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COOPERATION – A SPECIAL SURVIVAL STRATEGY FOR ECONOMIC ORGANIZATIONS IN THE BIOTECH-PHARMACEUTICAL INDUSTRY

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ABSTRACT

Medical biotechnology is used by two main types of companies. First, large companies, such as large pharmaceutical companies ("big pharma"), which draw on a long history in the given field and develop into more and more innovative biotechnology users. Second, modern biotechnological companies, from which the above mentioned large companies purchase knowledge, projects or services. In terms of developing and spreading technology, small biotech companies often play an important mediating role between science and industry. They provide technology-platforms, knowledge, services for larger companies, such as international pharmaceutical companies or enterprises in the food processing industry. The volume and complexity of biotech and pharmaceutical projects grew in relation to the amount of available information and acquired knowledge. This placed further emphasis on cooperations, and sharing of costs and risk. Due to the risk associated with biotechnology, the complexity of and adherence to rules and the amount of funds, companies were forced to cooperate. First, the necessary monetary tools are available only at the largest companies. Second, the necessary competencies are often missing, because no matter whether a smaller company is market leader in R+D, when it still does not have the necessary experience for production, not even the knowledge for clinical testing. As a consequence, cooperation is necessary to fill these gaps.
Keywords: red biotech, high uncertainty, biopharma strategies, cooperation)

INTRODUCTION

Biotechnology, just like other new and dynamically growing branches of industry, is undergoing very rapid changes. This is a very high risk – high benefit industry, and R+D phases often require several hundred millions of dollars. Participants seek to minimize and share uncertainties and risks. A possible solution for this is to promote cooperations. Thus, on one hand, biotech companies with specific knowledge become importers of knowledge for big pharmaceutical companies, while on the other hand, they receive share of the great companies' profit. Unique features and advantages of these cooperations may prevail, which can lead to further specifications.

THE WAY BIOTECH AND PHARMACEUTICAL COMPANIES DEPEND ON EACH OTHER

Medical biotechnology is used by two main types of companies. First, large companies, such as large pharmaceutical companies ("big pharma"), which draw on a long history in the given field and develop into more and more innovative biotechnology users. Second, modern biotechnological companies, from which the above mentioned large companies purchase knowledge, projects or services.

As for revenue and the number of employees, it is mainly the large companies that control the biotechnology industry. This, however, does not lead to strict adherence to traditions and the conservation of power relations. As a matter of fact, in terms of knowledge and the number of innovative projects, the mass of small biotech companies has the advantage.

In terms of developing and spreading technology, small biotech companies often play an important mediating role between science and industry. They provide technology-platforms, knowledge, services for larger companies, such as international pharmaceutical companies or enterprises in the food processing industry. Their products can be potential pharmaceuticals, new targets, diagnostic kits, or simply specific knowledge. Biotech companies use their networks to mediate knowledge between the scientific sphere and their own customers. These networks endeavour to find cutting edge research opportunities which are fit for commercial use.

Many biotech companies were founded in the 70s and 80s. They sought to become completely vertical companies, encompassing everything from R+D to production and sales. They focused their strategies on developing pharmaceuticals for previously non-curable or hard curable, but relatively common diseases. Examples for them are Genentech and Amgen, which were successful enough to become independent, that is, to encompass all the fields from research to sales. These companies brought new trends in their innovation strategies. Previously they used only closed innovation. The previously stated companies took to cooperating and used different business models. Accordingly, they developed a different organizational structure and a different organizational culture. These changed their position and behaviour towards their competitors. They marketed (sold, licensed) some protected technologies, which they themselves had developed, this way they helped their competitors to a certain extent, but helped their own markets to form at the same time, furthermore, they could spend their revenue on developing new technologies.

At first companies lacked two factors that kept them from reaching their goals: the lack of funds and experienced managers. It is precisely these two things, however, that are needed (in addition to technology) for a company to grow from a spin-off enterprise to a large pharmaceutical company. The classic pharmaceutical companies, enjoying their peak at the time, already possessed these resources. Some of them purchased biotech companies, while others were not open to biotechnology in terms of investment and cooperation (*Murray*, 2002).

In the 90s emphasis was shifted to pharma-biotechnology. That time it was less problematic to involve cooperating partners and capital, mainly in the USA.

The volume and complexity of biotech and pharmaceutical projects grew in relation to the amount of available information and acquired knowledge. This placed further emphasis on cooperations, and sharing of costs and risk.

Recently, biotech companies entered the early phases of research, selling their products, ideas and results to pharmaceutical producers (*Mark and Smith*, 2003). These companies were small. Therefore they could not even think about producing their own product. Selling their knowledge was something they could realize. Many of them went bankrupt, were not successful, but there were those that survived this early phase.

Large pharmaceutical companies usually purchase finished molecules, before or after the 2nd clinical phase from the small biotech companies. This means that with the technological development is already some win-win situation realized this way. Big companies reduce their risks, which however still remained considerable, even in this phase, but at the same time the cooperation with the smalls allow small biotech companies to prosper. New forms, new players were formed. CMO units (contracted place of production) for example, CRO organizations (contracted research unit), consulting and service companies. In other words the organizations share the risk, the same way they share the work and the income.

Figure 1 shows the risk sharing process (arrows were added by author). By their nature, completely new biotechnological projects, aiming at radical innovation, originally fall into the "suicide box". They are characterized by high market and technological uncertainty. In a given situation, a small biotech company, since it has no other choice, working out the right technology, sells it to the larger pharmaceutical company. From the point of views of the big company, the technological uncertainty is reduced considerably, since it is purchasing a technology that has been proven to work. (The technology is over the proof of the concept phase) The market uncertainty remains now to solve, which can be assessed and estimated by the purchaser. Another extreme case is when a small innovative company tries to become a supplier for one of the large market players. Trying to meet its needs, perhaps even relocating closer to the purchaser, is thus reducing market uncertainty for both parties. Thus the reason for cooperation is to decrease at least one, but preferably both (marked by dashed arrow) uncertainties. By sharing the associated risks, the organizations will not be able to reach the small innovation level, as this is not the goal of the cooperation. But at least they can decrease risk somewhat.

Due to the risk associated with biotechnology, the complexity of and adherence to rules and the amount of funds, companies were forced to cooperate. First, the necessary monetary tools are available only at the largest companies. Second, the necessary competencies are often missing, because no matter whether a smaller company is market leader in R+D, when it still does not have the necessary experience for production, not even the knowledge for clinical testing. As a consequence, cooperation is necessary to fill these gaps.

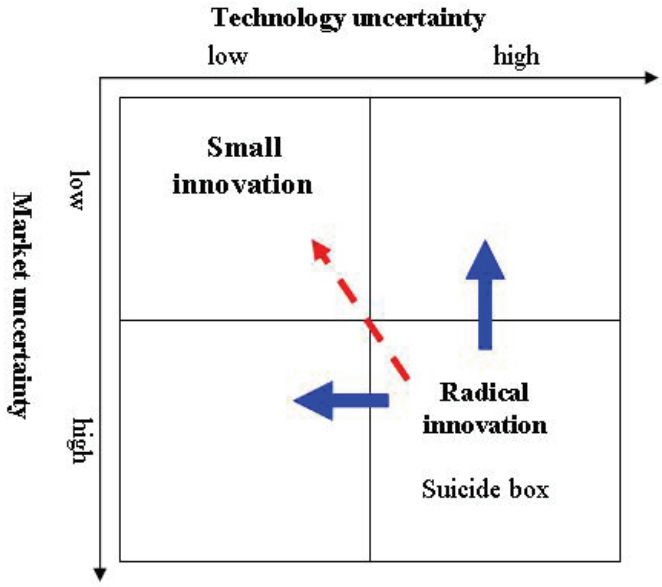
At the same time, the other perspective is sharing the uncertainties. They may be technology, market, regulation or competition related. The latter reflects on the segments of all the other risks, since the rapid development of China, South Korea

and India is clearly visible. The advantage against these new participants can only be quality and knowledge, precisely the areas where China and India are developing rapidly, while maintaining the seemingly natural price advantage. Europe and the USA can only compete with these products if they do not count on price advantage, but on therapeutic advantage. That is, they produce a newer, better molecule. However, this larger added intellectual value implies larger risks on behalf of technology, market and registration. These tendencies are also catalysts of cooperation.

It is precisely these different, yet interrelated risks that make pharmaceutical biotechnology complex. Complex processes and instability necessitate cooperation. Instabilities are cross-linked, they have effects on each other, they can even strengthen or weaken each other. An example for strengthening is the technological uncertainty of producing a new molecule, and the following registration and legalization processes.

Figure 1

2-dimensional uncertainties



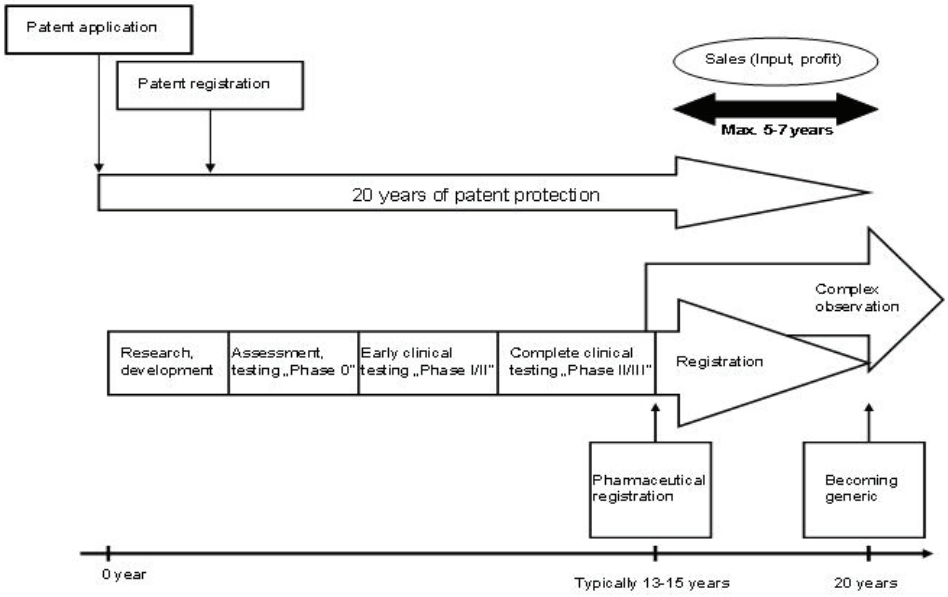
Source: Based on *Hronszky and Várkonyi*, 2006

Necessity of cooperation can be explained from another point of views as well (*Figure 2*). Validity period of a patent is 20years from the date of application, which, in case of pharmaceuticals can be extended by at most 5years (SPC). The product generally appears on the market 13-15years after the patent application. However, with the end of the patent period, one must also count with the appearance of generic and biosimilar products. As a result of this, there is at most 10, but more often only 5years to cover the entire costs of R+D and clinical trials. That is the reason why everyone

seeks to minimize R+D time as much as possible. One method could be open innovation, which supports cooperation and outsourcing instead of solving everything in-house. Since there is no time to localize new skills within the company, it is better to entrust R+D tasks to outsiders who are already experts in the given field. This method definitely saves time and possibly costs as well.

Figure 2

Typical timeline in biotech: R&D value chain and patent protection



BIOTECHNOLOGICAL STARTUPS, FEATURES OF THE PHARMACEUTICAL SECTOR

Biotechnological companies pursue B2B (business to business) strategy (the smaller they are the more they do so). That is, they hand on their products and services to other business organizations instead of end users/consumers. As for pharmaceutical development, from all the cooperating partners it is only the large pharmaceutical company that gets in contact with the B2C (business to consumer) model and the consumer.

For startup biotechnological enterprises, just like for other startup companies in the knowledge intensive sector, the existence of the following is crucial:

- Possessing new technologies, patents
- Academic or university background
- Workforce with great expertise in different sectors (professional expertise, e.g. from the industry or university, R+D; management and company leadership)
- Appropriate scientific and business environment.

New companies face many obstacles. It is difficult to find proper workforce, their employees are often not committed enough – or they cannot make them committed enough. Companies have little expertise in their new environment. All of their relations are new – with their costumers, their vendors, their partners, etc. These companies are small, and they are often unable to survive a performance decline, even if it occurs due to an exterior reason.

Startup companies are threatened by a lot of technological dangers, they often take part in the early phase of developments with the highest risk factor, so they and their technology have uncertain values. Furthermore, developments often require a considerable amount of capital, yet the amount of revenue is uncertain.

Innovative biotechnological companies have special characteristics. We can observe three remarkable features:

(I) Biotechnological developments are generally based on the appearance of a great number of small and medium-sized companies. As a rule, biotechnology is a great and turbulent population of innovators, where small companies are the engines of science-aided innovation. Large companies rather play a role in integrating new results in their products, after they have been developed by small companies.

(II) Biotechnology is a knowledge-intensive sector. The resulting special characteristics have two consequences. Start-up companies are near the source of the knowledge, e.g. universities, even if they are not university spin-offs. Second, founders come from scientific fields, they have a scientific background.

(III) Strategic cooperations are becoming a central feature in biotechnology.

These cooperations help companies gain considerable advantage over stand-alone companies in terms of resources and abilities. The competencies of cooperating partners complement each other, which leads to new opportunities, e.g. new technologies can be developed, new markets can be captured. Mason (*McCutchen and Swamidass*, 2004) and Calazo explained the advantages as follows: (1) the technological gap is filled, market is provided for replenishing production capacity; (2) initial cost and risk are reduced; (3) new products can be marketed faster; (4) size-efficiency is reached; (5) trade and legal obstacles are easier to overcome; (6) extended field of activity; (7) decreasing specific cost.

In biotechnology small companies use outer R+D capacities (as well). The reason for this is the lack of inner resources (money and knowledge). Yet other factors also support the idea to rely on outer resources: (1) the management endeavours to complete inner resources (2) the environment feels that R+D is too risky and difficult, because products and regulation are changing too fast; (3) the company seeks to reduce the risk; (4) the company has experience in using outer resources; (5) the management have a strong global approach (*Atuahene and Gima*, 1999).

Biotechnology and pharmaceutical companies often cooperated since the time they could achieve a "win-win" type (that is, advantageous for both parties) cooperation through helping each other. A small company can come in for the cooperation in different ways. Of course it cannot invest hundreds of million dollars and cannot wait for years for the payback. The small company gets a certain

ratio of the revenue of marketing, so its value and prestige is increasing, it can easier gain new partners and investors.

In biotechnology company success requires 3 different competencies: strong management, financial resources, good technology. Out of these criteria, strong management is the most important one, of course, since they can obtain money and control research directions. On the other hand, the available capital and technology alone are not enough for the success. Since in biotechnological strategies the product's or service's novelty are more important than their prize advantage, technology requires a considerable amount of investment, a long time before any revenue could be generated.

THE KEY TO SUCCESS: COOPERATION BETWEEN BIOTECHNOLOGICAL AND PHARMACEUTICAL COMPANIES

In the 90s organizations differentiated in the sector, platforms (cooperation samples) were formed and were often used (author's and patent royalties, research and licence agreements, spontaneous cooperations, formal and informal alliances between supplier companies, organizations). Nowadays this phenomenon is getting intensified because of the complexity of projects (e.g., human genome), the amount of knowledge in life sciences, as well as the complexity of pharmaceutical requirements. Today biotech companies' strategy allows the existence of more and more product-orientated enterprises in the medical industry.

The increasing complexity created paradoxes systematically: a global competition emerged, this, however, caused cooperations too. The reason for this was that cooperations helped reach the critical mass which ensured success.

Even these days, biotechnology companies are smaller than traditional pharmaceutical companies, but their small size is compensated by them being highly specialized and mobile, and reacting faster to tendencies. Their other advantage is cooperation, which they are forced to form, because cooperations are becoming more and more important. According to today's requirements, the development of the increasing number of new molecules and pharmaceuticals needs a lot more energy and money as it did a few decades ago. Companies need to cooperate since only a few companies can afford to invest 800-1200 M $ in a very risky pharmaceutical original project. As a consequence of this, risk and cost sharing are necessary.

The time available is another critical factor. The available 10-15years seem to be a long time, but in fact they are not. Clinical trials (3 phases) and the registration process last several years each. What is more, one have to act faster than its competitors, a few months of delay in the programme can result in another company entering the market sooner with a similar active substance. Because of special market and industrial property protectional customs and laws the second participant entering the market can gain only a small fragment of the turnover – which makes it doubtful whether development costs will return. That means companies are supposed to enter the market as soon as possible. Accordingly, there is a tendency that companies can accelerate the phase of development with the help

of knowledge obtained from other organizations rather than using their own research results, since pharmaceutical companies purchase already successful, immediately available concepts. That is, time limit also necessitates the preference of knowledge-brokering and the cooperation of organizations instead of strengthening in-house research potentials.

As for finances, cooperations are controlled and influenced by the large pharmaceutical company, even though it only takes part in the real work after Phase 2, or Phase 3. As a result of this, the large pharmaceutical company also becomes dependent on the small ones, which provide technology and knowledge, because it builds upon them while investing in markets and production potential. It is more economical for it to spend a part of its budget on supporting small companies and cooperations than to finance broad R+D. Accordingly, a power imbalance of participants is characteristic of biotechnological cooperations.

Today cooperation is a feature of not only biotechnological companies, but most pharmaceutical companies are also forced to form strategic cooperations. Small pharmaceutical and biotechnnology companies can achieve an impressive result only when they cooperate and share labour to a necessary extent.

These days the visible tendency is for certain biotechnology companies to establish long lasting strategic cooperations with certain pharmaceutical companies. That means the biotech company develops its portfolio, its knowledge importers in order that its products meet the requirements of the large company comprising its market. In certain cases topics and ideas come from the pharmaceutical company itself. Accordingly, knowledge importers are becoming more and more specialized. Of course these interrelations do not mean exclusivity. New companies and results are emerging all the time, new interactions can be formed alongside these interrelations. The reasons for interconnections are the important changes in knowledge-generation which dynamically influences this branch of industry and its specific isntitutes.

During the struggle for survival and growth, formal and informal cooperations, groups of strategy and interest are formed. One of the most importants groups are clusters.

The driving forces of biotechnology and the related modern pharmaceutical industry are innovation, the flow of knowledge, the appearance of new ideas and technologies in the industry.

In the sector, several practically realizable solutions were born for knowledge flow which innovation required and for cooperations between organizations. Their common features are that they bring academic and industrial spheres, as well as their needs together; they make new ideas and knowledge obtained in the academic sphere to be industrially usable. It is also of crucial importance to reach the "critical mass" necessary for the realization, in terms of involving technology – capacity, equipment, workforce, suppliers, background industry, infrastructure- as well as involving capital necessary for technology operation.

With cooperations and labour sharing costs and risks are also shared automatically. Since pharmaceutical companies prefer to find "knowledge importers" with the greatest knowledge and expertise in a certain field, they

probably won't need to develop a complete in-house knowledge-base, which results in reduced cost and time requirements. Successful projects, industrially realizable basic research results are chosen, cooperations are based upon them. Consequently, projects cost less in general, because a relatively less amount of money is needed to be invested to decide which research result can be utilized at the industrial level. That is, there is no need to develop in-house capacities to obtain research results, and, on the other hand, small companies and academic institutes cannot afford to invest considerable amounts of money in projects. In several cases, projects were marketed already after the proof of concept phase, but cooperation cost much less until that point.

At biotechnological companies innovation have special features which have been paid great attention to for the last years:

(1) Just like in every new branch of industry, small companies are typical to exist, for which cooperations are beneficial. A further similarity to information technology and telecommunication is that the great and stabile companies are present rather as key partners and costumers. Cluster organizations often depend on them financially, and they also determine strategic business directions. This phenomenon is emphasized in biotechnology as well: large pharmaceutical companies often establish start-up organizations and contact smaller companies, take part in the pharmaceutical production (generally around the Phase 2 of clinical research), whereas small biotechnology companies take projects from proof of the concept to the Phase 1 of clinical research. A significant prerequisite of biotech sector growth is the exponentially increasing number of small and medium-sized companies in the sector. The sector of biotechnology is often described as the great and turbulent population of innovators. Small and medium-sized enterprises represent the power in the innovation environment, whereas large companies play a role in integrating new developments in their products, after being developed by small and medium-sized enterprises.

(2) Biotech is a knowledge-intensive sector. This has two consequences. First, small and medium-sized enterprises are near the source of knowledge, even if they are not spin-off companies. Second, company founders have mainly a scientific background – with all its advantages and disadvantages.

SUMMARY

I presented that in the "high risk – high benefit" biotechnology industry participants seek to minimize and share uncertainties and risks. A practical, well functioning solution is forming cooperations, groups of interest, networks and strategic relations. As a result, biotechnology companies with a specific knowledge become knowledge importers for large pharmaceutical companies, on the other hand, they gain share of the large companies' profit. Unique features and advantages of these cooperations may prevail, which can lead to further specifications.

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