Hatch-Waxmann
&
CRISPR Review

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- Hatch-Waxmann
  - Exclusivity
  - Patent Term Extension
  - Orange Book
  - Generic Challenge
- Patent Law Overview
  - America Invents Act (AIA)
  - Patentability: Utility, Novelty, obviousness
  - Application Requirements: Enablement, Written description
  - Case Examples

The Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman)

NDA holder

- Market exclusivity
- Patent term extension to compensate for regulatory delay
- Automatic 30-month stay of FDA generic approval
- "Notice" process (para. IV)

Generic

- Abbreviated NDA (ANDA)
- Safe Harbor during drug development
- 180 day exclusivity for the first Para IV filer
- Orange Book and Patent Challenge Process

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Hatch-Waxman Market Exclusivity

- New chemical entity (NCE) - 5 years of exclusivity
  - No active ingredient has been approved in any other application.
  - active moiety "the molecule or ion, excluding the portions that cause the drug to be an ester, salt or other noncovalent derivative, responsible for the physiological or pharmacological action of the drug substance"
  - Abilify® (aripiprazole) vs. Aristada® (aripiprazole lauroxil)

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Hatch-Waxman Market Exclusivity

- New clinical investigations (other than bioavailability studies) essential to approval - 3 years of exclusivity
  - new indication
  - new dosage form
  - new strength
  - new dosing schedule
  - new route of administration
  - new patient population
  - Combinations unless at least one qualifies as a NCE*
  - Enantiomers*

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Hatch-Waxman Market Exclusivity

- Orphan Drug Act - 21 U.S.C. § 360aa
  - Rare disease or condition – less than 200,000 persons in the United States, or affects more than 200,000 and there is no reasonable expectation that costs will be recovered
  - 7 years exclusivity for specific indication
- Qualified pediatric studies - 21 U.S.C. 355a
  - 6 months exclusivity
  - Attaches to each exclusivity period/patent if studies are accepted 9 months prior to expiration

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Title search: Hatch-Waxmann and CRISPR Review

Also available as part of the eCourse
2017 Advanced Patent Law (Austin) eConference

First appeared as part of the conference materials for the
22nd Annual Advanced Patent Law Institute session
"Patenting in the Life Sciences: Prosecution Issues, Key Cases, and Hot Topics"