



Patent Resources Group

Pharma & Biotech Strategies for Patent Prosecution, Hatch-Waxman & Litigation 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. Polymorphs
 15. Methods of Treatment
 16. Screening Assays
 17. "Reach-Through" Claims
 18. New Uses for Old Compounds
 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* and *Ariad 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. Inventorship in Fields Characterized by Collaborations and Publications
 1. Inventorship and Joint Inventorship
 2. Authorship vs. Inventorship
 3. Inventorship vs. Ownership
 4. Correcting Mistakes in Inventorship



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D. Obviousness of Pharmaceutical and Biotech Inventions

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
4. *Ariad v. Lilly*

D. Statutory Subject Matter Under 35 USC §101 at Trial

1. Patentable Subject Matter
2. Product v. Process Patents
3. *Bilski v. Kappos* and Other Recent Cases

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 (following list of cases subject to updating as of time of distribution of written materials)

1. *North American Vaccine*
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*



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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. Infringement by Exportation-35 USC §271(f)
1. Applicability to processes? *Cardiac Pacemakers v. St. Jude Medical*
- J. Process Patents Amendment Act – 35 USC §271(g)
1. Meaning of "Process"
 2. Meaning of "Made By" and "Materially Changed"
 3. Timing
- K. ANDA Litigation Strategies
1. Pre-Suit
 2. Discovery: The Duty to Expedite a Hatch-Waxman Case
 3. Trial
 4. Injunctive Relief
 5. Thinking Appeal
- L. Practice Tips for Biotech Prosecutors From Litigation of Biotech Patents



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- M. 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

- N. 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. 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



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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” and “Proveris” Tests
 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. Life Cycle Management: Post Approval Use of Patents

IV. BIOSIMILARS

- A. Biologicals and Small Molecules: The Distinctions That Matter
- B. The Proposed Legislation
- C. Impact on Patent Strategies and Life Cycle Management