



Double Patenting

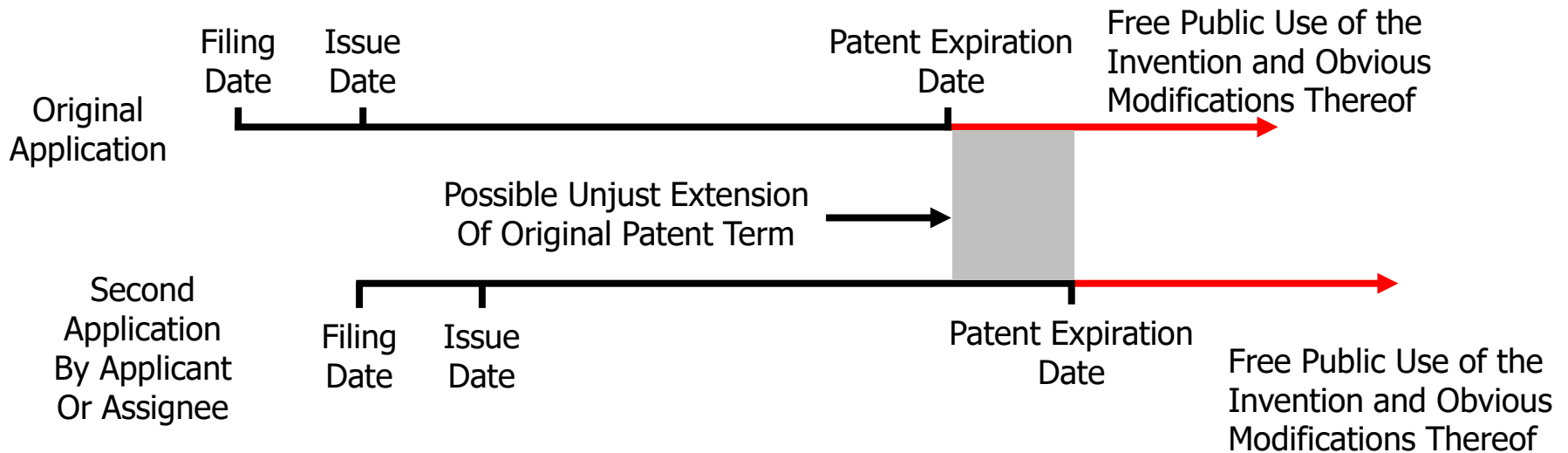
Anthony Caputa
Quality Lead
OPQA



The Purpose Behind the Policy

- Double Patenting
 - Prevents unjustified extension of exclusive rights
 - After expiration, public should be able to:
 - Freely use the claimed invention
 - Freely use obvious modifications of the claimed invention

A Graphical Representation of the Problem





Focus on the Claims

- Claims of the Potentially Conflicting Patent or Application vs. Examined Claims
- The Scope of the Claimed Invention Must be Clearly Determined by Giving the Claims the Broadest Reasonable Interpretation Consistent with the Specification



Types of Double Patenting Rejections

- Statutory (35 U.S.C. 101) Double Patenting
- Non-Statutory Double Patenting
 - Rejection based on obviousness analysis
 - Rejection based on anticipation analysis
 - Non-Statutory Double Patenting Based Solely on Improper Timewise Extension of Patent Rights



When Prohibition Under 35 U.S.C. 121 Does Not Apply

- Two or More Applications Filed – No Restriction Requirement Made
- Claims Amended in a Divisional are Not Consonant With the Restriction Requirement



When Prohibition Under 35 U.S.C. 121 Does Not Apply (con't)

- Restriction (Lack of Unity) Only Made in PCT Application
- Examiner Withdraws Restriction Before Patent Issues
 - Rejoinder
- Claims are Directed to Identical Subject Matter



When Prohibition Under 35 U.S.C. 121 Does Not Apply (con't)

- Claims in an issued or pending case are directed to a non-elected invention of another application and the case is not a divisional of that application
 - See *Pfizer Inc. v. Teva Pharmaceuticals USA Inc.*, 518 F. 3d 1353, 86 USPQ2d 1001 (Fed. Cir. 2008) which sets forth that section 121 applies exclusively to divisional applications.



Example

- 09/123,123, Filed 01/01/02
 - Claim 1 – Isolated novel Protein x
 - Claim 2 – A method of alleviating pain by administering to a patient a composition comprising novel protein X
 - Restricted between claims 1-2
 - Elected claim 2, cancelled claim 1
 - Issued 6/1/02
- 09/234,234, Filed 4/1/02
 - CIP of 09/123,123
 - Claim 1 – Isolated novel Protein x (same as original claim 1 of 09/123,123)
 - Claim 1 rejected under non-stat DP over the method claim of issued parent



Example (continued)

- Non-stat DP Rejection is **PROPER**
 - 35 U.S.C. 121 does not prohibit the rejection because `234 is a CIP of `123
- If `234 was filed as a divisional of 09/123,123 a Non-stat DP Rejection would not be proper



Statutory Double Patenting

35 U.S.C. 101



Same Invention

- Is the Same Invention Being Claimed Twice?
- Identical Subject Matter

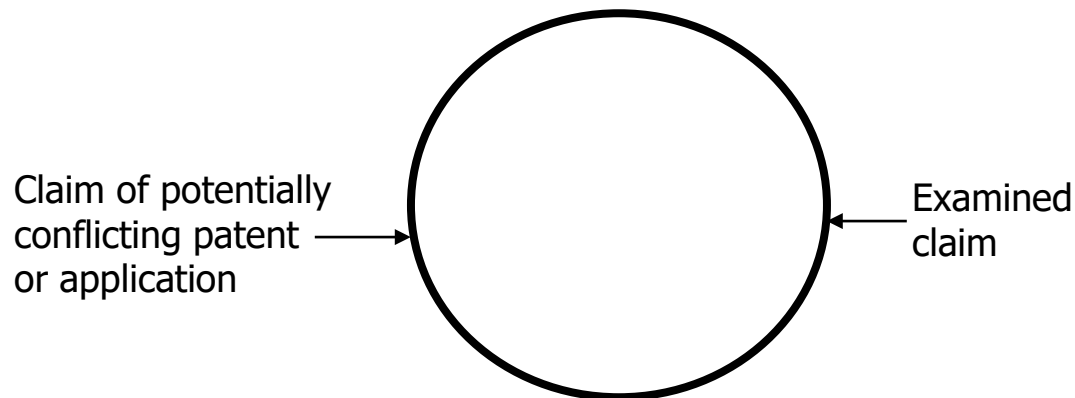


A Reliable Test

- Is There an Embodiment that Falls Within the Scope of One Claim, but Not the Other?
- Could One Claim be Literally Infringed Without Literally Infringing the Other Claim?

Statutory (35 U.S.C. 101) Double Patenting

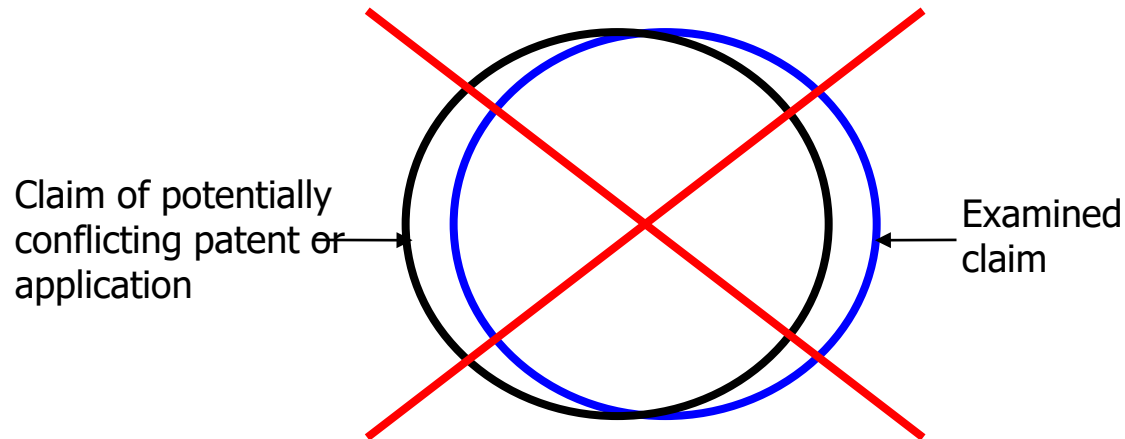
Venn Diagram



Examined claim and claim of potentially conflicting patent or application exactly match in scope – statutory (35 U.S.C. 101) double patenting appropriate.

Statutory (35 U.S.C. 101) Double Patenting

■ Venn Diagram



Examined claim and claim of potentially conflicting patent or application **DO NOT** exactly match in scope – **DO NOT** make a statutory (35 U.S.C. 101) double patenting rejection. Perform further analysis to determine whether a rejection on non-statutory double patenting grounds is appropriate.



Non-Statutory Double Patenting

- Obviousness Analysis
- Anticipation Analysis



Proper Uses of Disclosure

- Look at the Specification to Construe the Scope of the Claimed Invention
 - Dictionary for claim terminology
 - Portions of the disclosure which provide support for the claims in the potentially conflicting patent or application



Obviousness Analysis

- Analogous to 35 U.S.C. 103 Analysis
- Determine the Scope and Content of the Claims in the Conflicting Patent or Application
- Ascertain the Differences Between the Claims in the Conflicting Patent or Application and the Claim in Issue
- Resolve the Level of Ordinary Skill in the Art
- Evaluate Evidence of Secondary Considerations

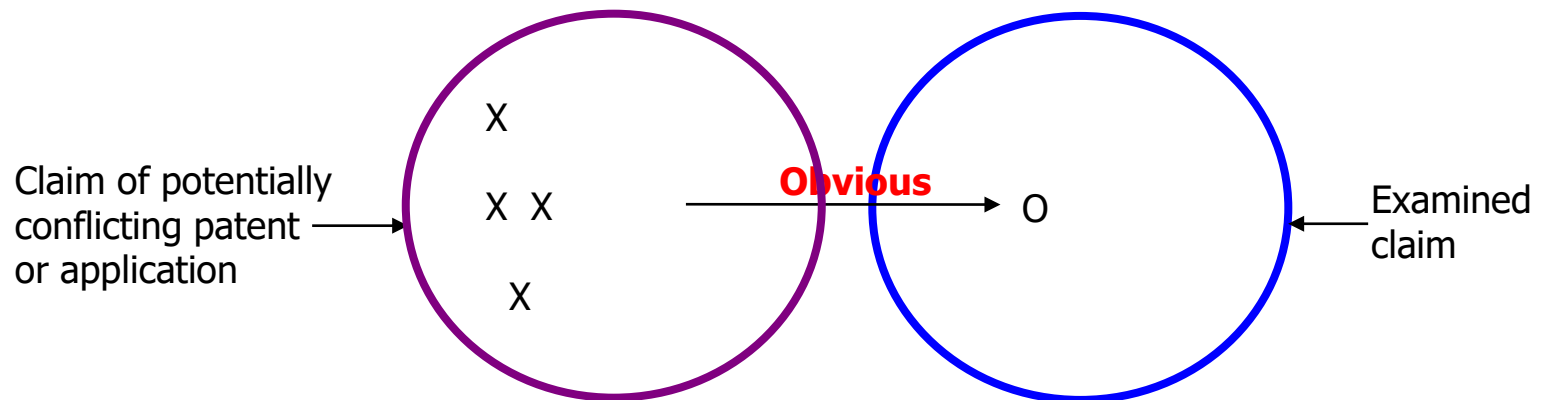


Obviousness Analysis – Written Rejection

- Any Non-Statutory Double Patenting Rejection Based on an Obviousness Analysis Should Make Clear:
 - The differences between a claim in the examined application compared to a claim in the reference patent (or copending application)
 - The reasons for concluding that the invention defined in the claim at issue would have been an obvious variation of the invention defined in a claim in the patent (or copending application)

Obviousness Analysis

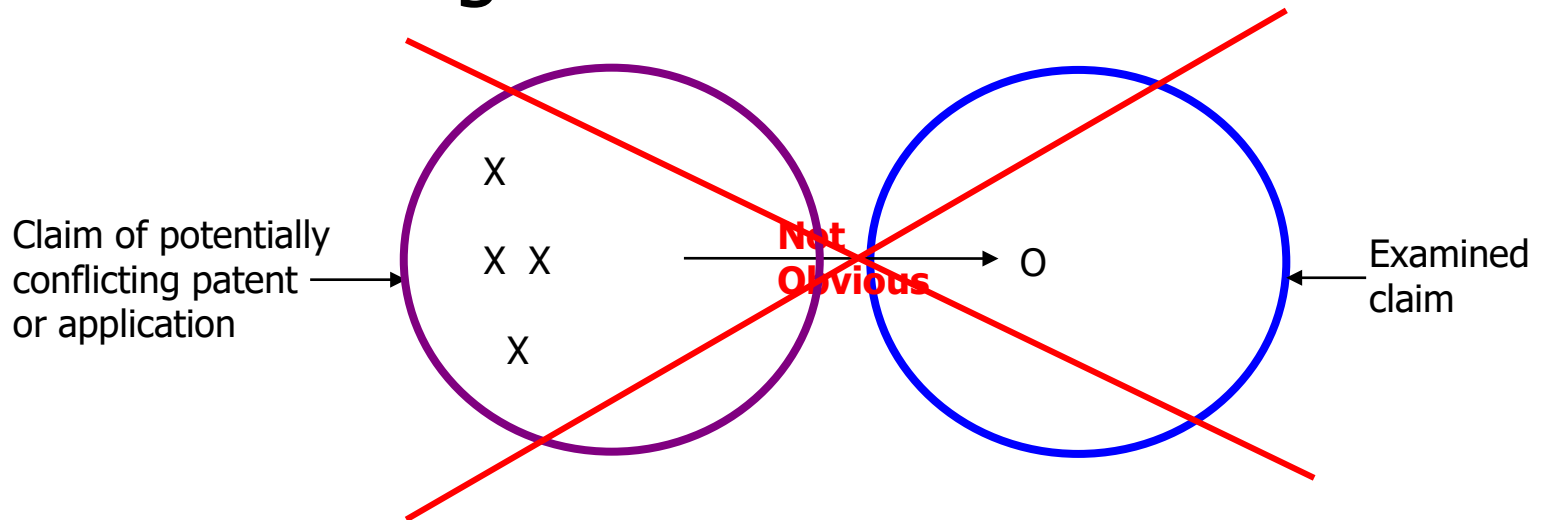
■ Venn Diagram



Non-Statutory Double
Patenting Rejection
Appropriate.

Obviousness Analysis

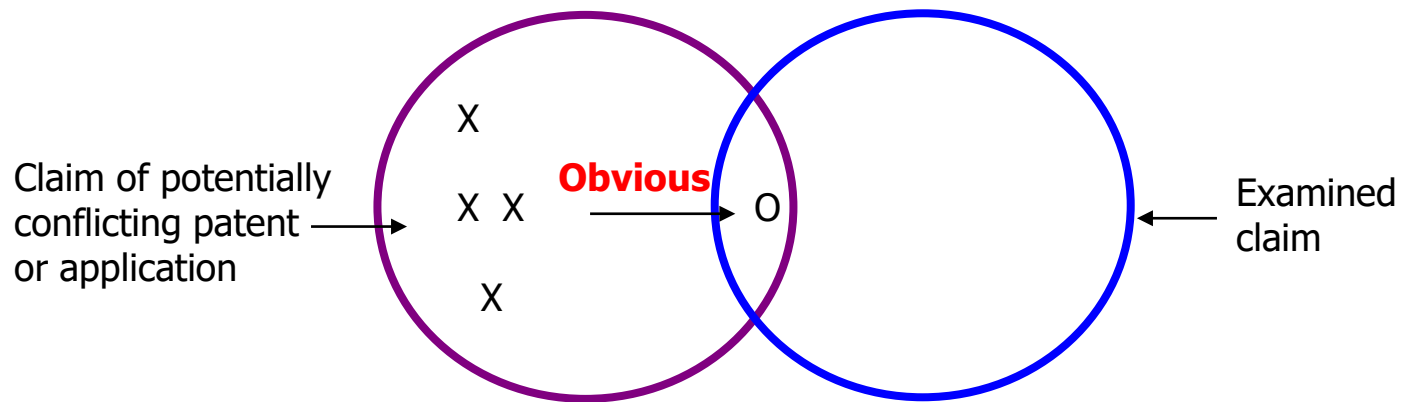
■ Venn Diagram



Non-Statutory Double
Patenting Rejection **NOT**
Appropriate.

Obviousness Analysis

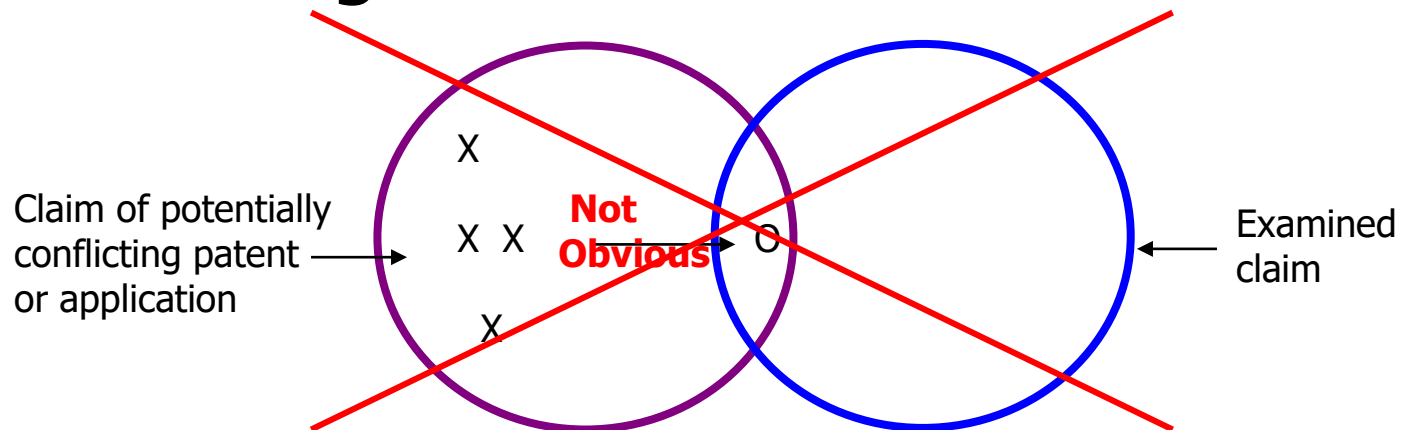
■ Venn Diagram



Non-Statutory Double
Patenting Rejection
Appropriate.

Obviousness Analysis

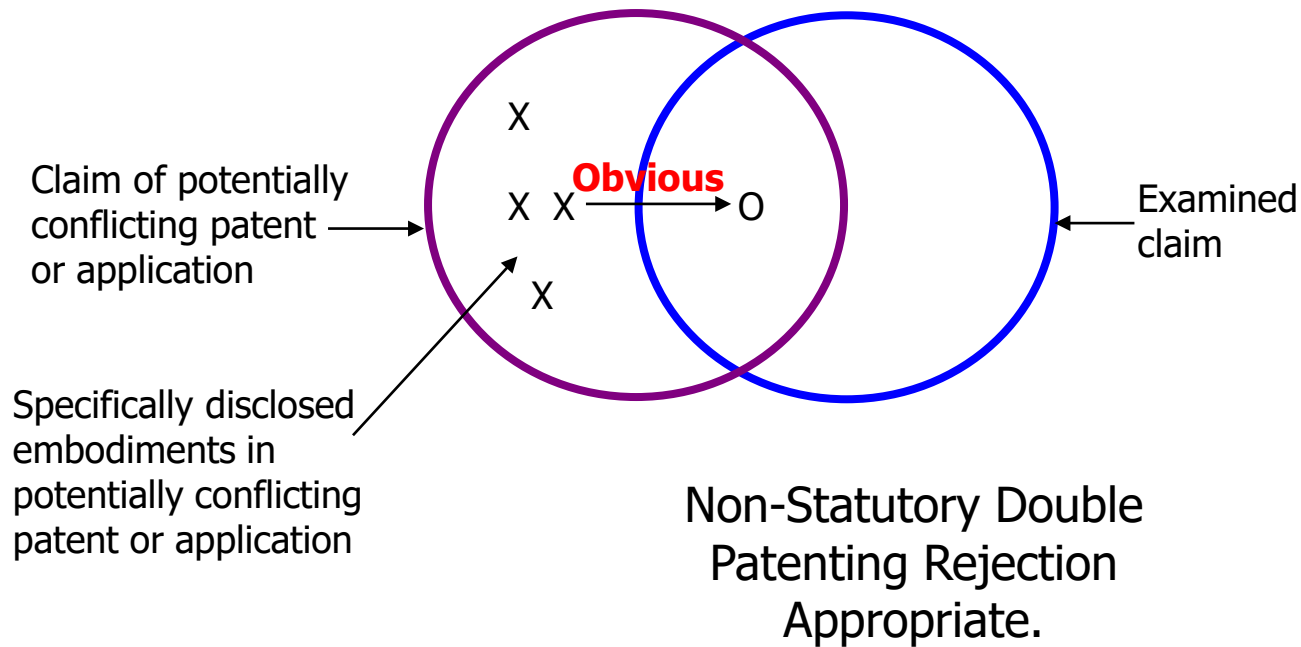
■ Venn Diagram



Non-Statutory Double
Patenting Rejection **NOT**
Appropriate.

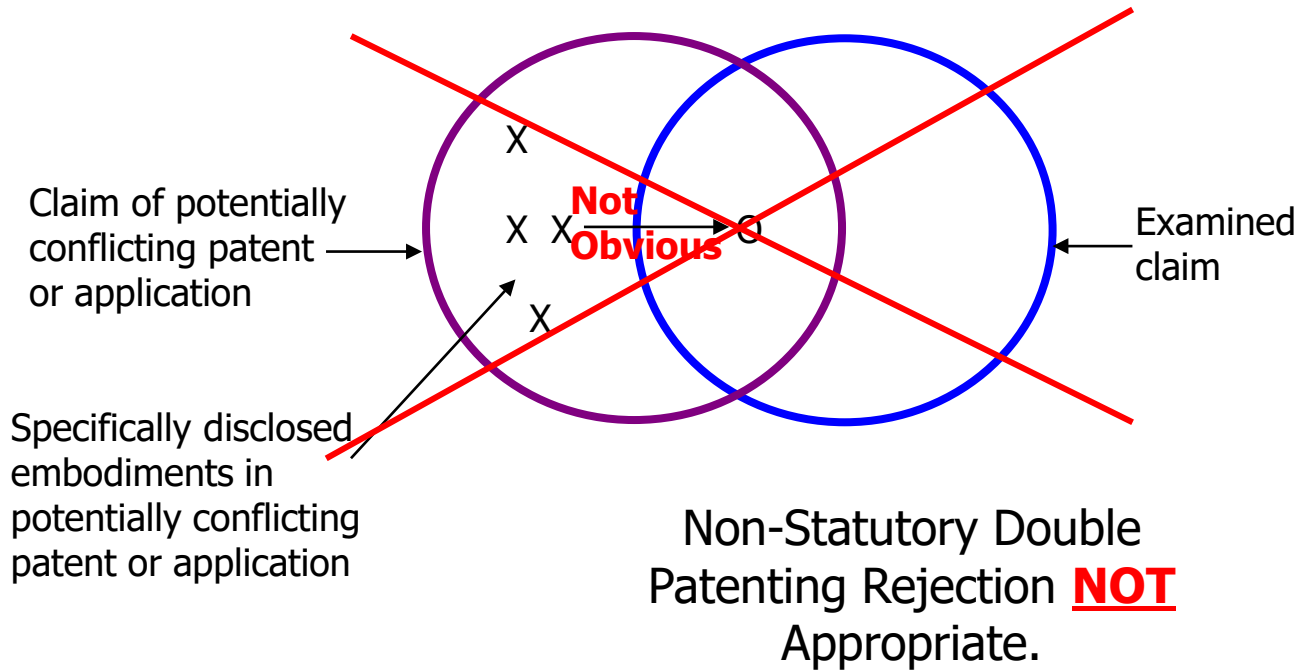
Obviousness Analysis

■ Venn Diagram



Obviousness Analysis

■ Venn Diagram



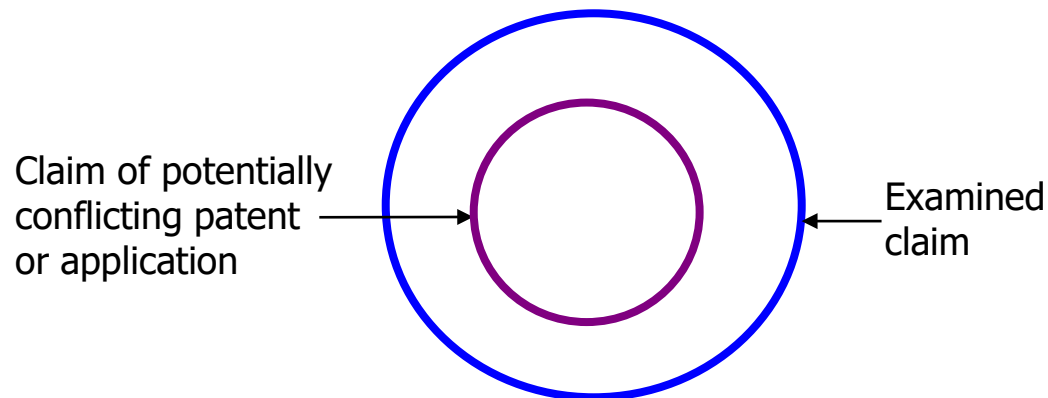


Anticipation Analysis

- Examined Claims
 - Fully encompasses a claim in the potentially conflicting patent or application
 - Anticipated by the claim in the potentially conflicting patent or application
- Written Rejection
 - No *Graham v. Deere* analysis needed
 - Explain how the examined claim is anticipated

Anticipation

■ Venn Diagram



Non-Statutory Double Patenting Rejection Appropriate.



How to Overcome a Proper Double Patenting Rejection

- Statutory (35 U.S.C. 101) Double Patenting
 - Amend the claim(s)
 - Cancel the claim(s)
 - A terminal disclaimer is **NOT** sufficient to overcome such a rejection
 - Declarations under 37 CFR 1.131 are **NOT** sufficient to overcome such a rejection



How to Overcome a Proper Double Patenting Rejection

- Non-Statutory Double Patenting (All Types)
 - Amend the claim(s)
 - Cancel the claim(s)
 - File a proper terminal disclaimer
 - Declarations under 37 CFR 1.131 are **NOT** sufficient to overcome such a rejection



Double Patenting vs. Art Rejection

- Double Patenting
 - Compares claims
 - The scope of the claimed invention must be clearly determined by giving the claims the broadest reasonable interpretation consistent with the specification
 - Can be overcome by a terminal disclaimer (Non-Statutory DP only)
 - TD removes potential harm to public



CREATE Act and Double Patenting Rejection(s):

- If applicant overcomes a 103(a) rejection by properly excluding a 102(e) type reference applied in the 103(a) rejection based upon a joint research agreement, the examiner will treat the application under examination and the prior art as if they were commonly owned for purposes of double patenting.



Example 1

- The Examiner rejected claims 1-15 under the doctrine of non-statutory double patenting over claims 1-21 of USSN 10/123,456
- Applicants replied and stated that a terminal disclaimer over USSN 10/123,456 is filed rendering the non-statutory DP rejection moot.



Example 1 (continued)

- The examiner responded by stating "The rejection of claims 1-10 under non-statutory double patenting...is maintained for reasons of record. Applicants argue that a terminal disclaimer was filed on date 03/06/2005. It is the examiner's position that the terminal disclaimer has not yet been accepted or denied by the patent office."
- This response is not proper. The Examiner should have had the terminal disclaimer reviewed and should withdraw the rejection if the TD was acceptable.



Example 2

- Examiner rejected claims 19-34 under 35 USC 101 as claiming the same invention as that of claims 1-34 of US Patent No. '123.
- Applicants assert that claims 19-34 of the present invention are not coextensive in scope from claims 1-34 and the double patenting under 35 USC 101 is improper.



Example 2 (continued)

- Applicants point out that the R1 substituent
 - of the instant claim recites R1 is hydrogen or phenyl, optionally substituted by 1, 2 or 3 V1
 - of the patented claim recites R1 is hydrogen or phenyl, optionally substituted at the 2-position with Rj, and optionally substituted by 1, 2 or 3 V1



Example 2 (continued)

- After reviewing applicant's response the examiner allowed the case.
- The examiner did correctly drop the rejection under 35 USC 101.
- However, the examiner should not have allowed the case since an non-stat DP rejection needed to be made of record.



Example 3

- **Examined Application (Inventors X and Y)**
 - Claim 1. Method of isolating the 44 kDa antigen from *S. aureus* using monoclonal antibody P3-6 produced by the hybridoma designated P3-6 (ATCC Accession No. PTA-1234).
- **Patent 8,500,000 (Inventors X and Y)**
 - Claim 70. Method of isolating the 44 kDa antigen from *S. aureus* using a monoclonal antibody which reacts with an antigen on the surface of *S. aureus* having an approximate molecular weight of 44 kDa.
 - Discloses an example and a preferred embodiment of isolating the 44 kDa antigen from *S. aureus* using monoclonal antibody P3-6
- **Non-Statutory Double Patenting – Obviousness Analysis Appropriate**
 - Using the specifically disclosed monoclonal antibody (P3-6) that support the monoclonal antibody in claim 70



Example 4

- **Examined Application (Inventors X and Y)**
 - **Claim 1. Method of estimating the frequency of a haplotype for a set of biallelic markers in a population comprising the steps of**
 - (a) Genotyping each individual in said population for a first biallelic marker
 - (b) Genotyping each individual in said population for a second biallelic marker by determining the identity of the nucleotides at said second biallelic marker for both copies of said second biallelic marker present in the genome; and
 - (c) Applying the haplotype determination method to the identities of the nucleotides determined in steps (a) and (b) to obtain an estimate of said frequency, wherein said biallelic markers are 10-123-456 and 12-123-789

- **Patent 8,500,000 (Inventors X and Y)**
 - **Claim 70. Method of estimating the frequency of a haplotype for a set of biallelic markers in a population comprising the steps of**
 - Steps (a), (b) and (c) are essentially the same as claim 1 of instant application.
 - The biallelic markers of the patented claim are from SEQ ID NO: 567
 - The specification discloses biallelic markers 10-123-456 and 12-123-789 are found in SEQ ID: 567 are a preferred embodiment

- **Non-Statutory Double Patenting – Obviousness Analysis Appropriate**
 - Using the specifically disclosed markers (10-123-456 and 12-123-789) that support these markers in claim 70



Example 5

- 09/123,123, Filed 01/01/02
 - Claim 1 – Protein
 - Claim 2 – DNA encoding the protein
 - Restricted between claims 1-2
 - Elected claim 2, cancelled claim 1
 - Issued 6/1/02
- 09/234,234, Filed 4/1/02
 - Divisional of 09/123,123
 - Claim 1 – Protein (same as original claim 1 of 09/123,123)
 - Claim 1 rejected under non-stat DP over the DNA claim of issued parent



Example 5 (continued)

- Non-stat DP Rejection – **NOT PROPER**
 - 35 U.S.C. 121 prohibits the rejection because of the restriction in the parent application



Example 6

- Examined Application (Inventor X)
 - Claim 1. A shampoo composition comprising water, a moisturizer, a surface-active agent, and a dye.
- Patent 8,500,000 (Inventors X and Y)
 - Issued less than one year before the effective filing date of examined application
 - Claim 37. A composition comprising water, a surfactant, a dye, and a moisturizer wherein the composition is a shampoo.
- No Claimed Benefit to Patent
- No Restriction Made



Example 6 (continued)

- Statutory (35 U.S.C. 101) Double Patenting is Appropriate
- Rejection Under 35 U.S.C. 102(e) Would Also Be Appropriate



Example 6 (Modifications)

- If Patent Issued More Than One Year Before the Effective Filing Date of the Application
 - Statutory double patenting still appropriate
 - 102(b) rejection would also be appropriate
- If Patent Issued Less Than One Year Before the Effective Filing Date of the Application No Common Inventor or Assignee
 - 102(e) rejection would be appropriate
 - If overcome - interference



Example 7

- **Examined Application (Inventors X and Y)**

- Claim 1. A compound having the following formula:



wherein R^1 is alky, alkyoxy, or hydroxy, R^2 is cycloalkyl, unsubstituted phenyl, or substituted phenyl, and n is 1-10.

- **Patent 8,500,000 (Inventors X and Y)**

- Filed before but issued after the effective filing date of the examined application
- Claim 10. A compound having the following formula:



- **Benefit to Patent Claimed**

- **No Restriction Made**



Example 7 (continued)

- Non-Statutory Type Double Patenting – Anticipation Analysis Appropriate



Example 8

- **Examined Application (Inventors A and B)**
 - Claim 1. A method of treating high blood pressure in a patient in need thereof comprising administering to the patient an aqueous solution of compound X wherein the aqueous solution includes a thickener in an amount such that the aqueous solution has a viscosity of 50-80 centipoise at 37 °C.
- **Patent 8,500,000 (Inventors A and B)**
 - Filed before but issued after the effective filing date of the examined application
 - Claim 20. A method of treating high blood pressure in a patient in need thereof comprising administering to the patient an aqueous solution of compound X.
- **CIP Benefit to Patent Claimed**
- **No Restriction Made**



Example 8 (continued)

- Specification of Patent No. 8,500,000
 - The aqueous solution of compound X can be administered by various routes including, subcutaneous, intravenous, and oral.
- Hill et al
 - More than one year before the effective filing date of the application
 - Better results are obtained from drugs that are administered subcutaneously
 - When the viscosity of the composition is 50-60 centipoise at 37°C
 - Better drug availability at the disclosed viscosity
 - Viscosity can be adjusted using thickening agents.



Example 8 (continued)

- Non-Statutory-Type Double Patenting – Obviousness Analysis Appropriate



Example 8 (Modifications)

- Patent and Hill et al Issued More Than One Year Before the Effective Filing Date of the Application
 - 103 rejection would be appropriate
 - Non-statutory double patenting rejection not necessary
 - Any argument/evidence overcoming 103 rejection would necessarily overcome ODP rejection
- No Common Inventor or Assignee
 - 103 rejection would be appropriate
 - Non-statutory double patenting rejection not appropriate



Rule 105 Requests

- Available for use in very limited situations where there is a reasonable potential for an extreme number of double patent rejections in an application
- The examiner must present an exemplary number of possible related co-pending applications by serial number and provide several actual non-statutory double patenting rejections that exist between specifically identified applications



Rule 105 Requests

- Rule 105 requests in TC1600 that require Applicant to identify double patenting issues require a Director's signature
- Contact a QAS if you think that you have an application where such a request would be appropriate



QUESTIONS????

Anthony Caputa

Office of Patent Quality Assurance

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