



Patent Resources Group

ANDA Litigation: Critical Issues and Winning Strategies Course Syllabus

I. ANDA Litigation Background

- A. Scale and scope of litigation
 - 1. Prevalence
 - 2. Economics of generic challenges

- B. Hatch-Waxman statutory scheme
 - 1. Benefits to innovator
 - a. 30-month stay
 - 2. Benefits to generic
 - a. Reliance on innovator efficacy and safety data
 - b. 180 day first-filer exclusivity
 - c. Challenge to validity

- C. Timeline
 - 1. NDA approval
 - 2. Orange Book Listing
 - 3. ANDA Filing
 - 4. Notice letter
 - 5. 45-day period to file suit
 - 6. 30-month stay

- D. Special features of ANDA litigation

- E. Preparation and strategies for ANDA challenge, including jurisdiction issues



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II. SUBSTANTIVE LEGAL ISSUES IN ANDA LITIGATION FOR DIFFERENT TYPES OF CLAIMS

- A. New Chemical Entities
 - 1. Structural Obviousness

- B. Methods of Treatment, especially, New Indications
 - 1. Inherency
 - 2. Obviousness
 - a. Animal testing
 - b. Screening of compounds
 - 3. Skinny labeling

- C. New Dosage Forms and Formulations
 - 1. Salts and crystal forms
 - 2. Obviousness of excipient selections
 - 3. Unexpected results and teaching away

III. THE END GAME – RISKS, REMEDIES AND SETTLEMENTS

- A. At-risk launches
- B. Preliminary injunctions
- C. Permanent injunctions
- D. Settlements and FTC Limitations