



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

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Aden Allen and Nicole Stafford



Brief Introduction to Pharmaceutical Patent Litigation



Brief Intro to Pharmaceutical Patent Litigation

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

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Brief Intro to Pharmaceutical Patent Litigation

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

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Brief Intro to Pharmaceutical Patent Litigation

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



Brief Intro to Pharmaceutical Patent Litigation

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

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