New Matter, Incorporation By Reference, Restriction and Claim Language for Nucleic Acid Molecules

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Objectives

- Potential Problems With Sequence Information
- New matter objections and rejections
- Incorporation by Reference- 37 CFR 1.57
  - Examples
- Reference to Tables
- Improper Dependent Claims
- Overview of 27 March 2007 OG Notice
  - Nucleic Acid Restriction Examples
- Nucleic Acid Sequence Open versus Closed Language
- Examination Practice for Combination Claims
- Linking Claims
- Summary

Potential Problems with Sequence Information

In patent specifications, every element or ingredient of the product should be set forth in positive, exact, intelligible language, so that there will be no uncertainty as to what is meant.

The relationship between sequence information submitted to a public database and the amino acid or nucleic acid product it identifies is sometimes indefinite, uncertain, and arbitrary.

Potential Problems with Sequence Information

The formula or characteristics of the sequence information submitted to the public database may change from time to time.

The changes may be made by

- the person who initially submitted the sequence,
- applicants or
- third parties.

This uncertainty raises questions about

- new matter
- adequate written description
- enablement
- determining effective priority date
- which version of the sequence may be entered by amendment and
- which version of the sequence may be searched by STIC.

Two Statutes Governing New Matter

There are two statutory provisions that prohibit the introduction of new matter:

35 U.S.C. 132 - No amendment shall introduce new matter into the disclosure of the invention; …

35 U.S.C. 251 - No new matter shall be introduced into the application for reissue.

New Matter Objections and Rejections

When new matter is introduced into the specification, the amendment should be objected to under 35 U.S.C. 132 (35 U.S.C. 251 if a reissue application) and a requirement made to cancel the new matter. The subject matter which is considered to be new matter must be clearly identified by the examiner.

If the new matter has been entered into the claims or affects the scope of the claims, the claims affected should be rejected under 35 U.S.C. 112, first paragraph, because the new matter is not described in the application as originally filed.

New Matter Guidance

In the examination of an application following amendment thereof, the examiner must be on the alert to detect new matter. 35 U.S.C. 132 (a) should be employed as a basis for objection to amendments to the abstract, specification, or drawings attempting to add new disclosure to that originally disclosed on filing. **See MPEP 706.03(o).**

The proscription against the introduction of new matter in a patent application (35 U.S.C. 132 and 251) serves to prevent an applicant from adding information that goes beyond the subject matter originally filed. See In re Rasmussen, 650 F.2d 1212, 1214, 211 USPQ 323, 326 (CCPA 1981). **See MPEP 2105.**

New Matter Added by Amendment

All amendments or claims must find descriptive basis in the original disclosure, or they involve new matter. Applicant may rely for disclosure upon the specification with original claims and drawings, as filed. See also 37 CFR 1.121(f) and MPEP § 608.04.

37 CFR 1.121. Manner of making amendments in applications.
*****

(f) No new matter . No amendment may introduce new matter into the disclosure of an application.

Relationship of Written Description and New Matter

"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." MPEP 2163.06

Reminder

What is conventional or well known to one skilled in the art need not be disclosed in detail

Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991).

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  - Open versus Closed Language
  - Other Language
- Summary

Incorporation by Reference

- Rule 37 CFR 1.57
  - 69 FR 56482 (Sept. 21, 2004); 1287 OG 67 (Oct. 12, 2004)
  - for questions, contact Office of Patent Legal Administration
  - at (571) 272-7701
- Sequence Disclosure and Examples
- Slides for initial BCP talk available at

http://www.cabic.com/bcp/031505/

37 CFR 1.57(b)

….an incorporation by reference must be set forth in the specification and must:

(1) Express a clear intent to incorporate by reference by using the root words “incorporat(e)” and “reference” (*e.g.*, “incorporate by reference”); and

(2) Clearly identify the referenced patent, application, or publication.

What is Clear Intent?

- The examiner has the task of determining whether applicants clearly intended to incorporate material by reference. This must be determined upon a case-by-case basis.
- In making the determination of clear intent the examiner will consider
  - language used in referencing the sequence
  - the context in which it is disclosed
  - any additional arguments/evidence presented by applicants.

What is Clear Intent?

- A claim that identifies a sequence by database accession number will usually be accepted as clear intent to incorporate the sequence by reference. This claim must be an original claim that is present as of the filing date.

- Language identifying a source only in passing as other prior work of no identified relevance is unlikely to be incorporated by reference.

37 CFR 1.57 (c)

"Essential material" may be incorporated by reference, but only by way of an incorporation by reference to a U.S. patent or U.S. patent application publication, which patent or patent application publication does not itself incorporate such essential material by reference….

What is “Essential Material”

Material that is necessary to meet requirements of

35 USC 112, 1st paragraph

35 USC 112, 2nd paragraph

and/or

35 USC 112, 6th paragraph

37 CFR 1.57 (d)

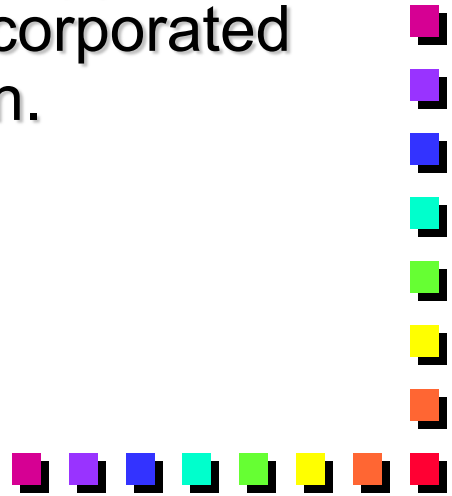
Other material ("Nonessential material") may be incorporated by reference to U.S. patents, U.S. patent application publications, foreign patents, foreign published applications, prior and concurrently filed commonly owned U.S. applications, or nonpatent publications.

An incorporation by reference by hyperlink or other form of browser executable code is not permitted.

37 CFR 1.57 (e)

The examiner may require the applicant to supply a copy of the material incorporated by reference.

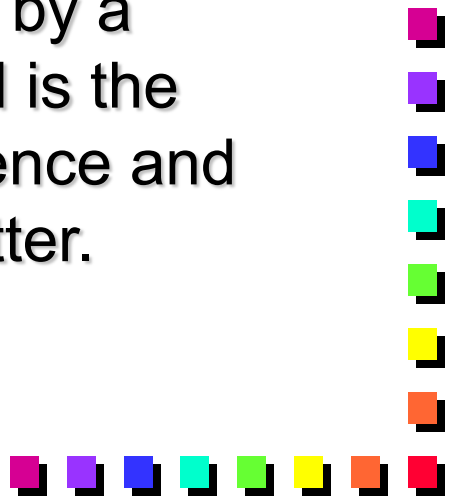
If the Office requires the applicant to supply a copy of material incorporated by reference, the material must be accompanied by a statement that the copy supplied consists of the same material incorporated by reference in the referencing application.



37 CFR 1.57 (f)

Any insertion of material incorporated by reference into the specification or drawings of an application must be by way of an amendment to the specification or drawings.

Such an amendment must be accompanied by a statement that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter.



What statements are required under 1.57(f)?

A statement that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter is also required. 37 CFR 1.57(f).

See also In re Hawkins, 486 F.2d 569, 179 USPQ 157 (CCPA 1973); In re Hawkins, 486 F.2d 579, 179 USPQ 163 (CCPA 1973); In re Hawkins, 486 F.2d 577, 179 USPQ 167 (CCPA 1973).

37 CFR 1.57 (g)(1)

A correction … is permitted only if the application as filed clearly conveys an intent to incorporate the material by reference.

A mere reference to material does not convey an intent to incorporate the material by reference.

No Clear Intent?

- If the examiner determines there was no clear intent to incorporate the sequence, the examiner will make and maintain 35 USC 112 rejection(s).
  - Final Rule “Discussion” indicates that “[i]f a reference to a document does not clearly indicate an intended incorporation by reference, examination will proceed as if no incorporation by reference statement has been made and the Office will not expend resources trying to determine if an incorporation by reference was intended.” [69 FR at 56500; 1287 OG at 82]

37 CFR 1.57 (g)(2)

A correction … is only permitted for material that was sufficiently described to uniquely identify the document.

What is “Uniquely Identify”

A sequence which has only one version submitted prior to the filing date may be considered uniquely identified.

If multiple versions of the sequence were submitted to the database prior to the effective filing date, the sequence may not be considered as uniquely identified.

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Example 1: Effective Incorporation of Essential Material

Claim 1. Isolated Protein ABC.

The amino acid sequence of Protein ABC is considered essential material because it is necessary to meet the requirements of 35 U.S.C. 112, 1st and 2nd paragraphs. 37 CFR 1.57(c).

Upon review, the examiner noticed that the specification did not include the amino acid sequence for Protein ABC. However, the specification included the following statement:

> "The amino acid sequence of Protein ABC has been disclosed as SEQ ID No 1 in U.S. Patent 6,123,456 and is hereby incorporated by reference."

U.S. Patent 6,123,456 contains SEQ ID No 1. The requirements of 37 CFR 1.57 are met.

Example 2: Ineffective Incorporation of Essential Material

Original Claim 1. Isolated Protein ABC.

Upon review, the examiner noticed that the specification did not include the amino acid sequence for Protein ABC. However, the specification included the following statement:

> "The amino acid sequence of Protein ABC has been disclosed as SEQ ID No 1 in U.S. Patent 6,123,456."

The statement does not use the root words "incorporat(e)" and "reference"

The examiner uses FP 6.19.01 to require applicants to comply with 1.57(b)(1) and makes any corresponding rejections under 112, 1st, paragraph.

Example 2: Ineffective Incorporation of Essential Material (cont)

FP 6.19.01 Ineffective Incorporation by Reference, General

The attempt to incorporate subject matter into this application by reference to [1] is ineffective because [2].

Examiner Note

1. In bracket 1, identify the document such as an application or patent number or other identification.
2. In bracket 2, give reason(s) why it is ineffective (e.g., the root words "incorporate and/or "reference have been omitted, see 37 CFR 1.57(b)(1); the reference document is not clearly identified as required by 37 CFR 1.57(b)(2)).
3. This form paragraph should be followed by form paragraph 6.19.03.

Example 2: Ineffective Incorporation of Essential Material (cont)

Because Protein ABC is recited in an original claim, applicant may comply with 1.57(b)(1) by amending the specification under 1.57(g) as follows:

> "The amino acid sequence of Protein ABC has been disclosed as SEQ ID No 1 in U.S. Patent 6,123,456 and is hereby incorporated by reference."

Applicant must also respond to any other rejections or objections.

Best Practice Tip for Applicants: Recommend amending the specification to include SEQ ID No 1 and complying with the sequence requirements to help examiners identify prior art.

Example 3: Incorporation of Essential Material

Claim 1. An isolated nucleic acid molecule encoding Protein ABC.

The amino acid sequence of Protein ABC is considered essential material because it is necessary to meet the requirements of 35 U.S.C. 112, 1st paragraph. 37 CFR 1.57(c).

Upon review, the examiner noticed that the specification did not include sequence for Protein ABC or for nucleic acid molecule which encoded Protein ABC.

However, the specification included an incorporation by reference statement incorporating essential material submitted at GenBank.

"The Protein ABC is encoded by the sequence of Gene ABC, which has been submitted at GenBank under Accession Number X-12345 and is incorporated by reference."

Example 3: Incorporation of Essential Material (cont.)

Only one version of the sequence has been submitted under Accession Number X-12345 prior to the filing date.

In an Office action, the examiner used FP 6.19 to require applicants to comply with 1.57(c) by

- providing a copy of the essential material,
- amending the specification to include the essential material,
- providing a statement under 1.57(e) and/or (f).

If applicant adds the sequence, Applicant should also comply with the sequence requirements 37 CFR 1.821-1.825. Applicant should respond to any corresponding rejections under 112, 1st.

Example 3: Incorporation of Essential Material (cont.)

FP 6.19 Incorporation by Reference, Unpublished U.S. Application, Foreign Patent or Application, Publication

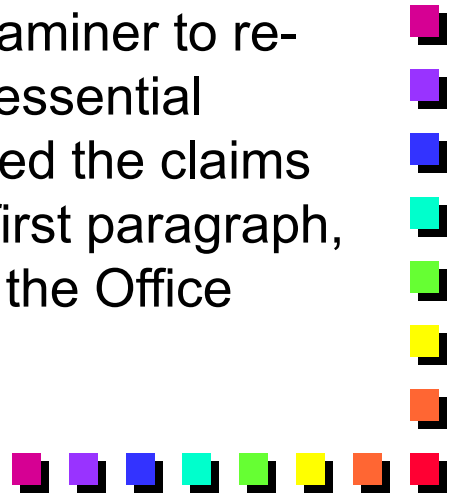
The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

Example 4: Non-essential Material

Upon review of the specification, the examiner determined that the subject matter incorporated by reference to a sequence submitted to GenBank was “non-essential material” and therefore, did not object to the incorporation by reference.

In reply to a non-final Office action, applicant filed an amendment to the claims to add a new limitation that was supported only by the GenBank deposit.

The amendment filed by the applicant caused the examiner to re-determine that the incorporated subject matter was “essential material” under 37 CFR 1.57(c). The examiner rejected the claims that include the new limitation under 35 U.S.C. 112, first paragraph, in a final Office action. FP 6.19 was also included in the Office action.



Example 4: Non-essential Material (cont.)

Because the rejection under 35 U.S.C. 112, first paragraph was necessitated by the applicant's amendment, the finality of the Office action is proper.

If the applicant wishes to overcome the rejection under 35 U.S.C. 112, first paragraph by filing an amendment under 37 CFR 1.57(f) to add the subject material disclosed in the GenBank into the specification, applicant may file the amendment as an after final amendment in compliance with 37 CFR 1.116.

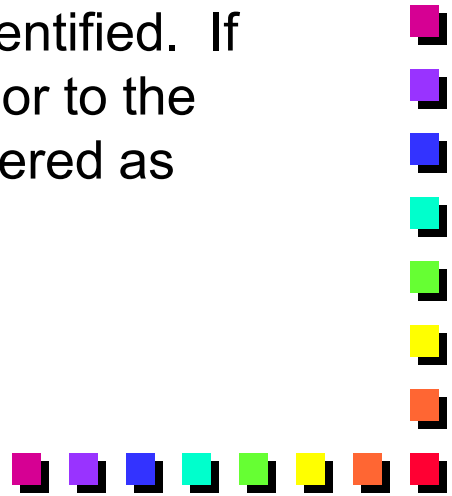
Alternatively, applicant may file an RCE under 37 CFR 1.114 accompanied by the appropriate fee, and an amendment per 37 CFR 1.57(f) within the time period for reply set forth in the final Office action.

Ex 5: Claim Refers to Database Accession Number

Original Claim 1. A nucleic acid molecule of Genbank Accession No X- 23456.

An original claim that identifies a sequence by database accession number will usually be accepted as clear intent to incorporate the sequence by reference.

A sequence which has only one version submitted to the database prior to the filing date may be considered uniquely identified. If multiple versions of the sequence were submitted prior to the effective filing date, the sequence may not be considered as uniquely identified.



Ex 5: Claim Refers to Database Accession Number

Final Rule “Discussion” indicates that “[i]f a reference to a document does not clearly indicate an intended incorporation by reference, examination will proceed as if no incorporation by reference statement has been made and the Office will not expend resources trying to determine if an incorporation by reference was intended.” [69 FR at 56500; 1287 OG at 82]

Use FP 6.19.01 to require applicants to comply with 1.57(b)(1) by adding root words “incorporat(e) and “reference” to the specification and to address 1.57(b)(2) as to whether the sequence was uniquely identified (only one version present in GenBank prior to the filing date).

The Examiner also made corresponding rejections under 112 1st paragraph.

Ex 5: Claim Refers to Database Accession Number

In an Office action, the examiner also used FP 6.19 to require applicants to comply with 1.57(c) by

- providing a copy of the essential material,
- amending the specification to include the essential material,
- providing a statement under 1.57(e) and/or (f).

Applicant should also comply with the sequence requirements 37 CFR 1.821-1.825 and any other rejections/objections.

Example 6: Reference to a Hyperlink

Upon review of the specification, the examiner noticed that the specification included an incorporation by reference statement incorporating essential material available at a website.

"The sequence has been submitted to www.geneseq.com."

Because the source material exists on a hyperlink or other form of browser executable code, incorporation by reference is not permitted. See 37 CFR 1.57(d). The examiner would reject the claims under 35 USC 112, first paragraph. Applicant may incorporate by reference the sequence submitted to a website by

- providing a copy of the essential material,
- amending the specification to include the essential material,
- providing a statement under 1.57(e) and/or (f).

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Reference to Tables

Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table “is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant’s convenience.”

Ex parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993)

Problem raised by reference to Tables

Claim 1. A nucleic acid molecule of Table 1.

Table 1.

Gene X	SEQ ID No 1	encodes SEQ ID No 4	87% identical to human CARP gene
Gene Y	SEQ ID No 2	encodes SEQ ID No 5	99 % identical to RASP gene
Gene Z	SEQ ID No 3	encodes SEQ ID No 6	99 % identical to RASP gene

What is the scope of the first nucleic acid molecule?

- A nucleic acid molecule having SEQ ID No 1?
- A nucleic acid molecule encoding SEQ ID No 4?
- A nucleic acid which is 87% identical to human CARP gene?

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“Dependent” Claims

Claim 1. An isolated nucleic acid molecule comprising SEQ ID No 1.

Claim 2. An isolated nucleic acid molecule fragment comprising residues 1-30 of the molecule of claim 1.

Claim 3. An isolated nucleic acid molecule comprising at least 70% sequence identity to the molecule of claim 1.

Claim 4. An isolated nucleic acid molecule that hybridizes under stringent conditions to the molecule of claim 1.

Claim 5. A polypeptide encoded by the isolated nucleic acid molecule of claim 1.

Claim 6. An antibody which binds to the polypeptide of claim 5.

Test for Improper Dependent Claims

The test for a proper dependent claim is whether the dependent claim includes every limitation of the parent claim. The test is not whether the claims differ in scope. A proper dependent claim shall not conceivably be infringed by anything which would not also infringe the basic claim.

MPEP 608.01(n)

Objection of Improper Dependent Claims

7.36 Objection, 37 CFR 1.75(c), Improper Dependent Claim

Claim [1] objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. [2].

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Official Gazette Notice 27 March 2007

In 1996, polynucleotide molecules were often claimed by simple reference to a nucleotide sequence (SEQ ID No).

The 1996 OG Notice permitted examination of up to ten molecules described by their nucleotide sequence.

See Examination of Patent Applications Containing Nucleotide Sequences, 1192 OG 68 (19 November 1996).

Official Gazette Notice 27 March 2007 (cont.)

Since 1996, the types of nucleic acid sequence-based claims have become more diverse and complex. Polynucleotide molecules are now often described in terms of

- homology
- percent identity
- hybridization
- variable positions specified within the sequence listing
- function of the nucleic acid
- partial linear nucleotide sequence
- single nucleotide polymorphisms (SNPs)
- the amino acid sequence of the protein encoded

Official Gazette Notice 27 March 2007

The Office has reconsidered the policy set forth in the 1996 Notice in view of changes in

- the complexity of applications filed,
- the types of inventions claimed and
- the state of the prior art in this technology.

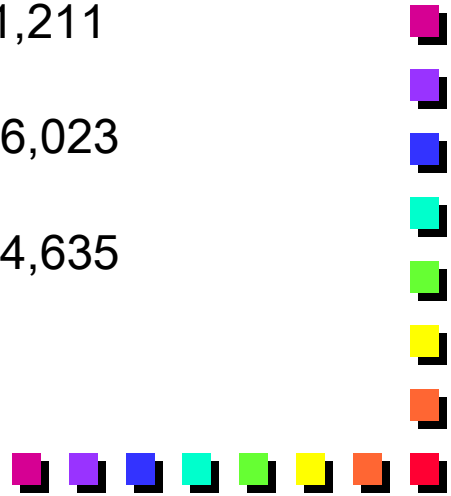
Official Gazette Notice 27 March 2007 (cont.)

Since 1996, we have seen

- exponential growth in the size of nucleic acid sequence databases
- an increase in the number of databases and
- an increase in the complexity of such databases.

Growth of the GenBank(R) database:

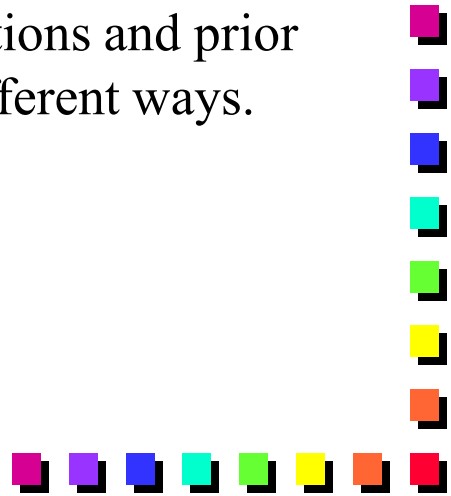
Year	Nucleotides	Sequences
1996	651,972,984	1,021,211
2000	11,101,066,288	10,106,023
2006	59,750,386,305	54,584,635



Official Gazette Notice 27 March 2007 (cont.)

It now requires significantly more computational time to run individual nucleotide sequence searches for examination purposes than in 1996, and there is significantly more pertinent prior art to consider.

In addition, it currently takes more Office resources to correlate the claimed polynucleotide with the polynucleotide as defined in the prior art because it is increasingly common for both patent applications and prior art references to describe a polynucleotide molecule in different ways.



Official Gazette Notice 27 March 2007 (cont.)

Consequently, with this Notice the Office rescinds the partial waiver of

- 37 CFR 1.141 et seq. for restriction practice in national applications filed under 35 U.S.C. 111(a), and

- 37 CFR 1.475 et seq. for unity of invention determinations in both PCT international applications and the resulting national stage applications under 35 U.S.C. 371.

Official Gazette Notice 27 March 2007 (cont.)

For National applications filed under 35 U.S.C. 111(a), in accordance with MPEP Chapter 800, polynucleotide inventions will be considered for

- restriction,
- rejoinder and
- examination practice.

As for other type of molecule, claims to polynucleotide molecules will be considered for

- independence,
- relatedness,
- distinction and
- burden.

Official Gazette Notice 27 March 2007 (cont.)

For International applications and national stage filings of international applications under 35 U.S.C. 371, unity of invention will be determined in view of:

- PCT Rule 13.2,
- 37 CFR 1.475 and
- Chapter 10 of the ISPE Guidelines.

In general, polynucleotide molecules, as claimed, must share a technical feature which makes a contribution over the prior art.

Official Gazette Notice 27 March 2007 (cont.)

This Notice is effective immediately and is applicable to all pending applications.

Note, however, that supplemental restriction requirements will not be advanced in applications that have already received an action on their merits in the absence of extenuating circumstances.

Basic Restriction Guidelines

- **Every restriction requirement has two criteria:**
  - **The inventions, as claimed, must be independent or distinct and**
  - **There would be a serious burden on the examiner if restriction were not required.**

MPEP 803, subsection I

Compare Claimed Subject Matter

- In passing upon questions of double patenting and restriction, it is the claimed subject matter that is considered and such claimed subject matter must be compared in order to determine the question of distinctness or independence. MPEP 806.01

Importance of Distinction

- When the inventions are ***not distinct as claimed***, restriction is never proper. MPEP 806

- Where restriction is required by the Office double patenting cannot be held, and thus, it is imperative the requirement should never be made where related inventions as claimed are not distinct. MPEP 806

Test for Distinctness Between Inventions/Species

- Inventions/Species are distinct when:
  - each invention/species, as claimed, requires a <u>mutually exclusive characteristic</u> not required for the other invention/species

    <u>AND</u>
  - the invention/species, as claimed, are not obvious variants of each other

MPEP 806.04(f) FPs 8.01, 8.02 and 8.14.01

In other words:

- Inventions/species are distinct in terms of restriction when:
  - Each invention/species, as claimed, does not anticipate another under 35 USC 102

  AND

  - each invention/species, as claimed, is not obvious over another under 35 USC 103(a)

One Sequence per Application?

- 35 U.S.C. 101 states “Whoever invents or discovers any new and useful process, machine, manufacture, composition of matter, or any new and useful improvement thereof, may obtain a patent therefor,…”
- A single invention may be defined by more than one sequence.
- Here’s some examples where restriction to a single sequence would and would not be appropriate.

One Sequence per Application?

Example I:	Different SEQ ID NOs describe a single invention.
Example II:	When sequences fully overlap.
Example III:	Practice for a Combination Claim.
Example IV:	Distinct nucleic acid molecules.
Example V:	A single SEQ ID NO: may encompass two or more species.
Example VI:	A claim that depends upon, but does not link, plural distinct inventions.

Example I: Different SEQ ID NOs describe a single invention.

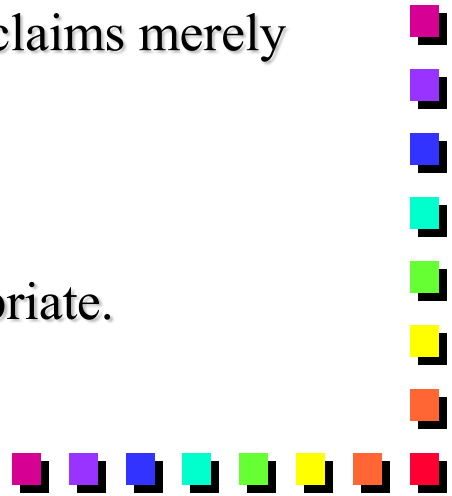
Claim 1. An isolated nucleic acid comprising SEQ ID NO: 1.

Claim 2. An isolated nucleic acid encoding a protein having SEQ ID NO: 2.

The specification discloses a nucleic acid comprising SEQ ID NO: 1 which contains the open reading frame for a protein having SEQ ID NO: 2.

Claims 1 and 2 are not distinct from each other because the claims merely define the nucleic acid using different limitations.

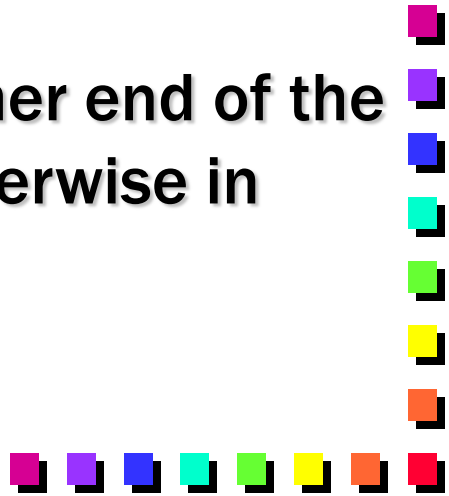
Restriction between Claims 1 and 2 would not be not appropriate.



Open Transitional Language

- "Comprising"
  - Permits additional nucleic acids at either end of the sequence
  - reads upon plural species

- "Consisting essentially of"
  - Permits additional nucleic acids at either end of the sequence, unless explicitly defined otherwise in specification
  - reads upon plural species



Closed Transitional Language

Closed Transitional Language “consisting of”

- Prevents additional nucleic acids at either end of the sequence
- generally reads upon a single fully defined species
- note that the sequence listing permits use of variables which read upon more than one nucleotide

Example II: When sequences fully overlap.

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

Claim 2. An isolated nucleic acid molecule comprising SEQ ID NO: 2.

Claim 3. An isolated nucleic acid molecule comprising SEQ ID NO: 3.

The term "comprising" permits additional nucleic acids at either end of the sequence.

Example II: When sequences fully overlap. (cont.)

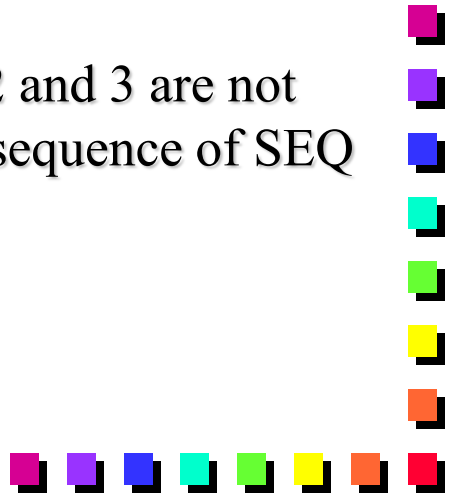
The sequence listing shows that SEQ ID NO: 1, 2 and 3 fully overlap with each other.

SEQ ID NO: 1:ATGTGCGATA

SEQ ID NO: 2:ATGTGCGATA ATCTG

SEQ ID NO: 3:ATGTGCGATA ATCTGTTATA

Because nucleic acid molecules comprising SEQ ID NO: 1, 2 and 3 are not distinct as claimed, from each other, restriction to a single sequence of SEQ ID NO: 1, 2 and 3 would not be proper.



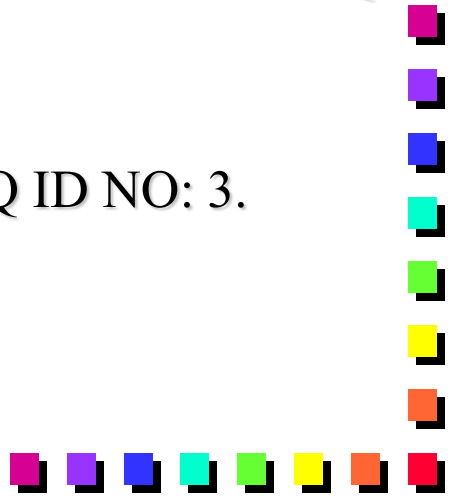
Example II: When sequences fully overlap. (cont.)

Practice Tip: To highlight the common region, consider providing a sequence alignment or using this claim format to refer to a single sequence:

Claim 1. An isolated nucleic acid molecule comprising residues 1-10 of SEQ ID NO: 3.

Claim 2. An isolated nucleic acid molecule comprising residues 1-15 of SEQ ID NO: 3.

Claim 3. An isolated nucleic acid molecule comprising SEQ ID NO: 3.



Effect of Claim Format

A plurality of elements may be claimed

- as a combination or
- in the alternative.

Example of a combination claim:

Claim 1. A kit comprising primers having SEQ ID NO: 1-100.

Example of a claim that uses alternative language to enumerate species, i.e., a Markush claim:

Claim 2. A primer selected from the group consisting of SEQ ID NO: 1-100.

Example III: A Combination Claim

Claim 1. A kit comprising primers having SEQ ID NO: 1-100.

A combination of nucleotide molecules will generally not be subject to a restriction requirement.

The presence of one novel and nonobvious sequence within the combination will render the entire combination novel and nonobvious.

Example III: A Combination Claim (cont.)

Claim 1. A kit comprising primers having SEQ ID NO: 1-100.

The combination will be searched until one nucleotide sequence or a combination of nucleotide sequences is found to be allowable.

The order of searching will be chosen by the examiner to maximize the identification of an allowable sequence(s).

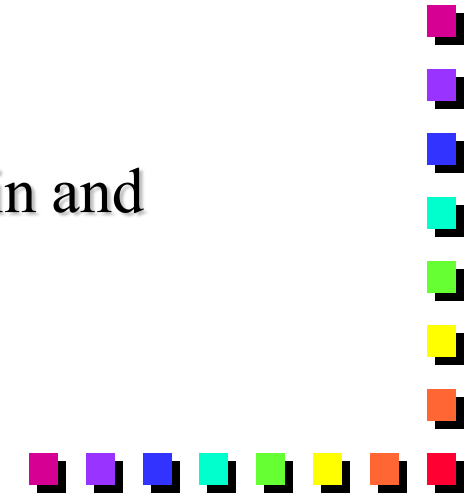
If no individual nucleotide sequence or subset of sequences is found to be allowable, the examiner will consider whether the entire combination of sequences taken as a whole renders the claim allowable.

Example IV: Distinct nucleic acid molecules.

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

The specification teaches that

SEQ ID NO: 1 encodes a ribosomal protein and
SEQ ID NO: 2 encodes an enzyme.



Example IV: Distinct nucleic acids molecules. (cont.)

Claim 1 and 2 are distinct from each other because:

Claim 1 requires the mutually exclusive characteristic of SEQ ID NO: 1 which is not encompassed by claim 2 and

Claim 2 requires the mutually exclusive characteristic of SEQ ID NO: 2 which is not encompassed by claim 1.

Examination of Claim 1 and 2 would be burdensome:

Each sequence requires a different search query.

Prior art teaching one sequence is not likely to teach another sequence.

Restriction between the nucleic acid molecules comprising SEQ ID NO: 1 and SEQ ID NO: 2 is proper.

Example V: A single SEQ ID NO: may encompass two or more species.

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

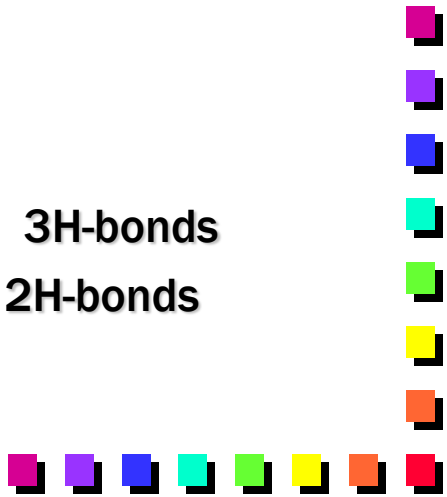
Claim 1

- refers to a single SEQ ID NO: and
- uses closed transitional language “consisting of.”

The phrase “consisting of” followed by a single SEQ ID NO: generally limits a claim to a single fully defined nucleic acid molecule.

A Partial List of Nucleotide Symbols

Symbol	Meaning	Original
a	a	adenine
g	g	guanine
c	c	cytosine
t	t	thymine
u	u	uracil
r	g or a	purine
y	t/u or c	pyrimidine
m	a or c	amino
k	g or t/u	keto
s	g or c	strong interactions 3H-bonds
w	a or t/u	weak interactions 2H-bonds



Example V: A single SEQ ID NO: may encompass two or more species (cont.)

The sequence listing shows that SEQ ID NO: 1 is ATGSTAMATR, where

S is G or C,

M is A or C and

R is G or A.

SEQ ID NO: 1 encompasses eight patentably distinct sequences:

ATGGTAAATG	ATGGTAAATA
ATGCTAAATG	ATGCTAAATA
ATGGTACATG	ATGGTACATA
ATGCTACATG	ATGCTACATA

In this situation, the examiner may require an election of species using FP 8.02, generic claim reads upon disclosed species.

Objectives

- Potential Problems With Sequence Information
- New matter objections and rejections
- Incorporation by Reference- 37 CFR 1.57
  - Examples
- Reference to Tables
- Improper Dependent Claims
- Overview of 27 March 2007 OG Notice
  - Nucleic Acid Restriction Examples
- Nucleic Acid Sequence Open versus Closed Language
- Examination Practice for Combination Claims
- Linking Claims
- Summary

Linking Claims

- Definition: A linking claim is a claim which, if allowable, would prevent restriction between two or more otherwise properly restrictable inventions.

- Linking claims and linked inventions are usually either
  - product claims linking properly restrictable product inventions, or
  - process claims linking properly restrictable process inventions.

- Most common types of linking claims are
  - A genus claim linking species claims or
  - A subcombination claim linking plural combinations

MPEP 809 and 809.03.

Linking Claims (cont.)

- Restriction can be required when there are linking claims and claims to distinct inventions.
- If a linked invention is elected, the linking claims are examined with the elected invention.
- If a linking claim is found allowable, the restriction requirement must be withdrawn and all linked inventions examined for patentability.

Dependent Claims that refer to the linked inventions in the alternative are not linking claims

- A linking claim must be broader in scope than all the linked inventions.

- A dependent claim which refers to two or more restrictable independent claims in the alternative is not a “linking claim.”

Example VI: A claim that depends upon, but does not link, plural distinct inventions.

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

Claim 2. An isolated nucleic acid having SEQ ID NO: 2.

Claim 3. A vector comprising the nucleic acid of claim 1 or claim 2.

Claim 4. A host cell comprising the vector of claim 3.

See a previous slide for discussion of specification and reasons why claim 1 and 2 are distinct from each other.

Example VI: A claim that depends upon, but does not link, distinct inventions. (cont.)

A linking claim must be broader in scope than the linked claims.

Claims 3 and 4 are NOT linking claims because claims 3 and 4 are narrower in scope that claims 1 and 2.

The claims may be grouped as follows:

Group I, claim 1, and claims 3 and 4, in part, drawn to nucleic acid, vector and host cell having SEQ ID NO: 1.

Group II, claim 2 and claims 3 and 4, in part, drawn to nucleic acid, vector and host cell having SEQ ID NO: 2.

It is permissible to use 3/1, 3/2 to refer to multiple dependent claims which depend from claims 1 or 2.

In Summary

For National applications filed under 35 U.S.C. 111(a), as for other type of invention, claims to polynucleotide molecules will be considered for restriction and rejoinder in accordance with MPEP Chapter 800

For International applications and national stage filings of international applications under 35 U.S.C. 371, unity of invention will be determined in view of PCT Rule 13.2, and Chapter 10 of the ISPE Guidelines.

Supplemental restriction requirements will not be advanced in applications that have already received an action on their merits in the absence of extenuating circumstances.

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