



LEGAL DIVISION

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# The Importance of Expert Reports in Patent Litigation Cases

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# IP protection is critically important to the pharmaceutical sector

- Without it, 65% of existing innovative products would not have been introduced
- Without it, 60% of existing innovative drug products would not have been developed

E. Mansfield, Management Science, (February 1986)



# Pharmaceutical Sector

- Drug Discovery is high risk
- Development costs for a new drug currently estimated at US\$2,800 million per drug\*
  - Out of pocket expenses \$1.4 Billion
  - Time Cost (expected returns) \$1.1 Billion
  - Post Approval R & D \$300 million
- Investment in high risk enterprises demand higher guarantees and degrees of capital return
- IP protection, and particularly patent protection, is one of the guarantees that investor will get a return on capital

\* Tufts Center for the Study of Drug Development (2016); Journal of Health Economics

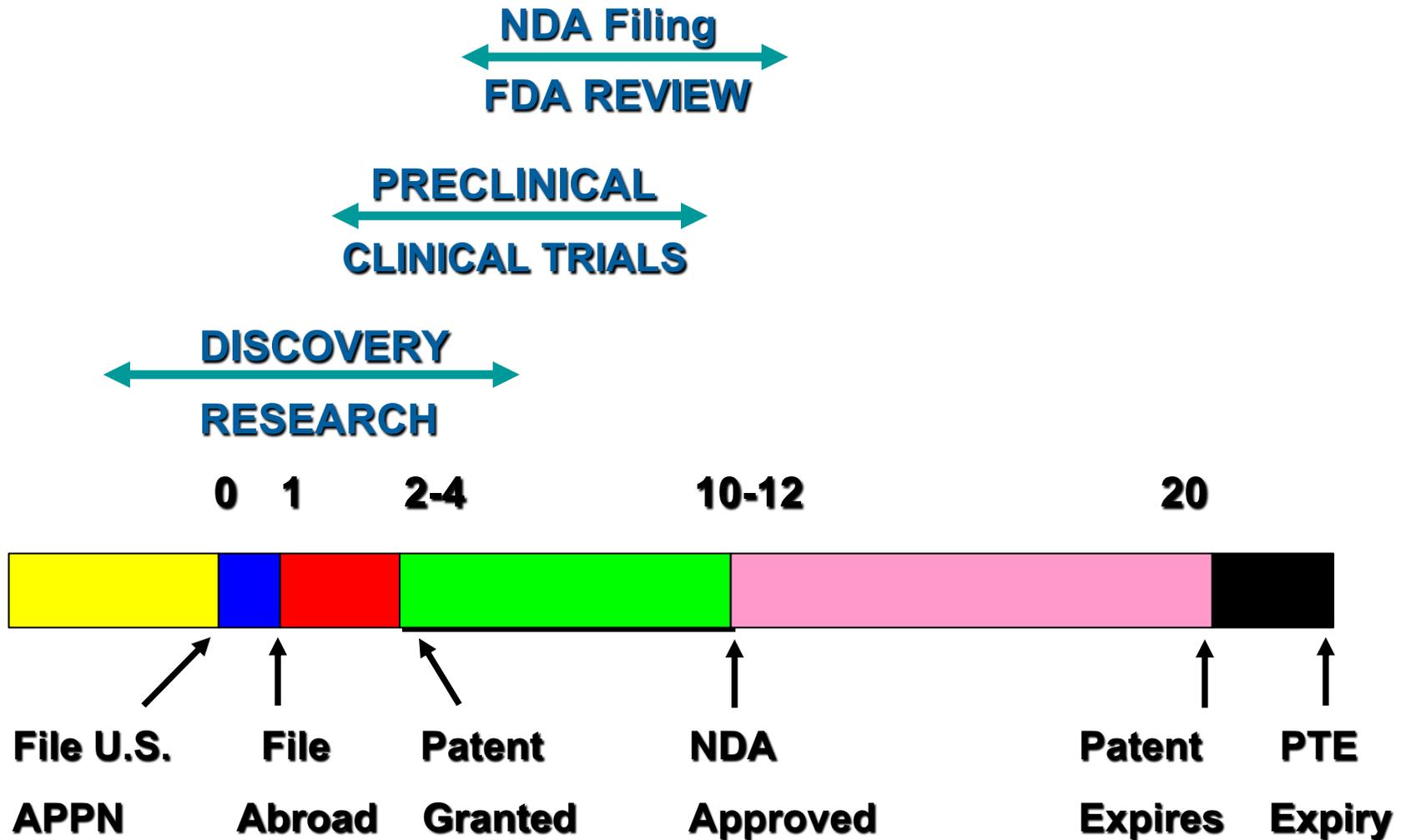


# The Patent Right

- A patent grants the owner the right to exclude others from making, using, selling, offering to sell, or importing claimed subject matter during patent term
- Term - 20 years from filing (WTO)
- Patents are territorial in nature (Paris Convention)
- Patent holder, not government, is responsible for enforcement.



# Patent Activity Relative To Drug Development Process



# Types of Patents

strongest



weakest

- ❑ **Product** - Covers active compound per se, regardless of process or use.
- ❑ **Enantiomers, Salts, Hydrates, Polymorphs**
- ❑ **Formulation/Composition** - Covers mixture of active drug with specific excipients.
- ❑ **Use** - Covers use of compound for particular use.
- ❑ **Process** - Covers chemical process to make active compound.
- ❑ **Combination** – Covers combination of two or more compounds
- ❑ **Metabolite** – Covers biodegraded compound

# Expert Witness

- A person who testifies at a trial because she/he has special knowledge in a particular field.
- In Pharmaceutical Patent Litigation:
  - **Chemist**
    - Crystallography
    - Chemical synthesis
  - **Pharmacologist**
    - Bioavailability
    - Bioequivalence
  - **Physician**
    - Prevalence of a Disease
    - Prescription trends
  - **Biologist**
    - Cell cultures

# Technical Background

- There are very few courts that specialize in IP
- There are no judges specialized in IP
- Just a few with experience in patent litigation
- Almost none with a Technical background
- Very large dockets (hundreds of cases at a time)

# Written Report vs. Cross Examination

- In common law countries like the US, expert witnesses are examined and cross examined by the parties:
  - Qualifications
  - Experience
  - Conclusions
- Most countries in Latin America don't have this system in place. (It's being implemented)
  - The Judge will receive only a written report

# The Expert Report

- **Thorough**
  - Analyze all technical aspects brought by the parties.
  - Attach all the support documents cited by the expert.
- **Clear**
  - Analyze argument by argument
  - What test are being performed and why
  - Include definitions of technical terms
- **Simplicity**
  - Be mindful of the complexity of the science behind the invention.
  - Help the Judge understand the science.
- **Concise**

# Role of the Litigant

- **Translation**

- Explain what tests will be performed and why.
- Explain the methodology used to perform the tests.
- Expected results vs. Actual results
- Explain the results of the test performed and the conclusions of the expert witness to the Judge.
- Make sure that the Judge understands our position and the relevance of the expert testimony vis-a-vis the granted claims.
- Expert report is probably the best tool to show the Judge why we are right.



# QUESTIONS





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**Thank You**