

Open Innovation



 **Pharmathen**

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Open innovation

“Necessity is the mother of all invention”

English Proverb ascribed to Plato.

Is Open Innovation an idea born out of necessity to survive for big Pharma?

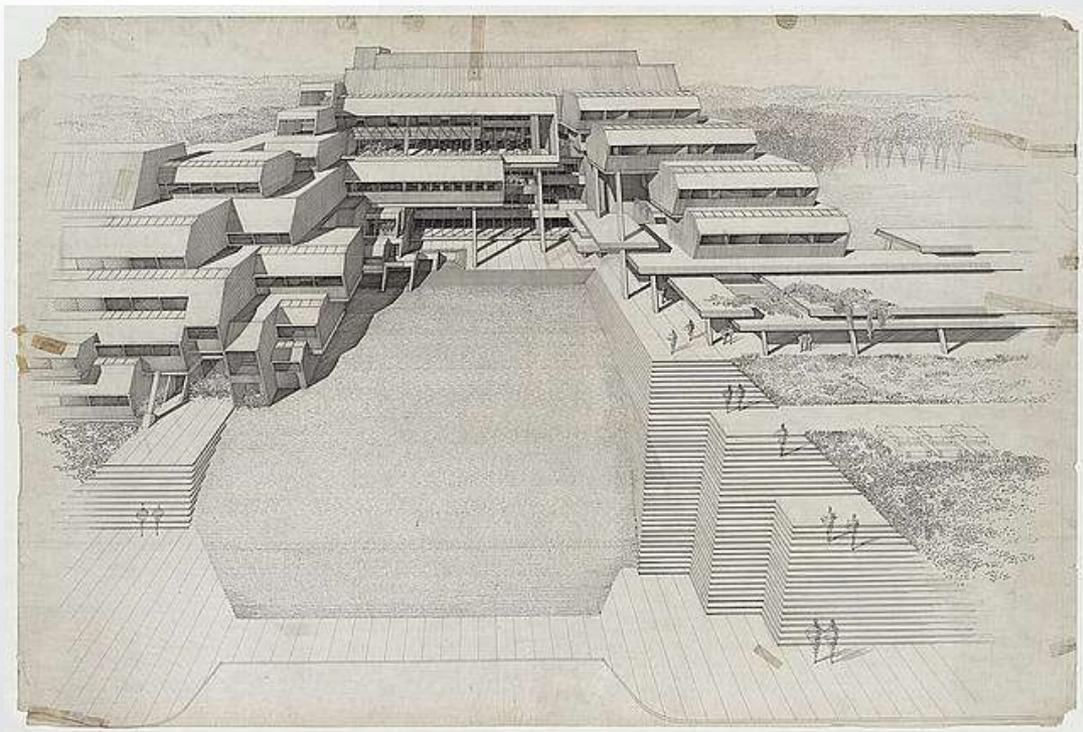
Open innovation in Drug research

- Traditional model
 - what was it and why did it work?
 - why is it not working now?
- What changed?
 - Leading science is not always in-house
 - Top scientists don't remain at the top for 30 years do they?
 - Big data – overwhelming
 - DNA revolution – proteomics, epigenetics, Medical data, pharmacodynamic
 - The regulatory environment got tougher

Traditional Model

Pharma History why it worked then

- Post war – critical steps
 - Formation of social welfare state in EU – large purchasers of drugs and access to large number of patients for clinical trials for new drugs
 - Emergence of biology – protein science – protein Xray crystallography etc. - **the lock**
 - Emergence of medicinal chemistry – **the key**
 - Emergence of study of toxicology – animal testing and histopathology



Large secretive R&D sites – all disciplines co-located in a huge campus. Burroughs Wellcome Campus in US

R&D sites closed in the UK alone

Charnwood – Astra

Sandwich – Pfizer

Nottingham – Boots

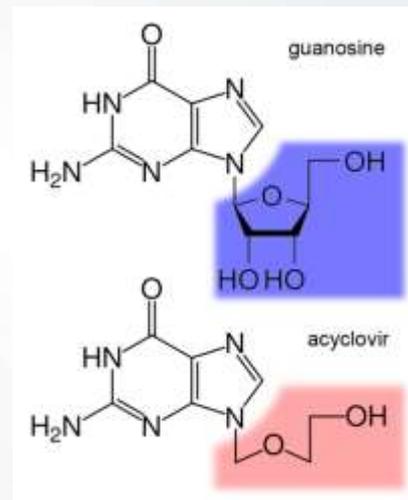
Beckenham – Wellcome

Greenford – Glaxo

Mereside - AstraZeneca

The high water mark? The Nobel Prize in Physiology or Medicine 1988 - Sir James W. Black/Gertrude B. Elion/George H. Hitchings –

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What Changed?

“What’s gone wrong?” The environment changed? It’s all very overwhelming

- Tools generate massive volumes of data and some efficiency gains
 - Combinatorial chemistry can create huge compound banks
 - High throughput screening can screen huge numbers of molecules on a single protein target
- Biologics – Mabs/proteins/antisense etc. new methods of treating open up new treatment tools – they can be very quick to bring to the market.

What’s missing? **Validated** targets. “Do X and disease Y changes” – “Biology is king”

- DNA revolution – sequencing the genome – we only learnt the alphabet
- “Omic technologies” (genomics, proteomics, structural genomics, interactomics, metabolomics, epigenomics etc. supported by bioinformatics)
- “Systems Medicine” the opposite of reductive science and the DNA revolution. Moving out from the cell.
- “Real World Data” is coming – not clinical trial data but patient data responders/side effects linked to genomic data?

Why is it harder to get a product approved and make money?

- Regulatory burden has gone up – pharmaco-economic data needed – premium price has to be justified by evidence
- Hard to improve – “I am standing on the shoulder’s of giants” – the easy disease are well catered for. Moving into harder spaces.

Open means open

	CLOSED INNOVATION	OPEN INNOVATION
CORPORATE ETHOS	Not invented here / “We can do it, we will do it”	Best from anywhere
ROLE OF CUSTOMERS	Passive recipients	Active co-innovators
CORE COMPETENCY	Vertically integrated product and service design	Core competitive differentiation and collaborative partner management
INNOVATION SUCCESS METRICS	Increased margins/revenues, reduced time-to-market, market share within existing market	R&D ROI, breakthrough product or business models
ATTITUDE TOWARDS IP	Own and protect	Buy, sell – the corporation is a knowledge broker using both licensing and commercial development to monetize IPR
ROLE OF R&D AND OPERATIONS	Design, develop and market in-house inventions	Optimize performance of owned assets through both in-house and external development; do enough R&D internally to recognize significant external R&D

The logic of Open Innovation

- Good ideas are widely distributed today; no one has monopoly
- First to discover is neither sufficient nor necessary for commercial success
- A better business model beats a better technology
- IP is a perishable asset: customer or markets don't wait

Open Innovation is not about...

open access to own technologies

outsourced R&D

technology only

technical invention

appropriating value

new ventures

partnerships only

cutting research costs

...but about

strategic IPR management

strategic R&D

both technology and business model

commercial innovation

win-win partnership

core product development process

innovation ecosystem building

improving R&D ROI

Some examples in Pharma

- <https://openinnovation.lilly.com/dd> - submit compounds anonymously to Lilly and they screen – right of first refusal to Lilly – you retain your IP
- Project Data Sphere – “share, integrate, and analyze patient-level, comparator arm, phase III cancer data, which providers are required to de-identify”
- Patients to Trial Consortium – Novartis Pfizer and Lilly – patient recruiting



What's the EU doing with your money?

- €2 billion Innovative Medicines Initiative (IMI), established under the European Union's seventh R&D framework programme (FP7).
 - European Lead Factory, a €196 million - seven pharma companies are making 300,000 compounds available for screening via an open platform
 - New Drugs for Bad Bugs, a €600 million, seven-year attempt to address the problem of antibiotic resistance
 - IMI 2 has been launched

When does Open innovation stop?

- First to market is still a major factor
- Still need and want exclusivity to get a return on investment – patents and data exclusivity but increasing Orphan exclusivity is important.
- IPR is still critical but happy with the tail end IPR – the precise molecule

Research Organisations. Wake up! A lot of capital is looking for investment

- Innovation Union – New Horizon 2020 – 78 Billion Euros to be spent between 2014 and 2020!
- What is your unique point of reference? Build on it, invest and sell it – what model?
- Collaboration is absolutely key - what's complimentary know-how will work with yours
 $2+2=5$
- Big pharma wants you. The EU wants you. You are in the right place at the right time if you do biology, well!