Licensing in Biotech: A Business Development View

Bus. 771 – Simon Fraser University
Intellectual Property Management for Biotech
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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!

The Biotech Window
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

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

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

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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

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Foundations of Effective Negotiation

- How is the royalty rate set?

Pharma’s View of Drug Revenues (Early Stage Acquisition)

<table>
<thead>
<tr>
<th>Cost Centre</th>
<th>Portion of Net Sales</th>
</tr>
</thead>
<tbody>
<tr>
<td>Royalties to Patent holder</td>
<td>7 – 15 %</td>
</tr>
<tr>
<td>Sales &amp; Marketing</td>
<td>25 – 40 %</td>
</tr>
<tr>
<td>Manufacturing</td>
<td>5 – 30 %</td>
</tr>
<tr>
<td>Profits</td>
<td>15 – 63 %</td>
</tr>
</tbody>
</table>

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
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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.

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
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