RESTRICTING BETWEEN PRODUCT and PROCESS INVENTIONS

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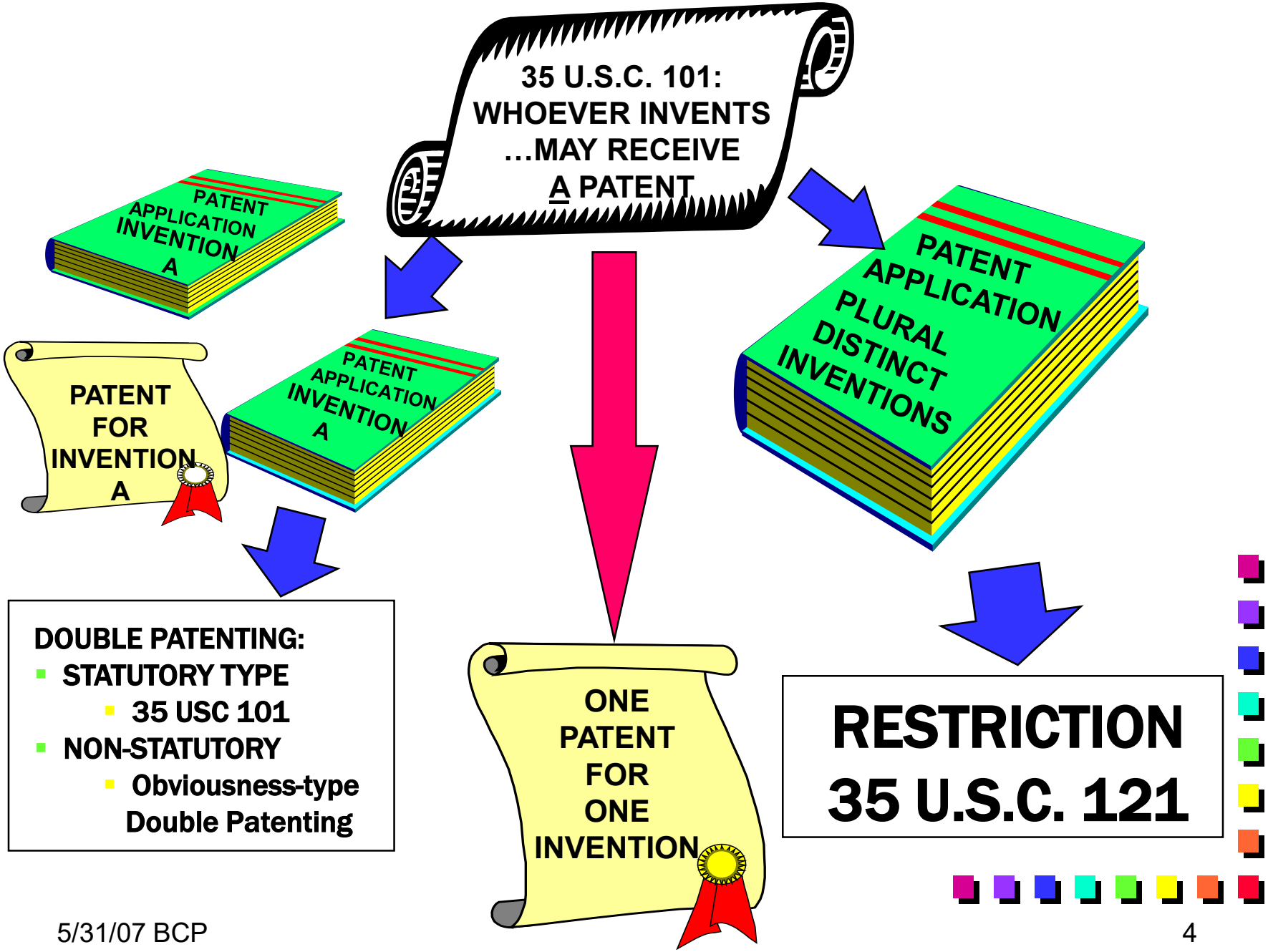
Objectives

The objectives of this talk are to:

- Focus on process and product inventions
- Provide ten TC1600 specific examples
- Review basic restriction guidelines
  - Burden- revised definition
  - Independence- new FP 8.20.03
  - Distinction between products and
    - Methods of making
    - Methods of using
    - Methods of screening or detecting

35 U.S.C. 101

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title"


35 U.S.C. 101:
WHOEVER INVENTS
…MAY RECEIVE
A PATENT
PATENT APPLICATION INVENTION A
PATENT FOR INVENTION A
PATENT APPLICATION INVENTION A
PATENT APPLICATION PLURAL DISTINCT INVENTIONS
DOUBLE PATENTING:
STATUTORY TYPE
35 USC 101
NON-STATUTORY
Obviousness-type Double Patenting
ONE PATENT FOR ONE INVENTION
RESTRICTION
35 U.S.C. 121

What is *RESTRICTION*?

Restriction is the practice of requiring an applicant to elect a single claimed invention (e.g., a combination or subcombination invention, a product or process invention, a species within a genus) for examination when two or more independent inventions and/or two or more distinct inventions are claimed in an application.

MPEP 802.02

When is Restriction Not an Option?

- When the inventions are ***not distinct as claimed***, restriction is never proper. MPEP 806.
- When the claims define the same essential characteristics of a single disclosed embodiment of an invention, restriction is not proper. MPEP 806.03
- To determine if process inventions are distinct, it is important to compare the
  - Claimed preamble,
  - Claimed active steps and
  - Specification

Example I: Different Preambles, same active step; Restriction Improper

Claim 1. A method of reducing pain

by administering compound ABC to a patient suffering from a cold.

Claim 2. A method of reducing fever

by administering compound ABC to a patient suffering from a cold.

Claim 3. A method of reducing congestion

by administering compound ABC to a patient suffering from a cold.

The specification teaches that compound ABC can be used to treat cold symptoms because it reduces the symptoms of pain, fever and/or congestion. A patient suffering from a cold when treated with compound ABC would experience relief from all of these symptoms.

Restriction among claims 1, 2 and 3 is not proper because claims 1, 2 and 3 require the same active step of administering compound ABC to the same patient and the specification teaches that compound ABC reduces pain, fever and congestion in a patient suffering from a cold.

Example II: Different Preambles, same active step; Restriction may be proper

Claim 1. A method of inhibiting leaf growth in a deciduous plant by administering the compound of Formula 1.

Claim 2. A method of enhancing needle longevity in a coniferous plant by administering the compound of Formula 1.

The specification teaches that compound of Formula 1, when applied to deciduous plants, reduces growth of new leaves but when applied to coniferous plants, lengthens the life of the needles.

The processes of claims 1 and 2 are specific for two different types of plants and result in two different outcomes

Restriction between claims 1 and 2 may be proper.

Basic Restriction Guidelines

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

MPEP 803

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

- Reasons must be provided why a serious burden would exist if restriction were not required.
- A serious burden may be *prima facie* shown if one or more of the following reasons apply - that the inventions have:
  - (a) separate classification
  - (b) separate status in the art
  - (c) a different field of search (as defined in MPEP 808.02)
  - (d) if the prior art applicable to one invention would likely not be applicable to another invention,
  - (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

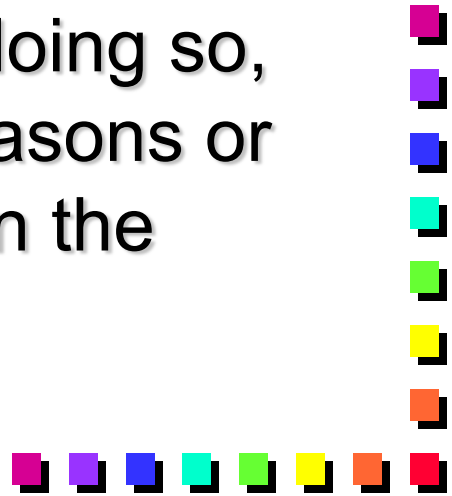
Showing Serious Burden (cont.)

- Serious burden may be established based on a different field of search if it is necessary to search for one of the inventions in a manner not likely to result in finding art pertinent to the other invention(s), e.g.,
  - searching different classes/subclasses
  - searching different electronic resources
  - employing different search queries

MPEP 808.02

Responding to applicant's traversal re: burden

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. (See MPEP § 803.01.) In doing so, the examiner should reply to the reasons or arguments advanced by applicant in the traverse. MPEP 821.01



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MPEP 803

Independent Inventions

- Independent inventions have **no disclosed relationship,** i.e., they are unrelated.

- Product and process inventions are unrelated if it can be shown that
  - the product cannot be used in the process
    AND
  - the product cannot be made by the process.

- See MPEP § 802.01 and § 806.06; FP 8.20.03

Example III: Independent Product and Process Inventions

Claim 1. An oligonucleotide molecule that hybridizes to a polynucleotide having SEQ ID No 1 which encodes Protein XYZ.

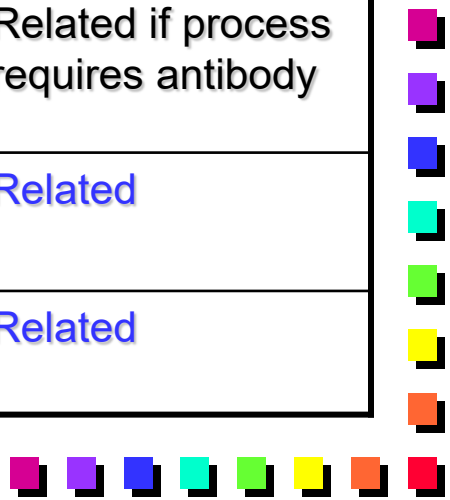
Claim 2. A process of inducing passive immunity by administering an antibody that binds to Protein XYZ.

The product of claim 1 is independent from the process of claim 2 because the oligonucleotide of claim 1 is neither used in nor made by the process of claim 2.

- See MPEP § 802.01 and § 806.06; FP 8.20.03

Independent Inventions Common in TC1600 Applications

Product: / Process of:	DNA that contains protein XYZ's open reading frame	Protein XYZ	Antibody that binds to protein XYZ
making DNA	Related	Often Independent	Often Independent
using DNA	Related	Related if process results in the protein	Often Independent
making protein	Related if process requires the DNA	Related	Related if process requires antibody
using protein	Often Independent	Related	Related if process requires antibody
making antibody	Often Independent	Related if process requires the protein	Related
using antibody	Often Independent	Related if process requires the protein	Related



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MPEP 803

Concepts Relevant to Determining Distinctness Between Product and Process Inventions

- **Obvious Variants**
- **Materially Different**
- **Mutually Exclusive**

Obvious variants are not distinct inventions

- **Distinctness between related inventions requires that at least one invention would not have been obvious over the other (i.e., that the inventions are not obvious variants).**

If the claims on their face are obvious over each other, restriction is not proper.

- **For example of obvious variants, the application claims a method of connecting two parts together.**
  - **In one embodiment, the method requires a screw.**
  - **In a second embodiment, the method requires a nail.**

The examiner should group together embodiments considered clearly unpatentable over each other; see MPEP 806.04(h).

What is “Materially Different”?

- Establishing distinction often requires showing
  - the claimed product can be used in, or made by, a materially different process than that claimed, or
  - the claimed process can result in, or be performed with, a materially different product than that claimed.
    - Two products or two processes are “materially different” when they are independent or distinct from one another.
- Burden on the examiner to provide a reasonable example of a materially different product/process
  - Example need not be documented
  - If applicant convincingly traverses the restriction requirement, a viable alternative process or product is needed to maintain the restriction.

What is "Mutually Exclusive"

- 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. 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)
- 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

Establishing Distinctness Between Related Inventions of different Statutory Categories (i.e., "Products" and "Processes")

- Process of using an apparatus & apparatus for its practice – See MPEP 806.05(e)
- Process of making a product & product made by the process – See MPEP 806.05(f)
- Product & process of using the product – See MPEP 806.05(h)

Test for Distinctness between Process and Apparatus for its Practice

- **Test:**
  - The process *as claimed* can be practiced by an apparatus that is materially different from the claimed apparatus, or by hand;

OR

  - The apparatus *as claimed* can be used to practice a process that is materially different from the claimed process.

MPEP 806.05(e); FP 8.17

Example IV: Process can be practiced by a materially different apparatus

- Claim 1. A process for producing protein XYZ having SEQ ID No 1 comprising the step of using a chemical synthesizer to create the amino-peptide bonds between individual amino acids as specified by the sequence of SEQ ID No 1, thus forming the polypeptide having SEQ ID No 1.
- Claim 2. Isolated protein XYZ having SEQ ID No 1.

- The specification teaches that protein XYZ can be isolated from nature using column chromatography, made via recombinant DNA expression systems or chemically synthesized.

- Because the protein can be made by materially different methods other than chemical synthesis, the process of claim 1 and the product of claim 2 are distinct.

MPEP 806.05(e); FP 8.17

Example V: Apparatus can be used to practice a materially different process.

- Claim 1. A process for producing a protein comprising the step of using a chemical synthesizer to create the amino-peptide bonds between individual amino acids as specified by a given sequence, thus forming the polypeptide having the given sequence.
- Claim 2. Isolated protein XYZ having SEQ ID No 1.

- The specification teaches that the chemical synthesizer can be programmed to produce any protein if given the protein's amino acid sequence.

- Human growth hormone of SEQ ID No 2 is materially different from Protein XYZ having SEQ ID No 1. Because the process of Claim 1 can make materially different proteins, such as human growth hormone, than the protein of claim 2, the process of claim 1 and the product of claim 2 are distinct.

MPEP 806.05(e); FP 8.17

Test For Distinctness Between Process of Making and Product Made

- **Test:**
  - The product *as claimed* can be made by a process that is materially different from the claimed process;

OR

  - The process *as claimed* can be used to make a product that is materially different from the claimed product.

MPEP 806.05(f); FP 8.18

Practical Tip on Process of Making and Product Made

- "Product-by-process" claims may be restricted from process of making claims if the product claimed in the "product-by-process" claims can be made by another materially different process than that claimed.
- "Product-by process" claims should generally be grouped with the product.
- See MPEP 806.05(f)

Example VI: Product can be made by a materially different process

- Claim 1. Compound XYZ having Formula 1.
- Claim 2. A process of making a compound XYZ having formula 1 by isolating compound XYZ from *lactobacillus*.

- The specification teaches that compound XYZ can be purified and isolated from lactobacillus. The specification also provides the chemical structure of compound XYZ and a process for synthesizing it.

- Because the product of claim 1, *as claimed,* can be made by a process that is materially different from the claimed process, the product of claim 1 is distinct from the process of claim 2.

MPEP 806.05(f); FP 8.18

Example VII: Process can make a materially different product

Claim 1. An antibody which binds to the N-terminal of protein X.

Claim 2. A method of producing an antibody which binds to protein X, comprising the steps of immunizing a mouse with protein X, fusing immunized B cells with myeloma cells to produce hybridomas, cloning the hybridomas which produce protein X-specific antibodies and isolating the antibodies produced by the hybridomas.

The specification teaches that the N-terminus of protein X contains a targeting domain while the C-terminus of protein X contains an activation domain shared by other members of that family. The specification teaches that some of the antibodies produced by the method of claim 2 bind to the activation domain of protein X and not to the targeting domain, while antibodies which bind to the N-terminus are specific for the targeting domain.

- Because the process of claim 2, *as claimed,* can produce antibodies to the C-terminal of protein X, that are materially different from the antibodies which bind to the N-terminus of protein X, the product of claim 1 is distinct from the process of claim 2.

MPEP 806.05(f); FP 8.18

Test for Distinctness Between Product and Process of Using

- **Test:**
  - The process of using the product *as claimed* can be practiced with another materially different product,

OR

  - The product *as claimed* can be used in a materially different process.

MPEP 806.05(h); FP 8.20

Example VIII: Process of using can be practiced with a materially different product

Claim 1. A method of detecting skin cancer comprising the step of contacting cells with an agent that binds to melanoma cells.

Claim 2. An antibody that binds to the PDQ receptor found on melanoma cells.

The specification provides 4 agents which bind to the PDQ receptor, including an antibody, a solubilized PDQ receptor, a compound having formula 1 and a lectin having Formula 2.

Because the method of claim 1, as claimed, can be practiced using a materially different agent, such as the solubilized receptor, the compound having Formula 1 or the lectin having Formula 2, than the antibody of claim 2, the process of claim 1 is distinct from the product of claim 2.

MPEP 806.05(h); FP 8.20

Example IX: The product *as claimed* can be used in a materially different process

Claim 1. A composition comprising the compound of Formula 1.

Claim 2. A method of enhancing needle longevity in a coniferous plants by administering the compound of Formula 1.

The specification teaches that compound of Formula 1, when applied to deciduous plants, reduces growth of new leaves but when applied to coniferous plants, lengthens the life of the needles.

Because the compound of claim 1, as claimed, can be used for a materially different process, such as reducing the growth of new leaves in deciduous plants, than the process of claim 2, the product of claim 1 is distinct from the process of claim 2.

MPEP 806.05(h); FP 8.20

Practical Tip – Distinction Between Products and Processes of Screening or Detecting

- The outcome of a screening method or a detection method is typically information- knowledge that a candidate compound has or lacks the desired activity.
- A screening or detection method usually does not result in the production, isolation or purification of the product possessing the desired activity.
- A screening or detection method usually does not require the presence of the product possessing the desired activity.
- As such, a process of screening or detecting is often NOT a process of making or using the product which possesses the desired activity.

Example X: Restriction Between a Product and Process of Screening for Activity of the Product

Claim 1. A process of screening for an inhibitor of Enzyme LMN by testing candidate compounds for their ability to inhibit the enzymatic activity of Enzyme LMN.

Claim 2. A compound identified by the process of claim 1, wherein the compound has Formula 1.

- The specification teaches that a compound having Formula 1 can inhibit the enzymatic activity of Enzyme LMN.
- The outcome of the process of claim 1 does not result in the production, synthesis, isolation or purification of the compound having Formula 1.
- As such, the method of claim 1 is not a process of making or using the compound of Claim 2.
- The process and product are distinct. If the product elected and found allowable, no need to rejoin the process as it does not depend from or require all the limitations of the product claim.

Practical Tip – Restriction Between Products and Processes

- If the product invention is elected and found allowable over the prior art, processes of making or using the allowable product would ordinarily be novel and nonobvious. Claims to the non-elected process(es) may be subject to "rejoinder". See MPEP 821.04(b).

- Notify applicants of potential opportunity for "rejoinder" via FP 8.21.04, which should be added to restriction requirements using either FP 8.18 or FP 8.20.

Any questions?