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Boston Seminar Series: *Patent Term Strategies (PTE) for Life Sciences Practitioners*

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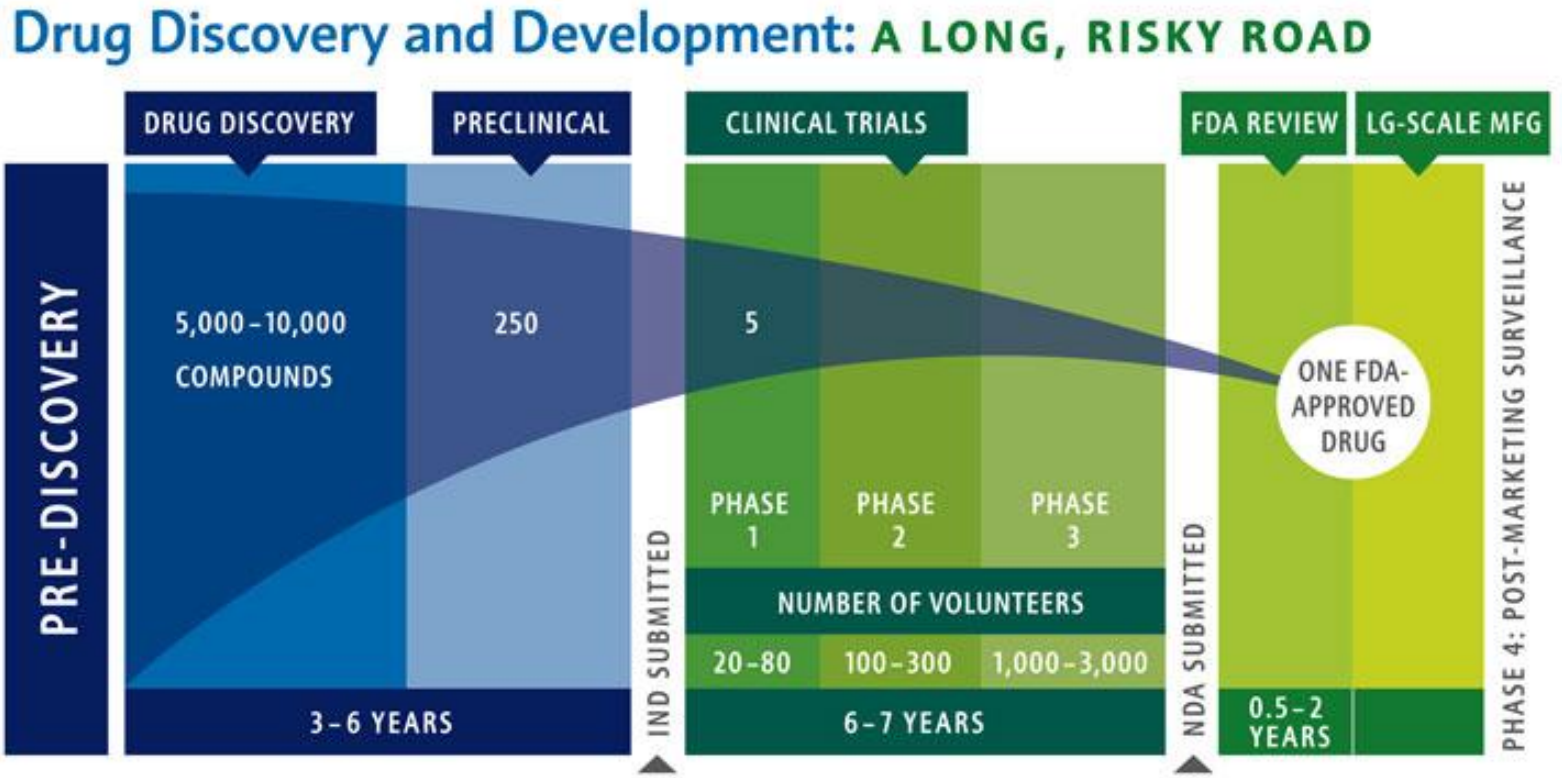
Patent Term Extension (USC § 156)

- Theory and Scope - 1984 Hatch-Waxman Act
  - Distortion of term by agency review
  - FDA and USDA only
  - Products, methods of using a product, methods of manufacturing a product

Timeline



Source: Pharmaceutical Research and Manufacturers of America

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Products

- “Active ingredient” of new drug, antibiotic drug, human biological product, new animal drug or non-GE veterinary biologic
  - Including any salt or ester of the AI
  - As a single entity or in combination with another AI
- Class III medical devices
- Color and food additives

Conditions for Term Extension

- Patent must be unexpired at time of agency approval
  - Patent not previously extended
  - Application submitted by owner of the record
  - Product subject to “regulatory review period” before commercial marketing or use
  - Agency approval must be “first permitted commercial marketing or use of product” under statute under which RRP occurred
    - Drug product
      - *Glaxo v. Quigg* (Fed Cir. 1990)
      - *Pfizer v. Dr. Reddys* (Fed. Cir. 2004)
      - *Photocure v. Kappos* (Fed Cir. 2010)
      - *Ortho-McNeil v. Lupin* (Fed Cir. 2010)

Conditions for Term Extension (cont.)

- Device: each PMA is a separate permitted marketing if device is “separate and distinct” for regulatory purposes
  - *Cardiac Pacemakers v. St. Jude* (CAFC 2004)
- Method of manufacturing using rDNA: first “marketing or use” of **any** product made by method
- Animal drugs or veterinarian biologics: first “administration” to a food producing animal even if AI approval earlier for non-food producing animals (i.e., pets)

- Extension cannot exceed 5 years

Conditions for Term Extension

- Total remaining term cannot exceed 14 years from date of FDA approval
- Limitation on extended rights (drugs/biologics)
  - Product/composition: any use approved for the AI
  - Method of use: any use claimed in patent **and** approved for AI
  - Method of manufacturing: method used to make any "product containing the AI."

Conditions for Term Extension

- Only one patent can be extended per a regulatory review period
- PTE application must be filed within 60 days of agency approval
- PTO “rule” - patentee or agent must be directly/indirectly involved in the agency review process
- Patent subject to Term/Disc eligible for PTE

Computing the Regulatory Review Period

- After a patent has issued
  - One-half of clinical trial period (IND)
  - All of agency review period (NDA/BLA)
  - Less time for failing to act with due diligence

- Example
  - IND accepted: 1/2007
  - NDA Filed: 1/2013
  - NDA Issued: 1/2014
  - Potential term extension: (6 ÷ 2) + 1 = 4 years

USPTO Procedures

- Interim extensions
- PTO: decides initial eligibility within 60 days
- FDA: computes RRP 30 days later
- FR publication: 180 days for public comment
- Multiple petitions for extension
- NDA holder has responsibility to update Orange Book

Prosecution Strategies

- Foreseeability
- Related Discoveries
  - Family of compounds
  - Metabolites and pro-drugs
    - AI “sameness” issue: isoforms, homologs, racemics
    - AI “sameness” issue: genus and species and claims

Prosecution Strategies

- Bundling of Claims
  - Why bundle claims
  - PTO restriction requirements and rejoinder
  - Multiple uses for AI
- Multiple patents claiming approved product
  - Which one to extend?
  - Is composition always preferred?
  - Joint ventures and multiple petitions

Prosecution Strategies

- Special Situations
  - Orphan approval triggers “first permitted commercial marketing” rule
  - Metabolites as method patents
  - Bootstrapping claims
    - Combination drug/device
    - New veterinary approval of old human drug – comp/use
    - New veterinary approval of old human drug – process
  - “New” medical device – default is Class III, but can be Class II by petition

Questions?

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Thank you!

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