Hot Topics in Hatch-Waxman, Pharmaceuticals, and Life Sciences Patent Litigation

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Brief Introduction to Pharmaceutical Patent Litigation

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Approval Pathways – Drugs

- **New Drug Application (NDA)**
  - Seeks approval of new drug
  - Time and resource intensive – Must submit full reports of detailed investigations into safety and efficacy
  - May list patents claiming drug or method of use in Orange Book
- **505(b)(2) Application**
  - Seeks approval of new drug
  - Less time and resource intensive – Applicant allowed to rely on third-party studies and references for safety and efficacy
  - May list patents claiming drug or method of use in Orange Book
  - May be required to provide Notice of Paragraph IV certification

Approval Pathways – Drugs, cont.

- **Abbreviated New Drug Application (ANDA)**
  - Seeks approval of therapeutic equivalent of previously approved drug
  - May be required to provide Notice of Paragraph IV certification

Regulatory Exclusivities – Drugs

- **New Chemical Entity (NCE) Exclusivity**
  - Given to drug that contains an active moiety that has never been approved by the FDA in an NDA submitted under § 505(b)
  - No other drug may be approved with that active moiety for five years after approval of NDA
  - Applications of such drugs may be submitted four years (NCE-1) after approval of NDA

Regulatory Exclusivities – Drugs, cont.

- **Orphan Drug Exclusivity (ODE)**
  - Given to drug designated and approved to treat rare diseases or conditions, which is defined as those affecting fewer than 200,000 people in the U.S.
  - No other drug may be approved for the same use or indication for seven years after approval of NDA
  - FDA still may approve additional indications or uses not protected by the exclusive approval and may even grant a new ODE

Title search: Hot Topics in Hatch-Waxman, Pharmaceuticals, and Life Sciences Patent Litigation

Also available as part of the eCourse
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