



Patent Resources Group

Pharma & Biotech Strategies for Patent Prosecution, Hatch-Waxman, Litigation & Licensing Course Syllabus

I. STRATEGIES FOR BIOTECH AND PHARMA PROSECUTION

- A. Biotech and Pharma Claim Strategies That Work
 - 1. Nucleic Acids, Vectors, and Transfected Cells
 - 2. Expressed Sequence Tags (ESTs)
 - 3. Antisense Nucleic Acids
 - 4. Ribozymes
 - 5. Double-Stranded RNA and RNA Interference
 - 6. Single Nucleotide Polymorphisms (SNPs)
 - 7. Transgenic and Knock-Out Animals
 - 8. Genetic Therapy
 - 9. Polypeptides
 - 10. Vaccines
 - 11. Antibodies and Hybridomas
 - 12. Bioinformatics Tools and Techniques
 - 13. Combinatorial Libraries
 - 14. Methods of Treatment
 - 15. Screening Assays
 - 16. "Reach-Through" Claims
 - 17. New Uses for Old Compounds
 - 18. Polymorphs
 - 19. The Chemical Genus: Markush and All That
- B. Writing the Biotech Disclosure and Overcoming Rejections Based on the Disclosure, in the Context of Claim Strategies That Work
 - 1. Written Description of Biological Molecules in the Aftermath of *Fiers, U.C. v. Lilly*
 - 2. Enabling the Biotech Invention: How Much Enabling Description Do You Need?
 - 3. Utility: Special Questions Raised by Early Stage Bioscience
 - 4. Best Mode Issues: Are Deposits Necessary?
- C. Overcoming Prior Art Rejections
 - 1. Determining What Qualifies as Prior Art
 - 2. Removing References With Declarations
 - 3. Obviousness
 - 4. Process Claims: 35 USC §103(b) for Biotechnology, and Rejoinder Procedure for Everyone



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- D. Inventorship in Fields Characterized by Collaborations and Publications
 - 1. Inventorship
 - 2. Joint Inventorship
 - 3. Authorship vs. Inventorship
 - 4. Inventorship vs. Ownership
 - 5. Correcting Mistakes in Inventorship
- E. Protecting Inventions Involving Plants
 - 1. Plant Patents
 - 2. Plant Variety Protection
 - 3. Utility Patents - Special Considerations for Plants
 - 4. Utility Patents - Claiming Transgenic Plants
 - 5. Utility Patents - Claiming Conventionally Bred Plants
 - 6. Contracts

II. STRATEGIES FOR ENFORCING PHARMACEUTICAL AND BIOTECHNOLOGY PATENTS

- A. Common Claim Strategies and Associated Problems at Trial
 - 1. Functional Limitations
 - 2. Percent Identity Claims and Hybridization Claims
 - 3. Impractical Limitations
- B. Breadth of Enablement at Trial
 - 1. Inequitable Conduct Based on Enablement
- C. Written Description at Trial
 - 1. Origins of the Written Description Requirement
 - 2. Turning Point: *U.C. v. Eli Lilly*
 - 3. The Aftermath of *U.C. v. Eli Lilly* in Biotechnology
- D. Statutory Subject Matter Under 35 USC §101 at Trial
 - 1. Patentable Subject Matter
 - 2. Product v. Process Patents
 - 3. Recent Relevant Case Law
- E. Principles of Infringement Determination
- F. Special Issues in Using/Making, and Conversion or Production *In Vivo*
 - 1. Self-Replication
 - 2. Conversion or Production *In Vivo*
- G. Markman Claim Interpretation in Biotech and Pharma Patent Litigation
 - 1. *North American Vaccine*



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2. *Novo v. Genentech*
3. *U.C. v. Lilly*
4. *Johns Hopkins Univ. v. CellPro, Inc.*
5. *Glaxo v. Torpharm*
6. *Key Pharmaceuticals v. Hercon Labs. Corp.*
7. *Enzo Biochem, Inc. v. Calgene Inc.*
8. *Genentech, Inc. v. Boehringer Mannheim GmbH*
9. *Schering v. Amgen*
10. *Griffin v. Bertina*
11. *Amgen v. Hoechst Marion Roussel*
12. *Abbott Laboratories v. Syntron Bioresearch*
13. *Jansen v. Rexall Sundown*
14. *Glaxo Wellcome v. Andrx Pharmaceuticals*
15. *Genzyme v. Transkaryotic Therapies*
16. *Norian Corp. v. Stryker Corp. (I)*
17. *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*
18. *Novartis Pharms. v. Abbott Laboratories*
19. *Norian Corp. v. Stryker (II)*
20. *Pfizer, Inc. v. Teva Pharmaceuticals USA, Inc.*
21. *Amgen v. Hoechst Marion Roussel (II)*
22. *Abraxis Bioscience v. Mayne Pharma (USA)*
23. *In re Gabapentin Patent Litigation*
24. *Ortho-McNeil Pharm. v. Mylan Labs.*
- H. Doctrine of Equivalents in Biotechnology
 1. The Doctrine in General
 2. The Doctrine in Decided Biotechnology Cases
- I. Process Patents Amendment Act – 35 USC §271(g)
 1. Meaning of "Process"
 2. Meaning of "Made By" and "Materially Changed"
 3. Timing
- J. ANDA Litigation Strategies
 1. Pre-Suit
 2. Discovery: The Duty to Expedite a Hatch-Waxman Case
 3. Trial
 4. Injunctive Relief
 5. Thinking Appeal



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- K. Practice Tips for Biotech Prosecutors From Litigation of Biotech Patents
 - L. What Corporate Counsel Can Expect From Involvement in Biotech Patent Litigation
 - 1. Clear Business Objectives
 - 2. Cost/Benefit Analysis
 - 3. Strategic Plan
 - 4. Tactical Plan and Presuit Investigation
 - 5. Communications
 - 6. Cost Control
 - 7. Informing Management
 - 8. Document Production
 - 9. Depositions
 - 10. Expert Witnesses
 - 11. Trial
 - 12. Appeal
 - M. Pre-Litigation and Litigation Checklists for Biotech Patent Litigation
 - 1. Pre-Litigation Checklist for Corporate Counsel
 - 2. Pre-Litigation Checklist for Outside Litigation Counsel
 - 3. Litigation Checklist for Corporate Counsel
 - 4. Litigation Checklist for Outside Litigation Counsel
- III. LICENSING BIOTECH AND PHARMA INVENTIONS**
- A. Pre-Agreement – Licensing Deal Process Issues
 - 1. Biotech and Pharma Licensing Overview
 - 2. The Incentives for Licensing
 - B. Agreement Terms – Licensing Deal Process Issues
 - 1. Background
 - 2. Grant
 - 3. Fixed Payments, Royalties or Both
 - 4. Confidentiality
 - 5. Enforcement Against Infringers
 - 6. Term and Termination
 - C. Impact of Recent Supreme Court Decisions on Licensing Deal Process
 - 1. *MedImmune v. Genentech*
 - 2. *KSR Int'l v. Teleflex*



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- D. Collaborations, Academic Institutions, and Other Special Notes
 - 1. Development Collaboration
 - 2. Sponsored Research
 - 3. Licensing From Academic Institutions
 - 4. Patent Misuse
 - 5. Licensing Tools for Drug Screening and Development
- IV. THE ROLE OF PATENT AND NON-PATENT EXCLUSIVITY UNDER THE HATCH-WAXMAN ACT**
 - A. Hatch-Waxman Introduction and Non-Patent Exclusivities (5-Year, 3-Year, Generic, Orphan and Pediatric)
 - 1. Overviews
 - 2. Drug Approvals
 - 3. Marketing Exclusivity - 21 USC §355
 - B. Orphan Drug and Pediatric Exclusivity
 - 1. Orphan Drug Exclusivity
 - 2. Pediatric Exclusivity
 - 3. Special Rules for "Old Antibiotics"
 - 4. Follow-On Biologics – The Future Is Now
 - C. Patent Term Extension
 - 1. Patents Eligible for Term Extension
 - 2. Conditions for Term Extension
 - 3. Scope of Term Extension
 - 4. Computing the Regulatory Review Period
 - 5. USPTO Procedures
 - 6. Patent Prosecution Strategies
 - D. Safe Harbor 35 USC §271(e)(1)
 - 1. The “Merck” Test
 - 2. Post-Approval Safe Harbor
 - E. Orange Book Practice
 - 1. 35 USC §271(e)(2) Litigation
 - 2. Drug Labels and Patents Generally
 - 3. FDA Rules on Patent “Carve Outs”
 - 4. Drug Labels-The New Orange Book