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# ***Pharmaceutical Industry Collaboration Experience with Biotechnology***

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# *Definition of Partnership*



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“A long-term, mutually beneficial agreement between two or more partners, in which resources, knowledge and capabilities are shared with the objective of enhancing each partner’s competitive position.”



# Outline

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- The Evolution in Pharmaceutical and Biotechnology Companies
- Early Collaborative Experiences
- The Changing Practice of Collaborations
- Captured Learning
- A Future Perspective
- Summary



## A Short History of Biotechnology

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- **1971 – Cetus founded**
- **1973 - first successful recombinant DNA experiments**
- **1975 - Monoclonal antibodies first produced at MRC**
- **1976 – Genentech founded**
- **1978 – Genentech cloned the gene for human insulin and signed alliance with Lilly**
- **1980 – Supreme court ruling allowing living organisms to be patented**
- **1980 – CRADAs introduced to spur cooperative relationships between academia and industry**
- **1980 – First biotech IPO (Genentech)**
- **1980 – Amgen formed**
- **1980 - Biogen scientists cloned interferon**
- **1982 – rDNA insulin marketed**
- **1983 – PCR invented at Cetus**
- **1990 – Human Genome Project initiated**
- **1991 – 36 Biotech company IPOs**

# The Evolution in Pharmaceutical and Biotechnology Companies



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## ■ 1970's

- Traditional Pharmaceutical companies dominate health care arena
- Largest company has 3-4% of world wide market value
- Few price restraints
- No substantial generic competition
- Cost and time of product development not regarded as too onerous
- Quality scientists easily recruited to the industry
- Biotechnology in its infancy. Genentech begins pioneering work on r-DNA insulin

# The Evolution in Pharmaceutical and Biotechnology Companies



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## ■ 1980's

- Lilly licenses Genentech technology and introduces recombinant human insulin
- Amgen, Biogen and others attract investors
- Large Pharma faces price restraints, increasing cost of development, beginning of consolidation
- Biotechnology companies begin to competitively attract quality scientists

# The Evolution in Pharmaceutical and Biotechnology Companies



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- 1990's and 2000's
  - Market value of some Biotechs exceeds those of some large traditional Pharma
  - Pharmaceutical companies create their own biotech divisions, acquire biotech companies, or create collaborations
  - By 2005 new product applications for biotechnology products matches those of traditional molecules
  - Contract organizations grow to support the needs of developing biotechnology companies
  - Pharmaceutical companies refocus on core technologies, attempt to reduce costs, and outsource many activities
  - Pharma consolidation continues
  - Licensing becomes a competitive business need

# Rationale for Pharmaceutical Company creating Alliances with Biotech Companies



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- Dearth of new products
- Expiry of patents on key products
- Investors expect accelerated growth
- Increasing costs of drug development
- Capitalize on philosophy of research without walls
- External opportunities can fill pipeline gaps
- Potential value of biotechnology products



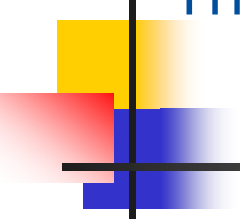


# Rationale for Biotechnology Companies creating alliances with Pharmaceutical Companies

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- Capital source to complete development
- Access to regulatory, manufacturing, distribution and marketing expertise
- Validation to investors
- Future learning in efforts to become fully integrated businesses

## Therapeutic Protein Market Values in 2002 (\$ billions)



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<b>Erythropoietins</b>	<b>8.4</b>
<b>Interferons</b>	<b>5.7</b>
<b>Insulin</b>	<b>4.4</b>
<b>Monoclonal Antibodies</b>	<b>4.2</b>
<b>Blood Factors</b>	<b>3.6</b>
<b>Colony Stimulating Factors</b>	<b>2.7</b>
<b>Growth Hormones</b>	<b>2.7</b>
<b>Interleukins</b>	<b>1.7</b>
<b>Growth Factors</b>	<b>0.2</b>
<b>Therapeutic Vaccines</b>	<b>0.07</b>
<b>Others (calcitonins, enzymes, TNF)</b>	<b>2.2</b>



# The Three Historical Phases of Alliances

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- Phase 1 – Early Alliances
- Phase 2 – Upsurge of Alliances
- Phase 3 – The Post-Genome Era



# Phase 1 – Early Alliances

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- Exploration phase with pharmaceutical companies trying to understand impact of biotechnology
- Small biotechnology groups set up within pharmaceutical companies
- Alliances often with academic centers (e.g. Hoechst with Mass General)
- Recombinant DNA and monoclonal antibodies form a therapeutic perspective primary focus



## Phase 2 – Upsurge of Alliances

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- Mid-1980s: over 1000 biotech companies in the US
- Large number of collaborations, acquisitions, and building of in-house capabilities
- Increase in use of biotechnology as enabling technology
- Cultural issues in pharmaceutical companies traditionally grounded in conventional research
- Biotechnology companies increasingly selective in choice of partners – not only interested in financing, but capabilities to add value
- Biotechnology companies benefited from process capabilities of pharmaceutical companies



## Phase 3 – the Post-Genome Era

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- Challenges from unprecedented growth in information and new research disciplines
- Most firms unable to meet knowledge needs alone
- Growth in companies offering services
- Multiple source collaborations/relationships established by pharmaceutical companies
- Biotechnology companies attempt to absorb knowledge to become integrated pharmaceutical companies



# Alliances Established by the 24 Leading Pharmaceutical Companies

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## Years

- 1982-86
- 1987-92
- 1993-97

## # of Alliances formed

- 27
- 76
- 112

Tapon and Thong, 1997



# Examples of Types of Alliances

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- **Codevelopment/Copromotion**
  - Imclone/BMS agreement for Erbitux in 2001
- **Technology Licensing**
  - Bayer AG with CuraGen for gene hunting technology to identify drugs for diabetes and obesity
- **Joint Venture**
  - ICOS with Lilly in 1998 with a 50:50 joint venture to develop Cialis
- **Acquisition**
  - 2003 Acquisition of Scios by J&J





# Points of Tension

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- Pharmaceutical company fears developing biotechnology companies, through transfer of capabilities, into future competitors
- Pharmaceutical companies and biotechnology companies operate in different time scales

# Why Partnerships Fail



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- 1) Cultural differences
- 2) Lack of strategic alignment
- 3) Poor leadership
- 4) Poor process integration
- 5) Change of perception of value
- 6) Technology failure
- 7) Change of business environment
- 8) Poor governance

*Adapted from Pricewaterhouse Coopers Survey, 1999*



# Early Collaborative Experiences not always positive

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- Genentech – Lilly: expensive legal battle on recombinant insulin technology
  - 1978 agreement with Lilly signed for development of rDNA insulin
  - Legal wrangles continued until 1999
- Amgen – J&J: protracted disputes
  - Amgen licensed EPO rights to Ortho (J&J) in 1985
  - Amgen retained US rights for kidney dialysis
  - 1988 – conflicts over distribution of revenue for dialysis and non-dialysis sales
  - Jury ruling reached in 2001

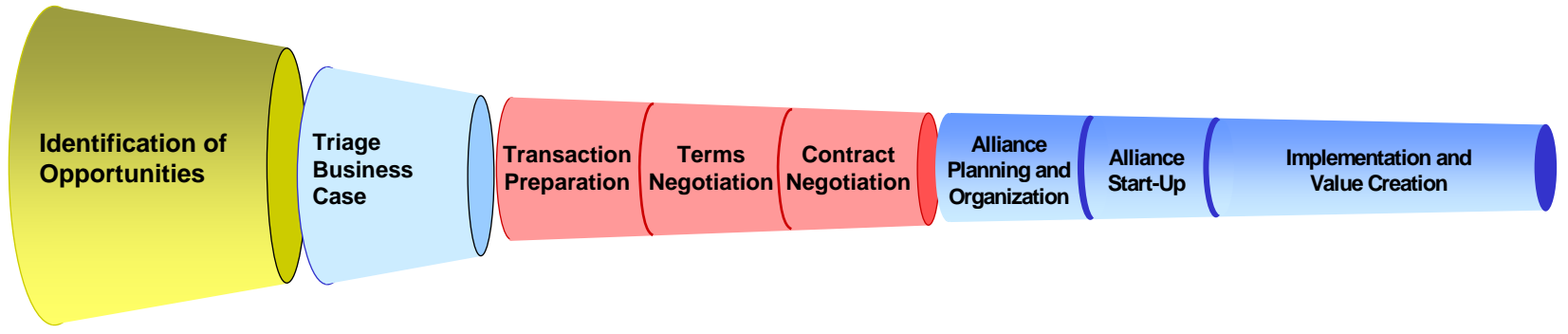


# Industry Response to Alliance Evolution

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- Internal processes refined
- Learning captured
- Performance measured
- Specific groups established to ensure value is created

# *Alliance Stage Process*





# Capturing Learning

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- There will be breakdowns – learn from them and keep moving
- Discuss how you would have done things differently
- Share learning throughout each organization
- Apply what was learned to future projects
- Measure ongoing alliance performance



# Building on Success

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- Success should be defined as a desire of the companies to work together again
- Learning to work together lessens barriers to repeat business
- True strategic partnerships can develop where technology from a partnership evolves proactively to meet the needs of an existing partner

# Changing the Face of Alliances

## From

## To

<b>Governance Structure</b>	<b>Ad Hoc</b>	<b>Templates/Disciplined Approach</b>
<b>Alliance Management Process</b>	<b>Individual Driven</b>	<b>Institutionalized</b>
<b>Shared Learning</b>	<b>Ad Hoc</b>	<b>Institutionalized</b>
<b>Contractual Obligations</b>	<b>Poor Visibility</b>	<b>Improved Awareness</b>
<b>Partners Voice in Decisions</b>	<b>Muffled</b>	<b>Improved</b>
<b>Milestone/Decision Dates</b>	<b>Surprises</b>	<b>More Visible</b>
<b>Alliance Portfolio Assessment</b>	<b>Difficult</b>	<b>Easy</b>
<b>Relationship Management</b>	<b>Good to Poor</b>	<b>Greatly Improved</b>
<b>Diagnostic Capabilities</b>	<b>Fair</b>	<b>Best in Class</b>
<b>Management Reporting</b>	<b>Ad Hoc</b>	<b>Systematic</b>





# Summary

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- Selection of a technology partner must be a thought through analysis of need, with careful structuring for success
- The majority of alliances will fail to deliver the value anticipated
- Alliances will continue to be an important part of the future of the pharmaceutical biotechnology industry