.
 - Original claim: A process comprising steps 1-4 wherein step 4 involves the use of a solvent which is methanol or ethanol.



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- Broadening Amendment
 - Addition of a generic claim
 - ◆ Original claim: A process comprising steps 1-4 wherein step 4 involves the use of a solvent which is methanol or ethanol.
 - ◆ Amended claim: A process comprising steps 1-4 wherein step 4 involves the use of a solvent wherein the solvent is an alcohol.



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- Narrowing Amendment
 - Amendments that render the claims narrower than the original disclosure may raise the issue of lack of written description.
 - ◆ Original claim: A process comprising steps 1-4 wherein step 4 involves the use of a solvent which is an alcohol.
 - ◆ Amended claim: A process comprising steps 1-4 wherein step 4 involves the use of a solvent wherein the solvent is butanol.*

*the original disclosure did not specifically disclose butanol



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- Ranges
 - Changes in range limitations can both broaden and narrow the claims.
 - Analysis must take into account which ranges one skilled in the art would consider supported by the discussion in the original disclosure.



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- Ranges
 - In re Wertheim, 541 F. 2d 257,191 USPQ 90 (CCPA1976)
 - ◆ 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.



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- Rephrasing
 - Amendments that rephrase something in the specification or claims may or may not raise the issue of lack of written description.
 - Rephrasing that retains the same meaning does not raise the issue of lack of written description
 - MPEP 2163.07 "The mere inclusion of dictionary or art recognized definitions known at the time of filing an application would 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."



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- Rephrasing
 - *Schering Corp. V. Amgen, Inc.*, 222 F.3d 1347, 1352-53, 55 USPQ2d 1650, 1654 (Fed. Cir. 2000).
 - ◆ In *Schering*, the original disclosure drawn to recombinant DNA molecules utilized 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.



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- Inherent Function, Theory, or Advantage
 - If an application discloses a device that inherently necessarily performs a function or has a property, operates according to a theory or has an advantage, then the application necessarily discloses that function, theory or advantage, even though the application does not explicitly say anything concerning it.
 - The application may later be amended to recite the function, theory or advantage without introducing new matter.
 - ◆ Must first establish that the function, theory or advantage is necessarily and always present and would have been recognized as such by those skilled in the art
 - ◆ Not sufficient where the function, theory or advantage *might* result from the description given in the application



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- Negative Limitations
 - Any negative limitation or exclusionary proviso must have basis in the original disclosure. If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. *In re Johnson*, 558 F.2d 1008, 1019, 195 USPQ 187, 196(CCPA1977).
 - A claim containing a negative limitation which does not have a basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph as failing to comply with the written description requirement. *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), aff'd. mem., 738 F. 2d 453 (Fed. Cir. 1984).



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Incorporation by Reference

Replacing the identified material incorporated by reference with the actual text is not new matter. See MPEP 608.01(p) and 37 CFR 1.57 regarding incorporation by reference.



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Incorporation By Reference (37 CFR 1.57 (a))

- Priority/benefit claims act as an incorporation by reference of a prior-filed application as to inadvertently omitted material (37 CFR 1.57(a))
 - Applies to applications filed **on or after September 21, 2004**
 - Requirements for corrective amendment under 37 CFR 1.57 (a):
 - ◆ The priority/benefit claim was present upon the filing date of the later-filed application
 - ◆ The material to be added was inadvertently omitted from the later-filed application
 - ◆ The omitted portion is completely contained in the prior-filed application



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Incorporation by Reference

- Mere reference to another co-pending application is not a benefit claim (e.g. a statement that prior patent application 09/123456 is copending with the current application), and will not be treated as an incorporation by reference of any subject matter found therein
- Applications filed prior to September 21, 2004
 - Applicant can only add to the current application material found in a prior application if the prior application was expressly incorporated by reference



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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 the error in the specification but also recognize the appropriate correction (*In re Oda*, 443 F.2d 1200, 170 USPQ 268 (CCPA 1971)).



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Obvious Errors

- Where a US 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.



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Correction Of Erroneous Data

- Examples include correction of erroneous nucleic acid or protein sequence data, or the molecular weight of a protein. In such cases, **the new information must be an inherent characteristic of the invention**, and there must be sufficient evidence that the invention itself was in the possession of the inventor at the time the application was filed.
 - If an application as filed includes sequence information and references a **deposit** of the sequenced material in accordance with the requirements of 37 CFR 1.801 *et seq.*, amendment may be permissible.
 - Corrections of **minor errors** in a sequence may be possible based on the argument that one of skill in the art would have resequenced the deposited material and would have immediately recognized the minor error.
 - Deposits made after the filing date can only be relied upon to provide support for the correction of sequence information if applicant submits a statement in compliance with 37 CFR 1.804 stating that the biological material which is deposited is a biological material specifically defined in the application as filed.
 - ◆ See MPEP 2163 I.B



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New Matter Introduced in a Preliminary Amendment (37 CFR 1.115)

- Preliminary amendments that are present on the filing date of an application are treated as **part of the original disclosure**.
- Effective date: This applies to applications filed on or after September 21, 2004.
- Prior Practice: Preliminary amendments present on the filing date are not part of the original disclosure unless referred to in the first executed oath or declaration.



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Procedure for Handling New Matter

- Specification
 - If new matter is added to the specification, the examiner should object to the specification under 35 U.S.C 132 and require applicant to cancel the material. The objection should be made using Form Paragraph 7.28.
- Claims
 - If new matter is added to the claims, the examiner should reject the claims under 35 U.S.C. 112, first paragraph and require cancellation of the new matter. The rejection should be made using Form Paragraph 7.31.01.



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Procedure for Handling New Matter

- The examiner has the initial burden of presenting by a preponderance of evidence why a person skilled in the art would not recognize in applicant's disclosure a description of the invention defined by the claims.
- In rejecting a claim, the examiner must set forth express findings of fact which support a lack of written description conclusion:
 - Identify the claims at issue
 - 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.



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MPEP 2163.06 (I)

- 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.



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MPEP 2163.06 (III)

Claimed subject matter not disclosed in remainder of specification

- The claims as filed in the original specification are part of the disclosure and therefore, if an application as originally filed contains a claim disclosing material not disclosed in the remainder of the specification, the applicant may amend the specification to include the claimed subject matter. *In re Benno*, 768 F.2d 1340, 226 USPQ 683 (Fed. Cir. 1985).
- **Form Paragraph 7.44** should be used where originally claimed subject matter lacks proper antecedent basis in the specification. See MPEP 608.01(o).



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Review of new matter objections and/or rejections

- A rejection of claims under 35 USC 112, first paragraph as containing new matter is reviewable by the Board of Patent Appeals and Interferences.
- An objection to the specification under 35 USC 132 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.
 - ◆ See MPEP 2163.06 (II)



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Example 1

- Claim 30 (new): A kit comprising compound Q.
- The specification and claims as originally filed only support a chemical compound Q for the treatment of eye infection.
- The term "kit" is considered new matter since the specification and claims as filed disclose only a composition comprising chemical compound Q and does not disclose additional components that would provide implicit support for a "Kit". There is no clear support for a "kit" comprising compound Q.



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Example 2

- Claim 5 (new): A vaccine comprising a peptide as set forth in SEQ ID NO. 3 and a synergistic effective amount of two stimulants.
- The specification discloses an unexpected result that adjuvant compound A acts synergistically with adjuvant compound B so that the inclusion of compound A as a co-adjuvant can reduce the total amount of adjuvant needed without loss of effectiveness of the vaccine. No adjuvant compounds other than compounds A and B are disclosed.
- The phrase two stimulants is considered new matter because the scope is broader than the two specifically disclosed species (compounds A and B).



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Example 3

- Specification (original): The Mab produced by hybridoma 4S7 binds to Factor VII.
- Specification (amended): The Mab (monoclonal antibody) produced by hybridoma 4S7 binds to Factor VII.
- The term "Mab" is an art-recognized abbreviation for the term "monoclonal antibody". Therefore, the amendment of the specification to insert the term "monoclonal antibody" does not introduce new matter.



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Example 4

- Claim 1 (original): A peptide having the formula Gly-Val-Pro-X wherein X can be any one of the naturally occurring amino acid residues.
- The specification as filed discloses the sequence Gly-Val-Pro-X and teaches that X can be anyone of the naturally occurring amino acid residues. The specification and claims as filed do not disclose any other definition for moiety X.



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Example 4 cont'd

- Claim 1 (amended): A peptide having the formula Gly-Val-Pro-X wherein X can be [any one of the naturally occurring] any amino acid residue[s].
- The amendment changing X from being one of the naturally occurring amino acids to any amino acid residue broadens the scope of the invention beyond that taught in the originally filed specification and claims. The phrase "any amino acid residue" also includes modified amino acids other than those that are naturally occurring.



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Example 5

- Claim 1 (original) A method of treating autoimmune diseases comprising administering compound X to a patient.
- The specification and claims as filed disclose only general concept of the treatment of autoimmune diseases using compound X.
- Claim 1 (amended)-A method of treating [autoimmune diseases] rheumatoid arthritis comprising administering compound X to a patient.



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Example 5 cont'd.

- A generic or sub-generic disclosure cannot support a species unless the species is specifically described. Therefore, changing “autoimmune diseases” to “rheumatoid arthritis” is considered to be new matter.



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Example 6

- The specification and claims as filed disclose a compound in which substituent R5 is "polyethylene".
- The specification is amended to recite that R5 is [polyethylene] "PVC polymer".
- Where the specification, claims, or drawings as originally filed only contain the term "polyethylene" the amendment to recite "PVC polymer is new matter.



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Example 7

- Specification (original): ...with a pH range from 4-8.
- Specification (amended):.....with a pH [range] up to [from 4 to] 8.
- The deletion from the specification of the lower limit so that the specification no longer contains any lower limit is considered new matter



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Example 8

- Claim 1 (original) A method of treating diabetes comprising parenterally administering a peptide consisting of 8 to 12 amino acid residues of SEQ ID NO: 1 to a mammal.
- The specification and claims as filed disclose only the administration of a peptide consisting of 8-12 residues of SEQ ID NO: 1.
- Claim 1 (amended) A method of treating diabetes comprising parenterally administering a peptide consisting of about 8 to about 12 amino acid residues of SEQ ID NO: 1 to a mammal.



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Example 8 cont'd.

- The insertion of the term “about” changes the scope of the claim to include the administration of peptides consisting of, for example, 7 to 13 residues. This represents a departure from the disclosure of the specification and claims as filed and thus, would be considered new matter.



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Example 9

- Claim 5 (original) A method of treating diabetes comprising parenterally administering 0.01 mg/Kg body wt. of the compound of claim 2.
- The specification and claims as originally filed disclose only the administration of the compound of claim 2 at a dosage of 0.01 mg/Kg body weight.



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Example 9 cont'd.

- Claim 5 (amended) A method of treating diabetes comprising parentally administering at least 0.01 mg/Kg body wt. of the compound of claim 2.
- The term "at least" broadens the scope of the specific dosage disclosed in the specification and claims as filed and is considered new matter.



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Example 10

- Specification (original): Protein M is obtained from eluates of a cross-linked cation exchange column wherein the eluting agent used is urea.
- The specification and claims as filed disclose only the use of urea as an eluting agent.



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Example 10 cont'd.

- Specification (amended): Protein M is obtained from eluates of a cross-linked cation-exchange column wherein the eluting agent is, for example, urea.
- The phrase "for example" broadens the scope of the eluting agent. As amended, the specification includes other types of eluting agents in addition to the single material, urea, that was originally disclosed. The amendment is new matter.



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Example 11

- The specification, claims and drawings as filed disclose a nucleic acid having the sequence of SEQ ID NO: 1 cloned into a microorganism that is deposited with the ATCC under accession number 12345. SEQ ID NO: 1 is disclosed as being 350 nucleotides in length and contains a "G" at position 215.
- The specification and drawings are amended to change the residue at position 215 of SEQ ID NO: 1 from "G" to "C".
- Applicant supplies a declaration under 37 CFR 1.132 accompanied by supporting evidence explaining that:



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Example 11 cont'd.

- The amendment is to correct an error;
- The error was discovered upon re-sequencing of the nucleic acid contained within the microorganism that is deposited with the ATCC under accession number 12345 which is the same microorganism disclosed in the specification as originally filed. Upon resequencing it was discovered that the nucleotide at position 215 is "C".
- The amendment is not considered to introduce new matter given that there is evidence and supporting explanation that establishes that the amended sequence is an inherent characteristic of the original material disclosed in the specification as filed.



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Example 12

- Claim (Original) A compound of the general formula Y, comprising substituents R1*, R2* and R3*.
- Claim (Amended) A compound of the general formula Y, comprising substituents R1, R2 and R3 wherein R3 is not a divalent sulfone group.
- The specification discloses that R3 can be any one of 5 different types of substituents, one type being a divalent sulfone group, and four others which are not divalent sulfones. The specification discloses numerous examples of the compound of formula Y wherein the substituent at R3 represents different examples of each of the 5 possible types of disclosed substituents.



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Example 12 cont'd.

- The exclusionary proviso has basis in the original disclosure. The limited genus defined by the amended claim is fully described by specific examples. The alternative elements positively recited in the specification may be explicitly excluded in the claims.

* Assume that R1, R2 and R3 are specifically defined.



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Example 13

- Claim (Original) The 1, 2 diaminocyclohexanetetracetic acid (CDTA) produced by the process of claim 1.
- Claim (Amended) The 1,2-diaminocyclohexanetetracetic acid (CDTA) produced by the process of claim 1, having a maximum content of metal impurities of 100 ppm.
- The specification contains no disclosure of the maximum metal content of the CDTA preparation produced by the process of claim 1. There is no indication in the specification that the metal content is less than or equal to that of the commercially available CDTA. The specification discloses only that commercially available CDTA containing even low amounts of metal ions (i.e. 100 ppm) exceeds the allowable limit for high grade solutions, of 10 ppm metal ions.
- The amendment constitutes new matter because there is no explicit or implicit support for the added limitation.



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Thank you

Deborah Reynolds
Quality Assurance Specialist, TC1600
571-272-0734