Commericalising Biomedical Research – From Bench-top to Marketplace

By Dr Tan Sze Wee

BIOTECHNOLOGY COMMERICALISATION ENVIRONMENT

Biotechnology is often described as the "exploitation of biological processes for industrial purposes". Biotechnology has also been defined as the "New Industrial Revoluation"[1].

Consider the following facts:

- There are more than 370 biotech drug products and vaccines currently in clinical trials targetting more than 200 diseases, including various cancers, Alzheimer's disease, heart disease, diabetes, multiple sclerosis, AIDS and arthritis (BIO report[2]).
- As of year 2003, there are 7,763 biotech patents granted by the US Patent and Trademark Office[2].
- US Food and Drug Administration approved 37 new biotech drug and vaccine approvals in 2003.
- The biotechnology industry has mushroomed since 1992, with US revenues increasing from US$8 billion in 1992 to US$29.2 billion in 2002[2].
- Biotechnology is one of the most research-intensive industries in the world. The US biotech industry spent US$20.5 billion on research and development in 2002[2].

U.S. Biotech Industry Statistics: 1993-2002*

Year:	2002	2001	2000	1999	1998	1997	1996	1995	1994	1993
Sales	24.3	21.4	19.3	16.1	14.5	13	10.8	9.3	7.7	7.0
Revenues	29.6	29.6	26.7	22.3	20.2	17.4	14.6	12.7	11.2	10
R&D Expense	20.5	15.7	14.2	10.7	10.6	9.0	7.9	7.7	7.0	5.7
Net Loss	9.4	4.6	5.6	4.4	4.1	4.5	4.6	4.1	3.6	3.4
No. of Public Companies	318	342	339	300	316	317	294	260	265	235
No. of Companies	1,466	1,457	1,379	1,273	1,311	1,274	1,287	1,308	1,311	1,272
Employees	194,600	191,000	174,000	162,000	155,000	141,000	118,000	108,000	103,000	97,000

* Amounts are U.S. dollars in billions

Source: Ernst & Young LLP, annual *Biotechnology Industry Report*: 1993–2003.
Financial data based primarily on fiscal-year financial statements of publicly traded companies.

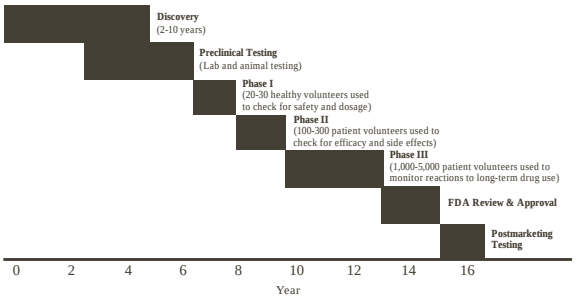
Sales of Biotechnology Products

Most biotech companies are single product companies, but the sales generated by each product is huge. For example, Amgen took 10 years to get Epogen to the market, and it now generates more than US$2.2 billion (2001) in sales. Likewise, Humulin generated US$1 billion (2001) of sales for Genetech.

Rewards and Risk

Therefore, the rewards in biotechnology research can be financially very high, but its risk is matched by the long time and high cost in taking the product to the marketplace. In the US, it usually takes an average of 10 to 12 years to bring a drug to the market, and costs about US$800 million in the process. With these high investments needed, intellectual property (IP) ownership and protection is critical, so that the returns to the parties funding these investments can be protected.

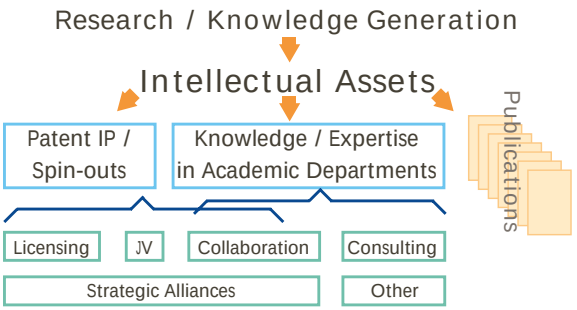
Biotech Drug Discovery Process



Source: Ernst & Young LLP, *Biotechnology Industry Report: Convergence*, 2000

STARTING OUT: THE PROCESS FROM RESEARCH TO COMMERICALISATION

Most research activities are based in universities and research institutes, and draw upon public funding from both governmental or university funds. The knowledge from the research conducted is intellectual asset which has tangible value. Most of the knowledge is usually published in publications, but it can also be commericalised via patented IP and licensed to external parties.



Commericalisation research centres (CRCs) help to bring public research and private industry expertise and involvement. In most instances, IP ownership is a key issue, and policies on technology transfer vary significantly between public research institutes in US, Europe and even Asia. The policies on technology transfer has to be very clear on who has what rights to the IP, and the issue of IP rights is usually

Page 6 ▶

About the author:
Dr Tan Sze Wee is the Managing Director / CEO of Rockeby biomed Corporation Ltd. He is also a Member on the 45th SMA Council and SMA Spokesperson. Dr Tan can be contacted at email: szewee.tan@rockeby.com

◄ *Page 5 – Commericalising Biomedical Research*

not very strong in Asia. An IP rights agreement has to be drawn to adequately protect and transfer the relevant rights by licensing or assignment agreements.

STEPS TO COMMERICALISE BIOTECHNOLOGY PRODUCTS

These are the four crucial steps that need to be considered for any biotechnology products to be commericalised.

1. Effective protection of intellectual property
2. Availability of skilled human resource
3. Develop the business plan
4. Funding

1. Effective protection of intellectual property

What is Intellectual Property?

"An intellectual property (IP) is any product of the human intellectual that is unique, novel, and unobvious (and has some value in the marketplace)." It can be an idea, invention, expression or literary creation, unique name, business method, industrial process, chemical formula, computer programme process or a presentation.

This is the essential step in commericalising technology, as the lack of IP right will deter investment to fund the commericalisation of the technology.

IP can be protected in various ways:

- Patent applications
- Trade secrets and know-how
- Trademarks and service marks
- Copyright

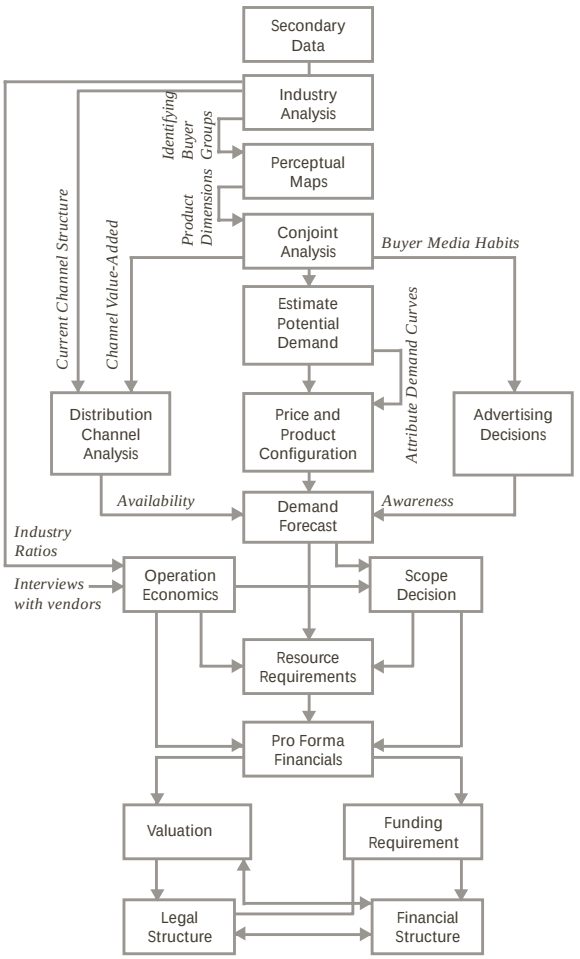
To develop an effective patent strategy, a preliminary IP audit is needed to identify and focus on the core technology. The next step would be to identify how the core technology will be commercially exploited by you and third parties. Research scientists need to be educated on basic patent laws, and the recording of a good laboratory logbook. A patent committee has to be established, and its role is to survey and monitor other research and patent activities within the organisation. Regular meetings with researchers, business developers and patent lawyers will be useful.

2. Availability of skilled human resource

The next step would be to form the management team, where the commercial decision is being undertaken by the Chief Executive Officer who has a proven track record in research commericalisation. He / she should have relevant industrial experience. The main scientist / researcher's role would be as the Chief Scientific / R&D Officer, and continue to develop internal ideas as well as bring in external collaborative research. A financial controller / Chief Financial Officer is important to determine the budget requirement for each phase of commericalisation from product development to prototype design, clinical validation, pilot manufacturing and full scale marketing.

3. Develop the business plan

The role of the CEO is to develop the business plan, and a good model proposed by Anne Marie Knott can be followed.



Source: Anne Marie Knott. Venture Design, an analytical toolkit. May 2000.

The business plan should comprise the following:

i) Feasibility analysis
   a. Is this industry hospitable to entry?
   b. Is there an unmet need?
   c. Is meeting that need profitable?

ii) Venture design
   a. What are the optimal:
      – Product configurations
      – Price
      – Distribution channel
      – Advertising vehicles
   b. How do these decisions translate into realised demand?
   c. What is the optimal scope of the firm?

Page 7 ►

◀ *Page 6 – Commericalising Biomedical Research*

d. Given the venture design and the expected demand, what physical and human resources are required?

iii) Resource requirements

a. What financial resources are required?

4. Funding

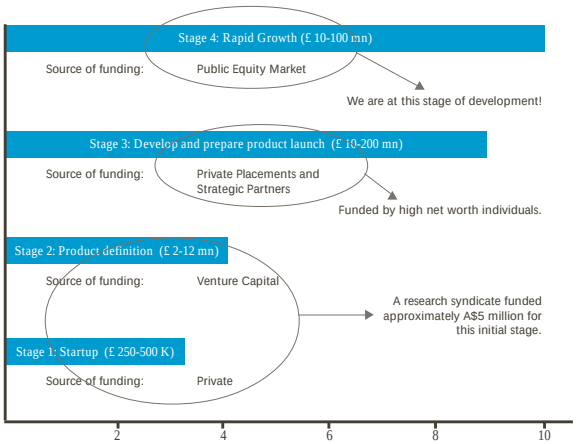
There are a variety of funding sources, and the list below is not exhaustive:

- Government grants
- Business angels, early-stage seed capital
- Strategic private equity
- Venture capital
- Partnerships, joint ventures and collaborative arrangements
- Licensing and cross-licensing
- Mergers and acquisition
- Public capital markets (IPO)

Strategic private equity and venture capital funding goes through the following steps:

1. Economic terms such as valuation and financing structure
2. Types of instrument
   – Debt, convertible debt, common stock, preferred stock, warrants, options
3. Control consideration
   – Board representation, stockholder rights, special voting arrangement
4. Due diligence
   – Scope of disclosure, checklist, organise documents, conduct your own review
5. Process and documentation
6. Exit strategies
   – Registration rights, rights of first-refusal, co-sale rights, sale / merger of company, IPO

The funding cycle usually follows the same pattern:



SUMMARY

The last twenty years have seen phenomenal growth in the biotechnology industry originating from the US to the rest of the world. Singapore is also embarking on this global race as the fourth pillar of its economy. However, since the cost of research and commericalisation is high, and the potential returns are linked to exclusivity, effective IP protection is critical to this burgeoning industry. It is essential that public and private sector researchers and technology managers have access to capabilities for managing IP and negotiating commercial arrangements. Access to trained commercial management and adequate financial capital are also crucial if Singapore is to succeed in this high-risk / high-return industry. ■

References:

1. Kondo, L. 17 Biotechnology Law Report (Number 6 November – December 1998) page 795.
2. Biotechnology Industry Organisation, Editor's and Reporter's Guide 2004-2005.

OUR NEW NOMINATED MEMBER OF PARLIAMENT

Dr Tan Sze Wee, 36, grew up in Tiong Bahru next to the Tiong Bahru Market, in a three-room HDB flat where his parents still live. His father was previously a bank officer, and his mother a retired primary school Chinese teacher. Dr Tan comes from a Mandarin-speaking background. He went to ACPS, ACS and ACJC. During his 'O' Levels, he scored 8 A1s and was awarded the Seow Poh Leng Award. He was also active in Boys' Brigade, canoeing, and continues to pursue his interest in computers. He obtained his MBBS from the National University of Singapore in 1992. Dr Tan was also one of the co-authors of the popular TanWongYap Notes for the MBBS Final Examinations, of which various versions are still being circulated amongst today's medics.

After serving his bond in the government hospitals and a stint as a health administration trainee in the Medical Audit & Accreditation Unit (now Licensing and Accreditation Unit), Dr Tan left to join Mead Johnson Nutritionals as Associate Medical Director (Asia Pacific). He then started Rockeby biomed Corporation Ltd, a biotechnology company specialising in fungal test kits.

Recently, Dr Tan was a recipient of the Spirit of Enterprise 2004 Award.

Dr Tan has been playing an active role in the SMA Council for the past eight years, variously as Honorary Treasurer, Honorary Assistant Treasurer, Honorary Assistant Secretary and Council Member. He is also the SMA Spokesman and represents SMA on various committees such as SMC CME Coordinating Committee and Advertising Standards Authority of Singapore. Dr Tan is married.