

# Licensing in Biotech: A Business Development View

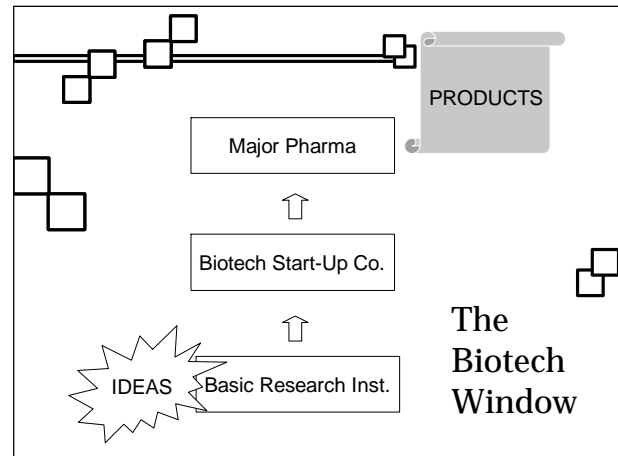
— □ □ □ —  
Bus. 771 – Simon Fraser University  
Intellectual Property Management for Biotech  
June 14, 2003  
Thomas J. Digby

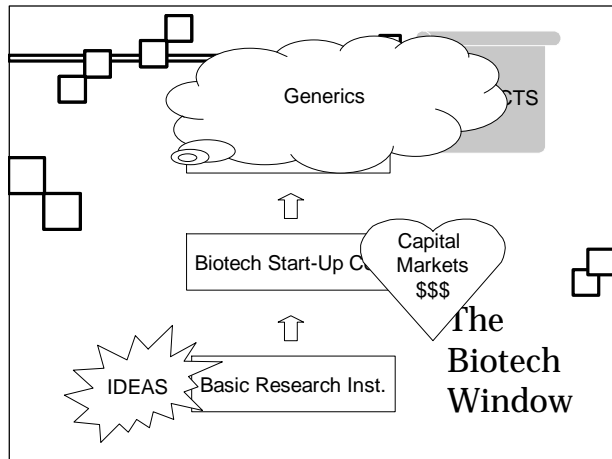
## Objectives of Presentation

- ≈ Identify the dynamic forces inside a biotech company that influence license negotiation process
- ≈ Understand the foundations of effective negotiation

## Definition of “Biotech”

- High risk start-up company
- Therapeutic products
- Potential sales of \$1b+/year
- No sales for foreseeable future!





- ## Dynamic Forces in Biotechs
- Need for source technology - In-licensing
  - Need for corporate partner - Out-licensing
  - Need for financing (Expand IP assets)
  - Need to solve problems - Freedom to operate
  - Non-Issue: Near term sales and revenues!

## Foundations of Effective Negotiation\*


\*Adapted from G. Richard Shell  
 "Bargaining for Advantage"  
 (Penguin Books, NY, 1999)

- ## Foundations of Effective Negotiation
- Your bargaining style
  - Your goals and expectations
  - Authoritative standards and norms
  - Relationships
  - The other party's interests
  - Leverage

**Foundations of Effective Negotiation**

- Your bargaining style
- Your goals and expectations
- Authoritative standards and norms
- Relationships
- The other party's interests
- Leverage

**The Game**



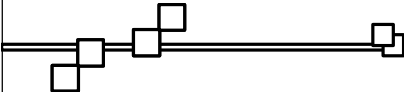
**The Game**

Picture this:

≈ You are one of 10 people, all strangers, sitting at a big round table in a conference room.


**The Question**

≈ [provided at class]



## Bargaining Styles

- Conflict Avoiders
- Accommodators
- Compromisers
- Competitors
- Problem Solvers




## Foundations of Effective Negotiation

- Your bargaining style
- Your goals and expectations
- Authoritative standards and norms
- Relationships
- The other party's interests
- Leverage



## Foundations of Effective Negotiation

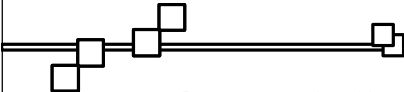
- Know your own priorities
- Keep your expectations high
- In a license agreement there is no one bottom line.
  - Royalty
  - Milestone payments
  - Performance requirements
  - Other rights and obligations



## Foundations of Effective Negotiation

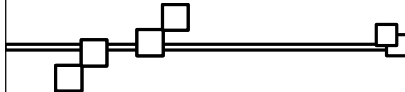

- Your bargaining style
- Your goals and expectations
- Authoritative standards and norms
- Relationships
- The other party's interests
- Leverage





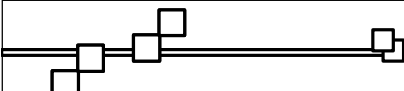

## Foundations of Effective Negotiation

≈ How is the royalty rate set?



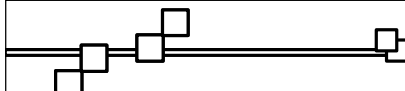

## Pharma's View of Drug Revenues (Early Stage Acquisition)

| Cost Centre                | Portion of Net Sales |
|----------------------------|----------------------|
| Royalties to Patent holder | 7 – 15 %             |
| Sales & Marketing          | 25 – 40 %            |
| Manufacturing              | 5 – 30 %             |
| Profits                    | 15 – 63 %            |



## Foundations of Effective Negotiation


≈ What is the chance of success of a new biotech product?



## Foundations of Effective Negotiation

Odds of reaching the market:

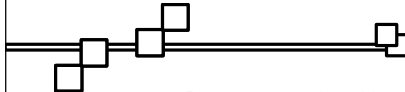
- 10% for drugs in phase I
- 30% for drugs in phase II
- 60% for drugs in phase III
- 80% for filed NDAs






## Foundations of Effective Negotiation

- Your bargaining style
- Your goals and expectations
- Authoritative standards and norms
- Relationships
- The other party's interests
- Leverage



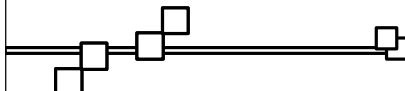
## Foundations of Effective Negotiation

- Personal trust opens doors
- Recognize early on what kind of negotiator you are dealing with
- But remember... that person is only a port-hole into her organization.



## Foundations of Effective Negotiation

- Your bargaining style
- Your goals and expectations
- Authoritative standards and norms
- Relationships
- The other party's interests
- Leverage




## Venture Capital

Interests:

- Portfolio investors

Leverage:

- Capital markets value biotech companies based on the product pipeline
- How much money do they have to invest?



Venture Capital

Leverage:

- Positive Leverage (improve the deal)
- Negative Leverage (threats)
- BATNA

In-Licensing – From Hospitals or Universities

Interests:

- Priority of research and teaching mission
- Highly risk averse

In-Licensing – From Hospitals or Universities

Leverage:


Basic research organizations are now very aggressive:

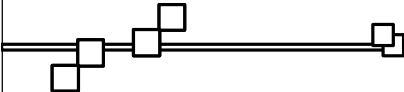
- Severe performance clauses
- Extract full indemnities
- Very limited reps and warranties

In-Licensing – From Hospitals or Universities

Reason:

Because power relationship between parties rapidly reverses, if the Biotech is successful

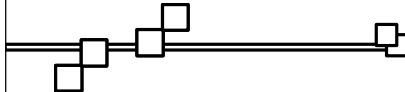





## Out-Licensing – Big Pharma

Interests:

- A marketing organization – highly skilled, highly paid sales force
- Extensive clinical & regulatory expertise
- Enormous technical challenges to fill their product pipeline

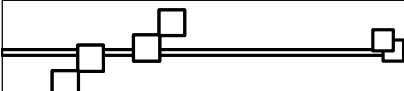



## Out-Licensing

Leverage:

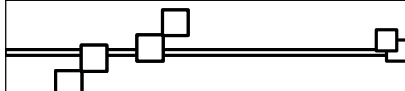

Who is Big Pharma?

- 10 companies over \$10B sales
- 30 companies \$1 – 10 B




## Licensing: Hard Lessons Learned

- What gets in-licensed needs to get out-licensed
- Keep the end game in mind: What are essential features of the approved drug product?
- The generics are waiting

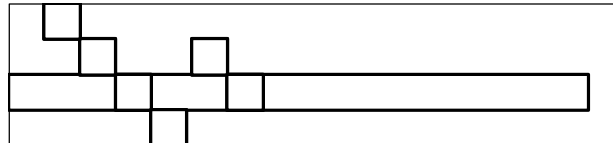


## Closing thoughts: License management

- Nothing ever goes as planned
- “License” agreements, by definition, have continuing obligations
- Follow through, follow through, follow through







**Licensing in Biotech:  
A Business Development View**

— □ □ □ —

Bus. 771 – Simon Fraser University  
Intellectual Property Management for Biotech  
June 14, 2003  
Thomas J. Digby