

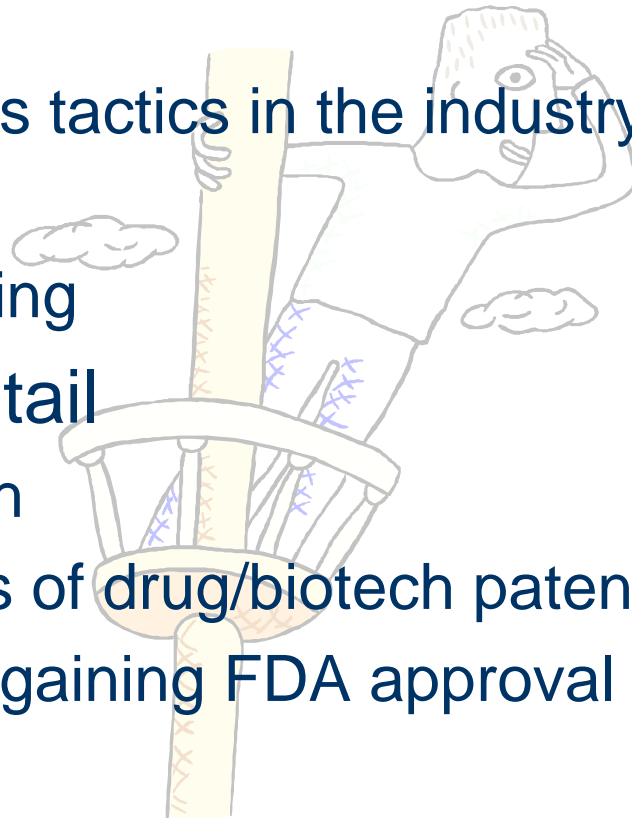
# **Fernandez & Associates, LLP**

The Patent Gives and the FDA  
Takes: What Biotechnology  
Companies Working on  
Therapeutic Applications Should  
Know About the Development  
and Marketing of Drugs



# Overview

- Covered:
  - Common business tactics in the industry
  - Industry trends
  - Strategic positioning
- Not covered in detail
  - Science of biotech
  - Legal peculiarities of drug/biotech patents
  - Nuts and bolts of gaining FDA approval



# Overview

- Biotechnology
- Drug development
- Pharmaceutical commercialization
- R & D commercialization
- Building a patent portfolio



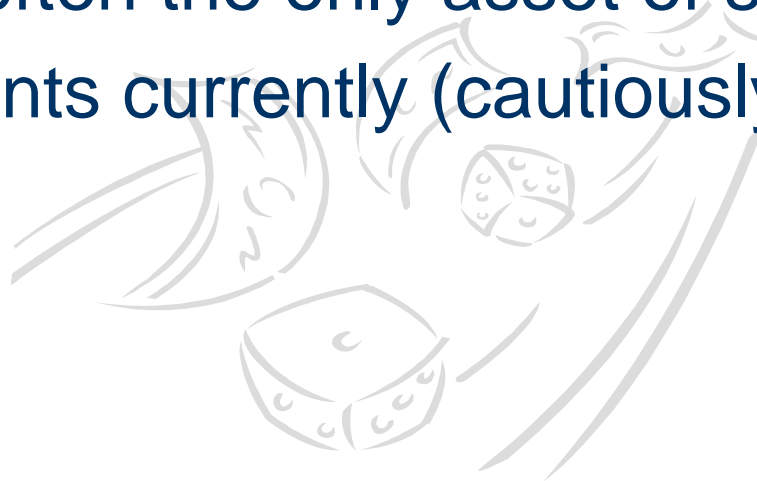
# Biotechnologies

- Agricultural biotechnology
- Biological computing
- Materials science
- Bioengineering
- Environmental bioengineering
- **Human therapeutics**



# Biotech Needs Investments

- High cost / high risk industry
- Patents often the only asset of startups
- Investments currently (cautiously) rising

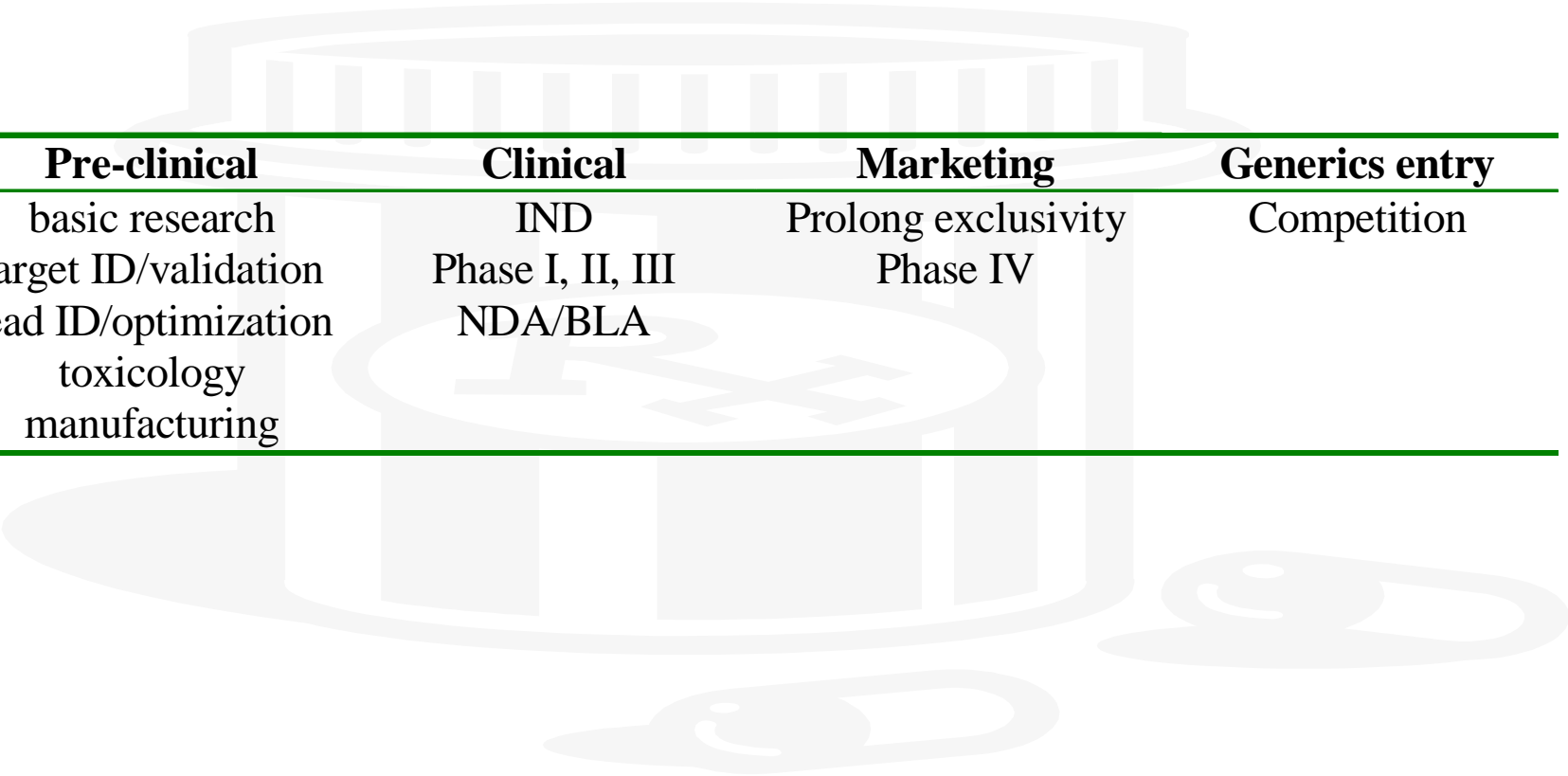


# Why Analyze the Industry?

- Set clearer business goals
- Identify opportunities/pitfalls
- Better prepare for future transactions
- Build an effective IP portfolio

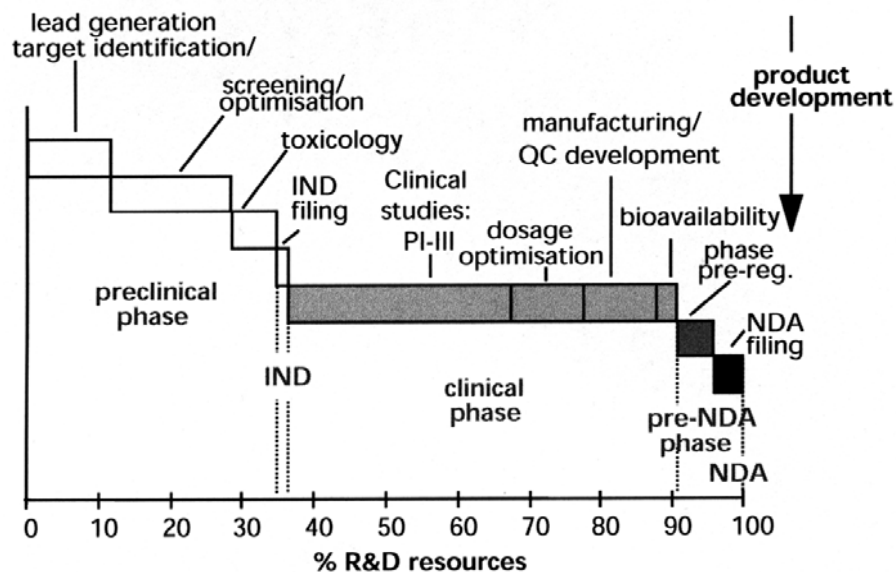


# Drug Development and Marketing



<b>Pre-clinical</b>	<b>Clinical</b>	<b>Marketing</b>	<b>Generics entry</b>
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



# Competence Areas

pre-clinical

clinical

marketing

generics



Little biotech

Big pharma

Generics manufacturers

# Markets / Patents

- Approved pharmaceuticals
- Drug development technology

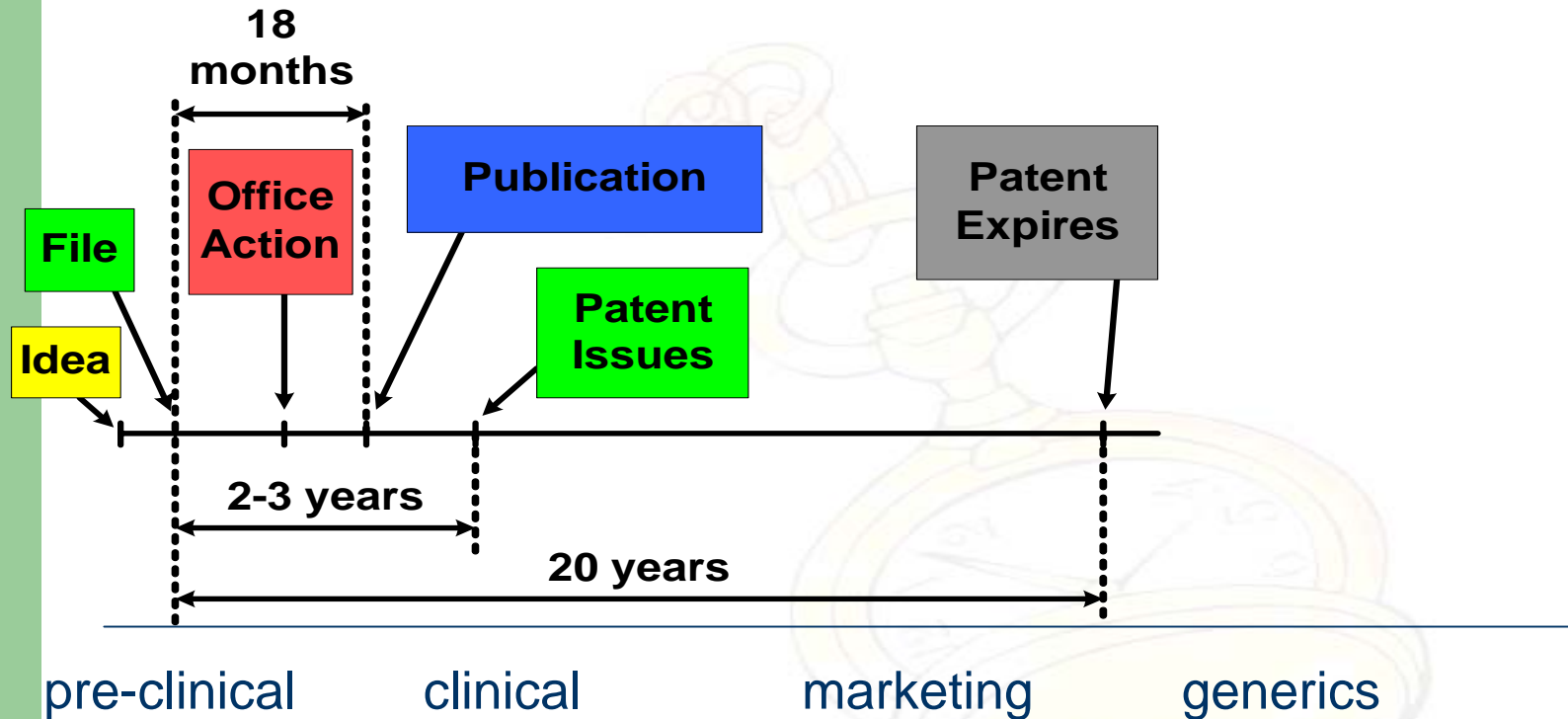


# Approved Pharmaceuticals



- Subject matter: chemical or biological active ingredients, reformulations, methods of treating patients, methods of manufacturing active ingredients
- Patents are crucial

# Patent/Commercialization Time Lines



# 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

# Maximizing Market Exclusivity

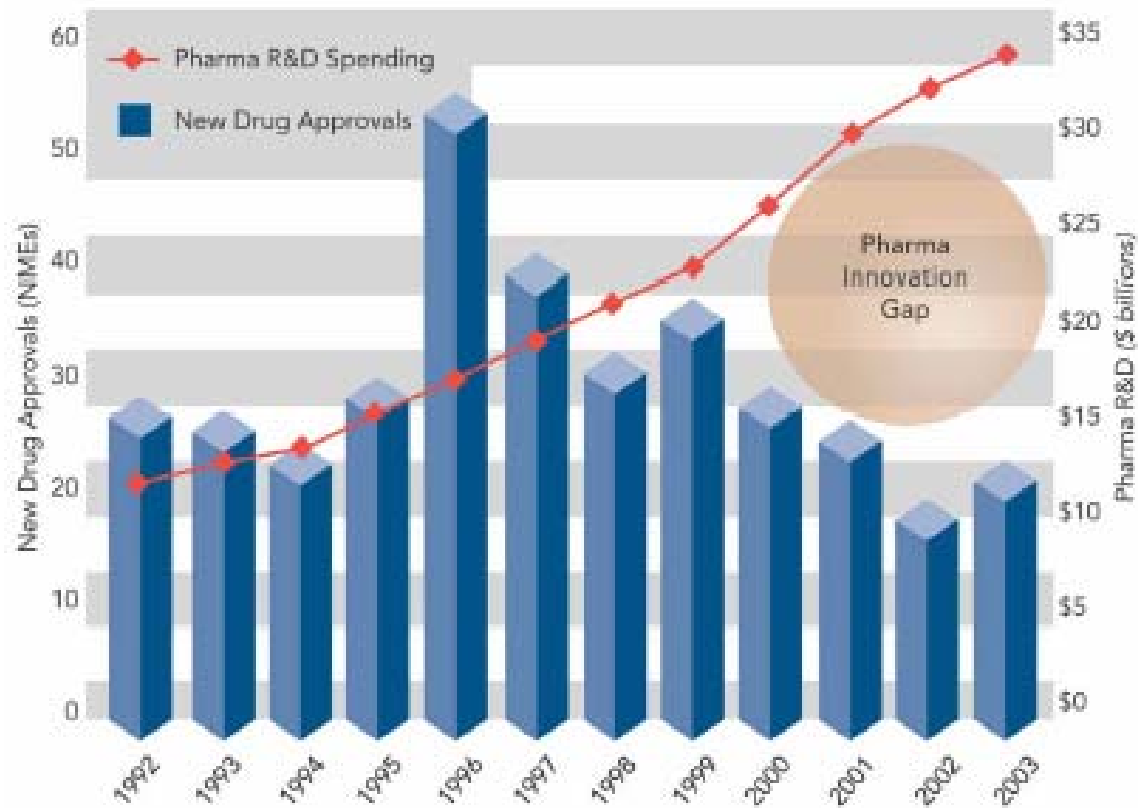
- Litigation
- Reformulations
- Line extensions
- OTC switching
- Orphan drug status
- Competing after expiration
- Pediatric extensions
- Metabolite defense
- Citizen petitions
- Accelerated approval
- Portfolio management

# Big Pharma Headaches

- The end of blockbuster drug patents is near
- Decreased productivity

Brand Name	Expiration Date	Marketer	Indication
Prilosec/Losec	2002	Astra	GI Disorders
Claritin	2002	Schering Plough	Allergic Rhinitis
Intron	2002	Schering Plough	Anti-viral
Glucophage	2002	BMS	Diabetes
Fluoxetine	2002	Pfizer	Major Depressive Disorder
Neurontin	2003	Pfizer	Antiepileptic
Advair	2003	GSK	Asthma
Flovent	2003	GSK	Asthma
Cipro	2003	Bayer	Anti-infective
Celebra	2003	Forest Labs	Depression
Procrit	2003	Pfizer	Anemia
Procrit	2003	Pfizer	Anemia
Zocor	2005	Merck	Cholesterol reduction
Zithromax	2005	Pfizer	Anti-infective
Zoloft	2005	Pfizer	Depression
Pravachol	2005/6	BMS	Cholesterol reduction
Paxil	2005/6	GSK	Depression
Prevacid	2005/6	TAP	GI Disorders
Neupogen	2006	Amgen	Anti-infective
Norvasc	2006	Pfizer	Hypertension
Fosamax	2007	Merck	Osteoporosis
Lipitor	2009	Pfizer	Cholesterol reduction
Zyprexa	2011	Lilly	Schizophrenia/Bipolar

# Innovation Gap





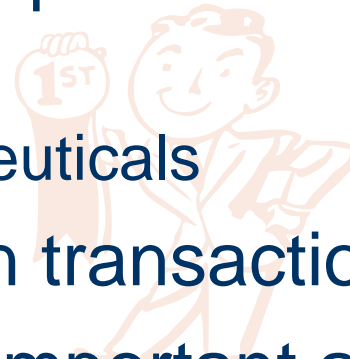
# Biotech



- Subject matter: target screening, potential targets, data analysis, combinatorial chemistry, stem cells, RNAi, gene therapy
- Sources of funding: grants, sales of products or services, collaborations, investments
- Patents still crucial

# Importance of Patents

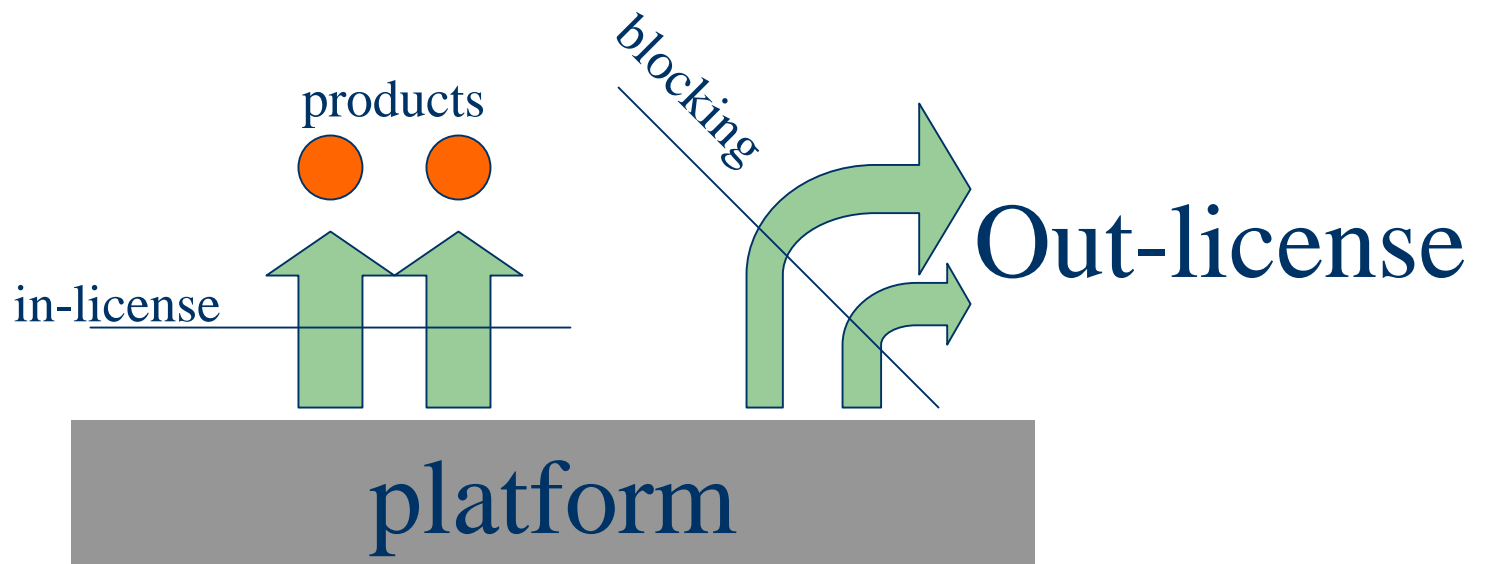
- Patents are often the only protection of investments
  - Bayer v. Housey Pharmaceuticals
- Patents are core assets in transactions
- Patents are the 2<sup>nd</sup> most important asset of biotech companies



# Why Build an IP Strategy?

- Patents:
  - Prevent competition
  - Generate license/royalty income
  - Cross-license for necessary technology
- Increase company value
- Make a more attractive investment/acquisition target
- Having patents is not an IP strategy

# Typical Patent Strategy

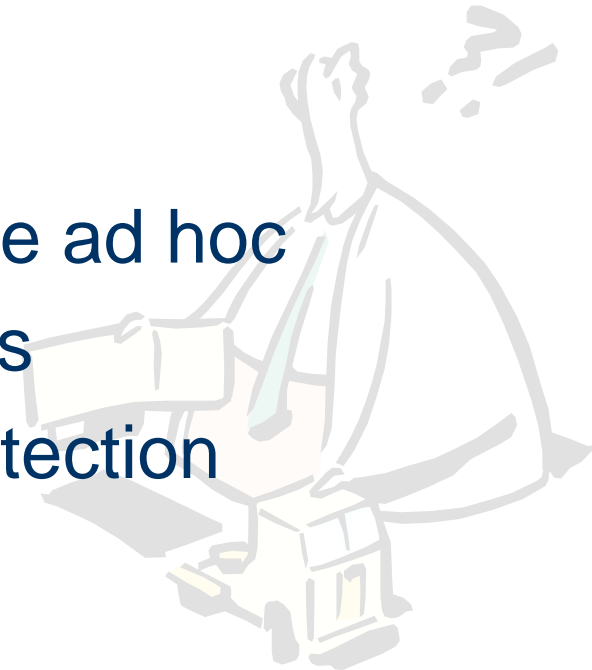


# Lesson

- Analyze strategy of relevant market players
- Plan up offensive patents
- Align business, R&D, and IP plans
- Build IP value

# Typical Problems

- Need a master vision
- Patent decisions made ad hoc
- Surprisingly high costs
- Less than optimal protection
- Pruning



# Conclusion

- Abundant opportunities for biotech start-ups at every stage of drug development
- To effectively build value need to stalk future partners



# Questions?

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