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NEW METHODS FOR STRUCTURAL DEVELOPMENT CAUSED BY OPEN INNOVATION IN RED BIOTECHNOLOGY

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Abstract: *Red (pharmaceutical) biotechnology is currently one of the most innovative industries. A good example of this is the fight to develop a vaccine against the COVID-19 pandemic, or even the incredible dynamism of the development of anti-cancer drugs. Innovations always carry uncertainty within them - the authors of this article see and experience this every day during their managerial work related to R&D in the biotechnology sector. Decisions often have to be made on uncertain grounds, with incomplete information. Mapping all these anomalies and their root causes is also necessary according to what has been experienced in various organizations, but at the same time it is a very interesting and challenging task. One of the possible means of sharing and reducing the risk is the so-called Open innovation, which required innovations in the fields of technical, industrial rights protection, privacy protection, but also cooperation platforms. All this required a new organizational and structural operation from the actors. This means that technological innovation attracts and results in project innovations. We assume that organizational development and structural innovations were also achieved through these transfers. We are trying to validate this hypothesis with the help of interviews with professionals. Our thesis: the challenges arising from the special innovation of red biotech also caused and necessitated the innovation of organizational structures and the development of its organizational and structural functioning, to which open innovation gave outstanding help.*

Keywords: *red biotechnology, open innovation, risk-sharing, structural development, organizational innovation, Structure an Operation of Organization (SO&OO)*
(JEL code: O33)

INTRODUCTION

In the case of biotechnology, uncertainty is often interpreted as "ignorance" or "real surprise". "We don't know what we don't know" is the original surprising range of little-known events and hard-to-determine distributions, which is gaining more and more importance, mostly supplemented by irreversibility. [1]

In the field of the drastic reduction of knowledge, sooner or later it is not a matter of uncertainty, but of ignorance, since we do not even know about the existence of the events that will occur, and we may not be able to know, not only about their probability of occurrence [2].

A problem is the not always adequate awareness of the events that become (may) become relevant. For example, if we look at the production of drugs with genetically modified

organisms, drug manufacturers have faced such new problems as the wave-like changes in the social and environmental acceptance of the technology, which has generalized the perception of working with recombinant organisms, regardless of the isolation of the organisms during use. At the same time, "classic" events that influence the behaviour of pharmaceutical companies continue to play a role: e.g. in the background, the intertwining of competitors, building on each other, takeovers, industrial rights protection situation.

At the same time, the "classical" processes that influence pharmaceutical production, such as cooperation and mergers of competing companies in the background, still play a role.

The other concern is probabilities. There are areas where probabilities can be estimated relatively easily (e.g. industrial rights protection), but in other areas very difficult (e.g. feasibility of technologies, changes in regulations, marketability, changes in price, demand, supply). The latter are the areas whose probabilities cannot be generalized from the more classic pharmaceutical or chemical industry examples, they are bio-specific. That is, overall there are probabilities that can be considered unknown. Of course, the most difficult thing is to include the dangers of unknown processes in the decision.

Red (medical) biotechnology is currently one of the most dynamically developing industries. Disruptive innovations in the field appear from time to time, each decision (e.g. the development of a drug) can be worth billions of USD. The pharmaceutical industry is one of the most research-intensive industries, with an average new product development (NPD) trajectory of 11.9 years. [3] So primarily the nature of the industry determines the uncertainty. The nature of the industry results in very long periods of time (on average approx. 10 years from the start of research to the market), very large amounts invested (approx. 1-2 billion USD for new molecules), and extremely strict regulations for the licensing of products.

The reduction of uncertainty can be facilitated by cooperation and division of tasks between companies, thereby supporting open innovation. Nothing exemplifies the importance and topicality of the topic better than a study predicting trends in the pharmaceutical industry published in 2019. According to a study predicting pharmaceutical industry trends, pharmaceutical expenditures worth USD 1.2 trillion in 2018 will reach USD 1.5 trillion by 2023 globally. These huge numbers also indicate the size and importance of the industry [4]. Thanks to the current COVID-19 pandemic, we can see further appreciation of the health industry. Thus, it is easy to see that important economic aspects, including related management-organizational and human resource management aspects, can be discussed in this area.

THEORETICAL BACKGROUND

The development of biotechnology from an economic and strategic decision point of view

Parallel to the development of biotechnology, new requirements were formulated for national innovation systems. The developed countries responded to the new challenges in different ways and with different results. The competitive position of some countries in biotechnology has changed significantly in a relatively short period of time. In the thesis, we looked for an answer to what economic conditions play a decisive role in biotechnology innovation, why individual countries have achieved different successes in the development of biotechnology.

The study of the international development experiences of biotechnology was one of the basic conditions of economic biotechnology research. In the first half of the 1980s, there was plenty of international information available regarding the development of biotechnology, but due to the novelty of the field of activity from an economic point of view, only a small portion of the information was systematized. Therefore, the most difficult part of the research was the economic definition of the special problems arising from the development of biotechnology, and the development of the research method.

The framework of classical economic theory proves to be narrow in the analysis of scientific and technical development, the strictest limitation is the static approach and the assumption of the existence of a pure market. The economics of scientific and technical development served as a reference point for creating the theoretical foundations of the research.

In the modern economy, a high level of vertical division of labor is coupled with innovation, as a result of which the market does not exist in its pure form. If companies' decisions were based only on pure market, quantitative signals (price, volume) in accordance with the postulates of neoclassical economic theory, product innovations would only be realized very rarely. The producers would not have information about the users' needs, and the users would not have information about the use value (quality characteristics) of the new products. The results of empirical studies conducted in developed industrial countries do not support this: product and process innovations have a similar weight in innovations. [5]; [6]

The market serves as a mechanism for discovering new demand, products and processes. Market success - which is an integral part of the performance of companies in the industry - directly contributes to the level and development of companies' market orientation. At the same time, the market expects strategic flexibility at the operational level from the companies involved, under conditions of intense competition and considerable uncertainty. (Yousuf et al., 2020; Yousuf et al., 2021) At the same time, product innovation affects consumer preferences and results in their change. In the market, the so-called "organized" elements play a significant role: apparently independent market players are mutually dependent, in addition to transactions based on price and volume, their relationship is also influenced by quality signals, and it also happens that they cooperate directly. These elements to compete must be integrated in the operation of the companies that must be mirrored in operational flexibility. (Yousuf et al., 2020)

Thus, part of the successful innovations of the producers is based on the knowledge of the needs of the users, but at the same time, an important condition for the spread of the innovations is that the users know the parameters of the new products, on the basis of which they decide on their purchases. Users can also participate in innovation (for example, as customers). Producers' decisions can be influenced not only by users, but also by signals from "external" institutions, the government and public opinion.

The level of organization is different in the market for different products. The degree of organization of the market depends on the complexity and cost of the products, as well as the rate of change of the parameters that form the basis of their value in use. In the market of products that are not complicated and the parameters that form the basis of their value in use change slowly, the market organization is low. The greater complexity of the products and the rapid change in the parameters that determine their value in use necessarily result in a higher degree of organization of their markets. [6]

The theory of economic growth and international trade is based on the assumption that technologies are freely available in all regions and countries, and that new technologies flow freely between countries. However, these assumptions are not in line with the processes taking place in the economy: we examine the appearance and spread of any new technology, some countries always play a leading role in its development, while other countries follow them with more or less delay. [6]; [7]

This trend prevails in scientific and technical development despite the fact that international cooperation and integration have significantly strengthened in the last twenty years, and the autonomy of nations has weakened. Part of the national capital has become international, less and less dependent on national governments and employees. Today, multinational companies play a significant role in national innovation systems. Despite all these conditions, nowadays the national innovation systems of individual regions and countries differ greatly from each other and represent a significant level of economic analysis. [7]

There are different points of view regarding the causes of innovation. The model based on demand pull serves as an argument for the raison d'être of the laissez-faire science and technology development policy: if demand triggers innovation, there is no need for state intervention. At the same time, overemphasizing the science push and recognizing the dominant role of the supply side presupposes state support for R&D and education, as well as the implementation of an active workforce policy. According to the so-called dualistic model, scientific results play a fundamental role in the birth of new technologies, but innovation is directly and strongly stimulated by the development of demand. The main driving force lies not in the volume of demand, but in its quality. It follows from this that the research and development policy should not only cover units located at the beginning of the innovation chain. [8], [6], [9], [10]

At the same time, technical development cannot simply be limited to the "practical implementation" of science, as it also has its own dimension: the scientifically based and socially organized implementation of technology. Alternatives to technological development are determined by the power structures and attitudes prevailing in society. Scientific and technical development is a dynamic adaptation between social and institutional development, the conditions of which are determined and structured by national policies. [11], [12]

The importance of national policies increases in the period of far-reaching innovations. The role of research and development policy becomes especially important due to the following three elements: the complexity of the relationships between institutions interested in innovation (regulation of the institutions' behavior and the use of new procedures, products, etc.); transformation of the content of corporate activity; the formation of new organizational forms (appearance of new activities related to the environment, etc.) [13]. This policy covers the entire system of research-technical development-business exploitation, because there are inputs and outputs at every level of this system (for example, research also affects production through vocational training) [11].

In the last decade, the biotechnology industry, as a potential source of regional and national economic development, has become the focus of growing academic and political interest [14], [15]. A strong innovative character is reflected in the research and development activity, which has a significant impact on performance, financial flexibility and bargaining power at the company level. (Tömöri et al., 2022) (27). Even though the current size of the industry is quite small, especially in terms of the number of employees, both local and international decision-makers – primarily in the United States – are effectively encouraging local and regional investments in the biotech industry. In many cases, politicians' interest in biotechnology is based on the belief that the traditional sectoral sources of employment and investment are subject to increasing destruction due to globalization, and the biotechnology industry is associated with higher earnings and a high level of economic recovery and growth [16]. The uptake of biotechnology investment programs shows an increase in the effectiveness of biotechnology as a driver of regional economic development – even in regions with little current/timely activity in the industry. In addition, these political initiatives will have a long-lasting effect on regional development patterns, as well as on the development and long-term structure of the industry.

Despite the great academic and political interest in the biotechnology industry, the field of application and extent of the industry cannot be precisely defined. The answers depend on which definition of biotechnology we want to use ([17], [18], [19], [14], [20]). In the most general terms, biotechnology is an industry that involves the placement of innovations related to life sciences on health, agricultural and industrial business bases, which are often called the "red", "green" or "white" biotechnology sectors.

While the international biotech industry includes activities from all three biotech spheres, the majority of political and academic studies focus on 'red' (i.e. health) biotechnology. Furthermore, although most private and public biotech ventures are located in the United States, the location of regional and international developments is quite different for red, green, and white biotechs. Despite the ambiguities arising from the industry's application area and the alternation between the three subsectors, "cluster-led" growth in biotechnology has emerged as a key economic development strategy for both regions and nations at all levels of economic and technological recovery. [14], [15]

Research results [21] suggest that biotechnology is a set of clustered economic activities strongly based on its interaction with science-based university research. The growing number of different locations in the United States is leading to a significant level of biotechnology activity, as well as an

increasing number of countries around the world supporting major activities within the biotechnology industry. Even more remarkable, many countries around the world are "embracing" the ever-changing importance of the biotechnology industry. In most countries, the activity is highly localized and often concentrated in a single city or capital area.

Open Innovation

As can be seen from the red biotechnological trends and processes, as well as the IP utilization studies, often only a few years (maximum 10, but sometimes only 5) are available to cover the entire R&D activity in the sector, as well as the clinical costs. That is why everyone is trying to shorten the time required for development. One element of this can be the application of open innovation, which supports collaborations and the outsourcing of activities instead of in-house forces. Because there is no time to internalize new skills within the company, there is no time to learn, the current R&D sub-tasks should be entrusted to an external unit that is already professional in the given field. This is definitely advantageous in terms of time, and may also be useful in terms of costs.

Of course, a conflict of different interests can be observed in this matter. The interest of the originator company (usually big pharma) is to maintain its monopoly as long as possible, which is exactly the opposite of the interest of the generic companies, which want to come to the market as soon as possible. Between the two interest groups are the consumers, the consumers of medicines, for whom some intermediate model would be most suitable. They benefit from the appearance of generic drugs in two ways: their appearance is accompanied by a price reduction, and at the same time, the original companies also have to develop new drugs, which will again protect them from generics. At the same time, a patent expiration that is too fast is no longer in the interest of consumers, since then it is no longer worth it for the originators to develop, or the testing of medicines will not be careful and long enough, which can be a potential source of danger from the point of view of patient safety.

How can pharmaceutical companies renew their innovation?

1. Separation of activities necessary for decision-making and implementation:
   - maximizing value creation through decision-making
   - limiting the internal implementation of labor- and/or capital-intensive tasks when the competitive advantages are only minimal
   - Example: planning clinical trials vs. clinical trial outsourcing (CRO)
2. Striving for operational excellence in all internal activities:
   - goal: to be first class in the industry and realize this in contracts
   - continuous comparison ensures operational excellence
   - example: during the production of chemical active ingredients, the experience gathered over a long period of time, slower innovation, significant capacities, established "professional workshops" and specialized manufacturers make/made resource allocation attractive
3. The activities carried out with the strategic long-term conclusions:
   - thanks to the ever-increasing power of suppliers, scarce capacities could lead to a redistribution of markets and profits (e.g. biological production of active ingredients)
   - Establishing rules, as already proven in computing, is the most powerful example: the pharmaceutical industry should work together and create standards as a basis for research and development, such as "Electronic Medical Records"
4. Possible franchise strategies:
   - typical examples are commercial activities, such as specialized sales, medical visitors, or key management for organizational customers
   - this regulation is also applied in R&D and especially in clinical developments
5. As we have seen, with organizational innovation, the creation of so-called PNOs - this is perhaps the most modern and the most effective way today. Of course, in order for this 5th point to be fulfilled, the organization must also successfully overcome the first 4 points and apply their results.

According to them, open innovation is nothing more than the exploration and exploitation of the ability to cooperate and co-create without being hindered by organizational restrictions with any possible cooperating party, in principle by mobilizing the entire globally distributed knowledge. The implementation of open innovation brings new "social technologies" to the fore. Its implementation is usually based on crowdsourcing or product development partnerships.

Open innovation is excellently illustrated by Chesbrough with the figure below:

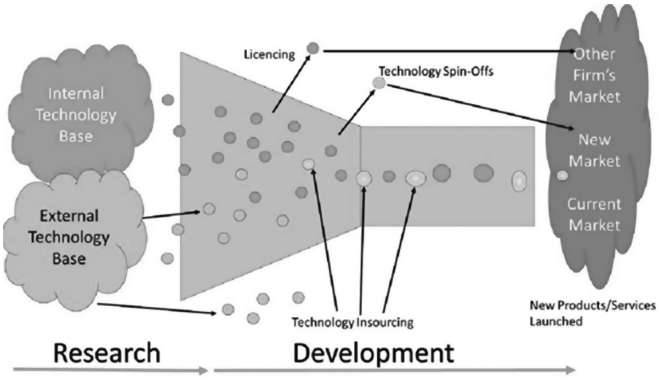

Figure 1: The open innovation model [22]

On the one hand, open innovation can be aimed at finding excellence that can be found beyond the boundaries of the company, but it can also be aimed at finding the "wisdom of the crowd". In this case, it is about the fact that the average knowledge of the crowd is closer to the exact solution of certain tasks under certain conditions than expert estimation. But the open call can simply be aimed at getting to know as best as possible what position the majority takes. To that extent, it is more of a marketing activity. Mass outsourcing

is now used for a wide variety of collaboration opportunities, including collaboration with consumers, suppliers, experts, and even competitors.

Perhaps most important is the open way of interactive value creation with consumers. There are extreme opinions about this. According to Von Hippel [23], the majority of innovative ideas already came from a specific group of users, the leading users, and by this he primarily meant people. That might be an exaggeration. Verganti's opinion is certainly very one-sided, as he radically denies the possibility of radically new product ideas for the consumer, even if there is an important truth in the fact that initially only those on the supply side can still know certain technological, organizational, legislative, marketing, etc. innovation opportunities.

Taking these into account, it can be seen that new types of risk reduction methods (collaborations, open innovation) can reduce the risk inherent in development costs over time. However, these steps have created new risks: in terms of knowledge sharing, IP, information flow and organizational innovation.

All in all, it can be concluded that the technological, risk reduction, and cooperation developments entailed the structural developments and the innovation of their development.

MATERIALS AND METHODS

Pharmaceutical value chain collaborations

Our research method is the literature, and after taking stock of our own experiences and industry trends, we conducted online interviews with experienced colleagues in the field.

Based on industry and confidentiality considerations, the interviews themselves cannot be published. However, they are definitely suitable for getting a comprehensive picture of the development of structures and opinions on collaborations, as well as mapping these trends and local/organizational specialties in this area.

So we conducted interviews based on a pre-prepared list of 43 questions. We grouped our questions into 9 main topics, and based on these, we conducted online discussions lasting 60-120 minutes per person. Although the authors focused on the topic areas, they tried to record the answers to all 43 questions.

When compiling the invitees, we also wanted to take into account interest in the industry, sectoral and capital supply, as well as academic/industrial spheres, as well as represent a kind of distribution in terms of company size. Based on these, our focus regarding the background of the interviewees was to conduct an interview:

- Hungarian/foreigner,
- big pharma/cdmo,
- small company/large company,
- academia/industry

with its representations.

RESULTS AND DISCUSSION

Project organizations

Investigating from project organisation point of view, the results of our research can be defined around 9 main points. These 9 points can be reviewed in Table 1.

Table 1: Decisive fields to manage

1	CDMO versus pharma: the goal is different, the innovation is different, the methods are different. It follows that the organization is different, its innovation and operational functioning are also different
2	One of the main risks: IP and secret protection. This changes the strategy, operation and structure as well.
3	A project pulls the organization along, the project generates its own organizational innovation
4	Capital-deficient environment: narrow immersion in professionals, projects, referrals to tenders: it works differently.
5	Small/undercapitalized organizations also understand the definitions of the basic terms differently: open innovation, hence the strategy and trajectory of innovation are of course different. The formation of a helix is unlikely.
6	Win-win situation: assigned partners: definitely at the project level: this requires organizational culture/learning.
7	Competence focus: there needs to be an area where the organization is the best, and it will be successful there.
8	For projects, a higher-level forum is needed, who represent the subordination (contract), but at more operational levels, the project is the goal (progress is important).
9	Product vs platform projects are different.

Source: Author's own construction

1. Biotechnological development and the management of innovations within it (technology, collaborations and structure) are the "playground" of large companies. This can be seen in the fact that, based on our interviews, a so-called The position of CDMO (Contract Manufacturing Organization) - which manufacture the medicine as part of contract manufacturing, but do not have their own product - and the big pharmaceutical companies (Big Pharma), because their goals are fundamentally different, and consequently the innovation and the methods used are different. Since CDMO only produces, it perceives the task as a "classic" project, Big Pharma considers the entire life cycle.

It follows that the organization is different, as is its innovation. Operative operation is also different from this. It is important that at the CDMO, the operative operation controls the innovation and the structure, at Big Pharma it is the other way around.

2. One of the main determining risks: industrial rights protection (IP), confidentiality and knowledge management. This also changes the strategy, operation and structure. Of course, every company reacts differently to this, but it can be said that the Western companies, which used to be on the biotechnology scene, start all kinds of collaborations armed with a very serious legal background. This is mostly unique, but it is influenced by:

- unique experiences,
- industry role
- vision / positioning
- the size of an existing, reliable partner circle.

3. In many cases, we see that the project "pulls" the organization along. This means that if there is a large/relevant project, the organization will generate its own organizational innovation from within (but for external motivation). This determines whether the organization is viable or not (in the sense of innovation). The primary experience is that the organization that can best achieve risk reduction is the one that can quickly and flexibly adapt to different project situations.

4. The innovation and perception of the organization in a capital-deficient environment is special. You have to live with the problem of narrow immersion (colleagues, resources, service providers) in specialists and projects. Referral to the tender is special (it is possible that it is a Hungarian specialty): all this gives the projects an additional "domestic" character. In addition to all of this, hierarchical relationships are typical, the totality of which can mean a negative spiral.

5. In the case of small/undercapitalized organizations, based on the answers to the question list, it can be established that in many cases the definitions of basic terms are understood differently than larger companies. For example, in the interpretation of "open innovation", it does not matter whether we mean a contractual partner/project partner/subcontractor, or only a partner outside the university or academic sector. Deduced from this, of course, the strategy and the trajectory of innovation are different. The achievement of the special helix structure is influenced by all of these. We will explain this helix model, the innovation of innovation, in our later writings.

6. Clear favoring of a win-win situation. Based on our responses from the Pharma company, it is important that the CDMO (Contract Development Manufacturing Origination, CRO (Contract Research Organisation), although they are subcontractors during the project, these units have a clearly assigned status during the project in practice they have, since a significant proportion of the capacities and specialized knowledge is focused in these organizations. That is, the project goal is the common one, if this is not successful, then the main goal (the goal of Big Pharma) will not be fulfilled either. All of this requires significant organizational culture/learning, which is consciously it is necessary to undertake and integrate it into the operation.

7. Competence focus: every actor needs an area where he is the best, what he knows best, and he will be successful there. Strategy, management and innovation must be adapted to this. It seems that Big Pharma companies are looking for industry excellence and will contract them. From this point of view, it is not a problem, and even an advantage, if our company has leading competences and references in even a narrower field, and does not represent the "everything available" model.

The strategic decision of this naturally depends on the characteristics of the market, competence, situation and industry.

8. If we focus on the internal operation of the projects, we found that a top-level forum is necessary, who represent the subordinate-superior order (contract), but at more operative, professional levels, the project goal (result-goal) is of paramount importance, should be the main line leader.

9. Product and platform projects are different: This can be considered a significant industry specialty, just as red, i.e. the value chain of pharmaceutical biotechnology, is also quite specialized. Product means that the given company will have a market product. This can mean an active ingredient or a finished product, i.e. a finished medicine. A platform project means that an assignment belonging to an element of the biotechnological value chain has been given, and it must be fulfilled accordingly. The assignment can be external (e.g. production of an active ingredient) or internal (e.g. process development). Both imply different organizations, structures and steps.

It can be concluded that our thesis is verified. (results 1-9). The challenges arising from the special innovation of red biotech also caused and necessitated the innovation of organizational structures and the development of its organizational operation (we called it: structure).

This can be seen in our model, in which we conducted interviews. We summarized our findings in 9 points. The findings we need to move forward are the following:

- In a large company: structure and operation are present as a kind of helix (strengtheningly), but also taking into account new elements of risk (IP)
- In the case of a capital-poor, small company or region (e.g. Hungary, or an academic background where appropriate), the attitude and thinking are also different, which brings with it a different methodology of innovation
- In addition to all this, flexibility, adaptability, and innovativeness are present and extremely important in thinking in the organization and in its innovation (1, 2, 3, 6, 8, 9)

CONCLUSION

Thesis: the challenges arising from the special innovation of red biotech also caused and necessitated the innovation of the development of the Structure and Operation of Organization (SO&OO). We have proven this, and we have identified further points that have yet to be researched below:

- In the case of a capital-poor, small company or region (e.g. Hungary) or academic background, the attitude and thinking are different, which brings with it a different methodology of innovation
- A special helix model can be developed, which more clearly supports the specialties of red biotech innovations

Recommendation:
Our article is recommended by our mutual friend, mentor, colleague, in honour of dr. Kálmán Könczöl (1954-2023).

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