Restriction Practice for Nucleic Acid Molecules

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Objectives

- Overview of 27 March 2007 OG Notice
- Basis for Requiring Restriction
  - Burden
  - Distinctness, Emphasis on “Mutually Exclusive”
- One Sequence per Application?
- Examples
- Summary

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

What is “Serious Burden”?

Basically, the search and examination for one of the claimed inventions is not required for another of the claimed inventions.

MPEP 808.02

Showing Serious Burden

- A serious burden may be *prima facie* shown if the inventions have:
  - (a) separate classification
  - (b) separate status in the art
  - (c) a different field of search
    - searching different classes/subclasses
    - searching different electronic resources
    - employing different search queries

MPEP 803, 808.02

Showing Serious Burden (cont.)

- A serious burden may be *prima facie* shown if:
  - (d) the prior art applicable to one invention would likely not be applicable to another invention, or
  - (e) the inventions are likely to raise different non-prior art issues under 35 USC 101 and/or 35 USC 112, ¶ 1.

MPEP 803, 808.02

If applicants traverse:

Where the initial requirement is traversed, it should be reconsidered.

If, upon reconsideration, the examiner is still of the opinion that restriction is proper, it should be repeated and made final in the next Office action.

In doing so, the examiner should reply to the reasons or arguments advanced by applicant in the traverse.

MPEP 821.01

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

Two Species must be Mutually Exclusive of each other

- Where two or more species are claimed, a requirement for restriction to a single species may be proper if the species are mutually exclusive. MPEP 806.04(f)

What does "Mutually Exclusive" Mean?

- Claims to different species are mutually exclusive if one claim recites limitations disclosed for a first species but not a second, while a second claim recites limitations disclosed only for the second species and not the first. MPEP 806.04(f)

- This may also be expressed by saying that to require restriction between claims limited to species, the claims must not overlap in scope. MPEP 806.04(f)

Explaining "mutually exclusive" in terms of the Infringement Test

Related inventions in the same statutory class are considered mutually exclusive, or not overlapping in scope, if a first invention would not infringe a second invention, and the second invention would not infringe the first invention. MPEP 806.05

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?

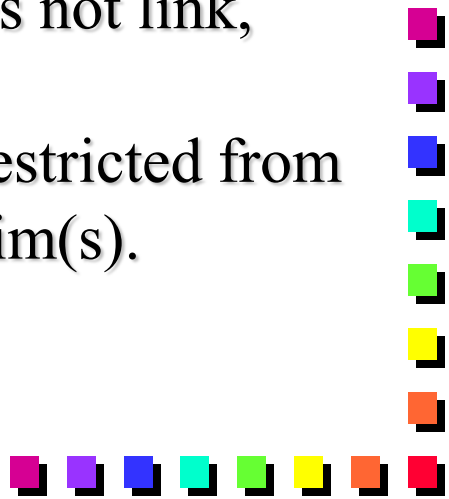
- 35 U.S.C. 101 states “Whoever invents or discovers any new and useful process, machine, manufacture, composition of matter, or any new and useful improvement thereof, may obtain a patent therefor,…”

- 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 VII:	A dependent claim that cannot be restricted from its independent and intervening claim(s).



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
  - always reads upon plural species

- "Consisting essentially of"
  - Permits additional nucleic acids at either end of the sequence, unless explicitly defined otherwise in specification
  - always 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.

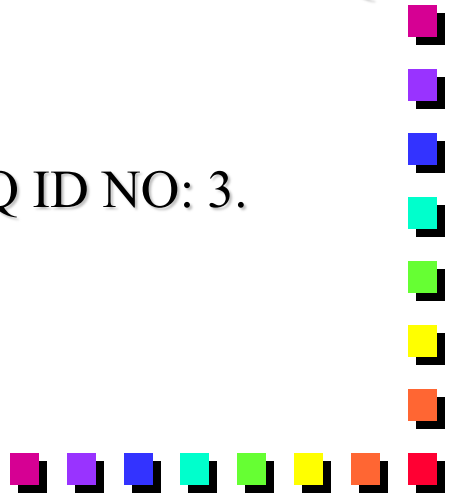
Example II: When sequences fully overlap. (cont.)

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 allowable.

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 is found to be allowable.

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

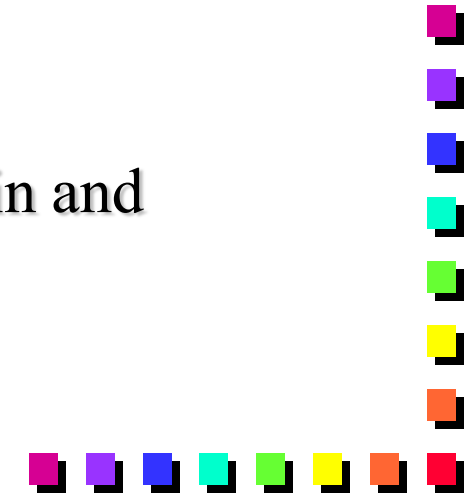
If no individual nucleotide sequence is found to be allowable, the examiner will consider whether the combination of sequences taken as a whole renders the claim allowable.

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.

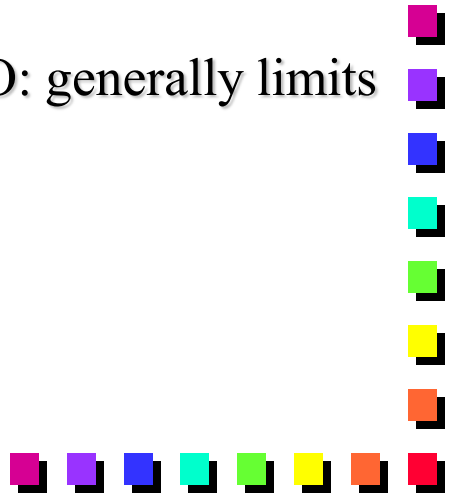
Example V: A single SEQ ID NO: may encompass two or more species.

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

Claim 1

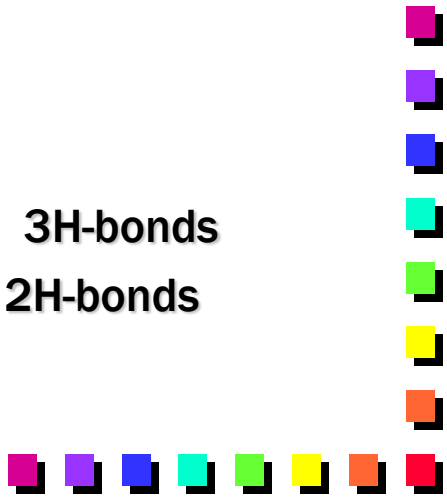
- refers to a single SEQ ID NO: and
- uses closed transitional language “consisting of.”

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.

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.

Example VII: A dependent claim cannot be restricted from its independent and intervening claim(s).

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

Claim 2. An isolated nucleic acid of claim 1, further comprising SEQ ID NO: 2 added to the 3' end.

Claim 3. An isolated nucleic acid of claim 2, further comprising SEQ ID NO: 3 added to the 3' end.

Alignment of the sequences shows that SEQ ID No 1, 2 and 3 are distinct from each other:

SEQ ID NO: 1: ATGTGCGATA

SEQ ID NO: 2: TGGTACATGC

SEQ ID NO: 3: ATTTAGCTATT

Example VII: A dependent claim cannot be restricted from its independent and intervening claim(s) (cont.)

However, claims 1, 2 and 3 are not distinct from each other. As set forth another way:

Claim 1. A nucleic acid comprising ATGTGCGATA.
Claim 2. A nucleic acid comprising ATGTGCGATA TGGTACATGC.
Claim 3. A nucleic acid comprising ATGTGCGATA TGGTACATGC ATTTAGCTATT.

Claims 1-3 vary in scope from broadest (claim 1) to narrowest (claim 3).

However, a dependent claim must require all the limitations of the independent and any intervening claims.

Requiring a restriction between the nucleic acids of claims 1, 2 and 3 is not proper.

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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