I. Hatch-Waxman Act
   a. New Drug Applications (505(b)(1) and 505(b)(2) Applications) and Abbreviated New Drug Applications (ANDA)
      ii. Labeling “Sameness” for ANDAs
   b. Drug Exclusivities
      i. Hatch-Waxman (New Chemical Entity Exclusivity, 3 yr. Exclusivity, First to File Generic)
      ii. Orphan Drugs; Pediatric Exclusivity; Qualified Infectious Disease Products (New Antibiotics)
   c. Orange Book Listing of Patents
      i. Eligibility
      ii. Use Codes
   d. Patent Certification by Generic Applicants
      i. Types of Certification
      ii. Paragraph IV Certification; Procedural Issues and 271(e)(2) Litigation
   e. Labeling Strategies for Brand Drugs
   f. Generic Exclusivity Forfeitures
   g. Patent Term Extensions
      i. Scope
      ii. Extendable Rights
   h. Patent Infringement Safe Harbor
      i. Post-Approval Activities
      ii. Research Tools

II. Biosimilar Act (BPCIA)
   a. Biosimilars and Interchangeable Biosimilars
   b. Exclusivities
      i. New Biological Structures
      ii. Orphan; Pediatric; QIDP
   c. 351(k) Applications
      i. Filing Requirements
      ii. Confidential Access to Pioneer
   d. Patent “Dance”
      i. First Wave Litigation
      ii. Second Wave Litigation
   e. Newly Issued Patents
   f. Limitations on DJs
III. Prosecution Strategies for Pharmaceutical and Biotech Inventions
   a. Claim Drafting Strategies to Maximize Likelihood of Infringement by Generics/Biosimilars While Minimizing Risk of Invalidity
   b. Coordinate Patent Strategy with Orange Book/Purple Book Considerations
   c. Claiming NCE
      i. Natural Product/101
      ii. Obviousness & Lead Compound Analysis
   d. Claiming Formulations
      i. Combination of Naturally Occurring Ingredients/101
      ii. Obviousness—Surprising Results and Teaching-Away
   e. Claiming Methods of Treatment
      i. 101: Mayo, Myriad and PTO Guidelines
      ii. Inherent Anticipation by Prior Use
      iii. Enablement
   f. Claiming Personalized Medicine/Companion Diagnostic Methods
      i. Inducement
      ii. 101
      iii. Claim Drafting Issues (Inherent Anticipation)
   g. Claiming Later-Discovered Inventions (“Evergreening” the Label)
      i. Safety or Efficacy (Avoiding Carve-Out)
      ii. Examples

IV. Litigation
   a. 30 Month Stay, Personal Jurisdiction and Venue
      i. Qualifying for 30 Month Stay
      ii. Protective Suits
      iii. Proving Jurisdiction and Maintaining Venue
      iv. Local Hatch-Waxman Rules
   b. Pleadings
      i. Complaint
      ii. Declaratory Judgment Counterclaims
      iii. Protective Orders and Other Miscellaneous Pleadings
   c. Infringement
      i. Direct
      ii. Inducement
      iii. Contributory
      iv. Unique Infringement in Hatch-Waxman Cases
   d. Validity Issues at Trial
      i. 112
      ii. 102/103
   e. Damages
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f. Injunctions
g. Settlement
   i. Reverse Payment
   ii. Authorized Generic
   iii. Early Entry
h. Appeal

V. Post-Grant Challenges
   a. IPR, PGR, and CBM: Essential Features
      i. Petition Requirements for Each
      ii. Burden of Proof
      iii. Claim Construction
      iv. Estoppel
   b. The PTAB vs. District Court: Strategic Considerations
      i. Obviousness/Formulation Claims
      ii. Inherency
      iii. Speed
      iv. Experts?
   c. Timing Issues
d. Interplay with Hatch-Waxman Litigation
   i. Stays
      ii. 180-day Exclusivity and Forfeiture
      iii. Multiple ANDA Filers
      iv. Appeal
e. Biosimilars
f. Prosecution Strategies