Intellectual Property Rights in Pharmaceuticals

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Patents

- Administered by USPTO
- Invention must be
  - Novel
  - Nonobvious
  - Useful
  - Patentable Subject Matter
- Inventor must submit application with an enabling disclosure

Patents

- 20-year term from filing date
  - But various extensions are possible
  - Patent term extension to account for regulatory approval delays
- Right to exclude
  - Not self-enforcing
  - Validity may be contested

Linkage

- Brands may identify patents to FDA
- FDA publishes patents in the Orange Book
- Generics must signal their intentions to FDA when seeking regulatory approval
- If generic challenges patent, brand may sue for infringement

Regulatory Exclusivities

- “Quasi-patents” administered by FDA
- Several different kinds with distinct
  - Terms of protection
  - Scope of coverage
- In combination with patents, a complex landscape of proprietary interests

Regulatory Exclusivities

- New Chemical Entities
- New Clinical Studies
- Qualified Infectious Disease Products
- Orphan Drugs
- Pediatric Studies
- Generic Patent Challenges
- Biologics