International BioScience

The Commercialization of Technology Concepts into Medical Products: Part 1 Introduction

Kevin J. Scanlon, Ph.D.

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Course Overview

- Overview
- Pharmaceutical Development
- Startups/Investment Community
- Medical Products for MS (Case study)

Claritin:
Does it Work?

Why?

ADMET

The Pharmaceutical Industry:
Selling Medical Products

- *Pharmaceutical Industry*
- International
- National
- Biotech companies
- Start up companies
- Entrepreneurs
- Concepts/Visions
- Patients/Physicians
- Insurers/Uninsured
- Government:State/Federal
- **Pharmaceutical Industry**
- Health Care Institutions
  Managed/Non-Profit
  National/ International
  $$$ drug pricing

Origins of the Pharmaceutical Industry

1880's Germany

Government, Business and Academics

Education; Technology Colleges

1930's England

Emigration of German Scientists

Clinical validation of Penicillin*

* (The Mold in Dr. Florey's coat by E. Lax)

Pre-War Drug Development

- US Government & the Pharmaceutical Industry:1940's
- Manufacturing of Penicillin
- Fermentation plants in the Pharmaceutical Industry produced kilogram quantities of Penicillin for the war effort.
- Penicillin became a wonder drug made on an industrial scale.

Post-War (1945-1990) Drug Development

- The College GI Bill sent veterans to college.
- US Government development of the Medical Centers and Universities by the NIH ($$$)
- Antibiotics (1940), Vaccines (1950), Cardiovascular (1960),Cancer (1970), AIDS (1980), Genome (1990), Diagnostics (2000), 2010?
- European Scientists attracted to the US by the scientific resources and NIH funding.
- Drug Research & Development (Pharma Industry)

Blockbusters (+$1 Billion)

- Brain: Anti-depressant:Psychiatric drugs
- Cardiovascular:
  Hypertension; Beta blockers (MCI),
  Lipid regulators; statins (Cholesterol)
  Angiotensin-converting enzyme (CHF)
- Digestive system: ulcers
- Lung: Asthma
- Antibiotics: 3rd generation

Blockbusters Coming off Patent

- Anti-depressants: Plavix & Zyprexa (~$2.6B)
- Cardiovascular: Lipid synthesis (~$4.0B)
  Hypertension (~$2.1B)
- Asthma:Advair/Singulair (~$2.8B)

Lipitor (Pfizer) ~$12 Billion in sales (2007)
and an additional
~$ 12 Billion in drug sales coming off patent

The Pharmaceutical Industry (2009)

Consolidation? ~ 3-5 big Pharma Companies
2007: Schering AG and Bayer AG
2008: Pfizer and Wyeth
2009: Merck and Schering-Plough; (J&J?)
2010: Roche and Genentech; (stock price~$96/share)

Niche Markets ? (Herceptin, Genentech)
Genetic diagnostics markers and therapy:
Herceptin; Breast Cancer

Biotechnology Industry:

Why California?
Why Dr. Boyer?
Why insulin?
The Future?

Why did Biotechnology start in California?

- 1970's Biotechnology
- Money (Investment Banking) meets Science (Molecular Biology).
- Why San Francisco? Germany 1880?
- Why not New York? US? Europe? Asia?
- Academics, Business and Government

Why Dr. Boyer in ~1975?

- Was Dr. Boyer the first to be approached?
- Why an academic at UCSF?
- Why was Insulin was the first product?
- What is the attitude in Academics today?
- Ask the Technology Transfer Office.

Insulin

- What was the source of insulin prior to genetically engineered insulin?
- Why was it not synthesized at Genentech?
- What was the impact of this product on the government, business and academics?
- "The Eight Day of Creation" by H. Judson (Molecular Biology from 1940-1980)

Biotechnology 2010

Where will these products be created?

Europe, Asia, USA?

Synergy between government, business and academics

Educational institutions (German Technology Colleges)

Information is digital and immediate.

Startups: Validating Concepts
University Technology
Start up essentials
Deal Flow

Entrepreneurs: Deal Flow

- Concept/vision
- Funding: Friends, Family and Fools ($250,000)
- Government funding: SBIR,STTR, NIH grants
- Angels: early stage validation ($.25-2 million)
- Funding Gap: $2-5 million
- Venture Capital: $5million and above

Investment Community
Angels
Venture Capital
Investment Criteria
Deal Flow

Funding Process

- Initial contact through the website (~100/month)
- Pre-screening (~50/month)
- Screening (~10/month)
- Mentor (~5 for 1-36 months)
- Presentation to the full membership (~4/month)
- Due Diligence (~3/month)
- Funding; individual angels invest (~1-2/month)

Incubators

- Building: Academics, Government or Industry
- Support services
- Entrepreneurs
- Network of management experts
- Venture capitalists
- Advisory Board Members

Medical Products

Therapeutics: (selective and non-toxic)

New Chemical Entities (NCE): small molecules

Biologicals: MCA, Vaccines, Proteins, Gene Therapy, …

Diagnostics (In Vitro/ In Vivo)

Nutritional Supplements

Medical Devices

Case Study: Interferon/MS

- Interferon gene discovered (~1980)
- Chiron: (E. coli synthesis)IM; 2X/weekly (1994)
- Berlex: (sales 100K patients but 450K) (1995)
- Biogen: (CHO cells)IM; 1X/weekly; lower dose(1997) FDA:orphan drug status
- Serono: (mammalian cells)SC; 1X/weekly;higher dose (2000) FDA approval; Pfizer sales in US
- Merck (Germany) buys Serono 2006

Challenges

- Scientific Education (Darwin)
- Academic Culture for Commercialization
- Conflict of Science with Business Culture
- Synergy: academics, business and government

Opportunities

- Strong business culture; can do it
- Not a risk adverse culture
- Mentoring from the Investment community
- Startup culture that is a model for the world

My Academic Career

- **Academic Medicine**
  - Molecular Biology (Univ. of London; Ph.D.)
  - Cancer Biochemical Pharmacology (Yale Med. School)
  - Clinical Cancer Pharmacology (Mt. Sinai Med. School)
  - Research: Anti-Oncogenes Ribozymes & Gene Therapy
  - Publications, Awards, Editor, President (ISCGT)

My Business Career

- **Pharmaceutical Industry**
  Berlex; Schering AG; Berlin, Germany
- **Graduate School**
  Science/Business course on the Pharmaceutical Industry
- **Venture Capital Community**
  Mentoring and Funding Entrepreneurs

***Three Start up companies;
Melanoma Diagnostics (2006-present)

Advisory Boards

- Dublin, Ireland: NICB (2000-)
- Altadena, CA: Business Technology Center (2004-)
- Shenyang, China: Biotechnology Center (2006-7)

Summary

- The process from “concept to market”
- Medical product: Validation, Scale up, Clinical, Sales & Marketing
- What is the role of an early investor?
- What is the role of an incubator?
- Biotech: Validation of the Market
- Pharmaceutical Industry: Sales & Distribution
- Role of Business, Academics and Government

Ireland:
Yesterday and Today

Ireland did not experience:

- Roman Rule
- The Reformation
- The Enlightenment
- Industrial Revolution

Ireland's advantage:

- Member of the EU
- An Adroit Economy
- College Educated
- English speaking
- Opportunist Culture
- Digital Information Age
- Globalized Economy