Components of Success; Challenges for Startups and the Role of Intellectual Property in Business

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Industry-university research collaborations in the pharma industry – value added results, pitfalls and practices

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Introductory thoughts

What is the driving force of the collaborations between the academia and industry?

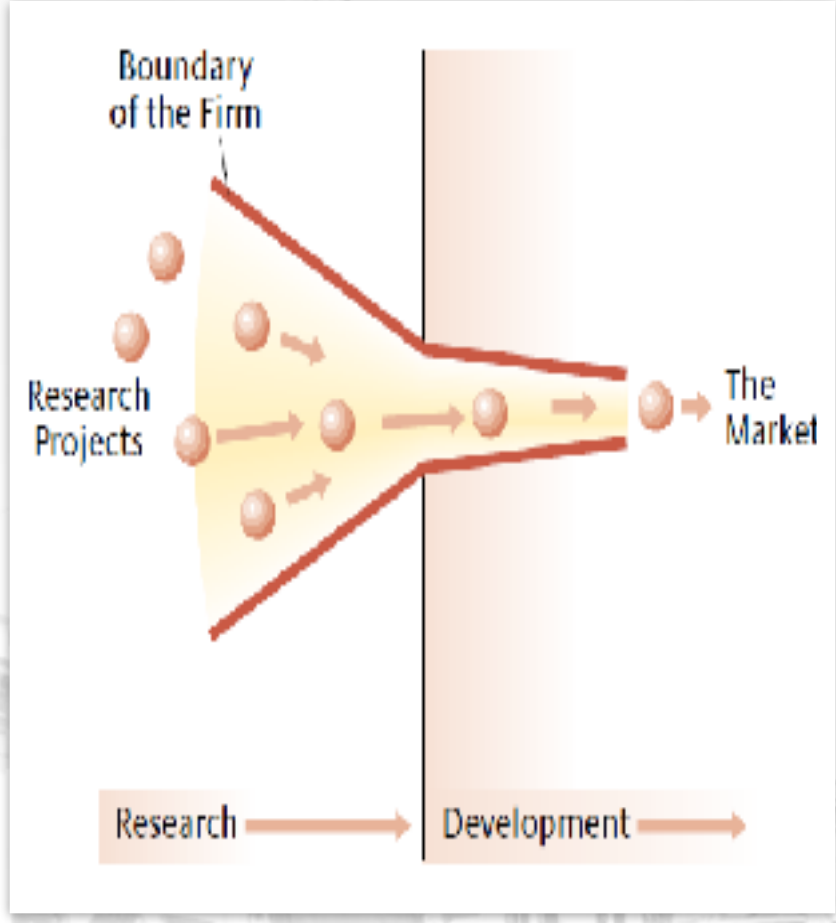
In the closed system of company innovation:

a) the projects start from the **<u>internal</u> scientific and technological base** of the firm;

b) the projects pass through an **<u>internal</u> development process**: stop or continuation;

c) a small group of the selected projects becomes **marketed products**;

d) **one way route without using of external knowledge.**



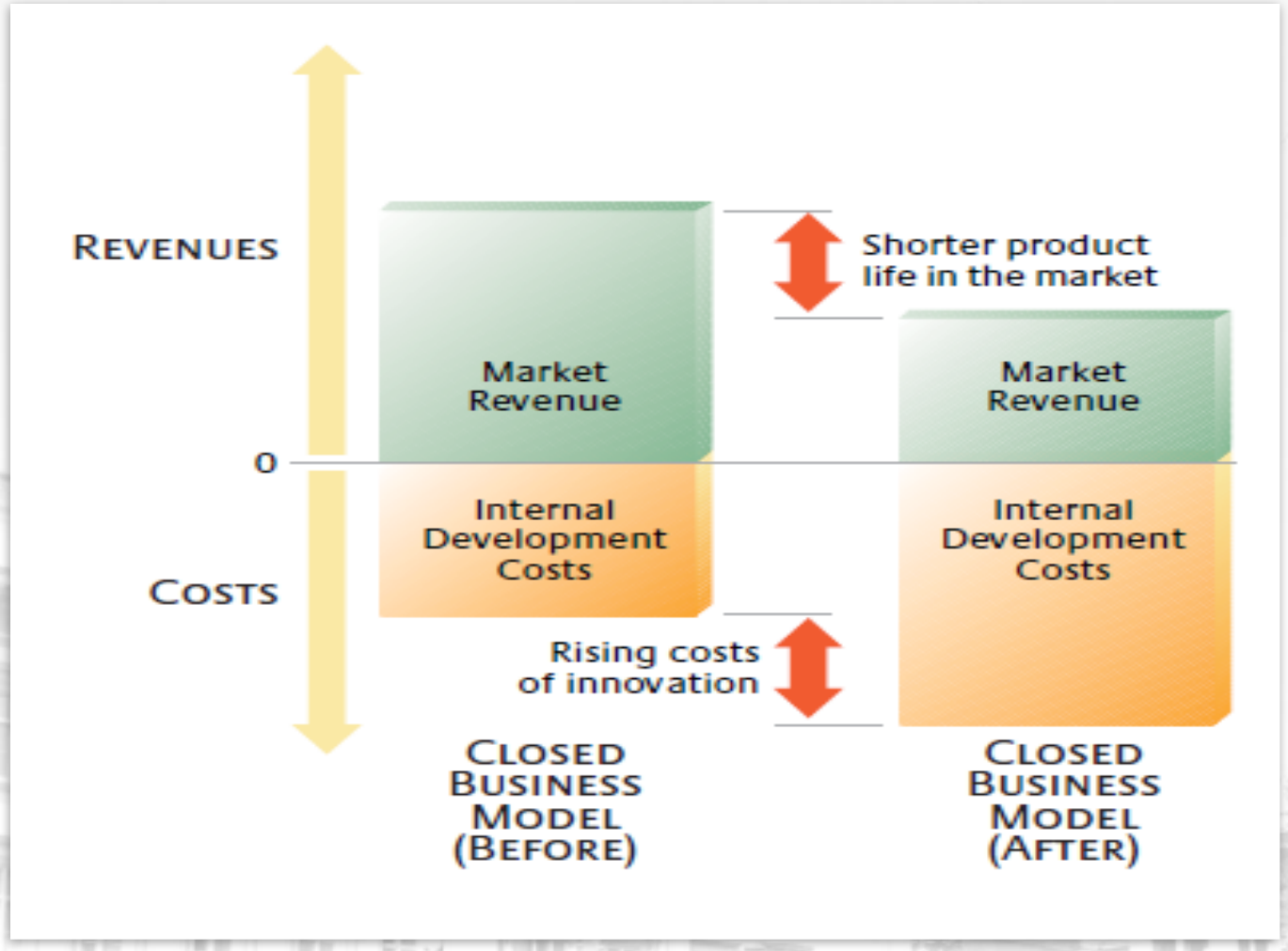
Consequences of the closed innovation

a) **the internal R&D** results in products developed internally and marketed by the company.

b) the **protected intellectual property is accumulated** by the company and

c) the primary aim is **to avoid infringement** of the intellectual property rights. The most of patents have low value, the companies **do not utilize** them in their own products.

The price of the closed system



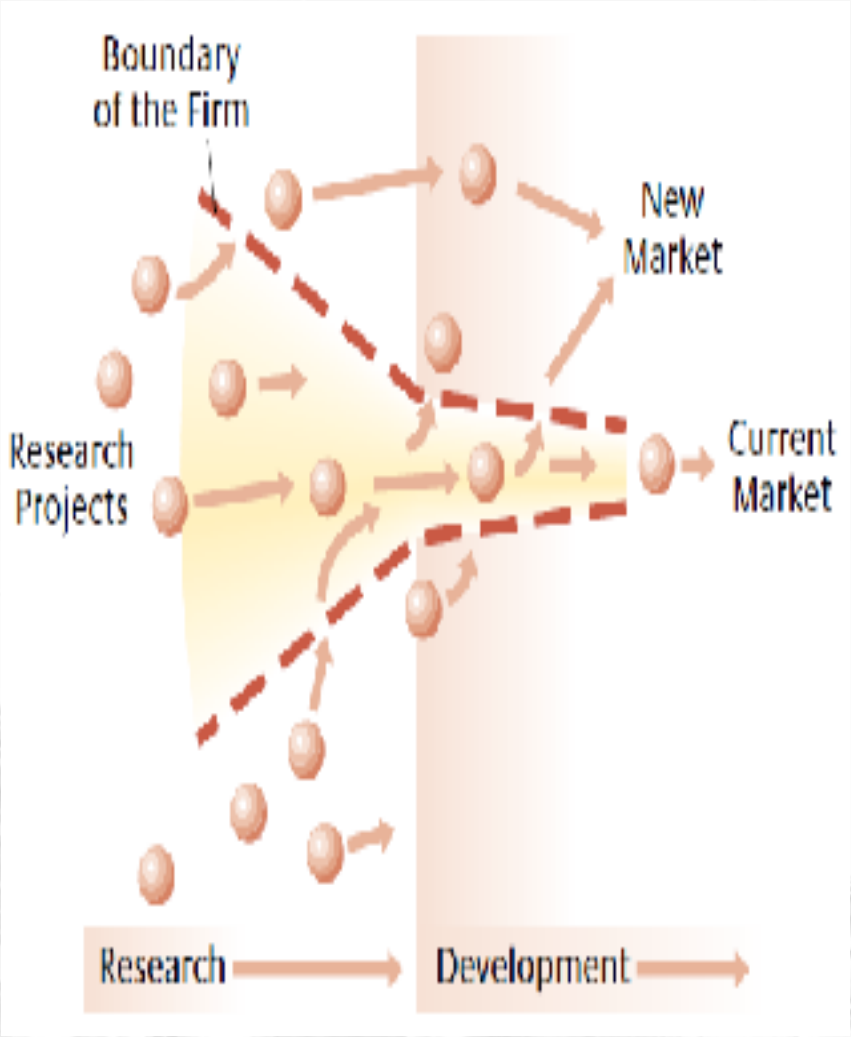
Source: *Henry W. Chesbrough (2011): Why Companies Should Have Open Business Models. In: Top 10 Lessons on the New Business of Innovation. Based on MIT Sloan Management Review*

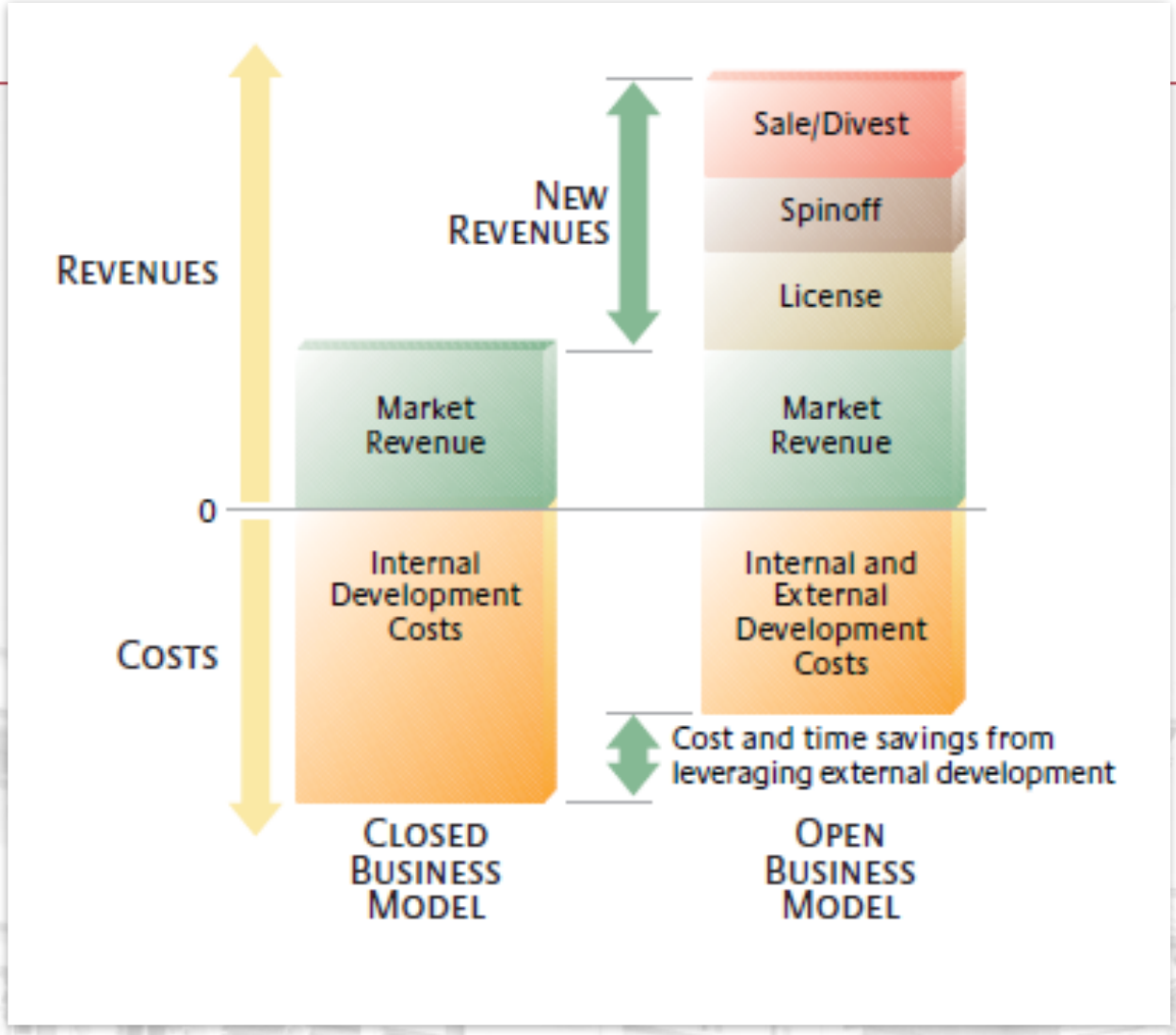
The pressure is increasing on the industry to switch to **open innovation**, where:

a) the projects may start from **either internal or external technological sources**, and

b) a new **project may enter** into the innovation process **at different phases**;

c) the **idea may have more than one different entry points and exit points** along the innovation process.





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Summary of the above:

a) The **internal costs** of R&D have extremely increased;

b) the **quality** requirements of the customers further increased the development costs;

c) the **product life times** shortened;

d) the **competition** between the companies does not always allows large investments in every aspect/ stage in the innovation process (esp. SMEs);

e) the **time to market** requirement shortened.

What can specifically be seen in the pharma industry?

a) The pharma innovation is based on patents (exclusive rights), the successful products' life time may theoretically be prolonged;

b) the case is though more complex in the generics ecosystem;

c) the development costs and time to market are still extremely high.

What can specifically be seen in the pharma industry?

Project type	R&D costs	Time to market
Building of a software application	USD 10k to 800+ k	6 months
Video game (Call of duty 250 M, Deadpool 100 M)	USD 50 M to 250 M	1 year
Developing of a new car	USD 1 Bn to 6 Bn	5 ys
Development of a NCE (small molecule)	USD 350 M to 1,8 Bn	10 ys
Development of a NCE (biopharmaceutical)	USD 2,5 Bn	10 ys
Development of a NCE (Phase IV)	even USD 5,5 Bn	10+ ys

What has happened in the pharma industry?

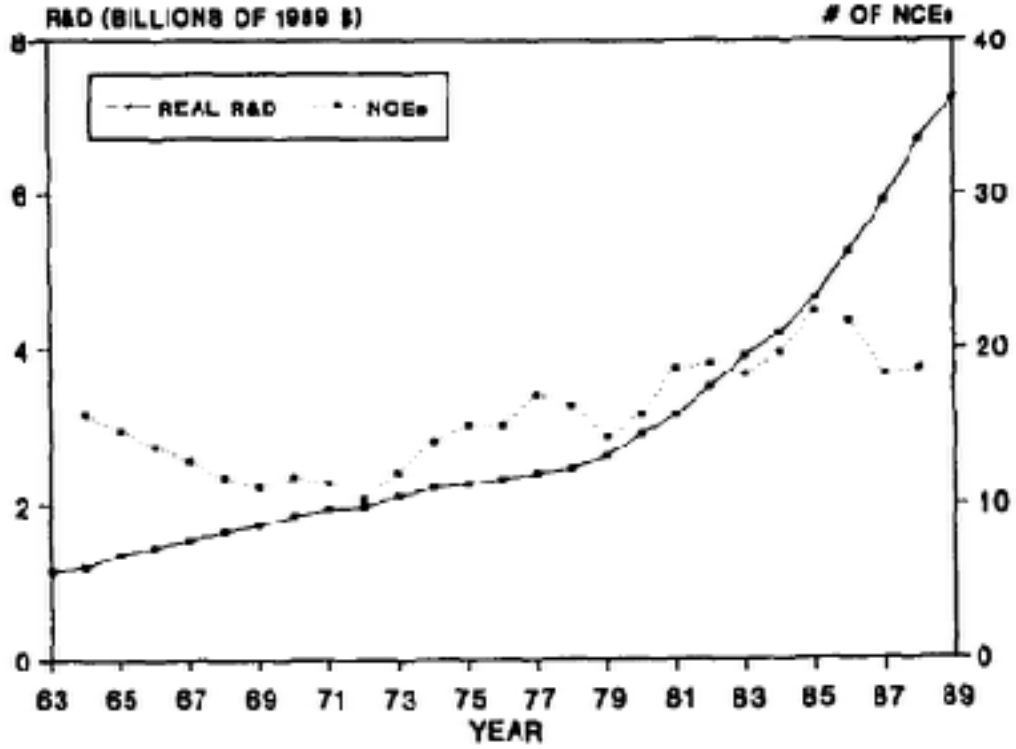

Fig. 1. Annual U.S. pharmaceutical industry real R&D expenditures and U.S. NCE approvals for the period 1963–1989. Expenditures are for PMA member firms and are indexed using the GNP Implicit Price Deflator. The NCE approval line is constructed from 3-year moving averages of annual approvals.

Biopharmaceuticals?

From drug discovery through FDA approval, developing a new medicine on average takes at least 10 years and costs $2.6 billion.* Less than 12% of the candidate medicines that make it into phase I clinical trials will be approved by the FDA.

The IRR for a new product improves substantially with a decrease in time to market.

Key: IND: Investigational New Drug Application, NDA: New Drug Application, BLA: Biologics License Application

Biopharmaceuticals?

Based on the above: the **pharma industry needs the availability of useful knowledge from external resources**, esp. universities, in order to cut costs.

The other side of the partnership:
What is the driving force for the academy in the collaborations?

a) Tax payers and media require the useful results of science;

b) governments require new products as project indicators in return of the grants;

c) the EU recommendation 1329/2008 require the IP based knowledge management at the universities;

- d) even the EU recommendation 2012/417/EU recommendation on the Open Access outlines: "*Such OA policies should be implemented taking into account the challenge of IP rights*."

To sum up: universities need the money of the industry.

However: the industry sponsorship is NOT and NEVER BE the main source of financing:

Stanford University	
Income from the commercialization of inventions	Annual budget
USD 95 M	USD 5.5 Bn
	Research expenditure USD 1 Bn

Thus: historically, next to the **unique knowledge base**, the university knowledge seems to be an **economic way** to be obtained by the industry.

Why then is it a challenge to cooperate?

There are some serious differences between the cultural background of the two:

Aspect	PRO	Industry
The human resource	the Researcher; freedom of science; the results serve the advance in the career	engineer under employment; specified project development plans; the generation of the results is in the job description
The value creation process	the knowledge is generated using public money, the scientist wants to publish because “it’s not fair” to monopolize the tax payers’ money	objective: generation profits, effectively; monopoly rights
Primary purpose with the IP generated	selling of the IP before finishing the innovative product = technology push	selling of the innovative products themselves = knowledge pull

The priority of profits and the priority of “other values” may confront with each other in the technology transfer process

The cor ogy:

a) licensin

b) researc ecified, but
the sol

risk of ru overing new
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of the project

"Products that come to market six months late but on budget will earn 33% less profit over five years. In contrast, coming out on time and 50% over budget cuts profits only 4%."

- McKinsey and Company

These factors may result in pitfalls in the collaboration.

What specific **concerns** may arise?

a) concerns with the research (service or science?);
b) payment terms;
c) the background knowledge;
d) delays in delivering of the results;
e) the foreground results;
f) representation for the services;
g) applied law.

Wrap up

1. Make the wording of the contract simple; use business English (DESCA) instead of the anglo-saxonic conventional terminology;

2. put the technical things in the Schedules; these are to be written by the key personnel, otherwise don't let the scientists become a lawyer;

3. be precise with the deliverables, payment terms, ownership of IP, and warranty; these may become deal breaker;

4. specify the background, even if it is painful!

5. The representation may be deal breaker; the company must evaluate the risks and benefits carefully; in house FTO search must be planned in the project by the sponsor;

6. the category of generally applicable know-how is to be avoided: focus the SoW, design the payment terms carefully. If the cooperation unsatisfactory, the GAKH is a serious risk.


Thank you for your ATTENTION!