STRATEGIC BALANCING OF PATENT AND FDA APPROVAL PROCESSES TO MAXIMIZE MARKET EXCLUSIVITY

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Therapeutics Commercialization

- The patent gives: 20 years of market exclusivity from the date of filing a patent application
- The FDA takes: 8-12 years of regulatory hurdles, running concurrently with patent term
- The problem: how to maximize market exclusivity

Patents Overview

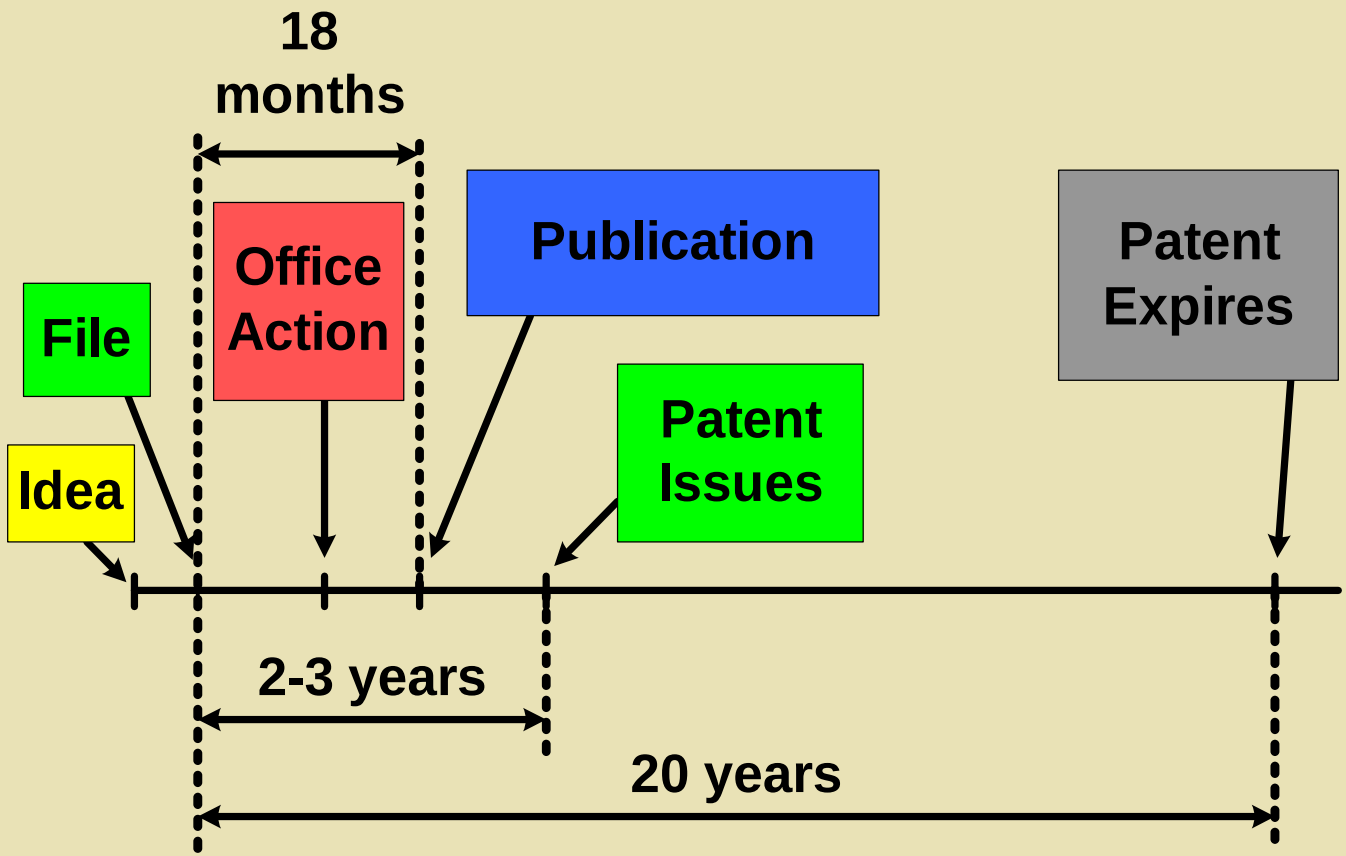
- Basic Patent Criteria
  - Novel
  - Useful
  - Non-obvious
- Basic idea behind patent protection:

  To grant period of monopoly to inventor/author in exchange for enriching the public domain

Patentable Subject Matter Relevant to FDA Approval

- New chemical entities
- Compositions of matter (pharmaceutical)
- Polymorphs
- Methods of treatment
- New indications
- First use/second use (Euro style)

Patent Timeline



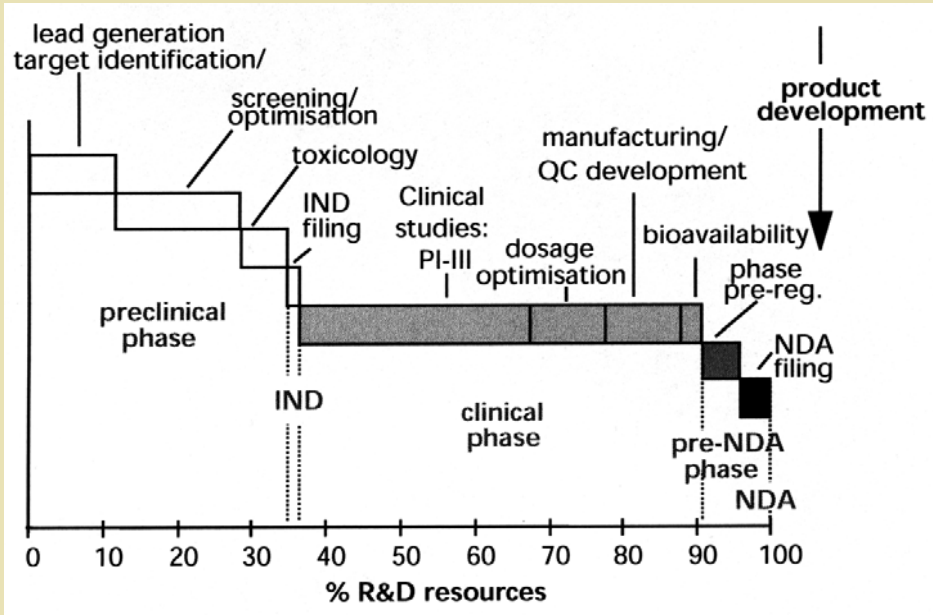
Drug Patents/Market Exclusivity

- Most valuable near the end of their term, but…
  - Delaying patent filing may be impractical for small biotech companies seeking funding
  - Delaying patent filing jeopardizes foreign patent rights

Lifecycle: R&D-Approval-Marketing

Pre-clinical	Clinical	Marketing	Generics entry
basic research target ID/validation lead ID/optimization toxicology manufacturing	IND Phase I, II, III NDA/BLA	Prolong exclusivity Phase IV	Competition

Drug Development



- $500M - $1B to bring a drug to market
- ~1 in 5000 leads make it to the market

Market Exclusivity

- Patents
  - Successive filings can cover different subject matter
- Supplementary patent certificates (Hatch-Waxman extensions in US, and non-US equivalents)
- Non-patent exclusivities

Hatch-Waxman Act

- Innovative pharma files NDA
  - May get patent term extension
  - Needs to list patents in Orange Book
- Generics manufacturer files ANDA
  - Exempt from patent infringement for FDA approval
  - Integra v. Merck
  - Paragraph IV certification/litigation

Non-Patent Exclusivities

- NCE - New Chemical Entities (5 years)
- Label Exclusivity (3 years)
- ODE - Orphan Drugs (7 years)
- Pediatric Exclusivity (6 months)
- Generic Exclusivity (180 days)

Accelerating Market Entry

- FDA's "Expanded Access" Exception
- FDA's "Accelerated Approval" Process
- USPTO Petition to "Make Special"
- FDA's "Well Characterized" product

Strategy Outline

- Begin with preclinical studies
- File a patent with the USPTO
- Publication of Innovation *only* after the patent is filed
- Initiate the FDA approval process after patent issuance and preclinical trials
- Assert market exclusivity after FDA approval

Start
0 yrs
1.5yr
3yr
4.4yr
14yr
16yr
20yr
Possible "special" status
FDA clinical trials + NDA
Market exclusivity for pioneer biotech company
Possible accelerated approval
Market exclusivity for pioneer biotech company
Possible term extension and strategically extending market exclusivity
Start
0 yrs
1.5yr
3yr
4.4yr
14yr
16yr
20yr
Idea
File patent idea
Publication of idea
Patent issues (avg biotech)
Start FDA approval process
Patent Prosecution
Preclinical studies
FDA clinical trials + NDA
Market exclusivity for pioneer biotech company
FDA approval
Patent term ends

Figure 1

How to Prolong Exclusivity

- Patent Term Restoration
  - Delays in USPTO Examination
  - Hatch-Watchman Act
- Pediatric extensions
- Metabolite defense
- Citizen petitions
- Accelerated approval
- Portfolio management

How to Prolong Exclusivity

- Litigation
- Reformulations
- Line extensions
- OTC switching
- Orphan drug status
- Competing after expiration

Conclusion

- No “one size fits all” advice strategy
  - Small biotech companies need patent protection early to attract investors
  - Large pharma can wait, though risks need to be evaluated (SmithKline Beecham v. Apotex)
- Strategy should be planned out decades in advance