



Patent Resources Group
Chemical Patent Practice
Course Syllabus

- I. PREDRAFTING CONSIDERATIONS**
 - A. Determination of the Inventorship Entity
 - 1. 35 USC §116
 - 2. Three Stages in Making an Invention
 - 3. Correction of Inventorship
 - B. Establishing Earliest Date of Invention Through Good Record-keeping
 - 1. Records of Invention
 - 2. Changes Resulting From Amendments to 35 USC §104
 - 3. Proving Date of Invention
 - 4. Importance of Good Record-keeping to Establishing the Date of Invention
- II. CONSIDERATIONS FOR DRAFTING A CHEMICAL PATENT SPECIFICATION**
 - A. Disclosure of the Invention
 - 1. Disclosure to the Public
 - 2. Satisfying 35 USC §112
 - B. Guidelines for Preparing Disclosure
 - 1. Define and Consistently Use Terms
 - 2. More Is Better
 - 3. Avoid Patent Profanity
 - 4. Focus on Objective of Literal Infringement
- III. CLAIM DRAFTING**
 - A. Claiming the Chemical Invention
 - 1. Determine How the Invention Distinguishes From the Prior Art and the Probable Scope of the Invention
 - 2. A Complete Understanding of the Invention and the Prior Art Will Aid in Determining How Best to Claim It
 - B. Parts of the Claim
 - 1. The Preamble
 - 2. Transition Terms – "Comprising," "Consisting of," "Consisting Essentially of"
 - 3. "Whereby"
 - 4. *Jepson* Claims
 - 5. Drafting Process Claims in View of 35 USC §271(g)
 - 6. What About Metabolites?
 - C. Claiming Suggestions
- IV. CLAIM CONSTRUCTION**
 - A. Claim Construction
 - 1. *Markman* and Its Progeny
 - 2. Construing the Preamble
 - 3. Construing Transition Terms – "Comprising," "Consisting of," "Consisting Essentially of"



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- B. Doctrine of Equivalents
 - 1. Prosecution History Estoppel: Presumption of Surrender
 - 2. All Elements Rule
 - 3. Insubstantial Differences
 - 4. Narrow Claim Language
 - 5. Prior Art as a Limitation on Equivalents
 - 6. Disclosed But Unclaimed Subject Matter
- C. Prosecution History Estoppel
 - 1. When Does Prosecution History Estoppel Arise?
 - 2. The Distinction Between Prosecution History in Claim Interpretation and in the Doctrine of Equivalents
 - 3. Effect of Prosecution History on Claim Interpretation
 - 4. Effect of Prosecution History Estoppel on Scope of Equivalents Under the Doctrine of Equivalents
- D. Acts That Give Rise to Prosecution History Estoppel
 - 1. Classical Prosecution History Estoppel: Amendments in Response to Prior Art Rejections
 - 2. Estoppel by Admission: Arguments Made to Examiners Without Amendment
 - 3. Amendments in Response to Non-Art Rejections
 - 4. Remarks Made After Allowance
 - 5. Multiple Arguments to Overcome Prior Art May or May Not Create Multiple Separate Estoppels
 - 6. Failure to Continue Prosecution
 - 7. Representation to Foreign Patent Offices
 - 8. Examiner Estoppel?
- E. Effect of Estoppel
 - 1. Effect of Estoppel on Other Claims in Same Patent
 - 2. Effect of Estoppel on Related Applications
 - 3. Effect of Estoppel on Same Claims
- F. Suggestions to Avoid Prosecution History Estoppel
- V. **RESPONDING TO A RESTRICTION REQUIREMENT AND AN ELECTION OF SPECIES REQUIREMENT**
 - A. Restriction Requirements
 - 1. Statutory and Regulatory Basis
 - 2. The USPTO's Burden to Substantiate a Proper Restriction Requirement
 - 3. Responding to the Restriction Requirement
 - 4. Rule 129(a) and (b) Restriction Practice
 - 5. Restriction Practice in PCT Applications That Designate the United States When Entering the National Stage



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- B. Election of Species Requirement
 - 1. Regulatory Basis
 - 2. Responding to an Election Requirement
 - 3. Markush Claims
- C. Divisional Applications
- VI. THE REQUIREMENT OF UTILITY UNDER 35 USC §101**
 - A. Requirements Under 35 USC §101
 - B. Statutory Class of Invention and Double Patenting
 - 1. "Use" Claims
 - 2. Non-Statutory Subject Matter Rejections
 - 3. Double Patenting
 - C. The Utility Requirement
 - 1. Historical Development of the Utility Requirement
 - 2. The "Practical" Utility Requirement
 - 3. The Modern Test of "Practical" Utility
 - D. Analysis of Utility Requirement in the Context of Prosecution
 - 1. Review of Utility Guidelines
 - 2. First Interpretation of Guidelines by CAFC
- VII. SECTION 102: DEFINING WHAT CONSTITUTES PRIOR ART AND DETERMINING NOVELTY**
 - A. 35 USC §102 – What Constitutes Prior Art
 - 1. 35 USC §102(a): Acts or Works of Those Other Than the Applicant
 - 2. 35 USC §102(b): The Statutory Bar Provision
 - 3. 35 USC §102(c): Abandonment
 - 4. 35 USC §102(d): Foreign Patenting
 - 5. 35 USC §102(e): Prior Art of Another
 - 6. 35 USC §102(f): Derivation
 - 7. 35 USC §102(g): Prior Invention of Another
 - B. What Constitutes Anticipation
 - 1. Generally
 - 2. Reference Must Be Enabled
 - 3. Using Extrinsic Evidence/Multiple References
 - 4. Compounds and Compositions
 - 5. Genus-Species
 - 6. No "Teaching Away"
 - 7. Anticipating Range Limitations
 - 8. Inherency
- VIII. UNDERSTANDING THE *PRIMA FACIE* CASE OF OBVIOUSNESS UNDER 35 USC §103 AND HOW TO ATTACK IT**
 - A. The Factual Inquiries and Indicia of Unobviousness of *Graham*
 - 1. Scope and Content of the Prior Art



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2. The Differences Between the Prior Art and the Claimed Invention
 3. The Level of Ordinary Skill in the Art
 4. Objective Indicia of Unobviousness
 - B. The *Prima Facie* Case of Obviousness: A Procedural Tool of Examination
 1. The USPTO's Burden of Establishing a *Prima Facie* Case
 - C. Responding to an Alleged *Prima Facie* Case by Attacking Its Premise
 1. *Prima Facie* Obviousness in Chemical Cases
 2. The Requisite Motivation Supporting the Modification
 3. The Prior Art Must Provide a Reasonable Expectation That the Proposed Modification Will Succeed
 4. Chemical Compounds: The Issue of Structural Similarity
 5. Compositions and Formulations
 6. Method of Use Claims
 7. Product-by-Process Claims
 8. Method of Making Claims
 - D. Classic LP-CD Techniques: Four Chemical Patent Real World Case Studies
 1. Using the Prosecution History of the Cited Prior Art to Rebut Motivation to Combine References
 2. Use of Prior Art Reference, an Interview, and the Statement of Reasons for Allowance to Attack *Prima Facie* Case of Obviousness
 3. Establishing Knowledge of Those Skilled in the Art by a Declaration From the Author of the Prior Art
 4. Showing Deficiency in Prior Art References
- IX. REBUTTING A *PRIMA FACIE* CASE OF OBVIOUSNESS**
- A. Rule 132 Affidavits
 - B. Proof of Unobviousness
 1. Unexpected Results
 - C. Objective Indicia of Unobviousness/Secondary Considerations
 1. Commercial Success
 2. Long-Felt Need
 3. Failure by Others
 4. Copying
 5. Teaching Away
 6. Initial Disbelief and Subsequent Acclaim by Experts
- X. COMPLYING WITH 35 USC §112: WRITTEN DESCRIPTION AND ENABLEMENT**
- A. The Second Paragraph
 1. General Considerations
 2. The "Precision and Definiteness" Requirement
 3. Defining What the Applicant Regards as the Invention



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- B. The First Paragraph
 - 1. General Considerations
 - 2. The "Written Description" Requirement
 - 3. The Enablement Requirement
- C. The Fourth Paragraph
- XI. COMPLYING WITH 35 USC §112: BEST MODE, ¶6 AND PRIORITY UNDER §§119 AND 120**
 - A. The Best Mode Requirement
 - 1. The Purpose of the Best Mode Requirement
 - 2. Best Mode Distinguished From Enablement
 - 3. Determining a Best Mode Violation
 - 4. Effect of a Best Mode Violation
 - 5. Is There More?
 - B. §112, ¶6
 - C. The Role of §112 in Obtaining Priority Under 35 USC §§119 or 120
- XII. COMPLYING WITH 35 USC §112: REBUTTING PATENT OFFICE REJECTIONS**
 - A. Preliminary Matters: Is There a Valid Rejection?
 - 1. Clarity
 - 2. Is There a Valid *Prima Facie* Case?
 - B. Rebutting the *Prima Facie* Case
 - 1. Data
 - 2. Art References
 - 3. Expert Declarations
 - 4. After-Arising Technology
- XIII. ANTEDATING REFERENCES BY SHOWING PRIOR DATE OF INVENTION UNDER 37 CFR §1.131**
 - A. Application of Rule 131
 - 1. When Appropriate
 - 2. How to Show Prior Invention
 - 3. Adequacy of the Showing of Prior Invention
 - B. Practical Considerations of Filing Rule 131 Declarations
 - 1. Distinctions Between Affidavits and Declarations
 - 2. Distinctions Between USPTO and Court Proceedings
 - 3. Typical Exhibits
 - 4. Timeliness of Submitting Rule 131 Declarations
 - 5. Provisional Applications as Evidence
 - 6. Whether to File a Rule 131 Declaration
- XIV. GENERAL PRINCIPLES OF DOUBLE PATENTING**
 - A. Introduction
 - 1. The First Type of Double Patenting: "Same Invention" Type



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- 2. The Second Type of Double Patenting: "Obviousness" Type
 - B. 35 USC §121 and Double Patenting
 - C. 35 USC §303 and Double Patenting
 - D. Comparison of Earlier-Filed to Later-Filed
 - E. Recent Chemical Double-Patenting Cases
- XV. INTERVIEWS AT THE UNITED STATES PATENT AND TRADEMARK OFFICE**
- A. Types of Interviews
 - B. When to Interview?
 - 1. Unknown Examiner Handling Many of Your Client's Cases
 - 2. Overcoming a *Prima Facie* Case of Obviousness by the Use of Test Results
 - 3. Opinion Declaration Testimony
 - 4. Use the Interview as a Way to Expedite the Examination Process
 - C. Preparation for the Interview
 - 1. Understand the Office Action, the Claims, and Any Relevant Prior Art
 - 2. Understand the Client's Objectives
 - 3. Draft Amendments and Summary Presentations
 - D. How to Conduct the Interview
 - 1. The Interview: Negotiate and Have an Open Mind
 - 2. Recommendations
 - E. After the Interview
- XVI. SETTING UP CHEMICAL INTERFERENCES DURING *EX PARTE* PROSECUTION**
- A. Is There Interfering Subject Matter?
 - 1. Identical Claims
 - 2. Non-Identical Claims: Avoiding Interference
 - 3. Non-Identical Claims: Desiring to Be in Interference
 - 4. Non-Identical Claims: Desiring to Be in the Interference, But Not With All Claimed Subject Matter
 - B. Interference Considerations
 - 1. 35 USC §135(b)
 - 2. 35 USC §102(g)
 - 3. 37 CFR §1.608
 - 4. 37 CFR §§1.606 and 607
 - C. Practical Example for Setting up an Interference in a Chemical Case
 - 1. Interfering Allowable Subject Matter
 - 2. Proposal of a Count and Claims Corresponding to the Count
 - 3. Proposal of a Claim to Be Designated as Not Corresponding to the Count
 - 4. Request for Interference



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5. Successful Outcome: The Interference Is Declared on Desired Terms

**XVII. PHARMACEUTICAL ISSUES: PATENT TERM EXTENSION FOR
PREMARKET REGULATORY REVIEW AND ANDA QUANDARIES**

- A. Statutory Basis for Patent Term Extension
- B. Application for Patent Term Extension
- C. Eligibility
 1. Patent
 2. Product
 3. Regulatory Review Period
 4. Filing Application for Patent Term Extension
- D. Processing of Patent Term Extension Application
- E. Certificate of Patent Term Extension
- F. About the Orange Book
 1. Failure to List
 2. No Authority to De-List
 3. No Authority to Re-List
 4. Applicable Statute for Actions Against FDA Is APA
 5. Non-Listed Use Not Infringing
 6. Listing Insufficient Basis for Subject Matter Jurisdiction
 7. Orange Book Listing and Anti-Competition Allegations
 8. Induced Infringement
 9. Willful Infringement

XVIII. CORRECTING ERRORS

- A. Introduction
 1. Types of Errors
 2. Which Errors Are Correctable?
 3. Impact of Corrections
 4. Principal Modes of Correction
- B. Certificates of Correction
 1. In General
 2. Fault of the USPTO
 3. Fault of Applicant
 4. Procedure
 5. Effect of Certificate of Correction
 6. Failure to Obtain a Certificate of Correction From the USPTO
- C. Correction of Named Inventor
- D. Statutory Disclaimer
- E. Reissue Patents
- F. Reexamination
- G. Strategies for Selecting a Correction Procedure



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- H. USPTO Activity on Correction of Patents
- I. USPTO Decisions
 - 1. *Dickinson v. Zurko*
 - 2. "Arbitrary, Capricious, or Abuse of Discretion" or "Unsupported by Substantial Evidence"
 - 3. Section 145 Actions